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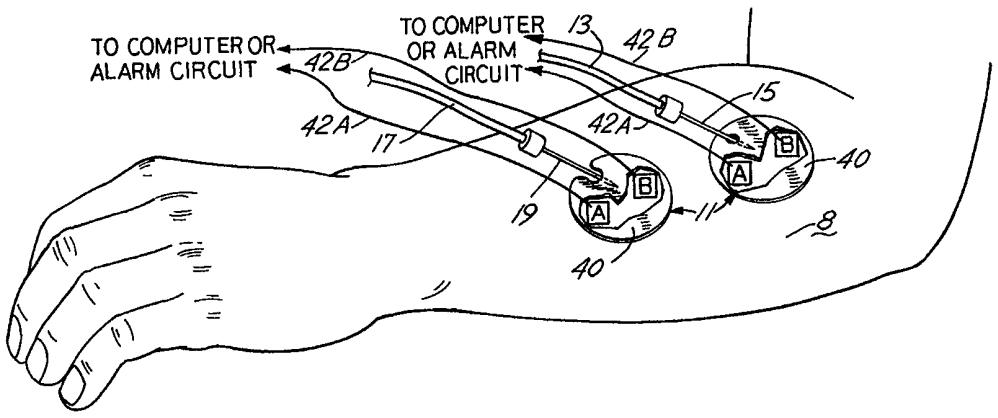
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(54) Title: BLOOD LINE SEPARATION WARNING DEVICE FOR EXTRACORPOREAL CIRCUITS



(57) Abstract

A fluid-sensing device (11) for detecting whether a fistula needle (15, 19) connecting a patient (8) to an extracorporeal blood circuit of a dialysis machine is described. The fluid sensing device (11) includes a pair of electrodes (A, B) that are placed on the surface of the patient's body (8) adjacent to where the fistula needle (15, 19) is inserted into the patient. The electrodes (A, B) are connected via a pair of wires (42A, 42B) to a computer control and alarm circuit for the dialysis machine. If the fistula needle (15, 19) becomes detached from the patient (8) the electrodes (A, B) will sense the leakage of blood and a signal is sent to the computer control and alarm circuit. The computer control and alarm circuit immediately stops the blood pump and activates an alarm, thereby preventing a potentially catastrophic loss of blood from occurring.

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BLOOD LINE SEPARATION WARNING DEVICE FOR EXTRACORPOREAL CIRCUITS

BACKGROUND OF THE INVENTION

A. Field of the Invention

This invention relates to the subject of extracorporeal blood circuits, such as typically found in artificial kidney systems. More particularly, the invention relates to a device for detecting the separation of a blood line of the extracorporeal circuit from a fistula needle that is inserted into the patient's body, or for detecting the separation of the fistula needle from the patient.

B. Description of Related Art

Dialysis machines are used for treating patients with inadequate kidney function. Hemodialysis machines include, among other things, an extracorporeal blood circuit typically comprising an arterial line, a blood pump, a dialyzer and a venous line. Blood is removed from the patient via the arterial line and pumped by the blood pump to the dialyzer, where blood-borne toxins and excess fluids are removed from the patient's blood. The blood is then returned to the patient via the venous line. A dialysis machine particularly suitable for use outside of a conventional dialysis clinic setting is set forth in the patent of Rodney S. Kenley et al., U.S. No. 5,591,344, assigned to the assignee of the present invention, which is incorporated by reference herein.

The arterial and venous lines of the extracorporeal circuit are typically connected to separate blood access sites on the patient's body. A fistula needle is employed for this purpose at each access site, with the tip thereof inserted into a blood vessel and the other end thereof connected to the respective arterial or venous line.

A potentially life-threatening situation can occur if the venous fistula needle should accidentally become separated from the patients body, or if the venous line becomes disconnected form the venous fistula needle, during the dialysis treatment. If this occurs, and the arterial fistula needle remains in the body with the blood pump still operating to remove blood from the patient, a rapid and potentially catastrophic loss of the patient's blood can occur. Ordinarily, if the venous fistula needle is accidentally separated from the body, the patient or another person in attendance will notice it and either call for help, stop the machine, reinsert the needle, or take other action. These measures are ineffective if the patient happens to be asleep when the needle pulls out, and if the patient is either alone or the attendant does not notice the situation.

There has been a long-felt, but here-to-fore unsolved need in the dialysis art for a method and apparatus for detecting when the venous fistula needle has become separated from the patient and automatically taking corrective action, such as to sound an alarm or shut off the blood pump. Most extracorporeal circuits include pressure monitoring devices in the arterial and venous lines for various purposes. However, pressure monitoring devices in the arterial and venous lines would not detect a loss of pressure if the venous fistula needle becomes separated from the patient. This is because the pressure variation associated with the tip of the venous fistula needle pulling out of the patient's body, measured upstream in the venous line, is negligible

in absolute terms, and hence essentially undetectable, especially when the pressure fluctuations in the extracorporeal circuit that typically occur in a normal two, three or four hour dialysis session are also taken into account.

Accordingly, it is an object of the invention to provide an apparatus and method for automatically detecting the occurrence of the separation of the venous fistula needle from the patient's body, and for taking corrective action to maximize the safety of dialysis patients.

The invention is also applicable to other types of medical equipment having extracorporeal blood circuits connected to the patient's circulatory system, such as found in heart-lung machines and liver-support machines.

SUMMARY OF THE INVENTION

A blood line separation device is provided comprising first and second electrodes that are applied to the patient's body in the vicinity of the insertion of the fistula needle into the patient. The electrodes may be incorporated into an adhesive patch applied to the patient's skin. The electrodes may, alternatively, be incorporated into a cuff that encircles the patient's arm adjacent to the needle access site. The electrodes are normally electrically isolated. If the needle separates from the patient, blood is ejected out of the tip of the needle onto surrounding surfaces, such as the adhesive patch or the cuff containing the electrodes. The blood creates a conductive path between the two electrodes. The electrodes are coupled to conductors that lead to a fluid sensing circuit that is incorporated into a dialysis machine computer system or, alternatively, an alarm circuit. The dialysis machine computer system shuts off the

blood pump when the fluid sensing circuit senses the presence of a conductive path between the two electrodes.

