EXHIBIT A

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Marttila

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[54] **MEDICINAL FLUID PUMP HAVING MULTIPLE STORED PROTOCOLS**

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[21] Appl. No.: **369,732**

[22] Filed: **Jan. 6, 1995**

[51] **Int. Cl.**[6] **A61M 1/00**

[52] **U.S. Cl.** **604/65**

[58] **Field of Search** ..... 604/65–67, 30, 604/31, 32–34, 246, 249; 128/DIG. 12, DIG. 13

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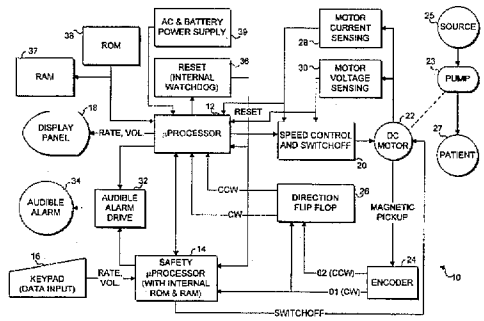
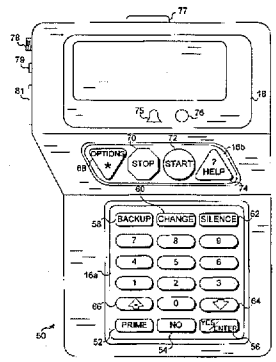
Attorney, Agent, or Firm—Neal D. Marcus

[57] **ABSTRACT**

A pump (**23**) used to infuse a fluid into a patient (**27**) is controlled in accordance with a plurality of parameters entered by an operator. These parameters define a protocol that is applied in controlling the operation of the pump to determine the rate, volume, and timing of the fluid infusion. The operator enters the parameters using a keypad (**16**) in response to prompts provided on a display (**18**). Once the parameters for a current protocol are entered, they can be stored as a speed protocol by selecting that option from a menu appearing on the display. Up to three speed protocols can be stored in memory in the disclosed preferred embodiment. When preparing to infuse a medicinal fluid, an operator can elect to enter a new protocol or to select an appropriate speed protocol stored in memory for loading as the current protocol. Use of stored speed protocols saves time and reduces the likelihood of errors that can occur when data defining the parameters controlling the infusion process are entered by an operator.

22 Claims, 8 Drawing Sheets





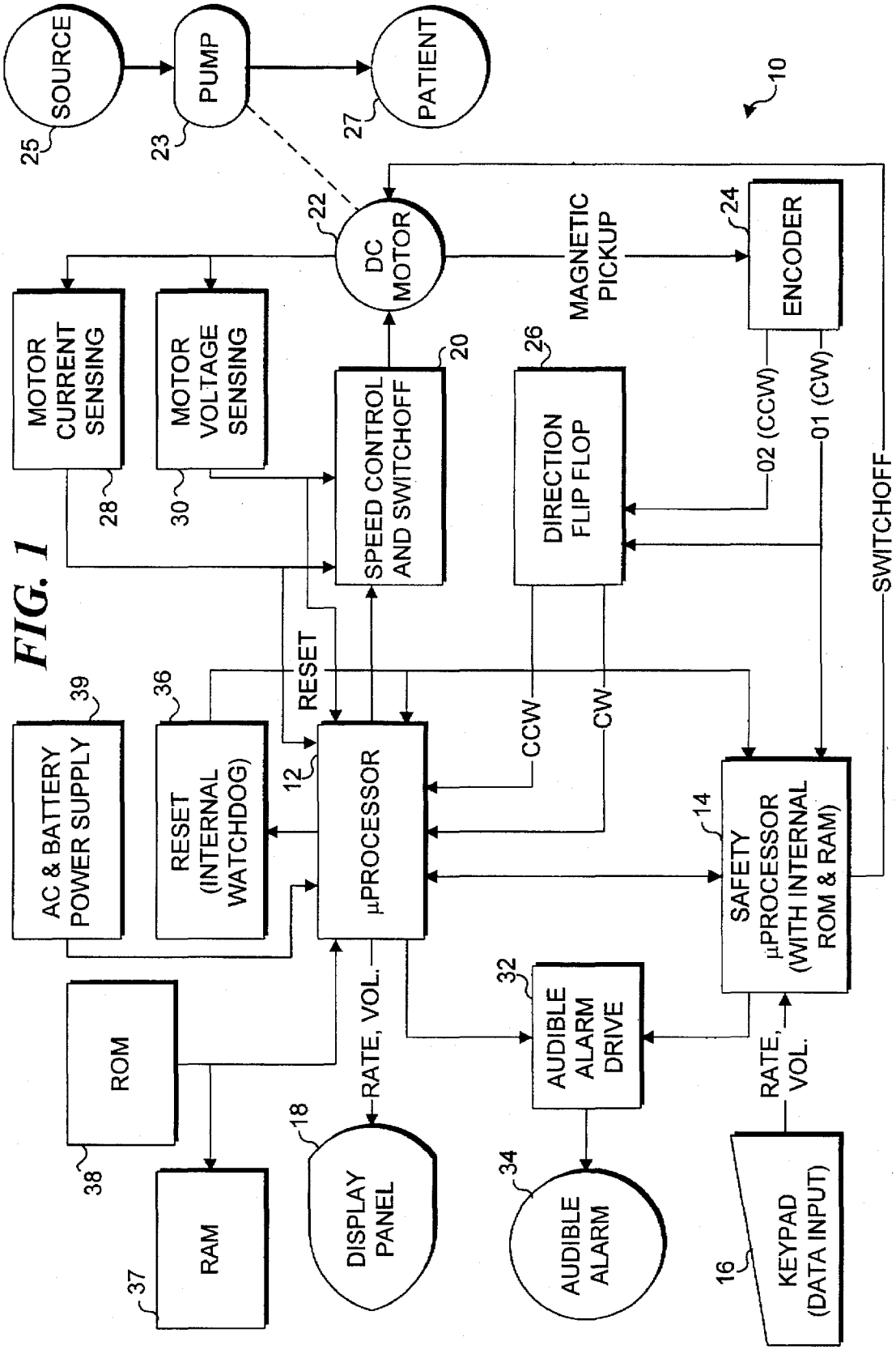

SOURCE
25
PUMP
23
PATIENT
27
10
22
DC MOTOR
MAGNETIC PICKUP
24
ENCODER
MOTOR CURRENT SENSING
28
MOTOR VOLTAGE SENSING
30
SPEED CONTROL AND SWITCHOFF
20
26
DIRECTION FLIP FLOP
02 (CCW)
01 (CW)
SWITCHOFF
RESET
39
AC & BATTERY POWER SUPPLY
36
RESET (INTERNAL WATCHDOG)
12
µPROCESSOR
CCW
CW
14
SAFETY µPROCESSOR (WITH INTERNAL ROM & RAM)
32
AUDIBLE ALARM DRIVE
ROM
38
RAM
37
RATE, VOL.
18
DISPLAY PANEL
34
AUDIBLE ALARM
RATE, VOL.
16
KEYPAD (DATA INPUT)

FIG. 1

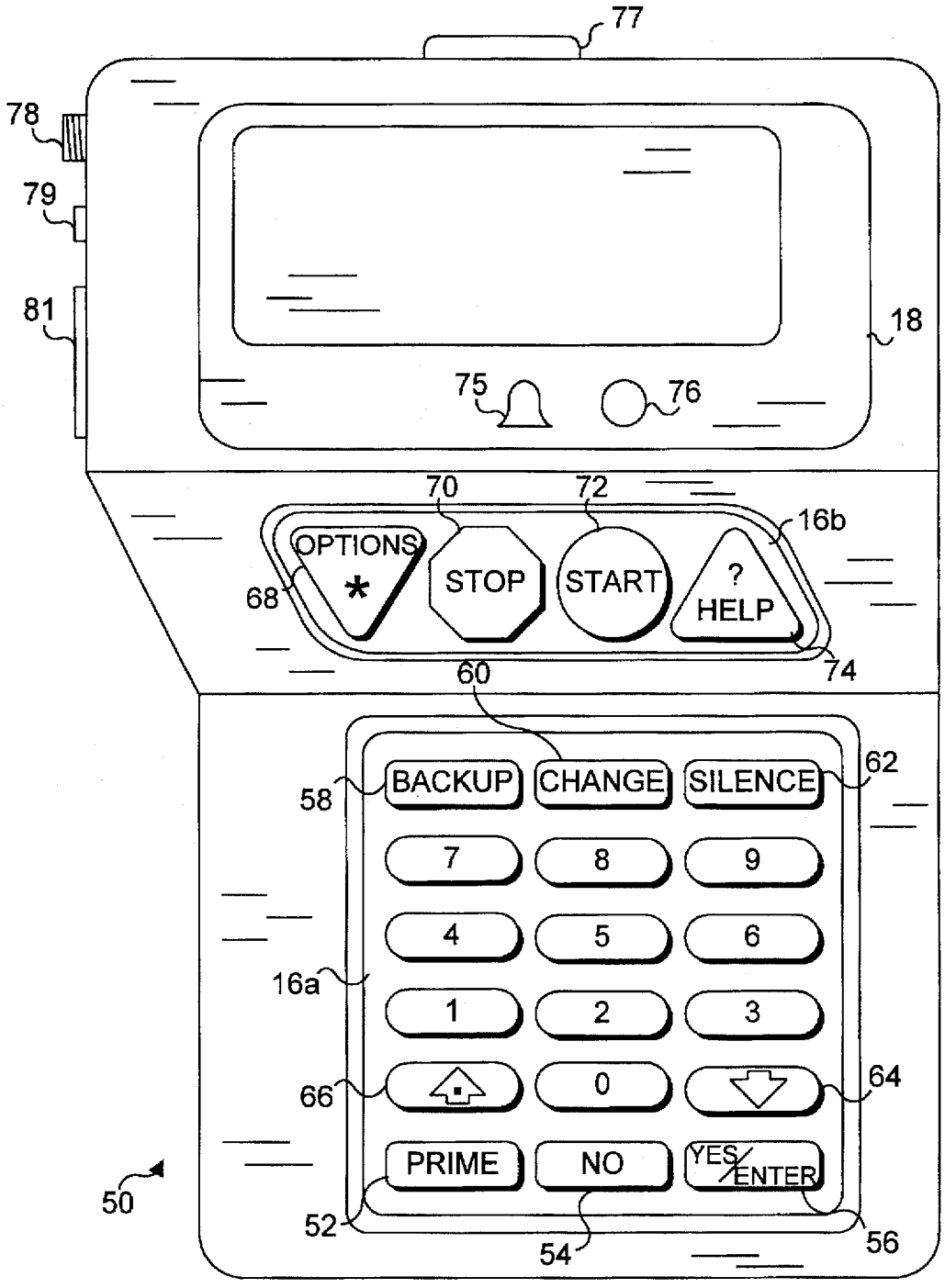

77
78
79
81
18
75
76
70
72
16b
OPTIONS
*
68
STOP
START
?
HELP
74
60
BACKUP
CHANGE
SILENCE
58
62
7
8
9
4
5
6
16a
1
2
3
66
0
64
PRIME
NO
YES
ENTER
50
52
54
56

FIG. 2

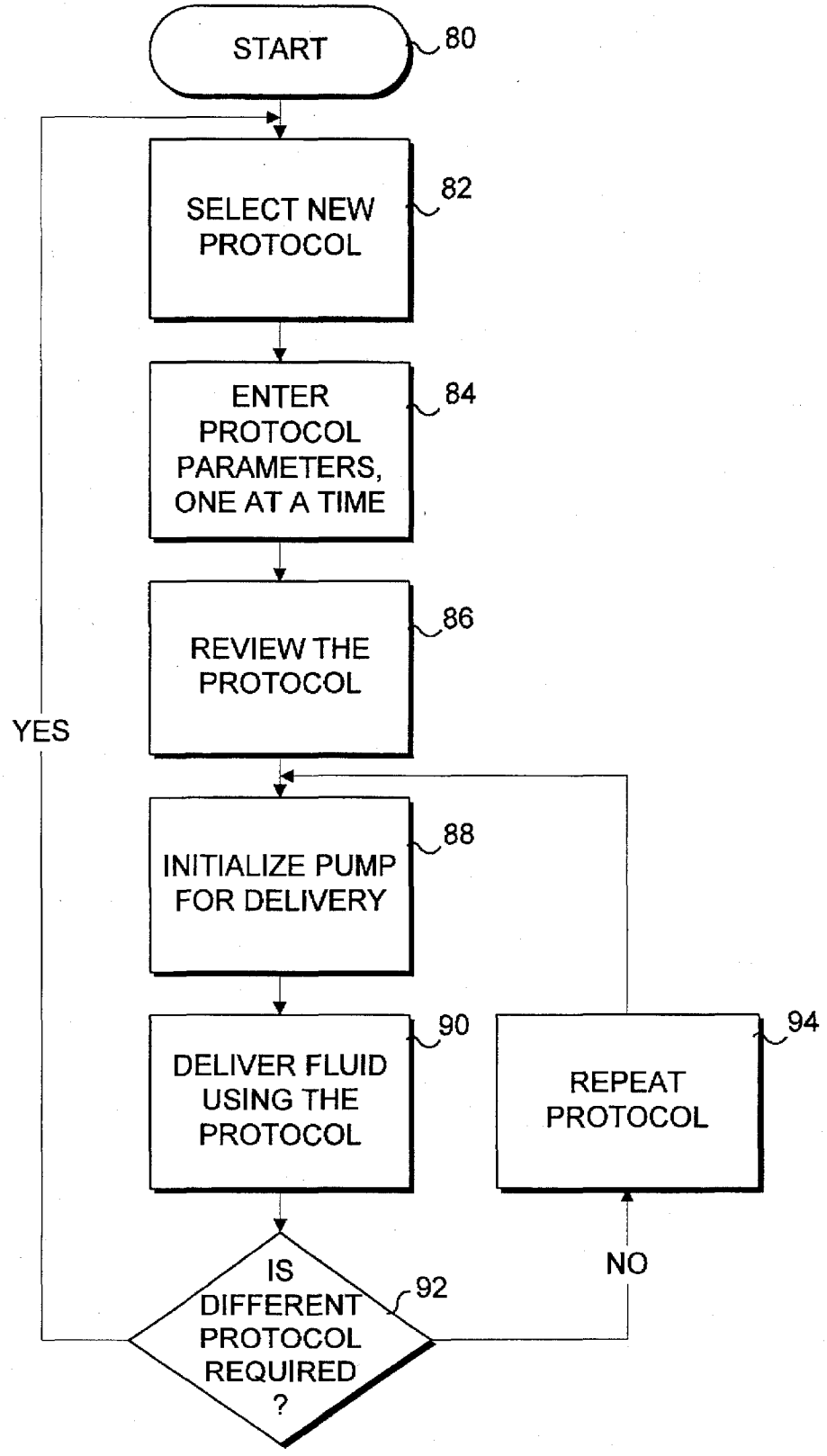

START
80
SELECT NEW PROTOCOL
82
ENTER PROTOCOL PARAMETERS, ONE AT A TIME
84
REVIEW THE PROTOCOL
86
YES
INITIALIZE PUMP FOR DELIVERY
88
DELIVER FLUID USING THE PROTOCOL
90
REPEAT PROTOCOL
94
NO
IS DIFFERENT PROTOCOL REQUIRED ?
92

FIG. 3

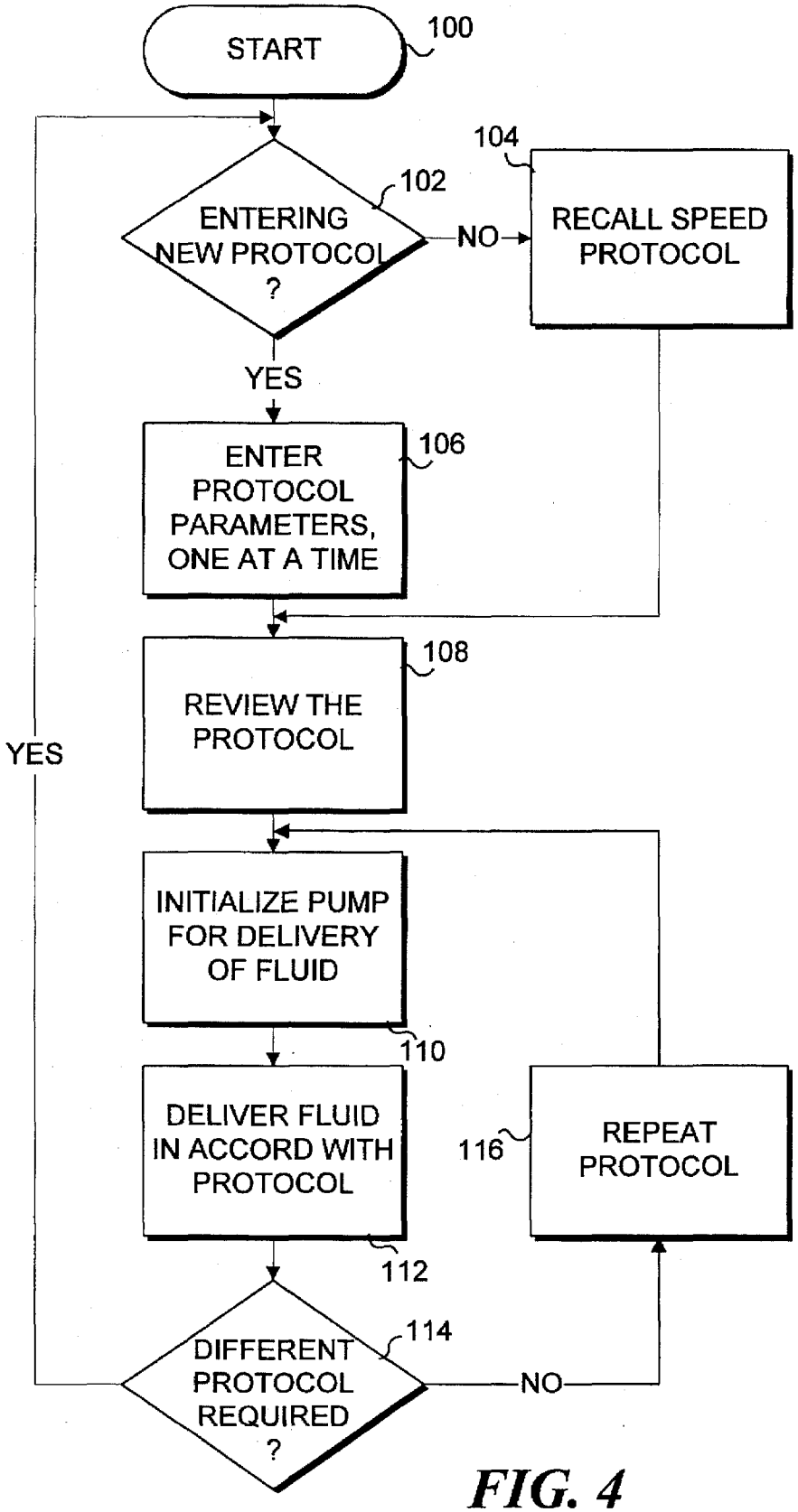

START
100
ENTERING NEW PROTOCOL ?
102
NO
104
RECALL SPEED PROTOCOL
YES
ENTER PROTOCOL PARAMETERS, ONE AT A TIME
106
REVIEW THE PROTOCOL
108
YES
INITIALIZE PUMP FOR DELIVERY OF FLUID
DELIVER FLUID IN ACCORD WITH PROTOCOL
110
112
REPEAT PROTOCOL
116
DIFFERENT PROTOCOL REQUIRED ?
114
NO

FIG. 4

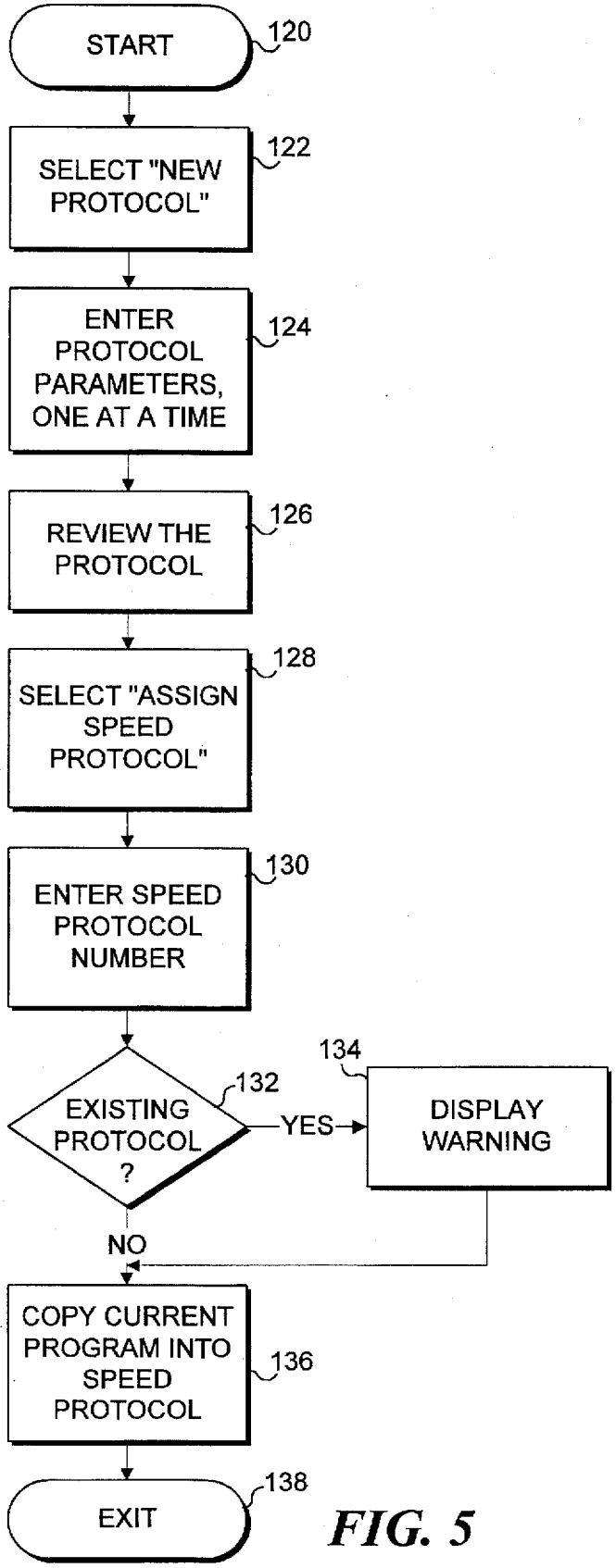

START
120
SELECT "NEW PROTOCOL"
122
ENTER PROTOCOL PARAMETERS, ONE AT A TIME
124
REVIEW THE PROTOCOL
126
SELECT "ASSIGN SPEED PROTOCOL"
128
ENTER SPEED PROTOCOL NUMBER
130
EXISTING PROTOCOL ?
132
YES
134
DISPLAY WARNING
NO
COPY CURRENT PROGRAM INTO SPEED PROTOCOL
136
EXIT
138

FIG. 5

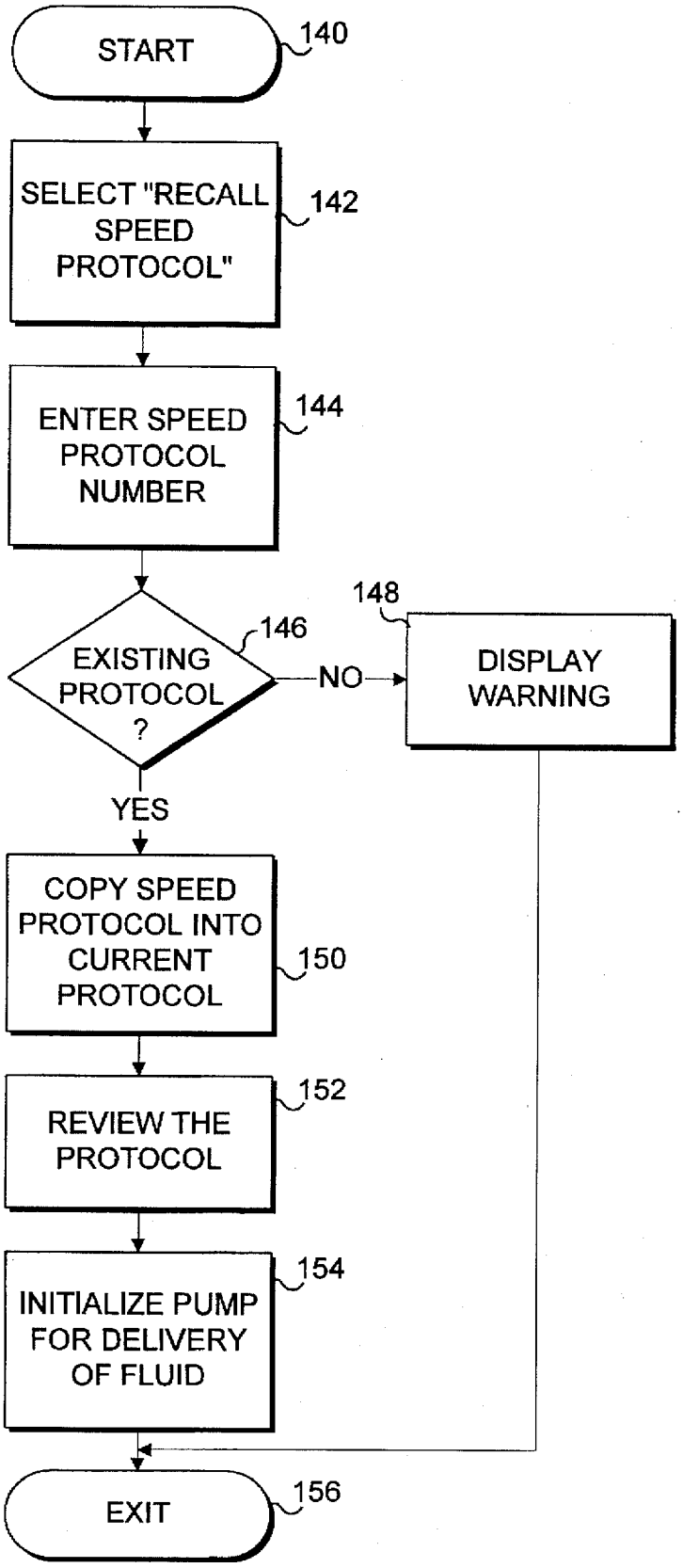

START
140
SELECT "RECALL SPEED PROTOCOL"
142
ENTER SPEED PROTOCOL NUMBER
144
EXISTING PROTOCOL ?
146
NO
148
DISPLAY WARNING
YES
COPY SPEED PROTOCOL INTO CURRENT PROTOCOL
150
REVIEW THE PROTOCOL
152
INITIALIZE PUMP FOR DELIVERY OF FLUID
154
EXIT
156

FIG. 6

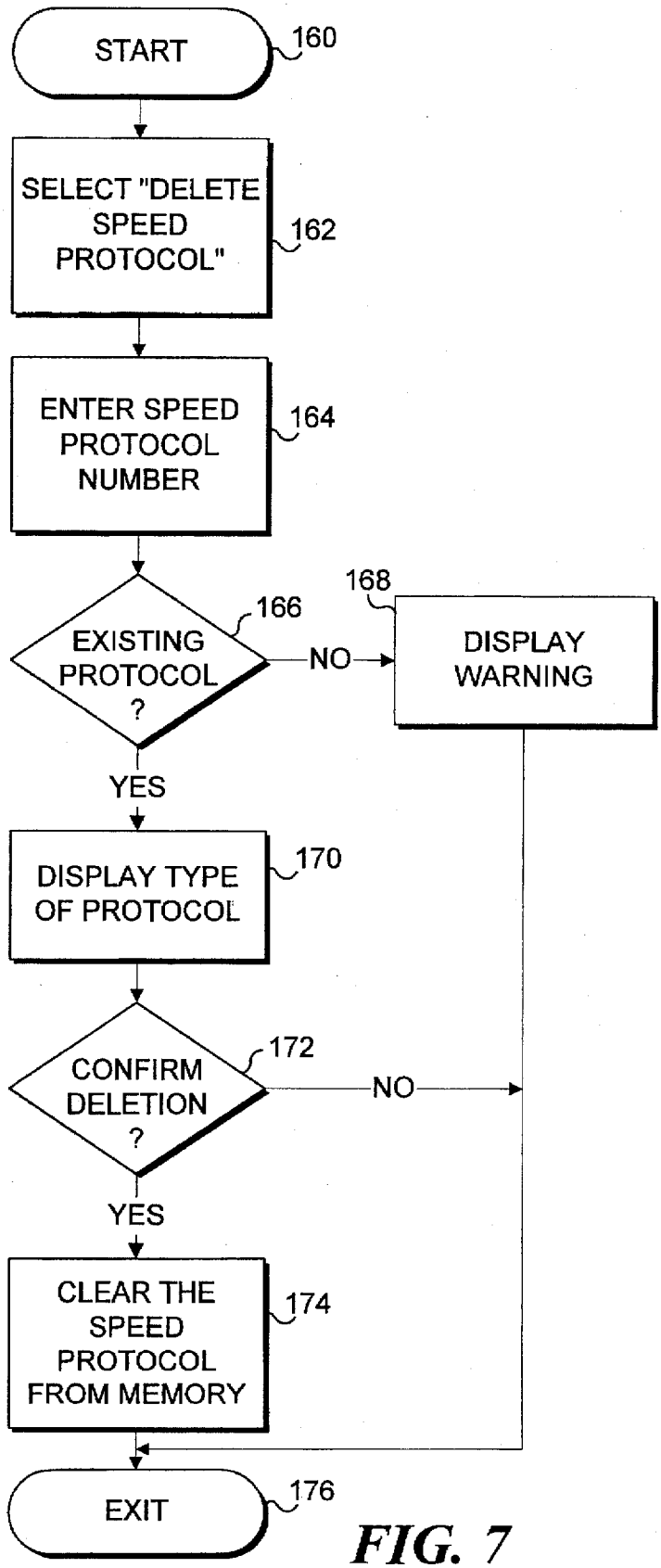

START
160
SELECT "DELETE SPEED PROTOCOL"
162
ENTER SPEED PROTOCOL NUMBER
164
EXISTING PROTOCOL ?
166
NO
168
DISPLAY WARNING
YES
DISPLAY TYPE OF PROTOCOL
170
CONFIRM DELETION ?
172
NO
YES
CLEAR THE SPEED PROTOCOL FROM MEMORY
174
EXIT
176

FIG. 7

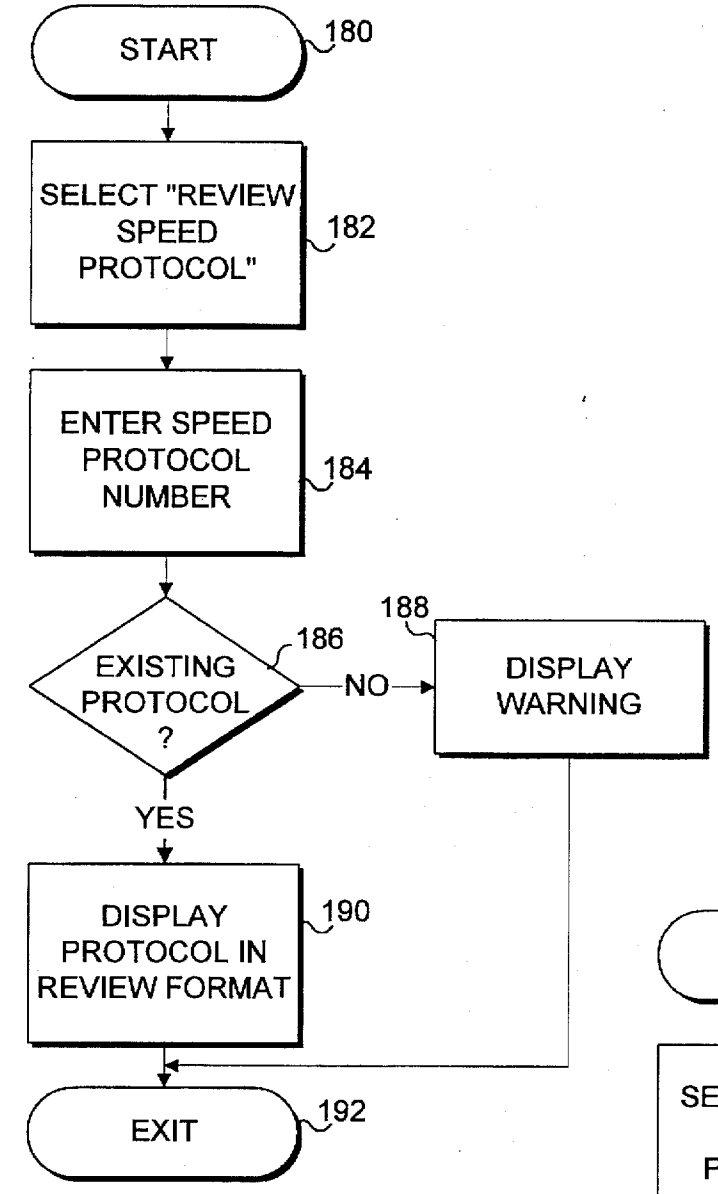

START
180
SELECT "REVIEW SPEED PROTOCOL"
182
ENTER SPEED PROTOCOL NUMBER
184
EXISTING PROTOCOL ?
186
NO
188
DISPLAY WARNING
YES
DISPLAY PROTOCOL IN REVIEW FORMAT
190
EXIT
192

FIG. 8

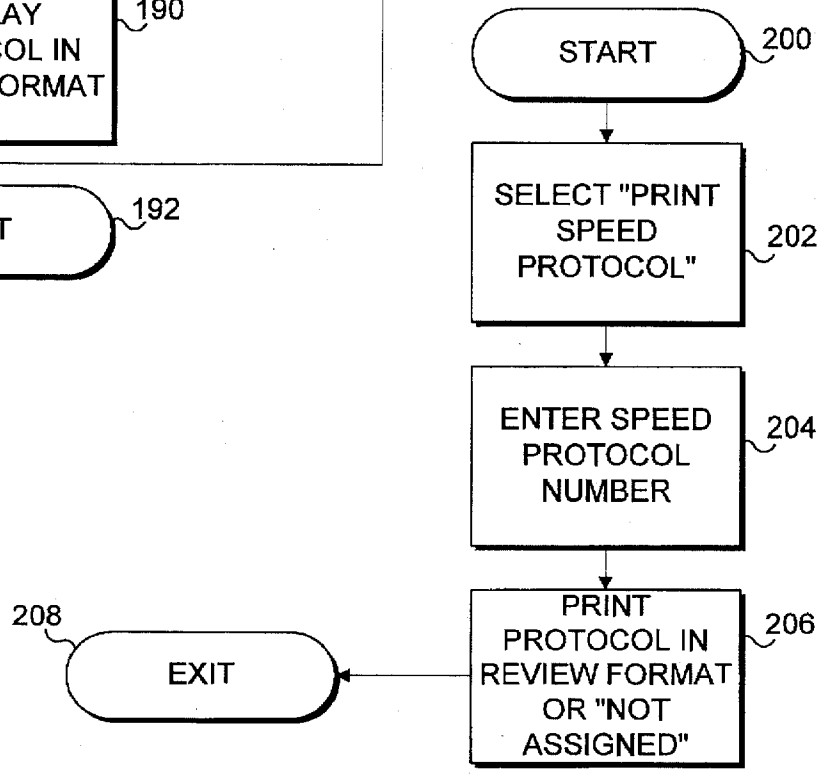

START
200
SELECT "PRINT SPEED PROTOCOL"
202
ENTER SPEED PROTOCOL NUMBER
204
PRINT PROTOCOL IN REVIEW FORMAT OR "NOT ASSIGNED"
206
EXIT
208

FIG. 9

MEDICINAL FLUID PUMP HAVING MULTIPLE STORED PROTOCOLS

FIELD OF THE INVENTION

The present invention generally pertains to a pump for infusing medicinal liquids into a patient, and more specifically, to a pump that is controlled in accordance with a plurality of parameters that are entered by an operator.

BACKGROUND OF THE INVENTION

Cassette, peristaltic, and other types of motor or solenoid driven pumps are widely employed to infuse medicinal fluids into the cardiovascular systems of patients. These pumps often include a controller that determines the rate at which the medication is infused, the volume or dosage of medicinal fluid administered, whether it is delivered as a bolus or continuous infusion, the time that the administration occurs, and/or the interval of time that the pump will operate. These parameters and others are usually entered into an electronic memory for the pump controller via a user interface control panel on the pump by medical personnel, based upon the type and concentration of the drug being administered, and patient specific data, such as the patient's weight, age, gender, and medical condition. Although entry of the parameters that control the pump's operation may be relatively straightforward, several minutes may be required to specify all of the data required to define a drug delivery protocol. More importantly, each time that a pump is programmed to administer a specific medicinal fluid, there is a risk that human error may cause improper values for the parameters to be entered.

To avoid the potential risks involved in programming a pump each time it is used to deliver a different type of medication, it is not uncommon for hospitals and other medical facilities to purchase and employ multiple pumps, with each pump programmed to administer a particular type of drug in a defined manner. Any programming required to tailor the administration of a drug to a patient is thereby minimized by using a separate pump for each type of drug and delivery protocol commonly required. Thus, one pump will be used to administer a certain pain management drug, and a different pump will be programmed to continuously administer a saline/glucose fluid. The only changes required for a use of a pump with each patient receiving the same type of medicinal fluid may be the entry of one or more patient dependent parameters, such as the total drug volume to be delivered. Alternatively, if a single pump of the conventional type is used to administer different drugs involving totally different protocols, a medical practitioner trained to program the pump must be available each time that it is used to infuse a different drug. A medical facility must therefore either maintain a pump programmed for each drug typically infused or must ensure that properly trained personnel are always available to reprogram a pump each time that it is used to administer a different drug. However, the latter solution to this problem increases the risk that a life-threatening error might occur when the pump is reprogrammed and requires that properly trained personnel always be available to reprogram the pumps that are used.

Clearly, it would be desirable if a pump could be used to administer different types of medicinal fluids without the need for manual reprogramming each time that the type of medicinal fluid infused is changed. In U.S. Pat. No. 4,676,776, a system is disclosed that includes a delivery unit, which is remotely coupled to a programming unit through a telephone line and modem. Alternatively, the system will

accept a programmable logic cartridge that is programmed by the programming unit and hand-carried to the pump. The remote programming unit includes an operationally independent computer that manages the protocols for operating the fluid delivery unit. The computer of the programming unit has access to a number of both predefined and operator programmed protocols that are stored in a database integral within its memory. The delivery unit does not require a microprocessor to define the protocol for delivering a fluid, since all of the operational parameters are set by the remote computer in the programming unit. Each time that the delivery unit is to be used to administer a different drug, the appropriate predefined or operator defined protocol for that drug is downloaded from the remote computer into a control and logic module of the delivery unit. However, only one protocol at a time can be loaded into the delivery unit. Either the telephone/modem interconnection or a programmable logic cartridge suitably programmed for the correct drug must be used to transfer the protocol that will be employed from the remote computer into the delivery unit.

The requirement for transferring the protocol from the remote computer to the delivery unit represents a significant drawback to this prior art infusion system, since it is often not convenient to physically transport a programmable logic cartridge between a remote computer and the delivery unit or to arrange for a modem and telephone line interconnection between the computer in the programming unit and the logic module of the delivery unit. The patent specifically teaches that it is advantageous to employ a remote computer for defining the protocol because microprocessors used to control pumps are subject to possibly undetected failures and have limited processing capability.

Other types of conventional pumps include multiple channels, each channel being capable of infusing a different type of drug into a patient according to a different delivery protocol. However, even these pumps do not enable the operator to select between different previously stored protocols for the administration of a medicinal fluid on a single channel. Accordingly, each time that a channel is used to deliver a different type of drug than that previously administered, the protocol for the new drug must be reentered into the pump for that channel.

None of the prior art pumps for administering drugs via a specific channel allow an operator to store protocols for different drugs integrally within the pump. Integral storage of the different protocols within the pump is important to obviate the need to transfer a selected protocol from a remote computer, and more importantly, to avoid the cost of a separate computer in which such protocols are stored in a database.

SUMMARY OF THE INVENTION

In accordance with the present invention, a pump is defined for administering a fluid to a patient. The pump includes a fluid drive unit that is adapted to couple with a fluid line and to force fluid from a source to the patient through the fluid line. A control is coupled to the fluid drive unit to control its operation. Also provided is a memory in which a plurality of protocols are stored. These protocols each specify at least one parameter that is used to control the fluid drive. A user interface that is integral with the pump and is coupled to the control and to the memory enables the operator to enter at least one parameter for any of the plurality of protocols. With the user interface, one of the protocols can be selected for use by the control in actively controlling the operation of the drive unit so as to administer the fluid to the patient.

Preferably, the parameter entered by the operator includes one of a continuous fluid flow, an intermittent fluid flow, and a bolus fluid flow. It can also include one of a rate of fluid flow, a volume of fluid flow, a time of fluid flow, and a duration of fluid flow. In addition, the parameter may comprise a varying rate of fluid flow.

The user interface enables the operator to define a current protocol and to store the current protocol as one of the plurality of protocols in the memory. The control cooperates with the user interface to enable the operator to review one of the plurality of protocols stored in the memory while the drive unit is being operated in accordance with a different one of the plurality of protocols. Furthermore, the user interface enables the operator to recall one of the plurality of protocols from memory so that it can be employed as a currently active protocol used by the control in controlling the drive unit. In addition, the user interface enables the operator to modify the currently active protocol prior to storing it in the memory. Since the plurality of protocols are integrally stored in memory, a change in the drug that is to be delivered is readily accommodated simply by recalling the protocol from memory that is appropriate for administering the drug. In most cases, there is no need to completely redefine the protocol that must be used each time that the pump is employed to administer a different drug.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. **1** is a schematic block diagram of a controller for a pump embodying the present invention;

FIG. **2** is a front elevational view of the pump of FIG. **1**;

FIG. **3** is a flow chart showing the steps for operating the pump without use of a speed protocol;

FIG. **4** is a flow chart illustrating the logic involved in operating the pump using speed protocols;

FIG. **5** is a flow chart showing the logical steps for assigning a new speed protocol;

FIG. **6** is a flow chart showing the logical steps for recalling a speed protocol that is stored in memory;

FIG. **7** is a flow chart illustrating the steps for deleting a speed protocol from among those stored in memory;

FIG. **8** is a flow chart showing the steps involved in reviewing a speed protocol; and

FIG. **9** is a flow chart showing the steps involved in printing a speed protocol.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to FIG. **1**, a block diagram illustrates the components comprising a control **10** for an integral pump **23** that is used for infusing medicinal fluids from a source **25** into a patient **27** in accordance with the present invention. While the preferred embodiment of this pump forces fluid to flow through a tube set (not shown) using a peristaltic pump **23**, it will be apparent from the following description that other types of pumping apparatus (such as a cassette pump) could also implement the present invention, thereby providing the benefits of accessing stored protocols when the pump is used to deliver different drugs or medicinal fluids.

Control **10** includes a microprocessor **12**, which implements the primary control functions required to operate pump **23**. These functions are defined by a set of program steps that are stored within a read only memory (ROM)**38**. The program steps stored in ROM **38** are in the form of a binary code, which is executed by microprocessor **12** to control the operation of various components of the pump following an operator defined protocol. To improve safety and reduce the number of single point failures, a redundant safety microprocessor **14** is included. Safety microprocessor **14** includes internal ROM and random access memory (RAM). In the preferred embodiment, a Motorola Corporation Model MC68L11K1 integrated circuit is used for microprocessor **12**, and a Motorola Corporation Type MC68HC705C8 integrated circuit is used for safety microprocessor **14**. The preferred embodiment employs an integrated circuit for ROM **38** that has a capacity to store up to 256K bytes of program steps and control data. In addition, an external integrated circuit RAM **37** with a capacity of 32K bytes is coupled to microprocessor **12** to provide storage for data and variables. Data stored within KAM **37** is maintained so long as electrical power is supplied to it. Electrical power is supplied to the pump from either an AC line power supply or a battery pack (conventional or rechargeable), as indicated by AC and battery power supply **39**. When both the AC and normal battery power supply is interrupted a backup (lithium) battery (not separately shown) provides power to the control circuitry. Thus, even when pump **23** is not operating, the data stored within the RAM are retained.

Safety microprocessor **14** is responsible for reading data input by an operator on a keypad **16**, monitoring motor speed, and providing data access through an RS-232 serial port (not shown). Using the keypad, the operator can specify parameters such as the percentage of volume, the rate, and/or the volume that will be used for administering a particular medicinal fluid. Microprocessor **12** is coupled to safety microprocessor **14** to receive these data for presentation to the operator on a display panel **18**, which is directly coupled to microprocessor **12**.

Operation of pump **23** is controlled by microprocessor **12** with signals that are input to a speed control and switch off circuit **20**. This circuit is connected to a DC motor **22** to control its rate of rotation. Since the preferred embodiment of the present invention pumps fluid using a peristaltic cassette, the rate at which fluid is administered to a patient is directly proportional to the rate at which DC motor **22** rotates. It will thus be apparent that speed control **20** is used for controlling DC motor **22** to achieve the desired rate for infusing fluid into the patient. DC motor **22** includes a Hall effect magnetic pickup (not separately shown) that produces rotational rate signals, which are applied as an input signal to an encoder **24**. Encoder **24** processes this input signal, producing a corresponding digital signal "01" indicating the rate of rotation in the clockwise (CW) direction or a corresponding digital signal "02" indicating the rate of rotation in the counterclockwise (CCW) direction. The digital signal corresponding to the rate of rotation in the CW direction is input to both a direction flip flop circuit **26** and to safety microprocessor **14**, while the digital signal indicative of the rate of rotation in the CCW direction is input only to direction flip flop **26**.

In normal operation, the DC motor and the pump rotate in a CW direction. The DC motor has an attached gearbox (not separately shown), but the encoder indicates shaft revolutions of the DC motor ahead of the gearbox—not at the gearbox output shaft. Slight rotation of the DC motor in the

CCW direction can occur due to gearbox "wind-up," especially when the DC motor is turned off and comes to a stop. When the DC motor is again energized, it turns a few degrees before the output shaft actually starts turning. There will thus be "extra" encoder pulses produced that do not accurately account for output gearbox shaft revolutions. On the average, the number of extra CW pulses produced when the DC motor starts will be equal to the number of CCW pulses produced when the DC motor stops. If the number of CCW pulses is subtracted from the total CW pulses, the error in the total CW pulses is corrected, thereby improving flow rate accuracy. This accuracy improvement is significant at low flow rates (less than 1 cc/hr).

Certain fault conditions, such as an empty fluid source container, can cause microprocessor **12** to stop the DC motor. Safety microprocessor **14** can also issue a switch off command to DC motor **22** if it detects that the pump is operating abnormally or requires operator intervention to correct a problem.

To enable control **10** to properly control the rate of rotation of DC motor **22**, a motor current sensing circuit **28** provides a current feedback signal to microprocessor **12** and to the speed control. Similarly, a motor voltage sensing circuit **30** provides another feedback signal indicative of the voltage across the windings of the DC motor to microprocessor **12** and to the speed control. These two feedback signals and control signals supplied by microprocessor **12** are employed by speed control and switch off circuit **20** to set and maintain the average rotational speed of DC motor **22** to achieve the desired drug infusion rate.

Either microprocessor **12** or safety microprocessor **14** will respond to conditions requiring operator intervention by activating an audible alarm drive circuit **32**. The audible alarm drive circuit produces a drive signal that is applied to an audible alarm **34**, causing it to produce a distinctive alarm sound that is used to attract the attention of the operator. Upon hearing the audible alarm sound, the operator knows to check the pump to determine the appropriate corrective action that must be taken. For example, an air-in-line sensor (not shown) monitors the infusion line to detect air bubbles. If air bubbles larger than a predefined size are detected in the infusion line, the air-in-line sensor produces a signal to which microprocessor **12** will respond by stopping the DC motor and activating the audible alarm.

A reset circuit **36** serves as an internal watchdog by checking the software strobing rate on microprocessor **12**. If software strobing (a timing signal indicative of the rate at which the microprocessor is executing machine instructions) is not within a predefined range, the reset circuit issues a reset command to both microprocessor **12** and safety microprocessor **14**.

Referring now to FIG. **2**, the user interface, which appears on the front of a pump **50**, includes a lower keypad section **16*a***, an upper keypad section **16*b***, and a display **18**, which is disposed above the upper keypad section. Lower keypad section **16*a*** includes 18 keys arranged in an array of three columns and six rows. In addition to the conventional numeric keys 0 through 9, lower keypad **16*a*** includes several special purpose keys. A "PRIME" key **52** is depressed by the operator to manually energize the pump in order to prime and clear air from the infusion line before it is connected to the patient's body. A key **54** labeled "NO" is depressed to enter a negative response to questions that appear on display **18**. Conversely, a key **56** labeled "YES/ENTER" is provided to enable the operator to respond in the affirmative to questions appearing on display **18** and to register a numeric entry or to advance to the next display screen when entering data. A key **58** labeled "BACKUP" is used to exit a history or a Help display. In addition, key **58** is used to access previous steps that were entered by the operator when programming the control for a new protocol. Furthermore, the BACKUP key is used for exiting "CHANGE" and "OPTIONS" modes.

A key **60**, which is labeled "CHANGE," is used to correct an entry when entering data, for reviewing a program, when changing containers, to enter a new program, and to change a therapy. A "SILENCE" key **62** temporarily silences audible alarm **34** (shown in FIG. **1**), enabling the operator to correct the condition that initially caused the alarm without the annoyance of the audible signal continuing.

A combined upwardly pointing arrow and a period appear on a key **66**. Similarly, a downwardly pointing arrow appears on a key **64**. The up and down arrow keys are used for scrolling through menu selections and through the history of drug infusion that can be selectively provided on display **18**. In addition, these two keys are used for scrolling through input selections when entering an infusion protocol. Key **66** is also used for entering a decimal point in numeric data.

In upper keypad **16*b***, an "OPTIONS" key **68** can be depressed to selectively review a protocol, display, print or clear a drug infusion history for a patient, selectively lock or unlock the keypad, set the air-in-line alarm, set an internal clock used by control **10**, access speed protocols, adjust screen contrast and sound level, and to display an alarm log. A hexagonal-shaped key **70**, which is labeled "STOP," is provided to enable the operator to selectively stop an infusion at any time. Similarly, a key **72** labeled "START" is provided to enable the operator to start the infusion. As already noted, the operator can access a help screen at any time by depressing key **74**.

In the lower portion of display **18** is included a bell-shaped visual signal (light emitting diode (LED))**75**, which is lighted when an alarm condition occurs. Another visual signal **76** is lighted when the pump is powered using AC line power (instead of the internal power pack batteries).

On the top surface of the pump is disposed a bolus switch **77**, which the operator can depress to manually deliver a bolus of the drug currently being infused if the pump is programmed to do so. A jack **79** is provided on the left upper side of the pump to accept a lead from a remote bolus switch (not shown). This remote bolus switch can be activated by the patient when the pump is being used to deliver a pain management drug or for variable time drug infusions (if programmed). Also disposed on the left upper side of the pump is a fitting **78** to which an AC line cord (not shown) can be coupled, and a slide switch **81** that is used for turning the pump off and on.

In the preferred embodiment, the pump can be used for five distinct types of medicinal fluid infusion. Tables 1 through 5 show the various parameters that are entered to define the protocol used to control the pump for each type of infusion. The parameters can selectively be set to read in units of ml, mg, or μg.

TABLE 1

CONTINUOUS ONLY	
PARAMETER	RANGE/COMMENT
Rate	0.1 ml/hr–400 ml/hr
Container Size (Total Volume)	0.1 ml–9999.9 ml

TABLE 1-continued

CONTINUOUS ONLY

PARAMETER	RANGE/COMMENT
Air-in-line Alarm Sensitivity (Hi, Low, Off)	Hi (Bubbles > 75 µl nominal) Low (Bubbles > 250 µl nominal) Off (Bubbles > 2 ml nominal)

TABLE 2

PARENTERAL NUTRITION

PARAMETER	RANGE/COMMENT
Container Size (Total Volume)	1 ml–9999 ml
All Combinations of Taper Up, Taper Down & Continuous	Taper is a gradually increasing or decreasing delivery rate
Parenteral Nutrition Volume	1 ml–9600 ml
Total Time for Infusion	1 min to 24 hr
Time Interval for Taper Infusion (If Selected)	1 min to 3 hr
Air-in-line Alarm Sensitivity (Hi, Low, Off) - Optional	Hi (Bubbles > 75 µl nominal) Low (Bubbles > 250 µl nominal) Off (Bubbles > 2 ml nominal)
Keep Vein Open (KVO) - Optional	1 ml/hr–5 ml/hr

Parenteral Nutrition provides infusion of nutrient fluids that are necessary when a patient is unable to eat food, for example, because of problems with the gastrointestinal system. The rate at which the nutrient solution is infused can be programmed to taper up or down, or to continue on a continuous basis, or any combination of these three variables. The KVO option ensures that sufficient fluid is infused between programmed infusions to prevent blood clots from forming in the vein or in the catheter through which the fluid is infused.

TABLE 3

PAIN MANAGEMENT

PARAMETER	RANGE/COMMENT
Select Delivery Mode	Bolus, Continuous, or Combo
Container Size (Total Volume)	0.1 ml–9999.9 ml
Rate	0.1 ml/hr–25.0 ml/hr
Size of Bolus (If Bolus Delivery Mode is Used)	Up to 25 ml (5 ml if subcutaneous infusion) - or subject to Limits
Bolus Lockout (If Bolus Used)	5 min–999 min (Time Between Boluses)
Infusion Site and Rate Limits at Each	Intravenous or Epidural: 25 ml/hr Subcutaneous: 5 ml/hr
Loading Dose (Clinician Administered Bolus)	Not subject to Lockout, but subject to Limits
Limit Number of Boluses Administered	For example, 2 boluses/hr
Four Hour Volume Limit	Max. total volume in 4 hr period
Subcutaneous Limit	5 ml/hour of Drug Delivery
Air-in-line Alarm Sensitivity (Hi, Low, Off) - Optional	Hi (Bubbles > 75 µl nominal) Low (Bubbles > 250 µl nominal) Off (Bubbles > 2 ml nominal)

Since pain management often enables patient controlled bolus infusion of pain killing drugs, this type of infusion protocol enables the clinician to limit the bolus infusions in several ways. The size of each bolus is defined by the protocol, as are the minimum time between successive boluses and the number of bolus infusions per hour. A further limit is the total volume delivered during a four-hour period. Medical personnel can selectively deliver a bolus infusion or loading dose more frequently than allowed by the bolus lockout time, but are limited by the total volume delivered. The infusion site selected introduces a limit on the volume of the drug delivered to the patient, whether by bolus, continuous, or a combination of bolus and continuous infusion.

TABLE 4

INTERMITTENT

PARAMETER	RANGE/COMMENT
Container Size (Total Volume)	0.1 ml–9999.9 ml
Dose Size	0.1 ml–9600.0 ml
Time Interval for Delivery of Dose	1 min–24 hr
Time Interval between Start of Dose Deliveries	Time interval for delivery of dose up to 24 hr
KVO (Optional)	0.1 ml/hr–5 ml/hr
Delayed Start Time (Optional)	
Air-in-Line Sensitivity (Hi, Low, Off) - Optional	Hi (Bubbles > 75 µl nominal) Low (Bubbles > 250 µl nominal) Off (Bubbles > 2 ml nominal)

The Intermittent type of infusion is often used to administer antibiotic therapy. Based on the two time intervals and the dose size, the control determines the appropriate rate of delivery.

TABLE 5

VARIABLE

PARAMETER	RANGE/COMMENT
Container Size (Total Volume)	0.1 ml–9999.9 ml
Phase Program: Enter Start Time, Stop Time, & Dose	1–12 Phases Chemotherapy - limited to 24 hr (One Phase Program required)
Optional Base Rate: Enter Start Time, Stop Time, & Rate	Rate- 0.1 ml/hr–400 ml/hr
Optional Bolus Dose (with Lockout Time)	Up to 25 ml
KVO (Optional)	0.1 ml/hr–5 ml/hr
Air-in-line Alarm Sensitivity (Hi, Low, Off) - Optional	Hi (Bubbles > 75 µl nominal) Low (Bubbles > 250 µl nominal) Off (Bubbles > 2 ml nominal)

The Variable type of infusion, which is typically used to administer chemotherapy, requires that at least one phase program be entered, by selecting the start and stop times, and the dose. In addition, an optional base rate infusion can be added to the protocol by selecting the start time, stop time, and rate.

In FIG. **3**, the steps required to enter parameters for use in controlling the pump to infuse a medicinal fluid are illustrated, beginning at a start block **80**. In a block **82**, the operator indicates that a new protocol is being selected. Specifically, the operator depresses button **60** and selects "NEW PROGRAM," indicating that the protocol is to be changed. In response, the control for pump **50** prompts the operator to select the type of infusion desired and then prompts the operator to enter each of the protocol parameters for the selected type of infusion, one at a time, as indicated in a block **84**. The various parameters that can be controlled by the operator in defining the protocol are noted in the preceding tables and depend upon the type of infusion selected. In addition, the operator can select the units that will be used for the parameters in defining the protocol.

In a block **86**, the protocol defined by the operator is shown on display **18** so that the operator can review it.

Assuming that it is correct, in a block **88**, the operator initiates the protocol to run by depressing START key **72**. As indicated in block **88**, this step initializes the pump for delivery of the fluid to be infused from the source container. When the control initializes, it zeroes out any prior values in memory and builds a control table based upon the protocol entered/selected by the operator. In a block **90**, the pump delivers the fluid to the patient, in accordance with the parameters comprising the protocol. A decision block **92** determines if a different protocol is required, based upon the operator depressing the CHANGE key and selecting "NEW PROGRAM," or alternatively, selecting "NEW CONTAINER" to repeat the previous protocol, as provided in a block **94**.

To repeat the current protocol, the control logic returns to block **88**. However, if the operator indicates that a different protocol should be used, the logic proceeds back to block **82**. The operator is then requested to indicate which new protocol is to be initiated, leading to the entry of each parameter employed for controlling the pump for that protocol. It should be evident that each time a new protocol is entered in this manner, the operator may inadvertently enter an incorrect parameter, which may result in an error in the delivery of medicinal fluid to the patient. Furthermore, entry of the parameters required to define a protocol each time that a different protocol is required is both inefficient and time consuming. Accordingly, the present invention provides an alternative.

Turning to FIG. **4**, control of the pump using a speed protocol that was previously entered is illustrated. The logic begins at a start block **100**. Thereafter, in a decision block **102**, the operator determines if a new protocol should be entered, i.e., whether the medicinal fluid currently being infused is one for which a stored protocol is not available. If the protocol required to infuse the current medicinal fluid is already stored in RAM **37** as a speed protocol, the logic proceeds to a block **104** wherein the required speed protocol is recalled from memory. However, if the protocol required for infusing the current medicinal fluid is not available among the three protocols that are stored, the logic proceeds to a block **106**, which requires that the operator enter the protocol parameters one at a time as explained above in connection with FIG. **3**.

After either a stored speed protocol is recalled from memory, or a new protocol is entered, the logic proceeds at a block **108**, enabling the operator to review the protocol on display **18**. Thereafter, a block **110** provides for initializing the pump for delivery of the fluid in accordance with the protocol, as indicated in a block **112**. At any time, the operator may determine that a different protocol is required, as indicated in a decision block **114**. Once the current protocol is completed, the operator may optionally repeat the protocol in accord with a block **116**, entering the logic stream at block **110**, or indicate that a different protocol is required, leading back to decision block **102**.

It should also be noted that the current protocol can be assigned to a speed protocol at any time after the protocol is manually entered, i.e., after block **106**. Once assigned to a speed protocol, the protocol can be reviewed without affecting the current operation of the pump under control of a different protocol. Due to design limitations, only three speed protocols are stored at one time in the preferred embodiment. Accordingly, if the current protocol is assigned to a speed protocol, it will replace one of three existing speed protocols stored in memory. If less than three speed protocols are stored, the current protocol can be stored as an additional speed protocol without replacing any other stored speed protocol.

The steps involved in assigning the parameters entered as a current protocol to a speed protocol are illustrated in FIG. **5**, beginning at a start block **120**. In a block **122**, the operator again indicates that a new protocol is to be entered. Thereafter, as provided in a block **124**, the operator is prompted to select the type of infusion and to enter the protocol parameters one at a time. Once the parameters have been entered, they are presented on display **18**, enabling the operator to review the protocol as indicated in a block **126**. The operator may change any of the parameters comprising the protocol, using the BACKUP key to return to the input screen. Display **18** can show three parameter lines at one time. A fourth line displays a prompt message to the operator, guiding the operator to carry out each of the steps necessary to review the protocol parameters.

In a block **128**, the operator assigns the current protocol just reviewed in block **126** to a selected speed protocol. To designate the speed protocol to which the current parameters are to be assigned, the operator presses the OPTIONS key, selects "SPEED PROTOCOL" from the menu on the display, selects "RECALL," and enters a speed protocol number (1 through 3), as indicated in a block **130**. The control then determines if the number entered by the operator is already assigned to an existing speed protocol in a decision block **132**. If so, the control causes the display to present a warning to the operator in a block **134**, noting that the selected number is assigned to an existing speed protocol. At this point, the operator can cancel the assignment of the speed protocol parameters to the selected number, enabling the previous speed protocol to be retained. However, if the operator elects to proceed with the replacement of the previous speed protocol that was assigned to the selected number, or if an existing speed protocol was not previously assigned to the number selected by the operator, the logic proceeds to a block **136**. In block **136**, the current program parameters are copied into memory, linked to the speed protocol number selected by the operator. The logic then exits at a block **138**.

If the operator determines that a medicinal fluid is to be infused into a patient for which a previously stored speed protocol can be used, the steps involved in recalling the speed protocol for use are implemented, as shown in FIG. **6**. From a start block **140**, the logic proceeds to a block **142** in which the operator selects a menu (displayed after the OPTIONS key is depressed and "SPEED PROTOCOL" is selected), which reads "RECALL." Assuming that the operator has selected this option, the control prompts the operator to enter a speed protocol number, as indicated in a block **144**. A decision block **146** then determines if the speed protocol number entered by the operator in accordance with the logic of block **144** corresponds to that of an existing speed protocol. If the response to decision block **146** is negative, the control displays a warning to the operator indicating that the selected speed protocol number does not correspond to one stored in memory, as noted in a block **148**. The logic then proceeds to exit, as provided in a block **156**.

An affirmative response to decision block **146** leads to a block **150**, wherein the selected speed protocol is copied into the current protocol for use in administering the medicinal fluid to the patient. At that point, the control causes the parameters of the now current protocol to be displayed to the operator for review, as indicated in a block **152**. It should be noted that a speed protocol must be reviewed before it is implemented as the current controlling protocol to insure that the operator does not inadvertently apply an inappropriate protocol to administer a specific medicinal fluid. After the review is completed, in a block **154**, the control initial-

izes the pump for delivery of the medicinal fluid in accordance with the parameters of the now current speed protocol, which was just recalled from RAM **37**. The procedure then exits in block **156**.

At times, an operator may wish to delete a speed protocol that is stored in memory. The steps required to carry out the deletion are illustrated in FIG. **7**, beginning with a start block **160**. In a block **162**, the operator presses the OPTIONS key, selects "SPEED PROTOCOL", and selects an option labeled "DELETE" from the menu in display **18**. In a block **164**, the operator is prompted to enter the speed protocol number that is to be deleted. The control then determines whether the number entered by the operator corresponds to a stored speed protocol in a decision block **166**. If not, a block **168** provides for displaying a warning to the operator, indicating that the operator has selected a non-valid speed protocol number for deletion. Thereafter, the logic proceeds to a block **176**, where it exits from this procedure.

