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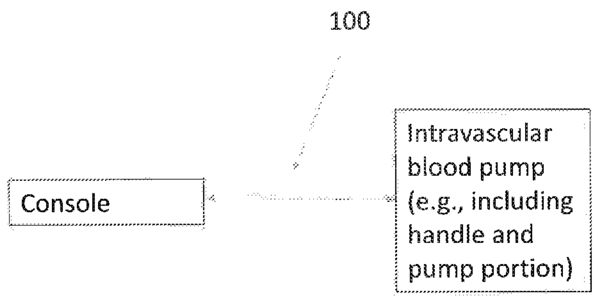

Figure 1

(57) Abstract: Intravascular blood pump systems that include a catheter assembly and an external console assembly. The catheter assembly may be in one or more of fluidic or electrical communication. The catheter assembly may include a controller with an executable method stored therein, wherein the executable method may be configured to receive sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway, at least a portion of the fluid pathway disposed within the catheter assembly, and cause an alert if any of the sensed information is indicative that the external console assembly is not functioning properly.

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INTRAVASCULAR BLOOD PUMPS AND CONTROL THEREOF

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 63/016,667, filed April 28, 2020, the disclosure of which is incorporated by reference herein for all purposes.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

[0003] Medical devices may be adapted to be coupled to an external console, wherein the external console is configured to monitor and/or control one or more aspects of the medical device. For example, without limitation, intravascular blood pumps may be adapted to be coupled to an external console, with the external console monitoring and/or controlling one or more aspects of the use of the external console and/or the intravascular blood pump.

[0004] Software and/or firmware on the external console may monitor and/or control one or more aspects of the external console and/or the intravascular blood pump. It may be suboptimal for the software and/or firmware on the external console to be under the control of one or more aspects of the external console, such as a console operating system ("OS"). For example, without limitation, if a console OS stops performing optimally or ceases to function altogether, software, firmware, and/or hardware within the external console that may be monitoring and/or controlling one or more aspects of the external console and/or the intravascular blood pump may not function properly or may stop functioning altogether. In some instances, the software and/or firmware on the external console may be unable to detect if hardware on the external console is not performing correctly, consequences of which may be severe or even life threatening depending on the particular application. Additionally, it may be desirable to have more control over software and/or firmware used with an intravascular blood pump (including development thereof) than if it is under the control of a third-party OS.

SUMMARY OF THE DISCLOSURE

[0005] Some aspects of this disclosure provide risk mitigation for intravascular blood pumps. In some embodiments the mitigation includes providing an alert or notification (manual and/or automatic) when one or more aspects of an external console is not performing optimally or has stopped performing altogether. In some particular but exemplary embodiments, an intravascular blood pump includes a controller that is adapted to cause an output to be provided if information indicative of a sensed characteristic of fluid in a fluid pathway indicates that one or more aspects of an external console are not performing as expected. For example only, if an operating system on an external console were to stop performing optimally or stop performing altogether (e.g., an OS crash), software and/or hardware used with the intravascular blood pump that is controlled by the OS may stop functioning properly, the consequences of which may be severe, perhaps even life-threatening. In some embodiments, a controller disposed within the intravascular blood pump may be adapted to receive information and initiate an output if the information is indicative that one or more aspects of the console are not performing as expected for any number of reasons. The received information may be, in some embodiments, information indicative of a sensed characteristic of fluid in at least a portion of a purge fluid pathway, such as in at least a portion of a clean purge fluid pathway and/or a purge fluid return pathway. In some embodiments, the received information may be indicative of fluid pressure and/or fluid flow. In some merely exemplary embodiments, the received information may be indicative that hardware on an external console is not performing or being controlled correctly. In some merely exemplary embodiments, external hardware that may not be performing or controlled correctly may be a fluid controller (e.g., a fluid pump, such as a peristaltic pump) for controlling the flow of fluid (e.g., purge fluid and/or sheath fluid). A portion of a clean purge fluid pathway may extend through at least a portion of the intravascular blood pump. A portion of a return purge fluid pathway may extend through at least a portion of the intravascular blood pump.

[0006] In some embodiments, the controller may include a control unit disposed within an intravascular blood pump (e.g., within a handle of the blood pump), wherein the intravascular blood pump is adapted to be coupled to an external console to put the external console and the intravascular blood pump in operable communication (e.g., one or more of electrical communication, mechanical communication, and/or fluid communication (e.g., liquid and/or gas).

[0007] In some merely exemplary embodiments, the controller may be adapted to cause an output to be provided (e.g., on the handle or on the external console) if there is an indication that, based on input information, a fluid controller in an external console may not be functioning properly. The fluid controller may be a fluid control that is adapted and positioned to control one or more aspects of a fluid that is being pumped into the intravascular blood pump, such as purge fluid and/or fluid pumped through an outer sheath of the intravascular blood pump. In some merely exemplary embodiments, the fluid controller may be a fluid pump that is adapted to cause fluid to move through a purge fluid pathway.

[0008] Some aspects of this disclosure may be related to maintaining fluid flow through one or more fluid flow paths. In some implementations, these aspects may include maintaining purge fluid pressure at one or more fluid flow locations.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 schematically illustrates an external console, which may be part of an external console assembly, coupled to an intravascular blood pump or catheter assembly.

[0010] Figure 2 schematically illustrates an external console, which may be part of an external console assembly, coupled to an intravascular blood pump or catheter assembly that includes a handle portion with a controller.

[0011] Figure 3 illustrates an exemplary intravascular blood pump system, wherein a catheter assembly is coupled to an external console assembly.

[0012] Figure 4A schematically illustrates an exemplary blood pump system.

[0013] Figure 4B illustrates exemplary fluid pathways of an exemplary intravascular blood pump.

[0014] Figure 5 provides a merely illustrative schematic representation of an exemplary blood pump system, including optional locations for optional pressure sensors.

[0015] Figure 6 provides exemplary flow and pressure waveforms, one or more aspects of which (e.g., a waveform, an amplitude, a temporal aspect) may be utilized according to any risk mitigation process or system herein.

[0016] Figure 7 schematically illustrates a portion of a catheter portion of an exemplary intravascular blood pump, including an optional pressure sensor location in a clean purge fluid pathway.

[0017] Figure 8 schematically illustrates a portion of the catheter portion from figure 7, including an optional pressure sensor location.

[0018] Figure 9 illustrates a merely exemplary fluid cassette that may be part of any of the external console assemblies herein.

[0019] Figure 10 illustrates a portion of a merely exemplary external console assembly, including portions of optional first and second fluid pathways.

[0020] Figure 11 illustrates a merely exemplary sequence of steps that may be part of computer executable methods herein.

DETAILED DESCRIPTION

[0021] Figure 1 schematically illustrates an external console assembly in operative communication with an intravascular catheter blood pump, which may optionally include a handle portion, a catheter portion, and a pump portion. Communication 100 can include one or more of electrical communication, fluid communication, or mechanical communication, any of which may be one way or two-way communication.

[0022] In some embodiments, risk mitigation may be accomplished by performing one or more actions with the intravascular blood pump. For example, without limitation, a controller or control unit disposed in, on, or otherwise carried by the intravascular blood pump (e.g., within a handle portion thereof) may be configured to receive information and perform one or more actions or events in response to the received information. A controller herein may comprise any number of software and/or hardware components alone or together that are associated with one or more components of the intravascular blood pump.

[0023] An exemplary benefit of exemplary systems herein in which one or more aspects of system monitoring or control are not under direct control of software or firmware controlling the external console (e.g., not controlled by an OS on the console) is that it is possible for the system to be able check or verify that the one or more aspects of the system are functioning properly when a part of the system that controls the aspect has stopped performing optimally or stopped functioning altogether (e.g., an OS on the console crashes). This may generally be referred to herein as being adapted to provide risk mitigation. For example, if software on the console (e.g., an OS) stops functioning, it may prevent one or more applications stored on the console from functioning. In some particular embodiments, an application on the console may be in control of hardware associated with the console (e.g., a peristaltic pump(s), a flow regulator(s), a valve), and if the console cannot control the application, the console may be unable to control the hardware on the console. Additionally, it may not be apparent to a user that control of the system component has stopped or become intermittent, which may create a serious risk to the patient's health. Some aspects of the systems herein provide risk mitigation by providing a different part of the system that can initiate (or cause) an output if there is an indication that part of the system is not performing as intended. There are a variety of ways in which to implement the risk mitigating functionality described herein.

[0024] Figure 2 schematically illustrates an exemplary embodiment of an intravascular blood pump system that is adapted to provide risk mitigation. A system in this context refers to an intravascular blood pump and one or more external components (such as an external console assembly), where the intravascular blood pump is adapted to be coupled with the one or more external components. In the exemplary system illustrated schematically in figure 2, the blood pump includes a controller (e.g., a microcontroller), which in this embodiment is within a handle portion of the blood pump as shown. The handle portion also includes a motor therein that is in rotational operation with one or more impellers in the pump portion (pump portion not shown for clarity). The shaft as shown is generally considered a catheter portion of the catheter assembly, and extends between handle portion and the pump portion. The controller may be in electrical communication with the external console assembly via the communication/connection(s) shown. The communication may be one-way (either direction) or two-way, and may include any number of lines. The catheter assembly controller may also be in communication with the motor. The external console assemblies herein may include a console that may include a user interface (e.g., including a touchscreen) that can allow for input to the console and/or is adapted to provide a variety of outputs to the user interface. The system shown schematically in figure 2 may include any other suitable components of any other system herein.