While the above description references a kidney dialysis machine, the operation of the invention is essentially the same in other types of machines having an extracorporeal circuit, in which case the alarm circuit or machine computer system is incorporated into the pertinent machine, whether it be a heart-lung machine, a liver-support machine or otherwise. Additionally, the alarm circuit may be entirely separate from the machine itself, such as a buzzer circuit positioned next to the patient or in a nurses station.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following detailed description of presently preferred and alternative embodiments of the invention, reference will be made to the accompanying drawing figures, wherein like reference numerals refer to like elements in the various views, and wherein:

Figure 1 is an illustration of a dialysis patient connected to a dialysis machine, showing the relationship of a preferred embodiment of the inventive needle withdrawal warning device in relationship to the patient and the machine.

Figure 2 is a detailed perspective view of a preferred embodiment of the needle withdrawal warning device of Figure 1, with the adhesive patches shown partially broken away in order to show the electrodes embedded therein;

Figure 3 is a detailed perspective view of alternative embodiment of the needle withdrawal warning device of Figure 2; and

Figure 4 is a cross-section of the cuff embodiment of Figure 3;

Figure 5 is a perspective view of an alternative embodiment of the invention in which a fluid detection device is placed at the connection of the venous line to the venous fistula needle;

Figure 6 is a perspective view of an alternative embodiment of the invention in which a fluid detection device is placed at the connection of the venous line to the venous fistula needle and at the connection between the arterial line and the arterial fistula needle;

Figure 7 is a block diagram of the computer control system of the dialysis machine of Figure 1, showing the relationship of the inventive needle withdrawal warning device of Figures 2- 6 in relation to host and backup microprocessors.

DETAILED DESCRIPTION OF THE PREFERRED AND ALTERNATIVE EMBODIMENTS

Figure 1 is an illustration of a dialysis patient 8 connected to a hemodialysis machine 10, showing the relationship of a preferred embodiment of the inventive needle withdrawal warning device 11 in relationship to the patient and the machine. The hemodialysis machine 10 includes an extracorporeal circuit having an arterial line 13 connected to the patient at an "arterial" access site via an arterial fistula needle 15, and a venous line 17 connected to the patient at a "venous" access site via a venous fistula needle 19. The arterial and venous lines 13 and 17 connect to the rest of the extracorporeal circuit which is located inside the cabinet 26 behind a door 27. A blood pump inside the cabinet 26 is placed in the arterial line for pumping blood through the extracorporeal circuit to a dialyzer in the cabinet 26, and returning the blood to the patient via the venous line 17.

The dialyzer has a membrane having a blood side thereof in communication with the arterial and venous lines and a dialysate side thereof. The dialysis machine includes a dialysate preparation system 25 having a source of dialysate solution and a dialysate pump for circulating the dialysate solution through a dialysate circuit to the dialysate side of the dialyzer membrane. The machine has a water treatment system 23 for treating water supplied to the dialysate circuit 25. A central computer control system is provided in the machine governing the operation of the blood pump, the dialysate preparation system and dialysate pump, and the other aspects of the dialysis machine.

The machine also has a user interface 12 for allowing the patient to input information and commands into the machine. In the particular machine illustrated in Figure 1, the user interface 12 includes a touch sensitive screen 14 and a set of three colored hard keys or physical buttons 16, 18, 20 that are pushed by the patient 8 in response to prompts displayed on the touch screen 14. The user interface 12 rotates about a tilt axis T, a vertical axis A, and the arm 30 pivots about a hinge 28 along axis H. The entire extracorporeal circuit housing 26 rotates about a vertical axis. These rotational features insure that the user interface and extracorporeal circuit are conveniently positioned relative to the patient 8 during the dialysis session.

The details of the dialysis machine 10 per se are not particularly important, and are known in the art. The reader is directed to the patent to Rodney S. Kenley, et al., U.S. No. 5,591,344, for a description of a presently preferred hemodialysis machine 10, which is incorporated by reference herein. However, the invention may be used with virtually any hemodialysis machine, such as the one described in the patent of Grogan, et al., U.S. No. 5,326,476.

The problem of potential catastrophic loss of blood from the patient described above occurs when the venous fistula needle 19 becomes disconnected from the patient 8. The problem also can occur if the venous blood line 17 becomes disconnected from the venous fistula needle 19. In either scenario, if the arterial line 13 and fistula needle 15 is connected to the patient 8 and the blood pump continues operation, blood will continue to be removed from the patient but not be returned, a life-threatening situation.

The present invention addresses this problem by providing a blood line separation warning device 11 comprising a fluid sensor having a pair of electrodes adapted for installation on the patient's body adjacent to the location at which the venous fistula needle 19 is inserted into the patient's body. Several different embodiments are contemplated for the fluid sensing device, described below. Conductors are provided as part of a leak detection circuit that connect the electrodes of the fluid sensing device to the central computer control system for the dialysis machine. The presence of blood between the electrodes is sensed by the leak detection circuit, which respc sively causes the computer control system to take corrective action to minimize blood loss, such as by stopping the blood pump. The computer control system may take other action, such as operating an audio or visual alarm.

Referring now to Figure 2, a preferred arrangement of a blood line separation warning device is shown, with a portion of the device broken away to shown the electrodes. The device 11 comprises a fluid sensor that is suited for installation adjacent to the location at which the venous fistula needle 19 is inserted into the patient's body 8. As shown in Figure 3, the device 11 is also suitable for use to detect the separation of the arterial fistula needle 15 from the patient's body 8. The

device 11 has first and second nominally isolated electrodes (items A and B, respectively) applied to a flexible material such as a patch 40 having an adhesive backing suitable for placement on the patient's body 8 or clothing immediately adjacent to the location where the fistula needles 15, 19 are inserted into the body. First and second conductors 42A, 42B from a leak detection circuit in the central computer control system are connected to the first and second electrodes, respectively. The conductors 42A, 42B supply a signal indicative of the presence of fluid between the first and second electrodes to the central computer system of the dialysis machine.

More specifically, the presence of blood between the first and second electrodes A and B closes a circuit between the electrodes or otherwise causes the signal indicative of the presence of blood adjacent to the fistula needle insertion site to be supplied to the dialysis machine 10. The computer control system responsively stops the operation of the blood pump to prevent a potentially catastrophic loss of blood from the patient.

