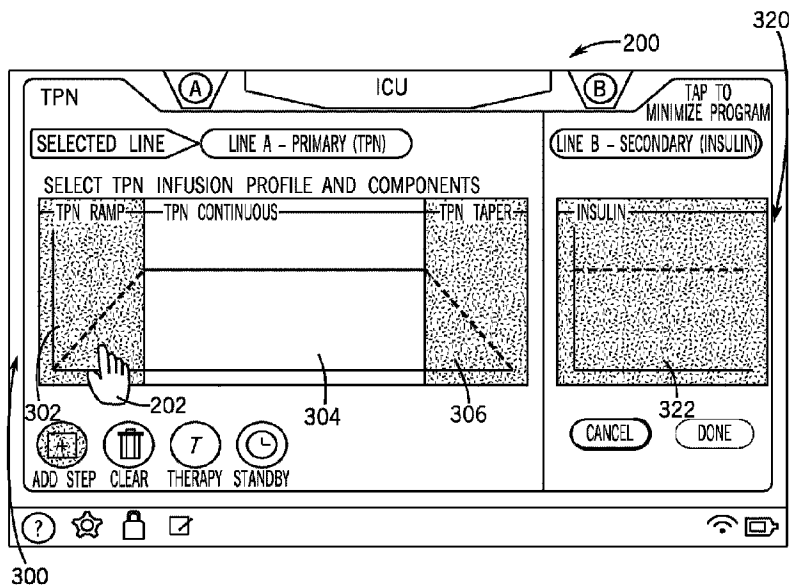




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(54) Titre : SYSTEME DE PERFUSION AVEC PERFUSION CONCOMITANTE DE NPT/INSULINE
(54) Title: INFUSION SYSTEM WITH CONCURRENT TPN/INSULIN INFUSION



(57) **Abrégé/Abstract:**

An infusion system to provide concurrent TPN/insulin infusion including: a fluid administration set having a primary line in fluid communication with the TPN source, a secondary line in fluid communication with the insulin source, and a common outlet line; a pump operable to removably receive the fluid administration set, the pump being operable to concurrently move the TPN solution through the primary line in response to a TPN solution flow rate signal and the insulin solution through the secondary line in response to an insulin solution flow rate signal; and a flow controller operable to provide the TPN solution flow rate signal and the insulin solution flow rate signal to the pump. The flow controller is further operable to vary the TPN solution flow rate signal and the insulin solution flow rate signal to vary a ratio of TPN solution to insulin solution provided to the common outlet line.

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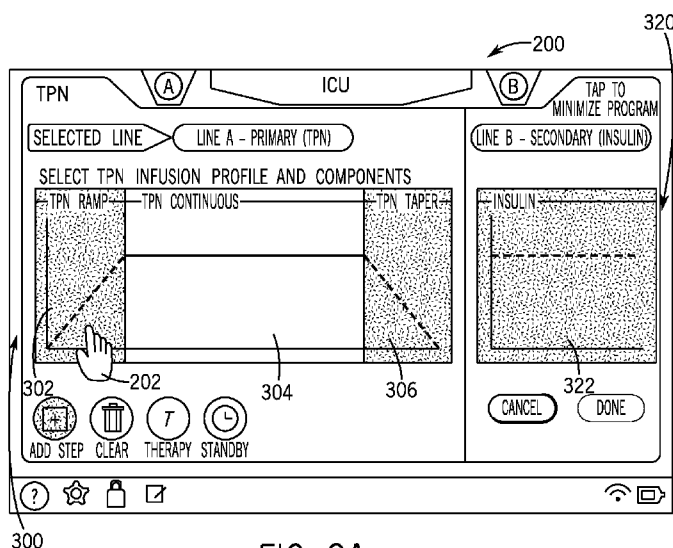


FIG. 3A

(57) Abstract: An infusion system to provide concurrent TPN/insulin infusion including: a fluid administration set having a primary line in fluid communication with the TPN source, a secondary line in fluid communication with the insulin source, and a common outlet line; a pump operable to removably receive the fluid administration set, the pump being operable to concurrently move the TPN solution through the primary line in response to a TPN solution flow rate signal and the insulin solution through the secondary line in response to an insulin solution flow rate signal; and a flow controller operable to provide the TPN solution flow rate signal and the insulin solution flow rate signal to the pump. The flow controller is further operable to vary the TPN solution flow rate signal and the insulin solution flow rate signal to vary a ratio of TPN solution to insulin solution provided to the common outlet line.

INFUSION SYSTEM WITH CONCURRENT TPN/INSULIN INFUSION

TECHNICAL FIELD

[0001] The present invention relates to medical devices. More specifically, the invention relates to infusion systems with concurrent total parenteral nutrition (TPN)/insulin infusion.

BACKGROUND OF THE INVENTION

[0002] Infusion pumps are medical devices that deliver fluids, including nutrients and medications such as antibiotics, chemotherapy drugs, and pain relievers, into a patient's body in controlled amounts. Many types of pumps, including large volume, patient-controlled analgesia (PCA), elastomeric, syringe, enteral, and insulin pumps, are used worldwide in healthcare facilities such as hospitals, and in the home. Clinicians and patients rely on pumps for safe and accurate administration of fluids and medications.

[0003] Total parenteral nutrition (TPN) is used to feed a person intravenously when the gastrointestinal tract is nonfunctional or impaired, so that nutrition cannot be provided to the patient through eating. TPN solution can include sugar, carbohydrates, proteins, lipids, electrolytes, trace elements, and various combinations thereof, as required for a particular patient.

[0004] Unfortunately, hyperglycemia is one complication associated with administration of TPN. Recent studies have highlighted that hyperglycemia is associated with increased risk of cardiac complications, infection, systemic sepsis, acute renal failure, and death for patients receiving TPN. Glycemic control in these patients is crucial in maintenance of tolerable blood glucose levels, a fact further substantiated by correlated adverse outcomes.

[0005] In present practice, TPN solution administration is tapered to 50% of the required dosing for the patient to minimize hyperglycemia and avoid glucose shock. Insulin is premixed in the same IV bag or container with the TPN solution based on calculated requirements for the patient, adding to clinician time and risk of error. Insulin dosing also

requires modulation based on monitored glucose levels during infusion. Subcutaneous insulin infusions can be administered to compensate for advancing hyperglycemia. For hypoglycemic situations, increased TPN (and specifically dextrose) delivery is indicated. Thus, infusion of both TPN and insulin as presently practiced is complex and time consuming.

[0006] It would be desirable to have an infusion system with concurrent TPN/insulin infusion that would overcome the above disadvantages.

SUMMARY OF THE INVENTION

[0007] One aspect of the present invention provides an infusion system for a patient for use with a TPN source of TPN solution and separate insulin source of insulin solution to provide concurrent TPN/insulin infusion, the infusion system including: a fluid administration set having a primary line in fluid communication with the TPN source, a secondary line in fluid communication with the insulin source, and a common outlet line in fluid communication with the primary line, the secondary line, and the patient; a pump operable to removably receive the fluid administration set, the pump being operable to concurrently move the TPN solution through the primary line in response to a TPN solution flow rate signal and the insulin solution through the secondary line in response to an insulin solution flow rate signal; and a flow controller operable to provide the TPN solution flow rate signal and the insulin solution flow rate signal to the pump. The flow controller is further operable to vary the TPN solution flow rate signal and the insulin solution flow rate signal to vary a ratio of TPN solution to insulin solution provided to the patient from the common outlet line.

[0008] Another aspect of the present invention provides a method to concurrently deliver a TPN solution from a TPN source and an insulin solution from separate insulin source, the method including: providing a fluid administration set having a primary line, a secondary line, a common outlet line, and a pumping/mixing chamber between and in fluid communication with the primary line, the secondary line, and common outlet line; connecting the primary line to the TPN source; connecting the secondary line to the insulin source; allowing TPN fluid into the pumping/mixing chamber; allowing insulin solution into the pumping/mixing chamber; mixing the TPN solution and the insulin solution to generate an

infusion mixture before the common outlet; with a positive displacement pump, driving the TPN solution through the common outlet line at a TPN dose rate and with a positive displacement pump, driving the insulin solution through the common outlet line at an insulin dose rate; and varying at least one of the TPN dose rate and the insulin dose rate to vary a ratio of TPN solution to insulin solution in the infusion mixture.

[0008a] According to an aspect of the invention is an infusion system for use with a total parenteral nutrition (TPN) source of TPN solution and an insulin source of insulin solution to provide concurrent TPN/insulin infusion, the infusion system comprising:

- a fluid administration set having a primary line in fluid communication with the TPN source, a secondary line in fluid communication with the insulin source, and a common outlet line connected to and in operative fluid communication with the primary line and the secondary line;

- a positive displacement pump operable to removably receive the fluid administration set, the pump having a drive mechanism being operable on the fluid administration set to concurrently move the TPN solution through the primary line to the outlet line in response to a TPN solution flow rate signal and the insulin solution through the secondary line to the outlet line in response to an insulin solution flow rate signal; and

- a flow controller operable to provide the TPN solution flow rate signal and the insulin solution flow rate signal to the drive mechanism of the pump,

- wherein the flow controller is further operable to vary the TPN solution flow rate signal and the insulin solution flow rate signal to vary a ratio of TPN solution to insulin solution provided to the common outlet;

- wherein the flow controller is further operable to ramp the TPN solution flow rate signal from a value corresponding to a TPN dose rate of zero to a value corresponding to a continuous phase TPN dose rate over a user selectable duration in a TPN ramp phase, and a glucose sensor operable to be connected to the patient to monitor glucose level and to provide a glucose signal to the flow controller, wherein the flow controller is further operable to vary the insulin solution flow rate signal from a first insulin solution flow rate signal to a second insulin solution flow rate signal in response to the glucose signal.

[0008b] According to a further aspect is a method of mixing a total parenteral nutrition (TPN) solution from a TPN source container and an insulin solution from an insulin source container that is separate from the TPN source container, the method comprising:

- providing a fluid administration set having a primary line, a secondary line, a common outlet line, and a pumping/mixing chamber located between and in fluid communication with the primary line, the secondary line and the common outlet line;

- connecting the primary line to the TPN source container;

- connecting the secondary line to the insulin source container;

- selectively allowing the primary line to feed TPN solution from the primary line to the pumping/mixing chamber;

- selectively allowing the secondary line to feed insulin solution to the pumping/mixing chamber;

- mixing the TPN solution and the insulin solution in the pumping/mixing chamber to generate an infusion mixture before the common outlet line;

- driving with a positive displacement pumping mechanism the TPN solution from the pumping/mixing chamber through the common outlet line at a TPN dose rate; and

- concurrently with said driving the TPN solution,

- driving with the positive displacement pumping mechanism the insulin solution from the mixing chamber through the common outlet line at an insulin dose rate;

- varying at least one of the TPN dose rate and the insulin dose rate to vary a ratio of TPN solution to insulin solution in the infusion mixture;

- ramping the TPN dose rate from a value corresponding to a TPN dose rate of zero to a value corresponding to a continuous phase TPN dose rate over a user selectable duration in a TPN ramp phase; and

- providing a glucose signal to a flow controller, which is obtainable by monitoring a glucose level with a glucose sensor operably connected to a patient, wherein the flow controller is further operable for varying the insulin solution flow rate signal from a first

insulin solution flow rate signal to a second insulin solution flow rate signal in response to the glucose signal.

[0009] The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[00010] **FIG. 1** is a block diagram of an infusion system with concurrent TPN/insulin infusion in accordance with the present invention;

[00011] **FIG. 1A** is a block diagram of an infusion system with concurrent TPN/insulin infusion in accordance with one embodiment of the present invention;

[00012] **FIG. 2** is an operating mode option screen for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention;

[00013] **FIGS. 3A - 3C** are infusion profile selection screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention;

[00014] **FIGS. 4A - 4I** are TPN infusion setup screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention;

[00015] **FIGS. 5A - 5F** are insulin infusion setup screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention;

[00016] **FIG. 6** is a confirmation screen for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention;

[00017] **FIGS. 7A - 7J** are operational screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention; and

[00018] **FIG. 8** is a flowchart of a method for concurrently administering a TPN solution and an insulin solution in accordance with the present invention.

[00019] **FIG. 9** is a flowchart of another method for concurrently delivering a TPN solution and an insulin solution in accordance with the present invention.

[00020] Like elements share like reference numbers throughout the various figures.

DETAILED DESCRIPTION OF PRESENTLY PREFERRED EMBODIMENTS

[00021] **FIG. 1** is a block diagram of an infusion system with concurrent TPN/insulin infusion in accordance with the present invention. The infusion system **100** for a patient **90** is for use with a TPN source or source container **102** of TPN solution and a separate insulin source or source container **104** of insulin solution. The infusion system **100** can concurrently deliver the TPN solution and the insulin solution, without requiring that the insulin be premixed in the same IV bag or container as the TPN solution or be administered by syringe boluses subcutaneously or a different pump or flow controller.

[00022] The infusion system **100** includes a fluid administration set **108**, a pump **120** operable to removably receive the administration set **108**, and a flow controller **130** operable to control flow through the administration set **108**. The administration set **108** has a primary line **112** in fluid communication with the TPN source **102**, a secondary line **114** in fluid communication with the insulin source **104**, and a common outlet line **116** connected to and in operative fluid communication with the primary line **112**, the secondary line **114**, and the patient **90**. The infusion system **100** can optionally include a glucose sensor **140** for providing feedback to the flow controller **130** and/or a user interface **200** providing input and/or output to a user **202**. The user interface **200** can be integral to or can be separate from the infusion system **100**. In one example, the user interface **200** is wired into the infusion system **100**. In another example, the user interface **200** communicates wirelessly with the infusion system **100**. The user **202** can be the patient **90** themselves or a caregiver of the patient **90**.

[00023] In one embodiment, the pump **120** is a positive displacement pump and has a drive mechanism **105** that is operable on the fluid administration set **108** to concurrently move the TPN solution through the primary line **112** to the outlet line **116** in response to a TPN solution flow rate signal **122** and the insulin solution through the secondary line **114** to the outlet line **116** in response to an insulin solution flow rate signal **124**. The flow controller **130** is operable to provide the TPN solution flow rate signal **122** and the insulin solution flow rate signal **124** to the drive mechanism **105** of the pump. The flow controller **130** is further operable to vary the TPN solution flow rate signal **122** and the insulin solution flow rate signal **124** to vary a ratio of TPN solution to insulin solution provided to the common outlet line **116**.

[00024] As best seen in **FIG. 1A**, in one embodiment the fluid administration set **108** comprises a cassette **110** including a primary inlet **113** joining a primary fluid passageway **112A** in the cassette **110** into fluid communication with the primary line **112**, a secondary inlet **117** joining a secondary fluid passageway **114A** in the cassette into fluid communication with the secondary line **114**, an outlet **109** in fluid communication with the outlet line **116**, and a pumping/mixing chamber **106** covered by a resilient flexible membrane **107** and in fluid communication with the primary fluid passageway **112A**, the secondary fluid passageway **114A**, and the outlet **109**. The drive mechanism **105** includes a motor **M** driving a plunger **P** into the membrane **107** covering the pumping/mixing chamber **106** in a reciprocating manner in response to a motor drive signal **123** from the flow controller **130**. In addition, the flow controller **130** provides control signals **122**, **124** and **125** respectively to operate a primary inlet valve **115**, a secondary inlet valve **119** and an outlet valve **121** so as to mix and displace fluid from the pumping/mixing chamber **106** through the outlet **109** into the outlet line **116** with each cycle of the plunger **P**. In one embodiment, the motor **M** is a stepper motor that extends and retracts the plunger **P** to displace fluid from the pumping/mixing chamber **106**. Therefore, the pump **120** acts on the cassette **110** and is operable to concurrently move the TPN solution through the primary line **112** in response to a TPN solution flow rate signal **122** and the insulin solution through the secondary line **114** in response to an insulin solution flow rate signal **124**. The flow controller **130** is operable to provide to the pump **120** the TPN solution flow rate signal **122** and the insulin solution flow rate signal **124**. The flow controller **130** is further

operable to vary the TPN solution flow rate signal **122** and the insulin solution flow rate signal **124** to vary a ratio of TPN solution to insulin solution provided from the common outlet **116** to the patient **90**. Thus, the flow controller **130** can vary the ratio of TPN solution to insulin solution in the infusion solution with time, as desired for a particular application. In one embodiment, the pump **120** is a Plum A+™ general purpose infusion system available from Hospira, Inc. of Lake Forest, Illinois. The cassette **110** is also available from Hospira, Inc. under the trademark PLUMSET™.

[00025] The TPN source **102** of TPN solution and the insulin source **104** of insulin solution can be any containers operable to hold liquid, such as an intravenous (IV) bag, rigid IV container, a syringe, or the like. The TPN solution can be any solution for total parenteral nutrition (TPN) and can include sugar, carbohydrates, proteins, lipids, electrolytes, trace elements, and the like, as required for a particular application. The insulin solution can include insulin in a solution such as in a saline solution, TPN solution, or the like. The concentration of the TPN solution and the insulin solution remain constant during the concurrent TPN/insulin infusion.

[00026] The pump **120** can be any pump operable to receive a fluid administration set in general or a cassette in particular. In one example, the cassette is a disposable cassette. In one example, the pump **120** pressurizes the primary line **112** and the secondary line **114**, and valves in each of the primary line **112** and the secondary line **114** of the disposable cassette **110** govern the flow rate in each of the primary line **112** and the secondary line **114**. In another example, the pump **120** varies impeller speed for impellers in each of the primary line **112** and the secondary line **114** to govern the flow rate in each of the primary line **112** and the secondary line **114**.

[00027] Those skilled in the art will appreciate that the flow controller **130** can include a processor and a memory coupled to the processor. The memory can contain programming code executable by the processor to carry out a method of concurrent TPN/insulin infusion as described herein.

[00028] The flow controller **130** can provide a TPN ramp phase, a TPN continuous phase, a TPN taper phase, and/or a TPN Keep Vein Open (KVO) phase during the concurrent TPN/insulin infusion as desired for a particular application. One skilled in the art will recognize in view of the present disclosure that the TPN KVO phase is really just a special case of a Continue at the Same or Different Rate TPN phase.

[00029] The TPN ramp phase ramps the TPN flow rate through the primary line **112** from zero to the TPN flow rate for the TPN continuous phase, such as can be used at the beginning of the concurrent TPN/insulin infusion. An exemplary TPN ramp phase is illustrated at Ramp portion **610** of **FIG. 6**. Referring to **FIG. 1**, for the TPN ramp phase the flow controller **130** can ramp the TPN solution flow rate signal from a value corresponding to a TPN dose rate of zero to a value corresponding to a continuous phase TPN dose rate. In one embodiment, the flow controller **130** can maintain the insulin solution flow rate signal **124** at a value corresponding to an insulin dose rate of zero during the TPN ramp phase. In another embodiment, the flow controller **130** can maintain the insulin solution flow rate signal **124** as a selected fraction of the TPN solution flow rate signal **122** during the TPN ramp phase to maintain the ratio of the TPN solution to the insulin solution as constant during the TPN ramp phase. In yet another embodiment, the flow controller **130** can maintain the insulin solution flow rate signal **124** at a value corresponding to a continuous phase insulin dose rate during the TPN ramp phase.

[00030] The TPN continuous phase can maintain the TPN flow rate through the primary line **112** as constant. An exemplary TPN continuous phase is illustrated at Continuous portion **620** of **FIG. 6**. Referring to **FIG. 1**, for the TPN continuous phase the flow controller and can maintain the TPN solution flow rate signal **122** at a value corresponding to a continuous phase TPN dose rate and to maintain the insulin solution flow rate signal **124** at a selected fraction of the TPN solution flow rate signal **122** during the TPN continuous phase. Those skilled in the art will appreciate that the insulin solution flow rate signal **124** can be adjusted during the TPN continuous phase as desired to manually or automatically adjust for measured glucose levels of the patient.

