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### Pressure sensing ventricular assist devices and methods of use

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#### Abstract

The invention generally relates to heart pump systems. In some embodiments, a pressure sensor is provided with a heart pump, either at the inflow or the outflow of the blood pump. The heart pump may further include a flow estimator based on a rotor drive current signal delivered to the rotor. Based on the rotor drive current signal, a differential pressure across the pump may be calculated. The differential pressure in combination with the pressure measurements from the pressure sensor may be used to calculate pressure on the opposite side of the pump from the pressure sensor. In some embodiments, the pressure sensor is located at the outflow of the pump and the pump is coupled with the left ventricle. The differential pressure and pressure measurement may be used to calculate a left ventricular pressure waveform of the patient. With such a measurement, other physiological parameters may be derived.

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References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
3911897	12/1974	Leachman, Jr.	N/A	N/A
5139517	12/1991	Corral	N/A	N/A
5318592	12/1993	Schaldach	N/A	N/A
5503615	12/1995	Goldstein	N/A	N/A
6066086	12/1999	Antaki et al.	N/A	N/A
6111520	12/1999	Allen et al.	N/A	N/A
6176822	12/2000	Nix et al.	N/A	N/A
6278379	12/2000	Allen et al.	N/A	N/A
6585635	12/2002	Aldrich	N/A	N/A
6634224	12/2002	Schoeb et al.	N/A	N/A
6643420	12/2002	Han et al.	N/A	N/A
6772011	12/2003	Dolgin	N/A	N/A
6855115	12/2004	Fonseca et al.	N/A	N/A
6984201	12/2005	Khaghani et al.	N/A	N/A
7029433	12/2005	Chang	N/A	N/A
7245117	12/2006	Joy et al.	N/A	N/A
7320706	12/2007	Al-Najjar	N/A	N/A
7439723	12/2007	Allen et al.	N/A	N/A
7498799	12/2008	Allen et al.	N/A	N/A
7520850	12/2008	Brockway	N/A	N/A
7550978	12/2008	Joy et al.	N/A	N/A
7679355	12/2009	Allen et al.	N/A	N/A
7839153	12/2009	Joy et al.	N/A	N/A

7853325	12/2009	Dabney et al.	N/A	N/A
7862501	12/2010	Woodard	N/A	N/A
7945333	12/2010	Jacobson	N/A	N/A
7963905	12/2010	Salmonsens et al.	N/A	N/A
7988728	12/2010	Ayre	N/A	N/A
7998054	12/2010	Bolling	N/A	N/A
8145324	12/2011	Stevenson et al.	N/A	N/A
8177838	12/2011	Vodermayer et al.	N/A	N/A
8180448	12/2011	Stevenson et al.	N/A	N/A
8224462	12/2011	Westlund et al.	N/A	N/A
8246530	12/2011	Sullivan	N/A	N/A
8295939	12/2011	Jacobson	N/A	N/A
8364283	12/2012	Halperin et al.	N/A	N/A
8506471	12/2012	Bourque	N/A	N/A
8543205	12/2012	Ostroff	N/A	N/A
8608636	12/2012	Choi et al.	N/A	N/A
8657733	12/2013	Ayre et al.	N/A	N/A
8682431	12/2013	Callaway et al.	N/A	N/A
8712544	12/2013	Dabney et al.	N/A	N/A
8771165	12/2013	Choi et al.	N/A	N/A
8794989	12/2013	Kearsley et al.	N/A	N/A
8852099	12/2013	Von Arx et al.	N/A	N/A
8864644	12/2013	Yomtov	N/A	N/A
8894561	12/2013	Callaway et al.	N/A	N/A
8897887	12/2013	Halperin et al.	N/A	N/A
9039595	12/2014	Ayre et al.	N/A	N/A
9090271	12/2014	Bartonek	N/A	N/A
9387284	12/2015	Heilman et al.	N/A	N/A
9433714	12/2015	Voskoboynikov et al.	N/A	N/A
9579432	12/2016	Tamez et al.	N/A	N/A
9579435	12/2016	Yomtov	N/A	N/A
9592327	12/2016	Wariar et al.	N/A	N/A
9833552	12/2016	Yomtov	N/A	N/A
10780209	12/2019	Harjes et al.	N/A	N/A
10835654	12/2019	Harjes	N/A	A61B 5/0031
11779234	12/2022	Harjes	600/17	A61B 5/029
2005/0071001	12/2004	Jarvik	N/A	N/A
2007/0088397	12/2006	Jacobson	N/A	N/A
2008/0281146	12/2007	Morello	N/A	N/A
2010/0241223	12/2009	Lee et al.	N/A	N/A
2011/0178361	12/2010	Yomtov	N/A	N/A
2011/0270331	12/2010	Peters et al.	N/A	N/A
2012/0253207	12/2011	Sarkar et al.	N/A	N/A
2012/0271367	12/2011	Qu et al.	N/A	N/A
2013/0072846	12/2012	Heide et al.	N/A	N/A
2014/0012067	12/2013	Poirier	N/A	N/A
2014/0046120	12/2013	Choi et al.	N/A	N/A
2014/0058190	12/2013	Gohean et al.	N/A	N/A
2014/0188148	12/2013	le Blanc et al.	N/A	N/A

