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(54) Title: DIALYSIS MACHINE WITH TRANSPORT MODE

(57) Abstract: A dialysis machine is provided comprising a non- volatile memory component into which patient data is stored. The patient data includes patient identification as well as prescribed patient treatment parameters. When data for a particular patient is entered by an operator into the non- volatile memory, the machine can be shut down and transported to the patient. The machine is then restarted, and performs a series of checks to ensure that all functions are ready to commence treatment. Patient treatment can then be achieved at a location remote from where the machine was first set up.

DIALYSIS MACHINE WITH TRANSPORT MODE

Background

[0001] The present invention relates to a dialysis machine for extracorporeal treatment of blood. More particularly, the invention relates to such a dialysis machine that can be transported from a set-up location to a treatment location while preserving data related to treatment parameters for one or more individuals to be treated.

[0002] Various types of medical equipment are designed with the knowledge that the equipment may be used in an ambulatory manner. For example, U.S. Patent No. 5,317,506 issued to Coutre et al. and entitled Infusion Fluid Management System discloses an infusion management and pumping system. Infusion prescriptions are generated and monitored by a pharmacy management system. Labels for each infusion to be given to a patient are generated and printed in a bar code format. Each label contains data regarding a prescribed infusion program, including the drug or drugs to be infused, the infusion regimen, the expiration date, and the patient to whom the infusion is to be administered. The management system checks for incompatibilities between drugs that are being prescribed for simultaneous infusion. Each label generated by the management system is attached to the container which holds the infusion solution. The data on the label is transferred to an infusion pumping system by a bar code reader at the infusion pumping system. The pumping system checks that all necessary data has been entered. During operation, the pumping system checks for a variety of alarm conditions and stores any alarms in a ranking according to urgency. The infusion pumping system is responsive to remote or biofeedback instructions to alter the planned infusion program. Central computer records processing receives infusion data and provides infusion, inventory, and use analysis.

[0003] Another example is U.S. Patent No. 5,376,070 issued to Purvis et al. and entitled Data Transfer System for an Infusion Pump. That patent discloses a data transfer system for communication with an infusion pump of the type used for programmable delivery of medication such as insulin to a patient. The data transfer system includes a communication station having a shaped pocket formed therein for seated reception of the infusion pump. Optical communication members including light emitting and detecting devices mounted on the pump and station are aligned for two-way data transmission when the pump is seated within the station pocket. The communication station can be used directly to monitor data received from the pump, and to transmit reprogrammed data to the pump, as desired. Alternately, the communication station can provide a data relay link to a remote site such as

to a computer via a computer data cable, or a modem. See also U.S. Patent No. 5,360,710 issued to Tune et al. and entitled Ambulatory Infusion Pump.

[0004] U.S. Patent No. 6,699,230 issued to Jaafar et al. and entitled Apparatus and Method for Out-Of-Hospital Thrombolytic Therapy discloses an apparatus and method for emergency administration or self-administration of thrombolytic therapy in early stage of a heart attack. The apparatus includes a needle injector for making a venipuncture, a battery operated micro cooler for maintaining low temperature environment for vials with lyophilized thrombolytic and adjuvant drugs, a container with a diluent for reconstitution of the lyophilized drugs, a programmable infusion pump, and a microprocessor for controlling the process of infusion and recording the data. As the system is activated, the container becomes fluidly communicable with the infusion pump and vials with drugs in the cooler. Designed for autonomous execution of several schedules of infusion, it also can be controlled remotely by a qualified operator via an Internet interface.

[0005] Finally, U.S. Patent No. 5,250,027 issued to Lewis et al. and entitled Peristaltic Infusion Device With Backpack Sensor relates to a sensed member and sensing member for use on a medical fluid infusion device and support device wherein the fluid infusion device is usable in a conventional manner such as on an IV pole and in an ambulatory manner such as in a support device for use in an ambulatory backpack. The sensing member of the present invention detects when the fluid infusion device is to be used in an ambulatory manner to adjust the operation of the infusion control member to account for the difference in fluid flow rates caused by the different fluid pressures within the fluid delivery set when the fluid infusion device is used in a conventional manner and an ambulatory manner.

[0006] Dialysis machines for the extracorporeal treatment of a patient's blood are well known. Such devices withdraw blood from a patient, circulate the blood through a treatment unit, and then return the treated blood to the patient. Dialysis machines have a number of variable parameters that are individually adjusted prior to each dialysis treatment in accordance with the prescribing physician's instructions for a particular patient. Such parameters include, for example, blood flow rate, the duration of treatment, the type of dialyzer used, the dialyzer values, the type of dialysate, the type of infusate, and values related to treatment with heparin or other anti-coagulant.

[0007] Setting up a dialysis machine prior to administration of dialysis to a patient can be a complex process. Each of the parameters identified above must be pre-set. In addition, the machine itself must be prepared. The dialyzer must be installed. Sources of heparin and saline must be connected. Separate sets of tubing must be installed to carry both blood and

dialysate. The tubing must be flushed and primed. The tubing must be checked for the presence of air bubbles, and any air bubbles found must be removed. The dialysate must be warmed to a pre-determined temperature. Only when all parameters have been set and set-up is complete can dialysis treatment of a patient commence.

[0008] Because of the complexity of the dialysis machine, set-up of a dialysis machine typically is performed by a trained professional. Dialysis generally occurs in a hospital setting or a dialysis treatment center. Dialysis treatments typically last for a duration of at least three hours, and often must be performed several times per week. For some patients, daily dialysis is required.

[0009] For some dialysis patients, travel to and from a dialysis treatment location, at least several times a week, and for several hours each time, can be difficult and burdensome. Such repeated travel can be especially difficult for some patients who are already in fragile health. For such patients, it would be desirable to bring a dialysis machine either to their home or to some other location closer to their home where dialysis treatment can be performed. Even for patients who are hospitalized, the movement from the hospital room to the location of the dialysis machine in the hospital can be stressful. Yet the complexity of appropriate set-up of the dialysis machine remains a significant obstacle to the performance of dialysis treatment in a remote location, or even at a patient's bedside. Thus, a need exists for an ambulatory dialysis machine.