[00031] The TPN taper phase can taper the TPN flow rate through the primary line **112** from the TPN flow rate for the TPN continuous phase, such as can be used at the end of the

concurrent TPN/insulin infusion. An exemplary TPN taper phase is illustrated at TPN Taper option **306** of **FIG. 3A**. Referring to **FIG. 1**, for the TPN taper phase the flow controller can taper the TPN solution flow rate signal **122** from a value corresponding to a continuous phase TPN dose rate to a value corresponding to a TPN dose rate of zero during the TPN taper phase. In one embodiment, the flow controller **130** can maintain the insulin solution flow rate signal **124** at a value corresponding to an insulin dose rate of zero during the TPN taper phase. In another embodiment, the flow controller **130** can maintain the insulin solution flow rate signal **124** as a selected fraction of the TPN solution flow rate signal **122** to maintain the ratio of the TPN solution to the insulin solution as constant during the TPN taper phase. In yet another embodiment, the flow controller **130** can maintain the insulin solution flow rate signal **124** at a value corresponding to a continuous phase insulin dose rate during the TPN taper phase.

[00032] The TPN Keep Vein Open (KVO) phase can step the TPN flow rate through the primary line **112** from the TPN flow rate for the TPN continuous phase to zero, such as can be used at the end of the concurrent TPN/insulin infusion. An exemplary TPN KVO phase is illustrated at KVO portion **630** of **FIG. 6**. Referring to **FIG. 1**, for the TPN KVO phase the flow controller **130** can decrease the TPN solution flow rate signal **122** from a value corresponding to a continuous phase TPN dose rate to a value corresponding to a Keep Vein Open (KVO) TPN dose rate after a TPN continuous phase. Again, one skilled in the art will recognize in view of the present disclosure that the TPN KVO phase is really just a special case of a Continue at the Same or Different Rate TPN phase.

[00033] The insulin flow rate can be adjusted by the user **202** on the fly, i.e., as the concurrent TPN/insulin infusion proceeds, as illustrated in **FIGS. 7E - 7H**. Referring to **FIG. 1**, the flow controller **130** can vary the insulin solution flow rate signal **124** from a first insulin solution flow rate signal to a second insulin solution flow rate signal in response to input of the second insulin solution flow rate signal by a user **202**.

[00034] The insulin flow rate can also be adjusted in response to current glucose measurements for the patient **90**. The infusion system **100** can also include a glucose sensor **140** operably connected to the patient **90** to monitor glucose level and to provide a glucose signal **92** to the flow controller **130**. In one embodiment, the flow controller **130** is further

operable to vary the insulin solution flow rate signal **124** from a first insulin solution flow rate signal to a second insulin solution flow rate signal in response to the glucose signal **92**. In one embodiment, the glucose sensor **140** can provide the glucose signal **92** to an insulin therapy calculation system or algorithm, which then automatically programs (auto-programs or auto-populates) the flow controller **130** and populates a user interface **200** with updated delivery parameters, such as rate, volume and duration, and the like.

[00035] The infusion system **100** can also include a user interface **200** operably connected to the flow controller **130** to provide information for and/or receive instructions from the user **202**. The user interface **200** is operable to display a TPN/Insulin Infusion Plot portion having a TPN Infusion profile and an Insulin Infusion profile. An exemplary TPN/Insulin Infusion Plot is illustrated at TPN/Insulin Infusion Plot portion **700** of **FIG. 7A**. Referring to **FIG. 1**, in one embodiment, the user interface **200** is further operable to display an Infusion Progression indicator on the TPN/Insulin Infusion Plot portion, the Infusion Progression indicator being operable to indicate a current state of the concurrent TPN/insulin infusion. In one embodiment, the user interface **200** is further operable to display an infusion portion selected from the group consisting of a Ramp portion, a Continuous portion, a Taper portion, and a KVO/continue rate portion. In one embodiment, the user interface **200** is a touch screen. In another embodiment, the user interface **200** is a combination of the electromechanical switches and a graphical display.

[00036] **FIGS. 2 - 7** illustrate exemplary screens on the user interface of an infusion system with concurrent TPN/insulin infusion in accordance with the present invention. For clarity of illustration, a hand icon in **FIGS. 2 - 7** indicates interaction of the user **202** with the user interface **200**.

[00037] **FIG. 2** is an operating mode option screen for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention. The user **202** can select Tap to Program TPN key **204** on the user interface **200** to initiate programming of a concurrent TPN/insulin infusion.

[00038] **FIGS. 3A - 3C** are infusion profile selection screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention. The user can select a desired profile for concurrent TPN/insulin infusion.

[00039] Referring to **FIG. 3A**, the user interface **200** displays a TPN portion **300** for selecting the TPN infusion profile and an insulin portion **320** for selecting concurrent insulin infusion. In this example, the TPN portion **300** is associated with the primary line A and the insulin portion **320** is associated with the secondary line B. The TPN portion **300** can include a TPN Ramp option **302**, a TPN Continuous option **304**, and a TPN Taper option **306**. The insulin portion **320** can include an Infusion option **322**. In this example, the TPN Continuous option **304** is selected by default, and the TPN Ramp option **302**, the TPN Taper option **306**, and the Infusion option **322** are unselected. The user **202** selects the TPN Ramp option **302** and leaves the TPN Taper option **306** unselected. In this example, the unselected options are grayed out and the selected options are highlighted on the user interface **200**.

[00040] In one embodiment, the TPN continuous option **304** is selected by default so that the user does not have to select the TPN continuous option **304**. In one embodiment, the TPN Ramp option **302**, the TPN Taper option **306**, and the Infusion option **322** are unselected by default. Those skilled in the art will appreciate that the selected and unselected options can be provided in any combination as desired for a particular application.

[00041] Referring to **FIG. 3B**, the user **202** selects the Infusion option **322** in the infusion portion **320**. Referring to **FIG. 3C**, the user **202** has completed selection of the concurrent TPN/insulin infusion profile and selects a Done key **330** to close out the profile selection and proceed to TPN infusion setup. The TPN Ramp option **302**, the TPN Continuous option **304**, and the Infusion option **322** are enabled as indicated by the highlighting.

[00042] **FIGS. 4A - 4I** are TPN infusion setup screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention.

[00043] Referring to **FIG. 4A**, the user interface **200** displays a TPN Infusion Setup portion **380** and a TPN Volume portion **410** displaying potential volumes of TPN solution available for selection, i.e., potential TPN solution container volumes. In this example, the user

202 selects 2 L as the TPN solution volume to match the TPN solution container volume of the TPN source connected to the disposable cassette.

[00044] Referring to **FIG. 4B**, the user interface **200** displays a TPN Continuous Phase portion **390** and a TPN Dose Unit portion **420**. The TPN Continuous Phase portion **390** includes a TPN Phase Being Programmed indicator **392** and a TPN Solution Volume indicator **394**. The TPN Dose Unit portion **420** displays potential dose units for selection. In this example, the user **202** selects mL/kg/day as the dose unit.

[00045] Referring to **FIG. 4C**, the user interface **200** displays a TPN Dose Unit indicator **396** in the TPN Continuous Phase portion **390**, and a Desired TPN Dose box **432** and entry keypad **434** in the TPN Dose portion **430**. The user can enter the desired TPN dose to be delivered during the TPN continuous phase in the Desired TPN Dose box **432** using the entry keypad **434**. Referring to **FIG. 4D**, the desired TPN dose appears in the Desired TPN Dose box **432** and the user **202** selects a Done key **436** to close out the TPN Dose & Unit selection and proceed to a Weight selection.

[00046] Referring to **FIG. 4E**, the user interface **200** displays a TPN Dose indicator **398** in the TPN Continuous Phase portion **390**, and a Weight box **442** and entry keypad **444** in the TPN Dose Unit portion **440**. The user can enter the weight of the patient in the Weight box **442** using the entry keypad **444**. Referring to **FIG. 4F**, the weight appears in the Weight box **442** and the user **202** selects a Done key **446** to close out the Weight selection and proceed to TPN Duration selection.

[00047] Referring to **FIG. 4G**, the user interface **200** displays a Weight indicator **400** and a TPN Rate indicator **402** in the TPN Continuous Phase portion **390**. The numerical value for the rate in the TPN Rate indicator **402** is automatically calculated based on the dose, dose unit, and weight. The user interface **200** also displays a TPN Duration box **452** and entry keypad **454** in the TPN Dose Unit portion **450**. The user can enter the desired TPN dose duration of the TPN continuous phase the TPN Duration box **452** using the entry keypad **454**. Referring to **FIG. 4H**, the desired TPN dose appears in the TPN Duration box **452** and the user **202** selects a Done key **456** to close out the TPN Duration selection and proceed to TPN Options selection.

[00048] Referring to **FIG. 4I**, the user interface **200** displays a TPN Duration indicator **404** and a TPN Volume to Be Infused (VTBI) indicator **406** in the TPN Continuous Phase portion **390**. The numerical value for the VTBI in the VTBI indicator **406** is automatically calculated based on the duration and rate. The user interface **200** also displays a TPN Continuous Program Options portion **460** including an End of Infusion Action section **462**, a Nearing End of Infusion Alarm section **464**, and an Air-in-Line Alarm section **468**. The End of Infusion Action section **462** includes options to be performed after the TPN infusion is complete, such as a Keep Vein Open (KVO) option with rate value input to continue infusion at a reduced rate, a Continue Rate option to continue infusion at the previous rate, and a Stop option to end the infusion. In this example, the Keep Vein Open (KVO) option with a rate value of one mL/hr is selected. The Nearing End of Infusion Alarm section **464** includes enabling or disabling (On or Off) an optional alarm as the TPN infusion nears completion, with a value time input for the amount of time before the End of Infusion alarm is to occur. In this example, the Nearing End of Infusion Alarm is turned off. The Air-in-Line Alarm section **468** provides an air volume input value at which the Air-in-Line Alarm is to occur. In this example, the Air-in-Line Alarm is set to occur at an error volume of **250** mL. The user **202** selects a Next key **470** to close out the Options selection and proceed to insulin infusion setup.

[00049] **FIGS. 5A - 5F** are insulin infusion setup screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention.

[00050] Referring to **FIG. 5A**, the user interface **200** displays an Insulin Infusion Setup portion **480** and an Insulin Concentration portion **510** displaying potential concentrations of insulin solution available for selection. In this example, the user **202** selects 1 unit / mL concentration as the insulin solution concentration.

[00051] Referring to **FIG. 5B**, the user interface **200** displays an Insulin Solution Concentration indicator **482** in the Insulin Infusion Setup portion **480** and potential volumes of insulin solution available for selection, i.e., potential insulin solution container volumes, in an Insulin Volume portion **520**. In this example, the user interface **200** switches from the Insulin Concentration portion to the Insulin Volume portion **520** automatically when the user selects the insulin solution concentration in the Insulin Concentration portion. In this example, the

user **202** selects a 100 mL as the insulin solution volume to match the insulin solution container volume of the insulin source connected to the disposable cassette.

[00052] Referring to **FIG. 5C**, the user interface **200** displays an Insulin Solution Concentration indicator **584** and an Insulin Solution Volume indicator **586** in an Insulin Infusion portion **490**, which also includes the Insulin Duration indicator **504** showing the previously entered desired TPN dose duration (being the same as the desired insulin dose duration). The user interface **200** also displays a Desired Insulin Dose box **532** and entry keypad **534** in the Insulin Dose portion **530**. The dose units are automatically selected to be the standard Units (of insulin) / L of TPN. The user can enter the desired insulin dose to be delivered during the TPN continuous phase in the Desired Insulin Dose box **532** using the entry keypad **534**. Referring to **FIG. 5D**, the desired insulin dose appears in the Desired Insulin Dose box **532** and the user **202** selects a Done key **536** to close out the Insulin Dose & Unit selection and proceed to Insulin Options selection.

[00053] Referring to **FIG. 5E**, the user interface **200** displays an Insulin Volume to Be Infused (VTBI) indicator **506** and an Insulin Rate indicator **508** in the Insulin Continuous Phase portion **490**. The insulin VTBI and insulin rate are automatically calculated from the insulin duration, the TPN VTBI, and the TPN rate entered and/or calculated previously. The user interface **200** also displays an Insulin Infusion Options portion **540** providing additional options for insulin administration and rate. The insulin infusion options allow independently titrating the insulin delivery or linking the insulin delivery to the TPN delivery in ways that cannot be achieved if the TPN solution and insulin solution are premixed in the same IV bag. When the Only When TPN in Continuous Phase button **542** is selected, insulin infusion is only provided when the TPN is in the continuous phase. In this example, the user **202** is selecting the Ramp and Taper button **544**.

[00054] Referring to **FIG. 5F**, the Ramp and Taper button **544** is selected and the Only When TPN in Continuous Phase button **542** is deselected. During the ramp and taper portion of the infusion, the insulin infusion rate can be linked to the TPN infusion rate by selecting a Rate Linked to TPN button **546** or can be maintained at the insulin infusion rate used in the TPN continuous phase by selecting the Keep Continuous Phase Rate button **548**. In this example,

the Rate Linked to TPN button **546** is selected. The user **202** selects a Next key **550** to close out the Insulin Infusion Options selection and proceed to infusion confirmation.

[00055] **FIG. 6** is a confirmation screen for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention. The user can check the confirmation screen to verify that the TPN infusion parameters and insulin infusion parameters have been entered and calculated as desired.

[00056] The user interface **200** displays a confirmation screen **600** having a Ramp portion **610**, a Continuous portion **620**, and a KVO portion **630**. The confirmation screen **600** further includes TPN infusion profiles **612**, **622**, **632** and insulin infusion profiles **614**, **624**, **634**. In this example based on the previously entered parameters, the TPN infusion ramp **612** increases from zero to 133.33 mL/hr over 2.0 hours. The insulin infusion ramp **614**, linked to the TPN infusion, increases from zero to 1.33 mL/hr over 2.0 hours. In this example, ramping is preset to 2 hours, but can also be altered as needed for a particular application. For the next 12 hours after the infusion ramp, the TPN continuous infusion **622** is maintained at 133.33 mL/hr and the insulin continuous infusion **624** is maintained at 1.33 mL/hr. Until stopped after the continuous infusion, the TPN KVO infusion **632** is maintained at 1.0 mL/hr and the insulin KVO infusion **634** is zero. The user **202** selects a Start key **650** to start the concurrent TPN/insulin infusion.

[00057] **FIGS. 7A - 7J** are operational screens for an infusion system with concurrent TPN/insulin infusion in accordance with the present invention. The operational screens display numerical and graphical information for the concurrent TPN/insulin infusion as planned and as the infusion proceeds.

[00058] Referring to **FIG. 7A**, the user interface **200** displays an Infusion Phase indicator **701**, a TPN/Insulin Infusion Plot portion **700**, a TPN Infusion portion **740**, and an Insulin Infusion portion **760**. The Infusion Phase indicator **701** displays the current phase of the concurrent TPN/insulin infusion.

[00059] The TPN/Insulin Infusion Plot of the TPN/Insulin Infusion Plot portion **700** displays infusion profiles and visual status for two concurrent drug deliveries. The TPN/Insulin Infusion Plot portion **700** has a Ramp portion **710** with a Ramp Phase Time Remaining indicator

712, a Continuous portion **720** with a Continuous Phase Time Remaining indicator **722**, and a KVO portion **730** with a KVO Phase Time Remaining indicator **732**. A TPN Infusion profile **702** and an Insulin Infusion profile **704** display the injection rates of the TPN infusion and Insulin Infusion with time over the concurrent TPN/insulin infusion. An Infusion Progression indicator **706** illustrates the current state of the concurrent TPN/insulin infusion. In this example, the TPN/Insulin Infusion Plot portion **700** preceding the Infusion Progression indicator **706** is grayed out.

[00060] The TPN Infusion portion **740** includes a Line A Activity indicator **742** (which can be animated to indicate that the Line A is pumping), a TPN Solution Volume indicator **744**, a TPN Dose indicator **746**, a TPN Dose Rate indicator **748**, and a TPN VTBI indicator **750**. The Insulin Infusion portion **760** includes a Line B Activity indicator **762** (which can be animated to indicate that the Line A is pumping), an Insulin Solution Volume indicator **764**, an Insulin Dose indicator **766**, an Insulin Rate indicator **768**, and an Insulin VTBI indicator **770**. The values presented in the TPN Infusion portion **740** and the Insulin Infusion portion **760** are updated as the concurrent TPN/insulin infusion proceeds. The values illustrated in the example of **FIG. 7A** are at the beginning of the ramp phase of the concurrent TPN/insulin infusion. The infusion rate of each line will gradually ramp over the next 2 hours until the continuous phase is reached.

[00061] Referring to **FIG. 7B**, this example shows the user interface **200** with 1:15 (hh:mm) of the ramp phase of the concurrent TPN/insulin infusion remaining, as indicated by the position of the Infusion Progression indicator **706** and the value of the Ramp Phase Time Remaining indicator **712**. The Infusion Phase indicator **701** displays the current phase of the concurrent TPN/insulin infusion as the ramp phase. The values presented in the TPN Infusion portion **740** and the Insulin Infusion portion **760** are updated for the present time in the concurrent TPN/insulin infusion.

[00062] Referring to **FIG. 7C**, this example shows the user interface **200** at the beginning of the continuous phase of the concurrent TPN/insulin infusion, as indicated by the position of the Infusion Progression indicator **706**, the value (0:00) of the Ramp Phase Time Remaining indicator **712**, and the value (12:00) of the Continuous Phase Time Remaining indicator **722**.

The Infusion Phase indicator **701** displays the current phase of the concurrent TPN/insulin infusion as the continuous phase. The values presented in the TPN Infusion portion **740** and the Insulin Infusion portion **760** are updated for the present time in the continuous phase.

[00063] Referring to **FIG. 7D**, this example shows the user interface **200** during the continuous phase of the concurrent TPN/insulin infusion, as indicated by the position of the Infusion Progression indicator **706** and the value (5:13) of the Continuous Phase Time Remaining indicator **722**. The VTBI values presented in the TPN Infusion portion **740** and the Insulin Infusion portion **760** are updated for the present time in the continuous phase. The dose values and rate values remain constant during the continuous phase.

[00064] **FIGS. 7E - 7H** illustrate action by the user to titrate the insulin dose, through on the fly changes or hot titration. For example, when the measured blood glucose levels of the patient are elevated above the optimum range, the user **202** can increase the relative insulin infusion (units/L of TPN). Referring to **FIG. 7E**, the user **202** selects the Insulin Dose indicator **766**. Referring to **FIG. 7F**, the user interface **200** displays a Desired Insulin Dose box **782** and entry keypad **784**. Referring to **FIG. 7G**, the user **202** has entered the new desired insulin dose on the entry keypad **784** and the value of the new desired insulin dose (20 units/L of TPN in place of the previous 10 units/L of TPN) appears in the Desired Insulin Dose box **782**. The user **202** selects a Start key **786** to restart the concurrent TPN/insulin infusion. Referring to **FIG. 7H**, the Insulin Dose indicator **766** displays the value for the new desired insulin dose (20 units/L of TPN), and the Insulin Rate indicator **768** and the Insulin VTBI indicator **770** display values of the insulin rate and the insulin VTBI, respectively, automatically calculated for the new desired insulin dose.

[00065] Referring to **FIG. 7I**, this example shows the user interface **200** during the continuous phase of the concurrent TPN/insulin infusion, as indicated by the position of the Infusion Progression indicator **706** and the value (1:00) of the Continuous Phase Time Remaining indicator **722**. The VTBI values presented in the TPN Infusion portion **740** and the Insulin Infusion portion **760** are updated for the present time in the continuous phase. The Insulin Dose indicator **766** continues to display the value for the new desired insulin dose (20 units/L of TPN). The dose values and rate values remain constant during the continuous phase.