The electrodes A and B may implemented as a mesh structure spread evenly in the adhesive patch 40 or they may be separated as shown. They should be nominally isolated from each other (i.e., not in electrical contact), such that the presence of blood within the patch creates a conductive path between electrode A and electrode B in order to close a circuit and send a signal along conductors 42A and/or 42 B that blood is present at the needle insertion site.

In the embodiment of Figure 3, the fluid sensing device is constructed as a wrap-around cuff-like member 50 that is installed surrounding to the venous fistula needle 19 access site. The cuff 50 has a slot 52 and a small aperture 54 to assist in the

placement of the needle 19. The cuff has an end portion 56 which has a VELCRO ® hook patch on its lower surface which is secured to a complimentary pile patch 58 on the cuff. The cuff 50 is shown in cross section in Figure 4. The bottom of the cuff 50 placed adjacent to the patient's skin is a first conductor 60 formed as a mesh. The first conductor is separated from a second conductor 64 by a hydrophilic material 62. The top surface of the cuff is a light hydrophilic cloth material 66. As shown in Figure 3, the cuff includes two electrodes 42A and 42B, which lead to a leak detection circuit in the dialysis machine computer system or to an alarm circuit. Electrode 42A is connected to the first mesh conductor 60 in the cuff 50, and the electrode 42B is connected to the second mesh conductor 64.

In use, if the needle 19 of Figure 3 should accidentally pull out of the patient 8, blood will pass out of the tip of the needle 18 into the area in the cuff 50 between the electrodes. This will establish a conductive path between the two electrodes and allow the leak detection circuit to sense the presence of blood and enable the computer control system to stop the blood pump or take other corrective action.

Figure 5 is a perspective view of an alternative embodiment, in which a disconnection of the venous line 17 from the venous fistula needle 19 is detected. The device comprises clamshell-type enclosure 70 having two halves 71, 72 connected by a hinge 73 which snaps closed by means of any suitable snap 74 or other type of fastener for closing the two halves 71,72. Each half of the enclosure 70 has its respective conductor, shown as a first mesh conductor A in half 71 and mesh conductor B positioned in half 72. Each conductor A, B is connected to its respective first and second conductor 42A, 42B leading to suitable leak detection circuitry in an alarm circuit or in the dialysis machine central computer system. Separation of the

line 17 from the needle 19 causes blood to leak into the interior of the enclosure 70, resulting in blood establishing a conductive path between electrodes A and B and causing the leak detection circuit connected to conductors 42A and 42B to responsively sound an alarm, stop the blood pump, or take other action.

Figure 6 shows an embodiment in which a single enclosure is provided for both the arterial and venous lines and their associated arterial and venous fistula needles. The principle of operation of the device is as described above.

Figure 7 is a block diagram of a computer control system 100 of the dialysis machine 10 of Figure 1, showing the relationship between the conductors 42A, 42B of the inventive needle withdrawal warning device of Figure 1 and the system 100. The central computer control system 100 is installed within the machine 10 and governs all aspects of the operation of the machine 10. The use of a central computer control module to control active components of a dialysis machine (such as a blood pump) is well known in the art and described in the above-referenced Kenley et al. and Grogan et al. patents, and hence the description here is merely representative of one possible control system.

Referring to Figure 7, the computer control system 100 controls the operation of user interface display 14' to display messages and information concerning the status of the machine and treatment. The module 100 operates the user interface display 14' to prompt the user to touch the touch screen 14 and hard keys 16, 18, 20 in the process of changing parameters or inputting information into the computer system 100.

The touch screen 14 inputs commands or information from the patient user into a human interface (HI) board 108. The hard keys 16, 18 and 20 are each a pair of physical switches and provide additional signals to the HI board 108 and a redundant or

backup safety central processing unit (CPU) 116. One switch in the hard keys 16, 18, and 20 is preferably directly hard wired to the safety CPU 116, and the other switch is connected to a host CPU 110 via the HI board 108. The emergency stop hard key 20 is preferably directly hard wired to both the host CPU 110 and the safety CPU, as shown by the dashed lines 101.

A set of indicators 104, including lights and audio indicators, a buzzer 121, and a speaker 106, alert the patient to abnormal conditions in the machine 10 (such as disconnection of the venous fistula needle from the patient or the fistula needle from the venous line), and provide information as to the status of the modes of operation of the machine. The indicators 104 receive input signals from the host or safety CPU via the HI board 108. The buzzer 121 receives input signals from the safety CPU 116. Thus, audio and visual alarm activities are split among the two microprocessors 110, 116 in case one of them fails to work properly.

The host CPU 110 is connected via high speed digital data busses 111 and 113 to a driver board 112 and an analog board 114. The host CPU 110 comprises a microprocessor and implements a software program governing the operation of the machine stored in a hard disk memory 130 or a read only memory (not shown). The hard disk 130 stores other operational information, such as the patient's prescription, data from the passive components, and data input from the patient via the touch screen. An analog board 114 contains analog to digital converters for converting incoming analog signals from the passive sensors in the machine 22 (such as thermistors, pressure sensors and conductivity cells) into digital signals. The analog board 114 also includes a leak detection circuit responsive to signals on the conductors 42A, 42B from the fluid sensing device.

The driver board 112 receives commands from the CPU 110 and sends the commands to the valves, pumps, heaters, motors, and other active components of the machine (represented by 120) to cause the components to change their status, e.g., commence or cease operation or change rate, as in the case of a pump, or open and close, as in the case of a valve. The signals from the passive components 122 of the system, for example, the conductivity sensors, pressure transducers, thermistors, etc. provide their inputs to the analog boards 114 and 118. The CPU 110 and driver board 112 together act as a controller for the active components.

The analog board 118 for the safety CPU 116 received inputs from the passive sensors in the dialysis machine 10 and also includes a leak detection circuit responsive to signals on the conductors 42A, 42B from the fluid sensing device. The analog board 118 provides digital information on a bus 117 to the safety CPU 116. The safety CPU 116 comprises a microprocessor and acts as watchdog of critical system sensors, and provides enable signals to the driver board 112 that allow certain driver commands to issue to the active components 120 (such as signals to the blood pump to cease operation of the blood pump in the extracorporeal circuit). Communications between the safety CPU 116 and host CPU 110 are passed on data bus 107. The safety CPU 116 activates a buzzer or other suitable alarm 121 if certain alarm conditions are present in the machine.

