DOCUMENT MADE AVAILABLE UNDER THE PATENT COOPERATION TREATY (PCT)

International application number: PCT/NZ2014/000040
International filing date: 14 March 2014 (14.03.2014)
Document type: Certified copy of priority document

Document details:
- Country/Office: US
- Number: 61/815,671
- Filing date: 24 April 2013 (24.04.2013)

Date of receipt at the International Bureau: 08 April 2014 (08.04.2014)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a),(b) or (b-bis)
THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

March 20, 2014

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 61/815,671
FILING DATE: April 24, 2013

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US61/815,671

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

M. K. CARTER
Certifying Officer
## Electronic Acknowledgement Receipt

<table>
<thead>
<tr>
<th><strong>EFS ID:</strong></th>
<th>15606047</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Number:</strong></td>
<td>61815671</td>
</tr>
<tr>
<td><strong>International Application Number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Confirmation Number:</strong></td>
<td>7654</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Title of Invention:</strong></th>
<th>NASAL CANNULA ASSEMBLY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Named Inventor/Applicant Name:</strong></td>
<td>Jason Allan Klenner</td>
</tr>
<tr>
<td><strong>Customer Number:</strong></td>
<td>20995</td>
</tr>
<tr>
<td><strong>Filer:</strong></td>
<td>Curtiss C. Dosier/Lori Larson</td>
</tr>
<tr>
<td><strong>Filer Authorized By:</strong></td>
<td>Curtiss C. Dosier</td>
</tr>
<tr>
<td><strong>Attorney Docket Number:</strong></td>
<td>FPHCR.341PR2</td>
</tr>
<tr>
<td><strong>Receipt Date:</strong></td>
<td>24-APR-2013</td>
</tr>
<tr>
<td><strong>Filing Date:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Time Stamp:</strong></td>
<td>19:56:17</td>
</tr>
<tr>
<td><strong>Application Type:</strong></td>
<td>Provisional</td>
</tr>
</tbody>
</table>

### Payment information:

<table>
<thead>
<tr>
<th><strong>Submitted with Payment</strong></th>
<th>yes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Payment Type</strong></td>
<td>Credit Card</td>
</tr>
<tr>
<td><strong>Payment was successfully received in RAM</strong></td>
<td>$660</td>
</tr>
<tr>
<td><strong>RAM confirmation Number</strong></td>
<td>6178</td>
</tr>
<tr>
<td><strong>Deposit Account</strong></td>
<td>111410</td>
</tr>
<tr>
<td><strong>Authorized User</strong></td>
<td>KNOBBE MARTENS OLSON AND BEAR</td>
</tr>
</tbody>
</table>

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

- Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)
- Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)
## File Listing:

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Document Description</th>
<th>File Name</th>
<th>File Size(Bytes)/ Message Digest</th>
<th>Multi Part./.zip</th>
<th>Pages (if appl.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Application Data Sheet</td>
<td>FPHCR_341PR2.pdf</td>
<td>1503203</td>
<td>no</td>
<td>8</td>
</tr>
</tbody>
</table>

### Warnings:

### Information:

| 2               | FPHCR_341PR2_Spec.pdf    | 5784214                  | yes                             | 110              |

#### Multipart Description/PDF files in .zip description

<table>
<thead>
<tr>
<th>Document Description</th>
<th>Start</th>
<th>End</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specification</td>
<td>1</td>
<td>84</td>
</tr>
<tr>
<td>Claims</td>
<td>85</td>
<td>109</td>
</tr>
<tr>
<td>Abstract</td>
<td>110</td>
<td>110</td>
</tr>
</tbody>
</table>

### Warnings:

### Information:

| 3               | Drawings-only black and white line drawings | FPHCR_341PR2_Drawings.pdf | 7152651 | no | 69 |

### Warnings:

### Information:

| 4               | Fee Worksheet (SB06) | fee-info.pdf | 31216 | no | 2 |

### Warnings:

### Information:

| Total Files Size (in bytes) | 14471284 |

---

Copy provided by USPTO from the IFW Image Database on 03/14/2014
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**
If a new international application is being filed and the International application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.
NASAL CANNULA ASSEMBLY

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present disclosure relates to devices and systems for providing gases to patients for respiratory therapy. More specifically, the present disclosure relates to nasal cannula interfaces for providing gases to patients via the nasal passages.

Description of the Related Art

[0002] Medical professionals may wish to provide patients with respiratory assistance in the form of supplemental oxygen or airflow for many reasons in ICU, other hospital, or home environments. Different types of interfaces for supplying gases to patients are available. For example, various nasal masks, full face masks, oral interfaces, nasal pillows, and nasal cannula interfaces exist. Nasal cannula interfaces typically include two nasal prongs that are placed in the patient’s nostrils to deliver gases to the patient.

SUMMARY OF THE INVENTION

[0003] The nasal cannula interfaces described herein can advantageously be used to deliver gases to patients over a wide range of concentrations and flow rates. The nasal cannula interfaces described herein also include various features designed to improve patient comfort, safety, ease of use, and/or efficiency, reduce costs, and/or provide other benefits.

[0004] In some embodiments, a nasal cannula system includes a cannula and a manifold. The cannula includes a central body portion, first and second side portions that extend in opposite lateral directions from the central body portion and contact a cheek of a user when the system is in use, and first and second nasal prongs extending from the central body portion. The central body portion includes a patient facing side and at least one retention strap that cooperate to define a cavity. The first and second nasal prongs communicate with the cavity. The manifold receives a supply of gas from a gas source and includes a gas inlet and a gas outlet. The manifold is receivable within the cavity of the cannula such that the gas outlet is aligned with the first and second nasal prongs. The at least one retention strap defines first and second lateral edges, and the first and second nasal prongs are located between the first and second lateral edges.
In some embodiments, a nasal cannula system includes a cannula and a supply tube. The cannula includes a central body portion, first and second side portions that extend in opposite lateral directions from the central body portion and contact a cheek of a user when the system is in use, and first and second nasal prongs extending from the central body portion. The cannula defines a cavity having an inlet at a first end and a second end communicating with first and second gas paths. The first and second gas paths communicate with the first and second nasal prongs, respectively. The inlet is located at one of the first and second side portions, and the first and second gas paths extend in a lateral direction toward the first and second nasal prongs. The supply tube has a first end connectable to a supply of gas from a gas source and a second end coupled to the inlet of the cavity of the cannula.

In some embodiments, a nasal cannula system includes a cannula, a manifold, and a supply tube. The cannula includes a central body portion, first and second side portions that extend in opposite lateral directions from the central body portion, and first and second nasal prongs extending from the central body portion. The central body portion defines a cavity and a forward-facing inlet to the cavity. The first and second nasal prongs communicate with the cavity. The manifold receives a supply of gas from a gas source and includes a gas inlet and a gas outlet. The manifold is connectable with the cannula such that the gas outlet is aligned with the forward-facing inlet of the cannula and the gas inlet faces a lateral direction. The supply tube is connected to the gas inlet of the manifold and positioned forward of the forward-facing inlet of the cannula.

In some embodiments, a nasal cannula patient interface includes first and second nasal prongs, each including an inlet end and an outlet end, and at least one support portion configured to rest upon the nose of a patient at a point at or above the tip of the nose. In use, no portion of the patient interface contacts an upper lip of the patient to provide any substantial support to the patient interface.

In some embodiments, a nasal cannula system comprises a cannula having a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. An integrated head strap includes a first section and a second section, wherein the first and second sections extend in opposite lateral directions from the central body portion.
The first section defines a rear portion of the head strap. An adjustable coupling arrangement permits coupling of the first and section sections in an adjustable manner such that a circumference of the head strap is adjustable. A supply tube has a first end connectable to a supply of gas from a gas source and a second end coupled to the cavity of the cannula.

[0009] In some embodiments, a nasal cannula system includes a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a lateral slot. A head gear strap extends through the lateral slot of the cannula. A supply tube has a first end connectable to a supply of gas from a gas source and a second end coupled to the cavity of the cannula.

[0010] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location. A valve body is movable within the cavity. A supply tube has a first end connectable to either one of the first opening or the second opening of the cannula and a second end connectable to a supply of gas from a gas source. When the first end of the supply tube is connected to the first opening of the cannula, the valve body moves in response to a flow of gas in the cavity from the gas source to block the second opening such that the flow of gas is directed to the first and second nasal prongs and, when the first end of the supply tube is connected to the second opening of the cannula, the valve body moves in response to the flow of gas in the cavity from the gas source to block the first opening such that the flow of gas is directed to the first and second nasal prongs.

[0011] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location. The cannula comprises a first valve that selectively closes the first opening and a second valve that
selectively closes the second opening. A supply tube has a first end connectable to either one of the first opening or the second opening of the cannula and a second end connectable to a supply of gas from a gas source. When the first end of the supply tube is connected to the first opening of the cannula, the second valve blocks the second opening such that a flow of gas from the gas source is directed to the first and second nasal prongs and, when the first end of the supply tube is connected to the second opening of the cannula, the first valve blocks the first opening such that the flow of gas is directed to the first and second nasal prongs.

[0012] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first end of the cavity and a second opening at a second end of the cavity. A supply tube has a first end comprising a first insert and a second end comprising a second insert. Each of the first insert and the second insert is positionable within the cavity to seal the first opening and the second opening and deliver a flow of gas from the gas source to the first and second nasal prongs. When the first end of the supply tube is connected to the cannula, the second end is connectable to the gas source and, when the second end of the supply tube is connected to the cannula, the first end is connectable to the gas source.

[0013] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. A supply tube has a first end coupled to the cavity of the cannula and a second end connectable to a supply of gas from a gas source. The first end of the supply tube defines a connection axis relative to the cannula. The supply tube comprises a flexible portion at or adjacent the first end that can be bent at least about 90 degrees to either the left or right side without significant occlusion of an internal passage of the supply tube.

[0014] In some embodiments, a nasal cannula system comprises a cannula comprising a cavity and a first nasal prong and a second nasal prong in communication with the cavity. A supply tube receives a flow of gas from a gas source. The supply tube is connected to the cannula to supply the flow of gas to the cavity of the cannula. A clip
removably receives the cannula. A retention arrangement secures the clip to the head of a patient. The cannula is positionable within the clip in a first orientation such that the supply tube extends in a first direction from the clip, and the cannula is positionable within the clip in a second orientation such that the supply tube extends in a second direction from the clip.

[0015] In some embodiments, a nasal cannula system comprises a cannula comprising a first nasal prong and a second nasal prong. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location. A supply tube assembly comprises a clip that can be releasably coupled to the cannula in either of a first orientation and a second orientation. The supply tube assembly further comprises a supply tube connectable to a supply of gas from a gas source. The clip supports the supply tube and comprises a sealing portion. When the clip is connected to the cannula in the first orientation, the supply tube is connected to the first opening of the cannula and extends in a first direction from the cannula and the sealing portion at least substantially seals the second opening and, when the clip is connected to the cannula in the second orientation, the supply tube is connected to the second opening of the cannula and extends in a second direction from the cannula and the sealing portion at least substantially seals the first opening.

[0016] In some embodiments, a nasal cannula system comprises a cannula clip comprising a first nasal prong and a second nasal prong. The cannula defines a cavity in communication with the first and second nasal prongs. A supply tube assembly comprises a manifold having at least one manifold opening and a supply tube connectable to a supply of gas from a gas source. The cannula clip is capable of being releasably coupled to the manifold in either of a first orientation and a second orientation in which the manifold is received within the cavity of the cannula clip and the first and second prongs are aligned with the at least one manifold opening such that a flow of gas is provided to the first and second prongs. When the cannula clip is connected to the manifold in the first orientation, the supply tube extends in a first direction relative to the first and second prongs and, when the cannula clip is connected to the manifold in the second orientation, the supply tube extends in a second direction relative to the first and second prongs.
[0017] In some embodiments, a nasal cannula system comprises a cannula comprising a main body defining a cavity and a first nasal prong and a second nasal prong extending from the main body and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. The first and second nasal prongs are tiltable relative to the main body of the cannula between at least a first position in which the first and second nasal prongs are tilted in a first direction relative to the main body and a second position in which the first and second nasal prongs are tilted in a second direction relative to the main body. A first surface of the main body defines a patient-facing surface of the cannula in the first position and a second surface of the main body defines the patient-facing surface of the cannula in the second position to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

[0018] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. The first and second nasal prongs are directionally-oriented relative to the cannula and are movable between at least a first position in which the first and second nasal prongs are oriented such that openings of the prongs generally face in a first direction relative to the cannula and a second position in which the first and second nasal prongs are oriented such that the openings of the prongs generally face in a second direction relative to the cannula. A first surface of the cannula defines a patient-facing surface in the first position and a second surface of the cannula defines the patient-facing surface in the second position to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

[0019] In some embodiments, a nasal cannula system comprises a cannula defining a patient-facing surface and a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A manifold supports the cannula for rotation about at least one axis between at least a first position and a second
position opposite the first position. A supply tube is coupled to the manifold and in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. When the cannula is in the first position, the supply tube is positioned on a first side of the first and second nasal prongs and, when the cannula is in the second position, the supply tube is positioned on a second side of the first and second nasal prongs to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

[0020] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A pressure line is in communication with the cavity and is configured to be connectable to a control unit of the gas source or a display unit to provide a signal to the control unit or display unit indicative of a pressure within the cavity.

[0021] In some embodiments, a nasal cannula comprises a cannula body defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. The cannula defines a patient-facing surface having one or more comfort features selected from a plurality of through-holes, a plurality of raised bumps, a plurality of grooves and a gel pad.

[0022] In some embodiments, a nasal cannula comprises a cannula body defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. The cannula body comprises a central portion containing the first and second nasal prongs and first and second side portions extending from each side of the central portion. The cannula body defines a patient-facing surface. The central portion is spaced forwardly of adjacent portions of the first and second side portions such that, in use, the patient-facing surface of the central portion is spaced from the upper lip of the patient.

[0023] In some embodiments, a supply tube for a nasal cannula comprises a tube body having a first end and a second end. The tube body comprises a malleable section that
permits the section to be shaped by an external force and that substantially retains the shape after the external force is removed.

[0024] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A support arrangement supports the supply tube at a spaced location from the cannula. The support arrangement comprises a fastener having a first portion coupled to the supply tube and a second portion located at the spaced location.

[0025] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A retention arrangement secures the cannula to the patient. A support arrangement supports the supply tube at a spaced location from the cannula, which is located on the retention arrangement.

[0026] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A support arrangement supports the supply tube at a spaced location from the cannula. The support arrangement comprises a fastener that engages a piece of fabric at the spaced location.

[0027] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a
gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A support arrangement supports the supply tube at a spaced location from the cannula. The support arrangement comprises at least one of an armband that engages the supply tube, an adhesive pad comprising a fastener for releasably fastening the supply tube to the adhesive pad, a generally U-shaped support that sits on the patient's shoulder and engages the supply tube, and a headgear strap comprising a strap extending over the top of the patient's head and engages the supply tube.

[0028] In some embodiments, a retention arrangement for a nasal cannula assembly comprises a headgear strap comprising a first ear loop and a second ear loop, each of which at least partially surround an ear of the patient. A connection portion connects the retention arrangement to the nasal cannula assembly. A strap portion extends around the back of the patient's head between the first and second ear loops.

[0029] In some embodiments, a retention arrangement for a nasal cannula comprises a headgear strap comprising a strap portion. A first pad and a second pad, in use, contact first and second cheeks of the patient. A connection portion connects the retention arrangement to the nasal cannula. The strap portion extends around the patient's head and extends from the first and second pads at an angle relative to the nasal cannula.

[0030] In some embodiments, a retention arrangement for a nasal cannula comprises a frame comprising a connection portion that connects the retention arrangement to the nasal cannula. A first ear stem portion and a second ear stem portion extend rearwardly from opposite sides of the connection portion. The ear stem portions are configured to be positioned above the ears of the patient.

[0031] In some embodiments, a nasal cannula system comprises a cannula having a central portion defining a cavity and comprising a first nasal prong and a second nasal prong extending from the central portion and in communication with the cavity. A first side portion and a second side portion extend in a lateral direction from opposing sides of the central portion. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A first adhesive pad and a second adhesive pad are configured to be adhesively secured to the face of the patient and connectable to a
respective one of the first and second side portions of the cannula through an adjustable fastening arrangement.

[0032] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A modular retention arrangement secures the cannula to the patient. The cannula is configured to be used with any one of the retention arrangements selected from a set of adhesive pads that attach to the patient's face, a headgear strap and a halo-style headgear strap that has a strap portion extending over the top of the patient's head.

[0033] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A modular retention arrangement secures the cannula to the patient. The retention arrangement comprises a nose strip coupled to the cannula and attachable to the nose of a patient and a headgear strap comprising a clip configured to receive the cannula. The cannula can be secured to the patient using either the nose strip or the headgear strap.

[0034] In some embodiments, a retention arrangement for a nasal cannula comprises a headgear strap that is connectable to a nasal cannula and capable of being tensioned around the head of a patient. The headgear strap comprises a tension indicator that provides a first indication when the tension is at an incorrect value and a second indication when the tension is at a correct value.

[0035] In some embodiments, a retention arrangement for a nasal cannula comprises a headgear strap that is connectable to a nasal cannula. At least one strap extends around the head of a patient from one side to the other of the cannula. A tension adjuster tensions the headgear strap by varying an effective length of the at least one strap by winding up a portion of the at least one strap.

[0036] In some embodiments, a headgear strap for a nasal cannula comprises a first portion that is connectable to a nasal cannula and a second, elastic portion that is positioned at a back of a head of a patient in use. A pad extends at least partially along the second, elastic portion.
[0037] In some embodiments, a nasal cannula assembly comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A head strap is positioned around the head and above the ears of the patient in use. A first arm is coupled to a first side of the cannula and a second arm is coupled to a second side of the cannula. Upper end portions of each of the first and second arms are attached to the head strap.

[0038] For purposes of summarizing the disclosure and the advantages achieved over the prior art, certain objects and advantages are described herein. Of course, it is to be understood that not necessarily all such objects or advantages need to be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the disclosure may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught or suggested herein without necessarily achieving other objects or advantages as may be taught or suggested herein. All of these embodiments are intended to be within the scope of the disclosure herein. These and other embodiments will become readily apparent to those skilled in the art from the following detailed description having reference to the attached figures, the disclosure not being limited to any particular disclosed embodiment(s).

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] These and other features, aspects and advantages of the present disclosure will be described with reference to the following drawings, which are illustrative but should not be limiting of the present disclosure.

[0040] Figure 1A illustrates an example embodiment of a nasal cannula assembly coupled to a patient;

[0041] Figure 1B illustrates a partial front perspective view of the nasal cannula assembly of Figure 1A;

[0042] Figure 1C illustrates an exploded view of the nasal cannula assembly of Figures 1A and 1B;

[0043] Figure 2A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;
[0044] Figure 2B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 2A;

[0045] Figure 3A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;

[0046] Figure 3B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 3A;

[0047] Figure 4 illustrates a partial front perspective view of an alternative configuration of the nasal cannula assembly of Figures 3A and 3B;

[0048] Figure 5A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula without a manifold;

[0049] Figure 5B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 5A;

[0050] Figure 6A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including cheek pads;

[0051] Figure 6B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 6A;

[0052] Figure 7A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula with an integrated headstrap;

[0053] Figure 7B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 7A;

[0054] Figure 7C illustrates an example embodiment of a lanyard connector for a nasal cannula assembly;

[0055] Figure 8A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;

[0056] Figure 8B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 8A;

[0057] Figure 8C illustrates an exploded view of the nasal cannula assembly of Figures 8A and 8B;

[0058] Figure 9A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;
[0059] Figure 9B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 9A;
[0060] Figure 9C illustrates a variation of the nasal cannula assembly of Figures 9A and 9B;
[0061] Figure 10A illustrates a side perspective view of an example embodiment of a nasal cannula assembly including a cannula and a nose strip attached to a patient’s face;
[0062] Figure 10B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 10A;
[0063] Figure 11 illustrates an alternative configuration of the nasal cannula assembly of Figures 10A and 10B;
[0064] Figure 12A illustrates a partial front perspective view of an example embodiment of a nasal cannula assembly including two cannulas;
[0065] Figure 12B illustrates top, front, and side views of one of the cannulas of Figure 12A;
[0066] Figure 12C illustrates a front perspective view of the nasal cannula assembly of Figure 12A coupled to a patient;
[0067] Figure 13A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and retainer;
[0068] Figure 13B illustrates a partial side perspective view of the nasal cannula assembly of Figure 13A;
[0069] Figure 13C illustrates a partial front perspective view of the nasal cannula assembly of Figures 13A and 13B coupled to a patient;
[0070] Figure 14A illustrates a front perspective view of a nasal cannula assembly including a manifold and a cannula having nasal flaps;
[0071] Figure 14B illustrates an exploded view of the nasal cannula assembly of Figure 14A; and
[0072] Figure 14C illustrates the nasal cannula assembly of Figures 14A and 14B coupled to a patient.
[0073] Figures 15A-G illustrate an example embodiment of a nasal cannula assembly with a shuttle valve.
Figures 16A-F illustrate example embodiments of a nasal cannula assembly with a manifold having a one way valve formed from an exhalation style valve with a loosely hinged flap.

Figures 16G-L illustrate embodiments of a nasal cannula assembly with a manifold having a one way valve formed from a slit valve of various types.

Figures 17A and 17B illustrate an example embodiment of a nasal cannula assembly with a tube threaded through the manifold to allow for selective side switching of the tube exit side.

Figures 18A and 18B illustrate an example embodiment of a nasal cannula assembly with each tubing exit hole sealed by a thin membrane that is pierced by a sharpened end of the supply tube.

Figures 19A and 19B illustrate an example embodiment of a manifold with a flexible tube exiting the front tubing exit hole of the manifold.

Figures 20A-C illustrate an example embodiment of a manifold that snaps into an assembly securing device or clip.

Figures 21A-F illustrate example embodiments of a nasal cannula assembly with a removable tubing assembly and manifold.

Figures 21G and 21H illustrate an example embodiment of a nasal cannula assembly with a manifold receiving structure, separate nasal prong insert and a manifold.

Figures 22A-D illustrate an example embodiment of a nasal cannula assembly with a manifold insert and a manifold receiving structure.

Figures 23A-C illustrate an example embodiment of a nasal cannula assembly with a manifold insert which can be clipped over a tubing assembly.

Figures 24A-C illustrate an example embodiment of a nasal cannula assembly having prongs formed with a ripple shape around the base to allow for flexibility of the prongs.

Figures 24D-F illustrate an example embodiment of the prongs formed with a corrugated geometry to allow for flexibility of the prongs.

Figure 25A illustrates an example embodiment of a nasal cannula assembly that includes individually rotatable prongs.
[0087] Figures 25B-C illustrate an example embodiment of a nasal cannula assembly that includes a pair of prongs mounted on a vertical shaft and rotatable as a unit.

[0088] Figures 26A-F illustrate an example embodiment of a nasal cannula assembly configured to allow insertion of a removable prong insert in at least two orientations.

[0089] Figures 27A-D illustrate example embodiments of a nasal cannula assembly that includes a manifold that is rotatable about an axis extending in a generally fore-aft direction.

[0090] Figures 28A and 28B illustrate example embodiments of a nasal cannula assembly that includes a manifold and supply tube that can be coupled to the cannula in at least two orientations.

[0091] Figure 29A illustrates an example embodiment of a respiratory assistance system with a nasal cannula assembly having pressure measurement capability.

[0092] Figures 29B-L illustrate example embodiments of nasal cannula assemblies having pressure measurement capability.

[0093] Figures 30A-I illustrate example embodiments of nasal cannula assemblies having features to address, reduce or minimize patient discomfort, especially at or near the upper lip area.

[0094] Figures 31A-F illustrate example embodiments of adjustable or formable supply tubes for nasal cannula assemblies.

[0095] Figures 32A-N illustrate example embodiments of nasal cannula assemblies having arrangements and features to manage the positioning of the supply tube.

[0096] Figures 33A-S illustrate example embodiments of arrangements for providing support to the supply tube.

[0097] Figures 34A-K illustrate example embodiments of headgear arrangements for securing the cannula to the face of a patient.

[0098] Figures 35A-G illustrate example embodiments of retention arrangements for nasal cannula assemblies.

[0099] Figures 36A-K illustrate example embodiments of retention arrangements, such as headgear straps, including an indicator of tightness, such as strap tension.
[0100] Figure 37A illustrates an example embodiment of a headgear strap having a strap pad.

[0101] Figures 37B-E illustrate example embodiments of an adjustable headgear strap arrangement for a nasal cannula assembly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0102] Although certain embodiments and examples are described below, those of skill in the art will appreciate that the disclosure extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the disclosure herein disclosed should not be limited by any particular embodiments described below. Various features described herein can be used individually or in various combinations and subcombinations in existing and/or improved respiratory interfaces.

[0103] With reference to Figures 1A-1C, an example embodiment of a nasal cannula assembly or system includes a manifold 12 and cannula 14. The cannula 14 includes nasal prongs 20a, b, side straps 22, and a tubular aperture 24 defined or encircled by a retention strap 26 and configured to receive the manifold 12. In some embodiments, the manifold is generally tubular and includes a circular inlet 16 and an elongated oval outlet 18. In use, the manifold 12 is coupled to the cannula 14 by inserting the manifold 12 into the aperture 24 so that the manifold outlet 18 is aligned and in fluid communication with the nasal prongs 20a, b. The manifold inlet 16 is configured to be coupled, removably or permanently, to a gas supply tube 50. In use, the gas supply tube 50 is coupled to and in fluid communication with a main delivery conduit 90, which is configured to be connected to and supply gases from a gas source, for example, a ventilator, gas tank, wall outlet, and/or humidifier that heats and/or humidifies gases before they are delivered to a patient. The gas supply tube 50 can be coupled to the main delivery conduit 90 by a connector 52.

[0104] The nasal cannula system can further include a securement mechanism to secure the cannula 14 to a user’s head in a proper operational position. In the illustrated embodiment, the securement mechanism includes a headgear strap 40. The strap 40 can be coupled to the side straps 22 of the cannula 14. The nasal cannula system can also include a
lanyard 46 that in use is placed around the patient’s neck. The lanyard 46 can be coupled to the supply tube 50 and/or the connector 52 via a lanyard connector 54, which can also allow for adjustment of a length of the lanyard. The lanyard 46 advantageously helps support the weight of the main delivery conduit 90 to reduce patient discomfort and the potential for dislodgement of the cannula 14. Further details regarding example nasal cannula assemblies or systems can be found in U.S. Publication 2010/0192957, the entirety of which is incorporated by reference herein. Various components and features of such nasal cannula assemblies can be selected and modified to achieve various benefits as described herein.

[0105] With reference to Figures 2A and 2B, an embodiment of a nasal cannula assembly or system includes a cannula 114, manifold 112, headgear strap 140, gas supply tube 150, and lanyard 146. The cannula 114 can be formed of a thermoplastic, silicone-like material and includes nasal prongs 120a, b, side straps 122, and two spaced manifold retention portions or straps 126a, b defining/encircling an aperture configured to receive the manifold 112. In some embodiments, the nasal prongs 120a, b, side straps 122, and manifold retention straps 126a, b are integrally formed. The cannula 114 is configured such that the manifold 112 can be inserted into the aperture of the manifold retention straps 126a, b from either side, so that the manifold inlet 116 can be positioned to either side of the cannula 114. The side straps 122 can include flex slots 128 to provide ventilation and allow the cannula 114 to bend or stretch more easily, for example, when adjusting the headgear strap 140 and when adjusting the cannula 114 against the user’s face to help achieve a more effective and/or comfortable fit. The flex slots 128 can be generally vertical as shown or diagonally slanted. As shown in Figure 2B, a patient facing and contacting side 130 of the cannula 114 can have a contoured surface to better and more comfortably fit the patient’s face, reduce the overall profile of the cannula system, and help align the supply tube 150. For example, transition portions 132 positioned between a central body portion 134 of the cannula 114 and the side straps 122 can curve toward the patient’s face to rest against the nasolabial folds. The side straps 122 can taper in thickness toward outer edges of the straps 122 to create a thin profile and help further reduce the cannula system profile.

[0106] The headgear strap 140 can be coupled to the side straps 122 via clips or buckles 142. The clips 142 can include an aperture 144 so that an inner edge 145 of the clip
142 on the side nearest the center of the cannula 114 can engage a corresponding undercut on the side strap 122. As shown in Figure 2B, the clips 142 do not substantially contact the patient's skin, thereby maintaining a smooth and more comfortable patient contacting surface. A side of the clip 142 farthest from the center of the cannula 114 can include a buckle mechanism configured to receive ends of the headgear strap 140 and allow for adjustment of the circumference of the headgear strap 140 to fit the patient's head. In some embodiments, the strap 140 can be flexible (e.g., elastic) to allow the strap 140 to accommodate a wide range of patient head sizes with minimal adjustment required.

[0107] In use, the manifold 112 is coupled to the cannula 114 by inserting the manifold 112 into the aperture 124 and stretching the flexible cannula 114 around the manifold 112. As described above, the manifold 112 can be inserted into the aperture 124 of the manifold retention straps 126a, b from either side, so that the manifold inlet 116 and, thus, the supply tube 150 can be positioned to either side of the cannula 114. In some embodiments, the manifold 112 is made of a relatively hard plastic material that can withstand relatively high loading conditions to protect the manifold 112 from being crushed. In addition, the retention straps 126a, b can be spaced apart from one another to provide support to the manifold 112 at spaced apart locations, which can inhibit or resist undesirable movement (e.g., rotation or twisting) of the manifold 112, such as that caused by forces acting on the supply tube 150, for example. In some configurations, the outer lateral edges of the retention straps 126a, b are spaced outwardly of the nasal prongs 120a, b such that the nasal prongs 120a, b are located between the lateral edges of the retention straps 126a, b. In some configurations, the inner edges of the retention straps 126a, b can be substantially aligned with or spaced outwardly from the nasal prongs 120a, b. Although a pair of retention straps 126a, b is illustrated, other suitable retention arrangements or structures are possible, such as a single retention strap, for example. In the illustrated embodiment, the manifold inlet 116 has an inner diameter slightly larger than an outer diameter of the supply tube 150 so that the tube 150 can be coupled to the manifold 112 by inserting an end of the tube 150 into the manifold inlet 116. The supply tube 150 can have a reduced diameter compared to other supply tubes to allow for this coupling. An end of the tube 150 opposite the manifold can include a connector 152 configured to couple the supply tube 150 to the main delivery conduit coupled
to the gas source. In the illustrated embodiment, the connector 152 is a 22 mm taper connector.

[0108] The cannula system can include a lanyard connector 154, which in the illustrated embodiment is located on the supply tube 150 proximal (nearer to the patient) the connector 152. The lanyard connector 154 can include mechanisms 155 for receiving ends of the lanyard 146 on either side. For example, each side of the lanyard connector 154 can include three or more offset slots or posts through which an end of the lanyard 146 is threaded. The slots or posts can be internal to the lanyard connector 154 or exposed. This configuration advantageously allows one or both ends of the lanyard to be adjusted as needed or desired, and allows the weight of the connector 152 (and the main delivery circuit 90) to be hung or oriented in a vertical orientation or direction. In some embodiments, the lanyard 146 is non-elastic. The lanyard 146 is secured to the lanyard connector 154 via friction between the lanyard 146 and slots or posts. The lanyard 146 can be ribbed to help secure the lanyard 146 to the lanyard connector 154. However, the lanyard 146 and lanyard connector 154 can be designed so that the friction force is overcome and the lanyard 146 releases from the lanyard connector 154 if the connector 154 is pulled too far away from the patient and/or pulled with sufficient force to avoid the lanyard 146 choking or otherwise causing discomfort to the patient. The lanyard connector 154 can include a grip 156 to allow the patient or others to better grasp the lanyard connector 154 for adjustments and/or for easy removal of the connector 152 from the main delivery conduit 90.

[0109] With reference to Figures 3A and 3B, a nasal cannula assembly or system includes a cannula 214, manifold 212, headgear strap 240, gas supply tube 250, and lanyard 246. The cannula 214 includes nasal prongs 220a, b, side straps 222, and a manifold retention strap 226 defining or encircling an aperture configured to receive the manifold 212. The cannula 214 is configured such that the manifold 212 can be inserted into the aperture of the manifold retention strap 226 from either side, so that the manifold inlet 216 can be positioned to either side of the cannula 214. In the illustrated embodiment, the manifold retention strap 226 is wide compared to the retention strap 26 shown in Figures 1A and 1B and straps 126a, b shown in Figure 2. The retention strap 226 can include a window 227 that allows part of the manifold 212 to be visible, for example, indicating that the manifold 212 is correctly
inserted into manifold retention strap 226. The window 227 can display, for example, branding, size, and/or other information printed, stamped, adhered or otherwise presented on the visible portion of the manifold 212.

[0110] The cannula 214 is generally soft and flexible for patient comfort. Outer portions 223 of the side straps 222 can be made to have increased strength, for example, by making the outer portions 223 thicker or otherwise reinforcing them, such as via strengthening ribs, which can be positioned at upper and/or lower edges of the side straps 222, for example. The added strength allows the headgear strap 240 to be coupled directly to the outer portions 223 of the side straps 222 without the need for additional clips, buckles, or other attachment mechanisms and allows the cannula 214 and side straps 222 to hold their moulded shape, preventing or inhibiting deformation during tension. The outer portions 223 of the side straps 222 can include two or more slits or apertures through which ends 243 of the strap 240 can be threaded and pulled through a desired length to obtain a headgear strap 240 circumference appropriate to fit the patient. The ends 243 of the headgear strap 240 can be folded back and removably secured to portions of the headgear strap 240 proximate the outer portions 223 of the side straps 222 via a hook and loop type closure. For example, a segment of fabric including hooks can be attached (e.g., sewn, adhered, etc.) to the ends 223 of the headgear strap 240, and a segment of fabric including loops can be attached (e.g., sewn, adhered, etc.) to the portions of the headgear strap 240 proximate the outer portions 223 of the side straps 222. An opposite side of the ends 243 of the strap 240 visible when worn can include branding or other information printed, stamped, adhered, or otherwise attached thereto.

[0111] As shown in Figure 3B, a rear or patient-facing side of the side straps 222 can include recessed areas 221 to accommodate the portions of the headgear strap 240 looped through the side straps 222 so that the strap 240 does not significantly press against the patient’s face. A section of the headgear strap 240 configured to be placed against the back of the patient’s head in use can include a padded section 241 for patient comfort. The padded section can be inserted between two halves of the headgear strap 240 or placed on top of or around the headgear strap 240.
[0112] In use, the manifold 212 is coupled to the cannula 214 by inserting the manifold into the aperture defined by the manifold retention strap 226. The manifold 212 can be inserted into the aperture of the manifold retention strap 226 from either side, so that the manifold inlet 216 can be positioned to either side of the cannula 214. In the illustrated embodiment, the manifold 212 includes a cylindrical inlet 216. The inlet 216 has an inner diameter slightly larger than an outer diameter of the supply tube 250 so that the tube 250 can be coupled to the manifold 212 by inserting an end of the tube 250 into the manifold inlet 216. An end of the tube 250 opposite the manifold 212 can include a connector 252 configured to couple the supply tube 250 to the main delivery conduit coupled to and in fluid communication with the gas source.

[0113] The cannula system can further include a lanyard connector 254 located on the supply tube 250 proximal to the connector 252. In some embodiments, the lanyard connector 254 is color coded to indicate size or other information. One side of the lanyard connector 254 can include a mechanism 255 for adjustably receiving one end of the lanyard 246. For example, one side of the lanyard connector 254 can include two slits or apertures through which the end of the lanyard 246 can be threaded. This mechanism 255 allows the lanyard 246 to be easily placed around the patient's neck and coupled to the lanyard connector 254 without having to put the lanyard 246 over the patient's head. The lanyard connector 254 can also include a grip 256 to allow the patient or others to better grasp the lanyard connector 254 for adjustments and/or easy removal the connector 252 from the main delivery conduit 90.

[0114] One side of the lanyard connector 254 can include a breakaway clip 257. An end of the lanyard 246 can include molding configured to be inserted into the breakaway clip 257 to secure the lanyard 246 to the lanyard connector 254. The breakaway clip 257 is designed so that if the lanyard 246 applies too great a force to the patient's neck due to, for example, the main delivery conduit, connector 252, supply tube 250, and/or lanyard connector 254 being pulled away from the patient with a force exceeding a certain threshold, the breakaway clip 257 releases the lanyard 246 or detaches from the lanyard connector 254 to avoid patient injury or discomfort. This configuration advantageously allows the weight of the connector 252 (and the main delivery circuit 90) to be hung or oriented in a vertical
orientation or direction. In some embodiments, the lanyard 246 is made of an inelastic material to improve the function of the breakaway clip 257 and so that the weight of the main delivery conduit coupled to the connector 252 does not stretch the lanyard 246 and apply additional force to the patient's neck. In some embodiments, the breakaway clip 257 allows the lanyard 246 to be easily looped around the patient's neck then inserted into the breakaway clip 257.

[0115] Figure 4 illustrates a cannula system having a cannula 314 and headgear strap 340 similar in some ways to the cannula 214 and headgear strap 240 illustrated in Figures 3A and 3B. However, the cannula system of Figure 4 lacks a manifold retention strap and includes a reversible manifold 312. The manifold 312 can pivot or rotate or be decoupled from the cannula 314 and turned 180° so that the inlet 316 can be located to either side of the cannula 214.

[0116] An embodiment of a nasal cannula assembly or system as illustrated in Figures 5A and 5B includes a cannula 414, headgear strap 440, and gas supply tube 450. The cannula 414 includes nasal prongs 420a, b, side straps 422, and an inlet 416. In the illustrated embodiment, an end of the gas supply tube 450 couples directly to the inlet 416 of the cannula 414. The supply tube 450 can have a reduced diameter so that the end of the supply tube 450 can be received within the inlet 416. The supply tube 450 can be secured to the cannula 414 by stretching the cannula inlet 416 over the end of the supply tube 450, using an adhesive (e.g., glue), mechanical interference features, and/or other means. The cannula 414 further includes two gas paths 417a, b extending from and in fluid communication with the inlet 416, so that a first gas path 417a extends to and is in fluid communication with a first nasal prong 420a, and a second gas path 417b extends to and is in fluid communication with a second nasal prong 420b. The geometry of the gas paths 417a, b can be designed to balance gas flow between the two gas paths 417a, b and nasal prongs 420a, b so that the patient receives balanced flow in both nostrils. The flow path has reduced, minimal or no significantly abrupt transitions or sharp corners, which advantageously reduces or minimizes resistance to flow.

[0117] Ends of the side straps 422 can include apertures or slots 421 designed to receive ends of the headgear strap 440. The headgear strap 440 can be formed of a highly elastic material capable of a large degree of stretch to allow the strap 440 to accommodate
and fit various patient head sizes, particularly where, as in the illustrated embodiment, the side straps 422 do not include clips or buckles to allow for adjustment of the circumference of the headgear strap 440. For example, the headgear strap 440 can be made of a material having a relatively flat force extension curve so that the strap 440 maintains the same or substantially the same tension over a range of degree of stretch. The ends of the headgear strap 440 can include a rigid material overmolded thereon to help secure the ends of the strap 440 within the apertures 421. The strap 440 can also or alternatively be secured to the cannula 414 with an adhesive (e.g., glue), ultrasonic welding, and/or other means.

[0118] The cannula system can include a tube clip 442 coupled (permanently or removably, immovably or movably) to the headgear strap 440. The tube clip 442 can be located on the side of the cannula 414 nearest the inlet 416 and can receive the supply tube 450 to help hold the tube 450 away from the mouth and face of the patient in use. An end of the supply tube 450 opposite the end coupled to the cannula inlet 416 can include a connector 452 configured to couple the supply tube 450 to the main delivery conduit. The cannula system can include a lanyard clip 454 positioned on the supply tube 450 proximal to the connector 452. The lanyard clip 454 can releasably clip to a lanyard worn around the patient’s neck in use. Alternatively, the lanyard clip 454 can be directly attached to, for example, the patient’s clothing or hospital gown, bed sheets, or another location nearby to help support the weight of the main delivery conduit. The nasal cannula system illustrated in Figures 5A and 5B does not include a manifold or clips or buckles for attaching the headgear strap 440 to the cannula 414. This configuration minimizes the parts of the nasal cannula system, which can advantageously help provide easier manufacturing and/or reduce the cost.

[0119] Another embodiment of a nasal cannula assembly or system includes a cannula 514, manifold 512, gas supply tube 550, and lanyard 546 as shown in Figures 6A and 6B. The cannula 514 includes nasal prongs 520a, b, a manifold retention strap 526, and cheek pads 522. The cheek pads 522 are designed to be positioned on the patient’s cheeks and/or upper cheeks in use. The cannula 514 includes thin flex areas 532 located at transition regions between a central body portion 534 of the cannula 514 and the cheek pads 522. The thin flex areas 532 have a reduced cross-sectional thickness to allow the cheek pads 522 to move and be adjusted relative to the central body portion 534 more easily to improve the fit, positioning,
and comfort of the cannula 514 on the patient's face. A rear or patient contacting side of the central body portion 534 can include soft and/or thin wall cushion details 535. The cushion details 535 can include, for example, a ribbed, rippled, folded or other surface designed to space the central body portion 534 of the cannula 514 away from the patient's face slightly. This advantageously allows for airflow between the central body portion 534 and the patient's face and provides a collapsible region to help absorb forces pressing the cannula 514 into the patient's face.

[0120] Rear surfaces of the cheek pads 522 include attachment pads 560 integrally formed with the cheek pads 522 or sewn, adhered, or otherwise attached thereto. The attachment pads 560 can include a releasable and reattachable adhesive to attach the cheek pads 522 to the patient's face. Alternatively, the attachment pads 560 can include one portion of a hook and loop fastener, for example, a fabric segment including the hooks. Patches containing the other portion of the fastener, for example the loops, can be attached to the patient's face at desired locations on the cheeks and/or upper cheeks to allow the attachment pads 560 to be releasably attached to the patient's face.

[0121] The manifold 512 includes an inlet 516 designed to receive the gas supply tube 550 and an outlet designed to be aligned and in fluid communication with the nasal prongs 520a, b in use. The manifold 512 is coupled to the cannula 514 by sliding the manifold 512 into an aperture defined by the manifold retention strap 526 so that the outlet aligns with the nasal prongs 520a, b and stretching the cannula 514 around edges of the manifold 512. The manifold 512 can be inserted into the aperture of the manifold retention strap 526 from either side, so that the manifold inlet 516 can be positioned to either side of the cannula 514. The retention strap 526 can include a window 527 that allows part of the manifold 512 to be visible, for example, indicating that the manifold 512 is correctly inserted into manifold retention strap 526. The window 527 can display, for example, branding, size, and/or other information printed, stamped, adhered or otherwise presented on the visible portion of the manifold 512.

[0122] In the illustrated embodiment, the supply tube 550 is a small diameter spiral tube. Other types of gas supply conduits are also possible. An end of the supply tube 550 opposite the end coupled to the manifold 512 can include a connector 552 configured to be
connected to the main delivery conduit. The cannula system can include a lanyard retention connector 554 located on the connector 552 or on the supply tube 550 proximal to the connector 552. One end of the lanyard 546 can be integrally formed with or coupled to one side of the lanyard retention connector 554. An opposite side of the lanyard retention connector 554 can include a slot designed to receive a free end 547 of the lanyard 546. The free end 547 of the lanyard 546 can include a series of protrusions or notches 548. The protrusions 548 can be pulled through the slot of the lanyard retention connector 554 to adjust the circumference of the lanyard 546 but resist sliding through the slot when not being adjusted to help secure the lanyard 546 at the desired circumference. The lanyard 546 can be made of a stamped fabric, for example, white non-woven laminated polyethylene, which can advantageously help reduce the cost of the cannula system.

[0123] An example embodiment of a cannula system as shown in Figures 7A-7B includes a cannula 614, gas supply tube 650, and lanyard 646. The cannula 614 includes nasal prongs 620a, b, a retention strap 626, and an integrated headgear strap 640. In some embodiments, the headgear strap 640 can include a break on one side so that the headgear strap 640 includes a first section 640a and a second section 640b. The free end of one section (first section 640a in the illustrated embodiment) can include a slot 642 configured to receive the free end of the other section (second section 640b in the illustrated embodiment). A segment of the strap 640 near the free end of the second section 640b can include teeth 643 configured to engage sides of the slot 642 to help inhibit the second section 640b from being pulled out of the slot 642. A rear portion 641 of the headgear strap 640, which is part of the first section 640a in the illustrated embodiment, can separate into a double strap configuration to aid stability of headgear strap 640 on the patient's head and/or help distribute forces on the patient's head and improve patient comfort.

[0124] In the illustrated embodiment, an end of the gas supply tube 650 is coupled directly to the cannula 614. The supply tube 650 can have a reduced diameter so that the end of the supply tube 650 can be received within an aperture defined by the retention strap 626. The supply tube 650 can be secured to the cannula 614 by stretching the manifold retention strap 626 over the end of the supply tube 650, using an adhesive (e.g., glue), mechanical interference feature, and/or other means. The cannula system can include a tube clip 642
coupled (permanently or removably, immovably or movably) to the supply tube 650. The tube clip 642 can include a hook configured to be placed on the headgear strap 640 to help hold the tube 650 away from the mouth and face of the patient in use.

[0125] An end of the supply tube 650 opposite the end coupled to the cannula 614 can include a connector 652 configured to be connected to the main delivery conduit. The cannula system can further include a lanyard retention connector 654. The connector 652 can include a lower portion and an upper portion 653 including grip features. In some embodiments, the connector 652 includes a reduced diameter section between the upper and lower portions to receive the lanyard retention connector 654. Alternatively, the upper and lower portions can be separate pieces. In use, the lanyard retention connector 654 is pressed over a portion of the connector 652 and held in place between the upper and lower portions or in the reduced diameter section.

[0126] In the illustrated embodiment, the lanyard 646 is integrally formed with one side of the lanyard retention connector 654. Alternatively, the lanyard 646 can be coupled to the lanyard retention connector 654. An opposite side of the lanyard retention connector 654 can include a slot designed to receive a free end 647 of the lanyard 646. The free end 647 of the lanyard 646 can include a series of notches 648 along the sides. In use, the lanyard 646 is wrapped around the patient’s neck and the free end 647 of the lanyard is threaded through the slot of the lanyard retention connector 654 to achieve the desired circumference of the lanyard 646. The notches 648 allow the free end 647 of the lanyard 646 to be pulled through the slot of the lanyard retention connector 654 to adjust the circumference of the lanyard 646 but resist sliding through the slot when not being adjusted to help secure the lanyard 646 at the desired circumference. The lanyard 646 can be made of a stamped fabric, for example, white non-woven laminated polyethylene, which can advantageously help reduce the cost of the cannula system.

[0127] In an alternative embodiment, shown in Figure 7C, the cannula system can include a connector 752, a lanyard connector 754 positioned on the supply tube 650 proximal to the connector 752, and a separate lanyard 746. The lanyard connector 754 includes two slots to receive the ends of the lanyard 746. Both ends of the lanyard 746 can include a series of notches 748 similar to the notches 648 described herein to allow for adjustment of one or
both ends of the lanyard 746. This configuration advantageously allows the weight of the connector 752 (and the main delivery circuit 90) to be hung or oriented in a vertical orientation or direction.

[0128] In some embodiments, for example as shown in Figures 8A-8C, a cannula system includes a cannula 814, manifold 812, headgear strap 840, gas supply tube 850, and lanyard 846. The cannula 814 includes nasal prongs 820a, b, and an inlet 824. As shown in Figure 8C, a flange 825 encircles a perimeter of the inlet 824. The manifold 812 includes an inlet 816 configured to receive the supply tube 850 and an outlet 818. The outlet 818 of the manifold 812 includes a recess 819 configured to receive the flange 825 of the cannula 814. In some embodiments, the manifold 812 and cannula 814 can be designed to have a reduced size to advantageously reduce the profile of the cannula system on the patient's face, which can improve patient comfort and reduce the chance of obstructing the face or mouth in some circumstances.

[0129] In use, the manifold 812 is coupled to the cannula 814 by inserting one side of the manifold 812 into the cannula 814 inlet 824 so that the flange 825 of the cannula 814 sits in the recess 819 of the manifold 812 and stretching the cannula 814 around the manifold 812 outlet 818 so that the flange 824 sits in the recess 819 around the entire perimeters of the cannula 814 outlet 824 and manifold 812 outlet 818. The flange 824 and corresponding recess 819 advantageously help secure the connection between the cannula 814 and manifold 812 and can also help prevent air leaks at the connection. The manifold 812 can further include a tab 880 designed to fit into a corresponding recess or aperture 882 on the cannula 814 to help further secure the manifold 812 to the cannula 814 and indicate that the manifold 812 is correctly inserted into the cannula 814. As shown in Figure 8C, the manifold 812 is reversible, i.e., the manifold 812 can be coupled to the cannula 814 so that the manifold inlet 816 extends to either side of the cannula 814. The manifold 812 can include a grip 815 to advantageously assist a user in grasping the manifold 812 to couple and/or remove the manifold 812 to and/or from the cannula 814.

[0130] In the illustrated embodiment, the headgear strap 840 is coupled directly to the cannula 814, and the cannula system does not include clips, buckles, or other mechanisms that allow for adjustment of the circumference of the strap 840. Sides of the cannula 814 can
include apertures or slots 821 designed to receive ends of the headgear strap 840. The ends of the strap 840 can be secured to the cannula 814 with an adhesive (e.g., glue), ultrasonic welding, and/or other means. The headgear strap 840 can be formed of a highly elastic material capable of a large degree of stretch to allow the strap 840 to accommodate and fit various patient head sizes. For example, the headgear strap 840 can be made of a material having a relatively flat force extension curve so that the strap 840 maintains the same or substantially the same tension over a range of degree of stretch. A pitch of threads of the headgear strap 840 material can be changed to adjust the tightness of the strap 840.

[0131] The gas supply tube 850 can be coupled to the manifold 812 inlet 816 at one end and a connector 852 configured to couple the supply tube 850 to the main delivery conduit at an opposite end. The gas supply tube 850 can have a reduced diameter so that the end of the tube 850 can be inserted into the manifold inlet 816. In some embodiments, the connector 852 can include grip details 856 to help the user grasp the connector 852 more easily to adjust various components of the cannula system. In some embodiments, the gas supply tube 850 can include a pressure line 870. The pressure line 870 can be configured to convey pressure feedback from the end of the supply tube 850 coupled to the manifold 812 to a pressure sensor and/or controller. The pressure line 870 can be integral with or coupled to the supply tube 850. In some embodiments, the pressure line 870 lies within the main flow path of the supply tube 850. In other embodiments, the pressure line 870 lies adjacent the main flow path of the supply tube 850. For example, in some embodiments, the supply tube 850 can be a spiral bubble tube, and the pressure line 870 can lie in the hollow spiral of the spiral bubble supply tube 850.

[0132] The cannula system can further include a lanyard connector 854 located on the supply tube 850 proximal to the connector 852. In some embodiments, the lanyard connector 854 is fixed relative to the tube 850. In other embodiments, the lanyard connector 854 is slidable relative to the tube 850. The lanyard connector 854 can include apertures or slots on either side to receive ends of the lanyard 846. In the illustrated embodiment, the lanyard connector 854 also acts as a point of separation of the pressure line 870 from the supply tube 850. In use, the lanyard 846 is wrapped around the patient’s neck and the ends of the lanyard 846 are threaded through the apertures or slots of the lanyard connector 854 to
achieve the desired circumference of the lanyard 846. Ends of the lanyard 846 can include notches 848 along the sides. The notches 848 allow the lanyard 846 to be pulled through the slots of the lanyard connector 854 to adjust the circumference of the lanyard 846 but resist sliding through the slots when not being adjusted to help secure the lanyard 846 at the desired circumference. This configuration advantageously allows the weight of the connector 852 (and the main delivery circuit 90 illustrated in Figure 1A) to be hung or oriented in a vertical orientation or direction. The lanyard 846 can be made of a stamped fabric, for example, white non-woven laminated polyethylene, which can advantageously help reduce the cost of the cannula system.