[00066] Referring to **FIG. 7J**, this example shows the user interface **200** at the beginning of the KVO phase of the concurrent TPN/insulin infusion, as indicated by the position of the Infusion Progression indicator **706**, the value (0:00) of the Continuous Phase Time Remaining indicator **722**, and the value (until stopped) of the KVO Phase Time Remaining indicator **732**. The Infusion Phase indicator **701** displays the current phase of the concurrent TPN/insulin infusion as the KVO phase. The values presented in the TPN Infusion portion **740** reflect the End of Infusion Action selected, i.e., the Keep Vein Open (KVO) option with a rate value of one mL/hr displayed in the TPN Dose Rate indicator **748**. The TPN VTBI indicator **750** displays KVO to indicate that the KVO phase will continue until stopped. The values presented in the Insulin Infusion portion **760** include the new desired insulin dose (20 units/L of TPN) from the previous continuous phase in the Insulin Dose indicator **766**, and values of zero for the Insulin Rate indicator **768** and the Insulin VTBI indicator **770** to indicate that no insulin infusion is being performed during the KVO phase.

[00067] Those skilled in the art will appreciate that the concurrent TPN/insulin infusion can include different phases as desired for a particular application. The concurrent TPN/insulin infusion can include TPN ramp, TPN continuous, TPN taper, and/or KVO phases, and combinations thereof. The example of **FIG. 7J** concludes with a KVO phase. In another example, the concurrent TPN/insulin infusion can conclude with a TPN taper. Those skilled in the art will appreciate that the various phases can be of different durations, which can be input or are selectable by the user **202** via the user interface **200**.

[00068] **FIG. 8** is a flowchart of a method for concurrently administering a TPN solution and an insulin solution in accordance with the present invention. In one embodiment, the method **800** can be performed using the infusion system **100** illustrated in **FIG. 1**.

[00069] Referring to **FIG. 8**, the method **800** can concurrently administer to a patient a TPN solution from a TPN source and an insulin solution from an insulin source. The method **800** includes: providing a disposable cassette **810** having a primary line, a secondary line, and a common outlet, the primary line and the secondary line being in fluid communication with the common outlet; connecting the TPN source to the primary line **820**; connecting the insulin source to the secondary line **830**; placing the common outlet in fluid communication with the

patient **840**; driving the TPN solution through the primary line **850** at a TPN dose rate; driving the insulin solution through the secondary line **860** at an insulin dose rate; mixing the TPN solution and the insulin solution in the disposable cassette to generate an infusion mixture before the common outlet **870**; varying at least one of the TPN dose rate and the insulin dose rate **880** to vary a ratio of TPN solution to insulin solution in the infusion mixture; and administering the infusion mixture to the patient **890**.

[00070] The varying at least one of the TPN dose rate and the insulin dose rate **880** can provide a TPN ramp phase, a TPN continuous phase, a TPN taper phase, and/or a TPN Keep Vein Open (KVO) phase during the concurrent TPN/insulin infusion as desired for a particular application.

[00071] To generate the TPN ramp phase, such as can be used at the beginning of the concurrent TPN/insulin infusion, the method **800** can include ramping the TPN dose rate from zero to a continuous phase TPN dose rate. An exemplary TPN ramp phase is illustrated at Ramp portion **610** of **FIG. 6**. In one embodiment, the method **800** can maintain the insulin dose rate at zero during the TPN ramp phase. In another embodiment, the method **800** can maintain the insulin dose rate at a selected fraction of the TPN solution flow rate during the TPN ramp phase. In yet another embodiment, the method **800** can maintain the insulin dose rate at a continuous phase insulin dose rate during the TPN ramp phase.

[00072] To generate the TPN continuous phase, which maintains the TPN dose rate constant, the method **800** can include maintaining the TPN dose rate at a continuous phase TPN dose rate and maintaining the insulin dose rate at a selected fraction of the continuous phase TPN dose rate. An exemplary TPN continuous phase is illustrated at Continuous portion **620** of **FIG. 6**. Those skilled in the art will appreciate that the insulin dose rate can be adjusted during the TPN continuous phase as desired to manually or automatically adjust for measured glucose levels of the patient.

[00073] To generate the TPN taper phase, such as can be used at the end of the concurrent TPN/insulin infusion, the method **800** can include tapering the TPN dose rate from a continuous phase TPN dose rate to a TPN dose rate of zero. An exemplary TPN taper phase is

illustrated at TPN Taper option **306** of **FIG. 3A**. In one embodiment, the method **800** can include maintaining the insulin solution dose rate at zero during the TPN taper phase. In another embodiment, the method **800** can include maintaining the insulin solution dose rate at a selected fraction of the TPN solution dose rate to maintain the ratio of the TPN solution to the insulin solution as constant during the TPN taper phase. In yet another embodiment, the method **800** can include maintaining the insulin solution dose rate at a continuous phase insulin and dose rate during the TPN taper phase.

[00074] To generate the TPN Keep Vein Open (KVO) phase, such as can be used at the end of the concurrent TPN/insulin infusion, the method **800** can include decreasing the TPN dose rate from a continuous phase TPN dose rate to a Keep Vein Open (KVO) TPN dose rate. An exemplary TPN KVO phase is illustrated at KVO portion **630** of **FIG. 6**. Those skilled in the art will appreciate that the various phases can be of different durations, which can be input or are selectable by the user **202** via the user interface **200**.

[00075] The method **800** can include the user adjusting the insulin flow rate on the fly, i.e., as the concurrent TPN/insulin infusion proceeds, as illustrated in **FIGS. 7E - 7H**. When the insulin dose rate of the driving the insulin solution through the secondary line **860** at an insulin dose rate is a first insulin dose rate, the method **800** can include driving the insulin solution at a second insulin dose rate in response to input of the second insulin dose rate by a user. The second insulin dose rate can adjust for measured glucose levels of the patient.

[00076] To avoid hyperglycemia or hypoglycemia in the patient, the method **800** can include monitoring glucose level in the patient and adjusting the insulin dose rate in response to the monitored glucose level. In one embodiment, the method **800** can include changing the insulin dose rate from a first insulin dose rate to a second insulin dose rate in response to the monitored glucose level. In one embodiment, a glucose sensor can provide the monitored glucose level to an insulin therapy calculation system or algorithm, which then automatically programs (auto-programs or auto-populates) the flow controller and populates the user interface with updated delivery parameters, such as rate, volume and duration, and the like.

[00077] To allow the user to monitor progress of the concurrent TPN/insulin infusion, the method 800 can include displaying planned values of the TPN dose rate and the insulin dose rate as a function of time on a TPN/Insulin Infusion Plot, and optionally displaying an Infusion Progression indicator at a present infusion time on the TPN/Insulin Infusion Plot. An exemplary TPN/Insulin Infusion Plot is illustrated at TPN/Insulin Infusion Plot portion **700** of **FIG. 7A**. The TPN/Insulin Infusion Plot portion can include a TPN Infusion profile and an Insulin Infusion profile. In one embodiment, the method **800** can include displaying an infusion portion selected from the group consisting of a Ramp portion, a Continuous portion, a Taper portion, and a KVO portion.

Another embodiment of the invention is shown in **FIG. 9**. In this embodiment, a method **900** is shown to concurrently deliver a TPN solution from a TPN source container and an insulin solution from an insulin source container that is separate from the TPN source container. The method **900** includes, in step **910**, providing a fluid administration set having a primary line, a secondary line, a common outlet line, and a pumping/mixing chamber located between and in fluid communication with the primary line, the secondary line and the common outlet line. The method **900** includes, in step **920**, connecting the primary line to the TPN source container and, in step **930**, connecting the secondary line to the insulin source container. The method **900** further includes, in step **940**, selectively allowing the primary line to feed TPN solution from the primary line to the pumping/mixing chamber and, in step **950**, selectively allowing the secondary line to feed insulin solution to the pumping/mixing chamber. The method **900** includes, in step **960**, mixing the TPN solution and the insulin solution in the pumping/mixing chamber to generate an infusion mixture before the common outlet line. The method **900** further includes, in step **970**, driving with a positive displacement pumping mechanism the TPN solution from the pumping/mixing chamber through the common outlet line at a TPN dose rate, and concurrently with said driving the TPN solution step, in step **980**, driving with the positive displacement pumping mechanism the insulin solution from the mixing chamber through the common outlet line at an insulin dose rate. The method **900** also includes, in step **990**, varying at least one of the TPN dose rate and the insulin dose rate to vary a ratio of TPN solution to insulin solution in the infusion mixture.

[00080] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes, rearrangement of steps, and modifications can be made without departing from the scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.

CLAIMS

1. An infusion system for use with a total parenteral nutrition (TPN) source of TPN solution and an insulin source of insulin solution to provide concurrent TPN/insulin infusion, the infusion system comprising:

a fluid administration set having a primary line in fluid communication with the TPN source, a secondary line in fluid communication with the insulin source, and a common outlet line connected to and in operative fluid communication with the primary line and the secondary line;

a positive displacement pump operable to removably receive the fluid administration set, the pump having a drive mechanism being operable on the fluid administration set to concurrently move the TPN solution through the primary line to the outlet line in response to a TPN solution flow rate signal and the insulin solution through the secondary line to the outlet line in response to an insulin solution flow rate signal; and

a flow controller operable to provide the TPN solution flow rate signal and the insulin solution flow rate signal to the drive mechanism of the pump,

wherein the flow controller is further operable to vary the TPN solution flow rate signal and the insulin solution flow rate signal to vary a ratio of TPN solution to insulin solution provided to the common outlet;

wherein the flow controller is further operable to ramp the TPN solution flow rate signal from a value corresponding to a TPN dose rate of zero to a value corresponding to a continuous phase TPN dose rate over a user selectable duration in a TPN ramp phase, and

a glucose sensor operable to be connected to the patient to monitor glucose level and to provide a glucose signal to the flow controller, wherein the flow controller is further operable to vary the insulin solution flow rate signal from a first insulin solution flow rate signal to a second insulin solution flow rate signal in response to the glucose signal.

2. The infusion system of claim 1, wherein the flow controller is further operable to maintain the insulin solution flow rate signal at a value corresponding to an insulin dose rate of zero during the TPN ramp phase.

3. The infusion system of claim 1, wherein the flow controller is further operable to maintain the insulin solution flow rate signal as a selected fraction of the TPN solution flow rate signal during the TPN ramp phase.
4. The infusion system of claim 1, wherein the flow controller is further operable to maintain the insulin solution flow rate signal at a value corresponding to a continuous phase insulin dose rate during the TPN ramp phase.
5. The infusion system of claim 1, wherein the flow controller is further operable to maintain the TPN solution flow rate signal at a value corresponding to a continuous phase TPN dose rate and to maintain the insulin solution flow rate signal at a selected fraction of the TPN solution flow rate signal during the TPN continuous phase.
6. The infusion system of claim 1, wherein the flow controller is further operable to taper the TPN solution flow rate signal over a user selectable duration from a value corresponding to a continuous phase TPN dose rate to a value corresponding to a TPN dose rate of zero during a TPN taper phase.
7. The infusion system of claim 6, wherein the flow controller is further operable to maintain the insulin solution flow rate signal at a value corresponding to an insulin dose rate of zero during the TPN taper phase.
8. The infusion system of claim 6, wherein the flow controller is further operable to maintain the insulin solution flow rate signal as a selected fraction of the TPN solution flow rate signal to maintain the ratio of the TPN solution to the insulin solution constant during the TPN taper phase.
9. The infusion system of claim 6, wherein the flow controller is further operable to maintain the insulin solution flow rate signal at a value corresponding to a continuous phase insulin dose rate during the TPN taper phase.

10. The infusion system of claim 1, wherein the flow controller is further operable to decrease the TPN solution flow rate signal over a user selectable duration from a value corresponding to a continuous phase TPN dose rate to a value corresponding to a Keep Vein Open (KVO) TPN dose rate after a TPN continuous phase.

11. The infusion system of claim 1, wherein the flow controller is further operable to vary the insulin solution flow rate signal from a first insulin solution flow rate signal to a second insulin solution flow rate signal in response to input of the second insulin solution flow rate signal by a user.

12. The infusion system of any one of claims 1 to 11, further comprising a user interface operably connected to the flow controller, the user interface being operable to display a TPN/Insulin Infusion Plot portion having a TPN Infusion profile and an Insulin Infusion profile.

13. The infusion system of claim 12, wherein the user interface is further operable to display an Infusion Progression indicator on the TPN/Insulin Infusion Plot portion, the Infusion Progression indicator being operable to indicate a current state of the concurrent TPN/insulin infusion.

14. The infusion system of claim 12, wherein the user interface is further operable to display an infusion portion selected from the group consisting of a Ramp portion, a Continuous portion, a Taper portion, and a KVO portion.

15. The infusion system of any one of claims 1 to 14, wherein the administration set comprises a cassette including a primary inlet joining a primary fluid passageway into fluid communication with the primary line, a secondary inlet joining a secondary fluid passageway into fluid communication with the secondary line, an outlet in fluid communication with the outlet line, and a pumping/mixing chamber covered by a resilient flexible membrane and in fluid communication with the primary fluid passageway, the secondary fluid passageway and the outlet.

16. The infusion system of claim 15, wherein the drive mechanism comprises a motor driving a plunger into the membrane covering the pumping/mixing chamber while operating a primary inlet valve, a secondary inlet valve and an outlet valve so as to mix and displace fluid from the pumping/mixing chamber through the outlet into the outlet line.

17. A method of mixing a total parenteral nutrition (TPN) solution from a TPN source container and an insulin solution from an insulin source container that is separate from the TPN source container, the method comprising:

- providing a fluid administration set having a primary line, a secondary line, a common outlet line, and a pumping/mixing chamber located between and in fluid communication with the primary line, the secondary line and the common outlet line;

- connecting the primary line to the TPN source container;

- connecting the secondary line to the insulin source container;

- selectively allowing the primary line to feed TPN solution from the primary line to the pumping/mixing chamber;

- selectively allowing the secondary line to feed insulin solution to the pumping/mixing chamber;

- mixing the TPN solution and the insulin solution in the pumping/mixing chamber to generate an infusion mixture before the common outlet line;

- driving with a positive displacement pumping mechanism the TPN solution from the pumping/mixing chamber through the common outlet line at a TPN dose rate; and

- concurrently with said driving the TPN solution,

- driving with the positive displacement pumping mechanism the insulin solution from the mixing chamber through the common outlet line at an insulin dose rate;

- varying at least one of the TPN dose rate and the insulin dose rate to vary a ratio of TPN solution to insulin solution in the infusion mixture;

- ramping the TPN dose rate from a value corresponding to a TPN dose rate of zero to a value corresponding to a continuous phase TPN dose rate over a user selectable duration in a TPN ramp phase; and

- providing a glucose signal to a flow controller, which is obtainable by monitoring a glucose level with a glucose sensor operably connected to a patient, wherein the flow controller is further

operable for varying the insulin solution flow rate signal from a first insulin solution flow rate signal to a second insulin solution flow rate signal in response to the glucose signal.

18. The method of claim 17, wherein the varying comprises maintaining the TPN dose rate at a continuous phase TPN dose rate and maintaining the insulin dose rate at a selected fraction of the continuous phase TPN dose rate.

19. The method of claim 17, wherein the varying comprises tapering the TPN dose rate from a continuous phase TPN dose rate to a TPN dose rate of zero during a user selectable duration.

20. The method of claim 17, wherein the varying comprises decreasing the TPN dose rate from a continuous phase TPN dose rate to a Keep Vein Open (KVO) TPN dose rate during a user selectable duration.

21. The method of claim 17, wherein the insulin dose rate is a first insulin dose rate and the method further comprises driving the insulin solution at a second insulin dose rate in response to input of the second insulin dose rate by a user.

22. The method of any one of claims 17 to 21, further comprising displaying planned values of the TPN dose rate and the insulin dose rate as a function of time on a TPN/Insulin Infusion Plot, and displaying an Infusion Progression indicator at a present infusion time on the TPN/Insulin Infusion Plot.

