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(54) Title: VOICE CONTROL OF AUTOMATED HEART-LUNG MACHINE

(57) Abstract: This present invention allows surgeon to control the heart-lung machine during heart surgery through voice commands. The control unit of the heart-lung machine is able to recognize the commands through the speech recognition software and it translates into electro-digital signals. This signals travels to the main-software that transform into electro-magnetic signals to the heart-lung machine executive parts. This parts are solenoid -actuators, solenoid valves, switches, and any electro-magnetic system that transform this signal into mechanical work. The solenoid actuators and valves are able to activate mechanical clamps, flow controllers, sensors, but not limited to those parts. The safety software ensures the command received is safe to be performed. The safety software analyses by comparison of the real time data and set-point values (flow, SvO2, Art Pressure, temperature, minimum volume in the reservoir and others. The safety software also is able to activate flow controller and clamps during routine control.



VOICE CONTROL OF AUTOMATED HEART-LUNG MACHINE

CROSS REFERENCE

Patent	Title	Owner	Issued date
5544654	Voice control of medical ultrasound machine	Murphy et al.	08/13/1996
6405939	Voice-activated shower system	Mazzenga et. al	06/18/2002
6579257	Automated occlusion clamp for centrifugal pump	Elgas et al.	06/17/2003
4597048	Digital flow regulation of liquid-level control for a continuous casting mold	Chester et al.	06/24/1986
20070005370	Voice-activated control system	Elshout et al.	01/04/2007
6594630	Voice activated control for electrical device	Zlokarnik et.al.	07/15/2003
7617011	Automation system	Kramer et al.	11/10/2009

FIELD OF THE INVENTION

The present invention relates to a heart-lung machine system with voice control and automated features like: automatic flow control, clamping control, cardioplegia delivery control. The tasks are monitored through safety software that analyses real time monitoring data and detecting error conditions that can be automatically corrected to expected set-point values.

BACKGROUND OF THE INVENTION

For more than thirty years, Heart diseases have been treated using open surgical procedures. Thousands of heart procedures, including coronary artery bypass grafting (CABG), valve replacements, and heart transplants are performed every year in the world. During a typical Heart procedure the patient is connected through tubing and lines to the cardiopulmonary bypass (Heart-lung machine) to deliver oxygen and many times stopping the heart through delivery of potassium solution. Stopping the heart allows the surgeon work inside the heart replacing valves or make easier to connect bypass arteries and veins in coronary surgery. Also the heart-lung machine helps to support the heart delivering oxygen and drugs to the whole body pumping blood during surgery.

Generally, previously-known CPB is accomplished by constructing an extracorporeal heart lung machine including, a venous line, a venous reservoir, a centrifugal or roller pump that pumps blood through the extracorporeal circuit and the patient, an oxygenator for oxygenating the blood, an arterial line for returning oxygenated blood to the patient, and an arterial filter located in the arterial line. The machine is operated by the perfusionist, who has to follow surgeon's orders. Many times perfusionist is delay in following directions or is not paying attention; the patient's life may be at risk. The first risk is the emptying of the reservoir, when air flows to patient's heart and brain causing injury or death, usually happens when your arterial flow (out) is faster than the return flow in the venous line (in) or venous line is blocked for some reason. Second the perfusionist must follow precisely the surgeon's order during the surgery allowing the surgeon to operate with safety (filling heart, emptying heart, delivering cardioplegia, vent on, sucker on, and other commands).

This invention has two parts, first the voice control recognition and second automatic safety controls. Through the voice recognition the surgeon gives orders directly to the machine and not to the operator and tasks can be performed in milliseconds; second the machine itself can verify if it is safe to perform such order and also the safety automated system can control oxygen flow, reservoir level and other data that should be under optimum and acceptable values for machine highest and best performance so patient can receive the best treatment.

BRIEF SUMMARY OF THE INVENTION

The first object of the present invention is to control the heart-lung machine by voice-command. A communication link between the voice control system and the heart-lung machine permits the activation of mechanisms of the state of the heart-lung machine so that subsets of the total vocabulary may control the heart-lung machine at real time. The executive mechanism in the heart-lung machine system provides many control valves and actuators coupled to a control unit. The control unit is adapted to store electric impulses representative of a predetermined vocabulary of voice commands. The system further includes a receiver for receiving a speech input from an user and delivering corresponding electric impulses to the control unit. The electric impulses of the speech input are compared by the control unit to the electric impulses of the vocabulary of voice commands. The

control unit actuating predetermined by voice recognition software (any available in the market that may suit this invention) can send the information to the safety software that controls valves and actuators upon recognizing upon a speech input as matching an appropriate command of said vocabulary of voice commands. So as to start, stop, slow down or increase the flow of the heart-lung machine and other mechanisms (cardioplegia, vent, suckers, clamps, valves, etc).

The goal of this invention is to improve safety of the Heart-lung machine and the heart surgery procedures. The perfusionist is in charge of operating the Heart-lung machine. The Heart-lung machine removes blood from the patient (venous line) and after passing through an oxygenator, it pumps back to the patient (arterial line). The system flows blood continuously from in line to out line. The flow should be equal or less than the volume received, if however any decrease or interruption in the receiving line the flow has to decrease also or air can be sent to patient. The perfusionist has to be aware to control flow decreasing or clamping off if there is no return from venous line. Unfortunately several cases was reported of accidents where the reservoir was empty out for complete because of slow reaction of the perfusionist, exposing patient's life at great risk. In cases like that, the perfusionist must clamp the arterial line but it depends of his time of reaction and if he is looking at the reservoir to observe the level going down and conclude that he must slow down flow or even to clamp the arterial line until discover why and how to solve the return of blood problem . This invention will increase safety and reliability, because an automated system can react to a decrease (or block) of blood return in milliseconds, this invention can accomplish surgeon's orders in milliseconds, thus preserving patient's life and delivering safety through an state of art technology system.

In order to provide reliable automated control of heart-lung machine through voice-command, the machine must have an automated monitor control mechanism at least for flow control, reservoir level and oxygen delivery, because the surgeon are not able to watch how much volume is left in the reservoir or how much blood is "come in" compared to how much is "coming out". The voice-command can be validated before being performed.

A voice-controller structured with a control unit provided with speech recognition software which can interpret the commands and send electrical signals to solenoids actuators and

control valves to perform the tasks required by the heart-lung machine and procedure. Where the subsets of voice commands are selected to fit the state of the heart-lung machine so as to afford complete control of the machine, little or no degradation of the control of the machine will result but not limited to, voice control, keyboard and foot-switch should be available.

