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(54) RELAY DEVICE FOR TRANSFERRING INFORMATION BETWEEN A SENSOR SYSTEM AND A FLUID DELIVERY SYSTEM

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(51) **Int. Cl.**[7] **G05D 7/00**

(52) **U.S. Cl.** **604/65**; 700/282; 128/920

(57) **ABSTRACT**

A relay device transfers information between a sensor system, which measures a physiological characteristic level of a user, and a fluid delivery system, which infuses a fluid into a user. The relay device includes a sensor system receiver for receiving communications from the sensor system in a sensor system format. The relay device also includes a processor for processing the communications from the sensor system and converting the communications for transmission in a delivery system format. The relay device further includes a delivery system transmitter for transmitting the converted communications in the delivery system format to the fluid delivery system. The sensor system and delivery system formats may utilize different frequencies and/or different communication protocols for communications transmitted between the sensor system and the fluid delivery system through the relay device.

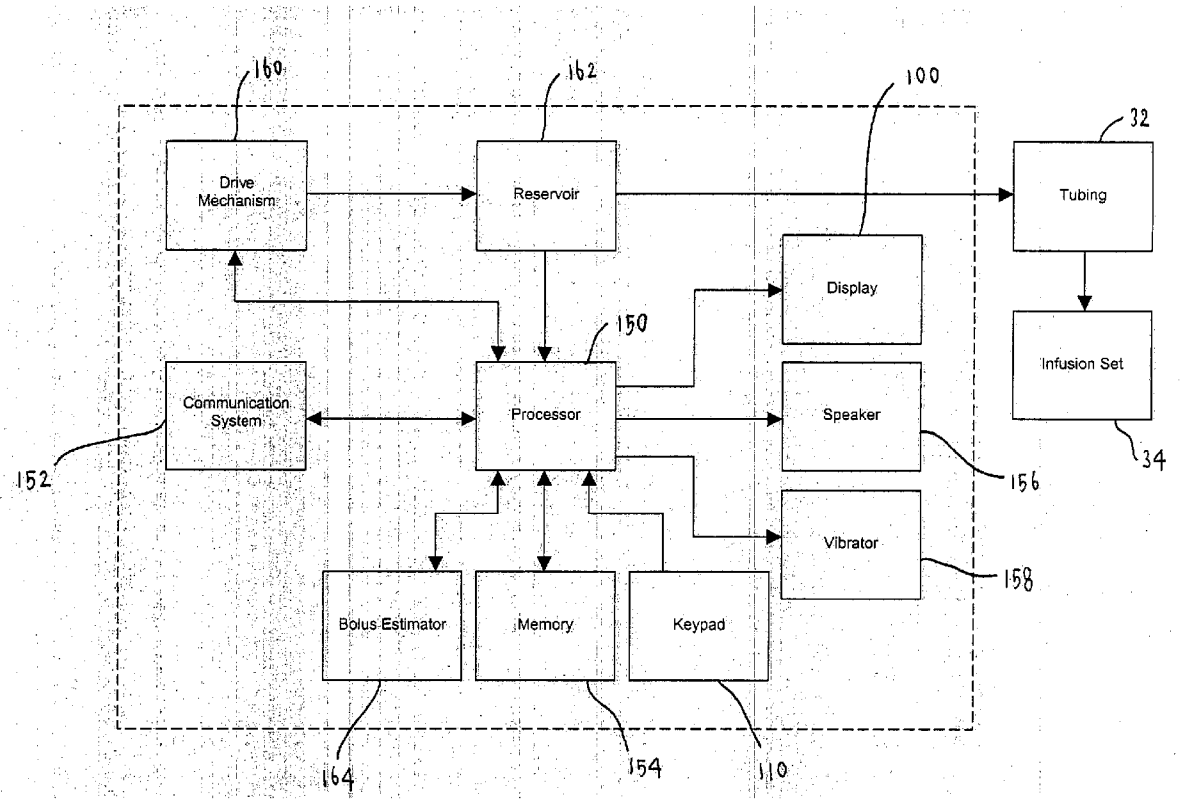

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FIG. 1

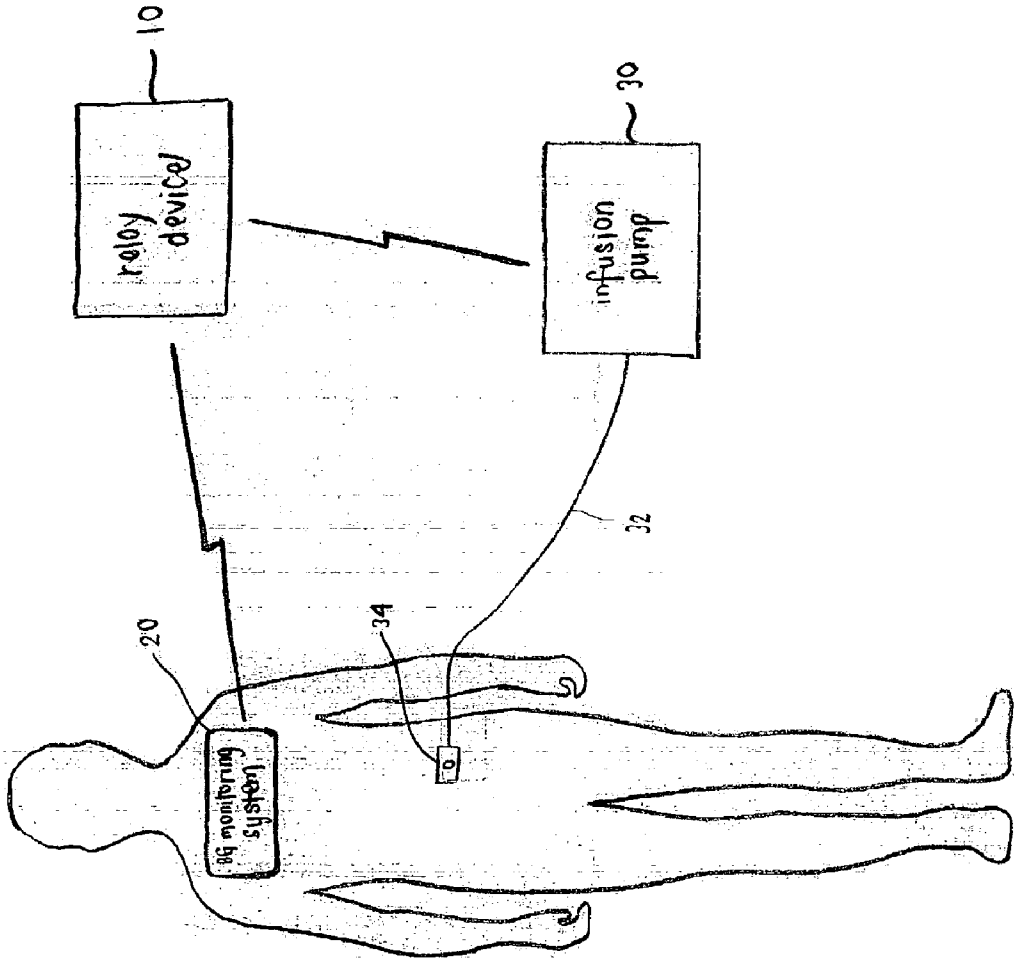
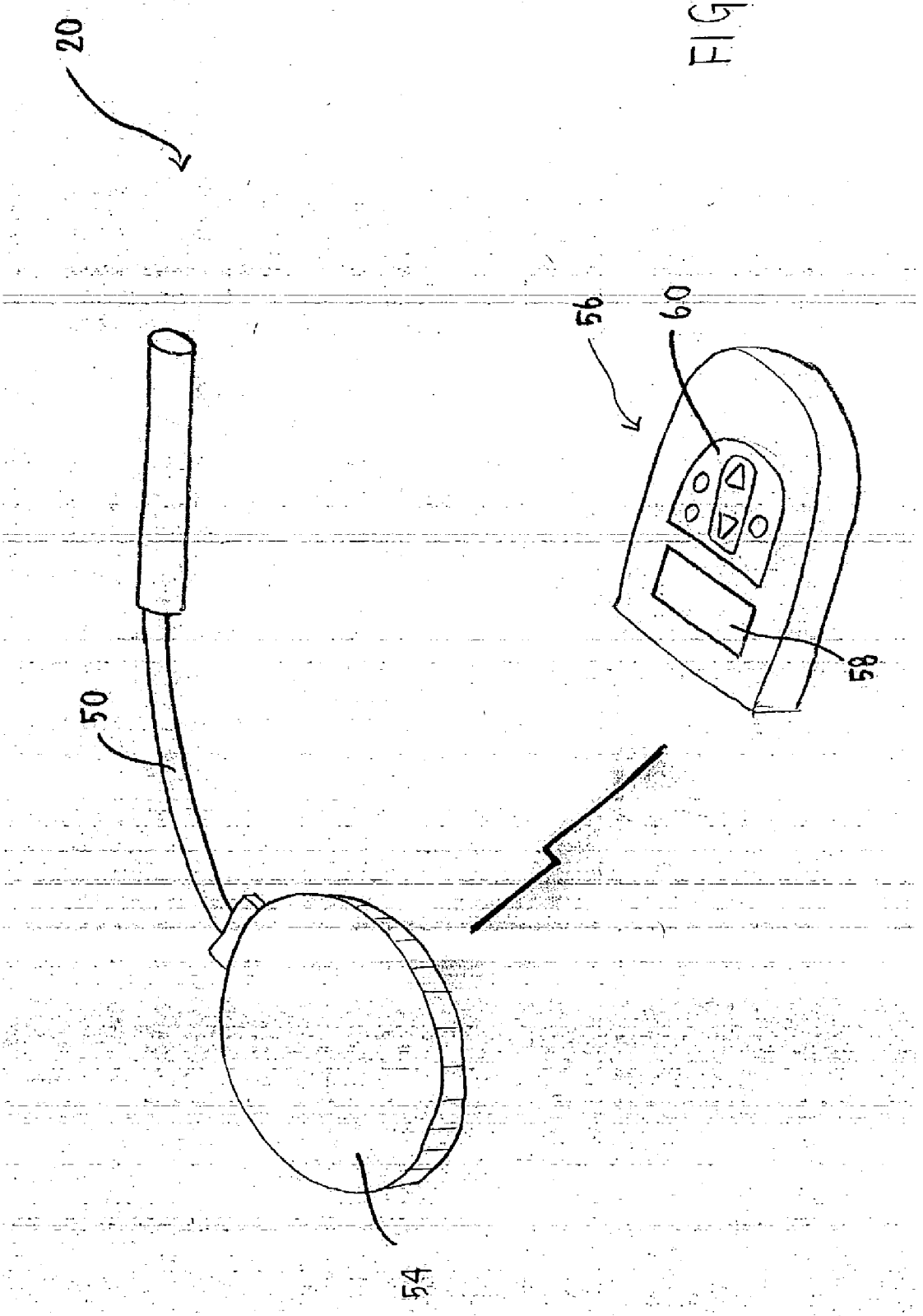

10
relay device
30
infusion pump
32
34
20
BG monitoring system

FIG. 2(a)



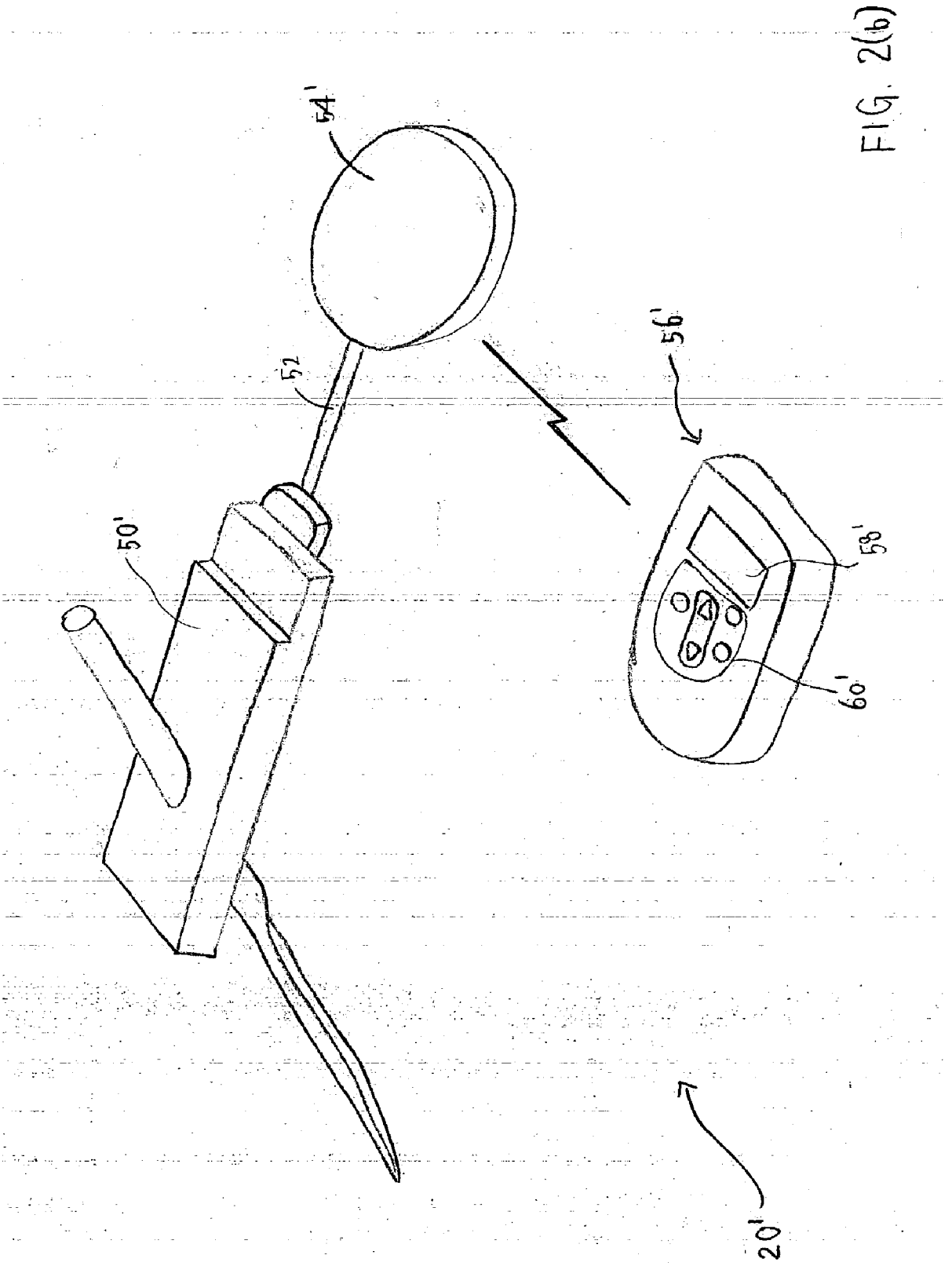


FIG. 2(b)

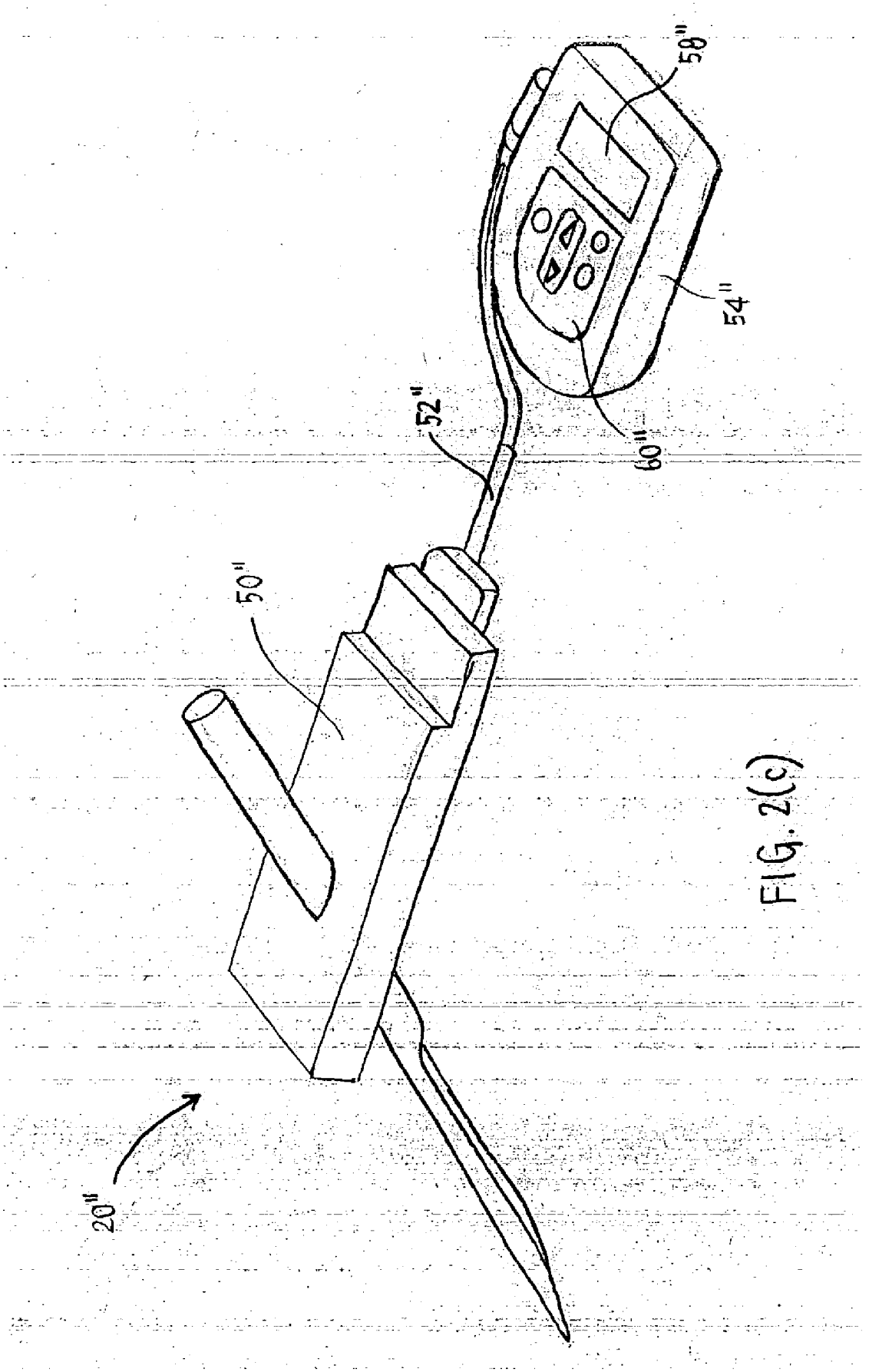


FIG. 2(c)

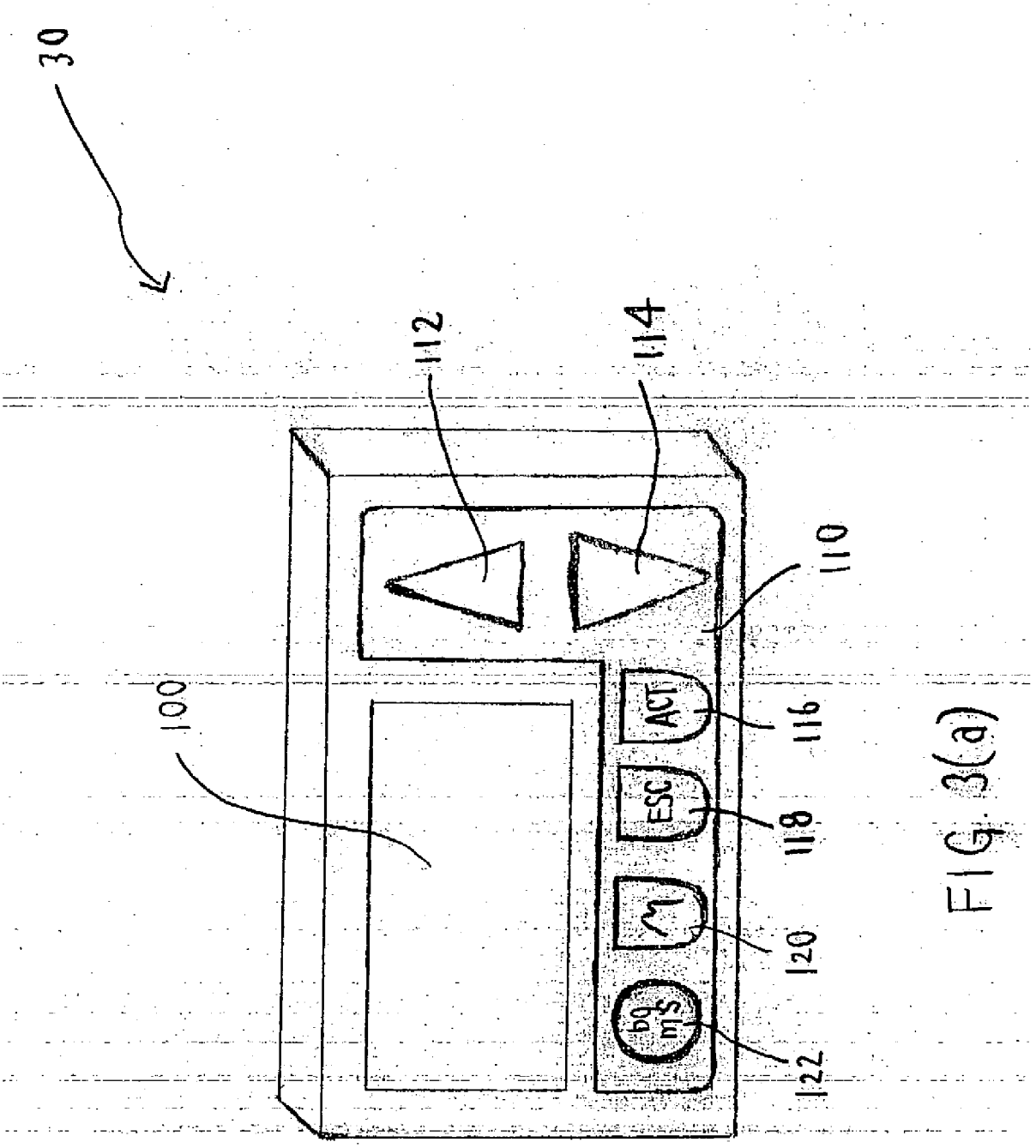


FIG. 3(a)

