US 20250262427A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2025/0262427 A1**

Tiferes Wang et al. (43) **Pub. Date: Aug. 21, 2025**

(54) **PERCUTANEOUS CIRCULATORY SUPPORT DEVICE WITH IN-VIVO LACTATE SENSOR**

(71) Applicant: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

(72) Inventors: **Judith Tiferes Wang**, Shoreview, MN (US); **Jennifer Gibbs**, White Bear, MN (US); **Michael Kaland**, White Bear Lake, MN (US); **Zachary Kumor**, Plymouth, MI (US)

(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

(21) Appl. No.: **19/056,996**

(22) Filed: **Feb. 19, 2025**

Related U.S. Application Data

(60) Provisional application No. 63/555,570, filed on Feb. 20, 2024.

Publication Classification

(51) **Int. Cl.**

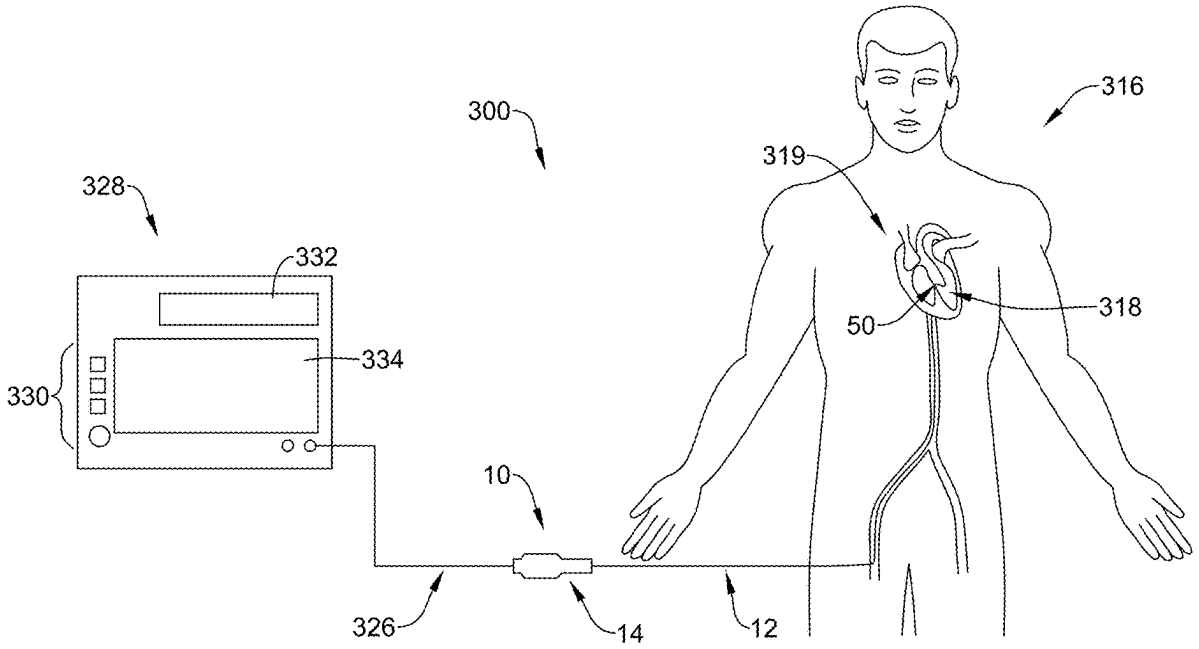
A61M 60/816	(2021.01)
A61B 5/00	(2006.01)
A61B 5/145	(2006.01)
A61B 5/1473	(2006.01)
A61M 60/13	(2021.01)
A61M 60/174	(2021.01)
A61M 60/216	(2021.01)
A61M 60/515	(2021.01)
A61M 60/865	(2021.01)

(52) **U.S. Cl.**

CPC ***A61M 60/816*** (2021.01); ***A61B 5/14546*** (2013.01); ***A61B 5/1473*** (2013.01); ***A61B 5/6852*** (2013.01); ***A61B 5/742*** (2013.01); ***A61M 60/13*** (2021.01); ***A61M 60/174*** (2021.01); ***A61M 60/216*** (2021.01); ***A61M 60/515*** (2021.01); ***A61M 60/865*** (2021.01); *A61M 2230/20* (2013.01)

(57) **ABSTRACT**

Example percutaneous circulatory support devices are disclosed. Example percutaneous circulatory support devices includes a catheter including an elongate shaft and a percutaneous blood pump positioned at a distal end of the elongate shaft, the percutaneous blood pump including a blood inlet, a blood outlet, and an impeller assembly positioned therebetween to pump blood from the blood inlet to the blood outlet during use. Further, the example percutaneous circulatory support devices include lactate sensor configured to sense an amount of lactate in the blood.