[0025] Figure 3 illustrates an exemplary intravascular blood pump system that includes an external console assembly that is adapted and configured to be in operative communication with a catheter assembly, which includes a pump portion that is configured to move blood. Figure 3 schematically illustrates an exemplary intravascular blood pump system 2600, which includes an external console assembly 2602 and a catheter assembly 2604, which are both configured to be coupled with one another and placed in operative communication. The catheter assembly 2604 includes a catheter portion 2624 and a handle portion 2622 at a proximal portion of the catheter portion 2624 and a blood pump or pump portion 2606 at a distal portion of the catheter portion 2624. The blood pump 2606 is adapted to be placed within a patient's body and the handle portion 2622 is spaced to remain outside of the patient. The handle portion 2622 may include one or more motors for driving the rotation of one or more impellers of blood pump 2606. The catheter assembly 2604 is adapted to be coupled to and placed into electrical and fluidic communication with console assembly 2602. The console 2610 may include one or more pumps (e.g., peristaltic pumps) to provide fluidic flow to the catheter 2624, and a controller (e.g., an OS, software) thereon configured to control the operation of the pump(s) to thereby control the fluid flow to the catheter. The console 2610 generally includes a user interface, including a display (e.g., touch display) for displaying and/or inputting information related to operation of the blood pump system, such as the console assembly 2602 and/or catheter assembly 2604. The console may also include a cassette receiving area 2608 that is configured to receive a removable fluid cassette that is adapted to facilitate fluid delivery (e.g., clean saline) from a clean fluid source 2612 (e.g., saline bag) into one or more fluid pathways, such a first fluidic pathway (e.g., catheter fluidic pathway) and a second fluidic pathway (e.g., sheath fluidic pathway). A catheter fluid pathway may be used to provide fluid from the console assembly 2602 through the catheter portion 2624, and a sheath fluidic pathway may be used to provide fluid from the console assembly 2602 to the space between an axially movable outer sheath 2605 and an outer surface of a catheter portion shaft. A waste fluid return line 2615 may be used to return waste fluid from the catheter assembly 2604 to a waste reservoir 2614 (e.g., a waste bag). In some cases, the waste reservoir 2614 is coupled to the console 2610. In some examples, the console 2610 includes one or more scales near the clean fluid source 2612 and/or the waste reservoir 2614 that are used to measure the weight of the clean fluid source 2612 and/or the waste reservoir 2614.

[0026] FIG. 4A schematically illustrates at least a portion of an exemplary blood pump system 3600. Any of the blood pump systems described herein may have the arrangement of system 3600. The exemplary blood pump system 3600 may include an optional external console assembly 3606 and a catheter assembly 3608, which may include catheter portion 3604 and pump portion 3602. Catheter portion 3604 in this example may also include a handle portion, such as any of the handle portions herein. Console assembly 3606 may include one or more controllers (e.g., an operating system and/or software) for controlling aspects of the external console assembly and/or a motor that is used to rotate one or more impellers of blood pump 3602. Console assembly 3606 may be in fluid and/or electrical communication with a motor assembly of the catheter assembly via, for example, one or more electrical wires and/or one or more fluidic channels. In some examples, the console assembly 3606 may be in fluid and/or electrical communication with the catheter assembly 3608 via, for example, one or more electrical wires and/or one or more fluidic channels (e.g., bypassing the motor assembly 3604).

[0027] FIG. 4B schematically illustrates an exemplary sectional view (distal to the right, proximal to the left) of at least a portion of an exemplary catheter assembly 3608, and illustrates exemplary and optional fluid pathways therein, which may be part of any of the catheter portions herein. The catheter assembly 3608 may include a plurality of coaxial tubular components including a hollow driveshaft 3620, a driveshaft tube 3622, a catheter shaft 3624 and an outer sheath 3626. The hollow driveshaft 3620 may be in rotational communication with one or more impellers of a pump portion of the blood pump 3602. The hollow driveshaft 3620 may be configured to rotate by being rotatably coupled to a motor of the system. The hollow driveshaft 3620 may include or define an inner lumen to accommodate, for example, a guidewire. The driveshaft tube 3622 may be sized and configured to house therein the rotatable driveshaft 3620. The catheter shaft 3624 (which may be referred to simply as a catheter, and which may include one or more layers of material) may be considered an outermost tubular member of the catheter portion along a substantially length of the catheter portion. A catheter shaft may house components of the blood pump 3602 at a distal portion of the catheter 3624, such as one or more bearing assemblies of the blood pump 3602. Once, in position, sheath 3626 may be retracted proximally to optionally allow expansion of the optionally expandable portions of the blood pump 3602. A motor assembly may be generally adapted to rotate the driveshaft 3620.

[0028] Depending on the particular design of the catheter portion, the catheter portion may include one or more fluid pathways to facilitate fluid flow in and through one or more annular spaces between components of the catheter portion 3608. For example, clean fluid (e.g., clean saline) may flow (e.g., by being pumped with a pump in the external console assembly) toward the blood pump 3602 via a sheath fluid pathway 3630 between the sheath 3626 and an outer surface of catheter shaft 3624. Fluid flow through the sheath fluid pathway 3630 may prevent blood from stagnating and forming clots in the annular space between the sheath 3626 and the catheter shaft 3624 at a distal end of the sheath 3626. Fluid from the sheath fluid pathway 3630 may enter the patient's body with no substantial return fluid pathway. Clean purge fluid (e.g., saline pumped from a saline bag disposed outside the patient) may also flow (e.g., by being pumped) toward the blood pump 3602 via a catheter clean fluid pathway 3632 between the catheter shaft 3624 and the driveshaft tube 3622. Some or all of the fluid in the catheter clean fluid pathway 3632 may return from the blood pump 3602 via a return fluid pathway 3634 (which may be referred to in any embodiment herein as a waste fluid pathway). Flowing fluid through the catheter fluid pathway 3632 and return fluid pathway 3634 may cool and/or lubricate moving components (e.g., the rotating driveshaft 3620 and bearings) within the blood pump 3602. The catheter clean fluid pathway 3632 and return fluid pathway 3634 may flush and keep possible debris (e.g., from wear of rotating components) from entering the patient's body. In some examples, where a wall of the driveshaft 3620 has some porosity, fluid within the return fluid pathway 3634 may passively enter the inner lumen of the driveshaft 3620.

[0029] In any of the embodiments herein, a driveshaft, a driveshaft tube, a catheter shaft and optionally an outer sheath may all be co-axial.

[0030] Optionally, clean fluid for the sheath fluid pathway 3630 and the catheter fluid pathway 3632 may be provided by a console 3606, which may include one or more clean fluid sources (e.g., saline bags) and a pump assembly (e.g., peristaltic pump assembly) for moving clean fluid distally toward the blood pump 3602. In some examples, the clean fluid may be provided to the catheter portion 3608 through a catheter fluid inlet and a sheath fluid inlet between the motor assembly 3604 and the blood pump 3602. In some cases, one or both of the catheter fluid inlet and the sheath fluid inlet are part of (or connected to) the motor assembly 3604. In some examples, the return fluid pathway 3634 may flow through a motor assembly (not shown) and toward a waste reservoir, which optionally may be connected to (or part of) such as by being secured to, a console assembly.

[0031] Any controller or control unit herein (e.g., the controller shown in figure 4) may include one or more of a microcontroller, hardware, software or firmware, for example.

[0032] In some particular exemplary embodiments, the blood pump systems are adapted with risk mitigation functionality to detect if one or more aspects of the console is not performing as intended. For example, some systems may be adapted to determine if fluid (e.g., clean fluid, return fluid, sheath fluid) is not flowing in a fluid pathway as intended or desired, or there is otherwise some problem with the fluid pathway. In some embodiments, the system is adapted to create or cause an output or alert or notification if fluid is not being controlled in a desired or intended manner. For example without limitation, some systems may include a fluid return pathway from the intravascular blood pump, the pathway including one or more fluid lines. An exemplary fluid pathway may be a purge fluid return pathway or a clean purge pathway, and in the case of a return pathway, at least a portion of purge fluid that is delivered to the blood pump moves away from the blood pump after passing through at least a portion of the blood pump. By way of example only, a system may include or more features that are adapted to modify flow in a fluid pathway, such as from switching from fluid flow to no fluid flow. Exemplary features in this regard include software on the console and/or hardware on the console such as a peristaltic pump.

[0033] In an exemplary implementation of figures 2 or 3, the console assembly may include one or more fluid flow regulators (e.g., one or more peristaltic pumps, valves, etc.) that are adapted to be controlled by software/firmware stored on the console, such as a console operating system. If the console fluid flow regulator can no longer be effectively controlled, firmware/software on the blood pump controller is adapted to be part of a detection and/or notification process that some aspect of the external console (e.g., a flow regulator) has stopped functioning properly, optionally due to a console operating system malfunction. The process may include causing an alert, notification, or otherwise provide an indication of an event that is indicative of the decrease in functionality. An exemplary alert may occur on the console or a blood pump handle portion, for example.

[0034] In some embodiments of the system, one or more sensors (e.g., pressure sensors, flow sensors) are in communication (directly or indirectly) with the blood pump controller. For example, without limitation, the controller may be in communication with one or more sensors that provide information indicative of one or more sensed characteristics of fluid in a fluid pathway extending from the handle (such as any of the pathways shown in figure 4B). The fluid pathway may be one or more of a clean fluid pathway, a return fluid pathway, or a sheath fluid pathway. Any of these sensors may be disposed in or carried by any suitable portion of the intravascular blood pump system, such as within an external console fluid pathway, within a fluid pathway within the handle portion, within a fluid pathway in a component removable from the console (e.g., a cassette), within a fluid pathway axially between the external console and the handle portion, within a fluid pathway in a catheter assembly or pump portion that is distal to a handle portion, etc. The one or more sensors may include a sensor adapted to sense flow along the fluid pathway, a sensor adapted to sense pressure along the fluid pathway, or both (and any number of each). Additionally, there may be sensors at a plurality of locations along any of the different fluid pathways herein that are adapted to sense information at the plurality of locations. For example, without limitation, an external console assembly (including a removable component such as a cassette) may include one or more pressure or flow sensors adapted to sense information indicative of one or more of fluid pressure or a flow rate in any of the fluid pathways herein.