Also the heart-lung machine has an automated safety control system receiving information through the data-sensors permitting simultaneous control by the control unit software. Comparing statistical optimal set point and real time data, what can trigger correction of the data through electromagnetic impulse to perform mechanical work controlling the heart-lung machine flow, for example.

If one compares the automated system control and the human operator; an operator may take between 10 to 30 seconds to react. For example, if the flow is 4 liters per minute, and an occlusion occurs at the venous line, how many seconds take for 600ml to run out the reservoir system? The answer is 8 seconds (4000ml in 60sec). If the volume in the reservoir is 600ml and the perfusionist may usually take 10 seconds to react properly and the reservoir with the centrifugal pump will empty out. Thus, the patient may suffer brain injury. Surgeons regularly give commands during the Heart-procedure for the perfusionist to perform in the Heart-lung machine (like, “fill the heart”, “down flow”, “decrease pressure”, “come off bypass”); many times the perfusionist does not hear or takes some time to respond. The new voice-command the control unit performs the task response in less than a second. It is precise, safe, reliable, and decrease patient’s risk of mortality and also speeds up the surgery procedure. Therefore, having less time on the heart-lung machine also decreases the patient’s risk of mortality.

The actual heart-lung machines in the market have no voice-command and are not able to control flow through automation of control unit system. This invention is a solution to increasing safety in the procedure where a patient’s life is at risk.

Second objective of this invention is to provide automated safety control of the Heart-lung machine. One of the most important features is to control arterial flow. The task is able

fulfilled after analyzing sensor- trigger-data, like: volume level in the reservoir, SvO2 oxygen venous saturation, SaO2 oxygen arterial saturation, patient's arterial pressure, air bubble detection and power failure. Diagram FIG.02 shows the interaction between sensor-triggers and flow. Fig 02 is an example of sensor-trigger action that can be customized following surgeon and perfusionist preferences; it is not definitely the only possibility of task action, but just an example of how the automated system can protect patient's safety.

BRIEF DESCRIPTION OF DRAWINGS

The above and other objects and advantages of the present invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

FIG. 1 is a flowchart depicting a first operational mode of the Voice command A. Heart-Lung machine ;

FIG. 2 is a flowchart depicting a second operational mode of the Voice command A. Heart-Lung machine ;

FIG. 3 is a schematic view of a preferred extracorporeal circuit incorporating the Voice control automatic System of the present invention;

Fig. 4 is a flowchart depicting an operational mode of the Voice command A. Heart-Lung machine ;

Fig 5 is a flowchart depicting a fith operational mode of the Voice command A. Heart-Lung machine ;

DETAILED DESCRIPTION OF THE INVENTION

The different elements of apparatus in FIGS. 3 illustrating the invention are described below:

(01) Microphone. Bluetooth preferred but any microphone suitable to speech recognition applications may be used. For example, a lapel microphone, a hand-held microphone, or a stand-mounted microphone would all work. In addition, it would also be possible to design the system using a "far-talk" microphone, which is a microphone mounted on the equipment itself (computer or control unit machine) instead of a microphone attached to the operator in some manner. The audio input may be in the form of a microphone or similar device for inputting audio signals to control unit. The input signals are then filtered and sent to amplifiers (not shown) having different gains.

(02) Wireless connection of microphone to speech recognition hardware. Or a wired connection is used. However, any microphone connection may be used.) IR Receiver at Control unit, if the microphone is wireless it is necessary a transmitter and a receiver

(03) Control unit-Host computer. The micro-controller unit first option is an 8-bit or 16-bit MCU embedded, fixed-point microprocessor as the central processing unit (CPU), an on-chip analog to digital (A/D) converter, a Read Only Memory (ROM) bank, a Static Random Access Memory (SRAM) bank, and a general purpose Input-Output (I/O) ports. Or as second option a PC system can be used. The first option the system does not have the ability to be modified once the program has been loaded into the chip; it does not have a disk drive or any other means of being changed. It has firmware as opposed to software, and it does not have a monitor or a keypad. It has a very specific purpose that once the system is loaded with the firmware (hardware), it is only allowed to perform one specific task which is to analyze incoming audio data and comparing that data to one or more sets of pre-stored data to thereby control an outside electrical device. Unlike a PC which has a general purpose of processing unit that, for instance; can do a multitude of tasks from word-processing to game play, to speech recognition.

(04) The control unit has printed circuit board with all of its components is preferably enclosed in a stand-alone housing (not shown), such as a plastic box, that has an electrical plug for connection with an electrical receptacle. Preferably, the housing should also include electrical receptacles for accepting electrical devices of one type or another to be controlled by voice command. Note that a full computer is not required, as the operator does not need to interact with the computer monitor or keyboard. An embedded computer could be used,

which would then be housed within the case of the heart-lung system. The choice of a type of computer depends on the choice of a speech recognition system.

(05) Network connection (automation system United States Patent 7617011- An automation system includes at least one device that detects measured values and is connected to a automated process, at least one field device connected to the at least one device detecting measured values, and a master computer connected to the at least one field device). The automation system is not part of this invention, but it is necessary to understand how the invention can work. When one measured value detection device (in heart lung machine) and the host computer are connected to a common data transmission network which is designed to transmit digital measured data using a first communication protocol between detection device and host computer. (detection device: level sensor, air bubble sensor, Svo2 sensors, arterial pressure sensor and others). The data transmission network can connect all of the components in order to allow both digital measured data and digital control to be transmitted via the data transmission network. The data transmission system must be in Real-Time Ethernet network, allowing real time applications to be carried out in the system.

(06) Connection of host computer to heart-lung system. This can be accomplished by an RS232 wired connection. Again, it is not limited to this wire connection just a suggestion. Other interfaces might be used, such as an RS422, or GPIB. Network connections may also be used, such as Ethernet or Apple-Talk. Another approach that could be taken with an embedded design is for the host computer to use the computer bus of the heart-lung system.

(07) Speech recognition software. This consists of the software required to perform speech recognition. Any suitable commercial or custom speech recognition system may be used. For example, Dragon-Medical (Nuance), e-speaking, Vox commando or a customized software.

