PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6:

A61M 31/00, G08B 21/00

A1

US

(11) International Publication Number:

WO 98/08564

(43) International Publication Date:

5 March 1998 (05.03.98)

(21) International Application Number:

PCT/US97/14996

(22) International Filing Date:

26 August 1997 (26.08.97)

(30) Priority Data:

08/702,880

26 August 1996 (26.08.96)

(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(72) Inventors; and

(75) Inventors/Applicants (for US only): MEADOR, James, W. [US/US]; 4715 Oakshire Drive, Houston, TX 77027 (US). SUTHERLAND, Byron, C. [US/US]; 2458 Country Club Drive, Pearland, TX 77581 (US). KEARNS, Joseph, C. [US/US]; 3730 Mossyrock Court, Kingwood, TX 77345 (US).

(71) Applicant (for all designated States except US): HIMEX

Towers, 1709 Dryden, Houston, TX 77030 (US).

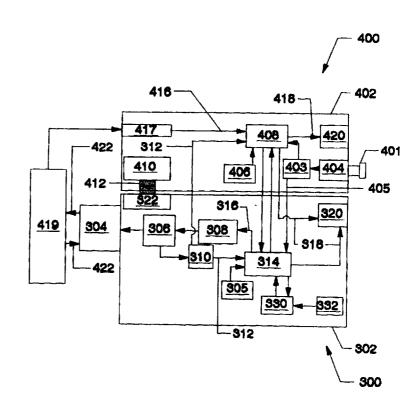
PRODUCTION COMPANY [-/US]; Suite 1508, Medical

(74) Agent: BURGESS, Tim, L.; Tim L. Burgess, P.C., 402 Oak Lane, Houston, TX 77024 (US).

(54) Title: CENTRIFUGAL BLOOD PUMP DRIVER APPARATUS AND METHOD

(57) Abstract

An intelligent centrifugal blood pump driver (300) comprises a motor housing (302) and the housing contains a motor (306) for rotationally driving the centrifugal blood pump (304) and a controller (308) operatively associated with the motor for controlling the rotational speed of the motor (306); a speed selector (404) for generating a selected speed signal (405) signifying a selected rotational speed for the motor (306); sensors (310) operatively associated with the motor or controller for sensing the rotational speed of the motor (306) and outputting a monitor signal (312) signifying such rotational speed; program memory (305) for storage of a program of microprocessor readable instructions; a microprocessor (314, 408) under program control, in electrical connection with the controller (308), the speed selector (404), the sensor (310) and the program memory (305, 406), for receiving the selected speed signal (405) and generating a speed control signal (316) to the controller (308) signifying the selected speed for the controller (308), and for receiving the monitor signal and outputting a display signal (318) and 418; a display (320), 420) in electrical communication with the



microprocessor (314, 408) and responsive to the display signal (318, 418) for displaying information.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
ΑZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	Tl	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
СН	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

CENTRIFUGAL BLOOD PUMP DRIVER APPARATUS AND METHOD

Field of the Invention

This invention relates to an apparatus and method to drive a centrifugal pump which takes over or assists a patient's heart by pumping blood throughout his or her body.

Background of the Invention

In open heart surgery, the heart and lungs are bypassed via a prosthetic or extracorporeal blood flow circuit so that the heart may be stopped and isolated for surgical repair. This extracorporeal blood flow circuit, popularly called a heart lung machine, contains the means to remove blood from the venous side of the patient, pump and oxygenate the blood, and return it to the arterial side of the patient. This circuit also has a variety of individual elements which perform certain functions such as heaters/coolers to elevate or decrease the temperature of the blood, components to add blood volume or cellular components, blood filters and so forth. These discrete elements of the circuit are interconnected by plastic tubing which, in turn, is connected to the patient completing the circuit. The means of pumping the blood throughout this bypass circuit has typically consisted of roller pumps. These roller pumps work by rotating a mechanical arm which radially impinges and collapses a portion of the plastic tubing, one side of which is confined against a rigid semicircular wall. This action acts to propel the blood through the circuit. The flow rate of the blood is directly proportional to the rotary speed of the pump as this type of pump is a positive displacement device. Pumps of this type have been used for many years and are still the predominant type of blood pumping mechanism in use for open heart surgery.

Centrifugal pumps are small disposable devices and round in planar shape. These pumps typically have two compartments, a magnet compartment and a blood compartment. The magnet compartment is sealed and contains a bearing supported disk which contains a number of radially placed magnets. Coupled to the disk and protruding from the magnet compartment into the blood compartment is a shaft. Seals around the shaft prevent fluid from the blood compartment from entering into the magnet compartment. Attached to the shaft is an impeller which is contained within the blood compartment. Two tubes extend from the housing of the blood compartment. An inlet tube extends axially from the blood compartment. An outlet tube extends orthogonal from the inlet tube and is located tangentially to the blood compartment. The pump is connected to the circuit by connecting the inlet connector of the pump to the inlet

tubing of the prosthetic circuit and connecting the outlet connector to the outlet tubing of the prosthetic circuit. The circuit is then primed with fluid to remove air.

A disc similarly configured with magnets of opposite poles in it facing the magnets of the centrifugal pump is coupled to the shaft of a motor. This motor/disc system is then placed adjacent to the magnet disc of the pump. The magnets of the motor disc will attract the magnets of the pump disc and align themselves to each other. Energizing the motor will cause the motor/disc to rotate which, in turn, will cause the pump disc to rotate identically via the coupled magnets. This rotation also turns the shaft and the impeller of the pump as they are mechanically linked and blood is pumped. The centrifugal pump, unlike the roller pump, is not a positive displacement system, rather the centrifugal pump generates pressure which is converted into blood flow as a function of the downstream head of the system.

Summary of the Invention

This invention in its basic aspect comprises an intelligent motor driver apparatus for a centrifugal blood pump. The apparatus comprises a motor housing separate from and tetherable to a console for monitoring one or more blood flow parameters in an extracorporeal blood flow circuit that includes a centrifugal blood pump. The motor housing contains motive means adapted to connect to the centrifugal pump to rotationally drive the centrifugal blood pump. The motive means includes a motor for rotationally driving the centrifugal blood pump and a controller operatively associated with the motor for controlling the rotational speed of the motor. A digital speed selector in the motor housing generates a selected speed signal signifying a selected rotational speed for the motor. Sensors operatively associated with the motive means sense the rotational speed of the motive means and output a monitor signal signifying such rotational speed. Programmable memory in the motor housing programmed with a program of microprocessor readable instructions for microprocessor execution includes instructions for receiving the selected speed signal and generating a speed control signal to the controller signifying the selected speed for the controller; and for receiving the monitor signal and outputting a display signal indicative of motor rotational speed. A microprocessor under program control, in electrical connection with the controller, the speed selector means, the sensor means and the program memory, executes the instructions from the programmed memory, including to generate the display signal. A display in electrical communication with the microprocessor and responsive to the display signal displays information. Motor housing circuitry provides electrical communication among electrical components in the motor housing,

and an electrically conductive cable connected to the motor housing circuitry transmits electrical DC power to the motor housing circuitry means from an external power source.

While it is not unique to simply provide an enclosed motor with a tethered cable to a perfusionist console, it is unique to provide a complete motor system with an on board microprocessor and speed selector which is detachable from a perfusionist console carrying the power source. Because the motor housing is detachable from a perfusionist console, the power cabled and tethered housing can be removed from the console and placed near to the patient. This flexibility of the motor/pump movement minimizes the length of the extracorporeal fluid circuit, and this benefits the patient.

The motor housing is suitably predominantly formed from cast aluminum which has a high heat transfer capability. Casting the aluminum also gives the ability to create geometric shapes within the housing with little cost impact and facilitates the exterior of the housing to have the capability to be pole mounted or otherwise placed adjacent to the patient.

The smart motor driver apparatus also suitably includes motor housing data recordation memory for electronic recordation of data. The microprocessor readable instructions suitably further include instructions for writing motor history to the data recordation memory means while power is supplied to the motor housing circuitry, for reading the motor history from the data recording means when power is initially supplied to the motor housing circuitry, and for generating signals representing the motor identification and/or motor use history. The motor housing display is also responsive to signals from the microprocessor on microprocessor execution of the motor history reading and signal generation instructions for displaying motor history. The motor history may include one or more of motor identification and cumulative motor revolutions.

The smart motor driver apparatus may include temperature detectors and signalers in the motor housing operatively associated with the motor, for detecting temperatures of the motor and for generating a signal indicative of the detected temperatures. In this case, the motor use history includes the motor temperature history of the motor, and the microprocessor readable instructions further include instructions for writing the motor temperatures to the data recordation memory means while power is supplied to the motor housing circuitry.

The memory of the smart motor driver apparatus suitably comprises volatile memory and the apparatus further includes a DC battery to provide power to the memory means when power from an external source is absent.

This basic configuration is unique and carries several advantages. The first advantage is system safety. Redundancy or back up is a key in motor systems which are connected to a

patient for support life. If the motor, motor controller or motor system microprocessor fail in some fashion, the motor system of this invention can be disconnected from a console to which it is tethered for power and replaced with another motor system. The battery backed memory of the microprocessor within the motor housing will note the motive system failure and preclude the motor housing from being attached to another console, by displaying an alarm, for example, flashing the display located at the rear of the housing and/or by disabling motive function. Since the memory of the resident microprocessor also records the life history of the components of the motor housing, notably the cumulative revolution hours of the motor (and controller) as well as its identification, this information is capable of being downloaded to the console and displayed on the below described graphics display of the console when the motor system is coupled to the console. Conversely, when a patient perfusion operation has ended, the resident motor system microprocessor (or as also described below, a console microprocessor) can update the microprocessor memory in the motor. Then if the motor system is subsequently uncoupled and moved to another console, the history of the motor system resides with the motor system.

The smart motor driver apparatus may include a keypad operatively associated with the microprocessor for digitally entering values for processing by the microprocessor. The keypad suitably includes sequential and accelerator incremental and decremental value selector keys, and an enter key for a selected value. The keypad can be and preferably is the speed selector for the motor driver apparatus, and can include an additional key for generation of a signal for microprocessor processing to stop rotation of the motor.

The smart motor driver apparatus may be tethered to a console housing separate from the motor housing that includes a console power supply for supplying a source of DC power, console circuitry for providing electrical communication among electrical components in the console, and an electrically conductive tethering cable for electrically interconnecting the console circuitry and the motor housing circuitry and for transmission of DC power to the motor housing circuitry from the console power. The console circuitry may include devices adapted to receive and store one or more input signals from one or more peripheral signaling sources adapted to sense one or more parameters of a patient connected in a blood flow circuit having an extracorporeal flow portion including a centrifugal blood pump, or one or more parameters of the extracorporeal portion of the circuit, or both. The console circuitry may and preferably does include a console microprocessor and console programmable memory programmed with microprocessor readable instructions for the console microprocessor, with the console microprocessor responsive to program instructions from the console program

memory to interpret the input signals from the one or more peripheral signaling sources into information values and into output signals to the console display means to display the input based information values. Provision of a microprocessor in the console offers redundancy in the system to eliminate a point of single point failure in this critical life support system.

The smart motor driver apparatus motor housing may further include selectors for selecting an extracorporeal circuit parameter including circuit flow rate, centrifugal pump inlet pressure and centrifugal pump outlet pressure, and keys for digitally entering values for a selected extracorporeal circuit parameter for processing by the microprocessor under control of the programmed memory, the programmed memory including instructions for execution by the motor housing or console microprocessor for setting the speed of the motor to achieve a value of a selected extracorporeal circuit parameter relative to a sensed value of the same parameter. The instructions for execution by the motor housing or console microprocessor for setting the speed of the motor may include a PID algorithm to change the motor speed to approach and intersect the selected extracorporeal circuit parameter without exceeding a predetermined extent of overshoot and within a predetermined range of error. PID algorithms are proportional integral differential algorithms and are well known in the programming arts. housing or console microprocessor auto controls maintenance of the selected parameter by continuously receiving signals representing the sensed value of the same parameter and continuously executing the PID algorithm to maintain the selected value for the same In order to prevent motor speed in response to abrupt changes in the sensed parameter. parameter caused by accident, such as an accidentally pinched return line in the extracorporeal circuit that suddenly decreases flow rate and increases line pressure, the programmed memory instructions include a rate of change boundary for any value of a selectable extracorporeal circuit parameter, for comparison by the microprocessor to a sensed same parameter, and if the boundary is exceeded, for control of motor speed to prevent change of motor speed to give the selected value.

The console may further include a speed selector for generating a selected speed signal signifying a selected rotational speed for the motor. The console speed selector means suitably includes a potentiometer for producing an analog speed signal and an analog to digital converter for converting the analog signal to a digital speed signal. The console programmed memory relatedly includes instructions for execution by the console microprocessor for generating a digital signal representing the selected motor speed value. The console further comprises a gate for receiving the digital speed signal from the console microprocessor and the digital speed signal from the motor housing microprocessor and allowing passage of only a preselected one

of the console and motor housing microprocessor speed values, and further has a gate keeper for receiving watch signals from each of the console and motor housing microprocessors. On failure to receive a watch signal from one of the microprocessors within a predetermined time, the gate keeper operates the gate to lock out the microprocessor whose watch signal was not received within the predetermined time and opens the gate to the other processor.

A unique feature of the tetherable motor driver system of this invention is the display on the rear of the motor housing. The purpose of this display on the rear of the motor housing is to provide redundancy as well as basic operation indication if the motor system/pump is moved adjacent to the patient. In this manner, the eyes of the operator are not always required to be on the main display of the console to ascertain the instant condition of the system. Suitably with or without the console display embodiment, the information displayed by the display means responsive to the display signal minimally includes motor rotational speed (RPM's), although in accordance with this invention any of the displays described below may be employed where as more fully described below a console microprocessor is not also used or the console microprocessor is locked out by the gate keeper. In the event a failure occurs, not only may motor housing or console alarms be triggered, but also the display on the motor housing can provide additional visual and auditory indication of alarm conditions (suitably by blinking or changing colors or both).

Another aspect of this invention is novel displays. The displays of the smart motor driver apparatus and the console suitably include a plurality of function keys (switches) and a light screen responsive to the motor system microprocessor means under program control-or in a different aspect involving dual microprocessors as more fully described hereinbelow, a console microprocessor means under program control-to display screen images including (a) information and (b) menu options for calling different screens. The screen suitably comprises a liquid crystal display ("LCD") screen. The function buttons suitably are adjacent one margin of the LCD display. These correspond to selection legends on the LCD display or portions of the display that vary depending on a menu or display function chosen.

Suitably the display comprises a front panel which is a silk-screened acetate circuit board and is adhesively backed and fitted to the frame of the front panel. This configuration makes the front panel splash proof. A portion of the front panel that is the back lit LCD graphics screen display allows substantial flexibility in the information that can be displayed as well as operator input flexibility. For example, this display can even be programmed in a variety of languages which, for example, can include even the graphics characters of Japanese and Chinese writing. Using a graphics LCD approach also allows different capabilities to be added

6

to the invention by simply upgrading the firmware in the reprogrammable program memory rather than have to replace the entire console or a console circuit board or retrofit it with other hardware modifications.

The console panel display means suitably includes, alternatively, or in addition to the screen display, a scalar display of a predetermined original range of values and high limit that is automatically convertible a predetermined number of times by the microprocessor under program control to a predetermined different range of values and high limit when the next previous high limit is reached. The scalar display suitably comprises an array of light emitting diodes and associated drivers. Two circular arrays of light emitting diodes ("LED's") are suitably employed. The inside arc illuminates proportionally to the RPM of the pump and is suitably green in color. The outside row is suitably red in color and illuminates proportionally to pump flow in liters per minute ("LPM"). The purpose of these rows is to give a graphical indication of both flow and RPM and their relationship to one another. Suitably, two numeric LED displays are also furnished, color coded to match the graphical displays, e.g., a green RPM numeric display and a red numeric flow display.

The motor system microprocessor means under program control-or in a different aspect involving dual microprocessors as more fully described hereinbelow, a console microprocessor means under program control-further includes means for writing the information sent to the motor housing display and to the console display to the motor housing volatile memory while power from the external source is present.

Other novel aspects of this invention include the motor system microprocessor means under program control-or in a different aspect involving dual microprocessors as more fully described hereinbelow, a console microprocessor means under program control-further comprising means requiring speed selector means to be set to zero before the motor can be rotated, and further includes means for inputting a minimum speed at which the motor system microprocessor means under program control will ignore a the selected speed signal lower than the minimum speed and generate an alert signal that the selected speed is lower than the minimum speed. Means controllable by an operator after the alert signal is generated permit the microprocessor means under program control to produce the control signal at the selected speed signal lower than the minimum speed until motor speed is reset above the minimum speed or electrical power to the motor housing circuitry is discontinued.

