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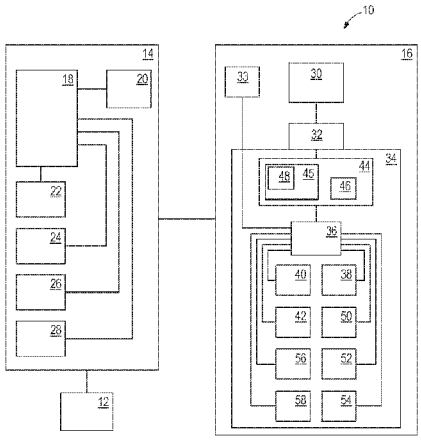

FIG. 1

(57) Abstract: A disposable electronically controlled infusion pump system includes at least one disposable infusion container and at least one disposable electronically controlled medication pumping system. The at least one disposable infusion container is configured to contain infusion fluid. The at least one disposable electronically controlled medication pumping system is fluidly connected to the at least one disposable infusion container. The disposable electronically controlled medication pumping system includes an infusion channel, a disposable electronically controlled micropump, and valves, but may further include a microprocessor, a memory, a battery or power receiver configured to wirelessly receive power, a wireless communication device, and other components. The memory is in electronic communication with the microprocessor. The wireless communication device is configured to receive a wireless signal which wirelessly controls the disposable electronically controlled medication pumping system. The disposable electronically controlled micropump is configured to pump the infusion fluid through the infusion channel. The valves are connected to the infusion channel.

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TECHNICAL FIELD

This disclosure relates to a disposable electronically controlled infusion pump system which includes a micropump and is configured for large volume drug delivery. This system is designed to be used only once for a particular patient, and then disposed of. The disposable electronically controlled infusion pump system is configured to be wirelessly controlled by a non-disposable microcontroller which has a micropump in electronic communication with an interface. The non-disposable microcontroller and the interface are configured to be reused to control additional disposable electronically controlled pump infusion systems after they are disconnected or decoupled from the first disposable electronically controlled infusion pump system. The disclosure further relates to a method for delivering infusion fluid to a patient utilizing the disposable electronically controlled infusion pump system, the non-disposable microcontroller, and the interface.

BACKGROUND

Existing infusion systems typically utilize bulky and complex electromechanical pump devices, which range from five pounds in weight up to 18 lbs., for large volume drug delivery. These electromechanical pump devices are large in size, heavy, require special mounting and handling hardware, are noisy, and are difficult to sterilize. Utilization of these electromechanical pump devices requires a substantial capital investment in procurement and periodic maintenance. Moreover, these electromechanical pump devices require the availability of adequate electric power and batteries. Other existing infusion systems may experience additional issues.

An infusion system and method is needed to reduce or eliminate one or more issues of one or more of the existing infusion systems.

It is desired to address or ameliorate one or more disadvantages or limitations associated with the prior art, or to at least provide a useful alternative.

SUMMARY

In one embodiment, an infusion pump system includes a non-disposable microcontroller, a single disposable infusion container and a plurality of disposable electronically controlled medication pumping systems. The single disposable infusion container is configured to contain infusion fluid. The plurality of disposable electronically controlled medication pumping systems are fluidly connected to the single disposable infusion container and in parallel with each other. Each of the plurality of disposable electronically controlled medication pumping systems include an infusion channel, a microprocessor, a memory, a battery or power receiver configured to

wirelessly receive power, a wireless communication device, and other components. The memory is in electronic communication with the microprocessor. The wireless communication device is configured to receive a wireless signal which wirelessly controls each of the plurality of disposable electronically controlled medication pumping systems. The infusion channel is fluidly connected to the single disposable infusion container. The disposable electronically controlled micropump is configured to pump the infusion fluid through the infusion channel. The valves are operably connected to the infusion channel to sequence and control a flow of the infusion fluid through the infusion channel. The infusion channels of the plurality of disposable electronically controlled medication pumping systems are joined together with a connector downstream of the disposable electronically controlled micropumps of the plurality of disposable electronically controlled medication pumping systems

In another embodiment, an infusion pump system includes a non-disposable microcontroller, a single disposable infusion container, and a plurality of disposable electronically controlled medication pumping systems. The non-disposable microcontroller includes a first microprocessor, a first memory in electronic communication with the first microprocessor, a battery or power source, a power transmitter connected to the battery or power source and configured to transmit power, and a first wireless communication device. The single disposable infusion container is configured to contain infusion fluid. The plurality of disposable electronically controlled medication pumping systems, powered and controlled by the non-disposable microcontroller, is fluidly connected to the single disposable infusion container and in parallel with each other. The plurality of disposable electronically controlled medication pumping system includes a second microprocessor, a second memory in electronic communication with the second microprocessor, a power receiver configured to wirelessly receive the power from the power transmitter, a second wireless communication device configured to wirelessly communicate with the first wireless communication device, an infusion channel, a disposable electronically controlled micropump configured to pump the infusion fluid through the infusion channel, r and valves operably connected to the infusion channel. The infusion channels of the plurality of disposable electronically controlled medication pumping systems are joined together with a connector downstream of the disposable electronically controlled micropumps of the plurality of disposable electronically controlled medication pumping systems.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the disclosure.

Figure 1 illustrates a block diagram of one embodiment of an electronically controlled infusion pump system configured to infuse infusion fluid;

Figure 2 illustrates a block diagram of another embodiment of an infusion pump system configured to infuse infusion fluid;

Figure 3 illustrates a block diagram of another embodiment of an infusion pump system configured to infuse infusion fluid;

Figure 4 illustrates a block diagram of another embodiment of an infusion pump system configured to infuse infusion fluid;

Figure 5 illustrates a block diagram of another embodiment of an infusion pump system configured to infuse infusion fluid; and

Figure 6 illustrates a flowchart of one embodiment of a method for delivering infusion fluid.

DETAILED DESCRIPTION

In another embodiment, an infusion pump system includes a non-disposable microcontroller, at least one disposable infusion container, and at least one disposable electronically controlled medication pumping system. The non-disposable microcontroller includes a first microprocessor, a first memory in electronic communication with the first microprocessor, a battery or other power source, a power transmitter connected to the power source and configured to transmit power, and a first wireless communication device. The at least one disposable infusion container is configured to contain infusion fluid. The at least one disposable electronically controlled medication pumping system, controlled by the non-disposable microcontroller, is a ganged system fluidly connected to the at least one disposable infusion container. The at least one disposable electronically controlled medication pumping system includes an infusion channel, at least two disposable electronically controlled micropumps configured to pump the infusion fluid through the infusion channel, and valves operably connected to the infusion channel. The at least one medication pumping system may also include a second microprocessor, a second memory in electronic communication with the second microprocessor, a power receiver configured to receive power from the power transmitter, a second wireless communication device configured to wirelessly communicate with the first wireless communication device, and other components. Other of at least one disposable electronically controlled medication pumping systems may further include a third microprocessor, a third memory in electronic communication with the third microprocessor, a power receiver configured to receive power from the power transmitter, a third wireless

communication device configured to wirelessly communicate with the first wireless communication device or the second wireless communication device.

In still another embodiment, a method is disclosed for delivering infusion fluid from an electronically controlled infusion system. In one step, a disposable infusion fluid delivery device is provided including at least one disposable infusion container and a disposable electronically controlled medication pumping system. In another step, a pre-determined amount of infusion fluid is disposed into the at least one disposable infusion container. In an additional step, the disposable infusion fluid delivery device containing the infusion fluid in the at least one disposable infusion container is delivered to a location at which the patient is located. In yet another step, the disposable electronically controlled medication pumping system of the disposable infusion fluid delivery device is wirelessly controlled and wirelessly powered with a non-disposable microcontroller to infuse the infusion fluid from the disposable infusion container of the disposable infusion fluid delivery device. In another step, the disposable infusion fluid delivery device is disposed of after the infusion fluid is infused so that the disposable infusion fluid delivery device is only used one time, for a single patient.

Figure 1 illustrates a block diagram of one embodiment of an infusion pump system 10 configured to infuse infusion fluid. The infusion pump system 10 comprises an interface 12, a dedicated non-disposable microcontroller other devices such as existing pump systems, PC, tablets, and smartphones can be used to control disposable pumps providing they have necessary power charging attachments and wireless communication capabilities 14, and a disposable infusion fluid delivery device 16. In other embodiments, the components of the infusion pump system 10 may vary in configuration, type, or function.

For purposes of this disclosure, the term "disposable" means used once for a particular patient and then disposed of (i.e. thrown away or destroyed). For purposes of this disclosure, the term "disposable" means that the component is made of a disposable material such as plastic or another inexpensive material, which is only needed for single patient, one-time use and will not have to be sterilized after first use due to its disposal instead of re-use for the same or different (multiple) patients. For purposes of this disclosure, the term "non-disposable" means that the component will be repeatedly used for the infusion of infusion fluid to the same or varying patients. Disposable items are sometimes used in the medical field because those items come in contact with hazardous medical fluids or bodily fluids. Disposable items can be disposed of rather than being used beyond the recommended time on a given patient or on a different patient with the risk of cross-contamination, infections, or other reactions. Non-disposable items are advantageously reusable with proper isolation, cleaning, disinfection, or sterilization between uses on the same or different patients. In the case of uses on different

patients, isolation, cleaning, disinfecting, or sterilizing an item between uses can help reduce the likelihood of transmission of germs, staff, bacteria or other contamination, but can be difficult to accomplish completely or effectively.

