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(54) Title: BLOOD PUMP SYSTEM

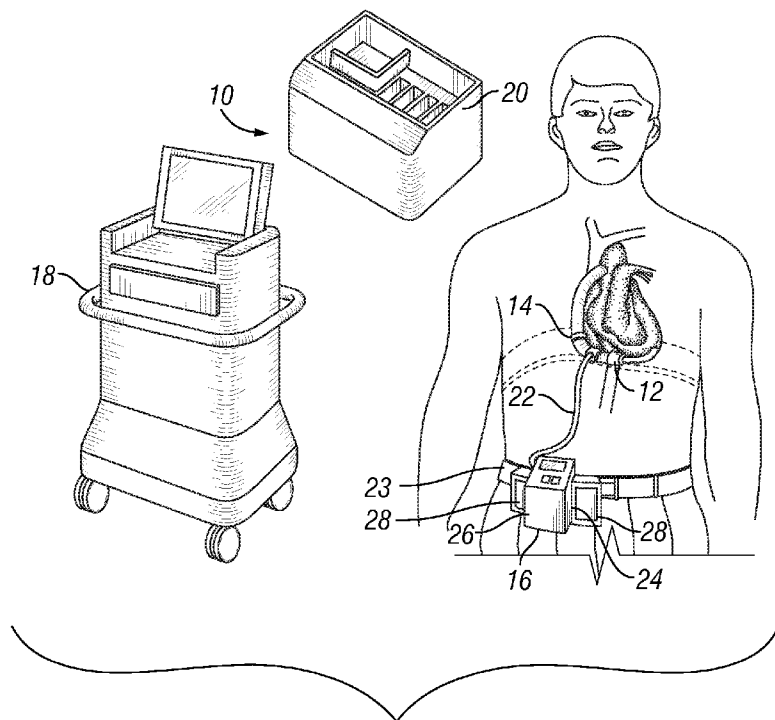


FIG. 1

(57) Abstract: A blood pump system and methods for the use and operation of such a blood system is described, wherein the blood pump system includes an implantable pump and an implantable flow measurement device. A processing device receives indications of a number of pump parameters such as pump voltage, pump current and pump speed. Flow rate is determined based on the pump parameters, and this determined flow rate is compared to the actual flow rate as measured by the flow measurement device. In certain embodiments, the flow measurement device may be periodically energized to make the comparison, then powered off to reduce power consumption. The time period in which the flow measurement device is powered off is based on the difference between the determined and the actual flow rates.

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[0001] TITLE OF THE INVENTION

[0002] BLOOD PUMP SYSTEM

[0003] CROSS REFERENCE TO RELATED APPLICATIONS

5 **[0004]** The present application claims priority to U.S. Provisional Patent Application Serial No. 60/910,369, filed April 5, 2007, the contents of all of which are incorporated herein by reference.

10 **[0005]** STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0006] Not applicable.

[0007] REFERENCE TO APPENDIX

[0008] Not applicable.

15

[0009] BACKGROUND OF THE INVENTION

20 **[0010]** Field Of The Invention. This disclosure relates generally to blood pump systems, and more particularly to blood pump systems and operation methods associated therewith.

[0011] Description Of The Related Art.

25 **[0012]** Generally, blood pump systems are employed in either of two circumstances. First, a blood pump may completely replace a human heart that is not functioning properly, or second, a blood pump may boost blood circulation in patients whose heart is still functioning although pumping at an inadequate rate.

[0013] For example, U.S. Patent No. 6,183,412, which is commonly assigned and incorporated herein by reference in its entirety, discloses a

ventricle assist device (VAD) commercially referred to as the "DeBakey VAD[®]." The VAD[®] is a miniaturized continuous axial-flow pump designed to provide additional blood flow to patients who suffer from heart disease. The device is attached between the apex of the left ventricle and the aorta.

5 [0014] Many known blood pump systems typically are controlled in an open loop fashion where a predetermined speed is set and the flow rate varies according to the pressure differential across the pump. The pump itself may be controlled in a closed loop fashion, wherein the actual pump speed is fed back to a motor controller that compares the actual speed to the desired
10 predetermined speed and adjusts the pump accordingly. Other pumps may be controlled in a closed loop fashion, in which the pump speed is varied according to a monitored parameter of the patient, such as the patient's pulse or blood flow rate.

15 [0015] Whether the pump is operated in a closed loop or open loop fashion, it is desirable to monitor several pump operating parameters, such as voltage level, current level, pump speed, flow rate, and the like. Adding additional measurement devices to the pump system, however, can complicate the system and add to the power requirements for the system.

20 [0016] BRIEF SUMMARY OF THE INVENTION

[0017] The teachings of the present disclosure concern a blood pump system such as a VAD (ventricle assist device) system. The pump system includes, for example, an implantable pump and a controller for controlling the pump. The system further includes an implantable flow measurement device.
25 A processing device receives indications of pump parameters such as pump voltage, pump current and pump speed. Flow rate is determined based on the pump parameters, and this determined flow rate is compared to the actual flow rate as measured by the flow measurement device. The flow measurement

device may be periodically energized to make the comparison, then powered off to reduce power consumption. The time period in which the flow measurement device is powered off is based on the difference between the determined and the actual flow rates.

5 **[0018]** Thus, in accordance with a first aspect of the present disclosure, a blood pump system is described, wherein the blood pump system comprises a pump, a flow measurement device configured to measure the flow rate of fluid being pumped, and a processing device receiving indications of pump parameters, the processing device being programmed to determine flow rate
10 based on the pump parameters and compare the determined flow rate to the measured flow rate. In further accordance with this aspect of the disclosure, the determined flow rate may be periodically compared to the measured flow rate, and the flow measurement device may periodically be powered off. Additionally, in the event of the flow measurement device periodically
15 powering off, the device is powered off for a period of time that is determined in response to the difference between the flow rate and the measured flow rate. In further accordance with the first aspect of the disclosure, the pump parameters may be selected from a group comprising pump voltage, pump current, and pump speed, as well as combinations of such parameters, and the
20 processor accesses a look-up table or uses a polynomial modeling or similar such system to determine the flow rate, although the processor may directly calculate the flow rate based on the pump parameters.

