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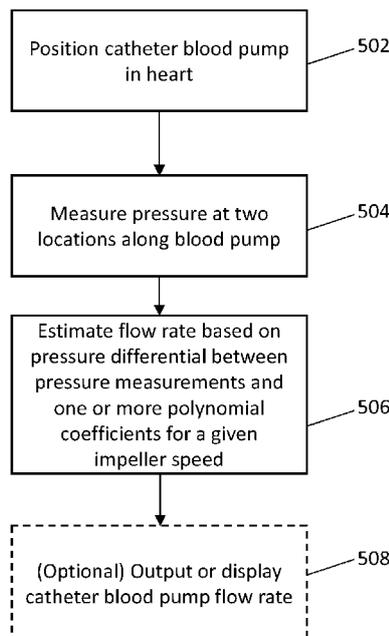
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17 April 2025 (17.04.2025)

(54) Title: CATHETER BLOOD PUMPS AND ASSOCIATED METHODS

FIG. 5



(57) Abstract: Catheter blood pump positioning techniques, methods, and algorithms are described. In one embodiment, pressure sensor measurements are used to determine the distance to the aortic valve and the left ventricle. An optimal positioning location can be determined based on the pressure sensor measurements. The catheter blood pump can then be optimally positioned to locate the inlet in the ventricle and the outlet in the aorta.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/26768

A. CLASSIFICATION OF SUBJECT MATTER IPC - INV. A61M 60/816, A61M 60/531, A61M 60/538 (2024.01) ADD. A61M 60/13, A61M 60/178, A61M 60/216, A61M 60/855, A61M 60/90 (2024.01) CPC - INV. A61M 60/816, A61M 60/531, A61M 60/538 ADD. A61M 60/13, A61M 60/178, A61M 60/216, A61M 60/855, A61M 60/90, A61M 60/00 According to International Patent Classification (IPC) or to both national classification and IPC																						
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) See Search History document Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched See Search History document Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) See Search History document																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
<table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X ---</td> <td>US 2010/0222634 A1 (Poirier) 2 September 2010 (02.09.2010), entire document, especially Fig 1, para [0007], para [0017]-[0018], para [0061]-[0070]</td> <td>1-6, 8, 21</td> </tr> <tr> <td>Y</td> <td></td> <td>7, 9-10</td> </tr> <tr> <td>Y</td> <td>US 2022/0241578 A1 (Abiomed Europe GmbH) 4 August 2022 (04.08.2022), entire document, especially Fig 1-2, Fig 8, para [0078]-[0080], para [0091]-[0092], para [0134]-[0135]</td> <td>7</td> </tr> <tr> <td>Y</td> <td>US 8,631,680 B2 (Fleischli et al.) 21 January 2014 (21.01.2014), entire document, especially col 2, ln 46-50; col 3, ln 12-17; col 4, ln 11-35; col 5, ln 31-42</td> <td>9-10</td> </tr> <tr> <td>A</td> <td>US 2013/0072846 A1 (Heide et al.) 21 March 2013 (21.03.2013), entire document</td> <td>1-10, 21</td> </tr> <tr> <td>A</td> <td>US 2013/0030240 A1 (Schima et al.) 31 January 2013 (31.01.2013), entire document</td> <td>1-10, 21</td> </tr> </tbody> </table>	Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X ---	US 2010/0222634 A1 (Poirier) 2 September 2010 (02.09.2010), entire document, especially Fig 1, para [0007], para [0017]-[0018], para [0061]-[0070]	1-6, 8, 21	Y		7, 9-10	Y	US 2022/0241578 A1 (Abiomed Europe GmbH) 4 August 2022 (04.08.2022), entire document, especially Fig 1-2, Fig 8, para [0078]-[0080], para [0091]-[0092], para [0134]-[0135]	7	Y	US 8,631,680 B2 (Fleischli et al.) 21 January 2014 (21.01.2014), entire document, especially col 2, ln 46-50; col 3, ln 12-17; col 4, ln 11-35; col 5, ln 31-42	9-10	A	US 2013/0072846 A1 (Heide et al.) 21 March 2013 (21.03.2013), entire document	1-10, 21	A	US 2013/0030240 A1 (Schima et al.) 31 January 2013 (31.01.2013), entire document	1-10, 21	
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* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family																						
Date of the actual completion of the international search 22 July 2024 (22.07.2024)	Date of mailing of the international search report OCT 18 2024																					
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	Authorized officer Kari Rodriguez Telephone No. PCT Helpdesk: 571-272-4300																					

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 24/26768

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

- 1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

- 2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

- 3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
- see extra sheet -

- 1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
- 2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
- 3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

- 4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10, 21

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/26768

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-10 and 21 directed to a method and computing device readable medium for estimating a flow rate of a catheter blood pump.