The interface 12 comprises a device which is configured to interface with the non-disposable microcontroller 14 in order to power and electronically control the non-disposable microcontroller 14 which in turn powers and electronically controls the disposable infusion fluid delivery device 16. In other embodiments, the interface 12 may be used to only power or to only electronically control the non-disposable microcontroller 14 which in turns powers and/or

electronically controls the disposable infusion fluid delivery device 16. The interface 12 may comprise a smartphone, a laptop, a stand-alone computer, a nurse station, an infusion pump, or another type of device. The interface 12 may be in wired or wireless communication with the non-disposable microcontroller 14.

In one embodiment, the non-disposable microcontroller 14 and the disposable infusion fluid delivery device 16 are not configured to work at all until the non-disposable microcontroller 14 is connected to the interface 12. In another embodiment, the system 10 may be configured to operate without the interface 12 with the non-disposable microcontroller 14 exclusively powering and/or electronically controlling the disposable infusion fluid delivery device 16. The interface 12 and the non-disposable microcontroller 14 are configured to be used as many times as needed (i.e. non-disposable for repeated use) to electronically power and control differing disposable infusion fluid delivery devices 16 to deliver infusion fluid to varying patients without the interface 12 or the non-disposable microcontroller 14 ever coming into contact with either the disposable infusion fluid delivery device 16 or the infusion fluid delivered by the disposable infusion fluid delivery device 16.

The disposable infusion fluid delivery device 16, which contains a programmed pre-determined amount and type of infusion fluid for a particular patient, is configured to be a stand-alone device which is only used for the particular patient and then disposed of immediately after use. Due to the disposable infusion fluid delivery device 16 never coming into contact with either the interface 12 or the non-disposable microcontroller 14, neither the interface 12 nor the non-disposable microcontroller 14 need to be sterilized. Additionally, since the disposable infusion fluid delivery device 16 is disposed of immediately after use on the particular patient it was intended for, it also does not need to be sterilized after use. As a result, significant time and cost involved in sterilization is saved, in addition to decreasing the health risk which is typically associated with sterilization deficiencies.

The non-disposable microcontroller 14 comprises a first microprocessor 18, a first memory 20, a first wireless communication device 22, a power transmitter 24, a power source 26 such as A/C and/or a battery, and a multiplexer 28. The first processor 18 is in communication with each of the first memory 20, the first wireless communication device 22, the power transmitter 24, the battery 26, and the multiplexer 28. In other embodiments, the components of the non-disposable microcontroller 14 may vary in configuration, type, or function.

The disposable infusion fluid delivery device 16 comprises at least one disposable infusion container 30, a seal 32, a temperature sensor 33, air in line sensor, flow sensor, active valves and a disposable medication pumping system 34. In other embodiments, the components of the disposable infusion fluid delivery device 16 may vary in configuration, type,

or function. The disposable medication pumping system 34 comprises a second microprocessor 36, a second memory 38, a second wireless communication device 40, a power receiver 42, an infusion channel 44, a micropump 45, valves 46, one or more piezo actuators 48, a pressure detection sensor 50, a flow detection sensor 52, an air detection sensor 54, an optional one-dimensional, two-dimensional, holographic or other type of barcode 56, and a Radio Frequency Identification Tag 58. The second processor 36 is in communication with each of the temperature sensor 33, the second memory 38, the second wireless communication device 40, the power receiver 42, the micropump 45, the active valves 46, the piezo actuators 48, the pressure detection sensor 50, the flow detection sensor 52, the air detection sensor 54, the barcode 56, and the Radio Frequency Identification Tag 58. In other embodiments, the components of the disposable medication pumping system 34 may vary in configuration, type, or function. The disposable infusion fluid delivery device 16 may comprise an integral sealed cartridge containing all components of the disposable infusion fluid delivery device 16. In other embodiments, the disposable infusion fluid delivery device 16 and its components may vary in configuration, type, or function.

In one embodiment, the non-disposable microcontroller 14 has a size in a range of 9x6 cm and a weight in a range of 100-200 grams. In another embodiment, the non-disposable microcontroller 14 has a size in a range of 6x4 cm and a weight in a range of 50-100 grams. In still another embodiment, the non-disposable microcontroller 14 has a size in a range of 5x3cm and a weight in a range of 25-50 grams. In other embodiments, the size and weight of the non-disposable microcontroller 14 may vary.

The first microprocessor 18 operates based on programming instructions and data saved in the first memory 20. The programming instructions and data saved in the first memory 20 may be pre-stored, or obtained from any source in the hospital information system, for example through interface 12. The programming instructions and data can be obtained from the second memory 38 of the disposable infusion fluid delivery device 16, from the temperature sensor 33, from the pressure detection sensor 50, from the flow detection sensor 52, from the air detection sensor 54, from the barcode 56, from the Radio Frequency Identification Tag 58, or obtained from another source. The programming instructions and data may have been set-up in in the first memory 20 or in the second memory 38 by the drug preparer (i.e., the pharmacy) based on the patient's drug prescription from a doctor. In other embodiments, a doctor or other medical provider may set-up this information into the first memory 20 or into the second memory 38 of the disposable infusion fluid delivery device 16. In still other embodiments, the programming instructions and data may have been set-up in in the first memory 20 or in the second memory 38 in varying ways.

This data may comprise any combination of the following information: a name or identification of the drug preparer that prepared the infusion fluid contained in the disposable infusion fluid delivery device 16 (this could be a drug manufacturer, pharmacy or a compounder of the infusion fluid) ; a date the infusion fluid was placed into or added to the disposable infusion fluid delivery device 16; a date the infusion fluid contained in the disposable infusion fluid delivery device 16 is to expire; a manufacturing date, serial number, storage information (temperature/time) a time related to the infusion of the infusion fluid contained in the disposable infusion fluid delivery device 16; an identification of the infusion fluid contained in the disposable infusion fluid delivery device 16; a drug identification of the infusion fluid contained in the disposable infusion fluid delivery device 16, which may include a drug name and concentration, a drug identification number, and diluent information; a volume of the infusion fluid contained in the infusion delivery device 16 to be infused into the patient, or a volume of the infusion fluid infused into the patient; a flow rate (programmed and/or actual) of the infusion fluid; a duration or delivery time of the infusion fluid; a power status and/or used or remaining battery capacity of the interface 12, of the non-disposable microcontroller 14, or of the disposable infusion fluid delivery device 16; a charging status of the interface 12, of the non-disposable microcontroller 14, or of the disposable infusion fluid delivery device 16; an identification or name of the patient; a RX order number or order ID; a therapy start time; a therapy end time; a delivery time; one or more alarm conditions; a flow sensor output (flow rate); a pressure sensor output (pressure); an air-in-line sensor output (single bubble or cumulative air volume); temperature data; data regarding parameters for infusion of the infusion fluid for the particular patient; or other types of information.

The first wireless communication device 22 is configured to wirelessly communicate with the second wireless communication device 40 to allow the non-disposable microcontroller 14 and the disposable infusion fluid delivery device 16 to communicate with one another. In one embodiment, the first wireless communication device 22 and the second wireless communication device 40 may comprise a Near-Field communication device. In other embodiments, the first wireless communication device 22 and the second wireless communication device 40 may vary in type or configuration. The power transmitter 24 is configured to wirelessly transmit power or energy to the power receiver 42 (which may comprise a battery) of the disposable infusion fluid delivery device 16 in order to power the operation of disposable infusion fluid delivery device 16. In one embodiment, the power or energy transmitter 24 may utilize Near-Field Charging (capacitive, inductive energy charging) to wirelessly charge the power receiver 42. In other embodiments, the power transmitter 24 may charge the power receiver 42 utilizing varying charging methods.

The power source 26 (in non-disposable controller) is configured in one embodiment as one or more disposable or rechargeable batteries that store electrical energy and provide

energy to the power transmitter 24. The multiplexer 28 is configured to electronically and wirelessly control a plurality of the disposable electronically controlled medication pumping systems 34 (only one disposable electronically controlled medication pumping system 34 is shown in Figure 1, however Figure 3 discussed later shows an embodiment having a plurality of the disposable electronically controlled medication pumping systems 34 being concurrently electronically and wirelessly controlled by the multiplexer 28 to deliver different infusion fluids or to provide a redundant and highly reliable infusion system). Each disposable electronically controlled medication system 34 have capability to communicate with non-disposable controller and other disposable electronically controlled medication systems. This communication capability will further increase the redundancy and reliability of the entire system and would create a topology of a complex medication delivery system that in parallel can deliver a higher combined rate of fluid delivery or in series can deliver greater accumulated volumes.