Assuming that the operator has entered a valid speed protocol number for deletion, the logic proceeds from decision block **166** to a block **170**, which displays the type of protocol or infusion corresponding to the speed protocol number entered by the operator. The operator is then presented with the option of confirming the deletion (within the menu of display **18**). If the operator declines to confirm the deletion of the selected speed protocol, the logic exits at block **176**. However, if the operator confirms that the selected speed protocol should be deleted, the logic proceeds to a block **174**, wherein the speed protocol is cleared from memory in RAM **37** by the control. Thereafter, the procedure concludes at block **176**.

Since the operator may not be familiar with each of the speed protocols stored in memory, provision is made for reviewing a selected speed protocol. This procedure, which can be elected at anytime without any effect on the current protocol being implemented to control the pump, is shown in FIG. **8**, beginning with a start block **180**. In a block **182**, the operator is presented with an option in the menu displayed that reads "REVIEW." Once this option is selected, the logic proceeds to a block **184** in which the operator is prompted to enter the speed protocol number for the speed protocol that is to be reviewed. The control then determines if the number entered by the operator corresponds to a stored speed protocol in a decision block **186**. If not, the control displays a warning to the operator in a block **188**, indicating that an invalid speed protocol number has been entered and then proceeds to a block **192**, to exit the procedure.

Assuming that the operator has entered a valid speed protocol number, a block **190** provides for displaying the selected speed protocol in the review format within display **18**. This review format identifies the type of the speed protocol (i.e., the type of infusion) and any other parameters specific to that speed protocol. Once the operator has concluded reviewing the selected speed protocol, the logic exits in block **192**.

Finally, the operator can selectively print a copy of any of the speed protocols through a serial data link (not shown) on pump **50**. Beginning at a start block **200**, the operator is presented with a menu option labeled "PRINT," as indicated in a block **202**. Thereafter, the operator is prompted to enter the speed protocol number that is to be printed, as indicated in a block **204**. Once the speed protocol number is entered, the control transmits the data in the review format to an external printer (or to a computer coupled to a printer) through an RS-**232** port, which is disposed on the bottom of the pump. In the event that the operator has selected a speed protocol number that is not assigned to any speed protocol stored in memory, the control prints the notation "NOT ASSIGNED." Following the logic in block **206**, the procedure exits, as provided in a block **208**.

As will be evident from the foregoing disclosure, the use of stored speed protocols enables the operator to selectively infuse any medicinal fluid for which a stored speed protocol is appropriate without the need to reenter the parameters that control the pump during the infusion process. As a result, the likelihood of errors that might be introduced when reentering the parameters is decreased. More importantly, the operator is saved the trouble and time required to reenter parameters necessary to define protocols that are consistently used for infusing medicinal fluids, if the required protocol is among those stored in memory. By providing additional memory, the preferred embodiment disclosed above can readily be modified to enable more than three speed protocols to be stored.

Although the present invention has been described in connection with the preferred form of practicing it, it will be understood by those of ordinary skill in the art that many modifications can be made thereto within the scope of the claims that follow. Accordingly, it is not intended that the scope of the invention in any way be limited by the above description, but that it be determined entirely by reference to the claims that follow.

The invention in which an exclusive right is claimed is defined by the following:

1. A pump for administering a fluid to a patient, comprising:

(a) a fluid drive unit that is adapted to couple with a fluid line and to force fluid from a source to the patient through the fluid line;

(b) a control that is coupled to the fluid drive unit to contol its operation;

(c) a memory in which a plurality of protocols are stored, said protocols each specifying at least one parameter used to control the fluid drive; and

(d) a user interface that is integral with the pump and is coupled to the control and to the memory to enable the operator to enter said at least one parameter for any of said plurality of protocols, store said protocol with said at least one parameter included so that said at least one parameter is already set when said protocol is next selected, and to select one of said plurality of protocols to be the current protocol for use by the control in actively controlling the operation of the drive unit so as to administer the fluid to the patient in accordance with said protocol that is selected.

2. The pump of claim **1**, wherein the parameter comprises one of a continuous fluid flow, an intermittent fluid flow, and a bolus fluid flow.

3. The pump of claim **1**, wherein the parameter comprises one of a rate of fluid flow, a volume of fluid flow, a time of fluid flow, and a duration of fluid flow.

4. The pump of claim **1**, wherein the user interface enables the operator to define a current protocol and to store the current protocol as one of the plurality of protocols in the memory.

5. The pump of claim **1**, wherein the control cooperates with the user interface to enable the operator to review one of the plurality of protocols stored in the memory while the drive unit is being operated in accordance with a different one of the plurality of protocols.

6. The pump of claim **1**, wherein said at least one parameter comprises a varying rate of fluid flow.

7. The pump of claim 1, wherein the user interface enables the operator to recall one of the plurality of protocols from memory as a currently active protocol used by the control in controlling the drive unit, and enables the operator to modify said currently active protocol prior to storing it in the memory.

8. A pump for administering at least one medicinal fluid to a patient through a fluid line, said pump comprising:

(a) a microprocessor controller responsive to program steps stored in a memory associated with the microprocessor controller, said program steps effecting control of the pump in accordance with an operator selected protocol;

(b) a fluid pumping unit for forcing fluid into the patient through the fluid line, said fluid pumping unit being electrically coupled to the microprocessor controller and controlled thereby; and

(c) a control panel that is electrically coupled to the microprocessor controller, integral with the pump, said control panel including a display and a plurality of switches that enable an operator to enter parameters for each of a plurality of protocols that are stored in the memory, said parameters entered for each protocol being stored and appearing on the display when a protocol is next selected, said switches also enabling the operator to recall one of the plurality of protocols as a current protocol for controling the fluid pumping unit.

9. The pump of claim 8, wherein the microprocessor controller enables the operator to review parameters for one of the stored protocols while using a different protocol to control the fluid pumping unit.

10. The pump of claim 8, wherein the parameters that define the plurality of protocols comprise at least one of a fluid flow rate, a fluid volume, a duration for fluid flow through the pump, and a time to initiate fluid flow through the pump.

11. The pump of claim 8, wherein the plurality of protocols comprise at least one of a parenteral nutrition fluid delivery protocol, a pain management fluid delivery protocol, an intermittent fluid delivery protocol, a variable time fluid delivery protocol, and a continuous fluid delivery protocol.

12. The pump of claim 11, wherein the parenteral nutrition fluid delivery protocol comprises an operator selected parameter for at least one of a continuous fluid flow, and a continuous fluid flow with a tapering fluid flow rate.

13. The pump of claim 11, wherein the pain management fluid delivery protocol comprises an operator selected parameter for at least one of an intravenous fluid administration, an epidural fluid administration, and a subcutaneous fluid administration.

14. The pump of claim 11, wherein the variable time fluid protocol comprises an operator selected parameter for at least one dose designating at least one of a percentage of volume, a rate of flow, and a volume.

15. The pump of claim 8, wherein the program steps enable the operator to print a selected protocol while the pump is administering the fluid in accordance with a different protocol.

16. The pump of claim 8, wherein the parameters selected to define the plurality of protocols include a keep vein open fluid flow rate option.

17. The pump of claim 8, wherein the parameters selected to define the plurality of protocols include a bolus injection option.

18. The pump of claim 8, wherein the program steps enable the operator to recall one of the plurality of protocols as a current protocol and to modify said current protocol by changing at least one of the parameters that define it.

19. The pump of claim 8, wherein the program steps provide prompts to the operator on the display that indicate the parameters that are selectable by the operator.

20. The pump of claim 19, wherein the prompts indicate a plurality of units of measurement to enable the operator to select the units of measurement for at least one of the parameters that define the plurality of protocols stored in the memory.

21. The pump of claim 8, wherein the program steps require that any of the plurality of protocols recalled from memory be reviewed by the operator before the fluid pumping unit is controlled with said protocol.

22. The pump of claim 8, further comprising a backup battery power supply to maintain storage of the plurality of protocols in the memory when the pump is disconnected from another source of power.

* * * * *

EXHIBIT B

US005378231A

United States Patent [19]

Johnson et al.

[11] **Patent Number: 5,378,231**

[45] **Date of Patent: Jan. 3, 1995**

[54] **AUTOMATED DRUG INFUSION SYSTEM**

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[73] Assignee: **Abbott Laboratories**, Abbott Park, Ill.

[21] Appl. No.: **981,673**

[22] Filed: **Nov. 25, 1992**

[51] **Int. Cl.**[6] **A61M 31/00**

[52] **U.S. Cl.** **604/67**; 604/151; 128/DIG. 12; 128/DIG. 13

[58] **Field of Search** ..... 128/DIG. 12, DIG. 13; 604/65, 67, 151, 131, 81, 118, 246

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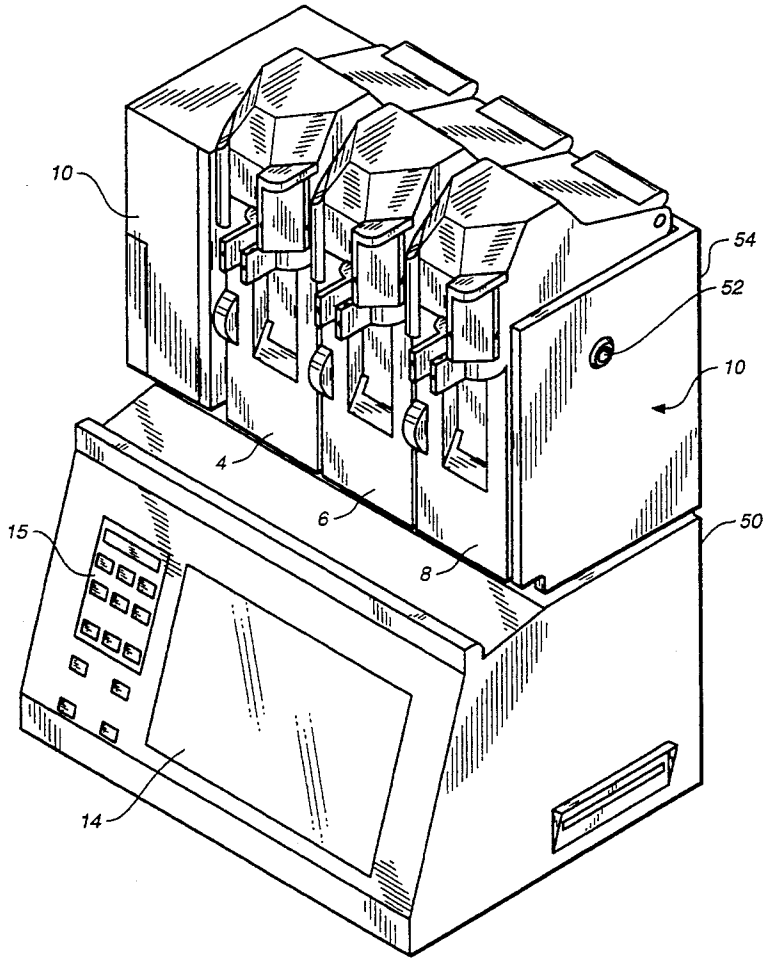
Assistant Examiner—N. Kent Gring
Attorney, Agent, or Firm—Tom Breininger; Harry G. Thibault

[57] **ABSTRACT**

The present invention relates to a control system for use with an automated intravenous drug and fluid infusion system having plural pumping channels that operate independently for intravenously infusing drugs and fluid. The pumping channels are controlled by a microprocessor-based host controller that monitors each of the channels concurrently. In an exemplary embodiment, the system functions include identifying the particular drug that is to be pumped through a channel, preventing priming of a channel unless verification is provided that the channel is not connected to a patient and initiating the priming of each of the pumping channels independently.

22 Claims, 4 Drawing Sheets



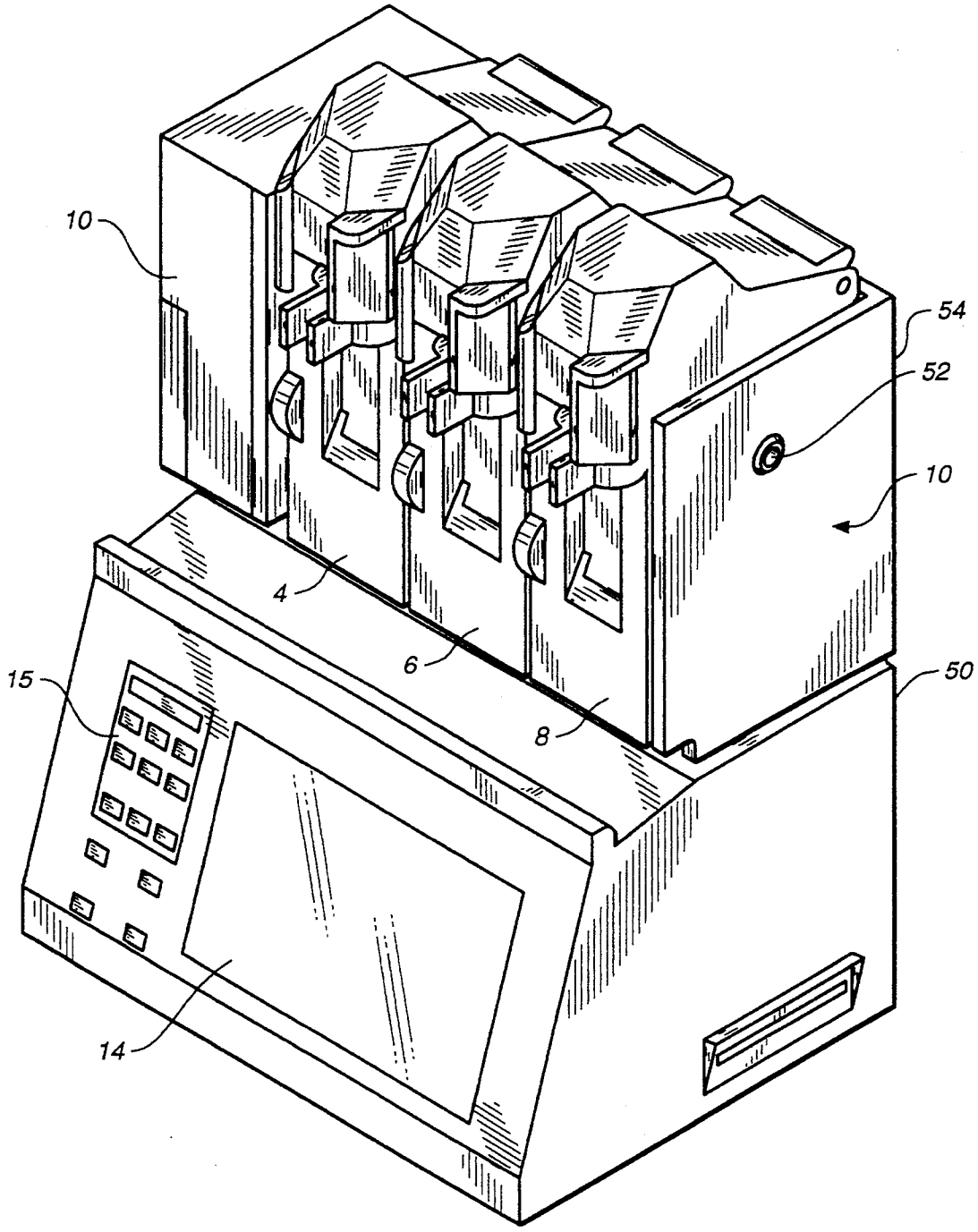


FIG._1

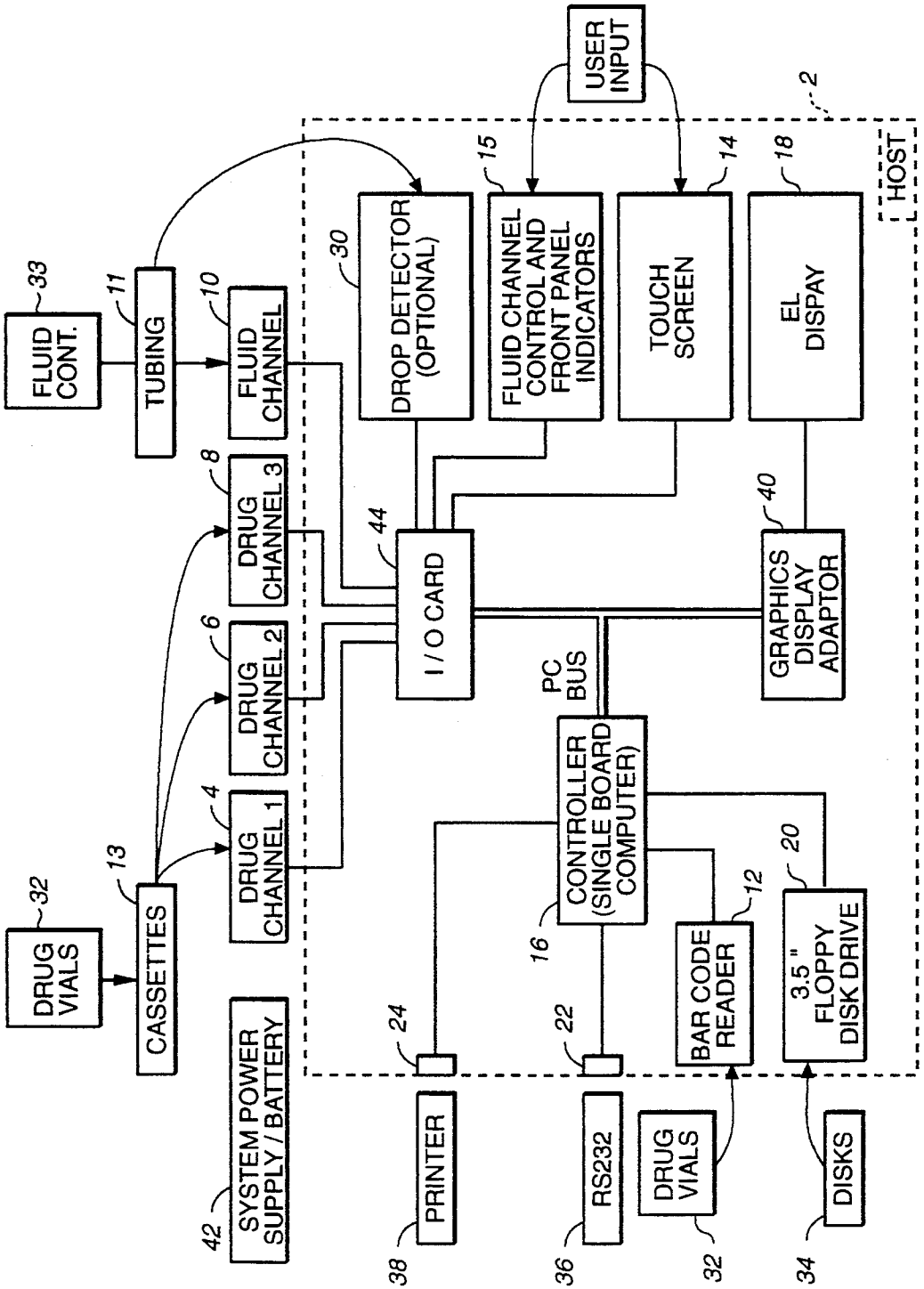

USER INPUT
2
HOST
15
14
18
FLUID CONT.
33
TUBING
11
FLUID CHANNEL
10
DROP DETECTOR (OPTIONAL)
30
FLUID CHANNEL CONTROL AND FRONT PANEL INDICATORS
TOUCH SCREEN
EL DISPAY
DRUG CHANNEL 3
8
DRUG CHANNEL 2
6
DRUG CHANNEL 1
4
I / O CARD
44
GRAPHICS DISPLAY ADAPTOR
40
PC BUS
CONTROLLER (SINGLE BOARD COMPUTER)
16
DRUG VIALS
32
CASSETTES
13
BAR CODE READER
12
3.5" FLOPPY DISK DRIVE
20
SYSTEM POWER SUPPLY / BATTERY
42
24
22
PRINTER
38
RS232
36
DRUG VIALS
32
DISKS
34

FIG._2

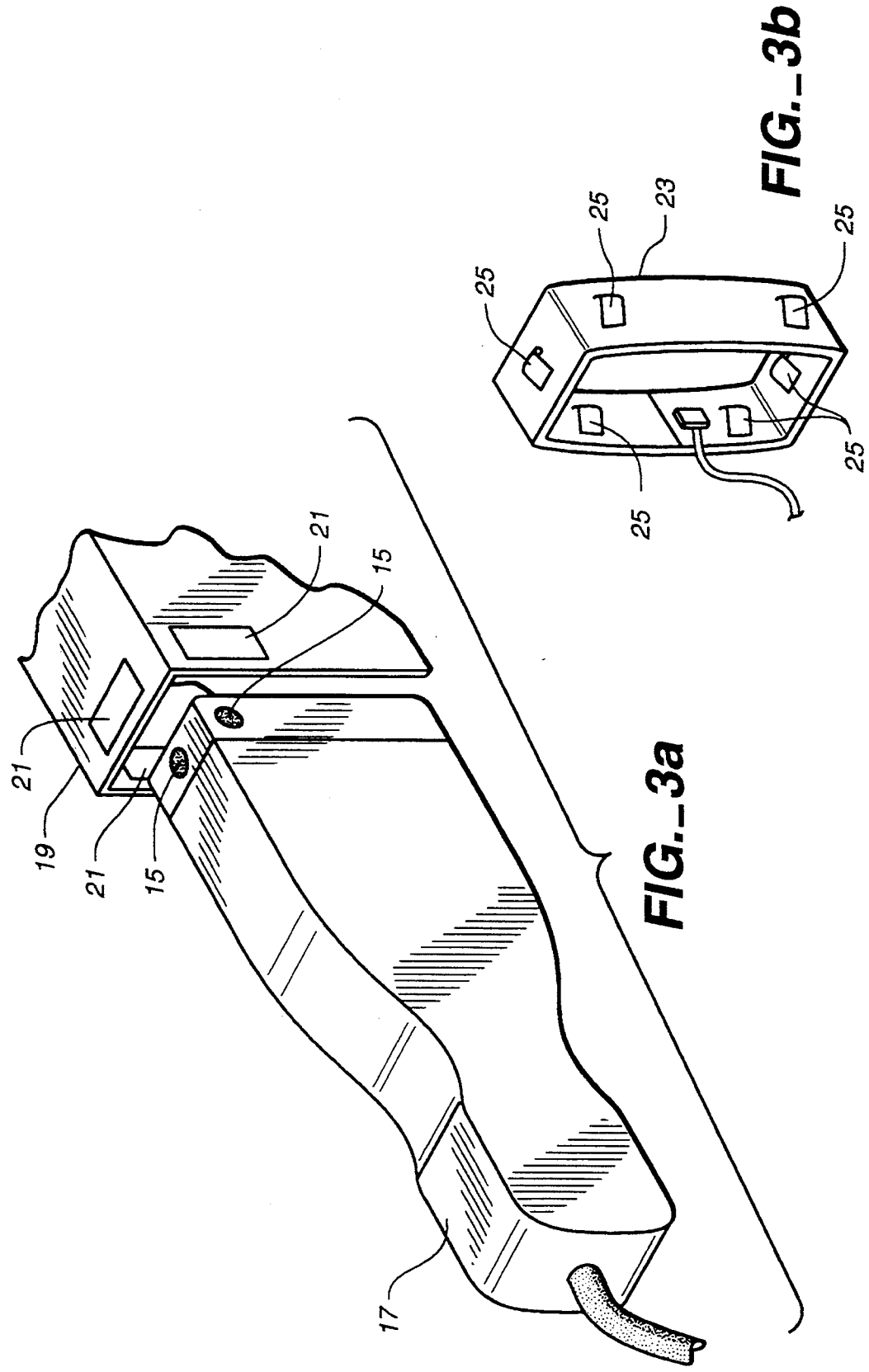


FIG._3b

FIG._3a

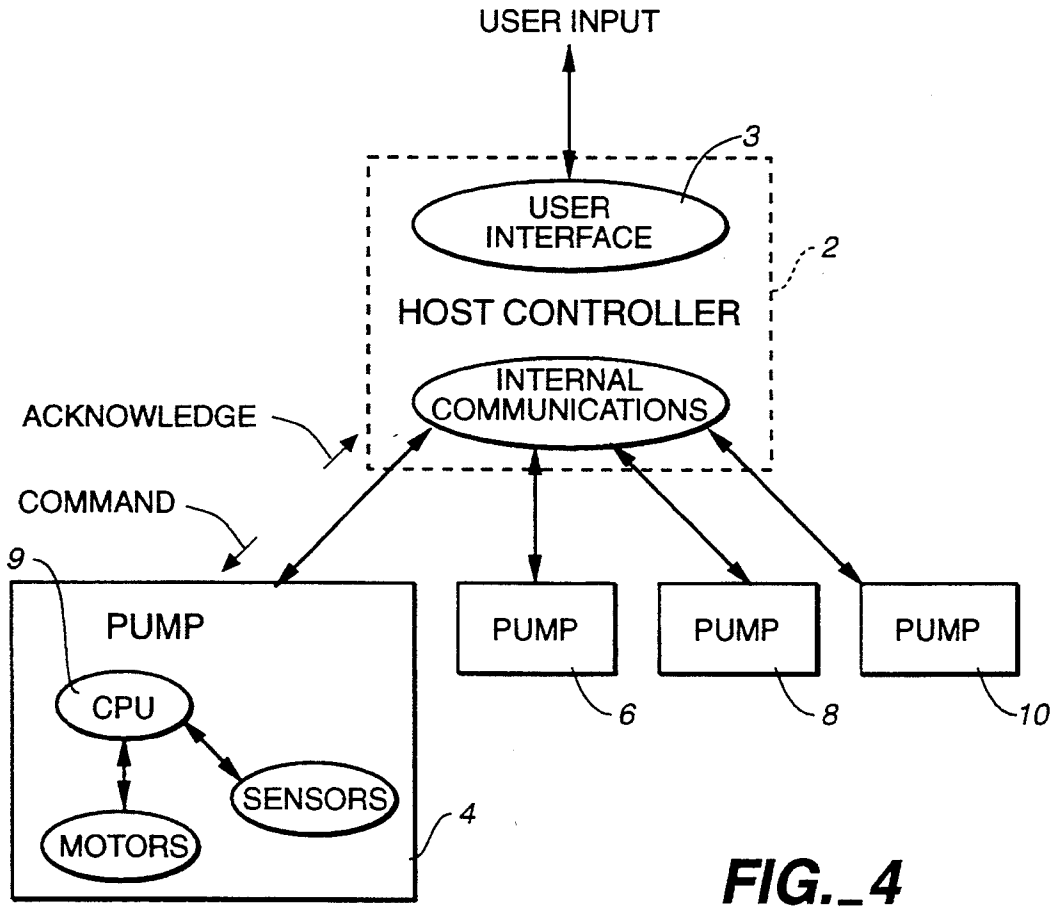

USER INPUT
3
USER INTERFACE
2
HOST CONTROLLER
INTERNAL COMMUNICATIONS
ACKNOWLEDGE
COMMAND
9
PUMP
CPU
SENSORS
MOTORS
4
PUMP
6
PUMP
8
PUMP
10

FIG._4

AUTOMATED DRUG INFUSION SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention generally relates to systems for delivering drugs and fluids to patients intravenously. More particularly, the present invention relates to a control system for an automated intravenous drug and fluid infusion system.

2. State of the Art

It is well known to use volumetric infusion pumping systems for delivering drugs to patients intravenously. Infusion pumping systems of conventional design have several significant drawbacks that limit their effectiveness. For example, manual entry via keys and knobs is required whenever a drug supply container is connected or replaced in the pumping system. Further, conventional pumping systems require manual identification of drugs and manual priming of pumping channels.

The foregoing manual procedures are time consuming, labor-intensive and susceptible to error. Because there is no procedure for identifying and approving use of a drug in an infusion pumping system, successive use of different drugs in the same delivery line can occur, resulting in drug contamination. Further, the lack of drug identification can result in the mixing of incompatible drugs from plural drug channels.

SUMMARY OF THE INVENTION

The present invention relates to a control system for use with an automated intravenous drug and fluid infusion system having plural pumping channels that operate independently. Each pumping channel is independently controlled by a single microprocessor-based central processing unit (CPU). A host controller monitors all of the channels concurrently. In an exemplary embodiment, the system further includes means for positively identifying the particular drug that is to be pumped through a channel; means for preventing priming of a channel unless verification is provided that the channel is not connected to a patient; and means for independently priming each of the pumping channels.

The present invention provides easy to use methods and systems which improve patient care by automating control during all phases of drug and fluid delivery. The system provides positive identification of drugs prior to their administration via the various pumping channels, and provides autopriming of the channels. Dosing and delivery (i.e., by bolus, continuous infusion, or pharmacokinetic model-based infusion) can be entered in user-selectable units which are internally converted to system units (ml/hr.).

The control system can also recognize incompatible drug combinations, and subsequently handle the incompatibility or alert the device user via an appropriate warning. Automatic dose limit checking, automatic data storage (e.g., patient record, user data and infusion data), and automatic detection and signaling of error conditions represent additional features of the control system.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention can be further understood with reference to the following description and the appended drawings, wherein like elements are provided with the same reference numerals. In the drawings:

FIG. **1** is an exemplary automated drug infusion (ADI) pumping system of the type that dispenses drugs and fluids to a patient intravenously from one or more drug and fluid supply containers;

FIG. **2** is a block diagram of a control system for the FIG. **1** pumping system;

FIGS. **3***a* and **3***b* illustrate an exemplary bar code reader for a pumping channel of the FIG. system;

FIG. **4** is a diagram displaying system and channel communication between the user, the host controller and the independent pumping channels of the FIG. **2** system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** shows an ADI pumping system for dispensing drugs and fluids for a patient intravenously from one or more drug and fluid supply containers. The FIG. **1** apparatus includes three substantially equal drug delivery channels **4**, **6** and **8**, and a fluid delivery channel **10**. Drug delivery parameters are entered and displayed via a touch screen **14**. Fluid parameters are entered via a key pad **15**. A base enclosure **50** encloses a host controller **2** for driving the overall system. A key lock **52** is disposed on a side of a pumping channel enclosure **54** and engages a security system. Detailed aspects of an exemplary drug identification and security system which can be used with the FIG. **1** apparatus are set forth in commonly assigned U.S. application Ser. No. 07/811,516, entitled "Drug Channel Identification And Security System For Infusion And Pumping Systems" and filed Dec. 20, 1991, the contents of which are hereby incorporated by reference.

FIG. **2** shows a general hardware block diagram of an automated drug and fluid infusion control system for intravenously infusing drugs and fluid to a patient via the FIG. **1** pumping system. The FIG. **2** system includes three general components: a host controller **2**; drug channels **4**, **6** and **8**; and a fluid channel **10**.

The FIG. **2** system represents a modular, multi-channel infusion device with each drug channel holding a captive drug vial exclusively compatible with the system and with a drug administration set. A master-slave control approach is used, with the host controller **2** overseeing operation of the four independent pump channel modules: three identical channels for the delivery of drug (e.g., anesthetic and cardiovascular agents), and one channel for fluid delivery.

For purposes of the following discussion, the term "drug channel" refers to an independent path through which drug is dispensed to a patient from at least one drug supply container, or vial **32**. In systems according to the present invention, each drug channel includes a cassette pumping device **13**. Access to a drug pumping cassette **13** within a drug channel is provided by lifting a protective hood on top of the pumping system. When not in use, the hood or hoods may be locked to prevent removal of the drugs.

Pump outlets in each independent drug channel may be connected to a manifold or connected directly to the patient. The preferred manifold contains four one-way check valves which connect all input lines to an outlet line through which drugs and fluid are dispensed to a patient intravenously, for example, a manifold such as described in commonly assigned U.S. application Ser.

No. 07/734,828, entitled "Multi-Valve Manifold For Drug Infusion Systems" filed Jul. 24, 1991.

A "fluid channel" refers to a path through which a fluid (e.g., flushing fluid) is dispensed via the manifold. The FIG. 2 fluid channel **10** can carry fluid such as a patient hydration solution. The fluid channel **10** includes a fluid supply container **33** which is compatible with a conventional drop sensor **30**. The drop sensor is connected to fluid conduit **11** that passes through a volumetric fluid channel pump. The fluid channel **10** also connects to the manifold via a one-way check valve.

The host controller **2** is a single microprocessor-based computer which responds to user commands, directs intravenous drug and fluid deliveries, automatically recognizes drug identities, stores and selectively activates a pharmacokinetic (PK) model useful in drug delivery to the patient, handles physical incompatibilities among drugs, and provides automatic record keeping. The host controller **2** includes a microprocessor **16** which monitors and controls the independent pumping channels concurrently. The host controller **2** includes a system user interface which enables the user to identify the drug installed in each drug channel, select infusion modes, set infusion rates, identify drug incomputabilities, prevent priming of a drug channel unless verification is provided that the channel is not connected to a patient, and related functions. Further, the host controller **2** causes automatic priming of each pumping channel independently.

The automatic priming removes air from each of the pump cassettes **13** and associated tubing independently. A discussion of the autoprime feature is provided in commonly assigned U.S. patent application Ser. No. 07/811,195, entitled "Automated Drug Infusion System With Autopriming" filed Dec. 20, 1991. Because an understanding of the auto-prime feature of the system described herein may be useful for a better understanding of the present invention, the above-noted U.S. patent application is herein incorporated by reference.

The FIG. 2 system includes means for identifying the particular drug that is to be pumped through a drug channel. A modular bar code reading system **12** identifies the drug contained in a drug vial **32** installed in a drug channel of the system.

The drugs normally are in liquid form in a drug container which is secured mechanically to a drug channel. A bar code which includes the drug name is included on a drug label. A bar code reader **17** is held manually as shown in FIG. 3*a*, or can be located internally within each drug channel pump. When the bar code reader **17** is placed in a vicinity of the drug container, the bar code reader electronically senses the bar code. Further, the pumping system can use a unique arrangement of electromagnetic Hall sensors and magnetic strips in each drug channel to determine which drug channel is currently being read so that the reading of the drug supply container can be tied to the appropriate drug channel.

For example, in FIG. 3*a*, Hall sensors **15** on the bar code reader **17** detect the presence of magnetic strips **21** placed on a receptacle **19** of a drug channel. The bar code reader must be placed in a vicinity of the receptacle **19** to read a bar code on the label of a drug vial secured in the drug channel. FIG. 3*b* shows an alternate configuration of a receptacle **23** which completely surrounds an end of a bar code reader **17**. In this embodiment, Hall sensors **15** are replaced by a magnetic strip around a perimeter of the bar code reader. The receptacle includes Hall sensors **25** mounted thereon to detect the magnetic strip located about the perimeter of the bar code reader **17**.

The FIG. 2 host controller **2** operates displays **18** and peripherals (e.g., floppy disk drive **20** for disks **34**, system bus interface **22** for bus **36**, parallel printer interface **24** for printer **38**, graphics display adapter **40** for display **18** and input/output (I/O) card **44**). The host controller **2** also controls an A/D converter, a key lock switch, optional VGA compatible graphics, audio output circuitry, a timer circuit, non-volatile memory, battery backed static RAM memory for storage of non-volatile data (e.g., drug information stored in a drug table) and dynamic RAM. Power supply **42** is provided for the FIG. 2 system.

The host controller **2** can set the audio volume of an audio output signal to be one of a plurality of selected volume levels. In a preferred embodiment, eight separate volumes are provided. However, the number of selected volume levels can be greater or lesser than the number of volume levels selected for the preferred embodiment. The audio output signal is used to provide warnings or alarms to the user for when a failure, malfunction, or other alarm condition occurs within the FIG. 2 system.

The host controller **2** sends commands to an independent controller **9** (i.e., CPU) for each of the drug channels (**4**,**6**,**8**) and fluid channel **10** shown in FIG. **4**. For example, these commands include signals to stop pumping, set rate or dose, prime a drug channel, change pumping rate, read dose, initiate a backprime, start a pumping operation, perform a fluid prime, change fluid pumping rate, and read a dose from the fluid channel. In addition, the host controller **2** receives responses and cases from each of the pumps.

The independent controller **9** for each drug channel controller controls and monitors pumping from drug vials, provides automatic priming of drug sets in response to host controller **2** commands, and communicates status, alarm and error conditions within a drug channel to the host controller **2**. The independent controller for a fluid channel controls and monitors pumping from fluid containers, provides automatic priming of fluid lines in response to host controller **2** commands, and communicates fluid line status, alarm and error conditions to the host controller **2**.

The three drug channel modules are based on the known LifeCare 5000, and the fluid pump module is based on the known LifeCare 175, both available from Abbott Laboratories, Inc. The independent controllers of the drug and fluid channels are independent microprocessors which communicate to the host controller **2** through a communication link. Because the drug and fluid channel modules are, for the most part, known modules which do not themselves constitute a portion of the present invention, only features of these modules necessary for understanding the present invention will be provided.

A user interface provides a connection between various pumping channel controllers (FIGS. **1** and **2**) and the user. This interface includes a user accessible panel which is divided into four regions: three drug channel regions, each directly beneath one of the three drug channel mechanisms, and one fluid channel region directly beneath the fluid channel. The user can access all functions of the FIG. **2** system via the interface at any time after power-up, with the exception of selfdiagnos-

tics, system administrator functions, and floppy drive use.

In the FIG. 2 embodiment, a touch screen **14** represents a module which is accessible to the user and controlled by the host controller **2**. A key pad included on a host controller interface panel includes 16 front panel buttons in a preferred embodiment of the present invention. The panel can accommodate additional buttons if they are needed in alternate embodiments of the present invention, including several hidden buttons. Both an identity of a button being depressed and its state are read by the host controller **2**.

The buttons which control drug delivery to a patient remain visible on the interface panel during the entire time delivery is occurring or is possible on that drug channel. The user is therefore not required to exit a current function to start or stop drug delivery. The drug name, current delivery rate, dose or a setpoint of the PK model, and a pumping activity indicator are displayed for each drug channel on the interface panel.

The portion of the user interface located beneath the fluid channel mechanism includes a five digit display to identify delivery rate or total value delivered. LEDs are also included on the user interface panel to identify a power-on condition and to indicate when the system is running on battery power.

The host controller **2** provides channel set up functions for each of the drug channels **4**, **6**, **8** and fluid channel **10** shown in FIG. **2**. This includes automatic identification and channel association of drugs placed in each drug channel and overseeing automatic priming of the drug and fluid channels. In addition, the host controller **2** provides drug and fluid delivery functions, system maintenance functions, data storage functions and handling of exceptional cases (e.g., malfunctions and alarm indications to the user).

The drug identification feature is implemented during a drug channel set up, after the host **2** is notified by an independent controller **9** that a drug channel door has been closed with a drug cassette in place. At that time, the host controller **2** prompts the user to scan a bar code included on a drug vial label. For the host controller **2** to accept the scan as valid, the bar coded label must be accessible to the bar code reader. The bar code reader remains active as long as a drug channel door has been closed with a cassette in place and the associated bar code label has not yet been successfully scanned.

As described previously, two sensors provided in each channel indicate the presence or absence of the bar code reader directly in front of that channel. The drug vial to be scanned must be properly positioned in a drug channel to be identified by the bar code reader, otherwise its label will not be recognized by the system.

After a drug has been loaded into a drug channel and a valid bar code has been read and the drug name has been recognized, the host controller **2** displays the name of the drug on a host display position below the drug channel receiving the drug vial. Once the bar code reader identifies the drug contained in a drug vial installed in a drug channel, the host controller **2** prompts the user to enter drug delivery information associated with that drug. The host controller **2** will not permit a drug channel to prime or pump any drug until the drug vial loaded into the channel has been successfully identified using the bar code reader.

A significant delivery function of the present invention is the ability to provide drug specific functions. For example, the host controller **2** allows the user to pick from allowed unit conversion sets specified for a particular drug being used. Unit conversion sets available for each drug are retained in the drug table of the host controller **2** memory. Drug delivery quantities in weight based units require entry of patient weight.

More particularly, after drug identification via the bar code reader, the host controller **2** displays all delivery control quantities (i.e., rate, dose and plasma level) using default units specified by a unit conversion set in the host controller's drug table for that drug, or, if preferred by the user, the units that were used during the most recent delivery of that drug. If other unit conversion sets are permitted for that drug, the host controller **2** permits the user to select one. Afterwards, all quantities are displayed using the new units for rate, dose and plasma level specified by the new unit conversion set.

As mentioned above, one of the primary functions of the host controller **2** is to oversee drug and fluid delivery. With regard to drug delivery, the host controller **2** is designed to control infusion rate and bolus dose delivery or PK model-based drug delivery. The host controller **2** permits either bolus delivery or infusion delivery, but when both a bolus delivery and an infusion delivery are requested simultaneously, the bolus delivery takes priority, causing delay of the infusion delivery until the bolus has been completed.

For a bolus delivery, a bolus dose in units selected by the user must be input by the user before the start of delivery. The host controller **2** will only permit a bolus delivery to occur for drugs which have been identified in a drug table of the host controller's memory as being deliverable by bolus. To prevent accidental delivery, the user must confirm the request for a bolus delivery prior to starting delivery. In a preferred embodiment, the user can also select desired duration for bolus delivery ranging from default (i.e., the shortest time over which the drug can be delivered) to durations which are multiples of the default duration).

A bolus may be paused during delivery, after which the bolus may be resumed (i.e., causing the remaining dose to be delivered) or the bolus may be stopped, cancelling delivery of the remaining dose. No confirmation is required to resume a bolus once paused, and pausing does not affect the status of simultaneously delivered infusion delivery on the same channel.

Infusion delivery is only permitted for drugs which have been defined in the drug table as being deliverable by infusion. Continuous infusion requires that the user input a desired infusion rate and infusion units before the start of infusion delivery. A default value of infusion units is provided by host controller **2**. The infusion rate is, in an exemplary embodiment, equivalent to a range of 0.1 ml/hr to 1200 ml/hr.

A PK model is maintained in the host controller's memory for all drugs that are listed in the drug table as having PK models. When delivery of these drugs is initiated, the host controller **2** starts a PK model to continuously predict the theoretical plasma level of the drug being delivered. The selected PK model allows the user to query the predicted plasma level of the drug in a patient at any time during its delivery. Again, PK model-based delivery is only permitted for drugs which have been so defined in the drug table of the host controller **2**. The system can provide the user with predicted (theoretical) plasma levels (i.e., level of drug in patient bloodstream) when delivering drugs by bolus or

continuous infusion because a background calculation of the theoretical plasma level is continuously updated.

Before initiating a PK model-based delivery, the user must input a plasma level set point in user selectable units. The host controller **2** will not accept a plasma level set point greater than the maximum plasma level defined in the drug table for that drug. Further, PK delivery cannot be initiated until certain patient parameters, such as weight, have been confirmed by the user. Upon initiation of a PK delivery, the host controller **2** displays setpoint plasma level in user selected units, the predicted (theoretical) plasma level in the same units, and the infusion rate in default units throughout the entire PK model-based delivery.

In the fluid channel **10**, only continuous infusion is permitted. The user must enter a delivery rate (e.g., between 1 and 1200 ml/hr) before fluid infusion can be initiated. In an exemplary embodiment, only ml and ml/hr are used to define fluid rate and cumulative dose units.

A key feature of the present invention is its ability to handle incompatibility between drugs administered to a patient via the FIG. **2** system. For this purpose, the host controller **2** detects and informs the user of possible physical incompatibilities between drugs identified by the bar code reader. The host controller **2** allows the user to decide whether to allow the system to automatically handle incompatible drug pairs involving bolus delivery. If the user decides to let the system automatically handle the incompatibility, the host controller **2** provides a visible indication on those channels that an incompatibility exists and that it will be automatically handled.

On channels where compatibility handling is active, bolus deliveries are preceded by and followed by a flush delivery from the fluid channel. Once a flush delivery for an incompatible bolus is completed, the fluid channel reverts to its previous delivery rate. The volume of each flush delivery is added to the total fluid delivered during the current patient case and stored in memory of the host controller **2**.

The host controller can be designed to handle incompatibilities in all infusion mode combinations. In the preferred embodiment, the host controller **2** does not provide special handling for infusions, PK deliveries, or for three incompatible drugs loaded into the system at the same time, on channels where compatibility handling is active. Rather, the host controller **2** informs the user upon identification of incompatible drug conditions. Further, a visual indication of any currently incompatible drugs is provided to the user.

For each drug loaded and identified on the FIG. **2** system, the user can view the current total amount of drug delivered from the start of delivery to a particular patient. This information is stored in the host memory and is continuously updated throughout the delivery. For each drug loaded and identified, the user can specify a maximum dose limit for the duration of delivery to the patient. Once reached, the user is informed, but pumping continues. The user dose limit is reset and disabled when the patient case ends.

The host controller **2** also includes a global stop which deactivates all 3 drug channels at once. Each channel must then be individually restarted to resume pumping.

Similarly, fluid specific functions are provided for the fluid channel **10**. More particularly, the user can view the current total volume of fluid delivered to a patient from the beginning of the patient case. Further, the user can enter a maximum volume limit of fluid for each patient case. Once reached, the user is informed and fluid delivery is discontinued. The user volume limit is reset and disabled when the patient case ends.

The FIG. **2** host controller **2** also provides a plurality of system maintenance functions. These functions include a start up/shut down function, disk archiving function, configuration features, installation/security features, and system update.

The start up/shut down functions prevent drug and fluid delivery to a patient prior to user instruction to the host controller **2**. The host controller **2** allows the user to end a current patient case only when no channel is pumping. Upon ending the patient case, the host controller **2** displays total volumes delivered and used for priming the administration set for each drug used, as well as total volume of fluid delivered and used for priming. These volumes are expressed in display units used at the time the patient case ended.

The disk archiving function of the host controller **2** stores event history and patient case information to floppy disk for later use and analysis. Configuration functions of the host controller **2** provide a means for the current date and time to be set.

At the user's option, access to certain functions of the host controller **2** is restricted and requires the use of a password. Once the password is successfully entered, the host controller **2** can be controlled to access an exception conditions log, an event history, user information, patient case information, and installation record/drug usage. Further, at the user's option, entry of this password can be required before information stored in the system can be transferred to the floppy disk. In addition, entry of the correct password can be used to control entry of information into the host controller's memory (e.g., hospital name, drug table updates and names of users allowed access to the system).

The password cannot be changed unless access to the system has been obtained, nor can the password be viewed unless access to the system has been obtained following accurate entry of the current password. Use of the password can thus be used to control access to a variety of features of the host controller **2**.

As mentioned above, the present invention can provide data storage of event history, an exception conditions log, user information, patient case information, installation record/drug usage and drug tables. Event history data is stored by the host controller **2** as a chronological record of system cases associated with the FIG. **2** system alarms, malfunctions, and user interaction with the system. The event history data is stored in the non-volatile host controller's memory, and can be viewed by the user.

In an exemplary embodiment, the host controller **2** can store all cases that occur over a period of 7 days of continuous use. Once the case buffer is filled, old cases are discarded as new cases occur. The host controller **2** permits the user to disable and enable event history recording, and when disabled no subsequent cases are stored in the event history portion of the host controller's memory.

Exception conditions are stored by the host controller **2** as a chronological record of at least the last 30 exception conditions (i.e., malfunctions and alarms) applicable to the entire FIG. **2** system. Again, this log is stored in a non-volatile area of host controller's memory. Pumping channel exceptions are not stored in the

individual pumps, but are stored as data in this portion of host controller's memory. Exception data is recorded automatically and cannot be disabled or erased by the user.

The host controller **2** also stores user information. This information includes, for example, up to 100 alphanumeric user IDs in a non-volatile area of host controller's memory.

Patient case data can, in an exemplary embodiment, be retained on the last 50 patient cases. The host controller **2** allows the user to optionally store a patient ID as well as other information on age, sex, and weight. The patient weight can be input and displayed in pounds or kilograms.

For each patient case, the host controller **2** stores the user ID of the user who ended the patient case, the total number of users who identified themselves to the system during the patient case, the time the patient case started, and the duration of the patient case. The host controller **2** also records the number of drugs delivered during the patient case, the total volume delivered and total volume used in priming for each drug used during the patient case, as well as the total volume of fluid delivered and total volume used in priming. This information is expressed in display units currently being used at the time the patient case ended.

Installation record/drug usage data is retained by the host controller **2** and includes information regarding the installer's name, the site name, installation date and information pertaining to specific hardware configuration of the FIG. **2** system.

Drug table data is also stored by the host controller **2**. The drug table includes information (e.g., drug incompatibilities, suitability for bolus infusion delivery or PK delivery, PK model-based input parameters and maximum allowable infusion rates, bolus doses, and theoretical plasma levels) for each drug as described previously.

Another key feature of the present invention is its ability to handle exception conditions. More particularly, when a malfunction, audible alarm or audible warning occurs, audio signal is emitted by the host controller **2** to alert the user. This audio signal is only discontinued when the user has acknowledged the condition, but may be temporarily stopped using a silence alarm button on the host controller interface panel. When a non-audible alarm or non-audible warning occurs, a discrete audio signal is optically generated to alert the user.

The host controller **2** detects malfunctions in the FIG. **2** system. Malfunctions which are identified by the host controller **2** and communicated to the user include signals indicating that a fluid or drug channel is unavailable due to an internal malfunction, indication that the system is unavailable due to a malfunction, and indications that the disk drive or other peripheral components are unavailable due to a malfunction.

The system can be configured to require presence of a drop detector in the fluid channel. When so configured, the host controller **2** requires the user to discontinue fluid channel operation when an alarm indicating the absence of a drop detector occurs. The fluid channel cannot be restarted until the exception condition regarding absence of the drop detector is rectified.

Alarms associated with the fluid delivery channel **10** include, for example, indications that the fluid channel autoprime mechanism has failed, that there is air in the fluid channel line, that the fluid channel door has been opened while pumping or that the fluid channel bag is empty. When fluid is unavailable, the host controller **2** allows the user to stop the fluid channel **10** and enter a new pumping rate, but the fluid channel **10** cannot be restarted until the exception condition is rectified. Alarms are also generated when there is a proximal occlusion or distal occlusion in the fluid channel pump, when there is a pressure error in the fluid channel **10**, when the fluid channel volume limit is reached. In a preferred embodiment, the foregoing alarms are the minimum alarm conditions provided. Those skilled in the art will recognize that any number of alarms based on detection of any desired condition can be provided.

In a preferred embodiment, alarms associated with the drug channels **4**, **6**, **8** are, at a minimum, provided to the user when there is proximal or distal air detection in the drug channel cassette **13**, when a channel door has been opened while pumping, when there is a proximal or distal occlusion in the cassette, when distal pressure is out of range, or when drug is unavailable. Non-audible alarms generated by host controller **2** include when AC power is not available or when the battery becomes discharged, failure to recognize a bar code, failure to associate a bar code with a channel, or alarms associated with floppy disk operation.

In a preferred embodiment, audible warnings (i.e., potential alarm condition) include, at a minimum, when the battery is low or when a drug container is near empty. Non-audible warnings include detection of excess air in an air trap chamber of a pumping cassette, loss of AC power or potential drug incomputabilities.

Drug and fluid channel status conditions are also continuously provided from the pumping channels to the host controller **2** for display. Status conditions which are displayed to the user via the host controller interface panel include, channel unavailable status, inactive status, autopriming status, backpriming status, testing cassette status, cassette test failure status, prime needed status, backprime needed status, prime verification needed status, infusion on hold status, bolus on hold status.

System status conditions which can be displayed via the host controller interface panel include: battery low status, security covers locked status, fluid channel unavailable status, drop detector missing status, volume limit reached status, disk drive unavailable status, patient parameters needed status, and user ID needed status.

As illustrated by FIG. **4**, user interaction with the FIG. **2** system is via a user interface **3** in the host controller **2**. Communication of commands, data, exception conditions, status and other information between the host controller **2** and drug and fluid channels is via the aforementioned serial communication link, capable of two-way communication. Communication is, for example, via packets limited to 30 bytes to ensure real time operation. Typical communications between the host controller **2** and pumping channels is via a command-acknowledgement loop. The host controller **2** (master) sends a command packet to one of the four pumping channel controllers **9** (slave), or vice versa. The targeted channel sends back an acknowledgement indicating receipt and initiation of appropriate action in response to the command.

Master-slave polling is used to detect synchronous communications between the host controller **2** and pumping channels **4**, **6**, **8** and **10**. These synchronous communications include, for example, the aforementioned alarms and door open/door closed conditions.

When, alarm conditions are sent from a pumping channel **4**, **6**, **8** and **10** to the host controller **2**, the pumping channel awaits acknowledgement from the host controller **2**. If an event is not acknowledged within a set time frame, the event is retransmitted until acknowledgement is received. After acknowledging the pump channel communication, the host controller **2** can either send a reset command to the pump or report failure to the user. For multi-event conditions, a pumping channel module will queue cases until all are acknowledged.

When multiple command packets are received or sent by the host controller **2**, either the entire command packet is completed or the entire command packet is aborted. Thus, if an alarm condition occurs during execution of a multi-command packet, the partial command packet is not processed. Rather, the entire packet must be resent and executed in its entirety.

Where an illegal command is attempted, command is ignored. An illegal command represents a command that cannot be processed at the time it is received. For example, when a drug channel **4**, **6** and **8** is an unprimed state, a start command which is received cannot be executed.

A more detailed discussion will now be provided of the drug channels **4**, **6** and **8**. Each drug channel **4**, **6** and **8** includes a pump which is preset at a position having an outlet valve closed, and an inlet valve open. A closed door switch is included in each drug pump to indicate when a drug channel door is closed with a cassette in place. An open door switch indicates that the drug channel door has been opened.

Pumping is accomplished in each drug channel via a pumping cassette which includes one or two proximal (inlet) lines and one distal (outlet) line. The pump includes a mechanical reciprocating plunger mechanism and a pumping cassette through which the drugs are pumped. The pumping cassette has a primary inlet port and a pumped-liquid outlet port. The primary inlet port is connected to a piercing pin for receiving drug from a vial. However, alternative drug containers and connection methods can be used. The cassette also includes a secondary inlet port which remains normally closed. However, if desired, the secondary inlet port can receive a second drug, or drug diluent, for mixing with drug which has been introduced to the cassette via the primary inlet port.

A principal function of the independent controller **9** in each drug channel is to control drug delivery, priming of the drug delivery line, communication with the host controller **2**, error detection and error reporting within the drug channel. The principal activity of the drug channel is drug delivery, whereby liquid is moved from one of the cassette inlet lines to the outlet line. The inlet lines, referred to herein as primary and secondary inlets, are typically configured with the primary line connected to a drug vial, and the secondary line disconnected. An exemplary delivery range is from 0.1 ml/hr to 1200 ml/hr.

For each pumping cassette, the drug channel controller responds to user commands to control bi-directional flow. Bi-directional flow control is critical for autopriming. During autopriming, the host controller **2** instructs operation of the valve actuators and plungers in each drug channel to displace air from the drug cassette. Further, the autopriming sequence can be used for priming the output line to the patient.

Each drug channel receives commands directly from the host controller **2** via the serial communication interface at an exemplary data rate 1200 baud. These commands include the aforementioned communications to set rate, start pumping and so forth. Each independent controller **9** detects anomalies within its own drug channel pumping line. Error conditions and significant cases are communicated by each channel controller to the host controller **2**.

Three different priming operations are required for the drug channel: the drug channel can fill, with drug, a cassette which is full of air distal to the air trap chamber (i.e., completely empty cassettes, cassettes with air in the pumping bowl, and cassettes with air in the distal tubing); the drug channel can remove air introduced into the cassette air trap without moving it to the outlet line; and the drug channel can remove air trapped between the secondary inlet and an optional secondary reservoir. The drug channel detects errors and reporting is performed by the drug channel to the host controller **2** with respect to four classes of errors: electronic, mechanical, cassette and communication.

Electronic integrity verification concerns the microprocessor memory, A/D lines and other microprocessor board and sensory apparatus. Mechanical integrity verification concerns verifying the mechanical pumping system is moving in accordance with commanded operation via the use of position detection feedback on three stepper motors included in each drug channel. Cassette integrity verification ensures that a cassette introduced to a drug channel is capable of withstanding pressures associated with pumping without leaking and is not occluded. Communication error detection is necessary to verify that transmitted data is accurate in accordance with the serial communication protocol. All failures are transmitted by the drug channel to the host controller **2**, and the drug channel will confirm that the host controller **2** is aware when an alarm condition exists.

More particularly, electronic integrity verification is used to verify electronic and software integrity. For example, on power-up, the drug channel performs a RAM test, a ROM test, an A/D converter test and a watchdog test. The drug channel verifies serial communication integrity by the on-going existence of incoming message packets. The drug channel verifies integrity of the air sensor by ensuring an air signal is seen whenever the door is open.

Mechanical integrity verification to ensure safety, involves verifying an ability of the pump channel mechanism and cassette to pump accurately. These tests are performed before pumping, and if any test fails, the drug channel is not permitted to pump. Motor position check and re-synchronization tasks (if necessary) are performed prior to pumping (e.g., when the system is activated), and no maximum time requirements are associated with these tasks.

Another function of each drug channel (**4**,**6**,**8**) is to perform a cassette integrity test to check for static occlusion and valve leaks when a cassette door is closed with a cassette in place. Occlusion detection is performed via the proximal and distal pressure sensors (i.e., pressure threshold is exceeded on proximal or distal side), after which an occlusion alarm is reported by the affected drug channel to the host controller **2**.

Leak tests are performed automatically whenever the cassette door is closed with a cassette in place. All of these tests are performed by monitoring pressure inside the cassette and are, for example, used to indicate the need for backpriming the cassette (automatic removal of air from the cassette done by pushing it back into the

drug container) or to indicate that a bad cassette needs to be replaced. The proximal pressure sensor self-test is used to ensure that the pressure sensor stays within a desired operating range.

A priming function of each drug channel (**4,6,8**) removes air from the drug delivery set. A drug delivery set includes a pumping cassette, distal tubing, and vial adapter. Priming operations perform both proximal and distal occlusion detection.

A pumping function is initiated in response to a start pumping command after all integrity tests have been implemented and passed. During pumping, mechanical motor position flags are monitored continuously by optical sensors.

The pumping function of the drug channel provides for proximal occlusion detection and distal occlusion detection using proximal and distal pressure sensors, respectively. A distal air in line alarm and stop pumping signal are generated by a drug channel if an air bubble (e.g., greater than, for example, 100 μl) (microliter), occurs at the distal air detector. The pump will also generate a distal air in line alarm if, for example, 200 μl out of the last 2.0 ml of volume was air.

The pumping function also includes an empty container detection when cumulative amount (e.g., 200 μl) of air has entered the cassette from at least one inlet line. This cumulative total is reset whenever the cassette door is opened, or a priming operation is performed.

A door open detection mode of the drug channels **4, 6,** and **8** is used to trigger return of the step motors in a given drug channel to a preset position. At all times except for electronic self-tests, (i.e., pumping, priming, and so forth), a "door opened" alarm is generated and transmitted to the host controller **2**. After the door is opened, the drug channel retains pumping parameters (i.e., rate, dose limit, delivered dose) except for pressure limit. When the door is again closed, the drug channel retains all of these parameters until commanded to change by the host controller **2**.

A description will now be provided of a fluid channel **10** control. A fluid pump within a fluid channel includes a plunger/inlet valve/outlet valve assembly and a DC motor to pump fluid.

The fluid channel controller **9** communicates with the host controller **2** via the serial communication interface to receive commands such as set rate, start and operational commands. Like the drug channels, the fluid channel **10** detects anomalies in the pumping line and communicates error conditions and significant cases to the host controller **2**.

The fluid channel **10** controls fluid delivery from inlet tubing to outlet tubing in an exemplary range of from 1 ml/hr to 1200 ml/hr. Further, the fluid channel **10** controls priming of air filled delivery tubing automatically. Like the drug channels, the fluid channel can detect four similar classes of errors: electronic, mechanical, fluid and communication.

Because pumping is the primary function of the fluid channel **10**, various parameters are accessible by the host controller **2** to configure the fluid channel behavior during pumping cycles. These parameters include delivery rate, dose limit, drop detector, priming time limit and door closed flag. The drop detector parameter determines whether detection of an empty fluid container is required during the delivery cycle. This parameter can be selectively requested by the host controller **2**. The priming time limit parameter provides fail-safe operation of the priming process. The door closed flag ensures that pumping and priming do not occur unless the delivery tubing is inserted and the pumping mechanism door latches closed. The flag is set whenever both the delivery tubing is inserted and the door latch is closed, and either a door opening or tubing removal will reset this flag.

Pumping functions of the fluid channel **10** include a priming cycle and a delivery cycle. Priming of the delivery tubing in response to a command from the host controller **2** consists of two phases: a proximal tubing filling phase and a distal tubing filling phase. During the proximal tubing filling phase, the fluid channel **10** activates its priming mechanism and starts pumping until a distal air sensor detects continuous fluid flow. After continuous fluid flow is detected, the priming mechanism is deactivated and control advances to a distal tubing filling phase. In the distal tubing filling phase, fluid is delivered at a specified delivery rate until the specified dose limit is reached as with a normal delivery cycle. The only difference is that when an air-in-line condition is detected during the distal tubing filling phase, the priming cycle returns to the proximal tubing filling phase instead of terminating the priming process.

Priming is discontinued when a specified dose limit is reached during the distal tube filling phase, upon receipt of a stop command from the host controller **2**, upon expiration of a priming time limit, upon detection of an empty container by a drop detector, or by an alarm in response to error detection. During the delivery cycle, the fluid channel **10** delivers fluid from its proximal tubing to its distal tubing at the specified delivery rate, until stopped by the user or the user specified dose limit is reached.

Error detection is similar to that of the drug channels and includes electronic, mechanical and fluid integrity checks. An error detected by these tests results in stoppage of the pumping process and communication of the error to the host controller **2**.

For example, electronic integrity verification includes use of a watchdog timer to interrupt the fluid channel CPU to ensure integrity of the fluid channel CPU, critical data storage verification, and sensor range verification with regard to temperature and power supply voltages. Mechanical integrity verification includes monitoring of motor slippage, monitoring of plunger motor shaft encoder slippage, pumping rate verification and motor voltage verification. Fluid integrity verification includes air-in-line detection, empty container detection, proximal occlusion detection, distal occlusion detection and differential distal occlusion detection (i.e., when average depositive pressure buildup of distal pressure, relative to the distal pressure at pumping start time, is detected). Detection of a drop detector (if required) and loss of the drop detector signal are also monitored.

It will be appreciated by those skilled in the art that the present invention can be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The presently disclosed embodiments are therefore considered in all respects to be illustrative and not restrictive. The scope of the invention is indicated by the appended claims rather than the foregoing description, and all changes that come within the meaning and range of equivalents thereof are intended to be embraced therein.

What is claimed is:

1. A control system for use with an automated intravenous drug and fluid infusion system, said control system comprising:

plural pumping channels that operate independently for intravenously infusing drugs and fluid, each of said pumping channels having a pumping channel controller for independent delivery in multiple infusion modes;

a host controller that monitors and controls each of the pumping channels concurrently; and

a bar code system for reading a bar code from a supply container to be used inn a pumping channel, said supply container holding a drug, a fluid or a combination of a drug and a fluid.

2. A control system according to claim 1 wherein said bar code system further includes:

sensors located within at least one of said pumping channels tom detect a presence of the bar code reader in a vicinity of at least one pumping channel.