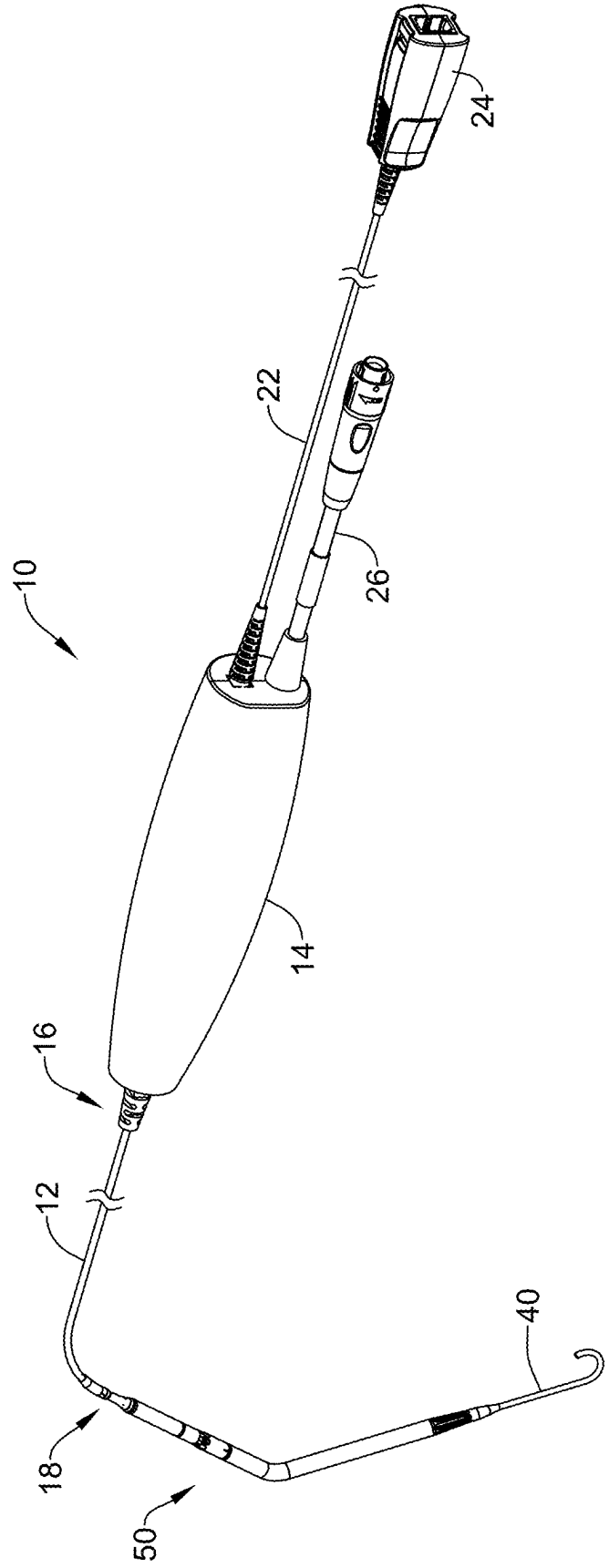


FIG. 1

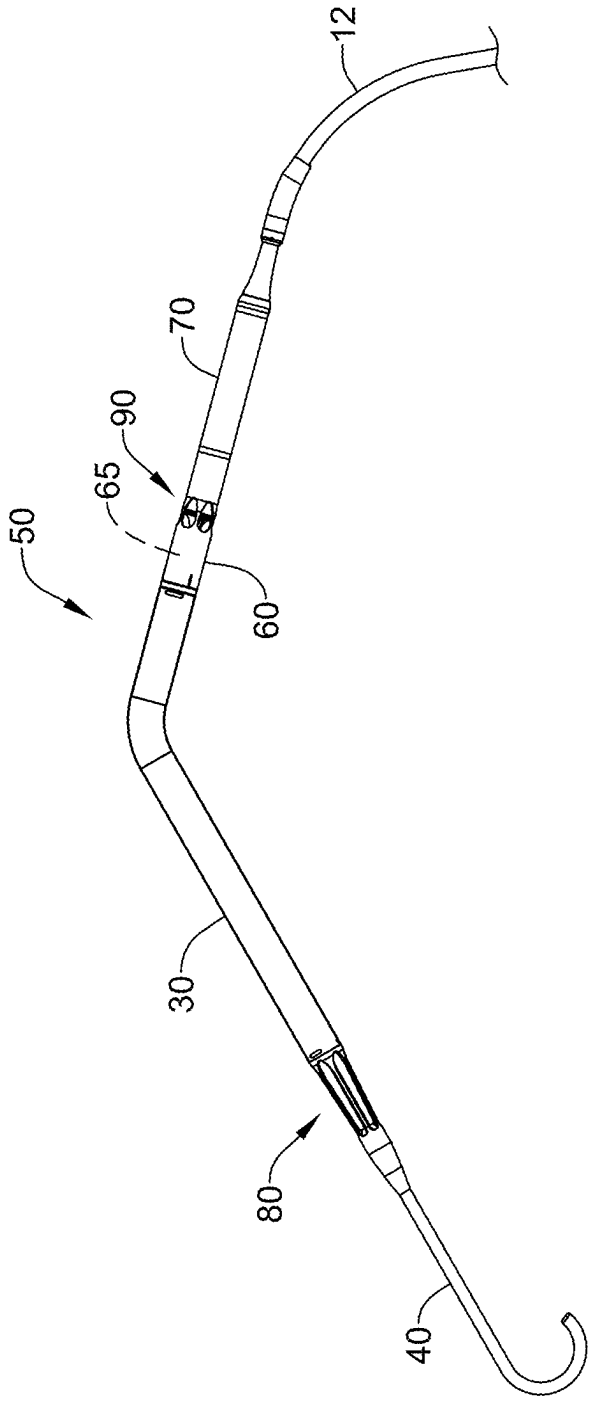


FIG. 2

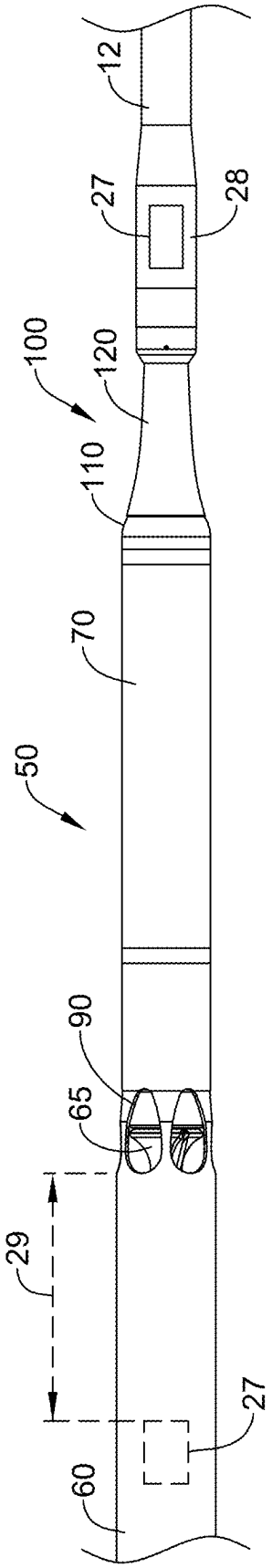

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FIG. 3A

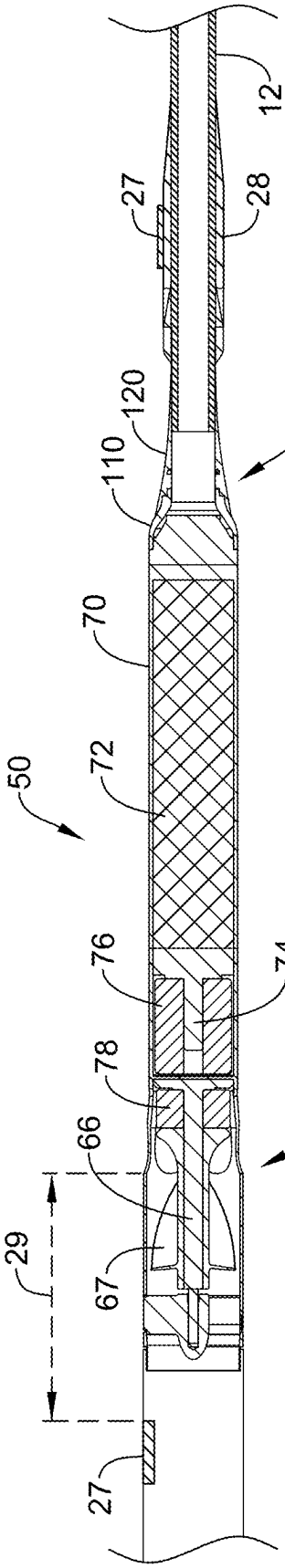
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FIG. 3B

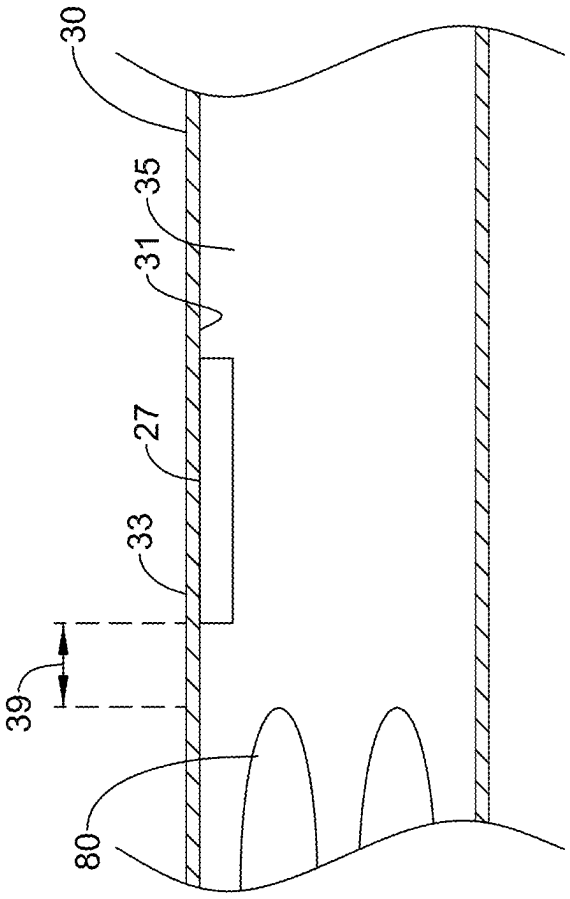


FIG. 3C

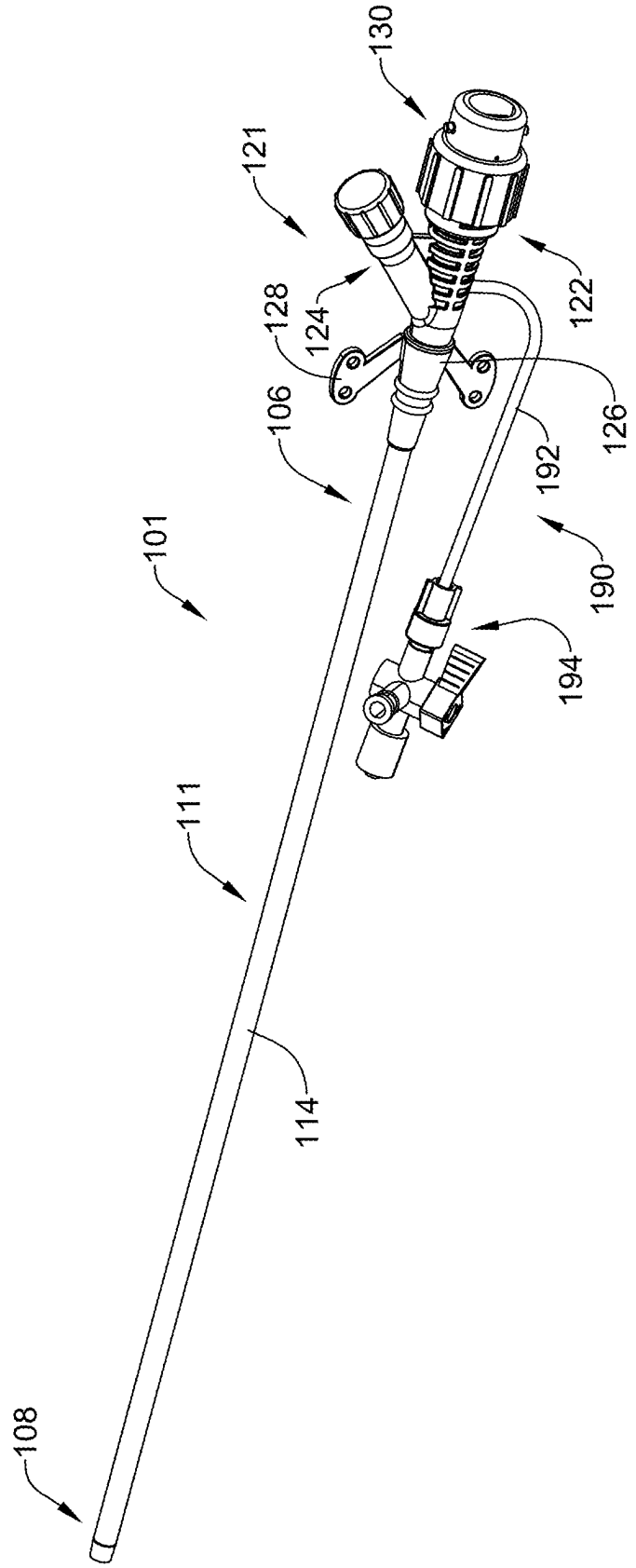
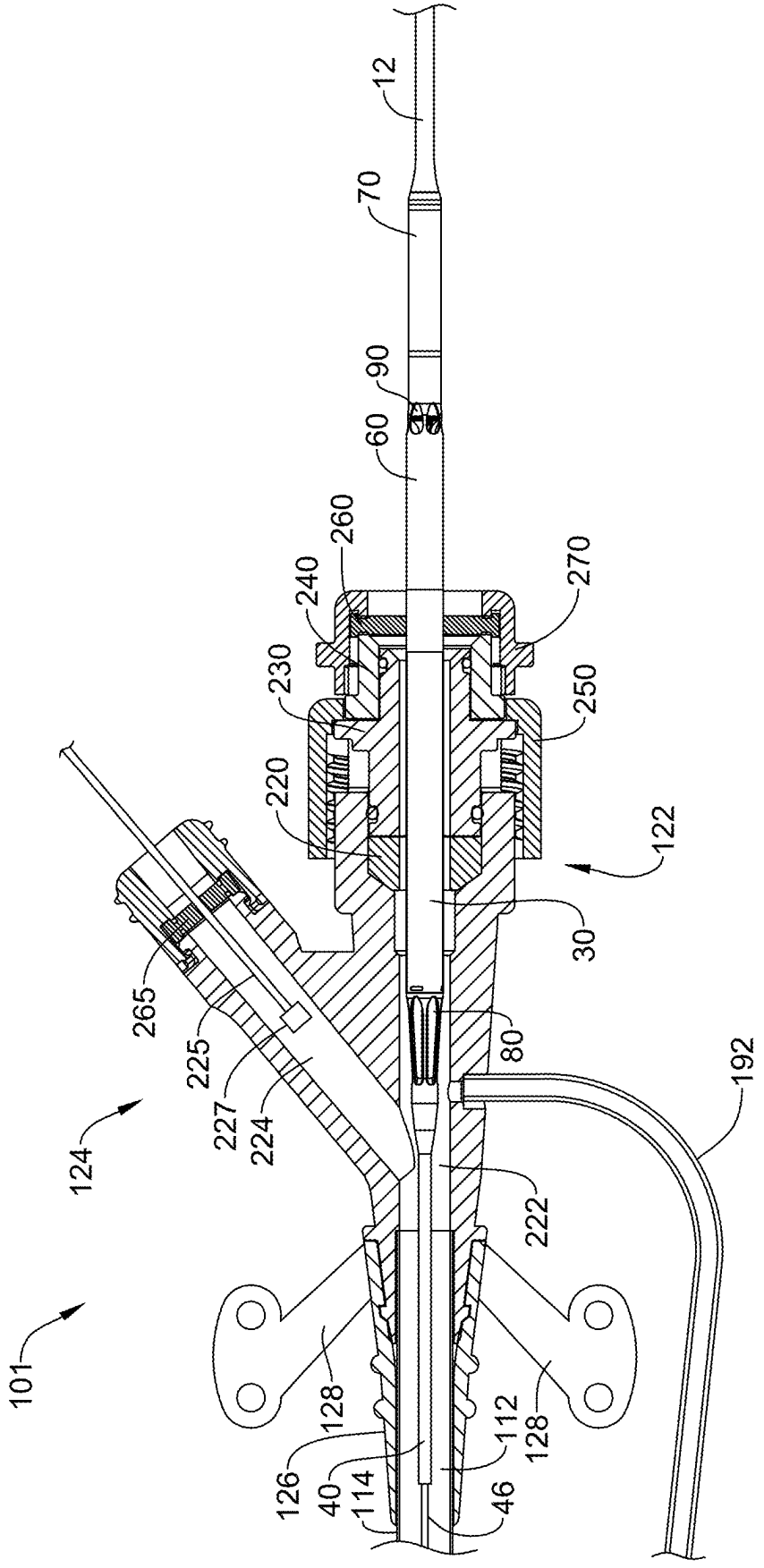