[0019] In accordance with a second aspect of the present disclosure, a method of operating a blood pump system is described, wherein the method
25 comprises sampling parameters of a blood pump, measuring the flow rate of fluid being pumped, determining flow rate based on the pump parameters, and comparing the determined flow rate to the measured flow rate. In further accordance with this aspect of the disclosure, the determined flow rate may be

periodically compared to the measured flow rate, and the flow measurement device may periodically be powered off. Additionally, in the event of the flow measurement device periodically powering off, the device is powered off for a period of time that is determined in response to the difference between the flow rate and the measured flow rate. In further accordance with the first aspect of the disclosure, the pump parameters may be selected from a group comprising pump voltage, pump current, and pump speed, as well as combinations of such parameters, and the processor accesses a look-up table or uses a polynomial modeling or similar such system to determine the flow rate, although the processor may directly calculate the flow rate based on the pump parameters.

[0020] BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0021] The following figures form part of the present specification and are included to further demonstrate certain aspects of the present invention. The invention may be better understood by reference to one or more of these figures in combination with the detailed description of specific embodiments presented herein.

[0022] FIG. 1 schematically illustrates various components of an implantable pump system in accordance with teachings of the present disclosure.

[0023] FIG. 2 illustrates a cross-sectional view of an exemplary implantable pump in accordance with teachings of the present disclosure.

[0024] FIG. 3 illustrates a block diagram illustrating aspects of a controller module in accordance with teachings of the present disclosure.

[0025] FIG. 4 illustrates a multi-dimensional data table correlating pump flow, pump speed, and pump power.

[0026] FIG. 5 illustrates a block diagram conceptually illustrating a flow rate determination system in accordance with teachings of the present disclosure.

[0027] FIG. 6 illustrates a block diagram showing a flow calculation process in accordance with teachings of the present disclosure.

[0028] While the inventions disclosed herein are susceptible to various modifications and alternative forms, only a few specific embodiments have been shown by way of example in the drawings and are described in detail below. The figures and detailed descriptions of these specific embodiments are not intended to limit the breadth or scope of the inventive concepts or the appended claims in any manner. Rather, the figures and detailed written descriptions are provided to illustrate the inventive concepts to a person of ordinary skill in the art and to enable such person to make and use the inventive concepts.

[0029] DETAILED DESCRIPTION

[0030] The Figures described above and the written description of specific structures and functions below are not presented to limit the scope of what Applicants have invented or the scope of the appended claims. Rather, the Figures and written description are provided to teach any person skilled in the art to make and use the inventions for which patent protection is sought. Those skilled in the art will appreciate that not all features of a commercial embodiment of the inventions are described or shown for the sake of clarity and understanding. Persons of skill in this art will also appreciate that the development of an actual commercial embodiment incorporating aspects of the present inventions will require numerous implementation-specific decisions to achieve the developer's ultimate goal for the commercial embodiment. Such implementation-specific decisions may include, and likely are not limited to,

compliance with system-related, business-related, government-related and other constraints, which may vary by specific implementation, location and from time to time. While a developer's efforts might be complex and time-consuming in an absolute sense, such efforts would be, nevertheless, a routine undertaking for those of skill this art having benefit of this disclosure. It must be understood that the inventions disclosed and taught herein are susceptible to numerous and various modifications and alternative forms. Lastly, the use of a singular term, such as, but not limited to, "a," is not intended as limiting of the number of items. Also, the use of relational terms, such as, but not limited to, "top," "bottom," "left," "right," "upper," "lower," "down," "up," "side," and the like are used in the written description for clarity in specific reference to the Figures and are not intended to limit the scope of the invention or the appended claims.

[0031] Particular embodiments of the invention may be described below with reference to block diagrams and/or operational illustrations of methods. It will be understood that each block of the block diagrams and/or operational illustrations, and combinations of blocks in the block diagrams and/or operational illustrations, can be implemented by analog and/or digital hardware, and/or computer program instructions. Such computer program instructions may be provided to a processor of a general-purpose computer, special purpose computer, ASIC, and/or other programmable data processing system. The executed instructions may create structures and functions for implementing the actions specified in the block diagrams and/or operational illustrations. In some alternate implementations, the functions/actions/structures noted in the figures may occur out of the order noted in the block diagrams and/or operational illustrations. For example, two operations shown as occurring in succession, in fact, may be executed

substantially concurrently or the operations may be executed in the reverse order, depending upon the functionality/acts/structure involved.

[0032] Computer programs for use with or by the embodiments disclosed herein may be written in an object oriented programming language, conventional procedural programming language, or lower-level code, such as assembly language and/or microcode. The program may be executed entirely on a single processor and/or across multiple processors, as a stand-alone software package or as part of another software package.

[0033] In general terms, Applicants have created a blood pump system and method of operating such a blood pump system, wherein the system can be programmed to determine flow rates based on pump parameters and the measured flow rate, wherein the power usage of the device may be controlled using such determined flow rates.

[0034] Turning to the figures, FIG. 1 illustrates an exemplary blood pump system in accordance with the teachings of this disclosure. The illustrated system is a ventricular assist device (VAD) system 10 such as disclosed in U.S. Patent No. 6,183,412, which is commonly assigned and incorporated herein by reference in its entirety. The VAD system 10 includes components designed for implantation within a human body and components external to the body. Implantable components include a rotary pump 12 and a flow sensor 14. The external components include a portable controller module 16, a clinical data acquisition system (CDAS) 18, and a patient home support system (PHSS) 20. The implanted components are connected to the controller module 16 via a percutaneous cable 22.

[0035] The VAD System 10 may incorporate an implantable continuous-flow blood pump, such as the various embodiments of axial flow pumps disclosed in U.S. Patent No. 5,527,159 or in U.S. Patent No. 5,947,892, both of which are incorporated herein by reference in their entirety. An example of a

blood pump suitable for use in an embodiment of the invention is illustrated in FIG. 2. The exemplary pump 12 includes a pump housing 32, a diffuser 34, a flow straightener 36, and a brushless DC motor 38, which includes a stator 40 and a rotor 42. The housing 32 includes a flow tube 44 having a blood flow path 46 therethrough, a blood inlet 48, and a blood outlet 50.