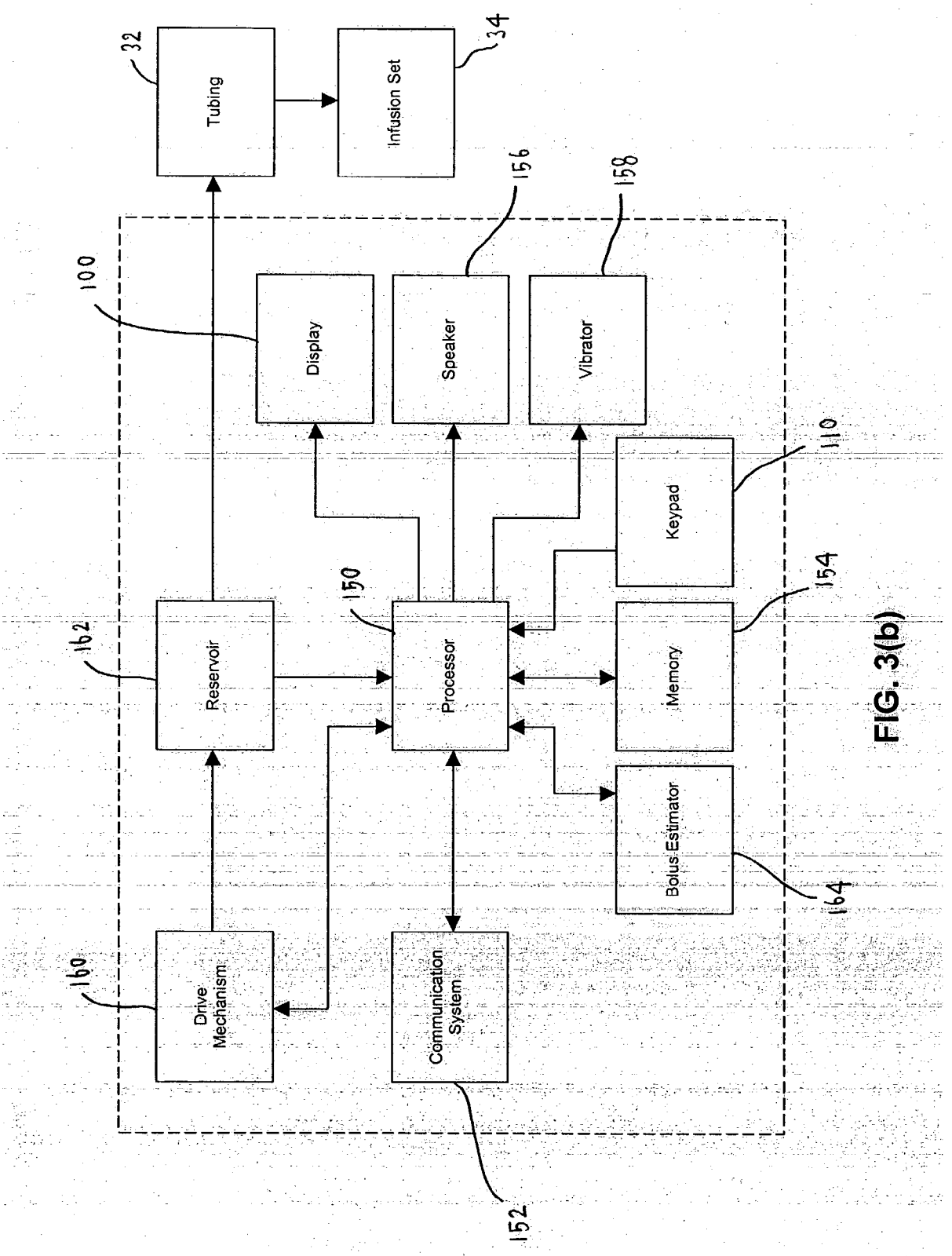

32
Tubing
Infusion Set
34
156
158
100
Display
Speaker
Vibrator
110
Keypad
150
154
162
Reservoir
Processor
Memory
Bolus Estimator
164
160
Drive Mechanism
Communication System
152

FIG. 3(b)

Fig. 4(a)

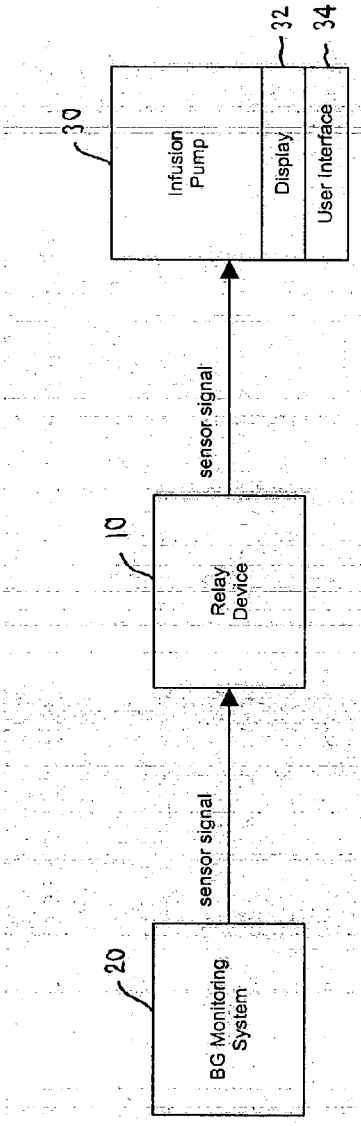


Fig. 4(b)

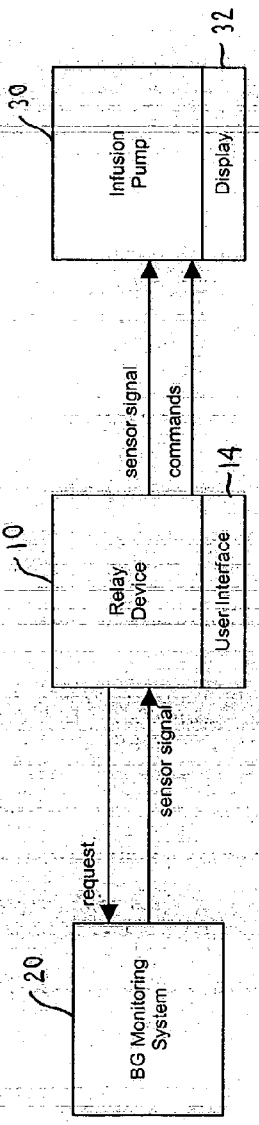


Fig. 4(c)

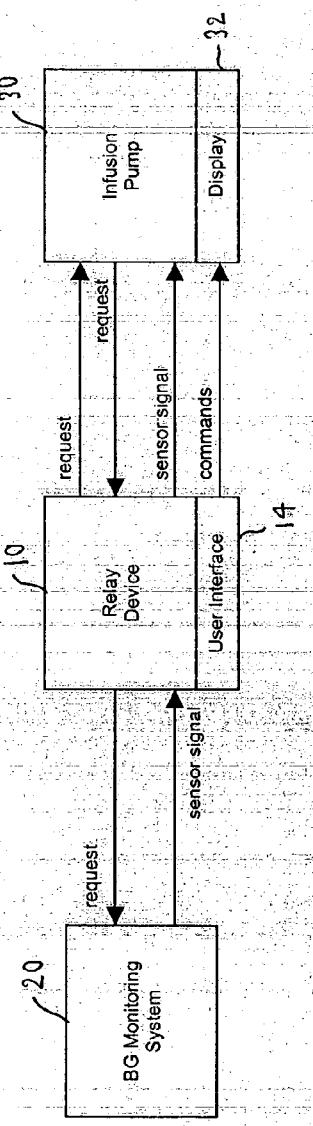


Fig. 4(d)

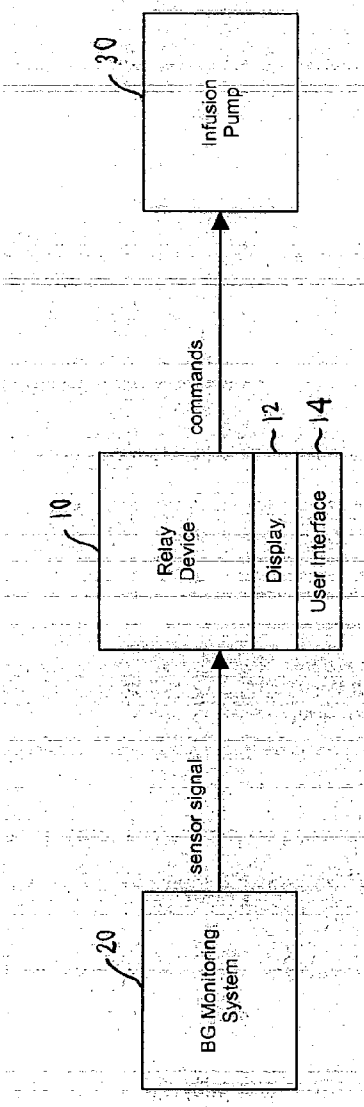


Fig. 4(e)

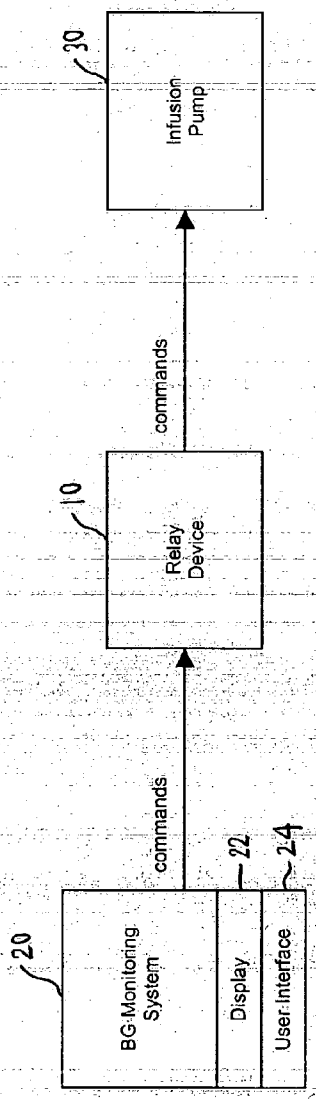


Fig. 4(f)

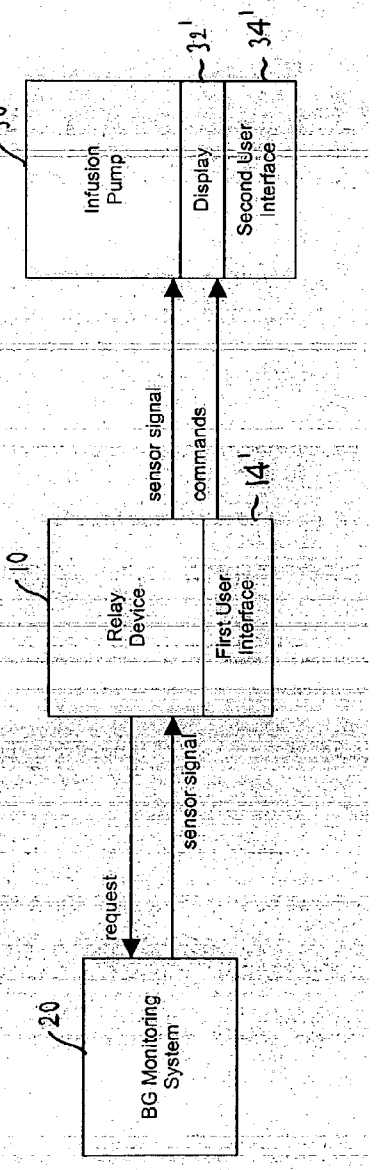


Fig. 5(a)

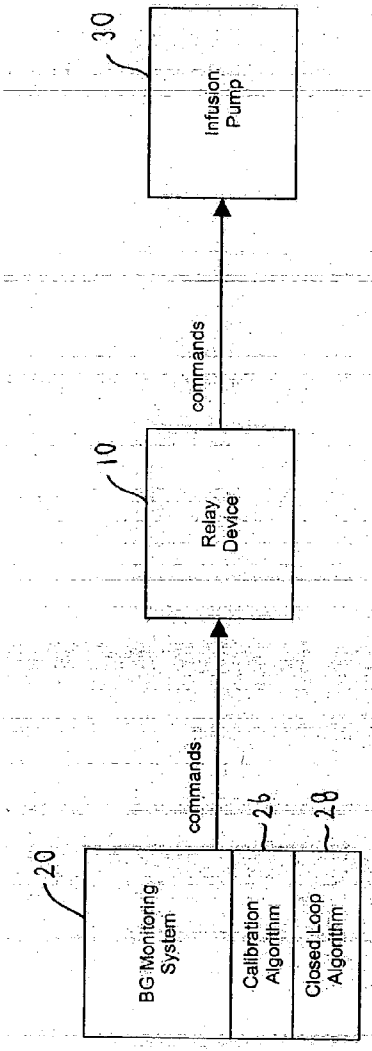


Fig. 5(b)

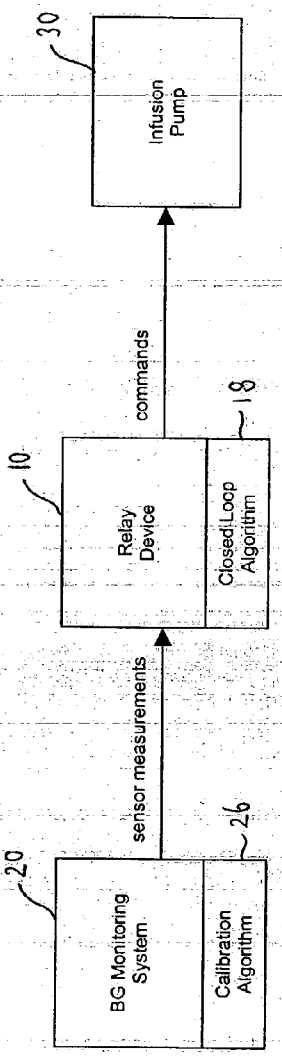


Fig. 5(c)

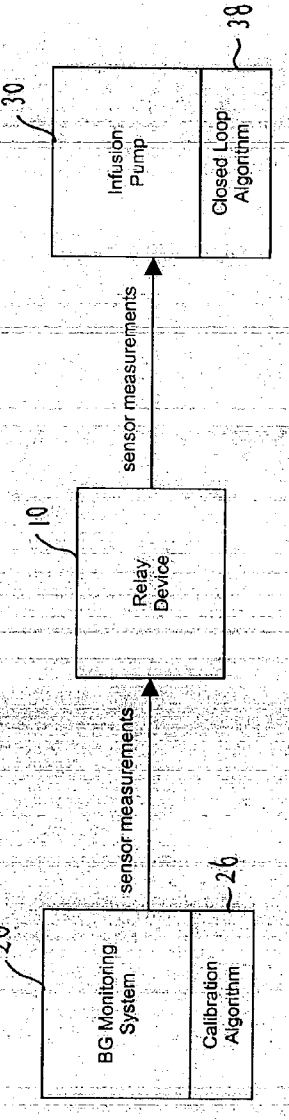


Fig. 5(d)

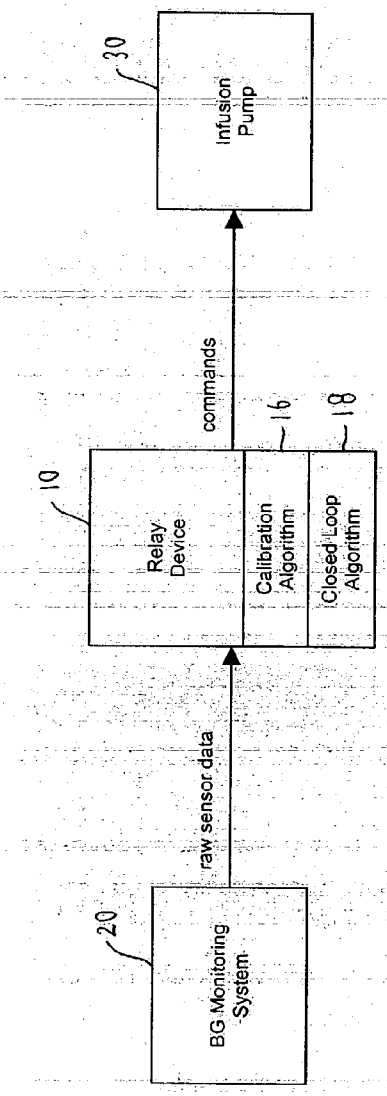


Fig. 5(e)

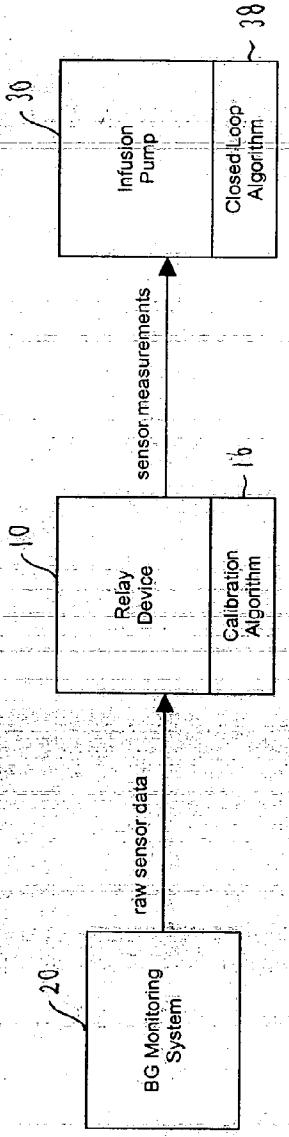
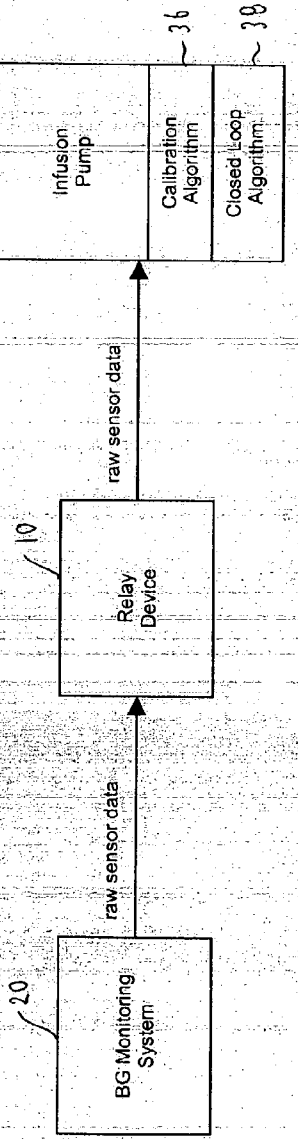


Fig. 5(f)



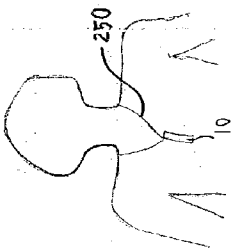


FIG. 7(a)

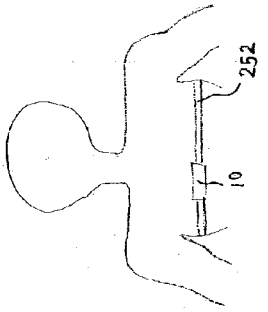


FIG. 7(b)

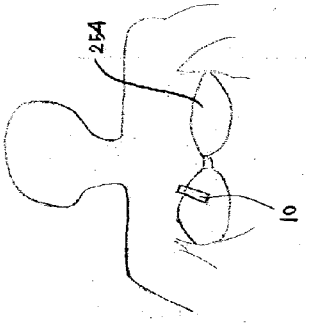


FIG. 7(c)

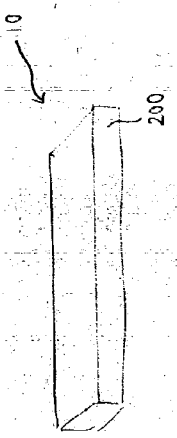


FIG. 6(a)

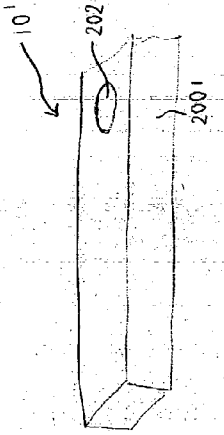
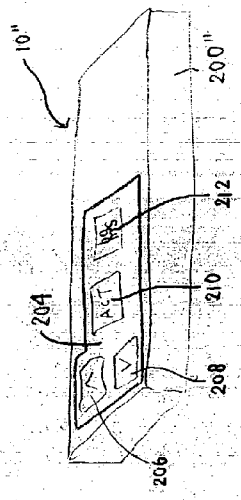


FIG. 6(b)



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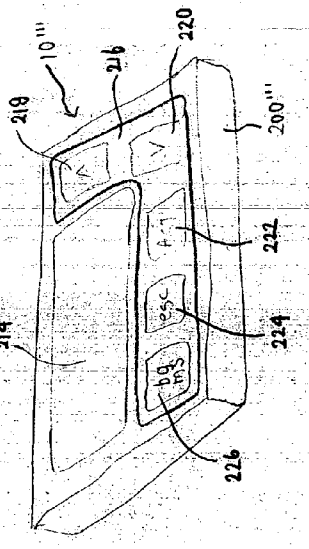


FIG. 6(d)