2015/0057488	12/2014	Yomtov	N/A	N/A
2015/0073203	12/2014	Wariar et al.	N/A	N/A
2015/0148587	12/2014	Bourque	N/A	N/A
2015/0151032	12/2014	Voskoboynikov et al.	N/A	N/A
2015/0174307	12/2014	Eckman et al.	N/A	N/A
2015/0290374	12/2014	Bourque et al.	N/A	N/A
2015/0328466	12/2014	Peters et al.	N/A	N/A
2016/0058929	12/2015	Medvedev et al.	N/A	N/A
2016/0058930	12/2015	Medvedev et al.	N/A	N/A
2016/0101230	12/2015	Ochsner et al.	N/A	N/A
2016/0193397	12/2015	Aber et al.	N/A	N/A
2016/0228628	12/2015	Medvedev et al.	N/A	N/A
2016/0263299	12/2015	Xu et al.	N/A	N/A
2017/0021070	12/2016	Petersen	N/A	N/A
2017/0080138	12/2016	Yomtov	N/A	N/A
2017/0128646	12/2016	Karch	N/A	N/A
2018/0050348	12/2017	Whitney	N/A	N/A
2018/0078689	12/2017	Yomtov	N/A	N/A
2018/0140760	12/2017	Cotter	N/A	N/A
2018/0280599	12/2017	Harjes et al.	N/A	N/A
2018/0280600	12/2017	Harjes et al.	N/A	N/A
2018/0280601	12/2017	Harjes et al.	N/A	N/A

#### **FOREIGN PATENT DOCUMENTS**

<b>Patent No.</b>	<b>Application Date</b>	<b>Country</b>	<b>CPC</b>
2570143	12/2012	EP	N/A
3213781	12/2016	EP	N/A
2007089500	12/2006	WO	N/A
2011123789	12/2010	WO	N/A
2016001284	12/2015	WO	N/A
2016137743	12/2015	WO	N/A
2017117185	12/2016	WO	N/A
2017117215	12/2016	WO	N/A
2017139113	12/2016	WO	N/A

#### **OTHER PUBLICATIONS**

Bedi et al., “Ventricular Arrhythmias During Left Ventricular Assist Device Support”, American Journal of Cardiology, vol. 99, No. 8, Apr. 15, 2007, pp. 1151-1153. cited by applicant

Brisco et al., “The Incidence, Risk, and Consequences of Atrial Arrhythmias in Patients with Continuous-Flow Left Ventricular Assist Devices”, Journal of Cardiac Surgery, vol. 29, No. 4, Jul. 2014, pp. 572-580. cited by applicant

Clark et al., “Hemodynamic Effects of an Irregular Sequence of Ventricular Cycle Lengths During Atrial Fibrillation”, Journal of the American College of Cardiology, vol. 30, No. 4, Oct. 1997, pp. 1039-1045. cited by applicant

Enriquez et al., “Clinical Impact of Atrial Fibrillation in Patients with the Heartmate II Left Ventricular Assist Device”, Journal of the American College of Cardiology, vol. 64, No. 18, Nov. 4, 2014, pp. 1883-1890. cited by applicant

Hayward et al., “Effect of Alteration in Pump Speed on Pump Output and Left Ventricular Filling with Continuous-Flow Left Ventricular Assist Device”, ASAIO Journal, vol. 57, No. 6, Nov. 2011, pp. 495-500. cited by applicant

Maeda et al., "Predictive Control by Physical Activity Rate of a Total Artificial Heart During Exercise", Transactions of the American Society of Artificial Internal Organs, vol. 34, No. 3, Jul.-Sep. 1988, pp. 480-484. cited by applicant

Maury et al., "First Experience of Percutaneous Radio-Frequency Ablation for Atrial Flutter and Atrial Fibrillation in a Patient with Heartmate II Left Ventricular Assist Device", Journal of Interventional Cardiac Electrophysiology, vol. 29, No. 1, Oct. 2010, pp. 63-67. cited by applicant

Oswald et al., "Implantable Defibrillator Therapy for Ventricular Tachyarrhythmia in Left Ventricular Assist Device Patients", European Journal of Heart Failure, vol. 12, No. 6, Jun. 2010, pp. 593-599. cited by applicant