Group II: Claims 11-20 directed to a catheter blood pump with a processor to estimate a flow rate.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of a method comprising positioning a catheter blood pump in a heart of a subject; activating an impeller of the catheter blood pump to move blood from an inlet, through a blood conduit, and out of an outlet of the catheter blood pump; continuously or intermittently recording first and second pressure signals with first and second pressure sensors of the catheter blood pump; and estimating a flow rate of the catheter blood pump based on a pressure differential between the first and second pressure signals and one or more polynomial or piecewise polynomial coefficients for a given impeller speed of the catheter blood pump; and a non-transitory computing device readable medium having instructions stored thereon, wherein the instructions are executable by a processor to cause a computing device to perform a method comprising: receive an impeller pump speed of a catheter blood pump; receive a first pressure signal from a first pressure sensor of the blood pump; receive a second pressure signal from a second pressure sensor of the blood pump; receive one or more polynomial or piecewise polynomial coefficients based on a given impeller speed; and estimate a flow rate of the catheter blood pump based on a pressure differential between the first and second pressure signals and the one or more polynomial or piecewise polynomial coefficients, not required by the claims of Group II.

The invention of Group II includes the special technical features of an expandable blood conduit defining a lumen between an inlet and an outlet; an impeller at least partially disposed within the blood conduit; not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of a catheter blood pump, comprising: a blood conduit defining a lumen between an inlet and an outlet; an impeller; a first pressure sensor configured to measure a first pressure signal; a second pressure sensor configured to measure a second (* see note below *) pressure signal; one or more processors operatively coupled to the impeller and the first and second pressure sensors, the one or more processors being configured to estimate a flow rate of the catheter blood pump based on a pressure differential between the first and second pressure signals and one or more polynomial or piecewise polynomial coefficients for a given impeller speed of the catheter blood pump. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US-2010/0222634 A1 to Poirier. Poirier discloses a catheter blood pump (see implanted blood pump 10, Fig 1; ventricular assistance pump with inflow and outflow conduits, para [0002], para [0017]), comprising: a blood conduit defining a lumen between an inlet and an outlet (see how 10 comprises a blood conduit defining a lumen between an inlet 60 and outlet 70, Fig 1; blood pump 10 inflow conduit 60 and outflow conduit 70, para [0017]); an impeller (see pump housing 50 including unshown impeller, Fig 1; pump housing 50, para [0017]; embodiment allows for determining blood pump flow, para [0019]; calculating blood flow based on measured rotations of an impeller, para [0007]); a first pressure sensor configured to measure a first pressure signal (see 65, Fig 1; sensor 65 to measure blood pressure at the inflow conduit 60, para [0018]); a second pressure sensor configured to measure a second pressure signal (see 75, Fig 1; sensor 75 to measure blood pressure at the outflow conduit 70, para [0018]); one or more processors (controller 80, para [0019]; controller 80 includes a processor, para [0067]-[0068]) operatively coupled to the impeller (80 is used in association with methods described, para [0067]; method for monitoring blood flow based on blood pump motor speed, para [0061]-[0065]; determining motor speed based on measured rotations of impeller, para [0007]) and the first and second pressure sensors (sensors 65 and 75 send information regarding blood pressure to 80, para [0018]-[0019]), the one or more processors being configured to estimate a flow rate of the catheter blood pump (80 is used in association with methods described, para [0067]; method for measuring blood flow through the pump, para [0007]; para [0061]) based on a pressure differential between the first and second pressure signals (blood flow calculated by the controller based on pump outlet pressure minus pump inlet pressure, para [0063]-[0064]) and one or more polynomial or piecewise polynomial coefficients (C, para [0064]) for a given impeller speed of the catheter blood pump (flow determined by using a look up table of flow as a function of the pressure drop in combination with motor speed, para [0065]; impeller coupled to the motor, para [0007]).

* Note: The recitation "a second pressure sensor configured to measure a first pressure signal" in claim 11 of the second group appears to be a typographical error and has been interpreted as "a second pressure sensor configured to measure a second pressure signal".

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.