[0036] The stator 40 is attached to the pump housing 32, is preferably located outside the flow tube 44, and has a stator field winding 52 for producing a stator magnetic field. In one embodiment, the stator 40 includes three stator windings and may be three phase "Y" or "Delta" wound. The rotor 42 is located within the flow tube 44 for rotation in response to the stator magnetic field, and includes an inducer 58 and an impeller 60. Excitation current is applied to the stator windings 52 to generate a rotating magnetic field. A plurality of magnets 62 are coupled to the rotor 42. The magnets 62, and thus the rotor 42, follow the rotating magnetic field to produce rotary motion.

[0037] FIG. 3 conceptually illustrates additional aspects of the exemplary pump system 10. More specifically, portions of the controller module 16 and the pump 12 are shown. The controller module 16 includes a processor, such as a microcontroller 80, which in one embodiment of the invention is a model PIC16C77 microcontroller manufactured by Microchip Technology, Inc. (Chandler, Arizona). The microcontroller 80 includes a multiple channel analog to digital (A/D) converter, which receives indications of motor parameters from the motor controller 84. Thus, the controller module 16 may monitor parameters such as instantaneous motor current, the AC component of the motor current, and motor speed.

[0038] In exemplary embodiments of the invention, the motor controller 84 comprises a Micro Linear ML4425 Motor Controller (available from Micro Linear corporation, San Jose, CA). The operation of the brushless DC motor

38 of the present invention requires that current be applied in a proper sequence to the stator windings 52 to create the rotating field. Two stator windings 52 have current applied to them at any one time, and by sequencing the current on and off to the respective stator windings 52, the rotating magnetic field is produced. In an embodiment of the invention, the motor controller 84 senses back electromotive force (EMF) voltage from the motor windings 52 to determine the proper commutation phase sequence using phase lock loop (PLL) techniques. Whenever a conductor, such as a stator winding 52, is "cut" by moving magnetic lines of force, such as are generated by the magnets 62 of the brushless DC motor 38, a voltage is induced. The voltage will increase with rotor speed 42. It is possible to sense this voltage in one of the three stator windings 52 because only two of the motor's windings 52 are activated at any one time, to determine the rotor 42 position.

[0039] An alternative method of detecting the rotor 42 position relative to the stator 40 for providing the proper stator winding 52 excitation current sequence is to use a position sensor, such as a Hall effect sensor or a fluxgate sensor. Implementing aspects of the present invention using a motor with rotor position sensors, rather than a sensorless motor, would be a routine undertaking for one skilled in the art having the benefit of this disclosure. However, adding additional components, such as Hall effect sensors, requires additional space, which is limited in any implanted device application. Further, using a position detection device adds sources of system failures.

[0040] The actual pump speed is determined and fed back to the controller module 16, which compares the actual speed to a desired predetermined speed and adjusts the pump 12 accordingly. In accordance with certain embodiments of the invention, the pump 12 may be controlled in a closed loop fashion wherein the desired pump speed is varied for events such as sleeping, normal activity or high energy exertion.

[0041] The embodiment shown in FIG. 3 further includes an integral flow meter 124. At least one flow sensor 14 is implanted down stream of the pump 12. Alternately, a flow sensor 14 may be integrated with the pump 12. The flow meter 124 is coupled between the implanted flow sensor 14 and the microcontroller 80. The flow meter 124 receives data from the flow sensor 14 and outputs flow rate data to the microcontroller 80, allowing the system to monitor instantaneous flow rate.

[0042] The flow sensor 14 and flow meter 124 may be employed to continuously measure real-time blood flow rate, providing a true, calibrated, and independent metric of blood flow while consuming approximately 0.5 Watts. Power reductions, however, may be obtained by deriving flow directly from intrinsic pump signals. The algorithmic approach to deriving blood flow rate described herein may function autonomously or in conjunction with the existing real-time flow meter 124.

[0043] A primary data table containing flow versus power and speed information is stored as a multidimensional matrix into the memory of the microcontroller 80. FIG. 4 shows an example of such a data table. The microcontroller 80 is then programmed to sample the pump's analog voltage, current and speed signals and, via a lookup into the primary data table, outputs the corresponding flow value for display and pump control purposes.

[0044] The real-time flow meter 124 is periodically energized and its output compared to the derived value. The duty cycle used to control the real-time flow meter 124 is proportional to the difference between the actual measured flow and derived flow values the more closely they match the less often the flow meter 124 is energized. Additionally, a secondary data table containing actual flow, derived flow, voltage, current, and speed information is stored and used to prove that the algorithm performs correctly over the course of its use. A compilation of secondary data tables from multiple patients may

also be used to further optimize the primary data table. While this particular aspect illustrates the use of look-up tables by the processor to determine flow rate, other appropriate measurements may be used, such as polynomial modeling systems and other known, suitable alternatives to look-up tables.

5 [0045] The application of this duty cycle control of the real-time flow meter 124 along with a flow estimation algorithm yields a system which can continually and reliably output accurate flow information while consuming less than one-tenth (1/10) the power of the flow meter 124 itself. This hybrid approach further allows the algorithm to be tested in a safe and controlled
10 manner and reduces power consumption by more than a magnitude while maintaining the precision of the existing real-time flow meter 124.

[0046] FIG. 5 is a block diagram conceptually illustrating the flow rate determination system 200, using the pump's intrinsic voltage, current, and speed signals together with the flow meter 124. The system 200 includes a
15 multi-channel analog-to-digital converter (ADC) 210 to sample the intrinsic pump signals 212, a single-channel digital-to-analog converter (DAC) 214 to output derived flow values as a voltage proportional flow, a precision voltage reference (VREF) 216 for use by both the ADC 210 and DAC 214, and the microcontroller 80 to coordinate necessary data acquisition, timing, and
20 discrete digital I/O (input/output) activities. The microcontroller's 80 functionality may be implemented using a low-power Programmable Read Only Memory (PROM), Field Programmable Gate Array (FPGA), Complex Programmable Logic Device (CPLD), or other suitable device.