The at least one disposable infusion container 30 is configured to contain infusion fluid. At least one hermetic seal 32 permanently seals the at least one disposable infusion container 30 to the disposable medication pumping system 34 so that after the drug preparer (manufacturer or pharmacy) disposes the infusion fluid within the at least one disposable infusion container 30 no one else comes in contact with the infusion fluid other than the patient since the disposable infusion fluid delivery device 16 is disposed of after the one-time use for the intended patient. The temperature sensor 33 keeps track of a temperature the disposable infusion fluid delivery device 16 is exposed to throughout its lifetime so that it is ensured that a temperature range requirement for the infusion fluid was not violated during storage, shipping or handling prior to infusion. If the temperature range was violated during the storage or transportation of the disposable infusion container, the infusion would not be permitted. Any of the interface 12, the non-disposable microcontroller 14, and the disposable infusion fluid delivery device 16 may be configured to analyze data emulating from the temperature sensor and to compare it to pre-set temperature parameters regarding the infusion fluid in order to ensure the temperature range requirement for the infusion fluid was not violated, and if it was, to prevent infusion of the infusion fluid.

In one embodiment, the micropump disclosed in US 2011/0005606 to Bartels et al., which is hereby incorporated by reference, may be used for the disposable electronically controlled micropump 45. The disposable electronically controlled micropump 45 may contain a plurality of electrically activated piezo-actuators 48 to control the pumping of infusion fluid through the infusion channel 44. In one embodiment, the disposable electronically controlled micropump 45 is configured to pump in a range of between 0.1 to 350 milliliters of the infusion fluid per hour with accuracy of +/- 10% or better., In one embodiment, the disposable electronically controlled micropump 45 has a size in a range of 8x4 cm and a weight in a range of 50-100 grams. In another embodiment, the disposable electronically controlled micropump

45 has a size in a range of 5x3 cm and a weight in a range of 30-50 grams. In still another embodiment, the disposable electronically controlled micropump 45 has a size in a range of 4x2 cm and a weight in a range of 20-40 grams. In other embodiments, the size and weight of the disposable electronically controlled micropump 45 may vary. The disposable pump can be packaged in a packaging that is capable of providing hermiticity and is compliant with FDA approved materials and capable of withstanding necessary sterilization methods including gamma irradiation, EtO, E-beam, and steam sterilization.

The second microprocessor 36 operates based on programming instructions and data saved in the second memory 38. The programming instructions and data saved in the second memory 38 may be pre-stored, or obtained from any source in the hospital information system, for example through interface 12. The programming instructions and data can be obtained from the first memory 20 of the disposable infusion fluid delivery device 16, from the temperature sensor 33, from the pressure detection sensor 50, from the flow detection sensor 52, from the air detection sensor 54, from the barcode 56, from the Radio Frequency Identification Tag 58, or obtained from another source.

This data may comprise any combination of the following information: a name or identification of the drug preparer that prepared the infusion fluid contained in the disposable infusion fluid delivery device 16; a date the infusion fluid was disposed in the disposable infusion fluid delivery device 16; a date the infusion fluid contained in the disposable infusion fluid delivery device 16 is to expire; a time related to the infusion of the infusion fluid contained in the disposable infusion fluid delivery device 16; an identification of the infusion fluid contained in the disposable infusion fluid delivery device 16; a drug identification of the infusion fluid contained in the disposable infusion fluid delivery device 16; a volume of the infusion fluid contained in the infusion delivery device 16 to be infused into the patient, or a volume of the infusion fluid infused into the patient; a flow rate of the infusion fluid; a delivery time of the infusion fluid; a power status of the interface 12, of the non-disposable microcontroller 14, or of the disposable infusion fluid delivery device 16; a charging status of the interface 12, of the non-disposable microcontroller 14, or of the disposable infusion fluid delivery device 16; an identification or name of the patient; a RX order number; a therapy start time; a therapy end time; a delivery time; one or more alarm conditions; a flow sensor output (flow rate); a pressure sensor output (pressure); an air-in-line sensor output (single bubble or cumulative air volume); temperature data; data regarding parameters for infusion of the infusion fluid for the particular patient; or other types of information. The data can be in the form of near real-time logs of the infusion delivery device's operation.

The infusion channel 44 is configured so that the infusion fluid from the at least one disposable infusion container 30 is flowed or pumped through the infusion channel 44 to the

patient. The valves 46 are operatively connected to the infusion channel 44 and, along with the micropump 45, control the flow of the infusion fluid through the infusion channel 44. The valves 46 may comprise passive or active input and output valves controlled by the first microprocessor 18 or the second microprocessor 36. Use of active valves provides inherent free-flow protection and reduces the impact of backpressure and head height variability thus assuring flow rate accuracy. In other embodiments, varying types and configurations of valves 46 may be utilized.

The pressure detection sensor 50 is configured to determine a pressure of the infusion fluid flowing through the infusion channel 44 to provide real-time feedback regarding the infusion fluid pressure. In one embodiment the pressure sensor is downstream or distal with respect to the micropump 45. The flow detection sensor 52 is configured to determine a flow rate of the infusion fluid flowing through the infusion channel 44 to provide real-time feedback regarding delivery accuracy. The air detection sensor 54 is configured to determine a quantity of air in the infusion fluid flowing through the infusion channel 44 to provide real time feedback regarding the air in the infusion fluid.

The barcode 56 provides information regarding the infusion fluid, the particular patient the infusion fluid is intended for, or other information regarding the patient, the infusion fluid, and/or its delivery. The Radio Frequency Identification Tag 58 provides information such as: drug lot; program details; patient information; pump lot; pharmacy information; day and time; or other information regarding the patient, the infusion fluid, and/or its delivery.

Any of the interface 12, the non-disposable microcontroller 14, and the disposable infusion fluid delivery device 16 may be configured to analyze the information provided by the barcode 56 and/or the Radio Frequency Identification Tag 58, to analyze information stored in the first memory 20 or the second memory 38 regarding the infusion fluid, its delivery, or the particular patient, to analyze information sensed by the temperature sensor 33, the pressure detection sensor 50, the flow detection sensor 52, or the air detection sensor 54, or to analyze other information provided from other sources regarding the infusion fluid, its delivery, or the particular patient in order to ensure that patient and infusion delivery parameters are met. This may include making sure that the right infusion fluid is being infused into the right patient, making sure that the infusion fluid is infused using the correct parameters (i.e. time, flow-rate, pressure, air-prevention, temperature, amount delivered, etc.), preventing the disposable infusion fluid device 16 from being reused after it has been used on the intended patient, or ensuring that other patient and/or infusion delivery parameters are followed. If the interface 12, the non-disposable microcontroller 14, or the disposable infusion fluid delivery device 16 determine that the appropriate patient and/or infusion delivery parameters are not being followed they may be configured to adjust the infusion delivery to ensure compliance with these

restraints and/or to provide an alert, alarm or stop the infusion.

Figure 2 illustrates a block diagram of another embodiment of an infusion pump system 10A configured to infuse medication. Components of the system 10A which are identical to the components of system 10 of Figure 1 have been labeled with identical reference numbers as to those used in Figure 1. The only difference structurally and functionally between the system 10A of Figure 2 relative to the system 10 of Figure 1 is that the power transmitter 24 and power receiver 42 have been removed in the embodiment of Figure 2, and a battery 60 has been added to the disposable medication pumping system 34 of Figure 2. In the embodiment of Figure 2, rather than transmitting power wirelessly from a power transmitter 24 of the non-disposable microcontroller 14 to the power receiver 42 of the disposable electronically controlled medication pumping system 34 to power the disposable electronically controlled medication pumping system 34 as done in Figure 1, the battery 60 of the disposable electronically controlled medication pumping system 34 is utilized to provide power to the disposable medication pumping system 34. In other embodiments, varying components may be utilized to power the disposable electronically controlled medication pumping system 34.

Figure 3 illustrates a block diagram of another embodiment of an infusion pump system 10B configured to infuse infusion fluid. Components of the system 10B which are identical to the components of system 10 of Figure 1 have been labeled with identical reference numbers as to those used in Figure 1. The only difference structurally and functionally between the system 10B of Figure 3 relative to the system 10 of Figure 1 is that the system 10B of Figure 3 comprises a plurality of the disposable infusion fluid delivery devices 16, each having at least one disposable infusion container 30 and a disposable electronically controlled medication pumping system 34, rather than having only one disposable infusion fluid delivery device 16 as in Figure 1. The multiplexer 28 of the non-disposable microcontroller 14 is configured to concurrently electronically wirelessly control the plurality of electronically controlled medication pumping systems 34 of the plurality of disposable infusion fluid delivery devices 16 to deliver different infusion fluids or to have a redundant system. In other embodiments, varying components may be utilized to concurrently control the plurality of electronically controlled medication pumping systems 34 of one or more disposable infusion fluid delivery devices 16.