[0035] Figure 5 provides a merely illustrative schematic representation of an exemplary blood pump system, which may include an external console assembly that includes a flow regulator (e.g., a peristaltic pump – “P.pump”). Components are represented electrically to illustrate concepts, additional disclosure of which can be found herein.

[0036] In some implementations, the blood pump system may be adapted to cause or initiate an output when received information indicates that one or more sensed characteristics of fluid in a fluid path (e.g., clean purge fluid, return fluid, sheath fluid, etc.) is indicative of a fluid path flow regulator that is not functioning properly. Malfunctioning as described here may be due to hardware error, such as a pump that is no longer working and/or a software error, such as a console operating system error. In some implementations, the system is adapted to create an output (e.g., an output from an algorithm) if an aspect of flow in a fluid pathway is not, or diverges from, an expected aspect of the flow. In some implementations, the system is adapted to create an output if an aspect of flow changes from a current state to a different state. Fluid flows aspects, or characteristics, that may be indicative of a problem include information indicative of, but are not limited to, a flow rate amplitude (an example of which is shown in figure 6), a flow rate waveform (an example of which is shown in figure 6), a temporal aspect of flow, etc. Exemplary temporal aspects of flow include, but are not limited to, duration and/or timing of an expected phase, such as expected duration of a flow path being open and/or closed; duration and/or timing of an expected flow rate amplitude. The exemplary flow waveform shown in figure 6 illustrates by way of illustration and example only flow characteristics that may be utilized. In the flow signal waveform shown, the vertical arrows generally indicate signal amplitude. The horizontal arrows each illustrate exemplary duration (time) of different phases, with the leftmost arrow indicating the duration/time of a relatively higher flow phase, such as if a flow regulator (e.g., valve) allows return fluid to flow, whereas the horizontal arrow on the right could indicate the duration/time of a phase in which flow decreases, which could indicate a flow decrease, or is stopped altogether (e.g., flow regulator closes the flow path).

[0037] In exemplary particular risk mitigation implementations, the system may alternatively or in addition to, be adapted to cause or create an output (e.g., from an algorithm) if an aspect of fluid pressure in one or more fluid pathways (e.g., purge fluid return) is not, or diverges from, an expected aspect (e.g., stored in memory) of the flow. In some implementations, the system is adapted to create an output if an aspect of fluid pressure changes from a current state to a different state. Fluid pressure aspects, or characteristics, that may be indicative of a problem include information indicative of, but are not limited to, a pressure amplitude (e.g., as shown in figure 6 in dotted line), a pressure waveform (e.g., as shown in figure 6), a temporal aspect of pressure, etc. Temporal aspects of pressure include, but are not limited to, duration and/or timing of an expected phase, such as expected duration of pressure to be at or near a known amplitude. The exemplary pressure waveform in figure 6 illustrates by way of illustration and example only pressure characteristics that may be utilized. In the pressure waveform, the amplitude is represented vertically. The adjacent horizontal arrows each illustrate exemplary duration (time) of different phases, with the leftmost arrow indicating the duration/time of a relatively lower pressure, such as if a flow regulator (e.g., valve) allows return fluid to flow, whereas the horizontal arrow on the right could indicate the duration/time of a phase in which flow increases, which could indicate a fluid pressure increase (e.g., flow regulator closes a return fluid flow path). Alternatively, a sensed pressure may indicate if one or more fluid pumps in the console are operating properly. For example, if a fluid pressure drops, it may indicate that a fluid pump in the console is not functioning properly. Additionally, if a fluid pressure is outside of an acceptable range, it may indicate that a fluid pump (e.g., a peristaltic pump) in the console is not functioning properly.

[0038] An exemplary additional advantage of some of the methods herein that receive information indicative of sensed information is that the methods may ease the burden on accuracy requirements of one or more sensors. For example, the methods herein can be adapted to determine if sensed signals are within an expected window, which may be easier to implement than if looking for sensed signals at more discrete values.

[0039] Any of the characteristics of fluid herein (which includes information that is indicative of the fluid characteristics), such as fluid flow characteristics and fluid pressure characteristics may be stored in one or more system memory units that are outside of the direct control of the external console. In some implementations, the stored characteristics may be stored in a blood pump controller, such as the controller associated with the blood pump handle shown in figures 1 and 2. Any of the fluid characteristics herein may be referred to herein as any of the following: stored characteristics, desired characteristics, expected characteristics, or other similar phrases or derivatives thereof.

[0040] The exemplary ways in which the systems herein are adapted to determine if one or more aspects of fluid are not, or if they diverge from, an expected aspect of fluid flow or fluid pressure are exemplary and do not limit the general concepts and processes herein.

[0041] Figure 9 illustrates a merely exemplary fluid cassette 404, showing a perspective view of an internal or inner side of the cassette that is configured to be inserted into and engaged with an external console, such as console 2610 in figure 3. The cassette in this embodiment includes a flow regulator in the form of pump or a portion of pump 428, optional pressure sensor 420, and optional fluid input reservoir regulator 422. The left side of the cassette 404 in the figure illustrates a portion of fluid lines or pathways that extend towards the catheter assembly (not shown) of the intravascular blood pump. In this example, one of the fluid lines may be part of a fluid pathway for waste fluid from the catheter assembly, which may flow to a waste reservoir. Two of the fluid input lines shown extending from the right side of the cassette in the figure reservoirs may receive fluid therethrough from one or more clean purge fluid reservoirs. Cassette 404 includes optional second flow controller or regulator 415 (e.g., a valve, optionally electrically controlled, optionally via feedback) that may be configured to control which fluid reservoir is input to the blood pump (in optional embodiments in which there are more than one clean fluid reservoir). Optional pressure sensor 420 may be a proximal pressure sensor for the system and may be configured to sense fluid pressure in the system at the location of the pressure sensor, although the system may include additionally placed or alternatively placed pressure sensors, which is described in more detail herein. The cassette may optionally (but not necessarily) have openings 430 (or any other kind of aperture) in the internal side surface, which may optionally allow hardware in the console to interface with one or more of the fluid lines shown (e.g., two lines in, one waste out) to optionally contribute to controlling the flow of fluid through one or more of the fluid lines. In the merely exemplary embodiment of figure 9, the external console may include one or more valves, such as pinch valves, that are adapted to function as a type of flow regulator or controller to allow flow to be controlled and directed towards or away from the blood pump.

[0042] In any of the embodiments herein, the return fluid pathway or line may also include one or more of pressure sensor(s) or flow sensor(s) at any location(s) along the fluid pathway to sense a characteristic of fluid in the line, the sensed information from which may be communicated to a controller in the handle as is described in more detail herein. Any of the sensors herein may be in electrical communication (directly or indirectly) with the blood pump controller. Fluid cable or connect 408 may be connected with the cassette 404 before or after cassette 404 in engaged and secured to the external console.

[0043] One of the optionally three catheter assembly input lines shown to the left in figure 9 may be in fluid communication with a sheath fluid pathway, and one of the optionally three fluid lines may be considered a clean fluid pathway to the catheter assembly. One of the optionally three lines may be a fluid waste line that may carry return fluid out of the catheter assembly to a waste reservoir.

[0044] Optional flow regulator 428 may be, or may be part of, a pulsatile pump to provide flow, and may be driven by a stepper motor in the external console (not shown). The pump may optionally be adapted to operate at one or more fixed speeds, with or without a speed feedback loop. Optional pressure sensor 420 may be configured to detect one or more of fluid pathway blockages, overpressure conditions, or under-pressure conditions that may be indicative of a leak in the fluid pathway.

[0045] FIG. 10 shows an example of an external console assembly that includes fluid cassette 2700 that is adapted to be mounted to a cassette receiving area of an external console. In this example, the external console assembly includes a first pump 2702 and a second pump 2704. The fluid cassette 2700 may be configured to releasably and operationally coupled with the fluid cassette receiving area 2701 of a console. The first pump 2702 and the second pump 2704 may be peristaltic pumps. In this example, the two-pump configuration can allow for separate and independent control of fluid through a first fluid pathway (e.g., catheter fluid pathway) and a second fluid pathway (e.g., a sheath fluid pathway). Fluid cassette 2700 includes a first fluid line as part of a first fluid pathway (e.g., catheter fluid pathway) and a second fluid line as part of a second fluid pathway (e.g., a sheath fluid pathway). An inlet tubing support 2714 of the cassette receiving area 2701 may be configured to support an inlet tubing from, for example, a clean fluid source 2612 (Figure 3). Fluid from the clean fluid source is directed to a manifold 2722 via a manifold inlet 2732, which directs the clean fluid to a first flexible tubing 2724 and a second flexible tubing 2726. A first pump head 2706 of the first pump 2702 is configured to operationally engage with and pump fluid through the first flexible tubing 2724. Likewise, a second pump head 2708 of the second pump 2704 is configured to operationally engage with and pump fluid through the second flexible tubing 2726. The clean fluid is pushed back through the manifold 2722 and out of the manifold through a first manifold outlet 2718 and a second manifold outlet 2720, which are connected to corresponding tubing to the catheter. The manifold 2722 includes a manifold inlet channel 2728 that directs fluid from the manifold inlet 2732 to the first flexible tubing 2724 and the second flexible tubing 2726. The manifold 2722 also includes a first manifold outlet channel 2730 that directs fluid from the first flexible tubing 2724 to the first manifold outlet 2718, and a second manifold outlet channel 2731 that directs fluid from the second flexible tubing 2726 to the second manifold outlet 2720. The first manifold outlet 2718 may optionally be connected to tubing that provides fluid communication to a catheter or a sheath, and the second manifold outlet 2720 may optionally be connected to tubing that provides fluid communication to the other of the catheter or the sheath. Figure 10 is a merely exemplary portion of an exemplary external console assembly that may be adapted to be in fluidic communication with any of the catheter assemblies herein.