Thus in one of the safety features of this invention, the front display panel also includes a low flow alarm and switch for the above program functions. Should the speed selector be accidentally be set to zero, the patient would be adversely affected. If the speed selector is set

to zero, an alarm is activated and the motor/pump RPM is limited to an operator configurable threshold, say 2,000 RPM. To intentionally go below this value, the operator must push the button included on the front panel and the RPM will fall to the value set by the speed selector. This is important as the thresholds will be different in adult and pediatric cases, and is unique in this threshold being configurable by the operator using the microprocessor under firmware program control in the program memory.

This method therefore comprises setting a minimum value for motor rotational speed, generating a the selected speed signal signifying a desired motor rotational speed lower than a predetermined minimum value, maintaining the rotational speed of the motor at the minimum value upon receipt of the selected signal signifying a value lower than the minimum value, generating an alarm signal signifying that the selected signal is lower than the predetermined value, and optionally discontinuing the step of maintaining the rotational speed of the motor at the minimum value and allowing the motor to rotate at the speed signified by the selected speed signal or a selected other speed below the set minimum value.

The console suitably includes a power cord for receiving AC power, power supply means electrically connected to the console circuitry and the power cord for converting AC line voltage to DC voltage, at least one onboard DC battery, and a connector for an external DC power source both connected to the console circuitry. In another novel aspect of this invention, the motor system microprocessor means under program control-or in a different aspect involving dual microprocessors as more fully described hereinbelow, a console microprocessor means under program control-further comprises:

means for determining what power is available from the console power sources comprising the power supply means, the onboard DC battery and the external DC power source connector, and if AC power is available, for determining whether it is 240V, 120V or 90V and for auto-configuring the power supply means to accept the power available;

means for prioritizing and distributing power such that if DC power is available from the console power supply means, it has priority, but if DC power is not available from the console power supply means and external DC power from the console external DC power source connector is available, then it has priority, but if both DC power from the console power supply means and from the console external DC power source connector are not available, then the onboard console battery has priority; and

means for trickle charging the onboard console battery when DC power from the console power supply means is available.

The auto-configuring feature allows a single unit configuration to be manufactured and used worldwide, rather than having a technician manually configure the unit for the power requirements of the destination or importing country.

Suitably, secondary function panel display LED's are also optionally provided for the console, advantageously all in a same color, e.g., amber, that distinguishes these secondary parameters from the primary LED's of the console, e.g., flow being red and the RPM being green. These color separations are deliberate so that the operator can simply glance at the display and quickly ascertain the status of a particular function by knowing its color. An example of a secondary function includable on the front display panel is a plurality of timer displays. These timers have individual start and stop/reset buttons, to measure particular events of the procedure such as total time on pump. Another secondary function is a temperature display (also differently colored, suitably amber, from the primary flow and RPM functions) that displays temperature input from a temperature probe either in the patient or at a point in the extracorporeal flow circuit, for example near a heat exchanger. Another secondary function is a pressure display which measures pressure from a remote line to the patient, suitably in either mmHg or kPa. These pressure units can be set to the preference of the operator by using the menus on the LCD. Suitably also on the front panel display is an alarm mute button giving the operator in an alarm conditions the opportunity to mute the alarm by depressing this button. The alarm mute is then reset when the alarm condition ceases.

When the onboard console battery is used to power the console, suitably all the secondary amber LED's go out and only the lead LED's illuminate on the RPM and flow rings around speed selector. This is to save electrical power. (During battery operation as described in detail below the LCD carries a DISPLAY key that when depressed illuminates the numeric amber LED's for five seconds after the operator releases pressure from the switch. This default value is also changeable in the UTILITY menu.)

In the dual microprocessor aspect of this invention noted above, the console circuitry includes a console microprocessor means and console program memory and the console microprocessor is responsive to program instructions from the console program memory to interpret the input signals from the one or more peripheral signaling sources into information values and output signals to the console display means to display the input based information values or to perform one or more of the above tasks described where dual microprocessors may be used.

Where dual microprocessors are used, program memory for one is suitably nonvolatile, e.g. an EPROM; the program memory for the other may be volatile, with the program being

loadable to the volatile memory by a transfer of instructions from the nonvolatile memory on system bootup. Preferably in such instance, the nonvolatile program memory would reside in the console and the volatile program memory would be resident in the motor housing. This would enable upgrades of software in all motors that are eventually connected to the console simply by reprogramming only the console nonvolatile memory. If the single microprocessor design where the microprocessor resides only in the motor housing, the program memory is nonvolatile. It is within the scope of this invention for program memory for both the console and motor housing microprocessors to be volatile and means provided to boot up and load the memory of one or both of them from a suitable permanent medium and medium reader such as a connected diskette and disk drive, but such complexity is unnecessary.

An advantage of using dual microprocessors is ability to assign to the console processor all processing duties except control of the motor controller, receipt of the monitor signal and output of the motor system display system.

In accordance with this advantage, this invention includes an aspect in which the speed selector means resides in the console, the microprocessor means in the motor system under program control is in electrical connection with the motor housing program memory and the console speed selector means (and as always, with the motor housing controller), for receiving the selected speed signal and generating a speed control signal to the controller signifying the selected speed for the controller. As always in this invention, the motor system includes a display in the motor housing in electrical communication with the motor housing microprocessor means and responsive to the display signal for displaying information. Power supply is in the console for supplying a source of DC power, and circuitry means are in the motor housing and in the console and electrically conductive cable means interconnect the circuitry means for transmission of DC power to the motor housing circuitry means from the console power means and provide electrical communication between the console speed selector means and the motor system microprocessor means, motor housing program memory the controller, the sensor means, and the display means.

In an embodiment of the foregoing design where the speed selector means resides in the console, the console comprises a console microprocessor means under program control, in electrical connection with console program memory, the speed selector means, the sensor means, and the motor housing microprocessor means, for receiving the speed signal and the monitor signal and determining whether the monitor signal is within a predetermined limit of allowable variance of the speed signal, and if within the allowable limit, then outputting a

display signal, but if outside the allowable limit under a predetermined sampling protocol, then outputting an alarm signal.

A method of controlling a centrifugal pump is accomplished by this structure. The method comprises generating a selected speed signal signifying a selected rotational speed for rotating a motor to rotationally drive the pump, interpreting the first signal and generating a speed control signal signifying the desired rotational speed output for a controller for controlling the motor, controlling the motor to rotate the motor according to the speed control signal, sensing the actual rotational speed of the motor and outputting a monitor signal signifying the actual rotational speed, checking the selected speed signal and the monitor signal and if the monitor value is within a predetermined limit of allowable variance of the speed signal, then outputting a display signal, but if the monitor signal is outside the limit, sampling the monitor and signal signals in a predetermined protocol and if the monitor signal remains outside the limit under the protocol, then outputting an alarm signal, and displaying the rotational speed of the motor responsive to the display signal or an alarm responsive to the alarm signal or displaying both the rotational speed and the alarm condition.

The screen images depicting information suitably include a MAIN screen displaying information which depends on whether the console is operating on line voltage or the console battery, and if operating on line voltage, then depicting information including: charge status of the onboard console battery, a histogram of pump flow in units of volume per minute over a period of time ending at current time, and one of a plurality of readouts including instantaneous pump flow (Q), blood flow per a patient weight unit (Q/wt) and blood flow per a patient body surface area unit (Q/BSA), but if operating on the console battery, then depicting information including: a notice that the battery is in use.

The screen images depicting options suitably include a MAIN screen displaying options which depend on whether the apparatus is operating on line voltage or the console battery, and if operating on line voltage, then depicting *battery*, *pressure*, *flow indices* and *system* options for calling respectively a BATTERY screen, a PRESSURE screen, a FLOW INDICES screen, and a SYSTEM screen, but if operating on the console battery, then depicting *pressure*, *flow indices and system* options for calling the PRESSURE screen, the FLOW INDICES screen, and the SYSTEM screen, and an *illuminate display* option.

The BATTERY screen is called upon keying a function switch operatively associated with the *battery* option on the MAIN screen, and depicts (a) battery status information including information based on the date of installation of the battery in the console, and (b) *main* and *system* options for calling respectively the MAIN or SYSTEM screens.

The PRESSURE screen is called upon keying a function switch operatively associated with the *pressure* option on the MAIN screen, and depicts at least (a) current calibration values for zero pressure and a high pressure alarms, and (b) *pressure alert, zero transducer, main* and *system* options for calling respectively PRESSURE ALERT or ZERO TRANSDUCER screens or the MAIN or SYSTEM screens,

The PRESSURE ALERT screen is called upon keying a function switch operatively associated with the *pressure alert* option on the PRESSURE screen, and depicts (a) a high pressure alarm value readout, and (b) *increase* or *decrease* options for increasing or decreasing the high pressure alarm value, an *OK* option for accepting a high pressure alarm value, a *zero transducer* option for calling the ZERO TRANSDUCER screen, and *system* and *main* options for calling respectively the SYSTEM or MAIN screens.

The ZERO TRANSDUCER screen is called upon keying a function switch operatively associated with the zero transducer option on the SYSTEM screen, and depicts (a) an open to air zero pressure value readout, and (b) a set zero option for setting the open to air zero pressure value, an OK option for accepting a set open to air zero pressure value, and system and main options for calling respectively the SYSTEM or MAIN screens.

The FLOW INDICES screen is called upon keying a function switch operatively associated with the *flow indices* option on the MAIN screen, and depicts at least (a) values for height and weight of a patient, and (b) *height*, *weight*, *Q/wt*, *Q/BSA* and *main* options for calling respectively HEIGHT, WEIGHT, Q/WT, Q/BSA screens and the MAIN screen.

The HEIGHT screen is called upon keying a function switch operatively associated with the *height* option, and depicts (1) a default patient height value readout, and (2) *increase* or *decrease* options for increasing or decreasing the patient height value, an *OK* option for accepting a selected patient height value, and a *main* option for calling the MAIN screens.

The WEIGHT screen is called upon keying a function switch operatively associated with the *weight* option, and depicts (1) a default patient weight value readout, and (2) *increase* or *decrease* options for increasing or decreasing the patient weight value, an *OK* option for accepting a selected patient weight value, and a *main* option for calling the MAIN screens.

The Q'WT screen is called upon keying a function switch operatively associated with the Q/wt option, and depicts at least (1) the histogram and a Q/wt value readout, and (2) Q/BSA, height, weight, flow indices and main options for calling respectively a Q/BSA screen or the HEIGHT. WEIGHT, FLOW INDICES or MAIN screens, the MAIN screen containing the Q/wt value when called from the Q/WT screen.

The Q/BSA screen is called upon keying a function switch operatively associated with the Q/BSA option, and depicts at least (1) the histogram and a Q/BSA value readout, and (2) height, weight, Q/wt, flow indices and main options for calling respectively the HEIGHT, WEIGHT, Q/WT, FLOW INDICES and MAIN screens, the MAIN screen containing the Q/BSA value when called from the Q/BSA screen.

The SYSTEM screen is called upon keying a function switch operatively associated with the *system* option on the MAIN screen, and depicts at least (a) the histogram and one of the plurality of Q, Q/wt and Q/BSA readouts, and (b) *alarms, status, battery,* and *main* options for calling respectively ALARMS and STATUS screens and the BATTERY and MAIN screens.

The ALARM screen is called upon keying a function switch operatively associated with the alarm option on the SYSTEM screen, the ALARM screen depicting at least (a) the histogram and one of the plurality of Q, Q/wt and Q/BSA readouts, and (b) and low flow alarm, negative flow alarm, alarm volume and main options for calling respectively a LOW FLOW ALARM screen, a NEGATIVE FLOW ALARM screen, an ALARM VOLUME screen, or the MAIN screen.

The LOW FLOW ALARM screen is called upon keying a function switch operatively associated with the *low flow alarm* option, and depicts (1) a low flow alarm threshold value readout, and (2) *increase* or *decrease* options for increasing or decreasing the low flow alarm threshold value, an *OK* option for accepting a selected low flow alarm threshold value, and *system* and *main* options for calling respectively the SYSTEM or MAIN screens.

The NEGATIVE FLOW ALARM screen is called upon keying a function switch operatively associated with the *negative flow alarm* option, and depicts (1) a negative flow alarm threshold value readout, *increase* or *decrease* options for increasing or decreasing low flow alarm threshold values, an *OK* option for accepting a selected low flow alarm threshold value, and *system* and *main* options for calling respectively the SYSTEM or MAIN screens.

The ALARM VOLUME screen is called upon keying a function switch operatively associated with the *alarm volume* option, and depicts (1) a readout of alarm volume as a percent of maximum, *increase* or *decrease* options for increasing or decreasing the percentage of alarm volume maximum, an *OK* option for accepting a selected alarm volume percentage, and *system* and *main* options for calling respectively the SYSTEM or MAIN screens.

The STATUS screen is called upon keying a function switch operatively associated with the *status* option on the SYSTEM screen, and depicts (a) system status readouts including time, date, motor hours, cumulative motor revolutions, battery life and memory capacity of the motor assembly circuit board, and (b) *utility*, *time-date*, *system* and *main* options for calling

respectively a UTILITY screen, a TIME-DATE screen, the SYSTEM screen, and the MAIN screen.

The motor system or console microprocessor memory under program control, according to the configuration as above described, also time tags and records alarm conditions. The console circuitry means advantageously includes a connector for a remote computer to make this data available through the connector, for example an RS-232 port on the console.

The UTILITY screen is called upon keying a function switch operatively associated with the *utility* option, and depicts *communication, defaults* and *diagnostics* options for calling respectively COMMUNICATION, DEFAULTS and DIAGNOSTICS screens, *increase* or *decrease* options for incrementing or decrementing to select one of the *communication, defaults and diagnostics* options, an *OK* option for accepting a selected the *communication, defaults* or *diagnostics* options, and *system* and *main* options for calling respectively the SYSTEM or MAIN screens. the COMMUNICATION screen is called upon keying a function switch operatively associated with the *communication* option, and depicts (1) a message to key an associated function switch when ready for a remote computer to receive data transfer from the apparatus, and (2) an *OK* option for initiating data the transfer, an *abort* option for canceling data transfer, and *utility* and *main* options for calling respectively the UTILITY or MAIN screens.

The DEFAULTS screen is called upon keying a function switch operatively associated with the defaults option, and depicts (a) default value readouts including a default time value for an illuminate display countdown when the apparatus is operating on the console battery and a default high pressure alarm value and (b) illuminate display countdown default and high pressure alarm default options for calling respectively an ILLUMINATE DISPLAY COUNTDOWN DEFAULT screen and a HIGH PRESSURE ALARM DEFAULT screen, increase or decrease options for incrementing or decrementing to select one of the illuminate display countdown default or high pressure alarm default options, an OK option for accepting a selected default option, and utility and main options for calling respectively the UTILITY or MAIN screens.

The ILLUMINATE DISPLAY COUNTDOWN DEFAULT screen is called upon keying a function switch operatively associated with the *illuminate display countdown default* option, and depicts (a) a default time value readout for the illuminate display countdown, *increase* or *decrease* options for increasing or decreasing the default time value, an *OK* option for accepting a selected default time value for the illuminate display countdown, a *more* option for

calling a MORE screen, and *utility* and *main* options for calling respectively the UTILITY or MAIN screens.

The HIGH PRESSURE ALARM DEFAULT screen is called upon keying a function switch operatively associated with the *high pressure alarm default* option, and depicts (a) a default high pressure alarm readout for high pressure alarm, *increase* or *decrease* options for increasing or decreasing the default high pressure alarm, an *OK* option for accepting a selected default high pressure alarm, a *more* option for calling a MORE screen, and *utility* and *main* options for calling respectively the UTILITY or MAIN screens.

The MORE screen is called upon keying a function switch operatively associated with the more option, and depicts (a) default value readouts including a default low flow alarm value and a default negative flow alarm value and (b) low flow alarm default and negative flow alarm default options for calling respectively an a LOW FLOW ALARM DEFAULT screen and a NEGATIVE FLOW ALARM DEFAULT screen, increase or decrease options for incrementing or decrementing to select one of the low flow alarm default or negative flow alarm default options, an OK option for accepting a selected such default option, and utility and main options for calling respectively the UTILITY or MAIN screens.

The TIME-DATE screen is called upon keying a function switch operatively associated with the *time-date* option, and depicts, and depicts (a) readouts including a time of day value and a date and (b) *time* and *date* options for calling respectively an TIME screen and a DATE screen, *increase* or *decrease* options for incrementing or decrementing to select one of the *time* or *date* options, an *OK* option for accepting a selected *time* or *date* option, and *system* and *main* options for calling respectively the SYSTEM or MAIN screens.

The TIME screen is called upon keying a function switch operatively associated with the *time* option, and depicts (a) a time of day readout, *increase* or *decrease* options for increasing or decreasing the time of day readout, an *OK* option for accepting a selected time of day, and system and *main* options for calling respectively the SYSTEM or MAIN screens.

The DATE screen is called upon keying a function switch operatively associated with the date option, and depicts (a) a date readout, *increase* or *decrease* options for increasing or decreasing the date readout, an *OK* option for accepting a selected date, and system and *main* options for calling respectively the SYSTEM or MAIN screens.