Summary of the Invention

[00010] A dialysis system of the present invention has a treatment mode and a transport mode. The dialysis system of the invention comprises a dialysis machine; an electronic control means; a non-volatile memory component; a data entry means for entering patient treatment parameters into the non-volatile memory; and a data display means. The dialysis machine can be prepared for dialysis treatment of a patient, with the dialysis treatment parameters for the patient entered through the data entry means for storage in the non-volatile memory component; the electronic control means then can be set to operate the system in transport mode; the system then can be removed from external power, transported to a patient location, and reconnected to external power, the electronic control means then being capable of operating the system in treatment mode in accordance with the patient treatment parameters stored in the non-volatile memory component.

[00011] In another aspect of the present invention, a method of operating a dialysis system comprises preparing the dialysis machine for treatment of a patient, entering dialysis treatment parameters for that patient via a data entry means into a non-volatile memory component, disconnecting the system from external power, transporting the system to a treatment location, reconnecting the system to external power, such that the machine will reset in accordance with the patient treatment parameters stored in the non-volatile memory component, and using the reset dialysis machine to treat the patient. In a preferred embodiment, the elapsed time between the disconnection of the system from external power and the beginning of patient treatment is monitored.

Description of the Figures

[00012] For the present invention to be easily understood and readily practiced, the invention will now be described, for purposes of illustration and not limitation, in conjunction with the following figures wherein:

[00013] FIG. 1 is a legend of symbols used in the flow charts of FIGS. 2-23.

[00014] FIG. 2 is a start-up menu and main menu of the system of FIG. 24.

[00015] FIG. 3 is a system menu for off-site use of the system of FIG. 24.

[00016] FIG. 4 is a system menu for acute treatment methods using the system of FIG. 24.

[00017] FIG. 5 is a set of defaults for the acute treatment using the system of FIG. 24.

[00018] FIG. 6 is a flowchart showing editing of the system-set prescriptions for off-site use of the system of FIG. 24.

[00019] FIG. 7 is a flowchart showing the treatment set-up procedures for off-site use of the system of FIG. 24.

[00020] FIG. 8 is a flowchart showing the treatment set-up procedures of acute treatment using the system of FIG. 24.

[00021] FIG. 9 is a flow chart illustrating the calculation of a UFR value for the system of FIG. 24.

[00022] FIG. 10 is a flowchart showing the establishment of dialysate prescription values and infusate prescription values for off-site use of the system of FIG. 24.

[00023] FIG. 11 is a flowchart showing the establishment of dialysate prescription values and infusate prescription values for acute treatment using the system of FIG. 24.

[00024] FIG. 12 is a flowchart showing the procedures for the installation of disposables in the system of FIG. 24.

[00025] FIG. 13 is a flowchart showing the procedures for priming the system of FIG. 24.

[00026] FIG. 14 is a flowchart showing the procedures for confirming the use of prescribed parameters of off-site use of the system of FIG. 24.

[00027] FIG. 15 is a flowchart showing the procedures for confirming the use of prescribed parameters for acute treatment using the system of FIG. 24.

[00028] FIG. 16 is a flowchart showing dialysis treatment using the system of FIG. 24.

[00029] FIG. 17 is an Appendix to FIG. 16.

[00030] FIG. 18 is a flowchart showing post-treatment procedures using the system of FIG. 24.

[00031] FIG. 19 is a flowchart showing procedures for alarms and one alert for use with the system of FIG. 24.

[00032] FIG. 20 is a flowchart showing procedures for two additional alerts for use with the system of FIG. 24.

[00033] FIG. 21 is a flowchart showing a procedure for the recovery of the system of FIG. 24.

[00034] FIG. 22 is a flowchart showing various quit scenarios for the system of FIG. 24.

[00035] FIG. 23 is a flowchart showing procedures for adjusting the dialysate of the system of FIG. 24.

[00036] FIG. 24 is a schematic view of an embodiment of a dialysis system of the present invention.

Detailed Description of a Preferred Embodiment

[00037] The dialysis system shown schematically in the drawings has parts that are examples of the elements recited in the apparatus claims, and can be operated in steps that are examples of the elements recited in the method claims. The illustrated system thus includes examples of how a person of ordinary skill in the art can make and use the claimed invention. They are described here to meet the enablement and best mode requirements of the patent statute without imposing limitations that are not recited in the claims.

[00038] FIGs. 1-23 depict flowcharts for a preferred embodiment of the dialysis system of the present invention. FIG. 24 is a schematic of a dialysis system 10 of the present invention. Referring to FIG. 24, the system 10 is a renal dialysis system for the extracorporeal treatment of blood from a patient 11 whose kidney function is impaired. The illustrated embodiment of the dialysis system 10 of the present invention comprises a dialysis machine 12 as is generally known in the medical arts, and shown generally within the dotted line, plus various consumables as is known in the art.

[00039] In accordance with the present invention, the dialysis machine 12 is provided with a non-volatile memory component 16 adaptively coupled to electronic control means 14. Non-volatile memory component 16 can be any form of memory component that retains stored values when external power is turned off. For example, such non-volatile memory components can be selected from the group consisting of a hard disk, flash memory, battery-backed-up RAM, or other data storage device.

[00040] Dialysis machine 12 further includes a data entry device 18, such as a keyboard, touch-screen monitor, computer mouse, or the like. Dialysis machine 12 further includes a display device 20, such as a read-out monitor, for displays of operating values of the various individual components of the dialysis machine 12. The system 10 can be provided with a power source 22, a battery back-up 24, and a clock/timer 26. The processor 14, memory 16, data entry device 18, and clock/timer 26 represent one configuration of a control system.