[0133] An example embodiment of a cannula system as illustrated in Figures 9A and 9B includes a cannula 914, manifold 912, headgear strap 940, and gas supply tube 950. As shown, the cannula 914 can include a manifold aperture 924 configured to receive the manifold 912 and a headgear strap aperture 921 configured to receive the headgear strap 940. The manifold 912 can be inserted into the aperture of the cannula 914 from either side, so that the manifold inlet 916 can be positioned to either side of the cannula 914. In the illustrated embodiment, the manifold 912 is generally cylindrical, and the manifold aperture 924 is therefore also generally cylindrical. The manifold 912 can be substantially hollow to allow for gas flow. The cannula 914 can include a window 927 that allows part of the manifold 912 to be visible, for example, indicating that the manifold 912 is correctly inserted into cannula 914. The window 927 can display, for example, branding, size, or other information printed, stamped, adhered or otherwise presented on the visible portion of the manifold 912.

[0134] One end of the cylindrical manifold 912 is open and forms an inlet 916 configured to receive one end of the gas supply tube 950. An opposite end of the manifold 912 is closed, as shown in Figure 9B. In some embodiments, the closed end of the manifold 912 includes a removable cap. In some such embodiments, a solid cap can be interchangeable with a cap 913 that can include a pressure line 970, for example as shown in Figure 9C. As explained above, the manifold 912 can be inserted into the aperture of the cannula 914 from either side, so that the manifold inlet 916 can be positioned to either side of the cannula 914. The cap 913 therefore can also be located on either side of the cannula 914.
In the illustrated embodiment, the headgear strap 940 is threaded through the headgear strap aperture 921 of the cannula 914. In some embodiments, the headgear strap 940 is secured to the cannula 914 with an adhesive (e.g., glue), ultrasonic welding, or another mechanism. In some embodiments however, the cannula 914 and headgear strap 940 are slidable relative to each other. The headgear strap 940 can be a single length of strap. One end of the length of strap can be secured to clasp 943a, and an opposite end of the length of strap can be secured to clasp 943b. The clasps 943a, b are coupled to and slidable on the strap 940 to allow for adjustment of the circumference of the strap 940 to fit the patient's head. In some embodiments, the headgear strap 940 is made of a non-stretch material.

The cannula system can include a connector 952 on the supply tube 950 at an end opposite the manifold 912. The connector 952 can be configured to couple the supply tube 950 to the main supply conduit. The cannula system can further include a lanyard clip 954 encircling a proximal portion of the connector 952 or encircling the supply tube 950 proximal to the connector 952. The lanyard clip 954 can releasably receive a lanyard. Alternatively, the lanyard clip 954 can be directly clipped to, for example, the patient's clothing or gown, the bedding, or a lanyard placed around the patient's neck to help support the weight of the main supply conduit coupled to connector 952.

An example embodiment of a cannula system as shown in Figures 10A and 10B includes a cannula 1014, nose strip 1022, supply tube 1050, and nasal prongs 1020a, b. The cannula 1014 is shaped and sized to be positioned on top of the patient's nose. For example, a portion of the cannula 1014 can have a curved profile designed to follow the curvature of the nose. The cannula 1014 can be secured to the patient's nose via the nose strip 1022. In some embodiments, the nose strip 1022 resembles an adhesive bandage. A central portion of the nose strip 1022 can include a comfort pad 1035 configured to rest against the patient's nose and provide added cushioning in use. Adhesive portions of the nose strip 1022 extend from the central portion to adhere to portions of the patient's cheeks. A side of the nose strip 1022 facing away from the patient's face includes an attachment pad 1062 coupled (e.g., sewn, adhered, or otherwise attached) thereto. A patient facing side of the cannula 1014 includes a corresponding attachment pad 1060. For example, in some embodiments, the attachment pads 1060, 1062 are the components of a hook-and-loop
fastener, e.g., Velcro. The attachment pads 1060, 1062 therefore allow the cannula 1014 to be releasably attached to the nose strip 1022.

[0138] In some embodiments, the nose strip 1022 includes a strip 1064 designed to help hold the patient’s nasal passages open. In some embodiments, the strip 1064 can be made of a flexible, spring-like metal that is biased toward a substantially straight state. When the nose strip 1022 is placed across the curved nasal bridge, the strip 1064 attempts to straighten, thereby gently lifting the sides of the patient’s nose to open the nasal passages. In some embodiments, the strip 1064 can be made of a shape memory material such as nitinol, and heat from the patient’s face causes the strip 1064 to attempt to return to a straighter state. The strip 1064 can be located on either side of the nose strip 1022, i.e., on the side facing away from the patient or the side facing the patient, e.g., between the nose strip 1022 and comfort pad 1035. In some embodiments, the nose strip 1022 can also act as a blackhead removing strip. The patient contacting side of the nose strip 1022 can include bonding agents capable of bonding to dirt and/or other impurities in the patient’s pores so that they are removed with the nose strip 1022 when it is removed.

[0139] In the illustrated embodiment, the supply tube 1050 is a dual-tube including two small-diameter tubes extending between a main delivery conduit connector 1052 and nasal prongs 1020a, b. The cannula system can include an adapter 1053 designed to receive the small-diameter supply tubes 1050 and couple to the main delivery conduit connector 1052. The adapter 1053 can be integrally formed with, attached to, or proximal to the connector 1052. Each of the supply tubes 1050 can be integrally formed with or coupled to one of the nasal prongs 1020a, b. In some alternative embodiments, the supply tube 1050 can include a single tube over part or all of its length. The single tube can separate at the nasal prongs 1020a, b or can separate into two tubes distal to the nasal prongs 1020a, b. As shown in Figures 10A and 10B, the two supply tubes 1050 pass downward into a portion of the cannula 1014. The nasal prongs 1020a, b extend downward from the supply tubes 1050 and cannula 1014, then turn approximately 180° to extend upward on the patient contacting side of the cannula 1014. In the illustrated embodiment, the nasal prongs 1020a, b are molded or formed to retain their shape and orientation. In some embodiments, the nasal prongs 1020a, b can include a wire made of a shape memory material, for example, nitinol. Gas flow through the
nasal prongs 1020a, b or heat radiating from the patient’s face can cause the wire to assume and/or maintain the formed shape. The nasal prongs 1020a, b extend upwardly into the patient’s nostrils when the cannula 1014 is coupled to the nose strip 1022.

[0140] In some alternative embodiments, for example as shown in Figure 11, the cannula system can include nasal pillows 1120a, b instead of nasal prongs. As shown, the supply tubes 1050 pass downward through a portion of the cannula 1014 and hang freely. The nasal pillows 1120a, b are coupled to the free ends of the supply tubes 1050. In some embodiments, the nasal pillows 1120a, b can be self-inflating pillows. In use, the nasal pillows 1120a, b are turned upward and inserted into the patient’s nostrils and the cannula 1014 is coupled to the nasal strip 1022.

[0141] The cannula system can further include a cheek pad 1042. The cheek pad 1042 can include an adhesive strip that can be used to secure a portion of the supply tubes 1050 to the patient’s cheek. The cheek pad 1042 can advantageously help hold the supply tubes 1050 away from the patient’s mouth and help support some of the weight of the supply tubes 1050. The cheek pad 1042 can include branding or other information printed or otherwise displayed thereon. In some embodiments, the supply tubes 1050 include an anti-kink spring, which can advantageously help allow the tubes 1050 to be manipulated, for example when positioning the cannula 1014 or cheek pad 1042 on the patient, without interrupting the gas supply.

[0142] An example embodiment of a cannula system can include two cannulas 1220a, b, nose strip 1222, and supply tubes 1250a, b, as shown in Figures 12A-12C. The nose strip 1222 can be similar to nose strip 1022 shown in Figures 10A and 10B and described in the accompanying text. In the embodiment of Figures 12A-12C, however, the cannula is separated into a right cannula 1214a and a left cannula 1214b. In some embodiments, the cannulas 1214a, b are symmetrical rather than right and left biased. Right cannula 1214a includes an integral nasal prong 1220a, and left cannula 1214b includes an integral nasal prong 1220b. A patient facing surface of each cannula 1214a, b includes an attachment pad 1260a, b to removably attach the cannulas 1214a, b, to the attachment pad of the nose strip 1222. In some embodiments, nose strip 1222 includes a strip 1264 to help hold the patient’s nasal passages open as described with respect to Figures 10A and 10B.

-32-
The supply tube includes small diameter right 1250a and left 1250b supply tubes extending from a main delivery conduit connector 1252 to the right 1214a and left 1214b cannulas. The supply tubes 1250a, b are received into inlets 1224a, b of the cannulas 1214a, b. As shown, the supply tubes 1250a, b can be looped around the patient’s ears to help hold the tubes 1250a, b away from the patient’s mouth and support some of the weight of the tubes 1250a, b. The tubes 1250a, b can include spring winding to help provide kink-resistance and strength. In some embodiments, only one of the cannulas 1214a, b can be used at a given time for a certain patient as needed or desired.

An example embodiment of a cannula system as shown in Figures 13A-13C can include a cannula 1314, retainer 1322, and supply tube 1350. The cannula 1314 can have a minimal size and profile. In the illustrated embodiment, the cannula 1314 includes a generally cylindrical body having an inlet 1324 and integrally formed nasal prongs 1320a, b. The retainer 1322 includes a cannula engaging portion 1321 and a nasal strip portion 1323. In some embodiments, the cannula engaging portion 1321 is attached to the cylindrical body of the cannula 1314 with an adhesive, e.g., glue. In some embodiments, the cannula engaging portion 1321 is moulded as part of the cannula 1314. In some embodiments, the cannula engaging portion 1321 has a formed shape configured to snap or clip onto the cannula 1314. The nasal strip portion 1323 is designed to be adhered across the patient’s nose to help secure the cannula 1314 to the patient. A patient facing side of the nasal strip portion 1323 can include an adhesive strip covered by a protective backing 1366 for storage. The protective backing is peeled off to expose the adhesive strip when needed to secure the cannula 1314 to the patient. The retainer 1322 can be removed and replaced as needed during the duration of therapy. In embodiments in which the cannula engaging portion 1321 is moulded as part of the cannula 1314, the adhesive strip can be removed and/or replaced as needed.

In some embodiments, the supply tube 1350 is a small diameter spring tubing. The supply tube 1350 can be coupled to a main delivery conduit connector 1352 at one end and the cannula 1314 inlet 1324 at an opposite end. The supply tube 1350 diameter can be sized so that the supply tube 1350 can be inserted into the cannula inlet 1324 and the cannula 1314 stretched or otherwise formed or positioned around the tube 1350 to secure the tube 1350 to the cannula 1314. The cannula system can also include a lanyard clip 1354.
positioned on the connector 1352 or on the supply tube 1350 proximal to the connector 1352. The lanyard clip 1354 can releasably receive a lanyard placed around the patient’s neck. Alternatively, the lanyard clip 1354 can be attached to, for example, the patient’s clothing or hospital gown, bed sheets, or another location nearby to help support the weight of the main delivery conduit.

[0146] An example embodiment of a cannula system as shown in Figures 14A-14C includes a cannula 1414, manifold 1412, and gas supply tube 1450. The cannula 1414 includes nasal prongs 1420a, b, nose flaps 1422a, b, and a manifold retention strap 1426 defining/encircling an aperture 1424 configured to receive the manifold 1412. In use, the manifold 1412 is coupled to the cannula 1414 by inserting the manifold 1412 into the aperture 1424 and stretching the manifold retention strap 1426 around the manifold 1412. In the illustrated embodiment, the manifold includes an inlet or collar 1416 and two outlets 1418. In use, the outlets 1418 are aligned and in fluid communication with the nasal prongs 1420a, b.

[0147] The nose flaps 1422a, b extend from the sides of the cannula 1414 and are configured to fold over the sides of the patient’s nostrils. The nose flaps 1422a, b can include a thin section near the manifold retention strap 1426, allowing the nose flaps 1422a, b to bend easily and conform to the geometry of the nose. In some embodiments, each nose flap 1422a, b includes an attachment pad 1460, which can be one part of a hook-and-loop fastener. The attachment pads 1460 can be removably coupled to corresponding attachment pads 1462, which can be the other part of the hook-and-loop fastener, on the user’s nose. The attachment pads 1462 can be attached to the outsides of the patient’s nostrils with an adhesive. In some embodiments, the attachments pads 1460 of the nose flaps 1422a, b can be adhesive patches that are adhered directly to the user’s nose. In some embodiments, the nose flaps 1422a, b can comprise a malleable material that can hold its shape once deformed such that the nose flaps 1422a, b and remain substantially in place once folded. In such an arrangement, the attachment pads 1460 can be grip pads comprising a grip material to grip the skin of the patient and inhibit undesired movement of the cannula 1414.

[0148] In some embodiments, the supply tube 1450 is a small-diameter spring tube. The supply tube 1450 can be coupled to a main delivery conduit connector 1452 at one end and the manifold inlet or collar 1416 at an opposite end. In some embodiments, the
supply tube 1450 is permanently attached to the collar 1416 and/or the collar 1416 is permanently attached to the manifold 1412. Alternatively, the supply tube 1450 can be removably coupled to the collar 1416 and/or the collar 1416 can be removably coupled to the manifold 1412. As shown in Figure 14B, the manifold 1412 can be inserted into the aperture 1424 of the cannula 1414 from either side so that the supply tube 1450 can extend from either side of the cannula 1414. The cannula system can further include a lanyard clip 1454 positioned on the connector 1452 or on the supply tube 1450 proximal to the connector 1452. The lanyard clip 1454 can be releasably coupled to a lanyard placed around the patient’s neck or can be attached to, for example, the patient’s clothing or hospital gown, bed sheets, or another location nearby to help support the weight of the main delivery conduit.

[0149] Figures 15-18 illustrate embodiments of a nasal cannula assembly including a cannula, which preferably includes a pair of nasal prongs. The cannula can be integrated with a supply conduit or tubing or can connect to a separate supply conduit or tubing, such as through any of the manifold arrangements disclosed herein. In some configurations, the cannula has a tubular shape with a first end, a second end, and a body extending between the first and second ends and is coupled to a supply tube at one of the ends. Accordingly, the cannula body can define a hollow “manifold” volume that is at least partially defined by the manifold in other embodiments disclosed herein. Additionally, in some embodiments, the cannula can contain one or more prong exit holes in the middle of the cannula body which can be arranged to allow exit of gas to a pair of nasal prongs. In some embodiments, the cannula can be a hollow volume cannula containing at least one inlet that can be positioned and shaped to be attached to a supply tubing or conduit. In certain embodiments, the cannula can contain an inlet at each end of the cannula. The cannula can be configured to be connected to or integrated within an assembly securing device, for example a headgear strap. The cannula can be configured to be integrally connected or permanently connected to a supply tube or conduit, such as through any of the manifold arrangements described herein or through a connector. In some embodiments, the cannula can be integrated or unitary with a tube creating a cannula/tube assembly or structure. In certain embodiments, the cannula can be flexible to allow bending or manipulation of the cannula. In other embodiments, the manifold can be relatively stiff or rigid. Any of the cannula embodiments discussed herein can comprise
attached or clip-on or slide-on prongs and/or fixed or tilted/adjustable prongs as described herein.

[0150] In some embodiments, the cannula can have tubing exit holes at each end of a first end and a second end of the cannula. In some embodiments, the first end or the second end can be configured to be connected to the supply conduit or tubing that connects to the humidifier, circuit, or other gas or flow supply apparatus. The end not connected to the tubing can be selectively blocked. For example, the selective side switching of the device can occur through a system where when the first end is connected to the tubing allowing air to enter the manifold space of the cannula, the second end is blocked, and when the second end is connected to the tubing allowing air to enter the manifold space of the cannula, the first end is blocked. Figures 15-18 illustrate embodiments of the selective side switching in the manifold.

[0151] Figures 15A-D illustrate embodiments of a nasal cannula assembly incorporating a shuttle valve that selectively occludes one end of the cannula or manifold (hereinafter referred to as the "manifold"). In some embodiments, the manifold 1501 can have an opening, port or inlet 1507 or, preferably, openings 1507 on each side of the manifold 1501. In particular, a first opening 1507 can be positioned at a first end and a second opening 1507 can be positioned at a second end of the manifold 1501. In certain embodiments, a lightweight shuttle object or valve body 1508, for example a ball or disk, can move (e.g., slide or roll) freely inside the manifold volume or hollow cavity 1509. Preferably, the shuttle object 1508 has a larger diameter than the prongs 1505 and the openings 1507 to prevent the shuttle object 1508 from exiting the hollow cavity 1509.

[0152] In some embodiments, a supply tube 1502 can be connected to one of the openings or inlets 1507. The supply tube 1502 can supply resulting positive pressure from the flow of air or gas from the humidifier or other apparatus into the hollow cavity 1509. The resulting positive pressure from the flow of air or gas pushes the shuttle object 1508 along the hollow cavity 1509 until it blocks off the opposite opening 1507. The blocking of the opposite opening 1507 can prevent the air from traveling through that opening 1507 while still allowing the air to flow through the prongs 1505. In some embodiments, the supply tube 1502 can be attached to one opening 1507 of the manifold 1501 and the opposite opening 1507 is blocked.
by the shuttle object 1508. For example, to switch sides of the supply tube 1502 relative to the manifold 1501, the supply tube 1502 can be removed from one opening 1507 and put into the opposite opening 1507 and the shuttle object 1508 will swap sides automatically. In some embodiments, the opening 1507 can have a localized thin wall section 1510, preferably defining an annular shape surrounding the opening 1507. The localized thin wall section 1510 can deform relative to at least a surrounding portion of the manifold 1501 to aid in sealing the hollow cavity 1509 at that end when the shuttle object 1508 is pushed to that side. In certain embodiments, the shuttle object 1508 can be made of a relatively soft material, for example material used to make compressible earplugs (e.g., compressible PVC foam), to further assist in sealing of the hollow cavity 1509.

[0153] In some embodiments of the nasal cannula assembly 1500, the manifold 1501 has at least one prong 1505 and, preferably, a pair of prongs 1505. Preferably, the nasal cannula assembly 1500 contains prongs 1505 positioned on or configured to be positioned on the manifold 1501. In certain embodiments, the prongs 1505 on the manifold 1501 can be flexible or rotatable to allow use of the nasal cannula assembly 1500 in either direction. The prongs 1505 illustrated in Figure 15 comprise a distal end 1521 and a proximal end 1522. The distal end 1521 of each prong 1505 is configured to be placed within the nose of the user when in use. The proximal end 1522 of each prong 1505 is configured to be attached to or to be flush with the manifold 1501 and prong exit holes 1520 in the manifold 1501 that communicate with the interior spaces of the prongs 1505. In some embodiments, the prongs 1505 are twin nasal prongs and are located in the middle of body of the manifold 1501.

[0154] The supply tube 1502 can be coupled to the manifold 1501 by any suitable arrangement. For example, the supply tube 1502 can include a connector 1530 coupled to the end of the supply tube 1502 and configured to be coupled to the manifold 1501. The connector 1530 can have a snap-fit arrangement with the openings 1507 of the manifold 1501. In some configurations, the connector 1530 can comprise a groove that is engaged by either one of the openings 1507 of the manifold 1501 and the thin wall section 1510 can facilitate the seal between the manifold 1501 and the connector 1530.

[0155] Figures 15E-G illustrate an alternative coupling arrangement between the supply tube 1502 and the manifold 1501, which incorporates an insert 1540 that facilitates the
connection between the supply tube 1502 and the manifold 1501. In some configurations, the manifold 1501 is constructed from a soft and/or stretchable material, which can increase comfort for the user. The insert 1540 can be constructed from a relatively stiff material, which preferably has greater stiffness than the material of the manifold 1501 such that the insert 1540 can be positioned within one or both openings 1507 of the manifold 1501 with a relatively tight fit therebetween. In some configurations, the manifold 1501 and the insert 1540 can create at least a substantial seal therebetween at least at the expected working pressures of the nasal cannula system 1500. The insert 1540 can include one or more interference features that secure the insert 1540 relative to the manifold 1501 via complementary interference features of the manifold 1501. For example, the insert 1540 can include at least one protrusion, and preferably a pair of opposed protrusions 1542, that engage recesses or openings 1544 of the manifold 1501. In the illustrated arrangement, the protrusions 1542 are button-head or mushroom-head protrusions having an enlarged head portion distal of a shaft portion relative to the body of the insert 1540. The openings 1544 can engage the shaft portion of the protrusions 1542 when the inserts 1540 are assembled to the manifold 1501. The soft and/or stretchable material of the manifold 1501 can assist in assembling of the inserts 1540 into the manifold 1501 and passing of the protrusions 1542 through the openings 1544.

[0156] The connector 1530 can be shaped or otherwise configured to engage the insert 1540 to securely connect the supply tube 1502 to the manifold 1501. In the illustrated arrangement, the connector 1530 comprises at least one interlocking member, such as a resilient arm portion 1546. Preferably, the connector 1530 comprises a pair of resilient arm portions 1546. Each arm portion 1546 includes an engagement protrusion 1548 that engages a portion (e.g., an end surface) of the insert 1540. The illustrated connector 1530 includes a cylindrical base portion 1550 between a flange 1552 and the arm portions 1546. The flange 1552 has an enlarged diameter or circumferential dimension relative to the base portion 1550 to define a shoulder 1554 that can abut the end surface of the insert 1540 opposite the end surface engaged by the protrusions 1548. Thus, a linear distance between the shoulder 1554 and the protrusion 1548 can be approximately equal to a length of the insert 1540. In some configurations, the arm portions 1546 can flex toward a central axis of the connector 1530 to
facilitate passage of the arm portions 1546 through the interior space of the insert 1540. Preferably, a length of the manifold 1501 and a length of the inserts 1540 are configured such that neither the inserts 1540 nor the shuttle object 1508 block the prongs 1505.

[0157] Figures 16A-F illustrate embodiments of a nasal cannula assembly with a manifold having a one way valve at each end. Similar to the embodiment discussed in Figure 15, Figures 16A-F illustrate a nasal cannula assembly 1600 having a manifold 1601 with nasal prongs 1605 in a central portion, a hollow cavity 1609, and inlets or openings 1607 on each side of the manifold 1601. A supply tube 1602 can be attached to either opening 1607 of the manifold 1601. However, instead of or in addition to a shuttle object (e.g., valve body 1508) to seal the hollow cavity 1609 at one opening 1607, a one way valve 1608 is used. In some embodiments, the one way valve 1608 is positioned at one opening 1607 of the hollow cavity 1609 of the manifold 1601 and the supply tube 1602 is positioned within the opening 1607 by being pushed through the one-way valve 1608 or positioned up against the one-way valve 1608. In certain embodiments, the opposite one way valve 1608 will remain sealed and therefore the flow of air or gas from the supply tube 1602 will be directed toward the nasal prongs 1605. In some embodiments, the one way valve 1608 can be molded into the manifold 1601. In other embodiments, the one way valve 1608 can be assembled as inserts configured to be inserted into the manifold 1601. In certain embodiments, the one way valve 1608 can also function as a pressure pop-off safety valve to release any excess pressure.

[0158] Figures 16A-F illustrate embodiments of a nasal cannula assembly 1600 with the manifold 1601 having a one way valve 1608 formed from an exhalation style valve with a loosely hinged flap 1608a (Figure 16E). In some embodiments, the supply tube 1602 can be inserted through the one-way valve 1608 as illustrated in Figure 16C, thereby holding the flap opens with the supply tube 1602. In some embodiments, the supply tube 1602 is placed up against the one way valve 1608 and the valve 1608 is held open by the air flow from the supply tube 1602 as illustrated in Figure 16D. The supply tube 1602 can be connected to the manifold 1601 directly or through any suitable connector, such as any of the connectors disclosed herein. The valve 1608 can have any suitable shape, such as circular (Figures 16A-E) or rectangular (Figure 16F).
[0159] Figures 16G-L illustrate embodiments of a nasal cannula assembly 1600 with a manifold 1601 having a one way valve 1608 formed from a slit valve of various shapes. Preferably, the one way valve 1608 comprises a stretchable material. In some embodiments, the one way valve 1608 can be a slit valve (Figures 16G and 16H), which in particular can be a duck-billed valve (Figure 16I and 16J), a joker or tricuspid valve (Figure 16K), a slit-dome valve (Figure 16L), and/or any other slit valve known in the art. The supply tube 1602 can be connected to the manifold 1601 by any suitable arrangement, either directly or via a connector 1630.

[0160] Figure 17 illustrates an embodiment of a nasal cannula assembly 1700 with a supply tube 1702 threaded through the manifold 1701 to allow for selective side switching of the exit side of the supply tube 1702 relative to the manifold 1701. In some embodiments, the supply tube 1702 can have a first end 1710 and a second end 1711. The first end 1710 and the second end 1711 can have a respective manifold insert 1712, 1713 attached thereto. The manifold inserts 1712, 1713 can each have one or more manifold insert openings 1714 (e.g., a pair of openings 1714 on opposing sides of the inserts 1712, 1713) extending along a length of the manifold insert 1712, 1713. In addition, each insert 1712, 1713 can include a pair of spaced-apart flanges 1716 positioned on opposite sides of the openings 1714 and configured to create at least a substantial seal with the manifold 1701. A recess 1718 is defined between the flanges 1716 such that air or gas communication between the openings 1714 and the nasal prongs 1705 is assured despite the location of the openings 1714.

[0161] In certain embodiments, the tube exit side can be selectively chosen by pushing or pulling the supply tube 1702 one way or the other to whichever side is desired. In some embodiments, when the supply tube 1702 is pulled or pushed to one side, the manifold insert 1712, 1713 on the opposite side seals against the manifold 1701 and the manifold insert 1712, 1713 on the side pulled through can be connected to the gas or air supply circuit. For example, if the supply tube 1702 is pulled through the manifold 1701 and the manifold insert 1712 is sealed against the manifold 1701, the opposite end manifold insert 1713 would be connected to the gas or air supply circuit (Figure 17B). Alternatively, if the tube 1702 is pulled through the manifold 1701 and the manifold insert 1713 is sealed against the manifold 1701, the opposite end manifold insert 1712 would be connected to the gas or air supply.
circuit. In some embodiments, to connect the supply tube 1702 to the circuit may require a connector or adapter 1715 so that the appropriate fitting can be achieved for connection to the humidifier or other gas or air supply. Additionally, in other embodiments, a proprietary connection is used to connect the supply tube to the gas or air supply circuit, thereby eliminating the need for an adapter or connector 1715. In some embodiments, the manifold insert opening 1714 can be lined up with the nasal prongs 1705 on the manifold when the manifold insert 1712, 1713 is positioned inside the manifold 1701. Additionally, in some embodiments, the manifold insert 1712, 1713 can be held in position with a locking mechanism once the supply tube 1702 is pulled through to the desired side of the manifold 1701. In some embodiments, the locking mechanism can include a twist lock, press fit, screw, or any other locking mechanism known in the art.

[0162] Figures 18A and 18B illustrate embodiments of a nasal cannula assembly with each tubing exit hole sealed by a thin membrane or other member that can be pierced. Similar to the embodiment described with reference to Figures 15A-G, Figures 18A and 18 illustrate nasal cannula assemblies 1800 having a manifold 1801 with nasal prongs 1805 in a central portion, a hollow cavity (not shown) and openings 1807 on each side of the manifold 1801. A supply tube 1802 can be attached to either opening 1807 of the manifold 1801. In some embodiments, the openings 1807 of the manifold 1801 are sealed by a thin membrane 1810. The thin membrane 1810 can be a film, pierceable membrane, or other pierceable material known in the art. In some embodiments, the connector or end portion 1811 of the supply tube 1802 comprises a piercing portion, such as a sharpened point 1812 that is capable of piercing the membrane 1810 at whichever opening 1807 of the manifold 1801 the supply tube 1802 is inserted. The sharpened point 1812 can be located in any suitable location, such as at or near a circumferential edge (Figure 18A) or at or near a center (Figure 18B). When the sharpened point 1812 is at or near the center, the end portion 1811 can define one or more openings 1814 to permit air or gas to pass through the end portion 1811. In certain embodiments, the user can choose the side in which the supply tube 1802 is positioned and can puncture the membrane 1810 on that opening 1807 with the end portion 1811 of the supply tube 1802. In some embodiments, the membrane 1810 is a single-use arrangement such that, once the membrane 1810 is pierced on one side, the membrane 1810 cannot be re-sealed.
However, in some embodiments, the membrane 1810 can be replaceable or resealable. In some embodiments, the end portion 1811 can contain one or more barbs to assist in piercing the membrane 1810 and/or securing the end portion 1811 within the manifold 1801. In some embodiments, the barbs or sharp section can be removed before the supply tube 1802 is inserted and the supply tube 1802 can be press fit into the opening 1807 of the manifold 1801. In some embodiments, the barbs or end portion 1811 can remain on the supply tube 1802 and can assist in securing the supply tube 1802 within the manifold 1801. In some embodiments, the end portion 1811 can have a cover to prevent injury to a user or damage to the end portion 1811 when not in use and ensure the end portion remains clean and sterile before use.

[0163] In some embodiments, the selective side switching of the manifold and prongs relative to the supply tube can be accomplished by manipulation of the supply tube. Figures 19A and 19B illustrate embodiments of a manifold 1901 with a flexible supply tube 1902 exiting an opening 1907 of the manifold 1901. In the illustrated arrangement, because the flexible supply tube 1902 is used for selective side switching, only one opening 1907 is provided. However, in other arrangements, two or more openings 1907 can be provided. In some embodiments, the supply tube 1902 attached to and/or exiting the manifold 1901 can be a highly flexible tube. The highly flexible tube can allow for the supply tube 1902 to be routed to either side of the face and away from the mouth. In some embodiments, a highly flexible tubing is used that can be bent around a zero radius without substantial kinking or at least without fully occluding the internal passage of the tube. Preferably, bending of the highly flexible tube does not cause substantial occlusion of the internal passage of the tube. In some embodiments, the highly flexible supply tube 1902 can exit from the front of the manifold 1901 and routed to either side of the patient without disassembling the nasal cannula assembly 1900 and/or without moving any of the nasal cannula assembly parts. In certain embodiments, the flexible supply tube 1902 can exit from the front of the manifold 1901 from the opening 1907 and can be bent at least about 90 degrees to either the left or right side of the face.

[0164] Further, in some embodiments, the manifold can be configured to be inserted into an assembly securing device in either direction allowing for the nasal cannula assembly to be used interchangeably with the tube coming from either the right side of the patient or the left side of the patient. Figures 20A-C illustrate an embodiment of a nasal
cannula assembly 2000 including a manifold 2001 that snaps into a manifold securing device or clip 2003. In some embodiments, the manifold 2001 can interchangeably switch sides on which the supply tube 2002 is positioned by allowing the manifold 2001 to be inserted into the clip 2003 in at least two different orientations. In some embodiments, the manifold 2001 and supply tube 2002 can be integrated into one manifold/tubing assembly 2004. For example, to change the direction from which the supply tube 2002 extends relative to the nose of the patient, the manifold/tubing assembly 2004 can be unclipped from the clip 2003, flipped around 180 degrees and then clipped back in. Two available orientations of the supply tube 2002 are illustrated in Figures 20A and 20B, respectively. The clip 2003 can be coupled to a retention arrangement, such as any suitable type of headgear strap 2040, including those disclosed herein or other suitable arrangements.

[0165] Additionally, in some embodiments, the manifold can be configured for use with a clip-on supply tube. For example, Figures 21A-D illustrate a nasal cannula assembly 2100 with a separable supply tube assembly 2102 and manifold 2101. In some embodiments, the nasal cannula assembly 2100 can comprise a manifold 2101 that includes prongs 2105 and two openings 2107 at each end of the manifold 2101. In some embodiments, the manifold 2101 can be connected to a supply tube assembly 2111. In some embodiments, the supply tube assembly 2111 can include a supply tube 2102 and a manifold receiving structure 2112. The manifold receiving structure 2112 can be assembled to the supply tube 2102 at the time of manufacture or can be connectable to the supply tube 2102 prior to use. In certain embodiments, the manifold receiving structure 2112 can be a ‘C’ shaped manifold receiving structure or clip 2112 as illustrated in Figure 21A-D or the manifold receiving structure 2112 can have any shape that allows for complimentary coupling to the manifold 2101. In some embodiments, the manifold 2101 has a complimentary shape or matching shape to receive the manifold receiving structure 2112 which can either be slid onto, clipped onto, or otherwise attached through any means known in the field to the manifold 2101 with the supply tube 2102 positioned facing either way as desired. In certain embodiments, the manifold receiving structure 2112 can have location and/or sealing details 2113 incorporated on the inside of, or elsewhere on, the manifold receiving structure 2112 to ensure a secure connection and/or a proper seal with the manifold 2101. In some configurations, the sealing detail 2113 is a
protrusion, such as a spherical protrusion. The sealing detail 2113 preferably seals one of the openings 2107 and the end portion 2130 of the supply tube 2102, which can be defined by the manifold receiving structure 2112 or can be a separate component, engages the other opening 2107. The end portion 2130 can rest against and be flush with an outer surface of the manifold 2101 that surrounds the opening 2107 (Figure 21C) or can extend into the opening 2107 (Figure 21D).

[0166] In some embodiments, one or more stops 2104 can be molded into, or otherwise secured to, the manifold 2101 to inhibit or prevent downward movement of the manifold receiving structure 2112 when pulled during use. For example, as shown in Figure 21A, a pair of stops 2104, each defining a stop surface, can be formed on each side of the manifold 2101. In some embodiments, the manifold receiving structure 2112 can be slid upwardly relative to the manifold 2101 for removal and flipping of the tubing side. In some configurations, as shown in Figure 21E, portions of the manifold receiving structure 2112, such as end portions 2116, can engage complementary portions, such as recesses 2118, of the manifold 2101 to assist in securing the manifold receiving structure 2112 to the manifold 2101. As shown in Figure 21F, the manifold 2101 can include a recessed portion 2120 that is sized and shaped to receive the manifold receiving structure 2112. The recessed portion 2120 can be located on the forward and lateral portions of the manifold 2101 and can have a depth suitable to accommodate an entirety of the thickness of the manifold receiving structure 2112, such that an outward-facing surface of the manifold receiving structure 2112 is flush with or recessed within the outer surface of the manifold 2101. Such an arrangement assists in securing the manifold receiving structure 2112 to the manifold 2101 and/or can inform the user how to correctly locate and secure the manifold receiving structure 2112 to the manifold 2101. The recessed portion 2120 can be utilized separately or in combination with the recesses 2118.

[0167] Figures 21G and 21H illustrate an embodiment of a nasal cannula assembly 2100 having a manifold receiving structure 2132, a separate nasal prong insert 2125 and a manifold 2121. In some embodiments, the manifold 2121 can have no prongs and an opening 2126 in the manifold 2121 to communicate with the prong insert 2125. The prong insert 2125 can be formed with prongs 2105 of different sizes so that the appropriate sized prongs 2105
can be selected for different nose sizes and ensure correct prong sizing for the patient. In some embodiments, the manifold 2121 and the prong insert 2125 can be connected with a manifold receiving structure 2132, such as a C-shaped clip, for example. In some embodiments, the manifold receiving structure 2132 can be used to hold the prong insert 2125 in place and will complimentarily fit the manifold 2121. Thus, the manifold receiving structure 2132 can include one or more openings 2128 that accommodates the prongs 2105. The manifold 2121 can include a recess 2134 surrounding the opening 2126 and that accommodates a base of the prong insert 2125. The manifold 2121 can also include recessed portions 2136 on lateral sides thereof configured to accommodate the manifold receiving structure 2132 and assist in securing the manifold receiving structure 2132 to the manifold 2121. Although in the illustrated arrangement the opening 2126 is positioned on an upper surface of the manifold 2121, the opening 2126 could be positioned on other portions (e.g., a forward surface) of the manifold 2121 in addition or in the alternative.

[0168] Figures 22A-D illustrate an embodiment of a nasal cannula assembly 2200 having a manifold insert 2201 and a manifold receiving structure 2210. In some embodiments, the manifold insert 2201 can include prongs 2205 and an opening 2207 on each end of the manifold insert 2201. The manifold insert 2201 can be made of a soft or flexible material. The prongs 2205 on the manifold insert 2201 can be flexible or stiff. In some embodiments, the manifold insert 2201 can be inserted into a manifold receiving structure 2210. In some embodiments, the manifold receiving structure 2210 can be attached to or integrated with an assembly securing device 2203, such as a headgear strap. The manifold receiving structure 2210 has one closed end 2213 and one open end 2214. In some embodiments, the manifold receiving structure 2210 can be attached to a supply tube 2202 on the open end 2214 side of the manifold receiving structure 2210 allowing for the passage of air or gas. In some embodiments, the manifold insert 2201 can be clipped or slid into the manifold receiving structure 2210. In some embodiments, the manifold receiving structure 2210 can have a round or spherical boss or protrusion 2211 at one end 2213 of the manifold receiving structure 2210 which can provide an effective radial seal with one opening 2207 of the manifold insert 2201 and assist in holding the manifold insert 2201 in place. The other end 2212 can include a connector 2214 that can be unitary with or separate from the supply tube 2202 and engage the
other opening 2207 of the manifold insert 2201. In some embodiments, once the manifold insert 2201 is placed within the manifold receiving structure 2210, the manifold insert 2201 and/or the prongs 2205 can be turned or tilted to the correct comfort configuration for the user. For example, in some embodiments, to flip the tubing side, the manifold insert 2201 is removed and the remainder of the nasal cannula assembly, including the manifold receiving structure 2210, the assembly securing device 2203, and/or the supply tube 2202, is flipped around so that the supply tube 2202 faces the desired direction, and then the manifold insert 2201 with prongs 2205 are re-assembled to point back toward the nose of the patient.

[0169] Figures 23A-C illustrate an embodiment of a nasal cannula assembly with a manifold receiving structure or cannula that can be clipped over a supply tubing assembly, which includes a manifold. In some embodiments, the nasal cannula assembly 2300 includes a supply tube assembly 2311, which comprises a manifold 2301 and a supply tube 2302. The nasal cannula assembly 2300 also includes a manifold receiving structure or cannula 2310, which comprises a pair of prongs 2305. The supply tube 2302 connects the manifold 2301 to an air or gas supply circuit. In some embodiments, the manifold receiving structure 2310 can be a generally tubular member with an opening or slot 2313 extending partially or completely along its length to form a ‘C’ shaped section which can be clipped over the manifold 2301. In some embodiments, the manifold 2301 can have a ledge or rib 2312 that is complementary with the opening or slot 2313 of the ‘C’ shaped manifold receiving structure 2310 such that the rib 2312 can be received in the slot 2313. Advantageously, such an arrangement assists in securing or locking the manifold receiving structure 2310 in place on the manifold 2301. In some embodiments, the supply tube assembly 2311 can be attached to or integrated within an assembly securing device 2303, such as a headgear strap. For example, in some embodiments, to reverse the direction of the supply tube 2302, the manifold receiving structure 2310 is removed or unclipped from the manifold 2301, flipped around and reconnected so that the supply tube 2302 faces the desired direction.

[0170] Figures 24A-F illustrate embodiments of flexible, tilting or directionally-adjustable prongs and embodiments of a nasal cannula assembly 2400 having such flexible, tilting or adjustable prongs 2405. With such prongs 2405, the exit side of the supply tube
2402 can be changed by simply adjusting the direction of the prongs 2405 and rotating the manifold/tubing assembly 2404 by 180 degrees on the patients face.

[0171] With reference to Figures 24A-C, in certain embodiments, the prongs 2405 can be flexed to the side of the manifold 2401 desired for use. In particular, the prongs 2405 can be formed with a ripple shape around the base of the prong 2405. Figures 24B and 24C illustrate an embodiment of a prong 2405 formed with a ripple shape 2408 around the base to allow for flexibility of the prong 2405. In some embodiments, the ripple shape 2408 comprises at least one and, preferably, multiple ripples. In the illustrated arrangement, two ripples are provided; however, in other embodiments, three or more ripples can be provided. The ripples are illustrated as being annular in shape and having a semi-circular cross-section. The ripples can have a reduced wall thickness relative to a portion of the manifold 2401 adjacent the ripples or can have the same or a similar wall thickness. The ripple shape 2408 allows the prong 2405 to be shaped in whichever direction is desired for use. In some embodiments, the prongs 2405 could have a ripple shape 2408 around the base which allows them to tilt in any direction. In certain embodiments, the prong 2405 can have a thickened section(s) or stiffening rib(s) 2407 to make the prong favor certain tilting directions, thereby allowing the prong 2405 to bend in a first direction but inhibiting or preventing the prong 2405 from bending in a second direction, which may be substantially perpendicular to the first direction. In the illustrated arrangement, two stiffening ribs 2407 are provided on each side of each prong 2405 and extend in a substantially radial direction relative to the prong 2405.

[0172] Figures 24D-F illustrate an embodiment of prongs 2405 comprising a collapsible corrugated concertina section, which can define a portion or a substantial entirety of a length of the prongs 2405. Preferably, the formation of the prongs 2405 with such geometry allows the prongs 2405 to be bent in any direction and hold that shape. In some embodiments, the prong 2405 can be compressed and extended to vary a length of the prong 2405, as illustrated in Figures 24D and 24E. In some embodiments, the prong 2405 can be expanded from the compressed shape and bent to the desired direction or shape, as illustrated in Figure 24F. For example, in certain embodiments, the prongs 2405 are packaged in the compressed form and are then expanded and bent as configured by a caregiver or the user to the appropriate direction and shape.
In some embodiments, the nasal cannula assembly can contain rotating prongs. Figures 25A-C illustrate embodiments of a nasal cannula assembly 2500 with rotating prongs. In some embodiments, the nasal cannula assembly 2500 can be flipped to change the side of the supply tube 2502, and then the prongs 2505 can be rotated to face the appropriate orientation toward the nose of the patient. Figure 25A illustrates an embodiment of a nasal cannula assembly 2500 that includes individually rotatable prongs 2505. In some embodiments, the prongs can rotate freely in a clockwise or counterclockwise direction relative to the manifold 2505. In some embodiments, the prongs 2505 can rotate to a limited degree when the manifold 2501 and prongs 2505 are constructed as a unit.

Figures 25B and 25C illustrate an embodiment of a nasal cannula assembly 2500 that comprises a prong insert 2506 having a pair of prongs 2505. Preferably, the prong insert 2506 is rotatable relative to the manifold 2501. The illustrated prong insert 2506 is mounted on and rotatable about a vertical shaft 2508 such that the prongs 2505 rotate together. In some embodiments, the prong insert 2506 is a separate component from the manifold/tubing assembly 2504 and the removable prong insert 2506 can allow for the use of different sizes of prongs 2505 for different nose sizes while using a single size manifold 2501. Additionally, in some embodiments, the manifold 2501 can have a lip 2510 on a surface of the manifold 2501 to which the prong insert 2506 connects. The prong insert 2506 can have a mating section 2511 that is complementary to the lip 2510. In some embodiments that contain a lip 2510 on the manifold 2501, the prong insert 2506 can be lifted from the surface of the manifold 2501 and rotated about the vertical shaft 2508 so that the prongs 2505 can be repositioned to the appropriate direction. The prong insert 2506 can be rotatable about a vertical, central axis of the manifold 2501 or an axis that is centrally located relative to openings 2518 in the manifold 2501 that communicate with the nasal prongs 2505, as shown in Figure 25B, such that the prongs 2505 switch openings 2518 between the two orientations.

In some embodiments, the manifold can have a prong exit hole in the midsection of the manifold configured to receive an insert or clip-on attachment including the prongs. Figures 26A-F illustrate an embodiment of a nasal cannula assembly 2600 configured to allow insertion of a removable prong insert 2606. In some embodiments, the prong insert 2606 can be pushed into an opening 2607 in the hollow manifold 2601. This allows the prongs...
2605 to be configured in the appropriate direction for use by the patient in the same manifold 2601 and/or manifold/tube assembly 2604. The manifold 2601 and/or manifold/tube assembly 2604 can be connected to an assembly securing device 2603, such as a headgear strap. For example, in some embodiments, the supply tube 2602 and manifold 2601 are assembled with the securing device 2603 and the nasal prongs 2605 are carried by the removable nasal prong insert 2606. The manifold/tube assembly 2604 and the assembly securing device 2603 can be symmetrical so it can be assembled to the face in one direction (e.g., Figure 26B) or an opposite direction (e.g., Figure 26C). In some embodiments, the assembly securing device 2603 and the manifold/tube assembly 2604 can be flipped around to suit whichever direction the supply tube 2602 is desired to be positioned. For example, in certain embodiments, to switch the side the supply tube 2602 is positioned, the nasal prong insert 2606 is removed and the remainder of the manifold/tube assembly 2604 is flipped around so that the supply tube 2602 faces the desired direction, and the nasal prong insert 2606 is then reinserted into the receiving opening 2607 of the manifold/tube assembly 2604 in the proper orientation to point toward the nose of the patient. Further, the nasal prong insert 2606 can be of different sizes (Figures 26D-F) and the different size inserts can be interchanged on the same assembly 2604 for use and adaptation for different patient nose sizes and to ensure correct prong sizing for the patient.

[0176] In some embodiments, a nasal cannula assembly can comprise a manifold, supply tube and a cannula that is removable from the manifold and/or adjustable about at least one axis relative to the manifold. The cannula can be adjustable about two axes relative to the manifold and can be available in different prong sizes to allow the assembly to fit a variety of patients. In particular, with reference to Figures 27A-D, a nasal cannula assembly 2700 includes a pivoting cannula 2714, which preferably incorporates a pair of nasal prongs 2705. The cannula 2714 is pivotally coupled to a moulding (head strap moulding) or manifold 2701, which can include side portions 2722 that extend in opposing lateral directions from the cannula 2714. A suitable retention assembly (not shown), such as a headgear strap, can secure the manifold 2701 and cannula 2714 to the patient. In some arrangements, the headgear strap is an elastic, high-stretch strap, which can assist in or improve the seal between
the manifold 2701 and the cannula 2714. The headgear strap can be unitary with, integral with, or separate from the manifold/moulding 2701.

[0177] Preferably, the manifold 2701 defines a conduit or passage 2709 that allows air or gas to pass from a supply tube 2702 to the cannula 2714. The passage 2709 can be defined by a molding from which the manifold 2701 and side straps 2722 are constructed (e.g., a single integrated structure) or can be defined by a separate member. The supply tube 2702 can be coupled to the manifold 2701 by any suitable arrangement, such as a jaw expander arrangement or any other arrangement disclosed herein. A clip 2742 can secure the supply tube 2702 to the side strap 2722. An end of the supply tube 2722 opposite the manifold 2701 can include a connector 2752, which permits coupling of the supply tube 2722 to an air or gas source.

[0178] In some embodiments, the cannula 2714 can be rotated relative to the manifold 2701 about an axis that extends in a generally fore-aft direction or a generally horizontal axis that lies in the sagittal plane. Preferably, the cannula 2714 can be rotated at least 180 degrees such that the prongs 2705 can be rotated from the top (the orientation of Figure 27A) to the bottom, which provides an effective change of the supply tube 2702 exit side. In some embodiments, the cannula 2714 is coupled to the manifold 2701 by a ball-and-socket joint 2726 such that the cannula 2714 is also rotatable about an axis that extends in a generally lateral direction or a generally horizontal axis that lies in the frontal plane. Such an arrangement not only provides a simple change of the supply tube 2702 exit side, but also allows adjustment of the nasal prong 2705 orientation relative to the manifold 2701 to increase patient comfort and/or fit a wider variety of patients.

[0179] In some embodiments, a size of the prongs 2705 is adjustable. For example, as shown in Figures 27B and 27C, the ball joint portion 2730 can be separable from a prong portion 2732 of the cannula 2714. Several prong portions 2732 can be included in a kit or can be otherwise made available that provide several different sizes of nasal prongs 2705. For example, three different prong portions 2732 are shown in Figure 27C, which include three differently-sized prongs 2705. An appropriate or desired one of the available prong portions 2732 can be coupled to the ball joint portion 2730, such as via a snap-fit or other suitable arrangement. Alternatively, two or more complete cannulas 2714 can be
provided, each with different size prongs 2705. Accordingly, with such an arrangement, the cannula 2714 could be constructed as a single piece.

[0180] However, it is not necessary that the cannula 2714 be rotatable in multiple axes, or even rotatable through an arc. Instead, the cannula 2714 can have discrete adjustment positions relative to the manifold 2701. Preferably, at least the position shown in Figure 27A and the 180 degree rotation of the cannula 2714 are provide such that the exit side of the supply tube 2702 can be switched. If desired, other discrete position options can be provided. The cannula 2714 and manifold 2701 could include interference surface features to assist in securing the cannula 2714 in a desired position relative to the manifold 2701. For example, as shown in Figure 27D, the cannula 2714 could include one or more teeth 2760 or other protrusions that engage corresponding recesses of the manifold 2701. In the illustrated arrangement, the cannula 2714 includes multiple teeth 2760 on each lateral side of the ball joint 2726, which can extend in a radial direction relative to the ball joint 2726. Other suitable arrangements can also be employed.

[0181] In some embodiments, as shown in Figure 28A, a nasal cannula assembly 2800 includes a manifold 2801 that is capable of being coupled to a cannula 2814 in at least two orientations to allow a simple switching of the exit side of the supply tube 2802. The cannula 2814 can include a central portion that includes prongs 2805 and side portions 2822 on each lateral side of the central portion. The manifold 2801 can include side portions 2812 that overlap with the side portions 2822 of the cannula 2814. The side portions 2812 and 2822 can facilitate a secure connection between the manifold 2801 and the cannula 2814. For example, the side portions 2812 or 2822 of one or both of the manifold 2801 and the cannula 2814 can include couplers or coupling mechanisms that couple or assist in coupling the manifold 2801 and the cannula 2814. In the illustrated arrangement, the side portions 2812 include a first component 2830 of a coupler (e.g., a hook and loop fastener) and the side portions 2822 of the cannula 2814 includes a second component 2832 of a coupler (e.g., a hook and loop fastener). One or both of the side portions 2812 of the manifold 2801 include a tab 2850 that provides a finger grip surface to facilitate removal of the manifold 2801 from the cannula 2814. In addition, one or both of the side portions 2812 can include flex slots 2828 to facilitate flexing of the side portions 2812, which can assist in removal of the manifold.
2801 from the cannula 1814 and can also facilitate the manifold 2801 conform to the shape of
the cannula 2814.

[0182] The manifold 2801 and the cannula 2814 can include cooperating
structures that create a seal between the two components. For example, the manifold 2801
can include a protruding portion 2860 that defines a cavity in communication with the supply
tube 2802 and includes at least one and preferably a pair of openings 2862 that allow air or
gas communication with the prongs 2805 when the manifold 2801 is assembled to the cannula
2814. The protruding portion 2860 engages an opening 2864 of the cannula 2814 and,
preferably, defines at least a substantial seal therewith. The seal can be created by contact or
engagement (e.g., a lip and groove) between the protruding portion 2860 and the opening
2864 or a separate sealing member (e.g., a perimeter seal or O-ring) can be used.