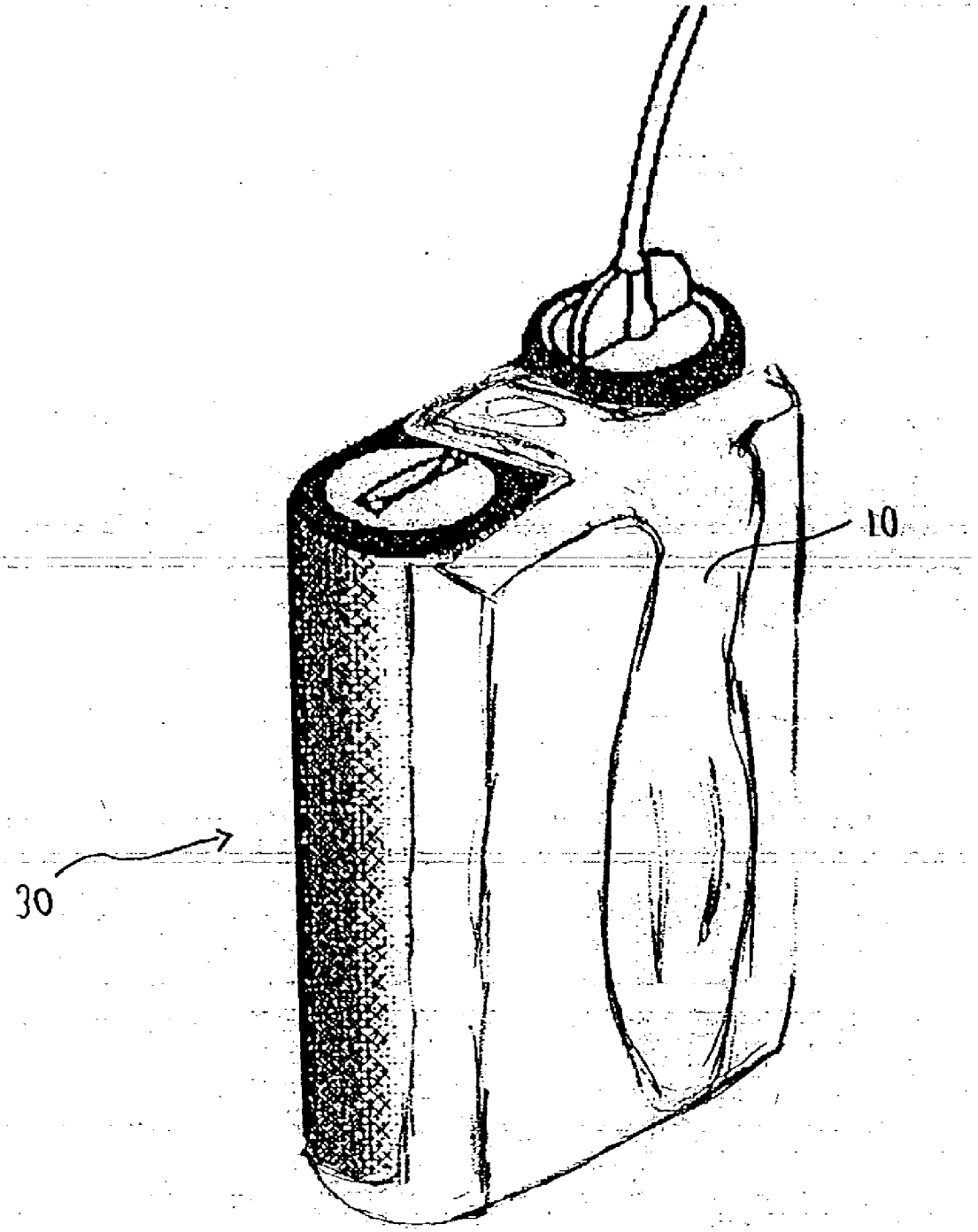


FIG. 8(a)

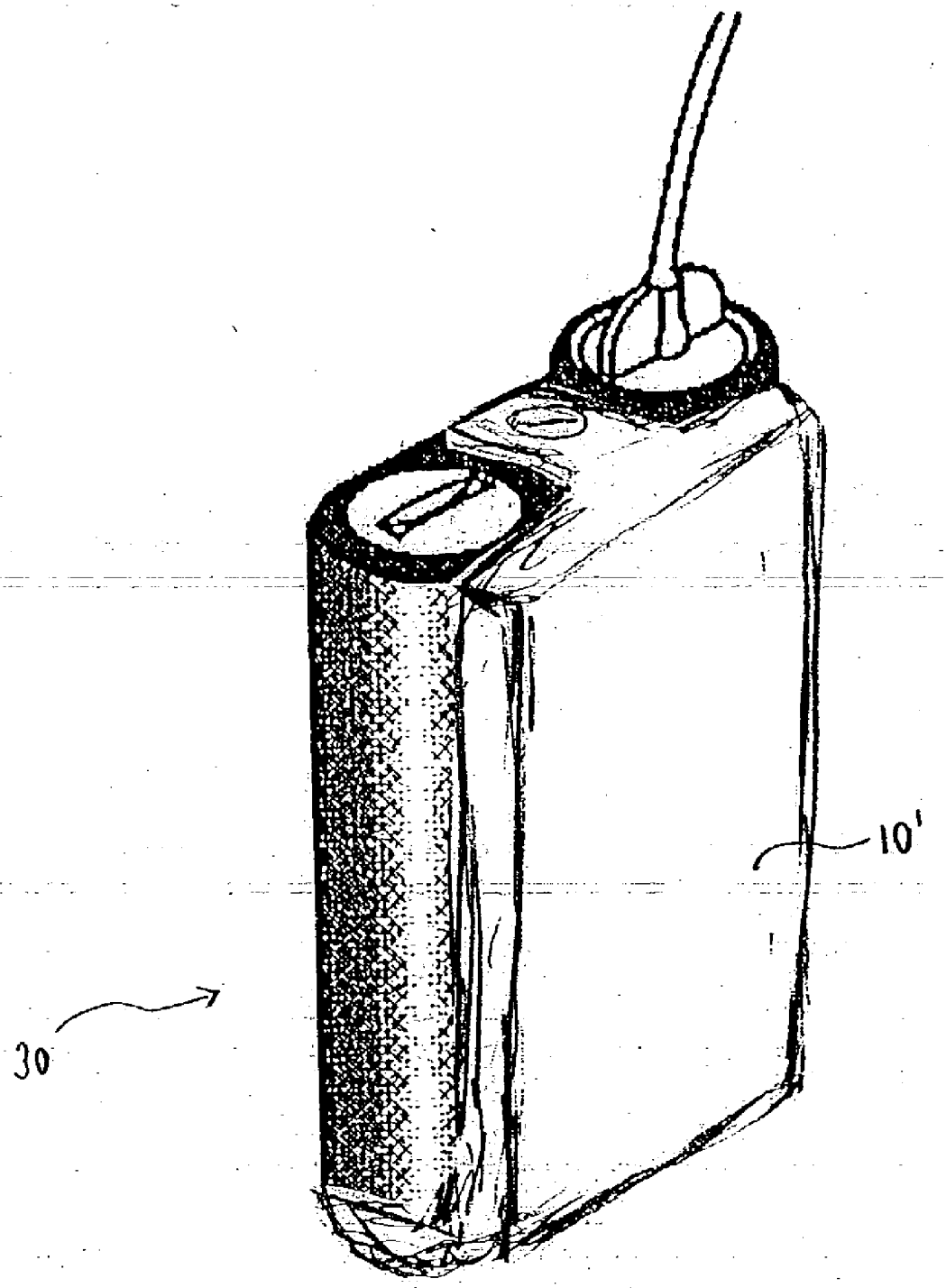


FIG. 8(b)

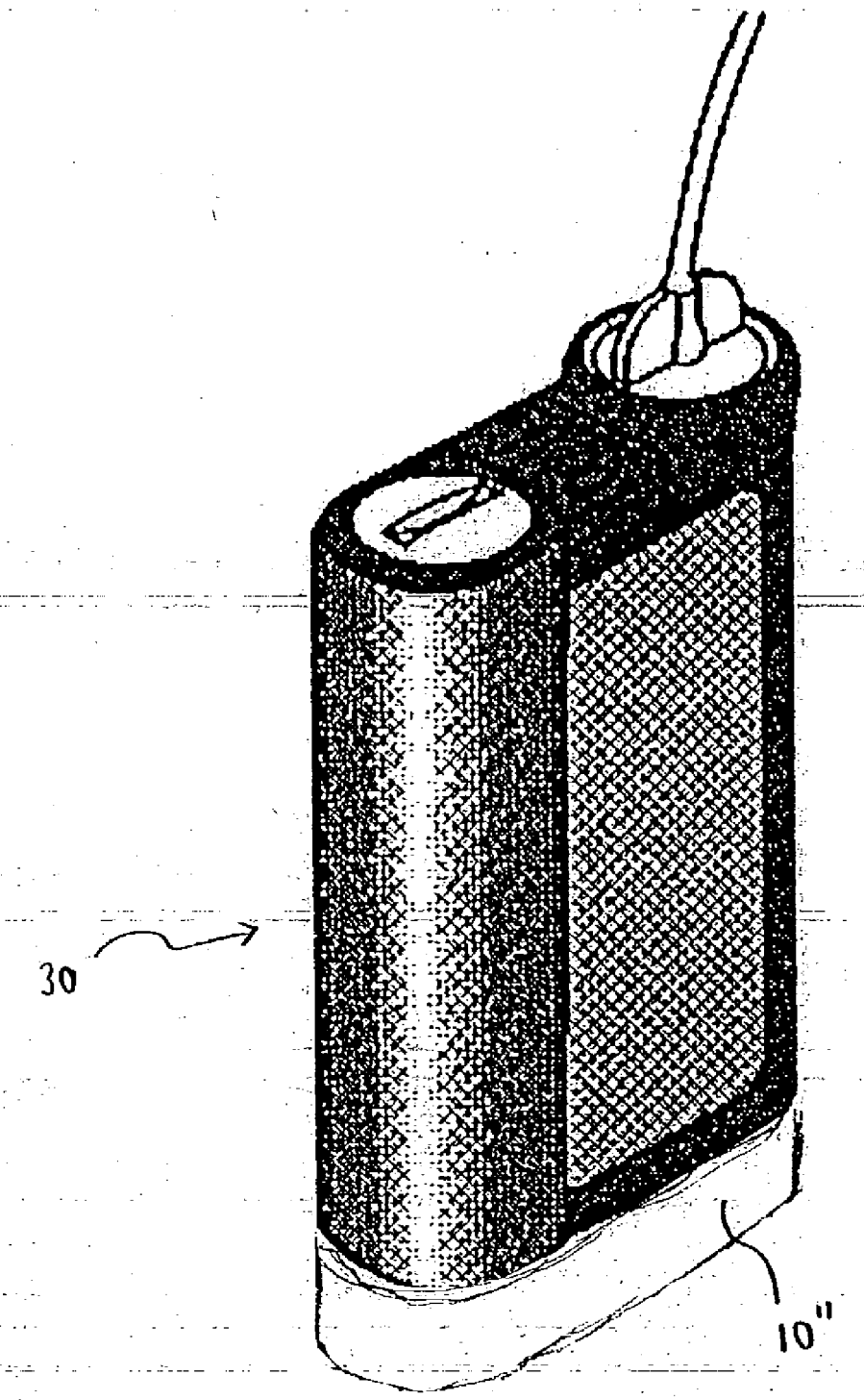


FIG. 8(c)

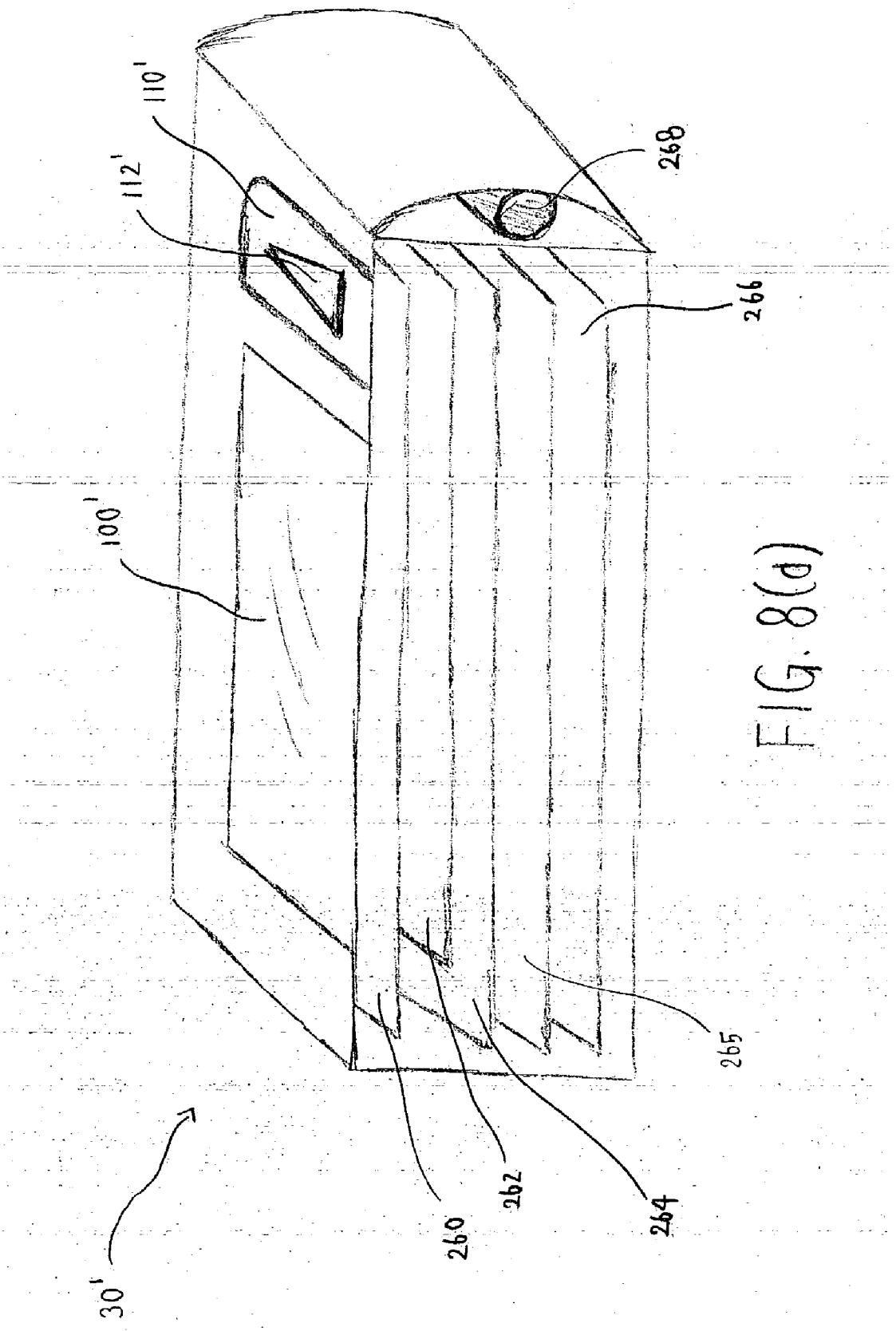


FIG. 8(d)

Fig. 9(a)

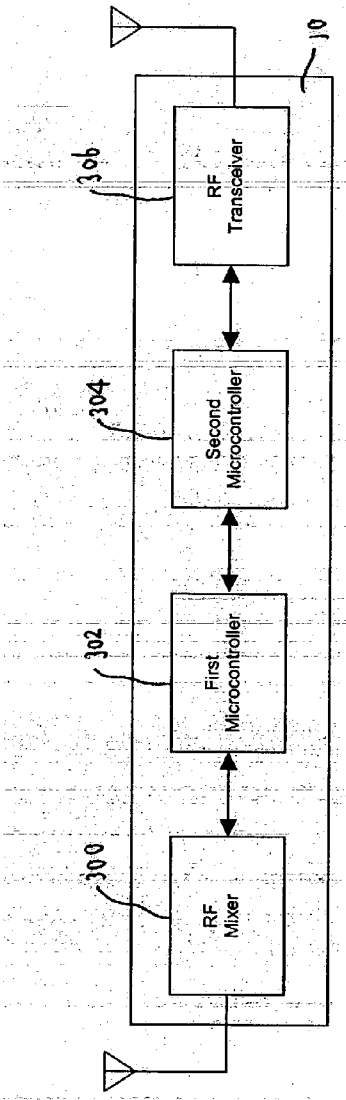


Fig. 9(b)

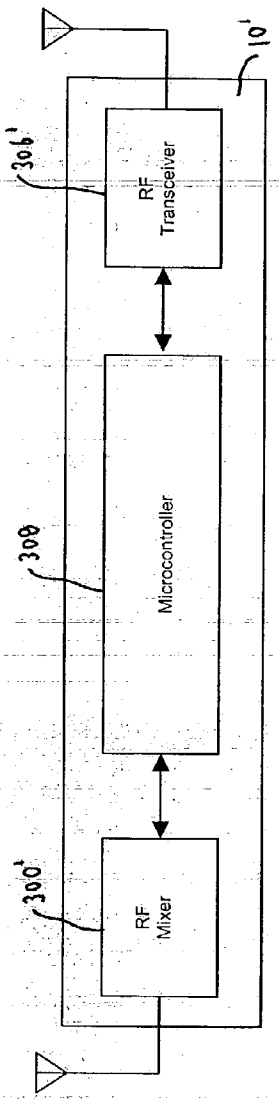


Fig. 9(c)

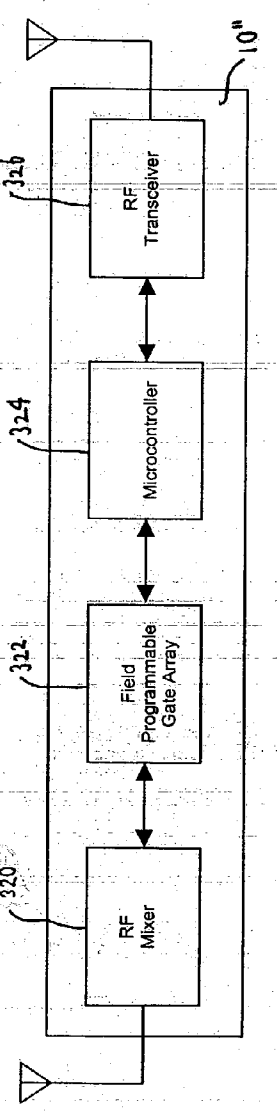


Fig. 9(d)

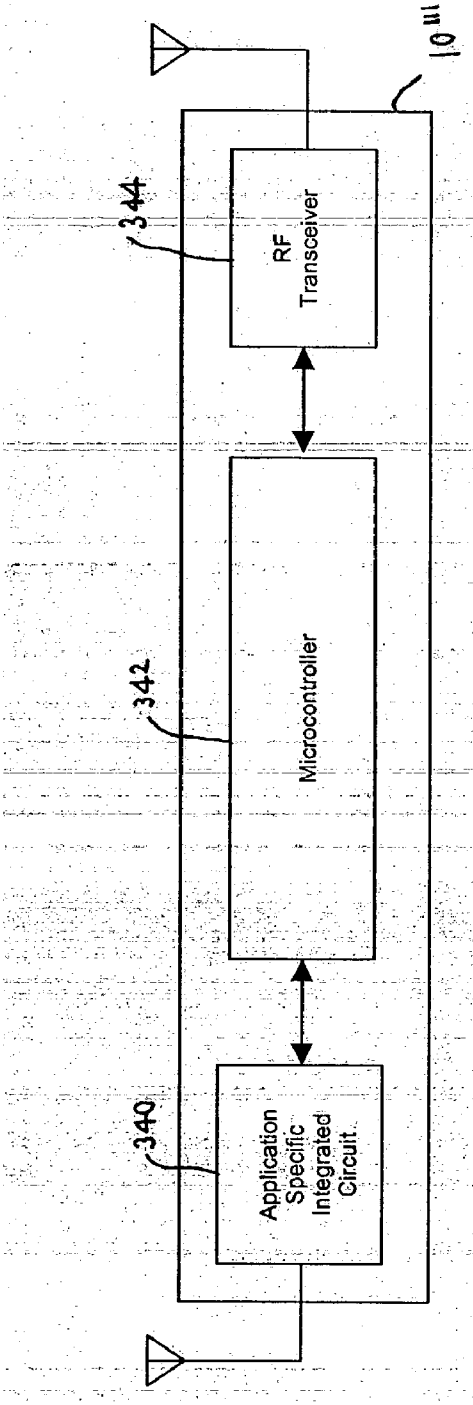
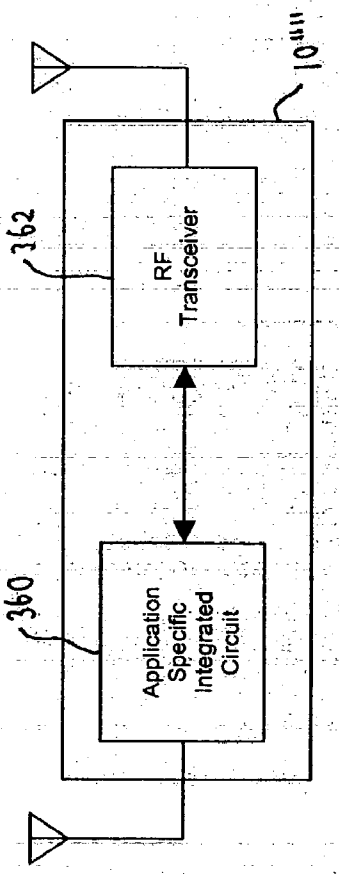

10'''
344
RF Transceiver
342
Microcontroller
340
Application Specific Integrated Circuit

Fig. 9(e)


