

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To: SONA DALAL  
NOVEL IP  
191 WEST SECOND STREET  
SANTA ANA, CA 92701

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 19/63793

International filing date (day/month/year)

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30 November 2018 (30.11.2018)

International Patent Classification (IPC) or both national classification and IPC

IPC - H01R 4/48 (2020.01)

CPC - H01R 13/6277, H01R 13/639, H01R 13/62933, A61B 5/04, A61B 5/04286

Applicant

CADWELL LABORATORIES, INC.

I. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-8300

Date of completion of this opinion

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Authorized officer

Lee Young

PCT Help Desk

Telephone No. 571-272-4300

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## Box No. 1 Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
  - the international application in the language in which it was filed.
  - a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2.  This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).
3.  With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
  - a.  forming part of the international application as filed:
    - in the form of an Annex C/ST.25 text file.
    - on paper or in the form of an image file.
  - b.  furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
  - c.  furnished subsequent to the international filing date for the purposes of international search only:
    - in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
    - on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4.  In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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**Box No. V** Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	18-20, 23-25, 27-29, 33-35	YES
	Claims	1-17, 21, 22, 26, 30-32	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-35	NO
Industrial applicability (IA)	Claims	1-35	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-17, 21, 22, 26 and 30-32 lack novelty under PCT Article 33(2) as being anticipated by US 2018/0161123 A1 to Cadwell Laboratories, Inc. (Hereinafter Cadwell).

Regarding claim 1, Cadwell discloses a system for neuro monitoring (a system for neuromonitoring; para [0009] & claim 1) comprising: a plurality of electrode groups (a plurality of electrode groups; para [0023], [0035] & claim 1), wherein each group of the plurality of electrode groups comprises electrodes (where each electrode group in said plurality of electrode groups comprises electrodes; para [0035] & claim 1), wherein each of the electrodes in each group has at least one of a similar monitoring functionality type or a similar deployment location (where each electrode group in said plurality of electrode groups comprises electrodes of a similar type having at least one of a similar monitoring functionality type and a similar deployment location; para [0035] & claim 1) and wherein each of the plurality of electrode groups has at least one electrode group lead (each of these electrodes is coupled to a wire lead; para [0003]); a plurality of connectors (a plurality of connectors; para [0035] & claim 1), wherein each of the at least one electrode group leads is coupled to at least one connector of the plurality of connectors (each of these electrode es is coupled to a wire lead; multiple leads (up to 16) into a single connector; para [0003], [0006], [0059], [0063], [0073]) and wherein each of the electrode group leads and/or each of connectors of the plurality of connectors are electronically associated with a unique identification code (each connector comprises a unique identification code; establishing an identity of each connector of said plurality of connectors by identifying each unique identification code associated with each connector of said plurality of connectors; para [0023] & claim 1); and, a control unit comprising at least one receiving unit configured for receiving the plurality of connectors (a control unit comprising at least one receiving unit configured for receiving the plurality of connectors; para [0009], [0059], [0063], [0073] & claim 1), wherein the control unit is configured to determine at least one of the unique identification code of each connector of the plurality of connectors or the unique identification code of each of the at least one electrode group leads (a control unit comprising at least one receiving unit configured for receiving said plurality of connectors, establishing an identity of each of said plurality of connectors by identifying each unique identification code associated with each of said plurality of connectors; para [0035]) and to associate each electrode in the plurality of electrode groups with a corresponding input channel in the control unit based on at least one of the unique identification code of each connector or the unique identification code of each of the at least one electrode group leads (configuring the system to associate each electrode with a corresponding input channel in the control unit based on said unique identification code of the connector; para [0009], [0059], [0063], [0073]).

Regarding claim 2, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein said unique identification code is in a 128 bit GUID format (unique identification code is in a 128 bit GUID format; para [0010], [0024] & claim 2).

Regarding claim 3, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein said at least one receiving unit comprises a plurality of input sockets configured to receive one or more connectors of said plurality of connectors (receiving unit includes a plurality of input sockets configured to receive one or more connectors of said plurality of connectors; para [0011] & claim 3).