FIG. 4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114
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FIG. 5

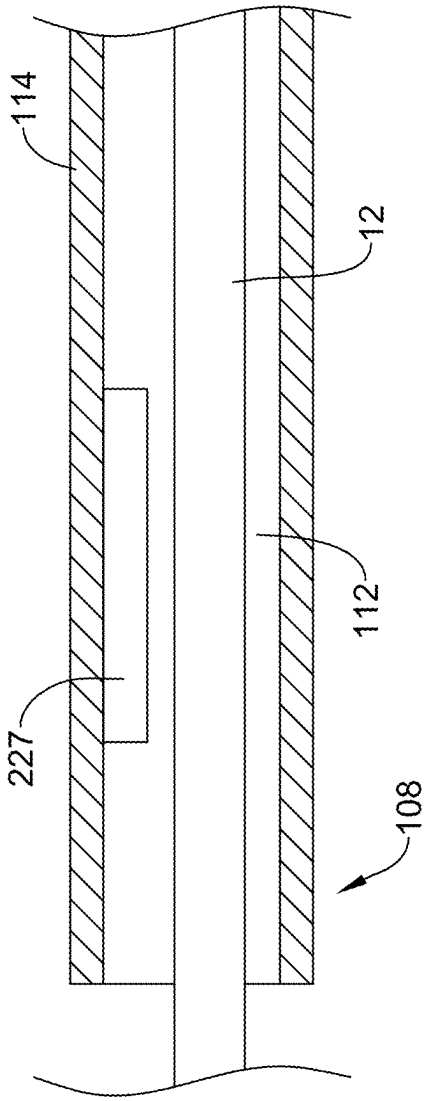

FIG. 6

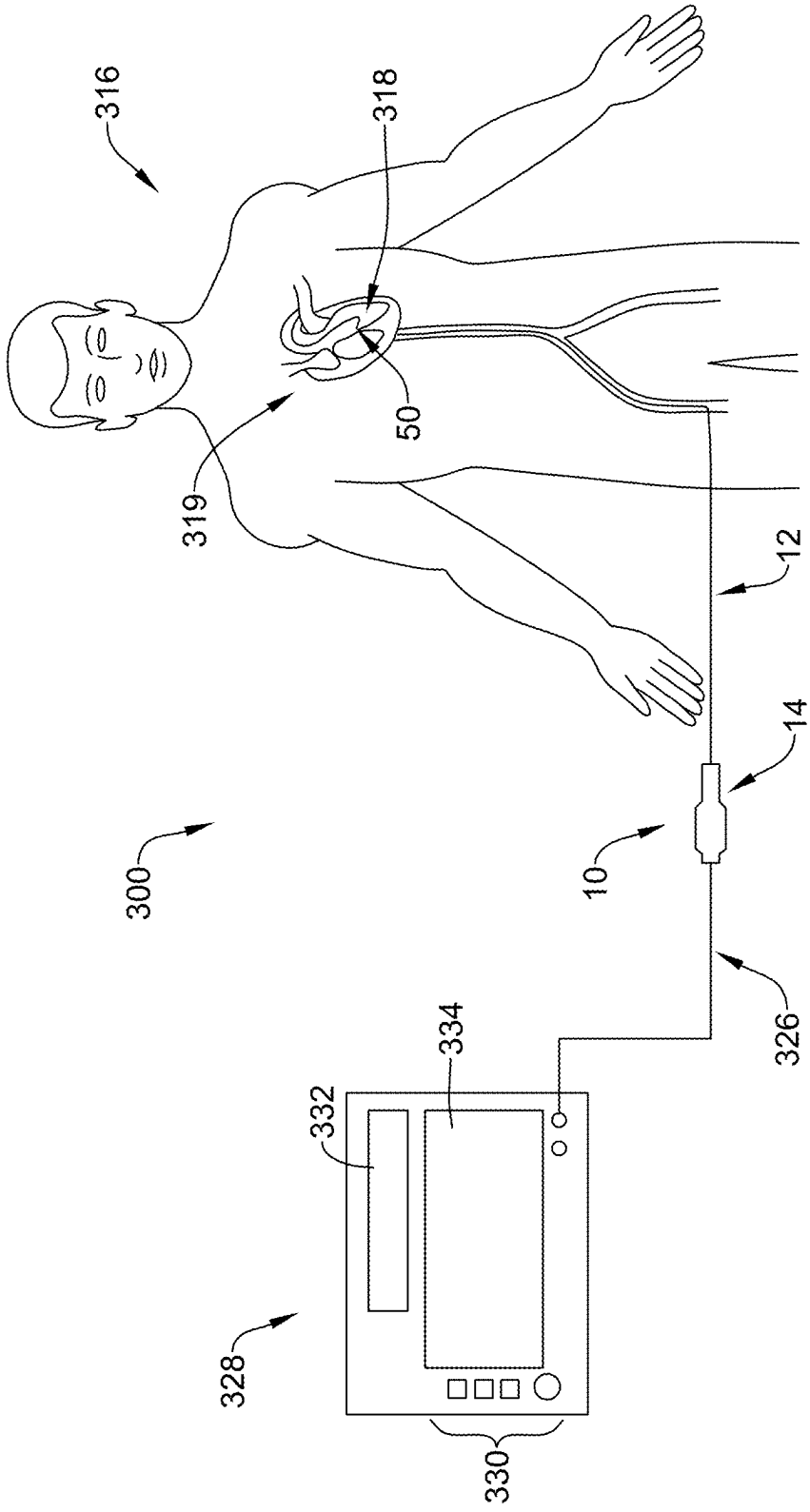

FIG. 7

PERCUTANEOUS CIRCULATORY SUPPORT DEVICE WITH IN-VIVO LACTATE SENSOR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Patent Application Ser. No. 63/555,570, filed Feb. 20, 2024, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure pertains to a catheter including a percutaneous blood pump. More particularly, the present disclosure pertains to a percutaneous circulatory support device with an in-vivo lactate sensor.