For example, in the embodiment shown in Figure 4 where the detailed components previously shown in Figures 1-3 can still be present but have been omitted from the figure merely for the sake of simplicity, the infusion pump system 10C includes a plurality of electronically controlled medication pumping systems 34 that are fluidly connected to a single container 30 by respective seals 32 to form a disposable infusion fluid delivery device 16. Thus, the plurality of electronically controlled medication pumping systems 34 are each configured with an infusion channel 44, one or more valves 46 operatively associated with the

infusion channel 44, and a micropump 45 to draw fluid sequentially or concurrently from a common source such as the disposable infusion container 30. The electronically controlled medication pumping systems 34 can be operated in series or in parallel to provide a desired cumulative flow rate in the range of about 0.1-2000 mL/hr. In the example shown in Fig. 4, a cumulative flow rate in the range of about 0.1-1000 mL/hr can be provided with three medication pumping systems 34 fluidly connected in parallel to a single container 30. A single second microprocessor 36 and second memory 38 can control and serve all of the plurality of medication pumping systems 34 from a location in one of the systems 34, or individual second microprocessors 36 and second memories 38 can control and serve individual electronically controlled medication pumping systems 34 respectively, or second microprocessors 36 and memories 38 can be distributed throughout the medication pumping systems in various other ways. The infusion channels 44 can be joined together with a connector 400 downstream of the micropumps 45 and upstream of the patient 402 to whom the fluid is delivered through a common output line 404. The connector 400 can be inside the disposable infusion fluid delivery device 16, as shown, or outside and downstream of it. Advantageously, the integrated disposable infusion delivery device 16 is a hermitically sealed system capable of withstanding necessary sterilization methods used on the medical fluid container 30, including gamma irradiation, EtO, E-beam, and steam sterilization.

Figure 5 illustrates another embodiment similar to those described above with respect to Figures 1-4 except that the infusion pump system 10D has a single seal 32 or gasket, which is used to integrally attach and fluidly connect the plurality of electronically controlled medication pumping systems 34 to the container 30 or flexible intravenous solution bag to form an integrated disposable infusion fluid delivery device 16.

Figure 6 illustrates a flowchart of one embodiment of a method 70 for delivering infusion fluid to a patient. The method 70 may utilize any of the systems of Figures 1-5. In other embodiments, the method may utilize 70 varying systems having differing components and arrangements or configurations. In step 72 a disposable infusion fluid delivery device, comprising at least one disposable infusion container and at least one disposable electronically controlled medication pumping system, is provided. In step 74 a pre-determined amount of infusion fluid for a particular patient is disposed by a drug preparer, such as a pharmacy, into the at least one disposable infusion container according to a prescription the drug preparer received for the particular patient. In step 76 information regarding the infusion fluid, its delivery, or the particular patient to which the medication is to be infused is stored by the drug preparer, who could be a drug manufacturer, compounder or pharmacist, to a barcode or a Radio Frequency Identification Tag attached to the disposable infusion fluid delivery device, to a first memory of a non-disposable microcontroller, to a second memory of the disposable infusion fluid delivery device, or to another memory.

This information may comprise drug lot, program details, patient information, pump lot, pharmacy information, day and time, or other information regarding the patient, the infusion fluid, and/or its delivery. This information may further comprise any combination of the following information: a name or identification of the drug preparer that prepared the infusion fluid contained in the disposable infusion fluid delivery device; a date the infusion fluid was disposed in the disposable infusion fluid delivery device; a date the infusion fluid contained in the disposable infusion fluid delivery device is to expire; a time related to the infusion of the infusion fluid contained in the disposable infusion fluid delivery device; an identification of the infusion fluid contained in the disposable infusion fluid delivery device; a drug identification of the infusion fluid contained in the disposable infusion fluid delivery device; a volume of the infusion fluid contained in the infusion delivery device to be infused into the patient, or a volume of the infusion fluid infused into the patient; a flow rate of the infusion fluid; a delivery time of the infusion fluid; a power status of the interface, of the non-disposable microcontroller, or of the disposable infusion fluid delivery device; a charging status of the interface, of the non-disposable microcontroller, or of the disposable infusion fluid delivery device; an identification or name of the patient; a RX order number; a therapy start time; a therapy end time; a delivery time; one or more alarm conditions; a flow sensor output (flow rate); a pressure sensor output (pressure); an air-in-line sensor output (cumulative air volume); data regarding parameters for infusion of the infusion fluid for the particular patient; or other types of information.

In step 78 the disposable infusion fluid delivery device containing the infusion fluid disposed in the at least one disposable infusion container is delivered from the drug preparer to a location at which the patient is located. In step 80, at the location at which the patient is located, the non-disposable microcontroller, with or without connection to an interface communicates with the disposable infusion fluid delivery device. In step 82 the information of the barcode or the Radio Frequency Identification Tag attached to the disposable infusion fluid delivery device, information contained in the second memory of the disposable infusion fluid delivery device, information contained in the first memory of the non-disposable microcontroller, or other information contained in another memory is wirelessly communicated to and/or read by the non-disposable microcontroller or the disposable infusion fluid delivery device microcontroller as the desired direction of the communication or information flow dictates. In step 84 the disposable electronically controlled medication pumping system of the disposable infusion fluid delivery device is wirelessly controlled and wirelessly powered with the non-disposable microcontroller to infuse the infusion fluid from the disposable infusion container of the disposable infusion fluid delivery device into the patient.

In one embodiment, in step 84 the non-disposable microcontroller wirelessly controls the disposable infusion fluid delivery device to infuse the infusion fluid into the patient utilizing the information of the barcode or the Radio Frequency Tag, utilizing the information saved in the

first memory of the non-disposable microcontroller or the second memory of the disposable infusion fluid delivery device, utilizing information saved in another memory, or utilizing other information regarding the infusion fluid, its delivery, or the particular patient to which the infusion fluid is being infused.

In one embodiment, in step 84 any of the interface, the non-disposable microcontroller, and the disposable infusion fluid delivery device may analyze the information provided by the barcode and/or the Radio Frequency Identification Tag, to analyze information stored in the first memory or the second memory regarding the infusion fluid, its delivery, or the particular patient, to analyze information sensed by the temperature sensor, the pressure detection sensor, the flow detection sensor, or the air detection sensor, or to analyze other information provided from other sources regarding the infusion fluid, its delivery, or the particular patient in order to ensure that patient, infusion fluid conditions such as age, storage/transit/delivery temperature, and the like, and infusion delivery parameters are met.

For instance this may include ensuring that the temperature range requirements for the infusion fluid have been followed during storage, shipment and delivery, ensuring that the infusion fluid is being infused into the right patient, ensuring that the infusion fluid is infused using the correct parameters (i.e. time, flow-rate, pressure, air-prevention, temperature, amount delivered, etc.), ensuring that the disposable infusion fluid device is not reused after it has been used on the intended patient, or ensuring that other patient and/or infusion delivery parameters are followed. If the interface, the non-disposable microcontroller, or the disposable infusion fluid delivery device determine that the appropriate patient and/or infusion delivery parameters are not being followed they may be configured to adjust the infusion delivery to ensure compliance with these restraints, provide an alert or alarm signal, and/or to stop the infusion.

In step 86 a log of the disposable infusion fluid delivery device, regarding the infusion of the infusion fluid to the patient, is wirelessly communicated from the disposable infusion fluid delivery device to the non-disposable microcontroller. In step 88 the disposable infusion fluid delivery device is disposed of after the medication is infused into the patient so that the disposable infusion fluid delivery device is only used for a single patient and single delivery before its disposal.

In step 90 the method is repeated using new disposable infusion fluid delivery devices with the interface and the non-disposable microcontroller being used to wirelessly control and wirelessly power the new disposable infusion fluid delivery devices to infuse infusion fluid contained in the new disposable infusion fluid delivery devices to the same or different patients on a one-time basis, after which the new disposable infusion fluid delivery devices are disposed of. Since the interface and the non-disposable microcontroller never came into contact with the disposable infusion fluid delivery device, the infusion fluid itself, or the bodily fluids of patients,

no sterilization of the interface or the non-disposable microcontroller is necessary.

In one embodiment, an additional step of the method 70 may comprise a multiplexer of the non-disposable microcontroller concurrently electronically and wirelessly controlling a plurality of disposable infusion fluid delivery devices, each comprising at least one disposable infusion container and a disposable electronically controlled medication pumping system, to deliver different infusion fluids to the patient or to provide a redundant system.

In another embodiment suggested in view of Figures 4-6, an additional step of the method 70 may comprise a multiplexer of the non-disposable microcontroller electronically and wirelessly controlling an integrated disposable infusion fluid delivery device having a plurality of electronically controlled medication pumping systems, each being fluidly connected to the same disposable infusion container, to deliver an infusion fluid to the patient in a series or parallel arrangement over time to provide an increased volume or increased volumetric flow rate than would be possible with a single micropump.

In one embodiment, the interface utilized in the method 70 comprises a smartphone, a laptop, a stand-alone computer, a nurse station, an infusion pump, or another type of device. In one embodiment, the non-disposable microcontroller utilized in the method 70 comprises a first microprocessor, a first memory in electronic communication with the first microprocessor, a battery, a power transmitter configured to wirelessly transmit power, and a first wireless communication device. In one embodiment, the disposable electronically controlled medication pumping system of the disposable infusion fluid delivery device utilized in the method 70 comprises a second microprocessor, a second memory in electronic communication with the second microprocessor, a power receiver configured to wirelessly receive power from the power transmitter, a second wireless communication device configured to wirelessly communicate with the first wireless communication device, an infusion channel, a disposable electronically controlled micropump, and valves connected to the infusion channel.