Regarding claim 4, Cadwell discloses the system of claim 3. In addition, Cadwell discloses wherein said one or more connectors are configured to be coupled to any of the plurality of input sockets of said at least one receiving unit (one or more connectors are configured to be coupled to any of the plurality of input sockets of said at least one receiving unit; para [0012] & claim 4).

Regarding claim 5, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is configured to determine at least one of the unique identification code of each connector of the plurality of connectors or the unique identification code of each of the at least one electrode group leads by receiving, via each connector of the plurality of connectors (coupling each connector of said plurality of connectors with at least one receiving unit in communication with a system control unit; establishing the identity of each connector of said plurality of connectors from its unique identification code, wherein said receiving unit is configured to establish said identity by identifying each unique identification code associated with each connector of said plurality of connectors; para[0023]), data indicative of at least one of the unique identification code of each connector of the plurality of connectors or the unique identification code of each of the at least one electrode group leads (establishing the identity of each connector of said plurality of connectors from its unique identification code; para [0023]).

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Regarding claim 6, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is configured to receive, via each connector of the plurality of connectors (the control unit configured for receiving said plurality of connectors; para [0035] & claim 1), data indicative of at least one of the unique identification code of each connector of the plurality of connectors or the unique identification code of each of the at least one electrode group leads through a direct pin-to-pin electrical pass through (identity of each connector of said plurality of connectors from its unique identification code, wherein said receiving unit is configured to establish said identity by identifying each unique identification code associated with each connector of said plurality of connectors; para[0023]).

Regarding claim 7, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is configured to determine at least one of the unique identification code of each connector of the plurality of connectors or the unique identification code of each of the at least one electrode group leads by receiving, via at least one connector of the plurality of connectors (coupling each connector of said plurality of connectors with at least one receiving unit in communication with a system control unit; establishing the identity of each connector of said plurality of connectors from its unique identification code, wherein said receiving unit is configured to establish said identity by identifying each unique identification code associated with each connector of said plurality of connectors; para[0023]), data indicative of at least one of the unique identification code of each connector of the plurality of connectors or the unique identification code of each of the at least one electrode group leads (establishing the identity of each connector of said plurality of connectors from its unique identification code; para [0023]).

Regarding claim 8, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is configured to receive, via each connector of the plurality of connectors (the control unit configured for receiving said plurality of connectors; para [0035] & claim 1), data indicative of at least one of a production date or authentication data (certain other information is stored in the connectors, such as the authentication information, production dates of the connector and the electrodes corresponding to each connector; para [0076]).

Regarding claim 9, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is configured to receive, via each connector of the plurality of connectors (the control unit configured for receiving said plurality of connectors; para [0035] & claim 1) and through a direct pin-to-pin electrical pass through (the electrodes couple directly with the connector and the ID information is very specific to the electrode; para [0077]), data indicative of at least one of a production date of the plurality of connectors or the electrodes or authentication data (certain other information is stored in the connectors, such as the authentication information, production dates of the connector and the electrodes corresponding to each connector; para [0076]).

Regarding claim 10, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein said connector has a designated output pin which is configured to transmit information related to the unique identification code to said control unit (each of the connectors has two designated output pins which are configured to transmit information related to the unique identification code to the control unit; para [0017], [0029]).

Regarding claim 11, Cadwell discloses the system of claim 10. In addition, Cadwell discloses wherein data indicative of the unique identification code is stored in a memory associated with the designated output pin (connector has a designated output pin which is configured to transmit information related to the unique identification code; the ID information is carried explicitly by the connector; the ID information is stored in electronically accessible memory on the connector; para [0013], [0056]).

Regarding claim 12, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein data indicative of the unique identification code comprises a bar code or a radio frequency code (RFID) (information related to the unique identification code is formatted as a bar code or a radio frequency code (RFID); para [0014], [0027] & claim 6).

Regarding claim 13, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein data indicative of the unique identification code is stored using at least one pin configured as at least one dip switch comprising at least one resistor (the information related to the identification code is stored using multiple pins that are configured as dip switches comprising resistors; para [0015] & claim 7).