3. A control system according to claim 2, wherein said sensors include:

electro-magnetic sensors which are arranged in each pumping channel to detect the presence of the bar code reader, the arrangement of sensors in each channel being different to uniquely identify each channel.

4. A control system according to claim 3, wherein said sensors are Hall effect sensors.

5. A control system according to claim 4, wherein said host controller receives signals generated within each of the pumping channels to identify a drug or fluid selected for use in that channel, and to control channel priming and delivery in response to the received signals.

6. A control system according to claim 5, wherein said host controller further includes:

a touch screen for user entry of control information, including drug dose and drug delivery rate for each drug pumping channel, and fluid delivery rate for each fluid pumping channel.

7. A control system according to claim 6, wherein said host controller further includes:

a display for displaying a selected drug, drug dose and delivery rate to the user for each drug channel, and for displaying fluid delivery rate for the fluid channel.

8. A control system according to claim 7, wherein each pumping channel control responds to commands from the host controller to perform pumping channel priming and delivery, and to signal error and status conditions of each pumping channel to the host controller, such that delivery of significant air to a patient is prevented.

9. A control system for use with an automated intravenous drug and fluid infusion system, said control system comprising:

plural pumping channels that operate independently for intravenously infusing drugs and fluid, each of said pumping channels having a pumping channel controller for independent delivery of drug and/or fluid in multiple drug infusion modes;

a host controller that monitors each of the pumping channels concurrently, each of said pumping channels further including:

automatic priming means for removing gases from each pumping channel independently to prevent delivery of significant air to a patient; and

means for preventing priming of a channel unless verification is provided that the channel is not connected to a patient.

10. A control system according to claim 9, wherein said preventing means further includes:

means for identifying a drug and fluid selected for use in each pumping channel.

11. A control system according to claim 10, further including:

a user touch screen for entering control information, said control information including drug dose and drug delivery rate for each drug pumping channel, and fluid delivery rate for each fluid pumping channel.

12. A control system according to claim 11, further including:

means for displaying a selected drug, drug dose and delivery rate to the user for each drug channel, and displaying fluid delivery rate for the fluid channel.

13. A control system according to claim 12, wherein each of said pumping channel controllers further includes:

means for responding to commands to perform channel priming and delivery, and for signaling error and status conditions of each pumping channel.

14. A control system according to claim 13, wherein said host controller includes:

means for determining whether drugs selected for one or more pumping channels are compatible; and

means for displaying incompatible drugs to the user.

15. A control system for use with an automated intravenous drug and fluid infusion system, said control system comprising:

plural pumping channels that operate independently for intravenously infusing drugs and fluid, each of said pumping channels having a pumping channel controller for independent delivery from each channel in multiple infusion modes;

a host controller that monitors each of the pumping channels concurrently, each of said pumping channels further including:

means for identifying a particular drug that is to be pumped through a drug pumping channel.

16. A control system according to claim 15, wherein said identifying means further includes:

a bar code system for reading a bar code from a drug supply container to be used in a pumping channel.

17. A control system according to claim 16, wherein said identifying means further includes:

means for detecting a presence of a bar code reader in a vicinity of at least one pumping channel.

18. A control system according to claim 17, wherein said detecting means includes:

electro-magnetic sensors in each pumping channel to detect the presence of the bar code reader, the arrangement of sensors in each channel being different to uniquely identify each channel.

19. A control system according to claim 15, wherein said host controller further includes:

means for prompting a user to input pumping channel control parameters; and

means for converting quantities designated by the user into units for processing by the host controller.

20. A control system according to claim 15, wherein said host controller and at least one pumping channel controller include:

means for controlling pharmacokinetic-based delivery of a drug; and

means for displaying predicted plasma level based on the pharmacokinetic-based delivery.

21. A control system according to claim **15**, further including:

means for maintaining an updated log of drug and fluid delivery, including a record of system errors which have occurred during delivery.

22. A control system for use with an automated intravenous drug and fluid infusion system, said control system comprising:

plural pumping channels that operate independently for intravenously infusing drugs and fluid, each of said pumping channels having a pumping channel controller for controlling independent delivery in multiple drug infusion modes, each of said pumping channels further including:

automatic priming means for removing gases from each pumping channel independently to inhibit delivery of air to a patient; and

means for preventing priming of a channel unless verification is provided that the channel is not connected to a patient.

* * * * *

EXHIBIT C

US007556616B2

(12) **United States Patent**
Fathallah et al.

(10) **Patent No.: US 7,556,616 B2**
(45) **Date of Patent: Jul. 7, 2009**

(54) **MEDICAL DEVICE SYSTEM**

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(73) Assignee: **Hospira, Inc.**, Lake Forest, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1089 days.

(21) Appl. No.: **10/823,220**

(22) Filed: **Apr. 13, 2004**

(65) **Prior Publication Data**

US 2005/0135047 A1 Jun. 23, 2005

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(63) Continuation-in-part of application No. 10/696,830, filed on Oct. 30, 2003.

(51) **Int. Cl.**
A61M 37/00 (2006.01)

(52) **U.S. Cl.** **604/131**

(58) **Field of Classification Search** ..... 604/65–67, 604/131, 250; 128/DIG. 12, DIG. 13; 24/455, 24/462, 563; 248/226.11, 316.1
See application file for complete search history.

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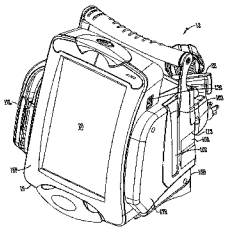
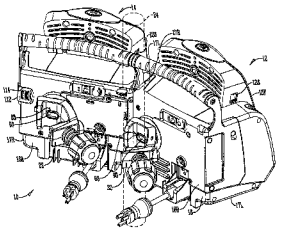
Primary Examiner—Manuel A Mendez
(74) *Attorney, Agent, or Firm*—Michael R. Crabb

(57) **ABSTRACT**

A first portable medical device is adapted for use in an interlocking system for interlocking the first medical device to a second medical device. The first device includes a housing having opposite sides, a selective element, a blocking element, and an optional clamp mechanism. At least one of the opposite sides includes a matable element to detachably attach a second medical device. The selective element restricts the attachment of the second device to only one side of the first device. The blocking element prevents a third medical device from attaching to the first and second devices once the first and second devices are attached. The clamp restricts the attachment of the second device to only one side of the first device when the clamp is attached to a support member. The clamp permits slide-ratcheting axial movement of a clamp shaft.

25 Claims, 9 Drawing Sheets





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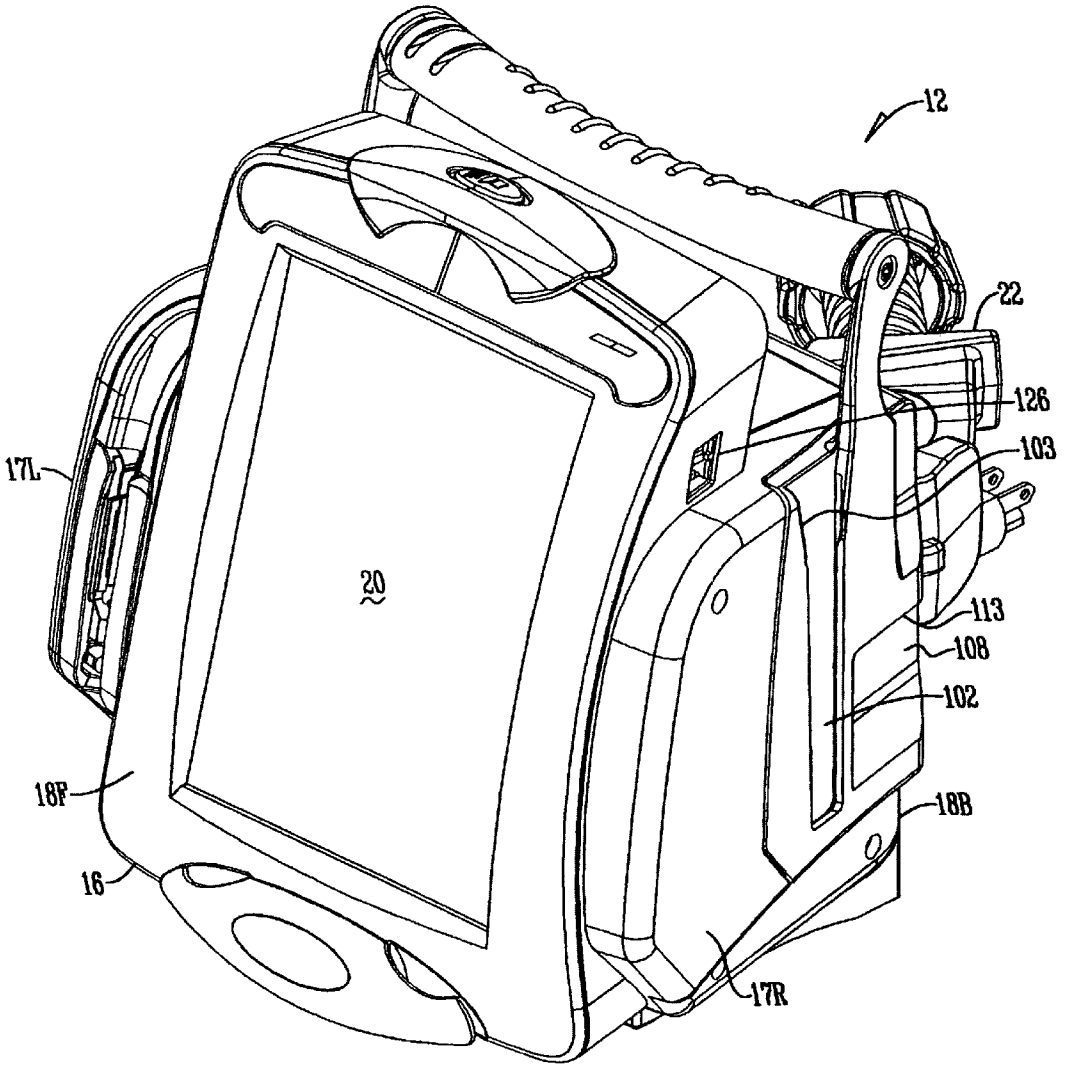


Fig. 1

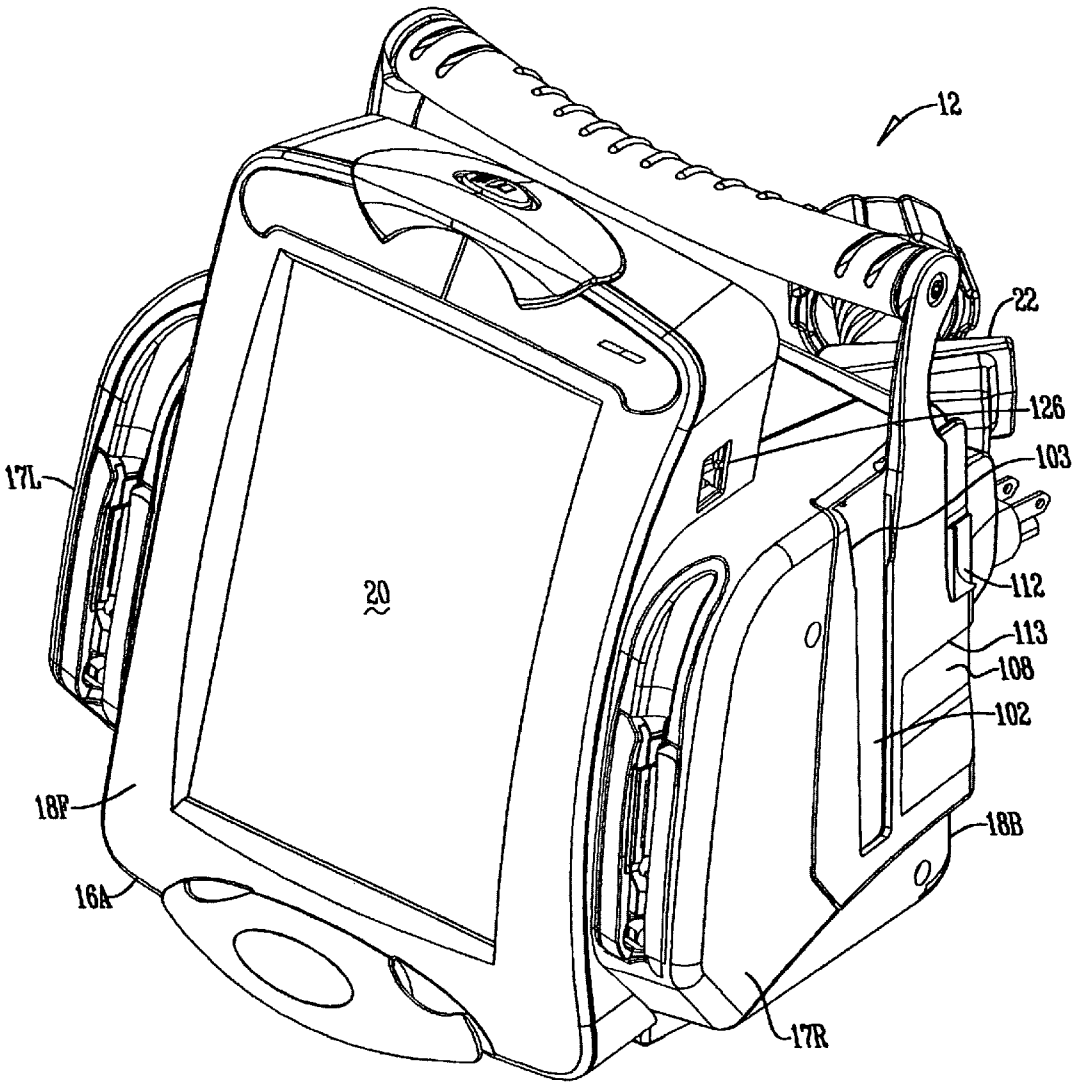
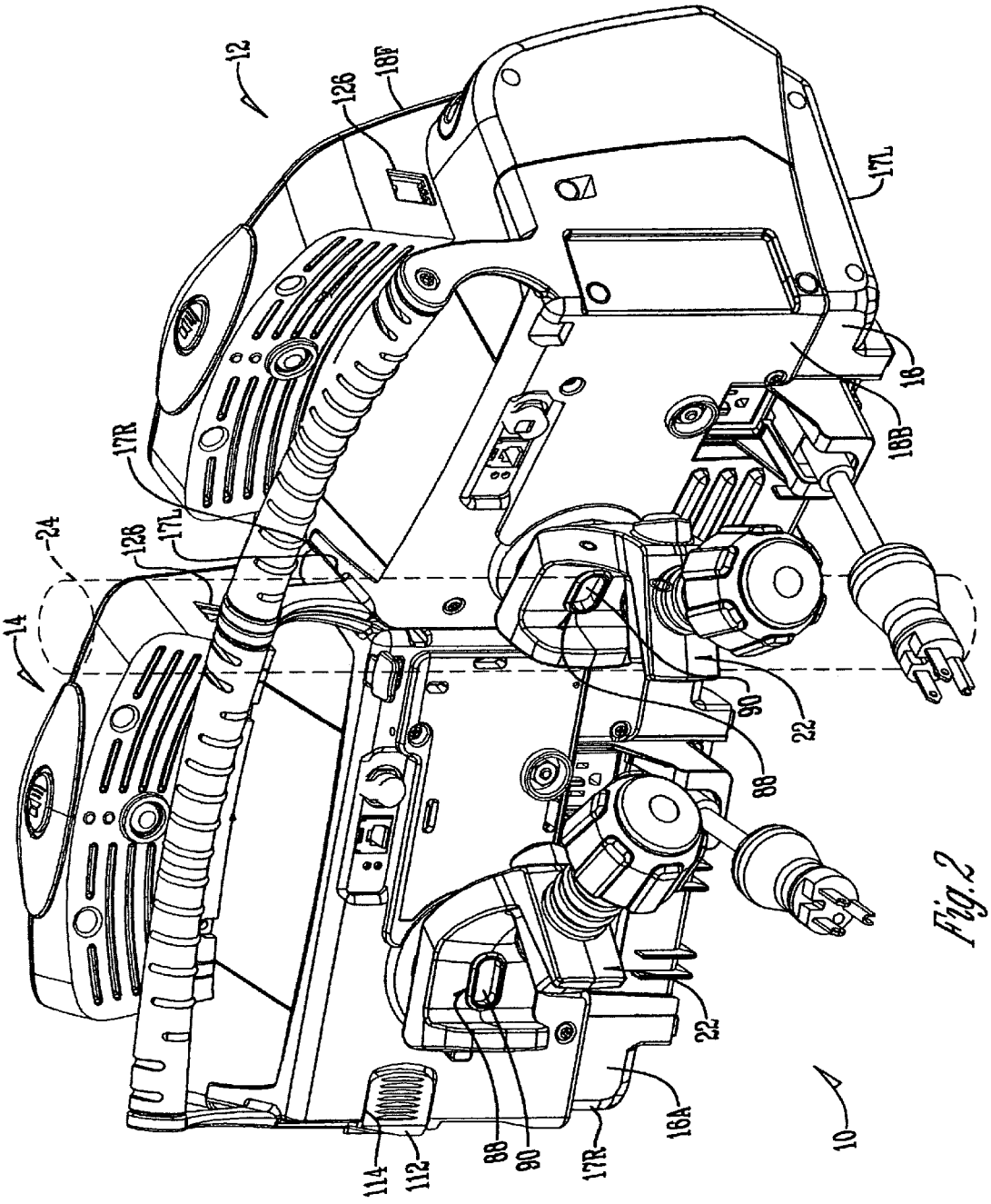


Fig. 1A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18
18B
17R
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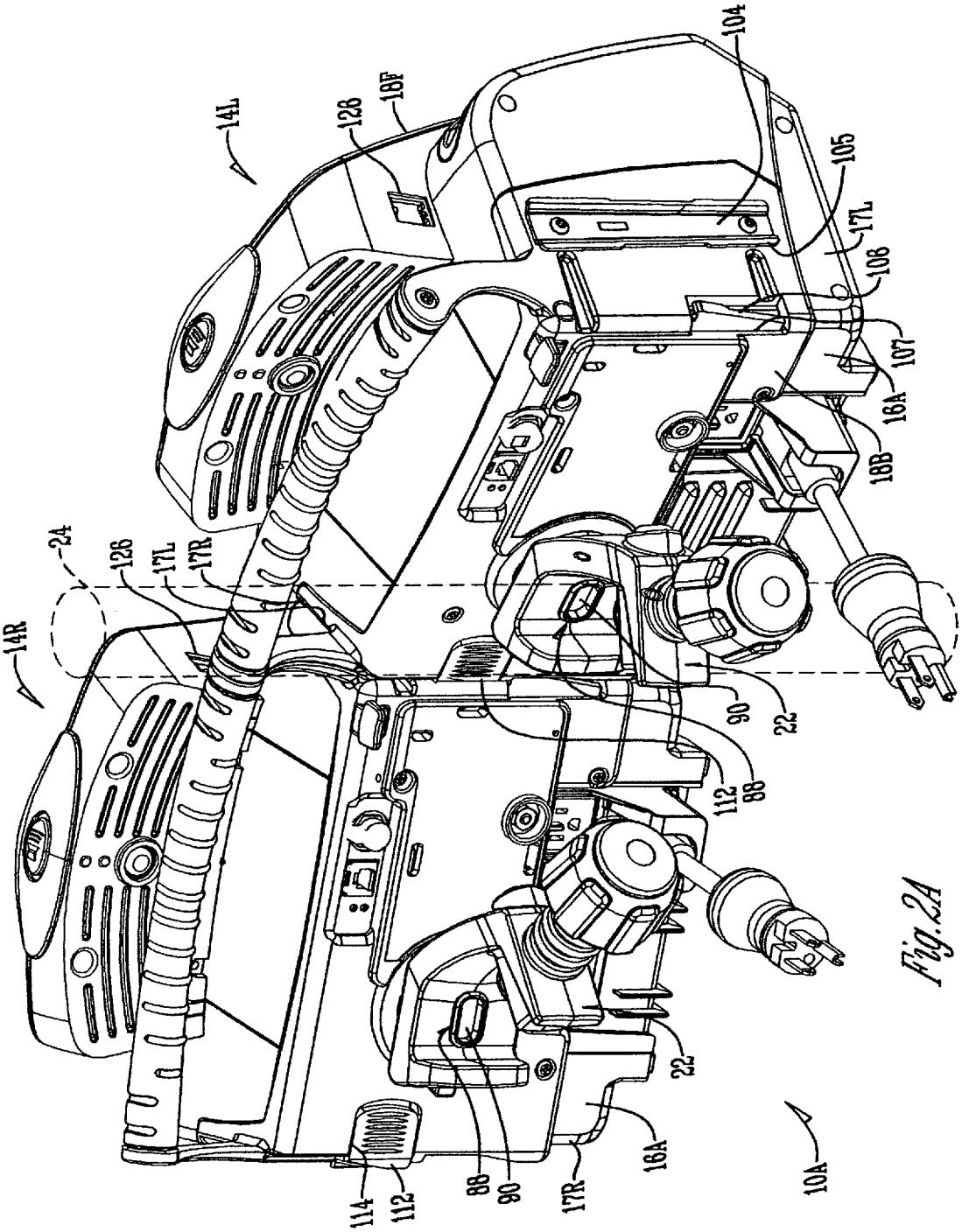
90
17R

Fig. 2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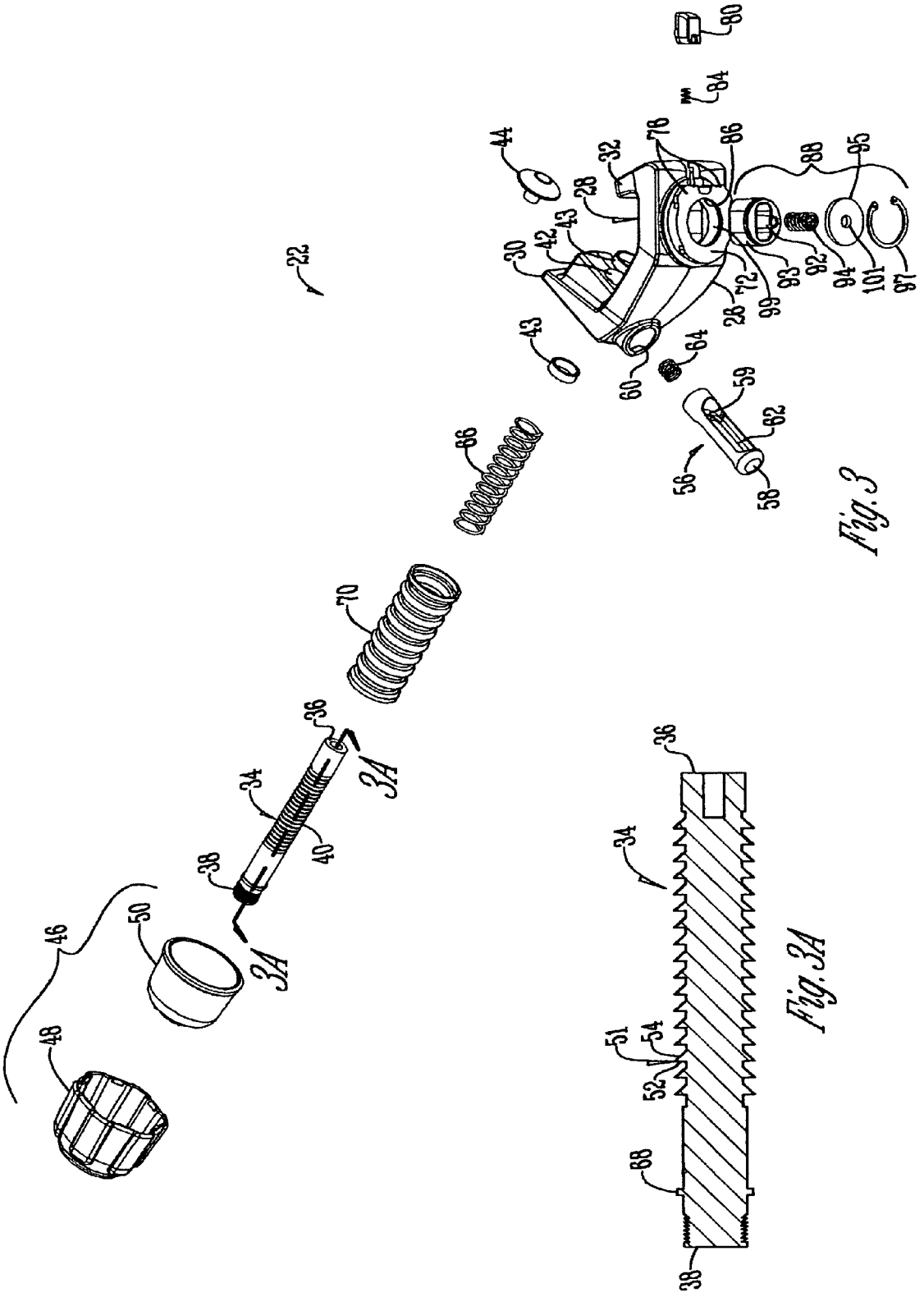
17R

Fig. 2A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64
59
62
56
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66
70
36
34
40
38
3A
3A
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48
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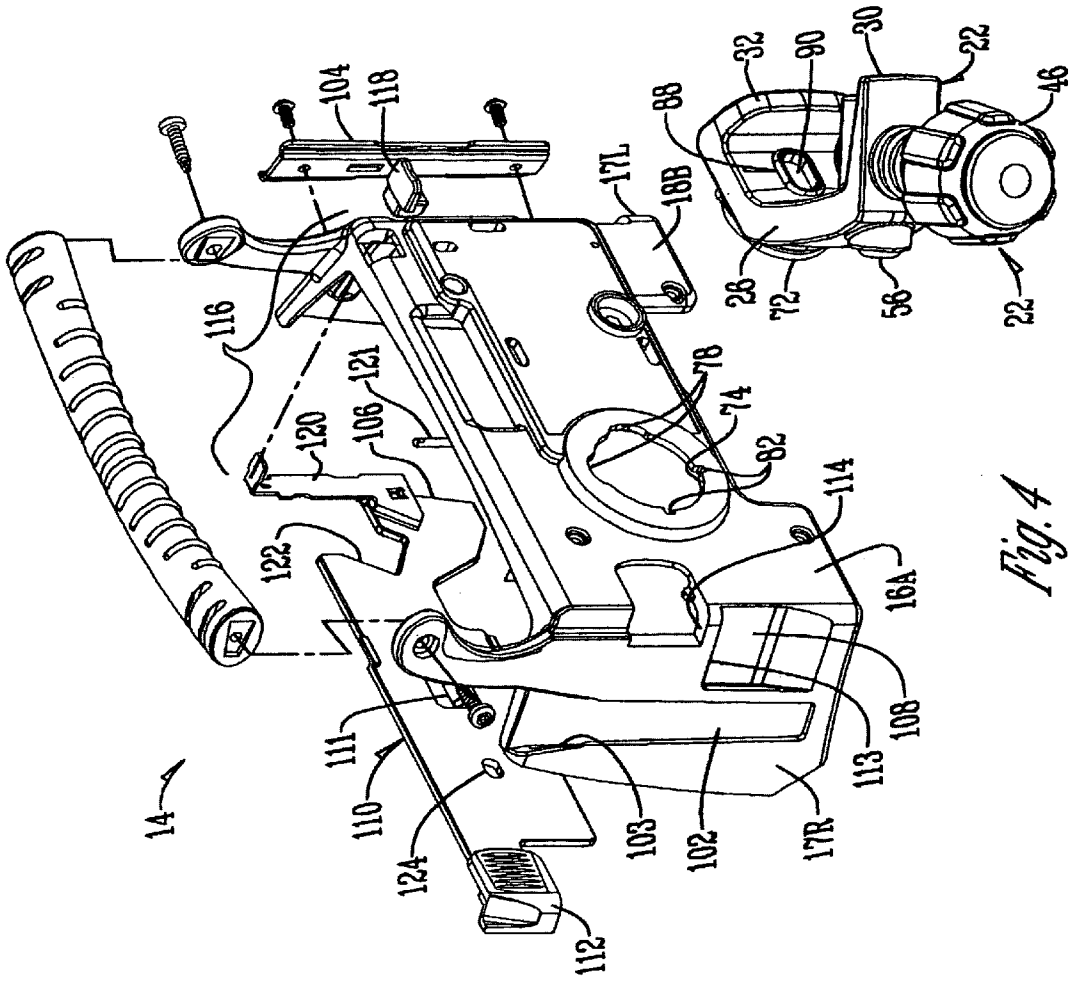
Fig. 3

Fig. 3A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46
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18B
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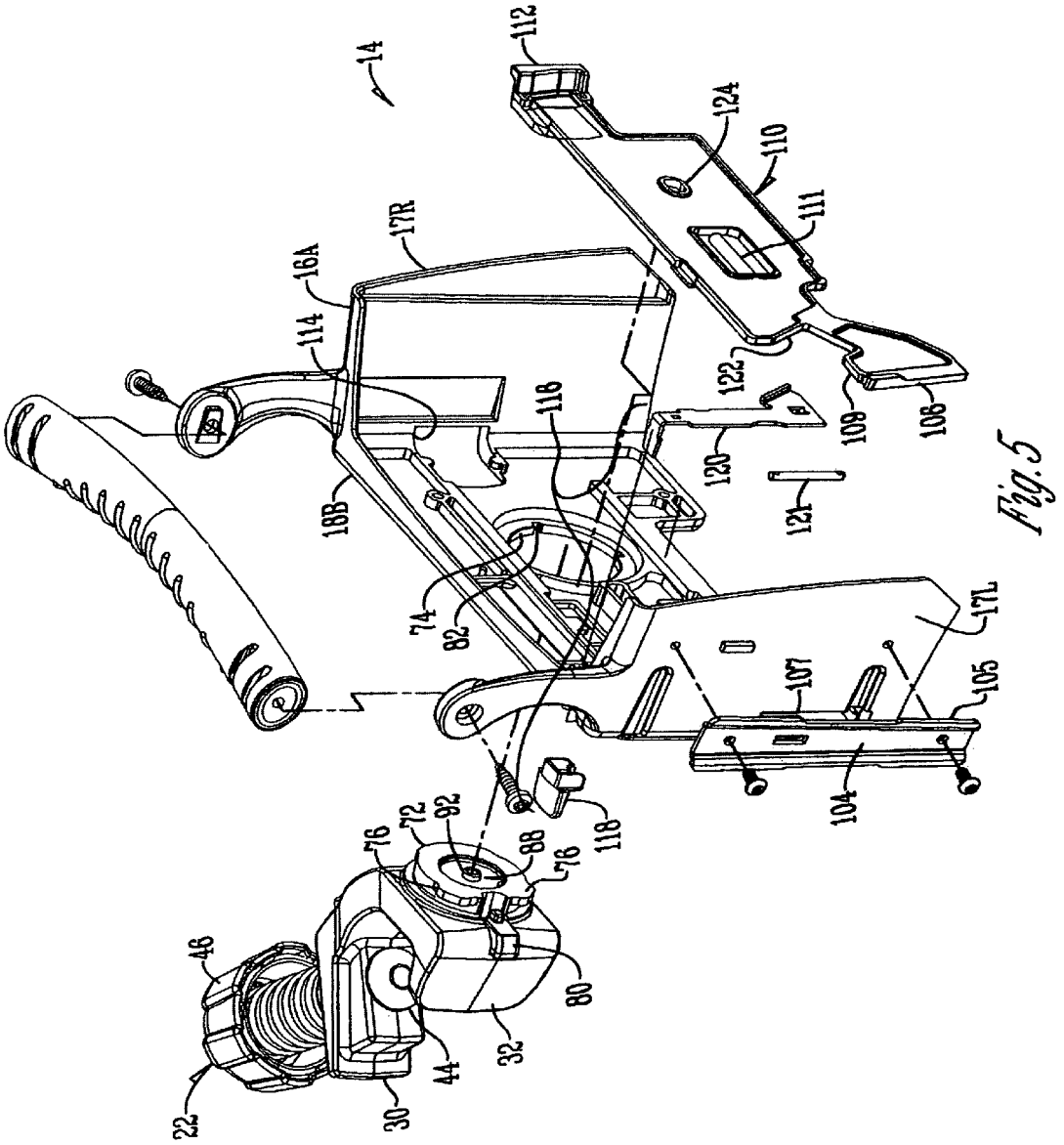
113
110
103
102
17R
14
124
112
26
72
56
22

Fig. 4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30

Fig. 5

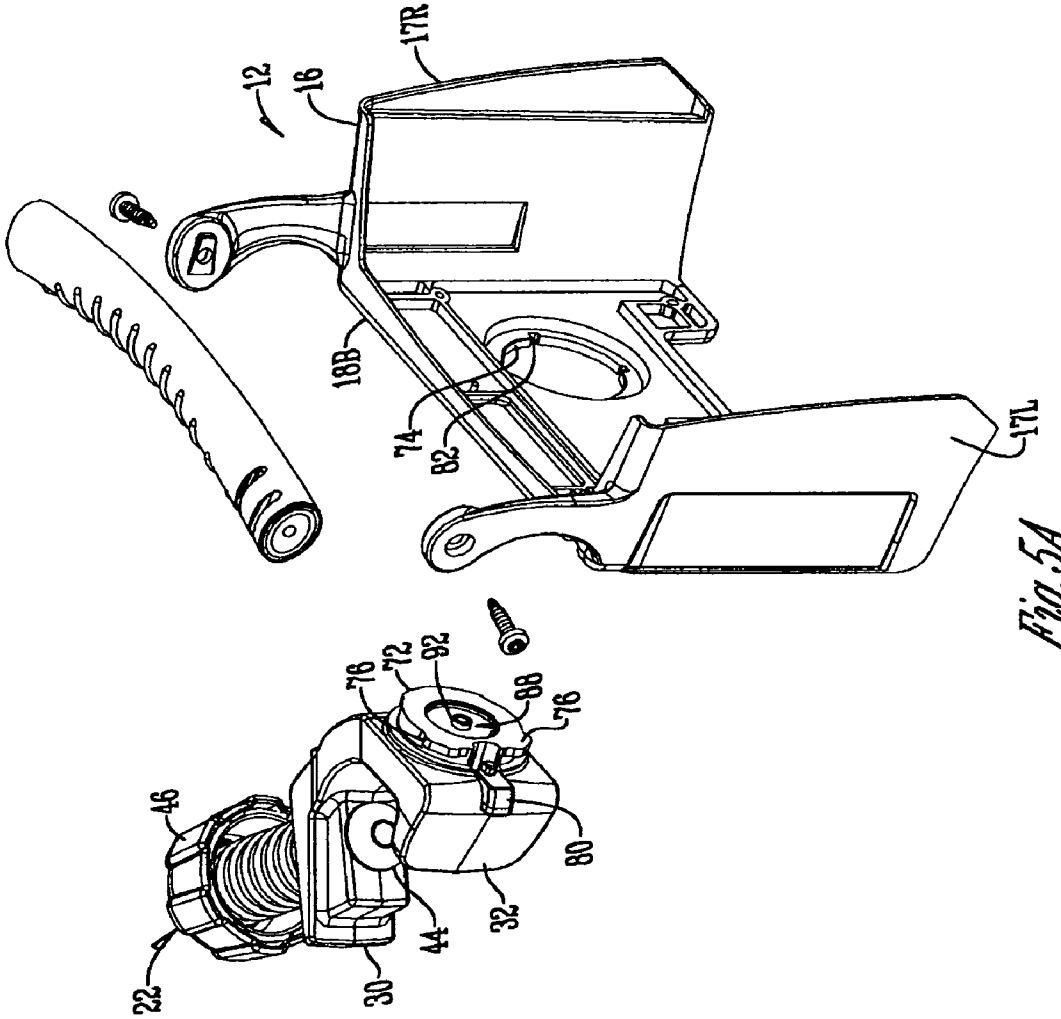

Fig. 5A

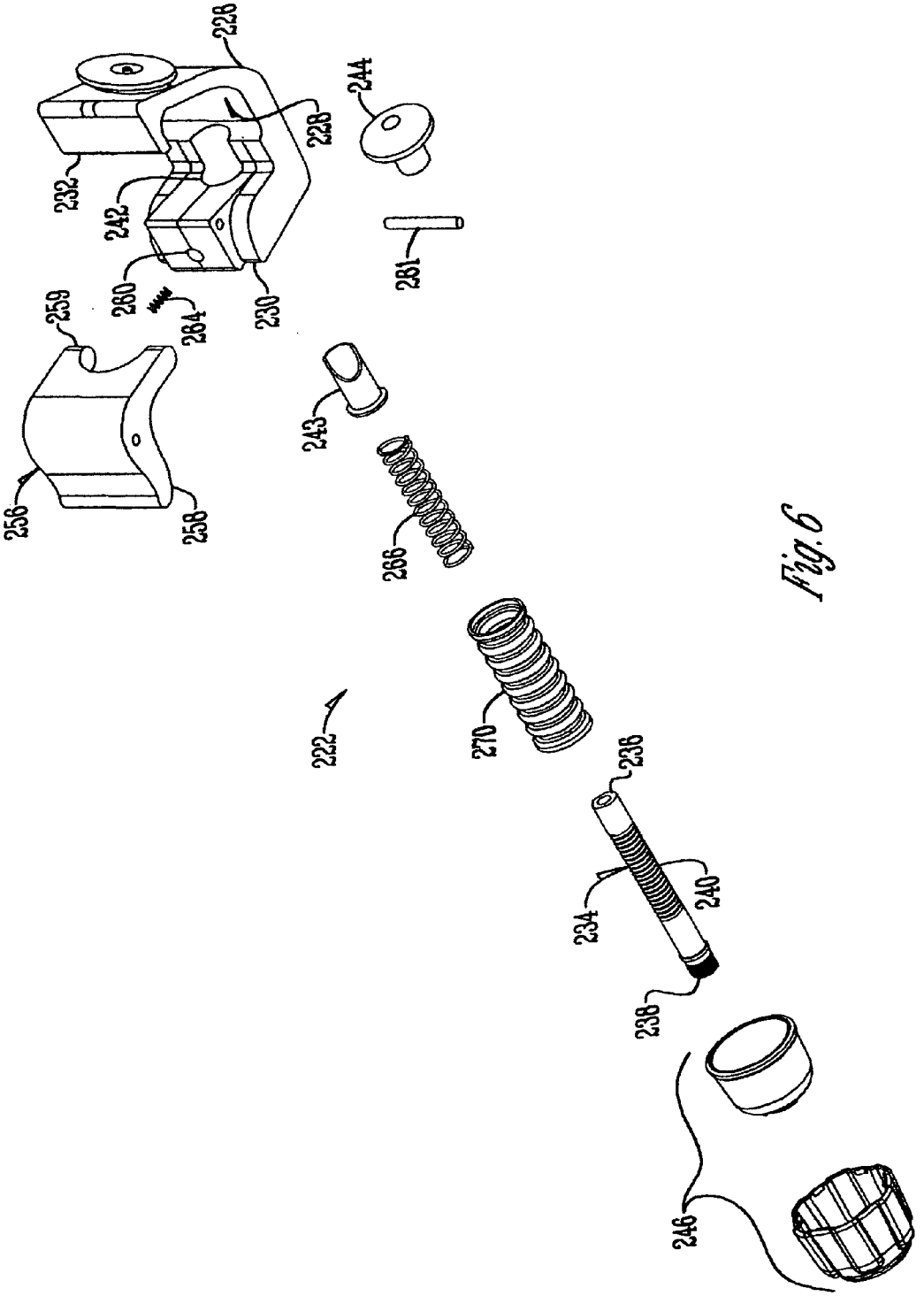
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Fig. 6

MEDICAL DEVICE SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 10/696,830, filed Oct. 30, 2003.

BACKGROUND OF THE INVENTION

The present invention generally relates to the field of medical devices, and more particularly to the field of point of care medical devices including but not limited to infusion pumps, monitors, and diagnostic equipment. The invention provides a portable point of care system that includes one or more medical devices mountable on a pole stand, bedrail or other supporting structure in close proximity to a patient. The invention includes means and methods for interlocking the medical devices together, preventing undesirable arrangements and combinations of medical devices, mounting the medical devices on the main supporting structure, and automatically providing wireless communication between the medical devices.

In modern medical practice a variety of diagnostic and therapeutic devices are used, sometimes to such a degree that floor and shelf space near the patient's bedside is at a premium. One known solution to the problem of mounting medical devices is the use a pole stand. Often such pole stands have wheels for the convenience of the patient or medical personnel in moving the devices where they are needed, but wheeled pole stands can become unbalanced upon, for example, crossing thresholds or exiting elevators.

Some manufacturers have mounted a central management unit and infusion pump modules in a vertically stacked configuration on a pole stand, as disclosed in U.S. Pat. Nos. 4,756,706 and 4,898,578. Vertically stacked configurations can make identification, routing and management of the associated intravenous (IV) tubes confusing and difficult. Manufacturers also have interlocked interchangeable independently functioning single channel pumps in a horizontal arrangement for attachment at a particular vertical location on a pole stand, as disclosed in U.S. Pat. No. 5,431,509. U.S. Pat. Nos. 5,713,856; 5,941,846 and 5,601,445 disclose a central control unit and a plurality of horizontally arranged detachable pump and/or sensor modules. Other manufacturers have developed multiple channel pumps, as disclosed in U.S. Pat. No. 5,378,231 and Des. 367,528. However, in the vast majority of applications a single channel pump or single pump module will suffice to meet the caregiver's needs, and customers generally are not inclined to pay the substantial premium needed to cover the manufacturing cost of a multiple channel pump or an elaborate interlocking means. Thus, there is a need for an improved system of medical devices.

A primary objective of the present invention is the provision of an improved system of interlockable portable medical devices that only allows two medical devices to be joined together.

Another objective of the present invention is the provision of an improved system of interlockable portable medical devices.

A further objective of the present invention is the provision of an improved clamp mechanism, for mounting a medical device to a support member, which restricts the attachment of a second medical device to only one side of a first medical device when the clamp mechanism is attached to a support member.

A still further objective of the present invention is the provision of an improved clamp mechanism that permits slide-ratcheting axial movement of the clamp shaft.

These and other objects will be apparent to those skilled in the art.

SUMMARY OF THE INVENTION

A first portable medical device is adapted for use in an interlocking system for interlocking the first medical device to a second medical device. The first device includes a housing having opposite sides, a selective element, a blocking element, a clamp mechanism, and wherein at least one of the opposite sides includes a first matable element to detachably interconnect a second medical device to the first medical device. The selective element restricts the attachment of the second device to only one of the opposite sides of the first device. The blocking element prevents a third medical device from attaching to either the first or second device once the first and second devices are attached. The clamp mechanism restricts the attachment of the second device to only one side of the first device when the clamp mechanism is attached to a support member. The clamp mechanism also permits slide-ratcheting axial movement of a clamp shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front perspective view of a medical device adapted for use in a medical device system according to the present invention;

FIG. **1**A is a front perspective view of another medical device adapted for use in a medical device system according to the present invention;

FIG. **2** is a rear perspective view of one embodiment of the medical device system of this invention wherein two medical devices are joined together in side-by-side relationship;

FIG. **2**A is a rear perspective view of another embodiment of the medical device system of this invention wherein two medical devices are joined together in side-by-side relationship;

FIG. **3** is an exploded perspective view of a clamping mechanism of the present invention;

FIG. **3**A is a cross sectional side view of the clamping mechanism of the present invention taken along line **3**A-**3**A in FIG. **3**;

FIG. **4** is a partial rear exploded perspective view of the device of FIG. **2**A;

FIG. **5** is a partial front exploded perspective view of the device of FIG. **2**A;

FIG. **5**A is a partial front exploded perspective view of the device of FIG. **1**, which is also the device on the right when viewed as in FIG. **2**; and

FIG. **6** is an exploded perspective view of an alternative clamping mechanism of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

In the description and figures, components that are similar or substantially identical in function or structure are designated with similar or identical reference numerals.

The medical device system **10** (FIG. **2**), **10**A (FIG. **2**A) of the present invention includes a plurality of portable medical devices **12** (FIG. **1**) and **14** (FIG. **1**A) or **14**L and **14**R (FIG. **2**A) that are capable of being detachably interlocked together. Devices **12**, **14**, **14**L, or **14**R can be devices for performing similar tasks or devices for performing different tasks as

described below. For the sake of brevity the devices **14**L, **14**R, which are labeled to indicate their respective positions on the left and right of the system **10**A when viewed from the front, are sometimes referenced in a generic sense by reference numeral **14**. In the context of the present invention, the term "medical device" includes without limitation a device that acts upon a cassette, reservoir, vial, syringe, or tubing to convey medication or fluid to or from a patient (for example, an infusion pump, a patient controlled analgesia (PCA) or pain management medication pump, or a suction pump), a monitor for monitoring patient vital signs or other parameters, or a diagnostic device.

For the purpose of exemplary illustration only, the medical devices **12**, **14**, **14**L, and **14**R are all disclosed as infusion pumps. More particularly, the medical device **12** can be a single channel infusion pump and the medical devices **14**L and **14**R can be dual channel infusion pumps. The pumps **12** and **14** have housings **16** and **16**A respectively. Each housing **16**, **16**A includes generally opposite side walls **17**L, **17**R and generally opposite back and front walls **18**B, **18**F. A user interface touch screen **20** is mounted in the front wall of housing **16**, **16**A so as to be visible and accessible from the front of the device.

As best seen in FIGS. **2** and **2**A, at least one, and more preferably both, of the medical devices or pumps **12**, **14** has a releasable clamping mechanism **22** attached thereto for detachably mounting the device **12** or **14** to a support structure or member, such as a tabletop edge or pole **24**. In the context of this invention, a "pole" should be understood to include without limitation an elongated bar, rail, tubular member, beam or pin on a pole stand, bed, wall or other structure for supporting the medical device. The pole **24** can be configured and oriented in a variety of known ways, including without limitation as a bed rail extending in a generally horizontal direction or as an upright tubular member extending in a generally vertical direction on a pole stand. For the sake of brevity only the clamping mechanism **22** on the pump **12** is described below, but the clamping mechanism **22** on pump **14**, if provided, can be substantially identical.

As best seen in FIGS. **2**, **2**A, **3** and **3**A, the clamping mechanism **22** of the present invention has a substantially rigid clamp body **26** that is pivotally and preferably removably attached to the pump housing **16** and includes a pole-receiving slot **28** for receiving the pole **24**. The clamp body **26** defines generally opposing first and second jaws **30**, **32** that at least partially surround the pole-receiving slot **28**. One skilled in the art will appreciate that many different clamp body shapes can be utilized without detracting from the invention, including without limitation a generally L-shaped, U-shaped, J-shaped, G-shaped or. C-shaped clamp body.

A clamp shaft **34** is movably mounted on the first jaw **30**. The clamp shaft **34** has opposite ends **36**, **38** and a ratchet portion **40** therebetween. The first jaw **30** has a clamp shaft receiving hole **42** formed therein, and more preferably therethrough, for receiving bushings **43** and the ratchet portion **40** of the clamp shaft **34**. The distal end **36** of the clamp shaft **34** extends from the first jaw **30** toward the second jaw **32**. A pressure pad **44** connects, or more preferably attaches, to the distal end **36**.

The proximal end **38** of the clamp shaft **34** has displacement means **46** connected thereto for selectively moving the clamp shaft **34** axially and applying a torque to the clamp shaft **34**. While one skilled in the art will appreciate that the displacement means **46** for moving or turning the clamp shaft could include a hydraulic or pneumatic cylinder, electric stepper motor, or other powered displacement devices, a simple manual hand knob **48** can be connected to the clamp shaft **34**, preferably to the proximal end **38** on the opposite side of the first jaw **30**.

A clutch mechanism **50** can be operatively interposed between the knob **48** and the clamp shaft **34**. The clutch mechanism **50** can be a ratchet type or any other known type for preventing the tightening torque applied to the clamp shaft from exceeding a predefined torque limit. Individuals manually installing the pump **12**, **14** on the pole **24** will have different strength capabilities for applying torque to the hand knob **48**. The clutch mechanism **50** insures that a consistent clamping force is applied to the pole **24** and prevents overtightening, which insures that the torque required to release the clamp mechanism from the pole is consistent and well within the capabilities of most individuals.

The ratchet portion **40** of the clamp shaft **34** has ratchet teeth. Preferably the ratchet teeth comprise external threads **51**. The threads **51** can be any type of helical threads without detracting from the invention, but more preferably the threads **51** are pull-type buttress threads. As is well known in the mechanical arts, buttress threads have a pressure, thrust or load flank that is nearly perpendicular (with less than ten, and more preferably about five to seven, and typically about five degrees inclination allowed for cutter clearance) to the thread axis of the shaft and a clearance flank, lead flank or thread angle that is about fifty to forty-five degrees. Preferably, the buttress threads utilized in this invention have a pressure flank **52** directed toward the proximal end **38** of the clamp shaft **34** and a lead flank **54** directed toward the distal end **36** of the clamp shaft **34**.

A selectively releasable positioning means or travel control means **56** is movably mounted on the clamp body **26**. The travel control means **56** includes a release button **58** that has at least one pawl **59** adapted to matingly engage the threads **51** on the clamp shaft **34** and means for biasing the pawl **59** into engagement with the threads **51**. The release lever or button **58** and pawl **59** are shown as a unitary body; however, it will be understood that the release lever **58** and pawl **59** may be provided as separate pieces. The release button **58** is movably mounted in a hole **60** in the first jaw **30**. The hole **60** intersects the clearance hole **42** as shown. The release button **58** is preferably an elongated pin with a slot **62** extending transversely therethrough. The slot **62** receives the clamp shaft **34** and has a length greater than the major diameter of the threads **51** on the clamp shaft **34**. The width of the slot **62** is slightly greater than the major diameter of the threads **51**. The slot **62** includes the pawl **59** as a portion thereof and has a thread on a wall thereof for matingly engaging the ratchet portion **40** of the clamp shaft **34**. The pawl **59** is normally biased into mating engagement with the ratchet portion **40** of the clamp shaft **34** by a biasing means **64** (such as a spring or other similar device) operatively interposed between the release button **58** and the first jaw **30**.

In operation, the travel control means **56** is configured and arranged to normally resist axial movement of the clamp shaft **34** in a direction away from the pole-receiving slot **28**. The travel control means **56** also permits a user to apply an axial force to the clamp shaft **34** sufficient to overcome the biasing force of the biasing means **64**, to permit slide-ratcheting axial movement of the clamp shaft **34** in a direction toward the opening or pole-receiving slot **28**.

Alternatively, in some applications it is desirable to prevent slide-ratcheting axial movement of the clamp shaft **34** if axial force is inadvertently applied to the clamp shaft **34**. In this case the biasing means **64** is selected to provide sufficient spring force to prevent normal user force on the clamp shaft

34 from causing slide-ratcheting axial movement of the clamp shaft 34 without the user also deactivating the travel control means 56.

A biasing means 66 (such as a spring or other similar device) is operatively interposed between the first jaw 30 and a ledge 68 on the clamp shaft 34. A bellows element 70 encloses the clamp shaft 34 and biasing means 66. The bellows element 70 protects a user from contacting the clamp shaft 34 and biasing means 66 moving parts.

As best seen in FIGS. 3 and 4, the clamp mechanism 22 is adapted to be rotatably associated with the medical device housing 16A or 16 (not shown). The clamp mechanism 22 includes a clamp lug 72 which rotationally mates with a housing lug 74. The clamp lug 72 includes extended ear elements 76 that correspond in shape and size to ear recesses 78 in the housing lug 74. The ear recesses 78 receive the extended ear elements 76. Once the clamp mechanism 22 is rotated, the clamp lug 72 mates with housing lug 74 to removably secure the clamp mechanism 22 to the medical device housing 16A.

A pivot latch 80 is movably mounted on the clamp body 26. The pivot latch 80 permits an operator to selectively lock the clamp mechanism 22 in a select one of a plurality of rotational positions with respect to the housing 16A. These rotational positions are defined by the recesses 82 of the housing lug 74. The pivot latch 80 is normally biased into mating engagement with the recesses 82 of the housing lug 74 by a biasing means 84 (such as a spring or other similar device) operatively interposed between the pivot latch 80 and the clamp body 26.

As best seen in FIGS. 3-5, the clamp body 26 has a hole 86 therein for slidably receiving a locking element 88. As will be discussed in greater detail below, the locking element 88 applies force on a component of the medical device 14 when the clamp body 26 is affixed to a support member 24 (FIG. 2A). As shown, the locking element 88 includes a support contact element 90 that contacts a support member 24 and is connected to a transfer pin 92 for locking the selected component of the medical device 14 to a restricted range of motion, and a main body 93 extending between the support contact element 90 and the transfer pin 92. Although the main body 93, support contact element 90, and transfer pin 92 are shown as a unitary member, one skilled in the art will appreciate that they can be separate components without detracting from the invention. For example, the contact element 90 and transfer pin 92 can be a unitary member that is movable with respect to the main body 93 or all three parts can be separate components.

The transfer pin 92 is normally biased toward the pole-receiving slot 28 and away from the housing 16A by a biasing means 94 (such as a spring or other similar device) operatively interposed between the main body 93 and the clamp body 26. A washer 95 provides a seat for the biasing means 94 and retains the main body 93 in the opening 86 when a retaining ring 97 is installed in a retaining groove 99 in the opening 86. The washer 95 has a hole 101 through which the transfer pin 92 slidably extends. Thus when the clamp body 26 is mounted on the housing 16A the biasing means 94 is also operatively interposed between the housing 16A and the main body 93.

Other designs of locking element are contemplated. For instance, the locking element 88 could apply only a frictional force to the selected component of the medical device 14.

As best seen in FIGS. 2A, 4 and 5, the medical device 14 includes a first matable element 102 positioned on the side wall 17R and a second matable element 104 positioned on the side wall 17L. The first matable element 102 is formed as a female T-slot in the housing 16A. The second matable element 104 is formed as a male T-slide attached to the housing 16A. Alternatively, the first matable element 102 is formed as a female dovetail in the housing 16A, and the second matable element 104 is formed a male dovetail attached to the housing 16A. Another alternative embodiment is to merely provide at least one of the opposite sides of the medical devices 14R, 14L with a matable element for detachably interconnecting to the matable element of the other medical device and attaching the first and second medical devices together. In other words, the unused matable elements in FIGS. 2A, 4, 5 and 5A could be removed or omitted.

The first matable element 102 includes a ramped portion 103 at its upper end. The ramped portion 103 allows for a greater degree of freedom when a user initially mates the first matable element 102 to the second matable element 104. Likewise, the second matable element 104 includes a tapered portion 105 at its lower end. The tapered portion 105 allows for a greater degree of freedom when a user initially mates the first matable element 102 to the second matable element 104. Without such ramped portion 103 and/or tapered portion 105, the first matable element 102 and second matable element 104 would need to be precisely aligned to properly mate together.

Although it may differ in the clinical function or task it performs, with respect to its attachment or connectology features, the second medical device 14R is substantially identical to the first medical device 14L. The second medical device 14R includes second matable element 104 positioned on the side wall 17L for detachably interconnecting to the corresponding first matable element 102 of the first medical device 14L, attaching the first and second medical devices 14L, 14R.

Once first and second medical devices 14L, 14R are joined, a latch element 106 extending through latch port 107 in the second medical device 14R side wall 17L mates with a corresponding latch notch 108 on the first medical device 14L side wall 17R. The latch element 106 detachably locks the first and second devices 14L, 14R together, and prevents the first and second matable elements 102 and 104 from being uncoupled.

The latch element 106 is formed as a portion of a transfer plate 110. The transfer plate 110 extends through both side walls 17L and 17R of the device 14. The transfer plate 110 also includes a biasing means 111 (such as a spring or other similar device) operatively interposed between the transfer plate 110 and the housing 16A for laterally biasing the latch element 106 toward the latch notch 108. When the latch element 106 is engaged to a corresponding latch notch 108, the transfer plate 110 is slightly displaced relative to the housing 16A and the side walls 17L and 17R. This displacement causes a blocking element 112 of the transfer plate 110 to extend through a blocking port 114 in the second medical device 14R side wall 17L. When the blocking element 112 is extended, no additional medical device can be joined to the second medical device 14R.

As best seen in FIGS. 1, 4 and 5, a latch post 109 is formed as a portion of a transfer plate 110. The latch post 109 is located along an upper edge of latch element 106 and mates with a corresponding undercut portion (not shown) located on the upper surface 113 of latch notch 108. In normal operation, the latch post 109 does not engage undercut portion of latch notch 108. However, in situations where a user is carrying two devices 12, 14 or 14L, 14R connected together by the handle of the right most device (14R), the latch post 109 prevents unintentional release of the latch element 106. Without latch post 109 and the undercut on surface 113, such an unintentional release would cause the left most device (14L or 12) to release out of attachment and to free fall. However, with the

latch post **109**, the latch element **106** mates with the corresponding undercut portion of latch notch **108** when the two devices (**12** and **14**R or **14**L and **14**R) are lifted only by the handle of the right most device (**14**R), and thus only slight relative movement is permitted between the two devices.

As best seen in FIGS. **2**A, **4** and **5**, likewise, the blocking element **112** of the first medical device **14**L abuts the second medical device **14**R side wall **17**L, and prevents the transfer plate **110** of the first medical device **14**L from moving. Thus, the latch element **106** of the first medical device **14**L is likewise prevented from moving, which will also block any additional medical device from being joined to the side wall **17**L of first medical device **14**L.

Thus both blocking element **112** of the second medical device **14**R and the latch element **106** of the first medical device **14**L act as a blocking means for preventing a third medical device **12** or **14** from attaching to either the first or second medical device **14**L or **14**R once the first and second medical devices **14**L, **14**R are attached. This operation of a blocking means for preventing the connection of a third medical device **12** or **14** prevents the support surface **24** from bearing too much weight or from having an unbalanced weight placed on it sufficient to topple the support surface **24**. For instance, the support surface **24** will typically be an IV stand. As shown in FIG. **2**, two devices **14**L, **14**R (as explained below, device **12** could replace the device **14**L) joined together place a somewhat unbalanced weight placed on the support surface **24**. The two of the devices **12** and/or **14** joined together do not have a weight sufficient to topple the support surface **24**. However, if a third medical device **12** or **14** was attached, there could be an unbalanced weight sufficient to topple the support surface **24**. Thus, the blocking means prevents the user from the hazard of hanging too many connected medical device **12** or **14** from the support surface **24**.

When it is desired to uncouple the first and second medical devices **14**L, **14**R, a release element **116** on the second medical device **14**R is actuated by the user. The release element **116** includes a tab **118** that permits the user to manually actuate the release element and base **120** extending from the tab **118** to contact the transfer plate **110** at a surface **122** thereof. The release element **116** also includes a biasing means **121** (such as a spring or other similar device) operatively interposed between the base **120** and the housing **16**A for downwardly biasing the release element **116**. When the release element **116** is actuated, the base **120** shifts the transfer plate **110**, uncoupling the latch element **106** of the second medical device **14**R from the corresponding latch notch **108** of the first medical device **14**L. When this is done the user can uncouple the male matable element **104** of the second medical device **14**R from the corresponding female matable element **102** of the first medical device **14**L.

As best seen in FIGS. **2**A, **4** and **5**, once a lone first medical device **14**L is attached to a support structure **24**, the support structure **24** presses on the support contact element **90** of the locking element **88**. The pressure on the support contact element **90** displaces the entire locking element **88**, thus moving the transfer pin **92** towards transfer plate **110**. The transfer pin **92** engages a corresponding pin slot **124** portion of the transfer plate **110**, securing the transfer plate **110** to a restricted range of motion. The pin slot **124** is shown as a hole in the transfer plate **110**, but may also be formed as depression in the transfer plate **110**. However, where other designs of locking element are utilized, the pin slot **124** may not be an essential component. For instance, it is contemplated that the locking element **88** could apply only a frictional force to the transfer plate **110** of the medical device **14**. In this case, the pin slot **124** would not be needed.

The pin slot **124** is oriented and arranged to receive the transfer pin **92**, even in cases where two devices are joined (FIGS. **2** and **2**A) and the device **14**L is attached to the support structure **24**. In this situation, the transfer plate **110** of device **14**R is slightly displaced when the latch element **106** of device **14**R is engaged to a corresponding latch notch **108** in either device **12** or **14**L.

Once the locking element **88** secures the transfer plate **110** to a restricted range of motion, the latch element **106** remains in an extended position through latch port **107** in the medical device **14**L side wall **17**L. The restricted extended latch element **106** of the first medical device **14**L will block any additional medical device from being joined to the side wall **17**L of first medical device **14**L. Thus the locking element **88** fixing the latch element **106** operates as a selective means for restricting the attachment of the second medical device **14**R to only the side wall **17**R of first medical device **14**L when first medical device **14**L has been previously secured to support structure **24**. Accordingly, it can be seen that when a separate first medical device **14**L has been secured to support structure **24**, any attachment of another device (e.g. second medical device **14**R) can only be made to a predetermined side, i.e., side wall **17**R, of first medical device **14**L.

This operation of a selective means for restricting the attachment of the second medical device **14**R to only one side of the first medical device **14**L lessens the potential for operator confusion when the second medical device **14**R is being attached to a first medical device **14**L that has been previously secured to support structure **24**. For instance, where the first medical device **14**L is a medical pump having defined first and second channels or pump mechanisms, when the first medical device **14**L is attached by itself to support structure **24**, there is little confusion as to where the first and second channels are located. Typically, the first channel will be located near side wall **17**L and the second channel will be located near side wall **17**R, with the user interface touch screen **20** disposed between the first and second channels. However, in instances where a second medical device **14**R having defined third and fourth channels is later added to the first medical device **14**L, placement of the second medical device **14**R adjacent to the side wall **17**L would increase the potential for user confusion. In such a case, the set of devices **14**L, **14**R would have a series of channels running from left to right in the following order: the third channel, the fourth channel, the first channel, and then the second channel. In order to prevent such confusion of channels in the use of the medical device system **10**, **10**A of the present invention, the selective means restricts the attachment of the second medical device **14**R to only the side wall **17**R of first medical device **14**L, so that the channels running from left to right will have the following order: the first channel, the second channel, the third channel, and then the fourth channel.

As best seen in FIGS. **1**, **2** and **5**, while the above system **10**A for interconnecting medical devices is operable with any device **14** having the same interconnectable design, it is also designed to operate with a device **12** of system **10**. As best understood in view of FIGS. **5** and **5**A, the portable medical device **12** includes some features similar to the device **14**, so that the devices **12** and **14** can be joined together; however, several components found in the device **14** (latch port **107**, transfer plate **110**, blocking port **114**, and release element **116**) are not included in the device **12**. This design permits a user to distinguish between the two devices **12**, **14**, prevents undesirable arrangements and combinations, and also

reduces the manufacturing cost as well as improving the reliability of the device **12** as compared to the device **14**.

Specifically, the device **12** includes a single matable element **102** on side wall **17**R. The single matable element **102** is formed as a female T-slot slot for mating with corresponding male T-slide **104** from the device **14**. The device **12** also includes a latch notch **108** for mating with corresponding latch element **106** from the device **14**.

However, unlike the device **14**, the device **12** has no elements on its opposite side wall **17**L for connecting to any other medical device **12** or **14**. This lack of elements on one side wall **17**L of device **12**, allows the device **12** to prevent a second medical device **14** from being attached to the left of a first device **12**, including when the first device **12** is secured to a support **24**. Thus the lack of elements on one side wall **17**L of device **12** acts as a selective means for restricting the attachment of a second medical device **14** to only one of the opposite sides of the first medical device **12**.