[00041] The dialysis system 10 comprises a blood circuit 28 through which the patient's blood travels, a dialyzer 30 that serves to separate the wastes from the blood, and a dialysate circuit 32 through which treatment fluid, specifically dialysate, travels carrying the waste away.

[00042] The dialysate circuit 32 includes a dialysate pump 34 for driving dialysate fluid through a tube set and through the dialyzer 30. The dialysate circuit 32 may further include other components such as those described in U.S. Patent Application Serial No. 11/148,928, entitled Dialysis System and filed on June 9, 2005, which is hereby incorporated by reference in its entirety.

[00043] The blood circuit 28 includes another tube set including an arterial line 36 for withdrawing blood from the patient 11 and delivering it to the dialyzer 30, and a venous line 38 for returning the treated blood to the patient 11. A blood pump 40 drives the blood around the blood circuit 28. A valve 41 is situated on a gas line 42 for supplying negative and positive pressure from a source 43 to the pump 40. The arterial line 36 also incorporates a valve 45 that can stop the flow of blood from the patient 11, an air detector 46 that can detect air in the arterial line 36, and a flow sensor 47 that measures the flow of blood. The arterial line 36 further includes a valve 48 upstream of the pump 40 and a valve 50 downstream on the pump 40. The blood pump 40 may be configured as described in U.S. Patent Application Serial No. 10/399,128, entitled Device and Methods for Body Fluid Flow Control In Extracorporeal Fluid Treatments, filed on July 28, 2003, which is hereby incorporated by reference in its entirety.

[00044] Other components which interact with the blood circuit 28 include a source of fluid, such as a saline bag 52, which communicates with the arterial line 36 via a branch line 54 and a valve 56 responsive to processor 14. Additionally, an anticoagulant solution such as a heparin supply 58 may communicate with the arterial line 36 through a branch line 60 and a pump 62 responsive to processor 14. It is understood by persons skilled in the art that additional elements may be added to the blood circuit 36, such as air detectors in the branch lines 54 or 60. These additional elements are omitted from the drawings for clarity of illustration. Finally, the venous line 38, which delivers the treated blood from the dialyzer 30 to the patient 11, also includes a valve 64, an air detector 66, and a flow sensor 68.

[00045] The processor 14 coordinates the operation of the dialysis system 10 by controlling the blood flow in the blood circuit 28, the dialysate flow in the dialysate circuit 32, and the flow of saline 52 or heparin 58 to the arterial line 36 via the branch lines 54 and 60, respectively. To achieve this, the processor 14 utilizes hardware and/or software configured for operation of these components and may comprise any suitable programmable logic controller or other control device, or combination of control devices, that is programmed or otherwise configured to perform as is known in the art. Thus, blood flow in the blood circuit 28 is controlled by operating the blood pump 40 and controlling the valves in the arterial and 36 and venous 38 lines. Dialysate flow in the dialysate circuit 32 is controlled by operating the dialysate pump 34.

[00046] The processor 14 is also responsive to various input signals it receives, such as input signals from one or more flow sensors 47, 68, air detectors 46, 66, and the clock/timer 26. Additionally, the processor 14 displays system status and various other treatment parameters, known in the art, on the display 20. That allows the operator to interact with the processor 14 via the data entry device 18 (which could include a touch sensitive display 20).

[00047] The present invention can be used with a variety of different commercially available dialysis machines; one such machine particularly suited for use with the present invention is a dialysis machine sold under the registered trademark ALLIENT by Renal Solutions, Inc., the assignee of the invention herein.

[00048] The dialysis system 10 must be set up before it can be used to provide dialysis treatment for a patient. Set-up procedures are typically performed by a medically trained professional. First, the power to the machine is turned on. Data pertaining to the patient to be treated is entered by the system operator into the system via data entry device 18, and this data is stored in non-volatile memory component 16. Such data will include information to identify the patient, such as name and address, or some other indicium such as a reference

number. Such data will further include prescription parameters for the dialysis process that are unique for that patient as prescribed by his or her physician. Such prescription dialysis parameters can include, for example, blood flow rate, the duration of treatment, the type of dialyzer used, the dialyzer values, the type of dialysate, the type of infusate, and values related to treatment with heparin or other anti-coagulant.

[00049] Once the applicable patient data has been entered into the non-volatile memory component 16, the operator continues to prepare the machine for patient treatment in accordance with standard medical procedures. The disposable blood lines and dialysate lines are installed, flushed, and primed. Dialysate, saline, and heparin are each loaded into their respective reservoirs. The blood lines are de-bubbled and the dialysate is warmed to the appropriate treatment temperature. These steps are carried out by the operator, interacting with electronic control means 14 via data entry device 18.

[00050] In accordance with the invention, once the dialysis machine has been set up for patient treatment, the system 10 either can proceed in treatment mode or it can be converted into "transport mode." Electronic control means 14 sends a query via display means 20 to the operator, by which the operator can instruct the electronic control means 14 via data entry device 18 to operate in either treatment mode or transport mode. If the operator elects to have the machine 12 operate in treatment mode, then the machine 12 is connected to the waiting patient, and treatment proceeds in the standard manner.

[00051] If, however, the operator instructs the machine via, for example, data entry device 18 that the machine 10 is to operate in "transport mode," then a different sequence of steps ensues which are shown by the sequence of steps 70 in FIG. 13. Processor 14 initiates a transport mode shutdown sequence. The processor 14 stores a value to indicate that "transport mode" has been selected. That value is obtained from the clock/timer 26. The value could be, for example, a reading of a current time from the clock. Alternatively, a counter could be reset so as to start counting clock pulses. Inputs to the non-volatile memory 16 are disabled so that the memory 16 will stay in the exact state that the operator left it before initiating the transport mode sequence. The operator then disconnects the machine 12 from an external power supply (not shown). The system 10 can now be relocated to a location closer to the patient for whom it was set up, such as in a hospital room, an emergency room, or another location.