[0046] Figure 6 provides exemplary flow and pressure waveforms, one or more aspects of which (e.g., a waveform, an amplitude, a temporal aspect) may be utilized according to any risk mitigation process or system herein. Fluid characteristics herein may be stored in one or more memory units disposed in a blood pump controller, wherein the sensed information may be compared against the stored information. The blood pump controller may be configured to detect, determine, compare, or otherwise indicate (e.g., via an output) if one or more sensed fluid characteristics or information indicative thereof indicates a problem with the external console.

[0047] In some exemplary embodiments, a blood pump controller (an example of which is shown in figure 2) may have stored therein one or more computer executable methods (e.g., one or more algorithms) that is adapted to compare stored information with sensed information (or information that is indicative of sensed information) to determine if the sensed information is, for example, different than the stored information, outside a range of expected information, above or below a threshold, or simply different than expected information. Any of these situations may be considered to a triggering event herein. In the event of a triggering event herein, the computer executable method may include taking or initiating an action (e.g., providing an output) indicating the triggering event, which may cause or initiate an alert to a user that one or more aspects of the system is not functioning properly.

[0048] The risk mitigation benefits herein may include the system performing or taking one or more actions if there is an indication that one or more sensed characteristics of fluid in a fluid path indicate that an aspect of an external console is not functioning properly (i.e., a triggering event). For example, an action may be performed if there is an indication that a fluid flow controller in an external console is not functioning properly, such as a fluid flow controller that is adapted to control or cause fluid flow through one or more fluid pathways herein.

[0049] In some embodiments, the action may include an output generated by a process such as an algorithm (e.g., firmware, software, etc.). The action may include providing or causing an alert that can provide an indication that one or more aspects of the external console assembly (e.g., one or more of software, firmware, or hardware) is not functioning properly. For example, a blood pump controller (an example of which is shown in figure 2) may provide an output to one or more system components that can initiate and/or provide a notification or alert.

[0050] In some embodiments, an alert or notification may be provided by the blood pump. For example, the blood pump may include any number of indicators that are adapted to provide an indication of the detected event. In some exemplary embodiments the blood pump may include any number of visual indicators (e.g., lights, such as LED(s), audible indicators (e.g., a sound such as a beep), and/or tactile indicators (e.g., vibratory) that are adapted to provide or indicate a notification or alert. In some embodiments, the blood pump is adapted to initiate a communication to an external device (e.g., an external console) to provide alert of the detected event. Any communications between the blood pump and the console may be wired or wireless.

[0051] The external console may be adapted to provide a notification or alert of the event. For example, an aspect of the console outside of the control of the operating system may be configured to provide a notification of the event, such as any of the indicators herein: visual (e.g., on a display, LED); audio (e.g., a sound), tactile (e.g., vibration), etc.

[0052] Figure 7 schematically illustrates a portion of a catheter portion of an exemplary intravascular blood pump, with the distal direction to the right and the proximal direction to the left. The disclosure related to figure 7 may be combined with the disclosure related to figure 4. Figure 7 illustrates a portion of a clean purge fluid in pathway, which may be delivered from a clean fluid reservoir using an external console. The fluid pathway, a highlighted region of which is shown in figure 8, includes fluid flowing radially inward from the clean purge fluid pathway, after which a portion of the fluid continues to flow distally, as shown, and a portion of which continues to flow proximally toward the external console, as shown. The fluid flowing proximally is shown as return fluid, which flows proximally out of the blood catheter assembly to a waste reservoir.

[0053] The blood pump may include one or more pressure sensors that are adapted to sense pressure at one or locations in the intravascular blood pump. For example, a pump portion of the blood pump may include one or more pressure sensors, such as at or adjacent to one or both of an inflow and/or an outflow. One or more pump portion pressure sensors are generally indicated by the pressure sensor on the right in figure 5. The system may also include a pressure sensor adjacent and downstream to a pump in the console, such as the pressure sensor shown in figure 5 on the left of the figure. The blood pump may also include a pressure sensor as shown in figures 5, 7 and 8, which may be generally disposed in a purge flow path and upstream (relative to a purge flow direction) to the pump portion that includes one or more impellers.

[0054] Any of the pressure sensors herein may be in wired communication with a controller, or any of the pressure sensors herein may be in wireless communication with a controller.

[0055] In some exemplary implementations, an external console and a catheter assembly may be put into operable communication with each other (e.g., as shown in figures 2 and 3). The stored fluid information herein that is used in the risk mitigation may initially be stored in the external console and/or the information may be stored outside of an external console (e.g., in the blood pump). If the information is initially stored in an external console (e.g., in a software application on the console), the information may be passed to the blood pump controller when they are connected and stored thereon after they have been placed in communication. For example, waveform data (such as that shown in figure 6) that may be expected once the blood pump is activated may be communicated to the blood pump and stored thereon. After the blood pump is activated, the controller may then be able to receive sensed information and determine if one or more aspects of the external console are not functioning properly by comparing the sensed information with the expected information. Any of the examples of sensed information and stored information herein may be utilized in this manner. For example, expected timing aspects of fluid flow and/or fluid pressure may be communicated from the console to the blood pump and stored thereon in, for example, a blood pump controller. During operation of the pump portion, the controller may then compare any received sensed information (e.g., related to or indicative of fluid flow and/or fluid pressure) with the stored information, and provide or cause an output that indicates that there is a difference between the expected information and the sensed information. As set forth, the stored information may be information indicative of a wide variety of aspects of flow and/or pressure, and the specific type(s) of information herein are merely exemplary and are not intended to be limiting.

[0056] In any of the embodiments herein, the blood pump controller may be adapted to receive and utilize information indicative of both fluid flow and/or fluid pressure. For example, in some merely exemplary embodiments, the controller may receive information indicative of sensed fluid flow and sensed fluid pressure, and compare the information with stored information indicative of flow and pressure, such as without limitation, indicative of one or more of expected amplitude, expected duration of a phase, etc.

[0057] Any of the processes or systems herein may include an intravascular blood pump with one or more processes initially stored in a blood pump controller. For example, a blood pump may include a controller with firmware on which one or more process are stored, such as for example without limitation, a timing protocol for hardware control, such as a flow regulator (e.g., a pump, a switch). After the blood pump and external console are put in operable communication, information (e.g., one or more algorithms) may be communicated from the catheter assembly and stored on the external console. The console may then have stored thereon one or more processes to control one or more hardware features on the console (e.g., one or more peristaltic pumps).

[0058] In some instances, one or more blood pumps may have different operating conditions stored thereon in one or more memory units. The operating conditions may be stored in the blood pump prior to being put into operable communication with the console, such as when a microcontroller with firmware stored thereon is coupled to electronics of a blood pump. For example, a first blood pump may have operating conditions stored thereon that are different than one or more operating conditions of a second blood pump (or second type of blood pump). Blood pumps with different operating conditions may have one or differences, such as without limitation, number of impellers, expanded diameter size, fluid conduit length, application, etc. Operating conditions that may be different for different blood pumps may include any of, for example without limitation, expected characteristics of flow, expected characteristics of pressure, operating conditions of hardware on an external console (e.g., peristaltic pumps, flow regulator(s)) operating conditions of hardware on the blood pump (e.g., motor). Implementations that include one or more blood pump characteristics stored on the blood pump that are communicated to an external console once coupled together provides for the benefit of being able to communicate any number of protocols or procedures to the external console for any number of blood pumps, and once communicated the console may then be able to control one or more console features in a manner that may be specific to the blood pump, patient, application, setting, etc. For example, there may be several different blood pump models, each of which may have different timing information. Passing (optionally automatically) this information from the blood pump to the console may allow the console to know to which blood pump it is connected/talking to.

[0059] Figure 11 illustrates an exemplary method, such as a computer executable method, that may be executed by a processor (e.g., microprocessor) and adapted for use with any of the intravascular blood pumps herein. The exemplary method shown in figure 10 includes optional first and second steps, although the method may optionally include any other suitable method step herein. Figure 10 is thus meant to illustrative of computer executable methods herein. Any of the methods herein may thus be represented as a flow diagram as shown in figure 10, even if the figure is not expressly included herein in the figure set. Additional method steps may include any suitable step herein, including any steps in one or more of the Detailed Description and Claims.

[0060] One optional aspect of the disclosure may be related to preventing blood from entering the catheter and/or contacting the drive assembly. In some implementations the aspect can use the delivery of purge fluid through the blood pump to prevent blood from entering into one or more spaces in the blood pump (other than through the fluid conduit, through which blood is pumped). That is, purge fluid can be pumped through and out of the catheter to prevent blood from entering into one or more purge fluid paths. In some illustrative examples, the pump portion includes one or more pressure sensors (e.g., one or both of an inflow and outflow sensors), schematically illustrated in figure 5 as the "pressure sensor" on the right side of the figure. There may be a sensor in the catheter disposed to sense pressure along an inflow purge fluid path, such as where the central "pressure sensor" is shown in figure 5. This exemplary pressure sensor location is also shown in figures 7 and 8. One way of preventing blood from flowing into the purge fluid pathway in the blood pump may be to make sure the pressure in the catheter (e.g., P.cath) is at least the same as and more likely greater than the pressure at the pump portion. Generally speaking, this ensure the pressure along the purge fluid pathway in the catheter is greater than pressure in the purge fluid pathway at the pump, making surge purge fluid is pumped at a rate/pressure to make sure it flows and prevents blood from coming into the catheter. The system can include one or more processes stored thereon that are adapted to receive sensed pressure information and control the delivery of purge fluid to maintain P.cath at least the same as and generally greater than pressure at the pump portion (which may also be referred to herein as pressure at the patient (blood pressure)).