Both the host and safety CPUs 110 and 116 have an associated random access memory 132 and 134, respectively, for use in processing input information from the touch screen 14, for temporary storage of data, and for performing other tasks. In a preferred embodiment, the host CPU 110 and hard disk 130 are based on an off-the-shelf IBM compatible personal computer platform based on an Intel 386 or 486

microprocessor, or the equivalent. A similar microprocessor platform may be used for the safety CPU 116. Of course, other types of microprocessor platforms may be used. The safety CPU 116 also has its own hard disk memory 123. Note that the Safety and Host CPUs 116 and 110 do not share a hard disk, but rather have their own hard disk, for safety and redundancy reasons.

The host CPU 110 preferably has a modem and telephone line interface, a local area network (LAN) gateway card and interface and/or an RS-232 serial port (not shown) for allowing the machine 10 to receive and send messages to remote locations by a suitable communication link. The choice of which type of input/output interface will depend on where the machine 10 is installed (e.g., the home (modem), in a hospital (LAN interface), in a nursing home (modem and/or RS-232 and/or LAN). Potential entities that may wish to access information from the machine include a physician or nurse, the machine manufacturer, a service technician, and a remote monitoring facility such as a central station monitoring a plurality of machines. Preferably, machine status and treatment information is stored in the hard disk 130 and is accessible to the outside via the modem and host CPU 110 using an interactive program running on the host CPU 110 and at the remote site. The host CPU computing platform 110 also preferably implements a Microsoft ™ graphical user interface operating system, and also Internet access software to allow messages to be sent to and retrieved from the machine 10 via the Internet.

The leak sensing circuit implemented on the analog boards 114 and 118 could be one of any number of known fluid leak detection circuits used for treating enuresis. Representative circuits are described in the patents to Brown, U.S. Patent 4,738, 260; Wilson, U.S. Patents 4,356,479 and 4,271,406, and Blakely, U.S. Patent

5,043,704, and Smith, U.S. Patent 5,341,127, the contents of each of which is incorporated by reference herein in its entirety. The adaptation of such circuits to a computer control system of a dialysis machine, such as the one shown in Figure 7, is considered to a well within the abilities of a person of ordinary skill in the art of electrical engineering and control systems. Basically, once the leak detection circuit in the analog boards 114 and/or 118 become active due to the closing of the conductive path between the two electrodes, the host and safety CPUs are notified of the condition and a signal is sent to the driver board 112 which responsively stops the blood pump of the extracorporeal circuit. Activation of an audio and or visual alarm (such as buzzer 121 or indicators 104), may also occur to alert the patient of the condition. Ideally, the alarms 121, 104 that are responsive to the leak detection circuit in the analog boards are part of the patient protective systems programmed into the dialysis machine.

As mentioned above, the applicability of the invention to other types of machines having an extracorporeal circuit will be considered clear to persons of ordinary skill in the art.

Presently preferred and alternative embodiments of the invention have now been set forth. Persons of skill in the art will appreciate that modifications from the disclosed embodiments may be made without departure from the spirit of the invention. This true scope and spirit is defined by the appended claims.

CLAIMS

1. A method of reducing the loss of blood from a patient caused by separation of a blood access needle from the patient, said blood access needle connected to a blood line for an extracorporeal circuit of a machine for treating the patient, said extracorporeal circuit comprising a blood pump, the method comprising the steps of :

installing a fluid sensing device adjacent to the location in which said blood line access needle is inserted into the patent's body, said fluid sensing device comprising a first electrode attached to a first conductor and a second electrode attached to a second conductor, said first and second conductors leading to a computer system of said dialysis machine, the presence of blood between said first and second electrodes closing a fluid detection circuit that includes said first and second conductors and said first and second electrodes;

detecting the presence of blood between said first and second electrodes, said presence of blood indicative of a separation of said blood access needle from the dialysis patient; and

responsive stopping said blood pump of the extracorporeal circuit in the event that the presence of blood between said first and second electrodes is detected.

2. The method of claim 1, wherein said fluid sensing device is installed by placing said first and second electrodes on the patient's body.

3. The method of claim 2, wherein said fluid sensing device is installed by placing said electrodes on the patient's body at the location where said blood line access needle is inserted into the patent's body.

4. The method of claim 1, further comprising the step of operating an audible or visual alarm upon the detection of the presence of blood between said electrodes.

5. In a machine for treating a patient, the machine having an extracorporeal circuit comprising a blood line and a blood pump for circulating blood from said patient to said machine and back to said patient, and a computer system controlling the operation of said blood pump, an improvement to said machine comprising:

a blood line separation warning device comprising a fluid sensing device for installation adjacent to the location at which said blood line attaches to a needle inserted into the patient's body; and

conductors connecting said fluid sensing device to said computer system for said machine;

said central computer system operative to stop said blood pump in the event that said fluid sensing device indicates that fluid is present at said location.

6. In a dialysis machine having an extracorporeal circuit comprising a blood line, a dialyzer membrane and a blood pump for circulating blood from said patient to said dialyzer membrane and back to said patient, and a computer system

controlling the operation of said blood pump, an improvement to said dialysis machine comprising:

a blood line separation warning device comprising a fluid sensing device adapted for installation adjacent to the location at which a needle connected to said blood line is inserted into the patient's body; and

conductors connecting said fluid sensing device to said computer system for said dialysis machine;

said central computer system responsive to said fluid sensing device and operative to stop said blood pump in the event that said fluid sensing device detects the presence of fluid adjacent to said location.

7. Apparatus for detecting the separation of a needle from a patient, said needle returning blood from an extracorporeal circuit back to said patient, comprising, in combination:

a blood line separation warning device comprising a fluid sensing device for installation adjacent to the location at which said needle is inserted into the patient's body, said fluid sensing device comprising first and second nominally isolated electrodes applied to a flexible material suitable for placement on the patient's body or clothing;

first and second conductors connected to said first and second electrodes, respectively; and

an alarm circuit connected to said first and second conductors;

whereby the presence of blood between said first and second electrodes activates said alarm circuit causing operation of an audio or visual alarm, alerting said patient to said condition of separation of said needle from said patient's body.