Oz et al., "Malignant Ventricular Arrhythmias are Well Tolerated in Patients Receiving Long-Term Left Ventricular Assist Devices", Journal of the American College of Cardiology, vol. 24, No. 7, Dec. 1994, pp. 1688-1691. cited by applicant

Raasch et al., "Epidemiology, Management, and Outcomes of Sustained Ventricular Arrhythmias After Continuous-Flow Left Ventricular Assist Device Implantation", American Heart Journal, vol. 164, No. 3, Sep. 2012, pp. 373-378. cited by applicant

Ziv et al., "Effects of Left Ventricular Assist Device Therapy on Ventricular Arrhythmias", Journal of the American College of Cardiology, vol. 45, No. 9, May 3, 2005, pp. 1428-1434. cited by applicant

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## **Background/Summary**

CROSS-REFERENCE TO RELATED APPLICATIONS (1) The present application is a Continuation of U.S. patent Application Ser. No. 17/028,687 filed Sep. 22, 2020 (Allowed); which is a Continuation of U.S. patent Application Ser. No. 15/939,105 filed Mar. 28, 2018 (now U.S. Pat. No. 10,835,654); which claims the benefit of U.S. Provisional Appln No. 62/478,492 filed Mar. 29, 2017; the full disclosures which are incorporated herein by reference in their entirety for all purposes.

### **BACKGROUND**

(1) Heart disease is a growing epidemic in the United States that can lead to heart failure. Heart failure is characterized as a progressive, downward spiral in heart function. In particular, cardiac injury can cause cardiac dysfunction, which results in reduced cardiac output. Some results of reduced cardiac output are endothelial dysfunction, neurohormonal activation, renal impairment, and vasoconstriction. These results can lead to fluid retention and increased systemic vascular resistance. An increase in systemic vascular resistance can create increased cardiac load which can cause further cardiac dysfunction. Thus a cycle of further cardiac dysfunction can be established.

(2) Although there are various treatments proposed and being developed for treating heart failure, such systems are generally limited to the hospital setting or at least require the patient to be very limited in mobility if not completely confined to a bed. Some patients have turned to implantable blood pumps, such as ventricular assist devices (VAD), for assisting in heart pumping or effectively replacing the natural heart's function. Most patients recover in a way where they improve in functional class, however, only a small percentage of patients exhibit restoration to the point of explant and the number of hearts available for heart transplant is insufficient to meet demand. As such, the blood pumps are typically required for life. Accordingly, it may be advantageous to further improve blood pump devices, systems, and methods to coordinate pumping functions and to

monitor patient physiological parameters during the long term implantation (e.g., destination therapy or bridge to transplantation) of the implantable blood pump so there is continuing need to improve pumps and LVAD therapy. Here, there is need for pressure reading to better provide therapy and/or actively adjust pump parameters based on the patient. For example, a patient may recover over time and the pump can be adjusted accordingly. Optionally, the pump may be adjusted for patient exercise or activity.

#### BRIEF SUMMARY

(3) The present invention generally relates to heart pump systems and methods of use. In some embodiments, a method of hemodynamic monitoring is provided for a patient having an implanted heart pump. In further embodiments, a heart pump is provided that may monitor physiological parameters of the patient and may adjust pumping (e.g., speed, mode, flow rate, or the like) in response to the monitored parameters and/or may report the monitored parameters to a physician.

(4) Many rotary blood pumps may estimate flow through the heart pump, for example, by sensing the electrical current required to drive the rotor at a particular speed. This information may be beneficial for clinicians for determining changes in pump performance associated with a physiological state (e.g., suction detection, patient hypertension, etc.). However, the pump flow rate information alone may be of limited value in diagnosing the patient's hemodynamic state and/or determining if the heart pump is providing adequate flow support (or too much or too little). Patients may have dramatically different cardiac output needs and these needs may change depending on a number of factors (e.g., rest, exercise, stress, left ventricular recovery, time of day, etc.).

(5) Cardiovascular pressure measurements can provide a host of valuable data that is directly applicable for determining a patient's hemodynamic state and optimizing blood pump settings. For example, a physician may want to specifically tailor a pump flow rate or pump speed depending on patient characteristics. To determine the appropriate flow rate or speed, the physician may benefit from additional information, such as the left ventricular pressure, pulmonary arterial pressure, etc. There are a number of potential sensor devices and locations applicable to the present invention. In particular, real time high speed (e.g., ~50 Hz) pressure measurements of the left ventricle and the aorta may be particularly valuable for left ventricular assist device (LVAD) applications. With such measurements, other clinical parameters may be derived, such as systolic arterial pressure, diastolic arterial pressure, mean arterial pressure, systemic resistance estimation, aortic compliance estimation, end diastolic pressure (LV filling pressure), end systolic pressure, LV contractility estimation, degree of aortic valve opening, stroke volume and/or cardiac output estimation. Additionally, pressure measurements may be used to increase the accuracy of flow rate estimations based on drive current, similar to the concepts described in U.S. patent Application Ser. No. 15/212,721 (now issued as U.S. Pat. No. 10,722,630), the contents of which are incorporated herein by reference in their entirety.