BACKGROUND

[0003] Percutaneous mechanical circulatory support devices, such as blood pumps can provide transient support for hours, days or months of use in patients whose heart function or cardiac output is compromised. The percutaneous mechanical circulatory support devices may be sufficiently flexible to be navigated through the vasculature to a patient's heart. For instance, such devices may be delivered percutaneously from the femoral artery, retrograde through the descending aorta, over the aortic arch, through the ascending aorta across the aortic valve, and into the left ventricle.

[0004] To assist a clinician using a circulatory support device during a medical procedure, a circulatory support device system may include one or more displays designed to provide easy-to-understand operational and alert information relating to one or more cardiac parameters of the percutaneous circulatory support device, the circulatory support device system and/or the patient. The displayed information may include information sensed by one or more sensors such as sensors which are deployed in-vivo to a patient. However, there is an ongoing need to provide circulatory support device systems including one or more sensors and/or one or more visual displays designed to provide simplified information corresponding to cardiac parameters of a percutaneous circulatory support device and/or a patient.

BRIEF SUMMARY

[0005] This disclosure provides design, material, manufacturing method, and use alternatives for medical devices, including percutaneous circulatory support devices and associated percutaneous blood pumps.

[0006] In some aspects, the present disclosure provides a percutaneous circulatory support device, the device comprising a catheter including an elongate shaft and a percutaneous blood pump positioned at a distal end of the elongate shaft, the percutaneous blood pump including a blood inlet, a blood outlet, and an impeller assembly positioned therebetween to pump blood from the blood inlet to the blood outlet during use; and a lactate sensor configured to sense an amount of lactate in the blood.

[0007] In some embodiments, which can be used in conjunction with the above aspects, the lactate sensor is an electrochemical sensor.

[0008] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the amount of lactate is based on an amount of lactate oxidase (LOD) in the blood.

[0009] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the amount of lactate is based on an amount of lactate dehydrogenase (LDH) in the blood.

[0010] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is configured to periodically detect the amount of lactate in the blood.

[0011] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is configured to continuously detect the amount of lactate in the blood.

[0012] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is in direct fluid communication with the blood.

[0013] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is located inside of or on an exterior surface of the percutaneous blood pump.

[0014] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is located between the blood inlet and the blood outlet of the percutaneous blood pump.

[0015] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is located inside of or on an exterior surface of the elongate shaft.

[0016] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is located proximal of the percutaneous blood pump.

[0017] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is mounted in a housing on the elongate shaft with the lactate sensor facing an exterior of the elongate shaft.

[0018] In some aspects the present disclosure provides a percutaneous circulatory support system, the system comprising: a percutaneous circulatory support device including: a catheter including an elongate shaft and a percutaneous blood pump positioned at a distal end of the elongate shaft, the percutaneous blood pump including a blood inlet, a blood outlet, and an impeller assembly positioned therebetween to pump blood from the blood inlet to the blood outlet during use in a heart of a patient; and a lactate sensor configured to sense a real-time serum lactate level in the blood of the patient during use of the percutaneous blood pump in the heart of the patient.

[0019] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is secured to an exterior of the elongate shaft proximal of the percutaneous blood pump.

[0020] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is mounted in a housing on the elongate shaft.

[0021] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is positioned between the blood inlet and the blood outlet.

[0022] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the system further comprising an introducer sheath, wherein the introducer sheath includes a lumen configured to deliver the percutaneous blood pump to the heart of the patient, and wherein the lactate sensor is secured to the introducer sheath.

[0023] In some aspects the present disclosure provides, an introducer sheath for gaining access to a vasculature of a patient comprising: a hub including a hemostasis valve; an elongate shaft extending distally from the hub, the elongate shaft including a lumen extending therethrough; and a lactate sensor configured to sense an amount of lactate in the blood.

[0024] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is mounted on a distal end region of the elongate shaft.

[0025] In some embodiments, which can be used in conjunction with the above aspects and embodiments, the lactate sensor is movably postionable through a passageway of the hub.

[0026] The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Detailed Description, which follow, more particularly exemplify some of these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

[0028] FIG. **1** is a perspective view of an exemplary percutaneous circulatory support device including a percutaneous blood pump with a lactate sensor;

[0029] FIG. **2** shows the distal end region of the percutaneous circulatory support device of FIG. **1** including the percutaneous blood pump with the lactate sensor;

[0030] FIG. **3**A is a side view of a portion of the percutaneous blood pump of FIG. **2**, with a lactate sensor;

[0031] FIG. **3**B is a cross-sectional view of the portion of the percutaneous blood pump of FIG. **3**A, with a lactate sensor;

[0032] FIG. **3**C is a cross-sectional view of a portion of the flexible cannula of the percutaneous blood pump of FIG. **2**, with a lactate sensor therein;

[0033] FIG. **4** is a perspective view of an exemplary introducer sheath;

[0034] FIG. **5** a cross-sectional view of the hub of the introducer sheath of FIG. **4**, illustrating a lactate sensor inserted into the insertion sheath;

[0035] FIG. **6** illustrates a view of a lactate sensor positioned proximate a distal end of the elongate shaft of the insertion sheath of FIG. **4**;

[0036] FIG. **7** illustrates an example percutaneous circulatory support system including a percutaneous blood pump with a lactate sensor positioned in the heart of a patient.

[0037] While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

[0038] For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

[0039] All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

[0040] The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. **1** to **5** includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[0041] As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

[0042] It is noted that references in the specification to "an embodiment", "some embodiments", "other embodiments", etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

[0043] The following detailed description should be read with reference to the drawings in which similar structures in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

[0044] A serum lactate level in a patient is an important biomarker that may be used to monitor tissue perfusion in the patient. For instance, lactic acidosis/hyperlactatemia is a prognostic factor in patients with acute myocardial infarction and cardiogenic shock. Current approaches for measuring a serum lactate level entail drawing a blood sample from a patient and transporting the blood sample to a lab for analysis (e.g., for measurement of a serum lactate level of the blood sample). However, such approaches may be costly, time-consuming, and/or do not reflect a real-time serum lactate level in the patient. For instance, such approaches may impart a large amount of delay between a time that the blood sample is drawn and a time when a serum lactate level (e.g., as measured by the lab) is conveyed to a clinician (e.g., doctor). Thus, any intervention (e.g., removal of a pump, alteration of a pump setting, etc.) performed by the clinician based on the serum lactate level may be delayed and/or is not based on real-time information. Further, any change in serum lactate level of the patient that occurs after the blood sample is drawn is not accounted for.

[0045] Accordingly, this disclosure is directed to percutaneous circulatory support devices and percutaneous circulatory support systems that include a lactate sensor. Notably,

the lactate sensor can provide real-time (e.g., continuous) in-vivo serum lactate measurements. The real-time in-vivo serum lactate measurements can be conveyed in real-time to a clinician. Thus, the devices and systems herein permit timely monitoring and, when needed, timely patient interventions (e.g., escalation or de-escalation of cardiac support therapy), unlike other approaches such as those that rely on separate laboratory testing and/or the addition of extraction reagents to a blood sample outside of a patient.

[0046] Additionally, the lactate sensor may be in direct contact with blood in-vivo a patient. As such, the devices and systems herein can provide accurate serum lactate levels, in contrast to other approaches such as those that seek to measure serum lactate levels indirectly (e.g., via skin/sweat measurement and/or via a subcutaneous patch) and therefore may be relatively inaccurate (e.g., may inaccurately measure an amount of lactate due to deployment issues/positioning variation and/or variation associated with changes in temperature and/or pH).

[0047] Moreover, in some embodiments, the in-vivo lactate measurements may be made continuously while the patient is being treated with a percutaneous circulatory support device. That is, it may be desirable to continuously measure an individual's lactate levels via an implanted lactate sensor while a percutaneous circulatory support device is in operation within the patient. For example, continuous (or near continuous) in vivo-lactate monitoring may be beneficial for people with chronic, slowly changing lactate levels and thereby permit graphing or other methods of determining a trend in the serum lactate levels over time during the operation of a percutaneous circulatory support device. In addition, continuous (or near continuous) in vivo-lactate monitoring may be beneficial for people and/or patients that may be prone to abrupt sizable changes in lactate levels (e.g., due to accelerated degradation of heart tissue). Further, such continuous monitoring of lactate levels may mitigate the pain and/or the expense that is typically associated with multiple blood draws to measure lactate levels via multiple laboratory assays.

[0048] FIG. **1** is a perspective view of an exemplary percutaneous circulatory support device (e.g., catheter) **10** including a percutaneous blood pump **50** with a lactate sensor (not shown in FIG. **1**). As illustrated in FIG. **1**, the percutaneous blood pump **50** may be located at a distal end region of the catheter **10**. The catheter **10** may be coupled to or include the percutaneous blood pump **50**, with an elongate shaft **12** of the catheter **10** extending proximally from the percutaneous blood pump **50** and a distal tip **40** extending distally from the percutaneous blood pump **50**. For instance, a proximal end **16** of the elongate shaft **12** may be coupled to a control module **14** and a distal end **18** of the elongate shaft **12** may be coupled to the percutaneous blood pump **50**. An electrical cable **22** may extend from the control module **14** to a connector **24** at a proximal end thereof. The connector **24** may be configured to be connected to a controller or console (not shown in FIG. **1**) for controlling the percutaneous blood pump **50**, such as providing electrical power to the blood pump **50**. The catheter **10** may also include an extension **26** connectable to the controller or console (not shown in FIG. **1**) for sending and/or receiving signals, such as from one or more sensors during operation of the percutaneous blood pump **50**. In some instances, the electrical power cable and/or sensor cables may be combined in a single cable harness, if desired. For instance, as detailed with respect to FIG. **7**, a console may include one or more displays that are configured to display information such as a real-time in-vivo lactate measurement measured be a lactate sensor, as described herein.