[0183] A securement device, such as a headgear strap 2840 can be used to secure
the cannula 2814 and, thus, the manifold 2801 to a patient. In some embodiments, the
headgear strap 2840 is a non-stretch strap that is coupled to the side portions 2822 of the
cannula 2814. The ends of the headgear strap 2840 can be heat-welded to the side portions
2822 and can include the second components 2832 of the coupler between the manifold 2801
and the cannula 2814. The headgear strap 2840 can include a suitable adjuster 2842 that
permits a circumference of the strap 2840 to be adjusted. In other arrangements, a stretchable
headgear strap 2840 can be used.

[0184] With reference to Figure 28B, the cannula 2814 can be of a composite
construction and include a frame member 2870 constructed from a relatively rigid material and
a body 2872 constructed from a relatively soft material. For example, the frame 2870 can be a
rigid plastic or a metal material, which may be deformable and substantially hold its shape
once deformed. The frame 2870 can be external of the body 2872 or the body 2872 can be
molded over the frame 2870. Preferably, the frame 2870 is located in the side portions 2822
of the cannula 2814 and can be formed to bridge the central portion containing the prongs
2805 away from the nose to reduce the pressure just below the nose and spread the pressure
applied to the patient over the side portions 2822 for increased comfort. The frame 2870 can
also surround or partially or completely define the opening 2864 instead of or in addition to
extending into the side portions 2822.
With reference to Figure 29A, in some embodiments of a respiratory assistance system utilizing a nasal cannula system 2900 it is desirable to be able to measure the pressure in the flow path near the patient (e.g., at or near the cannula or manifold 2901) for at least one or both of 1) monitoring of the pressure delivered to the patient and 2) pressure feedback control of a blower flow source (e.g., blower and humidifier 2990). Figure 29A illustrates a basic arrangement for providing pressure feedback control. In particular, a pressure line 2910 connects the manifold 2901 (or manifold/cannula assembly – hereinafter "manifold") to a flow source control system, which can be a part of the blower/humidifier 2990. With such an arrangement, the flow source 2990 can utilize the information regarding the pressure at or near the manifold 2901 provided by the pressure line 2910 in the operation of the flow source 2990, such as to adjust the supplied pressure to achieve a desired delivered pressure at the patient. Advantageously, this arrangement can compensate for factors that may cause the delivered pressure to be different than expected, such as supply tube 2902 length, cross-sectional area or other geometry, for example. If only pressure monitoring was required or desired, the pressure line 2910 could be connected to a pressure gauge or readout instead.

With reference to Figure 29B, the pressure line 2910 can be passed through a wall of the manifold 2901 and terminated within a manifold space of the manifold 2901. In the illustrated arrangement, a terminal end 2912 of the pressure line 2910 is perforated with a number of holes 2914 so that if some of the holes 2914 are blocked with condensation, there are other holes 2914 still functioning such that the pressure within the manifold 2901 can be communicated to the pressure source 2990. The terminal end 2912 of the pressure line 2910 can be positioned anywhere within the manifold 2901, such as between the supply tube 2902 and the prongs 2905 along a flow path of the supplied air or gas, for example but without limitation.

With reference to Figure 29C, the pressure line 2910 can permit direct or indirect communication between the manifold 2901 and the pressure source 2990. The arrangement of Figure 29C separates the manifold chamber 2909 of the manifold 2901 from a pressure chamber 2916 that is in direct communication or is directly sensed by the pressure line 2910. For example, a thin flexible diaphragm seal 2918 (or other movable membrane or
member, such as a floating or sliding piston) separates the manifold chamber 2909 from the pressure chamber 2916, which prevents condensate from entering the pressure line 2910 and keeps the pressure line 2910 clean.

[0188] With reference to Figure 29D, the pressure line 2910 can comprise a pressure sensor 2930, which can sense pressure within the manifold chamber 2909. The pressure sensor 2930 can be located within the manifold 2901, such as being configured as a plug that engages and/or closes one end of the manifold 2901. In some embodiments, a separator, such as a wall or membrane 2918 is positioned between the pressure sensor 2930 and the manifold chamber 2909. The membrane 2918 can be of any suitable type, such as an ultra-thin silicone membrane. The pressure sensor 2930 can be of any suitable type, such as an electrical pressure sensor. The pressure sensor 2930 can be pushed up against the membrane 2918, which can conform to the shape of the pressure sensor 2930, to measure the pressure without directly contacting the flow of air or gas, thus avoiding condensate accumulating on the pressure sensor 2930. In addition, with such an arrangement, the membrane 2918 can be constructed to close and seal the end of the manifold 2901 such that the nasal cannula assembly 2900 can be used with or without the pressure sensor 2930.

[0189] With reference to Figure 29E, the membrane 2918 can be a self-sealing slit valve through which the pressure line 2910 and/or the pressure sensor 2930 could be inserted, if desired. Advantageously, self-sealing slit valve 2918 can close in the absence of the pressure line 2910 and/or pressure sensor 2930 such that there would be no substantial leaking if it was removed. Therefore, the nasal cannula assembly 2900 could function with or without the pressure line 2910 and/or pressure sensor 2930.

[0190] With reference to Figure 29F, the pressure line 2910 and the supply tube 2902 can be integrated into one connector 2931 that is connectable to the manifold 2901 to permit connection of both the pressure line 2910 and the supply tube 2902 at one time. Advantageously, such an arrangement simplifies set up of the nasal cannula assembly 2900 by avoiding the need to connect multiple tubes or components to the manifold 2901.

[0191] With reference to Figure 29G, the pressure line 2910 can be connected as an optional accessory in series with the supply tube 2902. The pressure line 2910 can include a plug portion 2932 that connects to the manifold 2901 and the supply tube 2902 can connect
to the plug portion 2932. Alternatively, with reference to Figure 29H, the pressure line 2910 can be connected as an optional accessory separately from the supply tube 2902, such as on an opposite side of the manifold 2901 from the supply tube 2902. The pressure line 2910 can have a plug portion 2932 that replaces a plug 2934 of the manifold 2901.

[0192] With reference to Figure 29I, a small blower 2940 or other source of air or gas flow can be connected to the pressure line 2910 to apply a small flow of air or gas through the pressure line 2910 preferably sufficient to expel some or all of any condensate which accumulated inside the pressure line 2910. The flow of air through the pressure line 2910 can be provided intermittently or continually and can be considered by the control system in the calculation of the pressure within the manifold 2901.

[0193] With reference to Figure 29J, a thin flexible diaphragm seal 2918 (or other movable barrier) can separate the manifold chamber 2909 from the pressure measurement chamber 2916 to inhibit or prevent condensate from entering the pressure line 2910 and keep the pressure line 2910 clean. If the pressure measurement feature is not utilized and, thus, the pressure line 2910 is not needed, an opening or port 2942 of the manifold 2901 that receives the pressure line 2910 can be left open and can function as a vent to the pressure measurement chamber 2916. Alternatively, the port 2942 can be closed if desired, such as be a suitable plug.

[0194] In some embodiments, with reference to Figure 29K, for example, electrical wiring 2944 is incorporated into the spiral bead 2946 of the supply tube 2902. The electrical wiring 2944 can connect to an electrical pressure sensor 2930 mounted in the manifold 2901. The wiring 2944 (or additional wiring) could also be used to heat the supply tube 2902. In some arrangements, the wiring 2944 can switch between measuring pressure & temperature readings, and heating.

[0195] With reference to Figure 29L, the spiral reinforcement 2946 of the supply tube 2902 can be made hollow or otherwise contain a passage to act as a pressure line (similar to pressure lines 2910 disclosed herein). With such an arrangement, no additional pressure line (e.g., 2910) would need to be used. The spiral reinforcement 2946 could connect at one end to the chamber of the manifold 2901 and at the other end to the operating system of an air or gas source, or a pressure monitor or gauge 2948.
In some embodiments, the nasal cannula assembly includes features that improve patient comfort. Discomfort can exist for some patients using some nasal cannula assemblies. For example, two types of discomfort include: 1. a hot, damp, clammy feel of the cannula/manifold in contact with the skin on the upper lip, which may be caused by moisture originating from perspiration and the circulation of warm humidified gases in this area, and 2. pain and numbness associated with the pressure applied to the upper lip by the cannula/manifold. Some embodiments of a nasal cannula assembly 3000 address one or both of these types of discomfort to at least some degree.

With reference to Figure 30A, holes, recesses or depressions 3020 of any desired shape can be cut into or otherwise formed in the cannula or manifold (hereinafter "cannula") material, which allow fresh air to reach the skin helping to keep the area cool and reducing the buildup of moisture. In some embodiments, the holes, recesses or depressions 3020 are cut into or formed in areas that do not cause leakage of the therapy air flow from the cannula 3014. For example, the holes, recesses or depression 3020 are provided in the side portions 3022 of the cannula 3014 and not in the central portion that contains the prongs 3005. In the illustrated arrangement, holes 3020 that pass completely through the side portions 3022 of the cannula 3014 are provided. The holes, recesses or depressions 3020 can also improve flexibility of the cannula 3014, allowing it to conform more easily to the shape of the patient’s lip and distribute pressure more evenly for improved comfort.

With reference to Figure 30B, the cannula 3014 could also include small raised bumps or protrusions 3030 on the rear or patient-facing surface of the cannula 3014. The bumps 3030 hold some or all of the remaining rear or patient-facing surface of the cannula 3014 away from the lip of the patient, allowing fresh air to reach the skin, helping keep the area cool and reducing moisture buildup. The bumps 3030 can be provided over an entirety of the rear surface, as shown, or over only a portion of the rear surface, such as the side portions 3022 similar to the cannula 3014 of Figure 30A, for example.

With reference to Figure 30C, grooves 3040 can be cut into or otherwise formed in the rear surface of the cannula 3014. The grooves 3040 allow fresh air to reach the skin, helping keep the area cool and reducing moisture buildup. In some embodiments, the grooves 3040 extend in a generally vertical direction or perpendicular to the lateral direction.
of the cannula 3014. In addition, the grooves 3040 can extend partially through the cannula 3014 such that one end is closed or can extend completely through the cannula 3014 such that both ends are open, as shown in Figure 30C. The grooves 3040 can also improve flexibility of some portions (e.g., side portions 3022) or all of the cannula 3014, allowing it to conform more easily to the shape of the patient's lip and distribute pressure more evenly for improved comfort.

[0200] With reference to Figures 30D-H, in some embodiments, the cannula 3014 can include a cannula lip bridge arrangement in which the cannula 3014 is shaped so that it curves away from the face at the upper lip, reducing pressure or completely avoiding any contact with the upper lip thereby resulting in improved circulation of fresh air in the area, and reduced (e.g., little or none at all) pressure on the lip. The pressure is instead is applied by the side portions 3022 and absorbed by the cheeks, which are less sensitive to pressure. In some arrangements, the prongs 3005 are reverse mounted horizontally on the inside of the cannula 3014 and are curved up into the nares. This design has the additional benefit of allowing clearance for a moustache.

[0201] Preferably, such embodiments of the cannula 3014 have some rigidity, which can be accomplished by any suitable construction or arrangement, such as using a stiffer material for the cannula 3014 (Figures 30D-F), reinforcing ribs, or a structural member such as an internal (Figure 30G) or external (Figure 30H) wire or strip 3050, which could be malleable for adjustment to suit individual patients. The cannula 3014 can be of any suitable arrangement, such as having and integrated or directly-connected supply tube 3002 or by utilizing a manifold 3001 connected to the supply tube 3002 and received within the cannula 3014, for example.

[0202] With reference to Figure 30I, in some embodiments, a comfort pad or insert 3060, such as a gel pad or other type of pad can be provided on the rear or patient-facing surface of the cannula 3014. At least the rear surface of the cannula 3014 in contact with the patient's upper lip can be made of a soft gel material or can include a soft gel pad 3060 that, in some arrangements, moulds to the shape of an individual patient's lip to create a relatively large contact surface area to evenly distribute pressure across the skin. The pad 3060 can deform as the headgear strap or other retention mechanism (not shown) is tightened.
to accommodate a patient's facial geometry and prevent the occurrence of localized areas of pressure. The pad 3060 preferably occupies a substantial portion, such as substantially an entirety, of the rear surface. The pad 3060 could be scented to make the odor of the cannula 3014 more pleasing.

[0203] In some embodiments of a nasal cannula assembly, the supply tube can be manually shaped or positioned and remain in that shape or position or substantially in that shape or position. One of the major benefits of some nasal cannula assemblies, such as the Optiflow nasal cannula assemblies sold by Fisher & Paykel Healthcare Ltd., is to be able to eat, drink and talk while on therapy. In some cases, the shape or position of the supply tube exiting the cannula can inhibit these activities. Thus, in some embodiments, it may be desirable to be able to shape or position the supply tube as desired. Any suitable arrangement or technique can be used to allow shaping or positioning of the tubing, such as those described herein with reference to Figures 31A-F.

[0204] With reference to Figures 31A and 31B, the supply tube 3102 can comprise an internal axial malleable wire or strip 3150. The supply tube 3102 can be assembled or formed with the internal axial malleable wire or strip 3150 that can be deformed into a variety of shapes. Preferably, the stiffness of the wire is significantly greater than the stiffness of the supply tube 3102, such that the shape is retained or substantially retained after forming. The wire or strip 3150 may be contained within, formed within or otherwise coupled to the supply tube 3102 in any suitable manner. For example, as shown in Figure 31A, the wire or strip 3150 can be embedded into the wall of the supply tube 3102 external of a supply passage of the supply tube 3012. Alternatively, as shown in Figure 31B, the wire or strip 3150 can be provided within the supply passage or bore of the supply tube 3102. In such an arrangement, it may be desirable to construct the wire or strip 3150 from, or coat the wire or strip 3150 with, a suitable (e.g., inert) material to tolerate or be suitable for contact with the supplied air or gas. With reference to Figure 31C, the wire or strip 3150 may be a malleable spiral wound wire or strip wound around the circumference of the supply tube 3102, such as in a helical manner. The wire or strip 3150 can be covered or contained within another material (e.g., plastic) to form a bead 3152. The bead 3152 could give the tube structure (e.g., a reinforcement bead) as well as being shapeable or formable and retaining, or at least
substantially retaining, the adjusted shape or form of the supply tube 3102. Advantageously, with such an arrangement, the bead spiral 3152 wound around the outside of the supply tube 3102 keeps it out of the air or gas path.

**[0205]** With reference to Figures 31D and 31E, the supply tube 3102 can be in the form of a collapsing corrugated tube having a section or a substantial entirety of collapsing corrugations 3160 that could be used to set one or both of the length and position of the supply tube 3102, as desired. The corrugations 3160 can be manufactured such that when the supply tube 3102 is compressed in a length or axial direction, the corrugations 3160 would each fold into themselves. Figure 31D illustrates the supply tube 3102 in a axially compressed orientation and Figure 31E illustrates the supply tube 3102 in an axially uncompressed or elongated position. The supply tube 3102 can be coupled to the cannula 3114 by any suitable arrangement, such as directly or via a suitable connector. With reference to Figure 31F, alternatively, the supply tube 3102 can include a section or a substantial entirety that is constructed as a ball-and-socket chain. In particular, at least a section of the supply tube 3102 is constructed from a plurality of individual segments or members 3162 or similar that together form a sealed or substantially sealed, yet positionable or formable tube. Preferably, one end of each segment 3162 comprises a ball end 3164 and the other end comprises a socket 3166. Accordingly, a plurality of segments 3162 can be assembled with the ball end 3164 of one segment 3162 positioned within the socket 3166 of the adjacent segment 3162. In some arrangements, the fit of the ball end 3164 into the socket 3166 can be such that each segment 3162 can rotate or move relative to an adjacent segment 3152, yet provide enough frictional force to seal or substantially seal and remain in position or substantially within position once adjusted. If desired, an additional structure or arrangement can be used to hold the segments 3162 in an assembled state or assist in holding or sealing the segments 3162, such as a sleeve that extends over the segments 3162. Advantageously, these and similar embodiments can allow the supply tube 3102 to be positioned out of the patient’s way to reduce or minimize disruption to eating, drinking and talking while on the therapy.

**[0206]** In some existing nasal cannula assemblies, the supply tube hangs down from its attachment point to the cannula or manifold, which is often just above the corner of the mouth. Such an arrangement can cause, among other issues, the supply tube to hang very
close to the mouth, which can be a nuisance to the patient, as it interferes with eating, drinking and talking. In addition, the weight of the supply tube hanging down so close to the nose tends to drag one side of the cannula or manifold down, pulling it out of the nose. This is especially true in high flow therapies, which require a relatively large supply tube that cannot be comfortably routed behind the patient’s ears, as is the case with smaller low-flow systems. Accordingly, some embodiments route the supply tube to exit the nasal cannula assembly further away from the nose and/or mouth of the patient, to partially or completely address the two issues described above.

With reference to Figures 32A-C, one portion 3250 of a coupler, such as hook-and-loop fastener, is provided on the supply tube 3202 of a nasal cannula assembly 3200. For example, the portion 3250 can be a sheath of hook-and-loop material. The sheath 3250 can be coupled to the supply tube 3202 by any suitable arrangement, and may be removable or a non-removable from the supply tube 3202. In the illustrated embodiment, the sheath 3250 is permanently attached to the supply tube 3202. The sheath 3250 can be movable along the supply tube 3202 or can be provided at a fixed location on the supply tube 3202, preferably at a spaced location from the manifold or cannula 3214 (hereinafter “cannula”). The sheath 3250 can be secured to the other portion 3252 of the hook-and-loop fastener or other coupler, which can be appropriately positioned to align with the sheath 3250 and, preferably, space the vertical hanging portion of the supply tube 3202 away from the patient’s nose or mouth. Preferably, the other portion 3252 of the coupler is a pad of the other portion of the hook-and-loop fastener relative to the sheath 3250. In one arrangement, as illustrated in Figure 32A, the pad 3252 is provided on each side of a headgear strap 3240 or other retention mechanism of the nasal cannula assembly 3200. Thus, the supply tube 3202 can be routed to either side of the patient’s face, as desired, and supported to hang down at a spaced location from the patient’s nose and/or mouth. In another arrangement, as illustrated in Figure 32C, the pad 3252 is an adhesive pad positioned on the patient’s face, preferably at a location spaced from the nose and/or mouth, such as the cheek, for example. In such an arrangement, the pad 3252 can be applied only to the desired side of the face for the desired routing of the supply tube 3202.

-60-
[0208] In addition or in the alternative, other suitable mechanisms for similarly securing the supply tube 3202 can be used. Figures 32D-F illustrate several mechanical fastening mechanisms for securing the supply tube 3202 such that the downward hanging portion is spaced from the patient's nose and/or mouth. Preferably, a first portion 3250 of a mechanical fastener is positioned on the supply tube 3202, in a permanent or removable and fixed or movable fashion. A second portion 3252 of a mechanical fastener is positioned on a portion of the nasal cannula assembly 3200, such as the headgear strap 3240 (or, in another arrangement, side portions 3222 of the cannula 3214). Accordingly, in a manner similar to the arrangements of Figures 32A-C, the first portion 3250 can be coupled to the second portion 3252 of the mechanical fastener such that the supply tube 3202 can be supported away from the patient's nose or mouth. In Figure 32D, the mechanical fastener is a button and button loop. In Figure 32E, the mechanical fastener is a popper dome or other snap-fit arrangement. In Figure 32F, the mechanical fastener is a hook, which can engage the supply tube 3202 and the headgear strap 3240. Thus, in such an arrangement, the first portion 3250 and the second portion 3252 of the mechanical fastener are formed by a single component. Thus, the portions 3250 and 3252 can be permanently coupled to one another and removable from one or both of the supply tube 3202 and the headgear strap 3240 or other portion of the nasal cannula assembly 3200.

[0209] In some embodiments, the supply tube 3202 can be secured by a permanent securing device provided on a portion of the nasal cannula assembly 3200, such as the headgear strap 3240 or a side portion 3222 of the cannula 3214 – especially on cannula designs having extended or large side portions 3222. For example, the securing device can be a permanent loop 3260 on the headgear strap 3240. Preferably, a permanent loop 3260 is present on each side of the headgear strap 3240 to permit routing of the supply tube 3202 to either side. The supply tube 3202 can be threaded through either loop 3260 to provide support and positioning of the supply tube 3202. The loop 3260 can be injection molded or die cut, for example, or formed by any other suitable process. Figure 32G illustrates a loop 3260 that is a hoop or ring positioned generally in the plane of the headgear strap 3240. The illustrated loop 3260 extends below the headgear strap 3240; however, it could also be provided above the headgear strap 3240. Preferably, the loop 3260 can rotate relative to the
headgear strap 3240 to better accommodate the supply tube 3202 and any other component, such as a pressure measurement tube 3210, for example. The headgear strap 3240 could include a portion that spaces the loop 3260 away from the circumferential portion of the headgear strap 3240 to facilitate rotation of the loop 3260. Figure 32H illustrates a molded-in loop 3260 that is positioned beside the headgear strap 3240. Figure 32I illustrates a loop 3260 that is formed by a section 3262 of the headgear strap 3240 that is defined by a pair of spaced-apart slits 3264, which allows the section 3262 to be pulled away from adjacent portions of the headgear strap 3240 to form a passage therewith. The slits 3264 can be substantially parallel with one another and oriented in a substantially vertical direction or along an axial direction of the perimeter defined by the headgear strap 3240, as illustrated. However, in other arrangements, the slits 3264 can be non-parallel and oriented in other directions.

[0210] In some embodiments, the loop 3260 can be a breakable loop to facilitate positioning of the supply tube 3202 within the loop 3260. Preferably, at least one breakable loop 3260 is present on each side of the cannula assembly 3200, such as on the headgear strap 3240. The supply tube 3202 can be clipped into either loop 3260. The loop 3260 could be breakable via any suitable arrangement, such as hook-and-loop fastener (Figure 32J), die cut or otherwise formed tab-and-slot arrangement (Figure 32K), popper domes or other snap-fit arrangement (Figure 32L), injection-molded or otherwise formed mushroom-head-and-recess arrangement (Figure 32M), or push-in clips (Figure 32N), for example. The loop 3260 can be broken at any location, such as in a central portion of the loop 3260 or at the headgear strap 3240. Preferably, any of these arrangements for managing the supply tube 3202 can be used or modified to managing a pressure line 3210 in addition to or in the alternative to the supply tube 3202.

[0211] The circuit delivering air or gas to the patient interface (e.g., cannula or manifold) is reasonably long to reach between the flow source and the patient. The mass of this long circuit, without some circuit supporting device causes the load to be transferred directly to the patient interface. The load of the circuit can cause the cannula to move and be pulled from the patient’s nares thereby interrupting therapy. It also can be uncomfortable for the patient to support the load of the circuit directly on the face. The circuit includes the
supply tube described herein (e.g., supply tube 50 of Figure 1) and can also include other conduits (e.g., main delivery conduit of Figure 1 and/or pressure line 872 of Figure 8A). To address this issue, several techniques or arrangements can be used to support at least a portion of the load or mass of the circuit, as described in connection with Figures 33A-S.

[0212] Figures 33A-H illustrate support devices 3350 that can be coupled to a portion of the circuit, generally 3352, to the patient’s clothing, bed sheets or other fabric or thin material and use that to support at least a portion of the load or mass of the circuit 3352. Figures 33A and 33B illustrate a support device 3350 affixed to the circuit 3352 by any suitable arrangement and comprising a two-part dome 3354 that sandwiches the bedding/clothing 3356 between the parts 3354a, b when assembled, such as via a snap-fit arrangement.

[0213] With reference to Figures 33C-F, the support device 3350 can comprise a clip-and-post (e.g., mushroom head) arrangement 3354 that sandwiches the bedding/clothing 3356 between the clip 3354a and post or mushroom head 3354b when the clip 3354a is assembled to the post or mushroom head 3354b. Either portion of the support device 3350 can be affixed to the circuit 3352 by any suitable arrangement. In the illustrated arrangement, the post or mushroom head 3354b is secured to the circuit 3352 by a sleeve 3360. If desired, the clip 3354a can be coupled to the sleeve 3360 by a tether 3362. The clip 3354a can be of any suitable arrangement to be capable of secure engagement and disengagement with the post or mushroom head 3354b with clothing, sheeting or other fabric or material 3356 therebetween. For example, Figure 33C illustrates a simple C-shaped resilient clip 3354a. Figure 33D illustrates a clip 3354a that is capable of being engaged to the post or mushroom head 3354b in a radial or axial direction relative to the post or mushroom head 3354b. Figure 33E illustrates a hinged clip 3354a, which can have a snap-fit arrangement or other mechanism to couple the unhinged ends of the clip 3354a. Figure 33F illustrates a clip 3354a having an elastic retention portion 3364. The clip 3354a is illustrated as a hinged clip, but could also be unhinged. Alternatively, the clip 3354a could be entirely replaced with an elastic member.

[0214] In some embodiments, with reference to Figure 33G, the support device can comprise a tag 3350 that is coupled to the circuit 3352 and includes a button hole feature 3366 that can be attached to an existing button 3368 of a patient’s shirt or other article of
clothing. Alternatively, a specific garment or other piece of material could be provided with a specific button 3368 to engage the button hole feature 3366. The tag 3350 could feature a tear-away feature (e.g., a slit, score line or weakened portion) 3370 that would tear before the patient’s shirt or other article supporting the button 3368.

[0215] With reference to Figure 33H, the support device can comprise a clip 3350 having a portion 3372 that surrounds the circuit 3352 and a portion 3374 that can grip bedding, clothing or other fabric or thin material. In the illustrated arrangement, the clip 3350 has two arms that cross one another and are movable relative to one another between an open position and a closed position. The portion 3372 is defined by the portion of the arms that extend between the intersection or connection to one another and the point at which they cross one another. The portion 3374 is defined by the end portions of the arms. The clip 3350 can include finger grip portions 3376 that facilitate squeezing of the clip 3350 to move the clip to the open position. In addition, the clip 3350 can include retention, grip or friction-enhancing features or traction elements 3378 (e.g., knobs or protrusions) that assist in inhibiting the bedding, clothing or other material from being released from in between the arms of the clip 3350 when in the closed position.

[0216] In other arrangements, the support device can comprise a lanyard 3380 that can be placed around the patient’s neck or another body part or object and used to support at least a portion of the circuit 3352. With reference to Figure 33I, the lanyard 3380 can be used in combination with the clip 3350 of Figure 33H. For example, the clip 3350 can be a dual use clip that has at least one opening or hole 3382, such as in the centers of the arms within the portion 3374 so it can also be used to thread the lanyard 3380 and/or another supporting device through it. The lanyard 3380 can be used instead of or in combination with clipping the patient’s clothing, bedding or another piece of material.

[0217] The lanyard 3380 can be of any suitable construction. For example, with reference to Figure 33I, the lanyard 3380 can include a series of snaps, hook-and-loop fasteners or other fasteners 3384 that could be used to adjust the length of the lanyard 3380. In addition, the fasteners 3384 could act as a breakaway feature to avoid or minimize discomfort or injury to the patient should the lanyard 3380 get caught on something.
With reference to Figure 33K, the lanyard 3380 could be centered about the circuit 3352 with attachment points on opposing sides of the circuit 3352. The ends of the lanyard 3380 can be received within a support device 3350, which can surround the circuit 3352. Preferably, the ends of the lanyard 3380 pass through the support device 3350 in a substantially axial direction relative to the circuit 3352, which assists in holding the support device 3350 upright with the axis of the circuit 3352 generally in a vertical orientation or generally aligned with the patient's body and reduce or prevent awkward side angles when hanging from the patient's neck. In the illustrated arrangement, the support device 3350 is a connector between the supply tube and the main delivery conduit. Sliders or other retention devices 3386 on the lanyard could be used for adjustment and to allow asymmetric positioning.

With reference to Figure 33L and 33M, the support device can comprise a band 3350 that can engage the circuit and also be attached to the body of the patient or equipment near the patient. The band 3350 can be permanently connected to the circuit or can be removable from the circuit. In one arrangement, the band 3350 is a fabric coated thin metal, plastic or combination thereof band that is fixed to the circuit, such as with a loop 3390 that surrounds the circuit. The band 3350 can be deformable such that it can be secured to the patient's arm, bed frame or other object. The band 3350 can have a first layer 3392 that defines the loop 3390 and a second layer 3394 that comprises a deformable material such that the band 3350 can be deformed and substantially hold its shape. In another arrangement, the second layer 3394 comprises a bi-stable spring or similar element that can be straightened and hold its shape, but once bending of the spring or other element is initiated, it tends to collapse into a loop or roll. Such an arrangement can be opened to allow fitment and then collapsed about the patient's arm, a bed frame or another suitable object and, once fitted, can provide enough retention force to hold the circuit.

With reference to Figures 33N-P, the support device can comprise a fastener 3350 having a first portion 3350a affixed to the circuit 3352 and a second portion 3350b that can be affixed to another object, such as a bed frame or other equipment. The portions 3350a and 3350b can be coupled to support the circuit 3352. In the arrangement of Figure 33N, one portion 3350a of a hook-and-loop fastener 3350 is affixed to the circuit.
3352, such as by surrounding the circuit 3352, and the other portion 3350b of the hook-and-loop fastener 3350 is affixed (e.g., via adhesive) to an object, such as a bed frame or other equipment. The two portions 3350a and 3350b can be coupled to one another to provide support to the circuit 3352. In the arrangement of Figure 33Q, the portion 3350b includes a non-adhesive section that can loop over the circuit 3352 and then be connected to the adhesive section to provide a more secure support. In an alternative arrangement, the portion 3350a on the circuit 3352 can be omitted. In the arrangement of Figure 33P, the portion 3350b can be formed into or provided on an armband 3395 that can be wrapped around the patient’s arm (or another object). The armband 3395 could be an endless loop or, as illustrated, can be breakable or separable and selectively fixed in a loop by a suitable fastener 3396 (e.g., hook-and-loop fastener).

[0221] With reference to Figures 33Q and 33R, the support device 3350 can be or comprise an over the shoulder support that would loop over the patient’s shoulder to support the circuit 3352. One portion 3350a of the support 3350 can comprise a flexible or formable generally U-shaped section defining an opening that can receive and engage the circuit 3352. Another portion 3350b of the support 3350 can comprise a flexible or formable generally U-shaped portion that can receive and engage the patient’s shoulder or upper arm.

[0222] With reference to Figure 33S, the support device 3350 can be a portion of or be supported by the headgear strap 3340 or other cannula-supporting device or arrangement. With such an arrangement, the headgear strap 3340 can be utilized to support at least a portion of the weight of the circuit 3352. For example, the support device portion 3350 of the headgear strap 3340 can extend directly over and rest upon the top of the patient’s head and then continue down to a clip 3398 or similar to engage the circuit 3352 such that the support device portion 3350 of the headgear strap 3340 assists in supporting the weight of the circuit 3352.

[0223] Some embodiments involve retention assemblies for use with or integrated with the nasal cannula assemblies. In many existing systems, the cannula is retained on the face using a single elastic head strap or held onto the face by looping the supply tube(s) over the ears. In some such designs, the cannula is not secured to the patient’s face in an ideal manner and may allow shifting or movement from the desired position. Many factors can
cause the cannula to be moved from its ideal positioning, some of which include the weight of
the air or gas supply circuit may cause the cannula to hang in that direction, the cannula will
slide as the patient moves around during sleep, and the small surface area of single elastic head
straps may not be sufficient to secure the cannula. Over time the head strap may slide down
the patient’s head, further reducing the security of the head strap on the face. Thus, with
some existing systems, the cannula can easily become unsecure, especially over long periods
of time. Furthermore, cannula assemblies that rely on the ears to hang the supply tube(s)
usually have the supply tube(s) taped to the patients face as a secondary means of securement.
This technique is time consuming and does not allow for easy readjustment.

[0224] With reference to Figures 34A and 34B, a nasal cannula assembly 3400 includes a cannula 3414 and a retention arrangement 3450, which can be separate components
or assemblies or can be integrated with one another. In the illustrated arrangement, hook-and-
loop strips 3452 extend respectively from left and right sides of the cannula 3414. These
hook-and-loop strips 3452 can be threaded thorough openings or slots 3454 located in
annular or circular ear pads 3456. The ear pads 3456 may be made of any suitable material,
which preferably provides a soft comfortable feel to the patient while being strong enough to
cope with the force applied when the headgear strap 3440 is tightened. The shape of the ear
pads 3456 can be annular (e.g., circular) or any other geometry which allows for an
anatomical fit and, in at least some configurations, partially or completely surrounds a
patient’s ears.

[0225] The ear pads 3456 are then connected to the headgear strap 3440. The
headgear strap 3440 also can have hook-and-loop strips 3458 coupled thereto or integrated
therewith, which can be threading through additional openings 3454 of the ear pads 3456.
The headgear strap 3440 can be of any suitable arrangement, such as a bi-varicated style strap
and preferably is made from or incorporates a non-stretch material. In some configurations,
the cannula assembly 3400 is supplied with one or more of the components pre-assembled.
For example, three out of the four hook-and-loop strips 3452, 3458 threaded through the slots
3454 in the ear pads 3456. In such an arrangement, the patient or a caregiver would put on
the cannula assembly 3400 by strapping it around the head ensuring that the ears are inside the
hole of the ear pads 3456. The patient or a caregiver would then thread the open hook-and-
loop strip (or strips, in other arrangements) through the ear pads 3456 and tighten until comfortable.

[0226] Advantageously, with such an arrangement, the cannula 3414 will be more secure on the patient’s head than existing arrangements. For example, the patient’s ears will inhibit or prevent the ear pads 3456 from sliding out of position and hence inhibit or prevent the cannula 3414 dislodging from its intended position. This is especially beneficial to a patient who is asleep, as natural body movements during sleep will not affect the delivery of therapy through the cannula 3414. The foam (or other material) ear pads 3456 may also provide more comfort to the patient as they act as cushions during the event a patient is sleeping on his or her side. The bi-varicated strap 3440 will also contribute to the improved security of the cannula 3414 by increasing the area over which the cannula 3414 is attached to the head. The increased surface area will inhibit or prevent the headgear strap 3440 from sliding down and reducing the security of the cannula 3414 on the face.

[0227] With reference to Figures 34C and 34D, a cannula retention arrangement 3450 incorporates friction pads 3460 into the headgear strap 3440. The friction pads 3460 preferably are positioned to sit on the patient’s cheeks, or on portions of the face near the cheeks, and direct a line of action or force from the headgear strap 3440 away from the ears. In some arrangements, the friction pads 3460 are made from, or include, a soft material that allows for a comfortable fit on the face while providing enough friction to allow the headgear strap 3440 to change direction relative to a lateral direction or relative to lateral side portions 3422 of the cannula 3414 or lateral portions 3440a of the headgear strap 3440. The friction pads 3460 preferably are of a thickness that allows the cannula 3414 to bridge slightly from the skin of the patient, creating less pressure on the skin. Such pads 3460 would have the added benefit of preventing the cannula 3414 from moving on the face as a larger frictional force would need to be overcome for movement to begin. The pads 3460 can be affixed to the headgear strap 3440, if desired, by any suitable arrangement, such as sewing, adhesives, for example.

[0228] Advantageously, such an arrangement for attaching the cannula 3414 to the head of the patient is more secure than many existing techniques and arrangements. For example, the friction pads inhibit or prevent the cannula 3414 from easily moving on the face,
as is experienced by many existing arrangements. Furthermore, by elevating the cannula 3414 from the skin with the aid of the thickness of friction pads 3460 will reduce the pressure felt by the patient on the upper lip, thereby making the cannula 3414 more comfortable to wear. Comfort can also be increased by using the friction pads 3460 to spread the force of the headgear strap 3440 over a larger area on the face, which will inhibit or prevent localized pressure marks on the skin. By directing the line of action of the headgear strap 3440 away from the ears, a more comfortable position of the headgear strap 3440 can be achieved because the ears will not be compressed by the force of the headgear strap 3440 going over them.

[0229] With reference to Figure 34E, a cannula assembly 3400 includes a cannula 3414, a supply tube 3402 and a retention arrangement 3450. The retention arrangement 3450 straps onto the head using the ears as anchor points during the setup process. Preferably, the headgear strap 3440 is divided into two portions 3440a and 3440b, which are connectable to one another by a suitable fastening arrangement, such as a hook-and-loop fastener 3466, for example. Preferably, the fastening arrangement 3466 is adjustable, such that the circumferential length of the headgear strap 3440 can be adjusted. Preferably, each portion 3440a, 3440b of the headgear strap 3440 includes an ear loop 3456 that includes an opening that can be placed over the ear of a patient. In use, the cannula assembly 3400 is applied to the patient by first hanging the assembly 3400 on the ears via the ear loops 3456 and positioning the prongs 3405 of the cannula 3414 in the correct position. Once the cannula 3414 is in place, the fastener arrangement 3466 can be used to couple the two portions 3440a, 3440b of the headgear strap 3440. Preferably, the fastener arrangement 3466 permits the circumference of the headgear strap 3440 to be adjusted to a suitable tightness such that the headgear strap 3440 supports the cannula 3414 without substantially relying on engagement of the ear loops 3456 with the ears of the patient. In some arrangements, once the headgear strap 3440 is adjusted (e.g., tightened), the ear loops 3456 do not contact and/or apply any significant force to the ears of the patient. Preferably, the headgear strap 3440 (which can include the ear loops 3456) is made from or incorporates a material which stretches slightly to provide a relatively constant force on the face when the headgear strap 3440 is adjusted, such as by fastening the fastener arrangement 3466. In some arrangements, the loop section of the
hook-and-loop fastener 3466 is positioned closer to the head than the hook portion in order to prevent the hook material sticking to or grabbing the hair of the patient. In some arrangements, the material used to make the headgear strap 3440 is thick enough to allow the cannula 3414 to hang on the ears of the patient when put through the ear holes 3456.

[0230] Advantageously, such an arrangement for attaching the cannula 3414 is more secure than many existing techniques and arrangements. For example, the ears will inhibit or prevent the headgear strap 3440 from moving out of position and inhibit or prevent the cannula 3440 dislodging from its desired position. This is especially beneficial to a patient who is asleep, as natural body movements during sleep will not affect the delivery of therapy through the cannula 3414. The ear loops 3456 allow for easier application of the cannula assembly 3400 and the cannula 3414 can be positioned without the headgear strap 3440 being secured by hanging it from the patient’s ears. The caregiver or patient can move the cannula 3414 around until the correct positioning achieved and then easily secure the headgear strap 3440 using the fastening mechanism 3466. Advantageously, the headgear strap 3440 will inhibit or prevent the cannula 3414 from sliding down as a larger surface area of the strap 3440 is in contact with the head and the ear loops 3456 will act as an anchor point should the headgear strap 3440 be moved down by an external force.

[0231] With reference to Figure 34F, a cannula assembly 3400 includes a retention arrangement 3450, which comprises a headgear strap frame 3440 and a flexible mesh portion 3468 supported by the frame 3440. In some arrangements, at least a portion of the frame 3440 can be constructed from a substantially non-stretchable material or can otherwise be constructed to be substantially non-stretchable. The mesh portion 3468 can be in the form of a net and preferably is constructed from an at least somewhat stretchable material. Such an arrangement creates a hybrid stretch/non-stretch headgear that can be applied by sliding it over the head and positioning until the ears are within openings of ear loops 3456 of the frame 3440. The ear loops 3456 can partially or completely surround the ears of the patient. The frame 3440 can be adjusted using an adjustment mechanism 3470, which can include an adjustment tab 3472 that is utilized to shorten a circumferential length of the mesh portion 3468 of the retention arrangement 3450. In such an arrangement, a portion of the ear loops 3456 to which the mesh portion 3468 is attached (e.g., a rearward portion) can be constructed...
from a stretchable material or can at least be flexible relative to other portions of the frame 3440 to facilitate adjustment of the mesh portion 3468. In an alternative arrangement, the frame 3440 could also be made from an at least somewhat stretchable material. In such an arrangement, the adjustment mechanism 3470 could be optionally omitted because the stretch would allow for the retention arrangement 3450 to fit a multiple of patient sizes.

[0232] In at least some configurations, the flexible mesh portion 3468 conforms to the patient's head shape and increases the friction and surface area between the retention arrangement 3450 and patient. As a result, a much more secure fit is provided. This arrangement for securing the cannula 3414 is much more secure compared to many existing methods and arrangements. The large area in contact with the head will provide friction which will resist movement of the cannula during normal activity or motion during sleep. In addition, by spreading the force over a large area, the illustrated arrangement tends to reduce localized pressure on the back of the head as is experienced by many current methods and arrangements.

[0233] With reference to Figures 34G and 34H, a cannula assembly 3400 includes a cannula 3414, a supply tube 3402 and a retention arrangement 3450. In the illustrated arrangement, the cannula 3414 is mounted to a generally U-shaped frame 3440 that is configured to fit the face of a patient in a manner similar to an eyeglass. Thus, preferably, the frame 3440 supports the cannula 3414 and includes rearwardly-extending ear stem portions 3440a, 3440b that extend along the sides of the patient's head, preferably extending at least to the patient's ears. The frame 3440 preferably has substantial rigidity to hold its shape, but has enough flexibility to allow the movement of the ear stem portions 3440a, 3440b apart from one another such that the frame 3440 is suitable for a range of head sizes. In a preferred arrangement, the ends of the ear stem portions 3440a, 3440b (or portions above the ears) are generally straight and the frame 3440 relies on the resiliency of the frame 3440 to secure the frame 3440 to the patient's face. Such an arrangement can fit a wider variety of face sizes. However, in an alternative arrangement, the frame 3440 can include portions that wrap at least partially around (e.g., behind) the ears. Optional pads 3474 can be provided where the frame 3440 contacts the head (e.g., above the ears). Advantageously, the cannula assembly 3400 is easily applied and removed with one hand, such as in a manner similar to a pair of
glasses. Furthermore, because there is no strap applying a force behind the head, there will be less of an opposing force on the upper lip to cause discomfort.

[0234] With reference to Figures 34I and 34J, a cannula assembly 3400 includes a cannula 3414, a supply tube 3402 and a retention arrangement 3450. In the illustrated arrangement, a pair of adhesive pads 3480 is mounted on the patient with one pad 3480 applied to each cheek. The cannula 3414 is attached to the adhesive pads 3480 by any suitable arrangement. In the illustrated arrangements, the cannula 3414 is attached to the pads 3480 by an adjustable and removable system, so that the position and force of the cannula 3414 on the face can be adjusted or fine-tuned after the adhesive of the pads 3480 has set. Advantageously, with such an arrangement, the cannula 3414 can be removed temporarily without removing the adhesive pads 3480. The adjustable systems can be of any suitable arrangement, such as utilizing a hook-and-loop fastener 3482 (Figure 34I) or other reusable fastener that allows the pad 3480 to be adjustably coupled to the cannula 3414. With reference to Figure 34J, a ratchet-type adjustable fastener 3484 can be used to secure the pads 3480 to the cannula 3414 in an adjustable manner. The ratchet-type adjustable fastener 3484 can be integrated with the pads 3480 and/or cannula 3414, as illustrated, or can be a separate assembly or separate components that are coupled to the pads 3480 and/or cannula 3414. Advantageously, the use of adhesive pads 3480 means there is no strap applying a force behind the head, so there will be less of an opposing force on the upper lip to cause discomfort.

[0235] With reference to Figure 34K, an alternative adjustable fastener 3486 is illustrated for coupling the cannula 3414 to the pads 3480 in an adjustable manner. However, in other arrangements, the fastener 3486 can have a single position relative to the cannula 3414 and any adjustment can be addressed by placement of the pads 3480 on the patient. Preferably, the pads 3480 include a post or knob 3488 that clip into openings or notches 3490 on the cannula 3414. This arrangement could also be reversed. The knobs 3488 may be of any shape as long as the notches 3490 in the cannula 3414 are of a complimentary design. The shape of these pads 3480 can be of any suitable arrangement such that they conform to the facial geometry. The illustrated pads 3480 are generally hourglass-shaped. However, other suitable shapes can also be used. The notches 3490 in the cannula 3414 allow for
adjustment on the face. To increase the force of retention, notches 3490 closer to the prongs 3405 can be clipped into the knob 3488 on the adhesive pads 3480. Any suitable number of notches 3490 can be provided to allow a range of adjustment forces and/or fit a range of head sizes.

[0236] Advantageously, such an arrangement removes or reduces localized pressure that often present with the use of a tightened strap. In addition, it also reduces or prevents marking on the skin from a headgear strap being worn for long periods of time. It is also easier to apply and remove the cannula 3414 because no headgear strap needs to be passed over the head. This is especially beneficial for a patient who is lying on their back.

[0237] With reference to Figures 35A-D, in some embodiments, the nasal cannula assembly is a modular system that provides several different retention arrangements. Cannulas are used on patients in a range of different environments, from an intensive care unit (ICU), to a standard hospital ward, and to the home. In view of these different environments of use, a modular system in which the patient/caregiver may choose the form of retention used may be desirable. In some embodiments, a cannula assembly 3500 includes a cannula 3514, a supply tube 3502 and a retention arrangement 3550. The cannula 3514 comprises side portions 3522 of any suitable shape. In the illustrated arrangement, the side portions 3522 comprise enlarged, generally ovalized pads. The side portions 3522 can permit the cannula 3514 to be coupled to several types of retention arrangements 3550 by any suitable fastener, such as a hook-and-loop fastener, for example. In one arrangement, as shown in Figure 35A, the cannula 3514 can be coupled to a halo-type headgear strap assembly 3540, which includes at least one strap 3552 extending around the side of the patient’s head and a second strap 3554 that extends over the top of the patient’s head. In some arrangements, as illustrated, the headgear strap assembly 3540 can include a pair of straps 3552 extending around the side of the head and may position one strap 3552 above the ear and the other strap 3552 below the ear. If desired, a pad can be provided on one or more of the straps 3552, 3554. The straps 3552, 3554 can include a suitable fastener, such as a hook-and-loop fastener 3556, for example, to permit the headgear strap assembly 3540 to be applied, removed or adjusted. The halo-type headgear strap assembly 3540 can include end portions that utilize the complementary portion of the fastener of the side portions 3522. This form of retention can
be desirable for patients who are not compliant to the therapy. This larger, complex headgear can inhibit or prevent the cannula 3514 from moving on the face and further make it difficult to remove the cannula 3514 by pulling on it.

[0238] In other arrangements, as shown in Figure 35B, the side portions 3522 allow the cannula 3514 to be coupled to either a headgear strap 3540 or a set of adhesive pads 3580, which can be the same as or similar to any other straps or pads disclosed herein, or can be of any other suitable arrangement. The headgear strap 3540 can include end portions that utilize the complementary portion of the fastener of the side portions 3522 and may be used for patients who do not want pads 3580 stuck to the cheeks or for those taking the therapy intermittently on a regular basis. The headgear strap 3540 can be a single size or adjustable. The adhesive pads 3580 can also utilize the complementary portion of the fastener of the side portions 3522 and can have a shape that is complementary to or compatible with the side portions 3522. This type of retention can be desirable for patients who are compliant or are on the therapy for an extended time.

[0239] With reference to Figures 35C and D, each side of the retention arrangement 3550 and each of the side portions 3522 of the cannula 3514 can include more than one pad, such as two pads (a bivariated arrangement), for example. Such an arrangement includes a total of four hook-and-loop (or other) fastener locations, which can reduce the load experienced by each fastener and can spread the load over a larger area of the patient’s head for increased comfort. In addition, the spaced locations to which retention force is applied to the cannula 3514 can result in greater stability of the cannula 3514 on the patient’s face. In the illustrated arrangement of Figure 35C, the cannula 3514 is coupled to a halo-type headgear strap 3540, similar to the strap 3540 of Figure 35A. As illustrated in Figure 35D, a non-halo-type headgear strap 3540 can be employed, which can include two straps, or other numbers of straps, such as one or more than two straps, for example. This style of retention arrangement 3550 can also be applied to the face using adhesive pads or other suitable retention arrangements.

[0240] With many existing systems, if a patient inadvertently removes the cannula, the head strap is tightened further or the cannula is taped onto the face. The arrangements of Figures 35A-D provides the caregiver or patient the flexibility of choosing which form of
retention is desired, needed or best suited to the specific situation. By using a desirable level of retention, comfort for the patient can be increased as the method for securing the cannula on a non-compliant patient will not need to be used on a compliant patient. Another benefit of the illustrated modular system is that it allows for users to choose which method of retention is more comfortable to them. This gives the patient/user more in control of the therapy and can result in greater patient/user satisfaction and compliance.

[0241] With reference to Figures 35E-G, another modular retention arrangement 3550 is illustrated. The illustrated retention arrangement 3550 comprises a light weight and relatively small cannula 3514, which can stick on the patient’s nose via an adhesive pad or strip 3590. A supply tube 3502 is coupled to the cannula 3514 by any suitable arrangement, such as any of the coupling arrangements disclosed herein, for example. In the illustrated arrangement, the adhesive strip 3590 is affixed to, integral with or unitary with the cannula 3514 and configured to extend to the top portion of the patient’s nose, preferably at or above the tip of the nose, when the prongs 3505 are positioned into the patient’s nares. The adhesive strip 3590 can be adhered to the patient’s nose to retain the cannula 3514 in place. Alternatively, the strip 3590 could be adhered to the patient indirectly, such as using a fastener (e.g., hook-and-loop fastener) that couples the strip 3590 to a separate adhesive pad. This retention arrangement 3550 can be desirable for patients who are compliant and aware of the therapy they are on.

[0242] For patients who are not compliant, or in other suitable situations, the adhesive pad or strip 3590 can be removed (e.g., cut off) and the cannula 3514 can be inserted into a cannula holder 3592 that cooperates with a headgear strap 3540. The whole assembly can now be used as a standard cannula. The cannula holder 3592 can be of any suitable arrangement to hold the cannula 3514, when desired. For example, the cannula holder 3592 can include any type of snap-fit arrangement, which can include a support portion 3594 (e.g., a semi-cylindrical or other shape tray) and a retention portion 3596 (e.g., a clip). The headgear strap 3540 can be non-adjustable, adjustable or can be of any suitable arrangement, such as the same or similar to any of the straps disclosed herein.

[0243] With reference to Figures 36A-K, in some embodiments, the cannula retention arrangement 3650 is configured to facilitate achieving a desirable tightness or
retention force, which may be a value within (preferably, a relatively narrow) range. In many existing arrangements of cannula secured by a headgear strap, the tightness (tension) of the strap and resulting retention force applied to the cannula can be very dependent on the particular user and, therefore, can vary widely. If the cannula is applied too tightly, marks will be left on the skin due to the headgear strap and the headgear strap can apply uncomfortable pressure to the patient’s face. On the other hand, if the headgear strap is not sufficiently tight, it will slip over time and cause the cannula to move from its original or ideal position. This may result in discomfort for the patient. The embodiments of Figures 36A-K preferably address these issues to at least some degree. At least some of the embodiments illustrated in Figures 35A-K incorporate a tightness indicator, which provides the patient or caregiver with user feedback regarding the tightness of or tension within the headgear strap 3540. Such arrangements can provide, for example, either a qualitative or a quantitative of headgear strap tightness.

[0244] For example, with reference to Figures 36A-C, a cannula assembly 3600 includes a cannula 3614 and a retention arrangement, such as a headgear strap 3640, which secures the cannula 3614 to the patient. Preferably, the headgear strap 3640 includes a tightness indicator 3650, which provides the user (e.g., a patient or caregiver) with feedback regarding the tightness of the headgear strap 3640. For example, the tightness indicator 3650 may provide a first indication (which may be the absence of an indication) when the headgear strap 3640 is at an incorrect tightness value, which may be outside of a desired tightness range to either side (too tight or too loose). If desired, the first indication could indicate whether the actual tightness is above or below the desired or correct tightness value or range. The tightness indicator 3650 may provide a second indication when the headgear strap 3640 is at a correct or desired tightness value, which may be within a range of correct or desired tightness.