(6) In some embodiments of the present invention, a method for hemodynamic monitoring of a patient may be provided. The method may include receiving a differential pressure across the heart pump having an inflow and an outflow. A pressure measurement may be received from a pressure sensor positioned in the inflow or the outflow of the heart pump. A data waveform of interest may be calculated from the differential pressure across the heart pump and the pressure measurement from the pressure sensor positioned in the inflow or the outflow of the heart pump.

(7) In some embodiments, the calculated data waveform of interest may be outputted (e.g., to a patient or a clinician). In some embodiments, a pumping of the heart pump may be adjusted in response to the calculated data waveform. In some embodiments, the pressure sensor is positioned in the outflow of the heart pump. The differential pressure across the heart pump may be calculated based on a rotor drive current associated with the heart pump. In some embodiments, the data waveform of interest comprises a left ventricular pressure waveform and the left ventricular pressure waveform may be calculated by subtracting the differential pressure from the pressure

measurement.

(8) In further aspects of the present invention, a blood pump system may be provided. The system may include a blood pump comprising an inlet and an outlet. A pressure sensor may be provided that is coupled with the inlet or the outlet of the blood pump. A controller operably coupled with the blood pump and the pressure sensor may be configured to receive a differential pressure across the blood pump and a pressure measurement from the pressure sensor. The controller may be configured to calculate a data waveform of interest from the differential pressure across the blood pump and the pressure measurement from the pressure sensor.

(9) In some embodiments, the controller is configured to output the calculated data waveform. Optionally, the controller is configured to adjust a pumping of the heart pump in response to the calculated data waveform. In some embodiments, the sensor is positioned on the outflow of the blood pump. In some embodiments, the controller calculates the differential pressure across the blood pump based on a rotor driver current associated with the blood pump. In certain embodiments, the data waveform of interest comprises a left ventricular pressure waveform and the left ventricular pressure waveform may be calculated by subtracting the differential pressure from the pressure measurement.

(10) Embodiments of the disclosure covered by this patent are defined by the claims below, not this summary. This summary is a high-level overview of various aspects of the invention and introduces some of the concepts that are further described in the Detailed Description section below. This summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used in isolation to determine the scope of the claimed subject matter. The subject matter should be understood by reference to appropriate portions of the entire specification of this patent, any or all drawings, and each claim.

(11) The disclosure will be better understood upon reading the following description and examining the figures which accompany it. These figures are provided by way of illustration only and are in no way limiting on the invention.

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## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

(1) Further details, aspects, and embodiments of the invention will be described by way of example only and with reference to the drawings. In the drawings, like reference numbers are used to identify like or functionally similar elements. Elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale.

(2) FIG. 1 illustrates an exemplary method according to some embodiments.

(3) FIG. 2 illustrates an exemplary system according to some embodiments.

(4) FIG. 3 illustrates an exemplary I-Q curve lookup table.

(5) FIG. 4 illustrates an exemplary I-H curve lookup table.

(6) FIG. 5 illustrates an exemplary heart pump system according to some embodiments.

(7) FIG. 6 illustrates another exemplary heart pump system according to some embodiments.

(8) FIG. 7 illustrates another exemplary heart pump system according to some embodiments.

(9) FIG. 8 illustrates another exemplary heart pump system according to some embodiments.

(10) FIG. 9 illustrates another exemplary heart pump system according to some embodiments.

(11) FIG. 10 illustrates an exemplary implantation location of a heart pump according to some embodiments.

(12) FIG. 11 illustrates another exemplary implantation location of a heart pump according to some embodiments.

### DETAILED DESCRIPTION

(13) FIG. 1 illustrates an exemplary method **100** for estimating physiological waveforms of interest

of a patient with a blood pump according to some embodiments. The method **100** may include receiving a rotor drive current signal of the blood pump **102**. A pressure sensor signal that is associated with an input or an output of the blood pump may also be received **104**. A differential pressure across the blood pump may be calculated based on the received rotor drive current signal **106**. A physiological waveform of the patient may be calculated based on the received pressure sensor signal and the differential pressure across the blood pump **108**. Thereafter, the calculated physiological waveform may be outputted **110**. Additionally, a pumping operation of the blood pump may be adjusted in response to the calculated physiological waveform **112**.