(08) Vocabulary. The vocabulary contains all of the reference commands that can be spoken. The total vocabulary can be subdivided into groups, or sub-vocabularies, each of which may be selected or deselected as part of the active vocabulary. This function is also part of the speech recognition product, but it is customized to the particular application. Voice Control Systems provides the software tools to create the vocabulary, with the speech recognition engine using the active vocabulary to recognize the spoken commands. The vocabulary and

sub-vocabularies may be stored on disk or in the host computer memory. Similar resources for the creation and management of vocabularies exist for the other commercial speech recognition products.

(09) Automated heart-lung system in part is composed of some solenoid valves and actuators. The solenoids valves and actuators are an integrated device containing an electromechanical solenoid which actuates either a pneumatic or hydraulic valve, or a solenoid switch, which is a specific type of relay that internally uses an electromechanical solenoid to operate an electrical switch; for example.

For example, the heart-lung machine flow and pump motor switch can be controlled electrically and are integrated into a typical control circuit which circuit diagram are not shown. The control circuit to control the operation of the flow control system for centrifugal pumps as described in our invention is a type standard in the art and it would be known by any one skilled in the art how to construct such an electrical control system. This system does not represent part of this invention.

In either case, this would allow a user to adjust a parameter in an embedded system that would normally be fixed. The parameter can have either the effect of adding weight to the output probabilities of the command words or the output probabilities of the All Other Sounds Template. The effect of the adjustment would be to either change the number of false activation's or change the number of positive detections that a speech recognition system makes. Thus, when a stream of incoming data is compared to the data of the pre-stored templates, adjusting the threshold value S to a greater value permits a person to utter a command word that is less correlated with the templates in order for the speech recognition system to consider it a match. A sequence is generated that best describes the signal. That sequence of features is then compared to a series of features that stored in the templates. Each data point in the incoming signal is compared to a corresponding area of each stored template and scores are generated to represent how closely the input signal matches each one of the templates. Accordingly, data points that at one point can be rejected because the All Other Sounds Template have created the best score, will now be considered as a match because the All Other Sounds Template or the other command word templates were adjusted through the threshold value adjusting means. Although described specifically

for use with the Hidden Markov Model, it is to be understood that the threshold adjusting means can be applied to other speech recognition systems.

(10) Connection of executive module to speech recognition engine. The interface between the executive and the speech recognition engine depends on the choice of speech recognition system and control unit. An application programming interface (API) is a particular set of rules ('code') and specifications that software program follow to communicate with each other. It serves as an interface between different software programs and facilitates their interaction.

(11) Executive. The Executive is a customized software program that is specific for each type of surgery procedure and surgeon protocol. The software interfaces between the heart-lung machine and the speech recognition system. It is a software module whose operation is described below in reference to FIGS.1, FIG.4 and FIG.5 and it is run on the host computer (control unit). It implements the active vocabulary control, dynamic macros as described below, and the required state-tracking of the Heart-lung machine. FIG.4 does not show all the possible commands but a few examples of the commands that can be used.

Many of the devices components are solenoid valves -Electromechanical solenoids consist of an electromagnetically inductive coil, wound around a movable steel or iron slug (termed the armature). The coil is shaped such that the armature can be moved in and out of the center, altering the coil's inductance and thereby becoming an electromagnet. The armature is used to provide a mechanical force to some mechanism (such as controlling a pneumatic valve). Although typically weak over anything but very short distances, solenoids may be controlled directly by a controller circuit, and thus have very low reaction times.

(12) Foot-switch. Foot-switch extension by which operator can have remote access to limited functions of control unit (typically two keys at a time). A foot-switch attached to the heart-lung machine allows the operator to depress a small number of keys (typically two) by operating the switches with his or her feet. The foot-switch is a emergency control that can be defined by the operator to be the most critical functions that are necessary. This provides limited control of the heart-lung machine.

(13) Keyboard. Perfusionist can use the keyboard to execute commands.

(14) Selected Data can be transmitted to internet through a communication application (apps) available in the market and is not part of this invention) that allows data to be send to a web portal that collects the data (control unit has a modem and an internet connection wireless or wired to allow the information to be send). The perfusionist can access from any computer connected to the internet, iphone, ipad or any other device able to connect to the internet. Therefore if perfusionist leaves the room and the heart-lung machine is fully automated mode, perfusionist has access to most important information during real-time.

How works the safety mechanism and flow control:

First, the patient (set-point) flow (arterial side=out) is calculated by BSA body surface area for each patient multiplied by the cardiac index (CI=1.5 to 3.0), or be based on SvO₂ (oxygen venous saturation) above 65%, or flow venous return (in) or other set point pre-established by surgeon or perfusionist. Once decide the method to be used the control unit software calculates ideal flow for each patient, then this flow range becomes the set-point for this patient. Also range for ideal hemoglobin should be inputted (usually between hgb 8-10), because a lower hemoglobin will request a higher flow and a higher hemoglobin a lower flow to achieve the ideal transport of oxygen to reach the ideal oxygen saturation in venous and arterial blood.

During the case, if for example SvO₂ is lower than the set-point the pump can increase flow to adjust to ideal SvO₂ independent of voice command, the control unit follows software instructions to restore optimal SvO₂ above for example 65% - the effect is to increase flow in the amount predetermined by software (can be 10% or more) after checking (validate execution) if there is enough volume in the reservoir to accomplish the task. See FIG.2.

One limitation of this invention is the administration of drugs and blood transfusion. This task must be performed by anesthesiologist or perfusionist, the Heart-lung machine does not perform this type of task automatically.

Based on data input (data received real-time) the software-controller (control unit) can compare real-time data to ideal data(preset), and if it falls outside the ideal range the screen

shows a message and an alarm, informing perfusionist and anesthesiologist that the the specific data is out of range – correct what the machine is programmed to fix or show message of the data that the perfusionist or anesthesiologist is supposed to intervene like, hemoglobin is below ideal range or pressure is low (need pressor-drug).

The main safety device is the monitoring of the reservoir level during surgery. The venous line receives the blood from the patient and the excess blood is stored in the reservoir. The arterial line continuously delivers the blood at determined flow rate of ml/min back to patient. When is necessary to “increase flow” the level of reservoir must be checked. Voice commands must be validated by checking reservoir level of volume and then the command is allowed to be performed. Commands like “fill the heart”, coming off bypass and give 100, for example must check volume in the reservoir to avoid emptiness of reservoir and the risk of air getting to patient. This task is accomplished by level sensors placed at the reservoir. (this sensors already exist and is not part of this invention). The reservoir has at least one sensor, but is recommended three sensors or vertical continuous sensor for measurement of volume in the reservoir. The information is then send in real-time to the safety software in the control.