[0245] In the illustrated arrangement, the material used to make or otherwise provide on, the headgear strap 3640 is layered with at least two colors. While the strap 3640 remains in its relaxed position only one color will show (first indication) and as the strap 3640 stretches other color(s) incorporated into the strap 3640 begin to show (second indication). The point or range at which the change in color occurs is calibrated to correspond to a certain tensile force in the strap 3640. As a result, such an arrangement will allow the user to know
when a certain tightness of a strap 3640 has been achieved. The strap 3640 can be adjustable by any suitable arrangement, such as any of those disclosed herein, which can facilitate the user achieving a desired tightness via adjustment of the strap 3640. Alternatively, the strap 3640 can be non-adjustable, in which case the tightness indicator 3650 can allow the user to determine if the strap 3640 provides a correct fit, and may facilitate selecting a size of strap 3640 from two or more available sizes.

[0246] The feedback or tightness indication provided may be simple, such as the use of a strap 3640 that changes color (Figure 36B) or have symbols which appear as the strap 3640 achieves the correct or desired tightness. In some arrangements, only a section of the strap 3640 changes color, while in other arrangements the whole strap 3640 may change color. The user may also be warned when the strap 3640 is too tight in a similar manner. Such an arrangement provides a mechanism for easily determining whether correct tightness on a headgear strap 3640 has been achieved. Advantageously, it will inhibit or prevent the user from inadvertently over tightening and causing discomfort by displaying when correct fit has been achieved. In some arrangements, the headgear strap 3640 does not prevent the user from tightening the strap 3640 above the desired or indicated tension level should the user prefer such a level of tightness.

[0247] With reference to Figures 36D-G, the headgear strap 3640 includes a tightness indicator 3650, which provides the user with feedback regarding the tightness of the headgear strap 3640 by indicating movement of one portion 3640a of the headgear strap 3640 relative to another portion 3640b of the headgear strap 3640. For example, with reference to Figures 36D and 36E, the headgear strap 3640 includes a spring 3652 or other biasing member or arrangement inside the first portion 3640a (inner strap), which is fixed to the remaining second portion 3640b (outer strap) of the headgear strap 3640. The spring 3652 applies a force (either by compression or extension) tending to overlap the portions 3640a, 3640b thereby reducing a circumference of the strap 3640. The tightness indicator 3650 includes a window 3654 on a portion of the outer strap 3640b that, when an appropriate tightness has been achieved, allows a marker or indication 3656 (e.g., a green marking or band) carried by the inner strap 3640a or spring 3652 to be seen. As the strap 3640 is tightened, the tightness indicator 3650 changes color (e.g., displays the green band) to
indicate that the correct or desired tension has been achieved. The two portions 3640a, 3640b can be secured to one another by any suitable fastener, such as a hook-and-loop fastener 3658, for example.

[0248] With reference to Figure 36F, instead of a simple binary indicator, the strap 3640 could provide an indication of tightness over a range. For example, this can be achieved by replacing the window 3654 or providing on the window 3654 a gauge or scale 3660 and utilizing the indication 3656 (e.g., an arrow or thin line) to provide a quantitative display of strap 3640 tightness on the scale 3660. In yet another alternative arrangement, with reference to Figure 36G, the spring 3652 can be replaced with an elastic region 3662 coupled to or integrated with the inner strap 3640a. As the strap 3640 is tightened, a graduated colored indicator provides tightness information, such as through a window 3654 in the outer strap 3640b. The graduated color changing on the elastic system allows for a region over which ideal fit is achieved as opposed to a single point. The colored indicator could be replaced by numbers, words, symbols, etc.

[0249] Advantageously, the arrangements of Figures 36D-G a mechanism for easily and quickly determining if a desired or correct tightness of the head strap 3640 has been achieved. Such arrangements can inhibit or prevent the user from inadvertently over tightening and causing discomfort by displaying when correct fit has been achieved. The non-stretch portions of the headgear strap 3640 can be padded to increase comfort to the user. One benefit of having a quantitative display is that it provides repeatability by allowing a user to adjust to a value which is comfortable and secure and note the adjustment value. When the headgear strap 3640 is taken off and then put back on, the user can easily adjust the tightness of the headgear strap 3640 to the desired value using the tightness indicator 3650.

[0250] Figures 36H and 36I illustrate another headgear strap 3640 including a tightness indicator 3650 that provides an indication of how much force is being applied by the headgear strap 3640 to a patient. Preferably, the tightness indicator 3650 comprises a gauge 3670 (e.g., similar in appearance to a pressure gauge) that can be circular in shape in at least some arrangements. However, other shapes could also be used. However, a generally circular shape can be desirable to provide functional aspects to the strap 3640 in addition to tightness indication. For example, the gauge 3670 could have padding on the underneath
surface that contacts the skin. The gauge 3670 may also act to distribute pressure caused by
the headgear strap 3640 over a larger surface area and/or to change a direction of the strap
3640. The gauge 3670 preferably operates in a manner similar to the indicators 3650
disclosed herein in that tension applied to the strap 3640 transmitted to and displayed by the
gauge 3670. The strap 3640 can be adjustable or non-adjustable, as described herein. The
gauge 3670 can provide a binary indication of sufficient tightness or can provide qualitative
information as to the actual tightness within a range, as illustrated in Figure 36J. As with the
prior indicators 3650, the gauge 3670 (which can have a dial indicator-type display) provides
a means of reading a tightness value. This allows the cannula assembly to be taken off and,
when put back on, be easily and quickly adjusted to the desired value. The padded gauge
3670 can provide the added benefit of sitting on or near the cheeks of the patient to distribute
any pressure over a larger area, thus increasing comfort. If desired, a gauge 3670 can be
provided on each side of the strap 3640 or a pad similar to the gauge 3670 can be provided on
the side opposite the gauge 3670. If two gauges are provided, each can indicate the tension
of the strap 3640 or each can indicate the tension in a dedicated portion of the strap 3640
(e.g., upper and lower or left and right).

[0251] With reference to Figure 36J, in some embodiments, a very long and
stretchy single length headgear strap 3640 can be utilized. Advantageously the long, elastic
headgear strap 3640 provides a relatively flat force vs. extension curve, which makes the strap
3640 less likely to be over-tightened. In some arrangements, the headgear strap 3640 extends
around the patient’s head from one side to the other of the cannula 3614 at least twice and,
preferably, more than twice. For example, the strap 3640 can extend around the patient’s
head from one side of the cannula 3614 to the other between about three to about ten times.
The increased length of the strap 3640 assists in flattening the force vs. extension curve. The
headgear strap 3640 can be threaded back and forth between the left and right side of the
cannula 3614 (e.g., from one side portion 3622 to the other side portion 3622).

[0252] In some arrangements or for some applications, the strap 3640 can be non-
adjustable. However, in other arrangements, the strap 3640 is adjustable. For example, in the
illustrated arrangement, one end 3640a of the headgear strap 3640 can be pulled to adjust a
length of the strap 3640 extending between the sides of the cannula 3614 in order to tighten
the strap 3614. The strap 3640 can extend through a viewing window 3654 (e.g., moulded in the cannula 3614) and be colored to illustrate the tightness achieved when pulled through the viewing window. One or more colors, symbols or other indications may be used. In some arrangements, the tightness indicator 3650 is able to show qualitatively what tightness has been achieved by the color of the headgear strap 3640 displayed through the viewing window 3654. Advantageously, the multiple strands of the headgear strap 3640 extending from one side to the other of the cannula 3614 provide a larger surface area over which the strap 3640 attaches to the head. The illustrated arrangement provides a means of easily determining if the correct or desired tightness of the headgear strap 3640 has been achieved. The long elastic headgear strap 3640 can render the strap 3640 less likely to exhibit a sudden increase in tightness upon adjustment. This represents an improvement many existing straps, which exhibit a large increase in force for small change in length. In addition, the larger surface area and/or greater vertical distance over which the strap 3640 makes contact with the head improves stability of the cannula 3614 on the face.

[0253] With reference to Figure 36K, the headgear strap 3640 can comprise a torque driver or reel arrangement 3680, which is used to tighten the headgear strap 3640 or any individual portions or straps thereof, such as by winding portion(s) of the strap 3640 onto a reel member in response to rotation of a portion of the torque driver or reel arrangement 3680 by a user. The torque driver or reel arrangement 3680 can be a unidirectional, in which the headgear strap 3640 can only be tightened, or can be a bidirectional in which the headgear strap 3640 can be loosened and re-tightened. If desired, the torque driver or reel arrangement 3680 can have an upper torque limit that only permits the strap 3640 to be tightened up to a certain tightness or tension level. For example, a clutch mechanism could be used to inhibit or prevent over-tightening.

[0254] In use, the patient or caregiver can place the cannula assembly 3600 over the head and position the prongs 3605 of the cannula 3614 in the nares. The strap 3640 can be placed appropriately around the head and the dial of the torque driver or reel arrangement 3680 can be rotated to tighten the headgear strap 3640. In some arrangements, the torque driver or reel arrangement 3680 can be calibrated to a set tightness. Once this has been achieved, the torque driver or reel arrangement 3680 will not allow the headgear strap 3640
to be tightened further. The torque driver or reel arrangement 3680 may be padded to increase comfort for the patient when lying on the side. The padding would also increase friction, allowing the cannula 3614 to sit on the face with more stability without overtightening. If desired, a torque driver or reel arrangement 3680 can be provided on each side of the headgear strap 3640. Advantageously, with such an arrangement, the possibility of a user over-tightening the headgear strap 3640 is reduced or eliminated. The tightness level at which the dial will not tighten further can be a tightness predetermined to provide ample security for retaining the cannula 3614 in place, while maintaining a reasonably high comfort level. In some arrangements, a headgear strap or retention arrangement can include a torque driver or reel arrangement 3680 and a tightness indicator, such as any of those illustrated in Figures 35A-K, for example. In particular, a headgear strap could include a torque driver or reel arrangement 3680 and a tightness indicator in the form of a gauge 3670, such as those illustrated in Figures 36H and 36I. For example, the torque driver or reel arrangement 3680 could be positioned on one side of the headgear strap or retention arrangement and the gauge 3670 could be positioned on the other side, such as near or covering each ear of the patient, for example.

[0255] With reference to Figures 37A-E, further embodiments of a retention arrangement 3750 are illustrated, either alone or with a cannula assembly 3700. Tight headgear adjustments and unintended movement of the cannula can apply uncomfortable pressure to the patient’s face during use. In some applications or for some patients, methods of attachment that either adhere to the patient’s cheeks or rely on facial features (e.g., ears) to support the weight of the cannula can also cause discomfort. Furthermore, positioning the cannula to suit an individual’s facial geometry or body position, in some situations, can be difficult and incorrect positioning can result in prong misalignment and discomfort. In at least some embodiments, the retention arrangements 3750 securely support the cannula in a comfortable manner.

[0256] Figure 37A illustrates an embodiment of an improved retention arrangement 3750 that comprises a headgear strap 3740. The illustrated headgear strap 3740 includes a pad 3752 that is affixed to the strap 3740. In some arrangements, the pad 3752 surrounds the strap 3740 and can be moved along the length of the strap 3740 to a desired
location, such as a rearward portion of the strap 3740 that is opposite the cannula (not shown) when the cannula assembly 3700 is assembled or in use. The strap 3740 can have a first portion 3740a and a second portion 3740b. The first portion 3740a can be made from a substantially non-stretchable material or can otherwise be constructed to have limited stretch characteristics. The first portion 3740a can be or include the end portions that connect to the cannula (not shown). Preferably, the second portion 3740b comprises a rear portion of the headgear strap 3740 and can be made from an elastic material or otherwise be constructed to have significant stretch characteristics, or at least significantly greater stretch characteristics than the first portion 3740a. The pad 3752 can be a wide, cushioned pad and can cover the second portion 3740b. That is, the pad 3752 can have a length that is greater than a length of the second portion 3740b in either or both of a relaxed orientation and a stretched orientation. The pad 3752 can also have a height that is significantly greater than a height of the strap 3740. Thus configured, the pad 3752 can distribute pressure over a wider area of the patient's head, while the elastic region or second portion 3740b of the strap 3740 can provide a force on the face when stretched. Preferably, the large surface area of the pad 3752 will also provide substantial stability due to increased friction, thus reducing the chance of the cannula moving from its ideal or preferred position. The non-stretch end portions or first portion 3740a of the headgear strap 3740 can connect to one or both of the elastic region or second portion 3740b of the strap 3740 and the pad 3752. The pad 3752 can be fixed in place relative to the strap 3740 or, in some arrangements, the pad 3752 can slide along the strap 3740 to the desired location and may also act as protection against nearby objects, such as hard bed frames, other equipment, etc. Alternatively, the pad 3752 can be made from an elastic material or otherwise constructed to exhibit stretch characteristics. In such an arrangement, the elastic region or second portion of the headgear strap 3740 can be included or omitted. If desired, a pad 3752 could be used with a substantially or entirely non-stretch strap, which has no elastic region. In such an arrangement, the pad 3752 may still improve comfort and stability, as described above.

[0257] With reference to Figures 37B-E, a nasal cannula assembly 3700 includes a cannula 3714 and a retention arrangement 3750. Preferably, the retention arrangement 3750 contacts the patient only at an upper region of the head or at a position above a line extending
around the head and generally passing through the patient's eyebrows. Such an arrangement supports the cannula 3714 substantially entirely with the upper region of the head for improved comfort. In the illustrated arrangement, the weight of the cannula 3714 is supported by a strap 3740 that encircles the upper head region. Two arms 3760 are supported by or hang from the strap 3740 down either side of the patient's face. The cannula 3714 is attached to the arms 3760 or can be integrally or unitarily formed with the arms 3760. Advantageously, with such an arrangement, no weight is supported by the patient's cheeks or ears, or any region below the strap 3740, thus inhibiting or preventing uncomfortable pressure from being applied to sensitive areas of the patient's head and face.

[0258] In some embodiments, the arms 3760 and/or cannula 3714 can be adjusted, such as moved and/or rotated on or relative to the strap 3740 about a hinge point or axis 3762 on either side of the head. Preferably, the arms 3760 and/or cannula 3714 are adjustable relative to the strap 3740. For example, the position of the cannula 3714 can be adjusted by shifting the arms 3760 up and down relative to the strap 3740. In the illustrated arrangement, a retention element or hub 3764 is supported by the strap 3740 and adjustably supports the arms 3760, such as via a ratchet assembly or other suitable adjustment mechanism. In some arrangements, the arms 3760 are adjustable around the circumference of the strap 3740. For example, the arms 3760 can be infinitely adjustable relative to the strap 3740, such as by utilizing a clamp mechanism integrated or separate from the hubs 3764. As illustrated, the hubs 3764 and, thus, the arms 3760 are adjustable to one of a discrete number of adjustment positions, such as via slots 3766 that receive the hubs 3764 and define two or more (e.g., three, four, five or more) discrete adjustment positions. Alternatively, the slots 3766 could permit free movement of the hubs 3764 such that the arms 3760 can float relative to the strap 3740 within a path defined by the slots 3766. If desired, the arms 3760 could be biased toward a relaxed position relative to the strap 3740 (e.g., center of the slots 3766) and can be free to move against the biasing force of a biasing member (e.g., spring). The strap 3740 can be made of or contain an elastic material (e.g., a one-size strap) or can have some form of size adjustment. Advantageously, the illustrated retention arrangement 3750 does not rely on the ears to support the cannula weight, thereby reducing or preventing pressure points. Because existing single headgear straps often sit below the widest point of the head, a tight fit is often
required to ensure the strap does not slip down. By having the strap 3740 sit above the widest point of the head, the strap 3740 will not have to be as tight and will be more secure. The illustrated arrangement also allows for at least three modes of cannula position adjustment. In other arrangements, the retention arrangement 3750 may provide for non-discrete adjustment positions between the arms 3760 and the strap 3740. For example, the arms 3760 could be coupled to the strap 3740 via a hook-and-loop fastener, or other similar fastening mechanism, to possibly permit a greater number of and/or more finite adjustment positions relative to the illustrated embodiment.

[0259] Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise”, “comprising”, and the like, are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense, that is to say, in the sense of “including, but not limited to”.

[0260] Reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that that prior art forms part of the common general knowledge in the field of endeavour in any country in the world.

[0261] The invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, in any or all combinations of two or more of said parts, elements or features.

[0262] Where, in the foregoing description reference has been made to integers or components having known equivalents thereof, those integers are herein incorporated as if individually set forth.

[0263] It should be noted that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the invention and without diminishing its attendant advantages. For instance, various components may be repositioned as desired. It is therefore intended that such changes and modifications be included within the scope of the invention. Moreover, not all of the features, aspects and advantages are necessarily required to practice the present invention. Accordingly, the scope of the present invention is intended to be defined only by the claims that follow.
WHAT IS CLAIMED IS:

1. A nasal cannula system, comprising:
   a cannula comprising a central body portion, a first side portion and a second side portion, wherein the first and second side portions extend in opposite lateral directions from the central body portion and contact a cheek or other facial features of a user when the system is in use, a first nasal prong and a second nasal prong extending from the central body portion, the central body portion comprising a patient facing side and at least one retention strap that cooperate to define a cavity, wherein the first and second nasal prongs communicate with the cavity;
   a manifold that receives a supply of gas from a gas source, the manifold comprising a gas inlet and a gas outlet, wherein the manifold is receivable within the cavity of the cannula such that the gas outlet is aligned with the first and second nasal prongs;
   wherein the at least one retention strap defines a first lateral edge and a second lateral edge, and wherein the first and second nasal prongs are located between the first lateral edge and the second lateral edge.

2. The nasal cannula system of Claim 1, wherein the at least one retention strap comprises a first retention strap and a second retention strap.

3. The nasal cannula system of Claim 1, wherein the at least one retention strap comprises at least one window through which at least one portion of the manifold is visible.

4. The nasal cannula system of Claim 1, wherein the cavity has a first end and a second end and the manifold can be inserted through either one of the first and second ends and closes off the other of the first and second ends.

5. The nasal cannula system of Claim 1, wherein each of the first and second side portions comprises a flex-inducing feature selected from one of a plurality of flex slots and a reduced cross-section portion to facilitate flexing of the first and second side portions relative to the central body portion.

6. The nasal cannula system of Claim 1, each of the first and second side portions comprises a recessed area on the patient facing side of the first and second portions, the recesses configured to accommodate portions of a headgear strap.
7. The nasal cannula system of Claim 1, further comprising a supply tube having a first end coupled to the manifold and a second end coupled to a connector, which permits the supply tube to be coupled to a gas delivery conduit, and a lanyard coupled to the supply tube with a lanyard connector, wherein the lanyard connector comprises a breakaway portion and at least one end of the lanyard is coupled to the breakaway portion.

8. The nasal cannula system of Claim 1, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

9. The nasal cannula system of Claim 1, wherein the first and second side portions comprise cheek pads configured to be secured to the cheeks of a patient.

10. The nasal cannula system of Claim 9, wherein the cheek pads comprise an adhesive layer.

11. The nasal cannula system of Claim 9, further comprising a pair of attachment pads having an adhesive layer to allow attachment to the cheeks of a patient, wherein the pair of attachment pads comprise one portion of a hook and loop fastener and the cheek pads comprise the other portion of the hook and loop fastener such that the cheek pads can be secured to the attachment pads.

12. The nasal cannula system of Claim 1, wherein the patient facing side of the central body portion comprises cushion details configured to space the central body portion away from the patient's face.

13. The nasal cannula system of Claim 1, further comprising a supply tube having a first end coupled to the manifold and a second end coupled to a connector, which permits the supply tube to be coupled to a gas delivery conduit, and a lanyard coupled to the supply tube with a lanyard connector, wherein a portion of the lanyard coupled to the lanyard connector extends substantially along a longitudinal axis of the lanyard connector.

14. The nasal cannula system of Claim 1, wherein each of the first and second side portions comprises an undercut on a surface opposite the patient facing side, further comprising a headgear strap comprising a first clip and a second clip that engages the undercut of the respective first and second side portions to couple the headgear strap to the cannula on the surface opposite the patient facing side.
15. The nasal cannula system of Claim 1, wherein the cannula defines a lateral slot, further comprising a head gear strap extending through the lateral slot.

16. The nasal cannula system of Claim 15, wherein the cannula is slidable along the head gear strap.

17. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first side portion and a second side portion, wherein the first and second side portions extend in opposite lateral directions from the central body portion and contact a cheek of a user when the system is in use, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity having an inlet at a first end, the cavity having a second end communicating with a first gas path and a second gas path, which communicate with the first and second nasal prongs, respectively, wherein the inlet is located at one of the first and second side portions and the first and second gas paths extend in a lateral direction toward the first and second nasal prongs;

   a supply tube having a first end connectable to a supply of gas from a gas source and a second end coupled to the inlet of the cavity of the cannula.

18. The nasal cannula system of Claim 17, further comprising a headgear strap and a tube clip coupled to the headgear strap, the tube clip configured to hold the supply tube away from the mouth and face of the user in use.

19. The nasal cannula system of Claim 17, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

20. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first side portion and a second side portion, wherein the first and second side portions extend in opposite lateral directions from the central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the central body portion defining a cavity and a forward-facing inlet to the cavity, wherein the first and second nasal prongs communicate with the cavity;

   a manifold that receives a supply of gas from a gas source, the manifold comprising a gas inlet and a gas outlet, wherein the manifold is connectable with the
cannula such that the gas outlet is aligned with the forward-facing inlet of the cannula and the gas inlet faces a lateral direction;

a supply tube connected to the gas inlet of the manifold and positioned forward of the forward-facing inlet of the cannula.

21. The nasal cannula system of Claim 20, wherein the manifold can be connected to the cannula in either of a first orientation with the gas inlet facing in a first lateral direction and a second orientation with the gas inlet facing in a second lateral direction.

22. The nasal cannula system of Claim 20, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

23. The nasal cannula system of Claim 20, further comprising a releasable fastener located on each of the first and second side portions of the cannula and corresponding first and second side portions of the manifold.

24. The nasal cannula system of Claim 23, further comprising a headgear strap coupled to the first and second side portions of the manifold, wherein the releasable fasteners are located on top of portions of the headgear strap located on the first and second side portions of the manifold.

25. The nasal cannula system of Claim 23, wherein the cannula comprises a rigid frame portion surrounding the inlet and extending into the first and second side portions.

26. The nasal cannula system of Claim 25, wherein a body portion of the cannula is formed over and at least partially surrounds the rigid frame portion.

27. A nasal cannula patient interface, comprising:

a first nasal prong and a second nasal prong, each of the first and second prongs comprising an inlet end and an outlet end;

at least one support portion configured to rest upon the nose of a patient at a point at or above the tip of the nose;

wherein, in use, no portion of the patient interface contacts an upper lip of the patient to provide any substantial support to the patient interface.

28. The nasal cannula patient interface of Claim 27, further comprising a nose strip having an adhesive layer to permit attachment to the nose of a patient, wherein the at least one
support portion comprises an attachment pad that couples the at least one support portion to the nose strip.

29. The nasal cannula patient interface of Claim 27, wherein the at least one support portion comprises a first support portion and a second support portion.

30. The nasal cannula patient interface of Claim 29, wherein the first support portion is positioned on a first lateral side and the second support portion is positioned on a second lateral side of the patient’s nose.

31. The nasal cannula patient interface of Claim 29, wherein the first support portion and first nasal prong are separate from the second support portion and second nasal prong.

32. The nasal cannula patient interface of Claim 27, further comprising a first supply tube and a second supply tube, the first supply tube connected to the inlet end of the first nasal prong, and the second supply tube connected to the inlet end of the second nasal prong.

33. The nasal cannula patient interface of Claim 32, further comprising a cheek pad configured to secure a portion of the first and second supply tubes to one or both of the patient’s cheeks.

34. The nasal cannula patient interface of Claim 32, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

35. The nasal cannula patient interface of Claim 27, wherein each of the first and second nasal prongs has a molded shape having a turn of about 180° between the inlet end and the outlet end.

36. The nasal cannula patient interface of Claim 27, further comprising a central body portion defining a cavity having an inlet and an outlet, the outlet in communication with the first and second nasal prongs and the inlet configured to receive a manifold coupled to a supply tube.

37. A nasal cannula patient interface, comprising:

   a first nasal pillow and a second nasal pillow, each of the first and second nasal pillows comprising an inlet end and an outlet end;

   at least one support portion configured to rest upon the nose of a patient at a point at or above the tip of the nose;
wherein, in use, no portion of the patient interface contacts an upper lip of the patient to provide any substantial support to the patient interface.

38. The nasal cannula patient interface of Claim 37, wherein the nasal pillows are self-inflating.

39. The nasal cannula patient interface of Claim 37, further comprising at least one supply tube that couples the first and second nasal pillows to a source of gas.

40. The nasal cannula patient interface of Claim 39, wherein the at least one supply tube comprises a first supply tube coupled to the first nasal pillow and a second supply tube coupled to the second nasal pillow.

41. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs, an integrated head strap comprising a first section and a second section, wherein the first and second sections extend in opposite lateral directions from the central body portion, the first section defining a rear portion of the head strap, an adjustable coupling arrangement that permits coupling of the first and section sections in an adjustable manner such that a circumference of the head strap is adjustable;

   a supply tube having a first end connectable to a supply of gas from a gas source and a second end coupled to the cavity of the cannula.

42. The nasal cannula system of Claim 41, wherein the cannula, first section and second section of the head strap are of a unitary construction.

43. The nasal cannula system of Claim 41, wherein the adjustable coupling arrangement comprises a slot defined by one of the first and second sections and a teeth-defining portion that is adjustably-received within the slot.

44. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs, wherein the cannula defines a lateral slot;
a head gear strap extending through the lateral slot of the cannula;
a supply tube having a first end connectable to a supply of gas from a gas source and a second end coupled to the cavity of the cannula.

45. The nasal cannula system of Claim 44, wherein the cannula is slidable along the head gear strap.

46. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs, the cannula defining a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location, a valve body that is movable within the cavity;

   a supply tube having a first end connectable to either one of the first opening or the second opening of the cannula and a second end connectable to a supply of gas from a gas source;

   wherein, when the first end of the supply tube is connected to the first opening of the cannula, the valve body moves in response to a flow of gas in the cavity from the gas source to block the second opening such that the flow of gas is directed to the first and second nasal prongs and, when the first end of the supply tube is connected to the second opening of the cannula, the valve body moves in response to the flow of gas in the cavity from the gas source to block the first opening such that the flow of gas is directed to the first and second nasal prongs.

47. The nasal cannula system of Claim 46, wherein the first location is a first end of the cannula and the second location is a second end of the cannula.

48. The nasal cannula system of Claim 46, wherein the valve body is either a ball or a plate.

49. The nasal cannula system of Claim 46, wherein the valve body is a ball and the cannula comprises first and second thin wall sections extending radially inward into each of the first and second openings and that create a seal with the ball.
50. The nasal cannula system of Claim 46, further comprising a connector coupled to the first end of the supply tube, wherein the connector has an interlocking connection with either one of the first and second openings of the cannula.

51. The nasal cannula system of Claim 50, further comprising a first insert and a second insert within a respective one of the first opening and the second opening, wherein the connector engages the first insert when coupled to the first opening and the second insert when coupled to the second opening.

52. A nasal cannula system, comprising:

a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs, the cannula defining a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location, the cannula comprising a first valve that selectively closes the first opening and a second valve that selectively closes the second opening;

a supply tube having a first end connectable to either one of the first opening or the second opening of the cannula and a second end connectable to a supply of gas from a gas source;

wherein, when the first end of the supply tube is connected to the first opening of the cannula, the second valve blocks the second opening such that a flow of gas from the gas source is directed to the first and second nasal prongs and, when the first end of the supply tube is connected to the second opening of the cannula, the first valve blocks the first opening such that the flow of gas is directed to the first and second nasal prongs.

53. The nasal cannula system of Claim 52, wherein the first location is a first end of the cannula and the second location is a second end of the cannula.

54. The nasal cannula system of Claim 52, wherein the first and second valves comprise one of a flap valve, a slit valve and a pierceable membrane.
55. The nasal cannula system of Claim 52, further comprising a connector coupled to the first end of the supply tube, wherein the connector has an interlocking connection with either one of the first and second openings of the cannula.

56. The nasal cannula system of Claim 55, wherein the first and second valves are pierceable membranes and the connector comprises a piercing point.

57. A nasal cannula system, comprising:

    a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs, the cannula defining a first opening at a first end of the cavity and a second opening at a second end of the cavity;

    a supply tube having a first end comprising a first insert and a second end comprising a second insert, wherein each of the first insert and the second insert is positionable within the cavity to seal the first opening and the second opening and deliver a flow of gas from the gas source to the first and second nasal prongs;

    wherein, when the first end of the supply tube is connected to the cannula, the second end is connectable to the gas source and, when the second end of the supply tube is connected to the cannula, the first end is connectable to the gas source.

58. The nasal cannula system of Claim 57, further comprising a connector that is connectable to a gas supply conduit that is in communication with the gas source, wherein the connector defines a cavity that can accommodate either of the first end and the second end of the supply tube in a substantially sealed manner.

59. The nasal cannula system of Claim 57, wherein the supply tube can pass through the cavity of the cannula when switching from the first end to the second end being connected to the cannula.

60. A nasal cannula system, comprising:

    a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs;

    a supply tube having a first end coupled to the cavity of the cannula and a second end connectable to a supply of gas from a gas source, the first end of the
supply tube defining a connection axis relative to the cannula, the supply tube comprising a flexible portion at or adjacent the first end that can be bent at least about 90 degrees to either the left or right side without significant occlusion of an internal passage of the supply tube.

61. The nasal cannula system of Claim 60, wherein the first end of the supply tube exits the cannula in a forward direction relative to a patient-facing surface of the cannula.

62. A nasal cannula system, comprising:
   a cannula comprising a cavity and a first nasal prong and a second nasal prong in communication with the cavity;
   a supply tube that receives a flow of gas from a gas source, the supply tube connected to the cannula to supply the flow of gas to the cavity of the cannula;
   a clip that removably receives the cannula;
   a retention arrangement that secures the clip to the head of a patient;
   wherein the cannula is positionable within the clip in a first orientation such that the supply tube extends in a first direction from the clip, and wherein the cannula is positionable within the clip in a second orientation such that the supply tube extends in a second direction from the clip.

63. The nasal cannula system of Claim 62, wherein the retention arrangement comprises one of a strap, one or more adhesive pads or a support frame.

64. A nasal cannula system, comprising:
   a cannula comprising a first nasal prong and a second nasal prong, the cannula defining a cavity in communication with the first and second nasal prongs, the cannula defining a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location;
   a supply tube assembly comprising a clip that can be releasably coupled to the cannula in either of a first orientation and a second orientation, the supply tube assembly further comprising a supply tube connectable to a supply of gas from a gas source, wherein the clip supports the supply tube and comprises a sealing portion;
   wherein, when the clip is connected to the cannula in the first orientation, the supply tube is connected to the first opening of the cannula and extends in a first
direction from the cannula and the sealing portion at least substantially seals the second opening and, when the clip is connected to the cannula in the second orientation, the supply tube is connected to the second opening of the cannula and extends in a second direction from the cannula and the sealing portion at least substantially seals the first opening.

65. The nasal cannula system of Claim 64, wherein the clip is a generally C-shaped clip.

66. The nasal cannula system of Claim 64, wherein the clip comprises at least one engagement portion that engages a corresponding receiving portion in both the first orientation and the second orientation to lock the clip to the cannula.

67. The nasal cannula system of Claim 66, wherein the engagement portion comprises an end portion of the clip.

68. The nasal cannula system of Claim 67, wherein the sealing portion comprises a semi-spherical protrusion.

69. The nasal cannula system of Claim 64, wherein the cannula comprises a recess that accommodates at least a central section of the clip and inhibits movement of the clip relative to the cannula in at least one direction.

70. The nasal cannula system of Claim 64, wherein an end of the supply tube abuts a surface of the cannula surrounding a respective one of the first and second openings when the clip is connected to the cannula.

71. The nasal cannula system of Claim 64, wherein an end of the supply tube is positioned within a respective one of the first and second openings when the clip is connected to the cannula.

72. The nasal cannula system of Claim 64, wherein the first and second prongs are carried by a prong insert that is separate from a main body portion of the cannula that defines the cavity, the first opening and the second opening, wherein the clip secures the prong insert to the main body portion of the cannula.

73. The nasal cannula system of Claim 72, wherein the prong insert is selectable from a selection of at least two different sizes of prong inserts comprising at least two different sizes of prongs.
74. The nasal cannula system of Claim 64, wherein the cannula is rotatable relative to the clip to permit adjustment of an angle of the first and second prongs.

75. A nasal cannula system, comprising:

a cannula clip comprising a first nasal prong and a second nasal prong, the cannula defining a cavity in communication with the first and second nasal prongs;

a supply tube assembly comprising a manifold having at least one manifold opening and a supply tube connectable to a supply of gas from a gas source, wherein the cannula clip is capable of being releasably coupled to the manifold in either of a first orientation and a second orientation in which the manifold is received within the cavity of the cannula clip and the first and second prongs are aligned with the at least one manifold opening such that a flow of gas is provided to the first and second prongs;

wherein, when the cannula clip is connected to the manifold in the first orientation, the supply tube extends in a first direction relative to the first and second prongs and, when the cannula clip is connected to the manifold in the second orientation, the supply tube extends in a second direction relative to the first and second prongs.

76. The nasal cannula system of Claim 75, wherein the manifold extends in a lateral direction through the cannula clip.

77. The nasal cannula system of Claim 75, wherein the manifold comprises a rib that is positioned between first and second edges of the cannula clip when the cannula clip is assembled to the manifold in either of the first orientation or the second orientation.

78. A nasal cannula system, comprising:

a cannula comprising a main body defining a cavity and a first nasal prong and a second nasal prong extending from the main body and in communication with the cavity;

a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;
wherein the first and second nasal prongs are tiltable relative to the main body of the cannula between at least a first position in which the first and second nasal prongs are tilted in a first direction relative to the main body and a second position in which the first and second nasal prongs are tilted in a second direction relative to the main body, wherein a first surface of the main body defines a patient-facing surface of the cannula in the first position and a second surface of the main body defines the patient-facing surface of the cannula in the second position to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

79. The nasal cannula system of Claim 78, wherein the first nasal prong and the second nasal prong are tiltable separately from one another.

80. The nasal cannula system of Claim 78, further comprising one or more ripples surrounding each of the first nasal prong and the second nasal prong, wherein the ripples facilitate tilting of the first and second nasal prongs.

81. The nasal cannula system of Claim 80, further comprising a stiffening rib within the ripples that inhibit tilting of the first and second nasal prongs in at least one direction other than the generally first and second directions.

82. The nasal cannula system of Claim 78, wherein each of the first and second nasal prongs comprise a collapsible corrugated concertina section that facilitates tilting of the prongs.

83. A nasal cannula system, comprising:

    a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

    a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

    wherein the first and second nasal prongs are directionally-oriented relative to the cannula and are movable between at least a first position in which the first and second nasal prongs are oriented such that openings of the prongs generally face in a first direction relative to the cannula and a second position in which the first and

-97-
second nasal prongs are oriented such that the openings of the prongs generally face in a second direction relative to the cannula, wherein a first surface of the cannula defines a patient-facing surface in the first position and a second surface of the cannula defines the patient-facing surface in the second position to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

84. The nasal cannula system of Claim 83, wherein the first nasal prong and the second nasal prong are movable between the first position and the second position separately from one another.

85. The nasal cannula system of Claim 83, wherein the first nasal prong and the second nasal prong are supported by a prong insert that is separate from a main body of the cannula, which defines the cavity, wherein the prong insert is movable relative to the main body to move the prongs together between the first position and the second position.

86. The nasal cannula system of Claim 85, wherein prong insert is rotatable on a shaft of the main body of the cannula.

87. The nasal cannula system of Claim 86, wherein the shaft is located between the first nasal prong and the second nasal prong.

88. The nasal cannula system of Claim 87, wherein the shaft is either aligned with the first and second nasal prongs or offset from the first and second nasal prongs.

89. The nasal cannula system of Claim 85, wherein the main body defines an opening in communication with the cavity and that removably receives the prong insert.

90. The nasal cannula system of Claim 89, wherein the prong insert is selectable from a selection of at least two different sizes of prong inserts comprising at least two different sizes of prongs.
91. A nasal cannula system, comprising:

   a cannula defining a patient-facing surface and a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

   a manifold that supports the cannula for rotation about at least one axis between at least a first position and a second position opposite the first position;

   a supply tube coupled to the manifold and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

   wherein, when the cannula is in the first position, the supply tube is positioned on a first side of the first and second nasal prongs and, when the cannula is in the second position, the supply tube is positioned on a second side of the first and second nasal prongs to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

92. The nasal cannula system of Claim 91, wherein the cannula is connected to the manifold by a ball joint arrangement such that the cannula is rotatable relative to the manifold about at least two axes, such that a tilt of the first and second nasal prongs can be adjusted.

93. The nasal cannula system of Claim 91, wherein the cannula is selectable from a selection of at least two different sizes of cannulas comprising at least two different sizes of prongs.

94. The nasal cannula system of Claim 91, wherein the cannula comprises a prong portion and a connection portion that are separable from one another, wherein the prong portion is selectable from a selection of at least two different sizes of prong portions comprising at least two different sizes of prongs, which can be coupled to the connection portion for use.

95. The nasal cannula system of Claim 91, wherein the cannula and the manifold comprise interference surface features that assist in securing the cannula in a desired position relative to the manifold.
96. A nasal cannula system, comprising:

a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

a pressure line in communication with the cavity and configured to be connectable to a control unit of the gas source or a display unit to provide a signal to the control unit or display unit indicative of a pressure within the cavity.

97. The nasal cannula system of Claim 96, wherein the pressure line is a tube and the signal is gas pressure within the tube.

98. The nasal cannula system of Claim 97, wherein a portion of the pressure line located within the cavity comprises a plurality of openings along a length of the tube.

99. The nasal cannula system of Claim 97, wherein the pressure line is coupled to the gas source, which provides a flow of gas into the pressure line either intermittently or continuously.

100. The nasal cannula system of Claim 96, wherein the pressure line is an electrical line comprising an electrical pressure sensor and the signal is an electrical signal.

101. The nasal cannula system of Claim 96, wherein the pressure line is in indirect communication with the cavity.

102. The nasal cannula system of Claim 96, wherein the pressure line is coupled to a connector that is coupled to the cannula.

103. The nasal cannula system of Claim 102, wherein the supply tube is coupled to the cannula by the connector along with the pressure line.

104. The nasal cannula system of Claim 96, wherein the pressure line extends into the cavity through a one-way self-sealing valve.

105. The nasal cannula system of Claim 96, wherein the pressure line is integrated with the supply tube.

106. The nasal cannula system of Claim 105, wherein the pressure line is integrated with a reinforcing bead of the supply tube.
107. A nasal cannula, comprising:

a cannula body defining a cavity and comprising a first nasal prong and a
second nasal prong extending from the cannula and in communication with the cavity,
wherein the cannula defines a patient-facing surface having one or more comfort
features selected from a plurality of through-holes, a plurality of raised bumps, a
plurality of grooves and a gel pad.

108. The nasal cannula of Claim 107, wherein the cannula comprises a central
portion containing the first and second nasal prongs and first and second side portions
extending from each side of the central portion, wherein the comfort features are provided
only on the first and second side portions.

109. The nasal cannula of Claim 107, wherein each of the grooves extends from one
edge of the cannula to another edge of the cannula such that the grooves are open on each
end.

110. The nasal cannula of Claim 109, wherein the grooves extend from an upper
edge of the cannula to a lower edge of the cannula.

111. A nasal cannula, comprising:

a cannula body defining a cavity and comprising a first nasal prong and a
second nasal prong extending from the cannula and in communication with the cavity,
the cannula body comprising a central portion containing the first and second nasal
prongs and first and second side portions extending from each side of the central
portion, wherein the cannula body defines a patient-facing surface;

wherein the central portion is spaced forwardly of adjacent portions of the first
and second side portions such that, in use, the patient-facing surface of the central
portion is spaced from the upper lip of the patient.

112. The nasal cannula of Claim 111, wherein the first and second prongs extend
from the patient-facing surface of the central portion.

113. The nasal cannula of Claim 111, wherein the side portions comprise a malleable
material portion such that a shape of the side portions can be adjusted.

114. The nasal cannula of Claim 113, wherein the malleable material portion is
external or is embedded within the side portions.
115. A supply tube for a nasal cannula, comprising:

a tube body having a first end and a second end, the tube body comprising a malleable section that permits the section to be shaped by an external force and that substantially retains the shape after the external force is removed.

116. The supply tube of Claim 115, wherein the malleable section comprises a malleable member that located in one of the following: an internal passage of the tube body, embedded in a wall of the tube body, embedded in or forming a reinforcement bead of the tube body.

117. The supply tube of Claim 115, wherein the malleable section comprises a plurality of individual members adjustably coupled to one another.

118. The supply tube of Claim 117, wherein the individual members are coupled by a ball-and-socket arrangement.

119. The supply tube of Claim 115, wherein the malleable section comprises a collapsible corrugated concertina tubing.

120. A nasal cannula system, comprising:

a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

a support arrangement that supports the supply tube at a spaced location from the cannula, wherein the support arrangement comprises a fastener having a first portion coupled to the supply tube and a second portion located at the spaced location.

121. The nasal cannula system of Claim 120, wherein the support arrangement comprises an adhesive pad that can be affixed to the patient and the second portion of the fastener is located on the adhesive pad.

122. The nasal cannula system of Claim 120, further comprising a retention arrangement that secures the cannula to the patient, wherein the second portion of the fastener is located on the retention arrangement.
123. The nasal cannula system of Claim 120, wherein the fastener is one of a hook-and-loop fastener, a button-and-hole, and a snap-fit fastener.

124. A nasal cannula system, comprising:
   a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
   a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;
   a retention arrangement that secures the cannula to the patient;
   a support arrangement that supports the supply tube at a spaced location from the cannula, which is located on the retention arrangement.

125. The nasal cannula system of Claim 124, wherein the support arrangement comprises a clip that engages the supply tube and is supported by the retention arrangement.

126. The nasal cannula system of Claim 124, wherein the support arrangement comprises a loop that is carried by the retention arrangement.

127. The nasal cannula system of Claim 126, wherein the loop is integrated with the retention arrangement.

128. The nasal cannula system of Claim 126, wherein the loop is an interrupted loop or an uninterrupted loop.

129. A nasal cannula system, comprising:
   a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
   a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;
   a support arrangement that supports the supply tube at a spaced location from the cannula, wherein the support arrangement comprises a fastener that engages a piece of fabric at the spaced location.

130. The nasal cannula system of Claim 129, wherein the fastener is one of a clip, a snap-fit fastener or a clip-and-post fastener in which the piece of fabric is trapped between
portions of the fastener, or a button-and-hole fastener in which the button is provided on the piece of fabric.

131. The nasal cannula system of Claim 129, wherein the fastener is integrated with the supply tube.

132. The nasal cannula system of Claim 129, wherein the fastener comprises an opening configured to receive a lanyard.

133. A nasal cannula system, comprising:
   a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
   a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;
   a support arrangement that supports the supply tube at a spaced location from the cannula, wherein the support arrangement comprises at least one of an armband that engages the supply tube, an adhesive pad comprising a fastener for releasably fastening the supply tube to the adhesive pad, a generally U-shaped support that sits on the patient's shoulder and engages the supply tube, and a headgear strap comprising a strap extending over the top of the patient's head and engages the supply tube.

134. A retention arrangement for a nasal cannula assembly, comprising:
   a headgear strap comprising a first ear loop and a second ear loop, each of which at least partially surround an ear of the patient, a connection portion that connects the retention arrangement to the nasal cannula assembly, and a strap portion that extends around the back of the patient's head between the first and second ear loops.

135. The retention arrangement of Claim 134, wherein each of the first and second ear loops completely surround the ear of the patient.

136. The retention arrangement of Claim 134, wherein the strap portion is one-piece or separate pieces coupled by an adjustable fastener.
137. The retention arrangement of Claim 134, wherein the strap portion comprises a mesh section.

138. A retention arrangement for a nasal cannula, comprising:

   a headgear strap comprising a strap portion, a first pad and a second pad, which, in use, contact first and second cheeks of the patient, a connection portion that connects the retention arrangement to the nasal cannula, wherein the strap portion extends around the patient’s head and extends from the first and second pads at an angle relative to the nasal cannula.

139. The retention arrangement of Claim 138, wherein the strap portion is positioned above the ears of the patient.

140. A retention arrangement for a nasal cannula, comprising:

   a frame comprising a connection portion that connects the retention arrangement to the nasal cannula, a first ear stem portion and a second ear stem portion extending rearwardly from opposite sides of the connection portion, wherein the ear stem portions are configured to be positioned above the ears of the patient.

141. The retention arrangement of Claim 140, further comprising a pad on each of the ear stem portions.

142. A nasal cannula system, comprising:

   a cannula having a central portion defining a cavity and comprising a first nasal prong and a second nasal prong extending from the central portion and in communication with the cavity, a first side portion and a second side portion extending in a lateral direction from opposing sides of the central portion;

   a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

   a first adhesive pad and a second adhesive pad configured to be adhesively secured to the face of the patient and connectable to a respective one of the first and second side portions of the cannula through an adjustable fastening arrangement.

143. The nasal cannula system of Claim 142, wherein the adjustable fastening arrangement comprises a ratchet assembly between the side portions and the respective
adhesive pads, a strip of hook-and-loop fastener between the side portions and the respective adhesive pads, or a post-and-multiple-slot arrangement between the side portions and the respective adhesive pads.

144. A nasal cannula system, comprising:
    a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
    a modular retention arrangement that secures the cannula to the patient, wherein the cannula is configured to be used with any one of the retention arrangements selected from a set of adhesive pads that attach to the patient’s face, a headgear strap and a halo-style headgear strap that has a strap portion extending over the top of the patient’s head.

145. The nasal cannula system of Claim 144, wherein the cannula has multiple connection points with the retention arrangement on each side of the cannula.

146. The nasal cannula system of Claim 144, comprising a kit including the cannula and at least two types of the retention arrangements.

147. A nasal cannula system, comprising:
    a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
    a modular retention arrangement that secures the cannula to the patient, the retention arrangement comprising a nose strip coupled to the cannula and attachable to the nose of a patient and a headgear strap comprising a clip configured to receive the cannula, wherein the cannula can be secured to the patient using either the nose strip or the headgear strap.

148. The nasal cannula system of Claim 147, wherein the nose strip can be applied directly to the patient's nose via an adhesive layer or is applied via attachment to a separate adhesive strip.

149. The nasal cannula system of Claim 147, wherein the nose strip can be removed from the cannula.
150. A retention arrangement for a nasal cannula, comprising:

a headgear strap that is connectable to a nasal cannula and capable of being tensioned around the head of a patient, the headgear strap comprising a tension indicator that provides a first indication when the tension is at an incorrect value and a second indication when the tension is at a correct value.

151. The retention arrangement of Claim 150, wherein the tension indicator is one of a portion that changes color between the first indication and the second indication, a portion that displays a different symbol for the first indication and the second indication, a window that displays a marker in the second indication, a scale, and a gauge.

152. The retention arrangement of Claim 151, wherein the tension indicator is a gauge that is positioned on a cheek of the patient and comprises a padded patient-facing surface.

153. The retention arrangement of Claim 150, wherein the headgear strap comprises a first portion, a second portion and a biasing member that regulates movement between the first portion and the second portion.

154. The retention arrangement of Claim 153, wherein the biasing member is one of a spring and an elastic section of the headgear strap.

155. The retention arrangement of Claim 150, wherein the headgear strap is a single strap comprising multiple strap portions that each extend from one side to the other of the cannula.

156. The retention arrangement of Claim 155, wherein the headgear strap can be tightened by adjusting a total length of the strap extending between the sides of the cannula.

157. The retention arrangement of Claim 155, wherein the strap portions are spaced from one another in a top-to-bottom direction of the cannula.

158. A retention arrangement for a nasal cannula, comprising:

a headgear strap that is connectable to a nasal cannula and comprises at least one strap extending around the head of a patient from one side to the other of the cannula;

a tension adjuster that tensions the headgear strap by varying an effective length of the at least one strap by winding up a portion of the at least one strap.
159. The retention arrangement of Claim 158, wherein the at least one strap comprises multiple straps.

160. The retention arrangement of Claim 158, wherein the tension adjuster is bidirectional and can wind up or release the portion of the at least one strap to increase or decrease.

161. The retention arrangement of Claim 158, wherein the tension adjuster comprises a limiter to limit the tension of the at least one strap.

162. The retention arrangement of Claim 161, wherein the limiter is a clutch mechanism.

163. A headgear strap for a nasal cannula, comprising:
     a first portion that is connectable to a nasal cannula;
     a second, elastic portion that is positioned at a back of a head of a patient in use; and
     a pad that extends at least partially along the second, elastic portion.

164. The headgear strap of Claim 163, wherein the pad surrounds an entirety of the second, elastic portion.

165. A nasal cannula assembly, comprising:
     a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
     a head strap that is positioned around the head and above the ears of the patient in use;
     a first arm coupled to a first side of the cannula; and
     a second arm coupled to a second side of the cannula, wherein upper end portions of each of the first and second arms are attached to the head strap.

166. The nasal cannula assembly of Claim 165, wherein each of the first and second arms is adjustable in height relative to the head strap.

167. The nasal cannula assembly of Claim 165, wherein each of the first and second arms is adjustable in a circumferential direction of the head strap.