(14) Method **100** may be used to estimate the left ventricular pressure waveform. Additionally, the aortic pressure waveform may be calculated separate from or in addition to the left ventricular pressure waveform. With such measurements, other clinical parameters may be derived, such as: systolic arterial pressure, diastolic arterial pressure, mean arterial pressure, systemic resistance estimation, aortic compliance estimation, end diastolic pressure (LV filling pressure), end systolic pressure, LV contractility estimation, degree of aortic valve opening, stroke volume and cardiac output estimation. While generally discussed as estimating parameters associated with the left ventricle, it should be understood that the method **100** is applicable to measuring parameters associated with other chambers of the heart (e.g., right ventricle, left atrium, etc.), depending on where the heart pump is implanted.

(15) FIG. **2** illustrates an exemplary heart pump system **200** according to some embodiments that may be configured to carry out method **100** of FIG. **1** to estimate left ventricular pressure waveform, VAD flow waveform, and aortic pressure waveform. Heart pump system **200** comprises a left ventricular heart pump **202** and a controller **203**. In some embodiments, the pump **202** can be configured similar to an LVAD described in U.S. Pat. No. 9,694,123; U.S. Patent Publication 2014/0188148; U.S. Pat. Nos.: 9,091,271; 8,794,989, 8,682,431; and/or 8,894,561, the contents of which are incorporated herein by reference in their entirety. The heart pump **202** includes a housing **204**. Housing **204** encloses a motor **206** and rotor **208**. Housing **204** may also house a pressure sensor **210**. Optionally, pressure sensor **210** may be wired directly to the motor **206**. While pressure sensor **210** is illustrated as positioned in the outflow of heart pump **202**, in other embodiments, pressure sensor **210** may be positioned in the inflow of heart pump **202**.

(16) Controller **203** may be an on-board controller of heart pump **202** or may be an external controller (e.g., coupled to the heart pump **202** through a percutaneous cable, wirelessly, or the like). Controller **203** may be operably coupled with the motor **206** and the pressure sensor **210** and may receive a rotor drive current signal **212** and a pressure sensor signal **214** from the heart pump **202**. With the received rotor drive current signal **212**, the controller **203** may estimate a pump flow by accessing a lookup table **216** associating the received current signal (I) to pump flow rate (Q). FIG. **3** illustrates an exemplary I-Q curve lookup table **300**. In some embodiments, rotor rpm and/or hematocrit may be used, in addition with or alternatively to, current signal to provide an accurate flow rate calculation. By continuously estimating pump flow, the controller **203** may estimate a VAD flow waveform **218**. Additionally, with the received rotor drive current signal **212**, the controller **203** may also estimate a differential pressure across the pump by accessing a lookup table **220** associating the received current signal (I) to differential pressure across the pump (dP). In some embodiments, the rotor rpm and/or hematocrit may be used, in addition with or alternatively to, rotor current signal to provide an accurate differential pressure measurement. In some embodiments which use magnetic levitation rotors, hall effect sensor signals may be used to provide rotor positional information which may also be a pressure dependent phenomenon. Accordingly, rotor positional information and/or hall effect sensor signals may be used in addition, or alternatively, to rotor current, rotor rpm, and/or hematocrit to provide accurate differential pressure measurements. U.S. Pat. No. 9,901,666 describes systems and methods that use hall effect sensors to provide rotor positional information, the contents of which are incorporated herein by reference in their entirety, which may be used with embodiments of the present disclosure to



provide differential pressure measurements, ventricular pressure measurements, and proxies thereto. In some embodiments, both rotor current signal and positional information may be used to provide accurate differential pressure measurements. For example, rotor current signal may be more accurate for a first range, and positional information may be more accurate for a second range. FIG. 4 illustrates an exemplary I-H curve lookup table **400**. In some embodiments, heart rate, start of systole, and/or start of diastole may be identified using the methods and systems described in U.S. Pat. No. 10,052,420, the contents of which is incorporated herein by reference in its entirety, and the pump speed may be modulated accordingly based on one or more of those identified parameters. The controller **203** may calculate the left ventricular pressure waveform **222** by subtracting the estimated differential pressures from the received pressure sensor signal **214**. Additionally, the controller **203** may associate the pressure sensor signal **214** with an aortic pressure waveform **224** when the outflow of the heart pump **202** is coupled with the aorta of the patient. The controller **203** may output the VAD flow waveform **218**, the left ventricular pressure waveform **222**, and/or the aortic pressure waveform **224** to a user or clinician. As mentioned above, with such measurements, other clinical parameters may be derived, such as: systolic arterial pressure, diastolic arterial pressure, mean arterial pressure, systemic resistance estimation, aortic compliance estimation, end diastolic pressure (LV filling pressure), end systolic pressure, LV contractility estimation, degree of aortic valve opening, stroke volume and cardiac output estimation. Accordingly, these waveforms could be run through subsequent algorithms to calculate added clinical parameters of interest (e.g., cardiac output, heart rate, etc.).