[0061] In any of the embodiments herein, a flow regulator in the console may be any type of suitable flow regulator. In figure 5, the flow regulator is shown as an optional switch, which may be a binary switch (open/closed), but which may be a variable switch, to allow for finer control of return purge fluid flow characteristics. An external flow regulator may also be a pump, such as a peristaltic pump or a portion of a peristaltic pump.

[0062] The disclosure herein describes exemplary systems in which a blood pump may receive sensed information and may utilize that in risk mitigation processes. In some more generalized implementations, a blood pump may expect to receive information from an external console, and if that information is not received, it may indicate that one or more functions of the console are not functioning properly. For example, a blood pump controller may be adapted to expect a periodic signal/communication from an external console. If the controller does not receive the signal/communication as or when expected, the controller may then provide an output (such as any of those herein) that causes any number of actions to take place that indicate the discrepancy.

[0063] Even if not specifically indicated, one or more techniques described in this disclosure may be implemented, at least in part, in hardware, software, firmware or any combination thereof. For example, various aspects of the techniques or components may be implemented within one or more processors, including one or more microprocessors, digital signal processors (DSPs), application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), programmable logic circuitry, or the like, either alone or in any suitable combination. The term “processor,” “controller,” “control unit,” or derivatives thereof may generally refer to any of the foregoing circuitry, alone or in combination with other circuitry, or any other equivalent circuitry.

[0064] Such hardware, software, or firmware may be implemented within the same device or within separate devices to support various operations and functions described in this disclosure. In addition, any of the described units, modules or components may be implemented together or separately as discrete but interoperable logic devices. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components, or integrated within common or separate hardware or software components.

[0065] When implemented in software, functionality ascribed to systems, devices and techniques described in this disclosure may be embodied as instructions on a computer-readable medium such as random access memory (RAM), read only memory (ROM), non-volatile RAM (NVRAM), electrically erasable programmable ROM (EEPROM), Flash memory, and the like. The instructions may be executed by a processor to support one or more aspects of functionality described in this disclosure.

[0066] The Detailed Description includes an Appendix section. Any suitable aspect of the Detailed Description included in either the Appendix portion or the non-Appendix portion may be incorporated with aspects of the other portion of the Detailed Description, including without limitation devices, components, parts, portions, and method steps including methods of deployment and use. For example, any of the exemplary pump portions in the Appendix section may also include any suitable aspect described in the non-Appendix portion, such as, without limitation, methods executable by a processor. Reference numbers or figures in the non-Appendix portion of the Detailed Description figures, even if they are duplicative of reference numbers or figures in the Appendix section, are understood to apply to the non-Appendix section of the Detailed Description.

CLAIMS

1. A method executable by a processor, the method stored in an intravascular catheter blood pump, the executable method configured to:

receive sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway, at least a portion of the fluid pathway disposed within the intravascular catheter blood pump, the catheter blood pump including a pump portion having at least one impeller; and

cause an alert if any of the sensed information is indicative that an external console assembly disposed outside a patient with which the intravascular catheter blood pump is in operable communication is not functioning properly.

2. The method of claim 1, wherein causing an alert comprises causing an alert if any of the sensed information is indicative that an external console assembly fluid pump is not functioning properly, the fluid pump configured and disposed relative to the fluid pathway to pump fluid within the fluid pathway.

3. The method of Claim 2, wherein the fluid pathway is a clean purge fluid pathway, wherein the external console assembly fluid pump is configured and disposed relative to the clean purge fluid pathway to pump clean purge fluid within the clean purge fluid pathway.

4. The method of Claim 2, wherein the fluid pathway is a sheath fluid pathway that includes a section between an outer sheath and an outer surface of a catheter shaft of the catheter blood pump, wherein the external console assembly fluid pump is configured and disposed relative to the sheath fluid pathway to pump sheath fluid within the sheath fluid pathway.

5. The method of Claim 1, wherein the fluid pathway is a purge fluid return pathway in which fluid moves proximally through the catheter blood pump.

6. The method of Claim 1, wherein the sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway comprises information indicative of a sensed fluid pressure in the fluid pathway.

7. The method of Claim 6, wherein the sensed fluid pressure is sensed by a pressure sensor that is disposed in the external console assembly.

8. The method of Claim 6, wherein the sensed fluid pressure is sensed by a pressure sensor that is disposed in a handle portion of the catheter blood pump.

9. The method of Claim 6, wherein the sensed fluid pressure is sensed by a pressure sensor that is disposed distal to a handle of the catheter blood pump.

10. The method of any of Claims 7-9, wherein the pressure sensor is disposed so as to sense clean purge fluid pressure.

11. The method of any of Claims 7-9, wherein the pressure sensor is disposed so as to sense return fluid pressure.

12. The method of Claim 1, wherein receiving sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway comprises receiving sensed information that is indicative of a sensed pressure amplitude.

13. The method of Claim 1, receiving sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway comprises receiving sensed information that is indicative of a sensed pressure waveform over time.

14. The method of Claim 1, wherein causing the alert step comprises comparing the sensed information to stored information that is stored on the catheter blood pump, and initiating an output based on the result of the comparison step.

15. The method of Claim 14, wherein the stored information is indicative of a stored sensed pressure amplitude.

16. The method of Claim 14, wherein the stored information is indicative of a stored pressure waveform over time.

17. The method of Claim 14, wherein the stored information is indicative of a fluid pressure threshold.

18. The method of Claim 17, wherein the stored information is indicative of a low fluid pressure threshold or a high fluid pressure threshold.

19. The method of any of Claims 14-18, wherein causing the alert comprises causing the alert if the comparing step indicates that the sensed information is different in one or more ways to the stored information.

20. The method of any of claims 1-19, wherein the executable method is stored in a microcontroller disposed within a handle portion of the catheter blood pump, the handle portion spaced from an impeller such that the handle portion is disposed outside of a patient when the impeller is disposed in the patient.

21. The method of Claim 1, wherein causing the alert comprises causing an alert if any of the sensed information is indicative that an operating system on the external console assembly is not functioning properly, wherein the operating system is adapted to control a fluid pump within the external console assembly.

22. The method of any of Claims 1-21, wherein receiving the sensed information comprises receiving sensed information that is indicative of sensed fluid flow in the fluid pathway.

23. The method of any of Claims 1-22, wherein causing an alert comprises causing an alert on a handle portion of the catheter blood pump.

24. The method of any of Claims 1-22, wherein causing an alert comprises causing an alert on the external console assembly.

25. An intravascular blood pump system, comprising:

a catheter assembly including,

a handle portion, a catheter portion extending distally from the handle portion, and a pump portion disposed at a distal end of the catheter portion; and

an external console assembly, the catheter assembly and the external console assembly adapted and configured to be put into fluidic communication,

the handle portion sized and configured to be held by a user,

the handle portion comprising a controller with an executable method stored therein, the executable method configured to receive sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway, at least a portion of the fluid pathway disposed within the catheter assembly, and cause an alert if any of the sensed information is indicative that the external console assembly is not functioning properly.

26. The system of Claim 25, further comprising a pressure sensor disposed in the fluid pathway, the sensed characteristic indicative of fluid pressure in the fluid pathway.

27. The system of Claim 26, wherein the pressure sensor is disposed within the external console assembly.

28. The system of Claim 26, wherein the pressure sensor is disposed within the catheter assembly.

29. The system of Claim 28, wherein the pressure sensor is disposed within the handle portion.

30. The system of Claim 28, wherein the pressure sensor is disposed within the catheter portion.

31. The system of any of claims 25-30, wherein the fluid pathway is a clean purge fluid pathway.

32. The system of any of claims 25-30, wherein the fluid pathway is a return fluid pathway.

33. The system of any of claims 25-30, wherein the fluid pathway is a sheath fluid pathway that includes a section disposed between an outer axially movable sheath and an outer surface of an inner catheter shaft.

34. The system of claim 25, further comprising a fluid pump in the external console assembly, the fluid pump adapted and positioned to pump fluid in the fluid pathway, wherein the executable method is configured to cause an alert if the fluid pump is not functioning properly.

35. The system of claim 34, wherein the fluid pump is adapted and positioned to pump fluid in a clean purge fluid pathway.

36. The system of claim 34, wherein the fluid pump is adapted and positioned to pump fluid in a sheath fluid pathway that includes a section between an outer sheath and an outer surface of a catheter shaft of the catheter portion.

37. The system of claim 25, wherein receiving sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway comprises receiving sensed information that is indicative of a sensed fluid pressure amplitude.

38. The system of claim 25, wherein receiving sensed information that is indicative of a sensed characteristic of fluid in a fluid pathway comprises receiving sensed information that is indicative of a sensed fluid pressure waveform over time.

39. The system of claim 25, wherein the handle portion comprises an indicator that is adapted to communicate the alert.

40. The system of claim 25, wherein the external console assembly comprises an indicator that is adapted to communicate the alert.

41. The system of claim 25, wherein the causing step comprises comparing the sensed information to stored information that is stored in the controller, and initiating an output based on the result of the comparing step.

42. The system of claim 41, wherein the stored information is indicative of a stored sensed pressure amplitude.

43. The system of claim 41, wherein the stored information is indicative of a stored pressure waveform over time.

44. The system of claim 41, wherein the stored information is indicative of a fluid pressure threshold.

45. The system of claim 44, wherein the stored information is indicative of a low fluid pressure threshold or a high fluid pressure threshold.