8. The apparatus of claim 7, wherein said flexible material comprises an adhesive patch having said first and second electrodes applied thereto, said adhesive patch for application to the skin of said patient.

9. The apparatus of claim 7, wherein said flexible material comprises a cuff strapped around said patient adjacent to said needle.

10. The apparatus of claim 7, wherein said alarm is incorporated into a protective system of a dialysis machine.

11. Apparatus for detecting the separation of a needle from a patient, said needle returning blood from an extracorporeal circuit of a machine for treating said patient back to said patient, the extracorporeal circuit including a blood pump, comprising, in combination:

a blood line separation warning device comprising a fluid sensing device for installation adjacent to the location at which said needle is inserted into the patient's body, said fluid sensing device comprising first and second nominally isolated electrodes applied to a flexible material suitable for placement on the patient's body or clothing;

first and second conductors connected to said first and second electrodes, respectively, for supplying a signal indicative of the presence of fluid between said first and second electrodes to said dialysis machine;

whereby the presence of blood between said first and second electrodes causes said signal to be supplied to said machine, said machine responsively stopping the operation of said blood pump to prevent a potentially catastrophic loss of blood from said patient.

12. The apparatus of claim 11, wherein said flexible material comprises an adhesive patch having said first and second electrodes applied thereto, said adhesive patch for application to the skin of said patient.

13. The apparatus of claim 11, wherein said flexible material comprises a cuff for placement around an extremity of said patient adjacent to said needle.

14. A dialysis machine with a blood line separation warning device, comprising:

an extracorporeal circuit comprising an arterial line, a venous line, a blood pump for pumping blood through said extracorporeal circuit and a dialyzer membrane having a blood side thereof in communication with said arterial and venous lines and a dialysate side thereof,

a source of dialysate solution and a dialysate pump for circulating said dialysate solution through said dialysate side of said dialyzer membrane;

a central computer control system governing the operation of said blood pump; and

a blood line separation warning device comprising

(a) a fluid sensing device adapted for installation on the patient's body adjacent to the location at which a needle connected to said blood line is inserted into the patient's body; and

(b) conductors connecting said fluid sensing device to a leak detection circuit, said central computer control system responsive to said leak detection sircuit;

wherein said central computer control system of said dialysis machine is operative to stop the blood pump in the event that said leak detection circuit detects the presence of fluid adjacent to said location.

15. The dialysis machine of claim 14, wherein said fluid sensing device comprises first and second nominally isolated electrodes, and wherein said fluid sensing device further comprises an adhesive patch, containing said first and second electrodes, applied to the skin of said patient.

16. The dialysis machine of claim 14, wherein said fluid sensing device comprises first and second nominally isolated electrodes, and wherein said fluid sensing device further comprises a cuff for wrapping around an extremity of said patient adjacent to said needle.

17. A blood sensing device for detecting the disconnection of a blood line from a fistula needle, comprising:

(a) a housing having first and second hinged covers adapted to receive therebetween an end of said blood line and an end of said fistula needle, said blood line and fistula needle in a nominally connected condition with substantially no leakage of blood therebetween;

(b) said first and second covers constructed so as so close about said ends of said fistula needle and said blood line;

(c) a first electrode and a second electrode placed within said first and second hinged covers, said first and second electrodes nominally separated from each other and placed in close proximity to said ends of said blood line and said fistula needle;

(d) a first conductor and a second conductor connected to said first and second electrodes;

(e) said first and second conductors connected to a protective system for taking corrective action in the event that said ends of said fistula needle and said blood line become disconnected from each other and blood establishes a conductive path between said first and second electrodes.

18. The device of claim 17, wherein said protective system comprises an audio or visual alarm.

19. The device of claim 17, wherein said protective system comprises a computer control system of a dialysis machine, said computer control system operative to cease the operation of a pump pumping blood through said blood line.