[0047] Pump power is the product of pump voltage and current.
25 Therefore, the multi-dimensional matrix may be reduced in complexity by one dimension if the system first derives pump power by calculating the product of the sampled pump voltage and current signals. As discussed above, a derived flow value is extracted from a primary data table 220 containing a

multidimensional matrix filled with pump flow versus pump voltage, pump current, and pump speed data values, such as the table illustrated in FIG. 4. The sampled values function as pointers into the table. In exemplary systems, the multi-dimensional matrix is filled with linearly (evenly) distributed pump flow versus pump voltage, pump current, and pump speed data values. In other implementations, the multi-dimensional matrix is filled with non-linearly (non-evenly) distributed pump flow versus pump voltage, pump current, and pump speed data values to provide higher resolution and accuracy in areas where there may exist large changes in flow with respect to voltage, current, and/or speed. The system may interpolate the data in areas between programmed data points. Further, the type of interpolation used may be selected as a function of where on the pump's characteristic curves the system is operating.

[0048] Alternatively, the derived flow value may be calculated directly using the equation that determines the derived flow as a function of pump power and speed:

$\text{derived_flow} = f(\text{pump_power}, \text{pump_speed})$.

[0049] This method potentially provides greater accuracy with greater computational complexity and with greater power consumption. More specifically, benefits include increased system reliability, decreased component count, decreased power consumption, decreased heat dissipation, decreased conductor count (girth) within the percutaneous tether, decreased VAD interface connector size, decreased cost, decreased controller size/volume, and decreased amount of hardware implanted into patient.

[0050] For example, one method of directly deriving flow uses three equations to derive flow rate information from the pump motor's operating characteristics. The equations described below are based on several multiple regression analyses performed on empirical pump motor data (i.e.

characteristic curves) detailing various flow rates versus pump motor speed, power (the product of voltage and current), and differential pressure.

[0051] Non-linearities within the characteristic performance curves of an exemplary pump system motor suggest that blood flow rate is not a direct function of pump motor speed, motor voltage, and motor current. As such, there may exist multiple flow rates for a given speed and power (product of motor voltage and current). There are, however, unique flow rates for corresponding pump motor speeds, powers, and differential pressures. The pump system measures motor voltage, motor current, and motor speed but not the differential pressure across the pump. Unfortunately, this is not a parameter that is easily measured and would require additional electronic circuitry, software, and pressure transducers to be mounted on the inlet and outlet sides of the VAD pump motor. These pressure transducers and their related hardware and software would increase the complexity of the overall system.

[0052] Therefore, it becomes necessary to first calculate differential pressure from motor voltage, current, and speed. The calculated values for differential pressure can then be recombined with motor voltage, current, and speed to calculate unique values of flow rate. This mathematical derivation contains three equations including:

[0053] Calculation of motor power as a function of voltage and current:

$$\text{Power}(t) = f(\text{Voltage}(t), \text{Current}(t))$$

[0054] Calculation of Differential Pressure as a function of Power and Speed:

$$\text{DifferentialPressure}(t) = f(\text{Power}(t), \text{Speed}(t))$$

[0055] Calculation of Flow Rate as a function of Power, Speed, and Differential Pressure:

$$\text{Flow}(t) = f(\text{Power}(t), \text{Speed}(t), \text{DifferentialPressure}(t))$$

[0056] FIG. 6 is a block diagram illustrating the flow calculation process. The system must first sample motor voltage, motor current, and motor speed. It then must multiply motor voltage and motor current to calculate instantaneous motor power. Pump motor speed is then combined with the calculated instantaneous motor power to calculate differential pressure using the equation for DP(t) (two independent variables; power and speed). Calculated values for differential pressure and corresponding values of motor voltage, motor current, and motor speed are then combined to calculate flow rate using the equation for Flow(t) (three independent variables; power, speed, and differential pressure).

[0057] The equations for Power and Differential Pressure may be substituted for their respective independent variables in the equation for Flow. This will ultimately yield a single equation for Flow as a function of Power and Speed. In an exemplary implementation, the equations for Flow(t) and DP(t) were developed through the application of multiple regression techniques performed on empirical in-vitro pump performance data. Approximately five hundred (500) invitro data points were taken using a MicroMed Flow Loop (MicroMed Technologies, Inc., Houston, TX) and related electronic test equipment. Pump Motor voltage, current, inlet/outlet differential pressure, and flow rate were measured and logged. The data was taken between one thousand (1000) RPM and twelve thousand five hundred (12,500) RPM in five hundred (500) RPM graduations. The equation for Flow(t) is based on the use of three independent variables (power, speed, and differential pressure) and the equation for DP(t) is based on the use of two independent variables (power and speed).

[0058] The equation for Flow(t) was developed by first generating a simple regression equation ($y = a + b \cdot X1 + c \cdot X2 + d \cdot X3$), evaluating its correlation matrix, and then further refining the equation. This was repeated

such that better fits were achieved. Approximately fifty equations were generated and evaluated with the best fit having a coefficient of multiple determination of $R^2=0.9910$ and an adjusted coefficient of multiple determination of $R_a^2=0.9903$. This "best fit" equation is highly deterministic explaining over 99.1% of the variation within the data set.

[0059] A second regression analysis detailing the development of the equation for DP(t) was also performed in the same iterative fashion. Approximately four hundred equations were generated and evaluated with the best fit equation having a coefficient of multiple determination of $R^2=0.9334$ and an adjusted coefficient of multiple determination of $R_a^2=0.9303$. This "best fit" equation is also highly deterministic explaining 93.0% of the variation within the data set.

[0060] The accuracy of the equation for Power is 100% ($R^2=1.000$) because it is simply the product of motor voltage and current. The accuracy of the entire model is the product of each equation's multiple coefficient of determination with $R_{\text{Power}}^2=1.000$, $R_{\text{Flow}}^2=0.9910$, and $R_{\text{DP}}^2=0.9334$. The result is $R_{\text{Total}}^2=0.9250$ and therefore the entire model accounts for 92.5% of the variation within the data set.

[0061] A third regression analysis was performed to further justify the need for using the intermediate DP(t) calculation. This third regression analysis details the development of an equation for Flow as a function of Power and Speed. Approximately four hundred equations were generated and evaluated with the best fit equation having a coefficient of multiple determination of $R^2=0.8244$ and an adjusted coefficient of multiple determination of $R_a^2=0.8162$. The accuracy of the entire model is the product of each equation's multiple coefficient of determination with $R_{\text{Power}}^2=1.000$ and $R_{\text{Flow}}^2=0.8244$. The result is $R_{\text{Total}}^2=0.8244$ and therefore the entire model

accounts for 82.44% of the variation within the data set, ten (10) percent less accurate than the model which utilizes the intermediate DP(t) calculation.