The lack of elements on one side wall **17**L of first device **12** also prevents any device **12** or **14** from attaching to that side wall **17**L of the first device **12**. The latch notch **108** of the first device **12** also acts to activate the blocking element **112** on the second device **14** to prevent a third medical device **12** or **14** from being joined to the second device **14**. Thus the lack of elements acts as a blocking means for preventing a third medical device **12** or **14** from attaching to either the first or second medical devices once the first and second medical devices **12**, **14** are attached to one another.

As best seen in FIGS. **1**, **1**A, **2** and **2**A, each of the medical devices **12**, **14** includes at least one transceiver **126**. The medical device **12** is provided with one transceiver **126** located on the side **17**R of the device **12** that has the matable element **102** positioned thereon. Each medical device **14** is provided with one transceiver **126** on each side **17**L and **17**R of the device **14**. The transceiver **126** (not shown) positioned on side **17**R of the first medical device **14**L is aligned with the corresponding transceiver **126** positioned on side **17**L of the second medical device **14**R for communication between the medical devices **14**L, **14**R once the medical devices **14**L, **14**R are attached. The aligned transceivers **126** permit the medical devices **14**L, **14**R to communicate to one another. The transceivers **126** can be adapted for wireless communication or can physically contact each other once aligned. The transceivers **126** can be of various types, including but not limited to infrared, blue tooth, or radio frequency. For instance, the aligned transceivers **126** permit the medical devices **14**L, **14**R to synchronize activities and/or share data including but not limited to: time, patient information, drugs in use, pressure, flow data, total infusion volume, and historical logged information.

As best seen in FIG. **6**, an alternative clamping mechanism **222** of the present invention has a substantially rigid clamp body **226** that is pivotally and preferably removably attached to the pump housing **16** or **16**A (not shown) and includes a pole-receiving slot **228** for receiving the pole (not shown). The clamp body **226** defines generally opposing first and second jaws **230**, **232** that at least partially surround the pole-receiving slot **228**.

A clamp shaft **234** is movably mounted on the first jaw **230**. The clamp shaft **234** has opposite ends **236**, **238** and a ratchet portion **240** therebetween. The first jaw **230** has a hole **242** formed therein, and more preferably therethrough, for receiving bushing **243** and the ratchet portion **240** of the clamp shaft **234**. The distal end **236** of the clamp shaft **234** extends from the first jaw **230** toward the second jaw **232**. A pressure pad **244** connects, or more preferably attaches, to the distal end **236**. The proximal end **238** of the clamp shaft **234** has displacement means **246**. Biasing means **266** (such as a spring or other similar device) is operatively interposed between the first jaw **230** and the clamp shaft **234**. A bellows element **270** encloses the clamp shaft **234** and biasing means **266**.

A selectively releasable positioning means or travel control means **256** is movably mounted on the first jaw **230**. The travel control means **256** includes a release lever **258** that has at least one pawl **259** adapted to matingly engage the ratchet portion **240** on the clamp shaft **34** and means for biasing the pawl **259** into engagement with the ratchet portion **240**. The release lever **258** and pawl **259** are shown as a unitary body; however, it will be understood that the release lever **258** and pawl **259** may be provided as separate pieces. The release lever **258** is positioned adjacent a hole **260** in the first jaw **230**. The release lever **258** is pivotally mounted to the first jaw **230** by pin **261**. The pawl **259** is positioned exterior to the first jaw **230** at an outer end of the hole **242**, within the pole-receiving slot **228**. The pawl **259** is normally biased into mating engagement with the ratchet portion **240** of the clamp shaft **234** by a biasing means **264** (such as a spring or other similar device) positioned within hole **260**, and which is operatively interposed between the release lever **258** and the first jaw **230**.

In operation, the travel control means **256** is configured and arranged to normally resist axial movement of the clamp shaft **234** in a direction away from the pole-receiving slot **228**. The travel control means **256** also permits a user to apply an axial force to the clamp shaft **234** sufficient to overcome the biasing force of the biasing means **264**, to permit slide-ratcheting axial movement of the clamp shaft **234** in a direction toward the opening pole-receiving slot **228**.

Alternatively, in some applications it is desirable to prevent the slide-ratcheting axial movement of the clamp shaft **234** if axial force is inadvertently applied to the clamp shaft **234**. In this case the biasing means **264** is selected so as to have sufficient spring force to prevent normal user force on the clamp shaft **234** from causing slide-ratcheting axial movement of the clamp shaft **234** without the user also deactivating the travel control means **256**.

It is therefore seen that this invention provides an improved system of interlockable portable medical devices that only allows two medical devices to be joined together. The invention also provides an improved system of interlockable portable medical devices. In addition, the invention provides an improved clamp mechanism, for mounting a medical device to a support member, which restricts the attachment of a second medical device to only one side of a first medical device when the clamp mechanism is attached to a support member. Finally, the invention provides an improved clamp mechanism that permits quick slide-ratcheting axial movement of the clamp shaft.

It is therefore seen that this invention will accomplish at least all of its stated objectives.

What is claimed is:

1. A clamp mechanism for mounting a medical device to a support member, comprising:

a clamp body defining a first jaw, a second jaw and an opening therebetween adapted to receive a support member;

a clamp shaft including a forward end for extending into the opening, a rearward end, and an intermediate portion having a longitudinal axis and being mounted for axial movement on the first jaw of the clamp body;

ratchet and pawl means operatively interposed between the intermediate portion of the clamp shaft and the clamp body,

the ratchet and pawl means comprising ratchet teeth and a pawl;

biasing means for yieldingly urging the pawl and ratchet teeth into engagement with a biasing force; and

the biasing means, the ratchet teeth, and the pawl being configured and arranged to normally resist axial movement of the clamp shaft in a direction away from the opening and, upon application of an axial force to the clamp shaft sufficient to overcome the biasing force of the biasing means, to permit slide-ratcheting axial movement of the clamp shaft in a direction toward the opening.

2. A clamp mechanism in accordance with claim 1, wherein the clamp body has a hole therein for slidably receiving a locking element the locking element adapted to apply force on a component of the medical device when the clamp body is affixed to a support member.

3. A clamp mechanism in accordance with claim 1, wherein the first jaw and the second jaw are stationary.

4. A clamp mechanism in accordance with claim 1, wherein the first jaw of the clamp body has a clamp shaft receiving bore therein for slidably receiving the clamp shaft.

5. A clamp mechanism in accordance with claim 1, wherein the ratchet teeth are external threads formed on the intermediate portion of the clamp shaft, and wherein the threads have a forward lead flank and a rear load flank, the leading flank extending rearward to form an acute angle with a longitudinal axis of the clamp shaft and the load flank extending perpendicular to the longitudinal axis of the clamp shaft.

6. A clamp mechanism in accordance with claim 1, further comprising a release mechanism for overcoming the biasing force of the biasing means and disengaging the pawl and ratchet teeth, thereby permitting axial movement of the clamp shaft in the direction away from the opening.

7. A clamp mechanism in accordance with claim 6, wherein the release mechanism and the pawl means are a unitary body.

8. A clamp mechanism in accordance with claim 6, wherein the first jaw has a release bore therein and the release mechanism is an elongated pin slidably mounted in the release bore.

9. A clamp mechanism in accordance with claim 6, wherein the release mechanism has an adjustment slot extending therethrough for receiving the clamp shaft, the ratchet portion of the clamp shaft having threads with a major diameter and the adjustment slot having a length greater than the major diameter of the threads on the clamp shaft, the pawl being a portion of a wall of the adjustment slot having a thread thereon for matingly engaging the ratchet portion of the clamp shaft.

10. A clamp mechanism in accordance with claim 1, further comprising a hand knob attached to the second end of the clamp shaft.

11. A clamp mechanism in accordance with claim 10, further comprising a clutch mechanism operatively interposed between the hand knob and the clamp shaft, the clutch mechanism being adapted to prevent overtightening of the clamp shaft against a pole beyond a given torque value.

12. A clamp mechanism in accordance with claim 1, wherein the clamp mechanism is adapted to be rotatably associated with the medical device.

13. A clamp mechanism in accordance with claim 12, wherein the clamp mechanism includes a pivot latch adapted to selectively lock the clamp mechanism in a select one of a plurality of rotational positions with respect to the medical device.

14. A clamp mechanism for mounting a medical device to a support member, comprising:

a clamp body defining a first jaw, a second jaw and an opening therebetween adapted to receive a support member;

a clamp shaft including a forward end for extending into the opening, a rearward end, and an intermediate portion having a longitudinal axis and being mounted for axial movement on the first jaw of the clamp body;

ratchet and pawl means operatively interposed between the intermediate portion of the clamp shaft and the clamp body, the ratchet and pawl means comprising ratchet teeth and a pawl;

biasing means for yieldingly urging the pawl and ratchet teeth into engagement with a biasing force;

the biasing means, the ratchet teeth, and the pawl being configured and arranged to normally resist axial movement of the clamp shaft in a direction away from the opening; and

a release mechanism for overcoming the biasing force of the biasing means and disengaging the pawl and ratchet teeth, thereby permitting axial movement of the clamp shaft in the direction away from the opening; wherein the release mechanism and the pawl means are a unitary 10 body.

15. A clamp mechanism in accordance with claim 14, wherein the ratchet teeth are external threads formed on the intermediate portion of the clamp shaft.

16. A clamp mechanism in accordance with claim 15, wherein the threads have a forward lead flank and a rear load flank, the leading flank extending rearward to form an acute angle with a longitudinal axis of the clamp shaft and the load flank extending perpendicular to the longitudinal axis of the clamp shaft.

17. A clamp mechanism in accordance with claim 14, wherein the first jaw of the clamp body has a clamp shaft receiving bore therein for slidably receiving the clamp shaft.

18. A clamp mechanism in accordance with claim 14, wherein the first jaw has a release bore therein and the release mechanism is an elongated pin slidably mounted in the release bore.

19. A clamp mechanism in accordance with claim 14, wherein the release mechanism has an adjustment slot extending therethrough for receiving the clamp shaft, the ratchet portion of the clamp shaft having threads with a major diameter and the adjustment slot having a length greater than the major diameter of the threads on the clamp shaft, the pawl being a portion of a wall of the adjustment slot having a thread thereon for matingly engaging the ratchet portion of the clamp shaft.

20. A clamp mechanism in accordance with claim 14, wherein the release mechanism includes a release lever pivotally mounted to the first jaw.

21. A clamp mechanism in accordance with claim **20**, wherein the release mechanism including the release lever and pawl means are located on the exterior of the first jaw.

22. A clamp mechanism in accordance with claim **14**, further comprising a hand knob attached to the second end of the clamp shaft.

23. A clamp mechanism in accordance with claim **22**, further comprising a clutch mechanism operatively interposed between the hand knob and the clamp shaft, the clutch mechanism being adapted to prevent overtightening of the clamp shaft against a pole beyond a given torque value.

24. A clamp mechanism in accordance with claim **14**, wherein the clamp mechanism is adapted to be rotatably associated with the medical device.

25. A clamp mechanism in accordance with claim **24**, wherein the clamp mechanism includes a pivot latch adapted to selectively lock the clamp mechanism in a select one of a plurality of rotational positions with respect to the medical device.

* * * * *

EXHIBIT D

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Palmroos et al.

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(54) **SYSTEM FOR GUIDING A USER DURING PROGRAMMING OF A MEDICAL DEVICE**

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See application file for complete search history.

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2006/0258985	A1 *	11/2006	Russell	604/151
2007/0213598	A1	9/2007	Howard et al.	

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Bektas, et al, "Bluetooth Communication Employing Antenna Diversity", Computers and Communication, Jun. 30, 2003, pp. 652-657.

* cited by examiner

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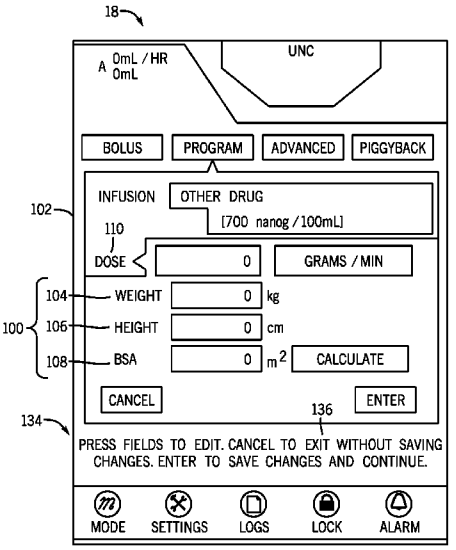
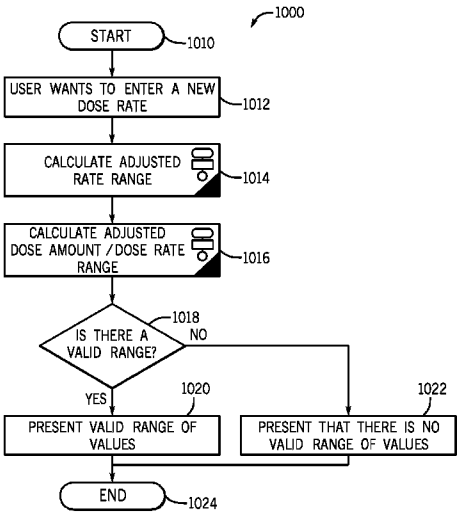
Assistant Examiner—Leah Stohr
(74) *Attorney, Agent, or Firm*—Michael R. Crabb

(57) **ABSTRACT**

A medical pump that provides advance guidance to a user regarding existence and limits of a valid input range for a pump programming parameter includes an input device for entering a value of a pump programming parameter, a memory for storing constraints related to the pump programming parameter, and a processor in communication with the memory and the input device. The processor dynamically utilizes the constraints to determine and generate a signal indicating whether a valid input range exists for a to-be-entered value of the pump programming parameter and notifies the user.

21 Claims, 56 Drawing Sheets





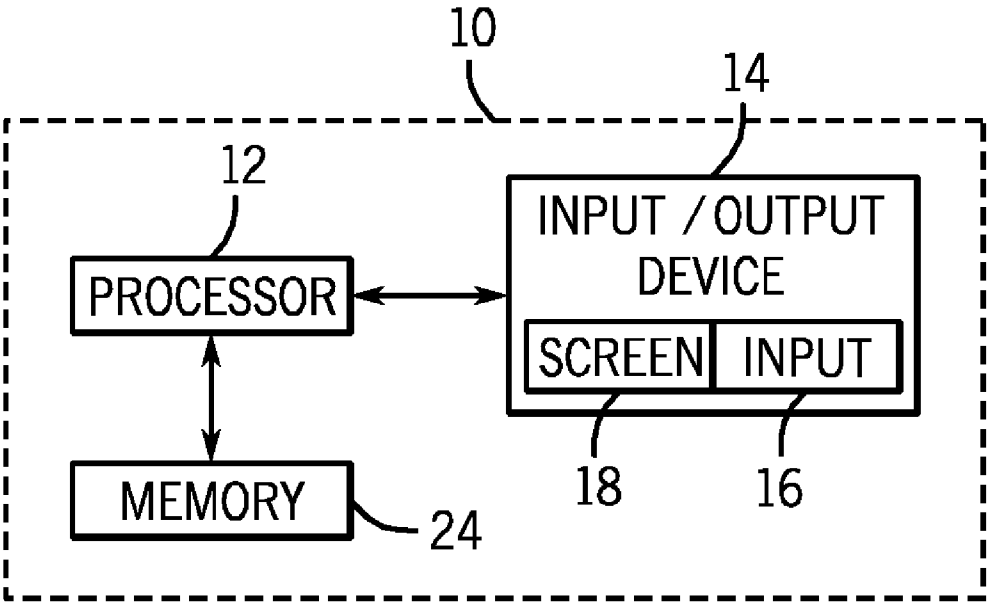

10
14
12
INPUT / OUTPUT DEVICE
PROCESSOR
SCREEN
INPUT
MEMORY
24
18
16

FIG. 1

FIG. 2

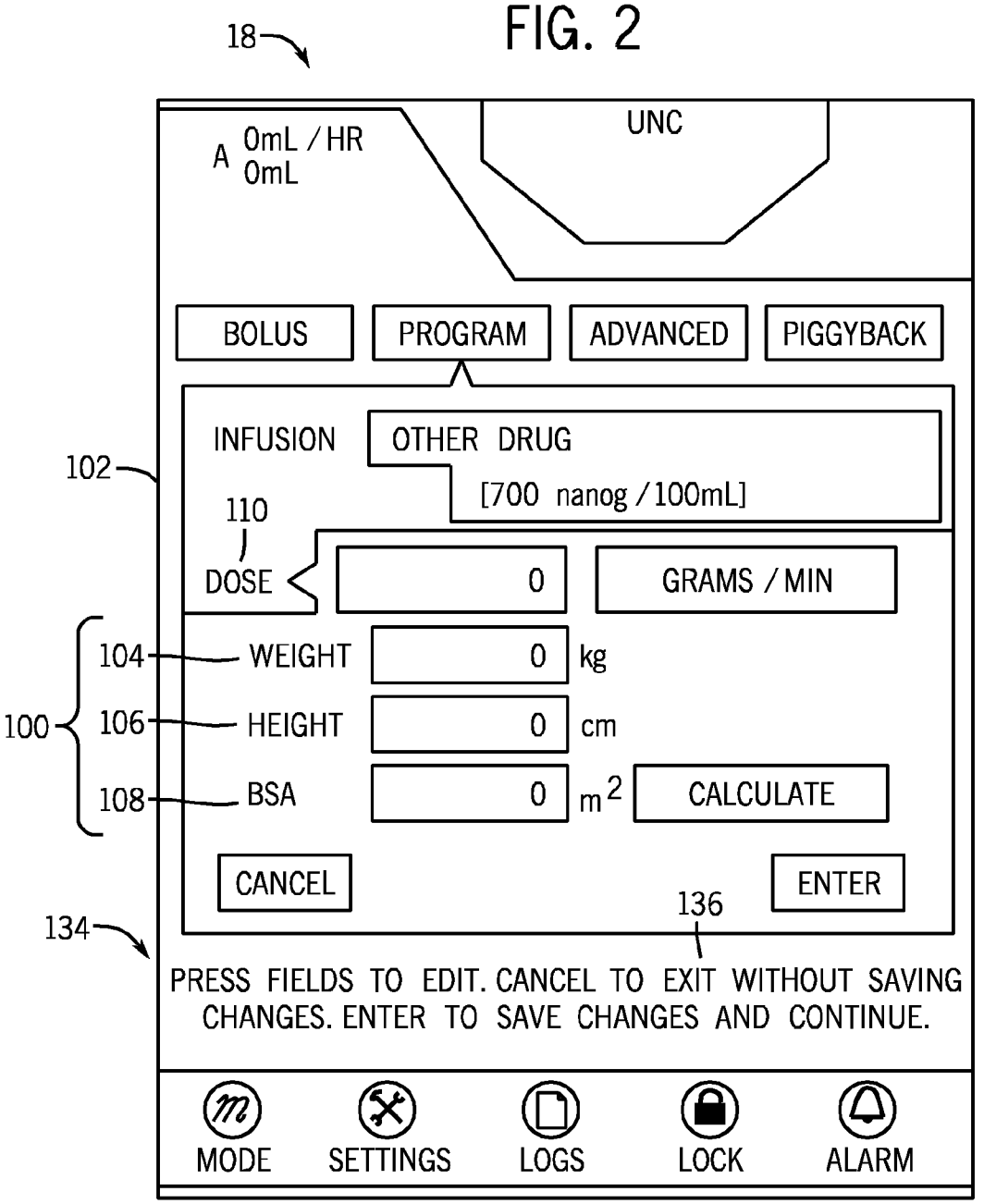

18
A 0mL / HR
0mL
UNC
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
OTHER DRUG
[700 nanog / 100mL]
102
110
DOSE
0
GRAMS / MIN
100
104
WEIGHT
0
kg
106
HEIGHT
0
cm
108
BSA
0
m2
CALCULATE
CANCEL
ENTER
134
136
PRESS FIELDS TO EDIT. CANCEL TO EXIT WITHOUT SAVING CHANGES. ENTER TO SAVE CHANGES AND CONTINUE.
MODE
SETTINGS
LOGS
LOCK
ALARM

FIG. 3

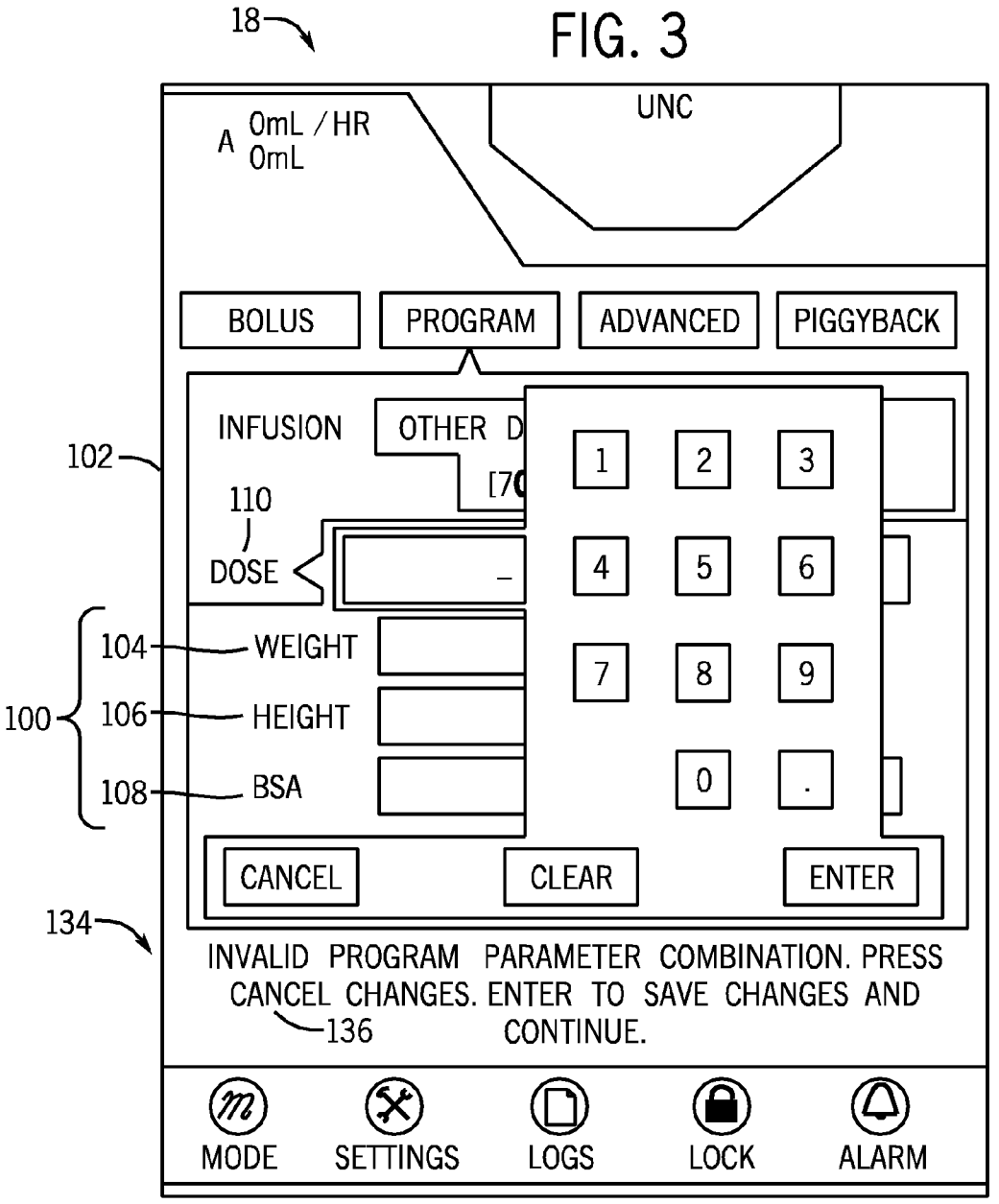

18
UNC
A 0mL / HR
0mL
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
OTHER D
102
110
DOSE
1
2
3
4
5
6
7
8
9
0
.
104
WEIGHT
100
106
HEIGHT
108
BSA
CANCEL
CLEAR
ENTER
134
INVALID PROGRAM PARAMETER COMBINATION. PRESS CANCEL CHANGES. ENTER TO SAVE CHANGES AND CONTINUE.
136
MODE
SETTINGS
LOGS
LOCK
ALARM

FIG. 4

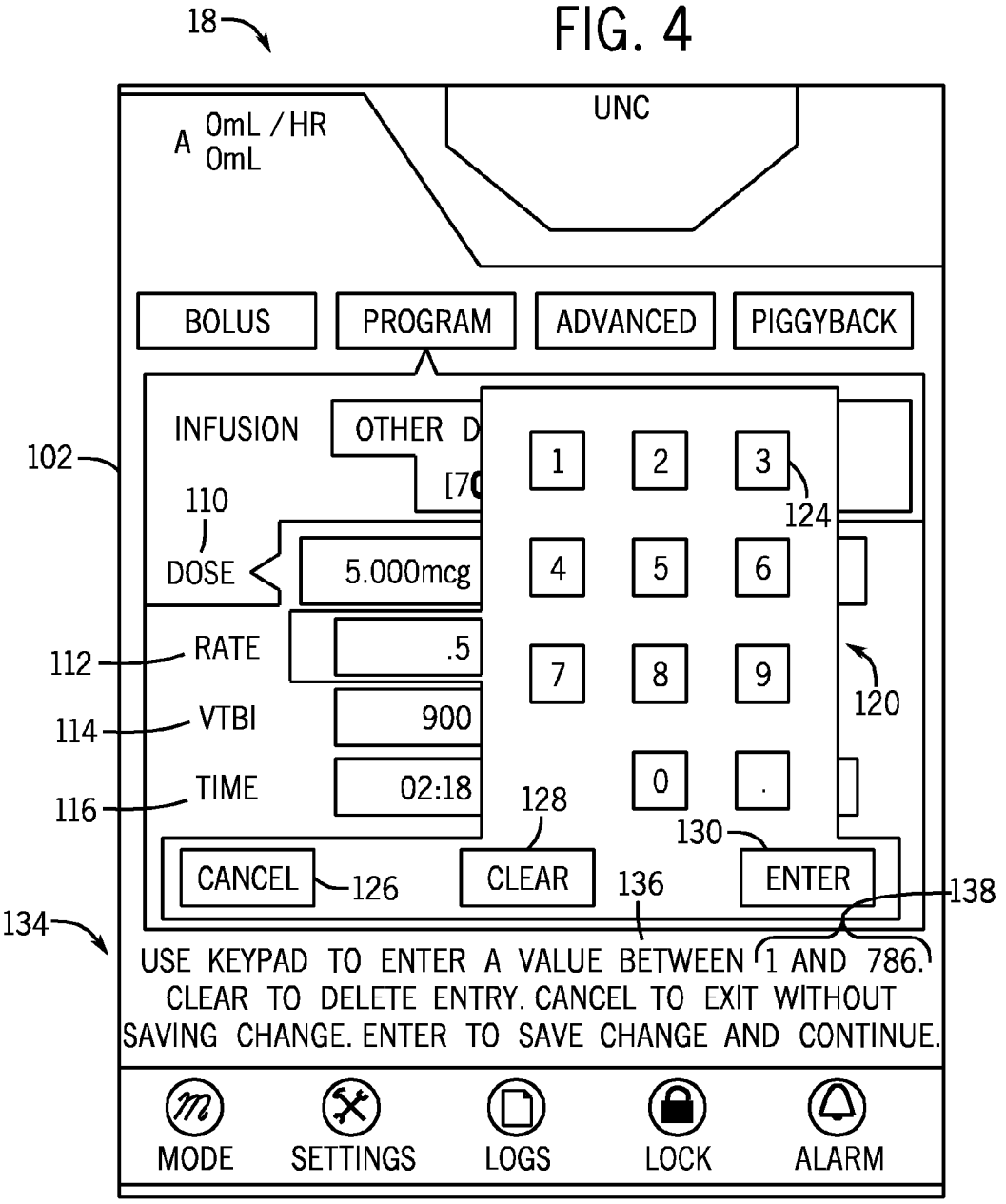

18
UNC
A 0mL / HR
0mL
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
OTHER D
102
110
DOSE
5.000mcg
RATE
.5
112
VTBI
900
114
TIME
02:18
116
1
2
3
124
4
5
6
7
8
9
120
0
.
128
130
CANCEL
126
CLEAR
136
ENTER
138
134
USE KEYPAD TO ENTER A VALUE BETWEEN 1 AND 786.
CLEAR TO DELETE ENTRY. CANCEL TO EXIT WITHOUT
SAVING CHANGE. ENTER TO SAVE CHANGE AND CONTINUE.
MODE
SETTINGS
LOGS
LOCK
ALARM

FIG. 5

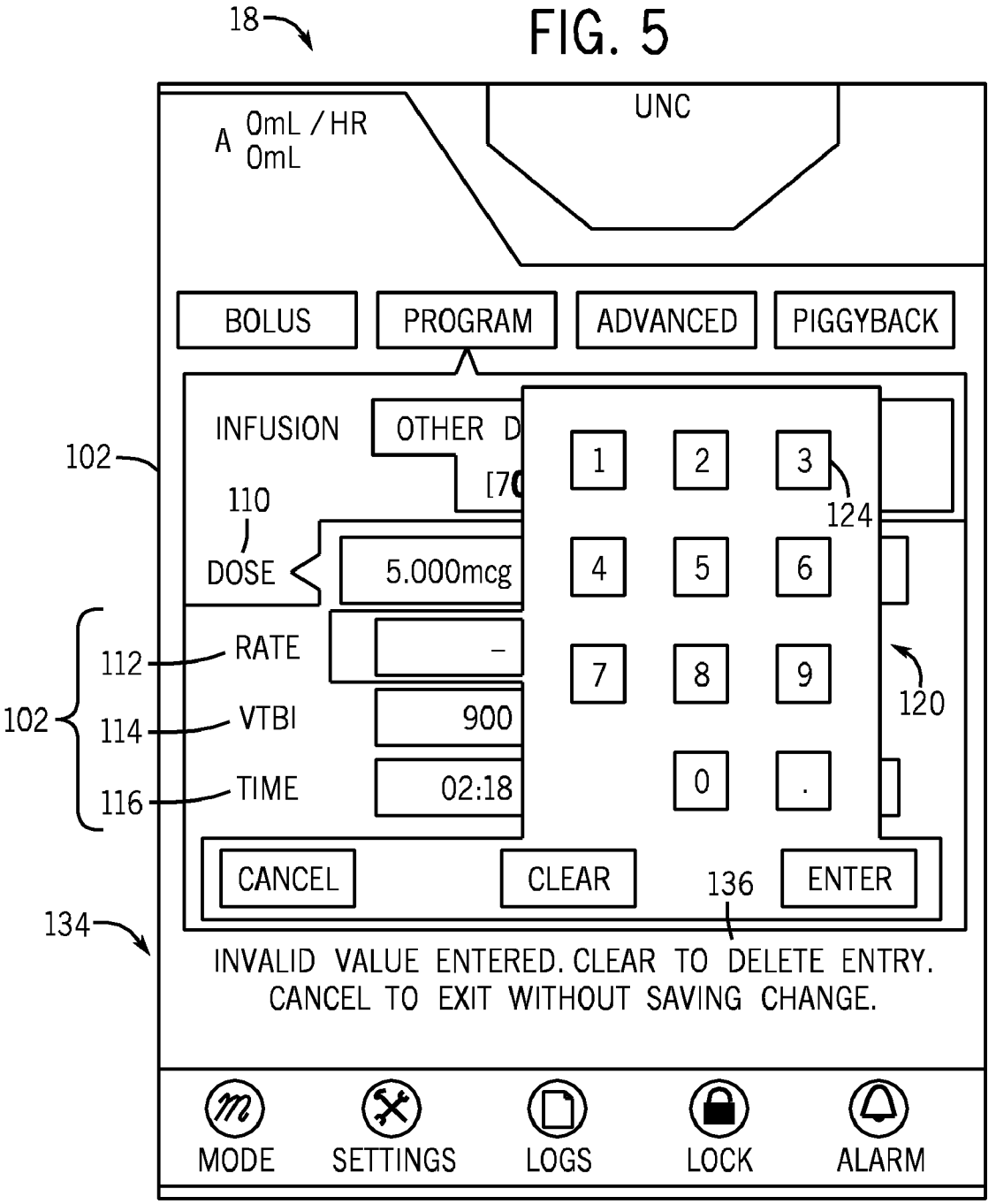

18
UNC
A 0mL / HR
0mL
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
OTHER D
102
110
DOSE
5.000mcg
1
2
3
124
4
5
6
112
RATE
7
8
9
120
102
114
VTBI
900
116
TIME
02:18
0
.
CANCEL
CLEAR
136
ENTER
134
INVALID VALUE ENTERED. CLEAR TO DELETE ENTRY.
CANCEL TO EXIT WITHOUT SAVING CHANGE.
MODE
SETTINGS
LOGS
LOCK
ALARM

FIG. 6

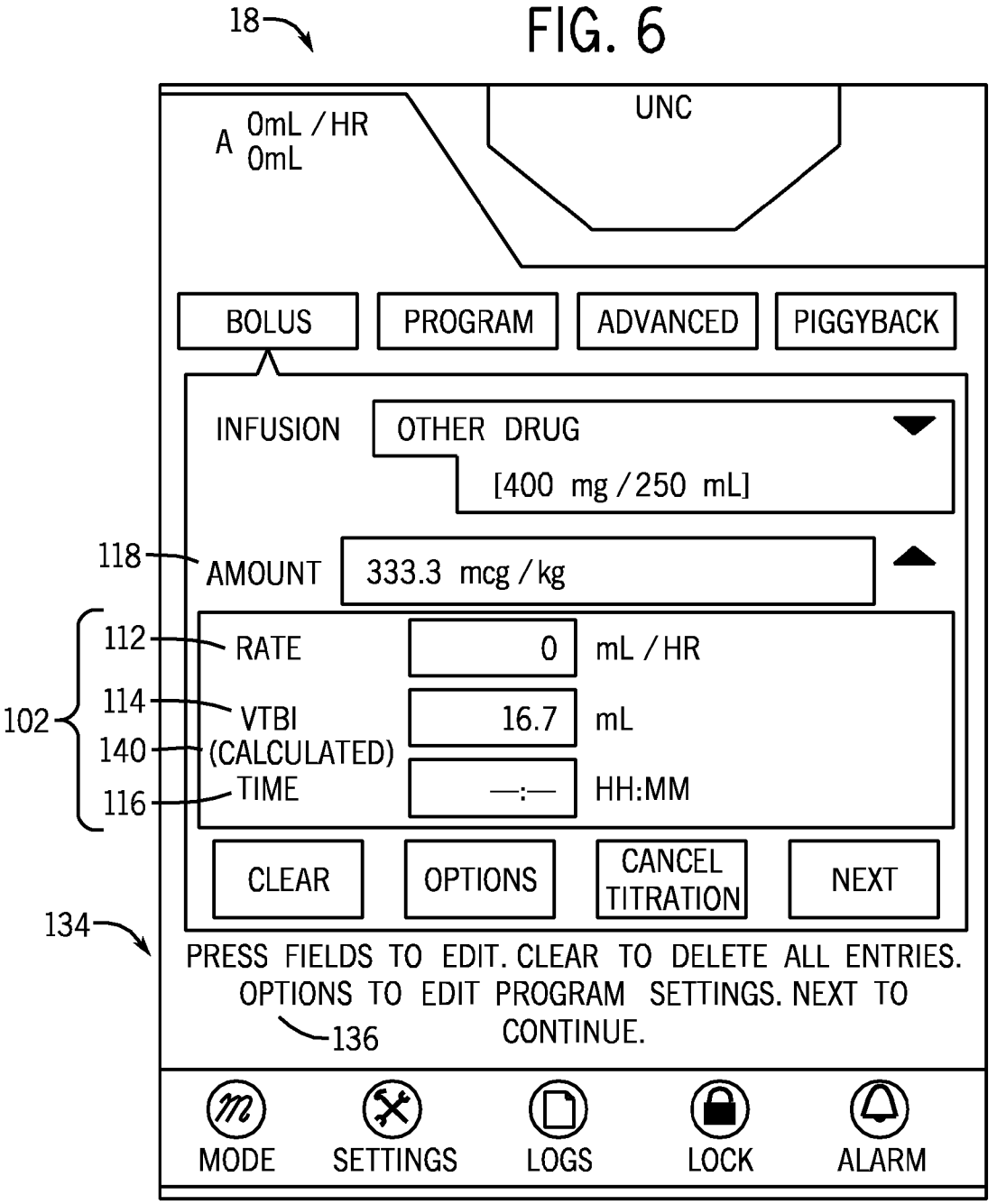

18
A 0mL / HR
0mL
UNC
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
OTHER DRUG
[400 mg / 250 mL]
118
AMOUNT
333.3 mcg / kg
102
112
RATE
0
mL / HR
114
VTBI
16.7
mL
140
(CALCULATED)
116
TIME
—:—
HH:MM
CLEAR
OPTIONS
CANCEL TITRATION
NEXT
134
PRESS FIELDS TO EDIT. CLEAR TO DELETE ALL ENTRIES. OPTIONS TO EDIT PROGRAM SETTINGS. NEXT TO CONTINUE.
136
MODE
SETTINGS
LOGS
LOCK
ALARM

FIG. 7

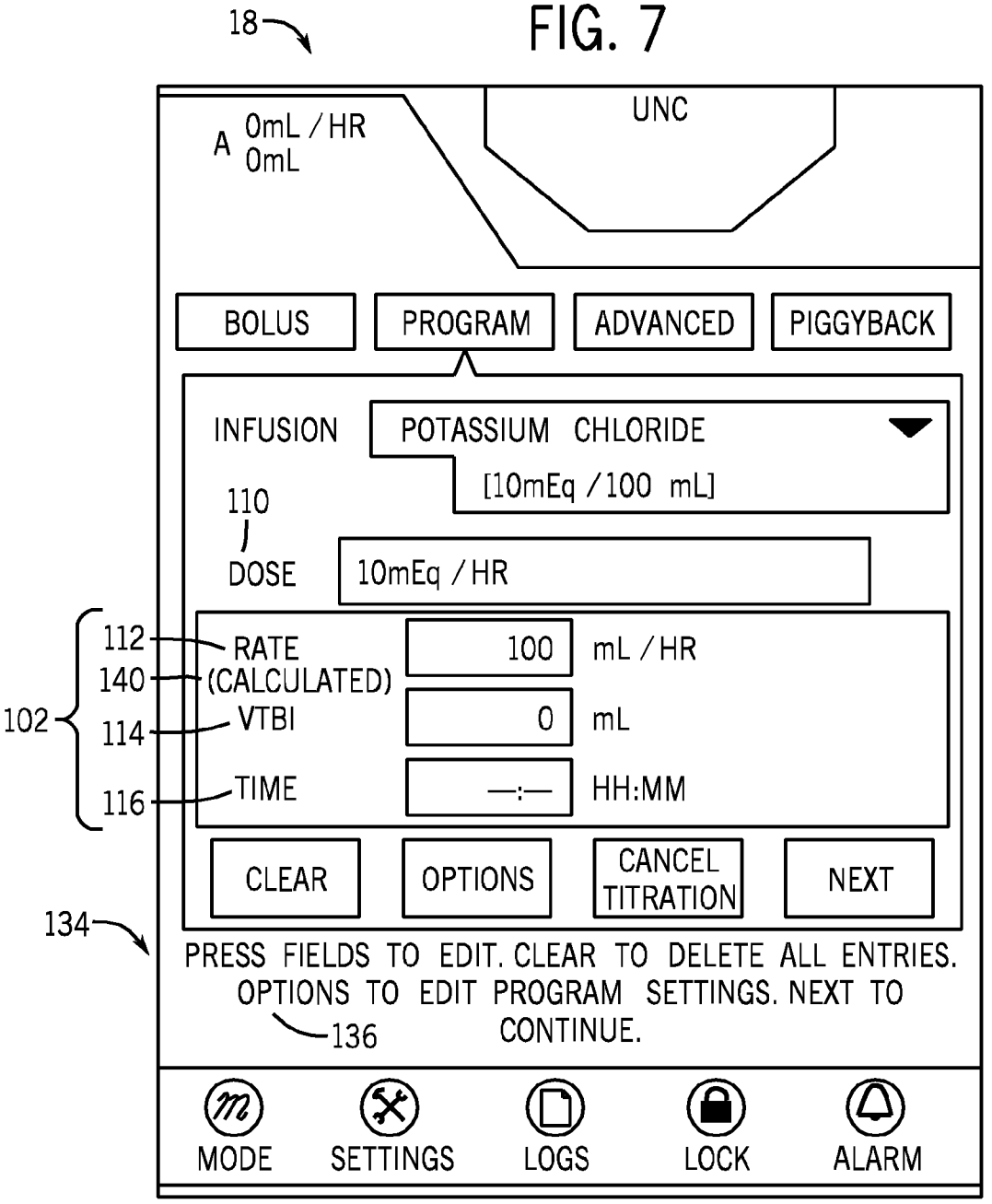

18
A 0mL / HR
0mL
UNC
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
POTASSIUM CHLORIDE
[10mEq / 100 mL]
110
DOSE
10mEq / HR
102
112
RATE
100
mL / HR
140
(CALCULATED)
114
VTBI
0
mL
116
TIME
—:—
HH:MM
CLEAR
OPTIONS
CANCEL TITRATION
NEXT
134
PRESS FIELDS TO EDIT. CLEAR TO DELETE ALL ENTRIES. OPTIONS TO EDIT PROGRAM SETTINGS. NEXT TO CONTINUE.
136
MODE
SETTINGS
LOGS
LOCK
ALARM

FIG. 8

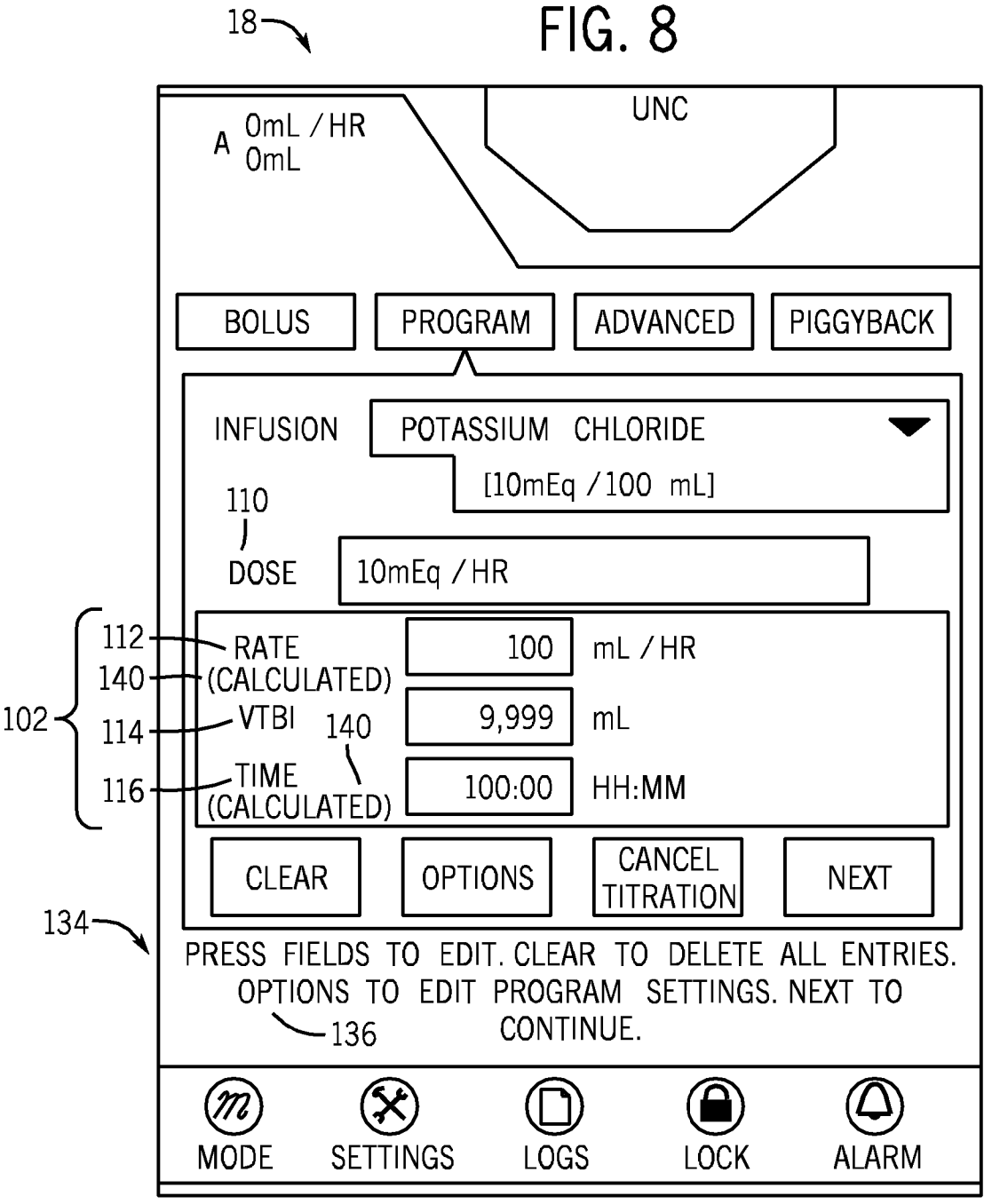
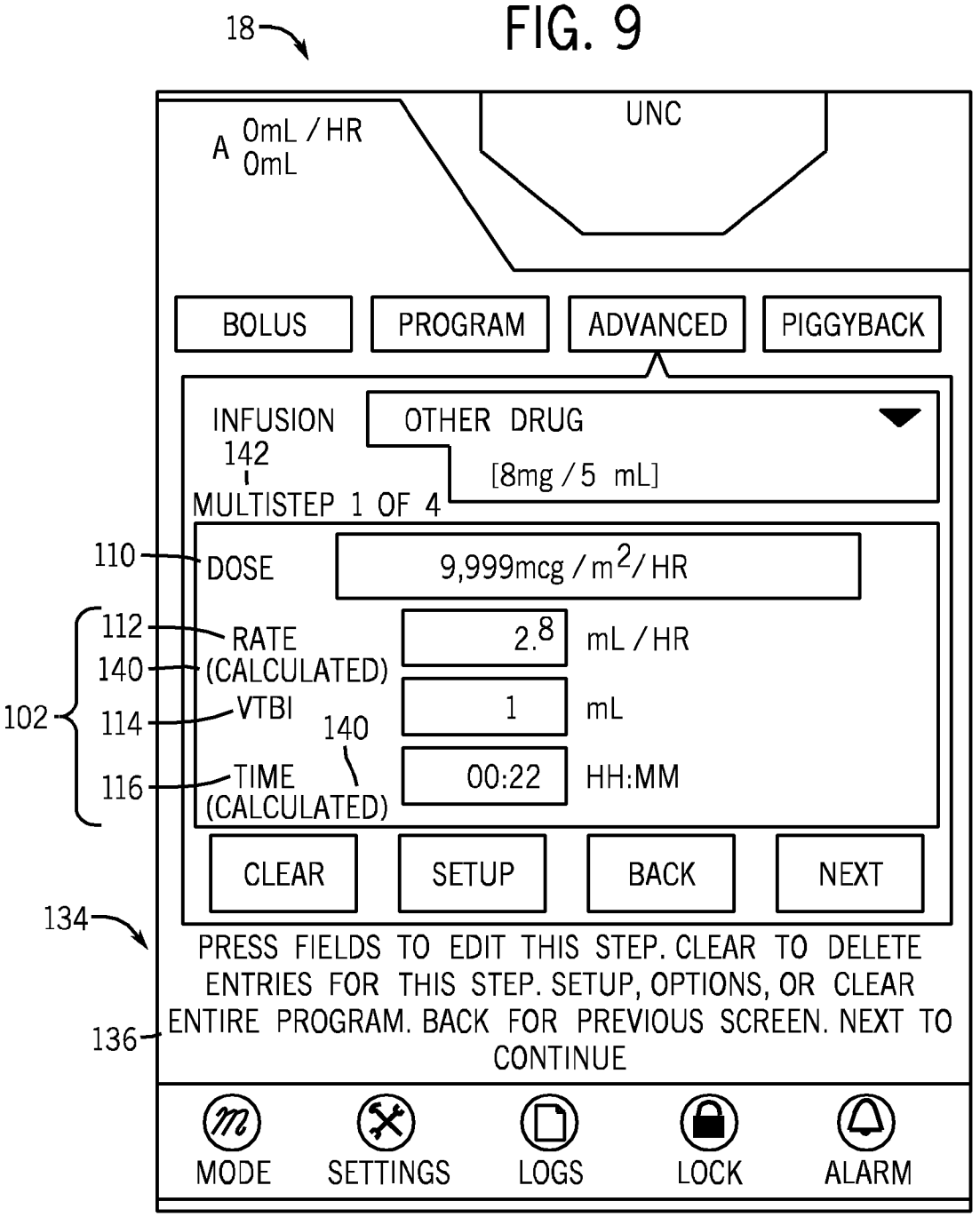

18
A 0mL / HR
0mL
UNC
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
POTASSIUM CHLORIDE
[10mEq / 100 mL]
110
DOSE
10mEq / HR
102
112
RATE
(CALCULATED)
100
mL / HR
140
140
VTBI
9,999
mL
114
TIME
(CALCULATED)
100:00
HH:MM
116
CLEAR
OPTIONS
CANCEL TITRATION
NEXT
134
PRESS FIELDS TO EDIT. CLEAR TO DELETE ALL ENTRIES.
OPTIONS TO EDIT PROGRAM SETTINGS. NEXT TO
CONTINUE.
136
MODE
SETTINGS
LOGS
LOCK
ALARM

FIG. 9


18
A 0mL / HR
0mL
UNC
BOLUS
PROGRAM
ADVANCED
PIGGYBACK
INFUSION
142
OTHER DRUG
[8mg / 5 mL]
MULTISTEP 1 OF 4
110
DOSE
9,999mcg / m2 / HR
112
RATE
140
(CALCULATED)
2.8
mL / HR
102
114
VTBI
140
1
mL
116
TIME
(CALCULATED)
00:22
HH:MM
CLEAR
SETUP
BACK
NEXT
134
PRESS FIELDS TO EDIT THIS STEP. CLEAR TO DELETE ENTRIES FOR THIS STEP. SETUP, OPTIONS, OR CLEAR ENTIRE PROGRAM. BACK FOR PREVIOUS SCREEN. NEXT TO CONTINUE
136
MODE
SETTINGS
LOGS
LOCK
ALARM

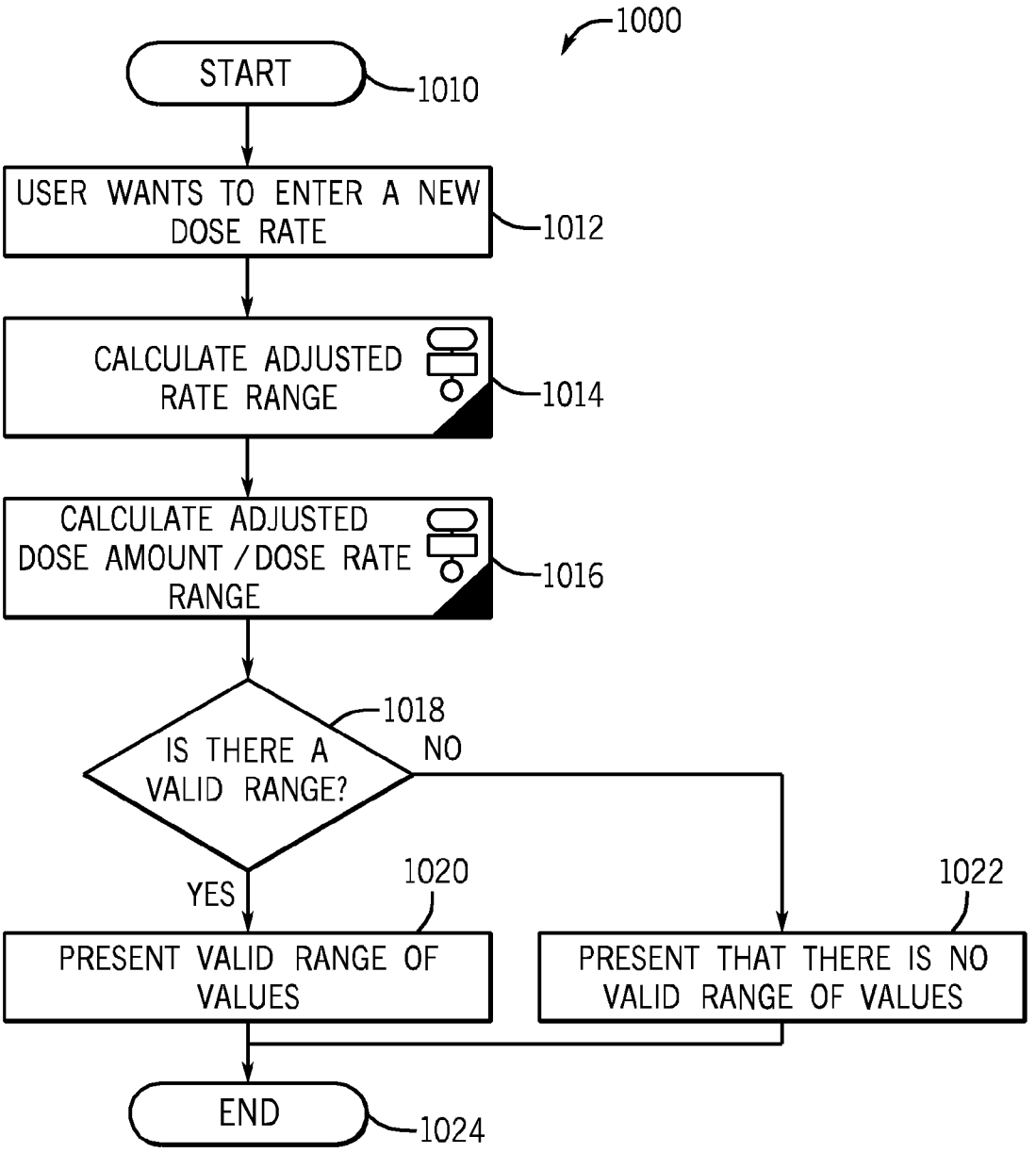

1000
START
1010
USER WANTS TO ENTER A NEW DOSE RATE
1012
CALCULATE ADJUSTED RATE RANGE
1014
CALCULATE ADJUSTED DOSE AMOUNT / DOSE RATE RANGE
1016
IS THERE A VALID RANGE?
1018
NO
YES
1020
PRESENT VALID RANGE OF VALUES
1022
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 10

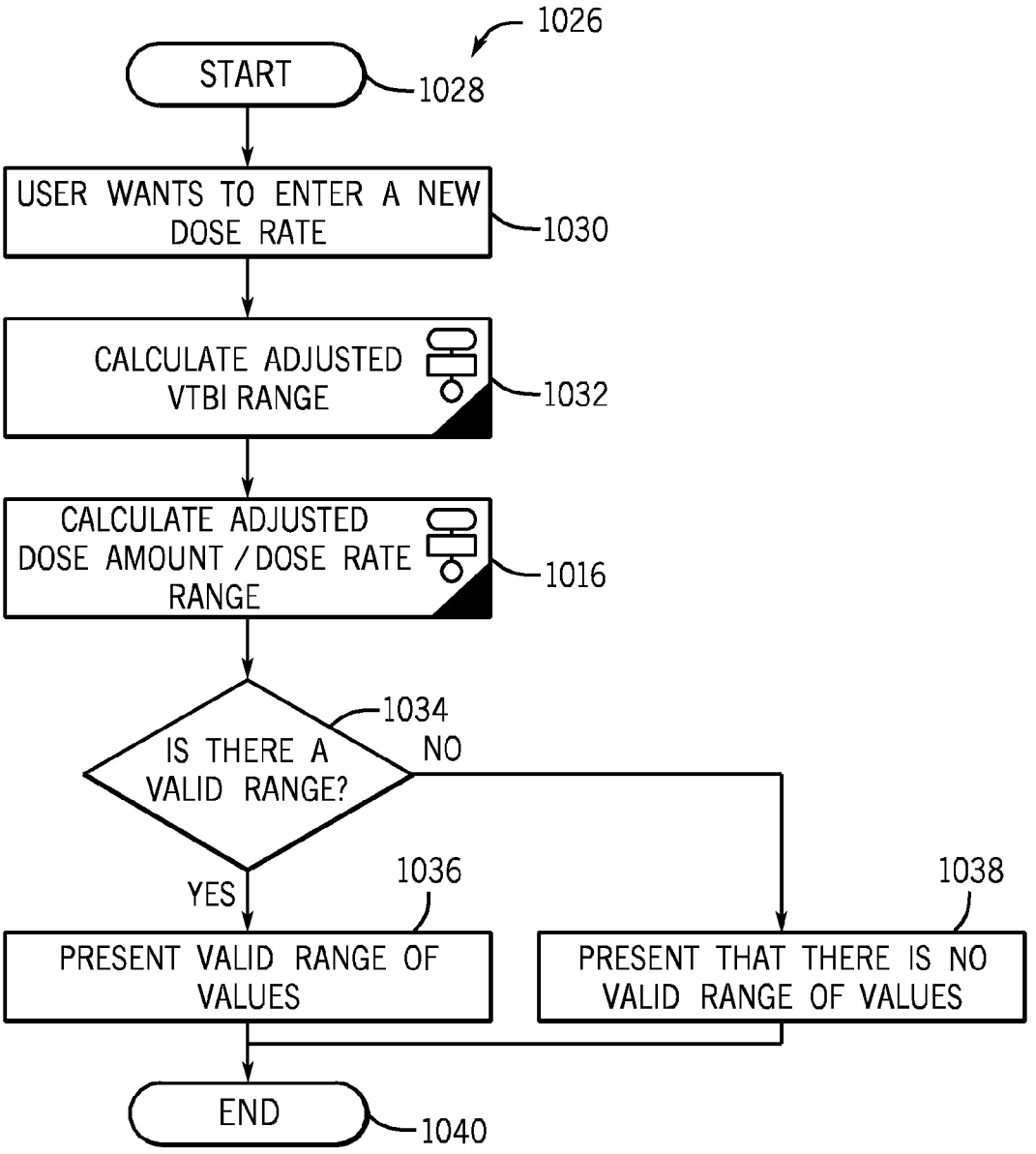

1026
START
1028
USER WANTS TO ENTER A NEW DOSE RATE
1030
CALCULATE ADJUSTED VTBI RANGE
1032
CALCULATE ADJUSTED DOSE AMOUNT / DOSE RATE RANGE
1016
1034
IS THERE A VALID RANGE?
NO
YES
1036
PRESENT VALID RANGE OF VALUES
1038
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1040

FIG. 11

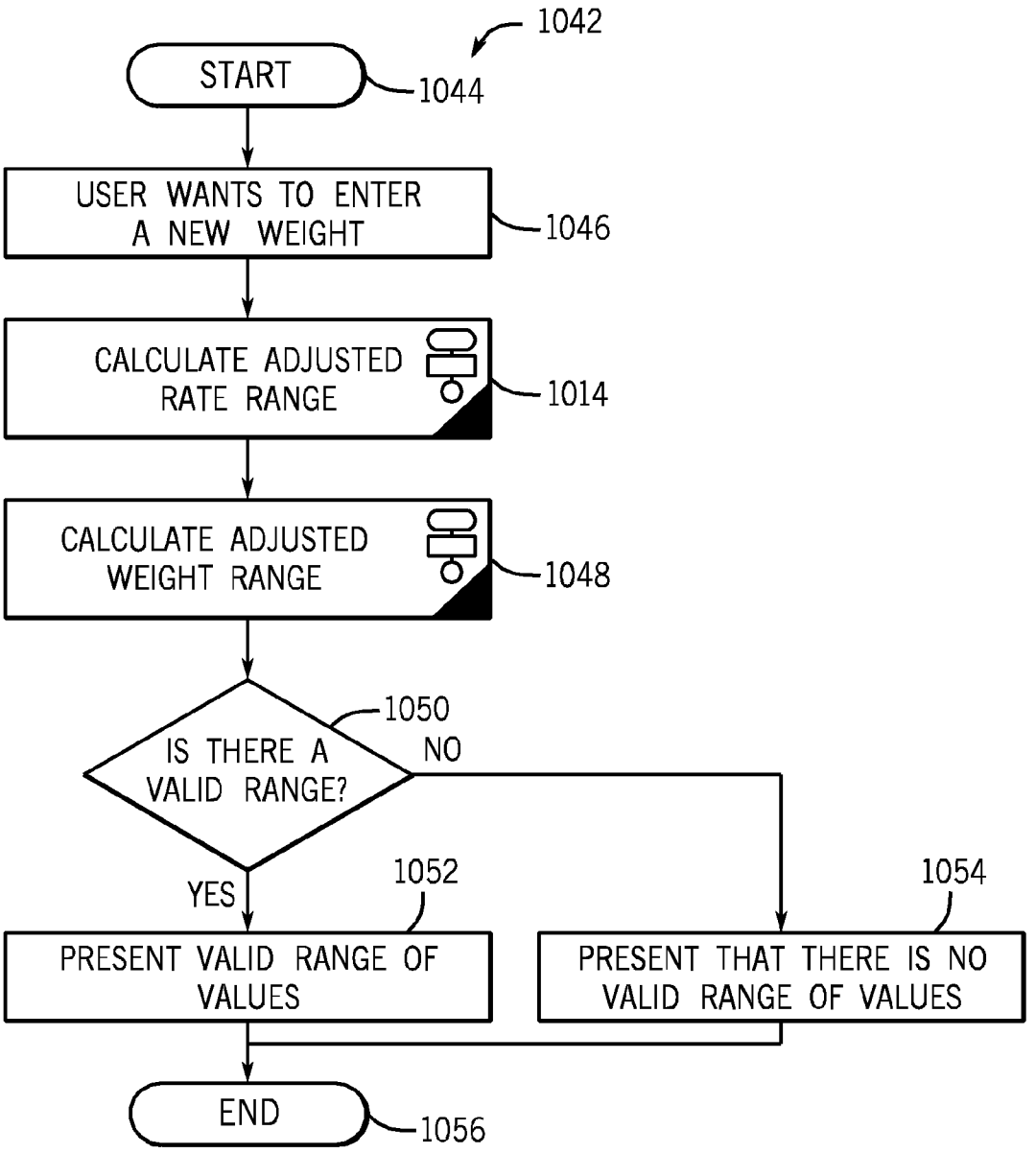

1042
START
1044
USER WANTS TO ENTER A NEW WEIGHT
1046
CALCULATE ADJUSTED RATE RANGE
1014
CALCULATE ADJUSTED WEIGHT RANGE
1048
1050
IS THERE A VALID RANGE?
NO
YES
1052
1054
PRESENT VALID RANGE OF VALUES
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1056