168. The nasal cannula assembly of Claim 167, wherein each of the first and second arms is adjustable to one of a discrete number of adjustment positions.
169. The nasal cannula assembly of Claim 165, wherein each of the first and second arms is rotatable relative to the head strap.
NASAL CANNULA ASSEMBLY

ABSTRACT OF THE DISCLOSURE

Nasal cannula assemblies for providing respiratory therapy to patients are provided. A nasal cannula assembly can include a cannula, an optional manifold, a gas supply tube, and a securement mechanism. Securement mechanisms can include headgear straps, cheek pads, or an adhesive nose strip. A nasal cannula assembly can also include a lanyard, lanyard clip, and/or lanyard connector to help support the weight of a main gas delivery conduit.
TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

March 20, 2014

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 61/815,671
FILING DATE: April 24, 2013

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US61/815,671

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

M. K. CARTER
Certifying Officer
Electronic Acknowledgement Receipt

<table>
<thead>
<tr>
<th>EFS ID:</th>
<th>15606047</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Number:</td>
<td>61815671</td>
</tr>
<tr>
<td>International Application Number:</td>
<td></td>
</tr>
<tr>
<td>Confirmation Number:</td>
<td>7654</td>
</tr>
<tr>
<td>Title of Invention:</td>
<td>NASAL CANNULA ASSEMBLY</td>
</tr>
<tr>
<td>First Named Inventor/Applicant Name:</td>
<td>Jason Allan Klenner</td>
</tr>
<tr>
<td>Customer Number:</td>
<td>20995</td>
</tr>
<tr>
<td>Filer:</td>
<td>Curtiss C. Dosier/Lori Larson</td>
</tr>
<tr>
<td>Filer Authorized By:</td>
<td>Curtiss C. Dosier</td>
</tr>
<tr>
<td>Attorney Docket Number:</td>
<td>FPHCR.341PR2</td>
</tr>
<tr>
<td>Receipt Date:</td>
<td>24-APR-2013</td>
</tr>
<tr>
<td>Filing Date:</td>
<td></td>
</tr>
<tr>
<td>Time Stamp:</td>
<td>19:56:17</td>
</tr>
<tr>
<td>Application Type:</td>
<td>Provisional</td>
</tr>
</tbody>
</table>

Payment information:

<table>
<thead>
<tr>
<th>Submitted with Payment</th>
<th>yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment Type</td>
<td>Credit Card</td>
</tr>
<tr>
<td>Payment was successfully received in RAM</td>
<td>$660</td>
</tr>
<tr>
<td>RAM confirmation Number</td>
<td>6178</td>
</tr>
<tr>
<td>Deposit Account</td>
<td>111410</td>
</tr>
<tr>
<td>Authorized User</td>
<td>KNOBBE MARTENS OLSON AND BEAR</td>
</tr>
</tbody>
</table>

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:
- Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)
- Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)
### File Listing:

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Document Description</th>
<th>File Name</th>
<th>File Size(Bytes)/Message Digest</th>
<th>Multi Part./.zip</th>
<th>Pages (if appl.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Application Data Sheet</td>
<td>FPHCR_341PR2.pdf</td>
<td>1503203</td>
<td>no</td>
<td>8</td>
</tr>
</tbody>
</table>

#### Warnings:

#### Information:

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Document Description</th>
<th>File Name</th>
<th>File Size(Bytes)/Message Digest</th>
<th>Multi Part./.zip</th>
<th>Pages (if appl.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>FPHCR_341PR2_Spec.pdf</td>
<td>5784214</td>
<td>yes</td>
<td>110</td>
</tr>
</tbody>
</table>

#### Multipart Description/PDF files in .zip description

<table>
<thead>
<tr>
<th>Document Description</th>
<th>Start</th>
<th>End</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specification</td>
<td>1</td>
<td>84</td>
</tr>
<tr>
<td>Claims</td>
<td>85</td>
<td>109</td>
</tr>
<tr>
<td>Abstract</td>
<td>110</td>
<td>110</td>
</tr>
</tbody>
</table>

#### Warnings:

#### Information:

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Document Description</th>
<th>File Name</th>
<th>File Size(Bytes)/Message Digest</th>
<th>Multi Part./.zip</th>
<th>Pages (if appl.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Drawings-only black and white line drawings</td>
<td>FPHCR_341PR2_Drawings.pdf</td>
<td>7152651</td>
<td>no</td>
<td>69</td>
</tr>
</tbody>
</table>

#### Warnings:

#### Information:

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Document Description</th>
<th>File Name</th>
<th>File Size(Bytes)/Message Digest</th>
<th>Multi Part./.zip</th>
<th>Pages (if appl.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Fee Worksheet (SB06)</td>
<td>fee-info.pdf</td>
<td>31216</td>
<td>no</td>
<td>2</td>
</tr>
</tbody>
</table>

#### Warnings:

#### Information:

**Total Files Size (in bytes)**: 14471284
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**
If a new international application is being filed and the International Application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.
NASAL CANNULA ASSEMBLY

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present disclosure relates to devices and systems for providing gases to patients for respiratory therapy. More specifically, the present disclosure relates to nasal cannula interfaces for providing gases to patients via the nasal passages.

Description of the Related Art

[0002] Medical professionals may wish to provide patients with respiratory assistance in the form of supplemental oxygen or airflow for many reasons in ICU, other hospital, or home environments. Different types of interfaces for supplying gases to patients are available. For example, various nasal masks, full face masks, oral interfaces, nasal pillows, and nasal cannula interfaces exist. Nasal cannula interfaces typically include two nasal prongs that are placed in the patient's nostrils to deliver gases to the patient.

SUMMARY OF THE INVENTION

[0003] The nasal cannula interfaces described herein can advantageously be used to deliver gases to patients over a wide range of concentrations and flow rates. The nasal cannula interfaces described herein also include various features designed to improve patient comfort, safety, ease of use, and/or efficiency, reduce costs, and/or provide other benefits.

[0004] In some embodiments, a nasal cannula system includes a cannula and a manifold. The cannula includes a central body portion, first and second side portions that extend in opposite lateral directions from the central body portion and contact a cheek of a user when the system is in use, and first and second nasal prongs extending from the central body portion. The central body portion includes a patient facing side and at least one retention strap that cooperate to define a cavity. The first and second nasal prongs communicate with the cavity. The manifold receives a supply of gas from a gas source and includes a gas inlet and a gas outlet. The manifold is receivable within the cavity of the cannula such that the gas outlet is aligned with the first and second nasal prongs. The at least one retention strap defines first and second lateral edges, and the first and second nasal prongs are located between the first and second lateral edges.
In some embodiments, a nasal cannula system includes a cannula and a supply tube. The cannula includes a central body portion, first and second side portions that extend in opposite lateral directions from the central body portion and contact a cheek of a user when the system is in use, and first and second nasal prongs extending from the central body portion. The cannula defines a cavity having an inlet at a first end and a second end communicating with first and second gas paths. The first and second gas paths communicate with the first and second nasal prongs, respectively. The inlet is located at one of the first and second side portions, and the first and second gas paths extend in a lateral direction toward the first and second nasal prongs. The supply tube has a first end connectable to a supply of gas from a gas source and a second end coupled to the inlet of the cavity of the cannula.

In some embodiments, a nasal cannula system includes a cannula, a manifold, and a supply tube. The cannula includes a central body portion, first and second side portions that extend in opposite lateral directions from the central body portion, and first and second nasal prongs extending from the central body portion. The central body portion defines a cavity and a forward-facing inlet to the cavity. The first and second nasal prongs communicate with the cavity. The manifold receives a supply of gas from a gas source and includes a gas inlet and a gas outlet. The manifold is connectable with the cannula such that the gas outlet is aligned with the forward-facing inlet of the cannula and the gas inlet faces a lateral direction. The supply tube is connected to the gas inlet of the manifold and positioned forward of the forward-facing inlet of the cannula.

In some embodiments, a nasal cannula patient interface includes first and second nasal prongs, each including an inlet end and an outlet end, and at least one support portion configured to rest upon the nose of a patient at a point at or above the tip of the nose. In use, no portion of the patient interface contacts an upper lip of the patient to provide any substantial support to the patient interface.

In some embodiments, a nasal cannula system comprises a cannula having a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. An integrated head strap includes a first section and a second section, wherein the first and second sections extend in opposite lateral directions from the central body portion.
The first section defines a rear portion of the head strap. An adjustable coupling arrangement permits coupling of the first and section sections in an adjustable manner such that a circumference of the head strap is adjustable. A supply tube has a first end connectable to a supply of gas from a gas source and a second end coupled to the cavity of the cannula.

[0009] In some embodiments, a nasal cannula system includes a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a lateral slot. A head gear strap extends through the lateral slot of the cannula. A supply tube has a first end connectable to a supply of gas from a gas source and a second end coupled to the cavity of the cannula.

[0010] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location. A valve body is movable within the cavity. A supply tube has a first end connectable to either one of the first opening or the second opening of the cannula and a second end connectable to a supply of gas from a gas source. When the first end of the supply tube is connected to the first opening of the cannula, the valve body moves in response to a flow of gas in the cavity from the gas source to block the second opening such that the flow of gas is directed to the first and second nasal prongs and, when the first end of the supply tube is connected to the second opening of the cannula, the valve body moves in response to the flow of gas in the cavity from the gas source to block the first opening such that the flow of gas is directed to the first and second nasal prongs.

[0011] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location. The cannula comprises a first valve that selectively closes the first opening and a second valve that
selectively closes the second opening. A supply tube has a first end connectable to either one of the first opening or the second opening of the cannula and a second end connectable to a supply of gas from a gas source. When the first end of the supply tube is connected to the first opening of the cannula, the second valve blocks the second opening such that a flow of gas from the gas source is directed to the first and second nasal prongs and, when the first end of the supply tube is connected to the second opening of the cannula, the first valve blocks the first opening such that the flow of gas is directed to the first and second nasal prongs.

[0012] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first end of the cavity and a second opening at a second end of the cavity. A supply tube has a first end comprising a first insert and a second end comprising a second insert. Each of the first insert and the second insert is positionable within the cavity to seal the first opening and the second opening and deliver a flow of gas from the gas source to the first and second nasal prongs. When the first end of the supply tube is connected to the cannula, the second end is connectable to the gas source and, when the second end of the supply tube is connected to the cannula, the first end is connectable to the gas source.

[0013] In some embodiments, a nasal cannula system comprises a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion. The cannula defines a cavity in communication with the first and second nasal prongs. A supply tube has a first end coupled to the cavity of the cannula and a second end connectable to a supply of gas from a gas source. The first end of the supply tube defines a connection axis relative to the cannula. The supply tube comprises a flexible portion at or adjacent the first end that can be bent at least about 90 degrees to either the left or right side without significant occlusion of an internal passage of the supply tube.

[0014] In some embodiments, a nasal cannula system comprises a cannula comprising a cavity and a first nasal prong and a second nasal prong in communication with the cavity. A supply tube receives a flow of gas from a gas source. The supply tube is connected to the cannula to supply the flow of gas to the cavity of the cannula. A clip
removably receives the cannula. A retention arrangement secures the clip to the head of a patient. The cannula is positionable within the clip in a first orientation such that the supply tube extends in a first direction from the clip, and the cannula is positionable within the clip in a second orientation such that the supply tube extends in a second direction from the clip.

[0015] In some embodiments, a nasal cannula system comprises a cannula comprising a first nasal prong and a second nasal prong. The cannula defines a cavity in communication with the first and second nasal prongs. The cannula defines a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location. A supply tube assembly comprises a clip that can be releasably coupled to the cannula in either of a first orientation and a second orientation. The supply tube assembly further comprises a supply tube connectable to a supply of gas from a gas source. The clip supports the supply tube and comprises a sealing portion. When the clip is connected to the cannula in the first orientation, the supply tube is connected to the first opening of the cannula and extends in a first direction from the cannula and the sealing portion at least substantially seals the second opening and, when the clip is connected to the cannula in the second orientation, the supply tube is connected to the second opening of the cannula and extends in a second direction from the cannula and the sealing portion at least substantially seals the first opening.

[0016] In some embodiments, a nasal cannula system comprises a cannula clip comprising a first nasal prong and a second nasal prong. The cannula defines a cavity in communication with the first and second nasal prongs. A supply tube assembly comprises a manifold having at least one manifold opening and a supply tube connectable to a supply of gas from a gas source. The cannula clip is capable of being releasably coupled to the manifold in either of a first orientation and a second orientation in which the manifold is received within the cavity of the cannula clip and the first and second prongs are aligned with the at least one manifold opening such that a flow of gas is provided to the first and second prongs. When the cannula clip is connected to the manifold in the first orientation, the supply tube extends in a first direction relative to the first and second prongs and, when the cannula clip is connected to the manifold in the second orientation, the supply tube extends in a second direction relative to the first and second prongs.
In some embodiments, a nasal cannula system comprises a cannula comprising a main body defining a cavity and a first nasal prong and a second nasal prong extending from the main body and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. The first and second nasal prongs are tiltable relative to the main body of the cannula between at least a first position in which the first and second nasal prongs are tilted in a first direction relative to the main body and a second position in which the first and second nasal prongs are tilted in a second direction relative to the main body. A first surface of the main body defines a patient-facing surface of the cannula in the first position and a second surface of the main body defines the patient-facing surface of the cannula in the second position to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. The first and second nasal prongs are directionally-oriented relative to the cannula and are movable between at least a first position in which the first and second nasal prongs are oriented such that openings of the prongs generally face in a first direction relative to the cannula and a second position in which the first and second nasal prongs are oriented such that the openings of the prongs generally face in a second direction relative to the cannula. A first surface of the cannula defines a patient-facing surface in the first position and a second surface of the cannula defines the patient-facing surface in the second position to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

In some embodiments, a nasal cannula system comprises a cannula defining a patient-facing surface and a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A manifold supports the cannula for rotation about at least one axis between at least a first position and a second
position opposite the first position. A supply tube is coupled to the manifold and in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. When the cannula is in the first position, the supply tube is positioned on a first side of the first and second nasal prongs and, when the cannula is in the second position, the supply tube is positioned on a second side of the first and second nasal prongs to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

[0020] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A pressure line is in communication with the cavity and is configured to be connectable to a control unit of the gas source or a display unit to provide a signal to the control unit or display unit indicative of a pressure within the cavity.

[0021] In some embodiments, a nasal cannula comprises a cannula body defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. The cannula defines a patient-facing surface having one or more comfort features selected from a plurality of through-holes, a plurality of raised bumps, a plurality of grooves and a gel pad.

[0022] In some embodiments, a nasal cannula comprises a cannula body defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. The cannula body comprises a central portion containing the first and second nasal prongs and first and second side portions extending from each side of the central portion. The cannula body defines a patient-facing surface. The central portion is spaced forwardly of adjacent portions of the first and second side portions such that, in use, the patient-facing surface of the central portion is spaced from the upper lip of the patient.

[0023] In some embodiments, a supply tube for a nasal cannula comprises a tube body having a first end a second end. The tube body comprises a malleable section that
permits the section to be shaped by an external force and that substantially retains the shape after the external force is removed.

[0024] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A support arrangement supports the supply tube at a spaced location from the cannula. The support arrangement comprises a fastener having a first portion coupled to the supply tube and a second portion located at the spaced location.

[0025] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A retention arrangement secures the cannula to the patient. A support arrangement supports the supply tube at a spaced location from the cannula, which is located on the retention arrangement.

[0026] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A support arrangement supports the supply tube at a spaced location from the cannula. The support arrangement comprises a fastener that engages a piece of fabric at the spaced location.

[0027] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a
gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A support arrangement supports the supply tube at a spaced location from the cannula. The support arrangement comprises at least one of an armband that engages the supply tube, an adhesive pad comprising a fastener for releasably fastening the supply tube to the adhesive pad, a generally U-shaped support that sits on the patient’s shoulder and engages the supply tube, and a headgear strap comprising a strap extending over the top of the patient’s head and engages the supply tube.

[0028] In some embodiments, a retention arrangement for a nasal cannula assembly comprises a headgear strap comprising a first ear loop and a second ear loop, each of which at least partially surround an ear of the patient. A connection portion connects the retention arrangement to the nasal cannula assembly. A strap portion extends around the back of the patient’s head between the first and second ear loops.

[0029] In some embodiments, a retention arrangement for a nasal cannula comprises a headgear strap comprising a strap portion. A first pad and a second pad, in use, contact first and second cheeks of the patient. A connection portion connects the retention arrangement to the nasal cannula. The strap portion extends around the patient’s head and extends from the first and second pads at an angle relative to the nasal cannula.

[0030] In some embodiments, a retention arrangement for a nasal cannula comprises a frame comprising a connection portion that connects the retention arrangement to the nasal cannula. A first ear stem portion and a second ear stem portion extend rearwardly from opposite sides of the connection portion. The ear stem portions are configured to be positioned above the ears of the patient.

[0031] In some embodiments, a nasal cannula system comprises a cannula having a central portion defining a cavity and comprising a first nasal prong and a second nasal prong extending from the central portion and in communication with the cavity. A first side portion and a second side portion extend in a lateral direction from opposing sides of the central portion. A supply tube is coupled to the cannula and is in communication with the cavity. The supply tube is connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs. A first adhesive pad and a second adhesive pad are configured to be adhesively secured to the face of the patient and connectable to a
respective one of the first and second side portions of the cannula through an adjustable fastening arrangement.

[0032] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A modular retention arrangement secures the cannula to the patient. The cannula is configured to be used with any one of the retention arrangements selected from a set of adhesive pads that attach to the patient’s face, a headgear strap and a halo-style headgear strap that has a strap portion extending over the top of the patient’s head.

[0033] In some embodiments, a nasal cannula system comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A modular retention arrangement secures the cannula to the patient. The retention arrangement comprises a nose strip coupled to the cannula and attachable to the nose of a patient and a headgear strap comprising a clip configured to receive the cannula. The cannula can be secured to the patient using either the nose strip or the headgear strap.

[0034] In some embodiments, a retention arrangement for a nasal cannula comprises a headgear strap that is connectable to a nasal cannula and capable of being tensioned around the head of a patient. The headgear strap comprises a tension indicator that provides a first indication when the tension is at an incorrect value and a second indication when the tension is at a correct value.

[0035] In some embodiments, a retention arrangement for a nasal cannula comprises a headgear strap that is connectable to a nasal cannula. At least one strap extends around the head of a patient from one side to the other of the cannula. A tension adjuster tensions the headgear strap by varying an effective length of the at least one strap by winding up a portion of the at least one strap.

[0036] In some embodiments, a headgear strap for a nasal cannula comprises a first portion that is connectable to a nasal cannula and a second, elastic portion that is positioned at a back of a head of a patient in use. A pad extends at least partially along the second, elastic portion.
In some embodiments, a nasal cannula assembly comprises a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity. A head strap is positioned around the head and above the ears of the patient in use. A first arm is coupled to a first side of the cannula and a second arm is coupled to a second side of the cannula. Upper end portions of each of the first and second arms are attached to the head strap.

For purposes of summarizing the disclosure and the advantages achieved over the prior art, certain objects and advantages are described herein. Of course, it is to be understood that not necessarily all such objects or advantages need to be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the disclosure may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught or suggested herein without necessarily achieving other objects or advantages as may be taught or suggested herein. All of these embodiments are intended to be within the scope of the disclosure herein. These and other embodiments may become readily apparent to those skilled in the art from the following detailed description having reference to the attached figures, the disclosure not being limited to any particular disclosed embodiment(s).

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects and advantages of the present disclosure will be described with reference to the following drawings, which are illustrative but should not be limiting of the present disclosure.

Figure 1A illustrates an example embodiment of a nasal cannula assembly coupled to a patient;

Figure 1B illustrates a partial front perspective view of the nasal cannula assembly of Figure 1A;

Figure 1C illustrates an exploded view of the nasal cannula assembly of Figures 1A and 1B;

Figure 2A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;
Figure 2B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 2A;

Figure 3A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;

Figure 3B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 3A;

Figure 4 illustrates a partial front perspective view of an alternative configuration of the nasal cannula assembly of Figures 3A and 3B;

Figure 5A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula without a manifold;

Figure 5B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 5A;

Figure 6A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including cheek pads;

Figure 6B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 6A;

Figure 7A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula with an integrated headstrap;

Figure 7B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 7A;

Figure 7C illustrates an example embodiment of a lanyard connector for a nasal cannula assembly;

Figure 8A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;

Figure 8B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 8A;

Figure 8C illustrates an exploded view of the nasal cannula assembly of Figures 8A and 8B;

Figure 9A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and manifold;
[0059] Figure 9B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 9A;

[0060] Figure 9C illustrates a variation of the nasal cannula assembly of Figures 9A and 9B;

[0061] Figure 10A illustrates a side perspective view of an example embodiment of a nasal cannula assembly including a cannula and a nose strip attached to a patient’s face;

[0062] Figure 10B illustrates a partial rear perspective view of the nasal cannula assembly of Figure 10A;

[0063] Figure 11 illustrates an alternative configuration of the nasal cannula assembly of Figures 10A and 10B;

[0064] Figure 12A illustrates a partial front perspective view of an example embodiment of a nasal cannula assembly including two cannulas;

[0065] Figure 12B illustrates top, front, and side views of one of the cannulas of Figure 12A;

[0066] Figure 12C illustrates a front perspective view of the nasal cannula assembly of Figure 12A coupled to a patient;

[0067] Figure 13A illustrates a front perspective view of an example embodiment of a nasal cannula assembly including a cannula and retainer;

[0068] Figure 13B illustrates a partial side perspective view of the nasal cannula assembly of Figure 13A;

[0069] Figure 13C illustrates a partial front perspective view of the nasal cannula assembly of Figures 13A and 13B coupled to a patient;

[0070] Figure 14A illustrates a front perspective view of a nasal cannula assembly including a manifold and a cannula having nasal flaps;

[0071] Figure 14B illustrates an exploded view of the nasal cannula assembly of Figure 14A; and

[0072] Figure 14C illustrates the nasal cannula assembly of Figures 14A and 14B coupled to a patient.

[0073] Figures 15A-G illustrate an example embodiment of a nasal cannula assembly with a shuttle valve.
[0074] Figures 16A-F illustrate example embodiments of a nasal cannula assembly with a manifold having a one way valve formed from an exhalation style valve with a loosely hinged flap.

[0075] Figures 16G-L illustrate embodiments of a nasal cannula assembly with a manifold having a one way valve formed from a slit valve of various types.

[0076] Figures 17A and 17B illustrate an example embodiment of a nasal cannula assembly with a tube threaded through the manifold to allow for selective side switching of the tube exit side.

[0077] Figures 18A and 18B illustrate an example embodiment of a nasal cannula assembly with each tubing exit hole sealed by a thin membrane that is pierced by a sharpened end of the supply tube.

[0078] Figures 19A and 19B illustrate an example embodiment of a manifold with a flexible tube exiting the front tubing exit hole of the manifold.

[0079] Figures 20A-C illustrate an example embodiment of a manifold that snaps into an assembly securing device or clip.

[0080] Figures 21A-F illustrate example embodiments of a nasal cannula assembly with a removable tubing assembly and manifold.

[0081] Figures 21G and 21H illustrate an example embodiment of a nasal cannula assembly with a manifold receiving structure, separate nasal prong insert and a manifold.

[0082] Figures 22A-D illustrate an example embodiment of a nasal cannula assembly with a manifold insert and a manifold receiving structure.

[0083] Figures 23A-C illustrate an example embodiment of a nasal cannula assembly with a manifold insert which can be clipped over a tubing assembly.

[0084] Figures 24A-C illustrate an example embodiment of a nasal cannula assembly having prongs formed with a ripple shape around the base to allow for flexibility of the prongs.

[0085] Figures 24D-F illustrate an example embodiment of the prongs formed with a corrugated geometry to allow for flexibility of the prongs.

[0086] Figure 25A illustrates an example embodiment of a nasal cannula assembly that includes individually rotatable prongs.
Figures 25B-C illustrate an example embodiment of a nasal cannula assembly that includes a pair of prongs mounted on a vertical shaft and rotatable as a unit.

Figures 26A-F illustrate an example embodiment of a nasal cannula assembly configured to allow insertion of a removable prong insert in at least two orientations.

Figures 27A-D illustrate example embodiments of a nasal cannula assembly that includes a manifold that is rotatable about an axis extending in a generally fore-aft direction.

Figures 28A and 28B illustrate example embodiments of a nasal cannula assembly that includes a manifold and supply tube that can be coupled to the cannula in at least two orientations.

Figure 29A illustrates an example embodiment of a respiratory assistance system with a nasal cannula assembly having pressure measurement capability.

Figures 29B-L illustrate example embodiments of nasal cannula assemblies having pressure measurement capability.

Figures 30A-I illustrate example embodiments of nasal cannula assemblies having features to address, reduce or minimize patient discomfort, especially at or near the upper lip area.

Figures 31A-F illustrate example embodiments of adjustable or formable supply tubes for nasal cannula assemblies.

Figures 32A-N illustrate example embodiments of nasal cannula assemblies having arrangements and features to manage the positioning of the supply tube.

Figures 33A-S illustrate example embodiments of arrangements for providing support to the supply tube.

Figures 34A-K illustrate example embodiments of headgear arrangements for securing the cannula to the face of a patient.

Figures 35A-G illustrate example embodiments of retention arrangements for nasal cannula assemblies.

Figures 36A-K illustrate example embodiments of retention arrangements, such as headgear straps, including an indicator of tightness, such as strap tension.
Figure 37A illustrates an example embodiment of a headgear strap having a strap pad.

Figures 37B-E illustrate example embodiments of an adjustable headgear strap arrangement for a nasal cannula assembly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Although certain embodiments and examples are described below, those of skill in the art will appreciate that the disclosure extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the disclosure herein disclosed should not be limited by any particular embodiments described below. Various features described herein can be used individually or in various combinations and subcombinations in existing and/or improved respiratory interfaces.

With reference to Figures 1A-1C, an example embodiment of a nasal cannula assembly or system includes a manifold 12 and cannula 14. The cannula 14 includes nasal prongs 20a, b, side straps 22, and a tubular aperture 24 defined or encircled by a retention strap 26 and configured to receive the manifold 12. In some embodiments, the manifold is generally tubular and includes a circular inlet 16 and an elongated oval outlet 18. In use, the manifold 12 is coupled to the cannula 14 by inserting the manifold 12 into the aperture 24 so that the manifold outlet 18 is aligned and in fluid communication with the nasal prongs 20a, b. The manifold inlet 16 is configured to be coupled, removably or permanently, to a gas supply tube 50. In use, the gas supply tube 50 is coupled to and in fluid communication with a main delivery conduit 90, which is configured to be connected to and supply gases from a gas source, for example, a ventilator, gas tank, wall outlet, and/or humidifier that heats and/or humidifies gases before they are delivered to a patient. The gas supply tube 50 can be coupled to the main delivery conduit 90 by a connector 52.

The nasal cannula system can further include a securement mechanism to secure the cannula 14 to a user's head in a proper operational position. In the illustrated embodiment, the securement mechanism includes a headgear strap 40. The strap 40 can be coupled to the side straps 22 of the cannula 14. The nasal cannula system can also include a
lanyard 46 that in use is placed around the patient’s neck. The lanyard 46 can be coupled to
the supply tube 50 and/or the connector 52 via a lanyard connector 54, which can also allow
for adjustment of a length of the lanyard. The lanyard 46 advantageously helps support the
weight of the main delivery conduit 90 to reduce patient discomfort and the potential for
dislodgement of the cannula 14. Further details regarding example nasal cannula assemblies
or systems can be found in U.S. Publication 2010/0192957, the entirety of which is
incorporated by reference herein. Various components and features of such nasal cannula
assemblies can be selected and modified to achieve various benefits as described herein.

[0105] With reference to Figures 2A and 2B, an embodiment of a nasal cannula
assembly or system includes a cannula 114, manifold 112, headgear strap 140, gas supply tube
150, and lanyard 146. The cannula 114 can be formed of a thermoplastic, silicone-like
material and includes nasal prongs 120a, b, side straps 122, and two spaced manifold retention
portions or straps 126a, b defining/encircling an aperture configured to receive the manifold
112. In some embodiments, the nasal prongs 120a, b, side straps 122, and manifold retention
straps 126a, b are integrally formed. The cannula 114 is configured such that the manifold
112 can be inserted into the aperture of the manifold retention straps 126a, b from either side,
so that the manifold inlet 116 can be positioned to either side of the cannula 114. The side
straps 122 can include flex slots 128 to provide ventilation and allow the cannula 114 to bend
or stretch more easily, for example, when adjusting the headgear strap 140 and when adjusting
the cannula 114 against the user’s face to help achieve a more effective and/or comfortable fit.
The flex slots 128 can be generally vertical as shown or diagonally slanted. As shown in
Figure 2B, a patient facing and contacting side 130 of the cannula 114 can have a contoured
surface to better and more comfortably fit the patient’s face, reduce the overall profile of the
cannula system, and help align the supply tube 150. For example, transition portions 132
positioned between a central body portion 134 of the cannula 114 and the side straps 122 can
curve toward the patient’s face to rest against the nasolabial folds. The side straps 122 can
taper in thickness toward outer edges of the straps 122 to create a thin profile and help further
reduce the cannula system profile.

[0106] The headgear strap 140 can be coupled to the side straps 122 via clips or
buckles 142. The clips 142 can include an aperture 144 so that an inner edge 145 of the clip
142 on the side nearest the center of the cannula 114 can engage a corresponding undercut on the side strap 122. As shown in Figure 2B, the clips 142 do not substantially contact the patient’s skin, thereby maintaining a smooth and more comfortable patient contacting surface. A side of the clip 142 farthest from the center of the cannula 114 can include a buckle mechanism configured to receive ends of the headgear strap 140 and allow for adjustment of the circumference of the headgear strap 140 to fit the patient’s head. In some embodiments, the strap 140 can be flexible (e.g., elastic) to allow the strap 140 to accommodate a wide range of patient head sizes with minimal adjustment required.

[0107] In use, the manifold 112 is coupled to the cannula 114 by inserting the manifold 112 into the aperture 124 and stretching the flexible cannula 114 around the manifold 112. As described above, the manifold 112 can be inserted into the aperture 124 of the manifold retention straps 126a, b from either side, so that the manifold inlet 116 and, thus, the supply tube 150 can be positioned to either side of the cannula 114. In some embodiments, the manifold 112 is made of a relatively hard plastic material that can withstand relatively high loading conditions to protect the manifold 112 from being crushed. In addition, the retention straps 126a, b can be spaced apart from one another to provide support to the manifold 112 at spaced apart locations, which can inhibit or resist undesirable movement (e.g., rotation or twisting) of the manifold 112, such as that caused by forces acting on the supply tube 150, for example. In some configurations, the outer lateral edges of the retention straps 126a, b are spaced outwardly of the nasal prongs 120a, b such that the nasal prongs 120a, b are located between the lateral edges of the retention straps 126a, b. In some configurations, the inner edges of the retention straps 126a, b can be substantially aligned with or spaced outwardly from the nasal prongs 120a, b. Although a pair of retention straps 126a, b is illustrated, other suitable retention arrangements or structures are possible, such as a single retention strap, for example. In the illustrated embodiment, the manifold inlet 116 has an inner diameter slightly larger than an outer diameter of the supply tube 150 so that the tube 150 can be coupled to the manifold 112 by inserting an end of the tube 150 into the manifold inlet 116. The supply tube 150 can have a reduced diameter compared to other supply tubes to allow for this coupling. An end of the tube 150 opposite the manifold can include a connector 152 configured to couple the supply tube 150 to the main delivery conduit coupled
to the gas source. In the illustrated embodiment, the connector 152 is a 22 mm taper connector.

[0108] The cannula system can include a lanyard connector 154, which in the illustrated embodiment is located on the supply tube 150 proximal (nearer to the patient) the connector 152. The lanyard connector 154 can include mechanisms 155 for receiving ends of the lanyard 146 on either side. For example, each side of the lanyard connector 154 can include three or more offset slots or posts through which an end of the lanyard 146 is threaded. The slots or posts can be internal to the lanyard connector 154 or exposed. This configuration advantageously allows one or both ends of the lanyard to be adjusted as needed or desired, and allows the weight of the connector 152 (and the main delivery circuit 90) to be hung or oriented in a vertical orientation or direction. In some embodiments, the lanyard 146 is non-elastic. The lanyard 146 is secured to the lanyard connector 154 via friction between the lanyard 146 and slots or posts. The lanyard 146 can be ribbed to help secure the lanyard 146 to the lanyard connector 154. However, the lanyard 146 and lanyard connector 154 can be designed so that the friction force is overcome and the lanyard 146 releases from the lanyard connector 154 if the connector 154 is pulled too far away from the patient and/or pulled with sufficient force to avoid the lanyard 146 choking or otherwise causing discomfort to the patient. The lanyard connector 154 can include a grip 156 to allow the patient or others to better grasp the lanyard connector 154 for adjustments and/or for easy removal of the connector 152 from the main delivery conduit 90.

[0109] With reference to Figures 3A and 3B, a nasal cannula assembly or system includes a cannula 214, manifold 212, headgear strap 240, gas supply tube 250, and lanyard 246. The cannula 214 includes nasal prongs 220a, b, side straps 222, and a manifold retention strap 226 defining or encircling an aperture configured to receive the manifold 212. The cannula 214 is configured such that the manifold 212 can be inserted into the aperture of the manifold retention strap 226 from either side, so that the manifold inlet 216 can be positioned to either side of the cannula 214. In the illustrated embodiment, the manifold retention strap 226 is wide compared to the retention strap 26 shown in Figures 1A and 1B and straps 126a, b shown in Figure 2. The retention strap 226 can include a window 227 that allows part of the manifold 212 to be visible, for example, indicating that the manifold 212 is correctly
inserted into manifold retention strap 226. The window 227 can display, for example, branding, size, and/or other information printed, stamped, adhered or otherwise presented on the visible portion of the manifold 212.

[0110] The cannula 214 is generally soft and flexible for patient comfort. Outer portions 223 of the side straps 222 can be made to have increased strength, for example, by making the outer portions 223 thicker or otherwise reinforcing them, such as via strengthening ribs, which can be positioned at upper and/or lower edges of the side straps 222, for example. The added strength allows the headgear strap 240 to be coupled directly to the outer portions 223 of the side straps 222 without the need for additional clips, buckles, or other attachment mechanisms and allows the cannula 214 and side straps 222 to hold their moulded shape, preventing or inhibiting deformation during tension. The outer portions 223 of the side straps 222 can include two or more slits or apertures through which ends 243 of the strap 240 can be threaded and pulled through a desired length to obtain a headgear strap 240 circumference appropriate to fit the patient. The ends 243 of the headgear strap 240 can be folded back and removably secured to portions of the headgear strap 240 proximate the outer portions 223 of the side straps 222 via a hook and loop type closure. For example, a segment of fabric including hooks can be attached (e.g., sewn, adhered, etc.) to the ends 223 of the headgear strap 240, and a segment of fabric including loops can be attached (e.g., sewn, adhered, etc.) to the portions of the headgear strap 240 proximate the outer portions 223 of the side straps 222. An opposite side of the ends 243 of the strap 240 visible when worn can include branding or other information printed, stamped, adhered, or otherwise attached thereto.

[0111] As shown in Figure 3B, a rear or patient-facing side of the side straps 222 can include recessed areas 221 to accommodate the portions of the headgear strap 240 looped through the side straps 222 so that the strap 240 does not significantly press against the patient's face. A section of the headgear strap 240 configured to be placed against the back of the patient's head in use can include a padded section 241 for patient comfort. The padded section can be inserted between two halves of the headgear strap 240 or placed on top of or around the headgear strap 240.
In use, the manifold 212 is coupled to the cannula 214 by inserting the manifold into the aperture defined by the manifold retention strap 226. The manifold 212 can be inserted into the aperture of the manifold retention strap 226 from either side, so that the manifold inlet 216 can be positioned to either side of the cannula 214. In the illustrated embodiment, the manifold 212 includes a cylindrical inlet 216. The inlet 216 has an inner diameter slightly larger than an outer diameter of the supply tube 250 so that the tube 250 can be coupled to the manifold 212 by inserting an end of the tube 250 into the manifold inlet 216. An end of the tube 250 opposite the manifold 212 can include a connector 252 configured to couple the supply tube 250 to the main delivery conduit coupled to and in fluid communication with the gas source.

The cannula system can further include a lanyard connector 254 located on the supply tube 250 proximal to the connector 252. In some embodiments, the lanyard connector 254 is color coded to indicate size or other information. One side of the lanyard connector 254 can include a mechanism 255 for adjustably receiving one end of the lanyard 246. For example, one side of the lanyard connector 254 can include two slits or apertures through which the end of the lanyard 246 can be threaded. This mechanism 255 allows the lanyard 246 to be easily placed around the patient’s neck and coupled to the lanyard connector 254 without having to put the lanyard 246 over the patient’s head. The lanyard connector 254 can also include a grip 256 to allow the patient or others to better grasp the lanyard connector 254 for adjustments and/or easy removal the connector 252 from the main delivery conduit 90.

One side of the lanyard connector 254 can include a breakaway clip 257. An end of the lanyard 246 can include molding configured to be inserted into the breakaway clip 257 to secure the lanyard 246 to the lanyard connector 254. The breakaway clip 257 is designed so that if the lanyard 246 applies too great a force to the patient’s neck due to, for example, the main delivery conduit, connector 252, supply tube 250, and/or lanyard connector 254 being pulled away from the patient with a force exceeding a certain threshold, the breakaway clip 257 releases the lanyard 246 or detaches from the lanyard connector 254 to avoid patient injury or discomfort. This configuration advantageously allows the weight of the connector 252 (and the main delivery circuit 90) to be hung or oriented in a vertical
orientation or direction. In some embodiments, the lanyard 246 is made of an inelastic material to improve the function of the breakaway clip 257 and so that the weight of the main delivery conduit coupled to the connector 252 does not stretch the lanyard 246 and apply additional force to the patient’s neck. In some embodiments, the breakaway clip 257 allows the lanyard 246 to be easily looped around the patient’s neck then inserted into the breakaway clip 257.

[0115] Figure 4 illustrates a cannula system having a cannula 314 and headgear strap 340 similar in some ways to the cannula 214 and headgear strap 240 illustrated in Figures 3A and 3B. However, the cannula system of Figure 4 lacks a manifold retention strap and includes a reversible manifold 312. The manifold 312 can pivot or rotate or be decoupled from the cannula 314 and turned 180° so that the inlet 316 can be located to either side of the cannula 214.

[0116] An embodiment of a nasal cannula assembly or system as illustrated in Figures 5A and 5B includes a cannula 414, headgear strap 440, and gas supply tube 450. The cannula 414 includes nasal prongs 420a, b, side straps 422, and an inlet 416. In the illustrated embodiment, an end of the gas supply tube 450 couples directly to the inlet 416 of the cannula 414. The supply tube 450 can have a reduced diameter so that the end of the supply tube 450 can be received within the inlet 416. The supply tube 450 can be secured to the cannula 414 by stretching the cannula inlet 416 over the end of the supply tube 450, using an adhesive (e.g., glue), mechanical interference features, and/or other means. The cannula 414 further includes two gas paths 417a, b extending from and in fluid communication with the inlet 416, so that a first gas path 417a extends to and is in fluid communication with a first nasal prong 420a, and a second gas path 417b extends to and is in fluid communication with a second nasal prong 420b. The geometry of the gas paths 417a, b can be designed to balance gas flow between the two gas paths 417a, b and nasal prongs 420a, b so that the patient receives balanced flow in both nostrils. The flow path has reduced, minimal or no significantly abrupt transitions or sharp corners, which advantageously reduces or minimizes resistance to flow.

[0117] Ends of the side straps 422 can include apertures or slots 421 designed to receive ends of the headgear strap 440. The headgear strap 440 can be formed of a highly elastic material capable of a large degree of stretch to allow the strap 440 to accommodate
and fit various patient head sizes, particularly where, as in the illustrated embodiment, the side straps 422 do not include clips or buckles to allow for adjustment of the circumference of the headgear strap 440. For example, the headgear strap 440 can be made of a material having a relatively flat force extension curve so that the strap 440 maintains the same or substantially the same tension over a range of degree of stretch. The ends of the headgear strap 440 can include a rigid material overmolded thereon to help secure the ends of the strap 440 within the apertures 421. The strap 440 can also or alternatively be secured to the cannula 414 with an adhesive (e.g., glue), ultrasonic welding, and/or other means.

[0118] The cannula system can include a tube clip 442 coupled (permanently or removably, immovably or movably) to the headgear strap 440. The tube clip 442 can be located on the side of the cannula 414 nearest the inlet 416 and can receive the supply tube 450 to help hold the tube 450 away from the mouth and face of the patient in use. An end of the supply tube 450 opposite the end coupled to the cannula inlet 416 can include a connector 452 configured to couple the supply tube 450 to the main delivery conduit. The cannula system can include a lanyard clip 454 positioned on the supply tube 450 proximal to the connector 452. The lanyard clip 454 can releasably clip to a lanyard worn around the patient’s neck in use. Alternatively, the lanyard clip 454 can be directly attached to, for example, the patient’s clothing or hospital gown, bed sheets, or another location nearby to help support the weight of the main delivery conduit. The nasal cannula system illustrated in Figures 5A and 5B does not include a manifold or clips or buckles for attaching the headgear strap 440 to the cannula 414. This configuration minimizes the parts of the nasal cannula system, which can advantageously help provide easier manufacturing and/or reduce the cost.

[0119] Another embodiment of a nasal cannula assembly or system includes a cannula 514, manifold 512, gas supply tube 550, and lanyard 546 as shown in Figures 6A and 6B. The cannula 514 includes nasal prongs 520a, b, a manifold retention strap 526, and cheek pads 522. The cheek pads 522 are designed to be positioned on the patient’s cheeks and/or upper cheeks in use. The cannula 514 includes thin flex areas 532 located at transition regions between a central body portion 534 of the cannula 514 and the cheek pads 522. The thin flex areas 532 have a reduced cross-sectional thickness to allow the cheek pads 522 to move and be adjusted relative to the central body portion 534 more easily to improve the fit, positioning,
and comfort of the cannula 514 on the patient’s face. A rear or patient contacting side of the central body portion 534 can include soft and/or thin wall cushion details 535. The cushion details 535 can include, for example, a ribbed, rippled, folded or other surface designed to space the central body portion 534 of the cannula 514 away from the patient’s face slightly. This advantageously allows for airflow between the central body portion 534 and the patient’s face and provides a collapsible region to help absorb forces pressing the cannula 514 into the patient’s face.

[0120] Rear surfaces of the cheek pads 522 include attachment pads 560 integrally formed with the cheek pads 522 or sewn, adhered, or otherwise attached thereto. The attachment pads 560 can include a releasable and reattachable adhesive to attach the cheek pads 522 to the patient’s face. Alternatively, the attachment pads 560 can include one portion of a hook and loop fastener, for example, a fabric segment including the hooks. Patches containing the other portion of the fastener, for example the loops, can be attached to the patient’s face at desired locations on the cheeks and/or upper cheeks to allow the attachment pads 560 to be releasably attached to the patient’s face.

[0121] The manifold 512 includes an inlet 516 designed to receive the gas supply tube 550 and an outlet designed to be aligned and in fluid communication with the nasal prongs 520a, b in use. The manifold 512 is coupled to the cannula 514 by sliding the manifold 512 into an aperture defined by the manifold retention strap 526 so that the outlet aligns with the nasal prongs 520a, b and stretching the cannula 514 around edges of the manifold 512. The manifold 512 can be inserted into the aperture of the manifold retention strap 526 from either side, so that the manifold inlet 516 can be positioned to either side of the cannula 514. The retention strap 526 can include a window 527 that allows part of the manifold 512 to be visible, for example, indicating that the manifold 512 is correctly inserted into manifold retention strap 526. The window 527 can display, for example, branding, size, and/or other information printed, stamped, adhered or otherwise presented on the visible portion of the manifold 512.

[0122] In the illustrated embodiment, the supply tube 550 is a small diameter spiral tube. Other types of gas supply conduits are also possible. An end of the supply tube 550 opposite the end coupled to the manifold 512 can include a connector 552 configured to be
connected to the main delivery conduit. The cannula system can include a lanyard retention connector 554 located on the connector 552 or on the supply tube 550 proximal to the connector 552. One end of the lanyard 546 can be integrally formed with or coupled to one side of the lanyard retention connector 554. An opposite side of the lanyard retention connector 554 can include a slot designed to receive a free end 547 of the lanyard 546. The free end 547 of the lanyard 546 can include a series of protrusions or notches 548. The protrusions 548 can be pulled through the slot of the lanyard retention connector 554 to adjust the circumference of the lanyard 546 but resist sliding through the slot when not being adjusted to help secure the lanyard 546 at the desired circumference. The lanyard 546 can be made of a stamped fabric, for example, white non-woven laminated polyethylene, which can advantageously help reduce the cost of the cannula system.

[0123] An example embodiment of a cannula system as shown in Figures 7A-7B includes a cannula 614, gas supply tube 650, and lanyard 646. The cannula 614 includes nasal prongs 620a, b, a retention strap 626, and an integrated headgear strap 640. In some embodiments, the headgear strap 640 can include a break on one side so that the headgear strap 640 includes a first section 640a and a second section 640b. The free end of one section (first section 640a in the illustrated embodiment) can include a slot 642 configured to receive the free end of the other section (second section 640b in the illustrated embodiment). A segment of the strap 640 near the free end of the second section 640b can include teeth 643 configured to engage sides of the slot 642 to help inhibit the second section 640b from being pulled out of the slot 642. A rear portion 641 of the headgear strap 640, which is part of the first section 640a in the illustrated embodiment, can separate into a double strap configuration to aid stability of headgear strap 640 on the patient’s head and/or help distribute forces on the patient’s head and improve patient comfort.

[0124] In the illustrated embodiment, an end of the gas supply tube 650 is coupled directly to the cannula 614. The supply tube 650 can have a reduced diameter so that the end of the supply tube 650 can be received within an aperture defined by the retention strap 626. The supply tube 650 can be secured to the cannula 614 by stretching the manifold retention strap 626 over the end of the supply tube 650, using an adhesive (e.g., glue), mechanical interference feature, and/or other means. The cannula system can include a tube clip 642
coupled (permanently or removably, immovably or movably) to the supply tube 650. The tube clip 642 can include a hook configured to be placed on the headgear strap 640 to help hold the tube 650 away from the mouth and face of the patient in use.

[0125] An end of the supply tube 650 opposite the end coupled to the cannula 614 can include a connector 652 configured to be connected to the main delivery conduit. The cannula system can further include a lanyard retention connector 654. The connector 652 can include a lower portion and an upper portion 653 including grip features. In some embodiments, the connector 652 includes a reduced diameter section between the upper and lower portions to receive the lanyard retention connector 654. Alternatively, the upper and lower portions can be separate pieces. In use, the lanyard retention connector 654 is pressed over a portion of the connector 652 and held in place between the upper and lower portions or in the reduced diameter section.

[0126] In the illustrated embodiment, the lanyard 646 is integrally formed with one side of the lanyard retention connector 654. Alternatively, the lanyard 646 can be coupled to the lanyard retention connector 654. An opposite side of the lanyard retention connector 654 can include a slot designed to receive a free end 647 of the lanyard 646. The free end 647 of the lanyard 646 can include a series of notches 648 along the sides. In use, the lanyard 646 is wrapped around the patient’s neck and the free end 647 of the lanyard is threaded through the slot of the lanyard retention connector 654 to achieve the desired circumference of the lanyard 646. The notches 648 allow the free end 647 of the lanyard 646 to be pulled through the slot of the lanyard retention connector 654 to adjust the circumference of the lanyard 646 but resist sliding through the slot when not being adjusted to help secure the lanyard 646 at the desired circumference. The lanyard 646 can be made of a stamped fabric, for example, white non-woven laminated polyethylene, which can advantageously help reduce the cost of the cannula system.

[0127] In an alternative embodiment, shown in Figure 7C, the cannula system can include a connector 752, a lanyard connector 754 positioned on the supply tube 650 proximal to the connector 752, and a separate lanyard 746. The lanyard connector 754 includes two slots to receive the ends of the lanyard 746. Both ends of the lanyard 746 can include a series of notches 748 similar to the notches 648 described herein to allow for adjustment of one or
both ends of the lanyard 746. This configuration advantageously allows the weight of the connector 752 (and the main delivery circuit 90) to be hung or oriented in a vertical orientation or direction.

[0128] In some embodiments, for example as shown in Figures 8A-8C, a cannula system includes a cannula 814, manifold 812, headgear strap 840, gas supply tube 850, and lanyard 846. The cannula 814 includes nasal prongs 820a, b, and an inlet 824. As shown in Figure 8C, a flange 825 encircles a perimeter of the inlet 824. The manifold 812 includes an inlet 816 configured to receive the supply tube 850 and an outlet 818. The outlet 818 of the manifold 812 includes a recess 819 configured to receive the flange 825 of the cannula 814. In some embodiments, the manifold 812 and cannula 814 can be designed to have a reduced size to advantageously reduce the profile of the cannula system on the patient’s face, which can improve patient comfort and reduce the chance of obstructing the face or mouth in some circumstances.

[0129] In use, the manifold 812 is coupled to the cannula 814 by inserting one side of the manifold 812 into the cannula 814 inlet 824 so that the flange 825 of the cannula 814 sits in the recess 819 of the manifold 812 and stretching the cannula 814 around the manifold 812 outlet 818 so that the flange 824 sits in the recess 819 around the entire perimeters of the cannula 814 outlet 824 and manifold 812 outlet 818. The flange 824 and corresponding recess 819 advantageously help secure the connection between the cannula 814 and manifold 812 and can also help prevent air leaks at the connection. The manifold 812 can further include a tab 880 designed to fit into a corresponding recess or aperture 882 on the cannula 814 to help further secure the manifold 812 to the cannula 814 and indicate that the manifold 812 is correctly inserted into the cannula 814. As shown in Figure 8C, the manifold 812 is reversible, i.e., the manifold 812 can be coupled to the cannula 814 so that the manifold inlet 816 extends to either side of the cannula 814. The manifold 812 can include a grip 815 to advantageously assist a user in grasping the manifold 812 to couple and/or remove the manifold 812 to and/or from the cannula 814.

[0130] In the illustrated embodiment, the headgear strap 840 is coupled directly to the cannula 814, and the cannula system does not include clips, buckles, or other mechanisms that allow for adjustment of the circumference of the strap 840. Sides of the cannula 814 can
include apertures or slots 821 designed to receive ends of the headgear strap 840. The ends of the strap 840 can be secured to the cannula 814 with an adhesive (e.g., glue), ultrasonic welding, and/or other means. The headgear strap 840 can be formed of a highly elastic material capable of a large degree of stretch to allow the strap 840 to accommodate and fit various patient head sizes. For example, the headgear strap 840 can be made of a material having a relatively flat force extension curve so that the strap 840 maintains the same or substantially the same tension over a range of degree of stretch. A pitch of threads of the headgear strap 840 material can be changed to adjust the tightness of the strap 840.

[0131] The gas supply tube 850 can be coupled to the manifold 812 inlet 816 at one end and a connector 852 configured to couple the supply tube 850 to the main delivery conduit at an opposite end. The gas supply tube 850 can have a reduced diameter so that the end of the tube 850 can be inserted into the manifold inlet 816. In some embodiments, the connector 852 can include grip details 856 to help the user grasp the connector 852 more easily to adjust various components of the cannula system. In some embodiments, the gas supply tube 850 can include a pressure line 870. The pressure line 870 can be configured to convey pressure feedback from the end of the supply tube 850 coupled to the manifold 812 to a pressure sensor and/or controller. The pressure line 870 can be integral with or coupled to the supply tube 850. In some embodiments, the pressure line 870 lies within the main flow path of the supply tube 850. In other embodiments, the pressure line 870 lies adjacent the main flow path of the supply tube 850. For example, in some embodiments, the supply tube 850 can be a spiral bubble tube, and the pressure line 870 can lie in the hollow spiral of the spiral bubble supply tube 850.

[0132] The cannula system can further include a lanyard connector 854 located on the supply tube 850 proximal to the connector 852. In some embodiments, the lanyard connector 854 is fixed relative to the tube 850. In other embodiments, the lanyard connector 854 is slidable relative to the tube 850. The lanyard connector 854 can include apertures or slots on either side to receive ends of the lanyard 846. In the illustrated embodiment, the lanyard connector 854 also acts as a point of separation of the pressure line 870 from the supply tube 850. In use, the lanyard 846 is wrapped around the patient's neck and the ends of the lanyard 846 are threaded through the apertures or slots of the lanyard connector 854 to
achieve the desired circumference of the lanyard 846. Ends of the lanyard 846 can include notches 848 along the sides. The notches 848 allow the lanyard 846 to be pulled through the slots of the lanyard connector 854 to adjust the circumference of the lanyard 846 but resist sliding through the slots when not being adjusted to help secure the lanyard 846 at the desired circumference. This configuration advantageously allows the weight of the connector 852 (and the main delivery circuit 90 illustrated in Figure 1A) to be hung or oriented in a vertical orientation or direction. The lanyard 846 can be made of a stamped fabric, for example, white non-woven laminated polyethylene, which can advantageously help reduce the cost of the cannula system.