In other embodiments, the interface, the non-disposable microcontroller, and the disposable infusion fluid delivery device may vary. In still other embodiments, any of the steps of the method 70 may be eliminated or changed in substance or in order, or one or more additional steps may be added in varying orders.

The systems and methods of the disclosure provide many benefits over existing infusion systems. For instance, substantial cost is saved in the manufacture of the infusion systems of the disclosure due to the use of the inexpensive disposable electronically controlled micropump which requires a fraction of the power required to run current infusion systems. Moreover, since the disposable infusion fluid delivery devices of the disclosure are sealed, delivered in a sterilized state, and only used once for a single patient and then disposed of, cleaning cost are effectively eliminated and the risk to medical personnel from being exposed to the infusion fluid

is similarly substantially eliminated. Additionally, the infusion systems of the disclosure are substantially smaller in weight and size than current infusion systems. These factors reduce shipping and storage cost, and make the infusion system easier to handle and interface with. Further, the infusion systems of the disclosure have significant noise reduction over current infusion systems due to the small disposable micropumps.

Moreover, the small size of the disposable infusion fluid delivery devices of the disclosure reduces the risk of over-exposure to the infusion fluid. Smaller and more concentrated amounts of the costly infusion fluids can be delivered. Additionally, the infusion systems of the disclosure utilize a multiplexed controller which allows multiple drug infusions simultaneously. Further, the disposable infusion fluid delivery devices of the disclosure can be shipped for medical control, i.e. insulin and glucose, in a single pumping mechanism. The infusion systems of the disclosure cover all therapies given via current technology and many others including: blood clotting (heparin and coagulant); blood pressure and heart rate control; oxygenation, SPO2 (saturation of peripheral oxygen); renal failure prevention (protect kidney); fluid volume balance; PCA (patient controlled analgesia) / cardiac arrest; and others. Additionally, the infusion systems of the disclosure provide for automatic data capture, recording, and near real-time feedback regarding the infusion delivery and the patient to ensure that the required parameters for the infusion are met in order to improve reliability and accuracy. Additionally, the infusion system allows configuration of highly redundant medication delivery system, which is impractical or very difficult to achieve using current pump technology.

The Abstract is provided to allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In addition, in the foregoing Detailed Description, it can be seen that various features are grouped together in various embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed embodiments require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separately claimed subject matter.

While particular aspects of the present subject matter described herein have been shown and described, it will be apparent to those skilled in the art that, based upon the teachings herein, changes and modifications may be made without departing from the subject matter described herein and its broader aspects and, therefore, the appended claims are to encompass within their scope all such changes and modifications as are within the true scope of the subject matter described herein. Furthermore, it is to be understood that the disclosure is

defined by the appended claims. Accordingly, the disclosure is not to be restricted except in light of the appended claims and their equivalents.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An infusion pump system comprising:

a non-disposable microcontroller;

a single disposable infusion container configured to contain infusion fluid; and

a plurality of disposable electronically controlled medication pumping systems fluidly connected to the single disposable infusion container and in parallel with each other, each of the plurality of disposable electronically controlled medication pumping systems comprising:

a microprocessor;

a memory in electronic communication with the microprocessor; a battery, or a power receiver configured to wirelessly receive power;

a wireless communication device configured to receive a wireless signal which wirelessly controls each of the plurality of disposable electronically controlled medication pumping systems;

an infusion channel fluidly connected to the single disposable infusion container;

a disposable electronically controlled micropump configured to pump the infusion fluid through the infusion channel; and

valves connected to the infusion channel to control a flow of the infusion fluid through the infusion channel;

wherein the non-disposable microcontroller is configured to wirelessly control the plurality of disposable electronically controlled medication pumping systems,

wherein the infusion channels of the plurality of disposable electronically controlled medication pumping systems are joined together with a connector downstream of the disposable electronically controlled micropumps of the plurality of disposable electronically controlled medication pumping systems.

2. The infusion pump system of claim 1, wherein the plurality of disposable electronically controlled medication pumping systems are configured to pump cumulatively in a range of between 0.1 to 2,000 milliliters of the infusion fluid per hour.

3. The infusion pump system of claim 1, wherein each of the plurality of disposable electronically controlled medication pumping systems is permanently hermetically sealed to the single disposable infusion container by at least one seal or gasket.

4. The infusion pump system of claim 1, wherein the plurality of disposable electronically controlled medication pumping systems further comprise a pressure detection sensor, a flow detection sensor, and an air detection sensor.

5. The infusion pump system of claim 1, wherein the plurality of disposable electronically controlled medication pumping systems further comprise a Radio Frequency Identification Tag or a barcode.

6. The infusion pump system of claim 1, wherein the wireless communication device comprises a near-field communication device.

7 The infusion pump system of claim 1, wherein the valves comprise active valves.

8. The infusion pump system of claim 1, wherein the plurality of disposable electronically controlled medication pumping systems are configured to be operated in parallel to pump the infusion fluid concurrently from the single disposable infusion container at a combined flow rate.

9. The infusion pump system of claim 1, wherein the memory contains data regarding parameters for infusion of the infusion fluid.

10. An infusion pump system comprising:

a non-disposable microcontroller comprising:

a first microprocessor;

a first memory in electronic communication with the first microprocessor;

a power source;

a power transmitter connected to the power source and configured to wirelessly transmit power; and

a first wireless communication device;

a single disposable infusion container configured to contain infusion fluid;

a plurality of disposable electronically controlled medication pumping systems, each of the plurality of disposable electronically controlled medication pumping systems powered and controlled by the non-disposable microcontroller, each of the plurality of disposable electronically controlled medication pumping systems fluidly connected to the single disposable infusion container and in parallel with each other, each of the plurality of disposable electronically controlled medication pumping systems comprising:

a second microprocessor;

a second memory in electronic communication with the second microprocessor;

a power receiver configured to wirelessly receive the power from the power transmitter;

a second wireless communication device configured to wirelessly communicate with the first wireless communication device;

an infusion channel;

a disposable electronically controlled micropump configured to pump the infusion fluid through the infusion channel; and

valves connected to the infusion channel

wherein the infusion channels of the plurality of disposable electronically controlled medication pumping systems are joined together with a connector downstream of the disposable electronically controlled micropumps of the plurality of disposable electronically controlled medication pumping systems.

11. The infusion pump system of claim 10, wherein the non-disposable microcontroller further comprises a multiplexer configured to wirelessly control the plurality of disposable electronically controlled medication pumping systems.

12. The infusion pump system of claim 10, further comprising an interface in communication with the non-disposable microcontroller.

13. The infusion pump system of claim 12, wherein the interface comprises a smartphone, a tablet, a laptop, a stand-alone computer, a nurse station, or an infusion pump.

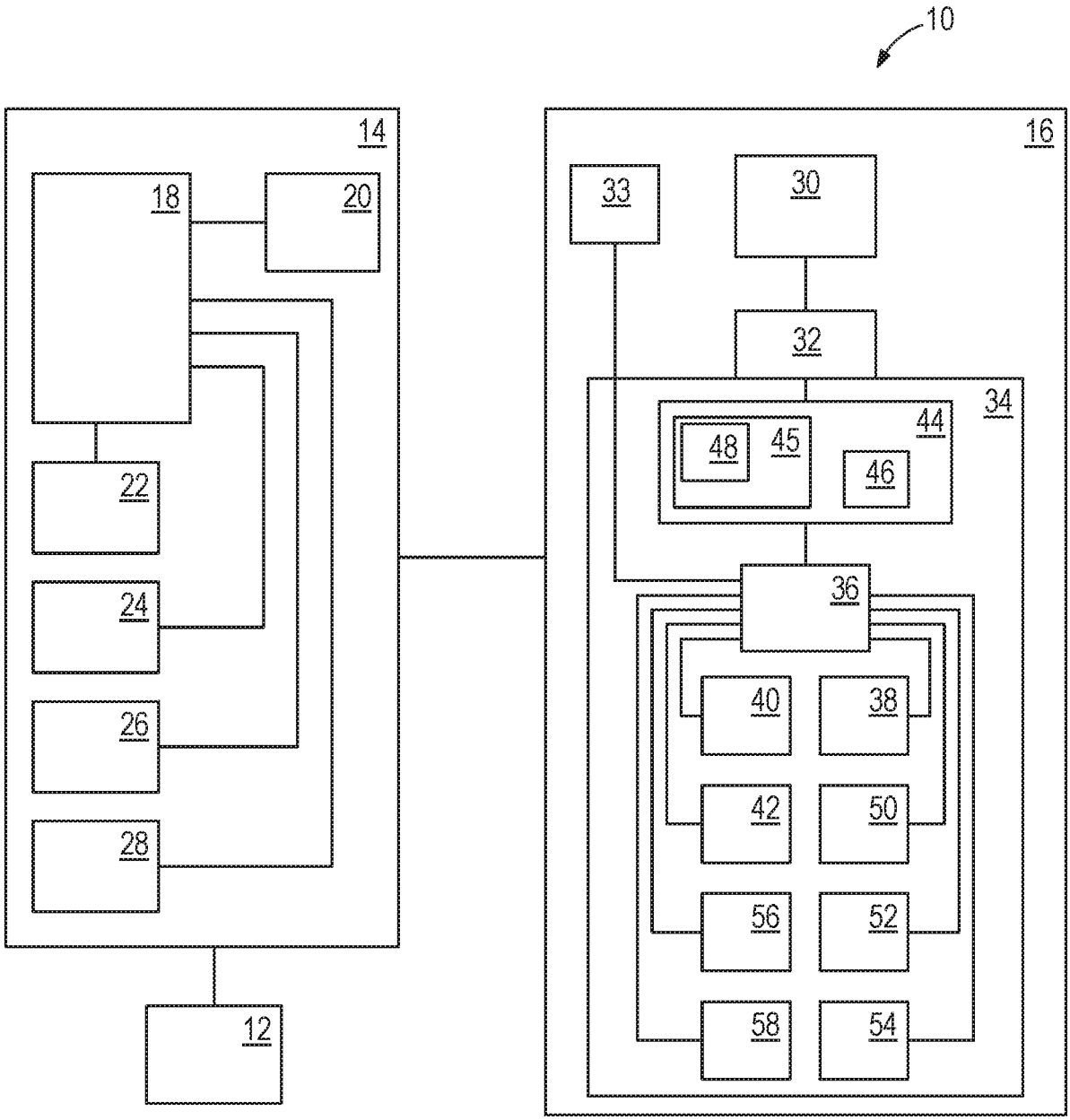
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FIG. 1