FIG. 12

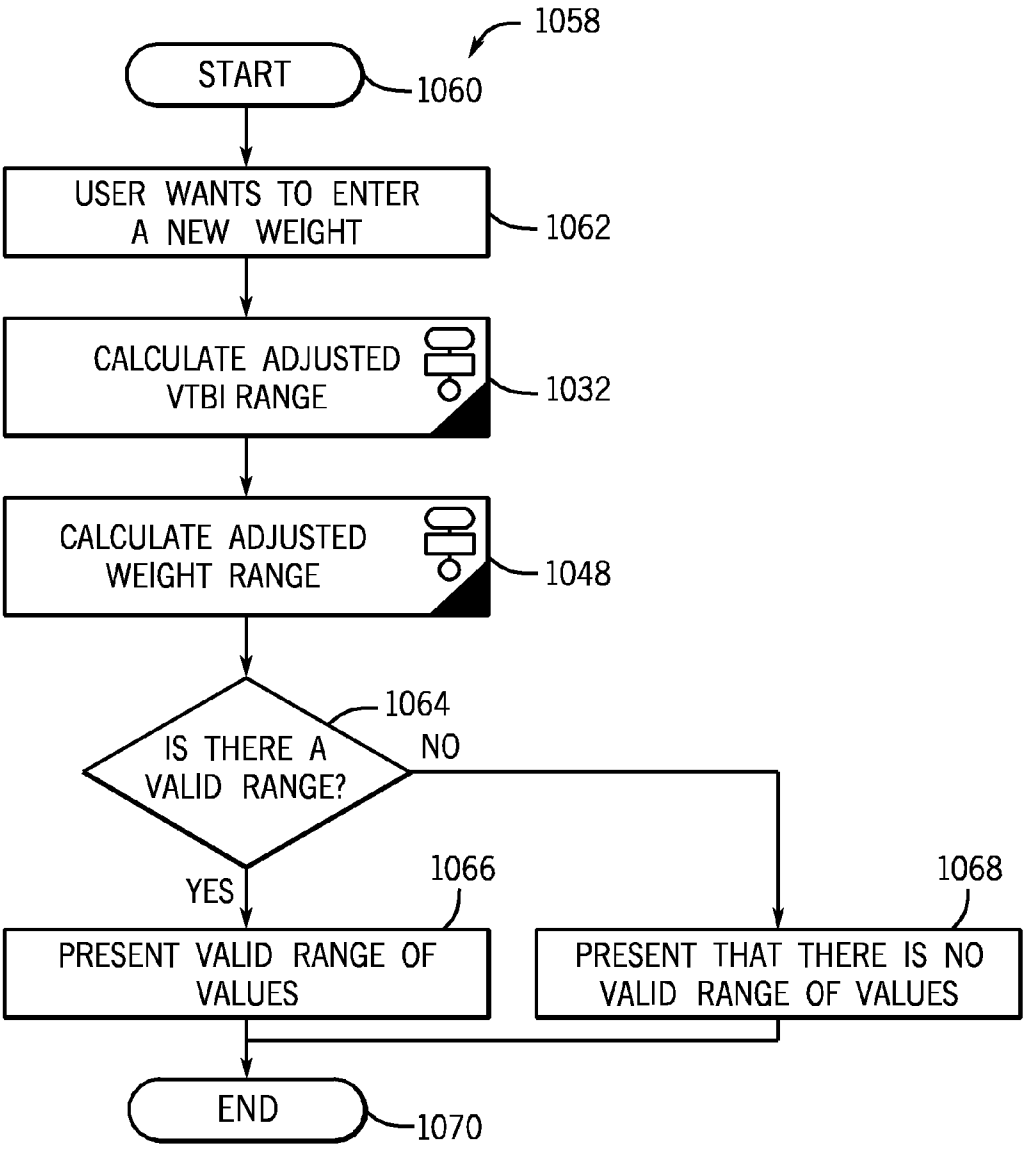

1058
START
1060
USER WANTS TO ENTER A NEW WEIGHT
1062
CALCULATE ADJUSTED VTBI RANGE
1032
CALCULATE ADJUSTED WEIGHT RANGE
1048
1064
IS THERE A VALID RANGE?
NO
YES
1066
PRESENT VALID RANGE OF VALUES
1068
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1070

FIG. 13

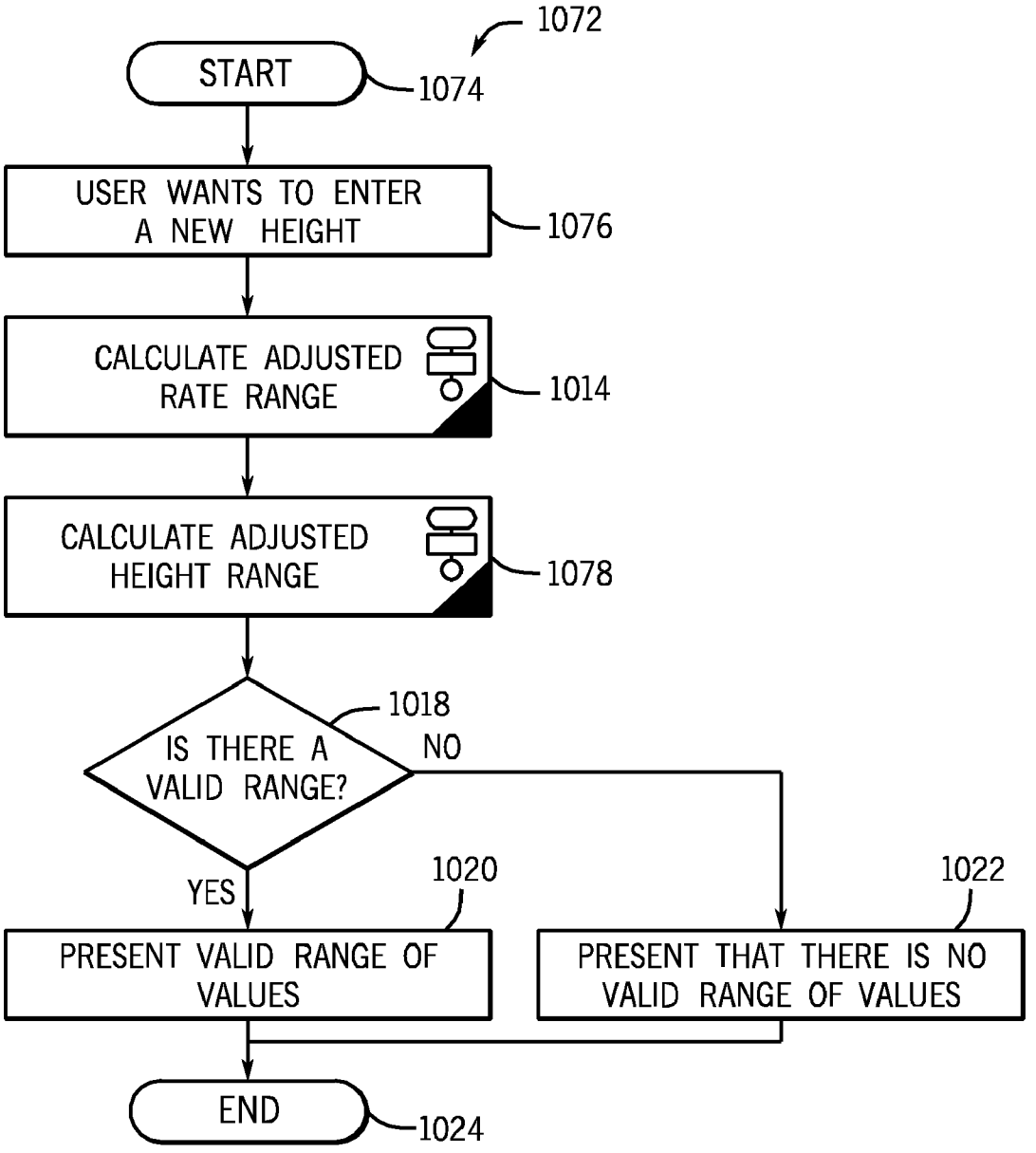

1072
START
1074
USER WANTS TO ENTER A NEW HEIGHT
1076
CALCULATE ADJUSTED RATE RANGE
1014
CALCULATE ADJUSTED HEIGHT RANGE
1078
1018
IS THERE A VALID RANGE?
NO
YES
1020
PRESENT VALID RANGE OF VALUES
1022
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 14

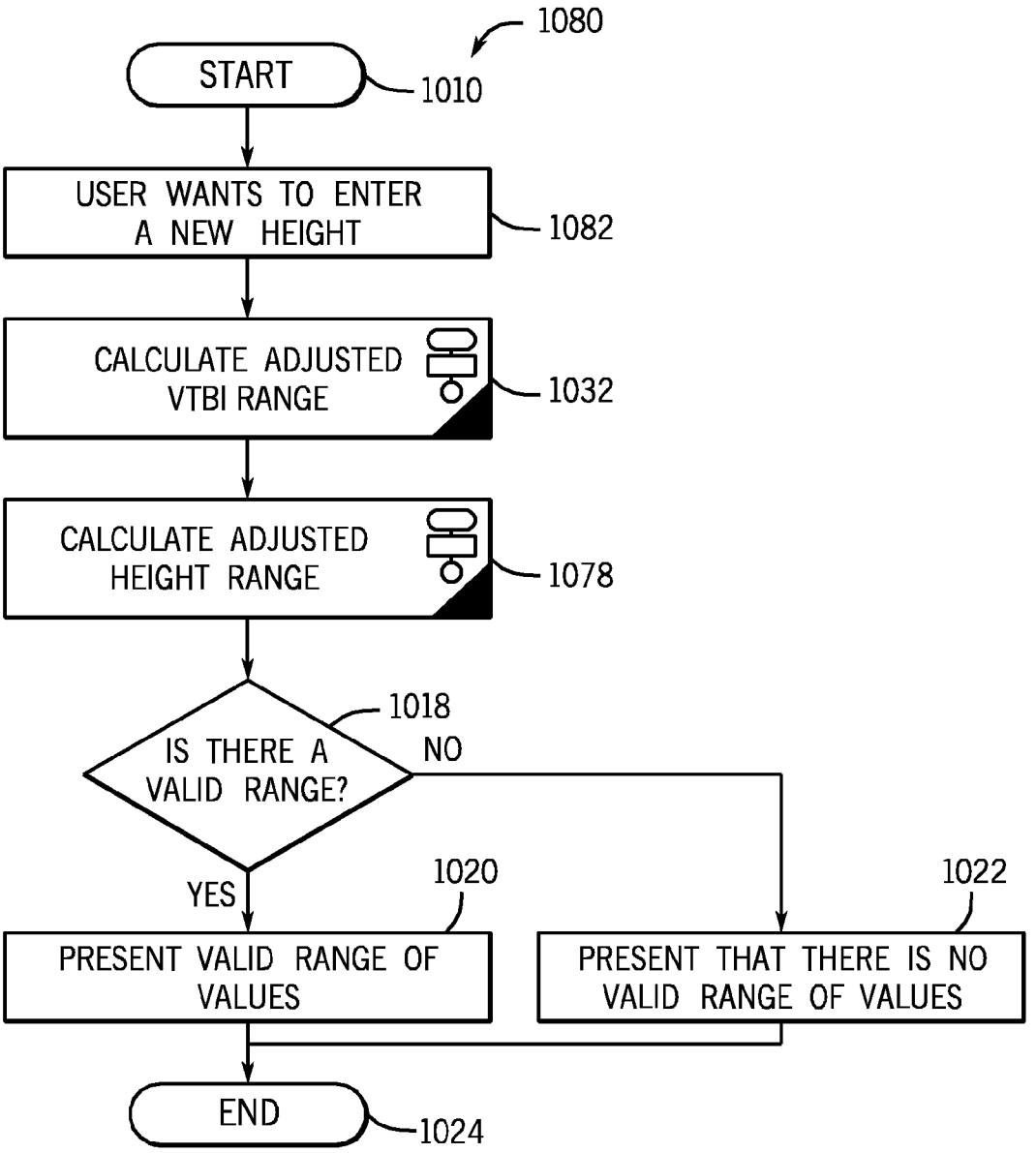

1080
START
1010
USER WANTS TO ENTER A NEW HEIGHT
1082
CALCULATE ADJUSTED VTBI RANGE
1032
CALCULATE ADJUSTED HEIGHT RANGE
1078
1018
IS THERE A VALID RANGE?
NO
YES
1020
PRESENT VALID RANGE OF VALUES
1022
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 15

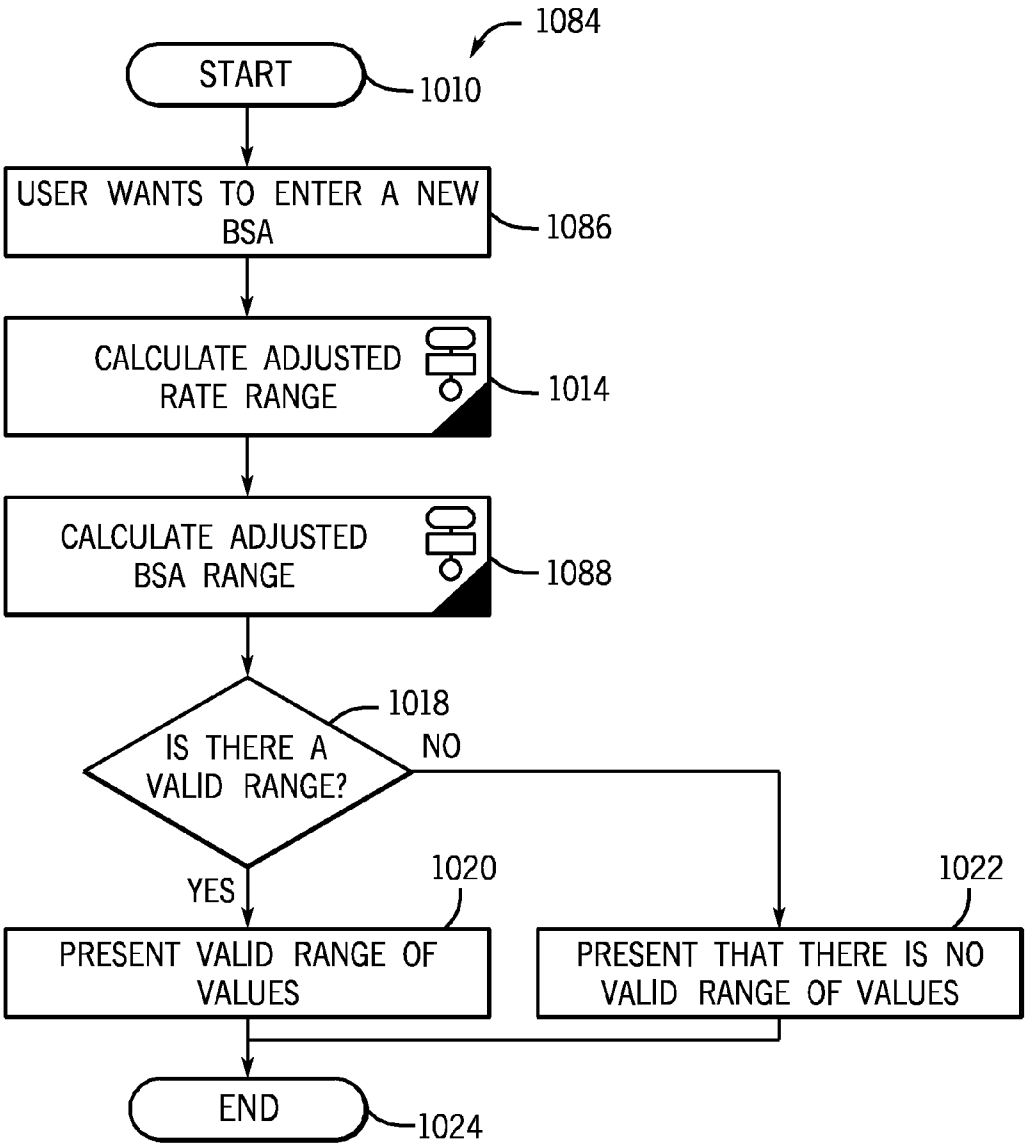

1084
START
1010
USER WANTS TO ENTER A NEW BSA
1086
CALCULATE ADJUSTED RATE RANGE
1014
CALCULATE ADJUSTED BSA RANGE
1088
1018
IS THERE A VALID RANGE?
NO
YES
1020
PRESENT VALID RANGE OF VALUES
1022
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 16

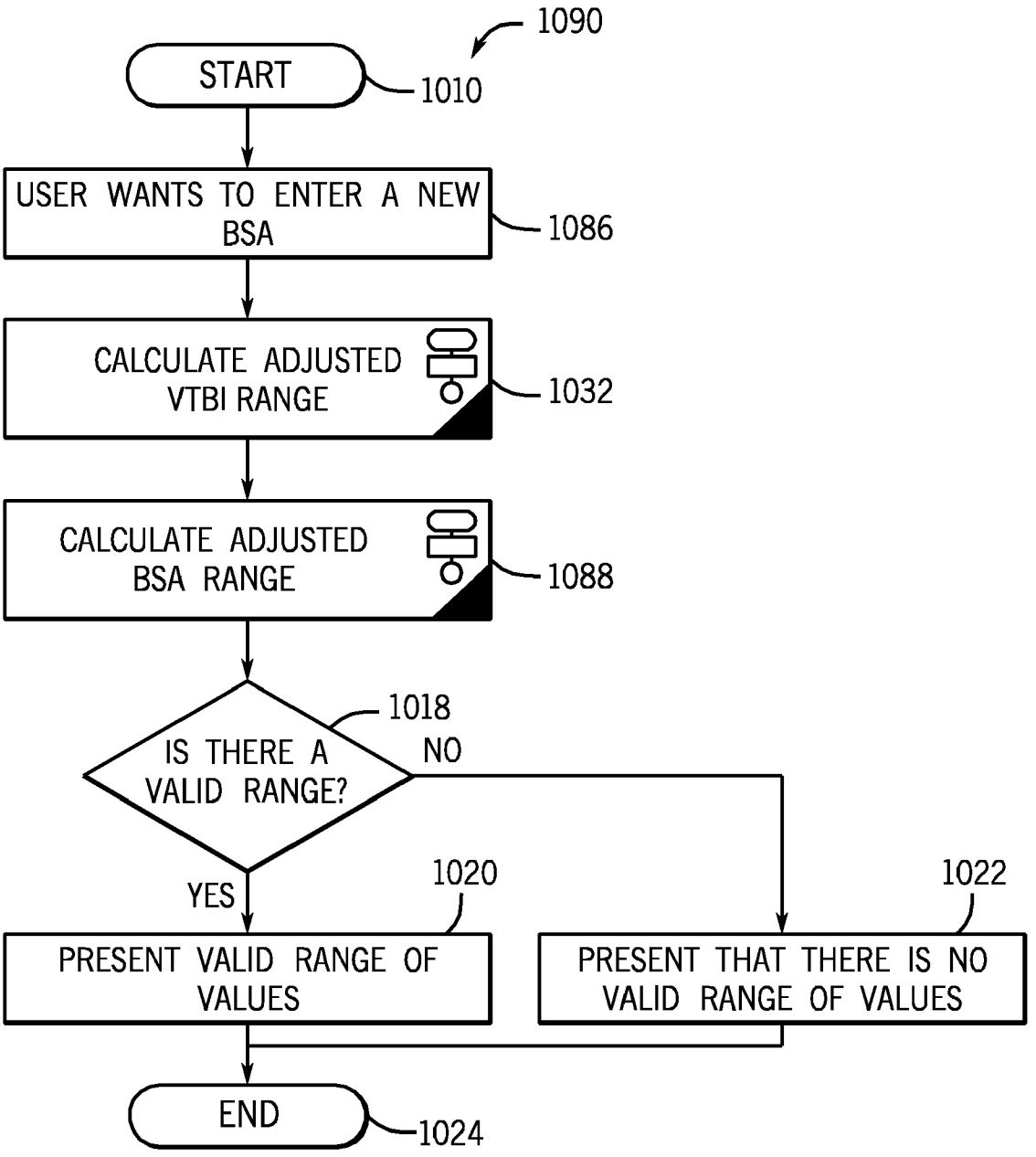

1090
START
1010
USER WANTS TO ENTER A NEW BSA
1086
CALCULATE ADJUSTED VTBI RANGE
1032
CALCULATE ADJUSTED BSA RANGE
1088
1018
IS THERE A VALID RANGE?
NO
YES
1020
PRESENT VALID RANGE OF VALUES
1022
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 17

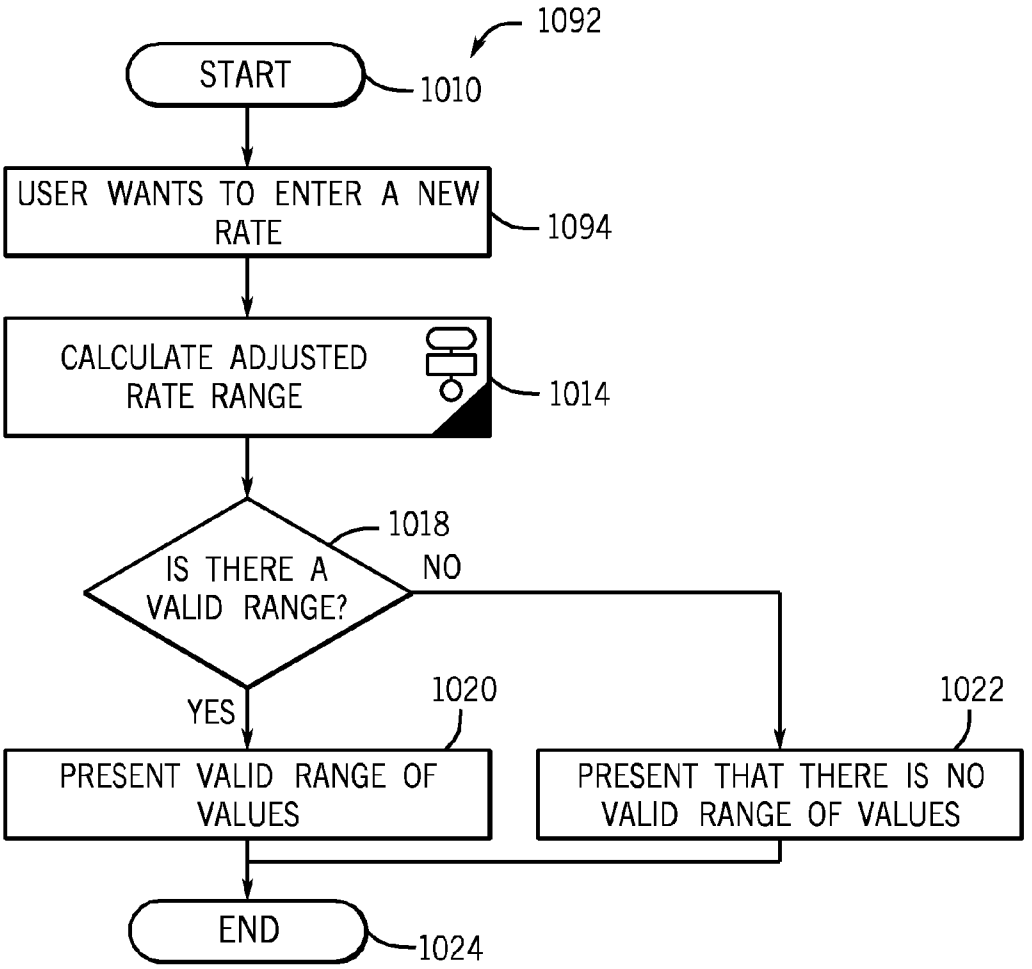

1092
START
1010
USER WANTS TO ENTER A NEW RATE
1094
CALCULATE ADJUSTED RATE RANGE
1014
1018
IS THERE A VALID RANGE?
NO
YES
1020
1022
PRESENT VALID RANGE OF VALUES
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 18A

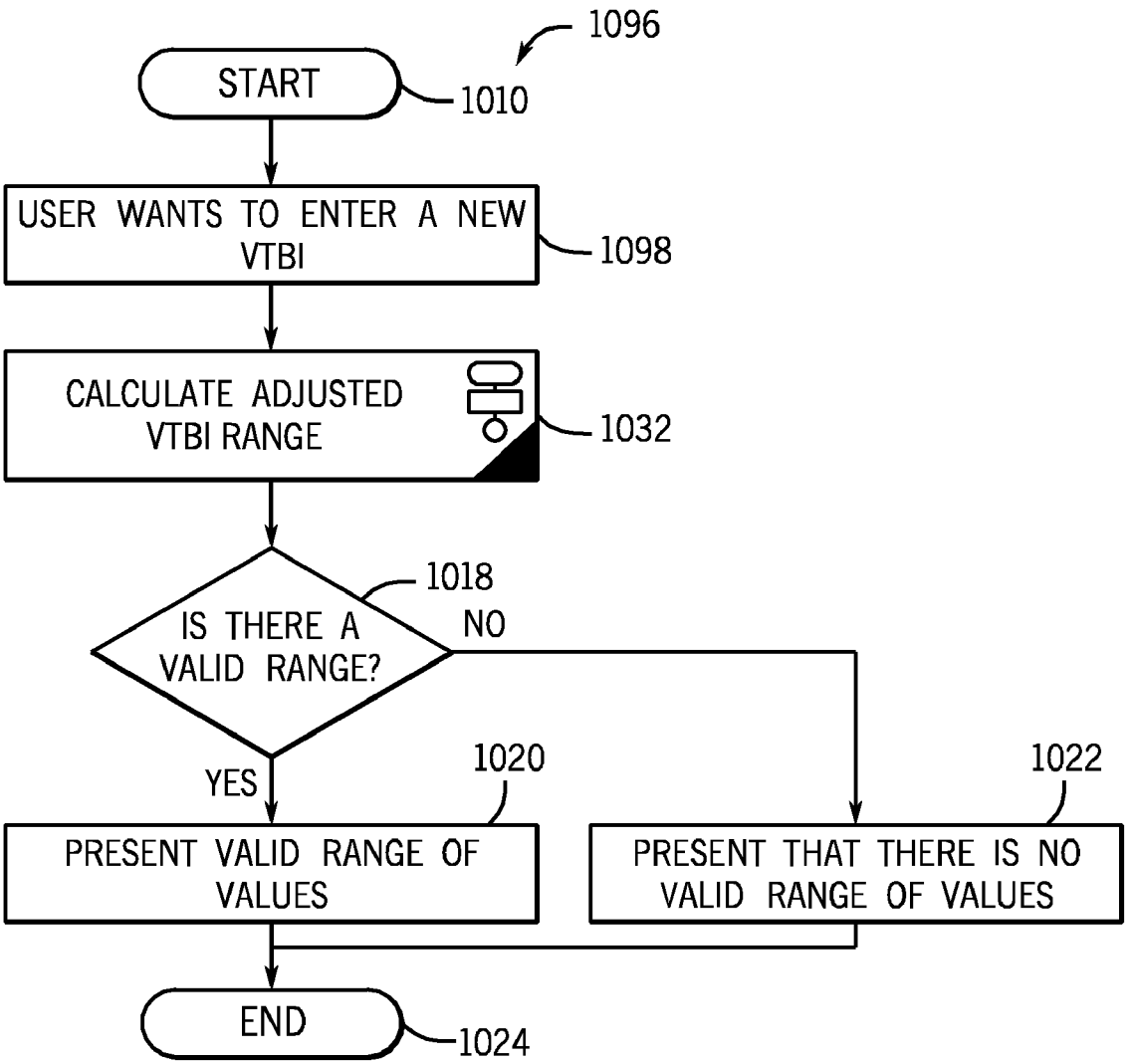

1096
START
1010
USER WANTS TO ENTER A NEW VTBI
1098
CALCULATE ADJUSTED VTBI RANGE
1032
1018
IS THERE A VALID RANGE?
NO
YES
1020
1022
PRESENT VALID RANGE OF VALUES
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 18B

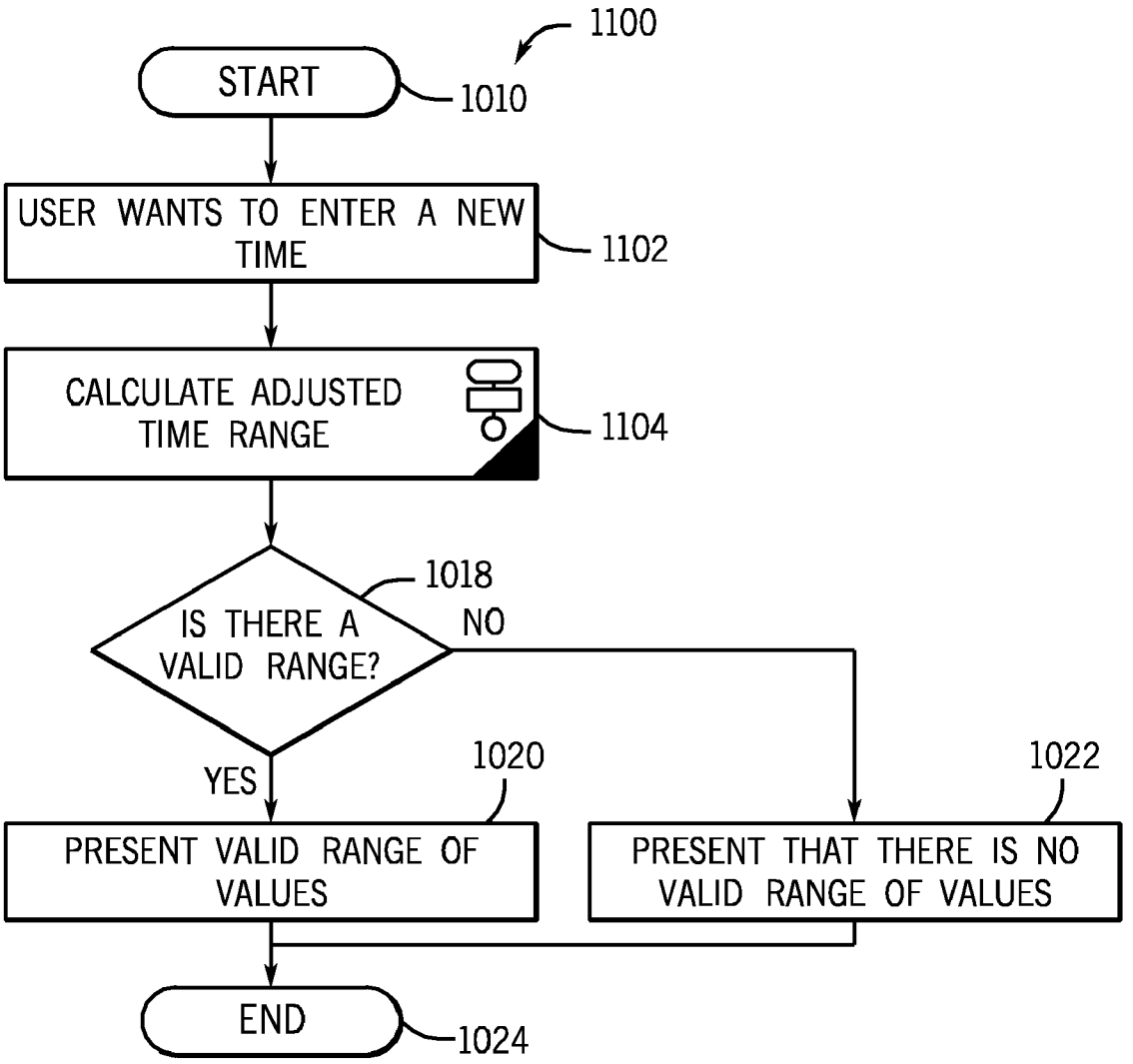

1100
START
1010
USER WANTS TO ENTER A NEW TIME
1102
CALCULATE ADJUSTED TIME RANGE
1104
1018
IS THERE A VALID RANGE?
NO
YES
1020
PRESENT VALID RANGE OF VALUES
1022
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 19

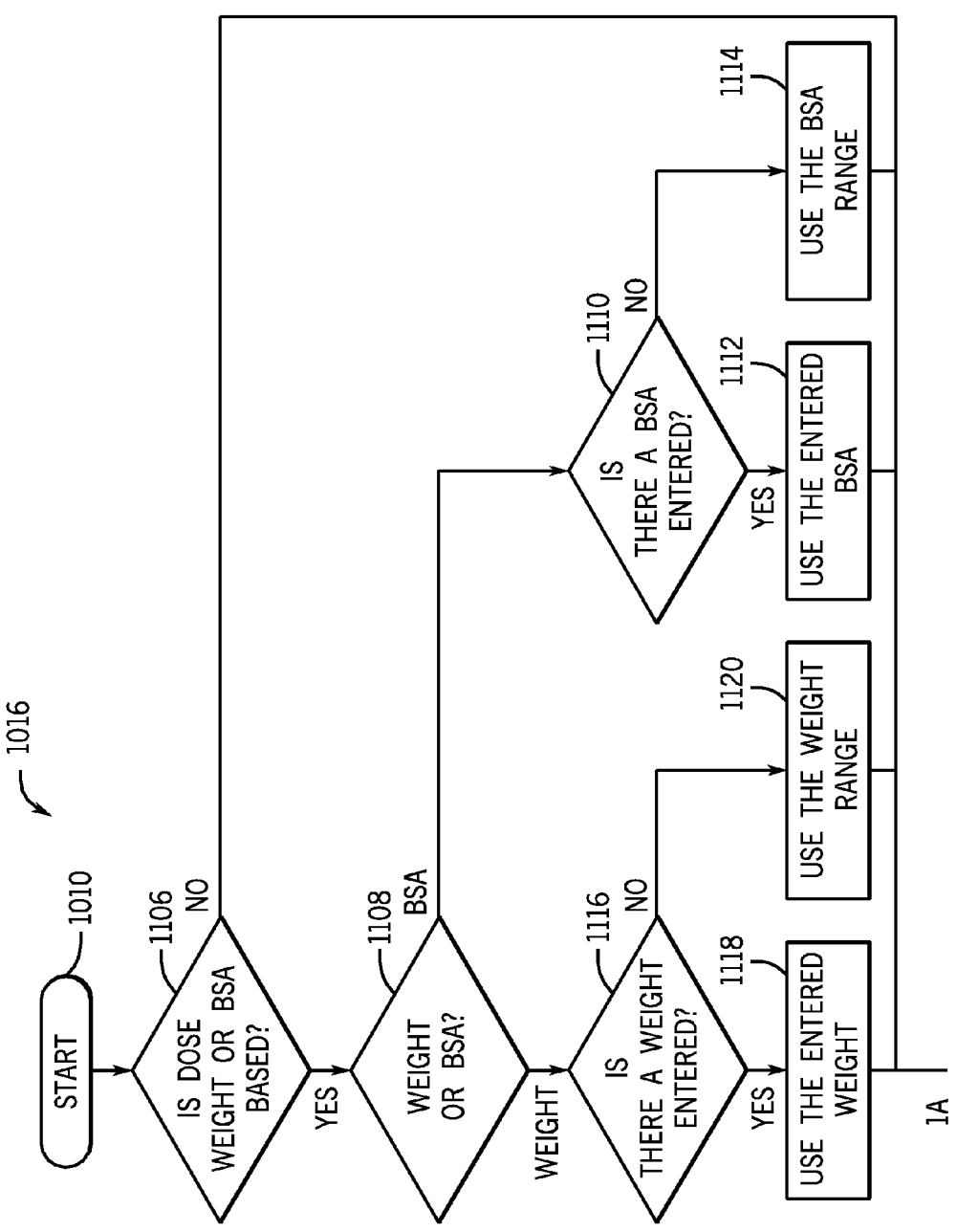
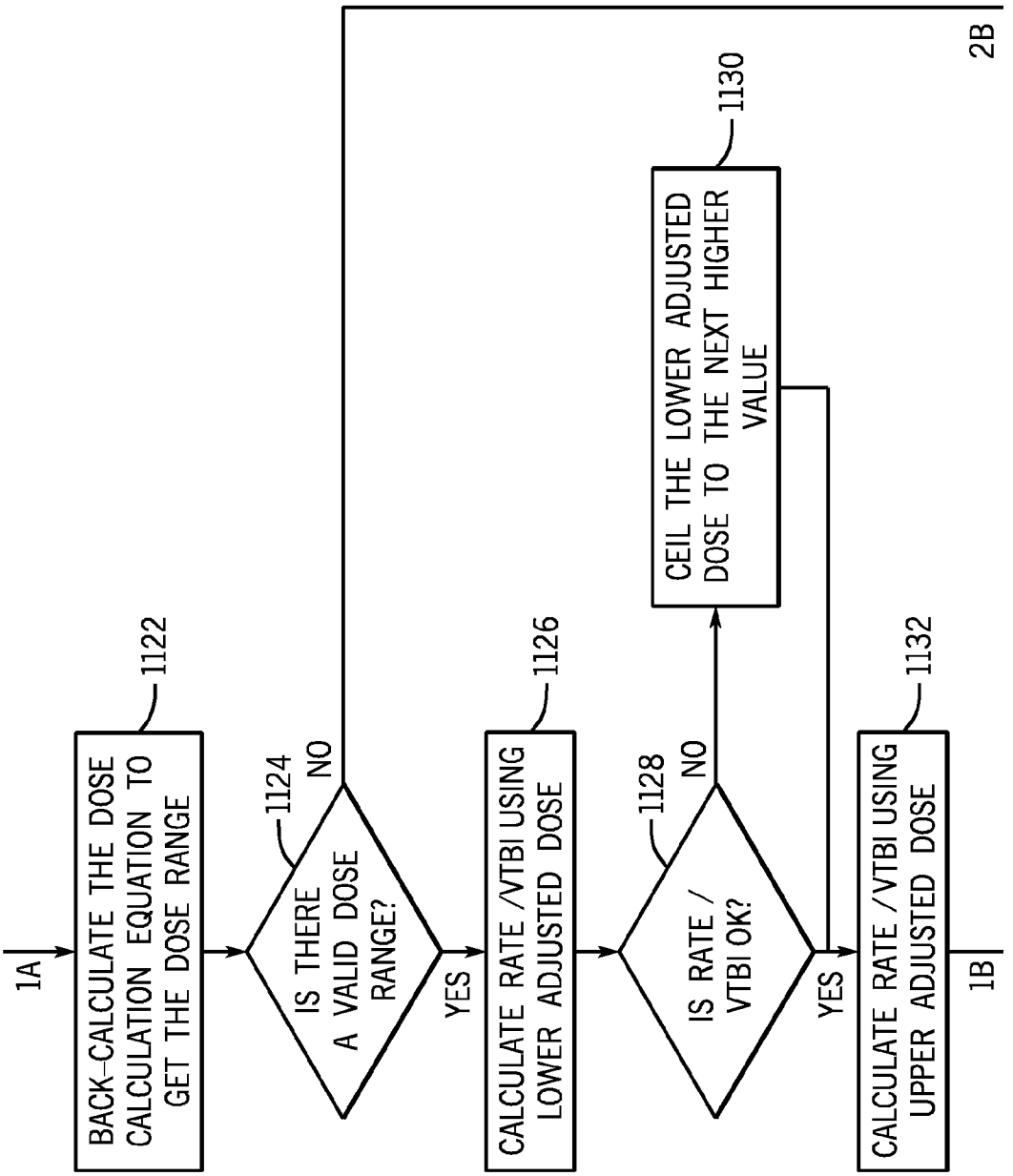

1016
START
1010
IS DOSE WEIGHT OR BSA BASED?
1106
NO
YES
WEIGHT OR BSA?
1108
BSA
WEIGHT
IS THERE A WEIGHT ENTERED?
1116
NO
YES
USE THE ENTERED WEIGHT
1118
USE THE WEIGHT RANGE
1120
IS THERE A BSA ENTERED?
1110
NO
YES
USE THE ENTERED BSA
1112
USE THE BSA RANGE
1114
1A

FIG. 20A

FIG. 20B


1A
BACK-CALCULATE THE DOSE CALCULATION EQUATION TO GET THE DOSE RANGE
1122
IS THERE A VALID DOSE RANGE?
1124
NO
YES
2B
CALCULATE RATE /VTBI USING LOWER ADJUSTED DOSE
1126
IS RATE / VTBI OK?
1128
NO
CEIL THE LOWER ADJUSTED DOSE TO THE NEXT HIGHER VALUE
1130
YES
CALCULATE RATE /VTBI USING UPPER ADJUSTED DOSE
1132
1B

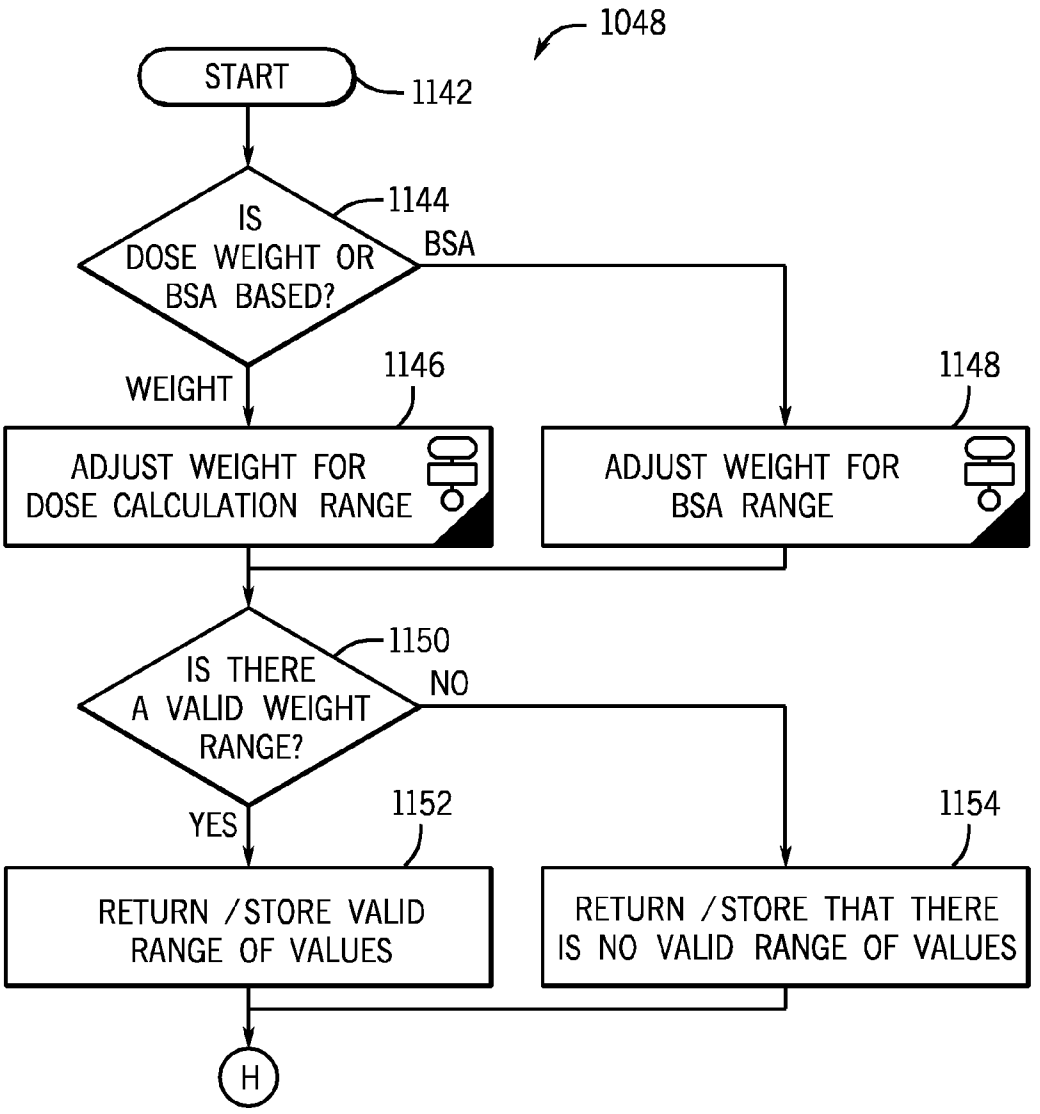

1048
START
1142
IS DOSE WEIGHT OR BSA BASED?
1144
BSA
WEIGHT
1146
1148
ADJUST WEIGHT FOR DOSE CALCULATION RANGE
ADJUST WEIGHT FOR BSA RANGE
IS THERE A VALID WEIGHT RANGE?
1150
NO
YES
1152
1154
RETURN /STORE VALID RANGE OF VALUES
RETURN /STORE THAT THERE IS NO VALID RANGE OF VALUES
H

FIG. 21

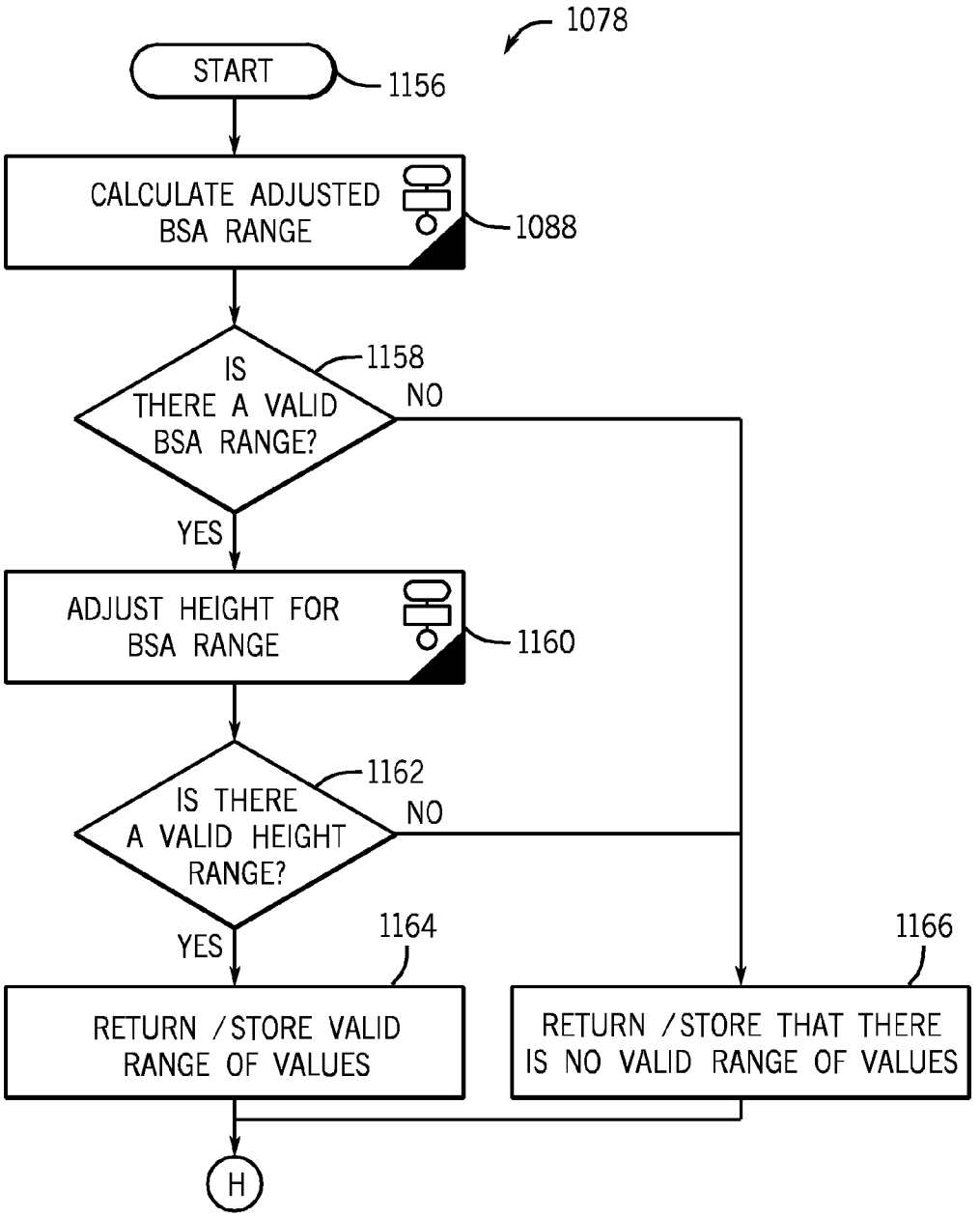

1078
START
1156
CALCULATE ADJUSTED BSA RANGE
1088
IS THERE A VALID BSA RANGE?
1158
NO
YES
ADJUST HEIGHT FOR BSA RANGE
1160
IS THERE A VALID HEIGHT RANGE?
1162
NO
YES
1164
1166
RETURN /STORE VALID RANGE OF VALUES
RETURN /STORE THAT THERE IS NO VALID RANGE OF VALUES
H

FIG. 22

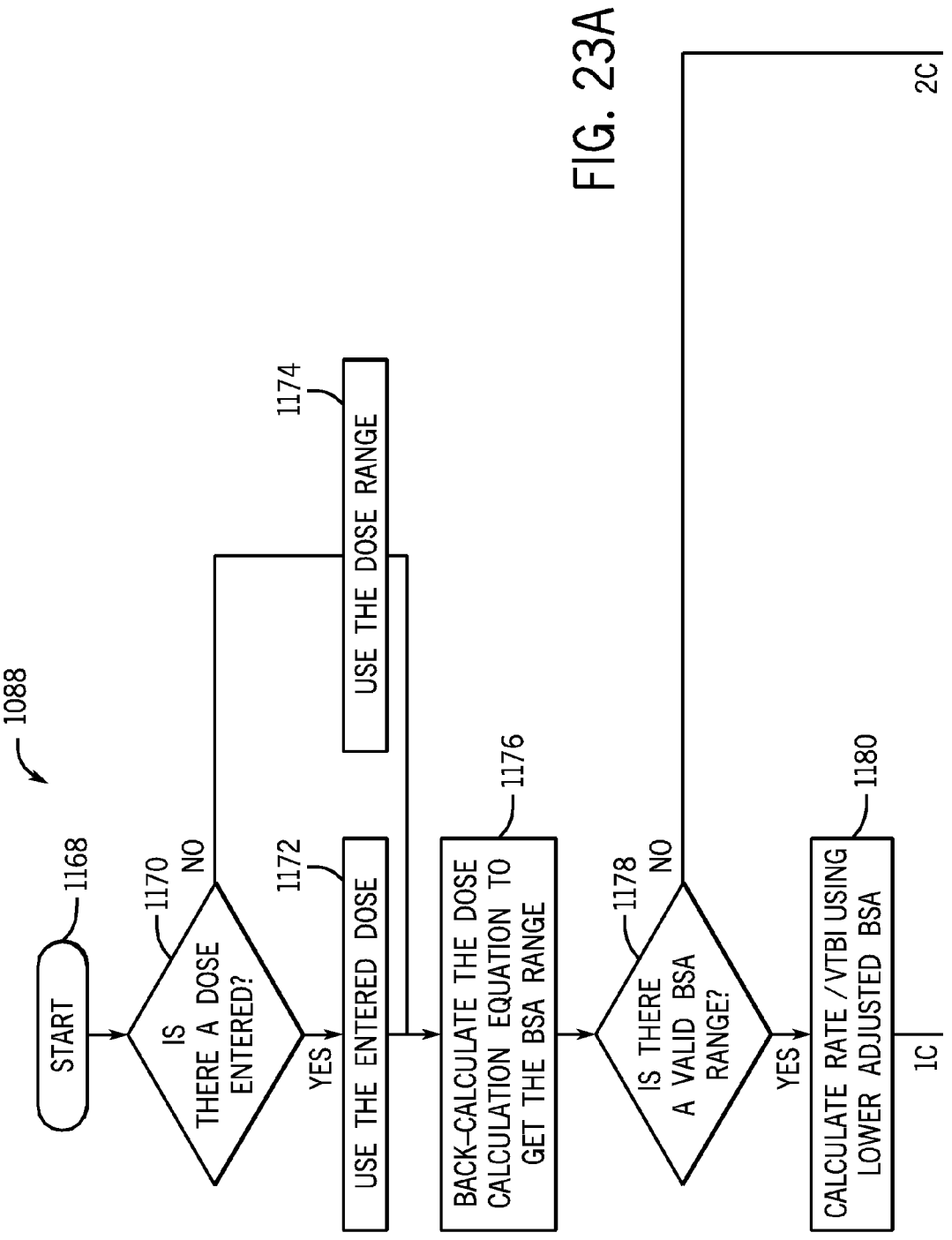

1088
START
1168
IS THERE A DOSE ENTERED?
1170
NO
YES
USE THE ENTERED DOSE
1172
USE THE DOSE RANGE
1174
BACK-CALCULATE THE DOSE CALCULATION EQUATION TO GET THE BSA RANGE
1176
IS THERE A VALID BSA RANGE?
1178
NO
YES
CALCULATE RATE / VTBI USING LOWER ADJUSTED BSA
1180
1C
2C

FIG. 23A

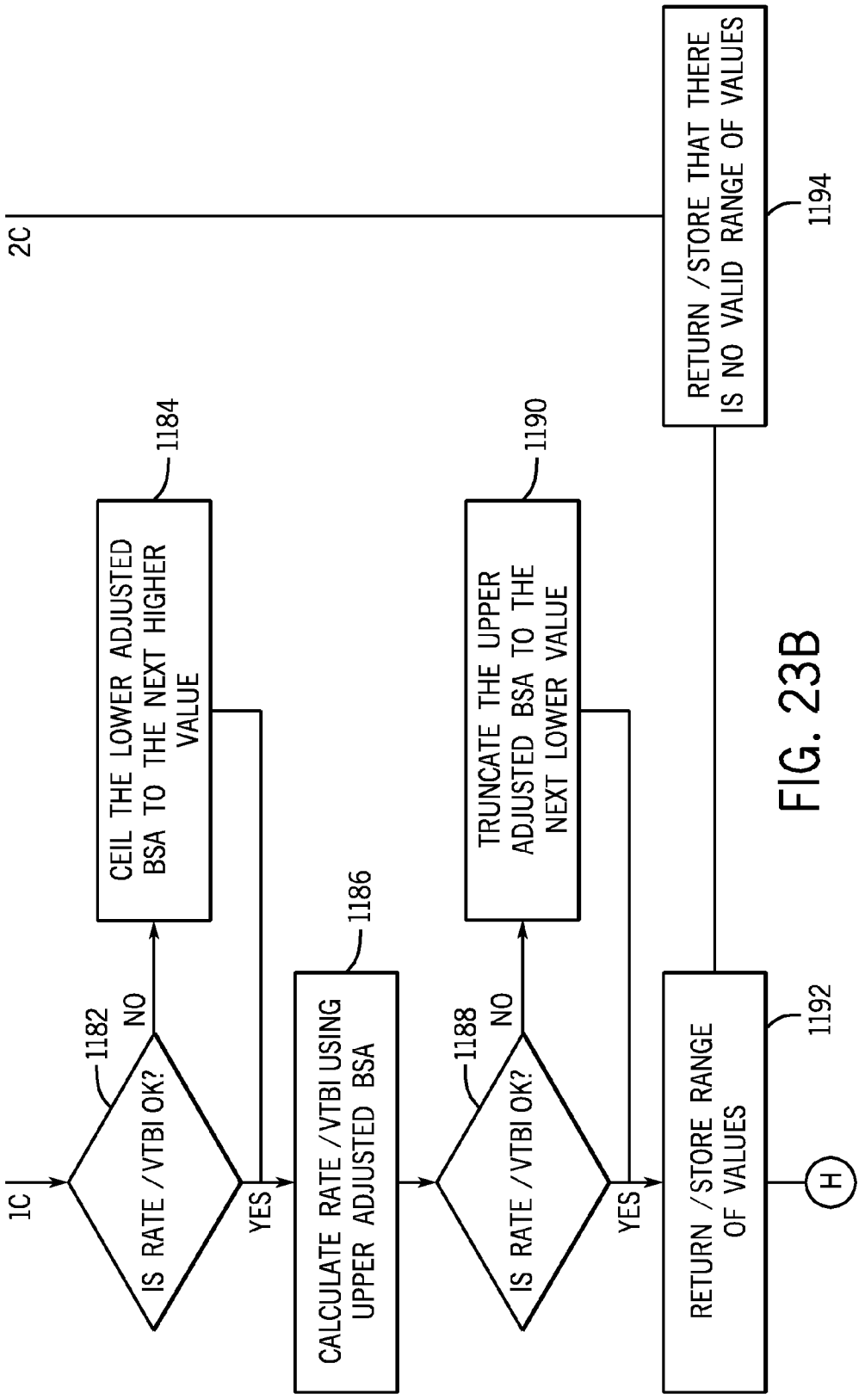

1C
IS RATE / VTBI OK?
1182
NO
YES
CEIL THE LOWER ADJUSTED BSA TO THE NEXT HIGHER VALUE
1184
CALCULATE RATE / VTBI USING UPPER ADJUSTED BSA
1186
IS RATE / VTBI OK?
1188
NO
YES
TRUNCATE THE UPPER ADJUSTED BSA TO THE NEXT LOWER VALUE
1190
RETURN / STORE RANGE OF VALUES
1192
H
RETURN / STORE THAT THERE IS NO VALID RANGE OF VALUES
1194
2C

FIG. 23B

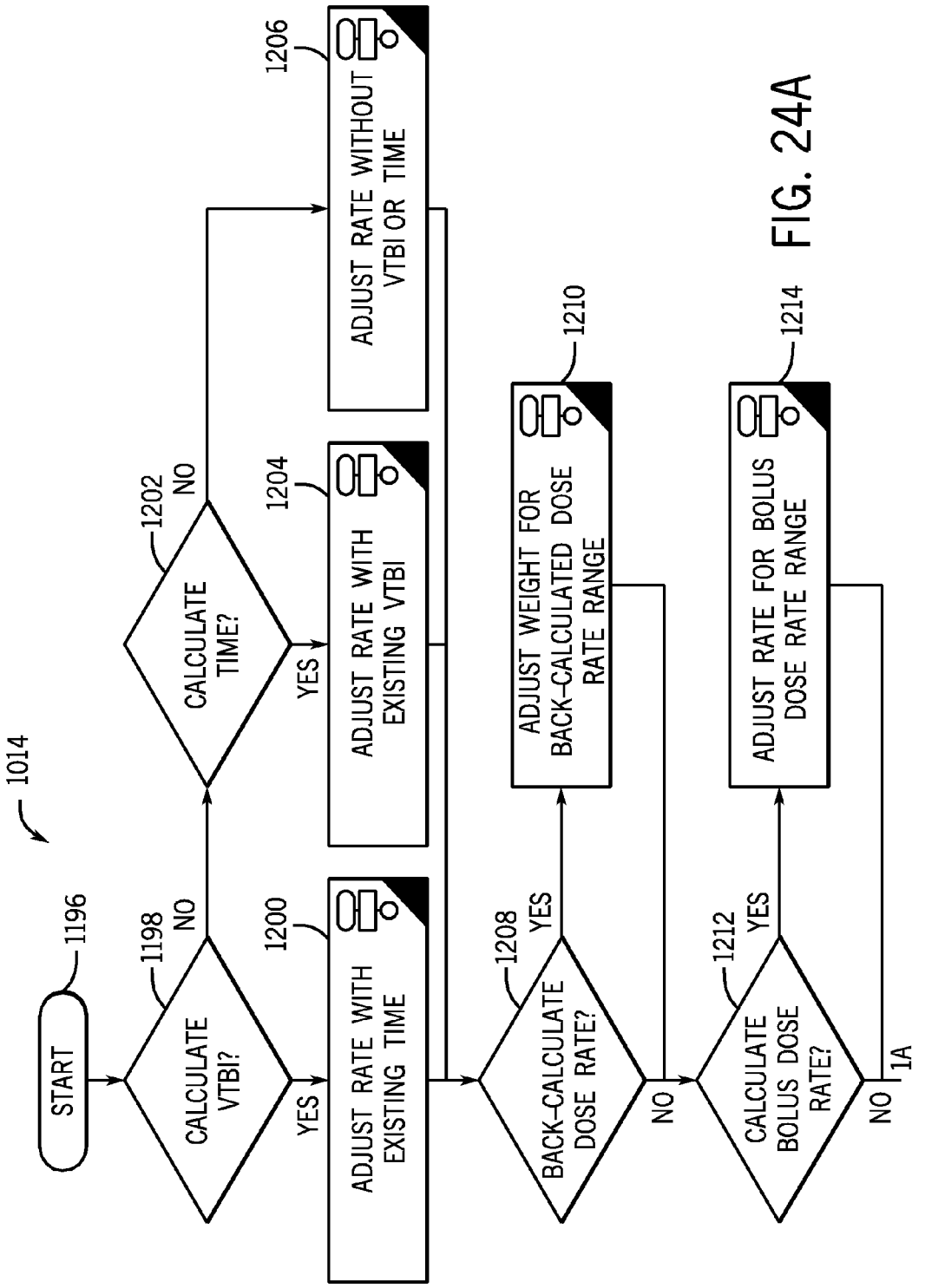

1014
START
1196
CALCULATE VTBI?
1198
NO
YES
ADJUST RATE WITH EXISTING TIME
1200
CALCULATE TIME?
1202
NO
YES
ADJUST RATE WITH EXISTING VTBI
1204
ADJUST RATE WITHOUT VTBI OR TIME
1206
BACK-CALCULATE DOSE RATE?
1208
YES
NO
ADJUST WEIGHT FOR BACK-CALCULATED DOSE RATE RANGE
1210
CALCULATE BOLUS DOSE RATE?
1212
YES
NO
ADJUST RATE FOR BOLUS DOSE RATE RANGE
1214
1A

FIG. 24A

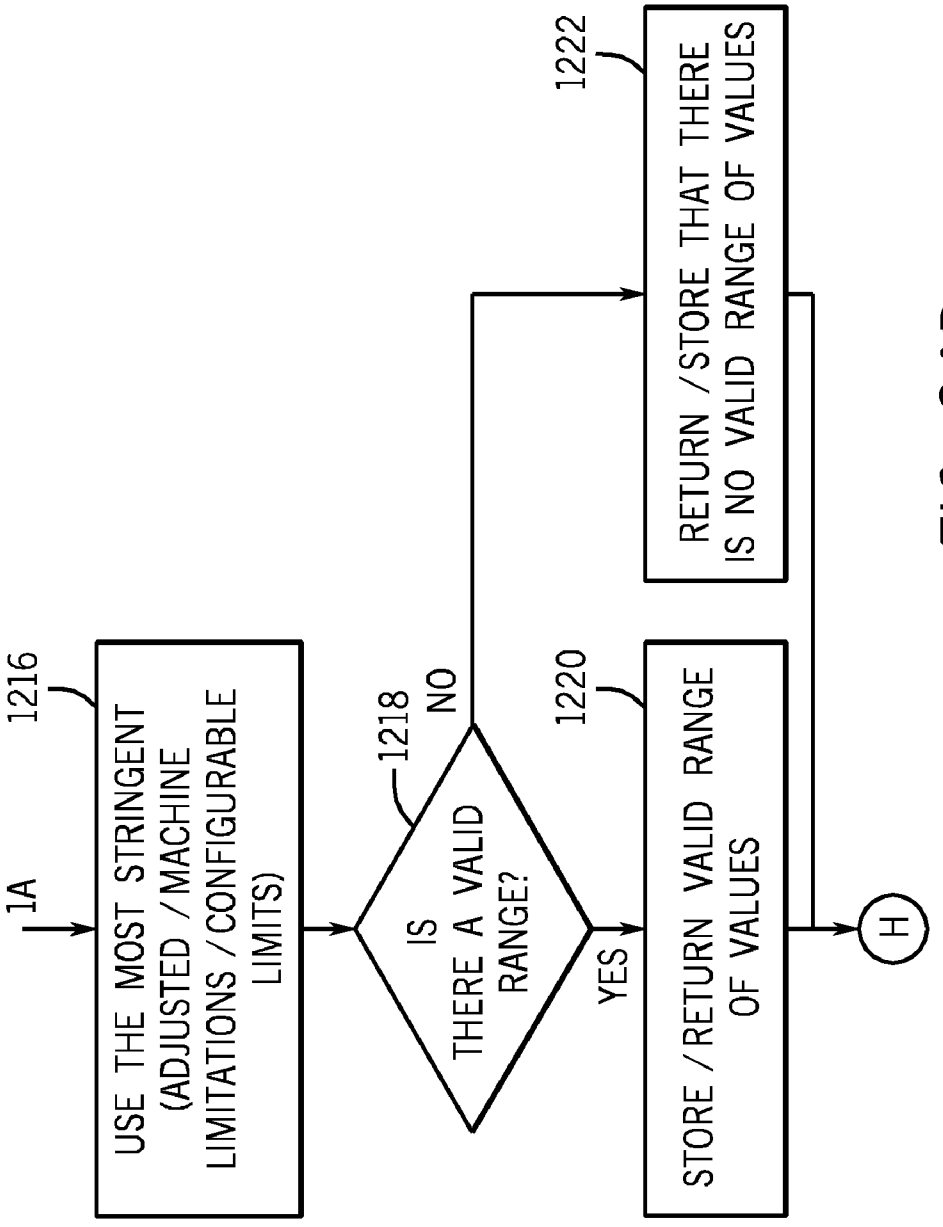

1A
1216
USE THE MOST STRINGENT (ADJUSTED / MACHINE LIMITATIONS / CONFIGURABLE LIMITS)
1218
IS THERE A VALID RANGE?
NO
YES
1220
STORE / RETURN VALID RANGE OF VALUES
1222
RETURN / STORE THAT THERE IS NO VALID RANGE OF VALUES
H