[0062] The mathematical derivation may be implemented in software and/or hardware. Software implementations include using the existing microcontroller 84, an additional stand-alone microcontroller, a Digital Signal Processor (DSP). Hardware implementations may include a Field Programmable Gate Array (FPGA), Complex Programmable Logic Device (CPLD) or Application Specific Integrated Circuit (ASIC), for example.

[0063] As noted above, the derived flow value is periodically compared to the actual flow value as measured with the dedicated real-time flow meter 124 and sensor 14, and the difference between the actual and calculated flow rate values is used as the basis for duty-cycle control of a dedicated real-time flow probe and flow meter. Small differences between the actual and derived flow values will allow the real-time flow meter to remain unpowered for longer periods of time saving valuable system power and, conversely, large differences will force the real-time flow meter to be powered on more often. Moreover, the magnitude of the difference between the actual and derived flow values may be used to indicate that a flow restriction, abnormality, or perturbation exists in the flow path to or from the pump.

[0064] The exemplary system 200 shown in FIG. 5 also contains additional programmable non-volatile memory (e.g. EEPROM, FLASH, etc.) used to store a secondary multi-dimensional data matrix 222. This memory is used to acquire in real-time actual pump flow, derived flow, pump speed, and pump power data for archival and post-processing purposes. The secondary multidimensional data matrix 222 may further be used for future refinement and optimization of the primary multi-dimensional matrix or directly implemented derived flow equation.

[0065] In still further implementations, the actual pump power is compared to derived pump power. The actual pump power is the product of pump voltage and pump current and the derived pump power is obtained based on the pump flow and speed. The derived power value may be extracted from a primary data table containing a multi-dimensional matrix filled with pump flow versus pump speed data values, wherein the sampled values of flow and speed function as pointers into the table. This multi-dimensional matrix may be filled with linearly (evenly) distributed pump flow versus pump speed data values, or with non-linearly (non-evenly) distributed pump flow versus speed data values to provide higher resolution and accuracy in areas where there may exist large changes in power with respect to flow and/or speed. The system interpolates the data in areas between programmed data points, and the type of interpolation used may be selected as a function of where on the pump's characteristic curves the system is operating.

[0066] The derived power value may be periodically compared to the actual power value, and the difference between the actual and calculated power values is used as the basis for duty-cycle control of the dedicated real-time flow sensor 14 and flow meter 124. Small differences between the actual and derived power values will allow the real-time flow meter 124 to remain unpowered for longer periods of time saving valuable system power and, conversely, large differences will force the real-time flow meter 124 to be powered on more often. Still further, the magnitude of the difference between the actual and derived power values may be used to indicate that a flow restriction, abnormality, or perturbation exists in the flow path to or from the pump.

[0067] The invention has been described in the context of preferred and other embodiments and not every embodiment of the invention has been described. Obvious modifications and alterations to the described

embodiments are available to those of ordinary skill in the art. The disclosed and undisclosed embodiments are not intended to limit or restrict the scope or applicability of the invention conceived of by the Applicants, but rather, in conformity with the patent laws, Applicants intends to protect all such
5 modifications and improvements to the full extent that such falls within the scope or range of equivalent of the following claims.

[0068] WHAT IS CLAIMED IS:

1. A blood pump system comprising:

5 a pump;

a flow measurement device configured to measure the flow rate of fluid being pumped; and

10 a processing device receiving indications of pump parameters, the processing device being programmed to determine flow rate based on the pump parameters and compare the determined flow rate to the measured flow rate.

15 2. The blood pump system of claim 1, wherein the determined flow rate is periodically compared to the measured flow rate.

3. The blood pump system of claim 1, wherein the flow measurement device is periodically powered off.

20 4. The blood pump system of claim 3, wherein the flow measurement device is powered off for a time period determined in response to the difference between the determined flow rate and the measured flow rate.

25 5. The blood pump system of claim 1, wherein the pump parameters are selected from a group including pump voltage, pump current, and pump speed.

6. The blood pump system of claim 1, wherein the processing device accesses a look-up table to determine the flow rate.

7. The blood pump system of claim 1, wherein the processing device using polynomial modeling to determine the flow rate.

8. The blood pump system of claim 1, wherein the processing device
5 directly calculates the flow rate based on the pump parameters.

9. A method of operating a blood pump system, the method comprising:
sampling parameters of a blood pump;
measuring the flow rate of fluid being pumped;
10 determining flow rate based on the pump parameters; and
comparing the determined flow rate to the measured flow rate.

10. The method of claim 9, wherein the determined flow rate is periodically compared to the measured flow rate.

11. The method of claim 9, wherein the flow rate is measured by a flow measurement device, the method further comprising periodically powering off the flow measurement device.

12. The method of claim 11, wherein the flow measurement device is powered off for a time period determined in response to the difference between the determined flow rate and the measured flow rate.

13. The method of claim 9, wherein the pump parameters are selected from
25 a group comprising pump voltage, pump current and pump speed.

14. The method of claim 9, wherein determining the flow rate includes accessing a look-up table.

15. The method of claim 9, wherein determining the flow rate includes using polynomial modeling to determine the flow rate.

5 16. The method of claim 9, wherein determining the flow rate includes directly calculating the flow rate based on the pump parameters.