Description of the Drawings

The present invention may be more completely understood when taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a sectioned side view schematic of the centrifugal pump driver apparatus including an intelligent motor housing driver and a console, illustrating the location of the interior components.

- FIG. 2 is a front view of the operations panel of a centrifugal pump apparatus console display.
- FIG. 3 is a view of the Start up Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display indicating that the internal systems are being checked.
- FIG. 4 is a view of the Start up Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display showing that the internal systems were checked and passed the examination.
- FIG. 5 is a view of the LCD on the operations panel of the centrifugal pump driver apparatus display requesting that the RPM knob be turned to zero.
- FIG. 6 is a view of the Main Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 7 is a view of the Main Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display when the console is being powered by batteries.
- FIG. 8 is a view of two of the label legends on the LCD showing their alternate blinking between two labels.
- FIG. 9 is a view of the Battery Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 10 is a view of the Pressure Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 11 is a view of the High Pressure Alarm Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 12 is a view of the Zero Transducer Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 13 is a view of the Flow Indices Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 14 is a view of the Screen to set the patient height of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 15 is a view of the Screen to set the patient weight of the LCD on the operations panel of the centrifugal pump driver apparatus display.

FIG. 16 is a view of the Main Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display showing flow in Q/Kg.

- FIG. 17 is a view of the Main Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display showing flow in Q/BSA.
- FIG. 18 is a view of the System Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 19 is a view of the Alarms Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 20 is a view of the Low Flow Alarms Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 21 is a view of the Negative Flow Alarms Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 22 is a view of the Alarm Volume Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 23 is a view of the Status Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 24 is a view of the Utility Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 25 is a view of the Communications Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 26 is a view of the Defaults Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display with Illuminate Display Countdown highlighted.
- FIG. 27 is a view of the Illuminate Display Countdown Default Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 28 is a view of the Defaults Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display with Hi Pressure Alert highlighted.
- FIG. 29 is a view of the High Pressure Alert Default Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 30 is a view of the Defaults Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display with Low Flow Alarm highlighted.
- FIG. 31 is a view of the Low Flow Alarm Default Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 32 is a view of the Defaults Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display with Neg Flow Alarm highlighted.

FIG. 33 is a view of the Negative Flow Alarm Default Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.

- FIG. 34 is a view of the Defaults Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display with Patient Height highlighted.
- FIG. 35 is a view of the Patient Height Default Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 36 is a view of the Defaults Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display with Patient Weight highlighted.
- FIG. 37 is a view of the Patient Weight Default Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
- FIG. 38 is a view of the Diagnostics Screen of the LCD on the operations panel of the centrifugal pump driver apparatus display.
 - FIG. 39 is a block diagram of an embodiment of the invention as illustrated in Fig. 1.
 - FIG. 40 is a block diagram of a smart motor driver apparatus of the invention.
 - FIG. 41 is a perspective view of a smart motor driver apparatus of the invention.
- FIG. 42 is a view of the screen of the centrifugal pump consoledisplay when a selected parameter for RPM autocontrol is flow rate in the extracorporeal circuit.

Description of a Preferred Embodiment

Figure 1 illustrates a sectioned side view of the centrifugal pump driver system, generally shown by 100. The housing for the motor driver of the centrifugal pump is shown as 102 and 104 is the front of the housing where the disposable centrifugal pump 105 mechanically attaches and is magnetically driven by disc 106 which is mechanically linked to the motor 108. The motor controller 110 is electronically coupled to motor assembly 108 and provides the electrical signals necessary to drive the motor and also determines the RPM of the motor by monitoring the Hall effect sensors in the motor assembly 108. The circuit board which is electrically connected to the motor controller 110 is shown as 112. Circuit board 112 contains a microprocessor and a display 114 which is positioned to be viewable from the rear of the motor assembly 102. The circuit board 112 is also electrically connected to a cable 116 exiting the bottom of the motor assembly 102. This cable carries electrical power to the motor controller 110, and signals to the microprocessor and related circuitry on circuit board 112. This cable also carries information from the microprocessor on circuit board 112 to the console 121. The cable 116 is approximately 6' long and can be wrapped around a cord wrap (not shown) on the back of the console 121. The cable 116 has a connector on it which fits into the console 121 via

connector 122 on the rear of the console 121. Console 121 has a plurality of connectors located on the rear of the console. Connector 124 is a connector for an ultrasonic flow probe. Connector 126 is a connector for a temperature probe. Connector 128 is a connector for electronic communications to a computer. Connector 130 is a connector for a 28 v DC input. Not shown is a leur connector which provides access to a pressure transducer located on circuit board 148. External electrical power is provided via power cord 144 which enters the bottom of console 121. The power circuit first goes to a power switch 152, then through a power filter (not shown) before it goes into a power supply 132 mounted to the rear of console 121. The power supply 132 converts the AC supply voltage to the appropriate DC voltages to operate the components within the system 100. There are two batteries 140 and 142 contained with console 121. These are two twelve volt batteries which are placed in series to yield 24 volts DC. A power distribution circuit board 134 takes input from the batteries 140 and 142, the power supply 132 which is fed from external power cord 144 and connections to the 28 volt power connector 130. The components on circuit board 134 determine what power is available and distributes it according to the circuit components. Circuit board 134 also prioritizes the power distribution. The first priority is AC power via the power cord, in this priority the electrical power is distributed and the batteries 140 and 142 are "trickle" charged to insure that they are at their peak. If AC power is not available then the second priority is the 28 volt inlet. Again, the circuits of the system 100 are supplied and batteries 140 and 142 are "trickle" charged. If AC nor external 28 v DC power is not available then internal batteries are used as the power source. This system examines the available power source(s) several times each second and sets the power configuration to the priority list just described as conditions warrant. Circuit board 138 is for conversion of the signals of the flow probe to flow information which can then be accessed by the microprocessor on circuit board 148. Circuit board 138 can be folded down for service once the case is removed from the console 121. Cooling for the console 121 is provided by a fan 136 located at the rear of the unit. Air inlet is provided by a grille 150 located near the front of the unit. The locations of the fan 136 and the grille 150 allow for air to be ducted through out the case and especially by the power supply 132 which generates the most heat within the unit. Circuit board 154 contains the circuitry necessary to drive the display of console 121 which also contains the LCD. Faceplate 162 is affixed to the front of the console and is also a circuit board. This faceplate has several switches on it and they are connected via a cable to the display circuit board 154. Faceplate 162 is sealed against the front of the console 121 and as such provides a splash proof enclosure. Knob 160 which extends from the faceplate 162 of console 121, controls the speed or RPM of the motor 108 and

thereby the centrifugal pump. This knob 160 is connected to a shaft 158, which is part of a potentiometer 156 which is electrically connected to circuit board 154. Rotating knob 160 changes the electrical resistance of potentiometer 156 which, in turn, proportionally changes a reference voltage. As circuit board 154 is in electrical communication with circuit board 148 this reference voltage is monitored by the microprocessor located on circuit board 148 and by the microprocessor located on circuit board 112.

The microprocessor on circuit board 112 controls the output of motor 108 (and thereby the centrifugal pump) via the motor controller 110. The microprocessor on circuit board 144 monitors this action by checking the value of the potentiometer against the RPM of the motor, which is fed back by the motor controller 110. If these values are within predetermined limits then the microprocessor on circuit board 148 does nothing. If these values are outside predetermined limits then the microprocessor on circuit board 148 signals an error via the display circuit board 154 and its associated alarms and displays and resets the microprocessor on circuit board 112. If, after several reset attempts, the microprocessor on circuit board 112 does not again fall within predetermined limits, then the operator is requested to change motor housing assembly 102 complete with tethered cable 116 with a new assembly or disconnect the centrifugal pump on the front 104 of housing 102 and use a handcrank to maintain the patient until the subsystem can be replaced. This system provides the optimum redundancy. As the motor 106 and motor controller 110 are key and pivotal components, then in this configuration they are easily replaceable by simply disconnecting them via the connector which mates with connector 122 and replacing this subassembly by connecting a new subassembly into connector 122 and moving the centrifugal pump to the new motor assembly.

The microprocessor on circuit board 148 provides overall control of console 121 by monitoring and displaying Flow, RPM, Pressure, Temperature and providing the data and operating the LCD at the request of the operator.

Figure 2 is a front view of faceplate 162. Around control knob 160 is a ring 181 and a ring 182. Ring 182 is made up of a number of green light emitting diodes (LED's) which illuminate in proportion to the RPM of the motor 108 and therefore the centrifugal pump. Ring 181 is made up of red LED's which also illuminate in proportion to the Flow of the centrifugal pump in liters per minute. It is useful to relate the two graphical indicators to each other during the course of pump operation.

Display 180 is a single digit numeral comprised of a seven segment red LED. This number represents the high end of the Flow graphical ring and is programmed so that the ring is in units of 0 - 3, 0 - 6 or 0 - 9 Liters per minute. This automatic scaling reduces granular effects of the

display in the low end if the scale were a constant 0 - 9 Liters per minute when the flow may be much nearer the low end, for example in pediatric cases.

The RPM numerical indication 186 is provided by four seven segment green LED's, the color of which matches the RPM flow ring 182. Adjacent to this display is a Low RPM switch 188 and indicator LED, 190. Should the knob 160 be inadvertently turned down below a preset threshold, for example 2,000 RPM, the microprocessor on circuit board 148 will sense this and instruct the microprocessor on circuit board 112 to maintain RPM at approximately 2,000 RPM. Simultaneously an audible alarm will sound and LED 190 will flash at approximately 1 second intervals. If the operator turns up the RPM above this threshold, or 2,000 RPM then the alarm condition will cease. If the operator wishes the RPM to be below this value then by pushing button 188 the alarm condition will cease and the RPM will fall to the set value of the knob. This feature exists for safety reasons. Pump flow in liters per minute is displayed by three, red, seven segment LED's 196. This color is also the same as the graphical flow ring 181. An audio alarm cancel button 192 is shown adjacent to the display. Its function is to mute audio alarms during any single given alarm condition. Once the alarm condition is cleared, this function reactivates. The LED 194 above this switch serves as a visual indicator of an alarm condition. The numeric pressure display 226 is made up of three, amber, seven segment LED's. Amber was chosen as an important yet somewhat neutral color for the numeric displays on the left side of the faceplate 162. In all cases, Flow is indicated in red and RPM is indicated in green. All other LED displays are amber, so that the operator may quickly glance and "fix" on the Flow and RPM parameters. The units of pressure are in KPa, (Kilo Pascals) 224 or as shown immediately below this mmHg (millimeters of Mercury). Two LED's behind the faceplate 162 on circuit board 154 will either illuminate the KPa units or the mmHg units depending on the operator's choice as set through the LCD. The default setting is mmHg. Below the Pressure display is the Temperature display. The numeric display for temperature 228 is identical to that for pressure, carrying the same type and color of LED's. The displayed units for temperature is in degrees Celsius or °C. Below the Temperature display are two timers. Timer 1, 230 and Timer 2, 236. Each of these timers have numerical displays 234 and 240 respectively which are amber, seven segment LED's. The first digit represents "hours" as reflected by the "H" below this character. The second two numbers are offset with periods and represent "minutes" as reflected by "Min" shown directly below these characters. The last numeral represents 1/10 minute or 6 seconds, which is reflected by the "1/10" directly below this number. Each timer has a start button 232 and 238 respectively and a Start/Stop button, 244 and 242 respectively. Pushing the start button activates the timer and pushing the

Start/Stop button once stops the timer. If the Start button is again pushed then the timer continues. If the Start/Stop button is pushed twice in succession then the timer resets to a "0.00.0" display. Two timers are frequently used in pump procedures. The first frequently measures total "pump time" of a extracorporeal bypass case. The second timer measures special events of interest during the case.

To the top of faceplate 162 is the graphics LCD 198. To the left of this display are shown six displayed menu labels, 200, 202, 204, 206, 208, and 210 respectively from top to bottom. These software driven labels correlate to the six buttons shown to the side of the display or 212, 214, 216, 218, 220, and 222 respectively. The software is structured that different options may present themselves on the labels 212, 214, 216, 218, 220, and 222. Operator selection of these menu labeled items is accomplished by pressing the corresponding button or 200, 202, 204, 206, 208, and 210. Thus a menu label presented on label 220 can be selected by pressing button 208, or switch "5". This approach allows for extreme flexibility on the part of the software with minimum impact on the hardware.

Figure 3 illustrates the display reading of the LCD 198. The menu legends 212, 214, 216, 218, 220 and 222 are blank. A "Battery in Use" message 250 is displayed only if the system is operating on battery power. This display will continually blink this message while the unit is operating on battery power. If the unit is operating with AC power then this message will not be displayed and 250 will be blank. The software version number 252 is displayed during this time period so that the operator can always verify the software version that the system is operating under. The "Systems Check" 254 message is displayed during the power up, as the software examines the components of the system 100 and determines that everything is operating correctly. Typically this examination takes approximately 10 seconds. The "Please Wait" message 256 is displayed during this portion of the circuit examination.

Figure 4 illustrates the second LCD 198. The message "PASS" is now displayed 257 is displayed, signifying that the system has examined the components of the console 100 and that everything was found to be in suitable working order. If the examination by the system found something in error then the message 257 would be replaced by "FAIL" and subsequent displays would detail the failures.

Figure 5 illustrates the next LCD display. The message in the box 266 tells the operator to "Set RPM Knob to Zero to Proceed". This message occurs if the RPM Knob 160 is not turned fully counter clockwise and is a safety concern. This forces the operator to start the pump from a stopped position. Figure 6 illustrates the "MAIN" display if AC power is used and Figure 7 illustrates the "MAIN" display if battery power is used.

Figure 6 shows that menu legends 212, 214, 216 and 218 now have legends and the space occupied by legends 220 and 222 are blank. At the top of the display 198 is a battery indicator 270. This indicator occupies this top portion of the display for all displayed screens except when the batteries are used to provide power. Displayed in the format of a gasoline gauge, the operator can easily determine the approximate charge of the battery. In this illustration, the batteries are slightly more than 3/4 charged. The flow of the pump as measured by the flowmeter and circuit 138 is displayed 272 and indicates "3.9", which would be identical to the reading of flow display 196. The units of flow are shown 274 and are expressed in L/Min or Liters per Minute. Below this display is a flow histogram 278. This is a graph which provides a flow history in Liters per Minute on the vertical axis 276 for the preceding twenty minutes on the horizontal axis 280. This histogram is useful for spotting trends which may be periodic in nature.

Figure 7 illustrates the information on the display 198 which would be shown if the system 100 were operated by batteries. Changes of this display are that the small battery charge indicator 270 in Figure 6 is replaced by a blinking "Battery in Use" message 250 in Figure 7. This histogram 278 in Figure 6 is replaced by an expanded battery charge indicator and legends 258, 260 and 262. While the system 100 is operated by batteries (refer to Figure 2) the amber LED's 226, 228, 234 and 240 are not illuminated to save power. Additionally only the furthest clockwise LED on displays 182 and 181 are illuminated also to save power. During battery operation, Legend 212 displays "Illuminate Display", if switch "1" 200 is pushed to activate this function then all of the deactivated LED displays operate for a period of time after switch "1" 200 has been released. This period of time can be set by the operator, but the default time is 5 seconds. This time is displayed in countdown fashion in the lower left of display 198 indicated by 264. This allows the operator to take pressure 226, temperature 228 and timer 234 and 240 data as needed with minimal compromise on the battery life.

Sometimes, as one patient case has ended, the operating room will be set up for the next case. As a result the console system 100 will not be turned off rather it will remained powered waiting for the next case. In this event, if the pump motor has been idle for a predetermined period of time, yet power is maintained to the console 100 then the patient data will not be current for the subsequent case. Consequently the system 100 will determine how much time has elapsed since the pump was turned off. If this elapsed time period exceeds a certain value or a default then the operator may need to be reminded to change the patient parameters of height, weight and pressure zeroing (the purpose of these parameters will be explained later). To accomplish this operator notification process Figure 8 illustrates the legend keys for

Pressure 214 and Flow Indices 216. On the Main Display such as Figure 6 these legends 214 and 216 will blink alternately. The Pressure legend will illustrate alternately between 214 and 215 as shown in Figure 8 so that the message is to "Check Pressure". Similarly, the Flow Indices legend will blink alternately between 216 and 217, as shown in Figure 8 to yield the message "Check Flow Indices".

Figure 9 illustrates the resultant display if switch "1" 200 is pressed when legend 212 illustrates "Battery" as depicted in Figure 6. In this figure only legends 216 and 218 have printed information on them which is "System" and "Main" respectively. If switch "3" 204 is pressed while "System" is displayed on legend 216, then the display 198 will switch to the System menu reflected in Figure 20. The "Main" legend is always displayed on each display menu so that the operator may quickly return to the "Main" menu, in this case by pressing switch the corresponding switch. In the case of Figure 9 pressing switch "4" 206 which corresponds to the legend 218 containing "Main" will cause the system to return the display 198 to the "Main" menu as indicated by Figure 6 for AC power. In Figure 9, the top of the display indicates that the last battery installation occurred on March 3, 1996. This date information is retained by the memory of the system when the batteries were actually replaced. Below this information, is a recommendation of when the batteries should again be replaced "6 Months" 290. This information is continually updated via a real time clock resident in the console. Should this recommendation time be sufficiently short or if this time has been exceeded then the message "Recommend Replacement" 292 will also be displayed. The battery information 260 is displayed to the lower portion of the display 198.