[00052] After the system 10 is relocated, the operator then reconnects the dialysis machine 12 to a power source, and initiates a start-up procedure shown generally in FIG. 2. The processor 14 first determines at step 70 whether the machine 12 had been left in transport

mode at the time of shut down. If it was, a determination of the venue is made at step 72. For the acute care venue, the process continues with the Confirm R_x AT_x procedure shown in FIG. 15. For the home care venue, the process continues with the Confirm R_x HT_x procedure shown in FIG. 14. In either case, the machine 12 performs several different checks of the system 10 to assure that transition into treatment mode is still a viable option. For example, the processor 14 checks that the disposable blood and dialysate lines are still connected and loaded; that the dialysate and infusate volumes are still correct; and that the tubing contains fluid. If any of these conditions are not met, then the processor 14 will send a signal to the display means 20 to advise the operator of the particular situation that must be corrected.

[00053] In a preferred embodiment, the control system is provided with a real-time clock or other timekeeping device 26 that maintains operation when external power has been disconnected. The processor 14 checks the timekeeping device 26 to determine if too much time has elapsed from the time external power was first disconnected. There are various ways in which that may be implemented. For example, upon entering the transport mode, a value from the clock may be read. Upon bringing the machine out of the transport mode, another reading from the clock may be taken. The length of time that the system was in the transport mode may be determined by comparing the two clock readings to calculate the difference between the clock readings. That difference may then be compared to a predetermined value.

[00054] In another embodiment, a counter may be reset or initiated when the machine is put into the transport mode. Upon bringing the machine out of the transport mode, the value of the counter may be read. The value which is read may then be compared to a predetermined value.

[00055] It is presently believed that no more than about two to two and one-half hours should elapse between the time that power is shut down for the transport mode of operation and the time patient treatment is initiated to protect against unacceptable bacterial growth that may occur in the various lines of the system. If too much time has elapsed, then the operator would dispose of the dialysate and infusate and begin the start-up sequence anew.

[00056] The dialysate reservoir will be provided with a temperature sensor in communication with the processor 14. The processor 14 will read the temperature sensor to determine whether the dialysate temperature is within an acceptable range, which according to general medical principles will be in the range of about 34-39°C. If the temperature is outside this range, the processor 14 will direct the machine to heat the dialysate or allow it to cool to bring it into the acceptable temperature range before the time limit expires. The

processor 14 will also cause the machine to initiate an automatic de-bubbling sequence to ensure that any air that may have been inadvertently introduced into the blood lines is eliminated. Completion of this sequence can be indicated on display means 20.

[00057] Once all system checks are complete, the system will provide a signal, such as a notice on display means 20, indicating that the system is ready to commence dialysis treatment of a patient. Preferably, the system displays the patient's identifying data a treatment parameters on display means 20, so that the operator can verify that the correct patient is about to be treated and that the treatment parameters are correct.

[00058] In one embodiment, if the system determines that none of the disposable elements are installed, it will assume that the operator purposely removed those components during the time when external power was disconnected. Then, instead of providing the operator with the option of treatment mode, the machine will resume normal start-up procedures and require the loading of disposable elements and entry of patient identification and treatment data as if transport mode had not been initiated.

[00059] As previously described, the transport mode allows the user to prepare the machine for treatment by loading disposables and proceeding through system prime. At that point the user may elect, instead of starting a treatment, to shutdown the machine to transport it to the point of use. There is a limit of two to two and one-half hours from the time that the dialysate is mixed to the actual start of dialysis (Prime Time). The following table details that process.

[00060] TABLE 1

MACHINE_STATE is IDLE.

- The User enters prescription information.
- The User mixes and measures the dialysate conductivity.
- The User enters the dialysate conductivity and presses the Accept button on the Dialysate screen.
- GUI sends TRT a SETUP_SIG.
- TRT changes MACHINE_STATE to TREATMENT.
- TRT sends DAT a DIALYSATE_MIXED message. DAT will record the real-time clock as the start time of Dialysate Mixed. TRT will initialize its Prime Timer count-down timer with 2.5 hours.
- TRT, GUI, and the User continue with infusate mixing, disposable loading, and System Prime.
- TRT sends GUI the BUBBLE_COND_MET and HEAT_COND_MET messages to signal GUI that it's OK to start Treatment or Transport.
- The operator decides to enter Transport Mode.

- GUI sends a TRANSPORT_SIG to TRT.
- TRT changes MACHINE_STATE to TRANSPORT.
- TRT sends DAT a DATA_CHANGE to set TRANSPORT_MODE data indicator to true.
- DAT sends GUI a START_SHUTDOWN message.
- GUI initiates the shutdown of the Main Controller (processor 14) by sending SSM a SHUTDOWN message.
- After SSM determines that all components have shutdown SSM sends GUI a SHUTDOWN_DONE message. GUI then puts up a screen to tell the operator to turn off power to the machine.
- **The machine is powered off and then back on. Subsequent steps start when the Main Controller enters the CHECKING MACHINE_STATE.**
- SFTY requests TRANSPORT_MODE from DAT and realizes that this machine is powered up in Transport Mode because TRANSPORT_MODE is true.
- SFTY sends a CHANGE_SCREEN to GUI to tell GUI to change the screen to "Transport Startup."
- SFTY sends the remotes several commands to determine if the disposables are installed on the machine (a Wet Check). SFTY does several tests:
  - If SFTY determines that there are no disposables on the machine the MACHINE_STATE is set to IDLE and TRANSPORT_MODE is set to false. GUI sees that MACHINE_STATE is IDLE and presents a non-transport Main Menu.
  - SFTY asks DAT for the elapsed Dialysate Mixed time, which is the difference between the current real-time clock and the time that the dialysate was first mixed. If the elapsed Dialysate Mixed time is over 2.5 hours SFTY changes MACHINE_STATE to RECOVER and offers a Recovery screen with only the Quit button available. Pressing the Quit button will cause the Unload screen to be presented. The machine must be unloaded and power-cycled to start another treatment.
  - If SFTY determines that there are some disposables missing the MACHINE_STATE is set to RECOVER and the user is given the opportunity to correct the missing disposable(s). Repeat Wet Check with MACHINE_STATE set to CHECKING if the user presses the Continue button on the Recovery screen.
- If all the disposables are loaded and the Dialysate Mixed time is under 2.5 hours SFTY changes MACHINE_STATE to RESUME (from CHECKING).
- GUI observes the MACHINE_STATE is RESUME and asks the operator to confirm the patient prescription.
- IF the operator confirms the patient prescription GUI will send TRT a TRANSPORT_SETUP_SIG to resume the treatment.
- TRT asks DAT for the elapsed Dialysate Mixed time.
- If the elapsed Dialysate Mixed time is greater than 2.5 hours TRT will post an Alarm Two.