10''''
362
RF Transceiver
360
Application Specific Integrated Circuit

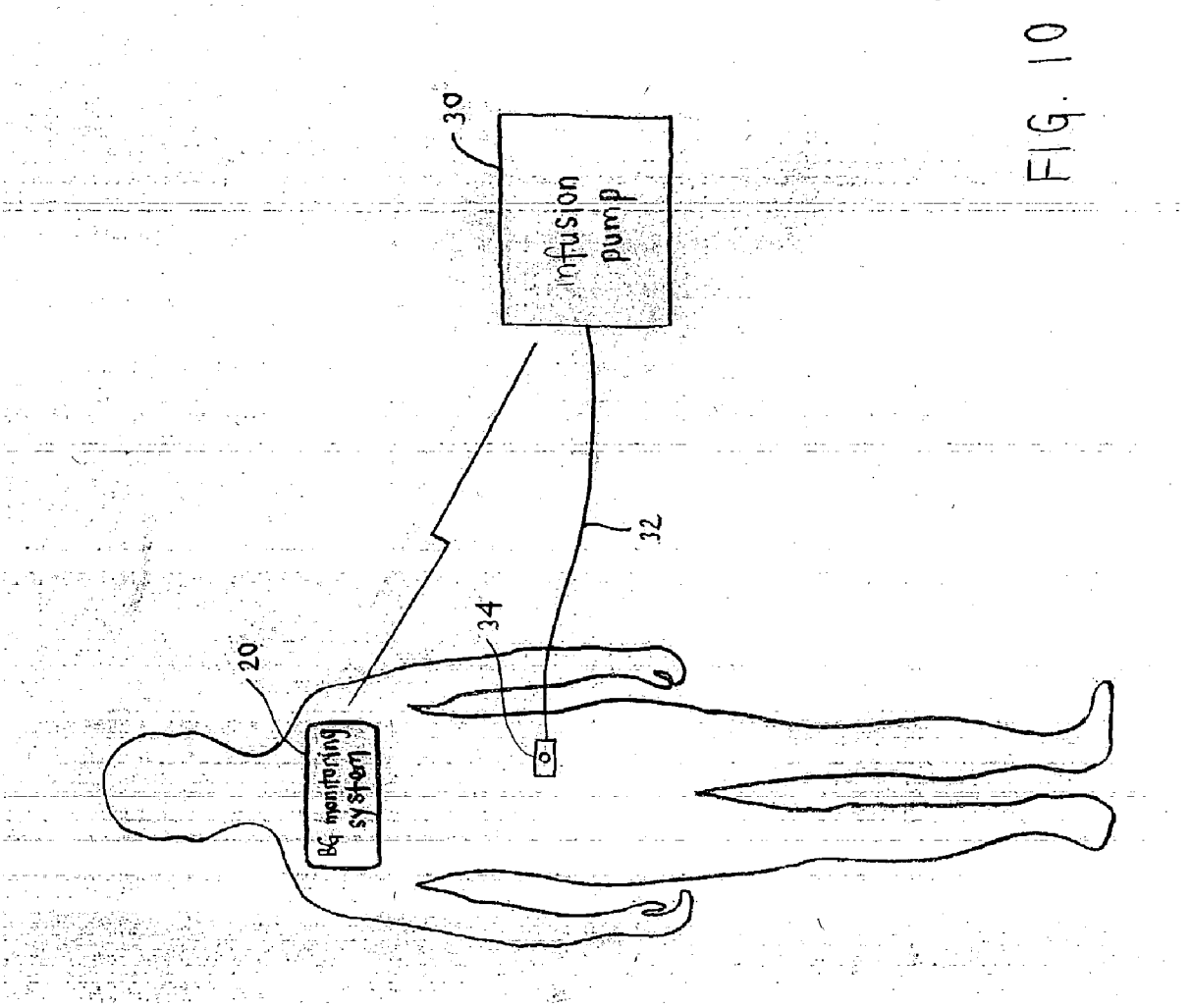


FIG. 10

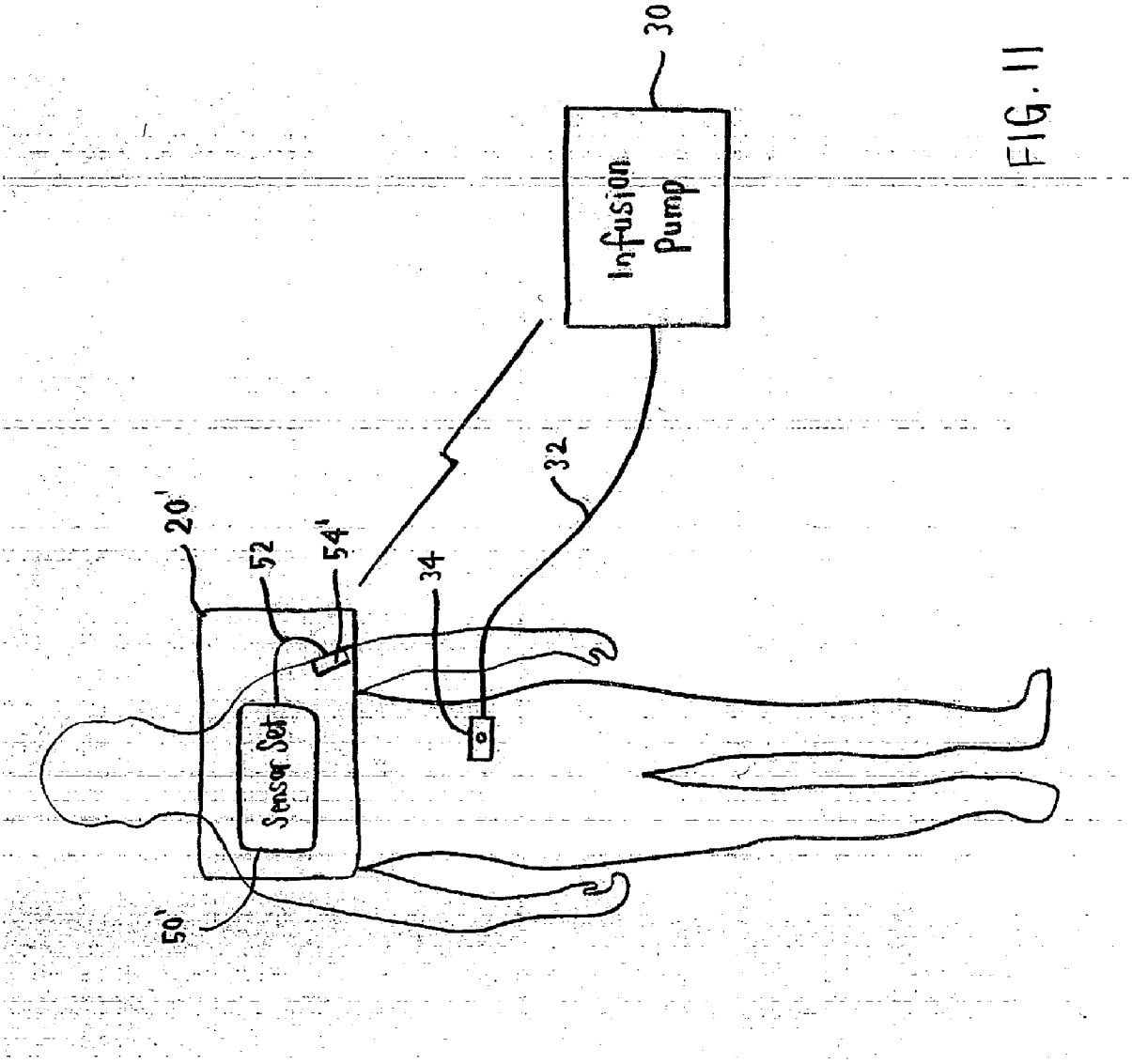
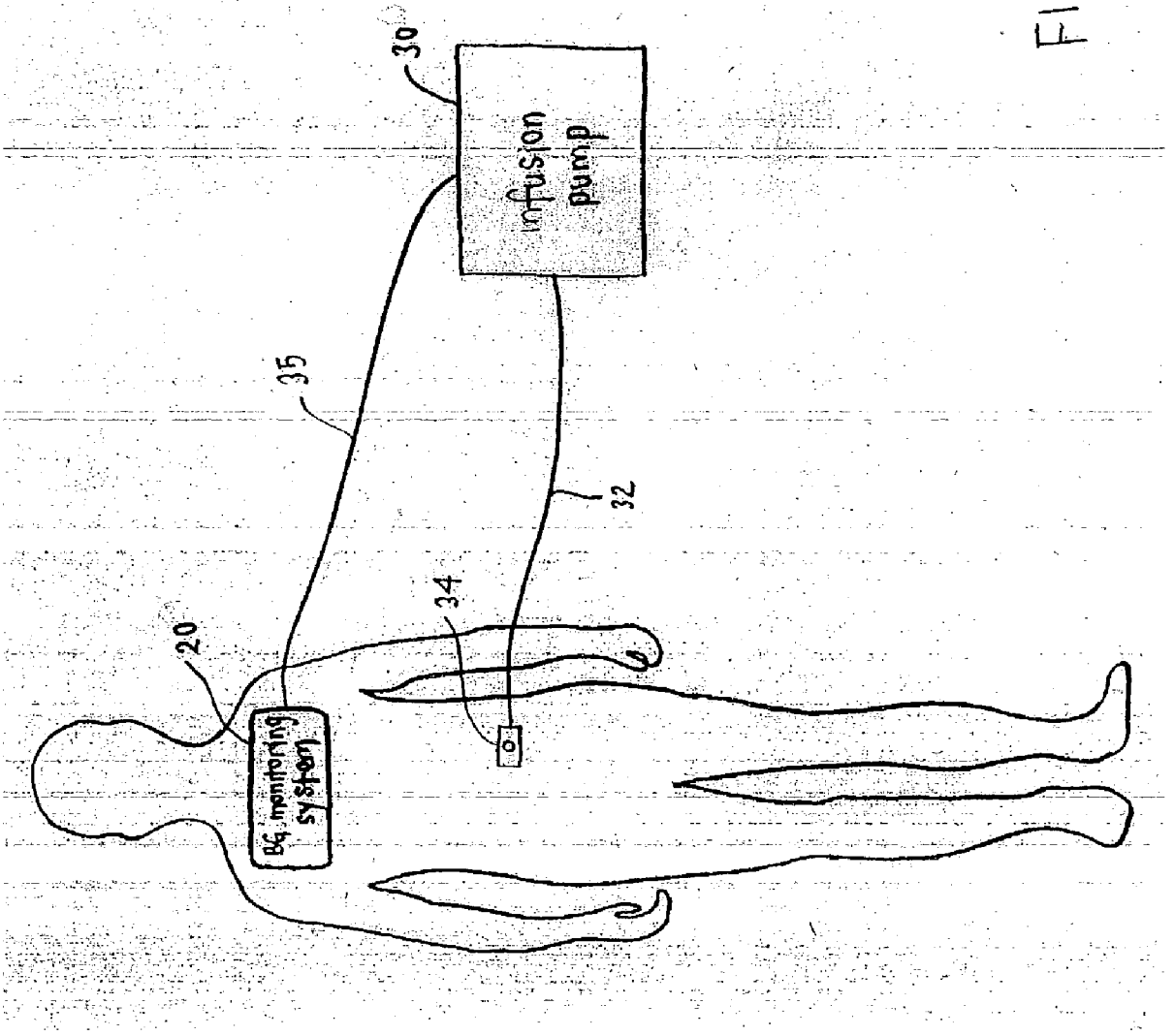


FIG. 11

FIG. 12



RELAY DEVICE FOR TRANSFERRING INFORMATION BETWEEN A SENSOR SYSTEM AND A FLUID DELIVERY SYSTEM

RELATED APPLICATIONS

[0001] This application claims priority on U.S. Provisional Patent Application filed Dec. 19, 2002 and entitled "Relay Device for Transferring Information Between a Sensor System and a Fluid Delivery System," which is herein specifically incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] Ambulatory pumps and hospital-based fluid delivery systems are used to deliver fluids into the bodies of patients. For some therapies, sensor measurements of a patient's physiological characteristics are used to calculate fluid dosage requirements. Typically, a sensor monitor is used to collect sensor data from a sensor, calibrate the sensor data to generate sensor measurements, and display the sensor measurements. Next, the patient or a caregiver manually calculates the required fluid dosage based on the displayed sensor measurements. Finally, the patient or caregiver programs the pump or fluid delivery system to adjust the fluid dosage.

[0003] For example, patients with Type 1 diabetes and some patients with Type 2 diabetes use insulin to control their blood glucose (BG) level. Typically, if a patient's BG level is too high, the patient can inject a "bolus" (dose) of insulin to lower his/her BG level from its present level to a desired target level. Furthermore, the patient may inject a bolus of insulin in anticipation of ingesting carbohydrates, thus heading off a sharp rise in his/her BG level. Presently, a patient or caregiver must measure the patient's blood glucose using a BG monitoring system, such as a continuous glucose measurement system, a test strip meter, a hospital-based measurement system, or an automated intermittent blood glucose measurement system. When the BG monitoring system has generated a BG measurement, the BG measurement is displayed on the BG monitoring system. Next, the patient or caregiver must visually read and then utilize the BG measurement to manually calculate a required insulin bolus (i.e., the amount of insulin to inject). Finally, once the required insulin bolus is calculated, the patient or caregiver must utilize an insulin delivery device (e.g., infusion pump, injection pen, IV meter, or the like) to deliver the insulin bolus into the patient's body.

[0004] Unfortunately, this process requires the patient or caregiver to handle several pieces of equipment, including the BG monitoring system and the insulin delivery device, which may discourage the patient or caregiver from using the BG measurements to adjust the insulin dosage, and thus, decrease the efficacy of the insulin delivery device. Additionally, if the BG monitoring system and the insulin delivery device are not developed in conjunction with one another, they typically communicate using different frequencies and/or modes of communication, and as a result, cannot communicate directly with one another. Thus, the patient or caregiver must manually calculate the required insulin bolus and program the insulin delivery device accordingly, which requires effort by the patient or caregiver and is subject to calculation errors. Alternatively, the patient or caregiver must manually enter the BG measurement into an electronic computing device with bolus estimation software for calculating the required insulin bolus (e.g., a computer, the Internet, a personal digital assistant (PDA), or an insulin delivery device, such as an infusion pump, injection pen, IV meter, or the like), which also requires effort by the patient or caregiver and is subject to transcription errors. For example, the patient or caregiver may not accurately enter the BG measurement that is displayed on the BG measurement device into the electronic computing device, and thus, the resulting bolus estimate calculation may not be accurate.

SUMMARY OF THE INVENTION

[0005] It is an object of an embodiment of the present invention to provide an improved infusion system including a relay device for transferring information between a sensor system and a fluid delivery system, which obviates for practical purposes, the above mentioned limitations.

[0006] According to an embodiment of the invention, an infusion system for infusing a fluid into a user includes a sensor system, a relay device, and a delivery system. The sensor system includes a sensor system housing, a sensor coupled to the sensor system housing for producing a signal indicative of a physiological characteristic level of the user, a sensor system processor contained in the sensor system housing for processing the signal indicative of the physiological characteristic level of the user, and a sensor system transmitter contained in the sensor system housing and coupled to the sensor system processor for transmitting one or more communications in a sensor system format. The relay device includes a relay device receiver for receiving the communications from the sensor system in the sensor system format, a relay device processor for processing the communications from the sensor system and converting the communications for transmission in a delivery system format, and a relay device transmitter for transmitting the converted communications in the delivery system format. The fluid delivery system includes a delivery system housing, a delivery system receiver contained in the delivery system housing for receiving the communications from the relay device in the delivery system format, and a delivery system processor contained in the delivery system housing and coupled to the delivery system receiver for processing the communications from the relay device in the delivery system format and controlling an amount of the fluid infused into the user. Further, the amount of the fluid infused into the user is determined based upon data indicative of the physiological characteristic level of the user.

[0007] In particular embodiments, at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user. Additionally, the communications including the data indicative of the physiological characteristic level of the user may be automatically transmitted from the sensor system through the relay device and received by the fluid delivery system. Further, the fluid delivery system may also include a display device contained in the delivery system housing and coupled to the delivery system processor for automatically displaying to the user the data indicative of the physiological characteristic level of the user. Alternatively, the fluid delivery system may further include a display device contained in the delivery system housing and coupled to the delivery system processor for displaying

data to the user, and a user interface contained in the housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs may cause the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system. Also, the user interface may be dedicated for interfacing with the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0008] In other particular embodiments, the fluid delivery system includes a memory contained in the delivery system housing for storing the data indicative of the physiological characteristic level of the user received by the fluid delivery system. Also, the fluid delivery system may include a display device contained in the housing and coupled to the delivery system processor for displaying to the user a historical trend or graph using the stored data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0009] In still other particular embodiments, the fluid delivery system may include a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user, and a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs may cause the display device to display the most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system. Also, at least a portion of the user interface may be dedicated for interfacing with the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0010] In yet other particular embodiments, the fluid delivery system includes a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user, and a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system. Further, at least a portion of the user interface may be dedicated for interfacing with the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0011] In still other embodiments, the fluid delivery system includes a user interface for accepting one or more inputs from the user, and the user interface is contained in the delivery system housing and coupled to the delivery system processor. At least one of the inputs programs the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system. In yet other embodiments, the fluid delivery system includes a bolus estimator used in conjunction with the delivery system processor for estimating the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system, an indication device coupled to the bolus estimator for indicating the estimated amount of fluid to be infused into the user, and a user interface for accepting one or more inputs from the user. At least one of the inputs accepts or modifies the estimated amount of the fluid to be infused into the user. In additional embodiments, the fluid delivery system includes a closed loop algorithm executed by the delivery system processor for automatically determining the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system and causing the fluid delivery system to infuse the determined amount of the fluid into the user. In further embodiments, the fluid delivery system includes an indication device for indicating when the data indicative of the physiological characteristic level of the user received by the fluid delivery system is above or below a target characteristic value.

[0012] In still additional embodiments, the fluid delivery system includes a delivery system transmitter contained in the delivery system housing and coupled to the delivery system processor for transmitting one or more communications in the delivery system format. The relay device receiver further receives the communications from the fluid delivery system in the delivery system format, the relay device processor processes the communications from the fluid delivery system and converts the communications for transmission in the sensor system format, and the relay device transmitter transmits the converted communications in the sensor system format. Also, the sensor system further includes a sensor system receiver coupled to the sensor system processor for receiving the communications from the relay device in the sensor system format.

[0013] In still further embodiments, the fluid delivery system includes a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user, and a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs generates a request for the data indicative of the physiological characteristic level of the user from the sensor system, at least one of the communications transmitted from the fluid delivery system through the relay device to the sensor system includes the request, and at least one of the communications including the data indicative of the physiological characteristic level of the user is transmitted from the sensor system through the relay device and received by the delivery system in response to the request. The display device then displays the data indicative of the physiological characteristic level of the user received by the fluid delivery system. Additionally, the user interface may be dedicated for interfacing from the fluid delivery system with the sensor system through the relay device. Also, the requested data is the most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0014] In yet other embodiments, the data indicative of the physiological characteristic level of the user received by the fluid delivery system is uncalibrated data. The fluid delivery system includes a calibration algorithm executed by the delivery system processor for calibrating the uncalibrated data to generate one or more measurements indicative of the physiological characteristic level of the user.

[0015] In alternative embodiments, the data indicative of the physiological characteristic level of the user received by the fluid delivery system includes one or more calibrated measurements indicative of the physiological characteristic

level of the user. In particular alternative embodiments, the sensor system includes a calibration algorithm executed by the sensor system processor for calibrating the signal indicative of the physiological characteristic level of the user to generate the one or more measurements indicative of the physiological characteristic level of the user, and the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the one or more measurements indicative of the physiological characteristic level of the user. In other particular alternative embodiments, the data indicative of the physiological characteristic level of the user received from the sensor system by the relay device is uncalibrated data. The relay device includes a calibration algorithm executed by the relay device processor for calibrating the uncalibrated data to generate one or more measurements indicative of the physiological characteristic level of the user, and the communications transmitted from the relay device and received by the fluid delivery system include the one or more measurements indicative of the physiological characteristic level of the user.

[0016] In additional alternative embodiments, at least one of the communications transmitted from the sensor system through the relay device and received by the delivery system includes one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user. In some embodiments, the sensor system includes a display device coupled to the sensor system processor for displaying data to the user, and a user interface coupled to the sensor system processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user obtained by the sensor system. Also, at least another one of the inputs generates the one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system. In other embodiments, the sensor system includes a closed loop algorithm executed by the sensor system processor for automatically generating the one or more commands for programming the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system.

[0017] In further alternative embodiments, at least one of the communications transmitted from the sensor system to the relay device includes the data indicative of the physiological characteristic level of the user, and at least one of the communications transmitted from the relay device and received by the fluid delivery system includes one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user. In particular embodiments, the relay device includes a display device coupled to the relay device processor for displaying data to the user, and a user interface coupled to the relay device processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user obtained by the sensor system. Also, at least another one of the inputs generates the one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system. In other particular embodiments, the relay device further includes a closed loop algorithm executed by the relay device processor for automatically generating the one or more commands for programming the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system.

[0018] In yet additional embodiments, the sensor system format and the delivery system format utilize different frequencies for communications transmitted from the sensor system through the relay device and received by the fluid delivery system. In some embodiments, the sensor system format and the delivery system format utilize different communication protocols for communications transmitted from the sensor system through the relay device and received by the fluid delivery system. The communication protocols may utilize different carrier media and/or information packaging for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

[0019] In particular embodiments, the delivery system processor has a unique identification code, and the sensor system processor has the capability to learn the unique identification code of the delivery system processor. Further, the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the delivery system processor to substantially avoid interference with other devices. In other particular embodiments, the sensor system processor has a unique identification code, and the delivery system processor has the capability to learn the unique identification code of the sensor system processor. Further, the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the sensor system processor to substantially avoid interference with other devices. In still other particular embodiments, the relay device processor has a unique identification code, and the sensor system processor has the capability to learn the unique identification code of the relay device processor. Also, the communications transmitted from the sensor system to the relay device include the unique identification code of the relay device processor to substantially avoid interference with other devices. In yet other particular embodiments, the relay device processor has a unique identification code, and the delivery system processor has the capability to learn the unique identification code of the relay device processor. Also, the communications transmitted from the relay device and received by the fluid delivery system include the unique identification code of the relay device processor to substantially avoid interference with other devices.

[0020] In additional embodiments, the relay device is coupled to the delivery system housing. In other embodiments, the relay device is contained in the delivery system housing. In still other embodiments, the relay device is coupled to the sensor system housing. In further embodiments, the sensor system is a glucose monitoring system, and the fluid delivery system is an insulin infusion device.

[0021] In another embodiment of the present invention, a relay device transfers information between a sensor system

and a fluid delivery system. The sensor system measures a physiological characteristic level of a user, and the fluid delivery system infuses a fluid into the user. The relay device includes a sensor system receiver for receiving one or more communications from the sensor system in a sensor system format, a processor for processing the communications from the sensor system and converting the communications for transmission in a delivery system format, and a delivery system transmitter for transmitting the converted communications in the delivery system format to the fluid delivery system.

[0022] In some embodiments, the relay device includes a delivery system receiver for receiving one or more communications from the fluid delivery system in the delivery system format. The processor further processes the communications from the fluid delivery system and converts the communications for transmission in the sensor system format. The relay device also includes a sensor system transmitter for transmitting the converted communications in the sensor system format to the sensor system. In other embodiments, at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user. In yet other embodiments, at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include one or more commands for programming an amount of the fluid to be infused into the user based upon data indicative of the physiological characteristic level of the user obtained by the sensor system.

[0023] In further embodiments, at least one of the communications transmitted from the sensor system to the relay device include data indicative of the physiological characteristic level of the user, and at least one of the communications transmitted from the relay device and received by the fluid delivery system include one or more commands for programming an amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user. Additionally, the relay device may include a display device coupled to the processor for displaying data to the user, and a user interface coupled to the processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user. Also, at least another one of the inputs generates the one or more commands for programming the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user.

[0024] In still other embodiments, the sensor system format and the delivery system format utilize different frequencies for communications transmitted from the sensor system through the relay device to the fluid delivery system. In yet other embodiments, the sensor system format and the delivery system format utilize different communication protocols for communications transmitted from the sensor system through the relay device to the fluid delivery system. The communication protocols may utilize different carrier media and/or information packaging for communications transmitted from the sensor system through the relay device to the fluid delivery system.