Figure 10 illustrates the display 198 if switch "2" 202 is pressed while "Pressure" is displayed in legend area 212 as in Figure 6. Figure 10 has four menu legends. Legend 212 has a label of "Pressure Alert" which provides for Alarm thresholds, legend 214 has a label of "Zero Xducer" which provides for zeroing the pressure transducer, legend 216 has a label of "System" which transfers the menu to the "System" menu to be described later and legend 218 has the label "Main" which transfers the menu to the "Main" menu described previously. The top of the display 198 carries the battery indication 270. Below the battery indication 270 are information lines. The "Current Cal" is the pressure transducer calibration header. The next line indicates "0 = 0.4 mv" which is the millivolt (mv) reading for zero pressure, determined by calibration. The next line is "150 = 200 mv" which is the millivolt reading of the pressure transducer at a pressure of 150 mmHg. The last line is a statement that the units of pressure are in "mmHg" or millimeters of Mercury. The units of pressure options are mmHg or KPa (Kilo Pascals) which are selectable in another menu option. If switch "1" 200 is pressed which

corresponds to label 212 carrying the legend "Pressure Alert" then the display 198 is represented by Figure 11.

Figure 11 shows the Pressure Alert screen and its function is to set the alarm threshold for high pressure. Legend label 212 is "OK", legend label 214 is "Zero XDCR", legend label 216 is "System", legend label 218 is "Main", legend label 220 is an up or increasing arrow, and legend label 222 is a down or decreasing arrow. Below the battery indicator 270 is the text "Set High Pressure Alarm" which indicates the function of the display which is to set the upper pressure threshold for the pressure alarm. The next line is "Value = 150 mmHg". This indicates that the current alarm threshold is 150 mmHg. If, during use, the pressure exceeds this value then the alarm will sound. At the bottom of the display 198 are instructions: "Press (up arrow, down arrow) to change 'OK' when done". If the operator wants to increase this threshold then the up arrow, legend label 220 corresponding to switch "5" 208 can be pressed by the operator and the threshold values will be increased accordingly and displayed on display 198. Similarly, by pressing switch "6" 210 which corresponds to label legend 222 which illustrates the down arrow, the pressure alarm threshold will decrease and be reflected by the change in the number on the display 198. Once the operator is satisfied with the alarm threshold, then switch "1" 212 is pushed which corresponds to the legend label "OK" which tells the computer that the selection is complete. The computer stores this new value as the pressure alarm threshold.

Figure 12 illustrates the display 198 if the "Zero XDCR" function, switch "2" 202 label legend 200 of Figure 10 (or Figure 11). The function of this display is to zero the pressure transducer. Below the battery indicator 250 are three text lines. The first "Open to Air" is instructional, telling the operator to open the transducer to air. The second line "Value = 1 mv" states that the current voltage value of the pressure transducer is 1 mv or 1 millivolt, this will obviously change with the transducer and pressure conditions and the operator will be expecting a suitable range of values. As the operator sets the height of the pressure line to the patient, this 1 mv value will also change. Once the operator is satisfied with the orientation of the pressure line then "OK" label legend 212 represented by switch "1" 200 will be pushed and the computer will store this mv (millivolt) value as the zero reference for the pressure transducer.

Figure 6 is the reference figure for the "Main" display where another menu option will be explored. Pressing switch "3" 204 corresponding to label legend 216 which carries the function "Flow Indices" in Figure 6 will yield the display illustration represented by Figure 13.

The purpose of this menu as shown in Figure 13 is to enter the patient height and weight so that flow per unit weight (label legend 216 "Q/Kg") or flow per body surface area (label legend 218 "Q/BSA") may subsequently be calculated and be offered as a display option on the "Main" menu (272, 274 of Figure 6). In Figure 13, below the battery indicator 250 are two basic statements on the display. The first is "Current Height = 150 cm". This represents the default value of the current height of the patient or 150 cm (centimeters). The second statement is "Current Weight = 50 Kg". This represents the default value of the current weight of the patient or 50 Kg (Kilograms). If the operator wishes to change the patient height then switch "1" 200 is pressed, representing label legend 212 which states "Height". The resultant display illustration 198 by undertaking this function is represented by Figure 14. If the operator wishes to change the patient weight then switch "2" 202 is pressed, representing label legend 214 which states "Weight". The resultant display illustration 198 by undertaking this function is represented by Figure 15. Again of note in Figure 13 is that the label legend 208 states "Main" so that simply pressing switch "6" 210 which corresponds to this legend, the operator is returned to the "Main" menu (Figure 6).

Figure 14 illustrates the Figure 13 option described above where the operator presses switch "1" 200, representing label legend 212 which states "Height". This display screen states "Enter Patient Height in cm" below the battery level indication 270. The number illustrated "150" is a default value. As in a prior menu the operator instructions are at the bottom of the display. "Press (up arrow, down arrow) to change 'OK' when done". If the operator wants to increase the value of the height then the up arrow, legend label 220 corresponding to switch "5" 208 can be pressed by the operator and the height value in centimeters will be increased accordingly and displayed on display 198. Similarly, by pressing switch "6" 210 which corresponds to label legend 222 which illustrates the down arrow, the height value will decrease and be reflected by the change in the number on the display 198. Once the operator is satisfied with the alarm threshold, then switch "1" 212 is pushed which corresponds to the legend label "OK" which tells the computer that the selection is complete. The computer stores this new value as the patient height value. The value 300 in Figure 13 will then be updated to the height selection just made by the operator. Legend 216 carries the label "Weight" which refers to changing the Patient Weight menu to be described next, and the legend 218 carries the "Main" menu label discussed earlier.

Figure 15 illustrates the Figure 13 option described above where the operator presses switch "2" 202, representing label legend 214 which states "Weight". This display screen states

"Enter Patient Weight in kg" below the battery level indication 270. The number illustrated "50" is a default value. As in a prior menu the operator instructions are at the bottom of the display. "Press (up arrow, down arrow) to change 'OK' when done". If the operator wants to increase the value of the weight then the up arrow, legend label 220 corresponding to switch "5" 208 can be pressed by the operator and the weight value in centimeters will be increased accordingly and displayed on display 198. Similarly, by pressing switch "6" 210 which corresponds to label legend 222 which illustrates the down arrow, the height value will decrease and be reflected by the change in the number on the display 198. Once the operator is satisfied with the weight value threshold, then switch "1" 212 is pushed which corresponds to the legend label "OK" which tells the computer that the selection is complete. The computer stores this new value as the patient weight value. The value 302 in Figure 13 will then be updated to the weight selection just made by the operator. Legend 216 carries the label "Height" which refers to changing the Patient Height menu previously described, and the legend 218 carries the "Main" menu label discussed earlier.

Referring back to Figure 13, the next options are "Q/Kg" reflected by legend 216, activated by depressing switch "3" 204 and "Q/BSA" reflected by legend 218, activated by depressing switch "4" 206. If the patient height and weight values are current, then Figure 16 is displayed if the "Q/Kg" option is chosen and Figure 17 is displayed if the "Q/BSA" option is chosen.

Figure 16 is a simple variant of the Main display, Figure 13. The difference is that the units of flow are in "ml/Kg-min" 306 and is simply the previous flow in Liters per minute, multiplied by 1,000/Patient Weight in Kg this result is shown 304. These units are useful for "normalizing" the flow of the patient based on the size of the patient. The display 198 also indicates, in large letters, that the screen indicates flow in units of "Q/Kg" 308. The values for the height "H" and weight "W" are also shown to the lower left of the display 198 occupying the space of legends 220 and 222. This will be the "new" Main display until other flow indices are selected. The numeric display of pump flow 196 remains at the "Liters per Minute" value.

Figure 17, like Figure 16 is a simple variant of the main display, Figure 13. The difference is that using the patient height and weight, the body surface area (BSA) is calculated and shown as 310. Flow is displayed as "ml/Sq M - min" or milliliters per square meter - minute 312 and the "Q/BSA is also shown in large letters 314. Q/BSA is also known as the cardiac index. The values for the height "H" and weight "W" are also shown to the lower left of the display 198 occupying the space of legends 220 and 222. This will be the "new" Main display until other flow indices are selected. The numeric display of pump flow 196 remains at the "Liters per Minute" value.

Returning back to Figure 6, the "Main" screen, switch "4" 206 can be pushed to activate the "SYSTEM" menu which is the label for legend 218. Figure 18 is the result of this switch activation.

Figure 18 is the same as Figure 6 except for the legend labels, 212, 214, 216 and 218. These labels are now "Alarms", "Battery", "Status" and "Main" respectively. "Battery" and "Main" have been previously discussed. Pressing switch "1" 200 corresponding to label legend 212 "Alarms" will activate the display 198 to indicate Figure 19.

Figure 19 carries the label legends, "Low Flow Alarms" 212, "Neg Flow Alarms" 214, "Alarm Volume" 216 and "Main" 218. The activation of the "Main" routine has already been discussed. Below the battery indication 270 in Figure 19 are the status' of the Low Flow Alarm as 1.0 LPM or Liters per Minute, the Neg. Flow Alarm or 0.3 Liters per Minute, and the Alarm Volume 100% Each of these three items are shown with the default values and are similarly changed. To choose to set the value of the "Low Flow Alarms" switch "1" 200 is pushed which corresponds to label legend 212 or "Low Flow Alarm". This changes the display to that of Figure 20.

The display screen in Figure 20 states "Low Flow: 1.0 LPM" below the battery level indication 270. The number illustrated "1.0" is a default value. The operator instructions are at the bottom of the display. "Press (up arrow, down arrow) to change OK when done". If the operator wants to increase the value of the Low Flow Alarm then the up arrow, legend label 220 corresponding to switch "5" 208 can be pressed by the operator and the alarm value in LPM will be increased accordingly and displayed on display 198. Similarly, by pressing switch "6" 210 which corresponds to label legend 222 which illustrates the down arrow, the alarm value will decrease and be reflected by the change in the number on the display 198. Once the operator is satisfied with the alarm threshold, then switch "1" 212 is pushed which corresponds to the legend label "OK" which tells the computer that the selection is complete. The computer stores this new value as the new Low Flow Alarm value. The value 320 in Figure 19 will then be updated to the height selection just made by the operator.

In Figure 19 the "Neg Flow" or Negative Flow Alarm is similarly changed as the Low Flow Alarm just described. To choose to set the value of the "Neg Flow Alarms" switch "2" 202 is pushed which corresponds to label legend 214 or "Neg Flow Alarm". This changes the display to that of Figure 21.

The Figure 21 display screen states "Neg Flow: 0.3 LPM" below the battery level indication 270. The number illustrated "0.3" is a default value. The operator instructions are at the bottom of the display. "Press (up arrow, down arrow) to change OK when done". If the

operator wants to increase the value of the Low Flow Alarm then the up arrow, legend label 220 corresponding to switch "5" 208 can be pressed by the operator and the alarm value in LPM will be increased accordingly and displayed on display 198. Similarly, by pressing switch "6" 210 which corresponds to label legend 222 which illustrates the down arrow, the alarm value will decrease and be reflected by the change in the number on the display 198. Once the operator is satisfied with the alarm threshold, then switch "1" 212 is pushed which corresponds to the legend label "OK" which tells the computer that the selection is complete. The computer stores this new value as the new Neg Flow Alarm value. The value 322 in Figure 19 will then be updated to the height selection just made by the operator.

In Figure 19, the "Alarm Volume" is changed from the default value by pushing switch "3" 204 which corresponds to label legend 216. This changes the display to that of Figure 22.

The Figure 22 display screen 198 states "Alarm Volume:" and then four values, 25%, 50%, 75% and the highlighted 100% below the battery level indication 270. The highlighted 100% is a default value. The operator instructions are at the bottom of the display. "Press (up arrow, down arrow) to change OK when done". If the operator wants to increase the value of the Low Flow Alarm, if the default were lower than 100%, then the up arrow, legend label 220 corresponding to switch "5" 208 can be pressed by the operator and the alarm value in percent will be increased accordingly and displayed on display 198. Similarly, by pressing switch "6" 210 which corresponds to label legend 222 which illustrates the down arrow, the alarm value will decrease and be reflected by the change in the highlighted number on the display 198. Once the operator is satisfied with the alarm threshold, then switch "1" 212 is pushed which corresponds to the legend label "OK" which tells the computer that the selection is complete. The computer stores this new value as the new Alarm Volume value. The value 324 in Figure 19 will then be updated to the Alarm Volume selection just made by the operator.

Figure 18 again illustrates the "System" display. The "Battery" function has been described. To activate the "Status" display as indicated by label legend 216, then switch "3" 204 would be pushed. This action would yield Figure 24.

Figure 23 is the System Status display 198. Below the battery indicator 270 is the header "System Status" and then the status information. The first status line is the current time which is shown to be 10:35 am and is updated from a real time clock in the console 121. The second status line is the current time, which is shown to be March 5, 1996 and is also updated from a real time clock in the console 121. The third line is the number of hours that the motor 108 has cumulatively operated. This value comes from monitoring the hours that the pump has operated and updating the memory on circuit board 112. This value is downloaded to a circuit

148 in the console 121 and updated by the microprocessor on circuit board 148. This value is updated on a periodic basis and copied to the memory on circuit board 112. The third status line is the number of motor revolutions in millions of cycles. This is a calculated value by the microprocessor on circuit board 148 and updated to the memory on circuit board 112 in a similar fashion to the motor hours values just described. The battery life is the next status value and is calculated from the current status of the batteries and mathematically predicted. The last status line is the memory capacity. This memory is shown to be approximately 75% full or 25% empty. This feature will be subsequently described. The label legends indicate "Utility" 212, "Time-Date" 214, "System" 216, and "Main" 218. Pressing switch "1" 200 activates the "Utility" display which is reflected in Figure 24.

Figure 24 illustrates the Utility menu and the label legends "OK" 212, "System" 216, "Main" 218, Up Arrow 220 and Down Arrow 222. Below the battery indicator 270 are three immediate lines: "Communications" which is highlighted, "Defaults" and "Diagnostics". Below these are the instructions "Press (up arrow, down arrow) to highlight "OK" to choose" As in previous menus the up arrow 220 is activated by pushing switch "5" 208 and the down arrow 222 is activated by pushing switch "6" 210. This action scrolls the highlighted display between "Communications", "Defaults" and "Diagnostics". Pressing "OK" switch "1" 200 to activate the "OK" label legend 212 transfers the display to the highlighted menu. Pressing switch "1" 200 with the highlighted menu indicating "Communications" will bring up the display 198 indicated by Figure 25.

Figure 25 is the Communications screen on display 198. The display carries instructional information below the battery indicator 270. The intent of this menu is to allow an external cable to another computer to be connected to connector 128 (Fig. 1). Figure 25 instructs the operator to establish this connection, prepare the other computer to receive information and to press switch "1" 200 corresponding to label 212 which carries the legend "OK" to initiate the computer communication process. If switch "2" 202 is pushed corresponding to label 214 which carries the legend "Abort" then the menu returns to that indicated by Figure 24. Once the communications link has been established and the console 100 has downloaded its information, the display returns to that as indicated by Figure 24.

Figure 26 illustrates the Defaults display as scrolled and selected from Figure 24 using the up and down arrow and the "OK" option as previously described. Below the battery indication 270 on this display 198 is the "Defaults" header and below that is a highlighted "Illum Display Cntdn" or Illuminate Display Countdown. In this instance the next line illustrates that the display countdown is 5 seconds which is highlighted. The next default is shown as the High

Pressure Alert and its default value of 150 mmHg. As in prior menus the up and down arrows are used to highlight the menu of interest and "OK" is activated by pressing switch "1" 200 which activates the selected menu. In this case Figure 27 illustrates the "Illum Display Cntdn" menu.

Figure 27 shows the Illuminate Display Countdown menu as shown below the battery indicator 270. The default value is shown as 5 seconds and is shown highlighted. As in prior menus, the up and down arrows are used to increase or decrease this value. In this case the default values are increased or decreased in one second increments. Once the operator is satisfied with the result then "OK" is pushed and the computer memory stores this value as the new default and returns the operator to Figure 26.

In Figure 26, if the up and down arrows are used to highlight "Hi Pressure Alert" then the display changes to represent Figure 28.

In Figure 28 if the "OK" is activated via pushing switch "1" 200 which corresponds to label 212 containing the legend "OK" then the screen changes to that represented by Figure 29.

Figure 29 is the High Pressure Alert Default Screen which carries this header below the battery indicator 270. The value of this default is highlighted as 150 mmHg. As before, the operator uses the up and down arrows to increase or decrease this value in increments of 5 mmHg and then presses switch "1" 200 which corresponds to label 212 containing the legend "OK" to change the default to the one selected. The screen then changes back to the one indicated in Figure 28.