- If the elapsed Dialysate Mixed time is less than 2.5 hours TRT will initialize its Prime Time count-down timer with 2.5 hours minus the elapsed Dialysate Mixed time received from DAT.
- TRT changes MACHINE_STATE to TREATMENT.
- TRT enters the SYSTEM_PRIME state to ensure that the dialysate is at the correct temperature and that the blood-side is still bubble free.
- When TRT has confirmed de-bubbling and dialysate temperature TRT sends GUI DEBUBBLE_COND_MET and HEAT_COND_MET messages.
- GUI receives DEBUBBLE_COND_MET and HEAT_COND_MET messages and asks the operator to connect the patient. The Transport Mode option is not allowed at this time. When the patient is connected GUI sends TRT a DIALYZE_SIG. DIALYZE_SIG must be sent before TRT's Prime Timer count-down timer expires.
- TRT will send DAT a DATA_CHANGE to set TRANSPORT_MODE to false. No more power cycles are allowed.
- TRT proceeds with dialysis if the Prime Timer count-down timer has not expired.

[00061] The foregoing description of a preferred embodiment of the invention is presented by way of illustration and not by way of limitation. It is to be understood that any changes, modifications and equivalents that come within the spirit of the invention are to be covered by the following claims.

What is claimed is:

1. A dialysis machine comprising a first pump and a first plurality of valves for moving blood through a blood circuit; a second pump for moving dialysate through a dialysate circuit; an input device for receiving information; a non-volatile memory device responsive to said input device for storing information; a processor responsive to said memory device for providing control signals to said first and second pumps and said first plurality of valves for implementing a treatment; and an output device responsive to said processor, said dialysis machine characterized by a clock and said processor being configured to enter a transport mode in response to said input device, said processor further configured to be responsive to said clock to prevent the implementing of said treatment if a predetermined time in said transport mode has elapsed.

2. The dialysis machine of claim 1 additionally comprising a first branch line responsive to a source of saline and a first branch line valve responsive to said processor for inputting saline to said blood circuit.

3. The dialysis machine of any of the preceding claims additionally comprising a second branch line responsive to a source of heparin and a branch line pump responsive to said processor for inputting heparin to said blood circuit.

4. The dialysis machine of any of the preceding claims additionally comprising a flow detector and an air detector for monitoring said blood circuit, said processor being responsive to said flow detector and said air detector.

5. The dialysis machine of any of the preceding claims wherein said information comprises instructions for implementing said treatment and for implementing said transport mode, said information additionally comprising parameters for said treatment.

6. The dialysis machine of any of the preceding claims additionally comprising a battery for supplying power to said non-volatile memory device.

7. The dialysis machine of any of the preceding claims wherein said predetermined time in said transport mode is about two and one-half hours.

8. A method of operating a dialysis machine, comprising receiving data at an input device and storing said received data in a non-volatile memory device, said method characterized by placing said dialysis machine in a transport mode, generating timing information about the length of time said dialysis machine is in the transport mode, and using said timing information to determine if said dialysis machine may be used to administer a treatment.

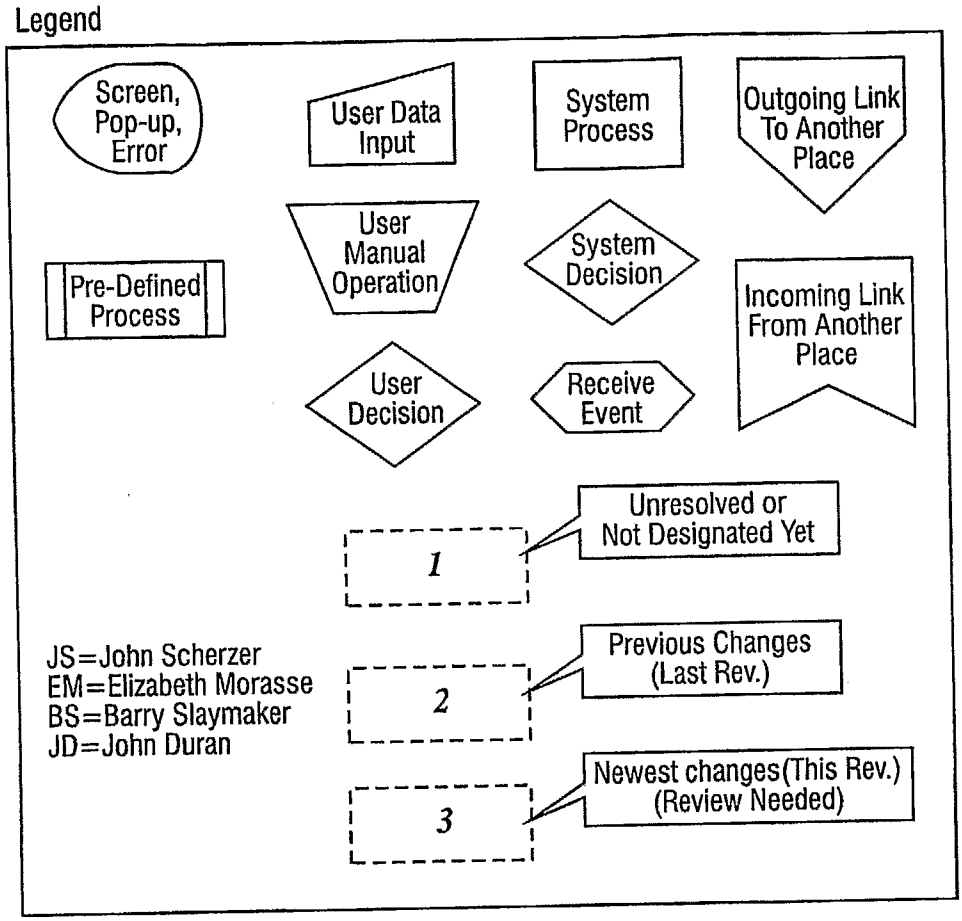
9. The method of claim 8 wherein said generating comprises saving a first clock reading when said machine is placed in a transport mode and saving a second clock reading when said machine is brought out of said transport mode, and wherein said using comprises calculating the difference between said first and second clock readings and comparing said difference to a predetermined value.