1 / 20

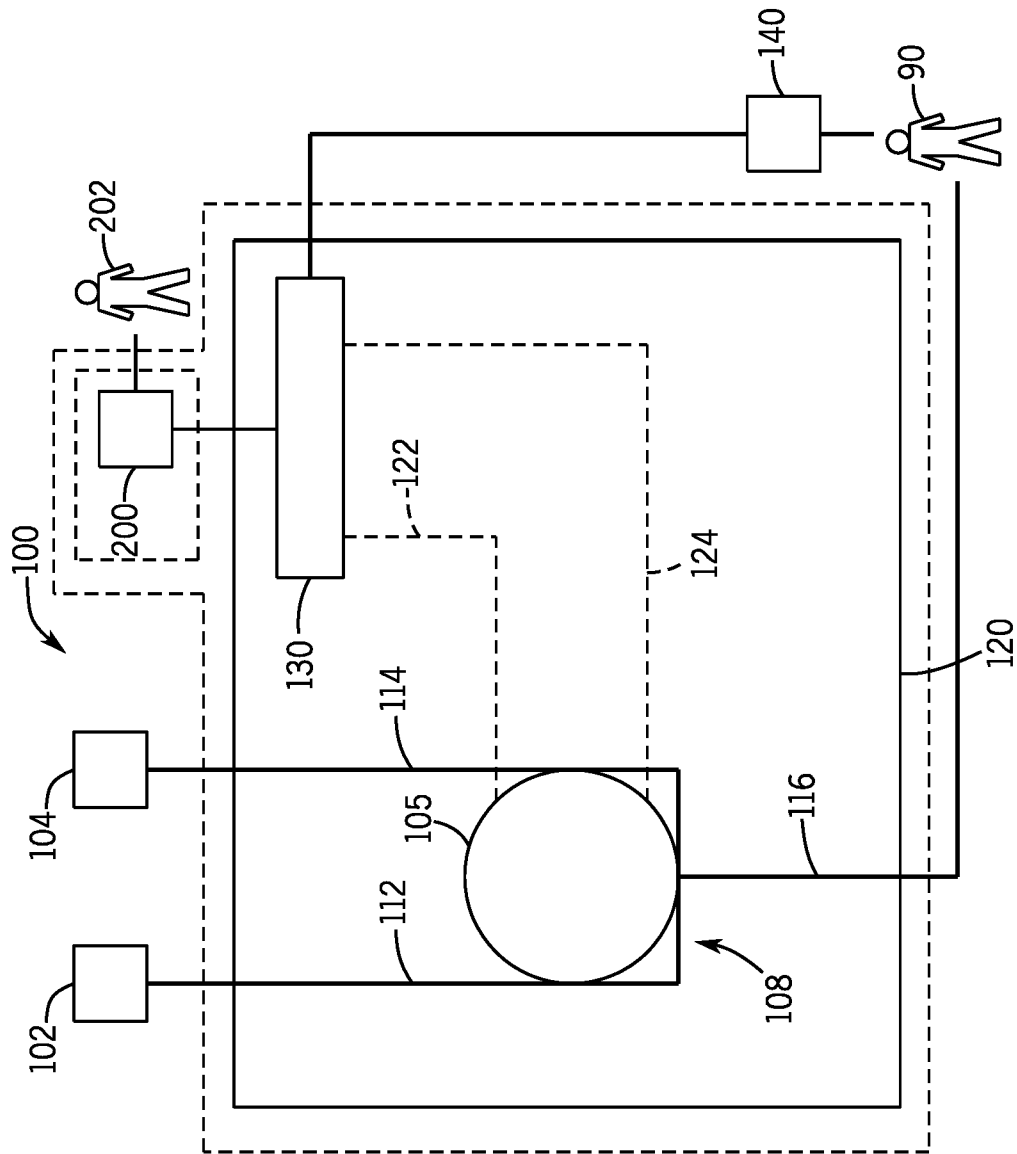
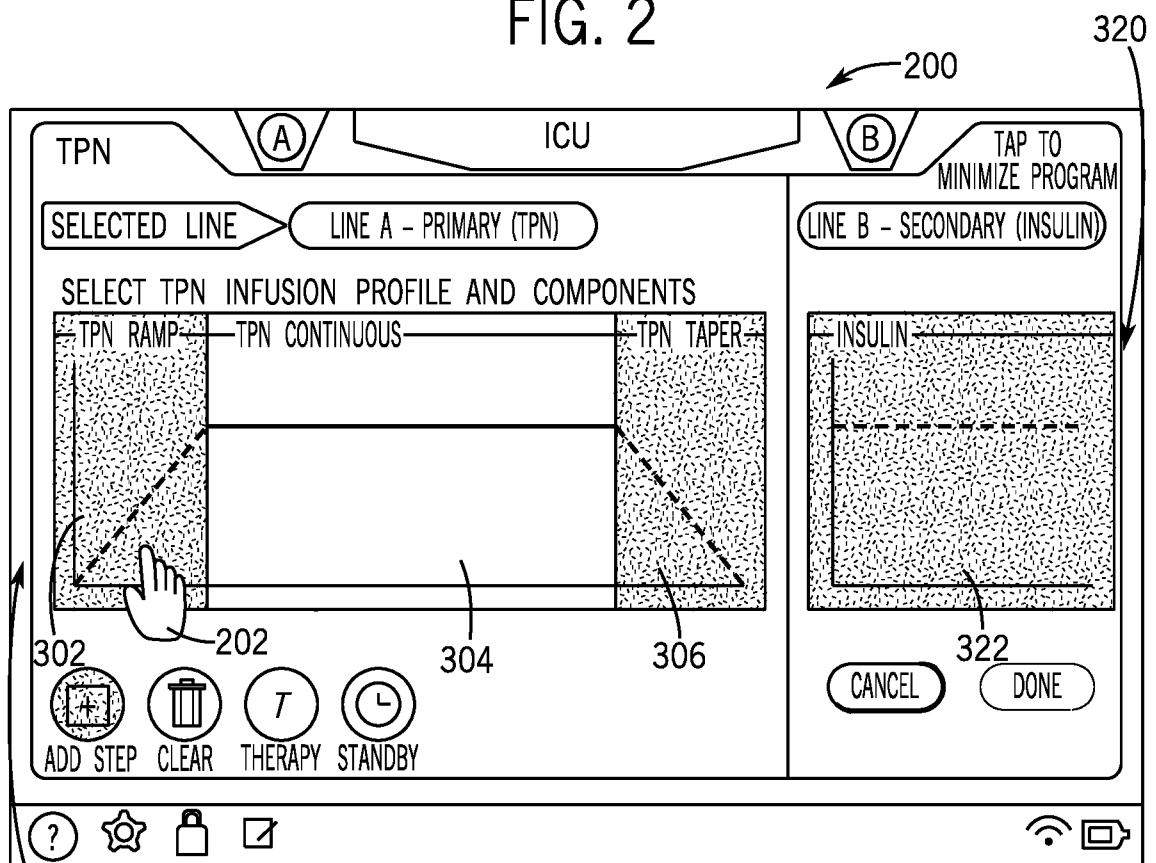
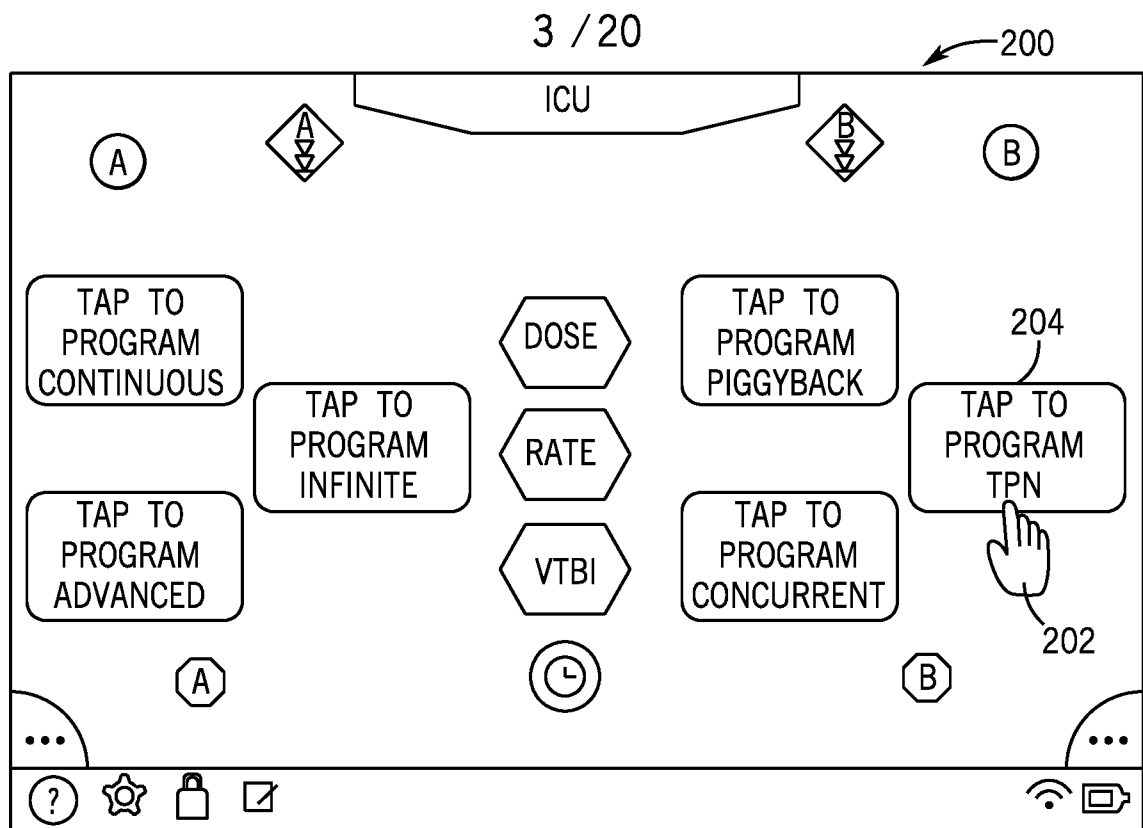


FIG. 1



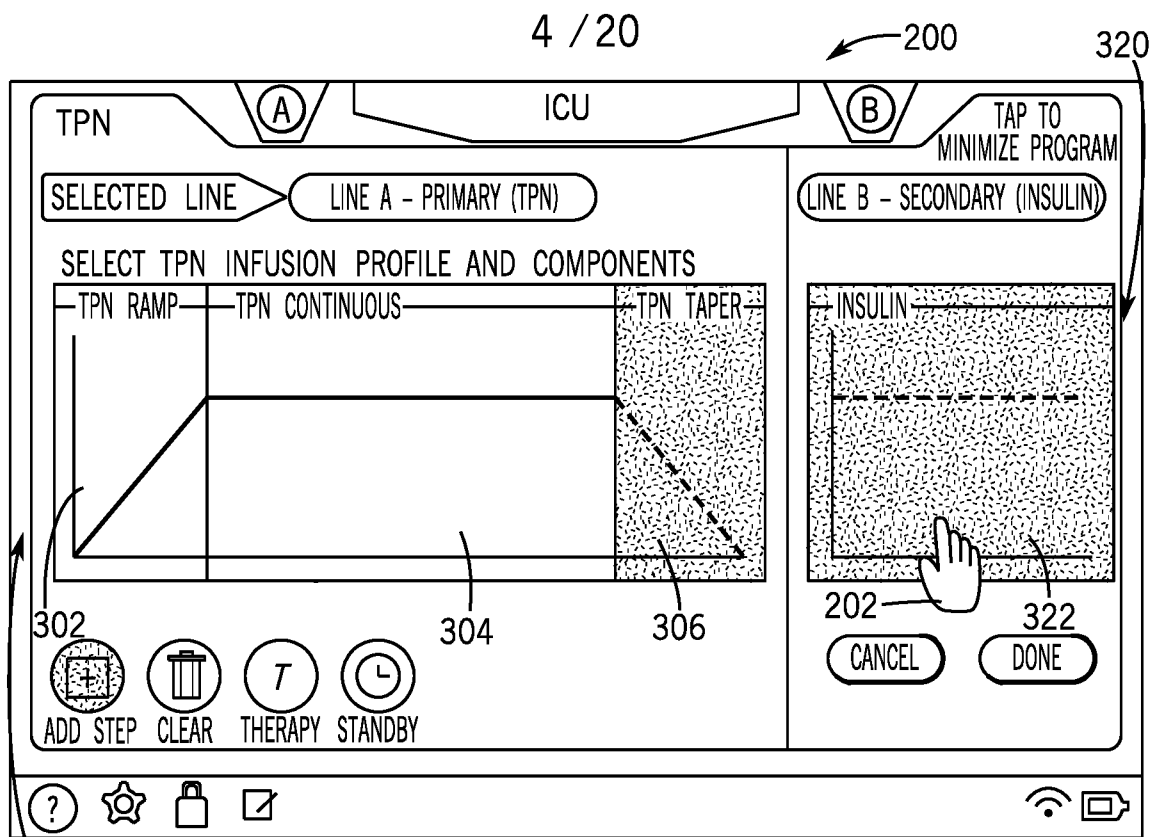


FIG. 3B

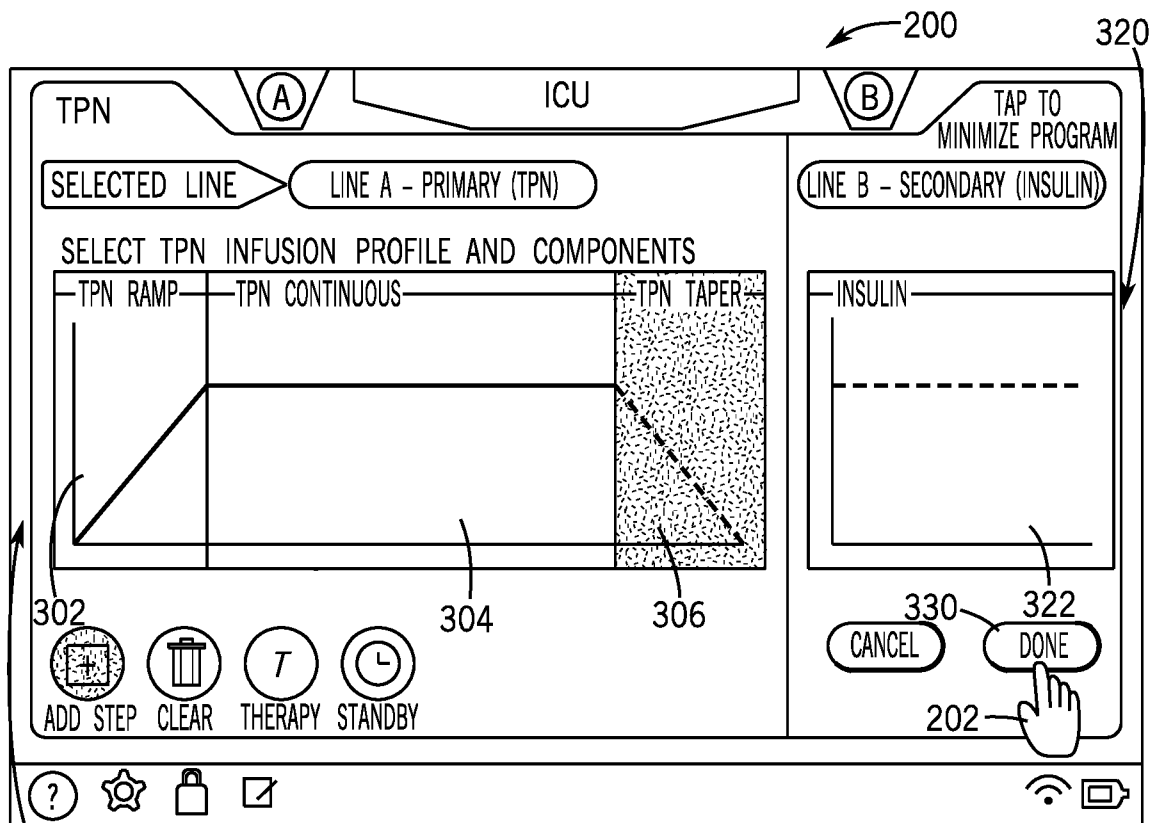
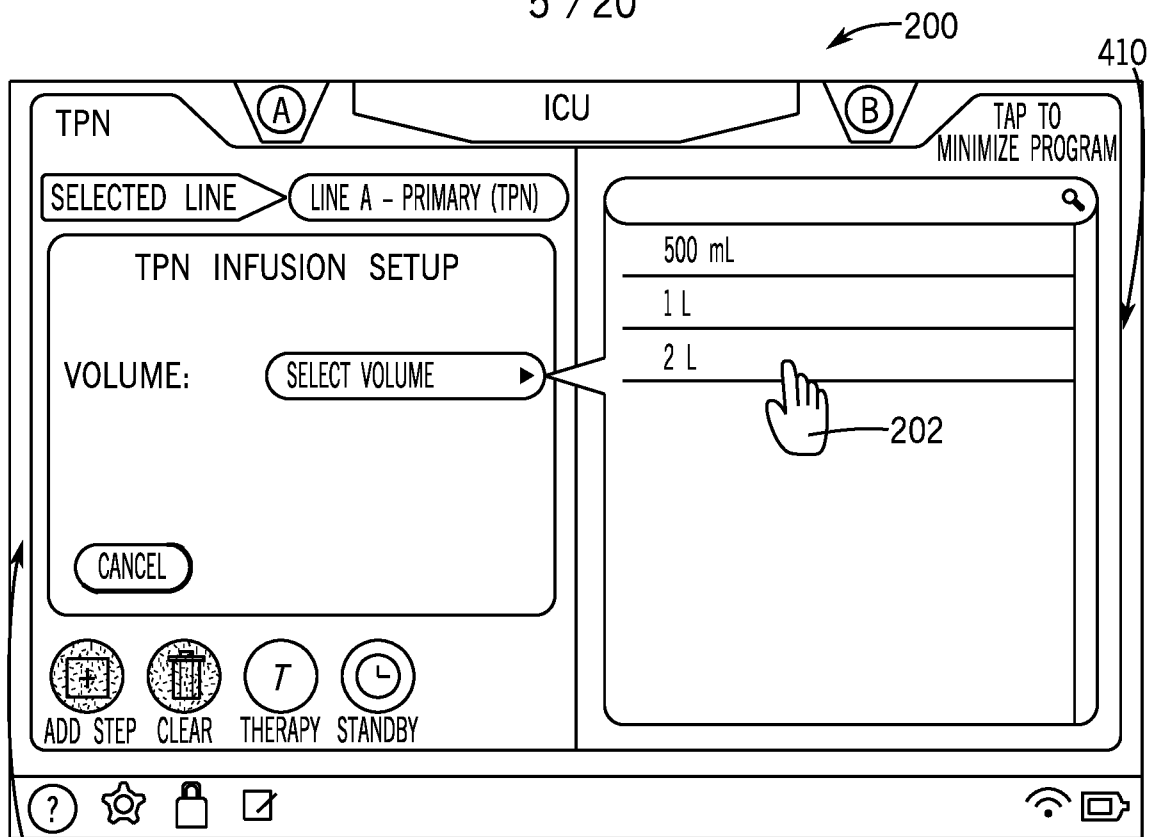


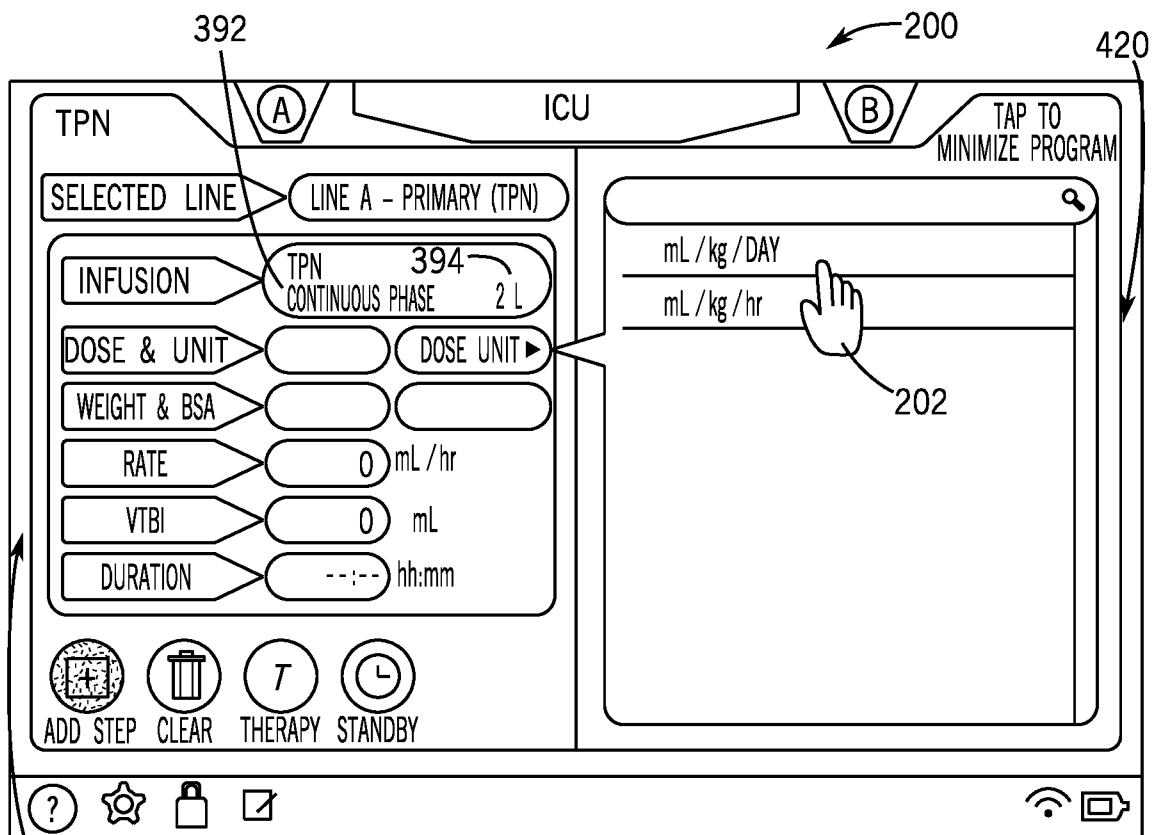
FIG. 3C

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380

FIG. 4A



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FIG. 4B

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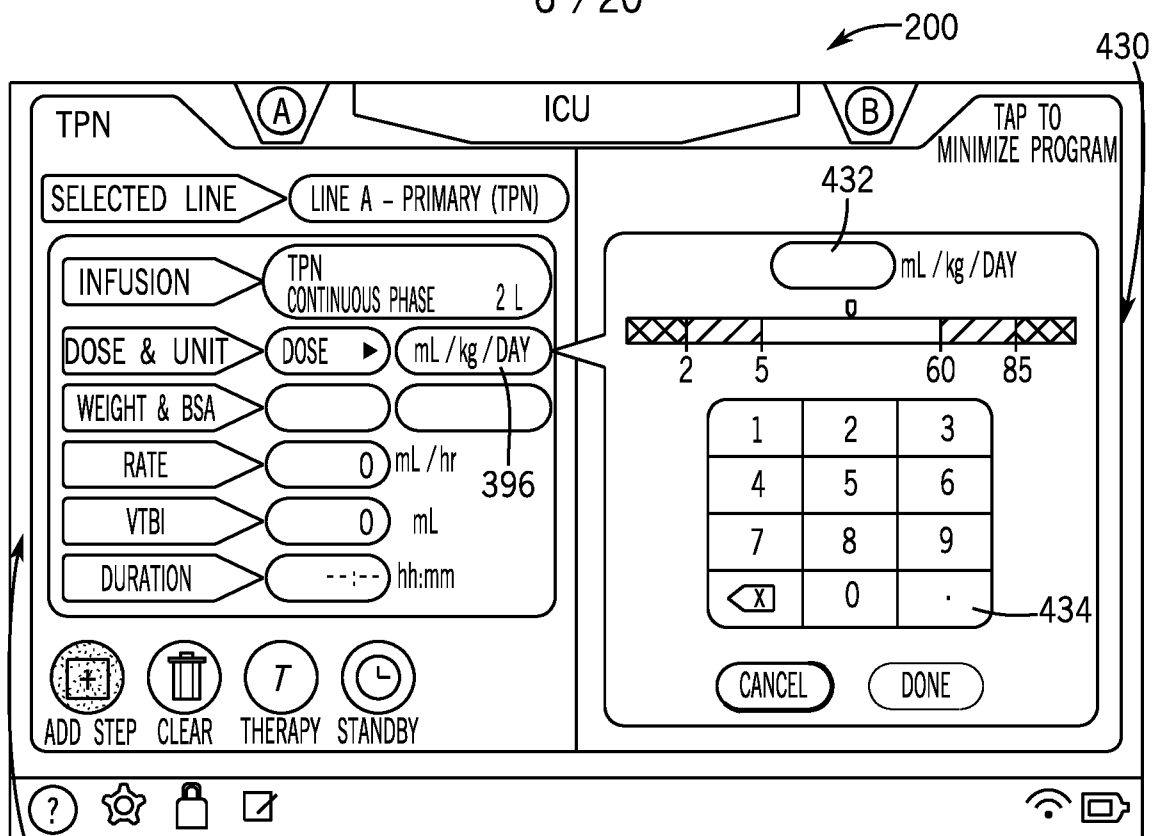