In Figure 28 label 214 carries the legend "More...". If this is chosen by pressing switch "2" 202 then Figure 30 is shown on the display 198.

The Figure 30 display 198 also has two defaults shown below the battery indicator 270. These defaults are "Low Flow Alarm" which is shown highlighted, whose default value is 1.0 LPM and "Neg. Flow Alarm" which is shown below this and carries an illustrated default value of 0.3 LPM. Selecting "OK", label legend 212 corresponding to switch "1" 200 with "Low Flow Alarm" highlighted changes the display to Figure 31.

Figure 31 is the Low Flow Alarm Default screen on display 198 which carries this header below the battery indicator 270. The value of this default is highlighted as 1.0 LPM. As before, the operator uses the up and down arrows to increase or decrease this value in increments of 0.1 LPM and then presses switch "1" 200 which corresponds to label 212 containing the legend "OK" to change the default to the one selected. The screen then changes to the one indicated in Figure 30.

If, in Figure 30 the highlight is scrolled from "Low Flow Alarm" to "Neg Flow Alarm" using the down arrow then the result is Figure 32.

As stated, Figure 32 is principally Figure 30 with "Neg Flow Alarm" now highlighted. This is accomplished by using the up and down arrows to move the highlighting to "Neg Flow Alarm" and selecting "OK", label legend 212 corresponding to switch "1" 200. Upon activating the "Low Flow Alarm" option the display changes to Figure 33.

Figure 33 is the Neg Flow Alarm Default screen on display 198 which carries this header below the battery indicator 270. The value of this default is highlighted as 0.3 LPM. As before, the operator uses the up and down arrows to increase or decrease this value in increments of 0.1 LPM and then presses switch "1" 200 which corresponds to label 212 containing the legend "OK" to change the default to the one selected. The screen then changes back to the one indicated in Figure 32.

In Figure 30, if the operator, selects "More...", label legend 214 by pressing switch "2" 202 then the display 198 will change to Figure 34.

Figure 34 is the Patient Height and Patient Weight Default menu as stated below the battery indicator 270. As in previous menus the up and down arrows can be used to highlight either the Patient Height or the Patient Weight. Activating the "OK" by highlighting the Patient Height using methods previously described will transfer the display to Figure 35.

Figure 35 is the display used to change the default for Patient Height. The value of this default is highlighted as 150 cm. As before, the operator uses the up and down arrows to increase or decrease this value in increments of 2 cm and then presses switch "1" 200 which corresponds to label 212 containing the legend "OK" to change the default to the one selected. The screen then changes back to the one indicated in Figure 34.

Figure 36 is the same display as Figure 33 except that Patient Weight is now highlighted. Activating the "OK" with the Patient Height highlighted using methods previously described will transfer the display to Figure 37.

Figure 37 is the display used to change the default for Patient Weight. The value of this default is highlighted as 50 Kg. As before, the operator uses the up and down arrows to increase or decrease this value in increments of 1 Kg and then presses switch "1" 200 which corresponds to label 212 containing the legend "OK" to change the default to the one selected. The screen then changes back to the one indicated in Figure 36.

Returning to Figure 24, if the down arrow is used to highlight "Diagnostics" and activating "OK" by methods previously described, Figure 38 is the result.

In the display 198 of Figure 38 the system will self check all of the internal systems and report any found anomalies on the display 198. This display is also useful for service technicians who may wish to use advanced status checks for determining the condition of the system 100.

Referring to Figure 39, the foregoing embodiments in Figures 1 - 38 are illustrated in block diagram. From this diagram and the foregoing description of the preferred embodiment, it will now be appreciated that a centrifugal pump motor system 300 and console system 400 have been described which comprise a motor housing 302, motive means in motor housing 302 adapted to connect to a centrifugal pump 304 to rotationally drive the centrifugal blood pump, the motive means including a motor 306 for rotationally driving centrifugal blood pump 304 and a controller 308 operatively associated with motor 306 for controlling the rotational speed of motor 306. Sensors 310 are operatively associated with motor 306 for sensing the motor rotational speed and outputting a monitor signal 312 signifying the rotational speed. A console 402 separate from motor housing 302 includes a speed selector 404. Speed selector 404 in console 402 includes a potentiometer 401 for producing an analog speed signal and analog to digital converter 403 for converting the analog signal to a digital speed signal for generating a selected speed signal 405. The selected speed signal 405 signifies a selected rotational speed for motor 306. Motor housing microprocessor 314 in motor housing 302 is in electrical connection with motor housing program memory 305, controller 308, and speed selector 404 via analog to digital converter 403, under program control of 305, receives selected speed signal 405 and generates a speed control signal 316 to controller 308 signifying the selected speed for controller 308.

Console microprocessor 408 in console 402 is in electrical connection with console program memory 406, speed selector 404 via analog to digital converter 403, speed sensors 310, and motor housing microprocessor 314, under program control of program memory 406, for receiving speed signal 405 and monitor signal 312 and determining whether monitor signal 312 is within a predetermined limit of allowable variance of the speed signal, and if within the allowable limit, then outputting display signal 318 and 418, but if outside the allowable limit under a predetermined sampling protocol, then outputting an alarm signal (also indicated by 318 and 418). A display 320 in motor housing 302 and display 420 in console 402 is in electrical communication with console microprocessor 408 and is responsive to display signal 318 and 418 for displaying information. Source power 410 in the console supplies a source of DC power. Circuitry in motor housing 302 and in console 402 (the circuitry is indicated generally by the lines connecting the block components) and electrically conductive cable 412

interconnect the console circuitry for transmission of DC power to the motor housing circuitry 322 from the console power source 410 and to provide electrical communication between all electrical components, including the speed selector 404, program memory 406 and console microprocessor 408, and motor housing microprocessor 314, controller 308, sensors 310, and display 320.

Volatile memory 330 is included in motor housing 302, as is a DC battery 332 to provide power to motor housing volatile memory 330 when power from the console is absent. The console microprocessor 408 under program control includes means for initially recording identification of the motor and for cumulatively recording motor revolutions, and for saving the identification and the cumulative revolutions to the motor housing battery backed volatile memory 330 while power is supplied to the motor housing circuitry by the external source, and means for reading the identification and cumulative revolutions from the motor housing memory 330 after power is initially supplied to the motor housing circuitry.

The circuitry in the console includes input connectors for receiving one or more input signals 416 from one or more peripheral signaling sources 417 adapted to sense a parameter of a patient 418 connected in a blood flow circuit having an extracorporeal flow portion 422 including centrifugal blood pump 304, or a parameter of the extracorporeal portion of the circuit, or both.

The more basic configuration of the invention is shown by block diagram in Figure 40, and comprises a motor housing 302 that contains motive means adapted to connect to a centrifugal pump 304 to rotationally drive the centrifugal blood pump, the motive means including a motor 306 for rotationally driving centrifugal blood pump 304 and a controller 308 operatively associated with motor 306 for controlling the rotational speed of motor 306. Speed selector 334 comprises a set of decrease/increase push digital switches (right double arrow for units of ten increase, right single arrow for single unit increase; left double arrow for units of ten decrease, left single arrow for single unit decrease) for generating a selected speed signal 336 signifying a selected rotational speed for motor 306. Sensors 310 are operatively associated with motor 306 (or controller 308) for sensing the rotational speed of the motive means and outputting a monitor signal 312 signifying the rotational speed. Program memory 305 is contained in motor housing 302 for storage of a program of microprocessor readable instructions. Motor housing microprocessor 314, in electrical connection with controller 308, speed selector 334, sensors 310 and the program memory 305, under program control of program memory 305, receives selected speed signal 336 and generates a speed control signal 338 to controller 308, signifying the selected speed for the controller, and receives monitor signal 312 and outputs display

signals 318 and 350. A motor housing display 320 and console display 420 are in electrical communication with microprocessor 314 and are responsive to display signals 318 and 350 for displaying information. Motor housing circuitry provides electrical communication between all electrical components including controller 308, speed selector 334, sensors 310, program memory 305, microprocessor 314, and displays 320 and 420, and electrically conductive cable 412 connected to the motor housing circuitry transmits electrical DC power to the motor housing circuitry from console power source 410.

Referring to FIG. 41, a perspective view of the smart motor driver apparatus of the invention depicts a motor housing 302 that contains a motor for rotationally driving the centrifugal blood pump and a controller operatively associated with the motor for controlling the rotational speed of the motor. A digital speed selector 334 generates a selected speed signal signifying a selected rotational speed for the motor. A display 312 displays information. An electrically conductive cable 412 transmits electrical DC power to the motor housing circuitry means from an external power source. A keypad 450 operative for digitally entering values for processing by microprocessor or by directly controlling RPM includes a sequential incremental value key 452, an accelerator incremental value key 454, a sequential decremental value key 456, an accelerator decremental value key 458 for selecting a desired value, and an enter key 460 for entering the selected value or to pause or hold the RPM setting in the RPM mode. Keypad 450 is also used to select and enter desired values for motor speed or for a selected prarameter of the extracorporeal flow circuit that is desired to be kept constant by auto control of the motor speed. An additional key 462 is used for generation of a signal for microprocessor processing to stop rotation of the motor. An RPM selection button 464 is first pressed if RPM is to be set using the keypad 450. This immediately disables any other program function. While the motor driver apparatus is in this direct control mode, an RPM indicator light 470 goes on.

Alternatively, entry of a desired RPM or extracorporeal flow circuit may be made using function keys associated with the motor or console display panel. The method of selection of the desired value is the same in either instance. FIG. 42 depicts a console LCD display 198 for controlling the motor speed without using the control knob 160 (Fig. 2). In FIG. 42, the control of the motor speed is undertaken using the menu legends and associated keys described earlier in respect to the console display. In Fig. 42, there is a double up (accelerator) incremental arrow 212, a single up (sequential incremental) arrow 214, a pause "bar" or dash" key 216, a single down (sequential decremental) arrow 218, a double down (accelerator decremental) arrow 220, and a "0" (zero) key 222 for stopping motor function. In use, if the operator wishes

to rapidly increase the speed of the motor then the double up (accelerator incremental) key 212 is pushed and the motor speed increases a predetermined multiple amount, for example, 500 RPM, of a predetermined unit amount, for example 100 RPM, with each key press. The single up key (sequential incremental) key 214 increases the motor speed by the predetermined unit amount (100 RPM) with each key press. Similarly, the single down arrow key 218 decreases the RPM by approximately 100 RPM with each key press and the double down arrow key 222 decreases RPM by approximately 500 RPM with each key press. In order to stop the motor, the "0" or zero stop key 222 is pushed and driving power is removed from the motor. The pause key 216 can be pressed to hold the current RPM setting. This is undertaken during changing RPM conditions. The increments of 100 and 500 RPM can be changed by the user in a default table to represent other values such as 50 RPM for the single arrows and 200 RPM for the double arrows as examples.

The smart motor driver apparatus motor housing includes a scroll display selector 466 for chosing a selectable extracorporeal circuit parameter function the value of which is to be set by the keypad 450 or value selectors on display 312. Parameter selector 466 is pressed to step through selectable extracorporeal circuit parameters of circuit flow rate, centrifugal pump inlet pressure and centrifugal pump outlet pressure. When a desired extracorporeal circuit parameter is reached using the scroll function selector 464, scrolling is discontinued and enter button 460 on the keypad is pressed to make the selection. Keys of keypad 450 allow digital selection and entry of a desired value for the selected extracorporeal circuit parameter. Referring to FIG. 42, console display 198 shows a selected parameter of flow rate in liters per minute. (The other features and functions of the display are as earlier described in connection with FIG. 6). After the desired value of the selected parameter is selected and entered, an auto control function button 468 is pressed to initiate microprocessor auto control of the selected parameter. This also may be undertaken as a menu option on console display 198. On engagement of auto control for the selected parameter, an auto control indicator 472 is lighted and the selected parameter is indicated on the console display 198. Auto control is the method by which a parameter is maintained during perfusion. As extracorporeal centrifugal pump RPM increases driven by the motor driver apparatus, flow rate increases and fluid pressure in the extracorporeal pump inlet line and pump outlet line decreases. In the auto control process, the pump RPM is varied by the microprocessor to attain and maintain the value of the selected parameter. The algorithm used is a mathematical control function in which the rate of change of the RPM (in this case) would be made to rapidly, yet carefully approach and then intersect

the desired parameter value with a minimum of overshoot and within an error window so that subsequent control oscillation is minimized.

In the instance where flow rate is the parameter chosen, such as the 3.9 liters per minute depicted in FIG. 42, the RPM of the motor is increased or decreased by the microprocessor in order to achieve that value against the external variable, pressure. If fluid line pressure were to increase, then flow would decrease. The system will then increase the RPM of the motor in order to achieve the desired 3.9 liters per minute of flow. Rate of change boundary error bands are placed around any value of a selectable extracorporeal circuit parameter, and if line pressure increases suddenly, such as when a person in the operating room steps on an extracorporeal fluid line thereby suddenly restricting flow, the programmed memory instructions compare the boundary factor to the sensed suddenly changed parameter, and if the boundary is exceeded, programmed instructions control RPM to prevent a change of RPM to the RPM that gives the selected value. Suitably an alarm sounds if the boundary is exceeded. Without the precaution of the alarm and the boundary error band, if the RPM were to automatically and rapidly increase to attain the desired flow, and then the offending person were to step off the fluid line allowing the fluid line to suddenly again become unrestricted, the pressure would quickly drop and the fluid surge at the higher RPM would be detrimental to the patient.

In this instance where the selected parameter is output pressure, similar to the above the RPM's would be auto-controlled so that if pressure rose, the RPM's would decrease to drop pressure. Similarly if the pressure dropped, the RPM's would increase to maintain the set point pressure.

Auto control of inlet pressure is especially helpful in surgeries where there is no venous reservoir. In traditional cardiopulmonary bypass surgeries, there is a venous reservoir, which accepts the blood from the patient and represents the reservoir from which the blood is pumped by the perfusionist. The perfusionist pumps blood from the reservoir, keeping an eye on the reservoir volume. If the reservoir begins to empty, the perfusionist may slow down the flow rate of the pump so that the reservoir is not emptied. Conversely, if the reservoir begins to fill above a certain level, the perfusionist will increase the flow rate. Overall then, the perfusionist will monitor the level of the venous return reservoir and pump from it, keeping the fluid reservoir level within a certain safety zone. Minimally Invasive Surgery (MIS) can use a femoral to femoral bypass technique for bypass. In this case there is no venous return reservoir. The blood flows from the cannulated femoral artery directly to the pump, which is frequently proximal to the patient. Overdriving or overpumping the pump in this instance will lead to collapse of the vein due to the suction pressure. Vein collapse terminates flow. Since in this

instance inlet pressures are low, the pump must be continually monitored so that the patient receives sufficient flow, yet not more than available or vein (and flow) collapse will occur. This is a highly dynamic situation over standard cardiopulmonary bypass as the venous reservoir also acts as a fluid capacitor in standard cardiopulmonary bypass, averaging out the subtle minute to minute dynamics of inflow volume. This does not occur in femoral-femoral bypass. Nearly second to second monitoring and control by the perfusionist necessary but is awkward at best, because there are a variety of personnel around the sterile operating field and the perfusionist is currently not one of them. Auto control of the pump to inlet pressure provides a solution to this problem. In this instance the inlet pressure threshold may be set at, for example, 5 mmHg. The controller of the motor driver under microprocessor control increases RPM of the motor and pump if this value is over 5 mmHg and slows it as the value decreases and approaches 5 mmHg. Accordingly, with this auto control of inlet pressures, the perfusionist simply monitors the parameters from the display (motor or console in the preferred redundant processor mode) without risk of setting up an oscillating situation (in which the vein collapses and flow is reduced, the vein then opens, fluid is available, and motor RPM is increased to the point of vein collapse).

As described above, the console in the dual or redundant microprocessor mode of this invention contains a speed selector for generating a selected speed signal signifying a selected rotational speed for said motor, and the console speed selector includes a potentiometer for producing an analog speed signal and an analog to digital converter for converting the analog signal to a digital speed signal. The console programmed memory includes instructions for execution by the console microprocessor for generating a digital signal representing said selected motor speed value. In this dual processor mode, the invention used a dual processor referee to determine microprocessor control of he system. The referee comprises a gate for receiving the digital speed signals from said console microprocessor and the digital speed signal from said motor housing microprocessor and allowing passage of only a preselected one of the console and motor housing microprocessor speed values. A gate keeper receives watch signals from each of said console and motor housing microprocessors and on failure to receive a watch signal from one of the microprocessors within a predetermined time, operates the gate to lock out the microprocessor whose watch signal was not received within the predetermined time and to open the gate to the other processor.