Briefly, the control system safety software according to the present invention monitors the reservoir level and generates a control signal representing the increase or decrease which the flow control must be moved from its present position to implement a desired degree of adjustment to the rate of liquid flow in line. The control signal is then converted into a pulse having a width corresponding to the desired degree of adjustment. The electromechanical adjustment mechanism is designed to move the flow control at a substantially constant rate in response to the presence of a pulse, so that control of the pulse width can be used to control the total adjustment amount.

Calculation of the pulse-time duration is preferably accomplished using the classical velocity form of the proportional, integral and derivative (PID) digital-control algorithm.

The algorithm used to calculate the pulse time duration can include the addition of some value to compensate for an anticipated propagation time of the control pulse through the

interface between the microprocessor and the final control element (e.g. flow control), such as interposing relays, hydraulic-cylinder solenoids, electric drives, etc.

The operational mode of the level control can be used as an example of how most of the sensors work and how they are compared to a set-point in the software and how the effect is a correction task to be performed by the control unit and the heart-lung machine.

The operation of the control system level measurement is obtained from a digital liquid-level indicator anyone available in the market. The output from the level indicator is then compared in comparator-software with a level set point signal representing the desired level of liquid within the reservoir. The polarity and magnitude of the output signal from comparator will therefore indicate the amount, respectively, by which the actual volume in the reservoir level differs from the desired reservoir level.

A comparator-software then examines the error signal E to determine if the error signal has exceeded a predetermined limit or limits. If yes, the software calculates a value corresponding to a desired flow rate in the arterial line and send signal-order to flow control circuit which will be necessary to correct the detected level error. Therefore, the flow in the arterial line is constantly compared to the ideal set-point, however the flow arterial line mainly depends on the level of volume in the reservoir and the return of blood in the venous line (in=out, if low level of volume), then the flow varies during the surgery.

The control unit safety-software receives data in real time from the heart-lung machine. The data is received from many sensors placed in the arterial line (detect air and measure flow), venous line (measure flow and blood speed), transducers (measure patient's arterial pressure, and cardioplegia pressure), reservoir (level), and others additional sensors if necessary. The control safety-software analyzes and activates a series of solenoid-controlled actuators and valves located in the venous line, reservoir, arterial line, oxygenator, also recirculation line, pump switches, flow control of the speed of centrifugal pump and roller pumps and others.

If the sensor is triggered (error) the control unit safety-software sends an electrical signal that actuates the solenoid-controlled valves to activate flow (down-or up) in the arterial line

and or venous line. If stops flow simultaneously opens the recirculation line to re-circulate blood to avoid blood clot of the system.

How works the voice-command:

The Heart-lung machine can be used in partial mode of voice-control allowing selected features to be automatic controlled or can be fully automated. The surgeon orally communicates with the heart-lung machine through wireless microphone, the machine receives the signal, reply to the surgeon a sound to communicate that is going to perform the task or is not going to perform the task (for example:yes, or no), message can be a sound or also a message on the screen or color code (for examplegreen or red). Most used vocabulary-commands during heart surgery (heart-lung machine= bypass) are: Go on bypass, fill heart, empty, flow down, suckers on or off, give cardioplegia, vent on or off, come off bypass, pump off and give 100. Other commands also can be included in the vocabulary command following surgeon's preference.

The commands can be performed per surgeon or perfusionist request, following we have an example of how can the tasks be performed, however is not limited to those steps, but just an example. For example "fill heart" (FIG.5) the speech recognition interprets the order and transform in electrical signal, sending the electrical signal to safety-software that validates the command (check level of volume-check if is possible to perform the task) if yes- send electrical signal a solenoid actuator or gate control circuit for generation of a control pulse having a duration corresponding to the desired amount of gate movement, and the control pulse is then provided to pneumatic or hydraulic cylinders for moving the gate through the appropriate distance, clamping and occluding partially the venous line delivering the appropriate amount of volume to "fill the heart" and then "hold" on flow equilibrium. Flow equilibrium means the amount of blood "gets in" through the venous line is the same as the volume "gets out" through arterial line. (To be able to monitor the in (venous) it can use a flow speed-sensor venous line and another flow-speed sensor arterial line). Equilibrium is what "gets in"="gets out".

Another command frequently used is "empty heart", the action is accomplished by momentarily flowing down and then restoring to normal flow.

Another example is “Go on bypass” (FIG.4), the software at control unit can release the following steps: electrical signal goes to solenoid actuator to open gate (clamp) on venous line, when reservoir sensor shows increase in volume above 300ml then electrical signal is send to open gate (clamp) in arterial line – the flow is set to 1800 rpm to get started, then flow slowly increases as volume increases in the reservoir up to set-point flow rate if possible. This is an example of how to accomplish the task, but is not limited to these steps only, easily can be customized as the perfusionist chief request and adapted to the software at control-unit.

Another command is “Coming off” bypass, where simple steps may be used : “ fill heart” and at the same time “go down on the flow” 30%, fill up to arterial pressure of 90 - 100 (systolic) , flow go down between 1.8 to 2 liters/min, if arterial pressure decreases “ fill” more (if still have volume- check volume left in reservoir, if not enough volume “hold”). Continue go down flow to 1.5 l/min until surgeon order “Pump off”, then both lines are clamped- venous and arterial.

Next important command is “cardioplegia on”. Usually, Cardioplegia is the delivery of the mixture of blood and potassium. To control flow delivery is necessary to monitor pressure in the cardioplegia line. Usually a pressure line transducer measures the pressure in the cardioplegia cannula and line; so this pressure values are compared to the set-points and flow go up or down to adjust to desired pressure, because increasing flow increases pressure in the line (directly proportional). The amount of cardioplegia to be delivered also can be controlled since is predetermined – preset by surgeon or perfusionist.

Other commands are “suckers on/off/up/down”, “vent on/off/up/down”, electrical signal is sent to solenoid switch to turn on or off the roller pump at predetermined rate. Alterations in speed of the roller pump can be controlled by solenoid-actuator switches, or other electro-mechanical switch, or other digital systems available able to perform the task. Electro-mechanical-actuator switches already exist is not part of the invention, this is an illustration of how can work, other digital systems are available, so any suitable device can perform the task. For example switches controlled by input AC(an ac input device is typically a mechanical switch) or DC (works with transistor outputs) signals which feeds into a zero-crossing detection circuit (not shown) and generates a trigger pulse which is used

as the clock input for several one-shots with time constants adjusted to provide pulse trains at 33% and 66% of the AC line frequency duty cycle. These pulse trains are supplied to a multiplexer (not shown) which can be controlled by the micro-controller adapted for selecting an appropriate digital pulse train to drive the opto-coupler.