Regarding claim 14, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein each connector of the plurality of connectors is configured to be inserted in the at least one receiving unit in at least two different orientations (each of said plurality of connectors is configured to be inserted in said receiving unit using at least two different orientations; para [0016], [0028] & claim 8).

Regarding claim 15, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein each connector of the plurality of connectors comprises at least two designated output pins (each of the plurality of connectors has two designated output pins; para [0017], [0029]), each of which being configured to convey data indicative of the unique identification code and an orientation of a connector of the plurality of connectors ( which are configured to transmit information related to the unique identification code and an orientation of the connector; para [0017], [0029]).

Regarding claim 16, Cadwell discloses the system of claim 15. In addition, Cadwell discloses wherein the at least two designated output pins are configured to be at different polarities or at different voltage levels to indicate the orientation of the connector of the plurality of connectors (two designated output pins are maintained at different polarities or voltage levels to indicate the orientation of the connector; para [0018], [0030] & claim 10).

Regarding claim 17, Cadwell discloses the system of claim 15. In addition, Cadwell discloses wherein a physical position of the at least two designated output pins is different in each of the at least two different orientations (a physical position of said two designated output pins is different in each of two orientations; para [0019], [0031], claim 11).

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Regarding claim 21, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is further configured to determine at least one of authentication data or data indicative of a production date of the plurality of connectors or the electrodes by receiving (apart from the unique ID, certain other information is stored in the connectors, such as the authentication information, production dates of the connector and the electrodes corresponding to each connector; para [0070]), via at least one connector of the plurality of connectors, data indicative of the at least one of authentication data or data indicative of the production dates of the plurality of connectors or the electrodes (certain other information is stored in the connectors, such as the authentication information, production dates of the connector and the electrodes corresponding to each connector; para [0070]).

Regarding claim 22, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is configured to generate data indicative of, or associated with, a three-dimensional image (the control unit is coupled to a data acquisition system through cable 810; the medical system being used for monitoring the neurological state of a patient; the first and the second views of connector 100, respectively depicting first and second configurations, are horizontally flipped images of each other, about the Z axis (three-dimensional image); para [0082], [0088]).

Regarding claim 26, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the control unit is configured to automatically populate at least one graphical user interface with data indicative representative of each of the electrodes based on the unique identification codes. Cordero discloses wherein the control unit is configured to automatically populate at least one graphical user interface with data indicative representative of each of the electrodes based on the unique identification codes (configuring the system to associate each electrode with its corresponding input channel in said control unit based on the unique identification code; system will remap the inputs to the correct channels; the ID information is for all electrodes in a group; the information needed to determine where the electrode is attached as a function of both the connector (using its unique ID) and a setup specified on a per connector basis by the user to a computer system; para [0023], [0056]).

Regarding claim 30, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein said electrodes are configured in groups of 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 or 16 electrodes (electrodes come in groups of 4, 5, 6, 8, 10 and 16 electrodes; electrodes, having 16 output pins, can support up to 16 electrodes; para [0073], [0074]).

Regarding claim 31, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein said system is configured to perform at least one of an electroencephalography, electrocardiogram, electromyography, polysomnography, or intraoperative neural monitoring procedure (the system discloses a novel electrode management solution for neuromonitoring applications such as electroencephalography (EEG) procedures; para [0054]).

Regarding claim 32, Cadwell discloses the system of claim 1. In addition, Cadwell discloses wherein the unique identification code associated with each said electrode group lead is stored in association with each electrode group lead (electrodes are coupled to the corresponding input channels in groups through connectors having a unique identification (ID); each of these electrodes is coupled to a wire lead; electrode leads in small groups; Abstract & para [0003], [0059]), and wherein the unique identification code is configured as any one of a crimp, an adhesive label or an embedded code on each electrode group lead (unique identification code is formatted as a bar code or a radio frequency code (RFID); the identification information is communicated through an RFID stored in the connector; para [0012], [0070]).

Claims 18-20 lack an inventive step under PCT Article 33(3) as being obvious over Cadwell in view of WO 2016/028822 A1 to Huntleigh Technology Limited (Hereinafter Huntleigh).