[0025] In yet another embodiment of the present invention, a relay device transfers information between a sensor system and a fluid delivery system. The sensor system measures a physiological characteristic level of a user, and the fluid delivery system infuses a fluid into the user. The relay device includes a sensor system transceiver for transmitting and receiving one or more communications to and from the sensor system. The communications are transmitted and received in a sensor system format. The relay device also includes a delivery system transceiver for transmitting and receiving one or more communications to and from the fluid delivery system. The communications are transmitted and received in a delivery system format. The relay device further includes a processor for processing the communications from the sensor system and the fluid delivery system. The processor converts the communications received from the sensor system in the sensor system format for transmission in the delivery system format to the fluid delivery system, and further converts the communications received from the fluid delivery system in the delivery system format for transmission in the sensor system format to the sensor system.

[0026] In particular embodiments, at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user. In other particular embodiments, at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include one or more commands for programming an amount of the fluid to be infused into the user based upon data indicative of the physiological characteristic level of the user obtained by the sensor system.

[0027] In additional embodiments, at least one of the communications transmitted from the sensor system to the relay device include data indicative of the physiological characteristic level of the user, and at least one of the communications transmitted from the relay device and received by the fluid delivery system include one or more commands for programming an amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user. Also, the relay device may include a display device coupled to the processor for displaying data to the user, and a user interface coupled to the processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user. Additionally, at least another one of the inputs generates the one or more commands for programming the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user.

[0028] In further embodiments, the sensor system format and the delivery system format utilize different frequencies for communications transmitted between the sensor system and the fluid delivery system through the relay device. In additional embodiments, the sensor system format and the delivery system format utilize different communication protocols for communications transmitted between the sensor system and the fluid delivery system through the relay device. The communication protocols may utilize different carrier media and/or information packaging for communi-

cations transmitted between the sensor system and the fluid delivery system through the relay device.

[0029] In still another embodiment of the present invention, an infusion system for infusing a fluid into a user includes a sensor system and a fluid delivery system. The sensor system includes a sensor for producing a signal indicative of a physiological characteristic level of the user, a sensor system processor coupled to the sensor for processing the signal indicative of the physiological characteristic level of the user, and a sensor system transmitter coupled to the sensor system processor for transmitting one or more communications in a sensor system format. The fluid delivery system includes a delivery system housing, a relay device contained in the delivery system housing, a delivery system receiver, and a delivery system processor. The relay device includes a relay device receiver for receiving the communications from the sensor system in the sensor system format, a relay device processor for processing the communications from the sensor system and converting the communications for transmission in a delivery system format, and a relay device transmitter for transmitting the converted communications in the delivery system format. The delivery system receiver is contained in the delivery system housing and receives the communications from the relay device in the delivery system format. The delivery system processor is also contained in the delivery system housing and is coupled to the delivery system receiver, and processes the communications from the relay device in the delivery system format and controls an amount of the fluid infused into the user. The amount of the fluid infused into the user is determined based upon data indicative of the physiological characteristic level of the user obtained by the sensor system.

[0030] In particular embodiments, at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user. Additionally, the communications including the data indicative of the physiological characteristic level of the user may be automatically transmitted from the sensor system through the relay device and received by the fluid delivery system. Further, the fluid delivery system may also include a display device contained in the delivery system housing and coupled to the delivery system processor for automatically displaying to the user the data indicative of the physiological characteristic level of the user.

[0031] In other particular embodiments, the fluid delivery system includes a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user, and a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0032] In still other embodiments, the fluid delivery system includes a memory contained in the delivery system housing for storing the data indicative of the physiological characteristic level of the user received by the fluid delivery system. Additionally, the fluid delivery system may include a display device contained in the delivery system housing and coupled to the delivery system processor for displaying to the user a historical trend or graph using the stored data indicative of the physiological characteristic level of the user received by the fluid delivery system. Alternatively, the fluid delivery system may include a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user, and a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0033] In additional embodiments, the fluid delivery system includes a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user, and a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system. In further embodiments, the fluid delivery system includes a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user. At least one of the inputs programs the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

[0034] In yet other embodiments, the fluid delivery system includes a bolus estimator used in conjunction with the delivery system processor for estimating the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system, an indication device coupled to the bolus estimator for indicating the estimated amount of fluid to be infused into the user, and a user interface for accepting one or more inputs from the user. At least one of the inputs accepts or modifies the estimated amount of the fluid to be infused into the user. In still further embodiments, the fluid delivery system includes a closed loop algorithm executed by the delivery system processor for automatically determining the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system and causing the fluid delivery system to infuse the determined amount of the fluid into the user. In still additional embodiments, the fluid delivery system includes an indication device for indicating when the data indicative of the physiological characteristic level of the user received by the fluid delivery system is above or below a target characteristic value. In even additional embodiments, the data indicative of the physiological characteristic level of the user received by the fluid delivery system is uncalibrated data, and the fluid delivery system further includes a calibration algorithm executed by the delivery system processor for calibrating the uncalibrated data to generate one or more measurements indicative of the physiological characteristic level of the user.

[0035] In some embodiments, the sensor system format and the delivery system format utilize different frequencies for communications transmitted from the sensor system

through the relay device and received by the fluid delivery system. In other embodiments, the sensor system format and the delivery system format utilize different communication protocols for communications transmitted from the sensor system through the relay device and received by the fluid delivery system. The different communication protocols may utilize different carrier media and/or information packaging for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

[0036] In yet further embodiments, the delivery system processor has a unique identification code, and the sensor system processor has the capability to learn the unique identification code of the delivery system processor. The communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the delivery system processor to substantially avoid interference with other devices. In yet additional embodiments, the sensor system processor has a unique identification code, and the delivery system processor has the capability to learn the unique identification code of the sensor system processor. The communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the sensor system processor to substantially avoid interference with other devices. Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, various features of embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

[0038] **FIG. 1** is a block diagram of a system for transferring information between a blood glucose monitoring system and an infusion pump through a relay device in accordance with an embodiment of the present invention.

[0039] **FIG. 2**(*a*)-**2**(*c*) are perspective views of a blood glucose monitoring system in accordance with embodiments of the present invention.

[0040] **FIG. 3**(*a*) is a perspective view of an external infusion pump in accordance with an embodiment of the present invention.

[0041] **FIG. 3**(*b*) is a simplified block diagram of an external infusion pump in accordance with an embodiment of the present invention.

[0042] FIGS. **4**(*a*)-**5**(*f*) are block diagrams of a system for transferring information between a blood glucose monitoring system and an infusion pump through a relay device in accordance with embodiments of the present invention.

[0043] FIGS. **6**(*a*)-**6**(*d*) are perspective views of a relay device in accordance with embodiments of the present invention.

[0044] FIGS. **7**(*a*)-**7**(*c*) are perspective views of a relay device placed on a body of a user in accordance with embodiments of the present invention.

[0045] FIGS. **8**(*a*)-**8**(*c*) are perspective views of a relay device placed on an infusion pump in accordance with embodiments of the present invention.

[0046] **FIG. 8**(*d*) is a cut-away perspective view of an infusion pump with a relay device included in the infusion pump in accordance with another embodiment of the present invention.

[0047] FIGS. **9**(*a*)-**9**(*e*) are block diagrams of a relay device in accordance with embodiments of the present invention.

[0048] **FIG. 10** is a block diagram of a system for transferring information between a blood glucose monitoring system and an infusion pump using a relay device incorporated into the infusion pump in accordance with another embodiment of the present invention.

[0049] **FIG. 11** is a block diagram of a system for transferring information between a blood glucose monitoring system and an infusion pump using a relay device incorporated into the infusion pump in accordance with yet another embodiment of the present invention.

[0050] **FIG. 12** is a block diagram of a system for transferring information between a blood glucose monitoring system and an infusion pump using a relay device incorporated into the infusion pump in accordance with still another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0051] As shown in the drawings for purposes of illustration, the invention is embodied in a relay device for transferring information between a sensor system for measuring a physiological characteristic level of a user's body and a fluid delivery system for delivering fluid into the user's body. The relay device receives information from one system in a first format, converts the information into a second format appropriate for the other system, and then transmits the converted information to the other system. Therefore, the relay device enables communication between the sensor system and the fluid delivery system, even if the systems are not developed in conjunction with one another. For example, sensor data or measurements may be communicated from the sensor system via the relay device to the fluid delivery system, and then utilized to adjust the amount of fluid delivered by the fluid delivery system into the user's body. Thus, the relay device encourages the user or caregiver to utilize the sensor data or measurements in order to adjust the amount of fluid delivered into the user's body by the fluid delivery system. Further, the sensor measurements may be displayed on the fluid delivery system for the user or caregiver to see. Therefore, the relay device allows the user or caregiver to interface with the sensor system (e.g., view the sensor measurements) utilizing a single device, the fluid delivery system. Particular embodiments are directed toward use of ambulatory sensor and fluid delivery systems that are programmed and adjusted primarily by the user or a caregiver, such as the user's parent. Other embodiments are directed toward use of hospital-based sensor and fluid delivery systems that are programmed and adjusted primarily by a caregiver, such as the user's physician or nurse.

[0052] In preferred embodiments, the sensor system is a blood glucose (BG) monitoring system, which utilizes a

sensor placed in a user to automatically measure the user's BG level, either periodically or continuously. In particular embodiments, the sensor may measure additional physiological characteristic levels of the user, such as blood oxygen, temperature, and the like. The sensor may be implanted in and/or through subcutaneous, dermal, sub-dermal, inter-peritoneal, or peritoneal tissue, and may be a sensor in contact with the user's body fluid, such as the user's blood, interstitial fluid, and the like. In preferred embodiments, the fluid delivery system is an insulin delivery device, such as an external insulin infusion pump, which regulates the amount of insulin delivered into the user's body. The relay device receives information from one system in a first format, converts the information into a second format appropriate for the other system, and then transmits the converted information to the other system. For example, the relay device may receive BG data or measurements from the BG monitoring system in a sensor system format (e.g., at a frequency of 131 kilohertz, utilizing radio frequency (RF) carrier media, in packets of 107 bytes), convert such data or measurements into a delivery system format appropriate for the insulin infusion pump (e.g., to a frequency of 916 megahertz, utilizing infrared (IR) carrier media, in packets of 71 bytes), and then transmit such converted data or measurements to the insulin infusion pump. The amount of insulin delivered into the user's body by the infusion pump may then be adjusted, either manually by the user or a caregiver or automatically, in response to the received BG data or measurements. In some embodiments, the BG measurements may also be displayed on the insulin infusion pump.

[**0053**] However, in alternative embodiments of the present invention, the sensor system may include other types of sensors, such as optical, enzymatic, fluorescent, or the like. In additional alternative embodiments, the sensor system may measure the user's BG level only when requested by the user, or a BG meter may be utilized to measure the user's BG level based on a sampling of the user's blood. In further alternative embodiments, the sensor system may measure other physiological characteristic levels of the user, such as heart rate, blood oxygen, pH, peroxide, respiratory rate, body temperature, blood pressure, perspiration, brain wave activity, cholesterol level, ketone level, medication concentration, viral load (e.g., HIV), and the like. The sensor system may also include multiple sensors—one or more sensors to measure the user's BG level and one or more sensors to measure such other physiological characteristic levels of the user. In other alternative embodiments, the sensor system may measure the physiological characteristic levels of the user from body fluids other than blood, such as interstitial fluid, spinal fluid, saliva, urine, tears, sweat, or the like. In still other alternative embodiments, the fluid delivery system may be an implantable infusion pump, an infusion pump that uses a combination of implantable and external components, a pen injector, a disposable pump, an intra venous drip system, or the like. In yet other alternative embodiments, the fluid delivery system may deliver fluids other than insulin, including peptides, proteins, sugars, vitamins, antigens, hormones, steroids, medicaments, drugs, pain killers, anti-cancer agents, anti-coagulants, stimulants, tranquilizers, sedatives, and the like. Particular embodiments are directed towards use in humans; however, alternative embodiments may be used in animals.

[**0054**] In preferred embodiments of the present invention, a relay device transfers information between a sensor system for measuring a physiological characteristic level of a user's body and a fluid delivery system for delivering fluid into the user's body. In the embodiment illustrated in **FIG. 1**, the sensor system is a BG monitoring system **20**, which utilizes a sensor that is placed in a user to measure the user's BG level. The sensor may measure additional physiological characteristic levels of the user, such as blood oxygen, temperature, or the like.

[**0055**] In particular embodiments, the BG monitoring system **20** is an implantable glucose monitoring system, and is generally of the type described in U.S. Pat. No. 6,368,274, and disclosed in U.S. patent application Ser. No. 10/034,740, filed Dec. 27, 2001 and entitled "Implantable Sensor Flush Sleeve," and U.S. Provisional Patent Application filed Sep. 27, 2002 and entitled "Implantable Sensor Method and System," which are herein incorporated by reference. Referring to **FIG. 2**(*a*), the BG monitoring system **20** includes a glucose sensor set **50** and a glucose monitor **54**. The sensor set **50** and glucose monitor **54** are implanted in the user's sub-dermal or inter-peritoneal tissue, and are in contact with the user's blood or other body fluid, to measure the user's BG level. For example, the sensor set **50** may be implanted into the central vein of the user's heart, and the glucose monitor **54** may be located in the user's chest cavity. Alternatively, the sensor set **50** may be placed in the user's peritoneum, and the glucose monitor **54** may be located in the user's abdominal cavity. The glucose monitor **54** includes a processor (not shown) for processing data as it is received from the sensor set **50**, and a transmitter and/or receiver (not shown) for transferring the data to and/or from a data processor, such as a dedicated processor **56** designed specifically to work with the glucose monitor **54**, a computer, communication station, or the like. The data processor **56** preferably comprises a relatively compact, portable housing that may be easily worn on clothing or jewelry, placed in a pocket, concealed under clothing, or the like. However, the BG monitoring system **20** may also be included in a hospital-based system, and the data processor **56** may comprise a housing that may be included in a monitor, placed on an intravenous (IV) pole, or the like near the patient's bed.

[**0056**] In other particular embodiments, the BG monitoring system **20** is a telemetered glucose monitoring system, and may generally be of the type described in U.S. patent application Ser. No. 09/377,472, filed Aug. 19, 1999 and entitled "Telemetered Characteristic Monitor System and Method of Using the Same," which is herein incorporated by reference. The BG monitoring system **20** may also be a vascular glucose monitoring system, and may generally be of the type described in U.S. patent application Ser. No. 10/036,93, filed Dec. 28, 2001 and entitled "Sensing Apparatus and Process," and U.S. Provisional Patent Application filed Sep. 27, 2002 and entitled "Multilumen Catheter," which are herein incorporated by reference. Referring to **FIG. 2**(*b*), the BG monitoring system **20'** may include a glucose sensor set **50'** and a glucose monitor **54'**. The sensor set **50'** includes a glucose sensor that is placed in and/or through the user's subcutaneous, dermal, sub-dermal, inter-peritoneal, peritoneal, muscle, lymph, or organ tissue, veins, arteries, or the like, and may be in contact with the user's blood or other body fluid, to measure the user's BG level. The sensor set **50'** is connected to the glucose monitor **54'** via a cable **52**, and the glucose monitor **54'** includes a processor

(not shown) for processing data as it is received from the sensor set **50'** via the cable **52**. For example, the sensor set **50'** may be placed in the user's subcutaneous tissue, and the glucose monitor **54'** may be adhered to the user's body. Alternatively, the sensor set **50'** may be inserted into one lumen of a multilumen catheter, which may then be implanted in the central vein of the user's heart and include an extension lead for connecting to the glucose monitor **54'** via the cable **52**, and the glucose monitor **54'** may be adhered to the user's body, as shown in **FIG. 11**. The other lumen(s) of the multilumen catheter may be utilized for sampling other physiological characteristic levels of the user and/or delivering fluids into the user's body, such as protein nutrition, blood products, medication, lipids, and the like. Such a multilumen catheter may generally be of the type described in U.S. Provisional Patent Application filed Sep. 27, 2002 and entitled "Multilumen Catheter," which is herein incorporated by reference.

[**0057**] The glucose monitor **54'** may also include a transmitter and/or receiver (not shown) for transferring the data to and/or from a data processor, such as a dedicated processor **56'** designed specifically to work with the glucose monitor **54'** , a computer, communication station, or the like. The data processor **56'** preferably comprises a relatively compact, portable housing that may be easily worn on clothing or jewelry, placed in a pocket, concealed under clothing, or the like. However, the BG monitoring system **20** may also be included in a hospital-based system, and the data processor **56'** may comprise a housing that may be included in a monitor, placed on an intravenous (IV) pole, or the like near the patient's bed. In alternative embodiments, the cable **52** may be omitted, and the sensor set **50'** may be directly connected to the glucose monitor **54'**.

[**0058**] In yet other particular embodiments, the BG monitoring system **20** may be a continuous glucose monitoring system, and may generally be of the type described in U.S. Pat. No. 6,424,847, which is herein incorporated by reference. Referring to **FIG. 2**(*c*), the BG monitoring system **20"** may include a glucose sensor set **50"** and a glucose monitor **5"**. The sensor set **50"** includes a glucose sensor that is placed in and/or through the user's subcutaneous, dermal, sub-dermal, inter-peritoneal, peritoneal, muscle, lymph, or organ tissue, veins, arteries, or the like, and may be in contact with the user's blood or other body fluid, to measure the user's BG level. The sensor set **50"** is connected to the glucose monitor **54"** via a cable **52'**, and the glucose monitor **54"** includes a processor (not shown) for processing data as it is received from the sensor set **50"** via the cable **52'**. The glucose monitor **54"** comprises a relatively compact, portable housing that may be easily worn on clothing or jewelry, placed in a pocket, concealed under clothing, or the like. However, the BG monitoring system **20** may also be included in a hospital-based system, and the glucose monitor **54"** may comprise a housing that may be included in a monitor, placed on an intravenous (IV) pole, or the like near the patient's bed. The glucose monitor **54"** may also include a transmitter and/or receiver (not shown) for transferring the data to and/or from a data processor (not shown), such as a computer, communication station, or the like. In alternative embodiments, the cable **52'** may be omitted, and the sensor set **50"** may be directly connected to the glucose monitor **54"**.

[**0059**] In alternative embodiments, the BG monitoring system **20** may include other types of sensors, such as optical, enzymatic, fluorescent, or the like. In further alternative embodiments, the sensor system may measure other physiological characteristic levels of the user, such as heart rate, blood oxygen, pH, peroxide, respiratory rate, body temperature, blood pressure, perspiration, brain wave activity, cholesterol level, ketone level, medication concentration, viral load (e.g., HIV), and the like. The sensor system may also include multiple sensors—one or more sensors to measure the user's BG level and one or more sensors to measure such other physiological characteristic levels of the user. For example, the BG monitoring system **20** may include a glucose sensor set **50** inserted in or on the user's body to measure the user's BG level and an oxygen sensor to measure the oxygen level at or near the insertion site of the sensor set **50**. The measured oxygen level may then be used to determine the effectiveness of the sensor set **50**, the formation of foreign bodies near the sensor set **50**, or the like. In other alternative embodiments, the sensor system may measure the physiological characteristic levels of the user from body fluids other than blood, such as interstitial fluid, spinal fluid, saliva, urine, tears, sweat, or the like.

[**0060**] In particular embodiments, the BG monitoring system **20** automatically measures the user's BG level on a periodic basis. In other particular embodiments, the BG monitoring system **20** automatically measures the user's BG level on a continuous basis. In alternative embodiments, the BG monitoring system **20** may not automatically measure the user's BG level. For example, the BG monitoring system **20** may include a user interface, such as a keypad **60**, which may be utilized by the user to request a BG measurement from the BG monitoring system **20**. Alternatively, the BG monitoring system **20** may include a BG meter, which measures the user's BG level based on a sampling of the user's blood.

[**0061**] In preferred embodiments, the BG monitoring system **20** includes a transmitter and/or receiver (not shown) for communicating with external devices, such as a remote programmer (not shown) for the BG monitoring system **20**, a BG meter (not shown), the relay device **10**, the infusion pump **30** via the relay device **10**, or the like. For example, the glucose monitor **54** and/or data processor **56** may include the transmitter and/or receiver. The BG monitoring system **20** preferably communicates with such external devices using radio frequency (RF) communication. Alternatively, other modes of communication may be utilized, such as infrared (IR), wired, ultrasonic, optical, or the like.

[**0062**] In particular embodiments, the BG monitoring system **20** may also include a display and a user interface. Referring to FIGS. **2**(*a*)-**2**(*b*), the data processor **56** includes a display **58** and a keypad **60** with one or more keys. The glucose monitor **54** utilizes the transmitter and/or receiver (not shown) to transfer data to and/or from the data processor **56**. Alternatively, referring to FIG. **2**(*c*), the glucose monitor **54"** may include the display **58"** and keypad **60"** with one or more keys. The user may utilize the display **58** and/or keypad **60** to display the user's current BG level, view other BG information recorded or calculated by the glucose monitor **54** and/or data processor **56** (e.g., average BG level, BG trends, graphs of historical BG measurements), view alarms or other messages, program the BG monitoring system **20**, enter calibration or other data into the

BG monitoring system **20**, download information from the BG monitoring system **20**, and the like. In particular embodiments, the user may also utilize the display **58** and/or keypad **60** to transmit data, delivery commands, and/or other information to the infusion pump **30** via the relay device **10**. In alternative embodiments, the user interface may include one or more buttons, switches, levers, joystick, roller ball, mouse, keyboard, and the like. In further alternative embodiments, the keypad **60** may be omitted, and the display **58** may be used as a touch screen input device. In other alternative embodiments, the display and/or user interface may be omitted from the BG monitoring system **20**, and instead included on the relay device **10** and/or infusion pump **30**.

[**0063**] In preferred embodiments, the BG monitoring system **20** stores information in a memory (not shown) of the BG monitoring system **20** for subsequent review and/or downloading to a storage media. Information stored by the BG monitoring system **20** may include one or more of raw BG data, calibrated BG measurements, time stamps, sensor alarms, sensor settings, calibration data, sensor performance data, sensor errors, sensor system diagnostics, statistics, user information, serial number, and the like. In preferred embodiments, information is transmitted from the BG monitoring system **20** to the infusion pump **30** via the relay device **10**, and then downloaded to a storage media from the infusion pump **30**. The storage media may include one or more of a personal computer (PC), a central server, an electronic memory, a personal digital assistant (PDA), a cell phone, a laptop computer, magnetic memory, silicon memory, a data storage device, and the like. In alternative embodiments, information may be downloaded to the storage media directly from the BG monitoring system **20** through an interface, such as a transmitter, a cable, a communication station, or the like. In particular alternative embodiments, information may be downloaded from the data processor **56** to the storage media. In other alternative embodiments, information may be downloaded from the glucose monitor **54** to the storage media. In further alternative embodiments, information may be transmitted from the BG monitoring system **20** to the relay device **10**, and then downloaded to the storage media from the relay device **10**. In other alternative embodiments, information may be downloaded to the storage media from more than one of the BG monitoring system **20**, relay device **10**, and infusion pump **30**.