10. The method of claim 8 wherein said generating comprises initiating a counter when said machine is placed in said transport mode and reading said counter when said machine is brought out of said transport mode, and wherein said using comprises comparing the read value to a predetermined value.

11. The method of either claim 9 or claim 10 wherein said predetermined value represents a time period that is about two and one-half hours.

12. The method of any of the preceding claims additionally comprising preparing the dialysis machine to deliver a treatment.

13. The method of claim 12 wherein said preparing a machine to deliver a treatment comprises attaching consumables to said dialysis machine and entering dialysis treatment parameters for a patient into said machine.



Tx = Treatment
ATx = Acute Treatment
HTx = Home Treatment
HRx = Home Patient Rx

Fig.1

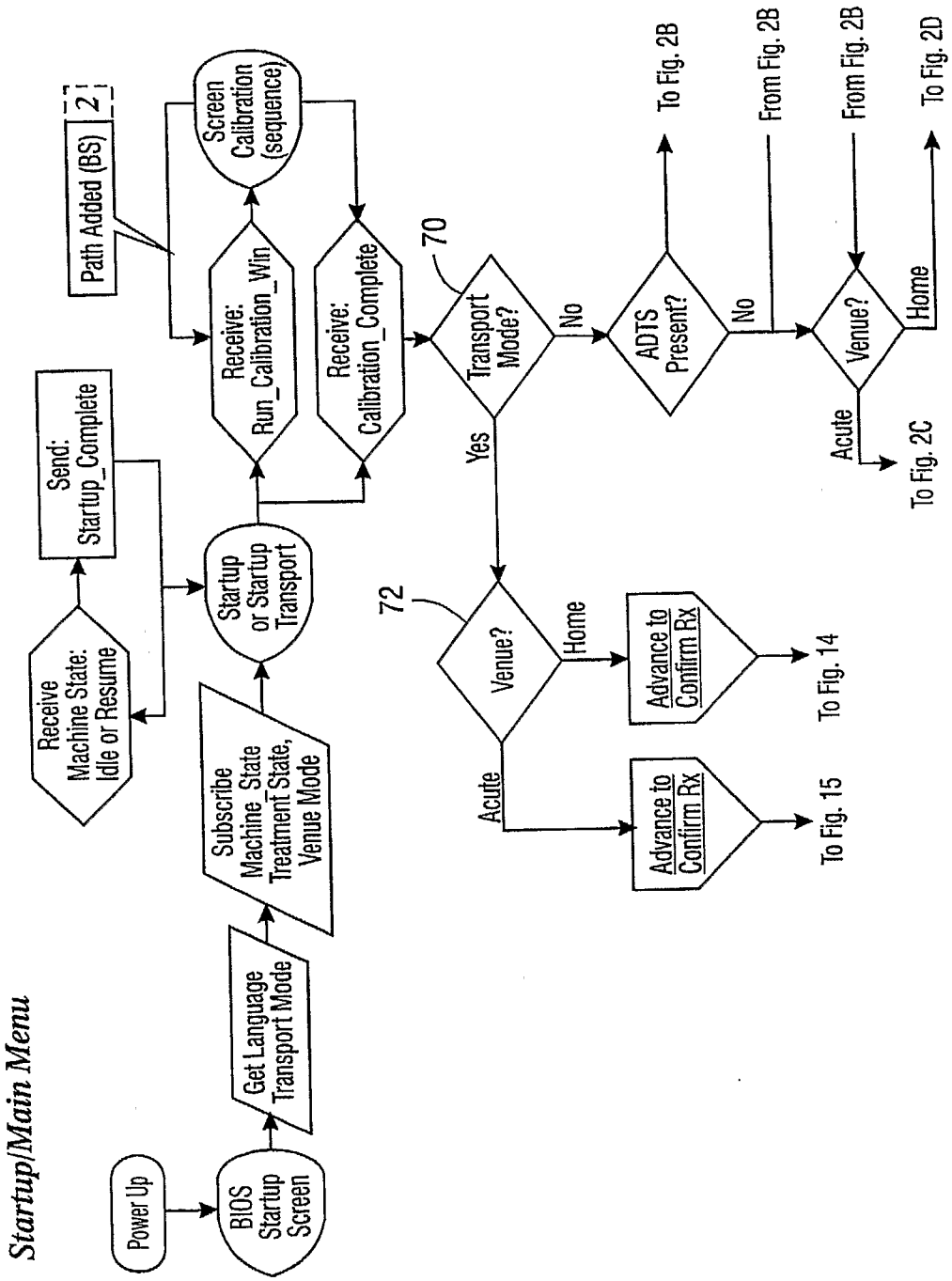

Startup/Main Menu
Power Up
BIOS Startup Screen
Get Language Transport Mode
Subscribe Machine_State Treatment_State, Venue Mode
Receive Machine State: Idle or Resume
Send: Startup_Complete
Startup or Startup Transport
Path Added (BS) 21
Receive: Run_Calibration_Win
Screen Calibration (sequence)
Receive: Calibration_Complete
70
Transport Mode?
Yes
No
72
Venue?
Home
Acute
Advance to Confirm Rx
To Fig. 14
Advance to Confirm Rx
To Fig. 15
ADTS Present?
No
To Fig. 2B
From Fig. 2B
Venue?
Home
Acute
To Fig. 2C
From Fig. 2B
To Fig. 2D

