### PATENT COOPERATION TREATY

# **PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT



(PCT Article 36 and Rule 70)

Applicant's or agent's file reference  NOVOSCI-4-PCT	FOR FURTHER ACTION	THER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/41				
International application No.	International filing date (day/mor	ith/year)	Priority date (day/month/year)			
PCT/US03/27782	03 September 2003 (03.09.2003)		03 May 2003 (03.05.2003)			
International Patent Classification (IPC)	or national classification and IPC		03 May 2003 (05.05.2003)			
IPC(7): A691M 1/14, 1/34, 37/00, 1/00;	B64D 47/00; A61B 19/00 and US C	EL: 422/44, 45; 60	04/6.14, 6.15, 408, 327			
Applicant						
NOVOSCI						
This international prelimit Examining Authority and	nary examination report has been is transmitted to the applicant ac	prepared by the cording to Arti	is International Preliminary cle 36.			
2. This REPORT consists of a total of 2 sheets, including this cover sheet.						
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).						
These annexes consist of a	a total of sheets.					
3. This report contains indica	ations relating to the following it	ems:				
I Basis of the rep	ort					
II Priority						
III Non-establishm	ent of report with regard to nove	elty, inventive s	tep and industrial applicability			
IV Lack of unity of		· · · · · · · · · · · · · · · · · · ·	Transfer of the second			
V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement						
VI Certain docume		mg such statem	Cent			
	in the international application					
	tions on the international application	ation				
	of participation of par					
Date of submission of the demand	Date	of completion of	of this report			
03 December 2004 (03.12.2004)		21 January 2006 (21.01.2006)				
Name and mailing address of the IPEA/US		ezed officer				
Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Pere 1450		ia M. Bianco				
P.O. Box 1450 Alexandria, Virginia 22313-1450		none No. (571) 2	72 2075			
acsimile No. (571) 273-3201 rm PCT/IPEA/409 (cover sheet)(July 19			12-2713			

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.	_
PCT/US03/27782	

I.	Basi	s of the report
1.	With	regard to the elements of the international application:*
	$\bowtie$	the international application as originally filed.
	$\boxtimes$	the description:
		pages 1-16 as originally filed pages NONE , filed with the demand
		pages NONE , filed with the letter of
	$\boxtimes$	the claims:
		pages 17-21, as originally filed
		pages NONE , as amended (together with any statement) under Article 19
		pages NONE , filed with the demand pages NONE , filed with the letter of
	$\boxtimes$	the drawings:
	<b>1</b>	pages 1-10 , as originally filed
		pages NONE, filed with the demand
	$\overline{}$	pages NONE, filed with the letter of
	Ш	the sequence listing part of the description:
		pages NONE, as originally filed pages NONE, filed with the demand
		pages NONE , filed with the letter of
2.	langı	regard to the language, all the elements marked above were available or furnished to this Authority in the mage in which the international application was filed, unless otherwise indicated under this item. see elements were available or furnished to this Authority in the following language which is:
		the language of a translation furnished for the purposes of international search (under Rule23.1(b)).
	Ħ	the language of publication of the international application (under Rule 48.3(b)).
		the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3.	With	regard to any nucleotide and/or amino acid sequence disclosed in the international application, the national preliminary examination was carried out on the basis of the sequence listing:
		contained in the international application in printed form.
		filed together with the international application in computer readable form.
		furnished subsequently to this Authority in written form.
		furnished subsequently to this Authority in computer readable form.
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
		The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4.		The amendments have resulted in the cancellation of:
		the description, pages <u>NONE</u>
		the claims, Nos. NONE
		the drawings, sheets/fig NONE
5.		This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**
ınıs	Replac repor	ement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in It as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17). Opplacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US03/27782

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)	Claims 4, 5, 8, 13, 18, 25, 30-32 Claims 1-3, 6, 7, 9-12, 14-17, 19-24, 26-29	YES NO
Inventive Step (IS)	Claims 4, 5, 18, 25, 30, 31 Claims 1-3, 6-17, 19-24, 26-29, 32	YES NO
Industrial Applicability (IA)	Claims <u>1-32</u> Claims NONE	YES NO

#### 2. CITATIONS AND EXPLANATIONS

Claims 1-3, 6, 7, 9-11, 14-17, 19-21, & 27-29 lack novelty under PCT Article 33(2) as being anticipated by Lindsay '164. Lindsay discloses a quick-changeover blood handling apparatus and method for use in cardiac bypass. The apparatus comprising a support structure for receiving a blood oxygenator and to connect to a blood suctioner (i.e. vacuum port). The device has a gasket connection and is capable of accommodating the priming volume for less than 100 cubic cm. The device is made of a durable polymer. The reservoir is a hard shell reservoir. See figures 1-8.

Claims 8, 13, 26, & 32 lack an inventive step under PCT Article 33(3) as being obvious over Lindsay '164. Lindsay discloses that the device is made of a resilient polymer, but does not explicitly teach that it is high-density polystyrene. At the time of the invention, it would have been obvious to one of ordinary skill in the art to choose high-density polystyrene as the material since it well known to use polystyrene in the medical arts.

Claims 1-3, 9-12, 14-17, 19, 21-24, & 26-29 lack novelty under PCT Article 33(2) as being anticipated by Lindsay '346. Lindsay discloses a blood circuit for extracorporeal blood handling and method for use in cardiac bypass. The apparatus comprising a support structure for receiving a blood oxygenator and to connect to a blood suctioner (i.e. vacuum port). The device has a gasket connection and is capable of accommodating the priming volume for less than 100 cubic cm. The device is made of a durable polymer. The reservoir may be a hard or soft shell reservoir for collecting blood. See figures 2, 49.

Claims 8, 13, 26, & 32 lack an inventive step under PCT Article 33(3) as being obvious over Lindsay '346. Lindsay discloses that the device is made of a resilient polymer, but does not explicitly teach that it is high-density polystyrene. At the time of the invention, it would have been obvious to one of ordinary skill in the art to choose high-density polystyrene as the material since it well known to use polystyrene in the medical arts.

Claims 4, 5, 18, 25, 30, & 31 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest that the apparatus holds a blood filter in combination with the other limitations in the claims.