[**0064**] In preferred embodiments, sensor calibration data is provided to the BG monitoring system **20** by communication with an external device, such as a BG meter or other BG measuring device (not shown). The BG monitoring system **20** preferably includes a transmitter and/or receiver (not shown) for communicating with such external devices. For example, the glucose monitor **54** and/or the data processor **56** may include the transmitter and/or receiver. The user obtains a BG reference reading utilizing a BG meter or other BG measuring device, which then transmits the BG reference reading to the BG monitoring system **20**, either directly or via the relay device **10**. In alternative embodiments, the user may manually enter sensor calibration data into the BG monitoring system **20**. In particular alternative embodiments, the user may utilize the display **58** and/or user interface **60** on the data processor **56**, as shown in FIGS. **2**(*a*)-**2**(*b*), to manually input the calibration data into the BG monitoring system **20**. In other particular alternative embodiments, the user may utilize the display **58**" and/or user interface **60**" on the glucose monitor **54**" , as shown in **FIG. 2**(*c*), to manually input the calibration data into the BG monitoring system **20**.

[**0065**] In the embodiment illustrated in **FIGS. 1 and 3**(*a*)-**3**(*b*), the fluid delivery system is an external infusion pump **30**, which regulates the flow of fluid, preferably medication such as insulin, through flexible tubing **32** and into an infusion set **34** or the like that is adhered to the user's body. Infusion sets **34** that may be used are described in, but not limited to, U.S. Pat. Nos. 4,723,947; 4,755,173; 5,176,662; 5,584,813; and 6,056,718, which are herein incorporated by reference. The infusion pump **30** is generally of the type described in U.S. Pat. Nos. 4,562,751; 4,685,903; 5,080,653; 5,097,122; 5,505,709; and 6,248,093; and disclosed in U.S. patent application Ser. No. 09/334,858, filed Jun. 16, 1999 and entitled "External Infusion Device with Remote Programming, Bolus Estimator and/or Vibration Alarm Capabilities," which are herein incorporated by reference. In alternative embodiments, the fluid delivery system may be an implantable infusion pump, an infusion pump that uses a combination of implantable and external components, a pen injector, disposable pump, an intra venous drip system, or the like. In still other alternative embodiments, the fluid delivery system may deliver fluids other than insulin, including peptides, proteins, sugars, vitamins, antigens, hormones, steroids, medicaments, drugs, pain killers, anti-cancer agents, anti-coagulants, stimulants, tranquilizers, sedatives, and the like.

[**0066**] Referring to FIGS. **3**(*a*)-**3**(*b*), the infusion pump **30** comprises a relatively compact, portable housing that may be easily worn on clothing or jewelry, placed in a pocket, concealed under clothing, or the like. However, the infusion pump **30** may also be included in a hospital-based system, and the infusion pump **30** may comprise a housing that may be included in a monitor, placed on an intravenous (IV) pole, or the like near the patient's bed. The infusion pump **30** preferably includes a processor **150** for running programs and controlling the infusion pump **30**. The processor **150** is coupled to an internal memory device **154** that stores programs, history data, user defined information and parameters. In preferred embodiments, the memory device **154** is a ROM and DRAM; however, in alternative embodiments, the memory device **154** may include other memory storage devices, such as RAM, EPROM, dynamic storage such as flash memory, energy efficient hard-drive, or the like. The processor **150** is also coupled to a drive mechanism **160** that is connected to a fluid reservoir **162** containing fluid that is delivered through the tubing **32** and into the infusion set **34** adhered to the user's body. The processor **150** may additionally be coupled to a bolus estimator **164**, which estimates an appropriate amount of insulin to be delivered to the user based on the user's BG level, the amount of carbohydrates to be consumed, and the like. The bolus estimator **164** may generally be of the type described in U.S. patent application Ser. No. 09/334,858, filed Jun. 16, 1999 and entitled "External Infusion Device with Remote Programming, Bolus Estimator and/or Vibration Alarm Capabilities," which is herein incorporated by reference.

[**0067**] The infusion pump **30** further includes a communication system **152** coupled to the processor **150** for communicating with external devices, such as a remote programmer (not shown) for the infusion pump **30**, the BG

monitoring system **20** via the relay device **10**, the relay device **10**, or the like. The communication system **152** may include a transmitter and/or receiver (not shown) for communicating with such external devices. The infusion pump **30** preferably communicates with such external devices using radio frequency (RF) communication. Alternatively, other modes of communication may be utilized, such as infrared (IR), wired, ultrasonic, optical, or the like.

[**0068**] In some embodiments, the transmitter and/or receiver (not shown) of the communication system **152** may be capable of communicating with certain external devices utilizing a particular frequency and/or communication protocol, such as the remote programmer (not shown) for the infusion pump **30** or the like. The infusion pump **30** may include another transmitter and/or receiver (not shown) as part of the relay device **10** incorporated in the infusion pump **30** itself (as shown and described below in the embodiment of FIGS. **8**(*d*) and **10-12**), which is capable of communicating with other external devices utilizing another particular frequency and/or communication protocol, such as the BG monitoring system **20** or the like. In other embodiments, the transmitter and/or receiver (not shown) of the communication system **152** may be capable of communicating with various external devices utilizing different frequencies and/or communication protocols.

[**0069**] The infusion pump **30** also includes a display **100** and/or a user interface **110**. In preferred embodiments, the display **100** is a monochromatic liquid crystal display (LCD). In alternative embodiments, the display **100** is a light emitting diode (LED) display, a cathode ray tube (CRT) display, a touch screen, a color LCD, or the like.

[**0070**] In preferred embodiments, the user interface is a keypad **110** including one or more keys with selectable functions. The infusion pump **30** is preferably programmed through the keypad **110**, or alternatively, by commands received from an external device, such as a remote programmer, the BG monitoring system **20** via the relay device **10**, the relay device **10**, or the like. The keypad **110** may generally be of the type, and operate in a manner similar to that, disclosed in U.S. patent applications Ser. No. 09/334,858, filed Jun. 16, 1999 and entitled "External Infusion Device with Remote Programming, Bolus Estimator and/or Vibration Alarm Capabilities," and Ser. No. 09/784,949, filed Feb. 15, 2001 and entitled "Improved Infusion Device Menu Structure and Method of Using the Same," which are herein incorporated by reference.

[**0071**] In the illustrated embodiment, the keypad **110** includes an Up-Arrow key **112**, a Down-Arrow key **114**, an ACT (activate) key **116**, an ESC (escape) key **118**, and an Express Bolus key **120** for programming the infusion pump **30**. The keypad **110** also includes a dedicated key **122** for interfacing with the BG monitoring system **20** via the relay device **10**. In particular embodiments, the user chooses a function and then selects which key will perform that function. For example, while the display **100** is blank, the user may select the Express Bolus key **120** to quickly set a bolus amount, or the ESC key **118** to show a status information screen on the display **100**. In other particular embodiments, the user selects one or more keystrokes to perform a function. For example, while the display **100** is blank, the user may first select the ACT key **116** to show a main menu screen, then the Up-Arrow and Down-Arrow keys **112** and **114** to scroll through the menu choices, and then the ACT key **116** again to select a menu option. The user selects the keys **112**, **114**, **116**, **118**, **120**, and/or **122** on the keypad **110** to perform functions on the infusion pump **30**, such as starting or stopping a bolus or basal delivery, accessing historical data or status information, setting a utility (e.g., date, time, serial number, or the like), turning on or off a feature (e.g., light, key lock, temporary operation, or the like), escaping to a home display screen, backing up to a previous screen, deleting or approving an input, scrolling, priming, resetting, and the like. In particular embodiments, the display **100** and/or user interface **110** may also be utilized to input information into and/or display information from the BG monitoring system **20** via the relay device **10**, such as viewing sensor measurements received from the BG monitoring system **20** on the display **100** of the infusion pump **30**. In alternative embodiments, the keypad **110** may include more or less keys, or have different key arrangements than those illustrated in the figures.

[**0072**] In further alternative embodiments, one or more keys on the keypad **110** may be programmable. In particular embodiments, the user may define one or more keystrokes to cause the infusion pump **30** to perform one or more functions. For example, a first user may define key **120** on a first infusion pump **30** to cause the display **100** to show the most recent sensor measurement, while a second user may define key **120** on a second infusion pump **30** to perform an express bolus function. In other alternative embodiments, the user interface may include one or more buttons, switches, levers, joysticks, roller balls, mice, keyboards, and the like. In still other alternative embodiments, the keypad **110** may be omitted, and the display **100** may be used as a touch screen input device.

[**0073**] The infusion pump **30** may provide feedback to the user on status or programming changes visibly on the display **100** and/or through lights (not shown) on the infusion pump **30**, audibly through a speaker **156**, and/or tactilely through a vibrator **158**. The infusion pump **30** may also provide the user with a visible alarm via the display **100** and/or lights, an audible alarm via the speaker **156**, and/or a vibration alarm via the vibrator **158**, such as a warning that is indicative of a low reservoir or low battery, an alarm or warning that is indicative of a sensor measurement received from the BG monitoring system **20** via the relay device **10** that is above or below target glycemic values, or the like. In alternative embodiments, the display **100**, keypad **110**, lights, speaker **156**, and/or vibrator **158** may be omitted from the infusion pump **30**, and instead, included on the relay device **10** and/or the BG monitoring system **20**. In further alternative embodiments, the display **100**, keypad **110**, lights, speaker **156**, and/or vibrator **158** may be omitted, the infusion pump **30** may be implanted in the user's body, and all programming may be handled through a communication system using wireless modes of communication, such as radio frequency (RF), infrared (IR), and the like.

[**0074**] In preferred embodiments, the infusion pump **30** stores information in a memory (not shown) of the infusion pump **30** for subsequent review and/or downloading to a storage media. Information stored by the infusion pump **30** includes one or more of insulin delivery rates, insulin bolus amounts, time stamps, alarms, errors, warnings, utility settings, statistics, profiles, user information, serial number, commands, force measurements, pressure measurements,

and the like. In preferred embodiments, information is downloaded directly from the infusion pump **30** to a storage media through an interface, such as a transmitter, cable, communication station, or the like. In particular embodiments, an external communication link (not shown) may be connected via a cable to a serial, USB, or the like port of a computer. The infusion pump **30** may include an RF transmitter or transceiver (not shown), which transmits information to an RF receiver or transceiver in the external communication link for downloading to the computer. In other particular embodiments, information may be downloaded from the infusion pump **30** through a communication station generally of the type disclosed in U.S. Pat. No. 5,376,070, which is herein incorporated by reference. In still other particular embodiments, information may be downloaded from the infusion pump **30** through a BG meter (not shown) as disclosed in U.S. Provisional Patent Application Serial No. 60/412,998, filed Sep. 23, 2002 and entitled "System for Providing Blood Glucose Measurements to Bolus Estimator," which is herein incorporated by reference. The storage media may include one or more of a personal computer (PC), a central server, an electronic memory, a personal digital assistant (PDA), a cell phone, a laptop computer, magnetic memory, silicon memory, a data storage device, and the like. In alternative embodiments, information may be transmitted from the infusion pump **30** to the BG monitoring system **20** via the relay device **10**, and then downloaded to a storage media from the BG monitoring system **20**. In further alternative embodiments, information may be transmitted from the infusion pump **30** to the relay device **10**, and then downloaded to the storage media from the relay device **10**. In other alternative embodiments, information may be downloaded to the storage media from more than one of the BG monitoring system **20**, relay device **10**, and infusion pump **30**.

[**0075**] In the embodiment illustrated in **FIG. 1**, the relay device **10** transfers information between the BG monitoring system **20** and the infusion pump **30**. In preferred embodiments, the relay device **10** comprises a relatively compact, portable housing **200** without a user interface or a display, as illustrated in **FIG. 6**(*a*). The relay device **10** may be easily worn on clothing or jewelry, placed in a pocket, concealed under clothing, or the like. In alternative embodiments, the relay device **10'** may include a housing **200'** with a single key **202**, as shown in **FIG. 6**(*b*). The single key **202** provides a user interface for the user to request new information from the BG monitoring system **20**.

[**0076**] In further alternative embodiments, the relay device **10"** may include a housing **200"** with a keypad **204**, as shown in **FIG. 6**(*c*). The keypad **204** may include more than one key, and at least one of the keys may be utilized by the user to send data or commands to the infusion pump **30**. In the illustrated embodiment, the keypad **204** includes an Up-Arrow key **206**, a Down-Arrow key **208**, and an ACT (activate) key **210** for programming the infusion pump **30** from the relay device **10** in a manner similar to that shown and described in the embodiment of **FIG. 3**(*a*). The keypad **204** also includes a dedicated key **212** for interfacing with and requesting data from the BG monitoring system **20**. However, in alternative embodiments, the keypad **204** may include more or less keys or different key arrangements than those illustrated in **FIG. 6**(*c*).

[**0077**] In other alternative embodiments, the relay device **10'"** may include a housing **200'"** with a display **214** and a keypad **216**, as shown in **FIG. 6**(*d*). In particular alternative embodiments, the display **214** may be a monochromatic liquid crystal display (LCD). In other particular alternative embodiments, the display **214** may be a light emitting diode (LED) display, a cathode ray tube (CRT) display, a touch screen, a color LCD, or the like. The keypad **216** may include more than one key, and at least one of the keys may be utilized by the user to send data or commands to the infusion pump **30**. In the illustrated embodiment, the keypad **216** includes an Up-Arrow key **218**, a Down-Arrow key **220**, an ACT (activate) key **222**, and an ESC (escape) key **224** for programming the infusion pump **30** from the relay device **10** in a manner similar to that shown and described in the embodiment of **FIG. 3**(*a*). The keypad **216** also includes a dedicated key **226** for interfacing with and requesting data from the BG monitoring system **20**. However, in alternative embodiments, the keypad **216** may include more or less keys or different key arrangements than those illustrated in **FIG. 6**(*d*). In still other alternative embodiments, the relay device **10** may be a computer system (not shown), such as a personal computer (PC), a personal digital assistant (PDA), a central data system (such as is used in hospitals to store or track data, Internet systems, or the like), or the like.

[**0078**] In preferred embodiments, the relay device **10** is positioned on the user's body near the BG monitoring system **20**. For example, the relay device **10** may be positioned on the user's is body using a necklace **250** to hold the relay device **10** like a pendant (as shown in **FIG. 7**(*a*)), using a belt or strap **252** to hold the relay device **10** in place (as shown in **FIG. 7**(*b*)), or by placing the relay device **10** in a clothing garment **254** or clipping the relay device **10** in place (as shown in **FIG. 7**(*c*)). Positioning the relay device **10** near the BG monitoring system **20** is especially useful to minimize the power required by the transmitter and/or receiver in the BG monitoring system **20** to send and/or receive signals between the BG monitoring system **20** and the relay device **10**. Other methods may be used to locate the relay device **10** near the BG monitoring system **20**, such as using tape or adhesive to hold the relay device **10** in place, holding the relay device **10** in a hand and bringing the hand near the BG monitoring system **20**, or the like.

[**0079**] In alternative embodiments, the relay device **10** may be incorporated with the infusion pump **30** to minimize the number of components that the user must handle. For example, the relay device **10** may be incorporated into a clip that is attached to the infusion pump **30** to hold the infusion pump **30** in place on the user's body, as shown in **FIG. 8**(*a*). Alternatively, the relay device **10'** may be mounted on a side of the infusion pump **30**, as shown in **FIG. 8**(*b*). Additionally, the relay device **10"** may be attached to a bottom of the infusion pump **30**, as shown in **FIG. 8**(*c*). In other alternative embodiments, the relay device **10** may be incorporated with the BG monitoring system **20** in a manner similar to that shown and described in the embodiments of FIGS. **8**(*a*)-**8**(*c*). For example, the relay device **10** may be incorporated into a clip that is attached to, or mounted on a side of, or attached to a bottom of, the data processor **56** shown in FIGS. **2**(*a*)-**2**(*b*) or the glucose monitor **54"** shown in **FIG. 2**(*c*).

[**0080**] In further alternative embodiments, the relay device **10** may be incorporated into the infusion pump **30**.

FIG. 8(*d*) illustrates a cut-away perspective view of the infusion pump **30** showing the electronic boards and modules that may be included in the infusion pump **30**. The infusion pump **30** may include a display module **260**, a mother board **262**, and an interface board **264**. The mother board **262** is the main control unit for the infusion pump **30**, and includes the processor and memory. The display module **260** includes the display **100**, and in particular embodiments, a backlight for the display **100**. The interface board **264** interfaces between different systems in the infusion pump **30**, and includes the drive mechanism and power supplies. The infusion pump **30** also includes a communication board **265** and an antenna **268**, which enable communication with external devices, such as a remote programmer (not shown) for the infusion pump **30**, the BG monitoring system **20**, and the like. The communication board **265** includes the communication system as well as the relay device components. During communications with the BG monitoring system **20**, the drive mechanism and power supplies on the interface board **264** are temporarily shutdown. Accordingly, the infusion pump **30** further includes a capacitor **266** for providing power to the infusion pump **30** and the communication board **265** during such communications.

[**0081**] For example, referring to FIGS. **10-12**, the relay device (not shown) may be incorporated into the infusion pump **30**. The BG monitoring system **20** may transmit communications to the infusion pump **30** in a sensor system format, the relay device incorporated into the infusion pump **30** may receive such communications and convert them to a delivery system format, and the infusion pump **30** may then process such converted communications. Conversely, the infusion pump **30** may format communications in the delivery system format, the relay device incorporated into the infusion pump **30** may convert such communications to the sensor system format and transmit such converted communications, and the BG monitoring system **20** may receive such communications in the sensor system format. In particular embodiments, the BG monitoring system **20** may communicate with the infusion pump **30** using wireless modes of communication, such as radio frequency (RF), infrared (IR), ultrasonic, sonic, optical, and the like, as shown in **FIGS. 10 and 11**. In other particular embodiments, the BG monitoring system **20** may communicate with the infusion pump **30** using a wired connection **35**, as shown in **FIG. 12**.

[**0082**] In particular embodiments, information may be downloaded directly from the relay device **10** to a storage media through an interface, such as a transmitter, a cable, a communication station, or the like. For example, information stored by the BG monitoring system **20** and/or the infusion pump **30** may be transmitted to the relay device **10**, and then downloaded from the relay device **10** to the storage media. The storage media may include one or more of a personal computer (PC), a central server, an electronic memory, a personal digital assistant (PDA), a cell phone, a laptop computer, magnetic memory, silicon memory, a data storage device, and the like. In alternative embodiments, information may be downloaded directly from the BG monitoring system **20** or the infusion pump **30** to a storage media. In further alternative embodiments, information may be downloaded to the storage media from more than one of the BG monitoring system **20**, relay device **10**, and infusion pump **30**.

[**0083**] In preferred embodiments, the relay device **10** communicates with the BG monitoring system **20** and the infusion pump **30** using radio frequency (RF) communication. In alternative embodiments, other modes of communication may be used, such as infrared (IR), wired, ultrasonic, sonic, optical, and the like. In further alternative embodiments, more than one mode of communication may be utilized by the relay device **10**.

[**0084**] In preferred embodiments, the relay device **10** includes an RF mixer **300**, a first microcontroller **302**, a second microcontroller **304**, and an RF transceiver **306**, as shown in **FIG. 9**(*a*). The RF mixer **300** receives an RF signal from the BG monitoring system **20** and forwards the signal to the first microcontroller **302**. The first microcontroller **302** decodes the RF signal received in a first format from the BG monitoring system **20** (e.g., at a frequency of 131 kilohertz), and forwards the decoded signal to the second microcontroller **304**. Next, the second microcontroller **304** processes and encodes the signal into a second format for the infusion pump **30** (e.g., at a frequency of 916 megahertz), and forwards the encoded signal to the RF transceiver **306**. The RF transceiver **306** then transmits the encoded signal to the infusion pump **30**. Conversely, the RF transceiver **306** receives an RF signal from the infusion pump **30** and forwards the signal to the second microcontroller **304**. The second microcontroller **304** decodes the RF signal received in the second format from the infusion pump **30**, and forwards the decoded signal to the first microcontroller **302**. Next, the first microcontroller **302** processes and encodes the signal into the first format for the BG monitoring system **20**, and forwards the encoded signal to the RF mixer **300**. The RF mixer **300** then transmits the encoded signal to the BG monitoring system **20**. Inclusion of the two microcontrollers **302** and **304** allows the relay device **10** to encode and decode signals for the BG monitoring system **20** and the infusion pump **30** simultaneously.

[**0085**] In alternative embodiments, the two microcontrollers **302** and **304** shown in **FIG. 9**(*a*) may be replaced with a single fast microcontroller **308**, as illustrated in **FIG. 9**(*b*). The fast microcontroller **308** encodes and decodes signals in appropriate formats respectively for the BG monitoring system **20** and the infusion pump **30** in a manner similar to that of the two microcontrollers **302** and **304** shown in **FIG. 9**(*a*). In further alternative embodiments, the relay device **10**" may include an RF mixer **320** and an RF transceiver **326**, as illustrated in **FIG. 9**(*c*), which are similar to the RF mixer **300** and RF transceiver **306** shown in FIGS. **9**(*a*) and **9**(*b*). The relay device **10**" may also include a field programmable gate array (FPGA) **322**, which performs functions similar to the first microcontroller **302** shown in **FIG. 9**(*a*), for encoding and decoding signals in an appropriate format for the BG monitoring system **20**. The relay device **10**" may further include a microcontroller **322**, which is similar to the second microcontroller **304** shown in **FIG. 9**(*a*), for encoding and decoding signals in an appropriate format for the infusion pump **30**.