FIG. 4C

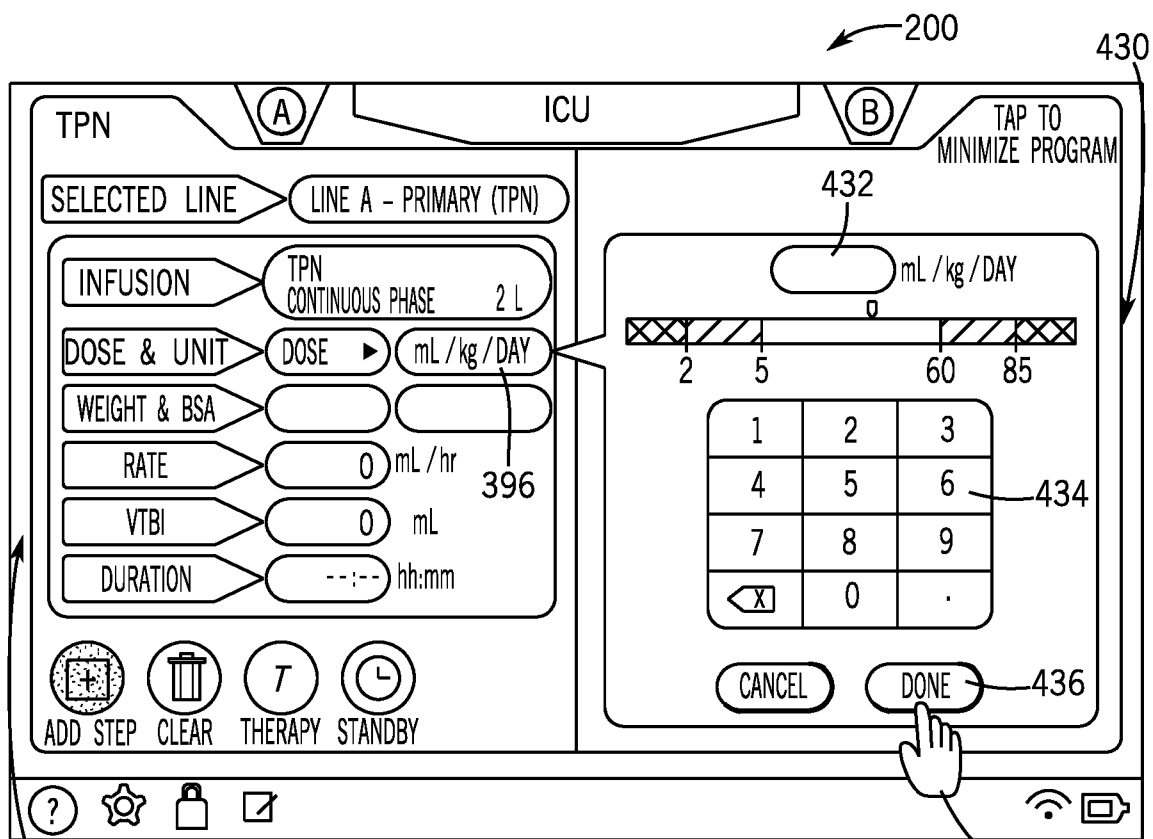


FIG. 4D

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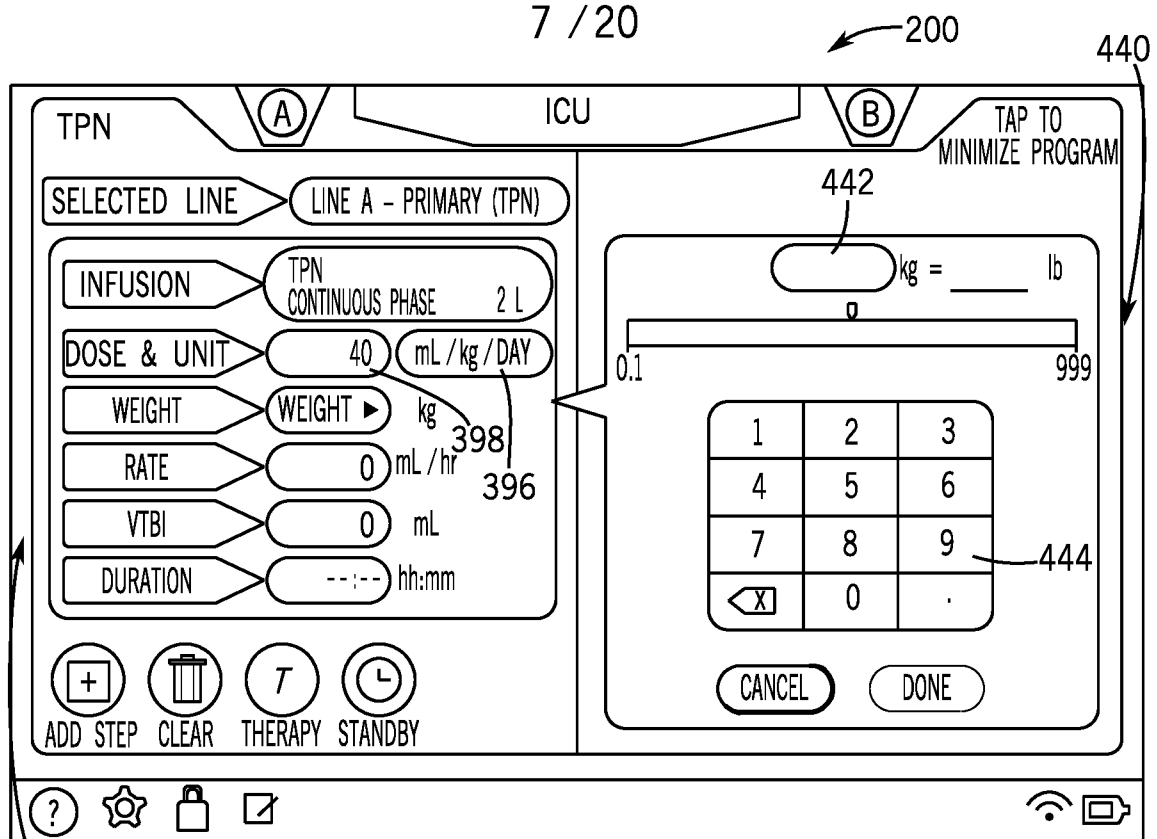


FIG. 4E

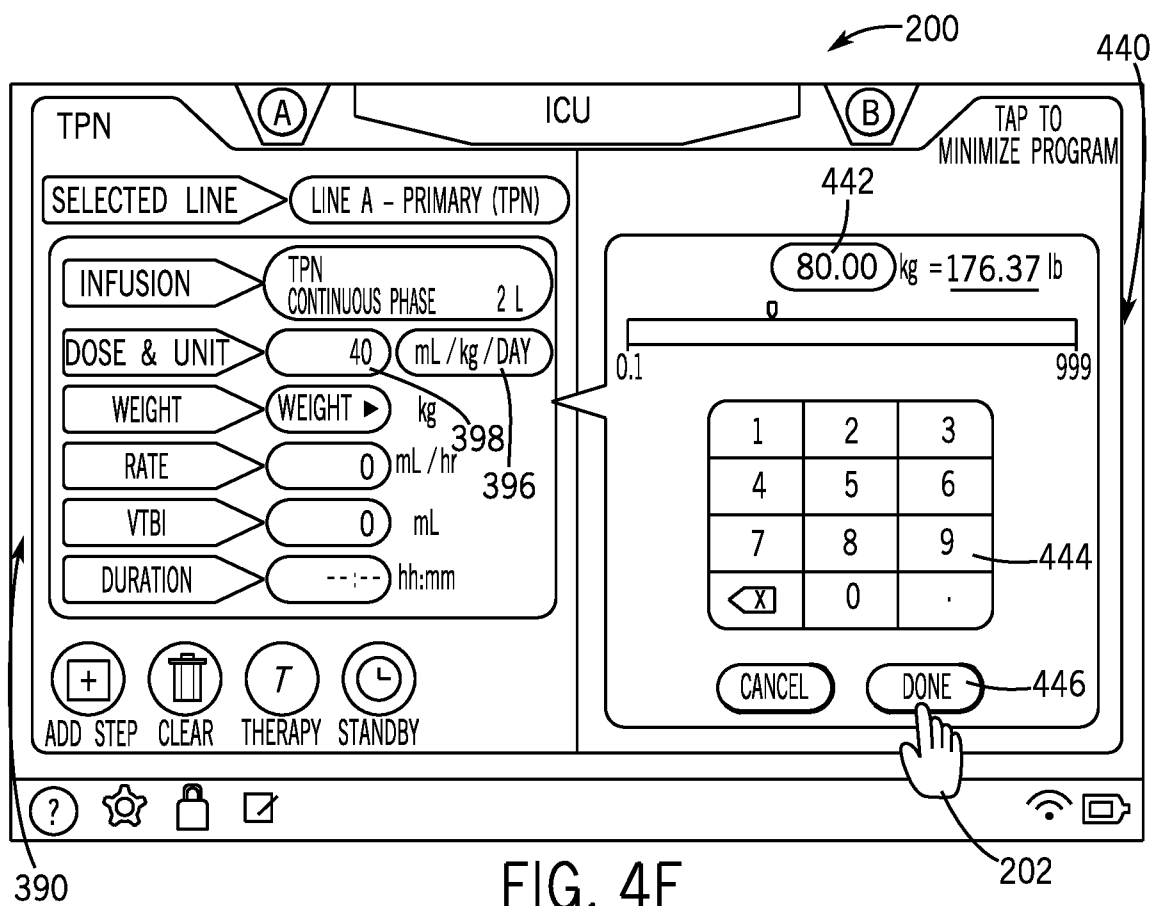


FIG. 4F

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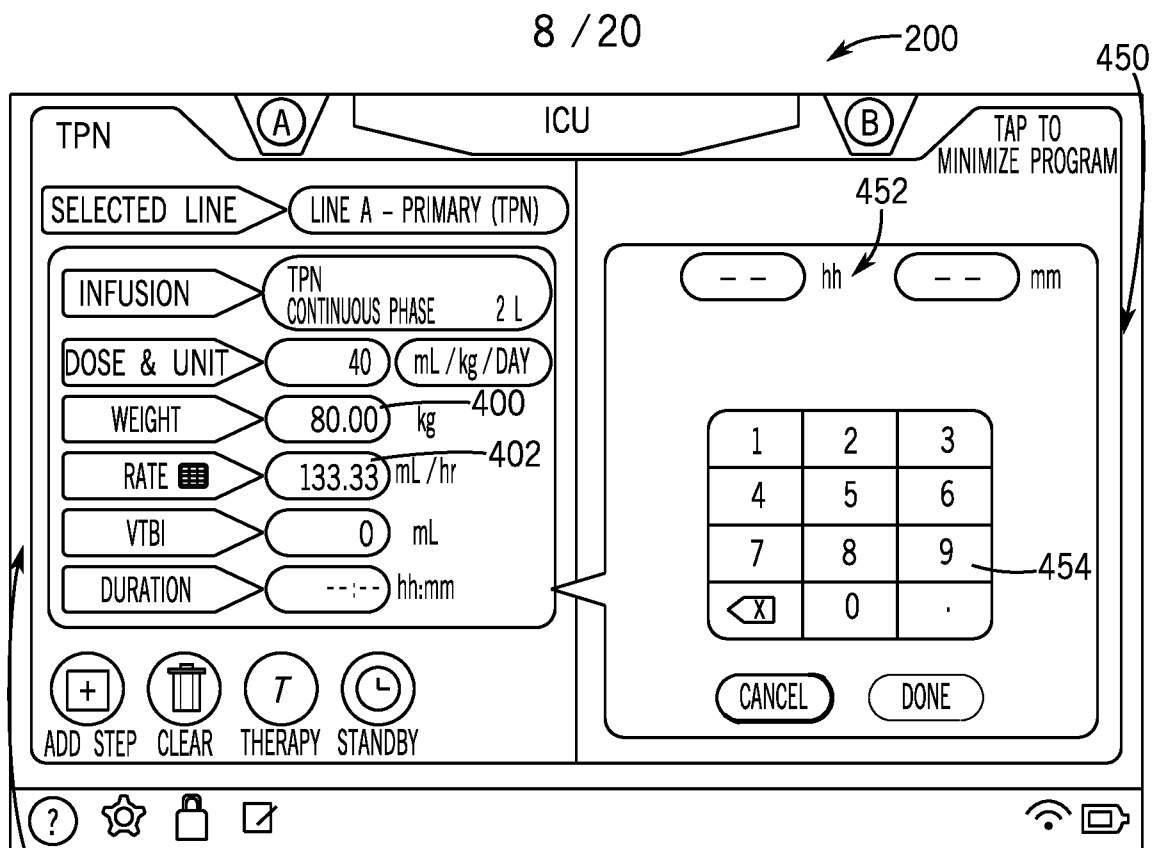


FIG. 4G

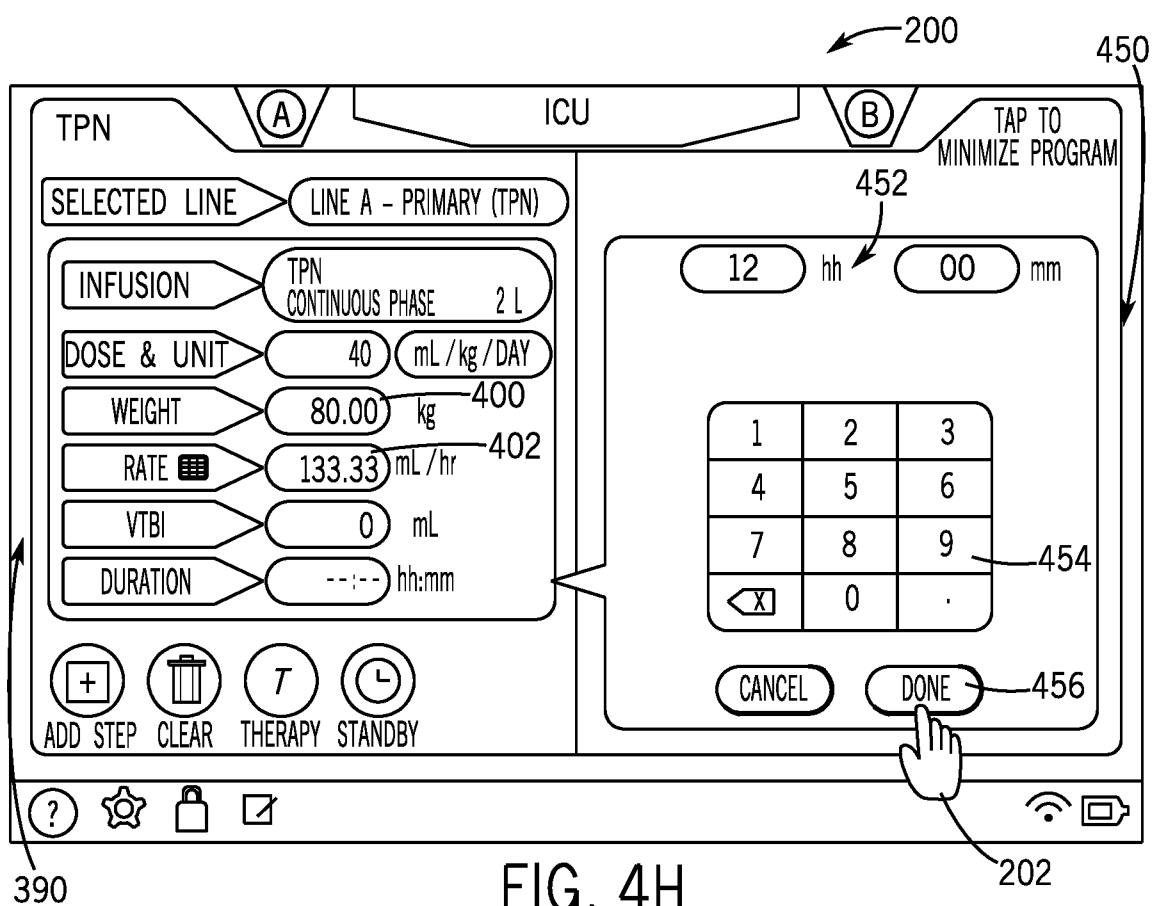


FIG. 4H

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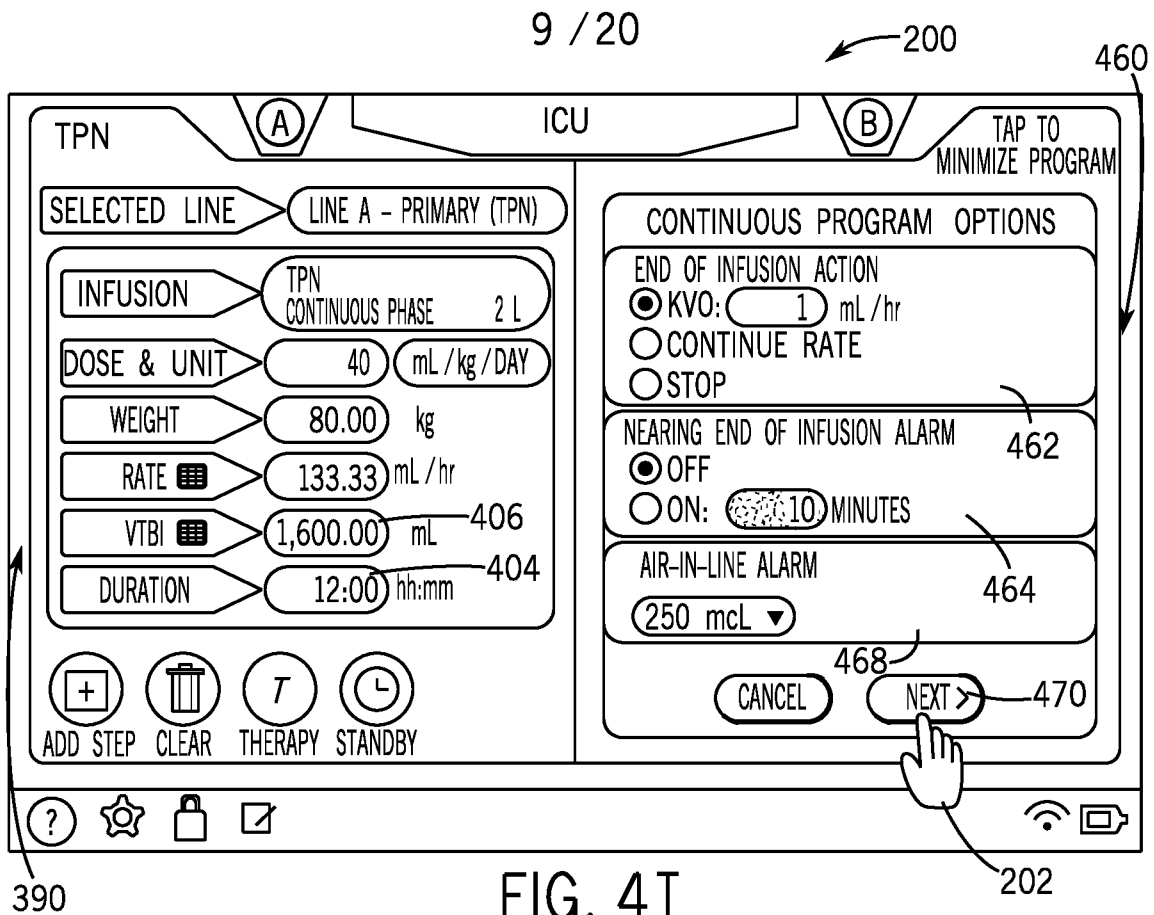