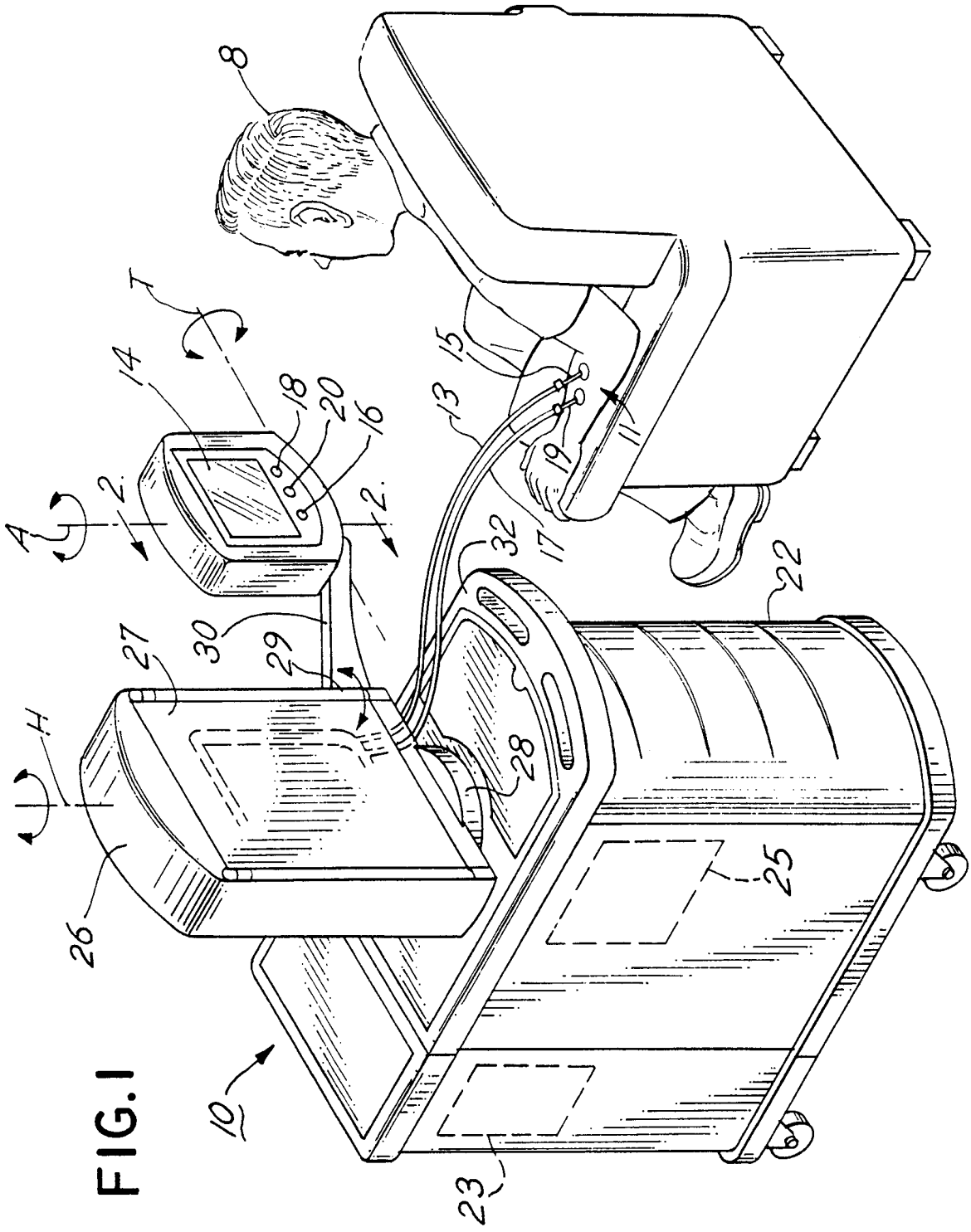
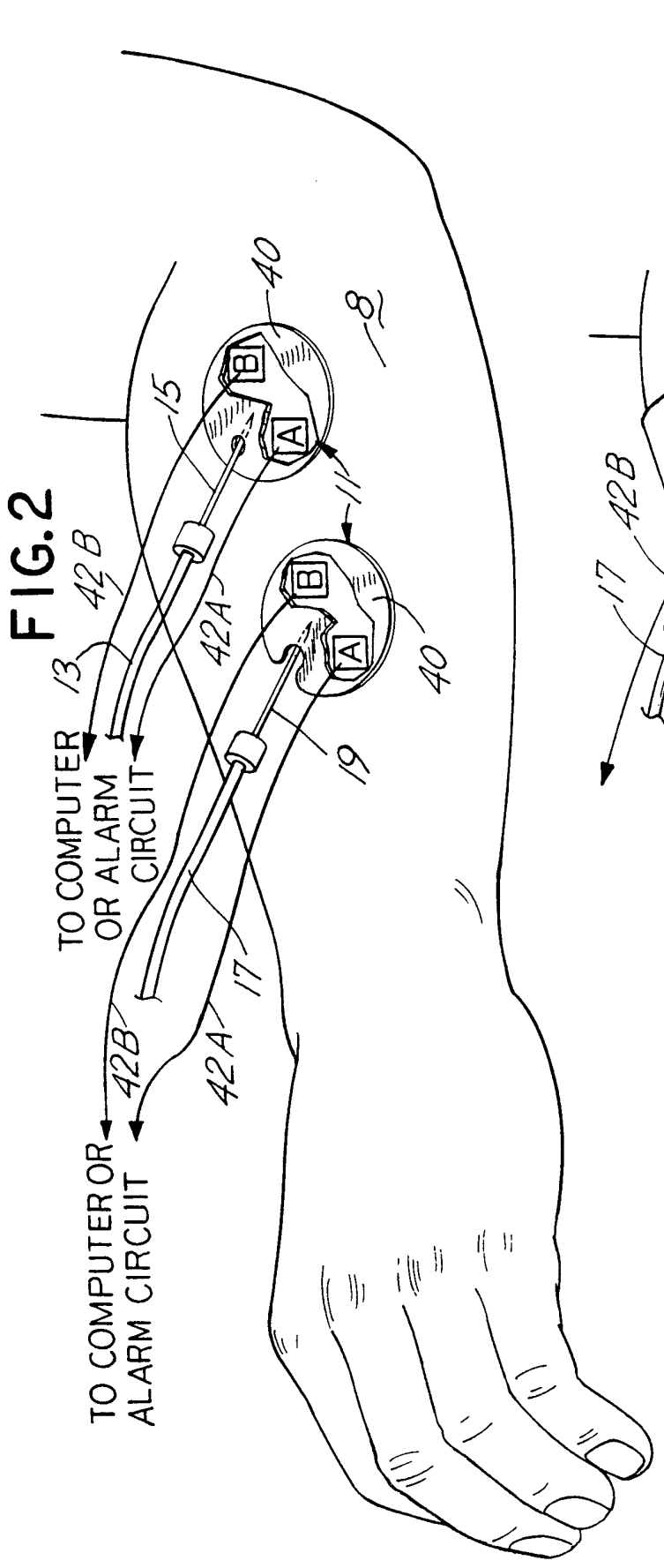
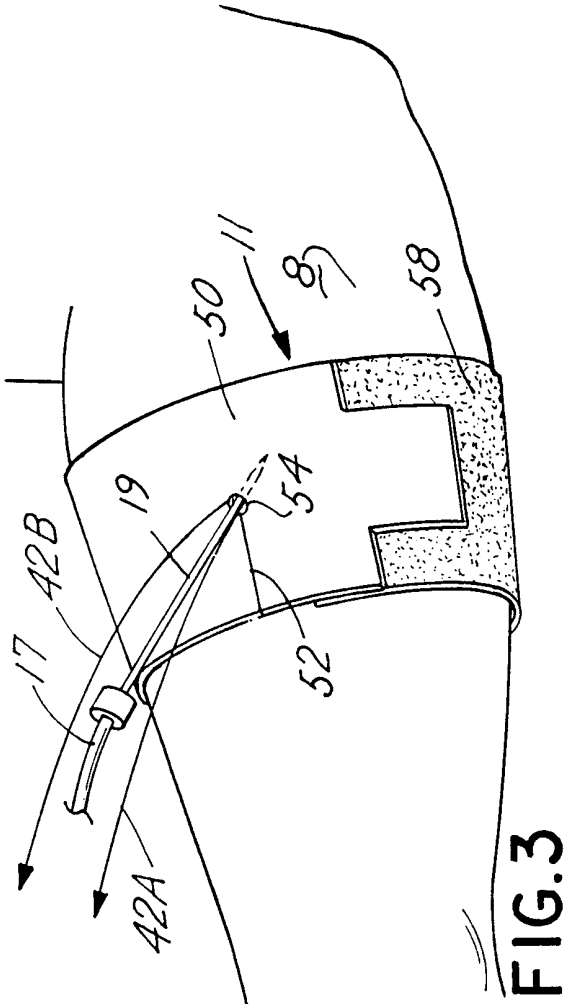
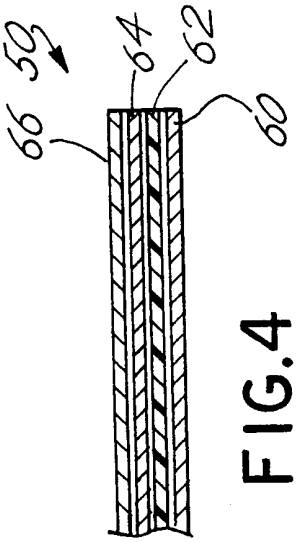