Fig. 2A

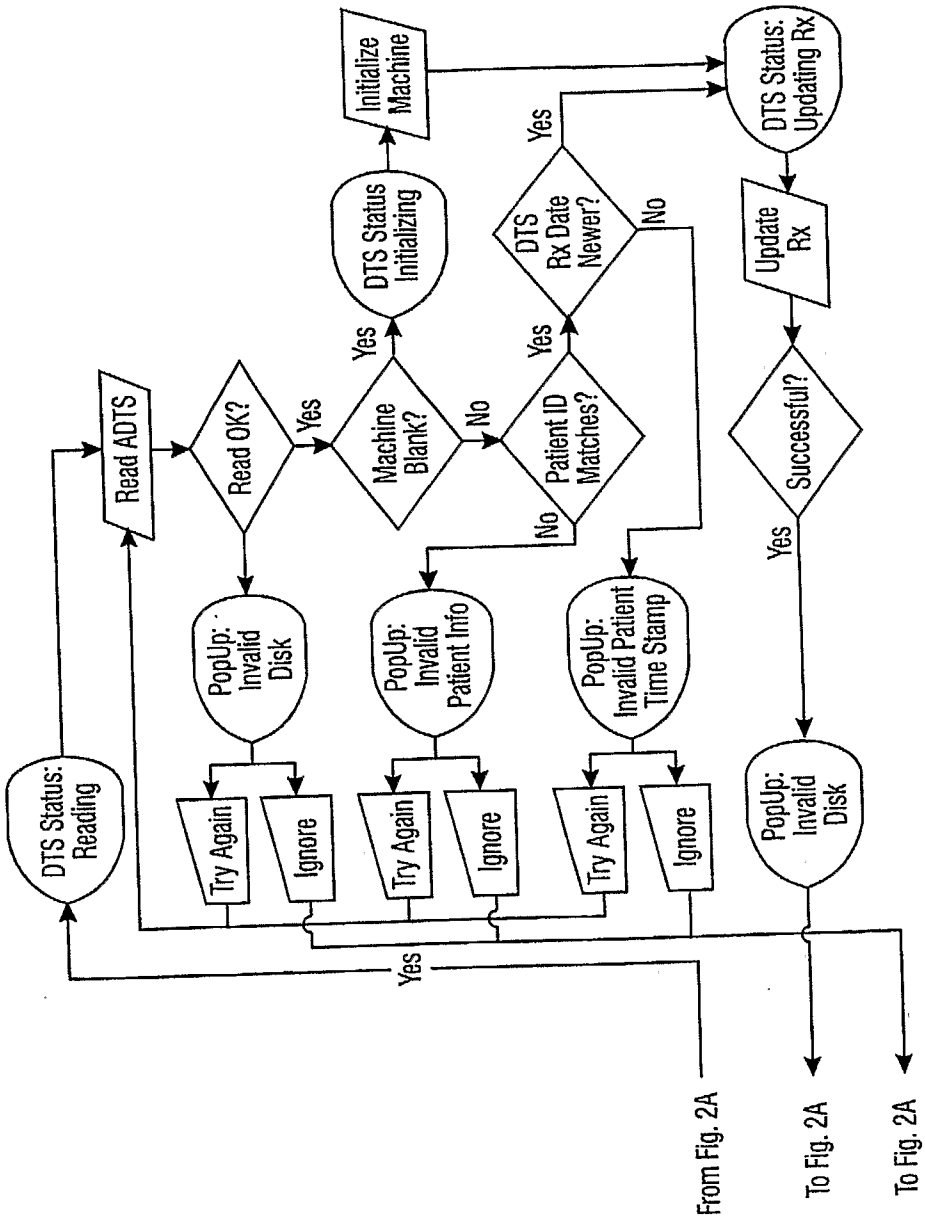

DTS Status: Reading
Read ADTS
Read OK?
Yes
Machine Blank?
No
Patient ID Matches?
No
DTS Rx Date Newer?
No
Successful?
Yes
DTS Status Initializing
Yes
Initialize Machine
Yes
DTS Status: Updating Rx
Update Rx
PopUp: Invalid Disk
PopUp: Invalid Patient Info
PopUp: Invalid Patient Time Stamp
PopUp: Invalid Disk
Try Again
Ignore
Try Again
Ignore
Try Again
Ignore
Yes
From Fig. 2A
To Fig. 2A
To Fig. 2A