This is not part of the invention just an example how can be implemented, but any reasonable means of digital connection between speech recognition and the electro-mechanical system can be used. For example, several bits from Port O of the speech recognition chip select the appropriate channel of the multiplexer which is adapted for driving this circuit. It may have four states:

Bit 1 Bit 0 State

0	0	ON
1	0	65% ON (speed)
0	1	35% ON (speed)
1	1	OFF

In the present invention, preferably, the means for adjusting the threshold value comprises a trim potentiometer that has a digital interface to the speech recognition system. The threshold adjusting means, no matter what form it takes, sets the point at which the speech recognition system recognizes an uttered command word, i.e. to set the degree of correlation between the incoming data and the template data to thereby trigger the system. This adjusting means allows selective adjustment by a user of the parameters of the similarity measurement, which could either be statistical or rule-based.

Overview of a Preferred Voice controlled automated Heart-lung machine System.

The Heart-lung machine can be used in partial mode of voice-control allowing selected features to be automatic controlled or can be fully automated.

Referring to FIG. 3, a preferred extracorporeal Heart-lung machine 1 suitable for use with the voice command automated flow control system of the present invention is described.

Extracorporeal blood handling system 1 is designed to maintain a patient on full or partial bypass support, for example, during a coronary artery bypass graft procedure, in either a full-bypass or beating heart (partial bypass) mode of operation, or open heart repair procedure, typically with full-bypass mode of operation.

Extracorporeal blood system 1 includes control unit 10 an extracorporeal blood circuit 2 having a perfusion circuit comprising venous line 3 , and arterial line 4 , and a priming/reservoir circuit comprising line 5, centrifugal pump 6, oxygenator 7 , arterial filter 8 and recirculation line 15 . Roller pumps 16,17,18 are used for suction or cardioplegia delivery 19. The ends of perfusion line segments venous 3, arterial 4 are shown extending into the sterile field as they would appear during use, where they are coupled to venous and arterial cannula placed in the patient, respectively.

As usual Heart-lung machines system 1 includes sensors 20 - 28. The sensors 20-22 are level sensors, sensor 24 Svo₂, sensor 25 venous flow, 26 arterial flow, 28 sensor air bubble, 27 patients arterial pressure transducer. Cardioplegia flow 27 and pressure transducer 30. The position of the sensors are merely suggestion, many other possibilities exist, even more sensors can be placed.

The centrifugal and roller pump flow can be controlled by digital control. The pumps are managed by an electronic speed driver for remote control or digital control. Any suitable unit-control available in the market, like magnetic Flux vector control.

This invention possesses at least two electro-magnetic-mechanical (solenoid) actuators and pinch-clamps located at venous line 13 and arterial line 14 and centrifugal and roller pump flow can be controlled by electro-magnetic-mechanical (solenoid) digital control. The control unit safety-software, after sensor-triggered or voice command, basically may activate at least a minimum of six important mechanisms: venous clamp, arterial clamp and centrifugal pump flow, roller pump flow, recirculation line, cardioplegia delivery.

Sensor is configured to sense a parameter indicative of a level or volume of blood or air or other gas, or detect the absence of blood, and preferably operates by a non-contact method. Suitable sensor methods include electrical-charge based, optical and acoustic methods. A

resistive contact method also could be employed, in which a low electrical current is passed between adjacent electrodes only in the presence of blood.

Sensor preferably is of a known capacitance type that detects a change in electrical capacitance between the bulk of a liquid (in this case, blood or saline). Alternatively, sensor may be optical in nature, and uses a light source that has a wavelength that is minimally attenuated by blood. In this case, the light source is directed, at an oblique angle, through the blood towards a photodetector, and sensor 25/26 is positioned to detect the change in the refractive index of the blood (or saline prime) caused by the presence of air or other gases. In another alternative embodiment, sensors 25 and 26 may use an ultrasonic energy source and receiver to detect the presence of gas or absence of blood by the change in acoustic transmission characteristics.

The output of sensor 20-23 is supplied to controller 10 (see FIG. 3), which in turn regulates centrifugal pump flow 6. When sensor 20 outputs a signal indicating that there is low volume in the reservoir in the extracorporeal blood system 1, controller 10 send a electric signal to centrifugal pump controller to decrease flow in x% (x is predetermined by algorithm statistical software calculation), thereby do not empty reservoir. Sensor detects 25 detects blood at an appropriate level, and changes its output so that controller increase flow to normal rate. In this manner, level is continuously monitored and then automatically “flow is down” when blood level is below threshold. This makes voice-commands safe even though the surgeon is not watching the reservoir. The system must respond “yes” when executing the order, and “no” when can not perform the voice-command, because must know if the command is going to be performed.

Another safety feature is sensor 28 monitors for entrained air in the arterial blood. Preferably, sensor 28 uses ultrasound to detect the presence of air entrained in arterial blood, and is coupled to controller 10 so that an output of the sensor is used to evaluate one or more trigger conditions. Arterial pressure sensor 27 may be any suitable pressure sensor such as a piezoelectric transducer or an electrostatic capacitance sensor, and is also coupled to controller 10 and provides an output corresponding to the pressure in arterial line.

Description of the Automatic Flow Control Systems of the Present Invention

In accordance with the principles of the present invention, microprocessor-based controller 10 of the extracorporeal Heart-lung machine system 1 of FIG. 3 is programmed to provide at least one automatic flow control feature. More particularly, controller 10 is programmed to evaluate the outputs of sensor 20 to 28 to evaluate the onset or existence of certain trigger conditions and to modulate system operation to avoid adverse impacts to system operation. In a preferred embodiment, modulation of system operation comprises regulating the flow speed of pump centrifugal pump and roller pumps.

For example, the outputs of sensors 20 - 22 may detect non-negligible levels of blood in the reservoir, this is a trigger condition and control unit correction is activating pump control system to reduce the speed of centrifugal pump 6 and the blood flow rate. When sensor measures level up flow comes back up.

Referring again to FIG. 3, extracorporeal blood system 1 with automatic flow control includes extracorporeal blood circuit 1 and controller 10 . Preferably, the controller 10 includes a microprocessor having software including machine-readable instructions for interpreting sensor input and regulating pump speed for flow control.