[0049] Additional features of the percutaneous blood pump **50** are illustrated in FIG. **2**. The percutaneous blood pump **50** may generally include a flexible cannula **30**, an impeller housing **60**, and a motor housing **70**. In some embodiments, the flexible cannula **30**, the impeller housing **60** and/or the motor housing **70** may be integrally or monolithically constructed. In other instances, the flexible cannula **30**, the impeller housing **60** and/or the motor housing **70** may be separate components. The impeller housing **60** carries an impeller assembly **65** therein. The impeller assembly **65** may include an impeller secured to an impeller shaft that rotates relative to the impeller housing **60** to drive blood through the blood pump **50**. In some embodiments, the impeller shaft and the impeller of the impeller assembly **65** may be integrally formed, whereas, in other embodiments the impeller shaft and the impeller may be separate components.

[0050] Rotation of the impeller causes blood to flow from a blood inlet **80** of the percutaneous blood pump **50**, such as at a distal end of the flexible cannula **30**, through the flexible cannula **30** and the impeller housing **60**, and out of a blood outlet **90** proximal of the impeller, such as through a sidewall formed on the impeller housing **60**. In some instances, the blood inlet **80** may include a plurality of blood inlet windows arranged around a circumference of the percutaneous blood pump **50** (e.g., the flexible cannula **30**). In some instances, the blood outlet **90** may include a plurality of blood outflow windows arranged around a circumference of the impeller housing **60**. In other embodiments, the blood inlet **80** and/or the blood outlet **90** may be formed on other portions of the percutaneous blood pump **50**.

[0051] With continued reference to FIG. **2**, the motor housing **70** carries a motor configured to rotatably drive the impeller of the impeller assembly **65** relative to the impeller housing **60**. Electrical power may be supplied to the motor through wiring extending through the elongate shaft **12**, for example. In some instances, the motor may be physically connected to the impeller. For example, in some embodiments the impeller may be mounted on the drive shaft of the motor. In other embodiments, the impeller shaft may be directly or indirectly coupled to the drive shaft of the motor. In some instances, the drive assembly may include a magnetic coupling between the motor and the impeller. For example, a driving magnet may be mounted on the drive shaft of the motor. Rotation of the driving magnet causes rotation of a driven magnet, which is connected to the impeller assembly **65**. More specifically, in embodiments incorporating an impeller shaft, the impeller shaft and the impeller of the impeller assembly **65** are configured to rotate with the driven magnet. In other embodiments, the motor may be coupled to the impeller assembly **65** via other components.

[0052] In some embodiments, the system herein includes a lactate sensor provided with the percutaneous circulatory support device **10** and/or provided with an introducer sheath configured to be used with introducing and/or maintaining the percutaneous circulatory support device **10** in a patient. Accordingly, in some embodiments, the lactate sensor can be located on an exterior (e.g., outer) surface of the percu-

taneous circulatory support device **10** (e.g., an exterior surface of the elongate shaft **12**, an exterior surface of the cannula **30**, an exterior surface of the motor housing **70**, or an exterior surface of the impeller housing **60**) and/or on an exterior surface of an introducer sheath, as described herein. However, in some embodiments the lactate sensors herein can be configured (e.g., sized, shaped, etc.) to be disposed within a lumen (e.g., on an inner surface of the cannula **30**) of the percutaneous circulatory support device **10** or within a lumen of an introducer sheath, as described herein.

[0053] In some embodiments, the lactate sensor may be an electrochemical sensor, namely an electrochemical lactate sensor. The lactate sensor may be configured to detect an in-vivo lactate level using coulometric, amperometric, voltammetric, and/or potentiometric electrochemical detection techniques. For instance, the lactate sensor may include a lactate-responsive analyte sensor such as a lactate-responsive-enzyme based analyte sensor. In some embodiments, the lactate sensor may be configured to detect lactate oxidase and/or lactate dehydrogenase in-vivo a patient. In some embodiments, the lactate sensor may be configured to detect lactate oxidase in-vivo a patient. In some embodiments, the lactate sensor may be configured to detect lactate dehydrogenase in-vivo a patient. In some embodiments, the lactate sensor can include a plurality of electrodes such as two-electrodes or three-electrodes. In other embodiments, the lactate sensor can include another quantity of electrodes, if desired. As is conventionally known, a two-electrode configuration may employ a first working electrode and a second electrode that functions as both a counter electrode and a reference electrode, while a three-electrode configuration may employ a working electrode, a counter electrode, and a reference electrode. In some embodiments, an electron transfer material can be present in the lactate sensors herein. A suitable electron transfer agent can facilitate the transfer of electrons to or from the working electrode when an analyte (enzyme substrate) such as lactic acid undergoes a redox reaction. In some embodiments, the lactate sensor can include a wireless transmitter configured to wirelessly transfer information (e.g., to a controller or computing device remotely located from the lactate sensor). For instance, the information can include information indicative of an in-vivo lactate level detected by the lactate sensor. In other embodiments, the lactate sensor can be wired to a controller or computing device for transmitting information indicative of an in-vivo lactate level detected by the lactate sensor.

[0054] In some instances, the lactate sensor can be non-removably coupled to a surface such as an exterior surface of the percutaneous circulatory support device **10** (e.g., an exterior surface of the elongate shaft **12**, an exterior surface of the cannula **30**, an exterior surface of the motor housing **70**, or an exterior surface of the impeller housing **60**) or an inner surface of a lumen of the percutaneous blood pump **50** (e.g., the lumen of the cannula **30**). Having the lactate sensor be non-removably coupled to the surface can ensure that the lactate sensor does not inadvertently become dislodged from the surface (e.g., an inner surface or exterior surface of the percutaneous circulatory support device **10**) and/or may promote other aspects herein such as providing an accurate in-vivo lactate measurement. However, in some instances, the lactate sensor can be removably coupled to a surface such as an exterior surface of the percutaneous circulatory support device **10** (e.g., an exterior surface of the elongate shaft **12**, an exterior surface of the cannula **30**, an exterior surface of the motor housing **70**, or an exterior surface of the impeller housing **60**) or an inner surface of a lumen of the percutaneous blood pump **50** (e.g., the lumen of the cannula **30**). Having the lactate sensor be removably coupled to the surface can permit the lactate sensor to be readily changed or cleaned (e.g., responsive to a malfunction of a lactate sensor, fouling of the lactate sensor, etc.), and thereby can promote aspects herein such as providing accurate in-vivo lactate measurements.

[0055] While generally described herein as an individual lactate sensor, in some embodiments a plurality of lactate sensors may be employed with the percutaneous circulatory support device **10** and/or introducer sheath. For instance, a plurality of lactate sensors may be employed in-vivo a patient, as described herein, to determine respective in-vivo lactate levels at different locations in a patient and/or to determine an average in-vivo lactate level.

[0056] FIG. **3**A is a side view of a portion of the percutaneous blood pump of FIG. **2**. As shown in FIG. **3**A, the percutaneous circulatory support device **10** including the percutaneous blood pump **50** can be connected to the elongate shaft **12** at a junction **100**. The junction **100** may be configured to mechanically connect the motor housing **70** (e.g., a metallic motor housing) of the blood pump **50**, or other component of the blood pump **50**, to the distal end region of the elongate shaft **12** (e.g., a polymeric tubular member). A proximal end of the impeller of the impeller assembly **65** is also visible through the outflow windows of the blood outlet **90**.

[0057] The junction **100** may include an end cap **110** having a proximal end region surrounding the distal end region of the elongate shaft **12**, and a fillet of material **120** surrounding the proximal end region of the end cap **110** and extending proximally therefrom. The fillet of material **120** may extend proximal of the end cap **110** and surround a portion of the elongate shaft **12** extending proximal of the end cap **110**, among other possible configurations.

[0058] FIG. **3**B is a cross-sectional view of the portion of the percutaneous blood pump of FIG. **2**. As shown in FIG. **3**B, the impeller assembly **65** includes a drive shaft **66** and an impeller **67** coupled thereto, where the drive shaft **66** is configured to rotate with the impeller **67**. As shown, the drive shaft **66** is at least partially disposed within the impeller **67**. The impeller assembly **65** further includes a driven magnet **78** coupled to, and at least partially surrounding, the drive shaft **66** and/or the impeller **67**. The driven magnet **78** may be any type of magnetic rotor capable of being driven by a driving magnet assembly. In this manner, as a magnetic field is applied to the driven magnet **78** by the driving magnet assembly, the driven magnet **78** rotates, causing the drive shaft **66** and impeller **67** to rotate.

[0059] As shown in FIG. **3**B, the driving magnet assembly includes a driving magnet **76** coupled to a drive line **74** configured to transfer torque from a motor **72** to the driving magnet **76**. The motor housing **70** may be configured to hermetically seal the driving magnet **76** and the motor within the motor housing **70**, and thus fluidly isolate the driving magnet **76** from the driven magnet **78**. Electrical wires, not shown, may extend through a lumen of the elongate shaft **12** to provide electrical power to the motor **72**. In other instances, the drive line **74** may be directly coupled to the impeller **67** and/or drive shaft **66**, or other driven trains may be provided to transfer torque from the motor **72** to the impeller **67**.