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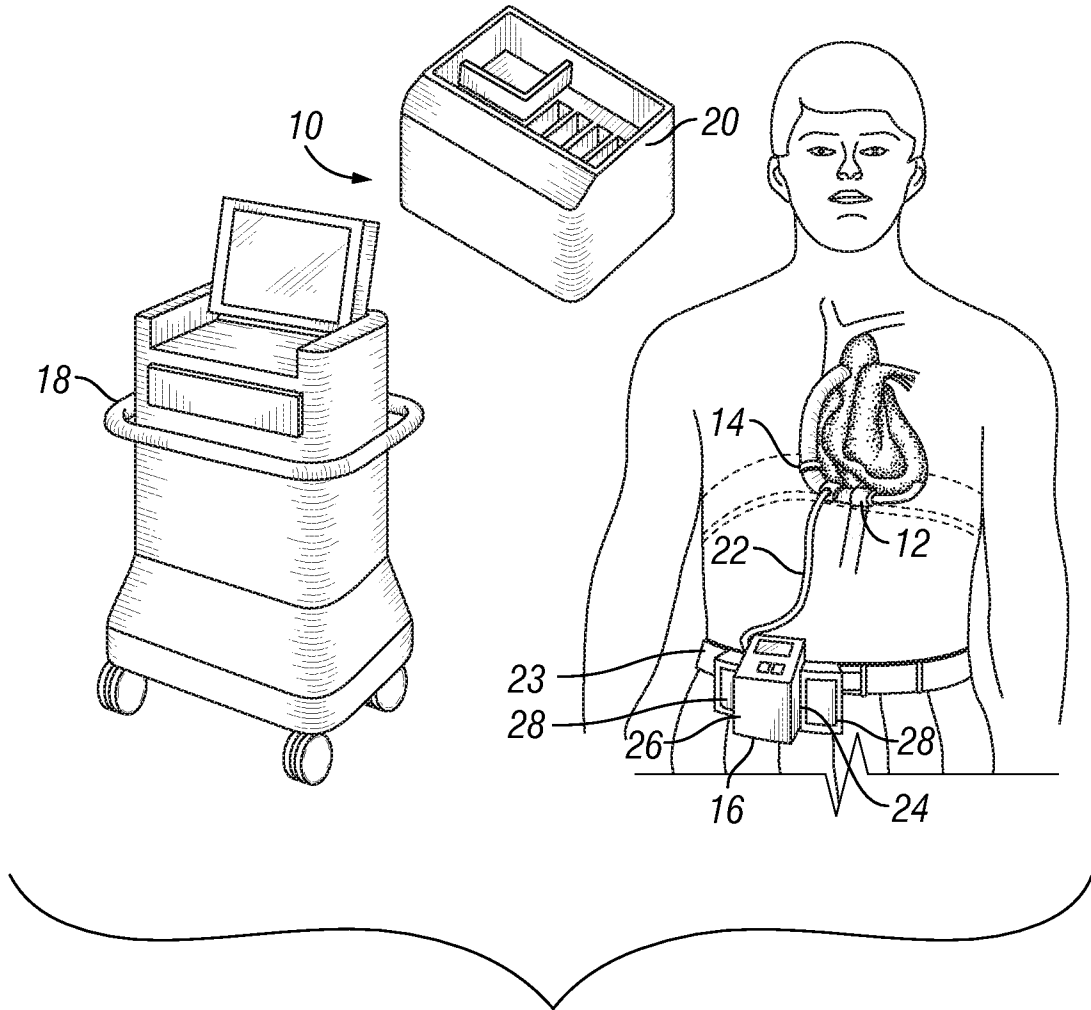