More particularly, the two processors both generate digital pulse width modulated ("PWM") signals in response to a setting of a speed selector. These signals both go to a gate where one of the processor signals, for example only the console processor signal, is allowed

from the console processor, the assumption is that the console processor has failed, and a reset signal is given to the failed console processor. In this invention a latch holds down the reset to a processor so it does not restart on receipt of a reset signal. At the same time, the gate opens and the failed processor is locked out and the PWM signal from the other processor, in this example, the motor housing processor, is allowed to pass through. Functionally this occurs almost instantaneously. Conversely, if the motor housing then processor fails, the WDT is triggered and that processor is held down by a latch, and the gate is kept open for the console processor PWM driver signal.

CLAIMS

- 1. An intelligent motor driver apparatus for a centrifugal blood pump, which apparatus comprises a motor housing separate from a console for monitoring one or more blood flow parameters in an extracorporeal blood flow circuit that includes a centrifugal blood pump, said housing containing:
 - motive means adapted to connect to said centrifugal pump to rotationally drive the centrifugal blood pump, said motive means including a motor for rotationally driving the centrifugal blood pump and a controller operatively associated with said motor for controlling the rotational speed of said motor,
 - speed selector means for generating a selected speed signal signifying a selected rotational speed for said motor,
 - sensor means operatively associated with said motive means for sensing the rotational speed of the motive means and outputting a monitor signal signifying such rotational speed,
 - programmable memory programmed with a program of microprocessor readable instructions for microprocessor execution including for receiving said selected speed signal and generating a speed control signal to the controller signifying the selected speed for the controller; and for receiving said monitor signal and outputting a display signal indicative of motor rotational speed,
 - microprocessor means under program control, in electrical connection with said controller, said speed selector means, said sensor means and said program memory, for executing said instructions from said programmed memory, including to generate said display signal,
 - display means in electrical communication with said microprocessor means and responsive to said display signal for displaying information,
 - motor housing circuitry means for providing electrical communication among electrical components in said motor housing, and
- electrically conductive cable means connected to said motor housing circuitry means for transmitting electrical DC power to said motor housing circuitry means from an external power source.
- 2. The apparatus of claim 1 comprising motor housing data recordation memory means for electronic recordation of data and in which said microprocessor readable instructions further include instructions for

writing motor history to said data recordation memory means while power is supplied to said motor housing circuitry, and

reading said motor history from said data recording means when power is initially supplied to said motor housing circuitry, and generating signals representing said motor identification and/or motor use history,

and wherein said display means is responsive to signals from said microprocessor on microprocessor execution of said motor history reading and signal generation instructions, for displaying motor history.

- 3. The apparatus of claim 2 in which said motor history includes one or more of motor identification and cumulative motor revolutions.
- 4. The apparatus of claim 2 further comprising temperature detection and signaling means in said motor housing and operatively associated with said motor, for detecting temperatures of said motor and for generating a signal indicative of the detected temperatures, wherein said motor use history includes the motor temperature history of said motor, and in which said microprocessor readable instructions further include instructions for writing said motor temperatures to said data recordation memory means while power is supplied to said motor housing circuitry.
- 5. The apparatus of claim 2 wherein said memory means comprises volatile memory and said apparatus further includes a DC battery to provide power to said memory means when power from an external source is absent.
- 6. The apparatus of claim 1 further comprising keypad means operatively associated with said microprocessor for digitally entering values for processing by said microprocessor.
- 7. The apparatus of claim 6 in which said keypad means comprises sequential and accelerator incremental and decremental value selector keys, and an enter key for a selected value.
- 8. The apparatus of claim 7 in which said keypad means is said speed selector means, and further includes an additional key means for generation of a signal for microprocessor processing to stop rotation of said motor.

9. The apparatus of claim 1 further comprising a console housing separate from said motor housing and including:

console power means for supplying a source of DC power,

- console circuitry means for providing electrical communication among electrical components in said console, and
- electrically conductive cable tethering means for electrically interconnecting said console circuitry means and said motor housing circuitry means and for transmission of DC power to said motor housing circuitry means from said console power means.
- 10. The apparatus of claim 9 in which said console circuitry means further comprises: means adapted to receive and store one or more input signals from one or more peripheral signaling sources adapted to sense one or more parameters of a patient connected in a blood flow circuit having an extracorporeal flow portion including a centrifugal blood pump, or one or more parameters of said extracorporeal portion of said circuit, or both.
- 11. The apparatus of claim 10 in which said motor housing further comprises: selection means for selecting an extracorporeal circuit parameter including circuit flow rate, centrifugal pump inlet pressure and centrifugal pump outlet pressure, and keypad means for digitally entering values for a selected extracorporeal circuit parameter for processing by said microprocessor under control of said programmed memory, and wherein said programmed memory includes instructions for execution by said microprocessor for setting the speed of the motor to achieve a value of a selected extracorporeal circuit parameter relative to a sensed value of the same parameter.
- 12. The apparatus of claim 11 in which said instructions for execution by said microprocessor for setting the speed of the motor comprise a PID algorithm to change the motor speed to approach and intersect the selected extracorporeal circuit parameter without exceeding a predetermined extent of overshoot and within a predetermined range of error.
- 13. The apparatus of claim 11 in which said microprocessor continuously receives signals representing the sensed value of said same parameter and continuously executes said PID algorithm to maintain said selected value for said same parameter.

14. The apparatus of claim 12 in which said instructions include a rate of change boundary for any value of a selectable extracorporeal circuit parameter, for comparison by said microprocessor to a sensed same parameter, and if said boundary is exceeded, for control of motor speed to prevent change of motor speed to give the selected value.

15. The apparatus of claim 10 in which

- said console circuitry means further comprises a console microprocessor means and console programmable memory programmed with microprocessor readable instructions for said console microprocessor means, and
- said console microprocessor is responsive to program instructions from said console program memory to interpret said input signals from said one or more peripheral signaling sources into information values and into output signals to said console display means to display said input based information values.

16. The apparatus of claim 15 further comprising

speed selector means in said console for generating a selected speed signal signifying a selected rotational speed for said motor in which said console speed selector means includes

potentiometer means for producing an analog speed signal and

analog to digital conversion means for converting said analog signal to a digital speed signal,

and wherein said console programmed memory includes instructions for execution by said console microprocessor for generating a digital signal representing said selected motor speed value,

and further comprising:

- a gate for receiving said digital speed signal from said console microprocessor and said digital speed signal from said motor housing microprocessor and allowing passage of only a preselected one of the console and motor housing microprocessor speed values, and
- gate keeper means for receiving watch signals from each of said console and motor housing microprocessors and on failure to receive a watch signal from one of the microprocessors within a predetermined time, operating said gate to lock out the microprocessor whose watch signal was not received within said predetermined time and to open the gate to the other processor.

17. The apparatus of claim 15 in which said console includes volatile memory and a connector for an external peripheral device for download of information from said console volatile memory to said external peripheral device.

- 18. The apparatus of claim 15 further including a console display and in which said console display means includes a light screen responsive to said console microprocessor means under program control to display screen images including information and menu options for calling different screens.
- 19. The apparatus of claim 18 in which said screen comprises a liquid crystal display screen.
- 20. The apparatus of claim 15 further including a console display and in which said console display means includes a scalar display of a predetermined original range of values and high limit that is automatically convertible a predetermined number of times by said console microprocessor under program control to a predetermined different range of values and high limit when the next previous high limit is reached.
- 21. The display of claim 20 in which said scaler display comprises an array of light emitting diodes and associated drivers.
- 22. The apparatus of claim 15 wherein said console microprocessor means under program control further comprises means requiring said speed selector means to be set to zero before said motor can be rotated.
- 23. The apparatus of claim 15 in which said console microprocessor means under program control further includes means for inputting a minimum speed at which said console microprocessor means under program control will ignore a said selected speed signal lower than said minimum speed and said console microprocessor will generate an alert signal that said selected speed is lower than the minimum speed.
- 24. The apparatus of claim 23 further comprising means controllable by an operator after said alert signal is generated for permitting the console microprocessor means under program control to produce the control signal at said selected speed signal lower than said minimum

speed until motor speed is reset above said minimum speed or electrical power to said motor housing circuitry is discontinued.

- 25. The apparatus of claim 14 in which said console has an exterior which comprises a portion of said console circuitry means, said portion including a plurality of function switches and a screen display, said screen display having means for displaying a plurality of screen images depicting (a) information and (b) options associated with said function switches.
- 26. The apparatus of claim 25 in which said of screen images depicting information include a MAIN screen displaying information which depends on whether the console is operating on line voltage or the console battery, and

if operating on line voltage, then depicting information including:

charge status of said on-board console battery,

- a histogram of pump flow in units of volume per minute over a period of time ending at current time, and
- one of a plurality of readouts including instantaneous pump flow (Q), blood flow per a patient weight unit (Q/wt) and blood flow per a patient body surface area unit (Q/BSA).

but if operating on the console battery, then depicting information including:

a notice that the battery is in use,

charge status of the battery or a projection of battery life or both, and

- one of a said plurality of readouts including instantaneous pump flow (Q), blood flow per a patient weight unit (Q/wt) and blood flow per a patient body surface area unit (Q/BSA).
- 27. The apparatus of claim 26 in which said screen images depicting options include a MAIN screen displaying options which depend on whether the apparatus is operating on line voltage or the console battery, and
 - if operating on line voltage, then depicting battery, pressure, flow indices and system options for calling respectively a BATTERY screen, a PRESSURE screen, a FLOW INDICES screen, and a SYSTEM screen, but
 - if operating on the console battery, then depicting pressure, flow indices and system options for calling the PRESSURE screen, the FLOW INDICES screen, and the SYSTEM screen, and an illuminate display option which when the corresponding

function switch is keyed illuminates Pressure, Temperature and Timer numerical displays while the switch is keyed plus a predetermined countdown time, then switches off such numerical displays.

28. The apparatus of claim 27 in which said BATTERY screen is called upon keying a function switch operatively associated with the *battery* option on the MAIN screen, and depicts (a) battery status information including information based on the date of installation of the battery in the console, and (b) *main* and *system* options for calling respectively the MAIN or SYSTEM screens.

29. The apparatus of claim 27 in which

said PRESSURE screen is called upon keying a function switch operatively associated with the *pressure* option on the MAIN screen, and depicts at least (a) current calibration values for zero pressure and a high pressure alarms, and (b) *pressure alert, zero transducer, main* and *system* options for calling respectively PRESSURE ALERT or ZERO TRANSDUCER screens or said MAIN or SYSTEM screens, and

said PRESSURE ALERT screen is called upon keying a function switch operatively associated with the *pressure alert* option on the PRESSURE screen, and depicts (a) a high pressure alarm value readout, and (b) *increase* or *decrease* options for increasing or decreasing said high pressure alarm value, an *OK* option for accepting a high pressure alarm value, a *zero transducer* option for calling the ZERO TRANSDUCER screen, and *system* and *main* options for calling respectively said SYSTEM or MAIN screens, and

said ZERO TRANSDUCER screen is called upon keying a function switch operatively associated with the zero transducer option on the SYSTEM screen, and depicts (a) an open to air zero pressure value readout, and (b) a set zero option for setting the open to air zero pressure value, an OK option for accepting a set open to air zero pressure value, and system and main options for calling respectively said SYSTEM or MAIN screens.

30. The apparatus of claim 27 in which

said FLOW INDICES screen is called upon keying a function switch operatively associated with the *flow indices* option on the MAIN screen, and depicts at least (a) values for height

and weight of a patient, and (b) height, weight, Q/wt, Q/BSA and main options for calling respectively HEIGHT, WEIGHT, Q/WT, Q/BSA screens and said MAIN screen.

- said HEIGHT screen is called upon keying a function switch operatively associated with said *height* option, and depicts (1) a default patient height value readout, and (2) *increase* or *decrease* options for increasing or decreasing said patient height value, an *OK* option for accepting a selected patient height value, and a *main* option for calling said MAIN screens;
- said WEIGHT screen is called upon keying a function switch operatively associated with said weight option, and depicts (1) a default patient weight value readout, and (2) increase or decrease options for increasing or decreasing said patient weight value, an OK option for accepting a selected patient weight value, and a main option for calling said MAIN screens;
- said Q/WT screen is called upon keying a function switch operatively associated with said Q/wt option, and depicts at least (1) said histogram and a Q/wt value readout, and (2) Q/BSA, height, weight, flow indices and main options for calling respectively a Q/BSA screen or said HEIGHT, WEIGHT, FLOW INDICES or MAIN screens, said MAIN screen containing said Q/wt value when called from said Q/WT screen; and
- said Q/BSA screen is called upon keying a function switch operatively associated with said Q/BSA option, and depicts at least (1) said histogram and a Q/BSA value readout, and (2) height, weight, Q/wt, flow indices and main options for calling respectively said HEIGHT, WEIGHT, Q/WT, FLOW INDICES and MAIN screens, said MAIN screen containing said Q/BSA value when called from said Q/BSA screen.
- 31. The apparatus of claim 27 in which said SYSTEM screen is called upon keying a function switch operatively associated with the *system* option on the MAIN screen, and depicts at least (a) said histogram and one of said plurality of Q, Q/wt and Q/BSA readouts, and (b) *alarms*, *status*, *battery*, and *main* options for calling respectively ALARMS and STATUS screens and said BATTERY and MAIN screens.

32. The apparatus of claim 31 in which

said ALARM screen is called upon keying a function switch operatively associated with the alarm option on the SYSTEM screen, the ALARM screen depicting at least (a) said histogram and one of said plurality of Q, Q/wt and Q/BSA readouts, and (b) and low flow alarm, negative flow alarm, alarm volume and main options for calling respectively a

LOW FLOW ALARM screen, a NEGATIVE FLOW ALARM screen, an ALARM VOLUME screen, or said MAIN screen, and

- said LOW FLOW ALARM screen is called upon keying a function switch operatively associated with said *low flow alarm* option, and depicts (1) a low flow alarm threshold value readout, and (2) *increase* or *decrease* options for increasing or decreasing said low flow alarm threshold value, an *OK* option for accepting a selected low flow alarm threshold value, and *system* and *main* options for calling respectively said SYSTEM or MAIN screens;
- said NEGATIVE FLOW ALARM screen is called upon keying a function switch operatively associated with said negative flow alarm option, and depicts (1) a negative flow alarm threshold value readout, increase or decrease options for increasing or decreasing low flow alarm threshold values, an OK option for accepting a selected low flow alarm threshold value, and system and main options for calling respectively said SYSTEM or MAIN screens; and
- said ALARM VOLUME screen is called upon keying a function switch operatively associated with said *alarm volume* option, and depicts (1) a readout of alarm volume as a percent of maximum, *increase* or *decrease* options for increasing or decreasing the percentage of alarm volume maximum, an *OK* option for accepting a selected alarm volume percentage, and *system* and *main* options for calling respectively said SYSTEM or MAIN screens.
- 33 The apparatus of claim 30 in which said console circuitry means include a connector for a remote computer and:
- said STATUS screen is called upon keying a function switch operatively associated with the *status* option on the SYSTEM screen, and depicts (a) system status readouts including time, date, motor hours, cumulative motor revolutions, battery life and memory capacity of the motor assembly circuit board, and (b) *utility, time-date, system* and *main* options for calling respectively a UTILITY screen, a TIME-DATE screen, said SYSTEM screen, and said MAIN screen, and
 - said UTILITY screen is called upon keying a function switch operatively associated with said utility option, and depicts communication, defaults and diagnostics options for calling respectively COMMUNICATION, DEFAULTS and DIAGNOSTICS screens, increase or decrease options for incrementing or decrementing to select one of said communication, defaults and diagnostics options, an OK option for accepting a

selected said communication, defaults or diagnostics options, and system and main options for calling respectively said SYSTEM or MAIN screens, and

said COMMUNICATION screen is called upon keying a function switch operatively associated with said *communication* option, and depicts (1) a message to key an associated function switch when ready for a remote computer to receive data transfer from the apparatus, and (2) an *OK* option for initiating data said transfer, an *abort* option for canceling data transfer, and *utility* and *main* options for calling respectively said UTILITY or MAIN screens, and

said DEFAULTS screen is called upon keying a function switch operatively associated with said defaults option, and depicts (a) default value readouts including a default time value for an illuminate display countdown when the apparatus is operating on the console battery and a default high pressure alarm value and (b) illuminate display countdown default and high pressure alarm default options for calling respectively an ILLUMINATE DISPLAY COUNTDOWN DEFAULT screen and a HIGH PRESSURE ALARM DEFAULT screen, increase or decrease options for incrementing or decrementing to select one of said illuminate display countdown default or high pressure alarm default options, an OK option for accepting a selected default option, and utility and main options for calling respectively said UTILITY or MAIN screens, and

said ILLUMINATE DISPLAY COUNTDOWN DEFAULT screen is called upon keying a function switch operatively associated with said *illuminate display* countdown default option, and depicts (a) a default time value readout for said illuminate display countdown, increase or decrease options for increasing or decreasing said default time value, an OK option for accepting a selected default time value for said illuminate display countdown, a more option for calling a MORE screen, and utility and main options for calling respectively said UTILITY or MAIN screens, and

said HIGH PRESSURE ALARM DEFAULT screen is called upon keying a function switch operatively associated with said high pressure alarm default option, and depicts (a) a default high pressure alarm readout for high pressure alarm, increase or decrease options for increasing or decreasing said default high pressure alarm, an OK option for accepting a selected default high pressure alarm, a more option for calling a MORE screen, and utility and main options for calling respectively said UTILITY or MAIN screens, and

said MORE screen is called upon keying a function switch operatively associated with said more option, and depicts (a) default value readouts including a default low flow alarm value and a default negative flow alarm value and (b) low flow alarm default and negative flow alarm default options for calling respectively an a LOW FLOW ALARM DEFAULT screen and a NEGATIVE FLOW ALARM DEFAULT screen, increase or decrease options for incrementing or decrementing to select one of said low flow alarm default or negative flow alarm default options, an OK option for accepting a selected such default option, and utility and main options for calling respectively said UTILITY or MAIN screens, and

said TIME-DATE screen is called upon keying a function switch operatively associated with said time-date option, and depicts, and depicts (a) readouts including a time of day value and a date and (b) time and date options for calling respectively an TIME screen and a DATE screen, increase or decrease options for incrementing or decrementing to select one of said time or date options, an OK option for accepting a selected time or date option, and system and main options for calling respectively said SYSTEM or MAIN screens, and said TIME screen is called upon keying a function switch operatively associated with said time option, and depicts (a) a time of day readout, increase or decrease options for increasing or decreasing said time of day readout, an OK option for accepting a selected time of day, and system and main options for calling respectively said SYSTEM or MAIN screens, and

said DATE screen is called upon keying a function switch operatively associated with said date option, and depicts (a) a date readout, *increase* or *decrease* options for increasing or decreasing said date readout, an *OK* option for accepting a selected date, and system and *main* options for calling respectively said SYSTEM or MAIN screens.