[0060] In some embodiments, a lactate sensor **27** can be included on an exterior surface or outer surface of the percutaneous circulatory support device **10**. FIGS. **3**A and **3**B show several possible locations of a lactate sensor **27** on the elongate shaft **12**. The intent is to show the possible locations, but not necessarily to indicate that more than one lactate sensor **27** is needed in embodiments of this disclosure, unless described otherwise herein. For instance, as shown in FIGS. **3**A and **3**B, a lactate sensor **27** can be disposed on an exterior surface of the elongate shaft **12** proximal of the percutaneous blood pump **50**, for example, proximal of the junction **100**. In some instances, the lactate sensor **27** may be indirectly secured to the elongate shaft **12** in a housing **28**, with the housing **28** in turn secured to the elongate shaft **12**. In other instances, the lactate sensor **27** may be directly secured to the elongate shaft **12**. While FIG. **3**A illustrates the lactate sensor **27** as being on an exterior surface of the elongate shaft **12**, the present disclosure is not so limited. In other instances, the lactate sensor **27** can be disposed on an exterior surface of the motor housing **70**, the impeller housing **60**, or the cannula **30**, if desired. Signal wires may extend from the lactate sensor **27** through a lumen of the elongate shaft **12** to a console or other controller configured to collect, store and/or display data from the lactate sensor **27**. In some embodiments the lactate sensor **27** can be disposed on a different exterior surface of the percutaneous circulatory support device **10**, such as on a different exterior surface of the percutaneous blood pump **50** or elongate shaft **12**. Having the lactate sensor **27** be disposed on an exterior surface may permit the lactate sensor **27** to be readily exposed to blood flowing past the lactate sensor and/or permitting the lactate sensor **27** to be cleaned or replaced and/or may otherwise promote aspects.

[0061] In some embodiments, the lactate sensor **27** may be secured to the elongate shaft **12** at a location that is at least a threshold distance from the percutaneous blood pump **50**. The threshold distance from the percutaneous blood pump **50** can be a value in a range from about 1.0 centimeters to about 30.0 centimeters. Having the lactate sensor **27** disposed on the elongate shaft **12** at least the threshold distance proximal of the percutaneous blood pump **50** can mitigate or eliminate an amount of turbulence or irregularity in flow of the blood that may otherwise be due to a proximity of the lactate sensor **27** to the percutaneous blood pump **50**. The lactate sensor **27** may be located distal of the control module **14** such that the lactate sensor **27** is positioned within the patient's vasculature when the percutaneous blood pump **50** is positioned across the aortic valve of the patient's heart. For example, the lactate sensor **27** may be a distance from the control module **14** of about 100 centimeters or more, about 80 centimeters or more, or about 50 centimeters or more.

[0062] Additionally or alternatively, a lactate sensor **27** can be included on an interior surface or inner surface of the percutaneous circulatory support device **10**. That is, in some embodiments the lactate sensor **27** can be included within the interior of a component of the percutaneous circulatory support device **10**. For instance, the lactate sensor **27** can be included in a lumen extending through at least a portion of the percutaneous blood pump **50** in contact with blood flowing therein. As illustrated in FIGS. **3**A and **3**B, the lactate sensor **27** may be located in a lumen in the percutaneous blood pump **50** at a first location between the blood inlet **80** and the blood outlet **90**. Specifically, the lactate sensor **27** may be located within the interior of the impeller housing **60**, such as secured to an inner surface of the impeller housing **60**, such as distal of the blood outlet **90**. In other instances, the lactate sensor **27** may be located within the interior of the cannula **30**, such as secured to an inner surface of the cannula **30**, at a location between the blood inlet **80** and the blood outlet **90**. In some instances, the location of the lactate sensor **27** may correspond to a location between the blood inlet **80** and the blood outlet **90** and that is relatively proximate to the blood outlet **90**, as illustrated in FIG. **3**B.

[0063] FIG. **3**C is a cross-sectional view of a portion of the flexible cannula **30**, with a lactate sensor **27** positioned within the interior of the flexible cannula **30**. That is, the lactate sensor **27** may be positioned on an inner surface **31** (opposite the exterior surface **33**) facing a lumen **35** extending through the flexible cannula **30**, among other possibilities. The location of the lactate sensor **27** in FIG. **3**C may correspond to a location between the blood inlet **80** and the blood outlet **90** that is relatively proximate to the blood inlet **80**. Thus, blood flowing through the lumen **35** of the flexible cannula between the blood inlet **80** and the blood outlet **90** may flow past and be in contact with the lactate sensor **27**.

[0064] Having the lactate sensor **27** disposed within the lumen of the percutaneous blood pump **50** may permit the lactate sensor **27** to directly contact blood flowing through the percutaneous blood pump **50** and/or permit accurate lactate measurements at least due to the proximity of the lactate sensor **27** relative to a heart of the patient.

[0065] In some embodiments, the lactate sensor **27** may be located on a surface (e.g., a surface in a lumen) of the percutaneous blood pump **50** at a location that is at least a threshold distance **39** from the blood inlet **80** and/or is at least a threshold distance **29** from the blood outlet **90**. The threshold distance **39** from the blood inlet **80** may be a value in a range from about 1.0 to about 5.0 centimeters, among other possibilities. Similarly, the threshold distance **29** from the blood outlet **90** may be a value in a range from about 1.0 to about 5.0 centimeters, among other possibilities. Having the lactate sensor **27** be located at a location that is a threshold distance **39** (FIG. **3**C) from the blood inlet **80** and/or is a threshold distance **29** (FIGS. **3**A and **3**B) from the blood outlet **90** may promote aspects herein such as promoting accurate in-vivo lactate measurements of blood in the percutaneous blood pump **50**. For instance, locating the lactate sensor at least the threshold distance **39** away from the blood inlet **80** and/or at least the threshold distance **29** from the blood outlet **90** may mitigate an amount of turbulence or irregularity in flow of the blood, as compared to locations that are more proximate to the blood inlet **80** and/or the blood outlet **90**. Furthermore, locating the lactate sensor proximal of the blood outlet **90** (as shown with the lactate sensor **27** placed on the exterior of the elongate shaft **12** proximal of the percutaneous blood pump **50**) may also mitigate an amount of turbulence or irregularity in flow of the blood passing the lactate sensor **27**.

[0066] While in some embodiments the lactate sensor **27** is described as being located in a lumen in the percutaneous blood pump **50**, as mentioned the disclosure is not so limited. Rather, in some embodiments, the lactate sensor **27** may be located on exterior surface of the percutaneous blood pump **50**, as illustrated in FIG. **3**A, or may be located outside of the percutaneous circulatory support device **10**. For example, the lactate sensor may be located in (e.g., on an

interior surface) or on (e.g., on an exterior surface) the elongate shaft **12** at a location that is proximal or distal to the percutaneous blood pump **50**. In some instances, the lactate sensor **27** may be located in a lumen extending through the elongate shaft **12** at a location between the percutaneous blood pump **50** and a control module **14** that is coupled to a proximal end of the elongate shaft **12**.

[0067] In other instances, the lactate sensor **27** may be located within a lumen of the elongate shaft **12** (not shown), if desired. That is, the lactate sensor **27** may be located in the elongate shaft **12** between the percutaneous blood pump **50** and the control module **14**. Having the lactate sensor **27** be located in a lumen in the elongate shaft **12** may mitigate an amount of turbulence or irregularity in flow of the blood may be reduced as compared to locations that are more proximate to the percutaneous blood pump **50**.

[0068] Moreover, in some embodiments the lactate sensor **27** may be provided with a device or instrument other than the percutaneous circulatory support device **10**. For instance, the lactate sensor **27** may be provided with an introducer sheath configured to be used in conjunction with the percutaneous circulatory support device **10**. FIG. **4** is a perspective view of an introducer sheath **101** for use in providing vascular access for introducing the percutaneous blood pump of FIG. **1** into a vasculature at a vascular access site. The introducer sheath **101** may include a hub **121**, as well as an elongate shaft **114** extending distally from the hub **121** to a distal end region **108** and defining the body portion **111** of the introducer sheath **101**. The introducer sheath **101** may also include a flush line **190** extending from the hub **121**. The flush line **190** may include a tubular member **192** extending from the hub **121** and in fluid communication with a lumen of the hub **121**. The tubular member **192** may extend to a stopcock **194**, such as a three-way stopcock.

[0069] The hub **121** may also include a strain relief **126** configured to provide a transition in flexibility along the proximal end region **106** of the elongate shaft **114**. The strain relief **126** may include a body attached to a main body of the hub **121**, as will be described further herein. The strain relief **126** may include one or more suture pads **128** configured to facilitate securing the hub **121** against the patient once the introducer sheath **101** has been positioned in the blood vessel of the patient.

[0070] The hub **121** may include a main port **122** and a side port **124** extending from the main port **122**. In some instances, the side port **124** may extend at an acute angle from the main port **122**. The main port **122** and/or the side port **124** may provide access to one or more lumens extending through the body portion **111** (e.g., through the elongate shaft **114**) of the introducer sheath **101**. In some instances, the main port **122** may be a tightening port **130**.