According to one aspect of the present invention, controller 10 is electrically coupled to drive unit 12 of pump 6 and to sensors 20 - 28 . As disclosed above, the sensors are positioned within extracorporeal blood circuit 1 to detect low level in the reservoir , or presence of air measured arterial line. When a trigger condition is detected, controller 10 modulates drive unit 12 to lower the speed of pump 6 , thus lowering the blood flow rate through arterial line 4 . Another scenario if data triggered is low arterial pressure 27 controller 10 modulates drive unit 12 to increase the speed of pump 6 to increase flow delivery of oxygen (up to a limit –checking level reservoir and calculated flow).

Automatic flow control software is programmed to provide a reduction phase, a hold phase and a resume phase in response to a trigger condition back to normal. During the reduction phase, pump speed is reduced to lower the rate of blood flow through extracorporeal blood circuit 1. Depending on the type and magnitude of the error condition, pump speed may be reduced by a fixed step, by a percentage of the initial pump speed or by rapidly dropping the

pump speed to a predetermined lower limit. In addition, pump speed may be manually regulated.

In the case of “low level of volume” in the reservoir. First step is to reduce the pump speed (for example 1800rpm), the automatic flow control algorithm enters a hold phase, wherein pump speed is maintained at the lower level. In the hold phase, for example waiting to increase volume in the reservoir, display message in the screen “need volume” so perfusionist and anesthesiologist can be aware. During the resume phase, pump speed is gradually increased back to the initial level when level increase in the reservoir.

The automatic flow control system includes algorithms to implement a number of different control modes of operation. The system preferably will not lower the pump speed below a predetermined lower limit, which is chosen so that forward blood flow is maintained through extracorporeal blood circuit 1 and to the sterile field.

While the invention has been taught with specific reference to the above-described embodiments, those skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and the scope of the invention. Thus, the described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

What is claimed is:

1. Claim 1 , a heart-lung machine comprising: a venous line; an arterial line; a blood pump to pump through the circuit and patient, a gas connected to a oxygenator, the blood processing system having an inlet to receive blood from a patient via the venous line and an outlet for delivering blood via the arterial line, many safety sensors, a microphone. A controller unit with a safety software programmed to modulate the operation of the pump speed and automated clamps, and a speech recognition software with wireless connection (or wired) microphone connected to speech recognition hardware, and also data transmission network for real-time data.
2. claim 2, wherein the control unit has at least one software programmed to understand through the speech recognition and another that activates the digital-electric signals that activate the execution through digital-electro-mechanical automated system.
3. claim 3, wherein solenoid valves or other digital-electro-magnetic mechanism (capable to execution of mechanical work) are configured to be selectively actuated by the controller sensor and safety-software or voice-command responsive to the output-execution of the tasks.
4. claim 4, wherein the controller validates the voice-commands and also is responsive to duration of actuation of the valves and sensors . The controller contains the steps to execute the command. The controller activates safety mechanisms when sensors detect an error or danger.
5. claim 5, wherein the speed pump (flow) is reduced or increased to a predetermined limit value or by a predetermined by the controller- software or order received through voice control.
- 6 claim 6, wherein sensors are disposed on many places at the circuit to send real-time data

information to unit control, including but not limited to air sensor, flow sensor in the venous and arterial line, pressure line transducers, reservoir level, temperature, PH, SvO₂, SaO₂ (oxygen saturation), etc. Control unit has a market application (apps) that allows the control-unit to send selected information to a website using the internet. Perfusionist can have remote access to main information through the internet.

7. claim 7, wherein one sensor monitors patient pressure, another sensor monitors Oxygen Venous saturation (data) and level of volume in the reservoir . Sensors send information to the control-unit to decide if flow has to be increased or decreased.

8. claim 8 wherein the speech recognition software, within the controller unit, receives oral information(commands-orders) from the surgeon or perfusionist and communicates with the safety software (control-unit) in real time that send the signal to heart-lung machine executive part to perform the command.

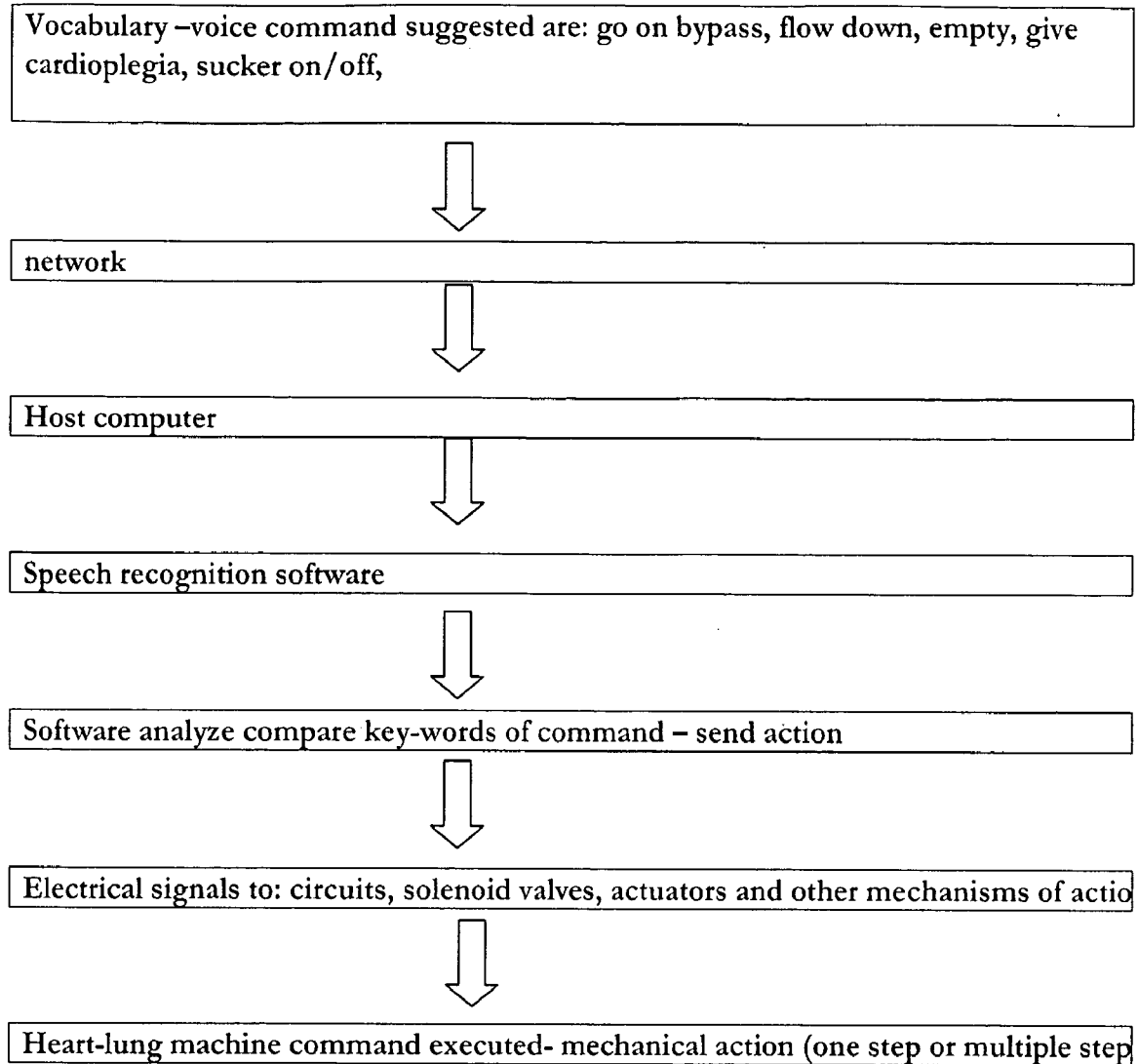
9. claim 9, wherein the safety software receives data from the voice system and the sensors, and effectively communicates to activate mechanisms in the Heart-lung machine like electro-mechanical actuating devices (clamps, flow,valves, solenoid valves and digital or mechanical switches).