FIG. 24B

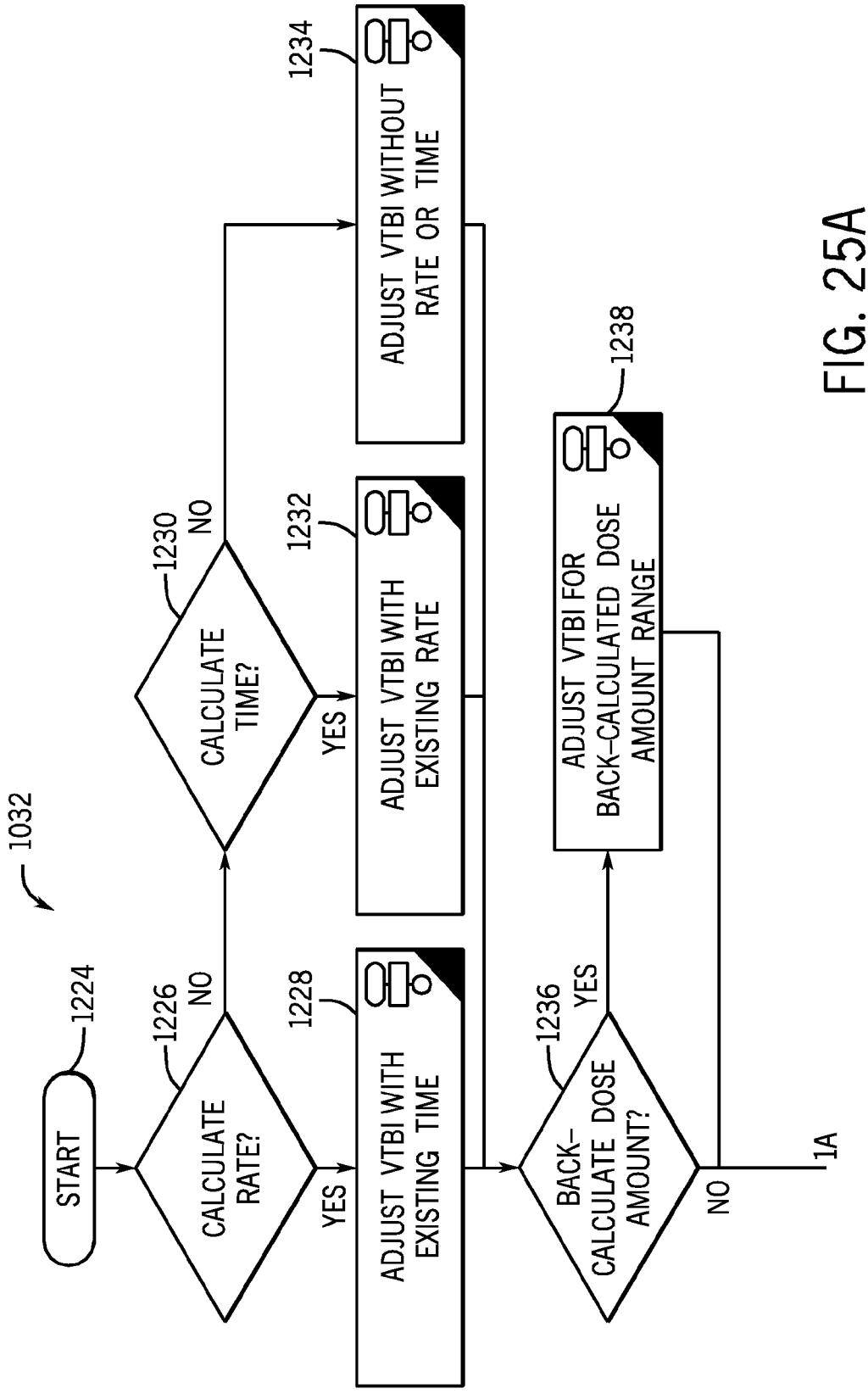

1032
START
1224
CALCULATE RATE?
1226
NO
YES
ADJUST VTBI WITH EXISTING TIME
1228
CALCULATE TIME?
1230
NO
YES
ADJUST VTBI WITH EXISTING RATE
1232
ADJUST VTBI WITHOUT RATE OR TIME
1234
BACK-CALCULATE DOSE AMOUNT?
1236
YES
NO
ADJUST VTBI FOR BACK-CALCULATED DOSE AMOUNT RANGE
1238
1A

FIG. 25A

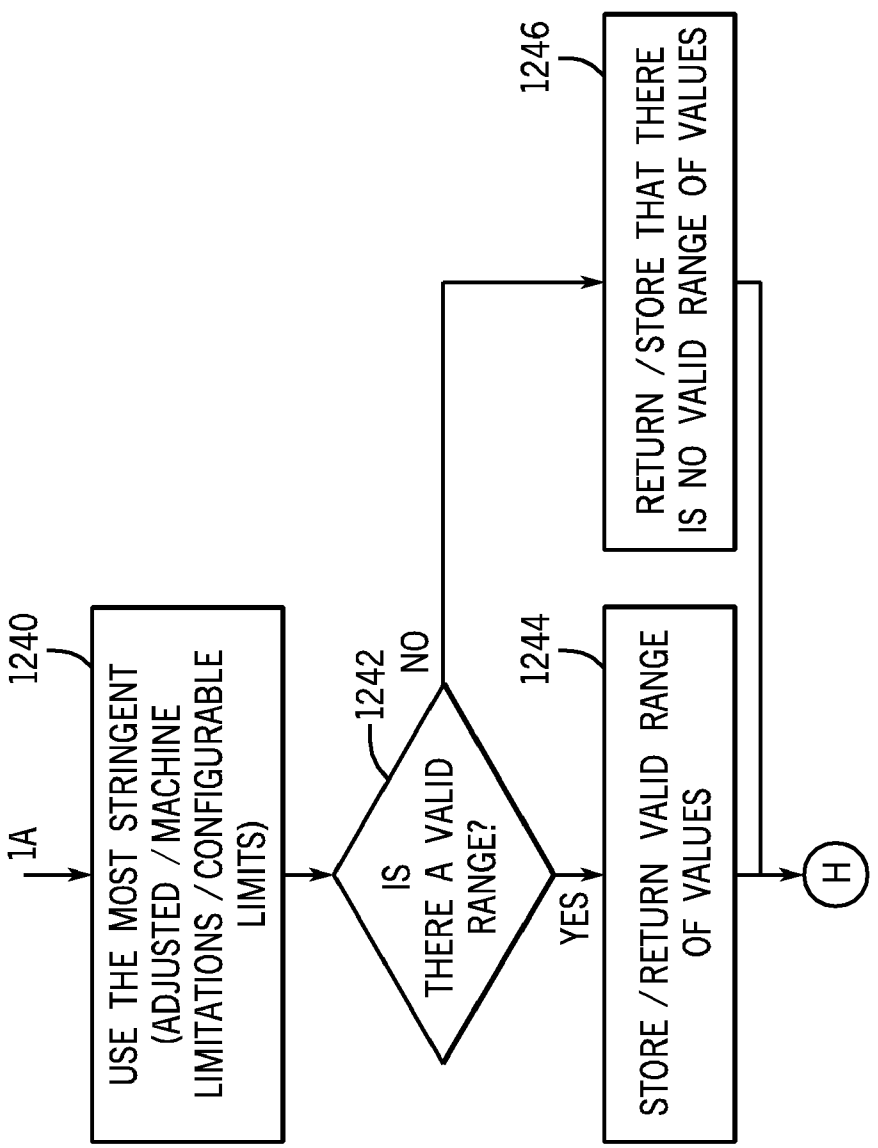

1A
1240
USE THE MOST STRINGENT (ADJUSTED /MACHINE LIMITATIONS /CONFIGURABLE LIMITS)
1242
IS THERE A VALID RANGE?
NO
YES
1244
STORE /RETURN VALID RANGE OF VALUES
1246
RETURN /STORE THAT THERE IS NO VALID RANGE OF VALUES
H

FIG. 25B

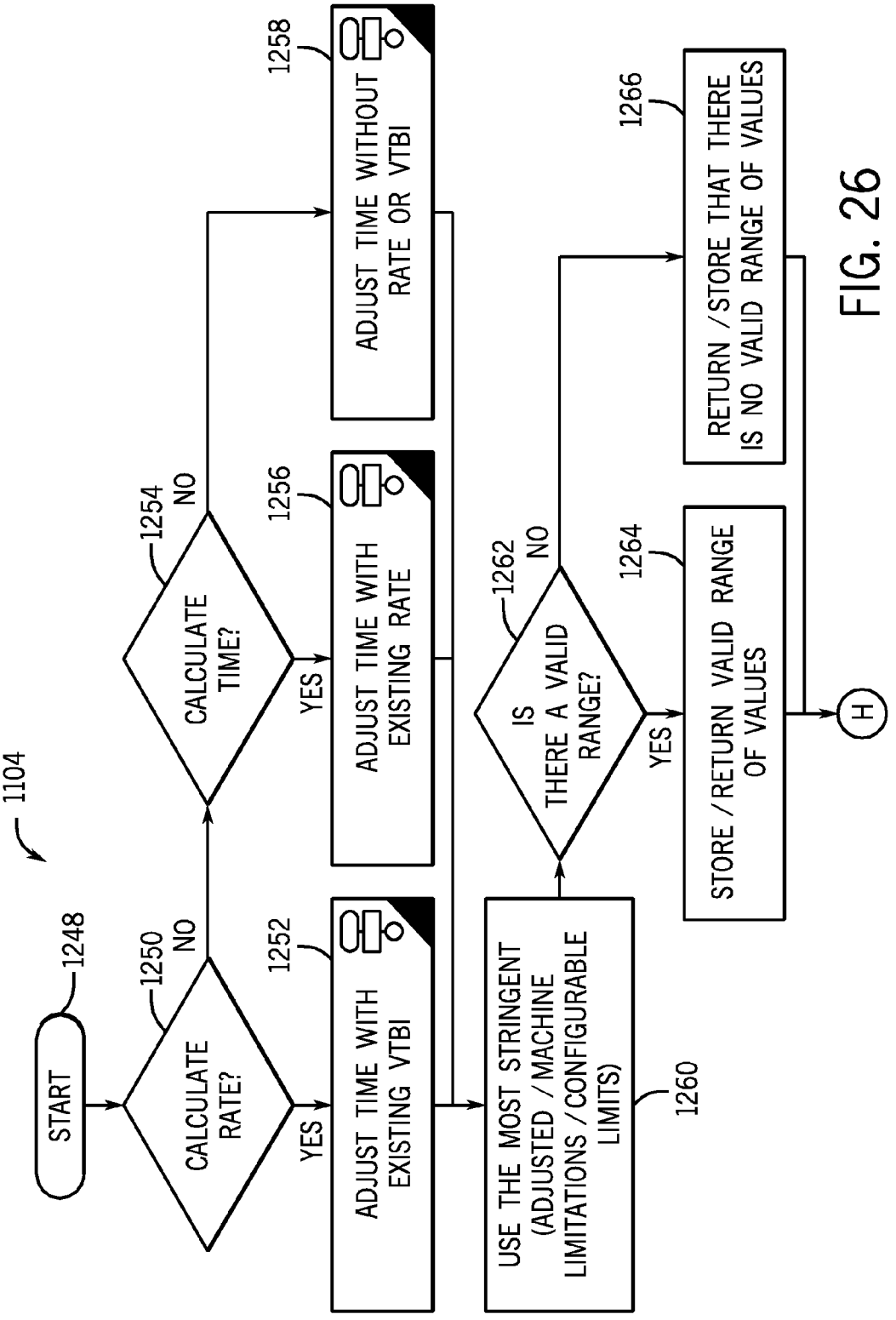

1104
START
1248
CALCULATE RATE?
1250
NO
YES
ADJUST TIME WITH EXISTING VTBI
1252
CALCULATE TIME?
1254
NO
YES
ADJUST TIME WITH EXISTING RATE
1256
ADJUST TIME WITHOUT RATE OR VTBI
1258
USE THE MOST STRINGENT (ADJUSTED / MACHINE LIMITATIONS / CONFIGURABLE LIMITS)
1260
IS THERE A VALID RANGE?
1262
NO
YES
STORE / RETURN VALID RANGE OF VALUES
1264
RETURN / STORE THAT THERE IS NO VALID RANGE OF VALUES
1266
H

FIG. 26

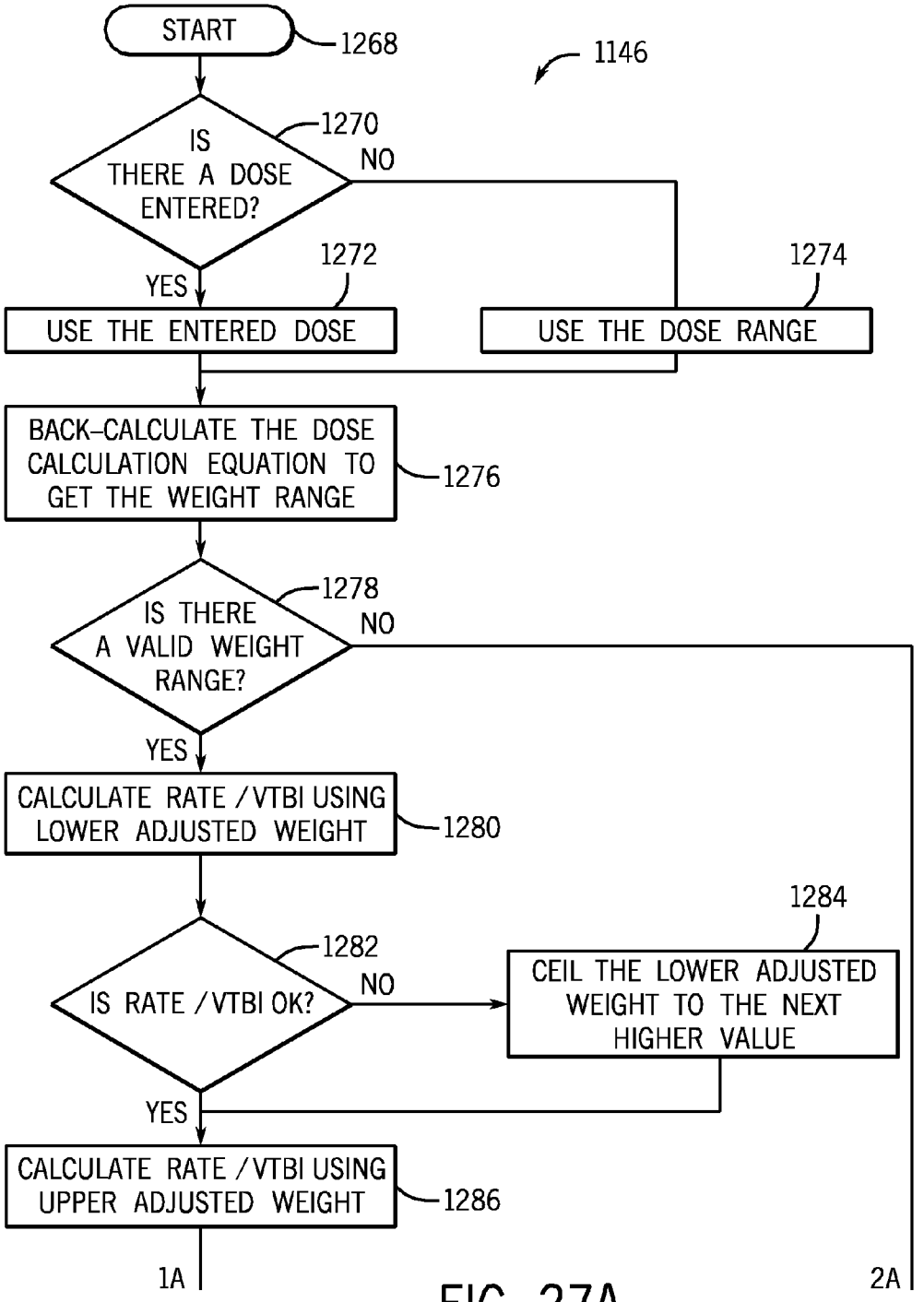

START
1268
1146
IS THERE A DOSE ENTERED?
1270
NO
YES
1272
1274
USE THE ENTERED DOSE
USE THE DOSE RANGE
BACK-CALCULATE THE DOSE CALCULATION EQUATION TO GET THE WEIGHT RANGE
1276
IS THERE A VALID WEIGHT RANGE?
1278
NO
YES
CALCULATE RATE / VTBI USING LOWER ADJUSTED WEIGHT
1280
1284
IS RATE / VTBI OK?
1282
NO
CEIL THE LOWER ADJUSTED WEIGHT TO THE NEXT HIGHER VALUE
YES
CALCULATE RATE / VTBI USING UPPER ADJUSTED WEIGHT
1286
1A
2A

FIG. 27A

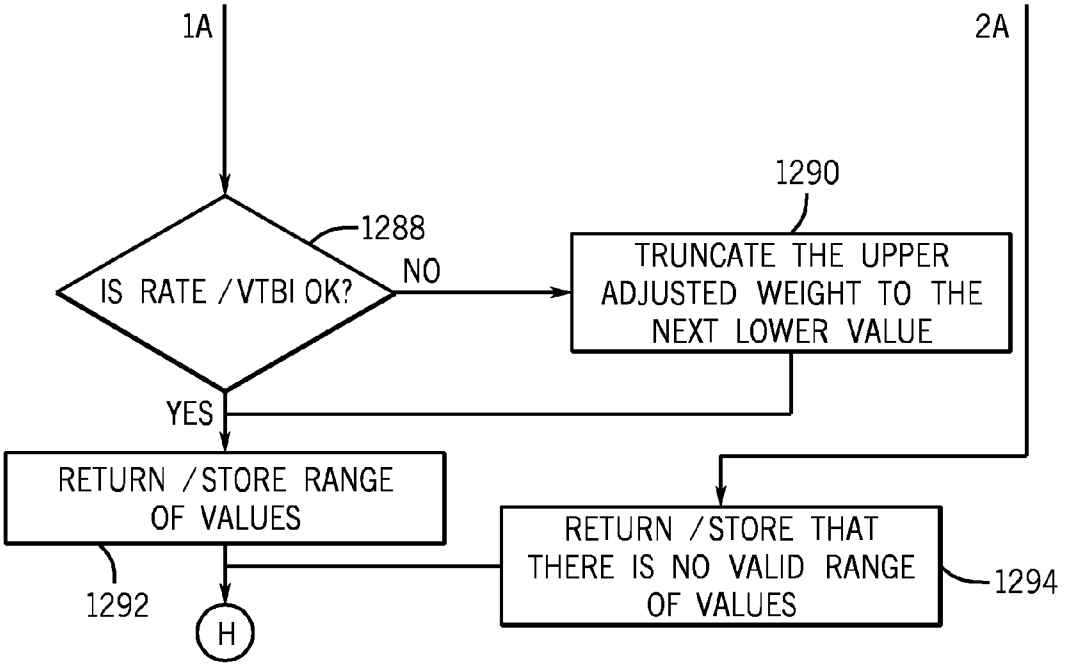

1A
2A
1290
1288
IS RATE /VTBI OK?
NO
TRUNCATE THE UPPER ADJUSTED WEIGHT TO THE NEXT LOWER VALUE
YES
RETURN /STORE RANGE OF VALUES
RETURN /STORE THAT THERE IS NO VALID RANGE OF VALUES
1294
1292
H

FIG. 27B

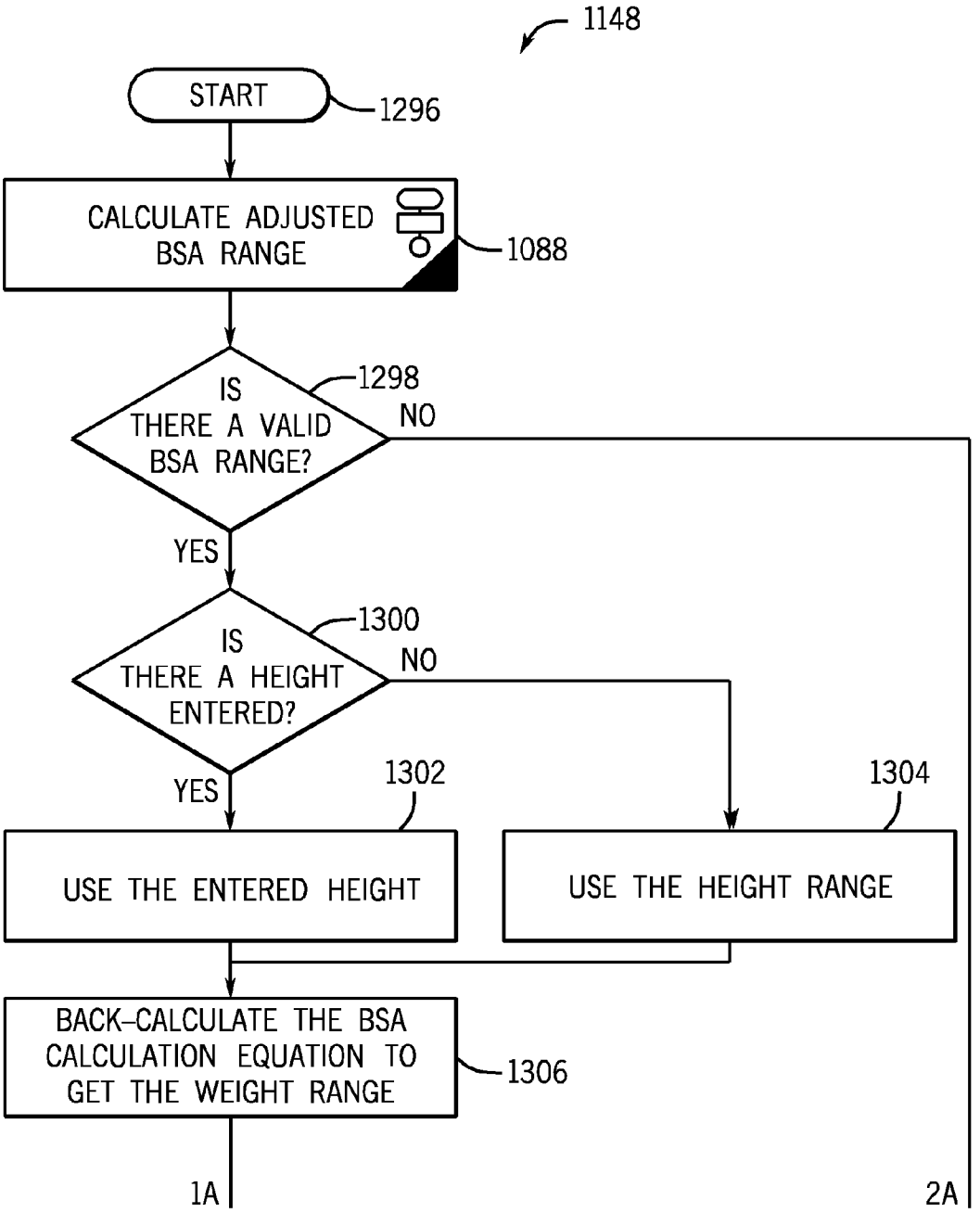
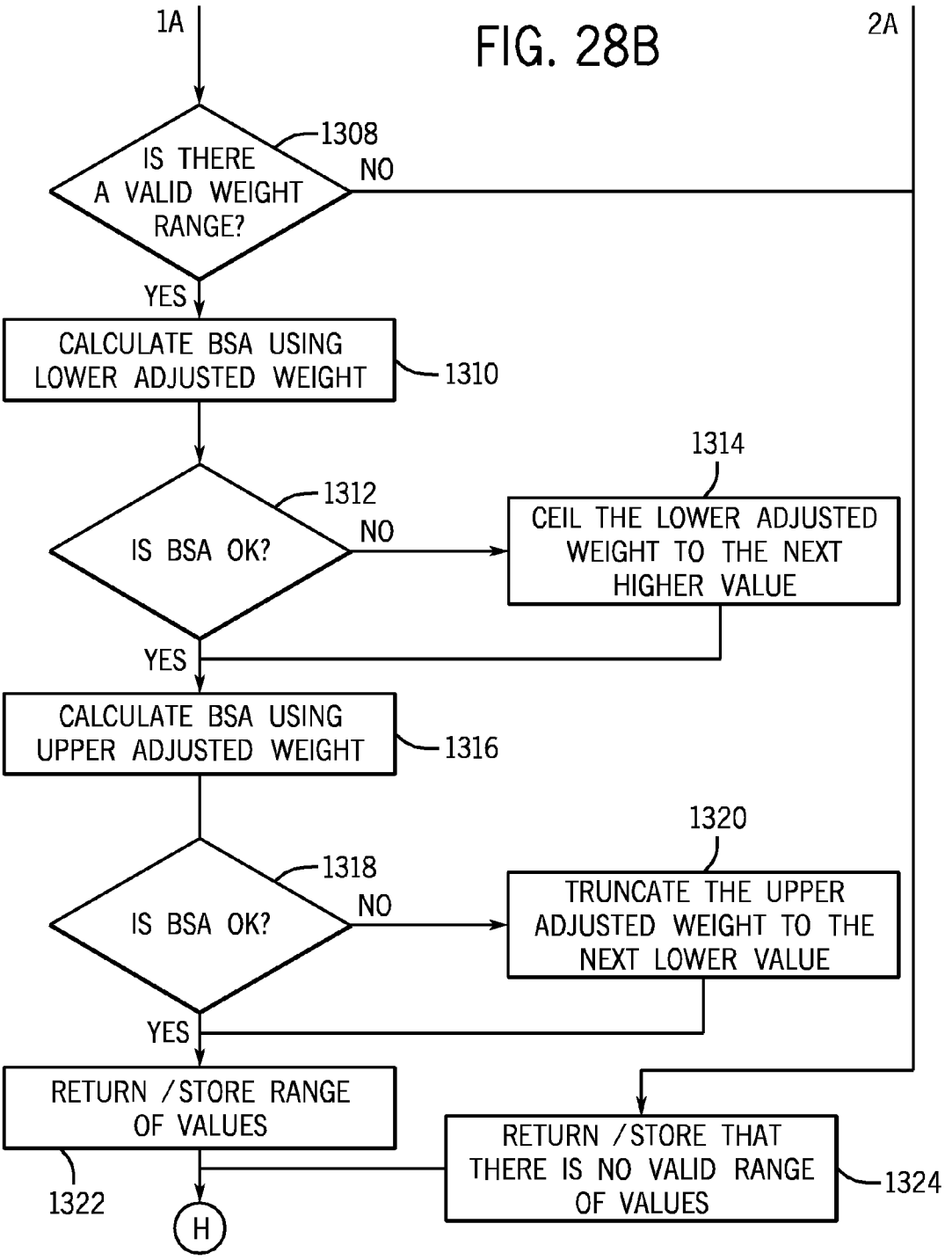

1148
START
1296
CALCULATE ADJUSTED BSA RANGE
1088
IS THERE A VALID BSA RANGE?
1298
NO
YES
IS THERE A HEIGHT ENTERED?
1300
NO
YES
1302
1304
USE THE ENTERED HEIGHT
USE THE HEIGHT RANGE
BACK-CALCULATE THE BSA CALCULATION EQUATION TO GET THE WEIGHT RANGE
1306
1A
2A

FIG. 28A

FIG. 28B


1A
2A
IS THERE A VALID WEIGHT RANGE?
1308
NO
YES
CALCULATE BSA USING LOWER ADJUSTED WEIGHT
1310
1314
IS BSA OK?
1312
NO
CEIL THE LOWER ADJUSTED WEIGHT TO THE NEXT HIGHER VALUE
YES
CALCULATE BSA USING UPPER ADJUSTED WEIGHT
1316
1320
IS BSA OK?
1318
NO
TRUNCATE THE UPPER ADJUSTED WEIGHT TO THE NEXT LOWER VALUE
YES
RETURN /STORE RANGE OF VALUES
1322
H
RETURN /STORE THAT THERE IS NO VALID RANGE OF VALUES
1324

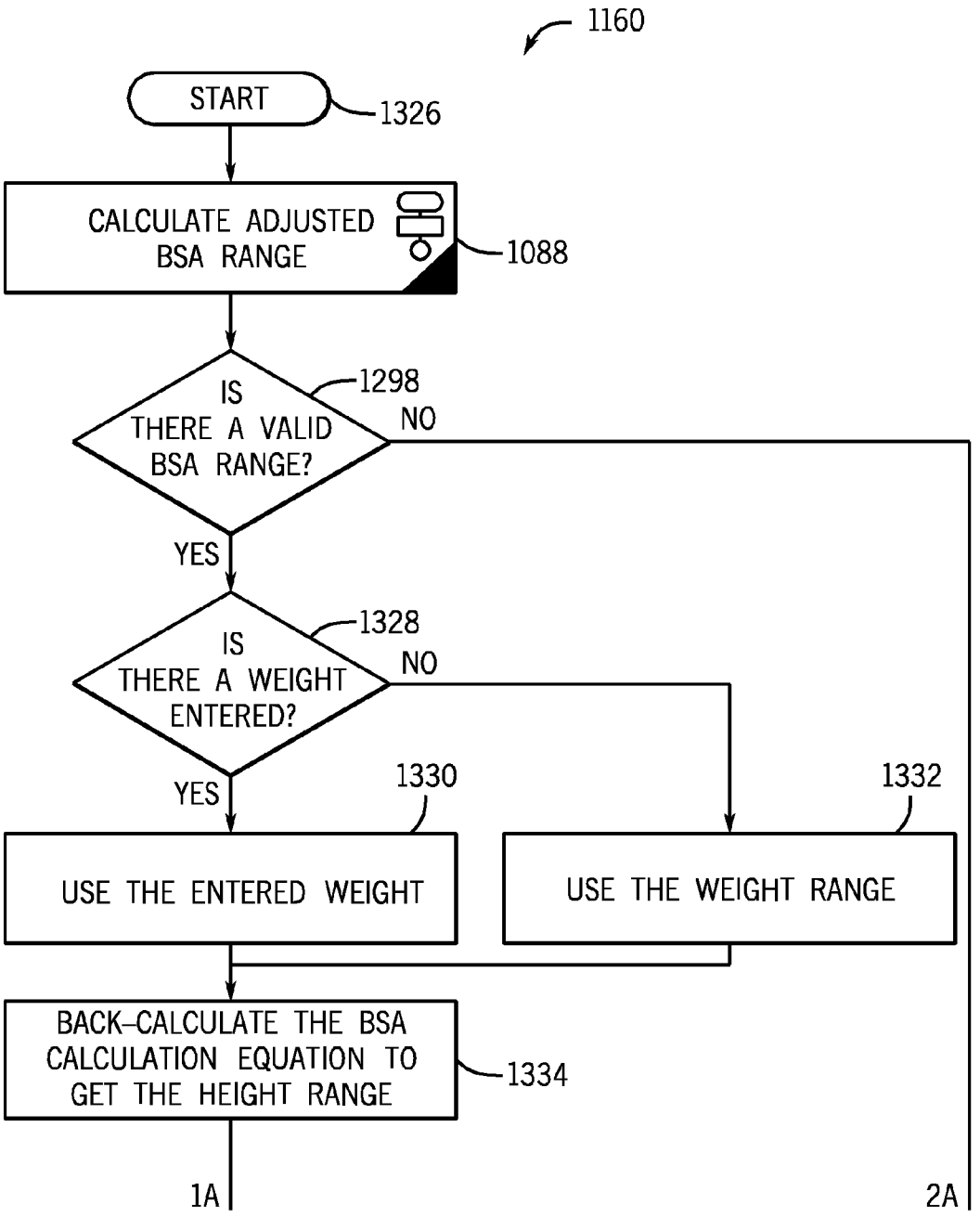
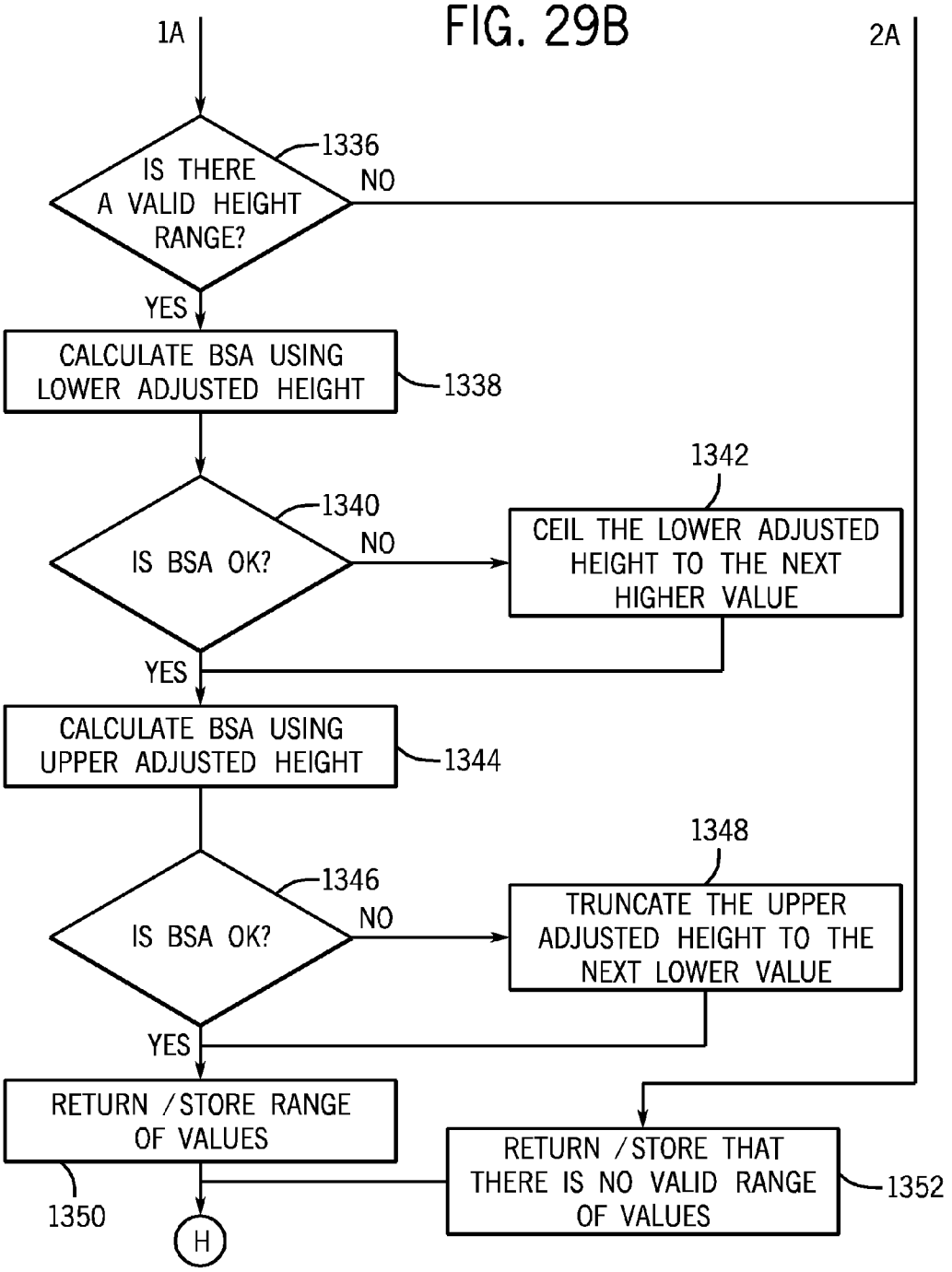

1160
START
1326
CALCULATE ADJUSTED BSA RANGE
1088
IS THERE A VALID BSA RANGE?
1298
NO
YES
IS THERE A WEIGHT ENTERED?
1328
NO
YES
1330
1332
USE THE ENTERED WEIGHT
USE THE WEIGHT RANGE
BACK-CALCULATE THE BSA CALCULATION EQUATION TO GET THE HEIGHT RANGE
1334
1A
2A

FIG. 29A

FIG. 29B


1A
2A
IS THERE A VALID HEIGHT RANGE?
1336
NO
YES
CALCULATE BSA USING LOWER ADJUSTED HEIGHT
1338
1342
IS BSA OK?
1340
NO
CEIL THE LOWER ADJUSTED HEIGHT TO THE NEXT HIGHER VALUE
YES
CALCULATE BSA USING UPPER ADJUSTED HEIGHT
1344
1348
IS BSA OK?
1346
NO
TRUNCATE THE UPPER ADJUSTED HEIGHT TO THE NEXT LOWER VALUE
YES
RETURN /STORE RANGE OF VALUES
1350
RETURN /STORE THAT THERE IS NO VALID RANGE OF VALUES
1352
H

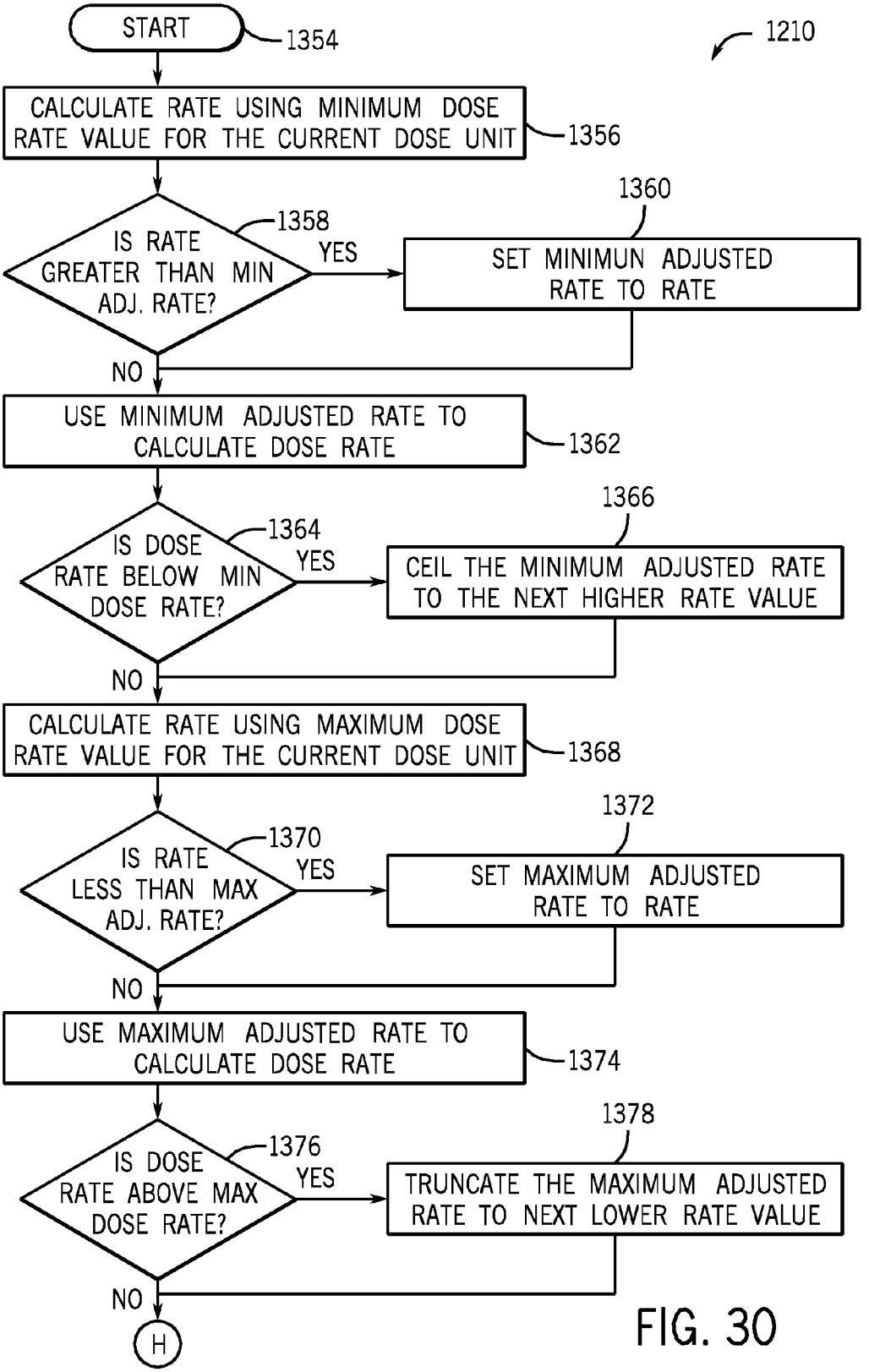

START
1354
1210
CALCULATE RATE USING MINIMUM DOSE RATE VALUE FOR THE CURRENT DOSE UNIT
1356
IS RATE GREATER THAN MIN ADJ. RATE?
1358
YES
1360
SET MINIMUN ADJUSTED RATE TO RATE
NO
USE MINIMUM ADJUSTED RATE TO CALCULATE DOSE RATE
1362
IS DOSE RATE BELOW MIN DOSE RATE?
1364
YES
1366
CEIL THE MINIMUM ADJUSTED RATE TO THE NEXT HIGHER RATE VALUE
NO
CALCULATE RATE USING MAXIMUM DOSE RATE VALUE FOR THE CURRENT DOSE UNIT
1368
IS RATE LESS THAN MAX ADJ. RATE?
1370
YES
1372
SET MAXIMUM ADJUSTED RATE TO RATE
NO
USE MAXIMUM ADJUSTED RATE TO CALCULATE DOSE RATE
1374
IS DOSE RATE ABOVE MAX DOSE RATE?
1376
YES
1378
TRUNCATE THE MAXIMUM ADJUSTED RATE TO NEXT LOWER RATE VALUE
NO
H

FIG. 30

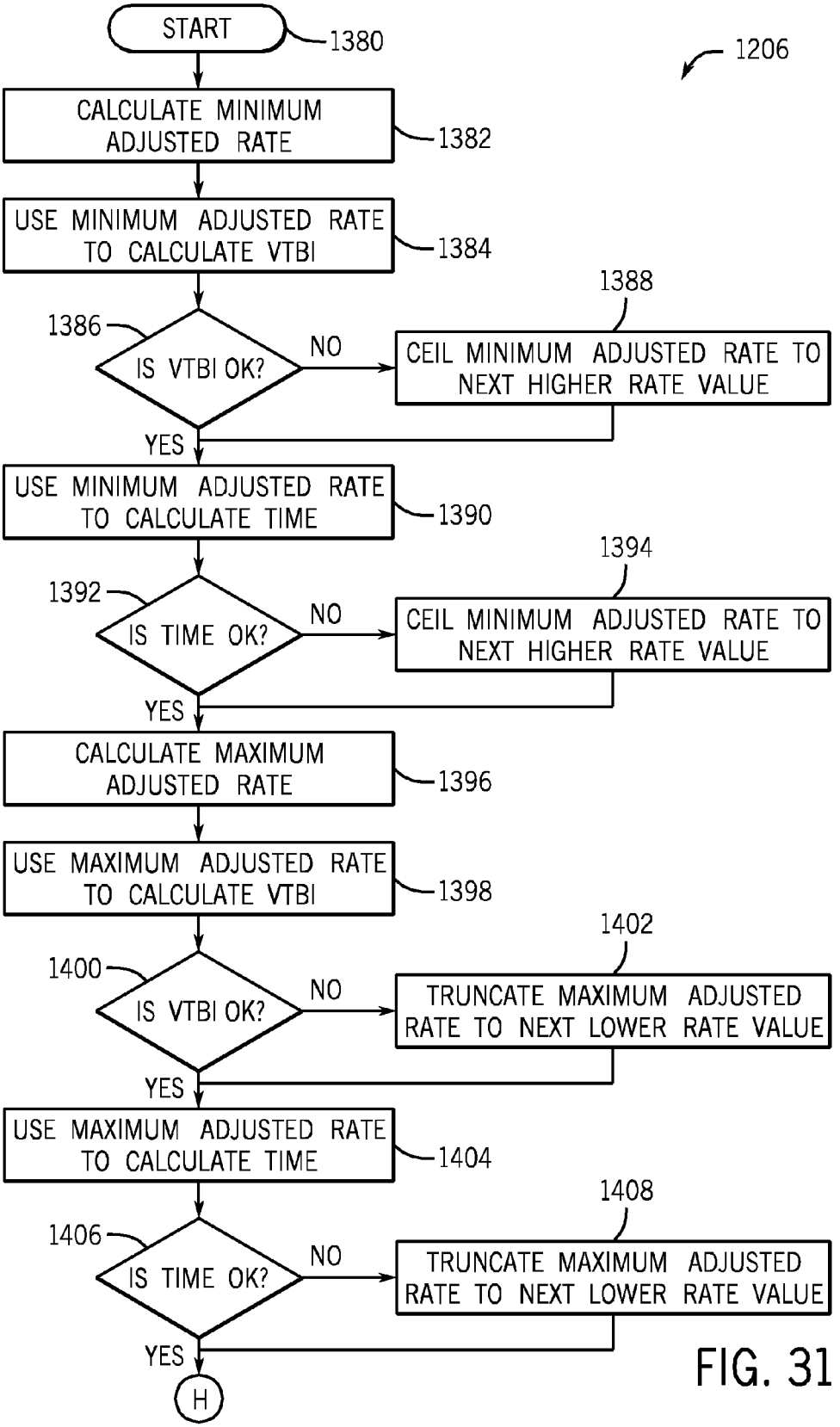

START
1380
1206
CALCULATE MINIMUM ADJUSTED RATE
1382
USE MINIMUM ADJUSTED RATE TO CALCULATE VTBI
1384
1386
IS VTBI OK?
NO
1388
CEIL MINIMUM ADJUSTED RATE TO NEXT HIGHER RATE VALUE
YES
USE MINIMUM ADJUSTED RATE TO CALCULATE TIME
1390
1392
IS TIME OK?
NO
1394
CEIL MINIMUM ADJUSTED RATE TO NEXT HIGHER RATE VALUE
YES
CALCULATE MAXIMUM ADJUSTED RATE
1396
USE MAXIMUM ADJUSTED RATE TO CALCULATE VTBI
1398
1400
IS VTBI OK?
NO
1402
TRUNCATE MAXIMUM ADJUSTED RATE TO NEXT LOWER RATE VALUE
YES
USE MAXIMUM ADJUSTED RATE TO CALCULATE TIME
1404
1406
IS TIME OK?
NO
1408
TRUNCATE MAXIMUM ADJUSTED RATE TO NEXT LOWER RATE VALUE
YES
H

FIG. 31

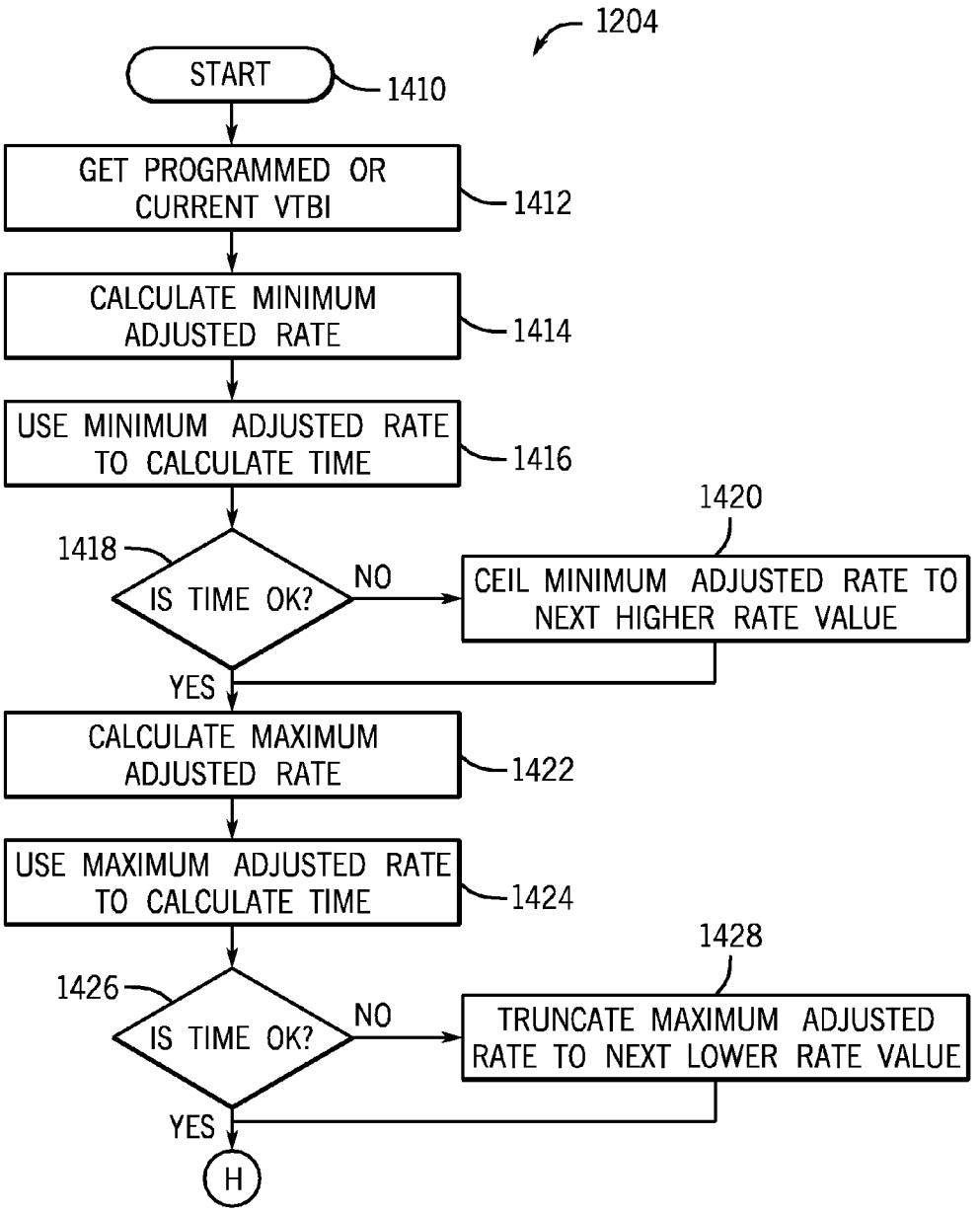

1204
START
1410
GET PROGRAMMED OR CURRENT VTBI
1412
CALCULATE MINIMUM ADJUSTED RATE
1414
USE MINIMUM ADJUSTED RATE TO CALCULATE TIME
1416
1418
IS TIME OK?
NO
1420
CEIL MINIMUM ADJUSTED RATE TO NEXT HIGHER RATE VALUE
YES
CALCULATE MAXIMUM ADJUSTED RATE
1422
USE MAXIMUM ADJUSTED RATE TO CALCULATE TIME
1424
1426
IS TIME OK?
NO
1428
TRUNCATE MAXIMUM ADJUSTED RATE TO NEXT LOWER RATE VALUE
YES
H

FIG. 32

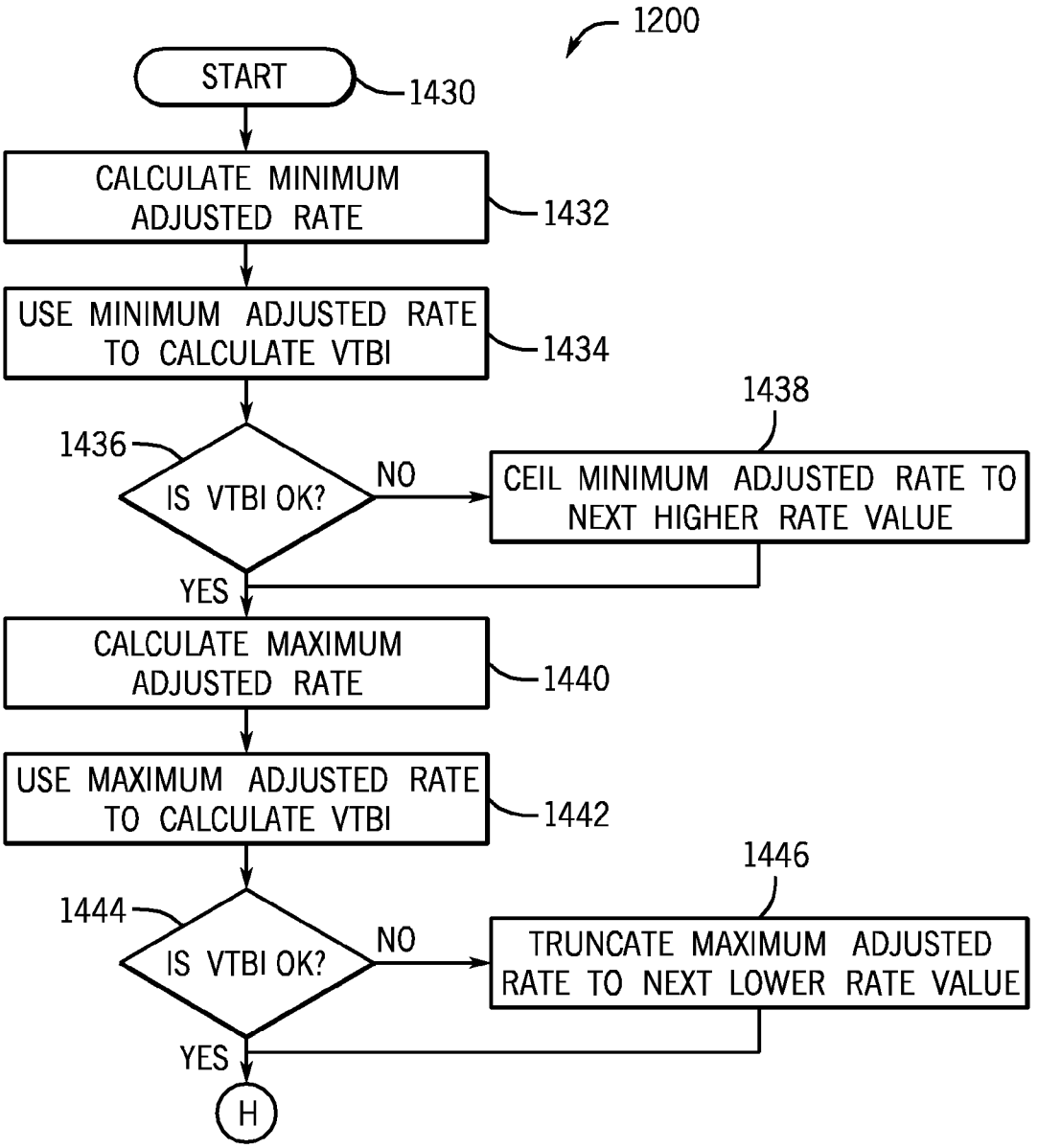

1200
START
1430
CALCULATE MINIMUM ADJUSTED RATE
1432
USE MINIMUM ADJUSTED RATE TO CALCULATE VTBI
1434
1438
1436
IS VTBI OK?
NO
CEIL MINIMUM ADJUSTED RATE TO NEXT HIGHER RATE VALUE
YES
CALCULATE MAXIMUM ADJUSTED RATE
1440
USE MAXIMUM ADJUSTED RATE TO CALCULATE VTBI
1442
1446
1444
IS VTBI OK?
NO
TRUNCATE MAXIMUM ADJUSTED RATE TO NEXT LOWER RATE VALUE
YES
H

FIG. 33A

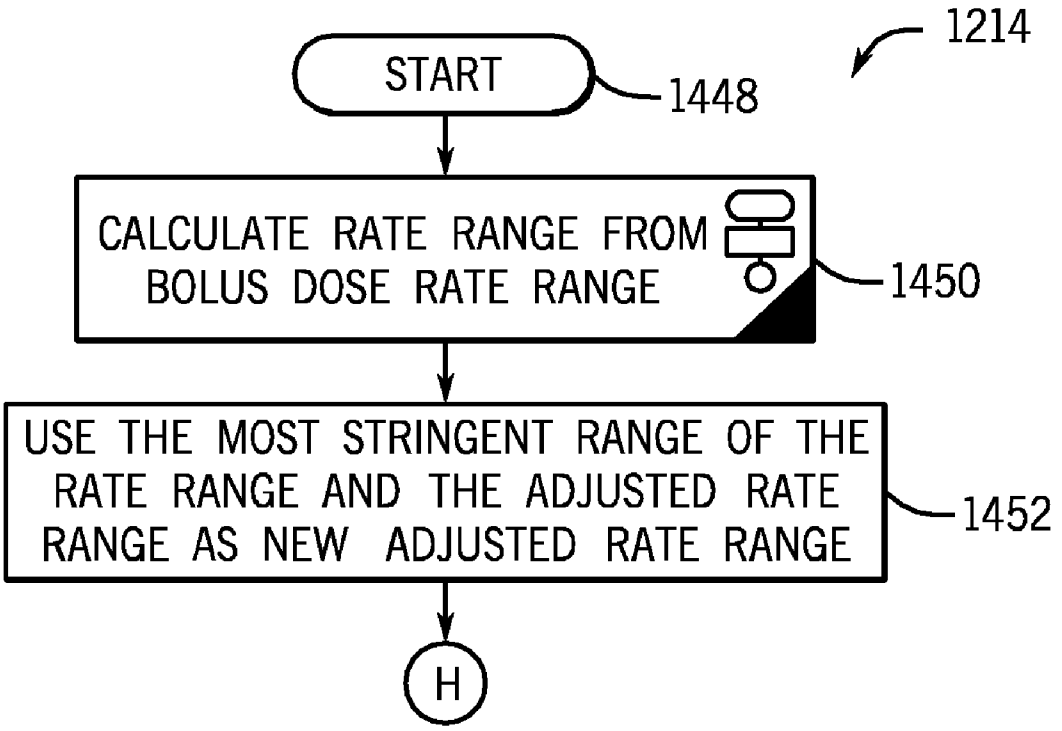

1214
START
1448
CALCULATE RATE RANGE FROM BOLUS DOSE RATE RANGE
1450
USE THE MOST STRINGENT RANGE OF THE RATE RANGE AND THE ADJUSTED RATE RANGE AS NEW ADJUSTED RATE RANGE
1452
H

FIG. 33B

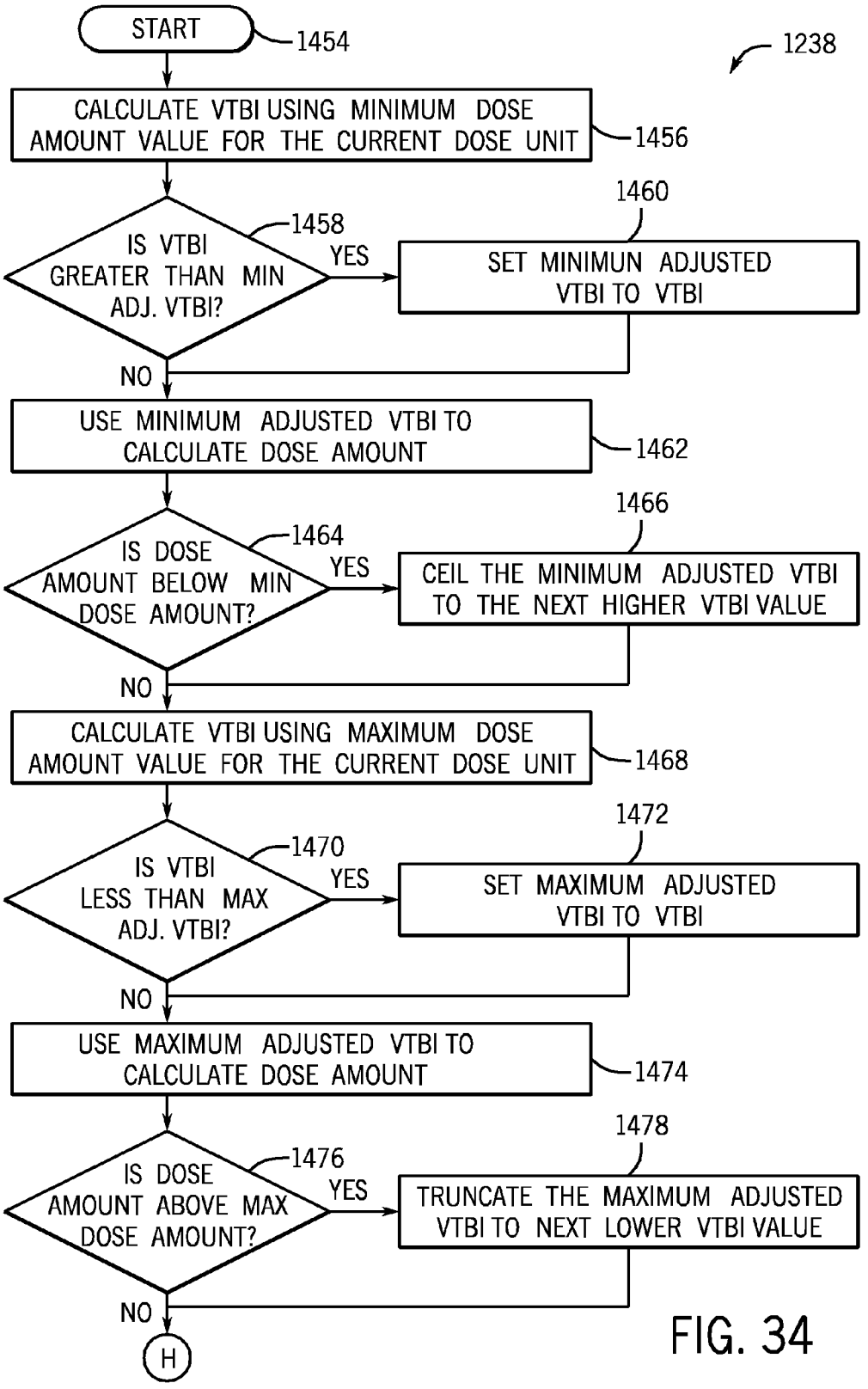

START
1454
1238
CALCULATE VTBI USING MINIMUM DOSE AMOUNT VALUE FOR THE CURRENT DOSE UNIT
1456
1460
1458
IS VTBI GREATER THAN MIN ADJ. VTBI?
YES
SET MINIMUN ADJUSTED VTBI TO VTBI
NO
USE MINIMUM ADJUSTED VTBI TO CALCULATE DOSE AMOUNT
1462
1466
1464
IS DOSE AMOUNT BELOW MIN DOSE AMOUNT?
YES
CEIL THE MINIMUM ADJUSTED VTBI TO THE NEXT HIGHER VTBI VALUE
NO
CALCULATE VTBI USING MAXIMUM DOSE AMOUNT VALUE FOR THE CURRENT DOSE UNIT
1468
1472
1470
IS VTBI LESS THAN MAX ADJ. VTBI?
YES
SET MAXIMUM ADJUSTED VTBI TO VTBI
NO
USE MAXIMUM ADJUSTED VTBI TO CALCULATE DOSE AMOUNT
1474
1478
1476
IS DOSE AMOUNT ABOVE MAX DOSE AMOUNT?
YES
TRUNCATE THE MAXIMUM ADJUSTED VTBI TO NEXT LOWER VTBI VALUE
NO
H