[**0086**] In other alternative embodiments, the relay device **10**"" may include an application specific integrated circuit (ASIC) **340**, which incorporates an RF mixer for transmitting and receiving signals to and from the BG monitoring system **20**, as illustrated in **FIG. 9**(*d*). The ASIC **340** may also encode and decode information in an appropriate format for the BG monitoring system **20**. Additionally, the relay

device **10**''' may include a microcontroller **342**, which is similar to the second microcontroller **304** shown in **FIG. 9**(*a*), for encoding and decoding signals in an appropriate format for the infusion pump **30**. The relay device **10**''' may further include an RF transceiver **344**, which is similar to the RF transceiver **306** shown in **FIG. 9**(*a*), for transmitting and receiving signals to and from the infusion pump **30**. In still other alternative embodiments, the microcontroller **342** shown in **FIG. 9**(*d*) may be omitted, and the functionality instead may be included in an application specific integrated circuit (ASIC_**360**, as shown in **FIG. 9**(*e*). The ASIC **360** transmits and receives signals to and from the BG monitoring system **20**. The ASIC **360** also encodes and decodes signals in appropriate formats respectively for the BG monitoring system **20** and infusion pump **30**. The relay device **10**'''' may further include an RF transceiver **362**, which is similar to the RF transceiver **306** shown in **FIG. 9**(*a*), for transmitting and receiving signals to and from the infusion pump **30**.

[**0087**] Referring to **FIG. 1**, the relay device **10** receives information from the BG monitoring system **20** in a sensor system format, converts the information into a delivery system format appropriate for the infusion pump **30**, and then transmits the converted information in the delivery system format to the infusion pump **30**. The relay device **10** may also receive information from the infusion pump **30** in the delivery system format, convert the information into the sensor system format appropriate for the BG monitoring system **20**, and then transmit the converted information in the sensor system format to the BG monitoring system **20**. In alternative embodiments, communication is in only one direction, either from the BG monitoring system **20** to the infusion pump **30**, or from the infusion pump **30** to the BG monitoring system **20**.

[**0088**] In preferred embodiments, the sensor system and delivery system formats include one or more frequencies, communication protocols, and the like that are used to transfer information between the BG monitoring system **20** and the infusion pump **30**. For example, the sensor system format utilized by the BG monitoring system **20** may include a lower frequency, such as 131 kilohertz, resulting in less tissue attenuation at and/or near the insertion site of the BG monitoring sensor set **50**. The delivery system format utilized by the infusion pump **30** may include a higher frequency, such as 916 megahertz or 402-405 megahertz, ensuring compliance with federal, state, regulatory, and other requirements for RF communications. However, other frequencies may be utilized by the BG monitoring system **20** and/or infusion pump **30**.

[**0089**] The communication protocols specify carrier media for communication, such as radio frequency (RF) (including frequency modulated (FM), amplitude modulated (AM), and the like RF), infrared (IR), ultrasonic, audio, light wave, Bluetooth, IRDA, conductive using wires or other direct contacts, and the like. The communication protocols also specify information packaging, which includes how the information is arranged and sent on the carrier media. For example, the information packaging may specify which data components are sent (e.g., the serial number of the relay device **10**, BG monitoring system **20**, and/or infusion pump **30**, a date and time stamp, a sensor measurement, a pump command, and the like). The information packaging may also specify the order in which data components are sent. Further, the information packaging may specify how the information is sent, such as in packets, bits, words, and the like. The information packaging may additionally specify how the information is expressed, such as in decimal, hexadecimal, DC balanced format, and the like.

[**0090**] The BG monitoring system **20** utilizes a sensor system communication protocol, and the infusion pump **30** utilizes a delivery system communication protocol. For example, the BG monitoring system **20** uses the sensor system communication protocol to communicate with the relay device **10**, and the infusion pump **30** uses the delivery system communication protocol to communicate with the relay device **10**. In particular embodiments, the BG monitoring system **20** and infusion pump **30** do not use the same communication protocol; thus, the relay device **10** converts information received from the BG monitoring system **20** into the delivery system communication protocol for communicating to the infusion pump **30**, and the relay device **10** converts information received from the infusion pump **30** into the sensor system communication protocol for communicating to the BG monitoring system **20**. For example, the relay device **10** may receive BG data or measurements from the BG monitoring system **20** formatted in the sensor system communication protocol utilizing radio frequency carrier media, in packets of 107 bytes, or the like. The relay device **10** converts such data or measurements into the delivery system communication protocol utilizing infrared carrier media, in packets of 71 bytes, or the like, and then transmits such converted data or measurements formatted in the delivery system communication protocol to the infusion pump **30**. However, other carrier media or information packaging may be utilized by the BG monitoring system **20** and/or infusion pump **30**.7 In preferred embodiments, the relay device **10**, BG monitoring system **20**, infusion pump **30**, and other devices capable of communicating with the relay device **10**, BG monitoring system **20**, and/or infusion pump **30** (e.g., remote programmer for the BG monitoring system **20**, remote programmer for the infusion pump **30**, and the like) each have a unique identification (ID) code, such as a serial number, identification number, password, or the like. The ID code may be included in communications transmitted to and received from the relay device **10**, BG monitoring system **20**, and/or infusion pump **30** in order to ensure security and/or to distinguish information from various sources. In particular embodiments, each packet of information that is transmitted to the relay device **10** may include the ID code for the relay device **10**, and the relay device **10** may use the ID code to discern whether the packet of information is intended for the relay device **10**. Similarly, each packet of information that is transmitted to the BG monitoring system **20** may include the ID code for the BG monitoring system **20**, and the BG monitoring system **20** may use the ID code to discern whether the packet of information is intended for the BG monitoring system **20**. Also, each packet of information that is transmitted to the infusion pump **30** may include the ID code for the infusion pump **30**, and the infusion pump **30** may use the ID code to discern whether the packet of information is intended for the infusion pump **30**. In further particular embodiments, the relay device **10**, BG monitoring system **20**, infusion pump **30**, and other devices capable of communicating with the relay device **10**, BG monitoring system **20**, and/or infusion pump **30** may know each other's unique ID code. The BG monitoring system **20** and/or the infusion pump **30** may

respond to commands and accept information only from devices for which they know such ID codes. For example, the BG monitoring system **20** may communicate with the infusion pump **30** through the relay device **10**, and thus, may know the ID codes for the relay device **10** and infusion pump **30**. Conversely, the infusion pump **30** may communicate with the BG monitoring system **20** through the relay device **10**, and thus, may know the ID codes for the relay device **10** and BG monitoring system **20**. The infusion pump **30** may also know the ID code for a remote programmer. In alternative embodiments, the relay device **10**, BG monitoring system **20**, infusion pump **30**, and other devices capable of communicating with the BG monitoring system **20** and/or infusion pump **30** have no ID code.

[**0091**] In preferred embodiments, the BG monitoring system **20** is continually synchronized with any device that communicates with the BG monitoring system **20**, such as the relay device **10**, the infusion pump **30** via the relay device **10**, and the like. The BG monitoring system **20** transmits information at fixed intervals (e.g., once every thirty seconds, minute, five minutes, ten minutes, twenty minutes, or the like) for exact time periods (e.g., for time periods of less than one second, one second, one to five seconds, more than five seconds, or the like). The devices that communicate with the BG monitoring system **20**"wake up" at the fixed intervals and "listen" to receive the information from the BG monitoring system **20**. This fixed interval communication method allows the BG monitoring system **20** and the devices that communicate with the BG monitoring system **20** to supply power to their communication systems on a periodic, rather than continuous, basis. Accordingly, the BG monitoring system **20** and the devices that communicate with the BG monitoring system **20** are able to save power when not communicating with one another. In alternative embodiments, the BG monitoring system **20** and the devices that communicate with the BG monitoring system **20** may supply power to their communication systems on a continuous basis, and thus, be capable of continuous communication. In further alternative embodiments, the BG monitoring system **20** and the devices that communicate with the BG monitoring system **20** may supply power to their communication systems only upon request from the user. For example, the user may select the dedicated key **122** on the infusion pump **30** shown in **FIG. 3**(*a*), or alternatively, the dedicated key **212** or **226** on the relay device **10** shown in FIGS. **6**(*c*) and **6**(*d*), to request information from the BG monitoring system **20**. The BG monitoring system **20** may periodically supply power to its communication system for a relatively short time period in order to detect whether another device is requesting information, and in response to such a request, the BG monitoring system **20** and the devices that communicate with the BG monitoring system **20** may supply power to their communication systems and then communicate the requested information. Accordingly, the BG monitoring system **20** and the devices that communicate with the BG monitoring system **20** are able to save power when not communicating with one another.

[**0092**] Referring to **FIG. 1**, the relay device **10** receives information from the BG monitoring system **20**, and then transmits the information to the infusion pump **30**. The relay device **10** may also receive information from the infusion pump **30**, and then transmit the information to the BG monitoring system **20**. In preferred embodiments, the infusion pump **30** includes a display **32** and a user interface **34**, as shown in **FIG. 4**(*a*). For example, the display **32** may be an LCD display **100**, and the user interface **34** may be a keypad **10** including one or more keys, as shown in FIGS. **3**(*a*)-**3**(*b*). The BG monitoring system **20** sends a sensor signal to the relay device **10**, and then the relay device **10** sends the sensor signal to the infusion pump **30**. In preferred embodiments, the sensor signal contains uncalibrated sensor data, and the infusion pump **30** calibrates the uncalibrated sensor data to generate sensor measurements, which are shown on the display **32**. In particular embodiments, the BG monitoring system automatically sends the sensor data to the infusion pump **30** on a periodic (e.g., once every thirty seconds, minute, five minutes, ten minutes, or the like) or continuous basis, and the infusion pump **30** automatically shows the sensor measurement on the display **32** once the sensor data has been received and calibrated. The user may also utilize the user interface **34** to cause the display **32** to show a sensor measurement. In other particular embodiments, once the infusion pump **30** generates the sensor measurement, the infusion pump **30** may provide an alarm or warning to the user if the sensor measurement is above or below target glycemic values. For example, if the sensor measurement is above a hyperglycemic limit (e.g., 250 mg/dl) or below a hypoglycemic limit (e.g., 70 mg/dl), the infusion pump **30** may provide the user with a visible alarm via the display **100** and/or lights, an audible alarm via the speaker **156**, and/or a vibration alarm via the vibrator **158**. The infusion pump **30** may also suspend insulin delivery if the sensor measurement is below the hypoglycemic limit, and notify the user to activate a bolus delivery if the sensor measurement is above the hyperglycemic limit. In further particular embodiments, the infusion pump **30** may include the bolus estimator **164**, which utilizes the sensor measurement to estimate an appropriate amount of insulin to be delivered to the user based on the user's BG level, the amount of carbohydrates to be consumed, and the like. The calculated bolus estimate may be shown to the user on the display **32**, and the user may then utilize the user interface **34** to accept or modify the bolus estimate for infusion into the user. In alternative embodiments, the BG monitoring system **20** calibrates the sensor data to generate sensor measurements, which are included in the sensor signal transmitted from the BG monitoring system **20** to the infusion pump **30** via the relay device **10**. In other alternative embodiments, the BG monitoring system **20** sends a sensor signal with uncalibrated sensor data to the relay device **10**, the relay device **10** calibrates the uncalibrated sensor data to generate sensor measurements, and the relay device **10** sends the sensor signal with the sensor measurements to the infusion pump **30**.

[**0093**] In additional alternative embodiments, the infusion pump **30** may include a display **32**, and the relay device **10** may include a user interface **14**, as shown in **FIG. 4**(*b*). For example, the display **32** may be an LCD display **100** (as shown in FIGS. **3**(*a*)-**3**(*b*)), and the user interface **14** may be a single key **202** (as shown in **FIG. 6**(*b*)), or a keypad **204** or **216** including one or more keys (as shown in FIGS. **6**(*c*) and **6**(*d*)). The user may utilize the user interface **14** on the relay device **10** to request new data from the BG monitoring system **20**. When the user interface **14** is activated (e.g., the user presses the single key **202** shown in **FIG. 6**(*b*), one or more keys on the keypad **204** shown in **FIG. 6**(*c*), or one or more keys on the keypad **216** shown in **FIG. 6**(*d*)), the relay

device **10** sends a request to the BG monitoring system **20** to transmit the most recent sensor data, as shown in **FIG. 4**(*b*). In other alternative embodiments, when the user interface **14** is activated, the relay device **10** sends a signal to the infusion pump **30** to request the most recent sensor data from the BG monitoring system **20**, and the infusion pump **30** then sends such a request to the BG monitoring system **20** through the relay device **10**, as shown in **FIG. 4**(*c*). Referring to FIGS. **4**(*b*) and **4**(*c*), in response to a request for the most recent sensor data, the BG monitoring system **20** sends a sensor signal to the relay device **10**, and then the relay device **10** sends the sensor signal to the infusion pump **30**, similar to the manner described above with respect to **FIG. 4**(*a*). In particular embodiments, the infusion pump **30** may automatically show a sensor measurement on the display **32** once the sensor signal is received by the infusion pump **30**. The user may also utilize the user interface **14** on the relay device **10** to cause the display **32** on the infusion pump **30** to show a sensor measurement. The user may also utilize the user interface **14** on the relay device **10** to send commands or data to the infusion pump **30**.

[**0094**] In further alternative embodiments, the relay device **10** may include a first user interface **14'**, and the infusion pump **30** may include a display **32** and a second user interface **34'**, as shown in **FIG. 4**(*f*). The user may utilize the first user interface **14'** on the relay device **10** to request new data from the BG monitoring system **20**. When the first user interface **14'** is activated, the relay device **10** sends a request to the BG monitoring system **20** to transmit the most recent sensor data. In response, the BG monitoring system **20** sends a sensor signal to the relay device **10**, and then the relay device **10** sends the sensor signal to the infusion pump **30**, similar to the manner described above with respect to **FIG. 4**(*a*). In particular embodiments, the infusion pump **30** may automatically show a sensor measurement on the display **32'** once the sensor signal is received by the infusion pump **30**. The user may also utilize the first user interface **14'** on the relay device **10** or the second user interface **34'** on the infusion pump **30** to cause the display **32** on the infusion pump **30** to show a sensor measurement. The user may additionally utilize the first user interface **14'** on the relay device **10** to send commands or data to the infusion pump **30**. Further, the user may utilize the second user interface **34'** on the infusion pump **30** to perform functions on the infusion pump **30**.

[**0095**] In other alternative embodiments, the relay device **10** may include a display **12** and a user interface **14**, as shown in **FIG. 4**(*d*). For example, the display **12** may be an LCD display **214**, and the user interface **14** may be a keypad **216** including one or more keys, as illustrated in **FIG. 6**(*d*). The BG monitoring system **20** sends a sensor signal with uncalibrated sensor data to the relay device **10**, and the relay device **10** calibrates the data to generate sensor measurements, which are shown on the display **12** of the relay device **10**. In particular embodiments, the relay device **10** may automatically show a sensor measurement on the display **12** once the sensor data is received and calibrated by the relay device **10**. The user may also utilize the user interface **14** to cause the display **12** to show a sensor measurement. The user may further utilize the user interface **14** on the relay device **10** to send commands or data to the infusion pump **30**. In particular embodiments, the relay device **10** may also receive data from the infusion pump **30** (not shown), such as the amount of insulin remaining, alarms indicating a low battery or no delivery by the infusion pump **30**, and the like. The relay device **10** may then utilize such data to adjust the commands sent to the infusion pump **30** and/or show such data on the display **12** to the user. In alternative embodiments, the BG monitoring system **20** calibrates the sensor data to generate sensor measurements, which are included in the sensor signal transmitted from the BG monitoring system **20** to the relay device **10**.

[**0096**] In still other alternative embodiments, the BG monitoring system **20** includes a display **22** and a user interface **24**, as shown in **FIG. 4**(*e*). For example, the display **22** may be an LCD display **58**, and the user interface **24** may be a keypad **60** including one or more keys, as shown in FIGS. **2**(*a*)-**2**(*c*). The BG monitoring system **20** calibrates the sensor data to generate sensor measurements, which are shown on the display **22** of the BG monitoring system **20**. In particular embodiments, the BG monitoring system **20** may automatically show a sensor measurement on the display **22** once the sensor data is calibrated. The user may also utilize the user interface **24** to cause the display **22** to show a sensor measurement. The user may further utilize the user interface **24** on the BG monitoring system **20** to send commands or data through the relay device **10** to the infusion pump **30**.

[**0097**] In preferred embodiments, the BG monitoring system **20** sends a sensor signal to the relay device **10**, and then the relay device **10** sends the sensor signal to the infusion pump **30**, as shown in **FIG. 4**(*a*). The infusion pump **30** includes a display **32** and a user interface **34**, such as the display **100** and user interface **110** shown in **FIG. 3**(*a*). In particular embodiments, the BG monitoring system automatically sends the sensor signal to the infusion pump **30** on a periodic (e.g., once every thirty seconds, minute, five minutes, ten minutes, or the like) or continuous basis. In other particular embodiments, the infusion pump **30** periodically sends a command signal to the BG monitoring system **20** via the relay device **10**, commanding the BG monitoring system **20** to send the sensor signal to the infusion pump **30**, and in response to the command, the BG monitoring system **20** sends the sensor signal to the infusion pump **30**. In further particular embodiments, the user interface **110** may be utilized to cause the BG monitoring system **20** to send the sensor signal to the infusion pump **30** via the relay device **10**. In preferred embodiments, the infusion pump **30** automatically shows a sensor measurement on the display **32** once the sensor signal is received by the infusion pump **30**. The user may also utilize the user interface **110** to cause the display **100** to show a sensor measurement.

[**0098**] The user interface **110** on the infusion pump **30** preferably includes a dedicated interface for requesting information from and/or inputting data to the BG monitoring system **20** via the relay device **10**. Additionally, in particular embodiments where bidirectional communication is not enabled continuously between the BG monitoring system **20** and the infusion pump **30**, utilizing the dedicated interface may initiate bi-directional communication between the infusion pump **30** and the BG monitoring system **20** via the relay device **10**. In further particular embodiments, the dedicated interface may be used to cause the display **100** of the infusion pump **30** to show historical data, such as trends of whether sensor measurements are increasing or decreasing, a plot of two or more sensor measurements, a graph of the past n-hours of sensor measurements, and the like. In other embodiments, the infusion pump **30** may automatically

show sensor measurements or historical data (e.g., trends, plots, graphs, or the like of sensor measurements) on the display **100** when the display **100** would otherwise be blank.

[**0099**] Referring to **FIG. 3**(*a*), the dedicated interface on the infusion pump **30** may include a dedicated key **122** for causing the display **100** to show the sensor measurement. In alternative embodiments, the user may select one or more keystrokes to cause the display **100** to show the sensor measurement. For example, the user may select the dedicated key **122** followed by the ACT key **116** to cause the display **100** to show the sensor measurement. In further alternative embodiments, the ability of the infusion pump **30** to communicate with the BG monitoring system **20** via the relay device **10** may be activated by entering the BG monitoring system's **20** serial number or other identifying information into the infusion pump **30**. In response, the infusion pump **30** may program certain keys for interfacing with the BG monitoring system **20** via the relay device **10**.

[**0100**] In other alternative embodiments, the dedicated interface may include a button, switch, lever, handle, touch screen, or the like, or combinations of keys, buttons, switches, levers, handles, touch screens, or the like. Combinations of interfaces include activating more than one interface simultaneously (in parallel), or activating more than one interface in sequence. In still other alternative embodiments, the dedicated interface may be located on another device that communicates with the infusion pump **30**, and the sensor measurement may be shown on a display of that device, such as the BG monitoring system **20** (for example, the glucose monitor **54** and/or data processor **56**), a remote programmer (not shown) for the infusion pump **30**, a personal digital assistant (PDA), a computer, a cell phone, or the like.

[**0101**] In preferred embodiments, one or more sensor measurements are stored in the memory **154** of the infusion pump **30**. Furthermore, selecting the dedicated key **122** (or other dedicated interface) causes the most recent sensor measurement to be shown on the display **100**. When the most recent sensor measurement is already shown on the display **100**, selecting the dedicated key **122** causes the next, most recent sensor measurement to be shown on the display **100**, and each subsequent selection of the dedicated key **122** causes older and older sensor measurements to be shown on the display **100**. In alternative embodiments, the infusion pump **30** may include other user interfaces to display older sensor measurements. In other alternative embodiments, the sensor measurements may be stored in a storage device other than the infusion pump **30**, and selecting the dedicated key **122** causes the infusion pump **30** to retrieve the sensor measurement from the storage device and then show it on the display **100**.

[**0102**] In additional alternative embodiments, the infusion pump **30** periodically sends a command signal to the BG monitoring system **20** via the relay device **10**, commanding the BG monitoring system **20** to send sensor data to the infusion pump **30**, so that the most recent sensor data is available to be shown on the display **100** of the infusion pump **30**. In response to the command from the infusion pump **30**, the BG monitoring system **20** sends the sensor data to the infusion pump **30**, and the infusion pump **30** calibrates the sensor data to generate a sensor measurement. The sensor measurement is then stored in the memory **154** of the infusion pump **30**. When the user desires to see the most recent sensor measurement, the user selects the dedicated key **122** (or other)dedicated interface) to retrieve the sensor measurement from the memory **154** of the infusion pump **30** and show the sensor measurement on the display **100** of the infusion pump **30**. In other alternative embodiments, the sensor data is stored in the memory **154** of the infusion pump **30**. When the user selects the dedicated key **122** to view the sensor measurement, the sensor data is retrieved from the memory **154** of the infusion pump **30**, and then calibrated to generate the sensor measurement. In further alternative embodiments, the BG monitoring system **20** sends calibrated sensor measurements to be stored in the memory **154** of the infusion pump **30**. In yet other alternative embodiments, the infusion pump **30** communicates with the BG monitoring system **20** to indicate that the sensor data has been received and/or to echo the sensor data so that the data can be retransmitted if it was received inaccurately.

[**0103**] In still other alternative embodiments, the dedicated key **122** (or other dedicated interface) is used to cause the BG monitoring system **20** to send the most recent sensor data, such as one or more raw sensor data points, one or more calibrated sensor measurements, or the like, to the infusion pump **30**. Once the sensor data is received, the infusion pump **30** shows the most recent sensor measurement on the display **100**. In particular alternative embodiments, the infusion pump **30** indicates to the BG monitoring system **20** the most recent sensor data that the infusion pump **30** has received, and in response, the BG monitoring system **20** sends any additional sensor data that the BG monitoring system **20** has that has not been received by the infusion pump **30**.

[**0104**] In another embodiment of the present invention, the BG level measured by the BG monitoring system **20** is used in a closed loop algorithm to automatically adjust the delivery of fluid, such as insulin, in the infusion pump **30**. A calibration algorithm is used to convert sensor data into sensor measurements, and then the sensor measurements are used in a closed loop algorithm to generate fluid delivery commands to operate the infusion pump **30**. In particular embodiments, the calibration algorithm **26** and closed loop algorithm **28** reside with and are executed by the processor of the BG monitoring system **20**, as shown in **FIG. 5**(*a*). Commands to control the infusion pump **30** are generated at the BG monitoring system **20**, and are sent through the relay device **10** to the infusion pump **30**.