(17) The controller **203** may also be configured to adjust the pumping operation of the pump in response to the estimated VAD flow waveform **218**, the left ventricular pressure waveform **222**, and/or the aortic pressure waveform **224**. For example, in some embodiments, the left ventricular pressure waveform **222** may be associated with a heart rate of a patient, thereby providing patient activity information. The heart rate may be automatically calculated by analyzing the rate of left ventricular pressure change in the estimated left ventricular pressure waveform **222** which can also indicates the start of systole. In some embodiments, a threshold rate of left ventricular pressure change may be used to identify individual heart beats in the calculated left ventricular pressure waveform. With changes in heart rate or activity of a patient, a pumping operation of a heart pump **202** may be increased (during increased heart rate/activity) or decreased (during decreased heart rate/activity) in response. This may be particularly advantageous as separate patient heart rate sensor or activity monitor may not be needed, thereby possibly reducing complexity and power consumption of a system **200**.

(18) In addition, a left ventricular contractility estimate may be estimated based on the left ventricular pressure waveform. For example, the contractility estimate may be associated with a gradient of a train of the left ventricular pressure waveform.

(19) The measured pressure may act as a proxy for one or more other clinical parameters, including but not limited to filling pressure, systolic arterial pressure, diastolic arterial pressure, mean arterial pressure, systemic resistance estimation, aortic compliance estimation, end diastolic pressure, end systolic pressure, LV contractility estimation, degree of aortic valve opening, and/or stroke volume and cardiac output estimation. For example, a left ventricular pressure waveform and an aortic pressure waveform may be used to calculate one or more of the above parameters.

(20) While heart pump **202** is generally illustrated as a centrifugal flow heart pump, it should be understood that heart pump **202** may have other configurations. For example, in some embodiments, heart pump **202** may be an axial flow blood pump or a mixed flow blood pump.

(21) Pressure sensor may be interrogated at a fast rate (~50 Hz) in combination with rotor torque measurements to provide real-time waveforms for LV pressure, VAD flow, and aortic pressure. Further, as mentioned above pressure sensor **210** may be integrated in the inflow of heart pump **202**. For example, FIG. 5 illustrates an exemplary heart pump system **500** that includes a pump **502** and an external controller **504**. The pump **502** and the external controller **504** may be operably

connected to one another (e.g., by a percutaneous cable **506** or the like). The pump **502** may include an inflow **508** coupled to a chamber of the heart and an outflow **510** coupled with an aorta of the patient. The heart pump system **500** may further include a pressure sensor **512** along a portion of the inflow **508** of the heart pump **502**. While inflow **508** is illustrated as coupled to the left ventricle, it should be understood that inflow **508** may be coupled to other chambers of the heart, such as the right ventricle or the left atrium. Depending on the implantation location, a pump **502** may be switched to alternative pre-programmed configurations for measuring particular heart parameters (e.g., right ventricular pressure waveforms, left atrium pressure waveforms, associated filling pressures/contractility, etc.).

(22) Alternatively, the pressure sensor **210** may be connected via flying lead (wired). In some embodiments, it may be advantageous to integrate the sensor **210** directly into the pump housing. For example, the sensor **210** could be directly wired to the motor electronics and the sensor **210** itself may be well protected from damage during use. In addition, the volute/outflow is typically less prone to tissue buildup/fouling than the LV or pump inflow. In such embodiments, the sensor **210** may be located anywhere from the volute to the aorta.

(23) Many traditional sensors could be used, including MEMS, strain gauges, piezo-based sensors, capacitive sensors, transonic, ultrasound Doppler, or the like. U.S. Provisional Patent Application No. 62/194,700 and U.S. Provisional Patent Application No. 62/194,608 describe pressure sensor configurations and pressure sensing methods that may be utilized in embodiments of the present disclosure. The contents of each provisional patent application are incorporated herein in their entirety for all purposes.

(24) Additionally, heart pump **202** is generally described for implantation in the left ventricle and for estimation of left ventricular parameters, but heart pump **202** may also be configured to couple with other portions of the heart. For example, in some embodiments, heart pump **202** may couple with the right ventricle, as illustrated in FIG. **10**, or the left atrium, as illustrated in FIG. **11**. The controller **203** may be switched to different pre-programmed configurations depending on the implantation location, so that the signal processing output is associated with the correct physiological parameters. For example, if the heart pump **202** is directly cannulated to the right ventricle, it may be programmed to output the right ventricular pressure waveform and/or the pulmonary arterial pressure waveform using similar signal processing described above. Similarly, if the heart pump **202** is directly cannulated to the left atrium, it may be programmed to output the left atrial pressure waveform using similar signal processing described above.