[0133] An example embodiment of a cannula system as illustrated in Figures 9A and 9B includes a cannula 914, manifold 912, headgear strap 940, and gas supply tube 950. As shown, the cannula 914 can include a manifold aperture 924 configured to receive the manifold 912 and a headgear strap aperture 921 configured to receive the headgear strap 940. The manifold 912 can be inserted into the aperture of the cannula 914 from either side, so that the manifold inlet 916 can be positioned to either side of the cannula 914. In the illustrated embodiment, the manifold 912 is generally cylindrical, and the manifold aperture 924 is therefore also generally cylindrical. The manifold 912 can be substantially hollow to allow for gas flow. The cannula 914 can include a window 927 that allows part of the manifold 912 to be visible, for example, indicating that the manifold 912 is correctly inserted into cannula 914. The window 927 can display, for example, branding, size, or other information printed, stamped, adhered or otherwise presented on the visible portion of the manifold 912.

[0134] One end of the cylindrical manifold 912 is open and forms an inlet 916 configured to receive one end of the gas supply tube 950. An opposite end of the manifold 912 is closed, as shown in Figure 9B. In some embodiments, the closed end of the manifold 912 includes a removable cap. In some such embodiments, a solid cap can be interchangeable with a cap 913 that can include a pressure line 970, for example as shown in Figure 9C. As explained above, the manifold 912 can be inserted into the aperture of the cannula 914 from either side, so that the manifold inlet 916 can be positioned to either side of the cannula 914. The cap 913 therefore can also be located on either side of the cannula 914.
In the illustrated embodiment, the headgear strap 940 is threaded through the headgear strap aperture 921 of the cannula 914. In some embodiments, the headgear strap 940 is secured to the cannula 914 with an adhesive (e.g., glue), ultrasonic welding, or another mechanism. In some embodiments however, the cannula 914 and headgear strap 940 are slidable relative to each other. The headgear strap 940 can be a single length of strap. One end of the length of strap can be secured to clasp 943a, and an opposite end of the length of strap can be secured to clasp 943b. The clasps 943a, b are coupled to and slidable on the strap 940 to allow for adjustment of the circumference of the strap 940 to fit the patient’s head. In some embodiments, the headgear strap 940 is made of a non-stretch material.

The cannula system can include a connector 952 on the supply tube 950 at an end opposite the manifold 912. The connector 952 can be configured to couple the supply tube 950 to the main supply conduit. The cannula system can further include a lanyard clip 954 encircling a proximal portion of the connector 952 or encircling the supply tube 950 proximal to the connector 952. The lanyard clip 954 can releasably receive a lanyard. Alternatively, the lanyard clip 954 can be directly clipped to, for example, the patient’s clothing or gown, the bedding, or a lanyard placed around the patient’s neck to help support the weight of the main supply conduit coupled to connector 952.

An example embodiment of a cannula system as shown in Figures 10A and 10B includes a cannula 1014, nose strip 1022, supply tube 1050, and nasal prongs 1020a, b. The cannula 1014 is shaped and sized to be positioned on top of the patient’s nose. For example, a portion of the cannula 1014 can have a curved profile designed to follow the curvature of the nose. The cannula 1014 can be secured to the patient’s nose via the nose strip 1022. In some embodiments, the nose strip 1022 resembles an adhesive bandage. A central portion of the nose strip 1022 can include a comfort pad 1035 configured to rest against the patient’s nose and provide added cushioning in use. Adhesive portions of the nose strip 1022 extend from the central portion to adhere to portions of the patient’s cheeks. A side of the nose strip 1022 facing away from the patient’s face includes an attachment pad 1062 coupled (e.g., sewn, adhered, or otherwise attached) thereto. A patient facing side of the cannula 1014 includes a corresponding attachment pad 1060. For example, in some embodiments, the attachment pads 1060, 1062 are the components of a hook-and-loop
fastener, e.g., Velcro. The attachment pads 1060, 1062 therefore allow the cannula 1014 to be releasably attached to the nose strip 1022.

[0138] In some embodiments, the nose strip 1022 includes a strip 1064 designed to help hold the patient's nasal passages open. In some embodiments, the strip 1064 can be made of a flexible, spring-like metal that is biased toward a substantially straight state. When the nose strip 1022 is placed across the curved nasal bridge, the strip 1064 attempts to straighten, thereby gently lifting the sides of the patient's nose to open the nasal passages. In some embodiments, the strip 1064 can be made of a shape memory material such as nitinol, and heat from the patient's face causes the strip 1064 to attempt to return to a straighter state. The strip 1064 can be located on either side of the nose strip 1022, i.e., on the side facing away from the patient or the side facing the patient, e.g., between the nose strip 1022 and comfort pad 1035. In some embodiments, the nose strip 1022 can also act as a blackhead removing strip. The patient contacting side of the nose strip 1022 can include bonding agents capable of bonding to dirt and/or other impurities in the patient's pores so that they are removed with the nose strip 1022 when it is removed.

[0139] In the illustrated embodiment, the supply tube 1050 is a dual-tube including two small-diameter tubes extending between a main delivery conduit connector 1052 and nasal prongs 1020a, b. The cannula system can include an adapter 1053 designed to receive the small-diameter supply tubes 1050 and couple to the main delivery conduit connector 1052. The adapter 1053 can be integrally formed with, attached to, or proximal to the connector 1052. Each of the supply tubes 1050 can be integrally formed with or coupled to one of the nasal prongs 1020a, b. In some alternative embodiments, the supply tube 1050 can include a single tube over part or all of its length. The single tube can separate at the nasal prongs 1020a, b or can separate into two tubes distal to the nasal prongs 1020a, b. As shown in Figures 10A and 10B, the two supply tubes 1050 pass downward into a portion of the cannula 1014. The nasal prongs 1020a, b extend downward from the supply tubes 1050 and cannula 1014, then turn approximately 180° to extend upward on the patient contacting side of the cannula 1014. In the illustrated embodiment, the nasal prongs 1020a, b are molded or formed to retain their shape and orientation. In some embodiments, the nasal prongs 1020a, b can include a wire made of a shape memory material, for example, nitinol. Gas flow through the
nasal prongs 1020a, b or heat radiating from the patient’s face can cause the wire to assume and/or maintain the formed shape. The nasal prongs 1020a, b extend upwardly into the patient’s nostrils when the cannula 1014 is coupled to the nose strip 1022.

[0140] In some alternative embodiments, for example as shown in Figure 11, the cannula system can include nasal pillows 1120a, b instead of nasal prongs. As shown, the supply tubes 1050 pass downward through a portion of the cannula 1014 and hang freely. The nasal pillows 1120a, b are coupled to the free ends of the supply tubes 1050. In some embodiments, the nasal pillows 1120a, b can be self-inflating pillows. In use, the nasal pillows 1120a, b are turned upward and inserted into the patient’s nostrils and the cannula 1014 is coupled to the nasal strip 1022.

[0141] The cannula system can further include a cheek pad 1042. The cheek pad 1042 can include an adhesive strip that can be used to secure a portion of the supply tubes 1050 to the patient’s cheek. The cheek pad 1042 can advantageously help hold the supply tubes 1050 away from the patient’s mouth and help support some of the weight of the supply tubes 1050. The cheek pad 1042 can include branding or other information printed or otherwise displayed thereon. In some embodiments, the supply tubes 1050 include an anti-kink spring, which can advantageously help allow the tubes 1050 to be manipulated, for example when positioning the cannula 1014 or cheek pad 1042 on the patient, without interrupting the gas supply.

[0142] An example embodiment of a cannula system can include two cannulas 1220a, b, nose strip 1222, and supply tubes 1250a, b, as shown in Figures 12A-12C. The nose strip 1222 can be similar to nose strip 1022 shown in Figures 10A and 10B and described in the accompanying text. In the embodiment of Figures 12A-12C, however, the cannula is separated into a right cannula 1214a and a left cannula 1214b. In some embodiments, the cannulas 1214a, b are symmetrical rather than right and left biased. Right cannula 1214a includes an integral nasal prong 1220a, and left cannula 1214b includes an integral nasal prong 1220b. A patient facing surface of each cannula 1214a, b includes an attachment pad 1260a, b to removably attach the cannulas 1214a, b, to the attachment pad of the nose strip 1222. In some embodiments, nose strip 1222 includes a strip 1264 to help hold the patient’s nasal passages open as described with respect to Figures 10A and 10B.
The supply tube includes small diameter right 1250a and left 1250b supply tubes extending from a main delivery conduit connector 1252 to the right 1214a and left 1214b cannulas. The supply tubes 1250a, b are received into inlets 1224a, b of the cannulas 1214a, b. As shown, the supply tubes 1250a, b can be looped around the patient’s ears to help hold the tubes 1250a, b away from the patient’s mouth and support some of the weight of the tubes 1250a, b. The tubes 1250a, b can include spring winding to help provide kink-resistance and strength. In some embodiments, only one of the cannulas 1214a, b can be used at a given time for a certain patient as needed or desired.

An example embodiment of a cannula system as shown in Figures 13A-13C can include a cannula 1314, retainer 1322, and supply tube 1350. The cannula 1314 can have a minimal size and profile. In the illustrated embodiment, the cannula 1314 includes a generally cylindrical body having an inlet 1324 and integrally formed nasal prongs 1320a, b. The retainer 1322 includes a cannula engaging portion 1321 and a nasal strip portion 1323. In some embodiments, the cannula engaging portion 1321 is attached to the cylindrical body of the cannula 1314 with an adhesive, e.g., glue. In some embodiments, the cannula engaging portion 1321 is moulded as part of the cannula 1314. In some embodiments, the cannula engaging portion 1321 has a formed shape configured to snap or clip onto the cannula 1314. The nasal strip portion 1323 is designed to be adhered across the patient’s nose to help secure the cannula 1314 to the patient. A patient facing side of the nasal strip portion 1323 can include an adhesive strip covered by a protective backing 1366 for storage. The protective backing is peeled off to expose the adhesive strip when needed to secure the cannula 1314 to the patient. The retainer 1322 can be removed and replaced as needed during the duration of therapy. In embodiments in which the cannula engaging portion 1321 is moulded as part of the cannula 1314, the adhesive strip can be removed and/or replaced as needed.

In some embodiments, the supply tube 1350 is a small diameter spring tubing. The supply tube 1350 can be coupled to a main delivery conduit connector 1352 at one end and the cannula 1314 inlet 1324 at an opposite end. The supply tube 1350 diameter can be sized so that the supply tube 1350 can be inserted into the cannula inlet 1324 and the cannula 1314 stretched or otherwise formed or positioned around the tube 1350 to secure the tube 1350 to the cannula 1314. The cannula system can also include a lanyard clip 1354...
positioned on the connector 1352 or on the supply tube 1350 proximal to the connector 1352. The lanyard clip 1354 can releasably receive a lanyard placed around the patient’s neck. Alternatively, the lanyard clip 1354 can be attached to, for example, the patient’s clothing or hospital gown, bed sheets, or another location nearby to help support the weight of the main delivery conduit.

[0146] An example embodiment of a cannula system as shown in Figures 14A-14C includes a cannula 1414, manifold 1412, and gas supply tube 1450. The cannula 1414 includes nasal prongs 1420a, b, nose flaps 1422a, b, and a manifold retention strap 1426 defining/encircling an aperture 1424 configured to receive the manifold 1412. In use, the manifold 1412 is coupled to the cannula 1414 by inserting the manifold 1412 into the aperture 1424 and stretching the manifold retention strap 1426 around the manifold 1412. In the illustrated embodiment, the manifold includes an inlet or collar 1416 and two outlets 1418. In use, the outlets 1418 are aligned and in fluid communication with the nasal prongs 1420a, b.

[0147] The nose flaps 1422a, b extend from the sides of the cannula 1414 and are configured to fold over the sides of the patient’s nostrils. The nose flaps 1422a, b can include a thin section near the manifold retention strap 1426, allowing the nose flaps 1422a, b to bend easily and conform to the geometry of the nose. In some embodiments, each nose flap 1422a, b includes an attachment pad 1460, which can be one part of a hook-and-loop fastener. The attachment pads 1460 can be removably coupled to corresponding attachment pads 1462, which can be the other part of the hook-and-loop fastener, on the user’s nose. The attachment pads 1462 can be attached to the outsides of the patient’s nostrils with an adhesive. In some embodiments, the attachments pads 1460 of the nose flaps 1422a, b can be adhesive patches that are adhered directly to the user’s nose. In some embodiments, the nose flaps 1422a, b can comprise a malleable material that can hold its shape once deformed such that the nose flaps 1422a, b and remain substantially in place once folded. In such an arrangement, the attachment pads 1460 can be grip pads comprising a grip material to grip the skin of the patient and inhibit undesired movement of the cannula 1414.

[0148] In some embodiments, the supply tube 1450 is a small-diameter spring tube. The supply tube 1450 can be coupled to a main delivery conduit connector 1452 at one end and the manifold inlet or collar 1416 at an opposite end. In some embodiments, the
supply tube 1450 is permanently attached to the collar 1416 and/or the collar 1416 is permanently attached to the manifold 1412. Alternatively, the supply tube 1450 can be removably coupled to the collar 1416 and/or the collar 1416 can be removably coupled to the manifold 1412. As shown in Figure 14B, the manifold 1412 can be inserted into the aperture 1424 of the cannula 1414 from either side so that the supply tube 1450 can extend from either side of the cannula 1414. The cannula system can further include a lanyard clip 1454 positioned on the connector 1452 or on the supply tube 1450 proximal to the connector 1452. The lanyard clip 1454 can be releasably coupled to a lanyard placed around the patient’s neck or can be attached to, for example, the patient’s clothing or hospital gown, bed sheets, or another location nearby to help support the weight of the main delivery conduit.

[0149] Figures 15-18 illustrate embodiments of a nasal cannula assembly including a cannula, which preferably includes a pair of nasal prongs. The cannula can be integrated with a supply conduit or tubing or can connect to a separate supply conduit or tubing, such as through any of the manifold arrangements disclosed herein. In some configurations, the cannula has a tubular shape with a first end, a second end, and a body extending between the first and second ends and is coupled to a supply tube at one of the ends. Accordingly, the cannula body can define a hollow “manifold” volume that is at least partially defined by the manifold in other embodiments disclosed herein. Additionally, in some embodiments, the cannula can contain one or more prong exit holes in the middle of the cannula body which can be arranged to allow exit of gas to a pair of nasal prongs. In some embodiments, the cannula can be a hollow volume cannula containing at least one inlet that can be positioned and shaped to be attached to a supply tubing or conduit. In certain embodiments, the cannula can contain an inlet at each end of the cannula. The cannula can be configured to be connected to or integrated within an assembly securing device, for example a headgear strap. The cannula can be configured to be integrally connected or permanently connected to a supply tube or conduit, such as through any of the manifold arrangements described herein or through a connector. In some embodiments, the cannula can be integrated or unitary with a tube creating a cannula/tube assembly or structure. In certain embodiments, the cannula can be flexible to allow bending or manipulation of the cannula. In other embodiments, the manifold can be relatively stiff or rigid. Any of the cannula embodiments discussed herein can comprise
attached or clip-on or slide-on prongs and/or fixed or tilted/adjustable prongs as described herein.

[0150] In some embodiments, the cannula can have tubing exit holes at each end of a first end and a second end of the cannula. In some embodiments, the first end or the second end can be configured to be connected to the supply conduit or tubing that connects to the humidifier, circuit, or other gas or flow supply apparatus. The end not connected to the tubing can be selectively blocked. For example, the selective side switching of the device can occur through a system where when the first end is connected to the tubing allowing air to enter the manifold space of the cannula, the second end is blocked, and when the second end is connected to the tubing allowing air to enter the manifold space of the cannula, the first end is blocked. Figures 15-18 illustrate embodiments of the selective side switching in the manifold.

[0151] Figures 15A-D illustrate embodiments of a nasal cannula assembly incorporating a shuttle valve that selectively occludes one end of the cannula or manifold (hereinafter referred to as the “manifold”). In some embodiments, the manifold 1501 can have an opening, port or inlet 1507 or, preferably, openings 1507 on each side of the manifold 1501. In particular, a first opening 1507 can be positioned at a first end and a second opening 1507 can be positioned at a second end of the manifold 1501. In certain embodiments, a lightweight shuttle object or valve body 1508, for example a ball or disk, can move (e.g., slide or roll) freely inside the manifold volume or hollow cavity 1509. Preferably, the shuttle object 1508 has a larger diameter than the prongs 1505 and the openings 1507 to prevent the shuttle object 1508 from exiting the hollow cavity 1509.

[0152] In some embodiments, a supply tube 1502 can be connected to one of the openings or inlets 1507. The supply tube 1502 can supply resulting positive pressure from the flow of air or gas from the humidifier or other apparatus into the hollow cavity 1509. The resulting positive pressure from the flow of air or gas pushes the shuttle object 1508 along the hollow cavity 1509 until it blocks off the opposite opening 1507. The blocking of the opposite opening 1507 can prevent the air from traveling through that opening 1507 while still allowing the air to flow through the prongs 1505. In some embodiments, the supply tube 1502 can be attached to one opening 1507 of the manifold 1501 and the opposite opening 1507 is blocked.
by the shuttle object 1508. For example, to switch sides of the supply tube 1502 relative to the manifold 1501, the supply tube 1502 can be removed from one opening 1507 and put into the opposite opening 1507 and the shuttle object 1508 will swap sides automatically. In some embodiments, the opening 1507 can have a localized thin wall section 1510, preferably defining an annular shape surrounding the opening 1507. The localized thin wall section 1510 can deform relative to at least a surrounding portion of the manifold 1501 to aid in sealing the hollow cavity 1509 at that end when the shuttle object 1508 is pushed to that side. In certain embodiments, the shuttle object 1508 can be made of a relatively soft material, for example material used to make compressible earplugs (e.g., compressible PVC foam), to further assist in sealing of the hollow cavity 1509.

[0153] In some embodiments of the nasal cannula assembly 1500, the manifold 1501 has at least one prong 1505 and, preferably, a pair of prongs 1505. Preferably, the nasal cannula assembly 1500 contains prongs 1505 positioned on or configured to be positioned on the manifold 1501. In certain embodiments, the prongs 1505 on the manifold 1501 can be flexible or rotatable to allow use of the nasal cannula assembly 1500 in either direction. The prongs 1505 illustrated in Figure 15 comprise a distal end 1521 and a proximal end 1522. The distal end 1521 of each prong 1505 is configured to be placed within the nose of the user when in use. The proximal end 1522 of each prong 1505 is configured to be attached to or to be flush with the manifold 1501 and prong exit holes 1520 in the manifold 1501 that communicate with the interior spaces of the prongs 1505. In some embodiments, the prongs 1505 are twin nasal prongs and are located in the middle of body of the manifold 1501.

[0154] The supply tube 1502 can be coupled to the manifold 1501 by any suitable arrangement. For example, the supply tube 1502 can include a connector 1530 coupled to the end of the supply tube 1502 and configured to be coupled to the manifold 1501. The connector 1530 can have a snap-fit arrangement with the openings 1507 of the manifold 1501. In some configurations, the connector 1530 can comprise a groove that is engaged by either one of the openings 1507 of the manifold 1501 and the thin wall section 1510 can facilitate the seal between the manifold 1501 and the connector 1530.

[0155] Figures 15E-G illustrate an alternative coupling arrangement between the supply tube 1502 and the manifold 1501, which incorporates an insert 1540 that facilitates the
connection between the supply tube 1502 and the manifold 1501. In some configurations, the manifold 1501 is constructed from a soft and/or stretchable material, which can increase comfort for the user. The insert 1540 can be constructed from a relatively stiff material, which preferably has greater stiffness than the material of the manifold 1501 such that the insert 1540 can be positioned within one or both openings 1507 of the manifold 1501 with a relatively tight fit therebetween. In some configurations, the manifold 1501 and the insert 1540 can create at least a substantial seal therebetween at least at the expected working pressures of the nasal cannula system 1500. The insert 1540 can include one or more interference features that secure the insert 1540 relative to the manifold 1501 via complementary interference features of the manifold 1501. For example, the insert 1540 can include at least one protrusion, and preferably a pair of opposed protrusions 1542, that engage recesses or openings 1544 of the manifold 1501. In the illustrated arrangement, the protrusions 1542 are button-head or mushroom-head protrusions having an enlarged head portion distal of a shaft portion relative to the body of the insert 1540. The openings 1544 can engage the shaft portion of the protrusions 1542 when the inserts 1540 are assembled to the manifold 1501. The soft and/or stretchable material of the manifold 1501 can assist in assembling of the inserts 1540 into the manifold 1501 and passing of the protrusions 1542 through the openings 1544.

[0156] The connector 1530 can be shaped or otherwise configured to engage the insert 1540 to securely connect the supply tube 1502 to the manifold 1501. In the illustrated arrangement, the connector 1530 comprises at least one interlocking member, such as a resilient arm portion 1546. Preferably, the connector 1530 comprises a pair of resilient arm portions 1546. Each arm portion 1546 includes an engagement protrusion 1548 that engages a portion (e.g., an end surface) of the insert 1540. The illustrated connector 1530 includes a cylindrical base portion 1550 between a flange 1552 and the arm portions 1546. The flange 1552 has an enlarged diameter or circumferential dimension relative to the base portion 1550 to define a shoulder 1554 that can abut the end surface of the insert 1540 opposite the end surface engaged by the protrusions 1548. Thus, a linear distance between the shoulder 1554 and the protrusion 1548 can be approximately equal to a length of the insert 1540. In some configurations, the arm portions 1546 can flex toward a central axis of the connector 1530 to
facilitate passage of the arm portions 1546 through the interior space of the insert 1540. Preferably, a length of the manifold 1501 and a length of the inserts 1540 are configured such that neither the inserts 1540 nor the shuttle object 1508 block the prongs 1505.

[0157] Figures 16A-F illustrate embodiments of a nasal cannula assembly with a manifold having a one way valve at each end. Similar to the embodiment discussed in Figure 15, Figures 16A-F illustrate a nasal cannula assembly 1600 having a manifold 1601 with nasal prongs 1605 in a central portion, a hollow cavity 1609, and inlets or openings 1607 on each side of the manifold 1601. A supply tube 1602 can be attached to either opening 1607 of the manifold 1601. However, instead of or in addition to a shuttle object (e.g., valve body 1508) to seal the hollow cavity 1609 at one opening 1607, a one way valve 1608 is used. In some embodiments, the one way valve 1608 is positioned at one opening 1607 of the hollow cavity 1609 of the manifold 1601 and the supply tube 1602 is positioned within the opening 1607 by being pushed through the one-way valve 1608 or positioned up against the one-way valve 1608. In certain embodiments, the opposite one way valve 1608 will remain sealed and therefore the flow of air or gas from the supply tube 1602 will be directed toward the nasal prongs 1605. In some embodiments, the one way valve 1608 can be molded into the manifold 1601. In other embodiments, the one way valve 1608 can be assembled as inserts configured to be inserted into the manifold 1601. In certain embodiments, the one way valve 1608 can also function as a pressure pop-off safety valve to release any excess pressure.

[0158] Figures 16A-F illustrate embodiments of a nasal cannula assembly 1600 with the manifold 1601 having a one way valve 1608 formed from an exhalation style valve with a loosely hinged flap 1608a (Figure 16E). In some embodiments, the supply tube 1602 can be inserted through the one-way valve 1608 as illustrated in Figure 16C, thereby holding the flap opens with the supply tube 1602. In some embodiments, the supply tube 1602 is placed up against the one way valve 1608 and the valve 1608 is held open by the air flow from the supply tube 1602 as illustrated in Figure 16D. The supply tube 1602 can be connected to the manifold 1601 directly or through any suitable connector, such as any of the connectors disclosed herein. The valve 1608 can have any suitable shape, such as circular (Figures 16A-E) or rectangular (Figure 16F).
Figures 16G-L illustrate embodiments of a nasal cannula assembly 1600 with a manifold 1601 having a one way valve 1608 formed from a slit valve of various shapes. Preferably, the one way valve 1608 comprises a stretchable material. In some embodiments, the one way valve 1608 can be a slit valve (Figures 16G and 16H), which in particular can be a duck-billed valve (Figure 16I and 16J), a joker or tricuspid valve (Figure 16K), a slit-dome valve (Figure 16L), and/or any other slit valve known in the art. The supply tube 1602 can be connected to the manifold 1601 by any suitable arrangement, either directly or via a connector 1630.

Figure 17 illustrates an embodiment of a nasal cannula assembly 1700 with a supply tube 1702 threaded through the manifold 1701 to allow for selective side switching of the exit side of the supply tube 1702 relative to the manifold 1701. In some embodiments, the supply tube 1702 can have a first end 1710 and a second end 1711. The first end 1710 and the second end 1711 can have a respective manifold insert 1712, 1713 attached thereto. The manifold inserts 1712, 1713 can each have one or more manifold insert openings 1714 (e.g., a pair of openings 1714 on opposing sides of the inserts 1712, 1713) extending along a length of the manifold insert 1712, 1713. In addition, each insert 1712, 1713 can include a pair of spaced-apart flanges 1716 positioned on opposite sides of the openings 1714 and configured to create at least a substantial seal with the manifold 1701. A recess 1718 is defined between the flanges 1716 such that air or gas communication between the openings 1714 and the nasal prongs 1705 is assured despite the location of the openings 1714.

In certain embodiments, the tube exit side can be selectively chosen by pushing or pulling the supply tube 1702 one way or the other to whichever side is desired. In some embodiments, when the supply tube 1702 is pulled or pushed to one side, the manifold insert 1712, 1713 on the opposite side seals against the manifold 1701 and the manifold insert 1712, 1713 on the side pulled through can be connected to the gas or air supply circuit. For example, if the supply tube 1702 is pulled through the manifold 1701 and the manifold insert 1712 is sealed against the manifold 1701, the opposite end manifold insert 1713 would be connected to the gas or air supply circuit (Figure 17B). Alternatively, if the tube 1702 is pulled through the manifold 1701 and the manifold insert 1713 is sealed against the manifold 1701, the opposite end manifold insert 1712 would be connected to the gas or air supply circuit.
circuit. In some embodiments, to connect the supply tube 1702 to the circuit may require a connector or adapter 1715 so that the appropriate fitting can be achieved for connection to the humidifier or other gas or air supply. Additionally, in other embodiments, a proprietary connection is used to connect the supply tube to the gas or air supply circuit, thereby eliminating the need for an adapter or connector 1715. In some embodiments, the manifold insert opening 1714 can be lined up with the nasal prongs 1705 on the manifold when the manifold insert 1712, 1713 is positioned inside the manifold 1701. Additionally, in some embodiments, the manifold insert 1712, 1713 can be held in position with a locking mechanism once the supply tube 1702 is pulled through to the desired side of the manifold 1701. In some embodiments, the locking mechanism can include a twist lock, press fit, screw, or any other locking mechanism known in the art.

Figures 18A and 18B illustrate embodiments of a nasal cannula assembly with each tubing exit hole sealed by a thin membrane or other member that can be pierced. Similar to the embodiment described with reference to Figures 15A-G, Figures 18A and 18 illustrate nasal cannula assemblies 1800 having a manifold 1801 with nasal prongs 1805 in a central portion, a hollow cavity (not shown) and openings 1807 on each side of the manifold 1801. A supply tube 1802 can be attached to either opening 1807 of the manifold 1801. In some embodiments, the openings 1807 of the manifold 1801 are sealed by a thin membrane 1810. The thin membrane 1810 can be a film, pierceable membrane, or other pierceable material known in the art. In some embodiments, the connector or end portion 1811 of the supply tube 1802 comprises a piercing portion, such as a sharpened point 1812 that is capable of piercing the membrane 1810 at whichever opening 1807 of the manifold 1801 the supply tube 1802 is inserted. The sharpened point 1812 can be located in any suitable location, such as at or near a circumferential edge (Figure 18A) or at or near a center (Figure 18B). When the sharpened point 1812 is at or near the center, the end portion 1811 can define one or more openings 1814 to permit air or gas to pass through the end portion 1811. In certain embodiments, the user can choose the side in which the supply tube 1802 is positioned and can puncture the membrane 1810 on that opening 1807 with the end portion 1811 of the supply tube 1802. In some embodiments, the membrane 1810 is a single-use arrangement such that, once the membrane 1810 is pierced on one side, the membrane 1810 cannot be re-sealed.
However, in some embodiments, the membrane 1810 can be replaceable or resealable. In some embodiments, the end portion 1811 can contain one or more barbs to assist in piercing the membrane 1810 and/or securing the end portion 1811 within the manifold 1801. In some embodiments, the barbs or sharp section can be removed before the supply tube 1802 is inserted and the supply tube 1802 can be press fit into the opening 1807 of the manifold 1801. In some embodiments, the barbs or end portion 1811 can remain on the supply tube 1802 and can assist in securing the supply tube 1802 within the manifold 1801. In some embodiments, the end portion 1811 can have a cover to prevent injury to a user or damage to the end portion 1811 when not in use and ensure the end portion remains clean and sterile before use.

[0163] In some embodiments, the selective side switching of the manifold and prongs relative to the supply tube can be accomplished by manipulation of the supply tube. Figures 19A and 19B illustrate embodiments of a manifold 1901 with a flexible supply tube 1902 exiting an opening 1907 of the manifold 1901. In the illustrated arrangement, because the flexible supply tube 1902 is used for selective side switching, only one opening 1907 is provided. However, in other arrangements, two or more openings 1907 can be provided. In some embodiments, the supply tube 1902 attached to and/or exiting the manifold 1901 can be a highly flexible tube. The highly flexible tube can allow for the supply tube 1902 to be routed to either side of the face and away from the mouth. In some embodiments, a highly flexible tubing is used that can be bent around a zero radius without substantial kinking or at least without fully occluding the internal passage of the tube. Preferably, bending of the highly flexible tube does not cause substantial occlusion of the internal passage of the tube. In some embodiments, the highly flexible supply tube 1902 can exit from the front of the manifold 1901 and routed to either side of the patient without disassembling the nasal cannula assembly 1900 and/or without moving any of the nasal cannula assembly parts. In certain embodiments, the flexible supply tube 1902 can exit from the front of the manifold 1901 from the opening 1907 and can be bent at least about 90 degrees to either the left or right side of the face.

[0164] Further, in some embodiments, the manifold can be configured to be inserted into an assembly securing device in either direction allowing for the nasal cannula assembly to be used interchangeably with the tube coming from either the right side of the patient or the left side of the patient. Figures 20A-C illustrate an embodiment of a nasal
cannula assembly 2000 including a manifold 2001 that snaps into a manifold securing device or clip 2003. In some embodiments, the manifold 2001 can interchangeably switch sides on which the supply tube 2002 is positioned by allowing the manifold 2001 to be inserted into the clip 2003 in at least two different orientations. In some embodiments, the manifold 2001 and supply tube 2002 can be integrated into one manifold/tubing assembly 2004. For example, to change the direction from which the supply tube 2002 extends relative to the nose of the patient, the manifold/tubing assembly 2004 can be unclipped from the clip 2003, flipped around 180 degrees and then clipped back in. Two available orientations of the supply tube 2002 are illustrated in Figures 20A and 20B, respectively. The clip 2003 can be coupled to a retention arrangement, such as any suitable type of headgear strap 2040, including those disclosed herein or other suitable arrangements.

[0165] Additionally, in some embodiments, the manifold can be configured for use with a clip-on supply tube. For example, Figures 21A-D illustrate a nasal cannula assembly 2100 with a separable supply tube assembly 2102 and manifold 2101. In some embodiments, the nasal cannula assembly 2100 can comprise a manifold 2101 that includes prongs 2105 and two openings 2107 at each end of the manifold 2101. In some embodiments, the manifold 2101 can be connected to a supply tube assembly 2111. In some embodiments, the supply tube assembly 2111 can include a supply tube 2102 and a manifold receiving structure 2112. The manifold receiving structure 2112 can be assembled to the supply tube 2102 at the time of manufacture or can be connectable to the supply tube 2102 prior to use. In certain embodiments, the manifold receiving structure 2112 can be a ‘C’ shaped manifold receiving structure or clip 2112 as illustrated in Figure 21A-D or the manifold receiving structure 2112 can have any shape that allows for complimentary coupling to the manifold 2101. In some embodiments, the manifold 2101 has a complimentary shape or matching shape to receive the manifold receiving structure 2112 which can either be slid onto, clipped onto, or otherwise attached through any means known in the field to the manifold 2101 with the supply tube 2102 positioned facing either way as desired. In certain embodiments, the manifold receiving structure 2112 can have location and/or sealing details 2113 incorporated on the inside of, or elsewhere on, the manifold receiving structure 2112 to ensure a secure connection and/or a proper seal with the manifold 2101. In some configurations, the sealing detail 2113 is a
protrusion, such as a spherical protrusion. The sealing detail 2113 preferably seals one of the openings 2107 and the end portion 2130 of the supply tube 2102, which can be defined by the manifold receiving structure 2112 or can be a separate component, engages the other opening 2107. The end portion 2130 can rest against and be flush with an outer surface of the manifold 2101 that surrounds the opening 2107 (Figure 21C) or can extend into the opening 2107 (Figure 21D).

[0166] In some embodiments, one or more stops 2104 can be molded into, or otherwise secured to, the manifold 2101 to inhibit or prevent downward movement of the manifold receiving structure 2112 when pulled during use. For example, as shown in Figure 21A, a pair of stops 2104, each defining a stop surface, can be formed on each side of the manifold 2101. In some embodiments, the manifold receiving structure 2112 can be slid upwardly relative to the manifold 2101 for removal and flipping of the tubing side. In some configurations, as shown in Figure 21E, portions of the manifold receiving structure 2112, such as end portions 2116, can engage complementary portions, such as recesses 2118, of the manifold 2101 to assist in securing the manifold receiving structure 2112 to the manifold 2101. As shown in Figure 21F, the manifold 2101 can include a recessed portion 2120 that is sized and shaped to receive the manifold receiving structure 2112. The recessed portion 2120 can be located on the forward and lateral portions of the manifold 2101 and can have a depth suitable to accommodate an entirety of the thickness of the manifold receiving structure 2112, such that an outward-facing surface of the manifold receiving structure 2112 is flush with or recessed within the outer surface of the manifold 2101. Such an arrangement assists in securing the manifold receiving structure 2112 to the manifold 2101 and/or can inform the user how to correctly locate and secure the manifold receiving structure 2112 to the manifold 2101. The recessed portion 2120 can be utilized separately or in combination with the recesses 2118.

[0167] Figures 21G and 21H illustrate an embodiment of a nasal cannula assembly 2100 having a manifold receiving structure 2132, a separate nasal prong insert 2125 and a manifold 2121. In some embodiments, the manifold 2121 can have no prongs and an opening 2126 in the manifold 2121 to communicate with the prong insert 2125. The prong insert 2125 can be formed with prongs 2105 of different sizes so that the appropriate sized prongs 2105
can be selected for different nose sizes and ensure correct prong sizing for the patient. In some embodiments, the manifold 2121 and the prong insert 2125 can be connected with a manifold receiving structure 2132, such as a C-shaped clip, for example. In some embodiments, the manifold receiving structure 2132 can be used to hold the prong insert 2125 in place and will complimentarily fit the manifold 2121. Thus, the manifold receiving structure 2132 can include one or more openings 2128 that accommodates the prongs 2105. The manifold 2121 can include a recess 2134 surrounding the opening 2126 and that accommodates a base of the prong insert 2125. The manifold 2121 can also include recessed portions 2136 on lateral sides thereof configured to accommodate the manifold receiving structure 2132 and assist in securing the manifold receiving structure 2132 to the manifold 2121. Although in the illustrated arrangement the opening 2126 is positioned on an upper surface of the manifold 2121, the opening 2126 could be positioned on other portions (e.g., a forward surface) of the manifold 2121 in addition or in the alternative.

[0168] Figures 22A-D illustrate an embodiment of a nasal cannula assembly 2200 having a manifold insert 2201 and a manifold receiving structure 2210. In some embodiments, the manifold insert 2201 can include prongs 2205 and an opening 2207 on each end of the manifold insert 2201. The manifold insert 2201 can be made of a soft or flexible material. The prongs 2205 on the manifold insert 2201 can be flexible or stiff. In some embodiments, the manifold insert 2201 can be inserted into a manifold receiving structure 2210. In some embodiments, the manifold receiving structure 2210 can be attached to or integrated with an assembly securing device 2203, such as a headgear strap. The manifold receiving structure 2210 has one closed end 2213 and one open end 2214. In some embodiments, the manifold receiving structure 2210 can be attached to a supply tube 2202 on the open end 2214 side of the manifold receiving structure 2210 allowing for the passage of air or gas. In some embodiments, the manifold insert 2201 can be clipped or slid into the manifold receiving structure 2210. In some embodiments, the manifold receiving structure 2210 can have a round or spherical boss or protrusion 2211 at one end 2213 of the manifold receiving structure 2210 which can provide an effective radial seal with one opening 2207 of the manifold insert 2201 and assist in holding the manifold insert 2201 in place. The other end 2212 can include a connector 2214 that can be unitary with or separate from the supply tube 2202 and engage the
other opening 2207 of the manifold insert 2201. In some embodiments, once the manifold insert 2201 is placed within the manifold receiving structure 2210, the manifold insert 2201 and/or the prongs 2205 can be turned or tilted to the correct comfort configuration for the user. For example, in some embodiments, to flip the tubing side, the manifold insert 2201 is removed and the remainder of the nasal cannula assembly, including the manifold receiving structure 2210, the assembly securing device 2203, and/or the supply tube 2202, is flipped around so that the supply tube 2202 faces the desired direction, and then the manifold insert 2201 with prongs 2205 are re-assembled to point back toward the nose of the patient.

[0169] Figures 23A-C illustrate an embodiment of a nasal cannula assembly with a manifold receiving structure or cannula that can be clipped over a supply tubing assembly, which includes a manifold. In some embodiments, the nasal cannula assembly 2300 includes a supply tube assembly 2311, which comprises a manifold 2301 and a supply tube 2302. The nasal cannula assembly 2300 also includes a manifold receiving structure or cannula 2310, which comprises a pair of prongs 2305. The supply tube 2302 connects the manifold 2301 to an air or gas supply circuit. In some embodiments, the manifold receiving structure 2310 can be a generally tubular member with an opening or slot 2313 extending partially or completely along its length to form a ‘C’ shaped section which can be clipped over the manifold 2301. In some embodiments, the manifold 2301 can have a ledge or rib 2312 that is complementary with the opening or slot 2313 of the ‘C’ shaped manifold receiving structure 2310 such that the rib 2312 can be received in the slot 2313. Advantageously, such an arrangement assists in securing or locking the manifold receiving structure 2310 in place on the manifold 2301. In some embodiments, the supply tube assembly 2311 can be attached to or integrated within an assembly securing device 2303, such as a headgear strap. For example, in some embodiments, to reverse the direction of the supply tube 2302, the manifold receiving structure 2310 is removed or unclipped from the manifold 2301, flipped around and reconnected so that the supply tube 2302 faces the desired direction.

[0170] Figures 24A-F illustrate embodiments of flexible, tilting or directionally-adjustable prongs and embodiments of a nasal cannula assembly 2400 having such flexible, tilting or adjustable prongs 2405. With such prongs 2405, the exit side of the supply tube
2402 can be changed by simply adjusting the direction of the prongs 2405 and rotating the manifold/tubing assembly 2404 by 180 degrees on the patients face.

[0171] With reference to Figures 24A-C, in certain embodiments, the prongs 2405 can be flexed to the side of the manifold 2401 desired for use. In particular, the prongs 2405 can be formed with a ripple shape around the base of the prong 2405. Figures 24B and 24C illustrate an embodiment of a prong 2405 formed with a ripple shape 2408 around the base to allow for flexibility of the prong 2405. In some embodiments, the ripple shape 2408 comprises at least one and, preferably, multiple ripples. In the illustrated arrangement, two ripples are provided; however, in other embodiments, three or more ripples can be provided. The ripples are illustrated as being annular in shape and having a semi-circular cross-section. The ripples can have a reduced wall thickness relative to a portion of the manifold 2401 adjacent the ripples or can have the same or a similar wall thickness. The ripple shape 2408 allows the prong 2405 to be shaped in whichever direction is desired for use. In some embodiments, the prongs 2405 could have a ripple shape 2408 around the base which allows them to tilt in any direction. In certain embodiments, the prong 2405 can have a thickened section(s) or stiffening rib(s) 2407 to make the prong favor certain tilting directions, thereby allowing the prong 2405 to bend in a first direction but inhibiting or preventing the prong 2405 from bending in a second direction, which may be substantially perpendicular to the first direction. In the illustrated arrangement, two stiffening ribs 2407 are provided on each side of each prong 2405 and extend in a substantially radial direction relative to the prong 2405.

[0172] Figures 24D-F illustrate an embodiment of prongs 2405 comprising a collapsible corrugated concertina section, which can define a portion or a substantial entirety of a length of the prongs 2405. Preferably, the formation of the prongs 2405 with such geometry allows the prongs 2405 to be bent in any direction and hold that shape. In some embodiments, the prong 2405 can be compressed and extended to vary a length of the prong 2405, as illustrated in Figures 24D and 24E. In some embodiments, the prong 2405 can be expanded from the compressed shape and bent to the desired direction or shape, as illustrated in Figure 24F. For example, in certain embodiments, the prongs 2405 are packaged in the compressed form and are then expanded and bent as configured by a caregiver or the user to the appropriate direction and shape.
In some embodiments, the nasal cannula assembly can contain rotating prongs. Figures 25A-C illustrate embodiments of a nasal cannula assembly 2500 with rotating prongs. In some embodiments, the nasal cannula assembly 2500 can be flipped to change the side of the supply tube 2502, and then the prongs 2505 can be rotated to face the appropriate orientation toward the nose of the patient. Figure 25A illustrates an embodiment of a nasal cannula assembly 2500 that includes individually rotatable prongs 2505. In some embodiments, the prongs can rotate freely in a clockwise or counterclockwise direction relative to the manifold 2505. In some embodiments, the prongs 2505 can rotate to a limited degree when the manifold 2501 and prongs 2505 are constructed as a unit.

Figures 25B and 25C illustrate an embodiment of a nasal cannula assembly 2500 that comprises a prong insert 2506 having a pair of prongs 2505. Preferably, the prong insert 2506 is rotatable relative to the manifold 2501. The illustrated prong insert 2506 is mounted on and rotatable about a vertical shaft 2508 such that the prongs 2505 rotate together. In some embodiments, the prong insert 2506 is a separate component from the manifold/tubing assembly 2504 and the removable prong insert 2506 can allow for the use of different sizes of prongs 2505 for different nose sizes while using a single size manifold 2501. Additionally, in some embodiments, the manifold 2501 can have a lip 2510 on a surface of the manifold 2501 to which the prong insert 2506 connects. The prong insert 2506 can have a mating section 2511 that is complementary to the lip 2510. In some embodiments that contain a lip 2510 on the manifold 2501, the prong insert 2506 can be lifted from the surface of the manifold 2501 and rotated about the vertical shaft 2508 so that the prongs 2505 can be repositioned to the appropriate direction. The prong insert 2506 can be rotatable about a vertical, central axis of the manifold 2501 or an axis that is centrally located relative to openings 2518 in the manifold 2501 that communicate with the nasal prongs 2505, as shown in Figure 25B, such that the prongs 2505 switch openings 2518 between the two orientations.

In some embodiments, the manifold can have a prong exit hole in the midsection of the manifold configured to receive an insert or clip-on attachment including the prongs. Figures 26A-F illustrate an embodiment of a nasal cannula assembly 2600 configured to allow insertion of a removable prong insert 2606. In some embodiments, the prong insert 2606 can be pushed into an opening 2607 in the hollow manifold 2601. This allows the prongs
2605 to be configured in the appropriate direction for use by the patient in the same manifold 2601 and/or manifold/tube assembly 2604. The manifold 2601 and/or manifold/tube assembly 2604 can be connected to an assembly securing device 2603, such as a headgear strap. For example, in some embodiments, the supply tube 2602 and manifold 2601 are assembled with the securing device 2603 and the nasal prongs 2605 are carried by the removable nasal prong insert 2606. The manifold/tube assembly 2604 and the assembly securing device 2603 can be symmetrical so it can be assembled to the face in one direction (e.g., Figure 26B) or an opposite direction (e.g., Figure 26C). In some embodiments, the assembly securing device 2603 and the manifold/tube assembly 2604 can be flipped around to suit whichever direction the supply tube 2602 is desired to be positioned. For example, in certain embodiments, to switch the side the supply tube 2602 is positioned, the nasal prong insert 2606 is removed and the remainder of the manifold/tube assembly 2604 is flipped around so that the supply tube 2602 faces the desired direction, and the nasal prong insert 2606 is then reinserted into the receiving opening 2607 of the manifold/tube assembly 2604 in the proper orientation to point toward the nose of the patient. Further, the nasal prong insert 2606 can be of different sizes (Figures 26D-F) and the different size inserts can be interchanged on the same assembly 2604 for use and adaptation for different patient nose sizes and to ensure correct prong sizing for the patient.

[0176] In some embodiments, a nasal cannula assembly can comprise a manifold, supply tube and a cannula that is removable from the manifold and/or adjustable about at least one axis relative to the manifold. The cannula can be adjustable about two axes relative to the manifold and can be available in different prong sizes to allow the assembly to fit a variety of patients. In particular, with reference to Figures 27A-D, a nasal cannula assembly 2700 includes a pivoting cannula 2714, which preferably incorporates a pair of nasal prongs 2705. The cannula 2714 is pivotally coupled to a moulding (head strap moulding) or manifold 2701, which can include side portions 2722 that extend in opposing lateral directions from the cannula 2714. A suitable retention assembly (not shown), such as a headgear strap, can secure the manifold 2701 and cannula 2714 to the patient. In some arrangements, the headgear strap is an elastic, high-stretch strap, which can assist in or improve the seal between
the manifold 2701 and the cannula 2714. The headgear strap can be unitary with, integral with, or separate from the manifold/moulding 2701.

[0177] Preferably, the manifold 2701 defines a conduit or passage 2709 that allows air or gas to pass from a supply tube 2702 to the cannula 2714. The passage 2709 can be defined by a molding from which the manifold 2701 and side straps 2722 are constructed (e.g., a single integrated structure) or can be defined by a separate member. The supply tube 2702 can be coupled to the manifold 2701 by any suitable arrangement, such as a jaw expander arrangement or any other arrangement disclosed herein. A clip 2742 can secure the supply tube 2702 to the side strap 2722. An end of the supply tube 2722 opposite the manifold 2701 can include a connector 2752, which permits coupling of the supply tube 2722 to an air or gas source.

[0178] In some embodiments, the cannula 2714 can be rotated relative to the manifold 2701 about an axis that extends in a generally fore-aft direction or a generally horizontal axis that lies in the sagittal plane. Preferably, the cannula 2714 can be rotated at least 180 degrees such that the prongs 2705 can be rotated from the top (the orientation of Figure 27A) to the bottom, which provides an effective change of the supply tube 2702 exit side. In some embodiments, the cannula 2714 is coupled to the manifold 2701 by a ball-and-socket joint 2726 such that the cannula 2714 is also rotatable about an axis that extends in a generally lateral direction or a generally horizontal axis that lies in the frontal plane. Such an arrangement not only provides a simple change of the supply tube 2702 exit side, but also allows adjustment of the nasal prong 2705 orientation relative to the manifold 2701 to increase patient comfort and/or fit a wider variety of patients.

[0179] In some embodiments, a size of the prongs 2705 is adjustable. For example, as shown in Figures 27B and 27C, the ball joint portion 2730 can be separable from a prong portion 2732 of the cannula 2714. Several prong portions 2732 can be included in a kit or can be otherwise made available that provide several different sizes of nasal prongs 2705. For example, three different prong portions 2732 are shown in Figure 27C, which include three differently-sized prongs 2705. An appropriate or desired one of the available prong portions 2732 can be coupled to the ball joint portion 2730, such as via a snap-fit or other suitable arrangement. Alternatively, two or more complete cannulas 2714 can be
provided, each with different size prongs 2705. Accordingly, with such an arrangement, the cannula 2714 could be constructed as a single piece.

[0180] However, it is not necessary that the cannula 2714 be rotatable in multiple axes, or even rotatable through an arc. Instead, the cannula 2714 can have discrete adjustment positions relative to the manifold 2701. Preferably, at least the position shown in Figure 27A and the 180 degree rotation of the cannula 2714 are provide such that the exit side of the supply tube 2702 can be switched. If desired, other discrete position options can be provided. The cannula 2714 and manifold 2701 could include interference surface features to assist in securing the cannula 2714 in a desired position relative to the manifold 2701. For example, as shown in Figure 27D, the cannula 2714 could include one or more teeth 2760 or other protrusions that engage corresponding recesses of the manifold 2701. In the illustrated arrangement, the cannula 2714 includes multiple teeth 2760 on each lateral side of the ball joint 2726, which can extend in a radial direction relative to the ball joint 2726. Other suitable arrangements can also be employed.

[0181] In some embodiments, as shown in Figure 28A, a nasal cannula assembly 2800 includes a manifold 2801 that is capable of being coupled to a cannula 2814 in at least two orientations to allow a simple switching of the exit side of the supply tube 2802. The cannula 2814 can include a central portion that includes prongs 2805 and side portions 2822 on each lateral side of the central portion. The manifold 2801 can include side portions 2812 that overlap with the side portions 2822 of the cannula 2814. The side portions 2812 and 2822 can facilitate a secure connection between the manifold 2801 and the cannula 2814. For example, the side portions 2812 or 2822 of one or both of the manifold 2801 and the cannula 2814 can include couplers or coupling mechanisms that couple or assist in coupling the manifold 2801 and the cannula 2814. In the illustrated arrangement, the side portions 2812 include a first component 2830 of a coupler (e.g., a hook and loop fastener) and the side portions 2822 of the cannula 2814 includes a second component 2832 of a coupler (e.g., a hook and loop fastener). One or both of the side portions 2812 of the manifold 2801 include a tab 2850 that provides a finger grip surface to facilitate removal of the manifold 2801 from the cannula 2814. In addition, one or both of the side portions 2812 can include flex slots 2828 to facilitate flexing of the side portions 2812, which can assist in removal of the manifold.
2801 from the cannula 1814 and can also facilitate the manifold 2801 conform to the shape of the cannula 2814.

[0182] The manifold 2801 and the cannula 2814 can include cooperating structures that create a seal between the two components. For example, the manifold 2801 can include a protruding portion 2860 that defines a cavity in communication with the supply tube 2802 and includes at least one and preferably a pair of openings 2862 that allow air or gas communication with the prongs 2805 when the manifold 2801 is assembled to the cannula 2814. The protruding portion 2860 engages an opening 2864 of the cannula 2814 and, preferably, defines at least a substantial seal therewith. The seal can be created by contact or engagement (e.g., a lip and groove) between the protruding portion 2860 and the opening 2864 or a separate sealing member (e.g., a perimeter seal or O-ring) can be used.

[0183] A securement device, such as a headgear strap 2840 can be used to secure the cannula 2814 and, thus, the manifold 2801 to a patient. In some embodiments, the headgear strap 2840 is a non-stretch strap that is coupled to the side portions 2822 of the cannula 2814. The ends of the headgear strap 2840 can be heat-welded to the side portions 2822 and can include the second components 2832 of the coupler between the manifold 2801 and the cannula 2814. The headgear strap 2840 can include a suitable adjuster 2842 that permits a circumference of the strap 2840 to be adjusted. In other arrangements, a stretchable headgear strap 2840 can be used.