46. The system of claim 25, wherein the external console assembly comprises an operating system adapted to be in direct or indirect control one or more fluid pumps in the external console assembly, one of the one or more pumps positioned and adapted to pump fluid in the pathway.

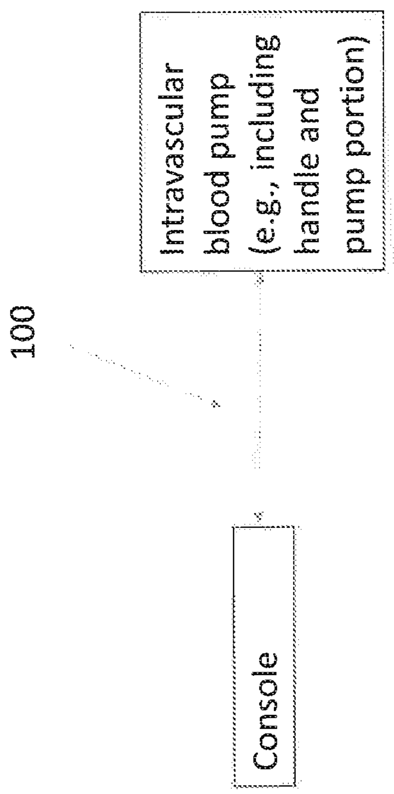

100
Intravascular blood pump (e.g., including handle and pump portion)
Console

Figure 1

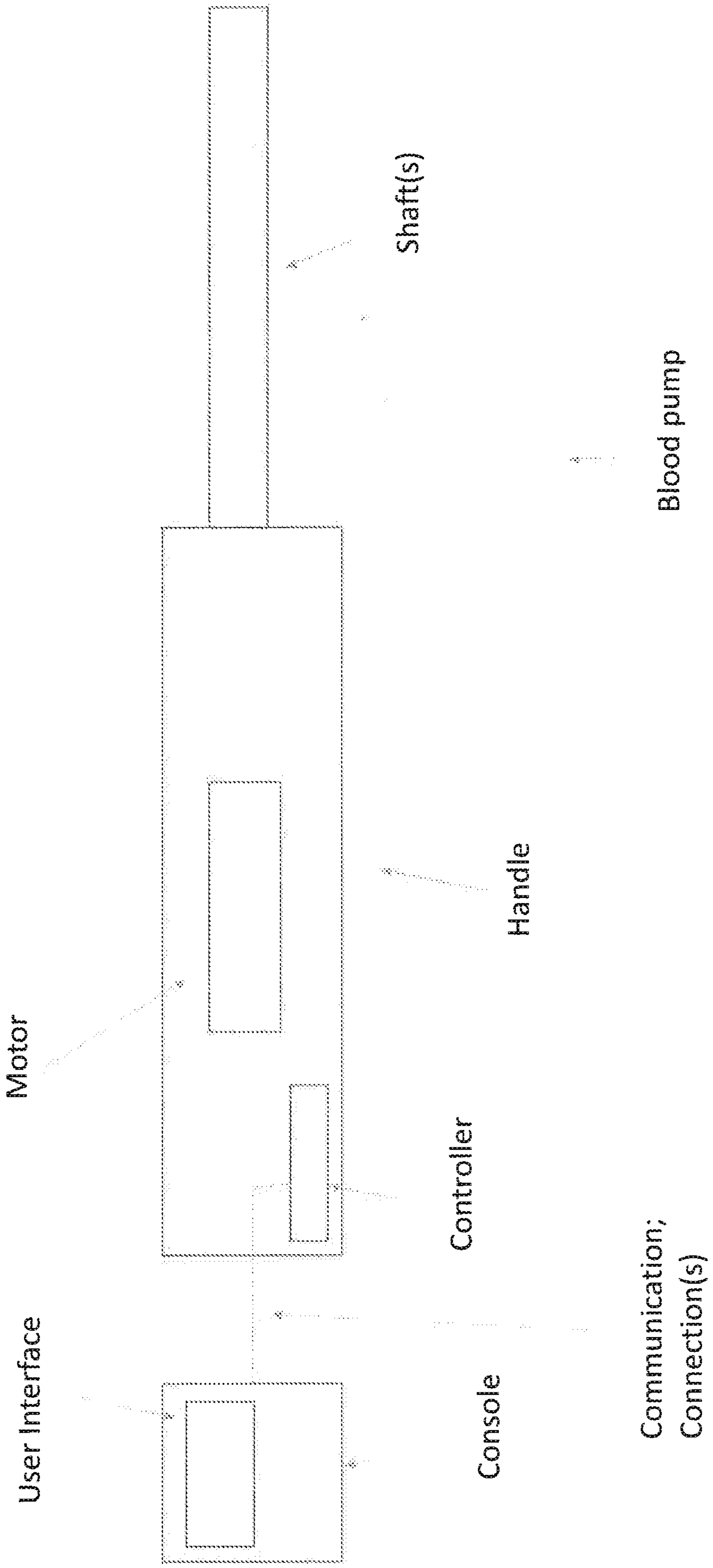

Shaft(s)
Blood pump
Handle
Motor
Controller
Communication;
Connection(s)
User Interface
Console

Figure 2

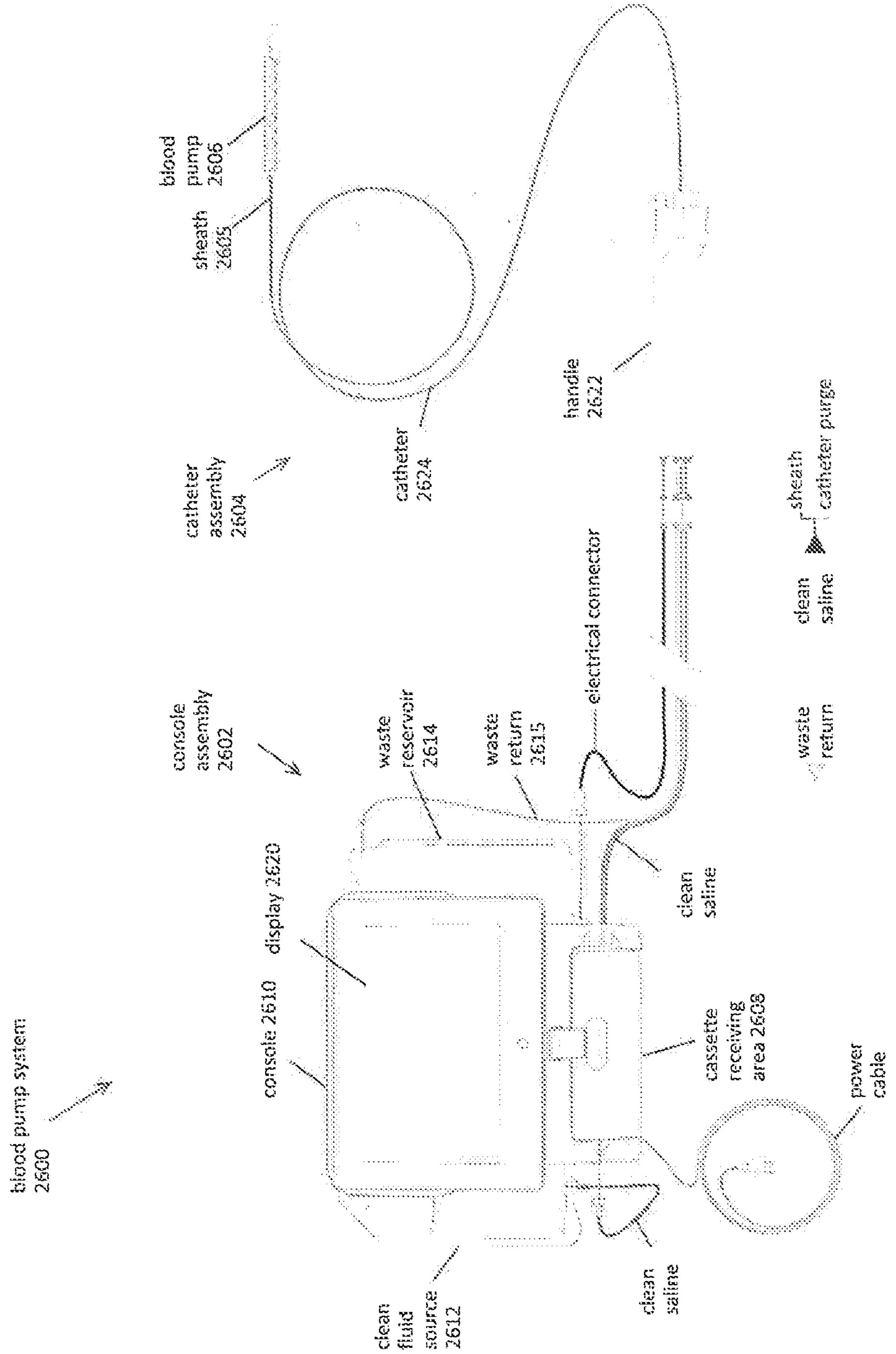
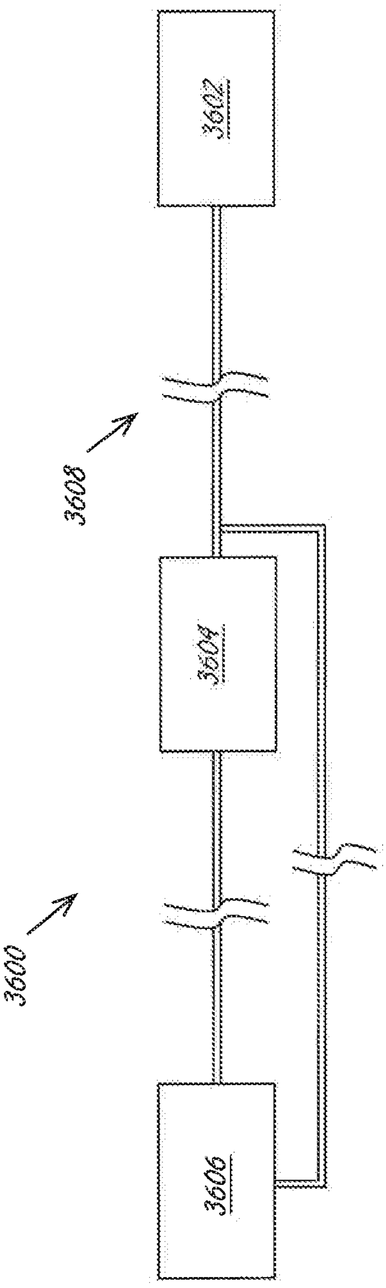

blood pump system 2600
console 2610
display 2620
console assembly 2602
waste reservoir 2614
waste return 2615
clean saline
electrical connector
cassette receiving area 2608
power cable
clean fluid source 2612
clean saline
catheter assembly 2604
catheter 2624
handle 2622
sheath 2605
blood pump 2606
waste return
clean saline
sheath
catheter purge