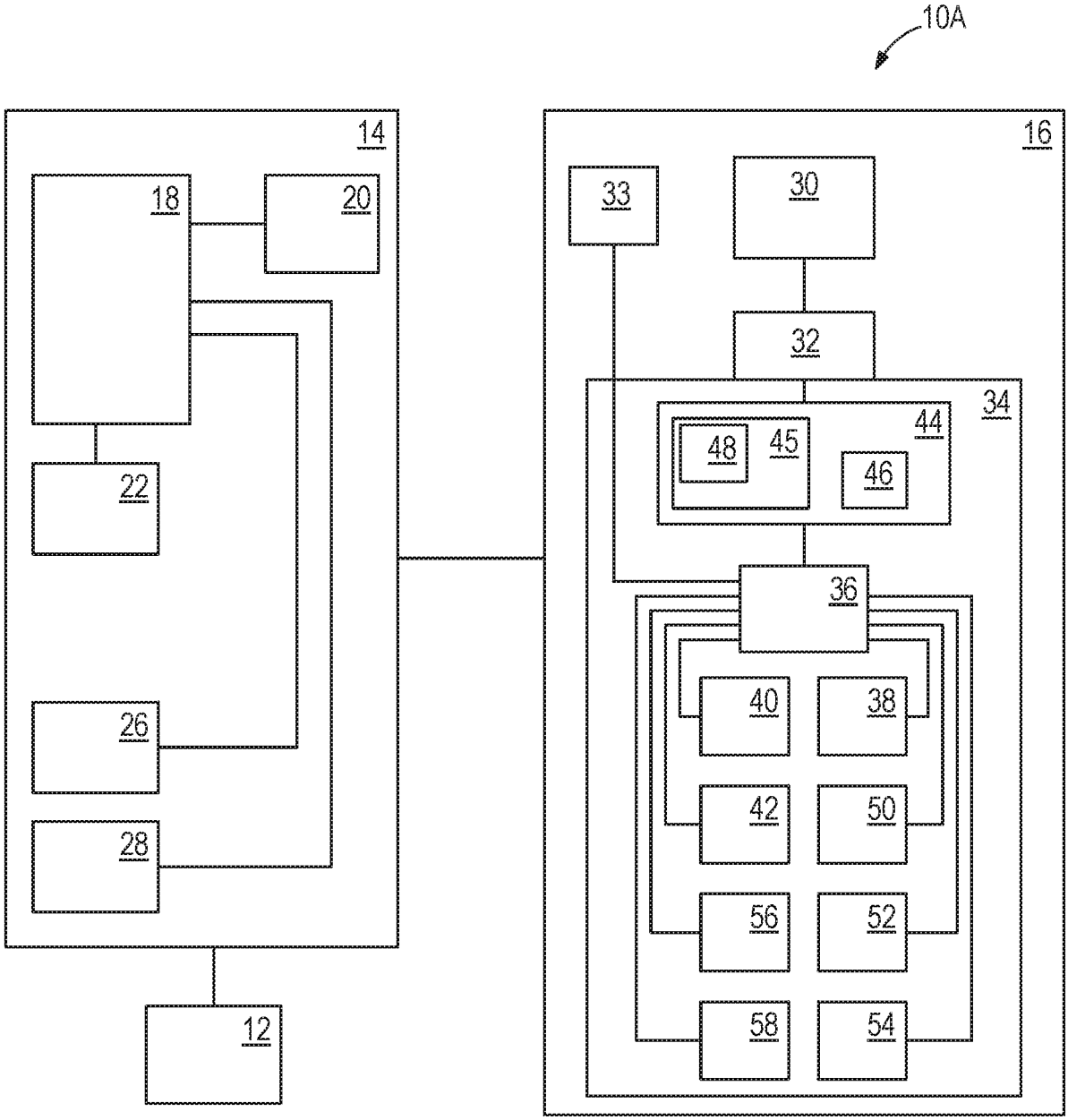
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FIG. 2

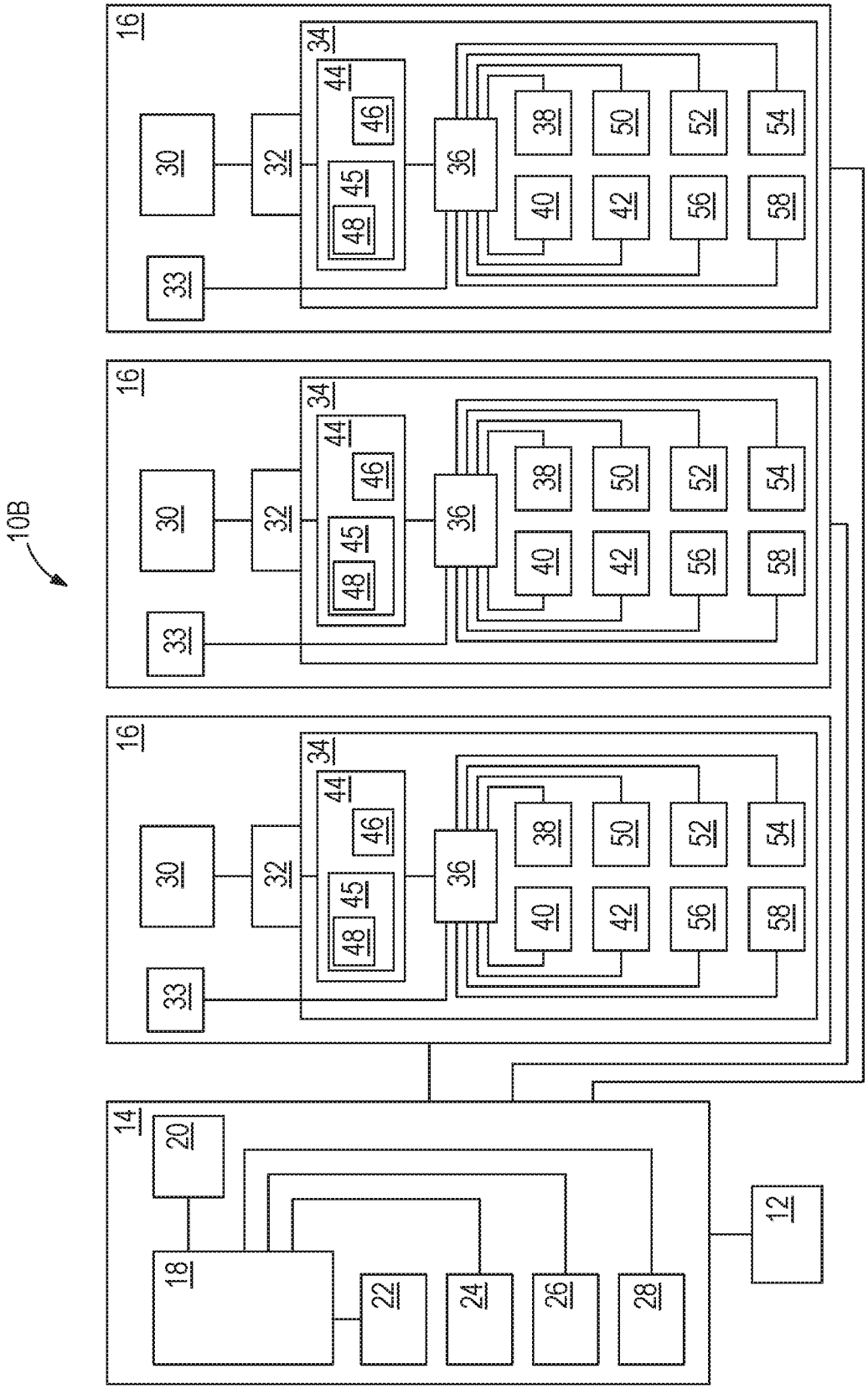
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FIG. 3