FIG. 34

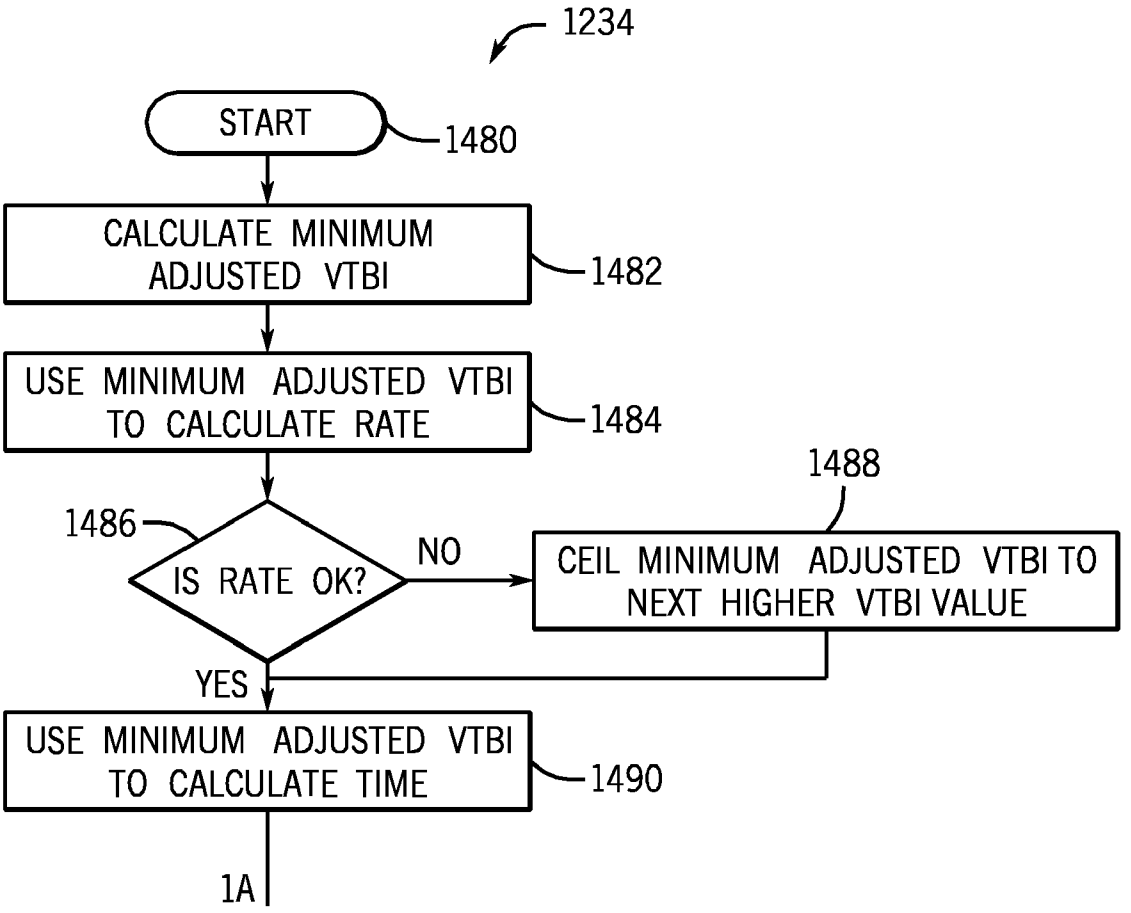

1234
START
1480
CALCULATE MINIMUM ADJUSTED VTBI
1482
USE MINIMUM ADJUSTED VTBI TO CALCULATE RATE
1484
1488
1486
IS RATE OK?
NO
CEIL MINIMUM ADJUSTED VTBI TO NEXT HIGHER VTBI VALUE
YES
USE MINIMUM ADJUSTED VTBI TO CALCULATE TIME
1490
1A

FIG. 35A

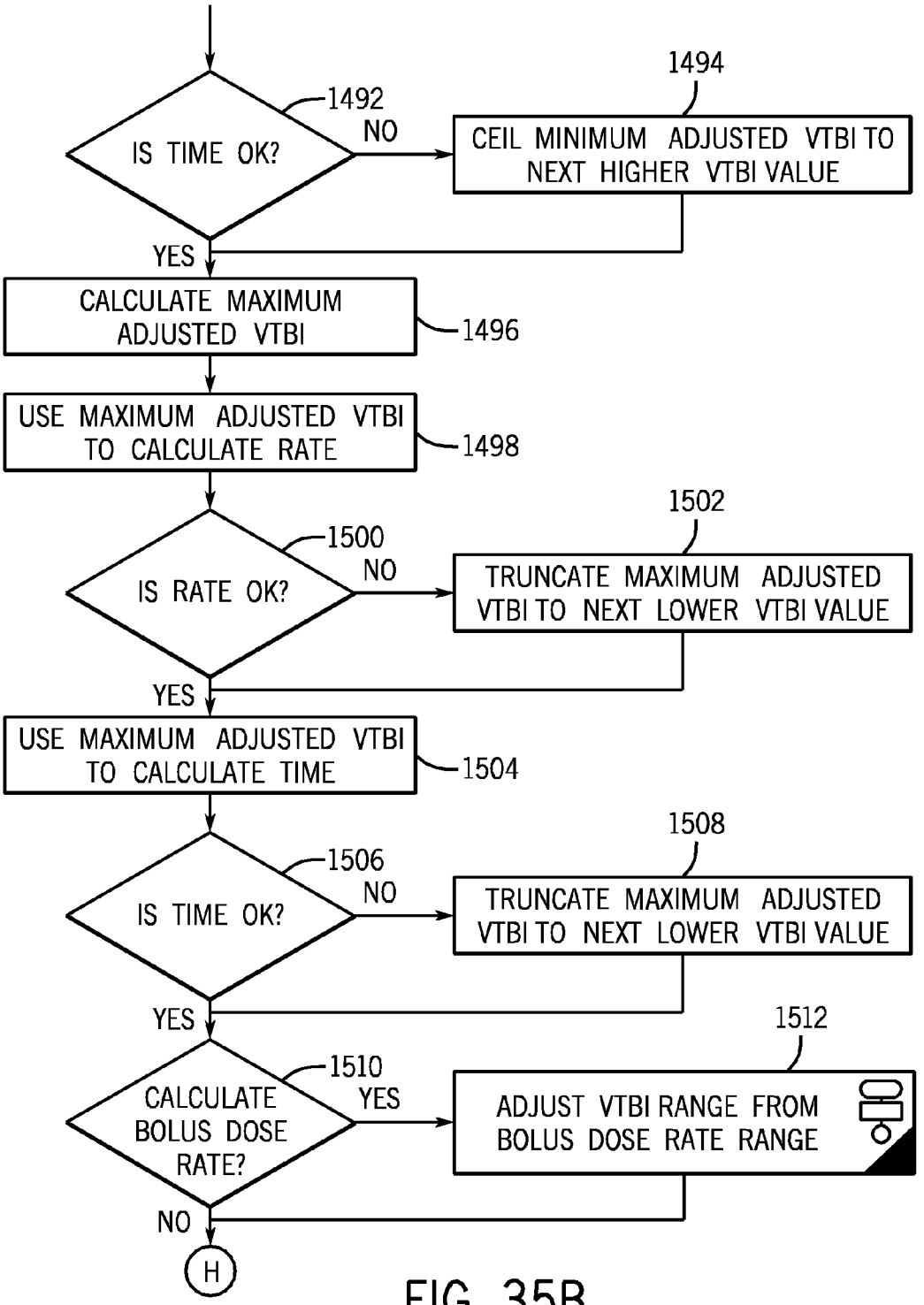

IS TIME OK?
1492
NO
1494
CEIL MINIMUM ADJUSTED VTBI TO NEXT HIGHER VTBI VALUE
YES
CALCULATE MAXIMUM ADJUSTED VTBI
1496
USE MAXIMUM ADJUSTED VTBI TO CALCULATE RATE
1498
IS RATE OK?
1500
NO
1502
TRUNCATE MAXIMUM ADJUSTED VTBI TO NEXT LOWER VTBI VALUE
YES
USE MAXIMUM ADJUSTED VTBI TO CALCULATE TIME
1504
IS TIME OK?
1506
NO
1508
TRUNCATE MAXIMUM ADJUSTED VTBI TO NEXT LOWER VTBI VALUE
YES
CALCULATE BOLUS DOSE RATE?
1510
YES
1512
ADJUST VTBI RANGE FROM BOLUS DOSE RATE RANGE
NO
H

FIG. 35B

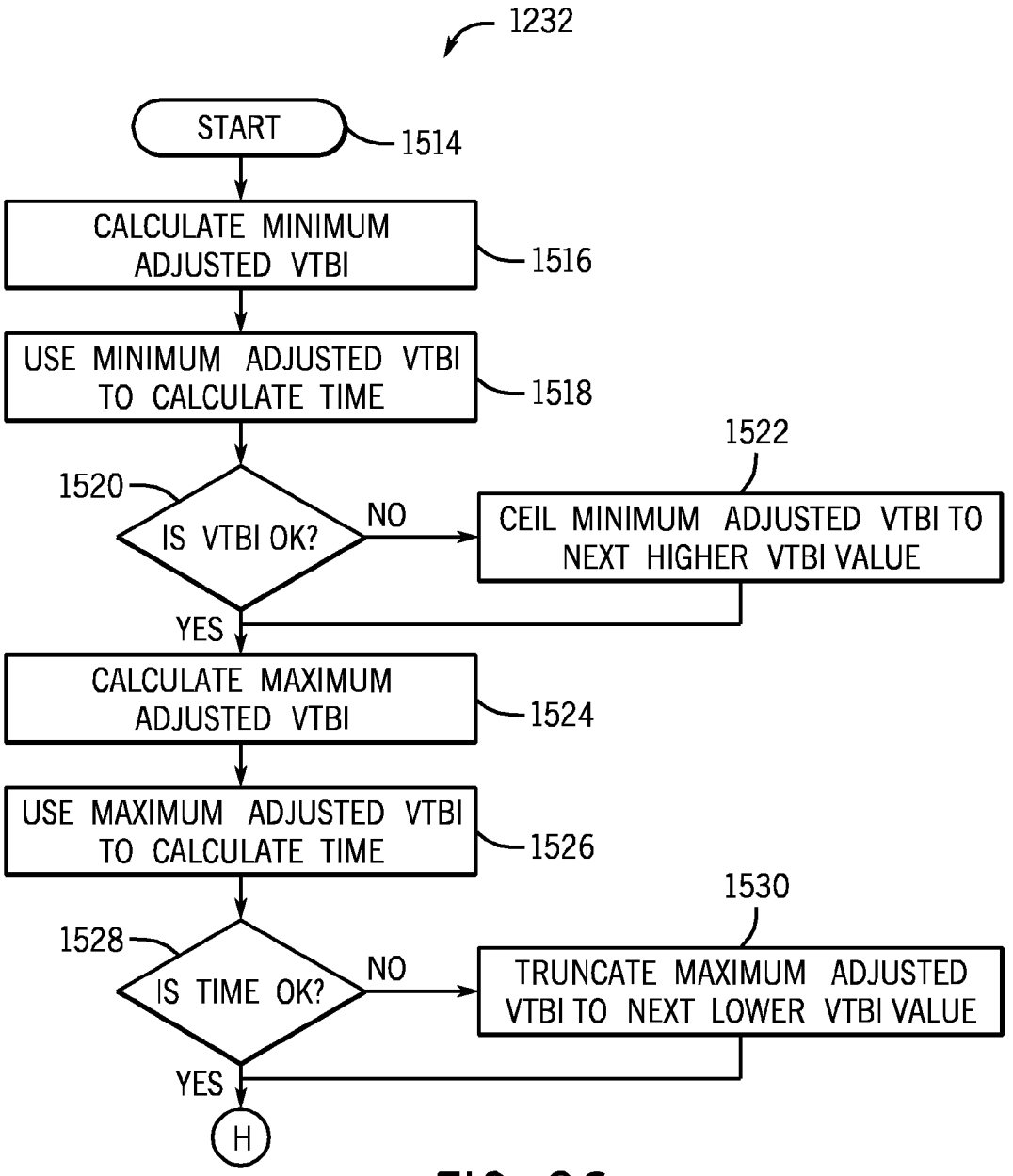

1232
START
1514
CALCULATE MINIMUM ADJUSTED VTBI
1516
USE MINIMUM ADJUSTED VTBI TO CALCULATE TIME
1518
1520
IS VTBI OK?
NO
1522
CEIL MINIMUM ADJUSTED VTBI TO NEXT HIGHER VTBI VALUE
YES
CALCULATE MAXIMUM ADJUSTED VTBI
1524
USE MAXIMUM ADJUSTED VTBI TO CALCULATE TIME
1526
1528
IS TIME OK?
NO
1530
TRUNCATE MAXIMUM ADJUSTED VTBI TO NEXT LOWER VTBI VALUE
YES
H

FIG. 36

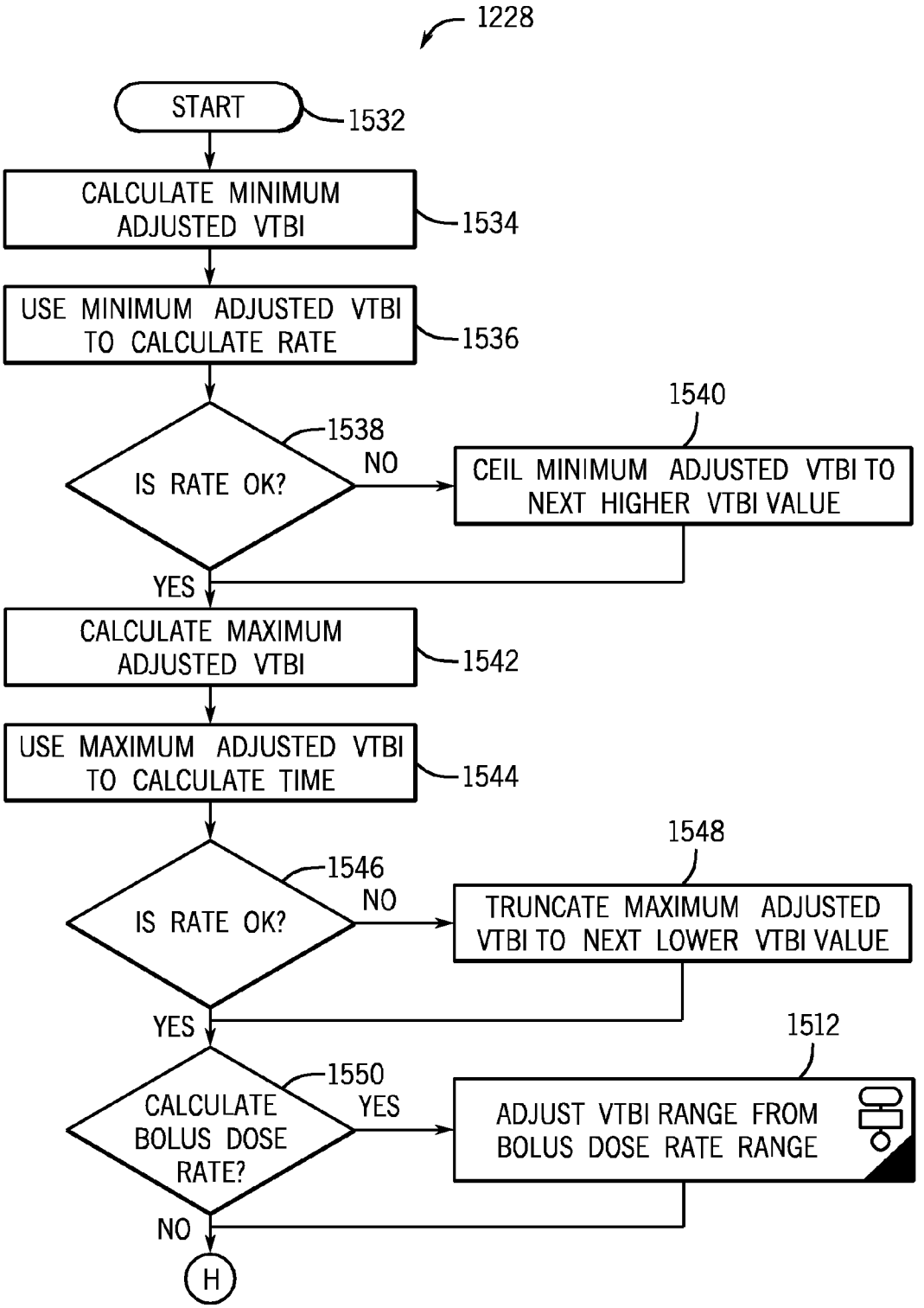

1228
START
1532
CALCULATE MINIMUM ADJUSTED VTBI
1534
USE MINIMUM ADJUSTED VTBI TO CALCULATE RATE
1536
1538
IS RATE OK?
NO
1540
CEIL MINIMUM ADJUSTED VTBI TO NEXT HIGHER VTBI VALUE
YES
CALCULATE MAXIMUM ADJUSTED VTBI
1542
USE MAXIMUM ADJUSTED VTBI TO CALCULATE TIME
1544
1546
IS RATE OK?
NO
1548
TRUNCATE MAXIMUM ADJUSTED VTBI TO NEXT LOWER VTBI VALUE
YES
1550
CALCULATE BOLUS DOSE RATE?
YES
1512
ADJUST VTBI RANGE FROM BOLUS DOSE RATE RANGE
NO
H

FIG. 37

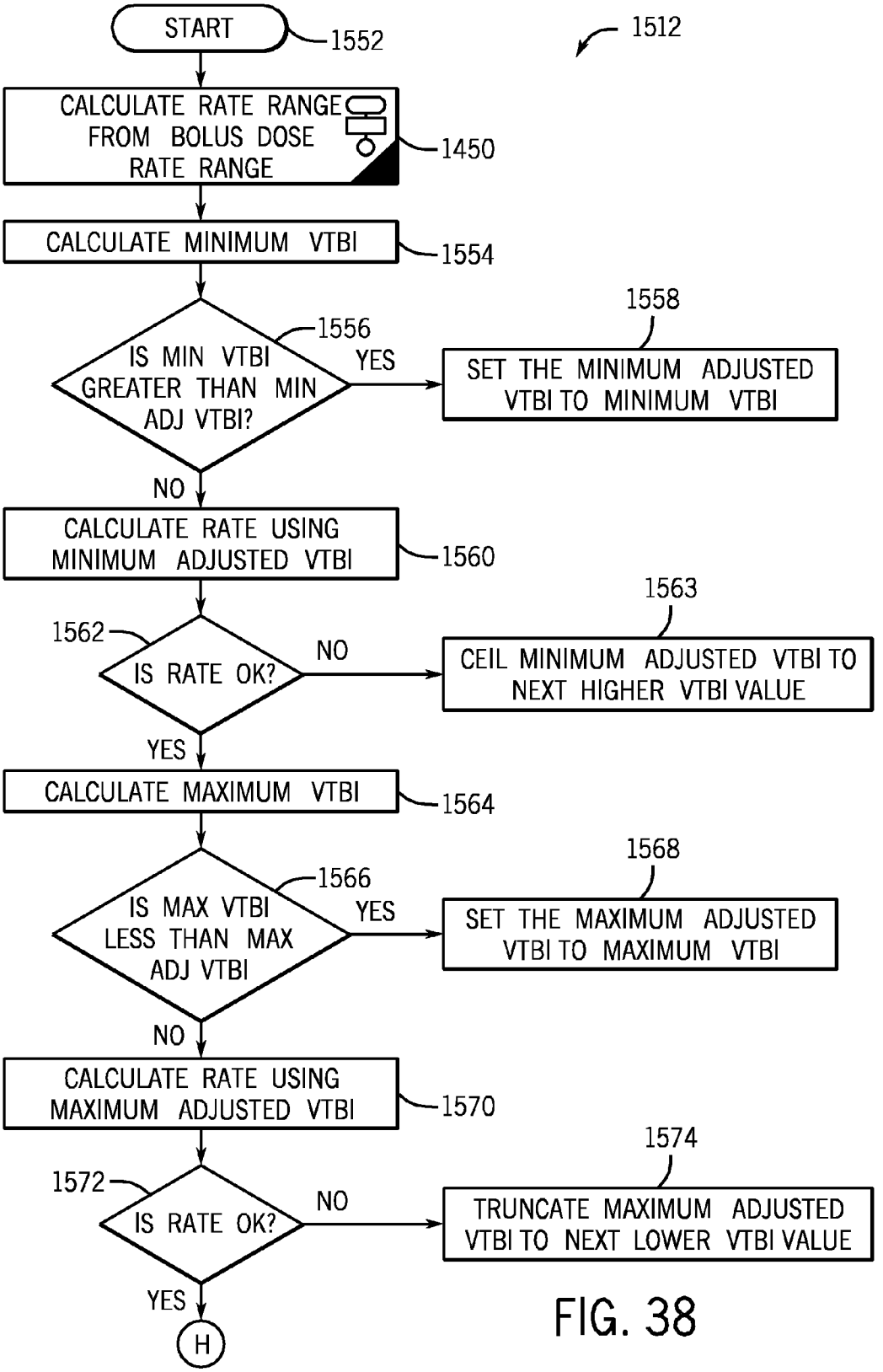

START
1552
1512
CALCULATE RATE RANGE FROM BOLUS DOSE RATE RANGE
1450
CALCULATE MINIMUM VTBI
1554
1556
IS MIN VTBI GREATER THAN MIN ADJ VTBI?
YES
1558
SET THE MINIMUM ADJUSTED VTBI TO MINIMUM VTBI
NO
CALCULATE RATE USING MINIMUM ADJUSTED VTBI
1560
1562
IS RATE OK?
NO
1563
CEIL MINIMUM ADJUSTED VTBI TO NEXT HIGHER VTBI VALUE
YES
CALCULATE MAXIMUM VTBI
1564
1566
IS MAX VTBI LESS THAN MAX ADJ VTBI
YES
1568
SET THE MAXIMUM ADJUSTED VTBI TO MAXIMUM VTBI
NO
CALCULATE RATE USING MAXIMUM ADJUSTED VTBI
1570
1572
IS RATE OK?
NO
1574
TRUNCATE MAXIMUM ADJUSTED VTBI TO NEXT LOWER VTBI VALUE
YES
H

FIG. 38

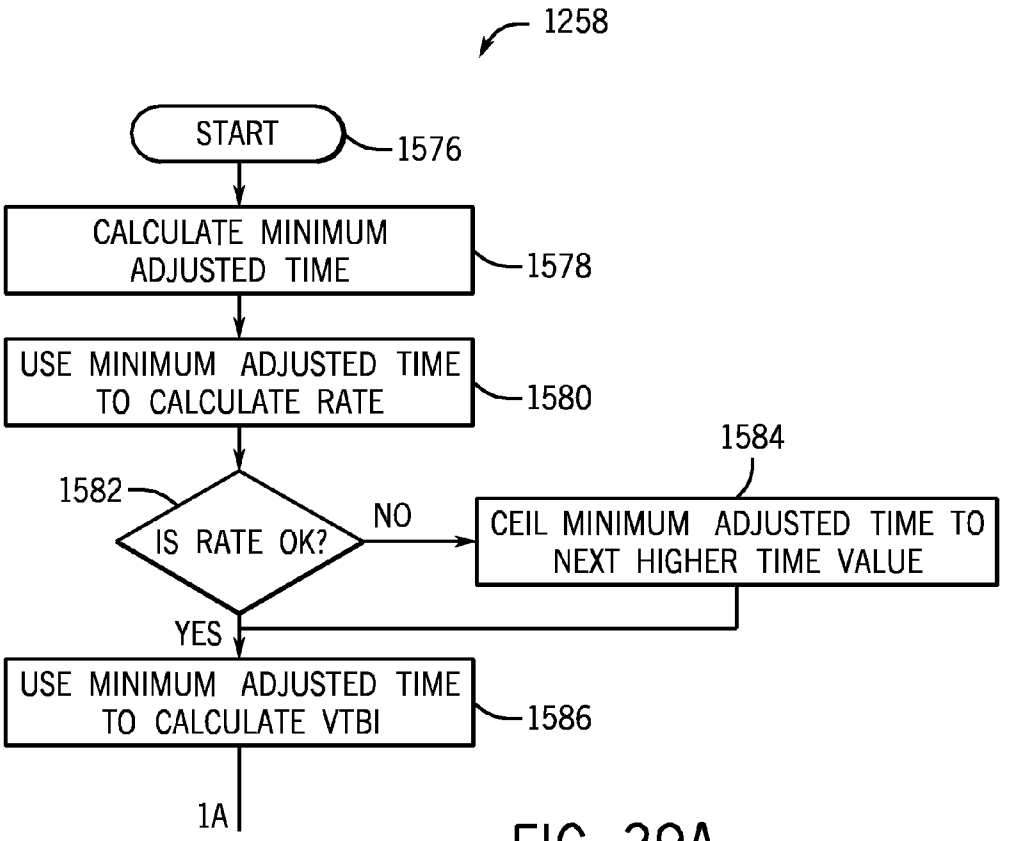

1258
START
1576
CALCULATE MINIMUM ADJUSTED TIME
1578
USE MINIMUM ADJUSTED TIME TO CALCULATE RATE
1580
1582
IS RATE OK?
NO
1584
CEIL MINIMUM ADJUSTED TIME TO NEXT HIGHER TIME VALUE
YES
USE MINIMUM ADJUSTED TIME TO CALCULATE VTBI
1586
1A

FIG. 39A

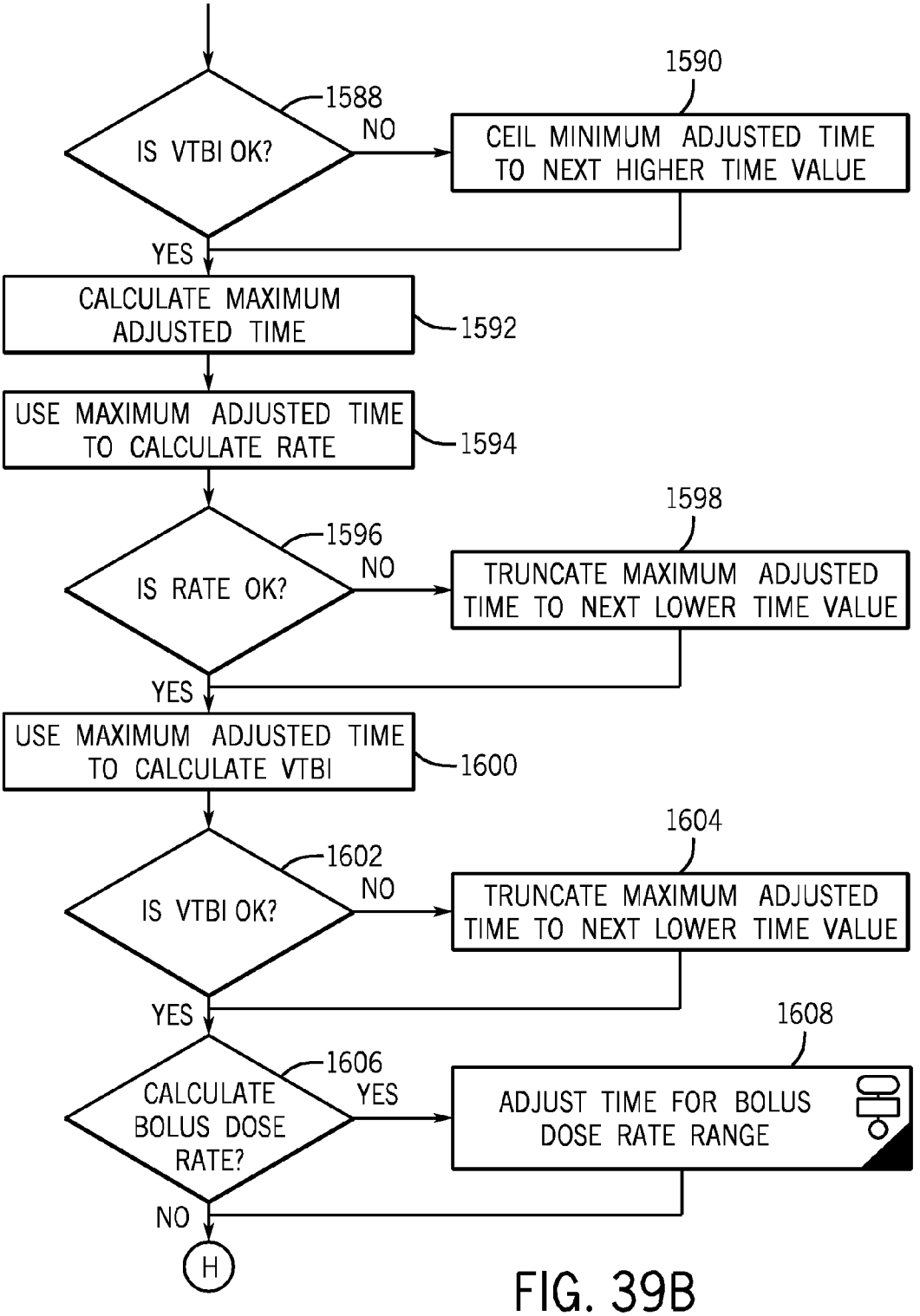

IS VTBI OK?
1588
NO
1590
CEIL MINIMUM ADJUSTED TIME TO NEXT HIGHER TIME VALUE
YES
CALCULATE MAXIMUM ADJUSTED TIME
1592
USE MAXIMUM ADJUSTED TIME TO CALCULATE RATE
1594
IS RATE OK?
1596
NO
1598
TRUNCATE MAXIMUM ADJUSTED TIME TO NEXT LOWER TIME VALUE
YES
USE MAXIMUM ADJUSTED TIME TO CALCULATE VTBI
1600
IS VTBI OK?
1602
NO
1604
TRUNCATE MAXIMUM ADJUSTED TIME TO NEXT LOWER TIME VALUE
YES
CALCULATE BOLUS DOSE RATE?
1606
YES
1608
ADJUST TIME FOR BOLUS DOSE RATE RANGE
NO
H

FIG. 39B

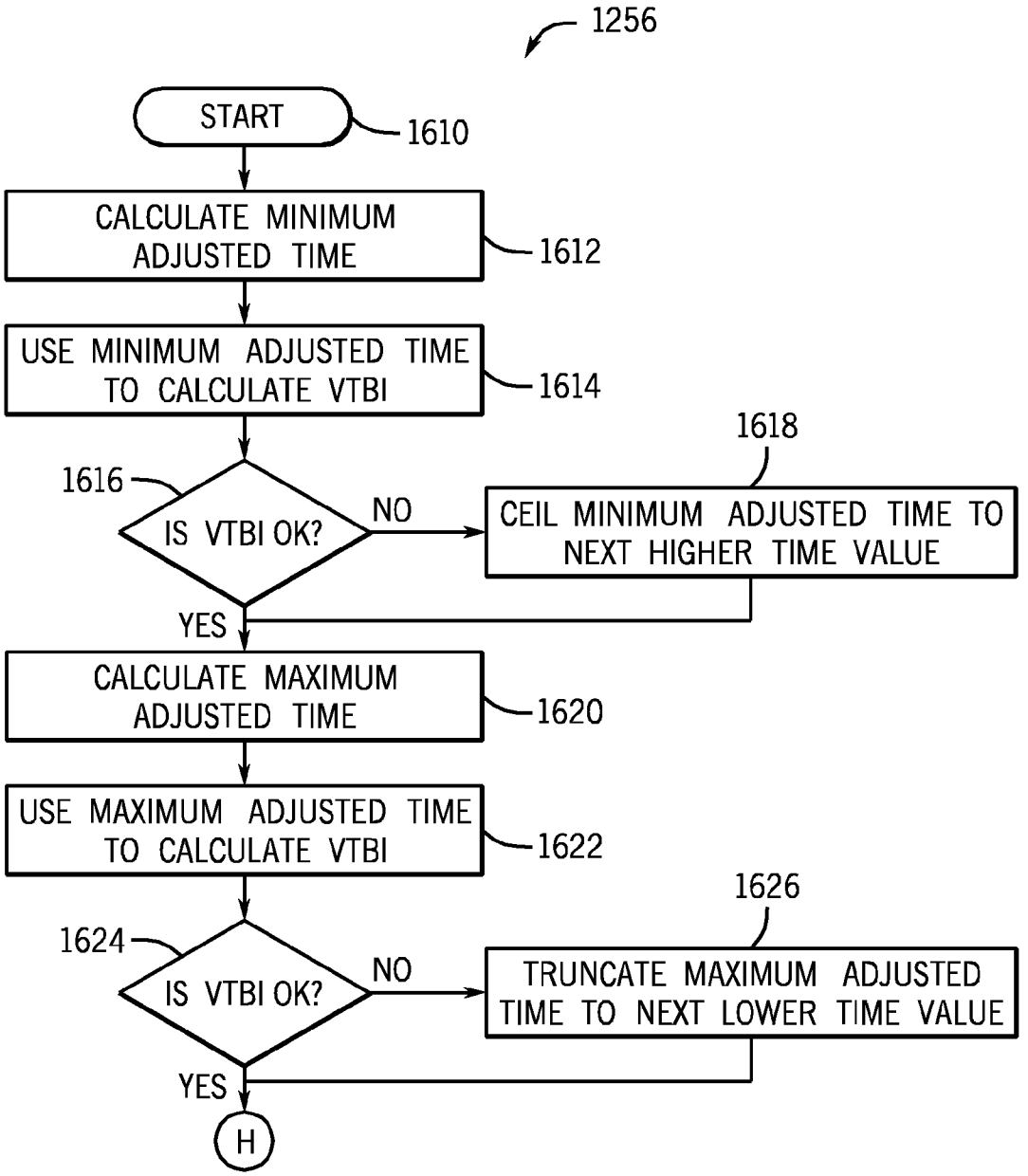

1256
START
1610
CALCULATE MINIMUM ADJUSTED TIME
1612
USE MINIMUM ADJUSTED TIME TO CALCULATE VTBI
1614
1618
1616
IS VTBI OK?
NO
CEIL MINIMUM ADJUSTED TIME TO NEXT HIGHER TIME VALUE
YES
CALCULATE MAXIMUM ADJUSTED TIME
1620
USE MAXIMUM ADJUSTED TIME TO CALCULATE VTBI
1622
1626
1624
IS VTBI OK?
NO
TRUNCATE MAXIMUM ADJUSTED TIME TO NEXT LOWER TIME VALUE
YES
H

FIG. 40

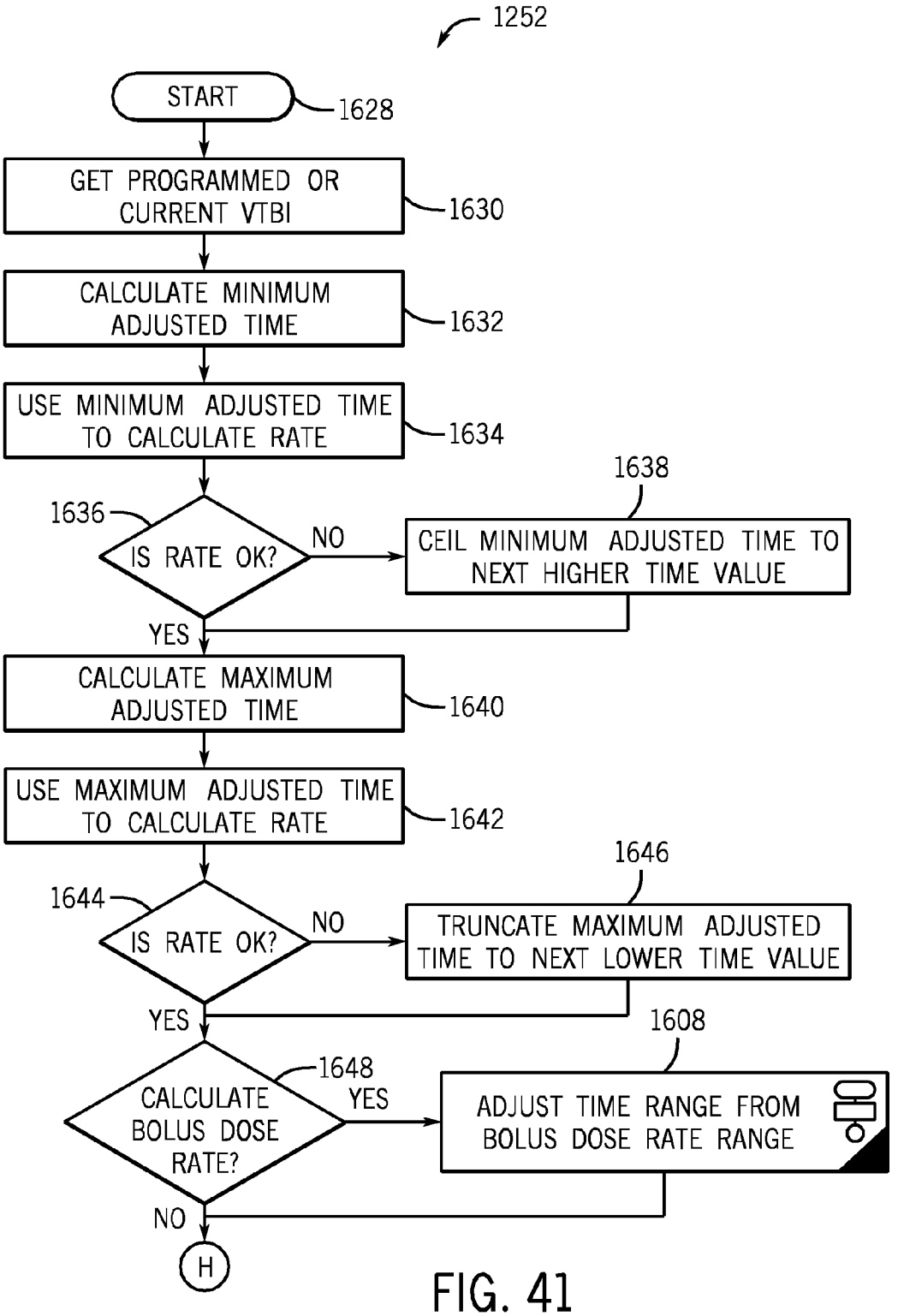

1252
START
1628
GET PROGRAMMED OR CURRENT VTBI
1630
CALCULATE MINIMUM ADJUSTED TIME
1632
USE MINIMUM ADJUSTED TIME TO CALCULATE RATE
1634
1636
IS RATE OK?
NO
1638
CEIL MINIMUM ADJUSTED TIME TO NEXT HIGHER TIME VALUE
YES
CALCULATE MAXIMUM ADJUSTED TIME
1640
USE MAXIMUM ADJUSTED TIME TO CALCULATE RATE
1642
1644
IS RATE OK?
NO
1646
TRUNCATE MAXIMUM ADJUSTED TIME TO NEXT LOWER TIME VALUE
YES
1608
1648
CALCULATE BOLUS DOSE RATE?
YES
ADJUST TIME RANGE FROM BOLUS DOSE RATE RANGE
NO
H

FIG. 41

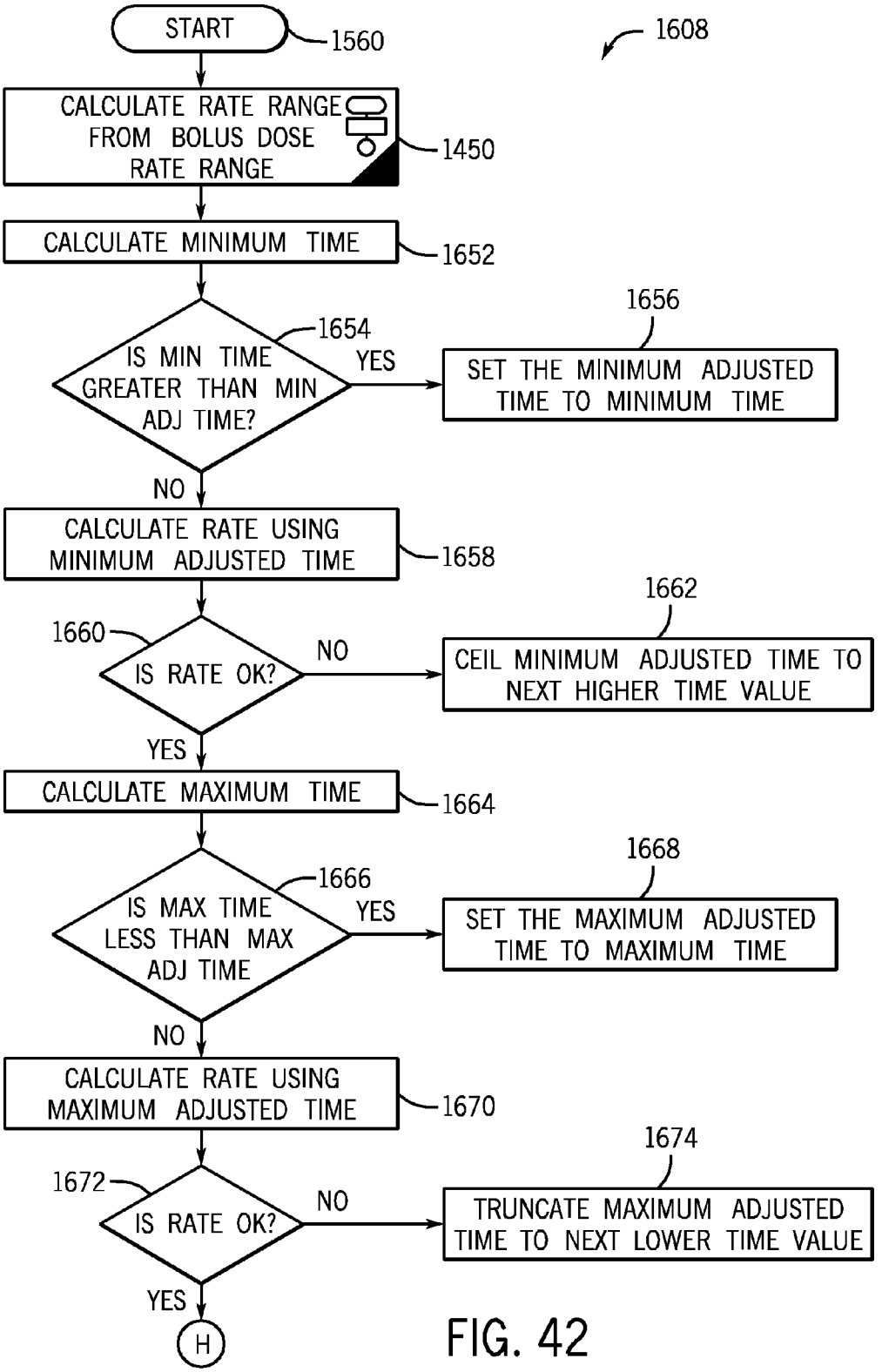

START
1560
1608
CALCULATE RATE RANGE FROM BOLUS DOSE RATE RANGE
1450
CALCULATE MINIMUM TIME
1652
1656
1654
IS MIN TIME GREATER THAN MIN ADJ TIME?
YES
SET THE MINIMUM ADJUSTED TIME TO MINIMUM TIME
NO
CALCULATE RATE USING MINIMUM ADJUSTED TIME
1658
1662
1660
IS RATE OK?
NO
CEIL MINIMUM ADJUSTED TIME TO NEXT HIGHER TIME VALUE
YES
CALCULATE MAXIMUM TIME
1664
1668
1666
IS MAX TIME LESS THAN MAX ADJ TIME
YES
SET THE MAXIMUM ADJUSTED TIME TO MAXIMUM TIME
NO
CALCULATE RATE USING MAXIMUM ADJUSTED TIME
1670
1674
1672
IS RATE OK?
NO
TRUNCATE MAXIMUM ADJUSTED TIME TO NEXT LOWER TIME VALUE
YES
H

FIG. 42

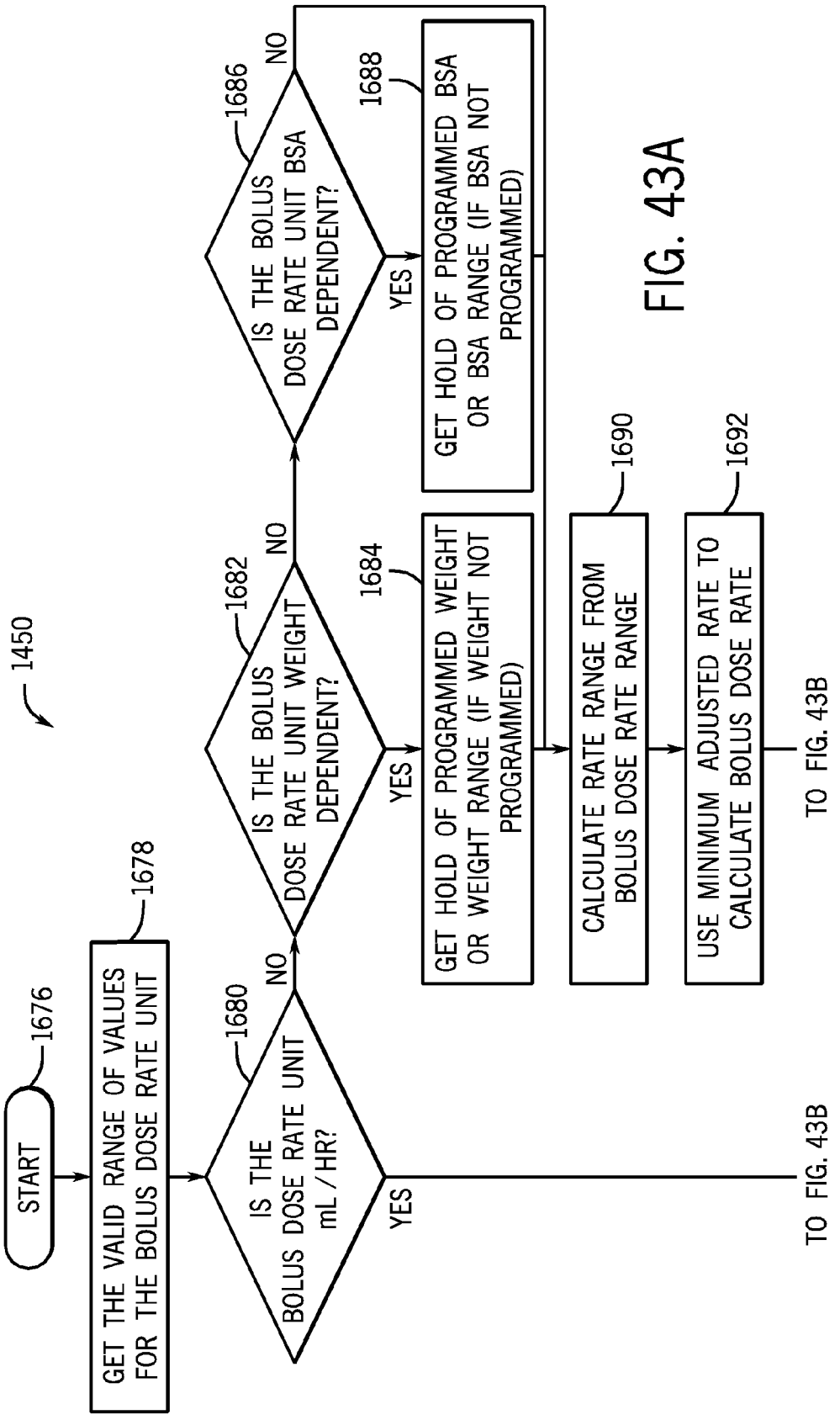

1450
START
1676
GET THE VALID RANGE OF VALUES FOR THE BOLUS DOSE RATE UNIT
1678
IS THE BOLUS DOSE RATE UNIT mL/HR?
1680
NO
YES
IS THE BOLUS DOSE RATE UNIT WEIGHT DEPENDENT?
1682
NO
YES
GET HOLD OF PROGRAMMED WEIGHT OR WEIGHT RANGE (IF WEIGHT NOT PROGRAMMED)
1684
IS THE BOLUS DOSE RATE UNIT BSA DEPENDENT?
1686
NO
YES
GET HOLD OF PROGRAMMED BSA OR BSA RANGE (IF BSA NOT PROGRAMMED)
1688
CALCULATE RATE RANGE FROM BOLUS DOSE RATE RANGE
1690
USE MINIMUM ADJUSTED RATE TO CALCULATE BOLUS DOSE RATE
1692
TO FIG. 43B
TO FIG. 43B

FIG. 43A

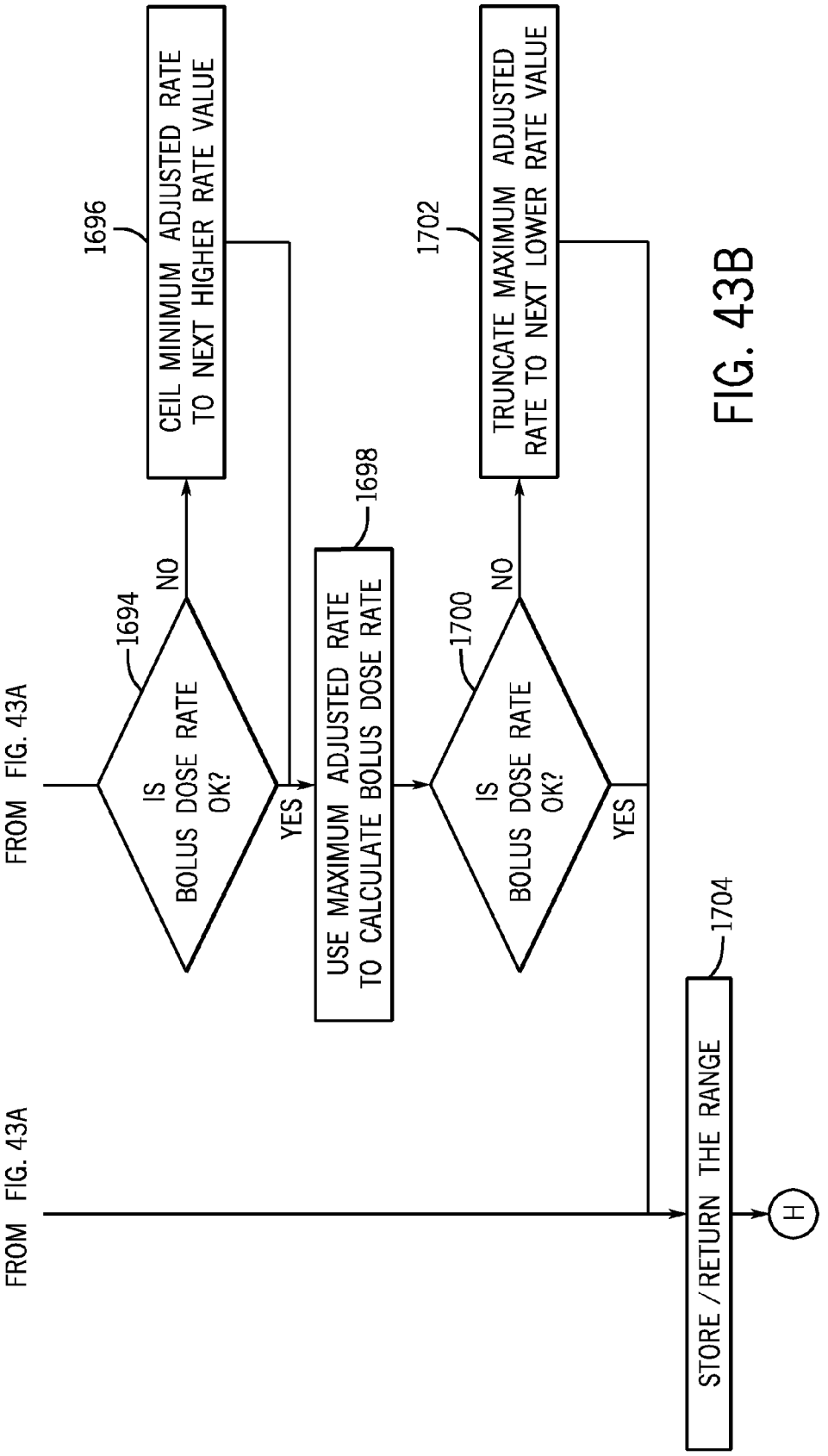

FROM FIG. 43A
IS BOLUS DOSE RATE OK?
1694
NO
CEIL MINIMUM ADJUSTED RATE TO NEXT HIGHER RATE VALUE
1696
YES
USE MAXIMUM ADJUSTED RATE TO CALCULATE BOLUS DOSE RATE
1698
IS BOLUS DOSE RATE OK?
1700
NO
TRUNCATE MAXIMUM ADJUSTED RATE TO NEXT LOWER RATE VALUE
1702
YES
FROM FIG. 43A
STORE / RETURN THE RANGE
1704
H

FIG. 43B

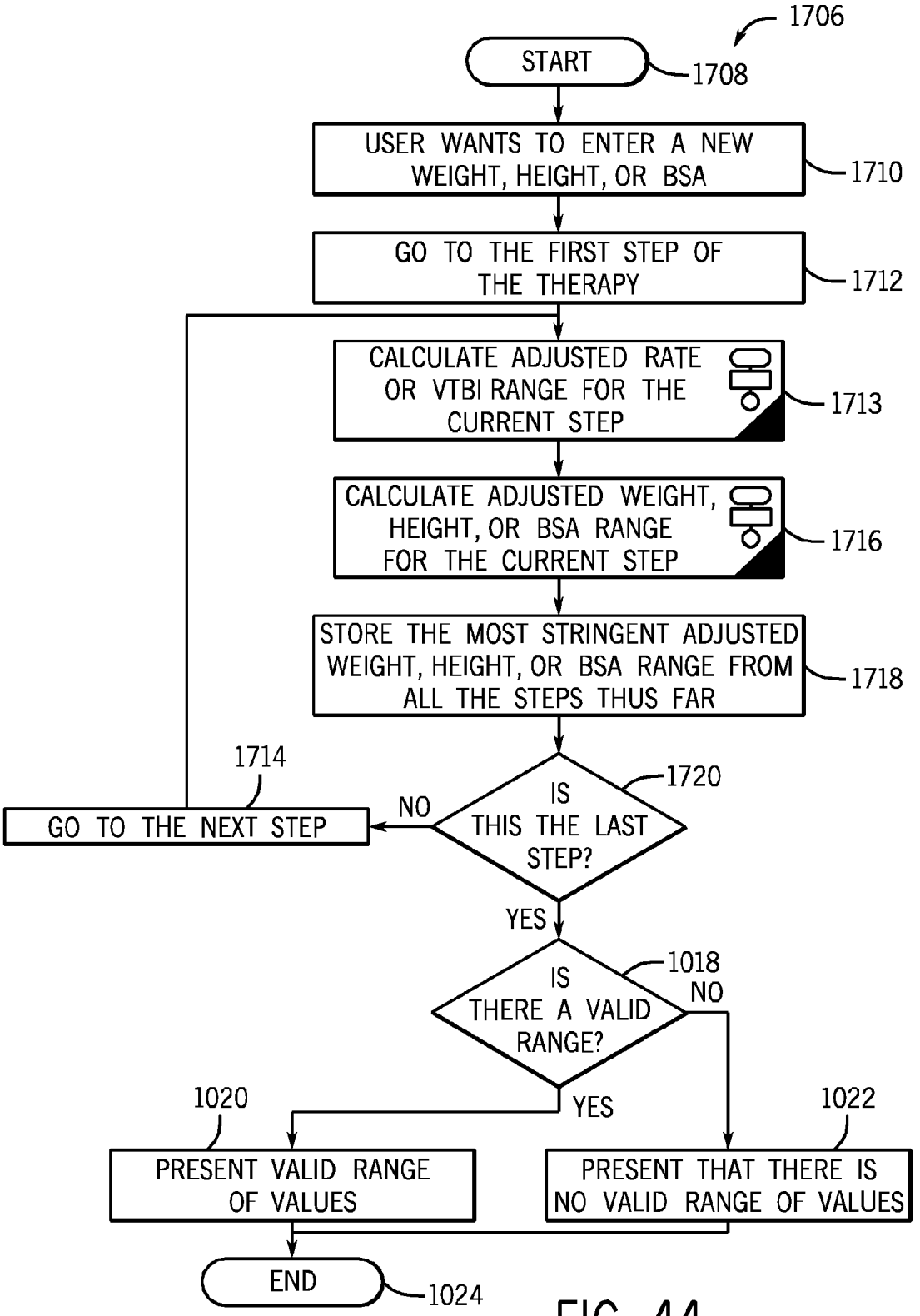

1706
START
1708
USER WANTS TO ENTER A NEW WEIGHT, HEIGHT, OR BSA
1710
GO TO THE FIRST STEP OF THE THERAPY
1712
CALCULATE ADJUSTED RATE OR VTBI RANGE FOR THE CURRENT STEP
1713
CALCULATE ADJUSTED WEIGHT, HEIGHT, OR BSA RANGE FOR THE CURRENT STEP
1716
STORE THE MOST STRINGENT ADJUSTED WEIGHT, HEIGHT, OR BSA RANGE FROM ALL THE STEPS THUS FAR
1718
1714
GO TO THE NEXT STEP
NO
IS THIS THE LAST STEP?
1720
YES
IS THERE A VALID RANGE?
1018
NO
YES
1020
PRESENT VALID RANGE OF VALUES
1022
PRESENT THAT THERE IS NO VALID RANGE OF VALUES
END
1024

FIG. 44

SYSTEM FOR GUIDING A USER DURING PROGRAMMING OF A MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Ser. No. 11/103,235, filed Apr. 11, 2005, the entire disclosure of which is hereby expressly incorporated by reference herein.

BACKGROUND OF THE INVENTION

This invention relates to systems that are used to dispense medication. More specifically, this invention relates to a system for guiding a user during the programming of a medical device, such as a pump or a processor in communication with a pump, wherein the system notifies the user in advance of whether a valid input range exists for a particular selected parameter that is about to be entered by the user and advises the user of the permissible values or valid range of values for the parameter selected.

Many medical devices such as infusion pumps that supply medication to a patient need to have a physician, pharmacist, nurse, the patient or the like manually or electronically enter information regarding the patient, the prescription or medication order, or pump operating parameters into a device. It is important for the safety of the patient that the information is entered accurately and that programming errors are avoided. At the same time, it is important that the information be entered as quickly as possible so that delivery of the medication can begin, especially in emergency situations. Caregivers are often a scarce resource in the healthcare field. Thus, there is a compelling need to save the time of the user or caregiver when programming programmable medical devices such as medical pumps.

Conventional medical pumps have been provided with factory established limits in memory for certain pump operating parameters, for example the maximum and minimum volumetric delivery rates permissible.

More recently, as electronically erasable programmable read only memories (EEPROM) and flash memories have become more common, it has also become possible for a hospital or similar institution to establish or predefine on a remote computer a customized "drug library" comprising limits for various pump operating parameters and settings or patient characteristics based upon device type, drug and concentration or clinical care area, and then download the customized drug library to a medical pump. The drug library limits are useful in preventing parameter entry errors. However, the user enters a parameter and is subsequently advised via an error message or alarm if the entered value is outside the permissible range or limits.

Another problem that exists is that the parameters to be entered are often interrelated with other parameters. For example, volumetric rate multiplied by volume to be infused (VTBI) determines the duration or time the pump must run.

Alternatively the processor takes predetermined information to calculate dosage amounts, dosage rates and the like. A problem exists in that these processors having the predefined ranges will have a predefined range for both the data point entered and the final result or rate that is calculated using that data point. As a result, when an individual enters incorrect information into a device and an error message is communicated to the data entry person, that person does not know whether the data that was entered was entered incorrectly or if a calculated parameter falls outside a predefined range.

Additionally, a problem in the art occurs in that the predefined ranges do not take into account differences between patients and differences in the other medical parameters associated with the providing of the dosage of medicine. For example, an individual of greater size and weight may be able to receive and need to receive a greater dosage of medicine than a person of lesser height and weight wherein predefined limit ranges do not account for these variations.

Thus, a principal object of the present invention is to provide a system for guiding a user in the programming of a medical device.

Another object of the present invention is to provide a medication delivery system that ensures accuracy of entered data and yet allows the user to program the medical device with speed and flexibility.

Another object of the present invention is to provide a system in which the user of a medical device is advised in advance of entering a selected parameter about the existence of a valid input range for the selected parameter.

Another object of the present invention is to provide a system in which the user of a medical device is advised in advance of entering a selected parameter about the limits of a valid input range for the selected parameter, thus saving the user time and reducing user frustration involved with post-entry notification of invalid entries.

Another object of the present invention is to provide a system in which the limits of the valid input range for a parameter are rounded, truncated or ceiled.

Yet another object of the present invention is to provide a system that displays information that allows a user to pinpoint where errors within the device and computations occur.

Another object of the present invention is to provide a system that displays information that accounts for multiple variable medical parameters to provide an improved system.

These and other features, improvements and advantages will become apparent from the specification, drawings and claims.

BRIEF SUMMARY OF THE INVENTION

The present invention relates to medical pump systems and methods that provide advance guidance to a user regarding existence and limits of a valid input range for a pump programming parameter. The system includes an input device for entering a value of a pump programming parameter; a memory for storing constraints related to the pump programming parameter; and a processor in communication with the memory and the input device, the processor being operable to utilize the constraints to determine and generate a signal indicating whether a valid input range exists for a to-be-entered value of the pump programming parameter.

The medical pump system can further include an output device in communication with the processor to receive the signal indicating whether a valid input range exists for a to-be-entered value of the programmable variable and generate a notification to a user of the medical pump system. The notification can indicate that a valid range is absent, a valid range is present, and if a valid range is present can disclose its upper and lower limits to the user. In one embodiment, the output device is a display screen and the message is generated on the display screen.

The processor dynamically back calculates and generates a signal indicative of a valid range for a to-be-entered pump programming parameter based upon constraints such one or more predetermined equations relating the to-be-entered pump programming parameter to other pump programming

parameters that may or may not have been entered already, medical device capabilities, and patient medical information.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic diagram of a medical device according to the present invention;

FIG. **2** is a screen shot of a medical device according to the present invention;

FIG. **3** is a screen shot of a medical device according to the present invention;

FIG. **4** is a screen shot of a medical device according to the present invention;

FIG. **5** is a screen shot of a medical device according to the present invention;

FIG. **6** is a screen shot of a medical device according to the present invention;

FIG. **7** is a screen shot of a medical device according to the present invention;

FIG. **8** is a screen shot of a medical device according to the present invention;

FIG. **9** is a screen shot of a medical device according to the present invention;

FIG. **10** is a flowchart of a process that calculates and displays the adjusted valid range for dose rate before a dose rate is entered;

FIG. **11** is a flowchart of a process that calculates and displays the adjusted valid range for dose amount before a dose amount is entered;

FIG. **12** is a flowchart of a process that calculates and displays the adjusted valid range for weight before a weight is entered when weight is part of a dose rate;

FIG. **13** is a flowchart of a process that calculates and displays the adjusted valid range for weight before a weight is entered when weight is part of a dose amount;

FIG. **14** is a flowchart of a process that calculates and displays the adjusted valid range for height before a height is entered when height is part of a dose rate;

FIG. **15** is a flowchart of a process that calculates and displays the adjusted valid range for height before a height is entered when height is part of a dose amount;

FIG. **16** is a flowchart of a process that calculates and displays the adjusted valid range for BSA before a BSA is entered when BSA is part of a dose rate;

FIG. **17** is a flowchart of a process that calculates and displays the adjusted valid range for BSA before a BSA is entered when BSA is part of a dose amount;

FIG. **18**A is a flowchart of a process that calculates and displays the adjusted valid range for rate;

FIG. **18**B is a flowchart of a process that calculates and displays the adjusted valid range for VTBI;

FIG. **19** is a flowchart of a process that calculates and displays the adjusted valid range for time;

FIG. **20** is a flowchart of a process that calculates the adjusted valid range for dose rate or dose amount;

FIG. **21** is a flowchart of a process that calculates the adjusted valid range for weight;

FIG. **22** is a flowchart of a process that calculates the adjusted valid range for height;

FIG. **23**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for BSA;

FIG. **23**B is a continuation of the flowchart of FIG. **23**A and shows the remaining portion of a process that calculates the adjusted valid range for BSA;

FIG. **24**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for rate;

FIG. **24**B is a continuation of the flowchart of FIG. **24**A and shows the remaining portion of a process that calculates the adjusted valid range for rate;

FIG. **25**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for VTBI;

FIG. **25**B is a continuation of the flowchart of FIG. **25**A and shows the remaining portion of a process that calculates the adjusted valid range for VTBI;

FIG. **26** is a flowchart of a process that calculates the adjusted valid range for time;

FIG. **27**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for weight when weight is part of a dose calculation;

FIG. **27**B is a continuation of the flowchart of FIG. **27**A and shows the remaining portion of a process that calculates the adjusted valid range for weight when weight is part of a dose calculation.