FIG. 3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3606
3608
3600

Fig. 4A

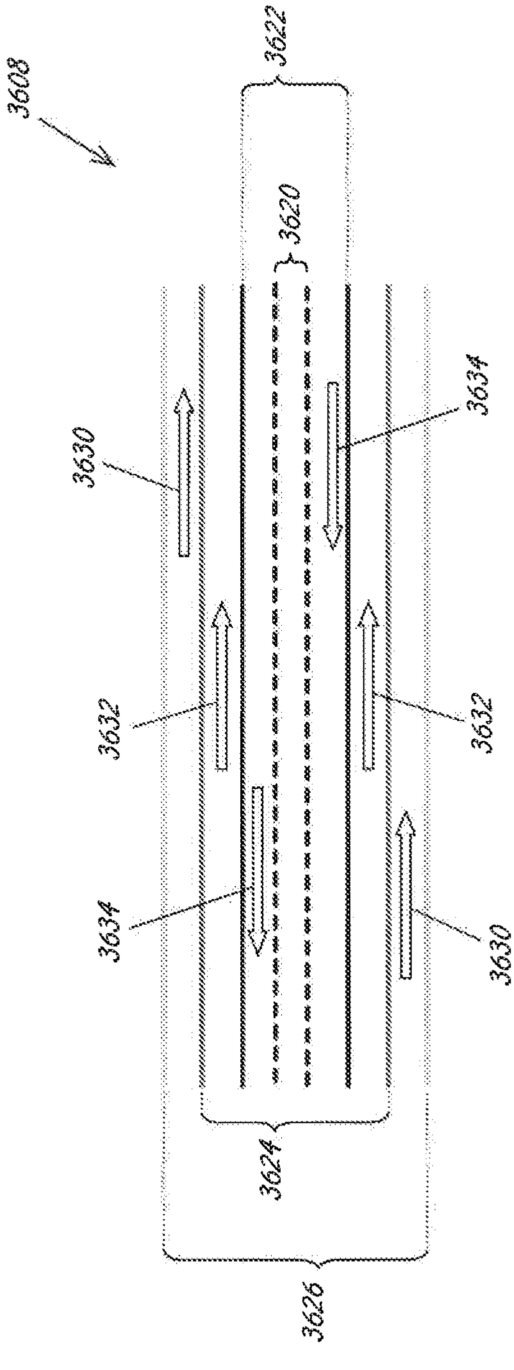
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Fig. 4B