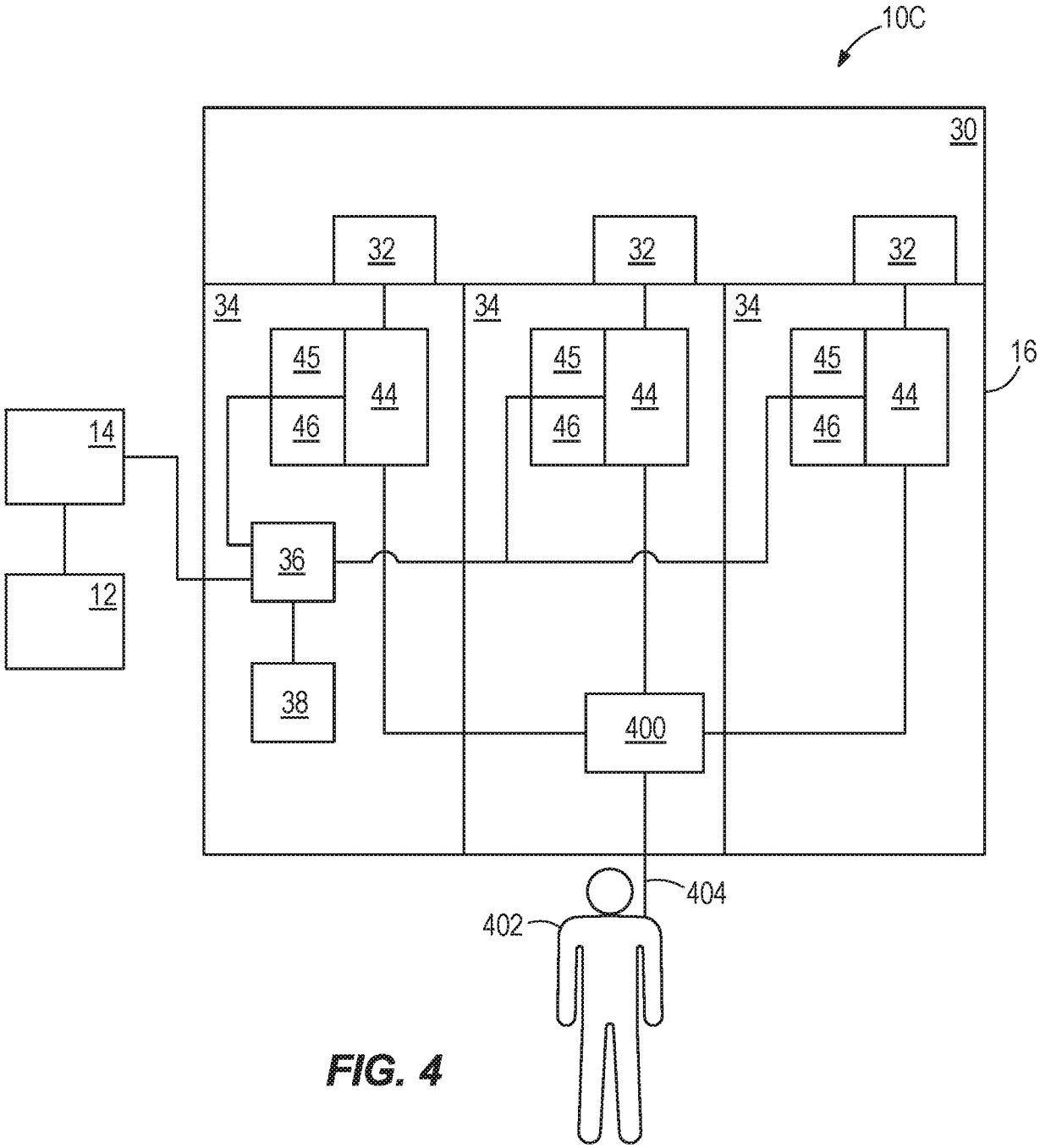
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FIG. 4

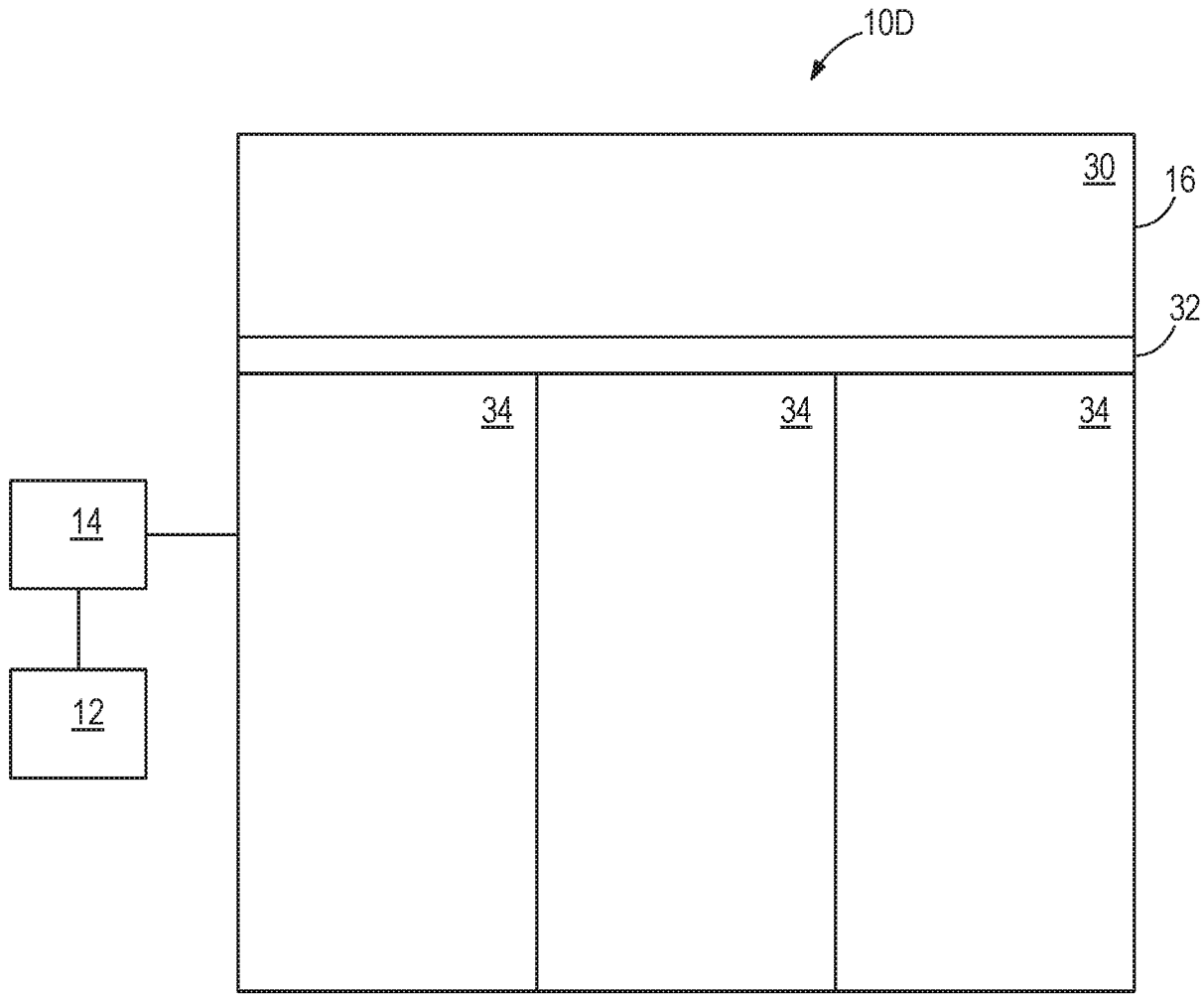
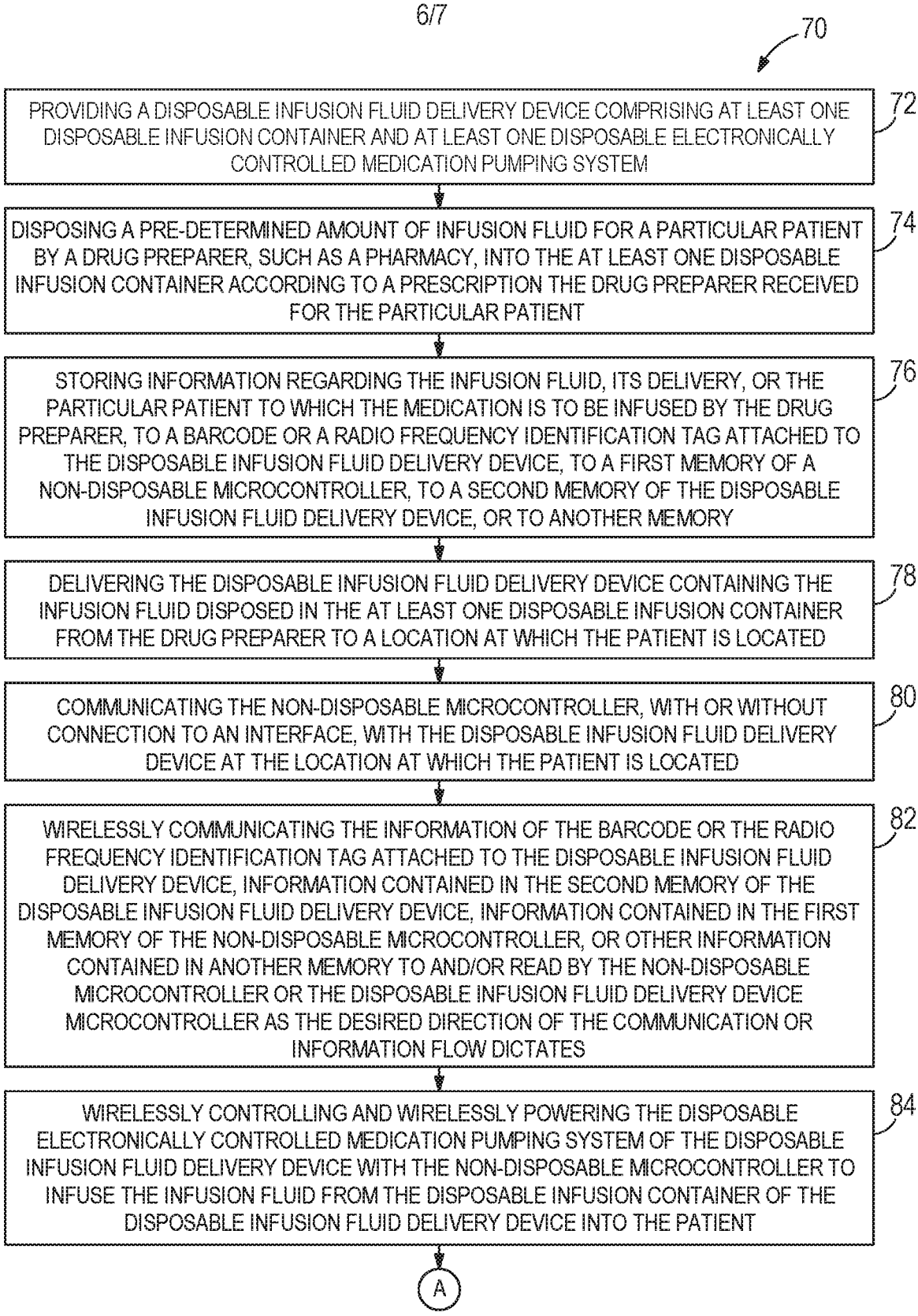