34. A method of controlling a centrifugal pump, which comprises:

generating a selected speed signal signifying a selected rotational speed for rotating a motor to rotationally drive said pump,

interpreting said first signal and generating a speed control signal signifying the desired rotational speed output for a controller for controlling said motor,

controlling said motor to rotate the motor according to said speed control signal,

sensing the actual rotational speed of the motor and outputting a monitor signal signifying the actual rotational speed,

checking said selected speed signal and said monitor signal and if the monitor value is within a predetermined limit of allowable variance of the speed signal, then outputting a display signal, but if said monitor signal is outside said limit, sampling said monitor and signal signals in a predetermined protocol and if said monitor signal remains outside said limit under said protocol, then outputting an alarm signal, and

- displaying the rotational speed of the motor responsive to said display signal or an alarm responsive to said alarm signal or displaying both said rotational speed and said alarm condition.
- 35. A method of controlling a centrifugal pump, which comprises:

setting a minimum value for motor rotational speed.

- generating a said selected speed signal signifying a desired motor rotational speed lower than a predetermined minimum value,
- maintaining the rotational speed of said motor at the minimum value upon receipt of said selected signal signifying a value lower than the minimum value,
- generating an alarm signal signifying that said selected speed signal is lower than the predetermined value, and
- optionally discontinuing said step of maintaining the rotational speed of said motor at the minimum value and allowing the motor to rotate at the speed signified by said selected speed signal or a selected other speed below the set minimum value.