[0071] Turning to the cross-sectional view of the hub **121**, shown in FIG. **5**, the side port **124** may include a passage **224** extending therethrough converging with a passage **222** of the main port **122**. The passage **222** and/or the passage **224** may be in fluid communication with the lumen **112** of the introducer sheath **101** extending to a distal opening of the elongate shaft **114**. An elastomeric seal **265** may be positioned along the passage **224** of the side port **124**. The elastomeric seal **265** may be a slit valve (e.g., a cross-slit valve), a dome valve, a duckbill valve, or any other desired valve configured to seal around an elongate shaft of a medical device when passed therethrough. In some instances, the elastomeric seal **265** may include one or more slits (e.g., crossing slits) extending entirely through the seal wall and/or one or more slits (e.g., crossing slits) extending only partially through the seal wall. For instance, the elastomeric seal **265** may be a cross-slit valve having a first slit extending into the wall of the seal from a first side of the seal but not extend entirely through the wall of the seal and a second slit extending into the wall of the seal from a second, opposite side of the seal but not extend entirely through the wall of the seal. The first slit may intersect the second slit within the wall of the valve. In some instances, the first slit may be arranged perpendicular to the second slit. The elastomeric seal **265** may be formed of any desired flexible material, such as silicone, polyurethane, etc.

[0072] The main port **122** may include a primary seal and a secondary seal spaced apart from the primary seal along a length of the main port **122**. The components of the main port **122** may form a hemostasis valve. For example, the main port **122** may include a compressible seal (e.g., Tuohy seal) **220** and an elastomeric seal **260** spaced apart from the compressible seal **220**. The main port **122**, which may be considered a tightening port, may further include a pusher **230**, a holder **240**, a lock nut **250**, and/or a main port lid **270**. Rotation of the lock nut **250** may actuate the pusher **230** toward/away from the compressible seal **220** to adjust the size of the opening through the compressible seal **220**. The compressible seal **220** may be movable between an open state, allowing a medical device to pass through the opening, and a closed state, sealing the compressible seal **220** around the medical device. The compressible seal **220** may be formed of any desired flexible material, such as silicone, polyurethane, etc.

[0073] In use, the percutaneous blood pump **50** of the percutaneous circulatory support device **10** may be inserted through the introducer sheath **101** along a guidewire **46**. For example, the percutaneous blood pump **50** may be advanced through the main port **122** and into the lumen of the elongate shaft **114** of the introducer sheath **101**. The elastomeric seal **260** may seal around an outer perimeter of the cannula **30** of the percutaneous blood pump **50** and substantially prevent blood from escaping from the main port **122**.

[0074] The elongate shaft **12** of the percutaneous circulatory support device **10** may be further advanced through the introducer sheath **101** into the body of the patient to position the percutaneous blood pump **50** in a desired location, such as across the aortic valve between the left ventricle of the heart and the aorta. Once the percutaneous blood pump **50** is positioned at a desired location within the vasculature of the patient (e.g., within the heart of the patient), the compressible seal **220** may be compressed or tightened around the perimeter of the elongate shaft **12** of the catheter **10** to prevent blood from leaking past the elongate shaft **12** and out of the main port **122** and/or lock the elongate shaft **12** of the catheter **10** from axial movement relative to the hub **121**.

[0075] As illustrated in FIG. **5**, in some instances a lactate sensor **227** may be insertable into the side port **124** of the introducer sheath **101** for use with the percutaneous circulatory support device **10** (positioned in the main port **122**). For instance, the lactate sensor **227** may be included with a catheter **225**, which can be inserted in the side port **124** and removable therefrom. The lactate sensor **227** can be inserted a distance into the passage **224** of the side port **124** to place the lactate sensor **227** in contact with blood. In some instances, the lactate sensor **227** may be maintained in the passage **224** of the side port **124**. However, in other

instances, the lactate sensor **227**, mounted on the catheter **225** may be advanced distally though the lumen **112** of the elongate shaft **114** of the introducer sheath **101**, such as along an exterior of the elongate shaft **12** of the percutaneous circulatory support device **10** disposed therein. In some instances, the lactate sensor **227** may be positioned within the lumen **112** of the elongate shaft **114**. However, in other instances, the lactate sensor **227** may be advanced distally beyond the elongate shaft **114** to a location within the patient's vasculature beyond the elongate shaft **114**.

[0076] In other embodiments the lactate sensor **227** may be secured to the introducer sheath **101**. For example, FIG. **6** is a cross-sectional view of a distal end region of the elongate shaft **114** of the introducer sheath **101**, illustrating the lactate sensor **227** secured within the lumen **112** of the insertion sheath proximate the distal end region **108** thereof. Signal wires may extend from the lactate sensor **227** through a lumen of the elongate shaft **114** to a console or other controller configured to collect, store and/or display data from the lactate sensor **227**. The elongate shaft **12** of the percutaneous circulatory support device **10** may extend through the lumen **112** of the elongate shaft **114** along the lactate sensor **227**. In other instances, the lactate sensor **227** may be secured to and open to an exterior of the elongate shaft **114**, such as on the exterior of the elongate shaft **114** proximate the distal end region **108**, or at the distal tip of the elongate shaft **114**, for example.

[0077] FIG. **7** illustrates an example percutaneous circulatory support system **300** including a console **328**, a percutaneous circulatory support device **10** including an elongate shaft **12** and a percutaneous blood pump **50** positioned at a distal end of the elongate shaft **12**. As shown in FIG. **7**, the percutaneous blood pump **50** can be positioned in the heart **319** of the patient **316**. In some embodiments, the lactate sensor (not shown in FIG. **7**) can be positioned in-vivo to the patient **316**. For instance, the lactate sensor can be positioned in a vasculature of the patient **316** and/or positioned in the heart **319** of the patient **316**.

[0078] The elongate catheter shaft **12** (e.g., a flexible elongate catheter shaft) may have a first end attached to a control module **14** and a second end attached to a percutaneous blood pump **50**. FIG. **7** illustrates the percutaneous blood pump **50** positioned in the left ventricle **318** of the patient **316**. The percutaneous blood pump **50** may be delivered (e.g., tracked) to the left ventricle **318** percutaneously over a guidewire. For example, the catheter shaft **12** and blood pump **50** may be tracked over a guidewire through the femoral artery and the descending aorta, over the aortic arch, through the ascending aorta, past the aortic valve and into the left ventricle **318**.

[0079] In some examples, the catheter shaft **12** of the percutaneous circulatory support device **10** may include one or more blood inlets located on a distal region of the catheter shaft **12**, and one or more blood outlets which are along a housing of the percutaneous blood pump **50**. In some examples, the percutaneous blood pump **50** may be positioned within the heart **319** such that the one or more blood inlets positioned along the distal region of the catheter shaft **12** may be positioned in the left ventricle **318** and the one or more blood outlets located along the housing of the percutaneous blood pump **50** may be positioned in the aorta. Additionally, the percutaneous blood pump **50** may include an electrically powered motor that drives rotation of an impeller (positioned within the housing of the blood pump **50**). In some examples, the motor may power the rotation of the impeller via electromagnetic induction. The spinning impeller may draw blood from the left ventricle (via the one or more blood inlets located on a distal region of the catheter shaft **12**) into the aorta (via the one or more outflow inlets located along the housing of the blood pump **50**). In other words, an electrically powered motor drives the impeller to pump blood from the left ventricle through the aortic valve and into the ascending aorta.

[0080] FIG. **7** further illustrates that a first end of the catheter shaft **12** may be attached to a control module **14**. The control module **14** may include a distal end region attached to the catheter shaft **12** and a proximal end region attached to an electrical power cable **326**. The electrical power cable **326** may include an end region connected to a console **328**. It can be appreciated that the control module **14** may include one or more actuators (e.g., buttons, levers, dials, switches, etc.) designed to permit a clinician to control various functions of the percutaneous blood pump **50**. For example, a clinician may be able to control the speed of the motor and/or the impeller located in the percutaneous blood pump **50** via actuation of one or more actuators located on the control module **14**. In some embodiments, the console may include a display a visual representation of the real-time amount of serum lactate

[0081] Additionally, the percutaneous circulatory support system **300** may include one or more sensors positioned along the console **328**, the control module **14**, the catheter shaft **12** and/or the percutaneous blood pump **50**. The one or more sensors positioned within the console **328**, the control module **14**, along the catheter shaft **12** and/or the percutaneous blood pump **50** may be designed to monitor blood pressures (e.g., arterial pressure, venous pressure), blood velocity, blood flowrate, blood lactate levels, or other parameters. Additionally, the one or more sensors positioned along the console **328**, within the control module **14**, the catheter shaft **12** and/or the percutaneous blood pump **50** may be designed to monitor other parameters of the percutaneous circulatory support system **300**, the catheter **10** and/or the patient **316**.

[0082] Example parameters that may be sensed and monitored may include the electrical connection of the electrical cable **326** to the console **328**, an optical and/or electrical connection to a pressure sensor positioned in the catheter shaft **12** and/or the percutaneous blood pump **50**, a power current to the percutaneous blood pump **50**, the speed of the impeller of the percutaneous blood pump **50**, an arterial pressure, a venous pressure, a power current to the motor, the speed of the motor, an in-vivo lactate measurement (such as from the lactate sensor **27**/**227**), rotations per minute measurement of a motor, the voltage driving the motor, the back-EMF from the motor, etc. and any combination or temporal pattern of signals corresponding to one or more of the parameters listed herein. Further, additional parameters (e.g., flow through the percutaneous blood pump **50**) may be derived by processing combinations of any signal listed herein in a time dependent manner.