FIG. 1

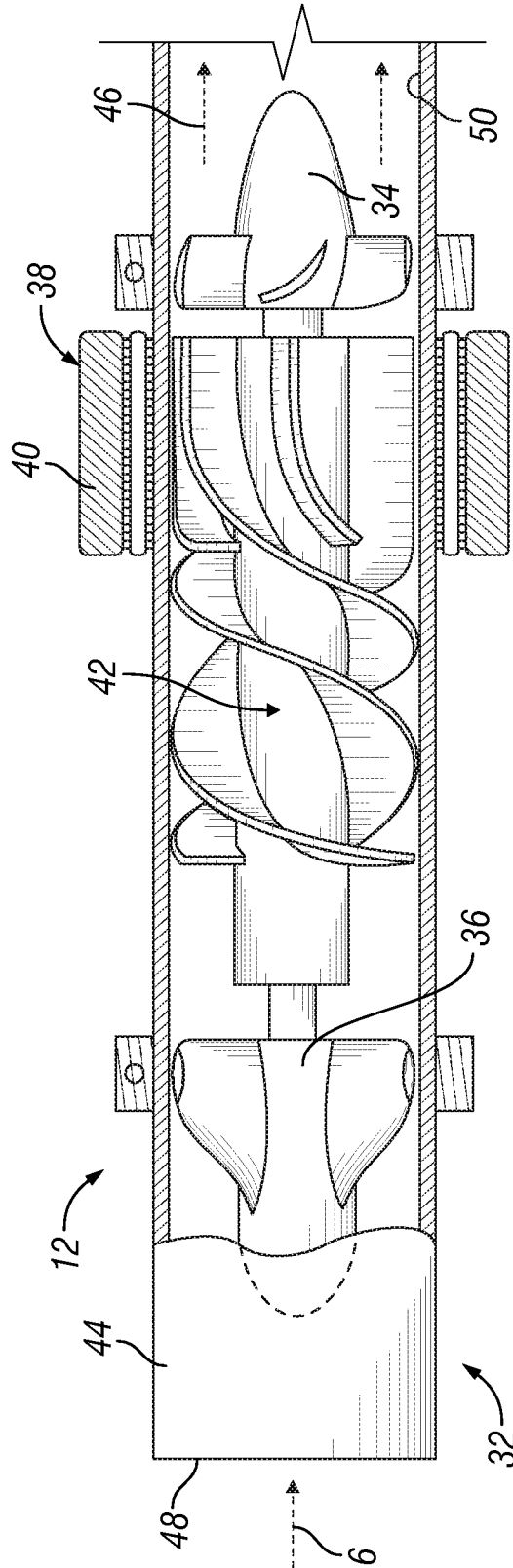


FIG. 2

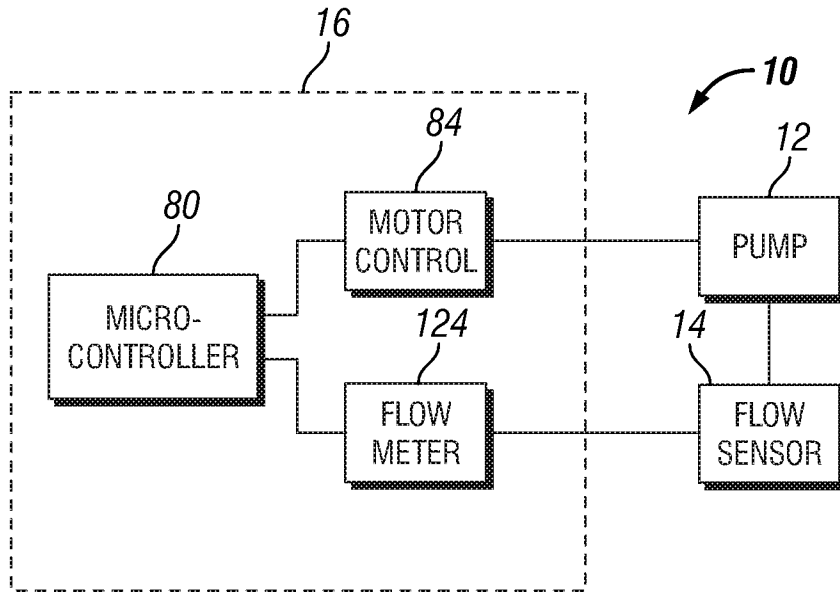


FIG. 3

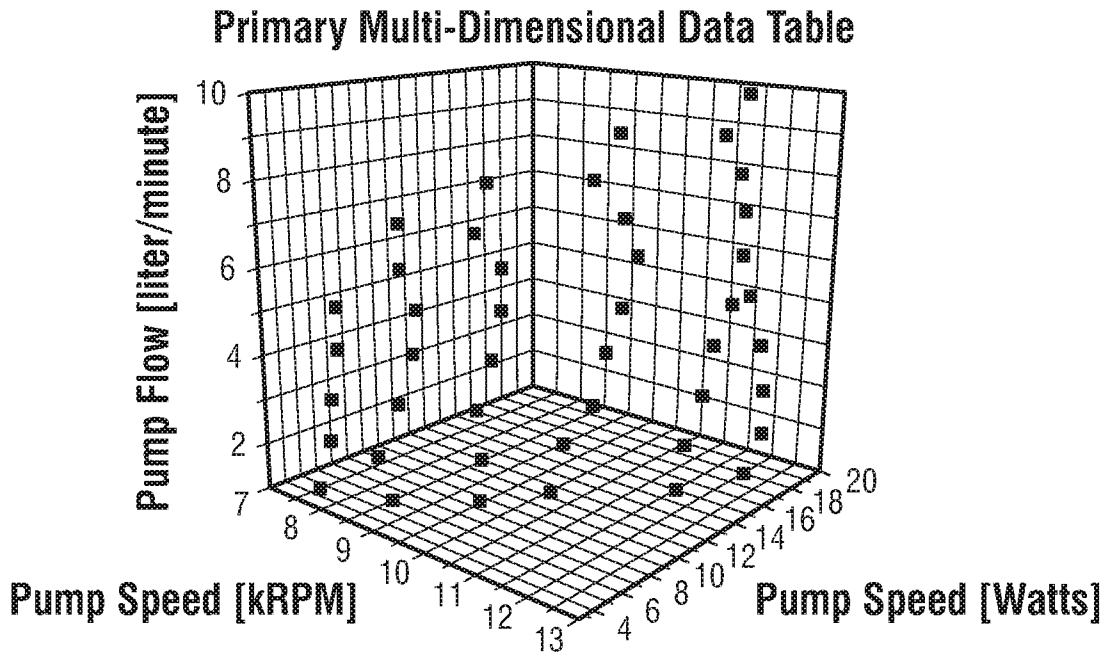


FIG. 4

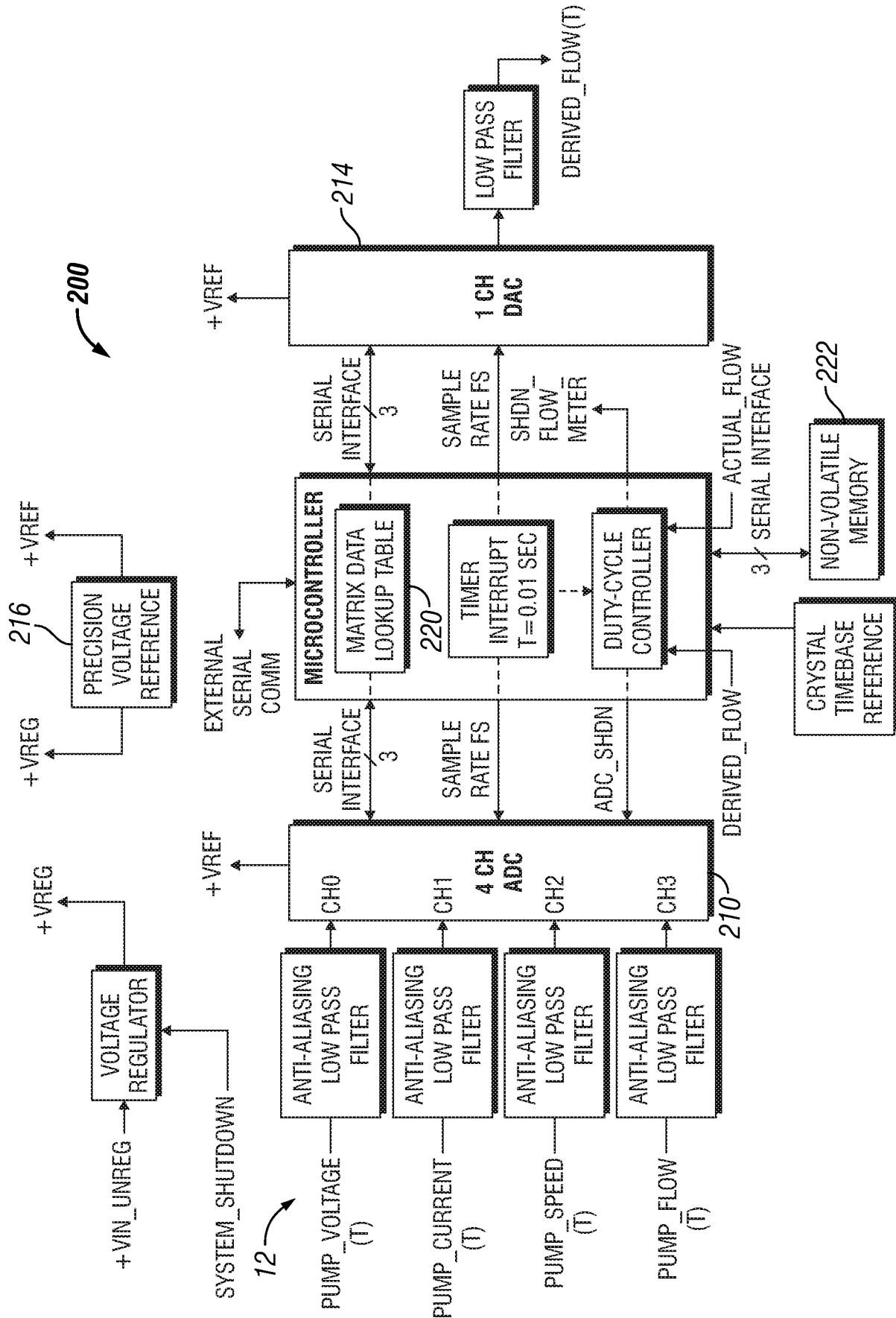


FIG. 5

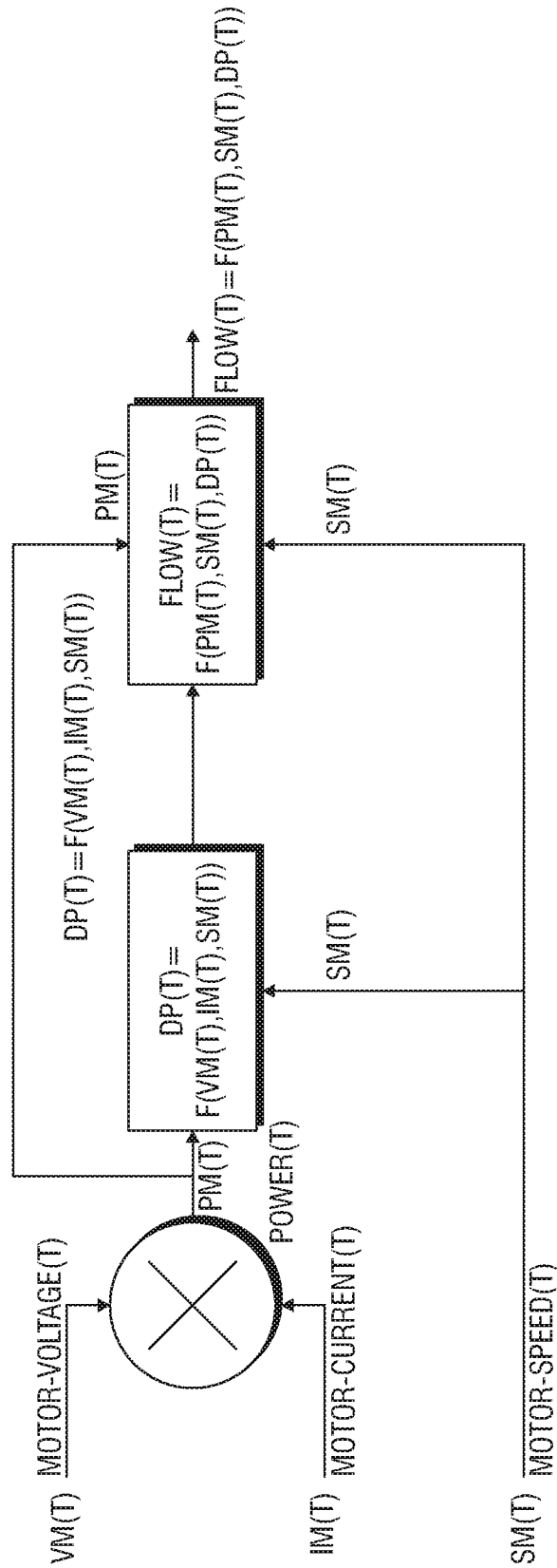


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/059585**A. CLASSIFICATION OF SUBJECT MATTER***A61M 1/12(2006.01)i, A61M 1/10(2006.01)i*

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)

IPC 8 A61M

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

Korean Utility models and applications for Utility models since 1975
Japanese Utility models and applications for Utility models since 1975

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

eKIPASS(KIPO internal) "blood" "pump" "flow rate"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,828,543 A (Paul I. Weiss et al.) 09 May 1989 see the abstract and claims 1-6.	1 - 8
X	WO 2004/012806 A1 (POTENCIA MEDICAL AG) 12 February 2004 see the abstract and claims 105-117.	1 - 8
A	US 4,718,903 A (Seoul National University Hospital) 12 January 1988 see the abstract.	1 - 8
A	US 5,147,388 A (Kenji Yamazaki et al.) 15 September 1992 see the abstract.	1 - 8

 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

"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 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

25 AUGUST 2008 (25.08.2008)

Date of mailing of the international search report