FIG. 5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PROVIDING A DISPOSABLE INFUSION FLUID DELIVERY DEVICE COMPRISING AT LEAST ONE DISPOSABLE INFUSION CONTAINER AND AT LEAST ONE DISPOSABLE ELECTRONICALLY CONTROLLED MEDICATION PUMPING SYSTEM
72
DISPOSING A PRE-DETERMINED AMOUNT OF INFUSION FLUID FOR A PARTICULAR PATIENT BY A DRUG PREPARER, SUCH AS A PHARMACY, INTO THE AT LEAST ONE DISPOSABLE INFUSION CONTAINER ACCORDING TO A PRESCRIPTION THE DRUG PREPARER RECEIVED FOR THE PARTICULAR PATIENT
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STORING INFORMATION REGARDING THE INFUSION FLUID, ITS DELIVERY, OR THE PARTICULAR PATIENT TO WHICH THE MEDICATION IS TO BE INFUSED BY THE DRUG PREPARER, TO A BARCODE OR A RADIO FREQUENCY IDENTIFICATION TAG ATTACHED TO THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE, TO A FIRST MEMORY OF A NON-DISPOSABLE MICROCONTROLLER, TO A SECOND MEMORY OF THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE, OR TO ANOTHER MEMORY
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78
COMMUNICATING THE NON-DISPOSABLE MICROCONTROLLER, WITH OR WITHOUT CONNECTION TO AN INTERFACE, WITH THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE AT THE LOCATION AT WHICH THE PATIENT IS LOCATED
80
WIRELESSLY COMMUNICATING THE INFORMATION OF THE BARCODE OR THE RADIO FREQUENCY IDENTIFICATION TAG ATTACHED TO THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE, INFORMATION CONTAINED IN THE SECOND MEMORY OF THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE, INFORMATION CONTAINED IN THE FIRST MEMORY OF THE NON-DISPOSABLE MICROCONTROLLER, OR OTHER INFORMATION CONTAINED IN ANOTHER MEMORY TO AND/OR READ BY THE NON-DISPOSABLE MICROCONTROLLER OR THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE MICROCONTROLLER AS THE DESIRED DIRECTION OF THE COMMUNICATION OR INFORMATION FLOW DICTATES
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WIRELESSLY CONTROLLING AND WIRELESSLY POWERING THE DISPOSABLE ELECTRONICALLY CONTROLLED MEDICATION PUMPING SYSTEM OF THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE WITH THE NON-DISPOSABLE MICROCONTROLLER TO INFUSE THE INFUSION FLUID FROM THE DISPOSABLE INFUSION CONTAINER OF THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE INTO THE PATIENT
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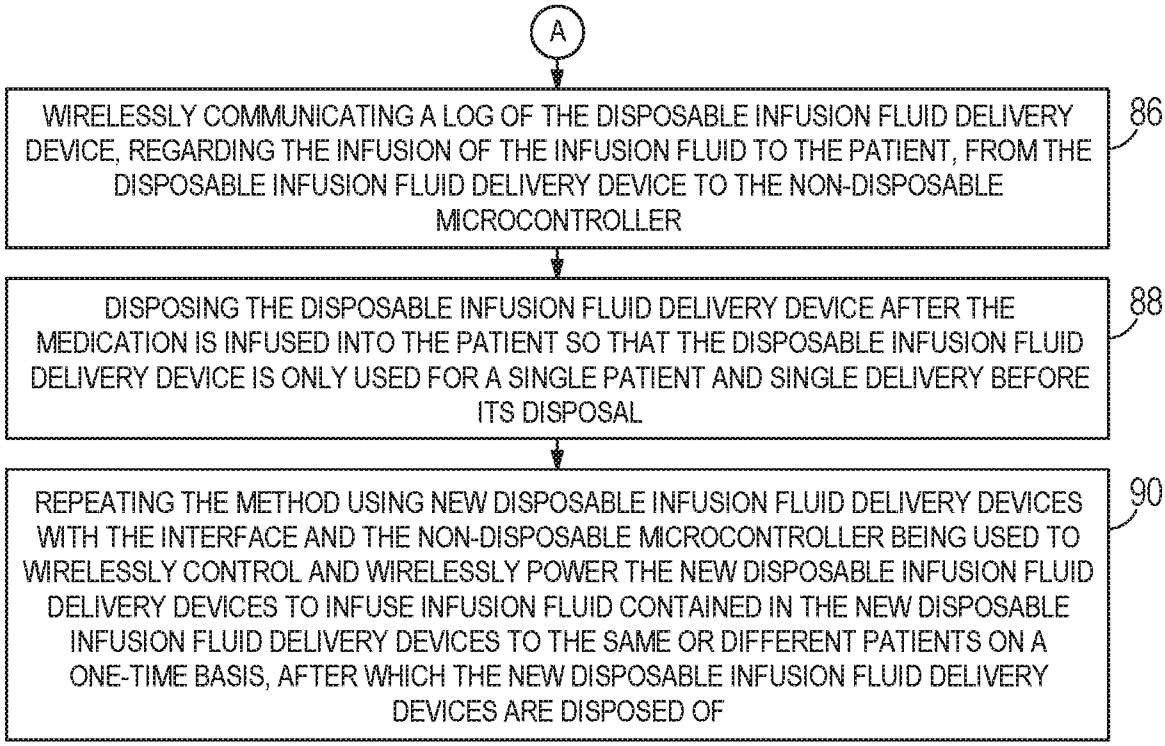
FIG. 6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WIRELESSLY COMMUNICATING A LOG OF THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE, REGARDING THE INFUSION OF THE INFUSION FLUID TO THE PATIENT, FROM THE DISPOSABLE INFUSION FLUID DELIVERY DEVICE TO THE NON-DISPOSABLE MICROCONTROLLER
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REPEATING THE METHOD USING NEW DISPOSABLE INFUSION FLUID DELIVERY DEVICES WITH THE INTERFACE AND THE NON-DISPOSABLE MICROCONTROLLER BEING USED TO WIRELESSLY CONTROL AND WIRELESSLY POWER THE NEW DISPOSABLE INFUSION FLUID DELIVERY DEVICES TO INFUSE INFUSION FLUID CONTAINED IN THE NEW DISPOSABLE INFUSION FLUID DELIVERY DEVICES TO THE SAME OR DIFFERENT PATIENTS ON A ONE-TIME BASIS, AFTER WHICH THE NEW DISPOSABLE INFUSION FLUID DELIVERY DEVICES ARE DISPOSED OF
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FIG. 6
(Con't)