FIG. 4I

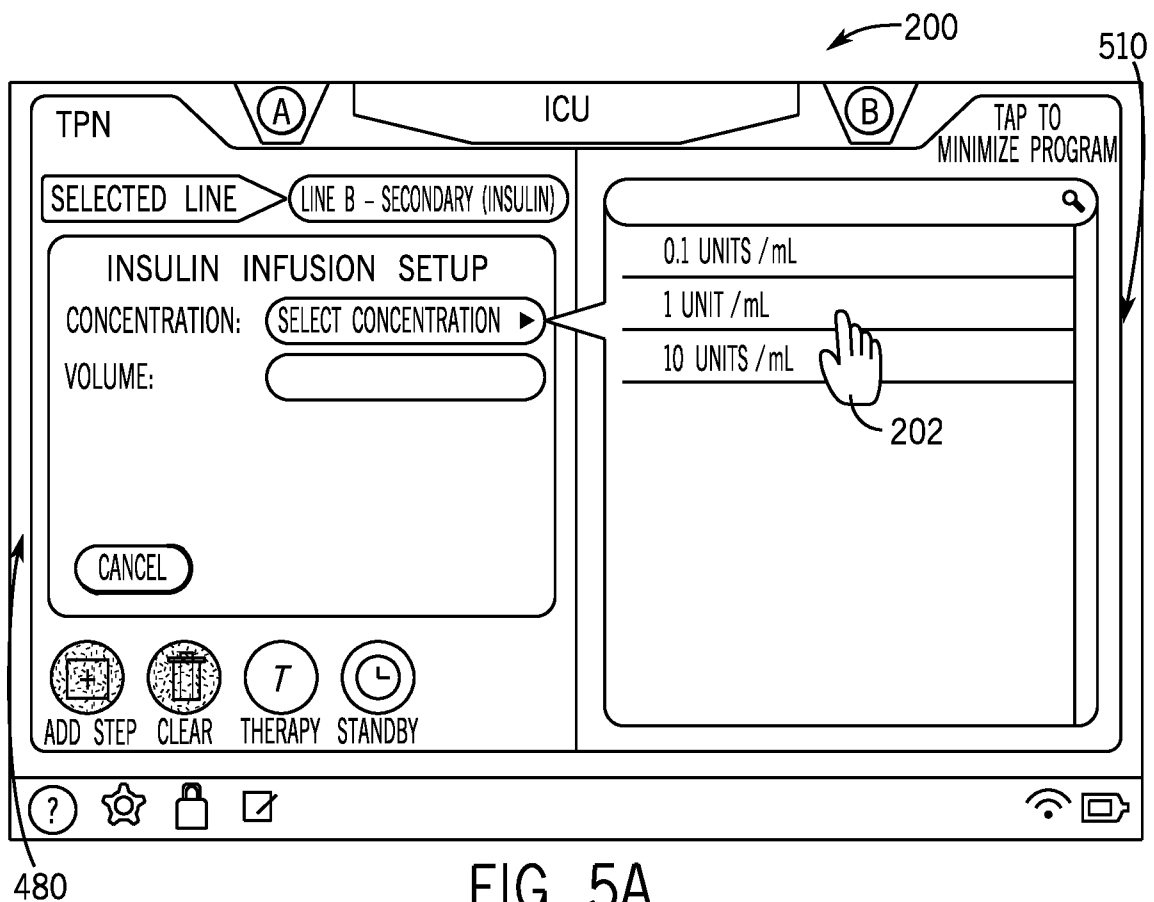


FIG. 5A

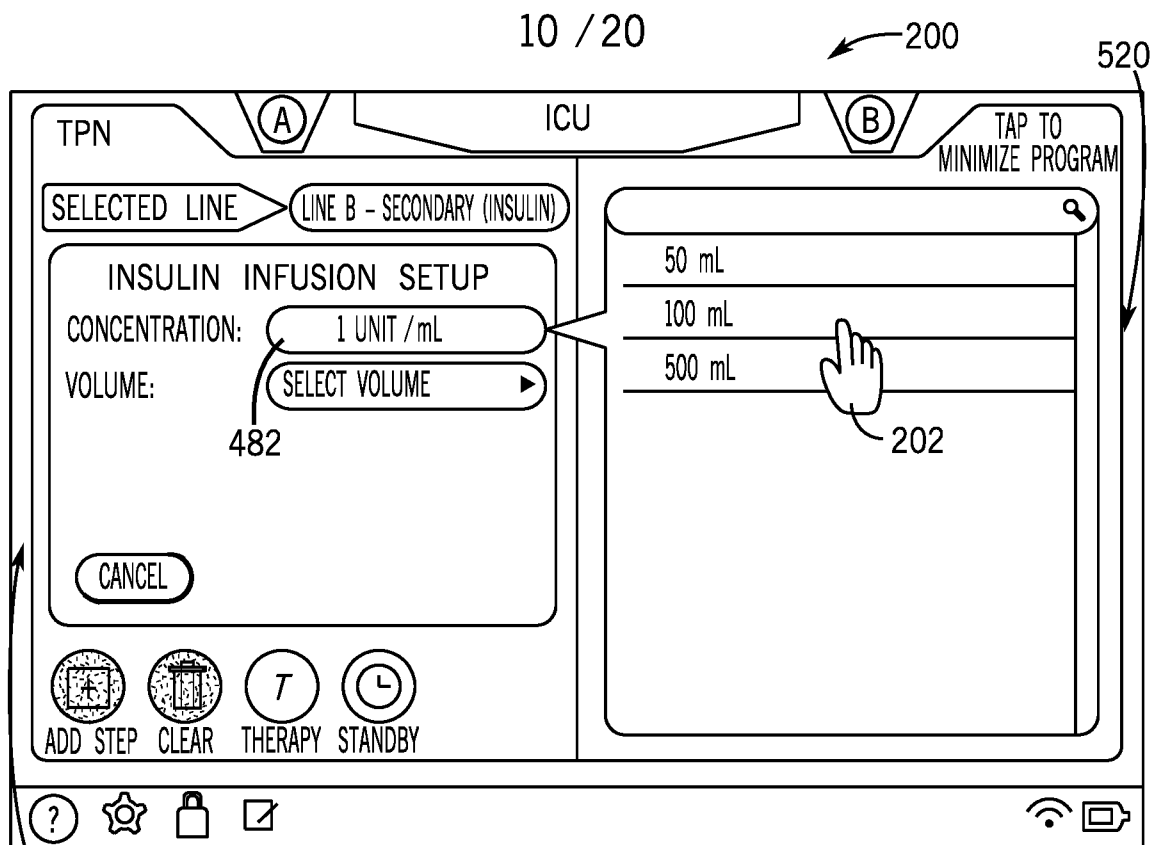


FIG. 5B

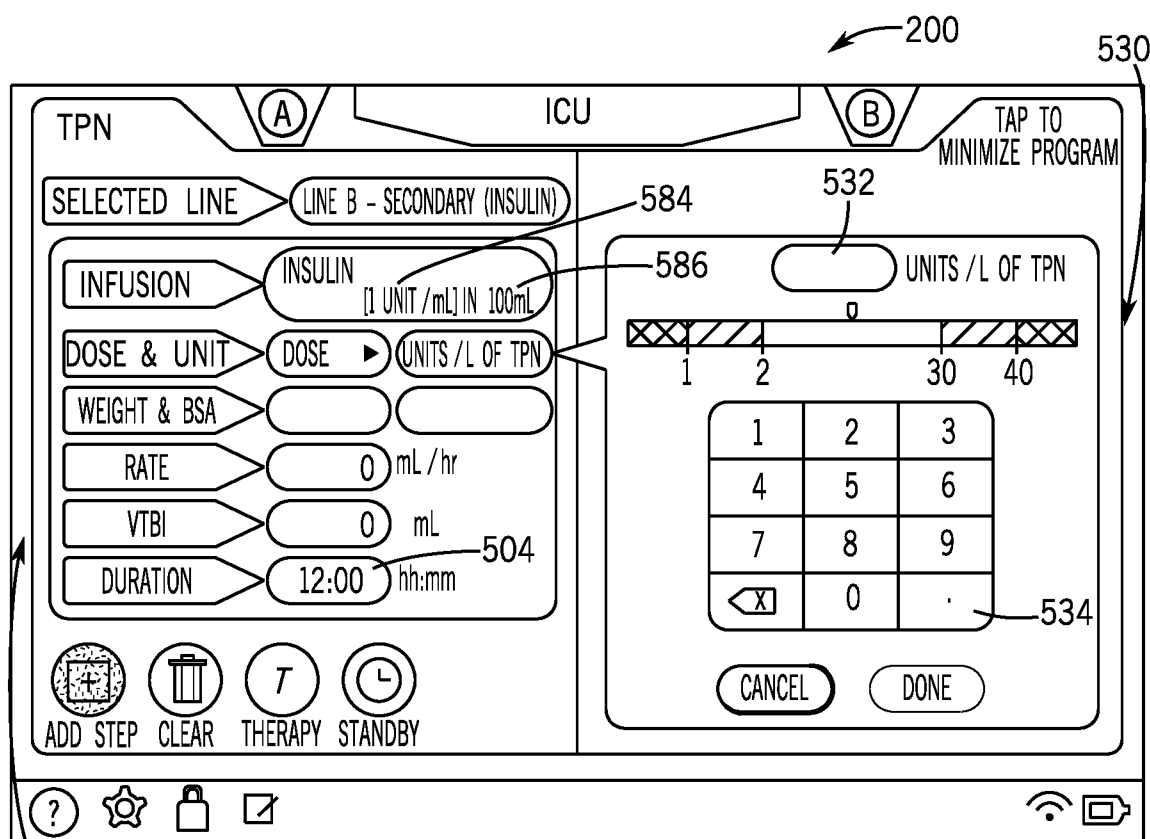


FIG. 5C

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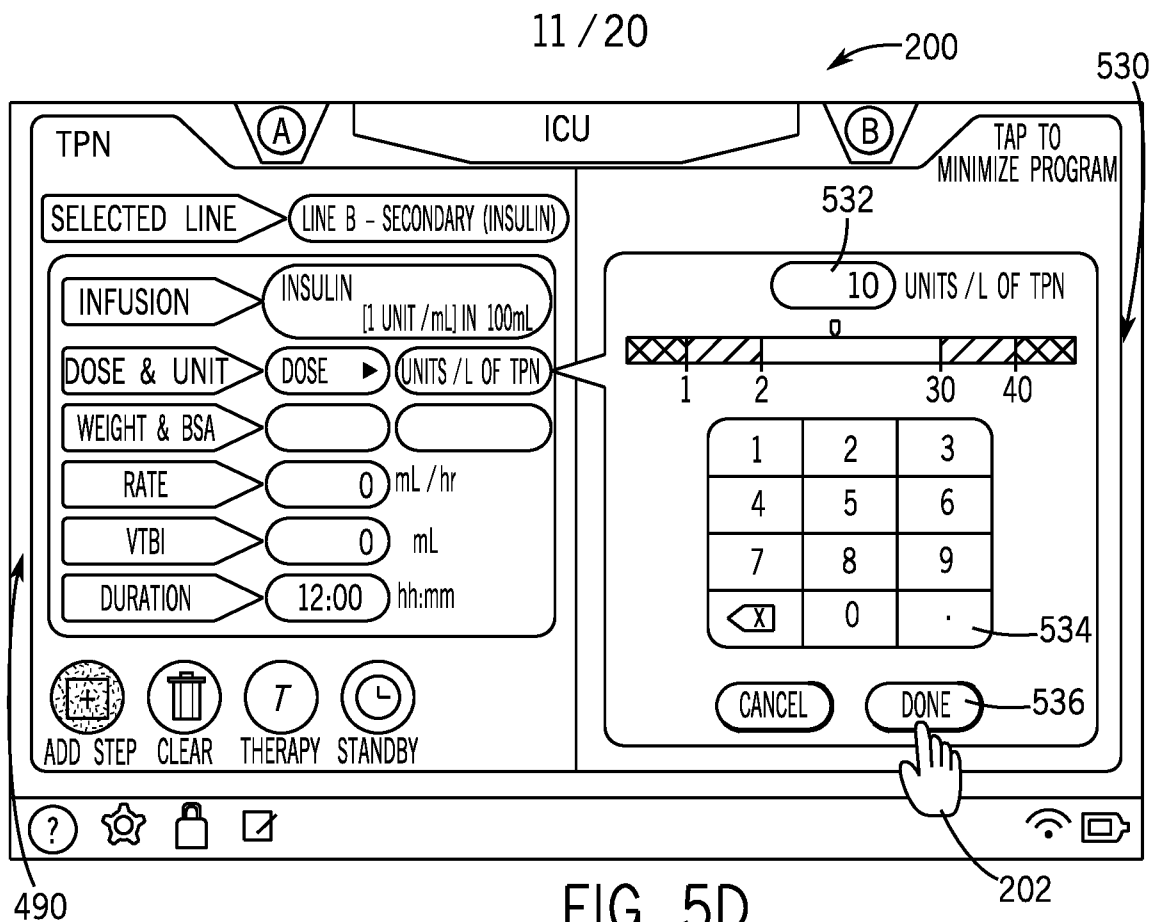