Regarding claim 18, Cadwell discloses the system of claim 15. Cadwell fails to disclose further comprising a rigid connector plate, wherein the connector plate comprises a plurality of openings, each opening of the plurality of openings being configured to receive each connector of the plurality of connectors, and wherein each opening of the plurality of openings is separated from an adjacent opening of the plurality of openings by a portion of the connector plate. Huntleigh discloses further comprising a rigid connector plate (rigid flange extending from an exterior surface of the elongated body towards the portion of the one or more connector plates; page 2, lines 16-20), wherein the connector plate comprises a plurality of openings (one or more connector plates defining the one or more openings; page 2, lines 16-20), each opening of the plurality of openings being configured to receive each connector of the plurality of connectors (conduit connectors positioned through one or more openings of the one or more connector plates; conduit connectors are pivotally connectable to the one or more connector plates and/or movably attachable to the one or more connector plates so as to be capable of lateral displacement within the one or more openings; page 2, lines 8-15), and wherein each opening of the plurality of openings is separated from an adjacent opening of the plurality of openings by a portion of the connector plate (one or more connector plates defining the one or more openings, wherein the elongated body is spaced apart from the portion of the one or more connector plates defining the one or more openings; page 2, lines 16-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include further comprising a rigid connector plate, wherein the connector plate comprises a plurality of openings, each opening of the plurality of openings being configured to receive each connector of the plurality of connectors, and wherein each opening of the plurality of openings is separated from an adjacent opening of the plurality of openings by a portion of the connector plate as taught by Huntleigh into the system of Cadwell for the purpose of providing a connector system useful for facilitating the installation, detachment, and interchange of various components.

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Regarding claim 19, Cadwell in view of Huntleigh discloses the system of claim 18. Cadwell fails to disclose wherein each connector of the plurality of connectors is partially positioned in each opening of the plurality of openings such that a first end of each connector extends outward from a first surface of the connector plate and a second end, opposing the first end, of each connector extends outward from a second surface of the connector plate, wherein the second surface opposes the first surface. Huntleigh discloses wherein each connector of the plurality of connectors is partially positioned in each opening of the plurality of openings such that a first end of each connector extends outward from a first surface of the connector plate and a second end (the conduit connectors, extends through the one or more connector plates; page 3, lines 2-4 & claim 17), opposing the first end, of each connector extends outward from a second surface of the connector plate (the conduit connectors, extends through the one or more connector plates; page 3, lines 2-4 & claim 17), wherein the second surface opposes the first surface (a connector system 40 of the present application may be arranged between any two surfaces; page 12, lines 23-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein each connector of the plurality of connectors is partially positioned in each opening of the plurality of openings such that a first end of each connector extends outward from a first surface of the connector plate and a second end, opposing the first end, of each connector extends outward from a second surface of the connector plate, wherein the second surface opposes the first surfaces taught by Huntleigh into the system of Cadwell for the purpose of a connector assembly that includes one or more conduit connectors extending through one or more openings of the one or more connector plates.