(25) In still further embodiments of the present disclosure, a pressure differential across the pump may be received from a plurality of pressure sensors of the heart pump in the alternative to (or in addition to) computing the pressure differential based on a rotor drive current signal. For example, FIG. **6** illustrates an exemplary heart pump system **600**. System **600** includes a pump **602** and an external controller **604**. The pump **602** and the external controller **604** may be operably connected to one another (e.g., by a percutaneous cable **606** or the like). The pump **602** may include an inflow **608** coupled to a chamber of the heart (illustrated as the left ventricle, but other chambers may be cannulated by inflow **608**) and an outflow **610**. The inflow **608** may include an upstream pressure sensor **612** and a downstream pressure **614**. The upstream and downstream pressure sensors **612**, **614** may provide differential pressure information between the upstream and downstream pressure sensors **612**, **614** and may also provide flow information. Further, the two sensors **612**, **614** may provide more accurate pressure measurements and may help calibrate measurements to account for sensor drift. In some embodiments, where the inflow has sufficient hydraulic resistance therethrough, the pressure sensors **612**, **614** may provide flow information.

(26) FIG. **7** illustrates another exemplary heart pump system **600a**. Heart pump system **600a** is similar to system **600** of FIG. **6**, except upstream pressure sensor **612a** is positioned along the inflow **608** and the downstream pressure sensor **614a** is positioned along the outflow **610**. The upstream and downstream pressure sensors **612a**, **614a** may provide differential pressure

information between the upstream and downstream pressure sensors **612a**, **614a** and may also provide flow information. Further, the two sensors **612a**, **614a** may provide more accurate pressure measurements and may help calibrate measurements to account for sensor drift. In some embodiments, where the fluid conduit between the inflow and outflow has sufficient hydraulic resistance therethrough, the pressure sensors **612a**, **614a** may provide flow information.

(27) FIG. **8** illustrates another exemplary heart pump system **600b**. Heart pump system **600b** is similar to system **600** of FIG. **6**, except upstream pressure sensor **612b** is positioned along the outflow **610** and the downstream pressure sensor **614b** is positioned along the outflow **610** downstream from upstream pressure sensor **612b**. The upstream and downstream pressure sensors **612b**, **614b** may provide differential pressure information between the upstream and downstream pressure sensors **612b**, **614b** and may also provide flow information. Further, the two sensors **612b**, **614b** may provide more accurate pressure measurements and may help calibrate measurements to account for sensor drift. In some embodiments, where the outflow has sufficient hydraulic resistance therethrough, the pressure sensors **612b**, **614b** may provide flow information.

(28) FIG. **9** illustrates another exemplary heart pump system **600c**. Heart pump system **600c** is similar to the system **600** of FIG. **6** but may further include a pressure sensor **800** that is configured to be implanted within the pulmonary artery of the patient. In some embodiments, the heart pump system **600c** does not include pressure sensors integrated with the heart pump **602**. The pressure sensor **800**, however, may be operably coupled (wired or wirelessly) with pump **602** to transmit pressure measurements from the pulmonary artery. The pump **602** or external controller **604** may analyze the pulmonary arterial pressure waveform and may estimate a left atrial pressure waveform or left ventricular pressure waveform based on the pulmonary arterial pressure waveform. In some embodiments, the ventricular pressure may serve as a proxy for pulmonary arterial pressure.

(29) One or more computing devices may be adapted to provide desired functionality by accessing software instructions rendered in a computer-readable form. When software is used, any suitable programming, scripting, or other type of language or combinations of languages may be used to implement the teachings contained herein. However, software need not be used exclusively, or at all. For example, some embodiments of the methods and systems set forth herein may also be implemented by hard-wired logic or other circuitry, including but not limited to application-specific circuits. Combinations of computer-executed software and hard-wired logic or other circuitry may be suitable as well.

(30) Embodiments of the methods disclosed herein may be executed by one or more suitable computing devices. Such system(s) may comprise one or more computing devices adapted to perform one or more embodiments of the methods disclosed herein. As noted above, such devices may access one or more computer-readable media that embody computer-readable instructions which, when executed by at least one computer, cause the at least one computer to implement one or more embodiments of the methods of the present subject matter. Additionally or alternatively, the computing device(s) may comprise circuitry that renders the device(s) operative to implement one or more of the methods of the present subject matter.

(31) Any suitable computer-readable medium or media may be used to implement or practice the presently-disclosed subject matter, including but not limited to, diskettes, drives, and other magnetic-based storage media, optical storage media, including disks (e.g., CD-ROMS, DVD-ROMS, variants thereof, etc.), flash, RAM, ROM, and other memory devices, and the like.