FIG. 5D

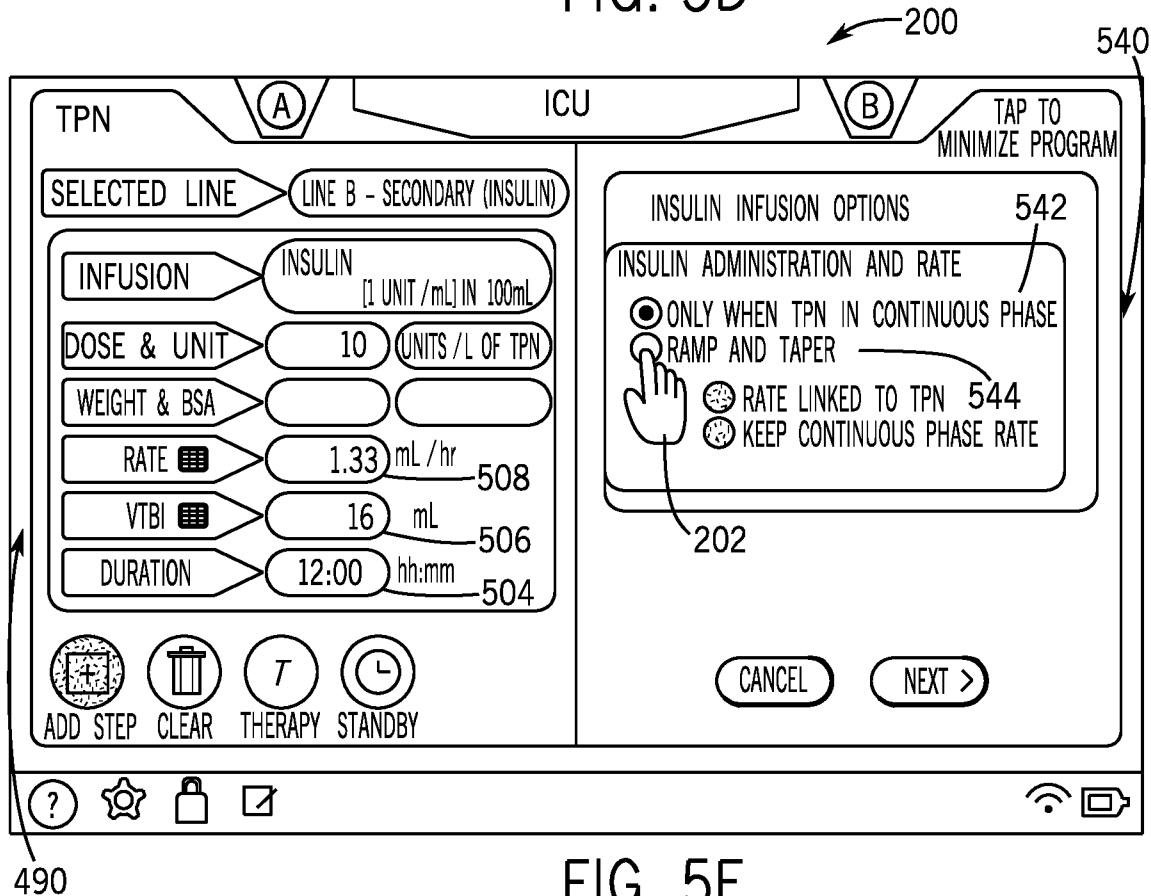


FIG. 5E

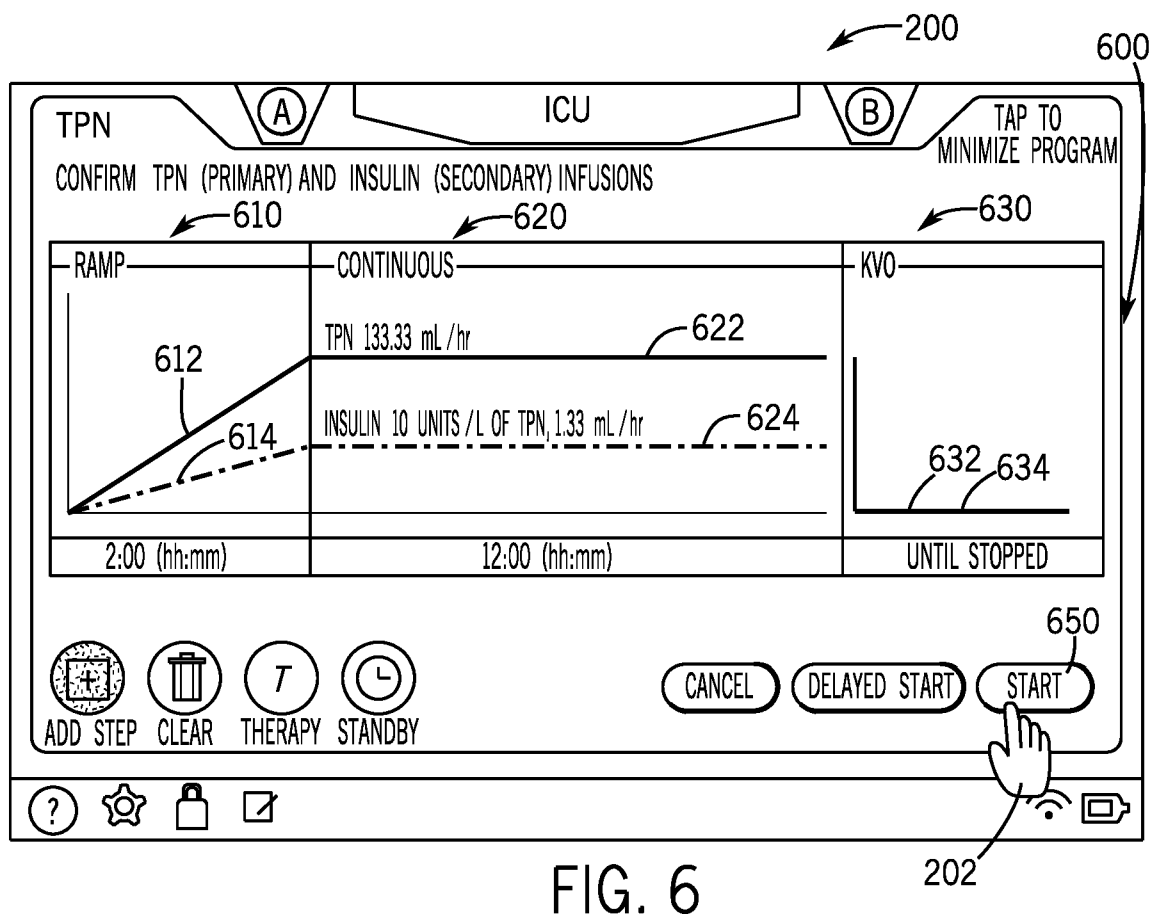
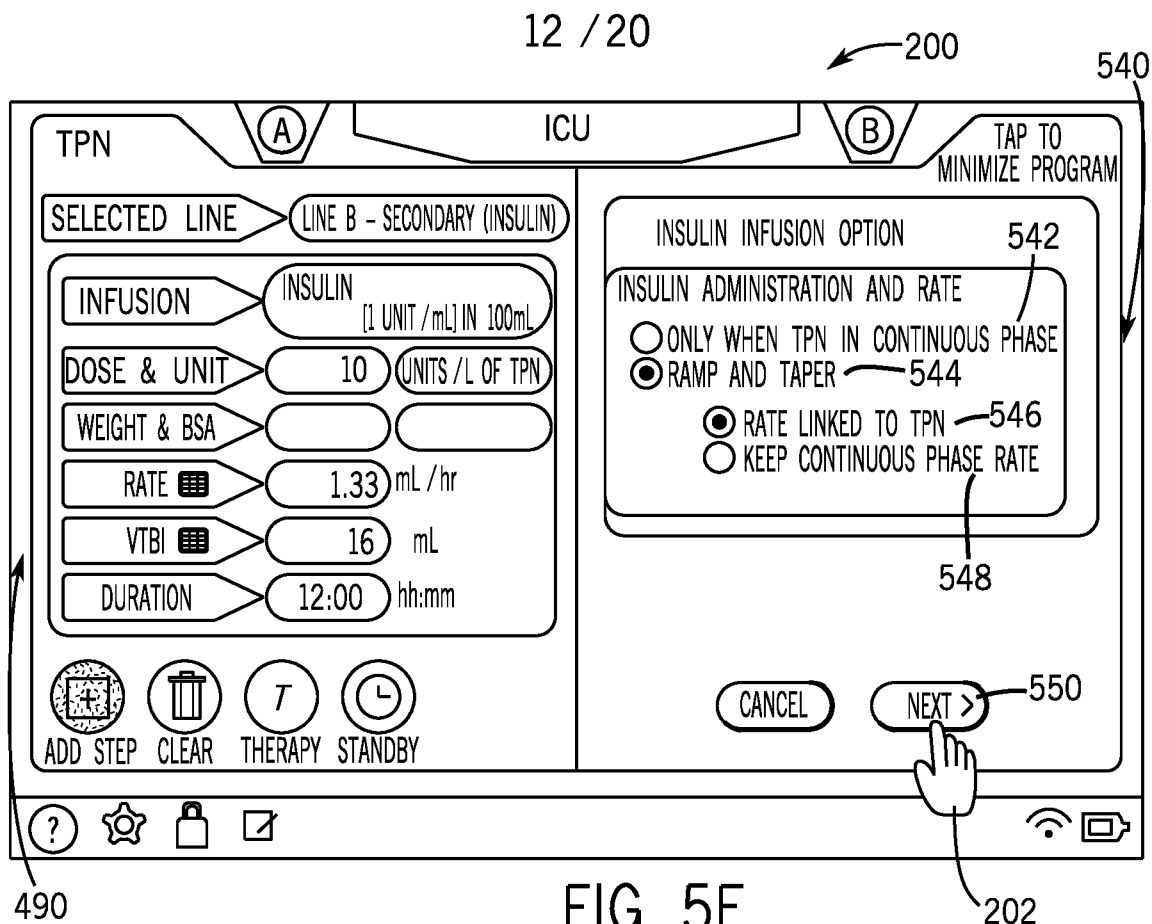


FIG. 7A

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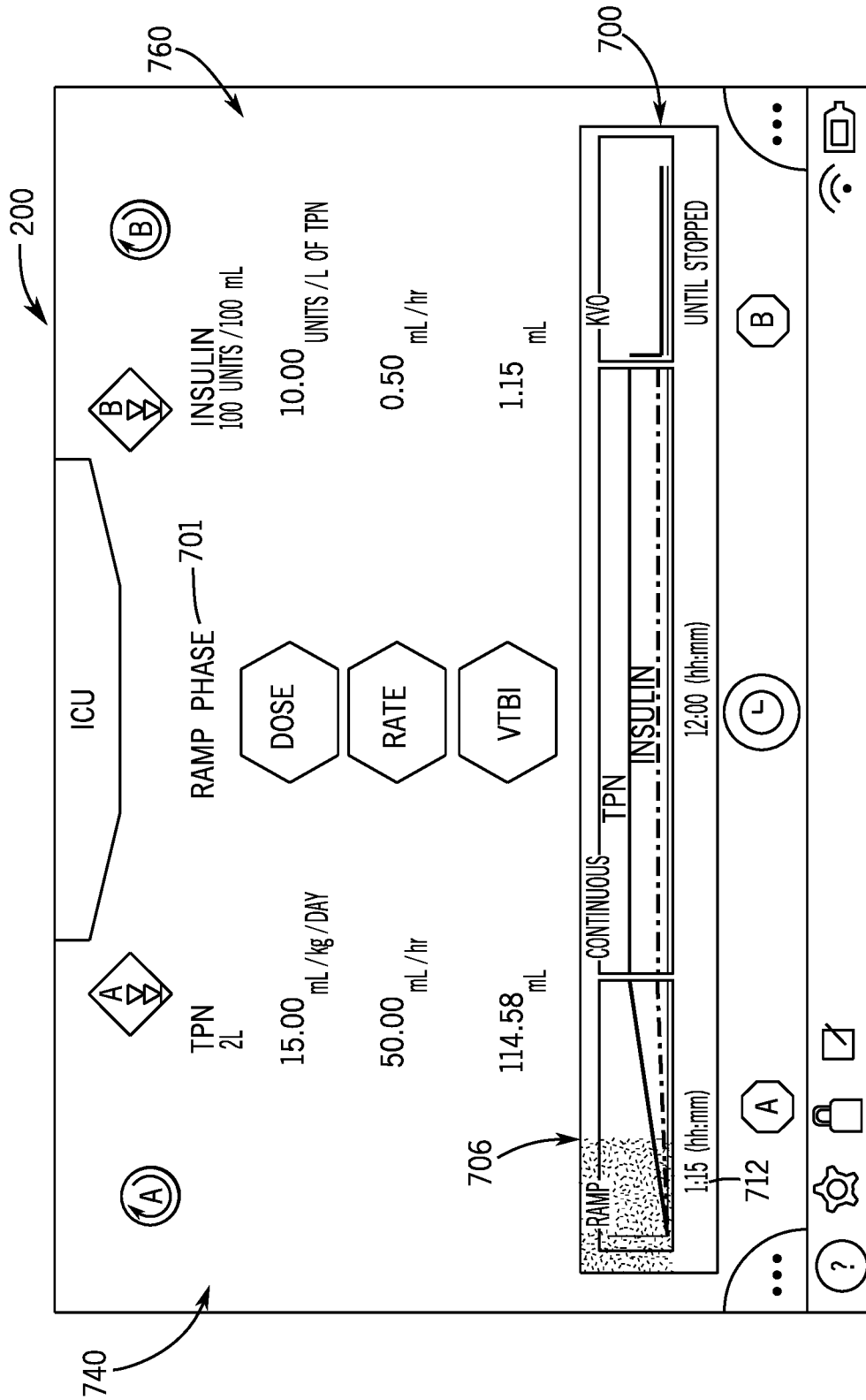