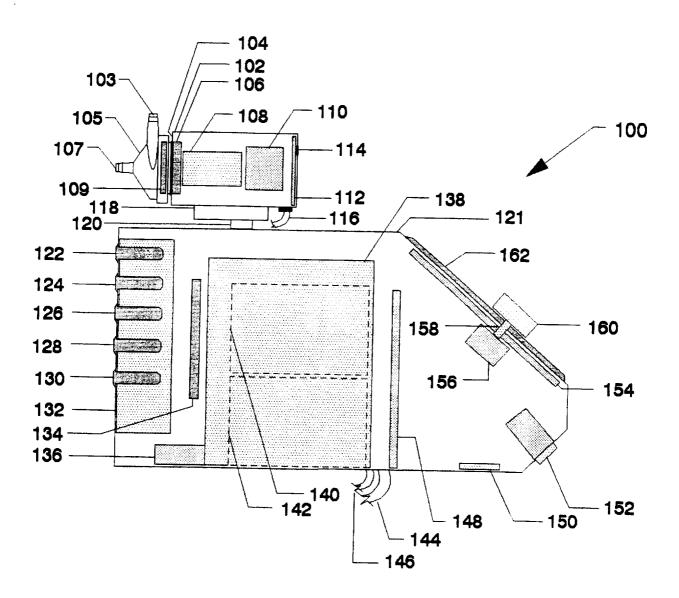


Fig. 1

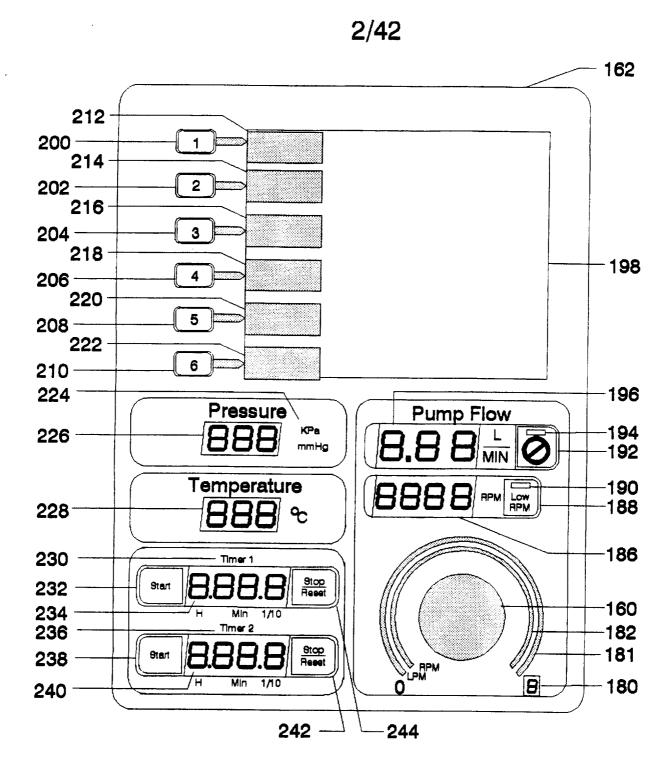


Fig. 2

3/42

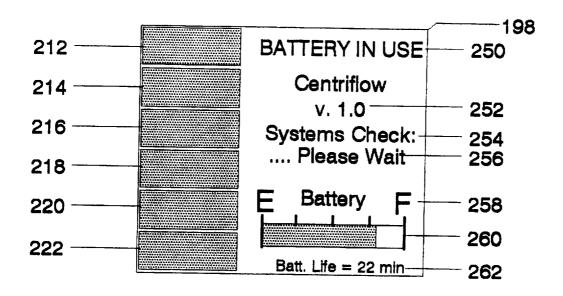


Fig. 3

4/42

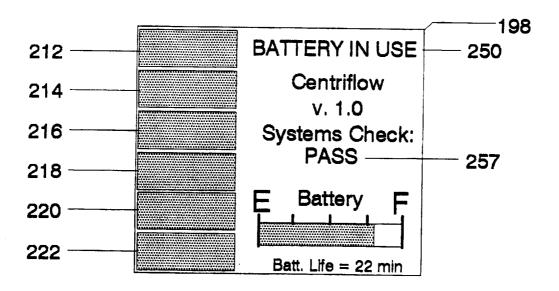


Fig. 4

5/42

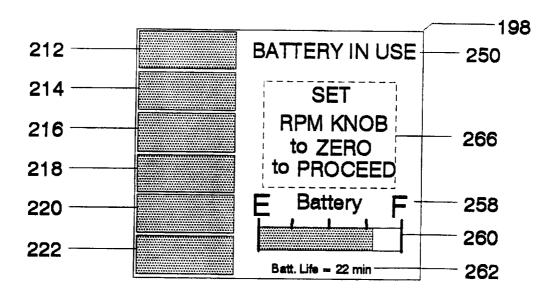


Fig. 5

6/42

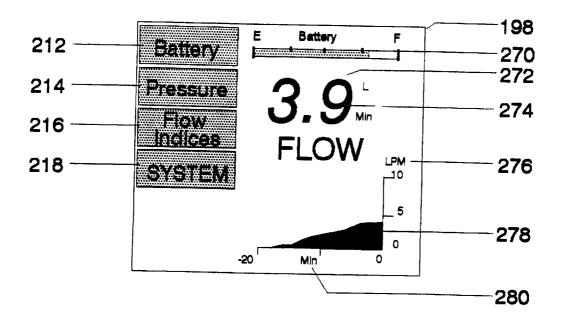


Fig. 6

7/42

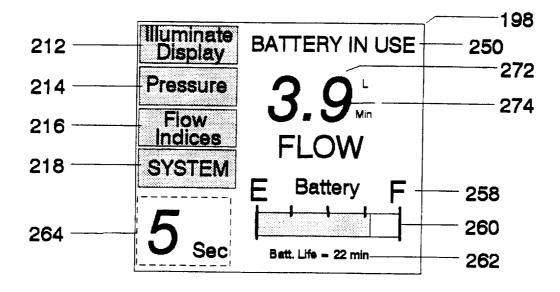


Fig. 7

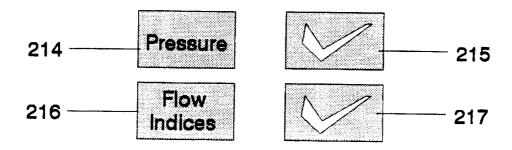


Fig. 8

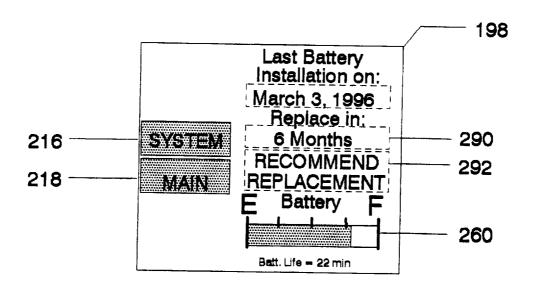


Fig. 9

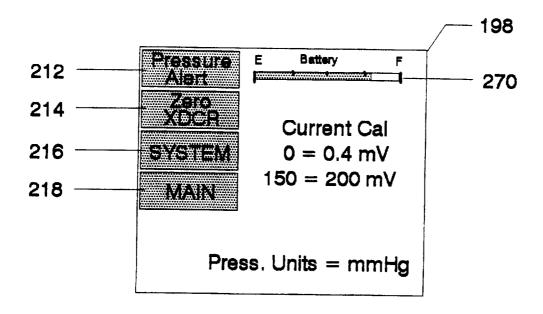


Fig. 10

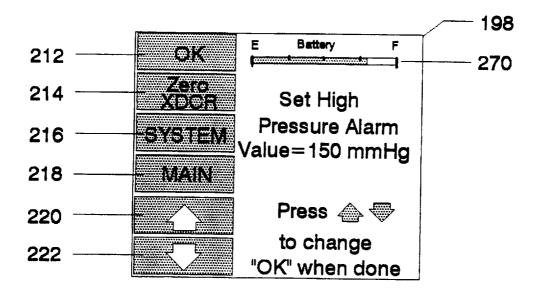


Fig. 11

12/42

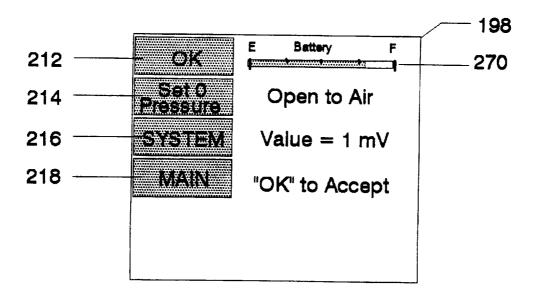


Fig. 12

13/42

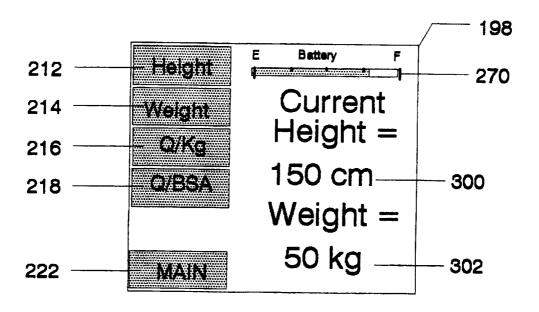


Fig. 13

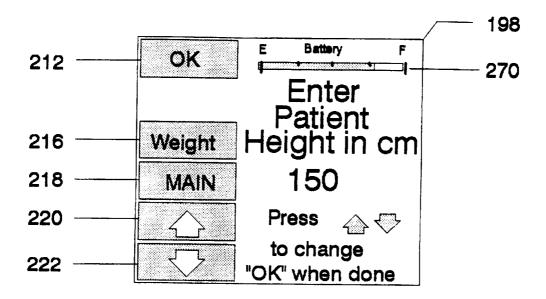


Fig. 14

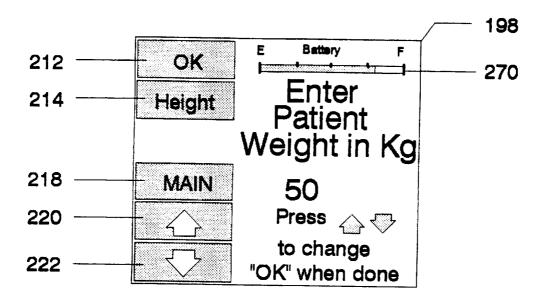


Fig. 15

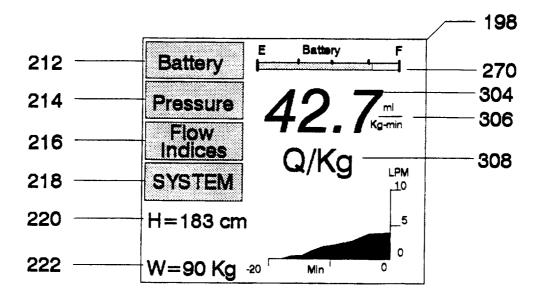


Fig. 16

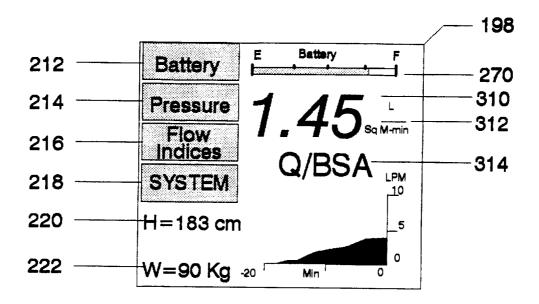


Fig. 17

18/42

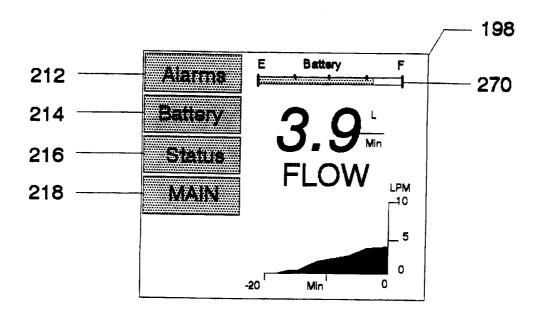


Fig. 18

19/42

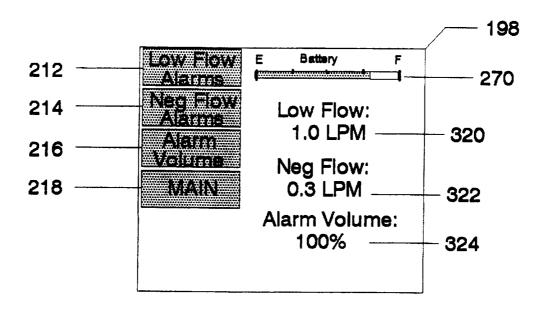


Fig. 19

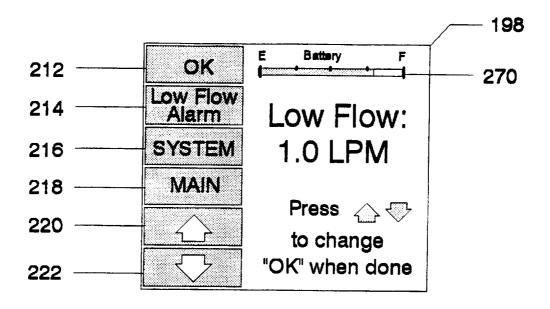


Fig. 20

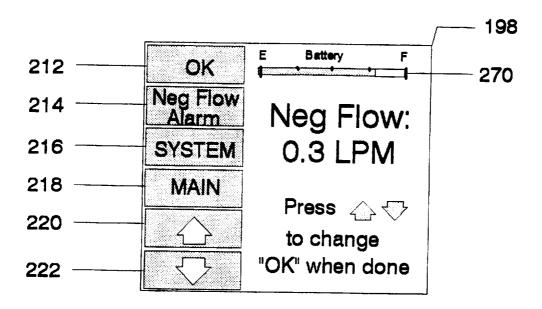


Fig. 21

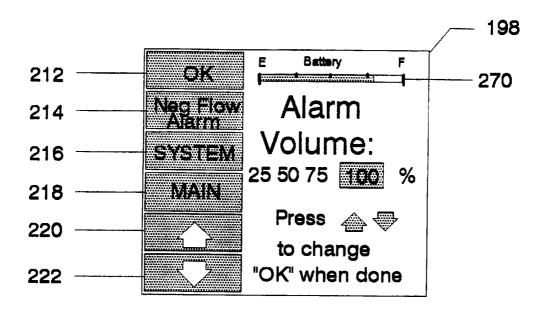


Fig. 22

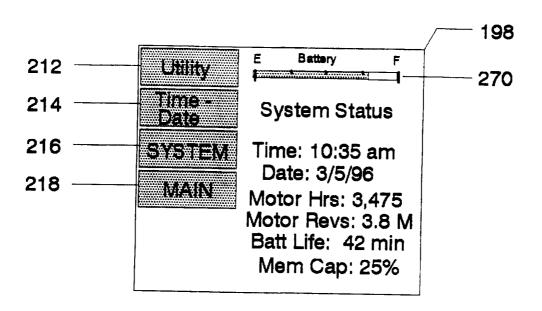


Fig. 23

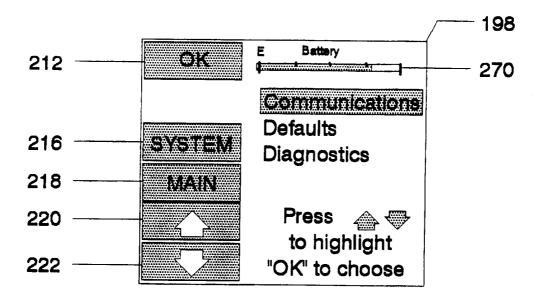


Fig. 24

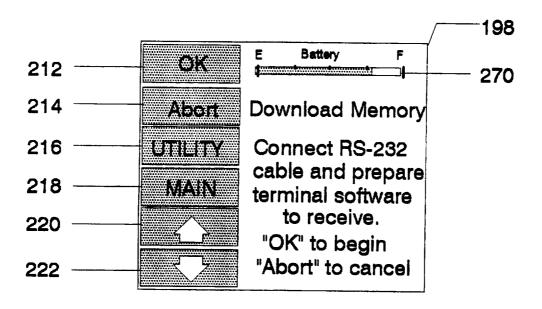


Fig. 25

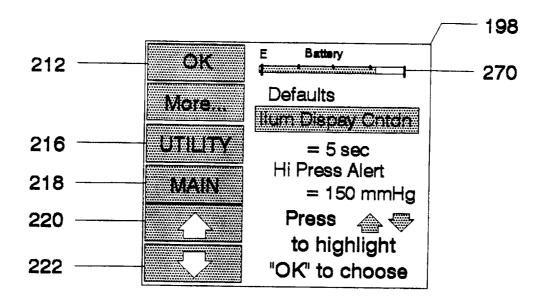


Fig. 26

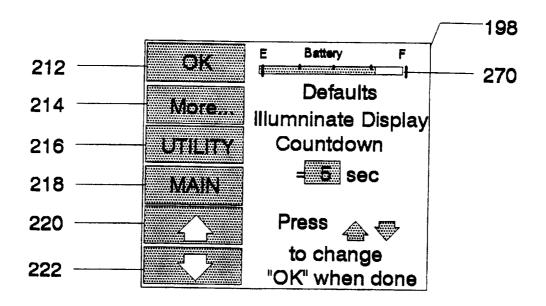


Fig. 27

28/42

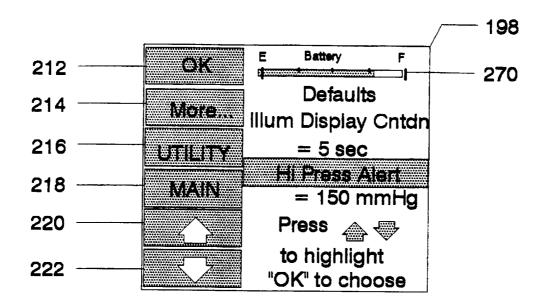


Fig. 28

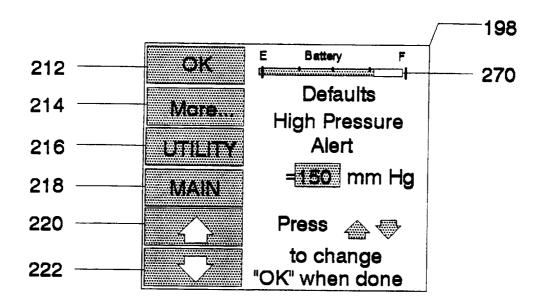


Fig. 29

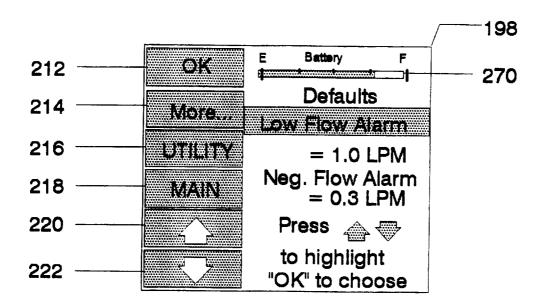


Fig. 30

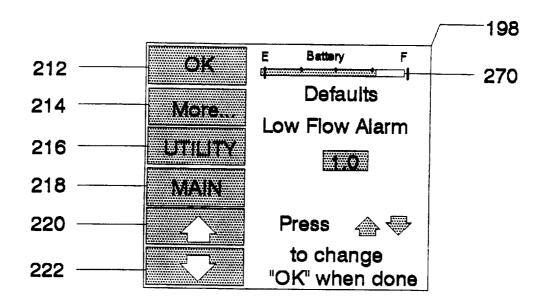


Fig. 31

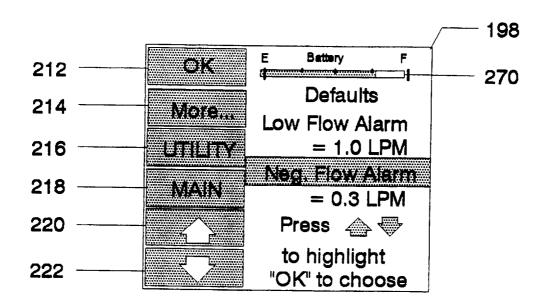


Fig. 32

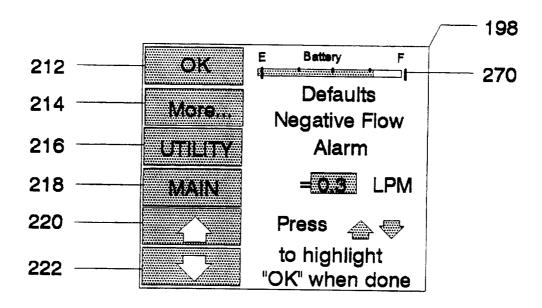


Fig. 33

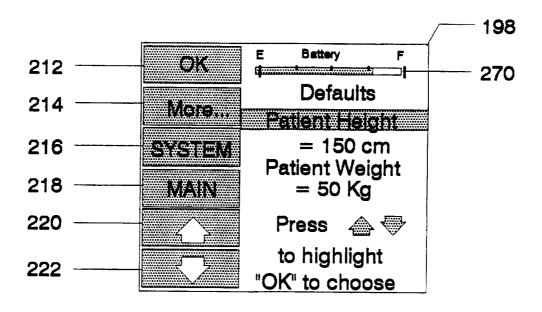


Fig. 34

35/42

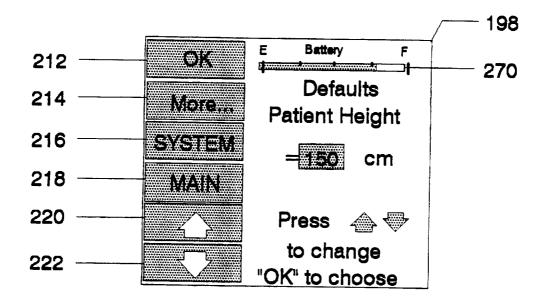


Fig. 35

36/42

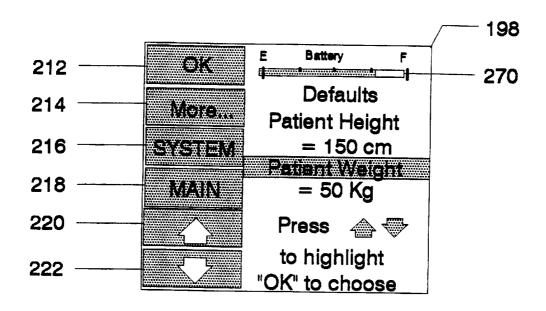


Fig. 36

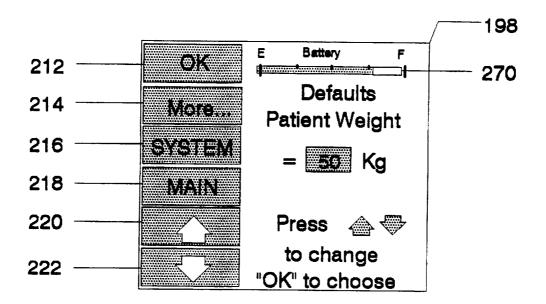


Fig. 37

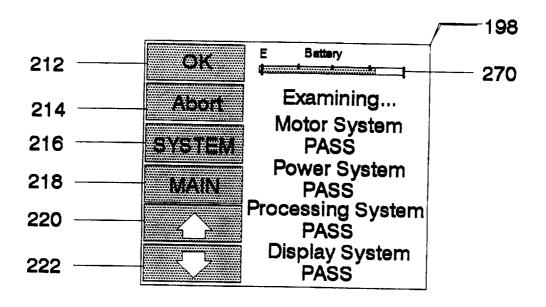


Fig. 38

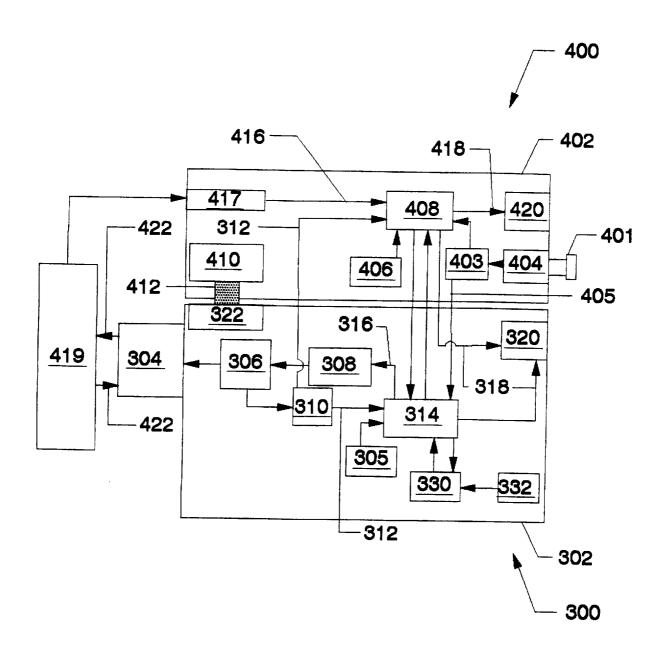


Fig. 39

SUBSTITUTE SHEET (RULE 26)

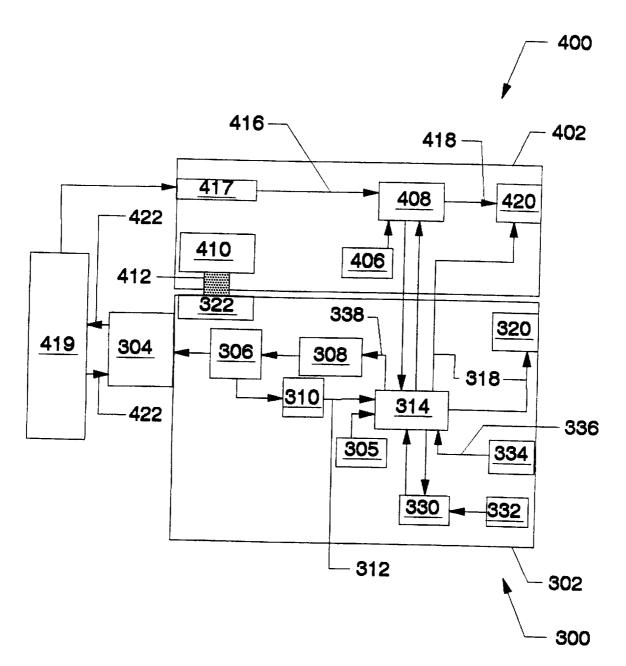


Fig. 40

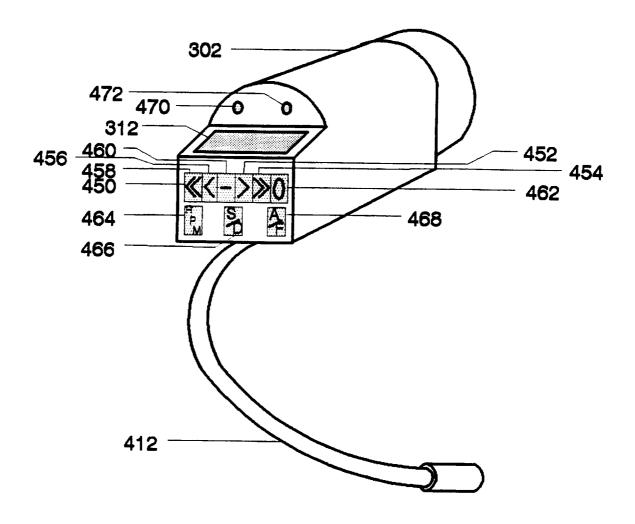


Fig. 41

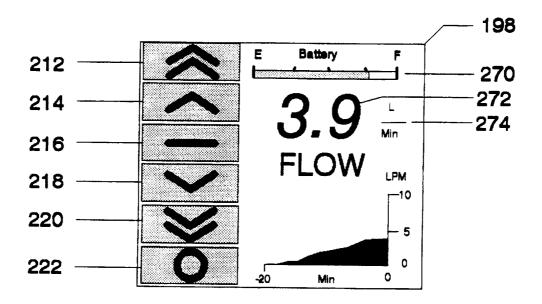


Fig. 42

INTERNATIONAL SEARCH REPORT

International application No. PCT/US97/14996

			
A. CLA IPC(6)	SSIFICATION OF SUBJECT MATTER: A61M 31/00; G08B 21/00		
US CL	: 604/65, 67; 304/606; 128/DIG. 12, DIG. 13		
	to International Patent Classification (IPC) or to be	oth national classification and IPC	
	locumentation searched (classification system follo	wed by classification symbols)	
U.S. :	604/65, 66, 67, 30, 31, 34, 131, 151; 304/606, 6	•	G. 13; 417/360, 420
Documenta	tion searched other than minimum documentation to	the extent that such documents are included	in the fields searched
Electronic	lata base consulted during the international search	(name of data base and, where practicable	c, search terms used)
C. DOC	UMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where	appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5,423,747 A (AMANO) 13 June 1995, col. 3, line 7-53, col. 4, 1-68, col. 5, line 1-25, col. 7, line 17-22		1, 2, 3, 5-25, 34, 35
•			4
Y	US 4,083,777 A (HUTCHISSON) 11 April 1978, col. 3, line 39-64, col. 5, line 38-46, col. 6, line 18-59, col. 7, line 5-12, 25-36 and 56-68, col. 8, line 1-16, col. 13, line 25-65 and col. 15, line 33-49.		4
A	US 5,437,634 A (AMANO) 01 Augu 3, line 1-64, col. 4, line 3-68, col. 4 col. 7-21.	37,634 A (AMANO) 01 August 1995, col. 2, line 34-68, col. 1-64, col. 4, line 3-68, col. 4, line 1-18, col. 6, line 30-68, 21.	
Further documents are listed in the continuation of Box C. See patent family annex.			
A decrement defining the person of the owner, it is a second to the second of the seco		"T" later document published after the interest date and not in conflict with the applic the principle or theory underlying the i	etion but cited to understand
"E" continued to setablish the publication date of another electrical another operation of the document of particular relevance; the claimed involve considered novel or cannot be considered to involve when the document is taken alone.			claimed invention cannot be d to involve an inventive step
special reason (as specified) O' document referring to an oral disclosure, use, exhibition or other means		"Y" document of particular relevance; the considered to involve an inventive a combined with one or more other such combined obvious to a person skilled in the	tep when the document is
document published prior to the international filing data but later than "A." document member of the same patent family			
ate of the actual completion of the international search 20 OCTOBER 1997		Date of mailing of the international search report 0 5 FEB 1998	
ame and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231		Authorized offices JEFFERY A. HOFSASS	
esimile No.	(703) 305-3230	Teléphone No. (703) 305-4717	