Regarding claim 20, Cadwell discloses the system of claim 1. Cadwell fails to disclose further comprising a rigid connector plate, wherein the connector plate comprises a plurality of sockets, each socket of the plurality of sockets being configured to receive each connector of the plurality of connectors, and wherein each socket of the plurality of sockets is separated from an adjacent socket of the plurality of sockets by a portion of the connector plate and is configured to electrically connect to a corresponding socket in the at least one receiving unit. Huntleigh discloses further comprising a rigid connector plate (rigid flange extending from an exterior surface of the elongated body towards the portion of the one or more connector plates; page 2, lines 16-20), wherein the connector plate comprises a plurality of sockets, each socket of the plurality of sockets being configured to receive each connector of the plurality of connectors (conduit connectors positioned through one or more openings of the one or more connector plates; conduit connectors are pivotally connectable to the one or more connector plates and/or movably attachable to the one or more connector plates so as to be capable of lateral displacement within the one or more openings; page 2, lines 8-15), and wherein each socket of the plurality of sockets is separated from an adjacent socket of the plurality of sockets by a portion of the connector plate (conduit connectors, movably mounted to the connector plate and mattress base 24, can be pivoted, rotated and laterally displaced with respect to connector plate; page 24, lines 5-10) and is configured to electrically connect to a corresponding socket in the at least one receiving unit (conduit connectors positioned through one or more openings of the one or more connector plates; conduit connectors are pivotally connectable to the one or more connector plates and/or movably attachable to the one or more connector plates; page 2, lines 8-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include further comprising a rigid connector plate, wherein the connector plate comprises a plurality of sockets, each socket of the plurality of sockets being configured to receive each connector of the plurality of connectors, and wherein each socket of the plurality of sockets is separated from an adjacent socket of the plurality of sockets by a portion of the connector plate and is configured to electrically connect to a corresponding socket in the at least one receiving unit as taught by Huntleigh into the system of Cadwell for the purpose of providing a connector assembly that includes one or more conduit connectors extending through one or more openings of the one or more connector plates in order to provide modular patient support apparatus that allows for rapid connection, detachment and interchange of various components.

Claims 23-25 lack an inventive step under PCT Article 33(3) as being obvious over Cadwell in view of US 2009/0196471 A1 to Goetz et al. (Hereinafter Goetz).

Regarding claim 23, Cadwell discloses the system of claim 22. Cadwell fails to disclose wherein the three-dimensional image comprises a plurality of pixel positions and wherein at least one of the plurality of pixel positions is associated, in a memory, with at least one of the electrodes. Goetz discloses wherein the three-dimensional image comprises a plurality of pixel positions and wherein at least one of the plurality of pixel positions is associated, in a memory, with at least one of the electrodes (the image analysis process can proceed in 3D with volume pixels (voxels); a characterization unit characterizes the electrode array; image analysis of pixels to identify electrodes and establishment of a pixel to distance dimensional scale to determine actual relative positioning of electrodes; para [0104], [0112], [0156]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the three-dimensional image comprises a plurality of pixel positions and wherein at least one of the plurality of pixel positions is associated, in a memory, with at least one of the electrodes as taught by Goetz into the system of Cadwell for the purpose of providing implanted electrical stimulation electrode arrays using post-implant imaging, where electrode arrays are carried by implanted leads, in order to determine the positions of the implanted leads or electrodes carried by the leads relative to one another.

Regarding claim 24, Cadwell in view of Goetz discloses the system of claim 22. Cadwell fails to disclose wherein the control unit is configured to receive data indicative of a user input selecting at least one of the plurality of pixel positions of the three-dimensional image and is configured to identify at least one electrode associated with the selected at least one of the plurality of pixel positions based on the user input. Goetz discloses wherein the control unit is configured to receive data indicative of a user input selecting at least one of the plurality of pixel positions of the three-dimensional image and is configured to identify at least one electrode associated with the selected at least one of the plurality of pixel positions based on the user input (the image analysis process that may be aided by user intervention; the image analysis process can proceed in 3D with volume pixels (voxels); image analysis of pixels to identify electrodes and establishment of a pixel to distance dimensional scale to determine actual relative positioning of electrodes; para [0104], [0156]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the control unit is configured to receive data indicative of a user input selecting at least one of the plurality of pixel positions of the three-dimensional image and is configured to identify at least one electrode associated with the selected at least one of the plurality of pixel positions based on the user input as taught by Goetz into the system of Cadwell for the purpose of providing image analysis in order to inhibit or prevent nonsensical electrode selections or parameters given the particular lead configuration implanted within the patient.

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Regarding claim 25, Cadwell in view of Goetz discloses the system of claim 24. In addition, Cadwell discloses wherein the control unit is further configured to determine data associated with the identified at least one electrode by using the unique identification code associated with the at least one electrode (configuring the system to associate each electrode with its corresponding input channel in the control unit based on the unique identification code; para [0023], [0035]).

Claim 27 lacks an inventive step under PCT Article 33(3) as being obvious over Cadwell in view of EP 1182965 B1 to Aspect Medical Systems LLC (hereinafter Aspect).