FIG. 7B

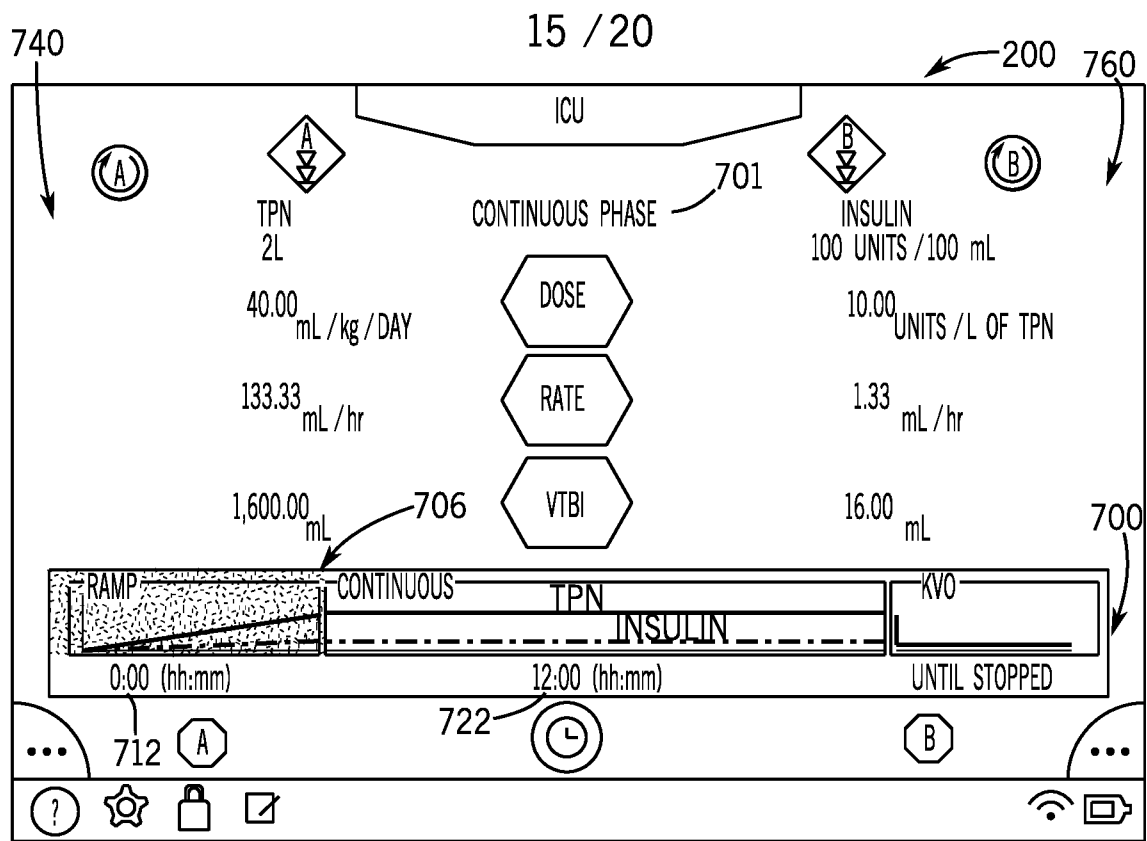


FIG. 7C

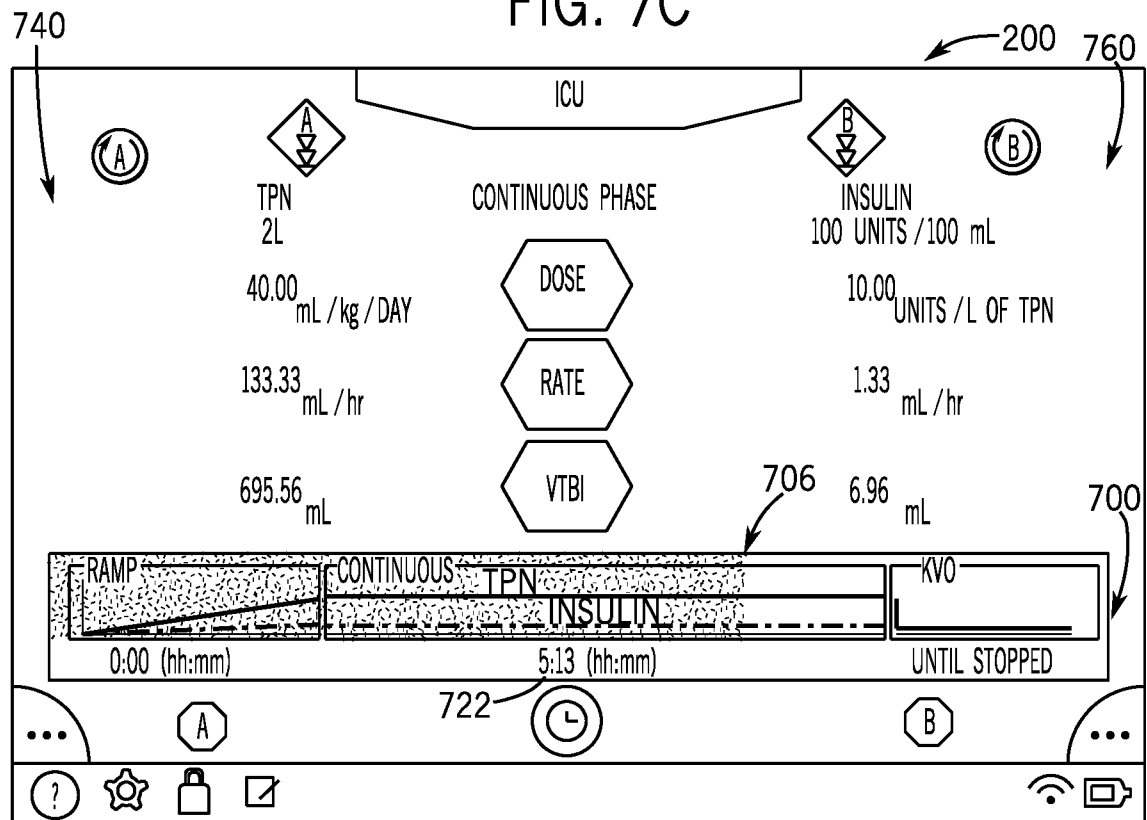


FIG. 7D

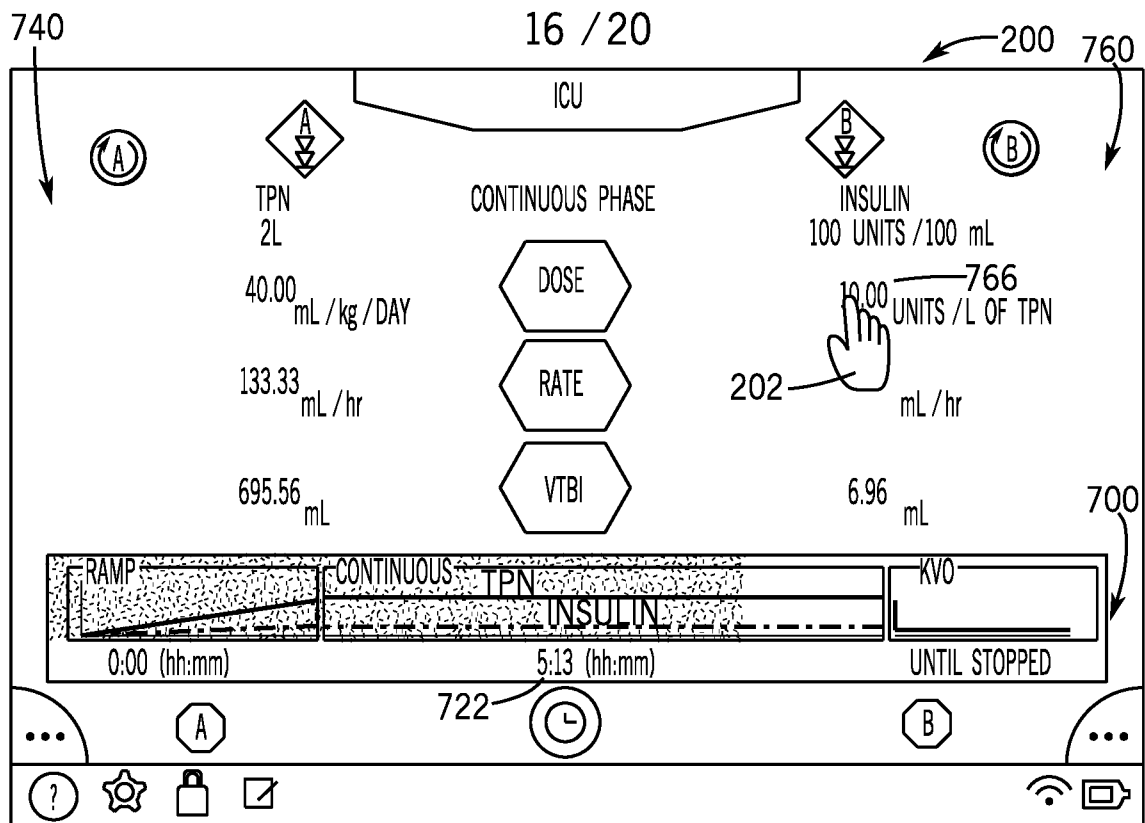


FIG. 7E

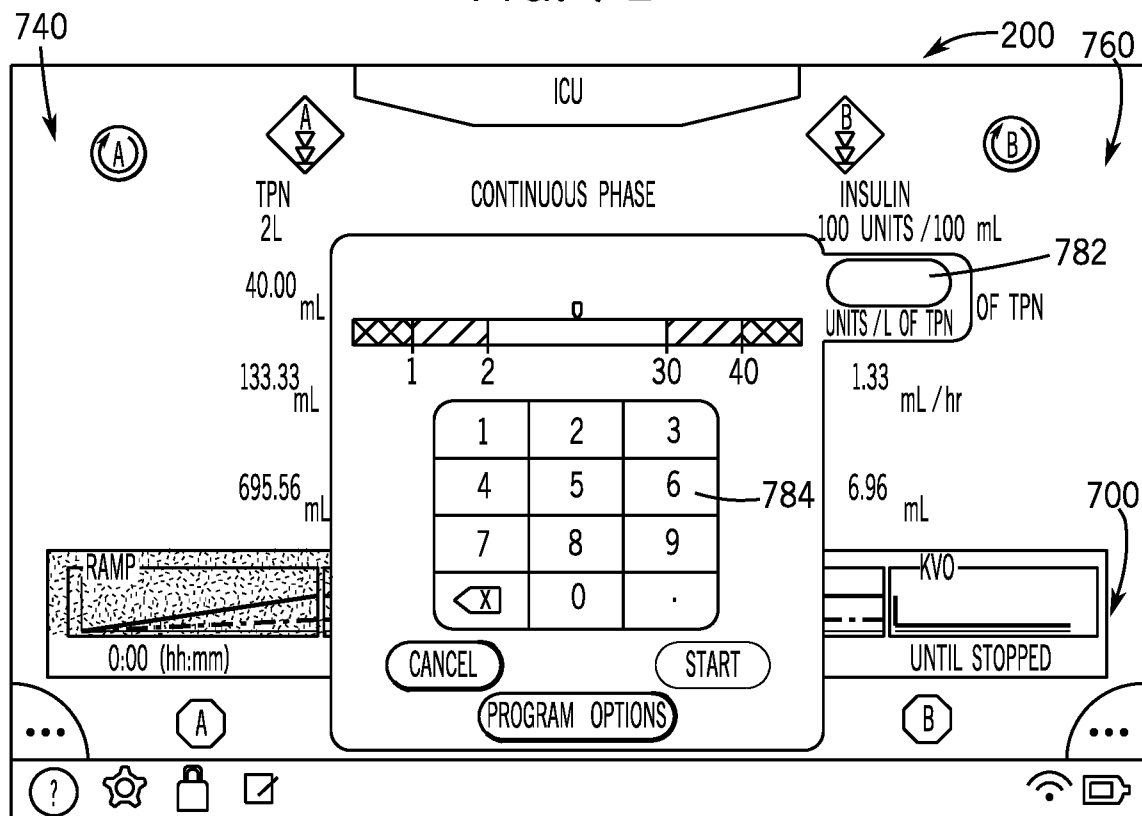


FIG. 7F

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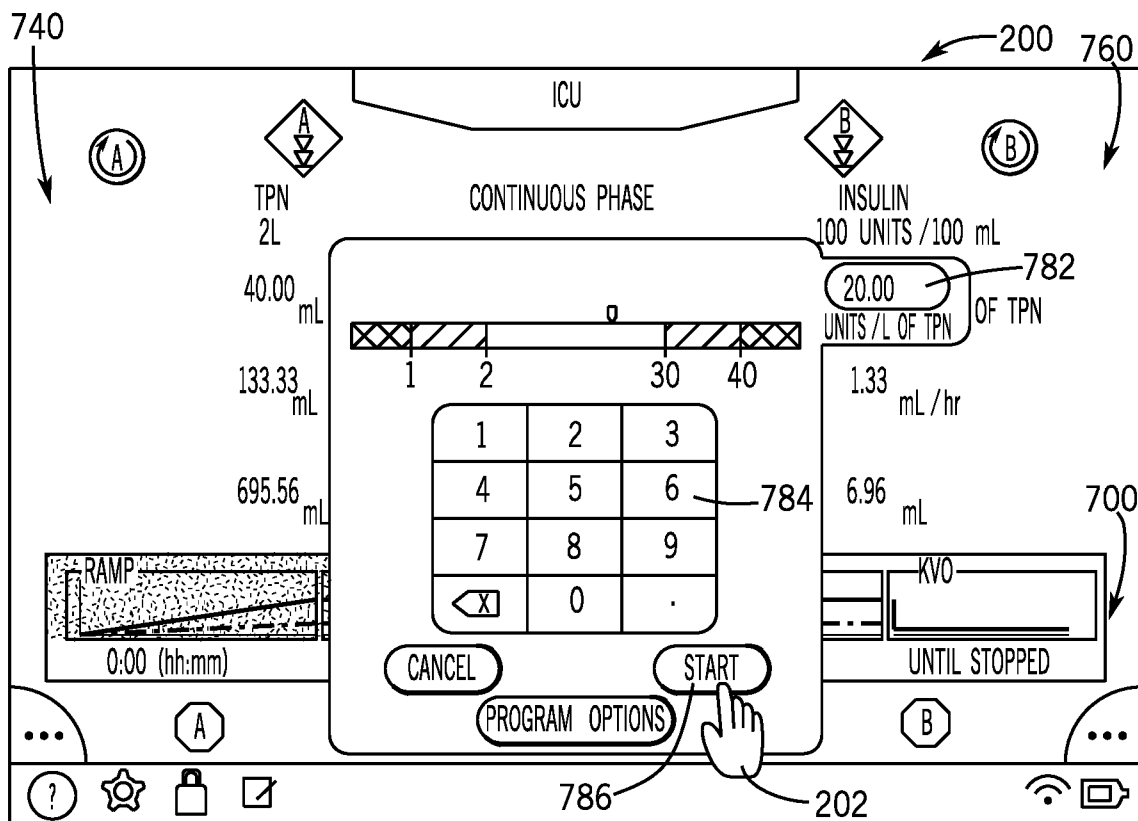


FIG. 7G

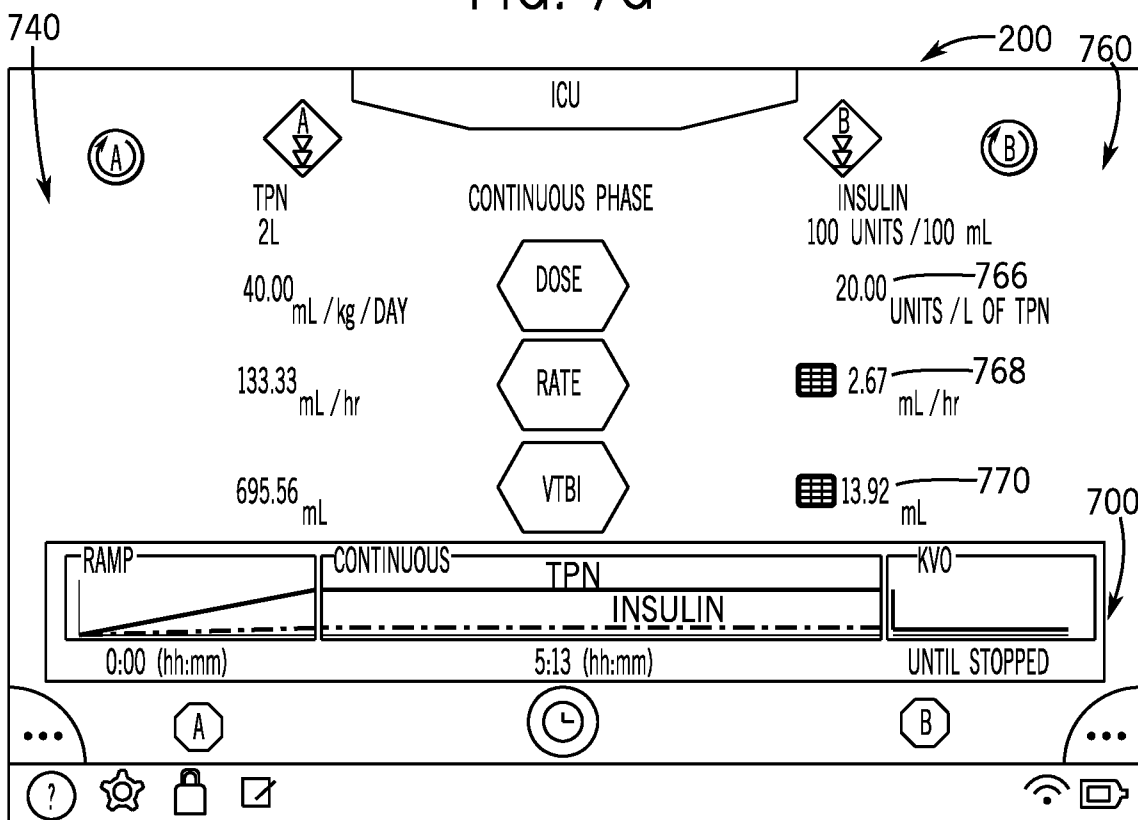


FIG. 7H

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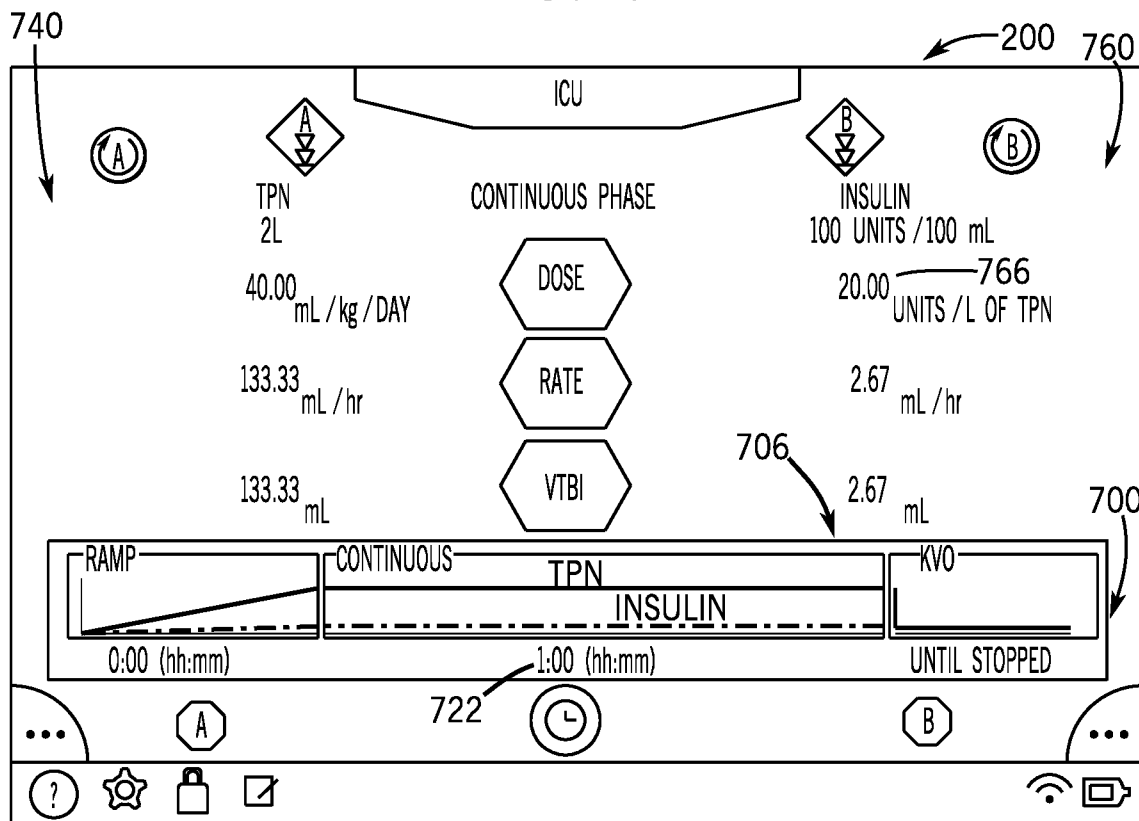


FIG. 7I

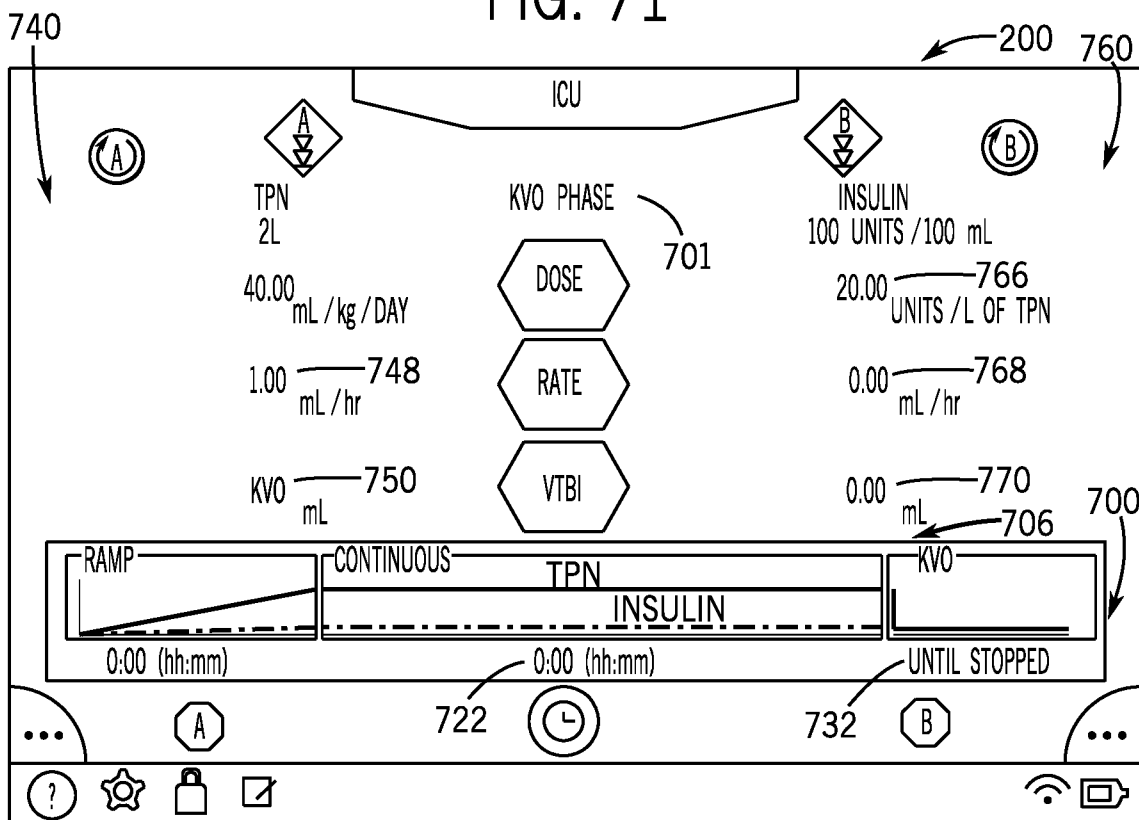


FIG. 7J

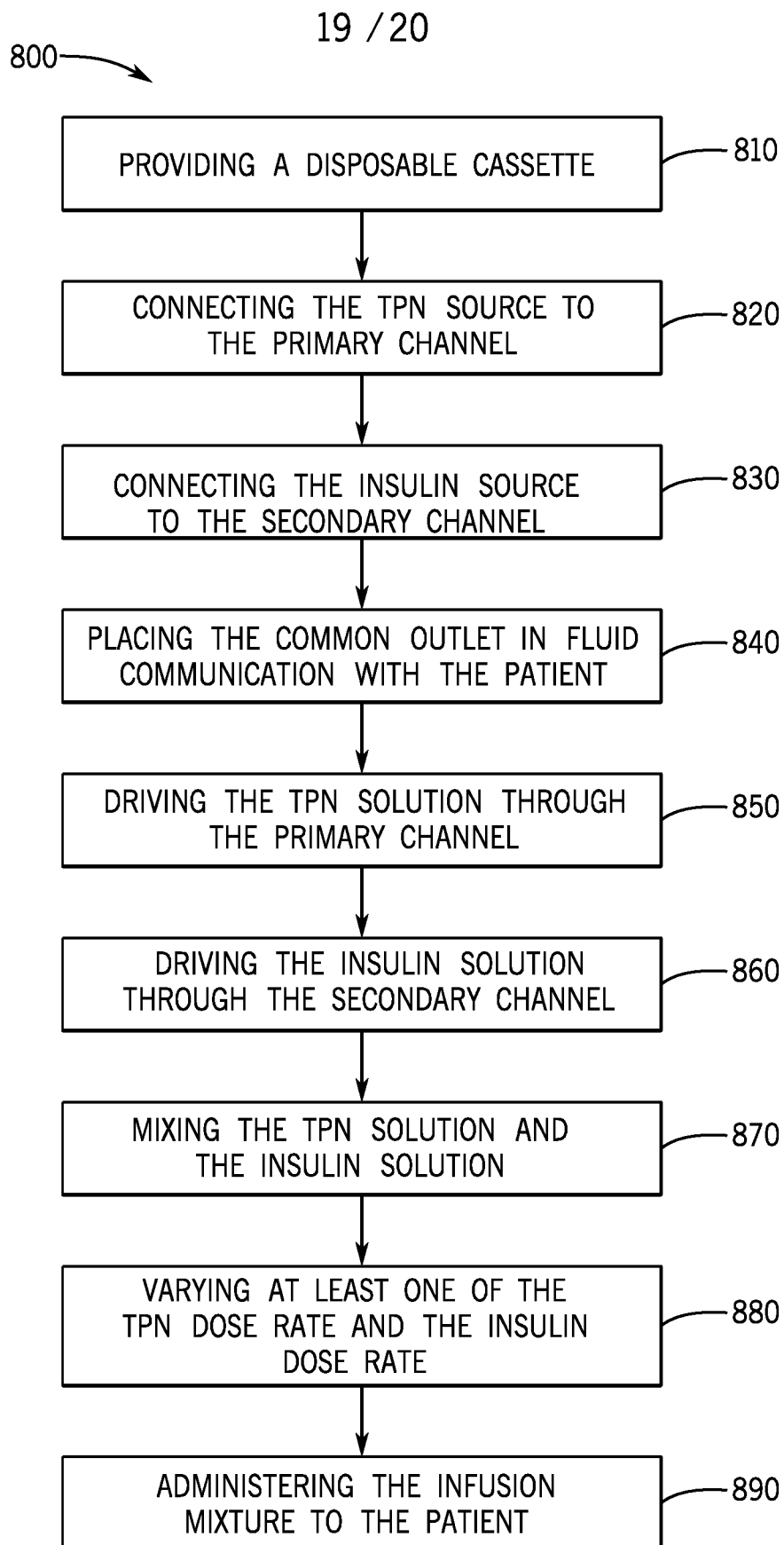


FIG. 8

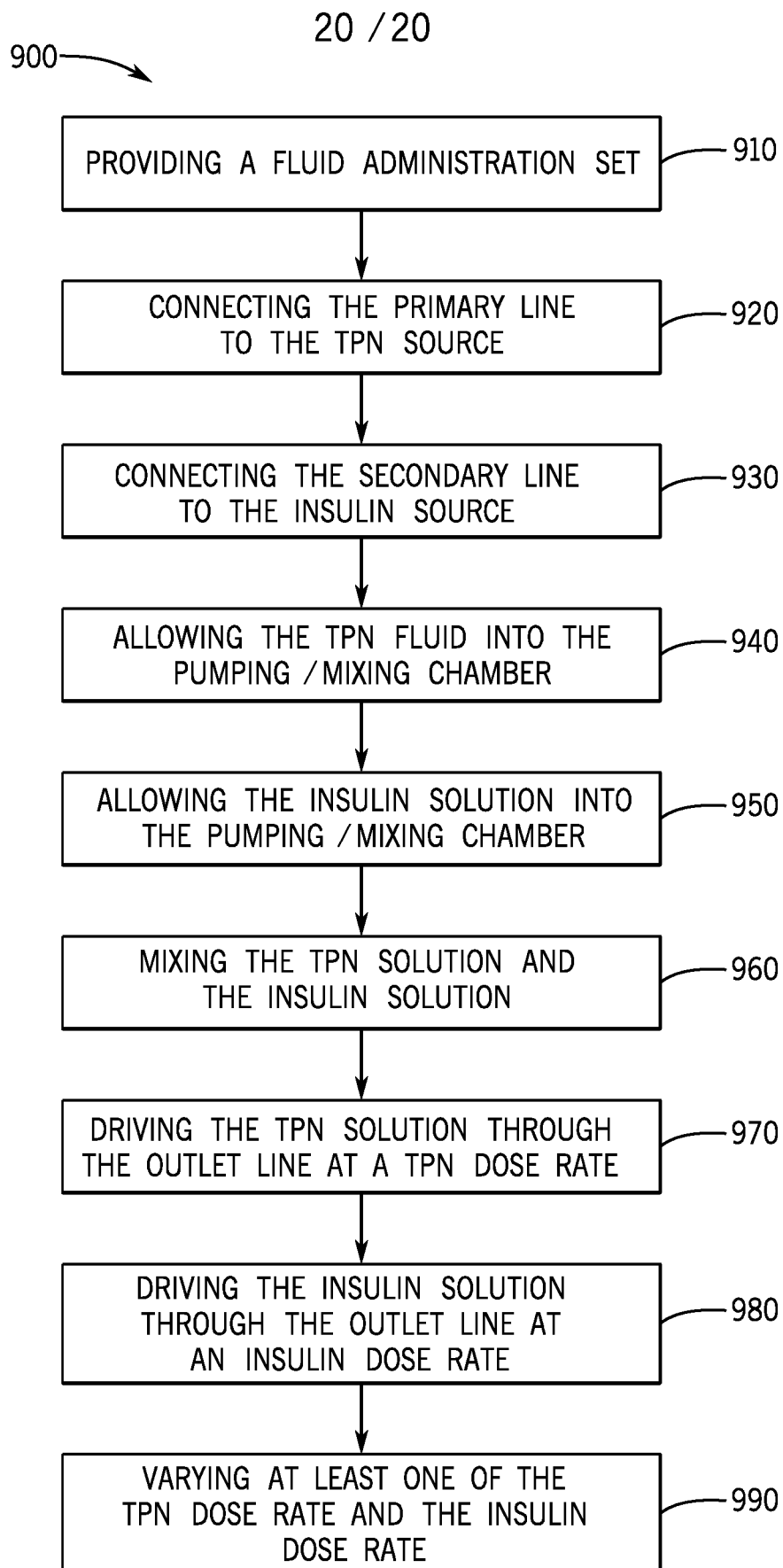


FIG. 9