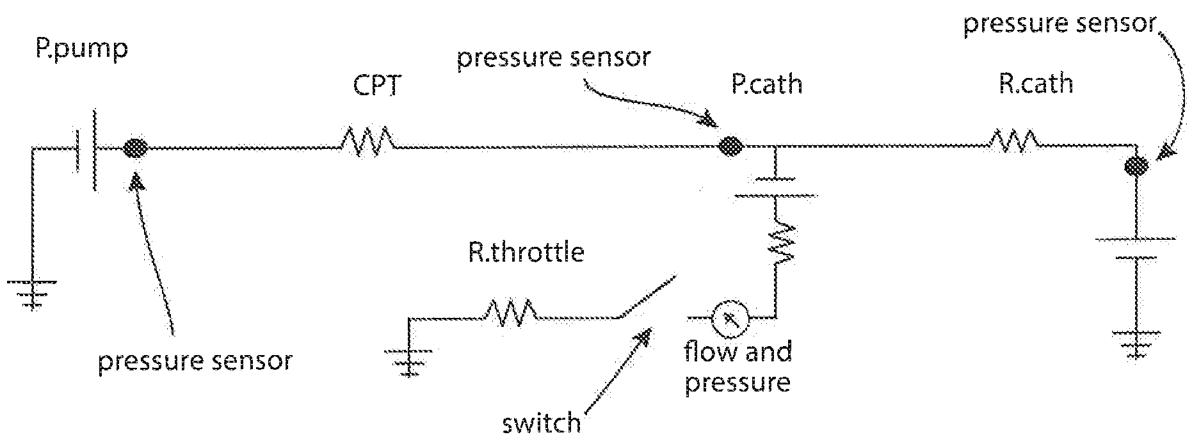

Fig. 5

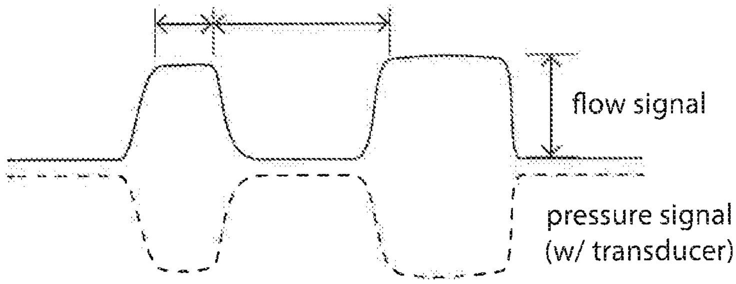

Fig. 6

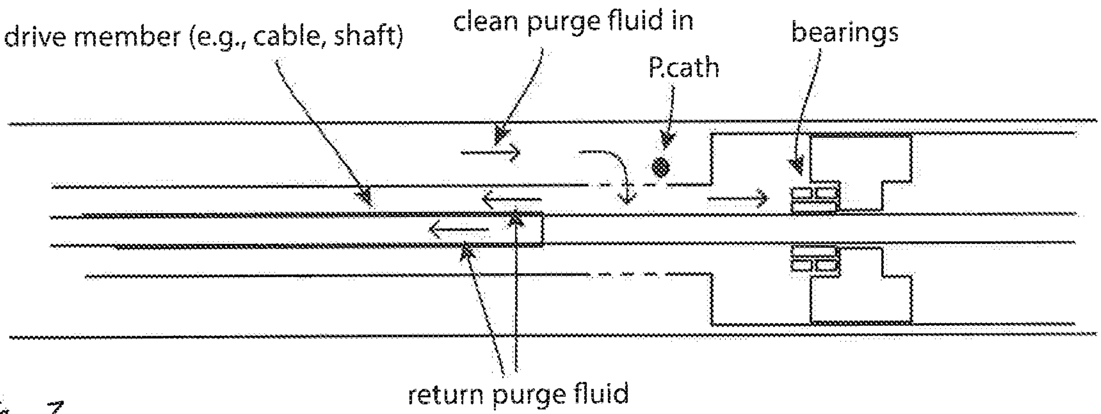

Fig. 7

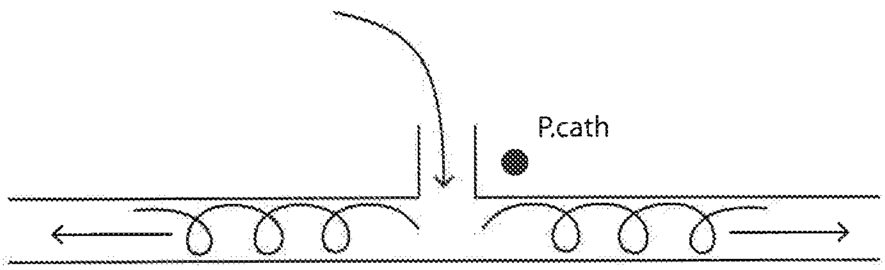

Fig. 8

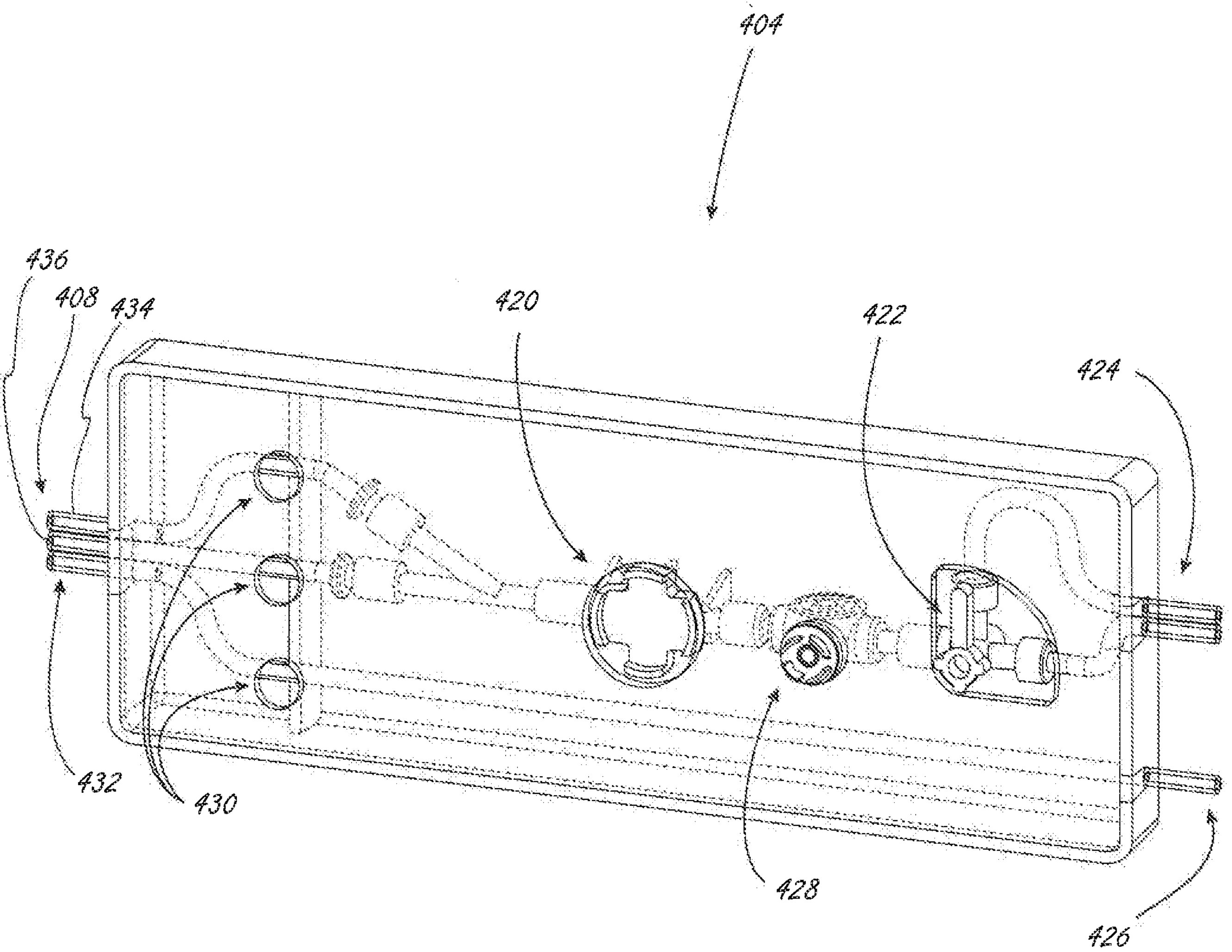

Fig. 9

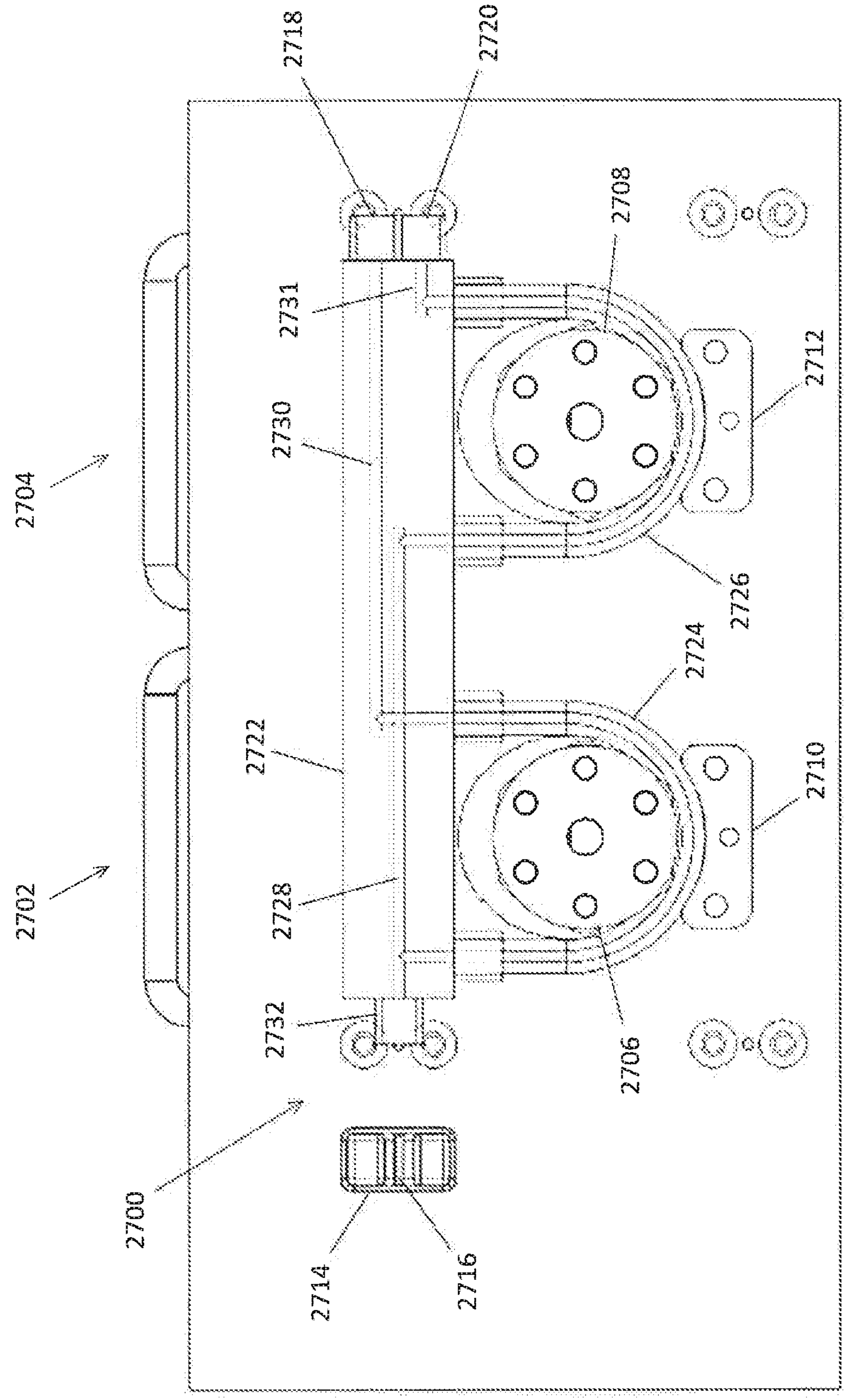
2718
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FIG. 10

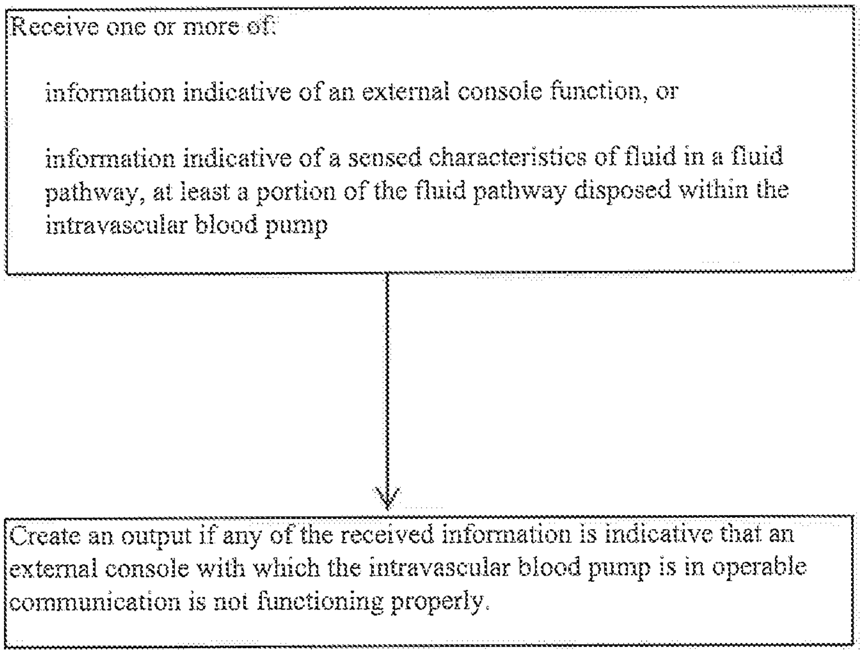
Receive one or more of:
information indicative of an external console function, or
information indicative of a sensed characteristics of fluid in a fluid pathway, at least a portion of the fluid pathway disposed within the intravascular blood pump
Create an output if any of the received information is indicative that an external console with which the intravascular blood pump is in operable communication is not functioning properly.

Figure 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/029640

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G01N 11/00; A61M 1/36; A61M 5/172; G01N 11/02 (2021.01)

CPC - G01N 11/00; A61M 1/3639; A61M 1/3653; G01N 11/02 (2021.05)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
see Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
see Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 9,612,182 B2 (OLDE et al) 04 April 2017 (04.04.2017) entire document	1-19, 21, 25-46
A	US 10,583,231 B2 (MAGENTA MEDICAL LTD) 10 March 2020 (10.03.2020) entire document	1-19, 21, 25-46
A	US 10,569,005 B2 (GAMBRO LUNDIA AB) 25 February 2020 (25.02.2020) entire document	1-19, 21, 25-46
A	US 10,149,684 B2 (WHITE SWELL MEDICAL LTD) 11 December 2018 (11.12.2018) entire document	1-19, 21, 25-46
A	US 5,711,753 A (PACELLA et al) 27 January 1998 (27.01.1998) entire document	1-19, 21, 25-46

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 July 2021	AUG 24 2021

Name and mailing address of the ISA/US	Authorized officer
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450	Harry Kim
Facsimile No. 571-273-8300	Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/029640

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

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

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

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

3. ☒ Claims Nos.: 20, 22-24
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.