(32) In the description above, various embodiments of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described. The subject matter of the present invention is described here with specificity, but the claimed subject matter may be embodied in other ways, may include different elements or steps,

and may be used in conjunction with other existing or future technologies.

(33) This description should not be interpreted as implying any particular order or arrangement among or between various steps or elements except when the order of individual steps or arrangement of elements is explicitly described. Different arrangements of the components depicted in the drawings or described above, as well as components and steps not shown or described are possible. Similarly, some features and sub-combinations are useful and may be employed without reference to other features and sub-combinations. Embodiments of the invention have been described for illustrative and not restrictive purposes, and alternative embodiments will become apparent to readers of this patent. Accordingly, the present invention is not limited to the embodiments described above or depicted in the drawings, and various embodiments and modifications may be made without departing from the scope of the claims below.

(34) Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

(35) The use of the terms “a” and “an” and “the” and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms “comprising,” “having,” “including,” and “containing” are to be construed as open-ended terms (i.e., meaning “including, but not limited to,”) unless otherwise noted. The term “connected” is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., “such as”) provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

(36) Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

(37) All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

## Claims

1. A medical system comprising: an implantable blood pump comprising an inflow and an outflow, wherein the inflow is configured to be coupled to a left ventricle of a patient to receive a flow of

blood from the left ventricle, and wherein the outflow is configured to be coupled to an aorta of the patient to transfer the flow of blood to the aorta; a pulmonary pressure sensor configured to be implanted within a pulmonary artery of the patient; and a controller operably coupled with the implantable blood pump and the pulmonary pressure sensor, the controller configured to: receive pulmonary pressure measurements from the pulmonary pressure sensor; determine at least one hemodynamic characteristic of the patient based on the pulmonary pressure measurements; and adjust a blood pump setting of the implantable blood pump based on the at least one hemodynamic characteristic to adjust pumping of the flow of blood by the implantable blood pump from the left ventricle to the aorta.

2. The medical system of claim 1, wherein the at least one hemodynamic characteristic comprises systolic arterial pressure.

3. The medical system of claim 1, wherein the at least one hemodynamic characteristic comprises diastolic arterial pressure.

4. The medical system of claim 1, wherein the at least one hemodynamic characteristic comprises mean arterial pressure.

5. The medical system of claim 1, wherein the at least one hemodynamic characteristic comprises heart rate.

6. The medical system of claim 1, wherein the pulmonary pressure sensor comprises a MEMS based sensor.

7. The medical system of claim 6, wherein the pulmonary pressure sensor is wirelessly coupled with the implantable blood pump.

8. The medical system of claim 6, wherein the pulmonary pressure sensor is hard wired to the implantable blood pump.

9. The medical system of claim 1, wherein the controller is further configured to estimate a left atrial pressure waveform or a left ventricular pressure waveform based on the pulmonary pressure measurements.

10. The medical system of claim 1, wherein the controller is configured to adjust a pumping mode of the implantable blood pump in response to the at least one hemodynamic characteristic.

11. The medical system of claim 1, wherein the controller is configured to adjust a pump rotor speed in response to the at least one hemodynamic characteristic.

12. A method for hemodynamic monitoring of a patient with a heart pump, the method comprising: receiving, with a controller of an implantable blood pump coupled with a heart of a patient, pulmonary pressure measurements from a pulmonary pressure sensor implanted within a pulmonary artery of the patient; determining, with the controller of the implantable blood pump, at least one hemodynamic characteristic of the patient based on the pulmonary pressure measurements; and adjusting a blood pump setting of the implantable blood pump based on the at least one hemodynamic monitoring characteristic to adjust pumping of blood by the implantable blood pump from a left ventricle of the patient to an aorta of the patient.

13. The method of claim 12, wherein the at least one hemodynamic characteristic comprises systolic arterial pressure.

14. The method of claim 12, wherein the at least one hemodynamic characteristic comprises diastolic arterial pressure.

15. The method of claim 12, wherein the at least one hemodynamic characteristic comprises mean arterial pressure.

16. The method of claim 12, wherein the at least one hemodynamic characteristic comprises heart rate.

17. The method of claim 12, further comprising estimating a left atrial pressure waveform based on the pulmonary pressure measurements.

18. The method of claim 12, further comprising estimating a left ventricular pressure waveform based on the pulmonary pressure measurements.

19. The method of claim 12, wherein adjusting comprises adjusting a pumping mode of the implantable blood pump in response to the at least one hemodynamic characteristic.

20. The method of claim 12, wherein adjusting comprises adjusting a pump rotor speed in response to the at least one hemodynamic characteristic.

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