[0184] With reference to Figure 28B, the cannula 2814 can be of a composite construction and include a frame member 2870 constructed from a relatively rigid material and a body 2872 constructed from a relatively soft material. For example, the frame 2870 can be a rigid plastic or a metal material, which may be deformable and substantially hold its shape once deformed. The frame 2870 can be external of the body 2872 or the body 2872 can be molded over the frame 2870. Preferably, the frame 2870 is located in the side portions 2822 of the cannula 2814 and can be formed to bridge the central portion containing the prongs 2805 away from the nose to reduce the pressure just below the nose and spread the pressure applied to the patient over the side portions 2822 for increased comfort. The frame 2870 can also surround or partially or completely define the opening 2864 instead of or in addition to extending into the side portions 2822.
[0185] With reference to Figure 29A, in some embodiments of a respiratory assistance system utilizing a nasal cannula system 2900 it is desirable to be able to measure the pressure in the flow path near the patient (e.g., at or near the cannula or manifold 2901) for at least one or both of 1) monitoring of the pressure delivered to the patient and 2) pressure feedback control of a blower flow source (e.g., blower and humidifier 2990). Figure 29A illustrates a basic arrangement for providing pressure feedback control. In particular, a pressure line 2910 connects the manifold 2901 (or manifold/cannula assembly – hereinafter “manifold”) to a flow source control system, which can be a part of the blower/humidifier 2990. With such an arrangement, the flow source 2990 can utilize the information regarding the pressure at or near the manifold 2901 provided by the pressure line 2910 in the operation of the flow source 2990, such as to adjust the supplied pressure to achieve a desired delivered pressure at the patient. Advantageously, this arrangement can compensate for factors that may cause the delivered pressure to be different than expected, such as supply tube 2902 length, cross-sectional area or other geometry, for example. If only pressure monitoring was required or desired, the pressure line 2910 could be connected to a pressure gauge or readout instead.

[0186] With reference to Figure 29B, the pressure line 2910 can be passed through a wall of the manifold 2901 and terminated within a manifold space of the manifold 2901. In the illustrated arrangement, a terminal end 2912 of the pressure line 2910 is perforated with a number of holes 2914 so that if some of the holes 2914 are blocked with condensation, there are other holes 2914 still functioning such that the pressure within the manifold 2901 can be communicated to the pressure source 2990. The terminal end 2912 of the pressure line 2910 can be positioned anywhere within the manifold 2901, such as between the supply tube 2902 and the prongs 2905 along a flow path of the supplied air or gas, for example but without limitation.

[0187] With reference to Figure 29C, the pressure line 2910 can permit direct or indirect communication between the manifold 2901 and the pressure source 2990. The arrangement of Figure 29C separates the manifold chamber 2909 of the manifold 2901 from a pressure chamber 2916 that is in direct communication or is directly sensed by the pressure line 2910. For example, a thin flexible diaphragm seal 2918 (or other movable membrane or
member, such as a floating or sliding piston) separates the manifold chamber 2909 from the pressure chamber 2916, which prevents condensate from entering the pressure line 2910 and keeps the pressure line 2910 clean.

[0188] With reference to Figure 29D, the pressure line 2910 can comprise a pressure sensor 2930, which can sense pressure within the manifold chamber 2909. The pressure sensor 2930 can be located within the manifold 2901, such as being configured as a plug that engages and/or closes one end of the manifold 2901. In some embodiments, a separator, such as a wall or membrane 2918 is positioned between the pressure sensor 2930 and the manifold chamber 2909. The membrane 2918 can be of any suitable type, such as an ultra-thin silicone membrane. The pressure sensor 2930 can be of any suitable type, such as an electrical pressure sensor. The pressure sensor 2930 can be pushed up against the membrane 2918, which can conform to the shape of the pressure sensor 2930, to measure the pressure without directly contacting the flow of air or gas, thus avoiding condensate accumulating on the pressure sensor 2930. In addition, with such an arrangement, the membrane 2918 can be constructed to close and seal the end of the manifold 2901 such that the nasal cannula assembly 2900 can be used with or without the pressure sensor 2930.

[0189] With reference to Figure 29E, the membrane 2918 can be a self-sealing slit valve through which the pressure line 2910 and/or the pressure sensor 2930 could be inserted, if desired. Advantageously, self-sealing slit valve 2918 can close in the absence of the pressure line 2910 and/or pressure sensor 2930 such that there would be no substantial leaking if it was removed. Therefore, the nasal cannula assembly 2900 could function with or without the pressure line 2910 and/or pressure sensor 2930.

[0190] With reference to Figure 29F, the pressure line 2910 and the supply tube 2902 can be integrated into one connector 2931 that is connectable to the manifold 2901 to permit connection of both the pressure line 2910 and the supply tube 2902 at one time. Advantageously, such an arrangement simplifies set up of the nasal cannula assembly 2900 by avoiding the need to connect multiple tubes or components to the manifold 2901.

[0191] With reference to Figure 29G, the pressure line 2910 can be connected as an optional accessory in series with the supply tube 2902. The pressure line 2910 can include a plug portion 2932 that connects to the manifold 2901 and the supply tube 2902 can connect
to the plug portion 2932. Alternatively, with reference to Figure 29H, the pressure line 2910 can be connected as an optional accessory separately from the supply tube 2902, such as on an opposite side of the manifold 2901 from the supply tube 2902. The pressure line 2910 can have a plug portion 2932 that replaces a plug 2934 of the manifold 2901.

[0192] With reference to Figure 29I, a small blower 2940 or other source of air or gas flow can be connected to the pressure line 2910 to apply a small flow of air or gas through the pressure line 2910 preferably sufficient to expel some or all of any condensate which accumulated inside the pressure line 2910. The flow of air through the pressure line 2910 can be provided intermittently or continually and can be considered by the control system in the calculation of the pressure within the manifold 2901.

[0193] With reference to Figure 29J, a thin flexible diaphragm seal 2918 (or other movable barrier) can separate the manifold chamber 2909 from the pressure measurement chamber 2916 to inhibit or prevent condensate from entering the pressure line 2910 and keep the pressure line 2910 clean. If the pressure measurement feature is not utilized and, thus, the pressure line 2910 is not needed, an opening or port 2942 of the manifold 2901 that receives the pressure line 2910 can be left open and can function as a vent to the pressure measurement chamber 2916. Alternatively, the port 2942 can be closed if desired, such as be a suitable plug.

[0194] In some embodiments, with reference to Figure 29K, for example, electrical wiring 2944 is incorporated into the spiral bead 2946 of the supply tube 2902. The electrical wiring 2944 can connect to an electrical pressure sensor 2930 mounted in the manifold 2901. The wiring 2944 (or additional wiring) could also be used to heat the supply tube 2902. In some arrangements, the wiring 2944 can switch between measuring pressure & temperature readings, and heating.

[0195] With reference to Figure 29L, the spiral reinforcement 2946 of the supply tube 2902 can be made hollow or otherwise contain a passage to act as a pressure line (similar to pressure lines 2910 disclosed herein). With such an arrangement, no additional pressure line (e.g., 2910) would need to be used. The spiral reinforcement 2946 could connect at one end to the chamber of the manifold 2901 and at the other end to the operating system of an air or gas source, or a pressure monitor or gauge 2948.
In some embodiments, the nasal cannula assembly includes features that improve patient comfort. Discomfort can exist for some patients using some nasal cannula assemblies. For example, two types of discomfort include: 1. a hot, damp, clammy feel of the cannula/manifold in contact with the skin on the upper lip, which may be caused by moisture originating from perspiration and the circulation of warm humidified gases in this area, and 2. pain and numbness associated with the pressure applied to the upper lip by the cannula/manifold. Some embodiments of a nasal cannula assembly 3000 address one or both of these types of discomfort to at least some degree.

With reference to Figure 30A, holes, recesses or depressions 3020 of any desired shape can be cut into or otherwise formed in the cannula or manifold (hereinafter “cannula”) material, which allow fresh air to reach the skin helping to keep the area cool and reducing the buildup of moisture. In some embodiments, the holes, recesses or depressions 3020 are cut into or formed in areas that do not cause leakage of the therapy air flow from the cannula 3014. For example, the holes, recesses or depression 3020 are provided in the side portions 3022 of the cannula 3014 and not in the central portion that contains the prongs 3005. In the illustrated arrangement, holes 3020 that pass completely through the side portions 3022 of the cannula 3014 are provided. The holes, recesses or depressions 3020 can also improve flexibility of the cannula 3014, allowing it to conform more easily to the shape of the patient’s lip and distribute pressure more evenly for improved comfort.

With reference to Figure 30B, the cannula 3014 could also include small raised bumps or protrusions 3030 on the rear or patient-facing surface of the cannula 3014. The bumps 3030 hold some or all of the remaining rear or patient-facing surface of the cannula 3014 away from the lip of the patient, allowing fresh air to reach the skin, helping keep the area cool and reducing moisture buildup. The bumps 3030 can be provided over an entirety of the rear surface, as shown, or over only a portion of the rear surface, such as the side portions 3022 similar to the cannula 3014 of Figure 30A, for example.

With reference to Figure 30C, grooves 3040 can be cut into or otherwise formed in the rear surface of the cannula 3014. The grooves 3040 allow fresh air to reach the skin, helping keep the area cool and reducing moisture buildup. In some embodiments, the grooves 3040 extend in a generally vertical direction or perpendicular to the lateral direction.
of the cannula 3014. In addition, the grooves 3040 can extend partially through the cannula 3014 such that one end is closed or can extend completely through the cannula 3014 such that both ends are open, as shown in Figure 30C. The grooves 3040 can also improve flexibility of some portions (e.g., side portions 3022) or all of the cannula 3014, allowing it to conform more easily to the shape of the patient's lip and distribute pressure more evenly for improved comfort.

[0200] With reference to Figures 30D-H, in some embodiments, the cannula 3014 can include a cannula lip bridge arrangement in which the cannula 3014 is shaped so that it curves away from the face at the upper lip, reducing pressure or completely avoiding any contact with the upper lip thereby resulting in improved circulation of fresh air in the area, and reduced (e.g., little or none at all) pressure on the lip. The pressure is instead applied by the side portions 3022 and absorbed by the cheeks, which are less sensitive to pressure. In some arrangements, the prongs 3005 are reverse mounted horizontally on the inside of the cannula 3014 and are curved up into the nares. This design has the additional benefit of allowing clearance for a moustache.

[0201] Preferably, such embodiments of the cannula 3014 have some rigidity, which can be accomplished by any suitable construction or arrangement, such as using a stiffer material for the cannula 3014 (Figures 30D-F), reinforcing ribs, or a structural member such as an internal (Figure 30G) or external (Figure 30H) wire or strip 3050, which could be malleable for adjustment to suit individual patients. The cannula 3014 can be of any suitable arrangement, such as having and integrated or directly-connected supply tube 3002 or by utilizing a manifold 3001 connected to the supply tube 3002 and received within the cannula 3014, for example.

[0202] With reference to Figure 30I, in some embodiments, a comfort pad or insert 3060, such as a gel pad or other type of pad can be provided on the rear or patient-facing surface of the cannula 3014. At least the rear surface of the cannula 3014 in contact with the patient's upper lip can be made of a soft gel material or can include a soft gel pad 3060 that, in some arrangements, moulds to the shape of an individual patient's lip to create a relatively large contact surface area to evenly distribute pressure across the skin. The pad 3060 can deform as the headgear strap or other retention mechanism (not shown) is tightened.

-57-
to accommodate a patient’s facial geometry and prevent the occurrence of localized areas of pressure. The pad 3060 preferably occupies a substantial portion, such as substantially an entirety, of the rear surface. The pad 3060 could be scented to make the odor of the cannula 3014 more pleasing.

[0203] In some embodiments of a nasal cannula assembly, the supply tube can be manually shaped or positioned and remain in that shape or position or substantially in that shape or position. One of the major benefits of some nasal cannula assemblies, such as the Optiflow nasal cannula assemblies sold by Fisher & Paykel Healthcare Ltd., is to be able to eat, drink and talk while on therapy. In some cases, the shape or position of the supply tube exiting the cannula can inhibit these activities. Thus, in some embodiments, it may be desirable to be able to shape or position the supply tube as desired. Any suitable arrangement or technique can be used to allow shaping or positioning of the tubing, such as those described herein with reference to Figures 31A-F.

[0204] With reference to Figures 31A and 31B, the supply tube 3102 can comprise an internal axial malleable wire or strip 3150. The supply tube 3102 can be assembled or formed with the internal axial malleable wire or strip 3150 that can be deformed into a variety of shapes. Preferably, the stiffness of the wire is significantly greater than the stiffness of the supply tube 3102, such that the shape is retained or substantially retained after forming. The wire or strip 3150 may be contained within, formed within or otherwise coupled to the supply tube 3102 in any suitable manner. For example, as shown in Figure 31A, the wire or strip 3150 can be embedded into the wall of the supply tube 3102 external of a supply passage of the supply tube 3012. Alternatively, as shown in Figure 31B, the wire or strip 3150 can be provided within the supply passage or bore of the supply tube 3102. In such an arrangement, it may be desirable to construct the wire or strip 3150 from, or coat the wire or strip 3150 with, a suitable (e.g., inert) material to tolerate or be suitable for contact with the supplied air or gas. With reference to Figure 31C, the wire or strip 3150 may be a malleable spiral wound wire or strip wound around the circumference of the supply tube 3102, such as in a helical manner. The wire or strip 3150 can be covered or contained within another material (e.g., plastic) to form a bead 3152. The bead 3152 could give the tube structure (e.g., a reinforcement bead) as well as being shapeable or formable and retaining, or at least

-58-
substantially retaining, the adjusted shape or form of the supply tube 3102. Advantageously, with such an arrangement, the bead spiral 3152 wound around the outside of the supply tube 3102 keeps it out of the air or gas path.

[0205] With reference to Figures 31D and 31E, the supply tube 3102 can be in the form of a collapsing corrugated tube having a section or a substantial entirety of collapsing corrugations 3160 that could be used to set one or both of the length and position of the supply tube 3102, as desired. The corrugations 3160 can be manufactured such that when the supply tube 3102 is compressed in a length or axial direction, the corrugations 3160 would each fold into themselves. Figure 31D illustrates the supply tube 3102 in a axially compressed orientation and Figure 31E illustrates the supply tube 3102 in an axially uncompressed or elongated position. The supply tube 3102 can be coupled to the cannula 3114 by any suitable arrangement, such as directly or via a suitable connector. With reference to Figure 31F, alternatively, the supply tube 3102 can include a section or a substantial entirety that is constructed as a ball-and-socket chain. In particular, at least a section of the supply tube 3102 is constructed from a plurality of individual segments or members 3162 or similar that together form a sealed or substantially sealed, yet positionable or formable tube. Preferably, one end of each segment 3162 comprises a ball end 3164 and the other end comprises a socket 3166. Accordingly, a plurality of segments 3162 can be assembled with the ball end 3164 of one segment 3162 positioned within the socket 3166 of the adjacent segment 3162. In some arrangements, the fit of the ball end 3164 into the socket 3166 can be such that each segment 3162 can rotate or move relative to an adjacent segment 3152, yet provide enough frictional force to seal or substantially seal and remain in position or substantially within position once adjusted. If desired, an additional structure or arrangement can be used to hold the segments 3162 in an assembled state or assist in holding or sealing the segments 3162, such as a sleeve that extends over the segments 3162. Advantageously, these and similar embodiments can allow the supply tube 3102 to be positioned out of the patient’s way to reduce or minimize disruption to eating, drinking and talking while on the therapy.

[0206] In some existing nasal cannula assemblies, the supply tube hangs down from its attachment point to the cannula or manifold, which is often just above the corner of the mouth. Such an arrangement can cause, among other issues, the supply tube to hang very
close to the mouth, which can be a nuisance to the patient, as it interferes with eating, drinking and talking. In addition, the weight of the supply tube hanging down so close to the nose tends to drag one side of the cannula or manifold down, pulling it out of the nose. This is especially true in high flow therapies, which require a relatively large supply tube that cannot be comfortably routed behind the patient’s ears, as is the case with smaller low-flow systems. Accordingly, some embodiments route the supply tube to exit the nasal cannula assembly further away from the nose and/or mouth of the patient, to partially or completely address the two issues described above.

[0207] With reference to Figures 32A-C, one portion 3250 of a coupler, such as hook-and-loop fastener, is provided on the supply tube 3202 of a nasal cannula assembly 3200. For example, the portion 3250 can be a sheath of hook-and-loop material. The sheath 3250 can be coupled to the supply tube 3202 by any suitable arrangement, and may be removable or a non-removable from the supply tube 3202. In the illustrated embodiment, the sheath 3250 is permanently attached to the supply tube 3202. The sheath 3250 can be movable along the supply tube 3202 or can be provided at a fixed location on the supply tube 3202, preferably at a spaced location from the manifold or cannula 3214 (hereinafter “cannula”). The sheath 3250 can be secured to the other portion 3252 of the hook-and-loop fastener or other coupler, which can be appropriately positioned to align with the sheath 3250 and, preferably, space the vertical hanging portion of the supply tube 3202 away from the patient’s nose or mouth. Preferably, the other portion 3252 of the coupler is a pad of the other portion of the hook-and-loop fastener relative to the sheath 3250. In one arrangement, as illustrated in Figure 32A, the pad 3252 is provided on each side of a headgear strap 3240 or other retention mechanism of the nasal cannula assembly 3200. Thus, the supply tube 3202 can be routed to either side of the patient’s face, as desired, and supported to hang down at a spaced location from the patient’s nose and/or mouth. In another arrangement, as illustrated in Figure 32C, the pad 3252 is an adhesive pad positioned on the patient’s face, preferably at a location spaced from the nose and/or mouth, such as the cheek, for example. In such an arrangement, the pad 3252 can be applied only to the desired side of the face for the desired routing of the supply tube 3202.
In addition or in the alternative, other suitable mechanisms for similarly securing the supply tube 3202 can be used. Figures 32D-F illustrate several mechanical fastening mechanisms for securing the supply tube 3202 such that the downward hanging portion is spaced from the patient’s nose and/or mouth. Preferably, a first portion 3250 of a mechanical fastener is positioned on the supply tube 3202, in a permanent or removable and fixed or movable fashion. A second portion 3252 of a mechanical fastener is positioned on a portion of the nasal cannula assembly 3200, such as the headgear strap 3240 (or, in another arrangement, side portions 3222 of the cannula 3214). Accordingly, in a manner similar to the arrangements of Figures 32A-C, the first portion 3250 can be coupled to the second portion 3252 of the mechanical fastener such that the supply tube 3202 can be supported away from the patient’s nose or mouth. In Figure 32D, the mechanical fastener is a button and button loop. In Figure 32E, the mechanical fastener is a popper dome or other snap-fit arrangement. In Figure 32F, the mechanical fastener is a hook, which can engage the supply tube 3202 and the headgear strap 3240. Thus, in such an arrangement, the first portion 3250 and the second portion 3252 of the mechanical fastener are formed by a single component. Thus, the portions 3250 and 3252 can be permanently coupled to one another and removable from one or both of the supply tube 3202 and the headgear strap 3240 or other portion of the nasal cannula assembly 3200.

In some embodiments, the supply tube 3202 can be secured by a permanent securing device provided on a portion of the nasal cannula assembly 3200, such as the headgear strap 3240 or a side portion 3222 of the cannula 3214 – especially on cannula designs having extended or large side portions 3222. For example, the securing device can be a permanent loop 3260 on the headgear strap 3240. Preferably, a permanent loop 3260 is present on each side of the headgear strap 3240 to permit routing of the supply tube 3202 to either side. The supply tube 3202 can be threaded through either loop 3260 to provide support and positioning of the supply tube 3202. The loop 3260 can be injection molded or die cut, for example, or formed by any other suitable process. Figure 32G illustrates a loop 3260 that is a hoop or ring positioned generally in the plane of the headgear strap 3240. The illustrated loop 3260 extends below the headgear strap 3240; however, it could also be provided above the headgear strap 3240. Preferably, the loop 3260 can rotate relative to the
headgear strap 3240 to better accommodate the supply tube 3202 and any other component, such as a pressure measurement tube 3210, for example. The headgear strap 3240 could include a portion that spaces the loop 3260 away from the circumferential portion of the headgear strap 3240 to facilitate rotation of the loop 3260. Figure 32H illustrates a molded-in loop 3260 that is positioned beside the headgear strap 3240. Figure 32I illustrates a loop 3260 that is formed by a section 3262 of the headgear strap 3240 that is defined by a pair of spaced-apart slits 3264, which allows the section 3262 to be pulled away from adjacent portions of the headgear strap 3240 to form a passage therewith. The slits 3264 can be substantially parallel with one another and oriented in a substantially vertical direction or along an axial direction of the perimeter defined by the headgear strap 3240, as illustrated. However, in other arrangements, the slits 3264 can be non-parallel and oriented in other directions.

[0210] In some embodiments, the loop 3260 can be a breakable loop to facilitate positioning of the supply tube 3202 within the loop 3260. Preferably, at least one breakable loop 3260 is present on each side of the cannula assembly 3200, such as on the headgear strap 3240. The supply tube 3202 can be clipped into either loop 3260. The loop 3260 could be breakable via any suitable arrangement, such as hook-and-loop fastener (Figure 32J), die cut or otherwise formed tab-and-slot arrangement (Figure 32K), popper domes or other snap-fit arrangement (Figure 32L), injection-molded or otherwise formed mushroom-head-and-recess arrangement (Figure 32M), or push-in clips (Figure 32N), for example. The loop 3260 can be broken at any location, such as in a central portion of the loop 3260 or at the headgear strap 3240. Preferably, any of these arrangements for managing the supply tube 3202 can be used or modified to managing a pressure line 3210 in addition to or in the alternative to the supply tube 3202.

[0211] The circuit delivering air or gas to the patient interface (e.g., cannula or manifold) is reasonably long to reach between the flow source and the patient. The mass of this long circuit, without some circuit supporting device causes the load to be transferred directly to the patient interface. The load of the circuit can cause the cannula to move and be pulled from the patient's nares thereby interrupting therapy. It also can be uncomfortable for the patient to support the load of the circuit directly on the face. The circuit includes the
supply tube described herein (e.g., supply tube 50 of Figure 1) and can also include other conduits (e.g., main delivery conduit of Figure 1 and/or pressure line 872 of Figure 8A). To address this issue, several techniques or arrangements can be used to support at least a portion of the load or mass of the circuit, as described in connection with Figures 33A-S.

[0212] Figures 33A-H illustrate support devices 3350 that can be coupled to a portion of the circuit, generally 3352, to the patient’s clothing, bed sheets or other fabric or thin material and use that to support at least a portion of the load or mass of the circuit 3352. Figures 33A and 33B illustrate a support device 3350 affixed to the circuit 3352 by any suitable arrangement and comprising a two-part dome 3354 that sandwiches the bedding/clothing 3356 between the parts 3354a, b when assembled, such as via a snap-fit arrangement.

[0213] With reference to Figures 33C-F, the support device 3350 can comprise a clip-and-post (e.g., mushroom head) arrangement 3354 that sandwiches the bedding/clothing 3356 between the clip 3354a and post or mushroom head 3354b when the clip 3354a is assembled to the post or mushroom head 3354b. Either portion of the support device 3350 can be affixed to the circuit 3352 by any suitable arrangement. In the illustrated arrangement, the post or mushroom head 3354b is secured to the circuit 3352 by a sleeve 3360. If desired, the clip 3354a can be coupled to the sleeve 3360 by a tether 3362. The clip 3354a can be of any suitable arrangement to be capable of secure engagement and disengagement with the post or mushroom head 3354b with clothing, sheeting or other fabric or material 3356 therebetween. For example, Figure 33C illustrates a simple C-shaped resilient clip 3354a. Figure 33D illustrates a clip 3354a that is capable of being engaged to the post or mushroom head 3354b in a radial or axial direction relative to the post or mushroom head 3354b. Figure 33E illustrates a hinged clip 3354a, which can have a snap-fit arrangement or other mechanism to couple the unhinged ends of the clip 3354a. Figure 33F illustrates a clip 3354a having an elastic retention portion 3364. The clip 3354a is illustrated as a hinged clip, but could also be unhinged. Alternatively, the clip 3354a could be entirely replaced with an elastic member.

[0214] In some embodiments, with reference to Figure 33G, the support device can comprise a tag 3350 that is coupled to the circuit 3352 and includes a button hole feature 3366 that can be attached to an existing button 3368 of a patient’s shirt or other article of
clothing. Alternatively, a specific garment or other piece of material could be provided with a specific button 3368 to engage the button hole feature 3366. The tag 3350 could feature a tear-away feature (e.g., a slit, score line or weakened portion) 3370 that would tear before the patient's shirt or other article supporting the button 3368.

[0215] With reference to Figure 33H, the support device can comprise a clip 3350 having a portion 3372 that surrounds the circuit 3352 and a portion 3374 that can grip bedding, clothing or other fabric or thin material. In the illustrated arrangement, the clip 3350 has two arms that cross one another and are movable relative to one another between an open position and a closed position. The portion 3372 is defined by the portion of the arms that extend between the intersection or connection to one another and the point at which they cross one another. The portion 3374 is defined by the end portions of the arms. The clip 3350 can include finger grip portions 3376 that facilitate squeezing of the clip 3350 to move the clip to the open position. In addition, the clip 3350 can include retention, grip or friction-enhancing features or traction elements 3378 (e.g., knobs or protrusions) that assist in inhibiting the bedding, clothing or other material from being released from in between the arms of the clip 3350 when in the closed position.

[0216] In other arrangements, the support device can comprise a lanyard 3380 that can be placed around the patient's neck or another body part or object and used to support at least a portion of the circuit 3352. With reference to Figure 33I, the lanyard 3380 can be used in combination with the clip 3350 of Figure 33H. For example, the clip 3350 can be a dual use clip that has at least one opening or hole 3382, such as in the centers of the arms within the portion 3374 so it can also be used to thread the lanyard 3380 and/or another supporting device through it. The lanyard 3380 can be used instead of or in combination with clipping the patient's clothing, bedding or another piece of material.

[0217] The lanyard 3380 can be of any suitable construction. For example, with reference to Figure 33J, the lanyard 3380 can include a series of snaps, hook-and-loop fasteners or other fasteners 3384 that could be used to adjust the length of the lanyard 3380. In addition, the fasteners 3384 could act as a breakaway feature to avoid or minimize discomfort or injury to the patient should the lanyard 3380 get caught on something.
With reference to Figure 33K, the lanyard 3380 could be centered about the circuit 3352 with attachment points on opposing sides of the circuit 3352. The ends of the lanyard 3380 can be received within a support device 3350, which can surround the circuit 3352. Preferably, the ends of the lanyard 3380 pass through the support device 3350 in a substantially axial direction relative to the circuit 3352, which assists in holding the support device 3350 upright with the axis of the circuit 3352 generally in a vertical orientation or generally aligned with the patient’s body and reduce or prevent awkward side angles when hanging from the patient’s neck. In the illustrated arrangement, the support device 3350 is a connector between the supply tube and the main delivery conduit. Sliders or other retention devices 3386 on the lanyard could be used for adjustment and to allow asymmetric positioning.

With reference to Figure 33L and 33M, the support device can comprise a band 3350 that can engage the circuit and also be attached to the body of the patient or equipment near the patient. The band 3350 can be permanently connected to the circuit or can be removable from the circuit. In one arrangement, the band 3350 is a fabric coated thin metal, plastic or combination thereof band that is fixed to the circuit, such as with a loop 3390 that surrounds the circuit. The band 3350 can be deformable such that it can be secured to the patient’s arm, bed frame or other object. The band 3350 can have a first layer 3392 that defines the loop 3390 and a second layer 3394 that comprises a deformable material such that the band 3350 can be deformed and substantially hold its shape. In another arrangement, the second layer 3394 comprises a bi-stable spring or similar element that can be straightened and hold its shape, but once bending of the spring or other element is initiated, it tends to collapse into a loop or roll. Such an arrangement can be opened to allow fitment and then collapsed about the patient’s arm, a bed frame or another suitable object and, once fitted, can provide enough retention force to hold the circuit.

With reference to Figures 33N-P, the support device can comprise a fastener 3350 having a first portion 3350a affixed to the circuit 3352 and a second portion 3350b that can be affixed to another object, such as a bed frame or other equipment. The portions 3350a and 3350b can be coupled to support the circuit 3352. In the arrangement of Figure 33N, one portion 3350a of a hook-and-loop fastener 3350 is affixed to the circuit
3352, such as by surrounding the circuit 3352, and the other portion 3350b of the hook-and-loop fastener 3350 is affixed (e.g., via adhesive) to an object, such as a bed frame or other equipment. The two portions 3350a and 3350b can be coupled to one another to provide support to the circuit 3352. In the arrangement of Figure 33O, the portion 3350b includes a non-adhesive section that can loop over the circuit 3352 and then be connected to the adhesive section to provide a more secure support. In an alternative arrangement, the portion 3350a on the circuit 3352 can be omitted. In the arrangement of Figure 33P, the portion 3350b can be formed into or provided on an armband 3395 that can be wrapped around the patient's arm (or another object). The armband 3395 could be an endless loop or, as illustrated, can be breakable or separable and selectively fixed in a loop by a suitable fastener 3396 (e.g., hook-and-loop fastener).

[0221] With reference to Figures 33Q and 33R, the support device 3350 can be or comprise an over the shoulder support that would loop over the patient's shoulder to support the circuit 3352. One portion 3350a of the support 3350 can comprise a flexible or formable generally U-shaped section defining an opening that can receive and engage the circuit 3352. Another portion 3350b of the support 3350 can comprise a flexible or formable generally U-shaped portion that can receive and engage the patient's shoulder or upper arm.

[0222] With reference to Figure 33S, the support device 3350 can be a portion of or be supported by the headgear strap 3340 or other cannula-supporting device or arrangement. With such an arrangement, the headgear strap 3340 can be utilized to support at least a portion of the weight of the circuit 3352. For example, the support device portion 3350 of the headgear strap 3340 can extend directly over and rest upon the top of the patient's head and then continue down to a clip 3398 or similar to engage the circuit 3352 such that the support device portion 3350 of the headgear strap 3340 assists in supporting the weight of the circuit 3352.

[0223] Some embodiments involve retention assemblies for use with or integrated with the nasal cannula assemblies. In many existing systems, the cannula is retained on the face using a single elastic head strap or held onto the face by looping the supply tube(s) over the ears. In some such designs, the cannula is not secured to the patient's face in an ideal manner and may allow shifting or movement from the desired position. Many factors can
cause the cannula to be moved from its ideal positioning, some of which include the weight of
the air or gas supply circuit may cause the cannula to hang in that direction, the cannula will
slide as the patient moves around during sleep, and the small surface area of single elastic head
straps may not be sufficient to secure the cannula. Over time the head strap may slide down
the patient’s head, further reducing the security of the head strap on the face. Thus, with
some existing systems, the cannula can easily become unsecure, especially over long periods
of time. Furthermore, cannula assemblies that rely on the ears to hang the supply tube(s)
usually have the supply tube(s) taped to the patients face as a secondary means of securement.
This technique is time consuming and does not allow for easy readjustment.

[0224] With reference to Figures 34A and 34B, a nasal cannula assembly 3400
includes a cannula 3414 and a retention arrangement 3450, which can be separate components
or assemblies or can be integrated with one another. In the illustrated arrangement, hook-and-
loop strips 3452 extend respectively from left and right sides of the cannula 3414. These
hook-and-loop strips 3452 can be threaded thorough openings or slots 3454 located in
annular or circular ear pads 3456. The ear pads 3456 may be made of any suitable material,
which preferably provides a soft comfortable feel to the patient while being strong enough to
cope with the force applied when the headgear strap 3440 is tightened. The shape of the ear
pads 3456 can be annular (e.g., circular) or any other geometry which allows for an
anatomical fit and, in at least some configurations, partially or completely surrounds a
patient’s ears.

[0225] The ear pads 3456 are then connected to the headgear strap 3440. The
headgear strap 3440 also can have hook-and-loop strips 3458 coupled thereto or integrated
therewith, which can be threading through additional openings 3454 of the ear pads 3456.
The headgear strap 3440 can be of any suitable arrangement, such as a bi-varicated style strap
and preferably is made from or incorporates a non-stretch material. In some configurations,
the cannula assembly 3400 is supplied with one or more of the components pre-assembled.
For example, three out of the four hook-and-loop strips 3452, 3458 threaded through the slots
3454 in the ear pads 3456. In such an arrangement, the patient or a caregiver would put on
the cannula assembly 3400 by strapping it around the head ensuring that the ears are inside the
hole of the ear pads 3456. The patient or a caregiver would then thread the open hook-and-
loop strip (or strips, in other arrangements) through the ear pads 3456 and tighten until comfortable.

[0226] Advantageously, with such an arrangement, the cannula 3414 will be more secure on the patient’s head than existing arrangements. For example, the patient’s ears will inhibit or prevent the ear pads 3456 from sliding out of position and hence inhibit or prevent the cannula 3414 dislodging from its intended position. This is especially beneficial to a patient who is asleep, as natural body movements during sleep will not affect the delivery of therapy through the cannula 3414. The foam (or other material) ear pads 3456 may also provide more comfort to the patient as they act as cushions during the event a patient is sleeping on his or her side. The bi-varicated strap 3440 will also contribute to the improved security of the cannula 3414 by increasing the area over which the cannula 3414 is attached to the head. The increased surface area will inhibit or prevent the headgear strap 3440 from sliding down and reducing the security of the cannula 3414 on the face.

[0227] With reference to Figures 34C and 34D, a cannula retention arrangement 3450 incorporates friction pads 3460 into the headgear strap 3440. The friction pads 3460 preferably are positioned to sit on the patient’s cheeks, or on portions of the face near the cheeks, and direct a line of action or force from the headgear strap 3440 away from the ears. In some arrangements, the friction pads 3460 are made from, or include, a soft material that allows for a comfortable fit on the face while providing enough friction to allow the headgear strap 3440 to change direction relative to a lateral direction or relative to lateral side portions 3422 of the cannula 3414 or lateral portions 3440a of the headgear strap 3440. The friction pads 3460 preferably are of a thickness that allows the cannula 3414 to bridge slightly from the skin of the patient, creating less pressure on the skin. Such pads 3460 would have the added benefit of preventing the cannula 3414 from moving on the face as a larger frictional force would need to be overcome for movement to begin. The pads 3460 can be affixed to the headgear strap 3440, if desired, by any suitable arrangement, such as sewing, adhesives, for example.

[0228] Advantageously, such an arrangement for attaching the cannula 3414 to the head of the patient is more secure than many existing techniques and arrangements. For example, the friction pads inhibit or prevent the cannula 3414 from easily moving on the face,
as is experienced by many existing arrangements. Furthermore, by elevating the cannula 3414 from the skin with the aid of the thickness of friction pads 3460 will reduce the pressure felt by the patient on the upper lip, thereby making the cannula 3414 more comfortable to wear. Comfort can also be increased by using the friction pads 3460 to spread the force of the headgear strap 3440 over a larger area on the face, which will inhibit or prevent localized pressure marks on the skin. By directing the line of action of the headgear strap 3440 away from the ears, a more comfortable position of the headgear strap 3440 can be achieved because the ears will not be compressed by the force of the headgear strap 3440 going over them.

[0229] With reference to Figure 34E, a cannula assembly 3400 includes a cannula 3414, a supply tube 3402 and a retention arrangement 3450. The retention arrangement 3450 straps onto the head using the ears as anchor points during the setup process. Preferably, the headgear strap 3440 is divided into two portions 3440a and 3440b, which are connectable to one another by a suitable fastening arrangement, such as a hook-and-loop fastener 3466, for example. Preferably, the fastening arrangement 3466 is adjustable, such that the circumferential length of the headgear strap 3440 can be adjusted. Preferably, each portion 3440a, 3440b of the headgear strap 3440 includes an ear loop 3456 that includes an opening that can be placed over the ear of a patient. In use, the cannula assembly 3400 is applied to the patient by first hanging the assembly 3400 on the ears via the ear loops 3456 and positioning the prongs 3405 of the cannula 3414 in the correct position. Once the cannula 3414 is in place, the fastener arrangement 3466 can be used to couple the two portions 3440a, 3440b of the headgear strap 3440. Preferably, the fastener arrangement 3466 permits the circumference of the headgear strap 3440 to be adjusted to a suitable tightness such that the headgear strap 3440 supports the cannula 3414 without substantially relying on engagement of the ear loops 3456 with the ears of the patient. In some arrangements, once the headgear strap 3440 is adjusted (e.g., tightened), the ear loops 3456 do not contact and/or apply any significant force to the ears of the patient. Preferably, the headgear strap 3440 (which can include the ear loops 3456) is made from or incorporates a material which stretches slightly to provide a relatively constant force on the face when the headgear strap 3440 is adjusted, such as by fastening the fastener arrangement 3466. In some arrangements, the loop section of the
hook-and-loop fastener 3466 is positioned closer to the head than the hook portion in order to prevent the hook material sticking to or grabbing the hair of the patient. In some arrangements, the material used to make the headgear strap 3440 is thick enough to allow the cannula 3414 to hang on the ears of the patient when put through the ear holes 3456.

[0230] Advantageously, such an arrangement for attaching the cannula 3414 is more secure than many existing techniques and arrangements. For example, the ears will inhibit or prevent the headgear strap 3440 from moving out of position and inhibit or prevent the cannula 3440 dislodging from its desired position. This is especially beneficial to a patient who is asleep, as natural body movements during sleep will not affect the delivery of therapy through the cannula 3414. The ear loops 3456 allow for easier application of the cannula assembly 3400 and the cannula 3414 can be positioned without the headgear strap 3440 being secured by hanging it from the patient’s ears. The caregiver or patient can move the cannula 3414 around until the correct positioning achieved and then easily secure the headgear strap 3440 using the fastening mechanism 3466. Advantageously, the headgear strap 3440 will inhibit or prevent the cannula 3414 from sliding down as a larger surface area of the strap 3440 is in contact with the head and the ear loops 3456 will act as an anchor point should the headgear strap 3440 be moved down by an external force.

[0231] With reference to Figure 34F, a cannula assembly 3400 includes a retention arrangement 3450, which comprises a headgear strap frame 3440 and a flexible mesh portion 3468 supported by the frame 3440. In some arrangements, at least a portion of the frame 3440 can be constructed from a substantially non-stretchable material or can otherwise be constructed to be substantially non-stretchable. The mesh portion 3468 can be in the form of a net and preferably is constructed from an at least somewhat stretchable material. Such an arrangement creates a hybrid stretch/non-stretch headgear that can be applied by sliding it over the head and positioning until the ears are within openings of ear loops 3456 of the frame 3440. The ear loops 3456 can partially or completely surround the ears of the patient. The frame 3440 can be adjusted using an adjustment mechanism 3470, which can include an adjustment tab 3472 that is utilized to shorten a circumferential length of the mesh portion 3468 of the retention arrangement 3450. In such an arrangement, a portion of the ear loops 3456 to which the mesh portion 3468 is attached (e.g., a rearward portion) can be constructed
from a stretchable material or can at least be flexible relative to other portions of the frame 3440 to facilitate adjustment of the mesh portion 3468. In an alternative arrangement, the frame 3440 could also be made from an at least somewhat stretchable material. In such an arrangement, the adjustment mechanism 3470 could be optionally omitted because the stretch would allow for the retention arrangement 3450 to fit a multiple of patient sizes.

[0232] In at least some configurations, the flexible mesh portion 3468 conforms to the patient’s head shape and increases the friction and surface area between the retention arrangement 3450 and patient. As a result, a much more secure fit is provided. This arrangement for securing the cannula 3414 is much more secure compared to many existing methods and arrangements. The large area in contact with the head will provide friction which will resist movement of the cannula during normal activity or motion during sleep. In addition, by spreading the force over a large area, the illustrated arrangement tends to reduce localized pressure on the back of the head as is experienced by many current methods and arrangements.

[0233] With reference to Figures 34G and 34H, a cannula assembly 3400 includes a cannula 3414, a supply tube 3402 and a retention arrangement 3450. In the illustrated arrangement, the cannula 3414 is mounted to a generally U-shaped frame 3440 that is configured to fit the face of a patient in a manner similar to an eyeglass. Thus, preferably, the frame 3440 supports the cannula 3414 and includes rearwardly-extending ear stem portions 3440a, 3440b that extend along the sides of the patient’s head, preferably extending at least to the patient’s ears. The frame 3440 preferably has substantial rigidity to hold its shape, but has enough flexibility to allow the movement of the ear stem portions 3440a, 3440b apart from one another such that the frame 3440 is suitable for a range of head sizes. In a preferred arrangement, the ends of the ear stem portions 3440a, 3440b (or portions above the ears) are generally straight and the frame 3440 relies on the resiliency of the frame 3440 to secure the frame 3440 to the patient’s face. Such an arrangement can fit a wider variety of face sizes. However, in an alternative arrangement, the frame 3440 can include portions that wrap at least partially around (e.g., behind) the ears. Optional pads 3474 can be provided where the frame 3440 contacts the head (e.g., above the ears). Advantageously, the cannula assembly 3400 is easily applied and removed with one hand, such as in a manner similar to a pair of
glasses. Furthermore, because there is no strap applying a force behind the head, there will be less of an opposing force on the upper lip to cause discomfort.

With reference to Figures 34I and 34J, a cannula assembly 3400 includes a cannula 3414, a supply tube 3402 and a retention arrangement 3450. In the illustrated arrangement, a pair of adhesive pads 3480 is mounted on the patient with one pad 3480 applied to each cheek. The cannula 3414 is attached to the adhesive pads 3480 by any suitable arrangement. In the illustrated arrangements, the cannula 3414 is attached to the pads 3480 by an adjustable and removable system, so that the position and force of the cannula 3414 on the face can be adjusted or fine-tuned after the adhesive of the pads 3480 has set. Advantageously, with such an arrangement, the cannula 3414 can be removed temporarily without removing the adhesive pads 3480. The adjustable systems can be of any suitable arrangement, such as utilizing a hook-and-loop fastener 3482 (Figure 34I) or other reusable fastener that allows the pad 3480 to be adjustably coupled to the cannula 3414. With reference to Figure 34J, a ratchet-type adjustable fastener 3484 can be used to secure the pads 3480 to the cannula 3414 in an adjustable manner. The ratchet-type adjustable fastener 3484 can be integrated with the pads 3480 and/or cannula 3414, as illustrated, or can be a separate assembly or separate components that are coupled to the pads 3480 and/or cannula 3414. Advantageously, the use of adhesive pads 3480 means there is no strap applying a force behind the head, so there will be less of an opposing force on the upper lip to cause discomfort.

With reference to Figure 34K, an alternative adjustable fastener 3486 is illustrated for coupling the cannula 3414 to the pads 3480 in an adjustable manner. However, in other arrangements, the fastener 3486 can have a single position relative to the cannula 3414 and any adjustment can be addressed by placement of the pads 3480 on the patient. Preferably, the pads 3480 include a post or knob 3488 that clip into openings or notches 3490 on the cannula 3414. This arrangement could also be reversed. The knobs 3488 may be of any shape as long as the notches 3490 in the cannula 3414 are of a complimentary design. The shape of these pads 3480 can be of any suitable arrangement such that they conform to the facial geometry. The illustrated pads 3480 are generally hourglass-shaped. However, other suitable shapes can also be used. The notches 3490 in the cannula 3414 allow for
adjustment on the face. To increase the force of retention, notches 3490 closer to the prongs 3405 can be clipped into the knob 3488 on the adhesive pads 3480. Any suitable number of notches 3490 can be provided to allow a range of adjustment forces and/or fit a range of head sizes.

[0236] Advantageously, such an arrangement removes or reduces localized pressure that often present with the use of a tightened strap. In addition, it also reduces or prevents marking on the skin from a headgear strap being worn for long periods of time. It is also easier to apply and remove the cannula 3414 because no headgear strap needs to be passed over the head. This is especially beneficial for a patient who is lying on their back.

[0237] With reference to Figures 35A-D, in some embodiments, the nasal cannula assembly is a modular system that provides several different retention arrangements. Cannulas are used on patients in a range of different environments, from an intensive care unit (ICU), to a standard hospital ward, and to the home. In view of these different environments of use, a modular system in which the patient/caregiver may choose the form of retention used may be desirable. In some embodiments, a cannula assembly 3500 includes a cannula 3514, a supply tube 3502 and a retention arrangement 3550. The cannula 3514 comprises side portions 3522 of any suitable shape. In the illustrated arrangement, the side portions 3522 comprise enlarged, generally ovalized pads. The side portions 3522 can permit the cannula 3514 to be coupled to several types of retention arrangements 3550 by any suitable fastener, such as a hook-and-loop fastener, for example. In one arrangement, as shown in Figure 35A, the cannula 3514 can be coupled to a halo-type headgear strap assembly 3540, which includes at least one strap 3552 extending around the side of the patient’s head and a second strap 3554 that extends over the top of the patient’s head. In some arrangements, as illustrated, the headgear strap assembly 3540 can include a pair of straps 3552 extending around the side of the head and may position one strap 3552 above the ear and the other strap 3552 below the ear. If desired, a pad can be provided on one or more of the straps 3552, 3554. The straps 3552, 3554 can include a suitable fastener, such as a hook-and-loop fastener 3556, for example, to permit the headgear strap assembly 3540 to be applied, removed or adjusted. The halo-type headgear strap assembly 3540 can include end portions that utilize the complementary portion of the fastener of the side portions 3522. This form of retention can
be desirable for patients who are not compliant to the therapy. This larger, complex headgear can inhibit or prevent the cannula 3514 from moving on the face and further make it difficult to remove the cannula 3514 by pulling on it.

[0238] In other arrangements, as shown in Figure 35B, the side portions 3522 allow the cannula 3514 to be coupled to either a headgear strap 3540 or a set of adhesive pads 3580, which can be the same as or similar to any other straps or pads disclosed herein, or can be of any other suitable arrangement. The headgear strap 3540 can include end portions that utilize the complementary portion of the fastener of the side portions 3522 and may be used for patients who do not want pads 3580 stuck to the cheeks or for those taking the therapy intermittently on a regular basis. The headgear strap 3540 can be a single size or adjustable. The adhesive pads 3580 can also utilize the complementary portion of the fastener of the side portions 3522 and can have a shape that is complementary to or compatible with the side portions 3522. This type of retention can be desirable for patients who are compliant or are on the therapy for an extended time.

[0239] With reference to Figures 35C and D, each side of the retention arrangement 3550 and each of the side portions 3522 of the cannula 3514 can include more than one pad, such as two pads (a bivariated arrangement), for example. Such an arrangement includes a total of four hook-and-loop (or other) fastener locations, which can reduce the load experienced by each fastener and can spread the load over a larger area of the patient’s head for increased comfort. In addition, the spaced locations to which retention force is applied to the cannula 3514 can result in greater stability of the cannula 3514 on the patient’s face. In the illustrated arrangement of Figure 35C, the cannula 3514 is coupled to a halo-type headgear strap 3540, similar to the strap 3540 of Figure 35A. As illustrated in Figure 35D, a non-halo-type headgear strap 3540 can be employed, which can include two straps, or other numbers of straps, such as one or more than two straps, for example. This style of retention arrangement 3550 can also be applied to the face using adhesive pads or other suitable retention arrangements.

[0240] With many existing systems, if a patient inadvertently removes the cannula, the head strap is tightened further or the cannula is taped onto the face. The arrangements of Figures 35A-D provides the caregiver or patient the flexibility of choosing which form of
retention is desired, needed or best suited to the specific situation. By using a desirable level of retention, comfort for the patient can be increased as the method for securing the cannula on a non-compliant patient will not need to be used on a compliant patient. Another benefit of the illustrated modular system is that it allows for users to choose which method of retention is more comfortable to them. This gives the patient/user more in control of the therapy and can result in greater patient/user satisfaction and compliance.

[0241] With reference to Figures 35E-G, another modular retention arrangement 3550 is illustrated. The illustrated retention arrangement 3550 comprises a light weight and relatively small cannula 3514, which can stick on the patient’s nose via an adhesive pad or strip 3590. A supply tube 3502 is coupled to the cannula 3514 by any suitable arrangement, such as any of the coupling arrangements disclosed herein, for example. In the illustrated arrangement, the adhesive strip 3590 is affixed to, integral with or unitary with the cannula 3514 and configured to extend to the top portion of the patient’s nose, preferably at or above the tip of the nose, when the prongs 3505 are positioned into the patient’s nares. The adhesive strip 3590 can be adhered to the patient’s nose to retain the cannula 3514 in place. Alternatively, the strip 3590 could be adhered to the patient indirectly, such as using a fastener (e.g., hook-and-loop fastener) that couples the strip 3590 to a separate adhesive pad. This retention arrangement 3550 can be desirable for patients who are compliant and aware of the therapy they are on.

[0242] For patients who are not compliant, or in other suitable situations, the adhesive pad or strip 3590 can be removed (e.g., cut off) and the cannula 3514 can be inserted into a cannula holder 3592 that cooperates with a headgear strap 3540. The whole assembly can now be used as a standard cannula. The cannula holder 3592 can be of any suitable arrangement to hold the cannula 3514, when desired. For example, the cannula holder 3592 can include any type of snap-fit arrangement, which can include a support portion 3594 (e.g., a semi-cylindrical or other shape tray) and a retention portion 3596 (e.g., a clip). The headgear strap 3540 can be non-adjustable, adjustable or can be of any suitable arrangement, such as the same or similar to any of the straps disclosed herein.

[0243] With reference to Figures 36A-K, in some embodiments, the cannula retention arrangement 3650 is configured to facilitate achieving a desirable tightness or
retention force, which may be a value within (preferably, a relatively narrow) range. In many existing arrangements of cannula secured by a headgear strap, the tightness (tension) of the strap and resulting retention force applied to the cannula can be very dependent on the particular user and, therefore, can vary widely. If the cannula is applied too tightly, marks will be left on the skin due to the headgear strap and the headgear strap can apply uncomfortable pressure to the patient's face. On the other hand, if the headgear strap is not sufficiently tight, it will slip over time and cause the cannula to move from its original or ideal position. This may result in discomfort for the patient. The embodiments of Figures 36A-K preferably address these issues to at least some degree. At least some of the embodiments illustrated in Figures 35A-K incorporate a tightness indicator, which provides the patient or caregiver with user feedback regarding the tightness of or tension within the headgear strap 3540. Such arrangements can provide, for example, either a qualitative or a quantitative of headgear strap tightness.

[0244] For example, with reference to Figures 36A-C, a cannula assembly 3600 includes a cannula 3614 and a retention arrangement, such as a headgear strap 3640, which secures the cannula 3614 to the patient. Preferably, the headgear strap 3640 includes a tightness indicator 3650, which provides the user (e.g., a patient or caregiver) with feedback regarding the tightness of the headgear strap 3640. For example, the tightness indicator 3650 may provide a first indication (which may be the absence of an indication) when the headgear strap 3640 is at an incorrect tightness value, which may be outside of a desired tightness range to either side (too tight or too loose). If desired, the first indication could indicate whether the actual tightness is above or below the desired or correct tightness value or range. The tightness indicator 3650 may provide a second indication when the headgear strap 3640 is at a correct or desired tightness value, which may be within a range of correct or desired tightness.

[0245] In the illustrated arrangement, the material used to make or otherwise provide on, the headgear strap 3640 is layered with at least two colors. While the strap 3640 remains in its relaxed position only one color will show (first indication) and as the strap 3640 stretches other color(s) incorporated into the strap 3640 begin to show (second indication). The point or range at which the change in color occurs is calibrated to correspond to a certain tensile force in the strap 3640. As a result, such an arrangement will allow the user to know
when a certain tightness of a strap 3640 has been achieved. The strap 3640 can be adjustable by any suitable arrangement, such as any of those disclosed herein, which can facilitate the user achieving a desired tightness via adjustment of the strap 3640. Alternatively, the strap 3640 can be non-adjustable, in which case the tightness indicator 3650 can allow the user to determine if the strap 3640 provides a correct fit, and may facilitate selecting a size of strap 3640 from two or more available sizes.