25 AUGUST 2008 (25.08.2008)

Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2008/059585**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.: 9 - 16
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 9 - 16 pertain to method for treatment of the human or animal body by therapy or diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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 an additional fee, this Authority did not invite payment of any additional fee.
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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/059585

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4828543	09.05.1989	DK 110187 A0	03.03.1987
		EP 0240101 A2	07.10.1987
		IL 81940 A0	20.10.1987
		JP 62-233166 A2	13.10.1987
		KR 10-1987-0009730	30.11.1987
WO 2004-012806 A1	12.02.2004	AU 2003-247322 AA	23.02.2004
		CA 2494387 AA	12.02.2004
		EP 1539294 A1	15.06.2005
		JP 2005-534400 T2	17.11.2005
		KR 10-2005-0043899	11.05.2005
		PA 05001229 A	08.06.2005
US 4718903	12.01.1988	KR 10-1987-0002814	13.04.1987
		KR 8800172 B1	12.03.1988
US 5147388	15.09.1992	AT 109664 E	15.08.1994
		AU 638339 B2	24.06.1993
		AU 1991-79223 A1	06.02.1992
		CA 2037622 AA	09.09.1991
		DE 69103295 T2	01.12.1994
		EP 0445782 A1	11.09.1991
		EP 0445782 B1	10.08.1994
		JP 04-126158	27.04.1992
		JP 6036821 B4	18.05.1994
		KR 10-1991-0016351	05.11.1991
		US 5275580 A	04.01.1994