Regarding claim 27, Cadwell discloses the system of claim 26. Cadwell fails to disclose wherein the control unit is configured to automatically update data displayed in the at least one graphical user interface with updated data indicative representative of each of the electrodes based on the unique identification codes after one or more of the electrodes is moved or disconnected and reconnected to the at least one receiving unit. Aspect discloses wherein the control unit is configured to automatically update data displayed in the at least one graphical user interface with updated data indicative representative of each of the electrodes based on the unique identification codes after one or more of the electrodes is moved or disconnected and reconnected to the at least one receiving unit (functionality may be added after the date of manufacture of the monitor by simply storing different configuration codes on the smart sensor and updating the monitor software; the monitor next logs the smart sensor identification data into its non-volatile memory; allowing for legitimate disconnection and reconnection and allows the monitor to warn the user if the connected smart sensor has already been used; para [0017], [0028]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the control unit is configured to automatically update data displayed in the at least one graphical user interface with updated data indicative representative of each of the electrodes based on the unique identification codes after one or more of the electrodes is moved or disconnected and reconnected to the at least one receiving unit as taught by Aspect into the system of Cadwell for the purpose of verifying the smart sensor meets various criteria for use and allowing reuse of the smart sensor to be limited for quality and infection control purposes.

Claim 28 lacks an inventive step under PCT Article 33(3) as being obvious over Cadwell in view of US 2016/0328991 A1 to DexCom, Inc. (Hereinafter DexCom).

Regarding claim 28, Cadwell discloses the system of claim 1. Cadwell fails to disclose wherein the control unit is configured to receive data indicative of a user selection of a trace displayed on a graphical user interface, wherein, upon receiving data indicative of the user selection of the trace, the control unit is configured to trigger a visual indicator positioned in physical proximity to or association with one of the electrodes that acquired data associated with said trace. DexCom discloses wherein the control unit is configured to receive data indicative of a user selection of a trace displayed on a graphical user interface (the output may include a trend graph indicating a trace signal representing the analyte concentration value over a time period associated with the program; the selected program may be associated with the desired analyte concentration value; para [0084]), wherein, upon receiving data indicative of the user selection of the trace (the output may include a trend graph indicating a trace signal representing the analyte concentration value over a time period associated with the program; the selected program may be associated with the desired analyte concentration value; para [0084]), the control unit is configured to trigger a visual indicator positioned in physical proximity to or association with one of the electrodes that acquired data associated with said trace (output may include a color indicating if a goal associated with the program; the output may include a trend graph indicating a trace signal representing the analyte concentration value over a time period associated with the program; electrodes can be used to detect the amount of glucose in a sample and convert that information into a signal; para [0084], [0156]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the control unit is configured to receive data indicative of a user selection of a trace displayed on a graphical user interface, wherein, upon receiving data indicative of the user selection of the trace, the control unit is configured to trigger a visual indicator positioned in physical proximity to or association with one of the electrodes that acquired data associated with said trace as taught by DexCom into the system of Cadwell for the purpose of providing an output that includes a trend graph indicating a trace signal representing a value over a time period associated with the program.

Claims 33-35 lack an inventive step under PCT Article 33(3) as being obvious over Cadwell in view of US 2007/0202005 A1 (Maschke).

Regarding claim 33, Cadwell discloses the system of claim 1. Cadwell fails to disclose wherein each connector of the plurality of connectors further comprises a value and wherein the value is representative of a number of permissible uses of the connector of the plurality of connectors. Maschke discloses wherein each connector of the plurality of connectors further comprises a value (medical objects can be any medical accessory, medical tools or instruments, such as catheters, endoscopes, needles, drill bits, etc.; maximum number Nmax (value) of permitted sterilization cycles for the medical object O (connector); para [0002], [0048]) and wherein the value is representative of a number of permissible uses of the connector of the plurality of connectors (maximum number Nmax of permitted sterilization cycles for the medical object O (connector); para [0002], [0048]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein each connector of the plurality of connectors further comprises a value and wherein the value is representative of a number of permissible uses of the connector of the plurality of connectors as taught by Maschke into the system of Cadwell for the purpose of providing a fully automatic and reliable manner to prevent a medical object, which is not permitted a further sterilization cycle, from incorrectly being resterilized and used once again.