FIG. **28**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for weight when weight is part of a BSA calculation;

FIG. **28**B is a continuation of the flowchart of FIG. **28**A and shows the remaining portion of a process that calculates the adjusted valid range for weight when weight is part of a BSA calculation;

FIG. **29**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for height when height is part of a BSA calculation;

FIG. **29**B is a continuation of the flowchart of FIG. **29**A and shows the remaining portion of a process that calculates the adjusted valid range for height when height is part of a BSA calculation;

FIG. **30** is a flowchart of a process that calculates the adjusted valid range for rate from a dose rate range;

FIG. **31** is a flowchart of a process that calculates the adjusted valid range for rate without any existing VTBI or time;

FIG. **32** is a flowchart of a process that calculates the adjusted valid range for rate when an existing VTBI is present such that time is calculated once the new rate is entered;

FIG. **33**A is a flowchart of a process that calculates the adjusted valid range for rate when an existing time is present such that VTBI is calculated once the new rate is entered;

FIG. **33**B is a flowchart of a process that calculates the adjusted valid range for rate from a bolus dose rate range;

FIG. **34** is a flowchart of a process that calculates the adjusted valid range for VTBI from a dose amount range;

FIG. **35**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for VTBI without any existing rate or time;

FIG. **35**B is a continuation of the flowchart of FIG. **35**A and shows the remaining portion of a process that calculates the adjusted valid range for VTBI without any existing rate or time;

FIG. **36** is a flowchart of a process that calculates the adjusted valid range for VTBI with an existing rate such that time is calculated once the new VTBI is entered;

FIG. **37** is a flowchart of a process that calculates the adjusted valid range for VTBI with an existing time such that rate is calculated once the new VTBI is entered;

FIG. **38** is a flowchart of a process that calculates the adjusted valid range for VTBI from a bolus dose rate range;

FIG. **39**A is the initial portion of a flowchart of a process that calculates the adjusted valid range for time without having an existing rate of VTBI;

FIG. **39**B is a continuation of the flowchart of FIG. **39**A and shows the remaining portion of a process that calculates the adjusted valid range for time without having an existing rate of VTBI;

FIG. **40** is a flowchart of a process that calculates the adjusted valid range for time when having an existing rate wherein VTBI is calculated once the new time is entered;

FIG. **41** is a flowchart of a process that calculates the adjusted valid range for time when having an existing VTBI such that a rate is calculated once the new time is entered;

FIG. **42** is a flowchart of a process that calculates the adjusted valid range for time from a bolus dose rate range;

FIG. **43** is a flowchart of a process that calculates the adjusted valid range for rate from a bolus dose rate range; and

FIG. **44** is a flowchart of a process that calculates the adjusted valid range for a plurality of parameters when entering height, weight, or BSA as part of a multistep infusion therapy.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention will be described as it applies to its preferred embodiment. It is not intended that the present invention be limited to the preferred embodiment. It is intended that the invention cover all modifications and alternatives that may be included within the scope of the appended claims.

FIG. **1** is a schematic diagram of a system that has a medical device **10** therein. FIG. **1** illustrates several functional components of the medical device **10** for implementing the present invention. Those of ordinary skill in the art will appreciate that the device **10** includes many more components than those shown in FIG. **1**. However, it is not necessary that all these components be shown in order to disclose an illustrative embodiment for practicing the present invention.

In the context of the present invention, the term "medical device" includes without limitation a device that acts upon a cassette, reservoir, vial, syringe, or tubing to convey medication or fluid to or from a patient (for example, an enteral pump, a parenteral infusion pump, a patient controlled analgesia (PCA) or pain management medication pump, or a suction pump), a monitor for monitoring patient vital signs or other parameters, a diagnostic device, or the like.

For the purpose of exemplary illustration only, the medical device **10** is disclosed as an infusion pump. More particularly, the medical device **10** can be a single channel infusion pump, a multi-channel infusion pump, or some combination thereof.

The following definitions are not intended to be limiting, but are included below to aid one skilled in the art in understanding this disclosure.

"Patient medical information" as used herein means information about a patient, including but not limited to weight, height, body surface area (BSA), known drug allergies or tolerances or permissible levels, name, or patient ID. It will be appreciated by one skilled in the programmable medical pump art from the description herein that patient medical information can be input and stored at the pump using the input device, received by the pump from a computer or storage device connected wirelessly or by hard wire to the pump, or received as part of a drug library by the pump from a computer or storage device connected wirelessly or by hard wire to the pump.

"Medication information" as used herein means information about the medication to be administered to a patient, including but not limited to drug name, drug alias, drug ID, drug trademark, drug generic name, concentration, drug amount, drug units, container volume, or dosing units.

"Pump operating parameters" as used herein means input parameters or information that affects the behavior of a pump and delivery of medication by it, including but not limited to dose, dosage, dose rate, dose amount, rate, time, volume infused or volume to be infused (VTBI).

"Pump programming parameters" as used herein broadly includes parameters that are programmed into a pump by the user or otherwise and may include one or more of pump operating parameters, medication information, patient medical information or calculations based thereon or combinations thereof. Pump programming parameters may have hard and/or soft limits applied to them through a factory or hospital customizable drug library that is resident in the device or electronically downloadable thereinto.

"Medical device capabilities" as used herein means capabilities or limitations on a pump or infuser as determined by the manufacturer's recommendations, hardware, software, administration set, primary/secondary line considerations, or other constraints. In one example, the infuser may have a minimum and/or maximum rate at which it can deliver. In another example, primary and secondary lines may have predetermined interrelated maximums so as to avoid creating any vacuum or inadvertent flow problems. By way of example only, the primary line maximum rate could be 1000 ml/hr while the secondary line rate could be limited to a maximum of 500 ml/hr.

With reference to FIG. **1** the medical device **10** includes a processor **12** that performs various operations described in greater detail below. An input/output device **14** allows the user to receive output from the medical device **10** and/or enter information into the medical device **10**. Those of ordinary skill in the art will appreciate that input/output device **14** may be provided as single devices such as a separate input device **16** and an output device **18** that in one embodiment is a display device such as an output screen and in another embodiment is a voice command that states ranges or outputs. In another embodiment the input device **16** is a touch screen.

In an alternative embodiment the medical device is a medication management system (MMS) and the input/output device **14** is a drug library editor as described in U.S. Publication No. 2005/0144043 and that reference is incorporated in full in this application. In this embodiment input **16** communicates with a MMU (Medication Management Unit) to assist in processing drug orders for delivery through the MMU. The input device **16** can be any sort of data input means, including those adapted to read machine readable indicia such as barcode labels; for example a personal digital assistant (PDA) with a barcode scanner. Alternatively, the machine readable indicia may be in other known forms, such as radio frequency identification (RFID) tag, two-dimensional bar code, ID matrix, transmitted radio ID code, human biometric data such as fingerprints, etc. and the input device **16** adapted to "read" or recognize such indicia. The input device **16** can be a separate device from the medical device **10**; alternatively, the input device **16** communicates directly with the medical device **10** or may be integrated wholly or in part with the medical device.

A memory **24** communicates with the processor **12** and stores code and data necessary for the processor **12** to perform the functions of the medical device **10**. More specifically, the memory **24** stores multiple programs and processes formed in accordance with the present invention for various functions of the medical device **10**.

Referring to FIGS. **2-9** various screen shots of output device **18** are shown for presentation of data to a user that is

entering data into a medical device **10**. In one embodiment the output device **18** is an output screen and in another embodiment output device **18** is a touch screen display and input device. The output device **18** is in the context of an infusion pump; however, this is for exemplary purposes only. Other instruments may incorporate aspects of the invention and generate audio output or present a graphic display to communicate data.

As shown, the output device **18** provides several entry points wherein patient medical information or medication information **102** and pump programming parameters **100** may be entered. Specifically, patient medical information such as a patient's weight **104**, height **106** or BSA (body surface area) **108** may be entered. Additionally, pump operating parameters **102** such as dose **110**, rate **112**, VTBI (volume to be infused) **114**, time **116** and dose amount **118** may be entered using a numerical key pad **120** that allows input of numerals **124** on the key pad **120**. The key pad **120** additionally has a CANCEL button **126** if a user does not desire to enter information, a CLEAR button **128** to clear an input and an ENTER button **130** to enter an amount. Thus, a numerical value can be given using the key pad **120** to provide a numerical value for the height, weight or BSA of the patient or the dose rate, dose amount, rate, VTBI or time to be provided. Additionally, on the output device **18** is a text box **134** wherein a message **136** can be provided to the user regarding the data to be entered or the entered data provided. Specifically, the text box **134** can provide whether the entered pump programming parameters are proper. The text box **134** can also provide the user advance guidance on the valid range of values that can be entered, or whether a valid range exists.

The message **136** provided depends upon the data entered into the medical device **10**. For example, the message can indicate that an invalid program parameter combination is entered (FIG. **3**). This indicates to a user that for the parameters selected there is no valid range that can be calculated. Alternatively, if a valid range **138** exists (FIG. **4**) this valid range is displayed. Whereas if the data point entered is invalid the message **136** indicates an invalid value has been entered (FIG. **5**).

As shown in FIGS. **6-8** the output device **18** additionally indicates when parameters have been calculated, as indicated by reference numeral **140**. As also shown multiple parameters may be calculated and displayed as will be discussed. The output device also provides an option for multi step infusion processes **142** as provided in FIG. **9**. FIGS. **2-9** are examples of several different outputs an output device **18** may present to a user.

By back calculating equations used in the system the user can be presented with a valid range **138** of values that may be entered (FIG. **4**) or if there is no valid value to be entered (FIG. **3**). There are two different scenarios for these back calculations: (1) there are no other parameters entered; or (2) other parameters are already entered.

In the first scenario minimum and maximum ranges for all patient medical information and parameters are used to back calculate the range for each piece of patient medical information and/or parameters currently being adjusted (about to be entered). In the second scenario the entered values for the information and/or parameters that are not affected by modifying the current parameter, and the range of information and/or parameters which are affected by a modification to the current information and/or parameters are used to back calculate the range of the information and/or parameter currently being adjusted (about to be entered). Below is an illustration of these two scenarios using rate, VTBI, and time dependency:

Rate=*VTBI*/time

Each parameter (rate, VTBI, and time) has its own minimum and maximum value which may be configurable.

When no other parameters that have already been entered, if the user wants to enter a new rate **112**, the valid range for rate **112** would be calculated as follows:

Rate Min=*VTBI* Min/Time Max

Rate Max=*VTBI* Max/Time Min

When there are other parameters such as VTBI already entered, if the user wants to enter a new rate **112**, the time is recalculated such that the valid range for rate **112** would be calculated as follows:

Rate Min=*VTBI*/Time Max

Rate Max=*VTBI*/Time Min

The possible values to be entered are also dependent upon the precision in which the user enters values. Depending on the precision/exactness of the internal math being used, the valid range calculation should use either rounding (may be used on both the upper and lower valid range), truncating (may be used on the upper valid range), or ceiling (may be used on the lower valid range) of the adjusted valid range values when calculating the range to be used.

Once the adjusted valid range has been calculated, the first time using rounding, the just calculated minimum and maximum values are used in the original equation to calculate what should be calculated when modifying the current parameter. If the calculated value ends up outside its valid range values (which may be either the machine limitations or adjusted valid ranges themselves) truncation for the upper valid range or ceiling for the lower valid range may be used.

To illustrate this with an example, if the machine limitations for rate **112** are 10 ml/hr-500 ml/hr and the user is able to program rate values **112** in one decimal place precision (0.1 ml/hr increments) then if rate (MIN) is calculated to 15.015 the value could be ceiled to 15.1. Meanwhile, if rate (MAX) value was calculated to 85.4996 the rate MAX value should be truncated to 85.4. If the rate (MIN) value and the rate (MAX) values are allowed to be entered as the rounded values 15.0 and 85.5 the result would have been that the calculated time would have ended up outside the machine limitations.

Flow equations are being used in the system during programming, and the same method can be reapplied multiple times each modifying a weight which is part of a BSA (body surface area) calculation, which is part of a dose calculation, which ultimately recalculates time **116**. Once the valid ranges for each of the parameters are calculated, the ranges should be compared against the machine/configurable limitations for the current information and/or parameter. The most stringent range is what should be used.

FIGS. **10-44** are a plurality of flowcharts that show the system processes used in order for the processor **12** to calculate valid ranges, determine what those ranges are (if they exist), and whether entered information or parameters fall outside of said range. If no valid range exists or the entry is outside of the valid range an indication of that fact is generated to the user. If a valid range exists, the valid range can also be indicated to the user prior to entry of the parameter. In one embodiment, the indication to the user is a user message **136** that is displayed on the display **18**. Thus, each flowchart represents a different process that can be involved in performing these functions.

Specifically, FIG. **10** shows a process **1000** for calculating and displaying an adjusted valid range for the dose rate before a dose rate is entered. After starting at step **1010** the processor **12** detects that the user wants to enter a new dose rate as shown at step **1012** in which time the processor, based upon the parameters already entered into the processor, calculates an adjusted valid range for rate at step **1014**. A process that provides for this calculation is seen in FIGS. **24**A and **24**B and will be discussed.

Once an adjusted valid range for the rate is calculated at step **1014** the processor **12** then at step **1016** calculates the adjusted valid range for the dose rate or dose amount (see FIGS. **20**A, **20**B and **20**C for greater detail on step **1016**). Dose rate is a term in the infusion device art that refers to delivering an amount of medication over a given unit of time. For example, a dose rate can be expressed in units including but not limited to mcg/hr or units/kg/day. Dose amount is a term in the infusion device art that refers to delivering an amount of medication, without regard to time, usually in a bolus. For example, a dose amount can be expressed in units including but not limited to mcg or units/kg. At step **1018** a determination is made whether there is a valid range for a new dose rate or dose amount. If there is a valid range then at step **1020** this valid range of values is presented in the text box **134** on the output device **18** (FIG. **4**) to alert a user what values may be entered. If there is not a valid range of values available then at step **1022** the processor **12** displays in the text box **134** that there is no valid range of values that may be entered. Thus, the process is ended at step **1024**.

FIG. **11** shows a process **1026** for calculating and displaying the adjusted valid range for a dose amount before a dose amount is entered. At step **1028** the process is started wherein the user desires to enter a new dose amount at step **1030**. At this time, the processor **12** calculates an adjusted valid range for VTBI (volume to be infused) at step **1032** (FIGS. **25**A and **25**B). After calculating an adjusted valid range for the VTBI the processor **12** then calculates an adjusted valid range for dose amount at step **1016** (shown in greater detail in FIGS. **20**A, **20**B and **20**C). Then at step **1034** a determination is made whether there is a valid range. If there is a valid range at step **1034** the processor **12** presents the valid range of values in the text box **134** at step **1036** and if there is not a valid range of values the processor **12** displays as such in the text box **134** of output device **18** as indicated by step **1038**. At this point the process has ended at step **1040**.

FIG. **12** shows a process **1042** for calculating and displaying the adjusted valid range for a weight before a weight is entered when weight is part of a dose rate. Specifically, after the start step **1044** a user decides to enter a new weight at step **1046**. The processor **12** then calculates an adjusted valid range for rate at step **1014** (shown in FIGS. **24**A and **24**B). After doing so, the processor **12** calculates an adjusted valid range of weight at step **1048** (FIG. **21**). Then at step **1050** a determination is made whether a valid range exists and if a valid range exists, this range is displayed at **1050** whereas if a valid range does not exist this is displayed as indicated by step **1054**, either of which provides an end at step **1056**.

FIG. **13** shows a process **1058** for calculating and displaying the adjusted valid range for a weight before a weight is entered when weight is part of a dose amount. Starting at step **1060** a user wants to enter a new weight at step **1062** and the processor **12** calculates an adjusted valid range for VTBI to be entered at step **1032** (FIGS. **25**A and **25**B). Once an adjusted valid range is calculated for VTBI the processor **12** then calculates an adjusted valid range for weight to be entered at **1048** (FIG. **21**) such that a determination of a valid range can be made at step **1064**. If a valid range is present the processor **12** displays the values in the text box **134** on the output device **18** at step **1066** and if not, then the fact that no valid range is present is displayed at step **1068** and thus provides an end at step **1070**.

FIG. **14** shows a process **1072** for calculating and displaying the adjusted valid range for a height before a height **106** is entered when height is part of a BSA (body surface area) which is part of a dose rate. At the start at step **1074** a user wants to enter a new height **106** at step **1076**. This time the processor **12** calculates an adjusted valid range for rate **110** at step **1014** (FIGS. **24**A and **24**B). After calculating an adjusted valid range for rate **110** the processor **12** then calculates an adjusted valid range for height **106** at step **1078** (FIG. **22**) so that a determination may be made at step **1018**. If yes, step **1020** requires the processor **12** to display the valid range on the output device **18**. Whereas if the answer is no, at step **1022** the fact that there is no valid range of values is presented on the output device **18** bringing the process **1072** to an end at step **1024**.

FIG. **15** shows a process **1080** for calculating and displaying the adjusted valid range for height before a height **106** is entered when height is part of a BSA (body surface area) which is part of a dose amount. After starting at step **1010** the user wants to enter a new height at step **1082**. At this time the processor **12** calculates an adjusted valid range for VTBI (volume to be infused) at step **1032** (FIGS. **25**A and **25**B). After calculating an adjusted valid range for VTBI the processor **12** then calculates an adjusted valid range for height **106** at step **1078** (FIG. **22**). At that time the processor **12** then makes a determination at step **1018** whether or not there is a valid range present and if so, displays the valid range at step **1020**, and if not, displays that there is no valid range to provide at step **1022** and ends as in step **1024**.

FIG. **16** shows a process **1084** for calculating and displaying the adjusted valid range for BSA (body surface area) before a BSA is entered when BSA is part of a dose rate. Starting at step **1010** a user wants to enter a new BSA (body surface area) at step **1086** and as such the processor **12** calculates an adjusted valid range for rate at step **1014** (FIGS. **24**A and **24**B). At this time the processor **12** calculates an adjusted valid range for BSA (body surface area) at step **1088** (FIGS. **23**A and **23**B). At step **1018** a determination is made whether or not there is a valid range present. If a valid range is present the processor **12** displays the values in text box **134** on the output device **18** at step **1020** and if not, then the fact that no valid range is present is displayed at step **1022** and thus provides an end at step **1024**.

FIG. **17** shows a process **1090** for calculating the adjusted valid range for BSA (body surface area) before BSA is entered when BSA is part of a dose amount. Starting at step **1010** a user wants to enter a new BSA (body surface area) at step **1086**. The processor **12** calculates an adjusted valid range for VTBI (volume to be infused) at step **1032** (FIGS. **25**A and **25**B). At this time the processor **12** then calculates an adjusted valid range for BSA (body surface area) at step **1088** (FIGS. **23**A and **23**B). At step **1018** a determination is made whether or not there is a valid range present. If a valid range is present the processor **12** displays the valid range at step **1020** and if not, then fact that there is no valid range is displayed at step **1022** and thus provides an end at step **1024**.

FIG. **18**A shows a process **1092** for calculating and displaying the adjusted valid range for rate before entering a new rate. After starting at step **1010** a user wants to enter a new rate at step **1094** the processor **12** calculates an adjusted valid range for the rate at step **1014** (FIGS. **24**A and **24**B). At step **1018** a determination is made whether or not there is a valid range present. If a valid range is present the processor **12**

displays the valid range at step **1020** and if not, the fact that there is no valid range is displayed at step **1022** and thus provides an end at step **1024**.

FIG. **18**B shows a process **1096** for calculating and displaying the adjusted valid range for VTBI (volume to be infused) before a VTBI is entered. Starting at step **1010** the user desires to enter a new VTBI as shown at step **1098**. At that point in time, the processor **12** calculates an adjusted valid range for the VTBI at step **1032** (FIGS. **25**A and **25**B). A determination is then made at step **1018** whether or not there is a valid range present. If there is a valid range present the valid range is displayed by the processor **12** at step **1020** and if not, the fact that there is no valid range present is displayed at step **1022** and thus provides an end at step **1024**.

FIG. **19** shows a process **1100** for calculating and displaying the adjusted valid range for time **116** before time **116** is entered. Specifically, after starting at step **1010** a user wants to enter a new time **116** at step **1102** the processor **12** calculates an adjusted valid range of time **116** at step **1104** (FIG. **26**). Thus, the processor **12** determines whether a valid range is present as step **1018**. I a valid range is present the valid range is displayed at step **1020** and if not, the fact that there is no valid range is displayed by the processor **12** at step **1022** and thus provides and end at step **1024**.

FIG. **20** shows the process **1016** used to calculate the adjusted valid range for dose rate or dose amount **118**. Specifically, after a start at step **1010** a determination is made at step **1106** regarding whether the dose is weight or BSA (body surface area) based. If the dose is weight or BSA based then the processor **12** makes a determination whether the dose is weight based or BSA based at step **1108**.

If the dose is BSA based then a determination is made at step **1110** whether a BSA has been entered previously. If yes, the entered BSA will be used during later calculations as indicated at step **1112** and if not, a BSA range will be used during later calculations as indicated at step **1114**. If instead, the dose is weight based at step **1108** the processor **12** determines if there is a weight previously entered at step **1116** and if yes, this weight will be used during later calculations as indicated by step **1118** and if no, a weight range will be used during later calculations as indicated by step **1120**.

Once the processor **12** determines whether an entered weight, a weight range, an entered BSA, a BSA range or that the dose is neither weight nor BSA based, the processor **12** back calculates the dose calculation equation to get an adjusted valid dose range at step **1122**. After the processor **12** back calculates the dose calculation equation to get the adjusted dose range at step **1122** a determination is made at step **1124** whether there is a valid dose range. If there is a valid dose range at step **1124** then at step **1126** the processor **12** calculates, using rounding, either rate (dose rate therapies) or the VTBI (dose amount therapies) using the lower limit value of the adjusted valid range for dose.

At this time a determination is made at step **1128** regarding whether the calculated rate or VTBI is proper. If not, at step **1130** the lower adjusted value of the adjusted valid range for rate or VTBI is ceiled to the next higher value. At this point, or if the rate or VTBI at step at **1128** is proper, rate or VTBI is then calculated, using rounding, using the upper adjusted dose range value at **1132**.

A determination is then again made if the rate or VTBI is proper and if not, the upper adjusted valid range value of the dose is truncated to the next lower value at step **1136**.

After the processor **12** determines that the rate or VTBI is proper at step **1134** or after truncation of the adjusted range limit at step **1136** a new valid range for the dose rate or dose amount is presented, returned, and/or stored within the memory **24** at step **1138**. If, on the other hand, at step **1124** there is not a valid dose range then the processor **12** determines that there is no valid range of values and this information is presented, retuned, and/or stored within the memory **24** instead of the new valid range of values at step **1140**. After either step **1138** or **1140** the process **1016** is ended and the processor **12** continues execution of the process which called process **1016**.

FIG. **21** shows the process **1048** for calculating an adjusted valid range for weight **104**. Specifically, at the start **1142** a determination is made whether the dose rate or dose amount is weight or BSA based at step **1144**. If weight based the valid range for the weight **104** is adjusted for the dose calculation range at step **1146** (FIGS. **27**A and **27**B). If instead, the dose rate is BSA (body surface area) based, the processor adjusts the valid range for the weight for the BSA range as shown in step **1148** (FIGS. **28**A and **28**B). At this time, the processor **12** determines if there is a valid range for weight at step **1150**. If there is a valid range for weight that valid range is returned and/or stored in the memory **24** at step **1152**. Whereas if there is not a valid weight range, that information similarly is returned and/or stored in the memory at step **1154**. After either step **1152** or **1154** the process **1048** is ended and the processor **12** continues execution of the process which called process **1048**.

FIG. **22** shows a process **1078** for calculating an adjusted valid range of height **106**. After starting at step **1156** the processor **12** calculates an adjusted valid range for BSA (body surface area) as shown in step **1088** (FIGS. **23**A and **23**B). A determination is then made at **1158** whether there is a valid BSA range. If there is a valid BSA range then the valid range for height **106** is adjusted for the BSA range at step **1160** (FIGS. **29**A and **29**B). A determination is then made at step **1162** whether there is a valid range for height. If there is a valid range for height, this valid range of values is returned and/or stored in the memory **24** of the processor **12** as indicated at step **1164**. If, however, there is either not a valid BSA range in regards to step **1158** or there is not a valid range for height in regard to step **1162** then the processor returns and/or stores within the memory **24** the information that there is not a valid range of values for height at step **1166**. After either step **1164** or **1166** the process **1078** is ended and the processor **12** continues execution of the process which called process **1078**.

FIGS. **23**A and **23**B show a process **1088** for calculating an adjusted valid range for BSA (body surface area). After starting at **1168** a determination is made whether a dose is entered at step **1170**. If a dose is entered, that dose will be used during later calculations as indicated at step **1172** whereas if a dose is not entered, the processor **12** uses a dose range during later calculations as indicated at step **1174**. Whether using an actual dose or a dose range the next step is to back calculate the dose calculation equation to get a BSA (body surface area) range at step **1176**.

After back calculating the dose calculation equation to get the BSA (body surface area) range at step **1176** a determination is made regarding whether there is a valid range for BSA at step **1178**. If there is a valid range for BSA the processor **12** then calculates, using rounding, rate **112** (dose rate therapies) or VTBI (dose amount therapies) using the lower limit value of the adjusted valid range for BSA at step **1180**. Then a determination is made if the rate or VTBI is proper at step **1182** and if not, the lower adjusted valid range limit value for BSA is ceiled to the next higher value at step **1184**.

Either after the rate or VTBI calculation is considered proper at step **1182** or is considered improper and the lower adjusted valid range value for BSA is ceiled at step **1184** the

processor **12** calculates, using rounding, the rate or VTBI using the upper limit value of the adjusted valid range for BSA at step **1186**. At this point in time the processor again determines if the calculated rate or VTBI is proper at step **1188**. If improper the processor **12** truncates the upper limit value of the adjusted valid range for BSA to the next lower value at step **1190**. Either after the rate or VTBI is considered proper at step **1188** or the upper limit value of the adjusted valid range for BSA is truncated at step **1190**, this range of values is returned and/or stored by the processor **12** in its memory **24** at step **1192**. In opposite, if at step **1178** there was not a valid BSA range, the processor **12** returns and/or stores this information instead in its memory at step **1194**. After either step **1192** or **1194** the process **1088** is ended and the processor **12** continues execution of the process which called process **1088**.

FIGS. **24**A and **24**B show a process **1014** for calculating an adjusted valid range for rate. At the start **1196** a determination is made at step **1198** whether or not to calculate VTBI (volume to be infused) once a new rate is entered. If VTBI is to be calculated then the valid range for rate is adjusted with the existing time at step **1200** (FIG. **33**A). If VTBI is determined not to be calculated once a new rate is entered at step **1198** then a second determination is made regarding whether time is to be calculated once a new rate is entered at step **1202**. If time is to be calculated then the valid range of rate is adjusted with the existing VTBI at step **1204** (FIG. **32**). Whereas if time is determined not to be calculated once a new rate is entered at step **1202**, the valid range of the rate is adjusted without any existing VTBI or time at step **1206** (FIG. **31**).

Once the valid range for rate is adjusted via steps **1200**, **1204** or **1206** a determination is made regarding whether or not the dose rate is to be back calculated once a new rate is entered at step **1208**. If the dose rate is to be back calculated the valid range for rate is again adjusted for the back calculated dose rate range at step **1210** (FIG. **30**).

After the valid range for rate is back calculated from the dose rate range at step **1210** or if the dose rate is not to be back calculated once a new rate is entered a second determination is made at step **1212** regarding whether or not the bolus dose rate **118** is to be calculated once a new rate is entered. If bolus dose rate is to be calculated, the valid range for rate is adjusted for the bolus dose rate range at step **1214** (FIG. **33**B). After the adjustment at step **1214** or if the bolus dose rate is determined not to be calculated once a new rate is entered at step **1212** the processor **12** then uses the most stringent valid range determined in accordance with the adjusted valid range, machine limitations and configurable limits at step **1216**. At that time a determination is made if there is a valid range at step **1218** and if there is, this valid range is considered to be the new adjusted valid range for rate and is returned and/or stored in the memory **24** at step **1220**. If there is not a valid range this means that there is no valid value of rate that may be entered and this is instead returned and/or stored in the memory **24** at step **1222**. After either step **1220** or **1222** the process **1014** is ended and the processor **12** continues execution of the process which called process **1014**.

FIG. **25** shows a process **1032** for calculating an adjusted valid range for VTBI (volume to be infused). After starting at step **1124** a determination is made whether or not rate is to be calculated once a new VTBI is entered at step **1226**. If rate is to be calculated then the valid range of the VTBI is adjusted with existing time information at step **1228** (FIG. **37**). If rate is determined not to be calculated once a new VTBI is entered at step **1126** the processor **12** will determine if time is to be calculated once a new VTBI is entered at step **1230**. If time is to be calculated then the valid range of the VTBI will be adjusted with the existing rate at step **1232** (FIG. **36**). If time is determined not to be calculated once a new VTBI is entered at step **1230** the valid range for the VTBI will be adjusted without any known rate or time at step **1234** (FIG. **35**).

Once a valid range for the VTBI has been adjusted in either step **1128**, **1232**, or **1234** the processor **12** makes a determination whether the dose amount is to be back calculated once a new VTBI is entered at step **1236**. If the dose amount is to be back calculated the adjusted valid range for VTBI will again be adjusted taking into account the dose amount range at step **1238** (FIG. **34**). Once readjusted at step **1238** or if a the dose amount is determined not to be back calculated once a new VTBI is entered at step **1236** the process then uses the most stringent valid range limitations in regard to the adjusted valid range, machine limitations, and configurable limits at step **1240**. Once the most stringent valid range limits are used the processor **12** determines if there is a valid range at step **1242**. If there is a valid range that valid range is considered the new adjusted valid range for VTBI and is returned and/or stored in the memory **24** at step **1244** whereas if there is not a valid range that means that there is no valid VTBI to be entered and that information is returned and/or stored in the memory **24** at step **1246**. After either step **1244** or **1246** the process **1032** is ended and the processor **12** continues execution of the process which called process **1032**.

FIG. **26** shows process **1104** for calculating the adjusted valid range of time **116**. After starting at step **1248** the process involves first determining whether rate is to be calculated once a new time is entered at **1250**. If rate is to be calculated, the processor **12** will adjust the valid range for time with the existing VBTI (volume to be infused) at step **1252** (FIG. **41**). If the rate is determined not to be calculated once the new time is entered the processor **12** will then determine if VTBI is to be calculated once a new time is entered at step **1254**. If VTBI is to be calculated, then the valid range of time will be adjusted in with the existing rate at step **1256** (FIG. **40**). If VTBI is determined not to be calculated once a new time is entered at step **1254** then the valid range for time will be adjusted without any known rate or VTBI at step **1258** (FIG. **39**).

Once the valid range for time is adjusted in one of the previous steps **1252**, **1256**, or **1258** the processor **12** then uses the most stringent valid range provided when accounting for the adjusted valid range, machine limitations, and configurable limits at step **1260**. The process then requires the processor **12** to determine if there is a valid range at step **1262**. If there is a valid range that valid range is considered to be the new adjusted valid range for time and is returned and/or stored in the memory **24** at step **1264** whereas if there is no valid range that means that there is no valid time to be entered and that information returned and/or stored in memory **24** at step **1266**. After either step **1264** or **1266** the process **1104** is ended and the processor **12** continues execution of the process which called process **1104**.

FIG. **27** shows process **1146** for calculating the adjusted valid range for weight when the dose is weight based and hence weight is part of the dose calculation. When starting at step **1268** the process **1146** first requires that the processor **12** determine if there is a dose entered at step **1270**. If a dose is entered at step **1272** the entered dose is used in later calculations whereas if there is not a dose entered then a dose range at step **1274** is used in later calculations instead. At this time at step **1276** using either the entered dose or a dose range, a dose calculation equation is back calculated to get a weight range.

Once a weight range is back calculated the processor **12** then determines if there is a valid weight range at step **1278**.

If there is, the next step is to calculate, using rounding, the rate (dose rate therapies) or VTBI (dose amount therapies) using the lower limit value of the adjusted valid range of weight at step **1280**. At that time, the processor **12** determines if the rate or VTBI is proper at step **1282** and if not, at step **1284**, the lower limit value of the adjusted valid range for weight is ceiled to the next higher value. Upon ceiling the lower limit at step **1284** or determining that the rate or VTBI is proper at step **1282** the upper limit value of the valid range for weight is used to calculate, using rounding, the rate or VTBI at step **1286**. Then at step **1288** the processor **12** determines if the rate or VTBI is proper. If not, the upper limit value of the adjusted valid range for weight is truncated to the next lower value at step **1290**. Either after the rate or VTBI is determined proper in step **1288** or the upper adjusted limit value for weight is truncated at step **1290** the valid range values are then considered the new adjusted valid range values for weight and returned and/or stored in memory at step **1292**. In contrast, if at step **1278** there was no valid weight range the processor **12** will return and/or store in its memory that there is not a valid range of values as provided in step **1294** which means that there are no valid weight values to be entered. After either step **1292** or **1294** the process **1146** is ended and the processor **12** continues execution of the process which called process **1146**.

FIGS. **28**A and **28**B show a process **1148** wherein the adjusted valid range for weight is calculated from a BSA (body surface area) range. Thus, the dose unit is BSA based and modifying the weight may calculate the BSA. After starting at step **1296** the adjusted valid range for BSA is calculated at step **1088** (FIG. **23**). The processor **12** then determines if there is a valid BSA range at step **1298**. If there is a valid BSA range then at step **1300** the processor **12** determines if there is a height **106** entered. If a height **106** is entered then at step **1302** that entered height will be used in later calculations whereas if a height is not entered then at **1304** the height range will be used during later calculations. Then at step **1306** by using either the entered height of **1302** or the height range of **1304** a BSA calculation equation is back calculated to determine a weight range.

The process **1148** then requires the processor **12** to determine whether the weight range of **1306** is a valid weight range at step **1308**. If there is a valid weight range at **1308** then at step **1310** the BSA is calculated, using rounding, using the lower limit value of the adjusted valid range for weight. Once BSA is calculated at **1312** the processor **12** determines if the BSA value is proper. If the BSA is not proper then the lower limit value of the adjusted valid range for weight is ceiled to the next higher value at step **1314**. After the BSA is found proper or the lower limit value of the adjusted valid range for weight is ceiled, BSA is calculated, using rounding, using the upper limit value of the adjusted valid range for weight at step **1316**. At step **1318** this BSA is checked to determine if it is proper or not. If not, the upper limit value of the adjusted valid range for weight will be truncated to the next lower value at step **1320**.

Once a proper BSA is found at step **1318** or the adjusted valid range for weight is truncated at step **1320** the adjusted valid range for weight is returned and/or stored in the memory **24** of the processor **12** at step **1322**. If during the process **1148** the processor **12** determines that there is not a valid BSA range at step **1298** or that there is not a valid weight range at step **1308** the fact no valid range values exist is instead returned and/or stored in the memory **24** by the processor at step **1324**. After either step **1322** or **1324** the process **1148** is ended and the processor **12** continues execution of the process which called process **1148**.

FIGS. **29**A and **29**B show a process **1160** for adjusting the valid range for height from a BSA (body surface area) range. Thus the dose unit is BSA (body surface area) based and modifying height may calculate the BSA. After starting at step **1326** the adjusted valid range for BSA is calculated at step **1088** (FIG. **23**). The processor **12** then determines if there is a valid BSA range at step **1298**. If there is a valid BSA range then at step **1328** the processor **12** then determines if there is a weight entered at step **1328**. If a weight is entered the processor **12** will use the entered weight in later calculations in step **1330**, however, if a weight is not entered then the processor **12** uses the weight range in later calculations as indicated in step **1332**. Once the processor **12** determines whether an entered weight or a weight range is to be used, the processor **12** back calculates the BSA calculation equation to get a height range in step **1334**.

Once calculating the height range in step **1334** the process **1160** then determines if the height range is valid at step **1336**. If the height range is valid then at step **1138** a BSA is calculated using the lower limit value of the adjusted valid range for height. Then in step **1340** the processor **12** determines if that calculated BSA is proper and if not, the processor **12** ceils the lower limit value of the adjusted valid range for height to the next higher value at step **1342**.

Either after the BSA was determined proper or the lower limit value was ceiled to the next higher value the processor **12** then calculates BSA using the upper adjusted valid range value for height at step **1344**. Again, this BSA is checked at step **1346** and if not proper, the upper limit value of the adjusted valid range for height is truncated to the next lower value at step **1348**. Thus, once the processor **12** determines if the upper and lower limit values of the height range need to be ceiled or truncated, the adjusted valid range for height is returned and/or stored within the memory **24** at step **1350**. If, in step **1298** the processor **12** determines there is not a valid adjusted BSA (body surface area) range, or in step **1336** the processor **12** determines there is not a valid height range this information is returned and/or stored in memory **24** at step **1352**. After either step **1350** or **1352** the process **1160** is ended and the processor **12** continues execution of the process which called process **1160**.

FIG. **30** shows process **1210** for adjusting the valid range for rate from the dose rate range. After starting at step **1354** the processor **12** calculates a rate using the minimum dose rate value for the current dose unit at step **1356**. Then, at step **1358** a determination is made whether or not the calculated rate is greater than the minimum adjusted rate value. If the calculated rate is greater then at step **1360** the minimum adjusted valid range value is set to the rate calculated in step **1356**. In step **1362** the minimum adjusted range value for rate is used to calculate a dose rate.

In step **1364** there is a determination made if the dose rate calculated in step **1362** is below the minimum dose rate value. If so, the minimum adjusted valid range value for rate is set to the next higher rate value in step **1366**. Once a proper minimum valid range value for rate is determined in either step **1364** or **1366** the processor **12** then calculates rate using the maximum dose rate value for the current dose unit at step **1368**. If the rate calculated in **1368** is less than the maximum adjusted valid range for rate as determined in **1370**, the maximum adjusted valid range value for rate is set to the calculated rate in step **1372**.

The lower adjusted range value for rate then is used to calculate dose rate at step **1374**. The processor **12** then determines at step **1376** if the dose rate calculated at step **1374** is above the maximum dose rate value for the current dose unit. If so, the maximum valid range value for rate is set to the next

lower rate value at step **1378**. After either step **1376** or **1378** the process **1210** is ended and the processor **12** continues execution of the process which called process **1210**.

FIG. **31** shows the process **1206** for adjusting the valid range for rate without any existing VTBI **114** (volume to be infused) or time **116**, i.e. neither VTBI nor time will be calculated once the new rate is entered. After starting at step **1380** the processor **12** calculates the minimum adjusted valid range value for rate at step **1382**. This minimum value is then used to calculate VTBI at step **1384**. Then the processor **12** determines in step **1386** whether the VTBI is proper. If the VTBI of step **1386** is not considered proper the minimum adjusted valid range value for rate is ceiled to the next higher rate value at step **1388**.

Once the calculated VTBI of **1384** is used to determine if the minimum adjusted valid range value for rate needs to be ceiled the processor **12** then uses the minimum adjusted valid range value for rate to calculate time **116** at step **1390**. The processor **12** then determines at step **1392** whether the time calculated in step **1390** is proper. If not, the minimum adjusted valid range value for rate is ceiled to the next higher rate value at step **1394**.

After the time calculation and adjustments of steps **1392** and **1394** the processor **12** then calculates a maximum value for the adjusted valid range for rate at step **1396**. At step **1398** this calculated maximum value for rate is used to calculate VTBI (volume to be infused). Once VTBI is calculated using the maximum value for rate the processor **12** determines if the VTBI is proper at step **1400**. If not, at step **1402** the processor **12** truncates the maximum adjusted valid range value for rate to the next lower rate value.

In step **1404** the processor **12** similarly uses the maximum adjusted valid range value for rate to calculate time **116**. Then using the time calculated in step **1404** the processor **12** determines in step **1406** whether this time falls within the valid range for time. If not, at step **1408** the processor **12** truncates the maximum adjusted valid range value for rate to the next lower rate value. After either step **1406** or **1408** the process **1206** is ended and the processor **12** continues execution of the process which called process **1206**.

FIG. **32** provides process **1204** for adjusting the valid range for rate using an existing VTBI (volume to be infused). As such, time is calculated from the existing VTBI and the new rate once a new rate is entered. After starting at step **1410** the programmed or current VTBI is retrieved at step **1412**. At this time the processor **12** calculates a minimum adjusted valid range value for rate at step **1414**. At step **1416** the processor **12** uses the calculated minimum adjusted valid range value for rate to calculate time **116**. Then at step **1418** a determination is made regarding the calculated time and whether it falls within the valid range for time. If the calculated time does not fall within the valid range then the minimum adjusted valid range value is ceiled to the next higher rate value at step **1420**.

Once the decision is made regarding whether the calculated time is correct or whether the minimum rate range value limit needed to be ceiled in steps **1418** and **1420** is complete the processor **12** then calculates the maximum adjusted valid range value for rate at step **1422**. Once calculated the processor **12** at **1424** uses the maximum adjusted valid range value for rate to again calculate time. Then a determination again is made at **1426** whether the time is proper. If not, the maximum adjusted valid range value for rate is truncated to the next lower rate value at **1428**. After either step **1426** or **1428** the process **1204** is ended and the processor **12** continues execution of the process which called process **1204**.

FIG. **33**A shows a process **1200** for adjusting the valid range of rate with an existing time **116** such that VTBI (volume to be infused) is calculated from the existing time and the new rate once a new rate is entered. In the process after the start at step **1430** the processor **12** calculates a minimum adjusted valid range value for rate at step **1432**. The processor **12** then uses that calculated value of **1432** to calculate VTBI at step **1434**. A determination at **1436** is then made regarding whether the VTBI is proper. If the VTBI of step **1436** is not proper the minimum limit value of the adjusted valid range for rate is ceiled to the next higher rate value at step **1438**.

After determining the VTBI is proper or after the minimum limit value is ceiled the processor **12** then calculates a maximum limit value for the adjusted valid range for rate at **1440**. At **1442** this maximum adjusted valid range value for rate is used to calculate VTBI. Then at step **1444** the processor **12** determines if the VTBI is correct and if not, truncates the maximum adjusted valid range value for rate to the next lower rate value at **1446**. After either step **1444** or **1446** the process **1200** is ended and the processor **12** continues execution of the process which called process **1200**.

FIG. **33**B shows the process **1214** for adjusting the valid range for rate from the bolus dose rate range. After starting at step **1448** the processor **12** calculates a valid rate range from the bolus dose rate range at step **1450** (FIG. **43**). Then, at step **1452** the processor **12** uses the most stringent range of the valid rate range and the adjusted valid range for rate as a new adjusted valid range for rate. After step **1452** the process **1214** is ended and the processor **12** continues execution of the process which called process **1214**.

FIG. **34** shows the process **1238** for adjusting the valid range of VTBI (volume to be infused) from the dose amount range for the current dose amount unit. After starting at step **1454** the processor **12** calculates VTBI using the minimum dose amount range value for the current dose unit at step **1456**. At step **1458** the processor **12** determines if the VTBI is greater than the minimum adjusted VTBI value. If yes, the minimum adjusted valid range value for VTBI is set to the calculated VTBI of step **1456** at step **1460**. Then at step **1462** the minimum adjusted valid range value for VTBI is used to calculate a dose amount. Once the dose amount is calculated at step **1464** the processor **12** determines if the dose amount is below the present minimum dose amount value. If so, the minimum adjust valid range is set to the next higher level of VTBI at step **1466**.

At step **1468** a VTBI is calculated using the maximum dose amount value for the current unit dose. As such, at step **1470** the processor **12** determines if the VTBI is less than the maximum adjusted VTBI value. If it is, then the maximum adjusted valid range value for VTBI is set to the calculated VTBI of step **1468** at step **1472**. Then the maximum range value for VTBI is used to calculate a dose amount at step **1474**. At step **1476** the processor **12** determines if the calculated dose amount is above the maximum dose amount value. If it is, the maximum adjusted valid range value is set to the next lower VTBI at step **1478**. After either step **1476** or **1478** the process **1238** is ended and the processor **12** continues execution of the process which called process **1238**.

FIG. **35** shows the process **1234** for adjusting the valid range of VTBI without using any existing rate or time, i.e. neither rate nor time will be calculated once a new VTBI is entered. After starting at step **1480** the processor **12** calculates the minimum adjusted valid range value for VTBI at step **1482**. This calculated VTBI value is then used to calculate rate at step **1484**. At step **1486** the processor **12** determines if the rate is proper. If not, the minimum adjusted valid range value for VTBI is ceiled to the next higher VTBI value at step **1488**. At that time the processor **12** uses the minimum adjusted valid range value for VTBI to calculate time at **1490**.

The processor then determines at step **1492** if the time is proper and if not, ceils the minimum adjusted valid range value for VTBI to the next higher VTBI value at step **1494**.

Next, the processor **12** calculates the maximum adjusted valid range value for VTBI at step **1496**. This maximum adjusted valid range value for a VTBI is then used to calculate rate at **1498**. The processor **12** determines if the rate is proper at step **1500** and if not, truncates the maximum adjusted valid range value for VTBI to the next lower VTBI value at step **1502**.

The processor **12** then takes the maximum adjusted range value for VTBI to calculate time at **1504**. At step **1506** the processor **12** determines if the time is proper and if not, the maximum adjusted valid range value for VTBI is truncated to the next lower VTBI value at **1508**. The processor **12** then determines if the bolus dose rate is to be calculated once a new VTBI is entered at step **1510** and if it is, the valid range for VTBI is adjusted from the bolus dose rate range at step **1512** (FIG. **38**). After either step **1510** or **1512** the process **1234** is ended and the processor **12** continues execution of the process which called process **1234**.

FIG. **36** shows the process **1232** for adjusting the valid range for VTBI with an existing rate such that time is calculated from the existing rate and the new VTBI once the new VTBI is entered. After starting at step **1514** the processor **12** calculates the minimum adjusted valid range value for VTBI at step **1516**. The processor **12** then uses this calculated value to calculate time at step **1518**. The processor **12** at step **1520** then determines if time is proper and if not, the minimum adjusted valid range value for VTBI is ceiled to the next higher VTBI value at step **1522**.

The processor **12** at step **1524** calculates a maximum adjusted valid range value for VTBI. Then at step **1526** that maximum adjusted valid range value for VTBI is used to calculate time. The processor **12** next determines if the calculated time is proper at step **1528**. If the time is not proper the maximum adjusted valid range value for VTBI is truncated to the next lower VTBI value at step **1530**. After either step **1528** or **1530** the process **1232** is ended and the processor **12** continues execution of the process which called process **1232**.

FIG. **37** shows a process **1228** for adjusting the valid range for VTBI with an existing time such that rate is calculated from the existing time and the new VTBI once a new VTBI is entered. Upon starting at step **1532** the processor **12** calculates the minimum adjusted valid range value for VTBI at step **1534**. This value is then used to calculate rate at **1536**. At step **1538** the processor **12** determines if the calculated rate is proper and if not, the minimum adjusted valid range value for VTBI is ceiled to the next higher VTBI value at step **1540**.

Next the processor **12** calculates the maximum adjusted valid range value for VTBI at step **1542**. At step **1544** the processor **12** uses the calculated maximum adjusted valid range value for VTBI to calculate rate. At step **1546** the processor **12** determines if the rate is proper and if not, the maximum adjusted valid range value for VTBI is truncated to the next lower VTBI value at step **1548**. Next, the processor **12** determines if a bolus dose rate is to be calculated once a new VTBI is entered at step **1550** and if so, the processor **12** adjusts the valid range for VTBI from the bolus dose rate range at step **1512** (FIG. **38**). After either step **1550** or **1512** the process **1228** is ended and the processor **12** continues execution of the process which called process **1228**.

FIG. **38** shows a process **1512** for adjusting the valid range for VTBI (volume to be infused) from the bolus dose rate range. After starting with step **1552** the processor **12** calculates a rate range from the bolus dose rate range at step **1450** (FIG. **43**). The processor **12** then calculates the minimum VTBI at step **1554** and determines if the minimum VTBI is greater than the minimum adjusted range value for VTBI at step **1556**. If the minimum VTBI is greater than the minimum adjusted range value for VTBI then the minimum adjusted valid range value for VTBI is set to the minimum VTBI at step **1558**.

Next, the processor **12** calculates rate using minimum adjusted valid range value for VTBI at step **1560**. At step **1562** the processor **12** determines if the rate is proper and if not, the minimum adjusted valid range value for VTBI is set to the next higher VTBI.

The next step **1564** involves the processor **12** calculating the maximum VTBI. Then the processor **12** determines at step **1566** if the maximum VTBI is less than the maximum adjusted range value for VTBI. If the maximum VTBI is less than the maximum adjusted range value for VTBI then the maximum adjusted valid range value for VTBI is set to the maximum VTBI at step **1568**. Then using the maximum adjusted valid range value for VTBI the processor **12** calculates rate at step **1570**. The processor **12** then determines if the rate is proper at step **1572** and if not, the maximum adjusted valid range value for VTBI is set to the next lower maximum VTBI at step **1574**. After either step **1572** or **1574** the process **1512** is ended and the processor **12** continues execution of the process which called process **1512**.

FIG. **39** provides the process **1258** used to adjust the valid range of time **116** without any existing rate or VTBI, i.e. neither rate nor time will be calculated once a new time is entered. After starting at step **1576** the processor **12** calculates a minimum adjusted valid range value for time at step **1578**. The processor **12** then uses the calculated value of **1578** to calculate rate at step **1580**. The processor **12** then determines if the rate is proper at step **1582** and if not, the minimum adjusted valid range value for time **116** is ceiled to the next higher time value at step **1584**. The minimum adjusted valid range value for time is then used to calculate VTBI at step **1586**. The processor **12** then determines at step **1588** if this calculated VTBI is proper and if not, the minimum adjusted valid range value for time is ceiled to the next higher time value at step **1590**.

The processor **12** then calculates a maximum adjusted valid range value for time at step **1592**. The processor **12** then uses the calculated value of **1592** to calculate rate at step **1594**. The processor **12** next determines at step **1596** if the rate is proper and if not, the maximum adjusted valid range value for time is truncated to the next lower time value at step **1598**.

The processor **12** uses the maximum adjusted valid range value for time to calculate VTBI at step **1600**. The processor **12** then determines if the VTBI calculated in steps **1600** is proper at step **1602**. If not, the maximum adjusted valid range value for time is truncated to the next lower time value at step **1604**. Next, the processor **12** determines if the bolus dose rate is to be calculated once a new time is entered at step **1606** and if it is, the valid range for time is adjusted from the bolus dose rate range at step **1608** (FIG. **42**). After either step **1606** or **1608** the process **1258** is ended and the processor **12** continues execution of the process which called process **1258**.

FIG. **40** shows the process **1256** for adjusting the valid range of time **116** with an existing rate **112** such that VTBI **114** is calculated from the existing rate and the new time once a new time is entered. At the start step **1610** the processor **12** calculates the minimum adjusted valid range value for time at step **1612**. The value calculated in step **1612** is then used to calculate VTBI at step **1614**. The processor **12** at step **1616** determines if the calculated VTBI of step **1614** is proper and

if not, ceils the minimum adjusted valid range value for time to the next higher time value at step **1618**.

The processor **12** then calculates the maximum adjusted valid range value for time at step **1620** and uses this calculated value to calculate VTBI at step **1622**. Then the processor **12** determines at step **1624** if the VTBI is proper. If not, the maximum adjusted valid range value for time is truncated to the next lower time value at step **1626**. Thus, the process **1256** is ended and the processor **12** continues execution of the process which called process **1256**.

FIG. **41** is the process **1252** for adjusting the valid range for time **116** with an existing VTBI **114** such that the rate **112** is calculated from the existing VTBI and the new time once a new time is entered. After the start at step **1628** the processor **12** retrieves the programmed or current VTBI at step **1630**. The processor **12** then calculates the minimum adjusted valid range value for time at step **1632**. Using the calculated value from step **1632** rate is calculated at step **1634**. The processor **12** then determines if the rate is proper at step **1636** and if not, at step **1638** the minimum adjusted valid range value for time is ceiled to the next higher time value.

Next, the processor **12** calculates a maximum adjusted valid range value for time at step **1640**. The processor **12** then uses the calculated value from step **1640** to calculate rate at step **1642**. At step **1644** the processor **12** determines if the rate is proper and if not, the maximum adjusted valid range value for time is truncated to the lower time value at step **1646**. The processor **12** additionally determines if the bolus dose rate is to be calculated once a new time is entered at step **1648** and if so, adjusts the valid range for time from the bolus dose rate range at step **1608** (FIG. **42**). Thus, the process **1252** is ended and the processor **12** continues execution of the process which called process **1252**.

FIG. **42** provides the process **1608** for adjusting the valid range for time **116** from the bolus dose rate range. Step **1650** starts the process and at step **1450** (FIG. **43**) the processor **12** calculates a rate range from the bolus dose rate range. Then the processor **12** calculates a minimum time at step **1652**. The processor **12** makes a determination at step **1654** regarding whether the minimum time is greater than the minimum adjusted valid range value for time. If so, the minimum adjusted valid range value for time is set to the minimum time as shown in step **1656**. Then using the minimum adjusted valid range value for time the processor **12** calculates rate at step **1658**. At step **1660** the processor **12** determines if the rate is proper and if not, the minimum adjusted valid range value for time is set to the next higher time value as shown in step **1662**.

The processor **12** calculates a maximum time at step **1664**. The processor **12** then determines if the maximum time is less than the maximum adjusted valid range value for time at step **1666** and if so, the maximum adjusted valid range value for time is set to the maximum time at step **1668**. Rate is then calculated using the maximum adjusted valid range value for time at step at **1670**. The processor **12** determines if the rate is proper at step **1672**. If the rate is not proper, the maximum adjusted valid range value for time is set to the next lower time value at step **1674**. Thus, the process **1608** is ended and the processor **12** continues execution of the process which called process **1608**.

FIG. **43** shows the process **1450** for calculating a valid range for rate from the bolus dose rate range. After the start at step **1676** the processor **12** gets the valid range of values for the current bolus dose rate unit at step **1678**. Then, the processor **12** determines if the bolus dose rate unit is ml/hr at step **1680**. If not, the processor **12** then determines at step **1682** whether the bolus dose rate unit is weight dependent. If the bolus dose rate unit is weight dependent the processor **12** finds a programmed weight or the weight range if there is no weight present as shown in step **1684**. If at step **1682** the bolus dose rate unit is not weight dependent then as shown in step **1686** the processor **12** determines if the bolus dose rate unit is BSA (body surface area) dependent. If it is, then the program accesses BSA or the BSA range if there is no BSA present at step **1688**. Once either the weight, weight range, BSA, BSA range, or if the bolus dose rate unit is not based on either weight or BSA is determined the processor **12** calculates a rate range from the bolus dose rate range as provided in step **1690**.

At step **1692** the minimum adjusted valid range value for rate is used to calculate a bolus dose rate. The processor **12** determines if the bolus dose rate is proper at step **1694**. If the bolus dose rate is not proper in step **1694** the minimum adjusted valid range value for rate is ceiled to the next higher rate value at step **1696**. The processor **12** then uses the minimum adjusted valid range value for rate to calculate a bolus dose rate in step **1698** and the processor **12** determines if this bolus dose rate is proper in step **1700**. If not, the minimum adjusted valid range value for rate is ceiled to the next higher rate value at step **1702**.

If the bolus dose rate unit is ml/hr at step **1680** the ml/hr range for bolus dose rate is then returned and/or stored at step **1704**. Similarly, if the bolus dose rate is proper in step **1700** or if the valid range of the rate is adjusted in **1702** this range is returned and/or stored in step **1704**. Thus, the process **1450** is ended and the processor **12** continues execution of the process which called process **1450**.

FIG. **44** provides a process **1706** that adjusts the valid range for weight, height, or BSA (body surface area) for therapies that have weight, height, or BSA common across multiple steps, e.g. a Multistep infusion therapy. Specifically, the process starts at step **1708** and at step **1710** the user desires to enter a new weight, height, or BSA (body surface area). At this time the process goes to the first step of the therapy at step **1712**. The processor **12** then calculates the adjusted valid range for rate (dose rate therapies) or VTBI (dose amount therapies) using processes **1014** (dose rate therapies, FIG. **24**) or **1032** (dose amount therapies, FIG. **25**) at step **1713**. At this point, the process calculates the adjusted valid range for weight, height, or BSA for the current step using processes **1048** (weight, FIG. **21**), **1078** (height, FIG. **22**), or **1088** (BSA, FIG. **23**) at step **1716**. Then, at step **1718** the most stringent weight, height, or BSA adjusted valid range values from the current and all the previous steps is stored. The minimum and maximum values may or may not be from the same step. The processor **12** at step **1720** must determine if the current step is the last step of the therapy. If not, the process **1706** goes to the next step of the therapy at step **1714** after which step **1713** will be executed again. If the current step is the last step of the therapy at step **1720**, the processor **12** then determines if there is a valid range available at step **1018**. If there is a valid range, the valid range is presented at step **1020** whereas if there is not a valid range this information is then presented to a user at step **1022**. At this point in time the process has ended at step **1024**.

Thus, disclosed is a system having a processor **12** that calculates and generates through an output device **18** a valid range of values for pump programming parameters based upon the constraints or other information entered by a user. This system allows for accurate data entry and additionally allows a user to know when and what exact information is being incorrectly entered when an error occurs. Additionally, the system has an array of calculations that can be made to constantly update and alter the valid range of values for the

pump programming parameters based upon information provided. Thus, at the very least all of the stated objectives have been met.

It will be appreciated by those skilled in the art that other various modifications could be made to the device without departing from the scope of this invention. It will be appreciated by those skilled in the art that special infusion methods and their associated predetermined equations or considerations (not specifically identified herein) could be statically or dynamically back calculated according to this invention. Those special considerations include but are not limited to therapy limitations (e.g. a Multistep therapy may only deliver 1000 mL total instead of 1000 mL per step, or patient daily, weekly, or lifetime limitations on medication, etc), or new ways of entering pump programming parameters (e.g. total time, ramp up time, plateau time, and ramp down time considerations for Taper therapies). All such modifications and changes fall within the scope of the claims and are intended to be covered thereby.

What is claimed is:

1. A medical pump system that provides advance guidance to a user regarding existence and non-existence of a valid input range for a pump programming parameter, comprising:

an input device for entering a value of a pump programming parameter;

a memory for storing constraints related to the pump programming parameter;

a processor in communication with the memory and the input device, the processor being operable to utilize the constraints to determine and generate a signal, determined from among an affirmative signal and a negative signal, indicating whether a valid input range exists for a to-be-entered value of the pump programming parameter; and

an output device in communication with the processor to receive the signal indicating whether a valid input range exists for a to-be-entered value of the pump programming parameter and, for both a determination that the signal is the affirmative signal and a determination that the signal is the negative signal, explicitly generate a notification to a user of the medical pump system based on the signal immediately prior to attempted input of the to-be-entered value of the pump programming parameter.

2. The medical pump system of claim **1**, wherein the notification indicates to the user that a valid input range for the to-be-entered value is absent.

3. The medical pump system of claim **1**, wherein the notification indicates to the user that a valid input range for the to-be-entered value is present.

4. The medical pump system of claim **3**, wherein the notification comprises a message identifying an upper limit and a lower limit of the valid input range based upon the signal.

5. The medical pump system of claim **4**, wherein the output device is a display screen and the message is generated on the display screen.

6. The medical pump system of claim **1**, wherein one of the constraints is derived from a medical device capability predetermined by a manufacturer of the medical pump system.

7. The medical pump system of claim **1**, wherein at least one of the constraints is derived from a drug library.

8. The medical pump system of claim **1**, wherein the constraints comprise multiple sets of constraints and a smallest maximum constraint among the constraints and a largest minimum constraint among the constraints are used to determine whether a valid range exists and to define the valid range.

9. The medical pump system of claim **1**, wherein one of the constraints comprises a predetermined equation that relates the to-be-entered pump programming parameter to a plurality of other pump programming parameters.

10. The medical pump system of claim **9**, wherein the predetermined equation is back calculated or solved for the maximum and minimum values of the to-be-entered pump programming parameter based upon a maximum and a minimum of one of the other pump programming parameters.

11. The medical pump system of claim **9**, wherein at least one of the plurality of other pump programming parameters has already been entered.

12. The medical pump system of claim **11**, wherein the to-be-entered pump programming parameter is rate and among the plurality of previously entered pump programming parameters is one of time and volume to be infused.

13. The system of claim **12** wherein the maximum and minimum values of the to-be-entered pump programming parameter are rounded during calculation.

14. The system of claim **12** wherein the maximum value of the to-be-entered pump programming parameter is truncated during calculation.

15. The system of claim **12** wherein the minimum value of the to-be-entered pump programming parameter is ceiled during calculation.

16. The system of claim **12** wherein when calculated at least one of the maximum and minimum values of the to-be-entered pump programming parameter is compared to a medical device capability constraint.

17. The system of claim **16** wherein the valid range is adjusted after comparison to the medical device capability constraint to create an adjusted valid range.

18. The medical pump system of claim **10**, wherein the back calculation of the valid range is dynamically back calculated anytime a related pump programming parameter is altered.

19. The medical pump system of claim **10**, wherein the to-be-entered pump programming parameter is recalculated using a second predetermined equation.

20. The medical pump system of claim **5**, wherein the message is displayed on the display screen concurrently with an input field for receiving input of the to-be-entered value of the pump programming parameter.

21. A medical pump system that provides advance guidance to a user regarding unavailability of a valid input range for a pump programming parameter, comprising:

an input device for entering a value of a pump programming parameter;

a memory for storing constraints related to the pump programming parameter;

a processor in communication with the memory and the input device, the processor being operable to utilize the constraints to determine and generate a signal indicating unavailability of a valid input range for a to-be-entered value of the pump programming parameter; and

an output device in communication with the processor to receive the signal indicating the unavailability of a valid input range for a to-be-entered value of the pump programming parameter and generate a notification of the unavailability of a valid input range to a user of the medical pump system based on the signal prior to attempted input of the to-be-entered value of the pump programming parameter.

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