10. claim 10, wherein the electro-mechanical clamps are placed in venous line and in the arterial line controlled by the control-unit.

11. claim 11, wherein the surgeon(or perfusionist) orally communicates with the heart-lung machine and the heart-lung machine performs the command requested by the surgeon (or perfusionist).

12. claim 12, wherein the controller further modulates operation of the Heart-lung machine through voice-command or keyboard by interpreting the command and send the correct electrical sign to active parts of the machine.

FIG.1



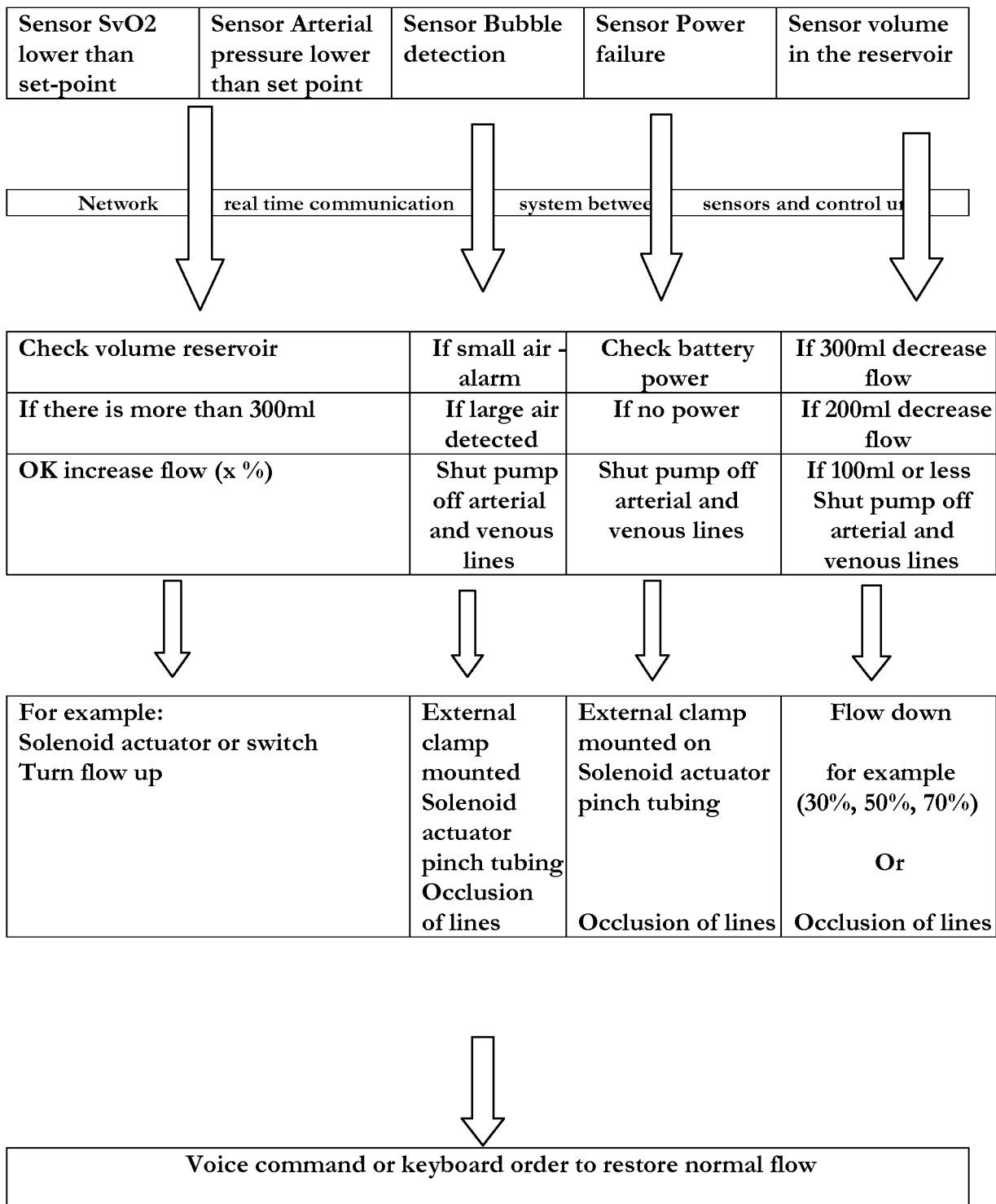


FIG.3

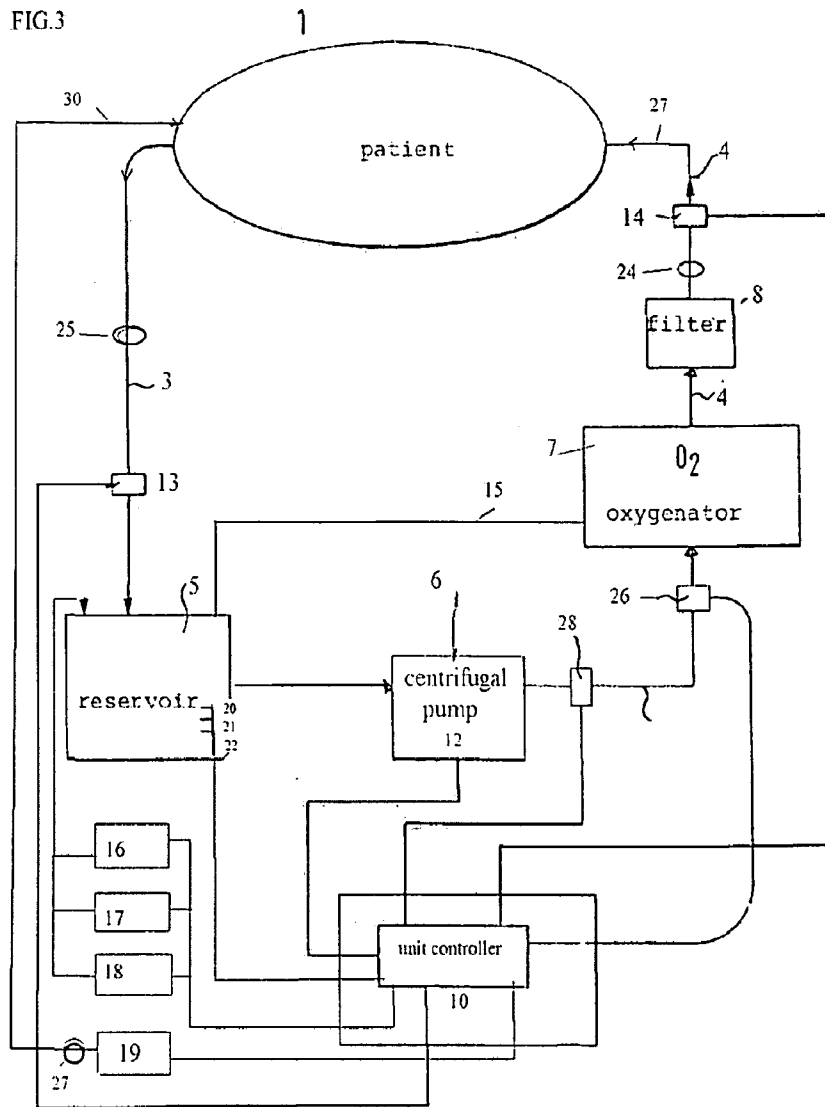


FIG.4 Example of automated software:

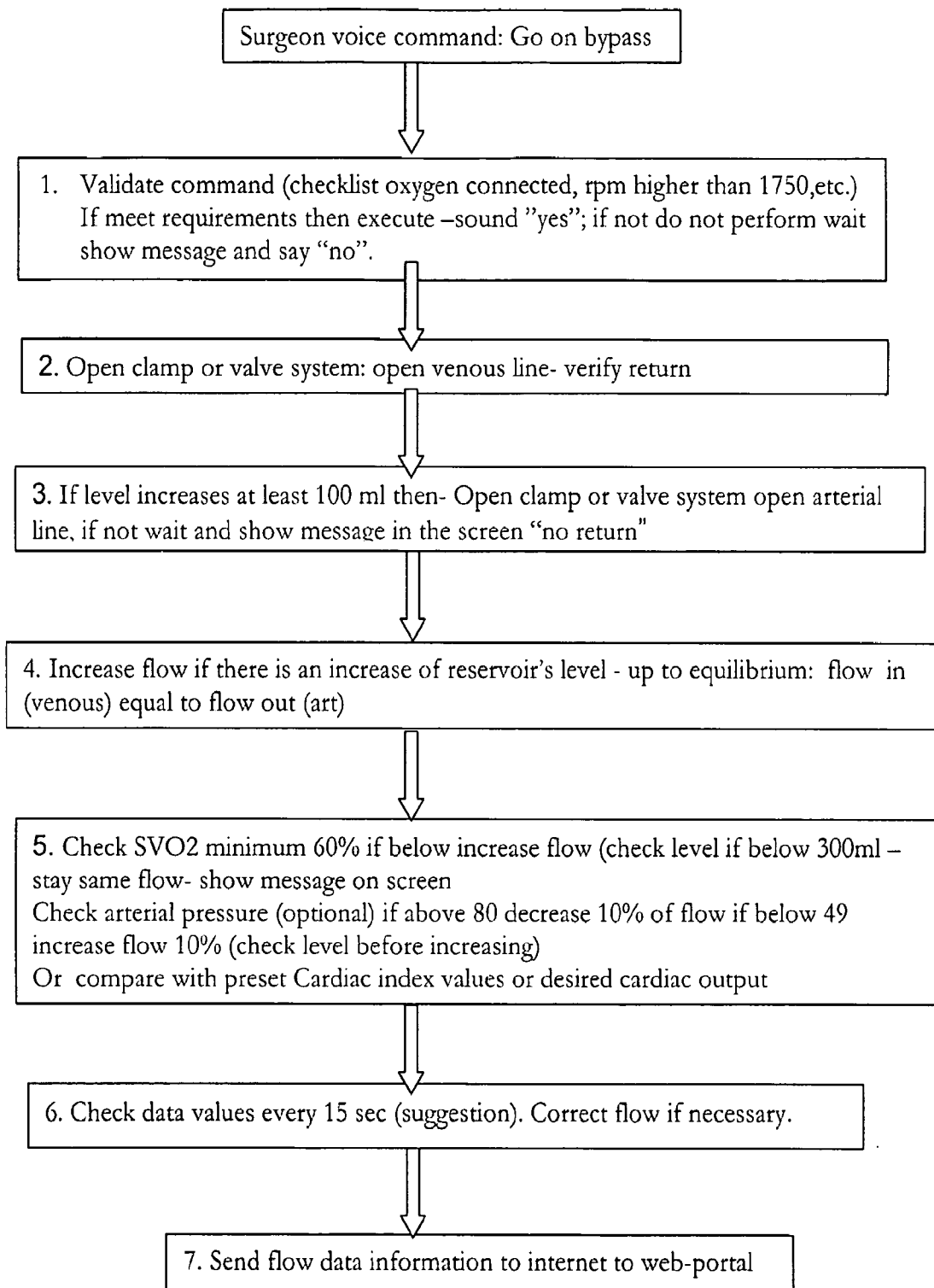


FIG.5 Example