Regarding claim 34, Cadwell and Maschke disclose the system of claim 33. Cadwell fails to disclose wherein the value is indicative of a maximum number of sterilization cycles of the connector of the plurality of connectors and wherein the maximum number of sterilization cycles is equal to, or less than, 20. Maschke discloses wherein the value is indicative of a maximum number of sterilization cycles of the connector of the plurality of connectors and maximum number of sterilization cycles (medical objects can be any medical accessory, medical tools or instruments, such as catheters, endoscopes, needles, drill bits, etc.; maximum number Nmax (value) of permitted sterilization cycles for the medical object O (connector); para [0002], [0048]). conti--

-Continuation in Supplemental Box-

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## Supplemental Box

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Continuation of:

Box V, 2: Citations and Explanations

CLAIM 34 conti--It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the value is indicative of a maximum number of sterilization cycles of the connector of the plurality of connectors and wherein the maximum number of sterilization cycles is equal to, or less than, 20 as taught by Maschke into the system of Cadwell for the purpose of providing data contained in an information code, whether a medical object has already undergone the maximum permitted number of sterilization cycles or whether it can be used again.

Regarding claim 35, Cadwell discloses the system of claim 1. Cadwell fails to disclose wherein the control unit is configured to access a value associated with each connector of the plurality of connectors, wherein the value is indicative of a maximum number of sterilization cycles of the connector of the plurality of connectors and wherein the maximum number of sterilization cycles is equal to, or less than, 20. Maschke discloses wherein the control unit is configured to access a value associated with each connector of the plurality of connectors (medical objects can be any medical accessory, medical tools or instruments, such as catheters, endoscopes, needles, drill bits, etc.; maximum number Nmax (value) of permitted sterilization cycles for the medical object O (connector); para [0002], [0048]), wherein the value is indicative of a maximum number of sterilization cycles of the connector of the plurality of connectors and the maximum number of sterilization cycles (medical objects can be any medical accessory, medical tools or instruments, such as catheters, endoscopes, needles, drill bits, etc.; maximum number Nmax (value) of permitted sterilization cycles for the medical object O (connector); para [0002], [0048]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the control unit is configured to access a value associated with each connector of the plurality of connectors, wherein the value is indicative of a maximum number of sterilization cycles of the connector of the plurality of connectors and wherein the maximum number of sterilization cycles is equal to, or less than, as taught by Maschke into the system of Cadwell for the purpose of providing data contained in an information code, whether a medical object has already undergone the maximum permitted number of sterilization cycles.

Claim 29 lacks an inventive step under PCT Article 33(3) as being obvious over Cadwell in view of DexCom and and in further view of US 2012/0003862 A1 to Newman et al. (Hereinafter Newman).

Regarding claim 29, Cadwell in view of DexCom discloses the system of claim 28. Cadwell and DexCom fails to disclose wherein the visual indicator is at least one of a light positioned on the one of the electrodes, a light positioned on a connector of the plurality of connectors in data communication with the one of the electrodes, or a light positioned on a lead attached to the one of the electrodes. Newman discloses wherein the visual indicator is at least one of a light positioned on the one of the electrodes, a light positioned on a connector of the plurality of connectors in data communication with the one of the electrodes, or a light positioned on a lead attached to the one of the electrodes (integrated electrode connector includes a light-transmitting housing having a conduit for engaging an electrode lead wire connector; the LED is visibly illuminated when the electrode lead is in electrical communication with the connector; para [0015], [0023]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the visual indicator is at least one of a light positioned on the one of the electrodes, a light positioned on a connector of the plurality of connectors in data communication with the one of the electrodes, or a light positioned on a lead attached to the one of the electrodes as taught by Newman into the system of Cadwell and DexCom for the purpose of incorporating an electrode connector and an indicator with which it is in electrical communication, where the indicator that shows whether or not an electrode is operating effectively.

Claims 1-35 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.



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