FIG. 1


FIG.2
TO COMPUTER OR ALARM CIRCUIT
TO COMPUTER OR ALARM CIRCUIT
40
8
15
B
A
11
42B
42A
13
19
17
40


FIG.3
50
11
8
58
19
54
42B
17
52
42A


FIG.4
53
64
62
66
60

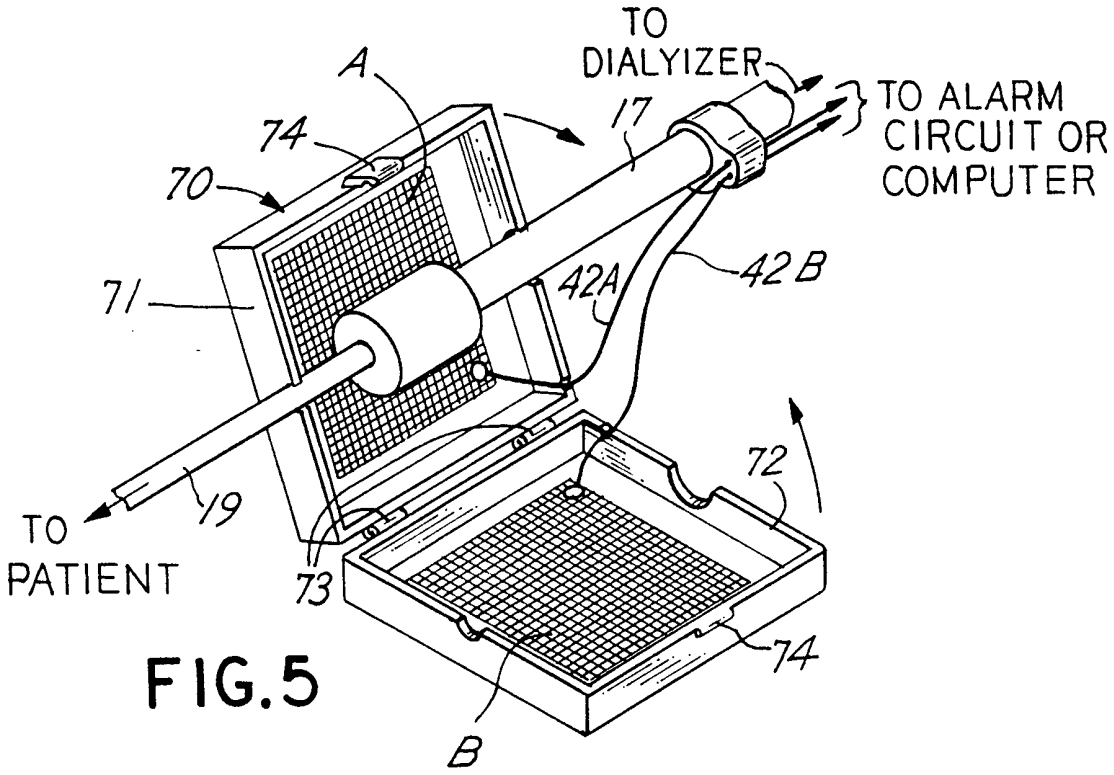

TO
DIALYZER
A
17
74
TO ALARM
CIRCUIT OR
COMPUTER
70
71
42A
42B
72
19
TO
PATIENT
73
74
B

FIG.5

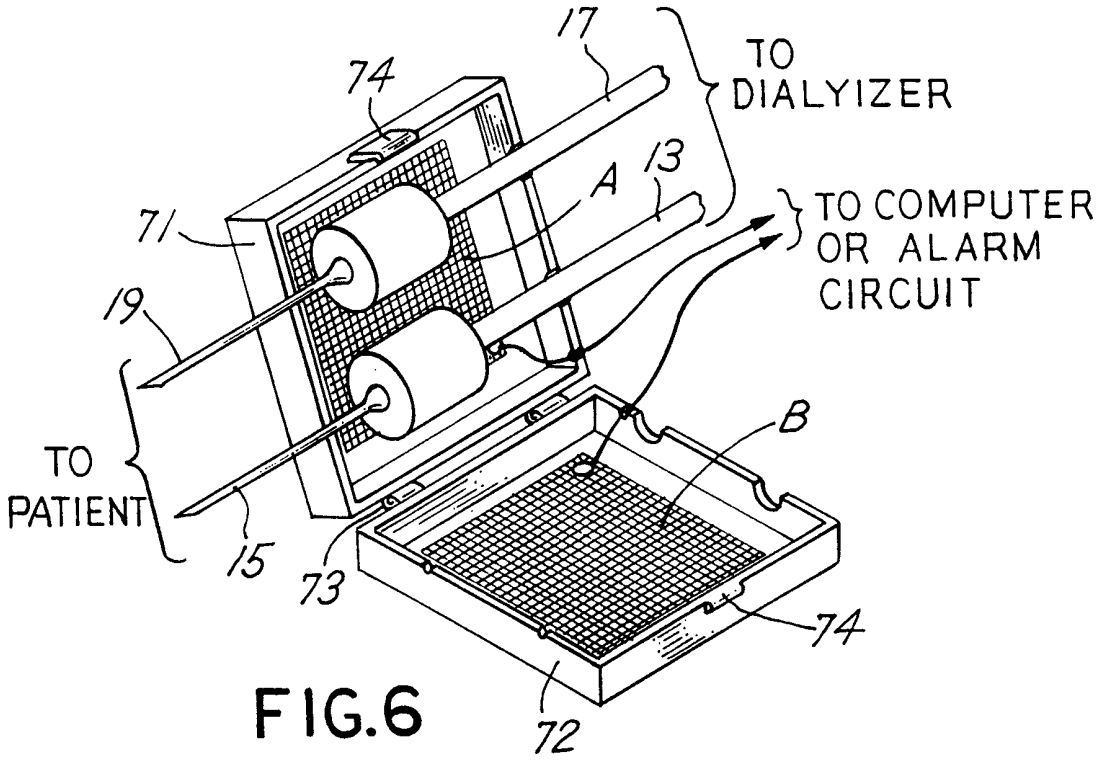
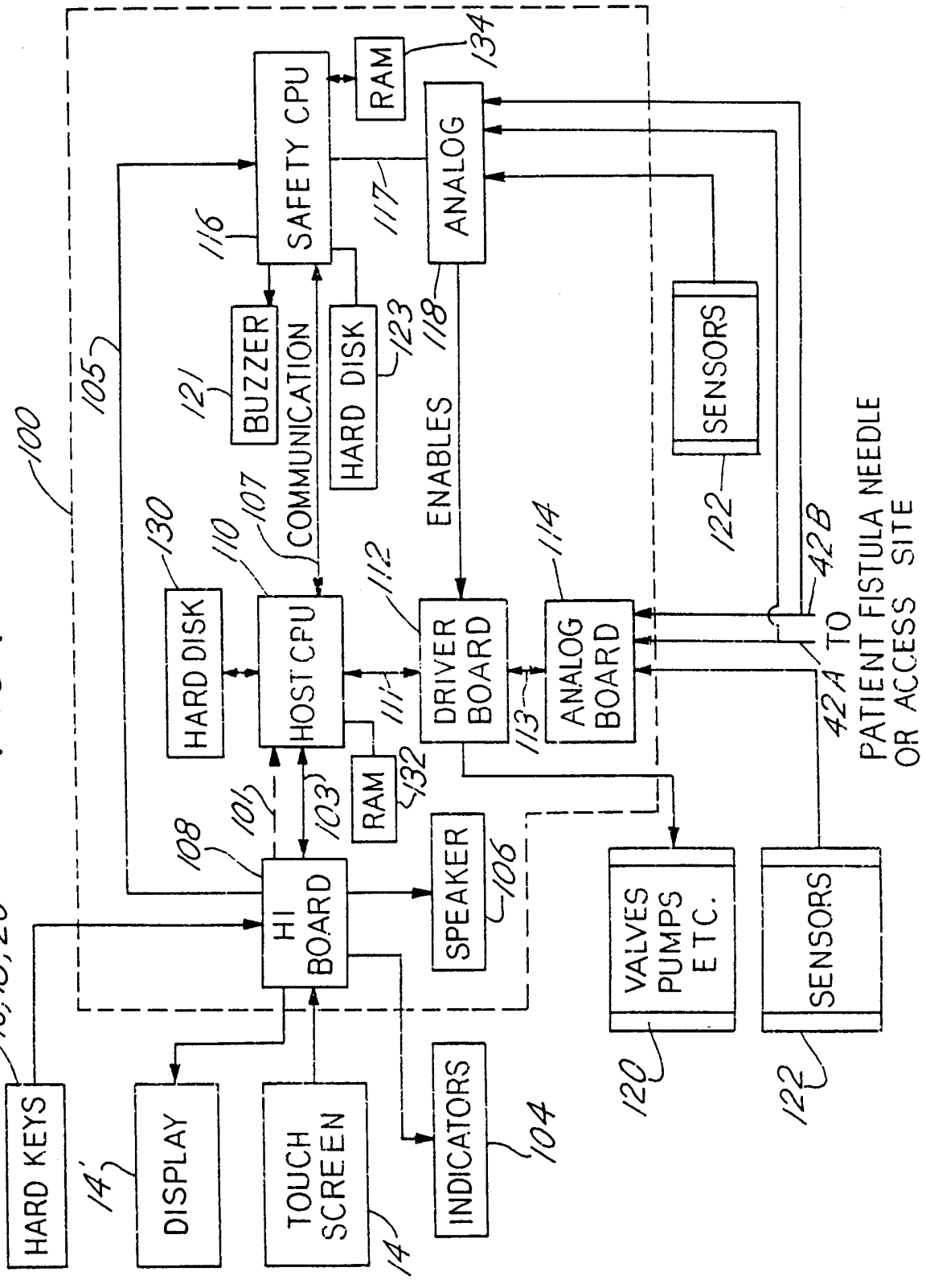

17
TO
DIALYZER
74
13
A
71
TO COMPUTER
OR ALARM
CIRCUIT
19
B
TO
PATIENT
15
73
74
72

FIG.6

FIG. 7


100
105
SAFETY CPU
RAM
134
116
ANALOG
117
BUZZER
121
COMMUNICATION
HARD DISK
123
118
ENABLES
SENSORS
122
130
HARD DISK
110
107
HOST CPU
112
DRIVER BOARD
114
ANALOG BOARD
428
42A TO PATIENT FISTULA NEEDLE OR ACCESS SITE
111
113
RAM
132
101
103
108
HI BOARD
SPEAKER
106
VALVES PUMPS ETC.
120
SENSORS
122
16, 18, 20
HARD KEYS
14'
DISPLAY
TOUCH SCREEN
14
INDICATORS
104

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19266

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B01D 35/00, 35/14, 35/143, 35/153
US CL : 210/085
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 210/085, 097, 143, 645, 646, 739, 746; 604/004, 005, 006

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

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

APS
search terms: blood, dialysis, pump, fistula, membrane

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 3,864,676 A (MACIAS ET AL) 04 February 1975; items 10, 12, 14, 22, 24, and 30; column 2, lines 29-36, 57-63; column 4, lines 48-57; column 1, lines 50-56.	7-10 ------- 1-6, 11-19
Y	US 4,083,777 A (HUTCHISSON) 11 April 1978; column 7, lines 4-19; items 11, 12, 15, 20, 24, and 35; column 5, lines 12-17; column 8, lines 26-32, 50-58.	1-6, 11-19

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
05 NOVEMBER 1998	17 DEC 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL FLEMING Telephone No. (703) 308-0651

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