[**0105**] In other particular embodiments, the calibration algorithm **26** resides with and is executed by the processor of the BG monitoring system **20**, and the closed loop algorithm **18** resides with and is executed by the processor of the relay device **10**, as shown in **FIG. 5**(*b*). Calibrated sensor measurements are sent from the BG monitoring system **20** to the relay device **10**, and fluid delivery commands are sent from the relay device to the infusion pump **30**.

[**0106**] In still other particular embodiments, the calibration algorithm **26** resides with and is executed by the processor of the BG monitoring system **20**, and the closed loop algorithm **38** resides with and is executed by the processor of the infusion pump **30**, as shown in **FIG. 5**(*c*). Calibrated sensor measurements are sent from the BG monitoring system **20** through the relay device **10** to the

infusion pump **30**, and fluid delivery commands are generated at the infusion pump **30**.

[**0107**] In yet other particular embodiments, the calibration algorithm **16** and the closed loop algorithm **18** both reside with and are executed by the processor of the relay device **10**, as shown in **FIG. 5**(*d*). Uncalibrated sensor data is sent from the BG monitoring system **20** to the relay device **10**, where they are calibrated and used in the closed loop algorithm **18** to generate fluid delivery commands, which are sent to the infusion pump **30**.

[**0108**] In further particular embodiments, the calibration algorithm **16** resides with and is executed by the processor of the relay device **10**, and the closed loop algorithm **38** resides with and is executed by the processor of the infusion pump **30**, as shown in **FIG. 5**(*e*). Uncalibrated sensor data is sent from the BG monitoring system **20** to the relay device **10**, where they are calibrated to generate sensor measurements. Then the sensor measurements are sent to the infusion pump **30** and used in the closed loop algorithm **38** to generate fluid delivery commands.

[**0109**] In additional particular embodiments, the calibration algorithm **36** and the closed loop algorithm **38** both reside with and are executed by the processor of the infusion pump **30**, as shown in **FIG. 5**(*f*). Uncalibrated sensor data is sent from the BG monitoring system **20** through the relay device **10** to the infusion pump **30**. Then, at the infusion pump **30**, the uncalibrated sensor data is calibrated and used in the closed loop algorithm **38** to generate fluid delivery commands.

[**0110**] In alternative embodiments, a semi-closed loop algorithm is used in place of a closed loop algorithm. A semi-closed loop algorithm generates recommended changes to the fluid delivery, which must be approved by the user or a caregiver using the user interface on the infusion pump **30**, the BG monitoring system **20**, or the relay device **10** before new commands are issued to the infusion pump **30**.

[**0111**] Although FIGS. **4**(*a*)-**5**(*f*) generally show communication flowing from the BG monitoring system **20** to the infusion pump **30**, it should be noted that communication signals might be generated by any of the devices. In particular embodiments, a signal may be sent from the infusion pump **30** through the relay device **10** to the BG monitoring system **20**. The signals from the infusion pump **30** may include signals to request information from the BG monitoring system **20**, verify receipt of information, echo information received, transmit information to be downloaded to the BG monitoring system **20**, and the like. In additional alternative embodiments, signals may be initiated at the relay device **10** and sent to the BG monitoring system **20** and/or the infusion pump **30**.

[**0112**] While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

[**0113**] The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. An infusion system for infusing a fluid into a user, the infusion system comprising:

a sensor system including:

a sensor system housing;

a sensor coupled to the sensor system housing for producing a signal indicative of a physiological characteristic level of the user;

a sensor system processor contained in the sensor system housing for processing the signal indicative of the physiological characteristic level of the user; and

a sensor system transmitter contained in the sensor system housing and coupled to the sensor system processor for transmitting one or more communications in a sensor system format;

a relay device including:

a relay device receiver for receiving the communications from the sensor system in the sensor system format;

a relay device processor for processing the communications from the sensor system and converting the communications for transmission in a delivery system format; and

a relay device transmitter for transmitting the converted communications in the delivery system format; and

a fluid delivery system including:

a delivery system housing;

a delivery system receiver contained in the delivery system housing for receiving the communications from the relay device in the delivery system format; and

a delivery system processor contained in the delivery system housing and coupled to the delivery system receiver for processing the communications from the relay device in the delivery system format and controlling an amount of the fluid infused into the user;

wherein the amount of the fluid infused into the user is determined based upon data indicative of the physiological characteristic level of the user obtained by the sensor system.

2. The infusion system according to claim 1, wherein at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user.

3. The infusion system according to claim 2, wherein the communications including the data indicative of the physiological characteristic level of the user are automatically transmitted from the sensor system through the relay device and received by the fluid delivery system.

4. The infusion system according to claim 3, wherein the fluid delivery system further includes a display device contained in the delivery system housing and coupled to the

delivery system processor for automatically displaying to the user the data indicative of the physiological characteristic level of the user.

5. The infusion system according to claim 3, wherein the fluid delivery system further includes:

a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user; and

a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

6. The infusion system according to claim 5, wherein at least a portion of the user interface is dedicated for interfacing with the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

7. The infusion system according to claim 3, wherein the fluid delivery system further includes a memory contained in the delivery system housing for storing the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

8. The infusion system according to claim 7, wherein the fluid delivery system further includes a display device contained in the delivery system housing and coupled to the delivery system processor for displaying to the user a historical trend or graph using the stored data indicative of the physiological characteristic level of the user received by the fluid delivery system.

9. The infusion system according to claim 7, wherein the fluid delivery system further includes:

a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user; and

a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system.

10. The infusion system according to claim 9, wherein at least another one of the inputs causes the display device to display the next most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system.

11. The infusion system according to claim 9, wherein at least a portion of the user interface is dedicated for interfacing with the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

12. The infusion system according to claim 9, wherein at least another one of the inputs causes the display device to display the stored data that is older than the most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system.

13. The infusion system according to claim 2, wherein the fluid delivery system further includes:

a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user; and

a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

14. The infusion system according to claim 13, wherein at least a portion of the user interface is dedicated for interfacing with the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

15. The infusion system according to claim 2, wherein the fluid delivery system further includes a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs programs the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

16. The infusion system according to claim 2, wherein the fluid delivery system further includes:

a bolus estimator used in conjunction with the delivery system processor for estimating the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system;

an indication device coupled to the bolus estimator for indicating the estimated amount of fluid to be infused into the user; and

a user interface for accepting one or more inputs from the user, wherein at least one of the inputs accepts or modifies the estimated amount of the fluid to be infused into the user.

17. The infusion system according to claim 2, wherein the fluid delivery system further includes a closed loop algorithm executed by the delivery system processor for automatically determining the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system and causing the fluid delivery system to infuse the determined amount of the fluid into the user.

18. The infusion system according to claim 2, wherein the fluid delivery system further includes an indication device for indicating when the data indicative of the physiological characteristic level of the user received by the fluid delivery system is above or below a target characteristic value.

19. The infusion system according to claim 2, wherein the fluid delivery system further includes:

a delivery system transmitter contained in the delivery system housing and coupled to the delivery system processor for transmitting one or more communications in the delivery system format,

wherein the relay device receiver further receives the communications from the fluid delivery system in the delivery system format, the relay device processor processes the communications from the fluid delivery system and converts the communications for transmis-

sion in the sensor system format, and the relay device transmitter transmits the converted communications in the sensor system format, and

wherein the sensor system further includes a sensor system receiver contained in the sensor system housing and coupled to the sensor system processor for receiving the communications from the relay device in the sensor system format.

20. The infusion system according to claim 19, wherein the fluid delivery system further includes:

a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user; and

a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs generates a request for the data indicative of the physiological characteristic level of the user from the sensor system,

wherein at least one of the communications transmitted from the fluid delivery system through the relay device to the sensor system includes the request,

wherein at least one of the communications including the data indicative of the physiological characteristic level of the user is transmitted from the sensor system through the relay device and received by the delivery system in response to the request, and

wherein the display device displays the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

21. The infusion system according to claim 20, wherein at least a portion of the user interface is dedicated for interfacing from the fluid delivery system with the sensor system through the relay device.

22. The infusion system according to claim 20, wherein the requested data is the most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system.

23. The infusion system according to claim 20, wherein the fluid delivery system further includes a memory contained in the delivery system housing for storing the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

24. The infusion system according to claim 23, wherein at least another one of the inputs causes the display device to display a historical trend or graph using the stored data indicative of the physiological characteristic level of the user received by the fluid delivery system.

25. The infusion system according to claim 2, wherein the data indicative of the physiological characteristic level of the user received by the fluid delivery system is uncalibrated data, and the fluid delivery system further includes a calibration algorithm executed by the delivery system processor for calibrating the uncalibrated data to generate one or more measurements indicative of the physiological characteristic level of the user.

26. The infusion system according to claim 2, wherein the data indicative of the physiological characteristic level of the user received by the fluid delivery system includes one or more measurements indicative of the physiological characteristic level of the user.

27. The infusion system according to claim 26, wherein the sensor system further includes a calibration algorithm executed by the sensor system processor for calibrating the signal indicative of the physiological characteristic level of the user to generate the one or more measurements indicative of the physiological characteristic level of the user, and the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the one or more measurements indicative of the physiological characteristic level of the user.

28. The infusion system according to claim 26, wherein the data indicative of the physiological characteristic level of the user received from the sensor system by the relay device is uncalibrated data, and the relay device further includes a calibration algorithm executed by the relay device processor for calibrating the uncalibrated data to generate one or more measurements indicative of the physiological characteristic level of the user, wherein the communications transmitted from the relay device and received by the fluid delivery system include the one or more measurements indicative of the physiological characteristic level of the user.

29. The infusion system according to claim 2, wherein the data indicative of the physiological characteristic level of the user received by the fluid delivery system is downloadable to an external storage device.

30. The infusion system according to claim 2, wherein the fluid delivery system further includes a memory contained in the delivery system housing for storing the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

31. The infusion system according to claim 1, wherein at least one of the communications transmitted from the sensor system through the relay device and received by the delivery system includes one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user.

32. The infusion system according to claim 31, wherein the sensor system further includes:

a display device coupled to the sensor system processor for displaying data to the user; and

a user interface coupled to the sensor system processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user obtained by the sensor system.

33. The infusion system according to claim 32, wherein at least another one of the inputs generates the one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system.

34. The infusion system according to claim 31, wherein the sensor system further includes a closed loop algorithm executed by the sensor system processor for automatically generating the one or more commands for programming the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system.

35. The infusion system according to claim 1, wherein at least one of the communications transmitted from the sensor system to the relay device includes the data indicative of the physiological characteristic level of the user, and at least one

of the communications transmitted from the relay device and received by the fluid delivery system includes one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user.

36. The infusion system according to claim 35, wherein the relay device further includes:

a display device coupled to the relay device processor for displaying data to the user; and

a user interface coupled to the relay device processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user obtained by the sensor system.

37. The infusion system according to claim 36, wherein at least another one of the inputs generates the one or more commands for programming the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system.

38. The infusion system according to claim 35, wherein the relay device further includes a closed loop algorithm executed by the relay device processor for automatically generating the one or more commands for programming the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user obtained by the sensor system.

39. The infusion system according to claim 1, wherein the sensor system format and the delivery system format utilize different frequencies for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

40. The infusion system according to claim 1, wherein the sensor system format and the delivery system format utilize different communication protocols for communications transmitted from the sensor system through the device and received by the fluid delivery system.

41. The infusion system according to claim 40, wherein the different communication protocols utilize different carrier media for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

42. The infusion system according to claim 40, wherein the different communication protocols utilize different information packaging for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

43. The infusion system according to claim 1, wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system are transmitted using radio frequency communication.

44. The infusion system according to claim 1, wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system are transmitted using infrared communication.

45. The infusion system according to claim 1, wherein the delivery system processor has a unique identification code, and the sensor system processor has the capability to learn the unique identification code of the delivery system processor, and further wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the delivery system processor to substantially avoid interference with other devices.

46. The infusion system according to claim 1, wherein the sensor system processor has a unique identification code, and the delivery system processor has the capability to learn the unique identification code of the sensor system processor, and further wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the sensor system processor to substantially avoid interference with other devices.

47. The infusion system according to claim 1, wherein the relay device processor has a unique identification code, and the sensor system processor has the capability to learn the unique identification code of the relay device processor, and further wherein the communications transmitted from the sensor system to the relay device include the unique identification code of the relay device processor to substantially avoid interference with other devices.

48. The infusion system according to claim 1, wherein the relay device processor has a unique identification code, and the delivery system processor has the capability to learn the unique identification code of the relay device processor, and further wherein the communications transmitted from the relay device and received by the fluid delivery system include the unique identification code of the relay device processor to substantially avoid interference with other devices.

49. The infusion system according to claim 1, wherein the relay device is coupled to the delivery system housing.

50. The infusion system according to claim 1, wherein the relay device is contained in the delivery system housing.

51. The infusion system according to claim 1, wherein the relay device is coupled to the sensor system housing.

52. The infusion system according to claim 1, wherein the sensor system is a glucose monitoring system, and the fluid delivery system is an insulin infusion device.

53. A relay device for transferring information between a sensor system and a fluid delivery system, wherein the sensor system measures a physiological characteristic level of a user, and the fluid delivery system infuses a fluid into the user, the relay device comprising:

a sensor system receiver for receiving one or more communications from the sensor system in a sensor system format;

a processor for processing the communications from the sensor system and converting the communications for transmission in a delivery system format; and

a delivery system transmitter for transmitting the converted communications in the delivery system format to the fluid delivery system.

54. The relay according to claim 53, further comprising:

a delivery system receiver for receiving one or more communications from the fluid delivery system in the delivery system format, wherein the processor further processes the communications from the fluid delivery system and converts the communications for transmission in the sensor system format; and

a sensor system transmitter for transmitting the converted communications in the sensor system format to the sensor system.

55. The relay device according to claim 53, wherein at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user.

56. The relay device according to claim 53, wherein at least one of the communications transmitted from the sensor system through the relay device and received by the delivery system includes one or more commands for programming an amount of the fluid to be infused into the user based upon data indicative of the physiological characteristic level of the user obtained by the sensor system.

57. The relay device according to claim 53, wherein at least one of the communications transmitted from the sensor system to the relay device includes data indicative of the physiological characteristic level of the user, and at least one of the communications transmitted from the relay device and received by the fluid delivery system includes one or more commands for programming an amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user.

58. The relay device according to claim 57, wherein the relay device further includes:

a display device coupled to the processor for displaying data to the user; and

a user interface coupled to the processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user.

59. The relay device according to claim 58, wherein at least another one of the inputs generates the one or more commands for programming the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user.

60. The relay device according to claim 53, wherein the sensor system format and the delivery system format utilize different frequencies for communications transmitted from the sensor system through the relay device to the fluid delivery system.

61. The relay device according to claim 53, wherein the sensor system format and the delivery system format utilize different communication protocols for communications transmitted from the sensor system through the relay device to the fluid delivery system.

62. The relay device according to claim 61, wherein the different communication protocols utilize different carrier media for communications transmitted from the sensor system through the relay device to the fluid delivery system.

63. The relay device according to claim 61, wherein the different communication protocols utilize different information packaging for communications transmitted from the sensor system through the relay device to the fluid delivery system.

64. A relay device for transferring information between a sensor system and a fluid delivery system, wherein the sensor system measures a physiological characteristic level of a user, and the fluid delivery system infuses a fluid into the user, the device comprising:

a sensor system transceiver for transmitting and receiving one or more communications to and from the sensor system, wherein the communications are transmitted and received in a sensor system format;

a delivery system transceiver for transmitting and receiving one or more communications to and from the fluid delivery system, wherein the communications are transmitted and received in a delivery system format;

a processor for processing the communications from the sensor system and the fluid delivery system, wherein the processor converts the communications received from the sensor system in the sensor system format for transmission in the delivery system format to the fluid delivery system, and further wherein the processor converts the communications received from the fluid delivery system in the delivery system format for transmission in the sensor system format to the sensor system.

65. The relay device according to claim 64, wherein at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user.

66. The relay device according to claim 64, wherein at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system includes one or more commands for programming an amount of the fluid to be infused into the user based upon data indicative of the physiological characteristic level of the user obtained by the sensor system.

67. The relay device according to claim 64, wherein at least one of the communications transmitted from the sensor system to the relay device includes data indicative of the physiological characteristic level of the user, and at least one of the communications transmitted from the relay device and received by the fluid delivery system includes one or more commands for programming an amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user.

68. The relay device according to claim 67, wherein the relay device further includes:

a display device coupled to the processor for displaying data to the user; and

a user interface coupled to the processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user.

69. The relay device according to claim 68, wherein at least another one of the inputs generates the one or more commands the for programming amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user.

70. The relay device according to claim 64, wherein the sensor system format and the delivery system format utilize different frequencies for communications transmitted between the sensor system and the fluid delivery system through the relay device.

71. The relay device according to claim 64, wherein the sensor system format and the delivery system format utilize different communication protocols for communications transmitted between the sensor system and the fluid delivery system through the relay device.

72. The relay device according to claim 71, wherein the different communication protocols utilize different carrier

media for communications transmitted between the sensor system and the fluid delivery system through the relay device.

73. The relay device according to claim 71, wherein the different communication protocols utilize different information packaging for communications transmitted between the sensor system and the fluid delivery system through the relay device.

74. An infusion system for infusing a fluid into a user, the infusion system comprising:

a sensor system including:

a sensor for producing a signal indicative of a physiological characteristic level of the user;

a sensor system processor coupled to the sensor for processing the signal indicative of the physiological characteristic level of the user; and

a sensor system transmitter coupled to the sensor system processor for transmitting one or more communications in a sensor system format; and

a fluid delivery system including:

a delivery system housing;

a relay device contained in the delivery system housing, the relay device including:

a relay device receiver for receiving the communications from the sensor system in the sensor system format;

a relay device processor for processing the communications from the sensor system and converting the communications for transmission in a delivery system format; and

a relay device transmitter for transmitting the converted communications in the delivery system format;

a delivery system receiver contained in the delivery system housing for receiving the communications from the relay device in the delivery system format; and

a delivery system processor contained in the delivery system housing and coupled to the delivery system receiver for processing the communications from the relay device in the delivery system format and controlling an amount of the fluid infused into the user;

wherein the amount of the fluid infused into the user is determined based upon data indicative of the physiological characteristic level of the user obtained by the sensor system.

75. The infusion system according to claim 74, wherein at least one of the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include data indicative of the physiological characteristic level of the user.

76. The infusion system according to claim 75, wherein the communications including the data indicative of the physiological characteristic level of the user are automatically transmitted from the sensor system through the relay device and received by the fluid delivery system.

77. The infusion system according to claim 76, wherein the fluid delivery system further includes a display device contained in the delivery system housing and coupled to the delivery system processor for automatically displaying to the user the data indicative of the physiological characteristic level of the user.

78. The infusion system according to claim 76, wherein the fluid delivery system further includes:

a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user; and

a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

79. The infusion system according to claim 76, wherein the fluid delivery system further includes a memory contained in the delivery system housing for storing the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

80. The infusion system according to claim 79, wherein the fluid delivery system further includes a display device contained in the delivery system housing and coupled to the delivery system processor for displaying to the user a historical trend or graph using the stored data indicative of the physiological characteristic level of the user received by the fluid delivery system.

81. The infusion system according to claim 79, wherein the fluid delivery system further includes:

a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user; and

a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the most recent data indicative of the physiological characteristic level of the user received by the fluid delivery system.

82. The infusion system according to claim 75, wherein the fluid delivery system further includes:

a display device contained in the delivery system housing and coupled to the delivery system processor for displaying data to the user; and

a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs causes the display device to display the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

83. The infusion system according to claim 75, wherein the fluid delivery system further includes a user interface contained in the delivery system housing and coupled to the delivery system processor for accepting one or more inputs from the user, wherein at least one of the inputs programs the amount of the fluid infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system.

84. The infusion system according to claim 75, wherein the fluid delivery system further includes:

a bolus estimator used in conjunction with the delivery system processor for estimating the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system;

an indication device coupled to the bolus estimator for indicating the estimated amount of fluid to be infused into the user; and

a user interface for accepting one or more inputs from the user, wherein at least one of the inputs accepts or modifies the estimated amount of the fluid to be infused into the user.

85. The infusion system according to claim 75, wherein the fluid delivery system further includes a closed loop algorithm executed by the delivery system processor for automatically determining the amount of the fluid to be infused into the user based upon the data indicative of the physiological characteristic level of the user received by the fluid delivery system and causing the fluid delivery system to infuse the determined amount of the fluid into the user.

86. The infusion system according to claim 75, wherein the fluid delivery system further includes an indication device for indicating when the data indicative of the physiological characteristic level of the user received by the fluid delivery system is above or below a target characteristic value.

87. The infusion system according to claim 75, wherein the data indicative of the physiological characteristic level of the user received by the fluid delivery system is uncalibrated data, and the fluid delivery system further includes a calibration algorithm executed by the delivery system processor for calibrating the uncalibrated data to generate one or more measurements indicative of the physiological characteristic level of the user.

88. The infusion system according to claim 74, wherein the sensor system format and the delivery system format utilize different frequencies for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

89. The infusion system according to claim 74, wherein the sensor system format and the delivery system format utilize different communication protocols for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

90. The infusion system according to claim 89, wherein the different communication protocols utilize different carrier media for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

91. The infusion system according to claim 89, wherein the different communication protocols utilize different information packaging for communications transmitted from the sensor system through the relay device and received by the fluid delivery system.

92. The infusion system according to claim 74, wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system are transmitted using radio frequency communication.

93. The infusion system according to claim 74, wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system are transmitted using infrared communication.

94. The infusion system according to claim 74, wherein the delivery system processor has a unique identification code, and the sensor system processor has the capability to learn the unique identification code of the delivery system processor, and further wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the delivery system processor to substantially avoid interference with other devices.

95. The infusion system according to claim 74, wherein the sensor system processor has a unique identification code, and the delivery system processor has the capability to learn the unique identification code of the sensor system processor, and further wherein the communications transmitted from the sensor system through the relay device and received by the fluid delivery system include the unique identification code of the sensor system processor to substantially avoid interference with other devices.

96. The infusion system according to claim 74, wherein the sensor system is a glucose monitoring system, and the fluid delivery system is an insulin infusion device.

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