[0083] Additionally, FIG. **7** illustrates that the console **328** may include one or more control knobs (e.g., buttons, knobs, dials, etc.) **330** and/or one or more displays. For example, FIG. **7** illustrates the console **328** may include a first display **332** and a second display **334**. It can be appreciated that the console **328** may include more than two displays. Additionally, while FIG. **7** illustrates the first display **332** and the

second display **334** integrated into the console **328**, it is contemplated that the percutaneous circulatory support system **300** may be designed such that the first display **332**, the second display **334** or both the first display **332** and the second display **334** are separate, distinct components of the catheter **10**. In other words, the first display **332**, the second display **334** or both the first display **332** and the second display **334** may be separate stand-alone displays, apart from the console **328**. In some examples, the first display **332** and the second display **334** may get their respective data from separate sources.

[0084] In some examples, the second display **334** may be designed to attach to the console **328** and/or the first display **332**. For example, the first display **332** may be integrated into the console **328** while the second display **334** may be configured to attach to portion of the console **328**. In yet other examples, both the first display **332** and the second display **334** may be a separate stand-alone display whereby the second display **334** may be configured to attach to the first display **332**, or wherein the first display **332** may be configured to attach to the second display **334**.

[0085] The console **328** may include, among other suitable components, one or more processors, memory, and an I/O unit. The processor of the console **328** may include a single processor or more than one processor working individually or with one another. The processor may be configured to execute instructions, including instructions that may be loaded into the memory and/or other suitable memory. Example processor components may include, but are not limited to, microprocessors, microcontrollers, multi-core processors, graphical processing units, digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), discrete circuitry, and/or other suitable types of data processing devices. In some examples, the processor of the console may be configured to execute program instructions. Program instructions may include, for example, firmware, microcode or application code that is executed by the processor, a microprocessor and/or microcontroller. The one or more processors may be configured to each manage different functions. They may also be configured to concurrently perform the same functions (e.g., redundant system). Further yet, they may be configured such that a first processor performs a given function and second processor checks the result of the function of the first processor for correctness (e.g., command-monitor system).

[0086] In some examples, the first display **332** may controlled primarily by the console's firmware control instructions and, therefore, may require relatively little processing power, relatively few instructions and very simple communication between the processor and the first display **332**, compared to the second display **334** (e.g., a touch screen display **34**), which may be controlled primarily by an embedded computer with a flexible and relatively complex communication protocol.

[0087] The memory of the console **328** may include a single memory component or more than one memory component each working individually or with one another. Example types of memory may include random access memory (RAM), EEPROM, FLASH, suitable volatile storage devices, suitable non-volatile storage devices, persistent memory (e.g., read only memory (ROM), hard drive, Flash memory, optical disc memory, and/or other suitable persistent memory) and/or other suitable types of memory. The memory may be or may include a non-transitory computer readable medium.

[0088] The I/O units of the console **328** may include a single I/O component or more than one I/O component each working individually or with one another. Example I/O units may be any type of communication port configured to communicate with other components of the percutaneous circulatory support system **300**. Example types of I/O units may include wired ports, wireless ports, radio frequency (RF) ports, Low-Energy Bluetooth ports, Bluetooth ports, Near-Field Communication (NFC) ports, HDMI ports, Wi-Fi ports, Ethernet ports, VGA ports, serial ports, parallel ports, component video ports, S-video ports, composite audio/video ports, DVI ports, USB ports, optical ports, and/or other suitable ports.

[0089] The console **328** may be configured to collect, record, monitor, save, evaluate and/or display data relevant to the lactate level in the blood sensed by the lactate sensor **27**/**227**. In some instances, the lactate level data generated by the lactate sensor **27**/**227** may be used to control one or more operations of the percutaneous circulatory support device **10**, such as the flow rate, motor speed of the percutaneous blood pump **50**. In some instances, the amount of lactate in the blood that is sensed by the lactate sensor **27**/**227** is based on an amount of lactate oxidase (LOD) in the blood. In some instances, the amount of lactate in the blood that is sensed by the lactate sensor **27**/**227** is based on the amount of lactate dehydrogenase (LDH) in the blood. The console **328** may be configured to periodically or continuously collect, record, monitor, save, evaluate and/or display the amount of lactate in the blood.

[0090] Additionally, the first display **332** and/or the second display **334** may include a CRT, LED, 3D display, other type of display, for example. The first display **332** and/or the second display **334** may present information relevant to functional and operational parameters of the percutaneous circulatory support system **300**, catheter **10** and/or physiological parameters of the patient **316** in a simple format useful to clinicians. For example, the first display **332** and/or the second display **334** may be configure to display information relevant to the lactate levels measured in the blood from the lactate sensor **27**/**227**. The first display **332** and/or the second display **334** may also be configured to display graphical information relevant to the electrical connection of the electrical cable **326** to the console **328**, an optical connection to a pressure sensor positioned in the elongate shaft **12** and/or the percutaneous blood pump **50**, a power current to the percutaneous blood pump **50**, the speed of the impeller of the percutaneous blood pump **50**, an arterial pressure, a venous pressure, a power current to the motor, the speed of the motor, rotations per minute measurement of a motor, the voltage driving the motor, the back-EMF from the motor, etc. and any combination or temporal pattern of signals corresponding to one or more of the parameters listed herein. Further, additional parameters (e.g., flow through the percutaneous blood pump **50**) may be derived by processing any combination or temporal pattern of signals corresponding to one or more of the parameters listed herein in a time dependent manner. Further, the first display **332** may indicate if the system **300** is operating normally, if the system **300** has detected a specific issue that may require additional (e.g., non-routine) procedures/adjustments, and/or if the system **300** has detected s specific issue that requires

emergency procedures. Furthermore, the first display **332** may include information which conveys that a particular response (e.g., action) is needed. For example, the first display **332** may be able to convey information that the percutaneous blood pump **50** has failed and needs to be replaced immediately during a medical procedure.

[0091] In some examples, the percutaneous circulatory support system **300** may be designed such that the type and/or arrangement of graphical information displayed on the first display **332** may be different than the information displayed on the second display **334**. For example, in some instances, the second display **334** may be designed to display detailed information about one or more functional, operational and/or physiological parameters (e.g., an in-vivo lactate measurement) relating to the circulatory system **300**, the catheter **10** and/or the patient **316** while the first display **332** may be designed to provide a simplified, "global" information status summary for one or more functional, operational or physiological parameters relating to the circulatory system **300**, the catheter **10** and/or the patient **316**.

[0092] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The scope of the disclosure is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A percutaneous circulatory support device comprising:
- a catheter including an elongate shaft and a percutaneous blood pump positioned at a distal end of the elongate shaft, the percutaneous blood pump including a blood inlet, a blood outlet, and an impeller assembly positioned therebetween to pump blood from the blood inlet to the blood outlet during use; and
- a lactate sensor configured to sense an amount of lactate in the blood.

2. The device of claim **1**, wherein the lactate sensor is an electrochemical sensor.

3. The device of claim **1**, wherein the amount of lactate is based on an amount of lactate oxidase (LOD) in the blood.

4. The device of claim **1**, wherein the amount of lactate is based on an amount of lactate dehydrogenase (LDH) in the blood.

5. The device of claim **1**, wherein the lactate sensor is configured to periodically detect the amount of lactate in the blood.

6. The device of claim **1**, wherein the lactate sensor is configured to continuously detect the amount of lactate in the blood.

7. The device of claim **1**, wherein the lactate sensor is in direct fluid communication with the blood.

8. The device of claim **1**, wherein the lactate sensor is located inside of or on an exterior surface of the percutaneous blood pump.

9. The device of claim **8**, wherein the lactate sensor is located between the blood inlet and the blood outlet of the percutaneous blood pump.

10. The device of claim **1**, wherein the lactate sensor is located inside of or on an exterior surface of the elongate shaft.

11. The device of claim **10**, the lactate sensor is located proximal of the percutaneous blood pump.

12. The device of claim **11**, wherein the lactate sensor is mounted in a housing on the elongate shaft with the lactate sensor facing an exterior of the elongate shaft.

13. A percutaneous circulatory support system, the system comprising:
- a percutaneous circulatory support device including:
  - a catheter including an elongate shaft and a percutaneous blood pump positioned at a distal end of the elongate shaft, the percutaneous blood pump including a blood inlet, a blood outlet, and an impeller assembly positioned therebetween to pump blood from the blood inlet to the blood outlet during use in a heart of a patient; and
  - a lactate sensor configured to sense a real-time serum lactate level in the blood of the patient during use of the percutaneous blood pump in the heart of the patient.

14. The system of claim **13**, wherein the lactate sensor is secured to an exterior of the elongate shaft proximal of the percutaneous blood pump.

15. The system of claim **14**, wherein the lactate sensor is mounted in a housing on the elongate shaft.

16. The system of claim **13**, wherein the lactate sensor is positioned between the blood inlet and the blood outlet.

17. The system of claim **13**, further comprising an introducer sheath, wherein the introducer sheath includes a lumen configured to deliver the percutaneous blood pump to the heart of the patient, and wherein the lactate sensor is secured to the introducer sheath.

18. An introducer sheath for gaining access to a vasculature of a patient comprising:
- a hub including a hemostasis valve;
- an elongate shaft extending distally from the hub, the elongate shaft including a lumen extending therethrough; and
- a lactate sensor configured to sense an amount of lactate in the blood.

19. The introducer sheath of claim **18**, wherein the lactate sensor is mounted on a distal end region of the elongate shaft.

20. The introducer sheath of claim **18**, wherein the lactate sensor is movably postionable through a passageway of the hub.

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