[0246] The feedback or tightness indication provided may be simple, such as the use of a strap 3640 that changes color (Figure 36B) or have symbols which appear as the strap 3640 achieves the correct or desired tightness. In some arrangements, only a section of the strap 3640 changes color, while in other arrangements the whole strap 3640 may change color. The user may also be warned when the strap 3640 is too tight in a similar manner. Such an arrangement provides a mechanism for easily determining whether correct tightness on a headgear strap 3640 has been achieved. Advantageously, it will inhibit or prevent the user from inadvertently over tightening and causing discomfort by displaying when correct fit has been achieved. In some arrangements, the headgear strap 3640 does not prevent the user from tightening the strap 3640 above the desired or indicated tension level should the user prefer such a level of tightness.

[0247] With reference to Figures 36D-G, the headgear strap 3640 includes a tightness indicator 3650, which provides the user with feedback regarding the tightness of the headgear strap 3640 by indicating movement of one portion 3640a of the headgear strap 3640 relative to another portion 3640b of the headgear strap 3640. For example, with reference to Figures 36D and 36E, the headgear strap 3640 includes a spring 3652 or other biasing member or arrangement inside the first portion 3640a (inner strap), which is fixed to the remaining second portion 3640b (outer strap) of the headgear strap 3640. The spring 3652 applies a force (either by compression or extension) tending to overlap the portions 3640a, 3640b thereby reducing a circumference of the strap 3640. The tightness indicator 3650 includes a window 3654 on a portion of the outer strap 3640b that, when an appropriate tightness has been achieved, allows a marker or indication 3656 (e.g., a green marking or band) carried by the inner strap 3640a or spring 3652 to be seen. As the strap 3640 is tightened, the tightness indicator 3650 changes color (e.g., displays the green band) to
indicate that the correct or desired tension has been achieved. The two portions 3640a, 3640b can be secured to one another by any suitable fastener, such as a hook-and-loop fastener 3658, for example.

[0248] With reference to Figure 36F, instead of a simple binary indicator, the strap 3640 could provide an indication of tightness over a range. For example, this can be achieved by replacing the window 3654 or providing on the window 3654 a gauge or scale 3660 and utilizing the indication 3656 (e.g., an arrow or thin line) to provide a quantitative display of strap 3640 tightness on the scale 3660. In yet another alternative arrangement, with reference to Figure 36G, the spring 3652 can be replaced with an elastic region 3662 coupled to or integrated with the inner strap 3640a. As the strap 3640 is tightened, a graduated colored indicator provides tightness information, such as through a window 3654 in the outer strap 3640b. The graduated color changing on the elastic system allows for a region over which ideal fit is achieved as opposed to a single point. The colored indicator could be replaced by numbers, words, symbols, etc.

[0249] Advantageously, the arrangements of Figures 36D-G a mechanism for easily and quickly determining if a desired or correct tightness of the head strap 3640 has been achieved. Such arrangements can inhibit or prevent the user from inadvertently over tightening and causing discomfort by displaying when correct fit has been achieved. The non-stretch portions of the headgear strap 3640 can be padded to increase comfort to the user. One benefit of having a quantitative display is that it provides repeatability by allowing a user to adjust to a value which is comfortable and secure and note the adjustment value. When the headgear strap 3640 is taken off and then put back on, the user can easily adjust the tightness of the headgear strap 3640 to the desired value using the tightness indicator 3650.

[0250] Figures 36H and 36I illustrate another headgear strap 3640 including a tightness indicator 3650 that provides an indication of how much force is being applied by the headgear strap 3640 to a patient. Preferably, the tightness indicator 3650 comprises a gauge 3670 (e.g., similar in appearance to a pressure gauge) that can be circular in shape in at least some arrangements. However, other shapes could also be used. However, a generally circular shape can be desirable to provide functional aspects to the strap 3640 in addition to tightness indication. For example, the gauge 3670 could have padding on the underneath
surface that contacts the skin. The gauge 3670 may also act to distribute pressure caused by the headgear strap 3640 over a larger surface area and/or to change a direction of the strap 3640. The gauge 3670 preferably operates in a manner similar to the indicators 3650 disclosed herein in that tension applied to the strap 3640 transmitted to and displayed by the gauge 3670. The strap 3640 can be adjustable or non-adjustable, as described herein. The gauge 3670 can provide a binary indication of sufficient tightness or can provide qualitative information as to the actual tightness within a range, as illustrated in Figure 36I. As with the prior indicators 3650, the gauge 3670 (which can have a dial indicator-type display) provides a means of reading a tightness value. This allows the cannula assembly to be taken off and, when put back on, be easily and quickly adjusted to the desired value. The padded gauge 3670 can provide the added benefit of sitting on or near the cheeks of the patient to distribute any pressure over a larger area, thus increasing comfort. If desired, a gauge 3670 can be provided on each side of the strap 3640 or a pad similar to the gauge 3670 can be provided on the side opposite the gauge 3670. If two gauges are provided, each can indicate the tension of the strap 3640 or each can indicate the tension in a dedicated portion of the strap 3640 (e.g., upper and lower or left and right).

[0251] With reference to Figure 36J, in some embodiments, a very long and stretchy single length headgear strap 3640 can be utilized. Advantageously the long, elastic headgear strap 3640 provides a relatively flat force vs. extension curve, which makes the strap 3640 less likely to be over-tightened. In some arrangements, the headgear strap 3640 extends around the patient’s head from one side to the other of the cannula 3614 at least twice and, preferably, more than twice. For example, the strap 3640 can extend around the patient’s head from one side of the cannula 3614 to the other between about three to about ten times. The increased length of the strap 3640 assists in flattening the force vs. extension curve. The headgear strap 3640 can be threaded back and forth between the left and right side of the cannula 3614 (e.g., from one side portion 3622 to the other side portion 3622).

[0252] In some arrangements or for some applications, the strap 3640 can be non-adjustable. However, in other arrangements, the strap 3640 is adjustable. For example, in the illustrated arrangement, one end 3640a of the headgear strap 3640 can be pulled to adjust a length of the strap 3640 extending between the sides of the cannula 3614 in order to tighten
the strap 3614. The strap 3640 can extend through a viewing window 3654 (e.g., moulded in the cannula 3614) and be colored to illustrate the tightness achieved when pulled through the viewing window. One or more colors, symbols or other indications may be used. In some arrangements, the tightness indicator 3650 is able to show qualitatively what tightness has been achieved by the color of the headgear strap 3640 displayed through the viewing window 3654. Advantageously, the multiple strands of the headgear strap 3640 extending from one side to the other of the cannula 3614 provide a larger surface area over which the strap 3640 attaches to the head. The illustrated arrangement provides a means of easily determining if the correct or desired tightness of the headgear strap 3640 has been achieved. The long elastic headgear strap 3640 can render the strap 3640 less likely to exhibit a sudden increase in tightness upon adjustment. This represents an improvement many existing straps, which exhibit a large increase in force for small change in length. In addition, the larger surface area and/or greater vertical distance over which the strap 3640 makes contact with the head improves stability of the cannula 3614 on the face.

With reference to Figure 36K, the headgear strap 3640 can comprise a torque driver or reel arrangement 3680, which is used to tighten the headgear strap 3640 or any individual portions or straps thereof, such as by winding portion(s) of the strap 3640 onto a reel member in response to rotation of a portion of the torque driver or reel arrangement 3680 by a user. The torque driver or reel arrangement 3680 can be a unidirectional, in which the headgear strap 3640 can only be tightened, or can be a bidirectional in which the headgear strap 3640 can be loosened and re-tightened. If desired, the torque driver or reel arrangement 3680 can have an upper torque limit that only permits the strap 3640 to be tightened up to a certain tightness or tension level. For example, a clutch mechanism could be used to inhibit or prevent over-tightening.

In use, the patient or caregiver can place the cannula assembly 3600 over the head and position the prongs 3605 of the cannula 3614 in the nares. The strap 3640 can be placed appropriately around the head and the dial of the torque driver or reel arrangement 3680 can be rotated to tighten the headgear strap 3640. In some arrangements, the torque driver or reel arrangement 3680 can be calibrated to a set tightness. Once this has been achieved, the torque driver or reel arrangement 3680 will not allow the headgear strap 3640
to be tightened further. The torque driver or reel arrangement 3680 may be padded to increase comfort for the patient when lying on the side. The padding would also increase friction, allowing the cannula 3614 to sit on the face with more stability without overtightening. If desired, a torque driver or reel arrangement 3680 can be provided on each side of the headgear strap 3640. Advantageously, with such an arrangement, the possibility of a user over-tightening the headgear strap 3640 is reduced or eliminated. The tightness level at which the dial will not tighten further can be a tightness predetermined to provide ample security for retaining the cannula 3614 in place, while maintaining a reasonably high comfort level. In some arrangements, a headgear strap or retention arrangement can include a torque driver or reel arrangement 3680 and a tightness indicator, such as any of those illustrated in Figures 35A-K, for example. In particular, a headgear strap could include a torque driver or reel arrangement 3680 and a tightness indicator in the form of a gauge 3670, such as those illustrated in Figures 36H and 36I. For example, the torque driver or reel arrangement 3680 could be positioned on one side of the headgear strap or retention arrangement and the gauge 3670 could be positioned on the other side, such as near or covering each ear of the patient, for example.

[0255] With reference to Figures 37A-E, further embodiments of a retention arrangement 3750 are illustrated, either alone or with a cannula assembly 3700. Tight headgear adjustments and unintended movement of the cannula can apply uncomfortable pressure to the patient’s face during use. In some applications or for some patients, methods of attachment that either adhere to the patient’s cheeks or rely on facial features (e.g., ears) to support the weight of the cannula can also cause discomfort. Furthermore, positioning the cannula to suit an individual’s facial geometry or body position, in some situations, can be difficult and incorrect positioning can result in prong misalignment and discomfort. In at least some embodiments, the retention arrangements 3750 securely support the cannula in a comfortable manner.

[0256] Figure 37A illustrates an embodiment of an improved retention arrangement 3750 that comprises a headgear strap 3740. The illustrated headgear strap 3740 includes a pad 3752 that is affixed to the strap 3740. In some arrangements, the pad 3752 surrounds the strap 3740 and can be moved along the length of the strap 3740 to a desired
location, such as a rearward portion of the strap 3740 that is opposite the cannula (not shown) when the cannula assembly 3700 is assembled or in use. The strap 3740 can have a first portion 3740a and a second portion 3740b. The first portion 3740a can be made from a substantially non-stretchable material or can otherwise be constructed to have limited stretch characteristics. The first portion 3740a can be or include the end portions that connect to the cannula (not shown). Preferably, the second portion 3740b comprises a rear portion of the headgear strap 3740 and can be made from an elastic material or otherwise be constructed to have significant stretch characteristics, or at least significantly greater stretch characteristics than the first portion 3740a. The pad 3752 can be a wide, cushioned pad and can cover the second portion 3740b. That is, the pad 3752 can have a length that is greater than a length of the second portion 3740b in either or both of a relaxed orientation and a stretched orientation. The pad 3752 can also have a height that is significantly greater than a height of the strap 3740. Thus configured, the pad 3752 can distribute pressure over a wider area of the patient's head, while the elastic region or second portion 3740b of the strap 3740 can provide a force on the face when stretched. Preferably, the large surface area of the pad 3752 will also provide substantial stability due to increased friction, thus reducing the chance of the cannula moving from its ideal or preferred position. The non-stretch end portions or first portion 3740a of the headgear strap 3740 can connect to one or both of the elastic region or second portion 3740b of the strap 3740 and the pad 3752. The pad 3752 can be fixed in place relative to the strap 3740 or, in some arrangements, the pad 3752 can slide along the strap 3740 to the desired location and may also act as protection against nearby objects, such as hard bed frames, other equipment, etc. Alternatively, the pad 3752 can be made from an elastic material or otherwise constructed to exhibit stretch characteristics. In such an arrangement, the elastic region or second portion of the headgear strap 3740 can be included or omitted. If desired, a pad 3752 could be used with a substantially or entirely non-stretch strap, which has no elastic region. In such an arrangement, the pad 3752 may still improve comfort and stability, as described above.

[0257] With reference to Figures 37B-E, a nasal cannula assembly 3700 includes a cannula 3714 and a retention arrangement 3750. Preferably, the retention arrangement 3750 contacts the patient only at an upper region of the head or at a position above a line extending
around the head and generally passing through the patient’s eyebrows. Such an arrangement supports the cannula 3714 substantially entirely with the upper region of the head for improved comfort. In the illustrated arrangement, the weight of the cannula 3714 is supported by a strap 3740 that encircles the upper head region. Two arms 3760 are supported by or hang from the strap 3740 down either side of the patient’s face. The cannula 3714 is attached to the arms 3760 or can be integrally or unitarily formed with the arms 3760. Advantageously, with such an arrangement, no weight is supported by the patient’s cheeks or ears, or any region below the strap 3740, thus inhibiting or preventing uncomfortable pressure from being applied to sensitive areas of the patient’s head and face.

[0258] In some embodiments, the arms 3760 and/or cannula 3714 can be adjusted, such as moved and/or rotated on or relative to the strap 3740 about a hinge point or axis 3762 on either side of the head. Preferably, the arms 3760 and/or cannula 3714 are adjustable relative to the strap 3740. For example, the position of the cannula 3714 can be adjusted by shifting the arms 3760 up and down relative to the strap 3740. In the illustrated arrangement, a retention element or hub 3764 is supported by the strap 3740 and adjustably supports the arms 3760, such as via a ratchet assembly or other suitable adjustment mechanism. In some arrangements, the arms 3760 are adjustable around the circumference of the strap 3740. For example, the arms 3760 can be infinitely adjustable relative to the strap 3740, such as by utilizing a clamp mechanism integrated or separate from the hubs 3764. As illustrated, the hubs 3764 and, thus, the arms 3760 are adjustable to one of a discrete number of adjustment positions, such as via slots 3766 that receive the hubs 3764 and define two or more (e.g., three, four, five or more) discrete adjustment positions. Alternatively, the slots 3766 could permit free movement of the hubs 3764 such that the arms 3760 can float relative to the strap 3740 within a path defined by the slots 3766. If desired, the arms 3760 could be biased toward a relaxed position relative to the strap 3740 (e.g., center of the slots 3766) and can be free to move against the biasing force of a biasing member (e.g., spring). The strap 3740 can be made of or contain an elastic material (e.g., a one-size strap) or can have some form of size adjustment. Advantageously, the illustrated retention arrangement 3750 does not rely on the ears to support the cannula weight, thereby reducing or preventing pressure points. Because existing single headgear straps often sit below the widest point of the head, a tight fit is often
required to ensure the strap does not slip down. By having the strap 3740 sit above the widest point of the head, the strap 3740 will not have to be as tight and will be more secure. The illustrated arrangement also allows for at least three modes of cannula position adjustment. In other arrangements, the retention arrangement 3750 may provide for non-discrete adjustment positions between the arms 3760 and the strap 3740. For example, the arms 3760 could be coupled to the strap 3740 via a hook-and-loop fastener, or other similar fastening mechanism, to possibly permit a greater number of and/or more finite adjustment positions relative to the illustrated embodiment.

[0259] Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like, are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense, that is to say, in the sense of "including, but not limited to".

[0260] Reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that that prior art forms part of the common general knowledge in the field of endeavour in any country in the world.

[0261] The invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, in any or all combinations of two or more of said parts, elements or features.

[0262] Where, in the foregoing description reference has been made to integers or components having known equivalents thereof, those integers are herein incorporated as if individually set forth.

[0263] It should be noted that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the invention and without diminishing its attendant advantages. For instance, various components may be repositioned as desired. It is therefore intended that such changes and modifications be included within the scope of the invention. Moreover, not all of the features, aspects and advantages are necessarily required to practice the present invention. Accordingly, the scope of the present invention is intended to be defined only by the claims that follow.
WHAT IS CLAIMED IS:

1. A nasal cannula system, comprising:
   a cannula comprising a central body portion, a first side portion and a second side portion, wherein the first and second side portions extend in opposite lateral directions from the central body portion and contact a cheek or other facial features of a user when the system is in use, a first nasal prong and a second nasal prong extending from the central body portion, the central body portion comprising a patient facing side and at least one retention strap that cooperate to define a cavity, wherein the first and second nasal prongs communicate with the cavity;
   a manifold that receives a supply of gas from a gas source, the manifold comprising a gas inlet and a gas outlet, wherein the manifold is receivable within the cavity of the cannula such that the gas outlet is aligned with the first and second nasal prongs;
   wherein the at least one retention strap defines a first lateral edge and a second lateral edge, and wherein the first and second nasal prongs are located between the first lateral edge and the second lateral edge.

2. The nasal cannula system of Claim 1, wherein the at least one retention strap comprises a first retention strap and a second retention strap.

3. The nasal cannula system of Claim 1, wherein the at least one retention strap comprises at least one window through which at least one portion of the manifold is visible.

4. The nasal cannula system of Claim 1, wherein the cavity has a first end and a second end and the manifold can be inserted through either one of the first and second ends and closes off the other of the first and second ends.

5. The nasal cannula system of Claim 1, wherein each of the first and second side portions comprises a flex-inducing feature selected from one of a plurality of flex slots and a reduced cross-section portion to facilitate flexing of the first and second side portions relative to the central body portion.

6. The nasal cannula system of Claim 1, each of the first and second side portions comprises a recessed area on the patient facing side of the first and second portions, the recesses configured to accommodate portions of a headgear strap.
7. The nasal cannula system of Claim 1, further comprising a supply tube having a first end coupled to the manifold and a second end coupled to a connector, which permits the supply tube to be coupled to a gas delivery conduit, and a lanyard coupled to the supply tube with a lanyard connector, wherein the lanyard connector comprises a breakaway portion and at least one end of the lanyard is coupled to the breakaway portion.

8. The nasal cannula system of Claim 1, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

9. The nasal cannula system of Claim 1, wherein the first and second side portions comprise cheek pads configured to be secured to the cheeks of a patient.

10. The nasal cannula system of Claim 9, wherein the cheek pads comprise an adhesive layer.

11. The nasal cannula system of Claim 9, further comprising a pair of attachment pads having an adhesive layer to allow attachment to the cheeks of a patient, wherein the pair of attachment pads comprise one portion of a hook and loop fastener and the cheek pads comprise the other portion of the hook and loop fastener such that the cheek pads can be secured to the attachment pads.

12. The nasal cannula system of Claim 1, wherein the patient facing side of the central body portion comprises cushion details configured to space the central body portion away from the patient’s face.

13. The nasal cannula system of Claim 1, further comprising a supply tube having a first end coupled to the manifold and a second end coupled to a connector, which permits the supply tube to be coupled to a gas delivery conduit, and a lanyard coupled to the supply tube with a lanyard connector, wherein a portion of the lanyard coupled to the lanyard connector extends substantially along a longitudinal axis of the lanyard connector.

14. The nasal cannula system of Claim 1, wherein each of the first and second side portions comprises an undercut on a surface opposite the patient facing side, further comprising a headgear strap comprising a first clip and a second clip that engages the undercut of the respective first and second side portions to couple the headgear strap to the cannula on the surface opposite the patient facing side.
15. The nasal cannula system of Claim 1, wherein the cannula defines a lateral slot, further comprising a head gear strap extending through the lateral slot.

16. The nasal cannula system of Claim 15, wherein the cannula is slidable along the head gear strap.

17. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first side portion and a second side portion, wherein the first and second side portions extend in opposite lateral directions from the central body portion and contact a cheek of a user when the system is in use, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity having an inlet at a first end, the cavity having a second end communicating with a first gas path and a second gas path, which communicate with the first and second nasal prongs, respectively, wherein the inlet is located at one of the first and second side portions and the first and second gas paths extend in a lateral direction toward the first and second nasal prongs;

   a supply tube having a first end connectable to a supply of gas from a gas source and a second end coupled to the inlet of the cavity of the cannula.

18. The nasal cannula system of Claim 17, further comprising a headgear strap and a tube clip coupled to the headgear strap, the tube clip configured to hold the supply tube away from the mouth and face of the user in use.

19. The nasal cannula system of Claim 17, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

20. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first side portion and a second side portion, wherein the first and second side portions extend in opposite lateral directions from the central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the central body portion defining a cavity and a forward-facing inlet to the cavity, wherein the first and second nasal prongs communicate with the cavity;

   a manifold that receives a supply of gas from a gas source, the manifold comprising a gas inlet and a gas outlet, wherein the manifold is connectable with the
cannula such that the gas outlet is aligned with the forward-facing inlet of the cannula and the gas inlet faces a lateral direction;

a supply tube connected to the gas inlet of the manifold and positioned forward of the forward-facing inlet of the cannula.

21. The nasal cannula system of Claim 20, wherein the manifold can be connected to the cannula in either of a first orientation with the gas inlet facing in a first lateral direction and a second orientation with the gas inlet facing in a second lateral direction.

22. The nasal cannula system of Claim 20, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

23. The nasal cannula system of Claim 20, further comprising a releasable fastener located on each of the first and second side portions of the cannula and corresponding first and second side portions of the manifold.

24. The nasal cannula system of Claim 23, further comprising a headgear strap coupled to the first and second side portions of the manifold, wherein the releasable fasteners are located on top of portions of the headgear strap located on the first and second side portions of the manifold.

25. The nasal cannula system of Claim 23, wherein the cannula comprises a rigid frame portion surrounding the inlet and extending into the first and second side portions.

26. The nasal cannula system of Claim 25, wherein a body portion of the cannula is formed over and at least partially surrounds the rigid frame portion.

27. A nasal cannula patient interface, comprising:

a first nasal prong and a second nasal prong, each of the first and second prongs comprising an inlet end and an outlet end;

at least one support portion configured to rest upon the nose of a patient at a point at or above the tip of the nose;

wherein, in use, no portion of the patient interface contacts an upper lip of the patient to provide any substantial support to the patient interface.

28. The nasal cannula patient interface of Claim 27, further comprising a nose strip having an adhesive layer to permit attachment to the nose of a patient, wherein the at least one
support portion comprises an attachment pad that couples the at least one support portion to the nose strip.

29. The nasal cannula patient interface of Claim 27, wherein the at least one support portion comprises a first support portion and a second support portion.

30. The nasal cannula patient interface of Claim 29, wherein the first support portion is positioned on a first lateral side and the second support portion is positioned on a second lateral side of the patient’s nose.

31. The nasal cannula patient interface of Claim 29, wherein the first support portion and first nasal prong are separate from the second support portion and second nasal prong.

32. The nasal cannula patient interface of Claim 27, further comprising a first supply tube and a second supply tube, the first supply tube connected to the inlet end of the first nasal prong, and the second supply tube connected to the inlet end of the second nasal prong.

33. The nasal cannula patient interface of Claim 32, further comprising a cheek pad configured to secure a portion of the first and second supply tubes to one or both of the patient’s cheeks.

34. The nasal cannula patient interface of Claim 32, further comprising a lanyard clip proximate the first end of the supply tube, the lanyard clip configured to releasably clip to a lanyard.

35. The nasal cannula patient interface of Claim 27, wherein each of the first and second nasal prongs has a molded shape having a turn of about 180° between the inlet end and the outlet end.

36. The nasal cannula patient interface of Claim 27, further comprising a central body portion defining a cavity having an inlet and an outlet, the outlet in communication with the first and second nasal prongs and the inlet configured to receive a manifold coupled to a supply tube.

37. A nasal cannula patient interface, comprising:
   a first nasal pillow and a second nasal pillow, each of the first and second nasal pillows comprising an inlet end and an outlet end;
   at least one support portion configured to rest upon the nose of a patient at a point at or above the tip of the nose;
wherein, in use, no portion of the patient interface contacts an upper lip of the patient to provide any substantial support to the patient interface.

38. The nasal cannula patient interface of Claim 37, wherein the nasal pillows are self-inflating.

39. The nasal cannula patient interface of Claim 37, further comprising at least one supply tube that couples the first and second nasal pillows to a source of gas.

40. The nasal cannula patient interface of Claim 39, wherein the at least one supply tube comprises a first supply tube coupled to the first nasal pillow and a second supply tube coupled to the second nasal pillow.

41. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs, an integrated head strap comprising a first section and a second section, wherein the first and second sections extend in opposite lateral directions from the central body portion, the first section defining a rear portion of the head strap, an adjustable coupling arrangement that permits coupling of the first and second sections in an adjustable manner such that a circumference of the head strap is adjustable;

   a supply tube having a first end connectable to a supply of gas from a gas source and a second end coupled to the cavity of the cannula.

42. The nasal cannula system of Claim 41, wherein the cannula, first section and second section of the head strap are of a unitary construction.

43. The nasal cannula system of Claim 41, wherein the adjustable coupling arrangement comprises a slot defined by one of the first and second sections and a teeth-defining portion that is adjustably-received within the slot.

44. A nasal cannula system, comprising:

   a cannula comprising a central body portion, a first nasal prong and a second nasal prong extending from the central body portion, the cannula defining a cavity in communication with the first and second nasal prongs, wherein the cannula defines a lateral slot;
a head gear strap extending through the lateral slot of the cannula;

a supply tube having a first end connectable to a supply of gas from a gas
source and a second end coupled to the cavity of the cannula.

45. The nasal cannula system of Claim 44, wherein the cannula is slidable along the
head gear strap.

46. A nasal cannula system, comprising:

a cannula comprising a central body portion, a first nasal prong and a second
nasal prong extending from the central body portion, the cannula defining a cavity in
communication with the first and second nasal prongs, the cannula defining a first
opening at a first location of the cavity and a second opening at a second location of
the cavity spaced from the first location, a valve body that is movable within the
cavity;

a supply tube having a first end connectable to either one of the first opening or
the second opening of the cannula and a second end connectable to a supply of gas
from a gas source;

wherein, when the first end of the supply tube is connected to the first opening
of the cannula, the valve body moves in response to a flow of gas in the cavity from
the gas source to block the second opening such that the flow of gas is directed to the
first and second nasal prongs and, when the first end of the supply tube is connected to
the second opening of the cannula, the valve body moves in response to the flow of
gas in the cavity from the gas source to block the first opening such that the flow of
gas is directed to the first and second nasal prongs.

47. The nasal cannula system of Claim 46, wherein the first location is a first end of the
 cannula and the second location is a second end of the cannula.

48. The nasal cannula system of Claim 46, wherein the valve body is either a ball or a
 plate.

49. The nasal cannula system of Claim 46, wherein the valve body is a ball and the
 cannula comprises first and second thin wall sections extending radially inward into each of
 the first and second openings and that create a seal with the ball.
50. The nasal cannula system of Claim 46, further comprising a connector coupled to
the first end of the supply tube, wherein the connector has an interlocking connection with
either one of the first and second openings of the cannula.

51. The nasal cannula system of Claim 50, further comprising a first insert and a
second insert within a respective one of the first opening and the second opening, wherein the
connector engages the first insert when coupled to the first opening and the second insert
when coupled to the second opening.

52. A nasal cannula system, comprising:

a cannula comprising a central body portion, a first nasal prong and a second
nasal prong extending from the central body portion, the cannula defining a cavity in
communication with the first and second nasal prongs, the cannula defining a first
opening at a first location of the cavity and a second opening at a second location of
the cavity spaced from the first location, the cannula comprising a first valve that
selectively closes the first opening and a second valve that selectively closes the
second opening;

a supply tube having a first end connectable to either one of the first opening or
the second opening of the cannula and a second end connectable to a supply of gas
from a gas source;

wherein, when the first end of the supply tube is connected to the first opening
of the cannula, the second valve blocks the second opening such that a flow of gas
from the gas source is directed to the first and second nasal prongs and, when the first
end of the supply tube is connected to the second opening of the cannula, the first
valve blocks the first opening such that the flow of gas is directed to the first and
second nasal prongs.

53. The nasal cannula system of Claim 52, wherein the first location is a first end of the
cannula and the second location is a second end of the cannula.

54. The nasal cannula system of Claim 52, wherein the first and second valves
comprise one of a flap valve, a slit valve and a pierceable membrane.
55. The nasal cannula system of Claim 52, further comprising a connector coupled to
the first end of the supply tube, wherein the connector has an interlocking connection with
either one of the first and second openings of the cannula.

56. The nasal cannula system of Claim 55, wherein the first and second valves are
pierceable membranes and the connector comprises a piercing point.

57. A nasal cannula system, comprising:
   
a cannula comprising a central body portion, a first nasal prong and a second
nasal prong extending from the central body portion, the cannula defining a cavity in
communication with the first and second nasal prongs, the cannula defining a first
opening at a first end of the cavity and a second opening at a second end of the cavity;
   
a supply tube having a first end comprising a first insert and a second end
comprising a second insert, wherein each of the first insert and the second insert is
positionable within the cavity to seal the first opening and the second opening and
deliver a flow of gas from the gas source to the first and second nasal prongs;
   
wherein, when the first end of the supply tube is connected to the cannula, the
second end is connectable to the gas source and, when the second end of the supply
tube is connected to the cannula, the first end is connectable to the gas source.

58. The nasal cannula system of Claim 57, further comprising a connector that is
connectable to a gas supply conduit that is in communication with the gas source, wherein the
connector defines a cavity that can accommodate either of the first end and the second end of
the supply tube in a substantially sealed manner.

59. The nasal cannula system of Claim 57, wherein the supply tube can pass through
the cavity of the cannula when switching from the first end to the second end being connected
to the cannula.

60. A nasal cannula system, comprising:
   
a cannula comprising a central body portion, a first nasal prong and a second
nasal prong extending from the central body portion, the cannula defining a cavity in
communication with the first and second nasal prongs;
   
a supply tube having a first end coupled to the cavity of the cannula and a
second end connectable to a supply of gas from a gas source, the first end of the
supply tube defining a connection axis relative to the cannula, the supply tube comprising a flexible portion at or adjacent the first end that can be bent at least about 90 degrees to either the left or right side without significant occlusion of an internal passage of the supply tube.

61. The nasal cannula system of Claim 60, wherein the first end of the supply tube exits the cannula in a forward direction relative to a patient-facing surface of the cannula.

62. A nasal cannula system, comprising:

   a cannula comprising a cavity and a first nasal prong and a second nasal prong in communication with the cavity;

   a supply tube that receives a flow of gas from a gas source, the supply tube connected to the cannula to supply the flow of gas to the cavity of the cannula;

   a clip that removably receives the cannula;

   a retention arrangement that secures the clip to the head of a patient;

   wherein the cannula is positionable within the clip in a first orientation such that the supply tube extends in a first direction from the clip, and wherein the cannula is positionable within the clip in a second orientation such that the supply tube extends in a second direction from the clip.

63. The nasal cannula system of Claim 62, wherein the retention arrangement comprises one of a strap, one or more adhesive pads or a support frame.

64. A nasal cannula system, comprising:

   a cannula comprising a first nasal prong and a second nasal prong, the cannula defining a cavity in communication with the first and second nasal prongs, the cannula defining a first opening at a first location of the cavity and a second opening at a second location of the cavity spaced from the first location;

   a supply tube assembly comprising a clip that can be releasably coupled to the cannula in either of a first orientation and a second orientation, the supply tube assembly further comprising a supply tube connectable to a supply of gas from a gas source, wherein the clip supports the supply tube and comprises a sealing portion;

   wherein, when the clip is connected to the cannula in the first orientation, the supply tube is connected to the first opening of the cannula and extends in a first
direction from the cannula and the sealing portion at least substantially seals the second opening and, when the clip is connected to the cannula in the second orientation, the supply tube is connected to the second opening of the cannula and extends in a second direction from the cannula and the sealing portion at least substantially seals the first opening.

65. The nasal cannula system of Claim 64, wherein the clip is a generally C-shaped clip.

66. The nasal cannula system of Claim 64, wherein the clip comprises at least one engagement portion that engages a corresponding receiving portion in both the first orientation and the second orientation to lock the clip to the cannula.

67. The nasal cannula system of Claim 66, wherein the engagement portion comprises an end portion of the clip.

68. The nasal cannula system of Claim 67, wherein the sealing portion comprises a semi-spherical protrusion.

69. The nasal cannula system of Claim 64, wherein the cannula comprises a recess that accommodates at least a central section of the clip and inhibits movement of the clip relative to the cannula in at least one direction.

70. The nasal cannula system of Claim 64, wherein an end of the supply tube abuts a surface of the cannula surrounding a respective one of the first and second openings when the clip is connected to the cannula.

71. The nasal cannula system of Claim 64, wherein an end of the supply tube is positioned within a respective one of the first and second openings when the clip is connected to the cannula.

72. The nasal cannula system of Claim 64, wherein the first and second prongs are carried by a prong insert that is separate from a main body portion of the cannula that defines the cavity, the first opening and the second opening, wherein the clip secures the prong insert to the main body portion of the cannula.

73. The nasal cannula system of Claim 72, wherein the prong insert is selectable from a selection of at least two different sizes of prong inserts comprising at least two different sizes of prongs.
74. The nasal cannula system of Claim 64, wherein the cannula is rotatable relative to the clip to permit adjustment of an angle of the first and second prongs.

75. A nasal cannula system, comprising:

   a cannula clip comprising a first nasal prong and a second nasal prong, the cannula defining a cavity in communication with the first and second nasal prongs;

   a supply tube assembly comprising a manifold having at least one manifold opening and a supply tube connectable to a supply of gas from a gas source, wherein the cannula clip is capable of being releasably coupled to the manifold in either of a first orientation and a second orientation in which the manifold is received within the cavity of the cannula clip and the first and second prongs are aligned with the at least one manifold opening such that a flow of gas is provided to the first and second prongs;

   wherein, when the cannula clip is connected to the manifold in the first orientation, the supply tube extends in a first direction relative to the first and second prongs and, when the cannula clip is connected to the manifold in the second orientation, the supply tube extends in a second direction relative to the first and second prongs.

76. The nasal cannula system of Claim 75, wherein the manifold extends in a lateral direction through the cannula clip.

77. The nasal cannula system of Claim 75, wherein the manifold comprises a rib that is positioned between first and second edges of the cannula clip when the cannula clip is assembled to the manifold in either of the first orientation or the second orientation.

78. A nasal cannula system, comprising:

   a cannula comprising a main body defining a cavity and a first nasal prong and a second nasal prong extending from the main body and in communication with the cavity;

   a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;
wherein the first and second nasal prongs are tiltable relative to the main body of the cannula between at least a first position in which the first and second nasal prongs are tilted in a first direction relative to the main body and a second position in which the first and second nasal prongs are tilted in a second direction relative to the main body, wherein a first surface of the main body defines a patient-facing surface of the cannula in the first position and a second surface of the main body defines the patient-facing surface of the cannula in the second position to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

79. The nasal cannula system of Claim 78, wherein the first nasal prong and the second nasal prong are tiltable separately from one another.

80. The nasal cannula system of Claim 78, further comprising one or more ripples surrounding each of the first nasal prong and the second nasal prong, wherein the ripples facilitate tilting of the first and second nasal prongs.

81. The nasal cannula system of Claim 80, further comprising a stiffening rib within the ripples that inhibit tilting of the first and second nasal prongs in at least one direction other than the generally first and second directions.

82. The nasal cannula system of Claim 78, wherein each of the first and second nasal prongs comprise a collapsible corrugated concertina section that facilitates tilting of the prongs.

83. A nasal cannula system, comprising:

a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

wherein the first and second nasal prongs are directionally-oriented relative to the cannula and are movable between at least a first position in which the first and second nasal prongs are oriented such that openings of the prongs generally face in a first direction relative to the cannula and a second position in which the first and
second nasal prongs are oriented such that the openings of the prongs generally face in
a second direction relative to the cannula, wherein a first surface of the cannula defines
a patient-facing surface in the first position and a second surface of the cannula defines
the patient-facing surface in the second position to effectively switch the side from
which the supply tube extends from the cannula between the first and second positions.

84. The nasal cannula system of Claim 83, wherein the first nasal prong and the second
nasal prong are movable between the first position and the second position separately from
one another.

85. The nasal cannula system of Claim 83, wherein the first nasal prong and the second
nasal prong are supported by a prong insert that is separate from a main body of the cannula,
which defines the cavity, wherein the prong insert is movable relative to the main body to
move the prongs together between the first position and the second position.

86. The nasal cannula system of Claim 85, wherein prong insert is rotatable on a shaft
of the main body of the cannula.

87. The nasal cannula system of Claim 86, wherein the shaft is located between the
first nasal prong and the second nasal prong.

88. The nasal cannula system of Claim 87, wherein the shaft is either aligned with the
first and second nasal prongs or offset from the first and second nasal prongs.

89. The nasal cannula system of Claim 85, wherein the main body defines an opening
in communication with the cavity and that removably receives the prong insert.

90. The nasal cannula system of Claim 89, wherein the prong insert is selectable from a
selection of at least two different sizes of prong inserts comprising at least two different sizes
of prongs.
91. A nasal cannula system, comprising:

a cannula defining a patient-facing surface and a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

a manifold that supports the cannula for rotation about at least one axis between at least a first position and a second position opposite the first position;

a supply tube coupled to the manifold and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

wherein, when the cannula is in the first position, the supply tube is positioned on a first side of the first and second nasal prongs and, when the cannula is in the second position, the supply tube is positioned on a second side of the first and second nasal prongs to effectively switch the side from which the supply tube extends from the cannula between the first and second positions.

92. The nasal cannula system of Claim 91, wherein the cannula is connected to the manifold by a ball joint arrangement such that the cannula is rotatable relative to the manifold about at least two axes, such that a tilt of the first and second nasal prongs can be adjusted.

93. The nasal cannula system of Claim 91, wherein the cannula is selectable from a selection of at least two different sizes of cannulas comprising at least two different sizes of prongs.

94. The nasal cannula system of Claim 91, wherein the cannula comprises a prong portion and a connection portion that are separable from one another, wherein the prong portion is selectable from a selection of at least two different sizes of prong portions comprising at least two different sizes of prongs, which can be coupled to the connection portion for use.

95. The nasal cannula system of Claim 91, wherein the cannula and the manifold comprise interference surface features that assist in securing the cannula in a desired position relative to the manifold.
96. A nasal cannula system, comprising:

    a cannula defining a cavity and comprising a first nasal prong and a second
    nasal prong extending from the cannula and in communication with the cavity;

    a supply tube coupled to the cannula and in communication with the cavity, the
    supply tube connectable to a supply of gas from a gas source to deliver a flow of gas
    to the cavity and the first and second nasal prongs;

    a pressure line in communication with the cavity and configured to be
    connectable to a control unit of the gas source or a display unit to provide a signal to
    the control unit or display unit indicative of a pressure within the cavity.

97. The nasal cannula system of Claim 96, wherein the pressure line is a tube and the
    signal is gas pressure within the tube.

98. The nasal cannula system of Claim 97, wherein a portion of the pressure line
    located within the cavity comprises a plurality of openings along a length of the tube.

99. The nasal cannula system of Claim 97, wherein the pressure line is coupled to the
    gas source, which provides a flow of gas into the pressure line either intermittently or
    continuously.

100. The nasal cannula system of Claim 96, wherein the pressure line is an electrical
    line comprising an electrical pressure sensor and the signal is an electrical signal.

101. The nasal cannula system of Claim 96, wherein the pressure line is in indirect
    communication with the cavity.

102. The nasal cannula system of Claim 96, wherein the pressure line is coupled to a
    connector that is coupled to the cannula.

103. The nasal cannula system of Claim 102, wherein the supply tube is coupled to
    the cannula by the connector along with the pressure line.

104. The nasal cannula system of Claim 96, wherein the pressure line extends into
    the cavity through a one-way self-sealing valve.

105. The nasal cannula system of Claim 96, wherein the pressure line is integrated
    with the supply tube.

106. The nasal cannula system of Claim 105, wherein the pressure line is integrated
    with a reinforcing bead of the supply tube.
107. A nasal cannula, comprising:

a cannula body defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity, wherein the cannula defines a patient-facing surface having one or more comfort features selected from a plurality of through-holes, a plurality of raised bumps, a plurality of grooves and a gel pad.

108. The nasal cannula of Claim 107, wherein the cannula comprises a central portion containing the first and second nasal prongs and first and second side portions extending from each side of the central portion, wherein the comfort features are provided only on the first and second side portions.

109. The nasal cannula of Claim 107, wherein each of the grooves extends from one edge of the cannula to another edge of the cannula such that the grooves are open on each end.

110. The nasal cannula of Claim 109, wherein the grooves extend from an upper edge of the cannula to a lower edge of the cannula.

111. A nasal cannula, comprising:

a cannula body defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity, the cannula body comprising a central portion containing the first and second nasal prongs and first and second side portions extending from each side of the central portion, wherein the cannula body defines a patient-facing surface;

wherein the central portion is spaced forwardly of adjacent portions of the first and second side portions such that, in use, the patient-facing surface of the central portion is spaced from the upper lip of the patient.

112. The nasal cannula of Claim 111, wherein the first and second prongs extend from the patient-facing surface of the central portion.

113. The nasal cannula of Claim 111, wherein the side portions comprise a malleable material portion such that a shape of the side portions can be adjusted.

114. The nasal cannula of Claim 113, wherein the malleable material portion is external or is embedded within the side portions.
115. A supply tube for a nasal cannula, comprising:
   a tube body having a first end and a second end, the tube body comprising a
   malleable section that permits the section to be shaped by an external force and that
   substantially retains the shape after the external force is removed.

116. The supply tube of Claim 115, wherein the malleable section comprises a
   malleable member that located in one of the following: an internal passage of the tube body,
   embedded in a wall of the tube body, embedded in or forming a reinforcement bead of the
   tube body.

117. The supply tube of Claim 115, wherein the malleable section comprises a
    plurality of individual members adjustably coupled to one another.

118. The supply tube of Claim 117, wherein the individual members are coupled by
    a ball-and-socket arrangement.

119. The supply tube of Claim 115, wherein the malleable section comprises a
    collapsible corrugated concertina tubing.

120. A nasal cannula system, comprising:
    a cannula defining a cavity and comprising a first nasal prong and a second
    nasal prong extending from the cannula and in communication with the cavity;
    a supply tube coupled to the cannula and in communication with the cavity, the
    supply tube connectable to a supply of gas from a gas source to deliver a flow of gas
    to the cavity and the first and second nasal prongs;
    a support arrangement that supports the supply tube at a spaced location from
    the cannula, wherein the support arrangement comprises a fastener having a first
    portion coupled to the supply tube and a second portion located at the spaced
    location.

121. The nasal cannula system of Claim 120, wherein the support arrangement
    comprises an adhesive pad that can be affixed to the patient and the second portion of the
    fastener is located on the adhesive pad.

122. The nasal cannula system of Claim 120, further comprising a retention
    arrangement that secures the cannula to the patient, wherein the second portion of the fastener
    is located on the retention arrangement.
123. The nasal cannula system of Claim 120, wherein the fastener is one of a hook-and-loop fastener, a button-and-hole, and a snap-fit fastener.

124. A nasal cannula system, comprising:

a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

a retention arrangement that secures the cannula to the patient;

a support arrangement that supports the supply tube at a spaced location from the cannula, which is located on the retention arrangement.

125. The nasal cannula system of Claim 124, wherein the support arrangement comprises a clip that engages the supply tube and is supported by the retention arrangement.

126. The nasal cannula system of Claim 124, wherein the support arrangement comprises a loop that is carried by the retention arrangement.

127. The nasal cannula system of Claim 126, wherein the loop is integrated with the retention arrangement.

128. The nasal cannula system of Claim 126, wherein the loop is an interrupted loop or an uninterrupted loop.

129. A nasal cannula system, comprising:

a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;

a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

a support arrangement that supports the supply tube at a spaced location from the cannula, wherein the support arrangement comprises a fastener that engages a piece of fabric at the spaced location.

130. The nasal cannula system of Claim 129, wherein the fastener is one of a clip, a snap-fit fastener or a clip-and-post fastener in which the piece of fabric is trapped between
portions of the fastener, or a button-and-hole fastener in which the button is provided on the piece of fabric.

131. The nasal cannula system of Claim 129, wherein the fastener is integrated with the supply tube.

132. The nasal cannula system of Claim 129, wherein the fastener comprises an opening configured to receive a lanyard.

133. A nasal cannula system, comprising:
    a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
    a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;
    a support arrangement that supports the supply tube at a spaced location from the cannula, wherein the support arrangement comprises at least one of an armband that engages the supply tube, an adhesive pad comprising a fastener for releasably fastening the supply tube to the adhesive pad, a generally U-shaped support that sits on the patient's shoulder and engages the supply tube, and a headgear strap comprising a strap extending over the top of the patient's head and engages the supply tube.

134. A retention arrangement for a nasal cannula assembly, comprising:
    a headgear strap comprising a first ear loop and a second ear loop, each of which at least partially surround an ear of the patient, a connection portion that connects the retention arrangement to the nasal cannula assembly, and a strap portion that extends around the back of the patient's head between the first and second ear loops.

135. The retention arrangement of Claim 134, wherein each of the first and second ear loops completely surround the ear of the patient.

136. The retention arrangement of Claim 134, wherein the strap portion is one-piece or separate pieces coupled by an adjustable fastener.
137. The retention arrangement of Claim 134, wherein the strap portion comprises a mesh section.

138. A retention arrangement for a nasal cannula, comprising:

a headgear strap comprising a strap portion, a first pad and a second pad, which, in use, contact first and second cheeks of the patient, a connection portion that connects the retention arrangement to the nasal cannula, wherein the strap portion extends around the patient’s head and extends from the first and second pads at an angle relative to the nasal cannula.

139. The retention arrangement of Claim 138, wherein the strap portion is positioned above the ears of the patient.

140. A retention arrangement for a nasal cannula, comprising:

a frame comprising a connection portion that connects the retention arrangement to the nasal cannula, a first ear stem portion and a second ear stem portion extending rearwardly from opposite sides of the connection portion, wherein the ear stem portions are configured to be positioned above the ears of the patient.

141. The retention arrangement of Claim 140, further comprising a pad on each of the ear stem portions.

142. A nasal cannula system, comprising:

a cannula having a central portion defining a cavity and comprising a first nasal prong and a second nasal prong extending from the central portion and in communication with the cavity, a first side portion and a second side portion extending in a lateral direction from opposing sides of the central portion;

a supply tube coupled to the cannula and in communication with the cavity, the supply tube connectable to a supply of gas from a gas source to deliver a flow of gas to the cavity and the first and second nasal prongs;

a first adhesive pad and a second adhesive pad configured to be adhesively secured to the face of the patient and connectable to a respective one of the first and second side portions of the cannula through an adjustable fastening arrangement.

143. The nasal cannula system of Claim 142, wherein the adjustable fastening arrangement comprises a ratchet assembly between the side portions and the respective
adhesive pads, a strip of hook-and-loop fastener between the side portions and the respective adhesive pads, or a post-and-multiple-slot arrangement between the side portions and the respective adhesive pads.

144. A nasal cannula system, comprising:
   a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
   a modular retention arrangement that secures the cannula to the patient, wherein the cannula is configured to be used with any one of the retention arrangements selected from a set of adhesive pads that attach to the patient’s face, a headgear strap and a halo-style headgear strap that has a strap portion extending over the top of the patient’s head.

145. The nasal cannula system of Claim 144, wherein the cannula has multiple connection points with the retention arrangement on each side of the cannula.

146. The nasal cannula system of Claim 144, comprising a kit including the cannula and at least two types of the retention arrangements.

147. A nasal cannula system, comprising:
   a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
   a modular retention arrangement that secures the cannula to the patient, the retention arrangement comprising a nose strip coupled to the cannula and attachable to the nose of a patient and a headgear strap comprising a clip configured to receive the cannula, wherein the cannula can be secured to the patient using either the nose strip or the headgear strap.

148. The nasal cannula system of Claim 147, wherein the nose strip can be applied directly to the patient’s nose via an adhesive layer or is applied via attachment to a separate adhesive strip.

149. The nasal cannula system of Claim 147, wherein the nose strip can be removed from the cannula.
150. A retention arrangement for a nasal cannula, comprising:

a headgear strap that is connectable to a nasal cannula and capable of being tensioned around the head of a patient, the headgear strap comprising a tension indicator that provides a first indication when the tension is at an incorrect value and a second indication when the tension is at a correct value.

151. The retention arrangement of Claim 150, wherein the tension indicator is one of a portion that changes color between the first indication and the second indication, a portion that displays a different symbol for the first indication and the second indication, a window that displays a marker in the second indication, a scale, and a gauge.

152. The retention arrangement of Claim 151, wherein the tension indicator is a gauge that is positioned on a cheek of the patient and comprises a padded patient-facing surface.

153. The retention arrangement of Claim 150, wherein the headgear strap comprises a first portion, a second portion and a biasing member that regulates movement between the first portion and the second portion.

154. The retention arrangement of Claim 153, wherein the biasing member is one of a spring and an elastic section of the headgear strap.

155. The retention arrangement of Claim 150, wherein the headgear strap is a single strap comprising multiple strap portions that each extend from one side to the other of the cannula.

156. The retention arrangement of Claim 155, wherein the headgear strap can be tightened by adjusting a total length of the strap extending between the sides of the cannula.

157. The retention arrangement of Claim 155, wherein the strap portions are spaced from one another in a top-to-bottom direction of the cannula.

158. A retention arrangement for a nasal cannula, comprising:

a headgear strap that is connectable to a nasal cannula and comprises at least one strap extending around the head of a patient from one side to the other of the cannula;

a tension adjuster that tensions the headgear strap by varying an effective length of the at least one strap by winding up a portion of the at least one strap.
159. The retention arrangement of Claim 158, wherein the at least one strap comprises multiple straps.

160. The retention arrangement of Claim 158, wherein the tension adjuster is bidirectional and can wind up or release the portion of the at least one strap to increase or decrease.

161. The retention arrangement of Claim 158, wherein the tension adjuster comprises a limiter to limit the tension of the at least one strap.

162. The retention arrangement of Claim 161, wherein the limiter is a clutch mechanism.

163. A headgear strap for a nasal cannula, comprising:
    a first portion that is connectable to a nasal cannula;
    a second, elastic portion that is positioned at a back of a head of a patient in use; and
    a pad that extends at least partially along the second, elastic portion.

164. The headgear strap of Claim 163, wherein the pad surrounds an entirety of the second, elastic portion.

165. A nasal cannula assembly, comprising:
    a cannula defining a cavity and comprising a first nasal prong and a second nasal prong extending from the cannula and in communication with the cavity;
    a head strap that is positioned around the head and above the ears of the patient in use;
    a first arm coupled to a first side of the cannula; and
    a second arm coupled to a second side of the cannula, wherein upper end portions of each of the first and second arms are attached to the head strap.

166. The nasal cannula assembly of Claim 165, wherein each of the first and second arms is adjustable in height relative to the head strap.

167. The nasal cannula assembly of Claim 165, wherein each of the first and second arms is adjustable in a circumferential direction of the head strap.

168. The nasal cannula assembly of Claim 167, wherein each of the first and second arms is adjustable to one of a discrete number of adjustment positions.
169. The nasal cannula assembly of Claim 165, wherein each of the first and second arms is rotatable relative to the head strap.
NASAL CANNULA ASSEMBLY

ABSTRACT OF THE DISCLOSURE

Nasal cannula assemblies for providing respiratory therapy to patients are provided. A nasal cannula assembly can include a cannula, an optional manifold, a gas supply tube, and a securement mechanism. Securement mechanisms can include headgear straps, cheek pads, or an adhesive nose strip. A nasal cannula assembly can also include a lanyard, lanyard clip, and/or lanyard connector to help support the weight of a main gas delivery conduit.