Fig. 2B

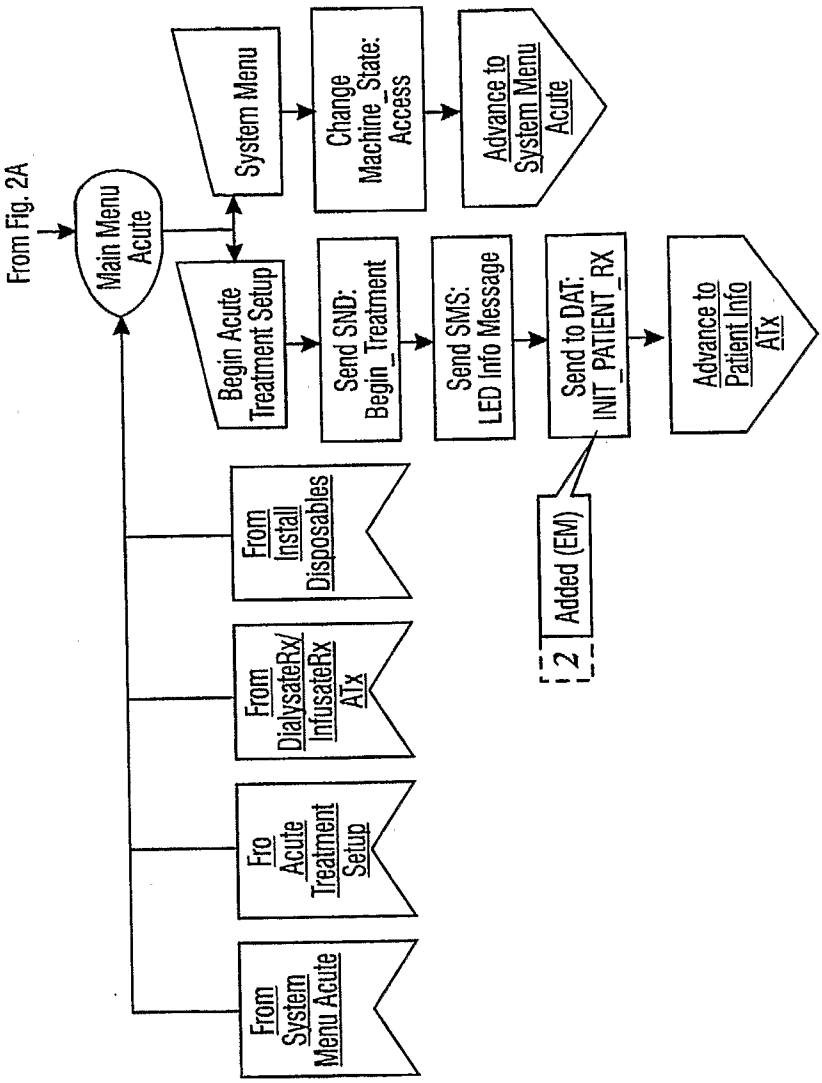

From Fig. 2A
Main Menu Acute
System Menu
Change Machine_State: Access
Advance to System Menu Acute
Begin Acute Treatment Setup
Send SND: Begin_Treatment
Send SMS: LED Info Message
Send to DAT: INIT_PATIENT_RX
Advance to Patient Info ATx
From Install Disposables
From DialysateRx/ InfusateRx ATx
Fro Acute Treatment Setup
From System Menu Acute
2 Added (EM)

Fig. 2C

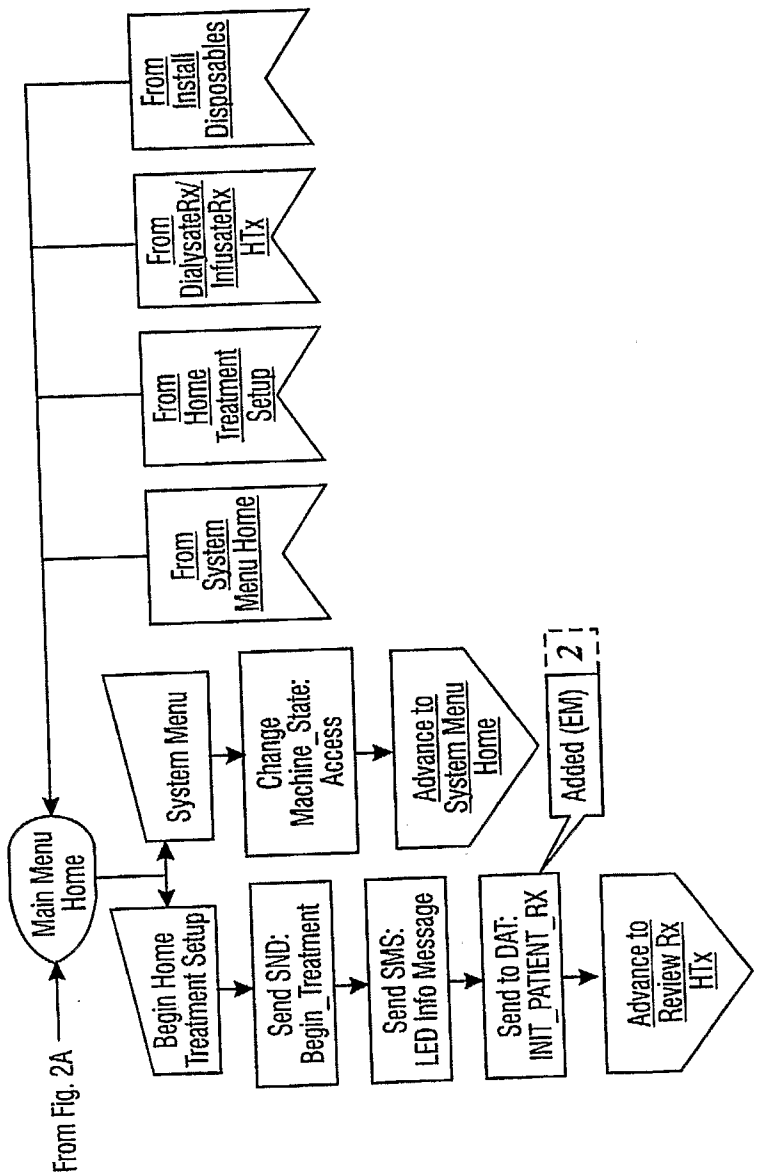

From Fig. 2A
Main Menu Home
Begin Home Treatment Setup
Send SND: Begin_Treatment
Send SMS: LED Info Message
Send to DAT: INIT_PATIENT_RX
Advance to Review Rx HTx
Added (EM)
2
System Menu
Change Machine_State: Access
Advance to System Menu Home
From System Menu Home
From Home Treatment Setup
From DialysateRx/ InfusateRx HTx
From Install Disposables

Fig.2D

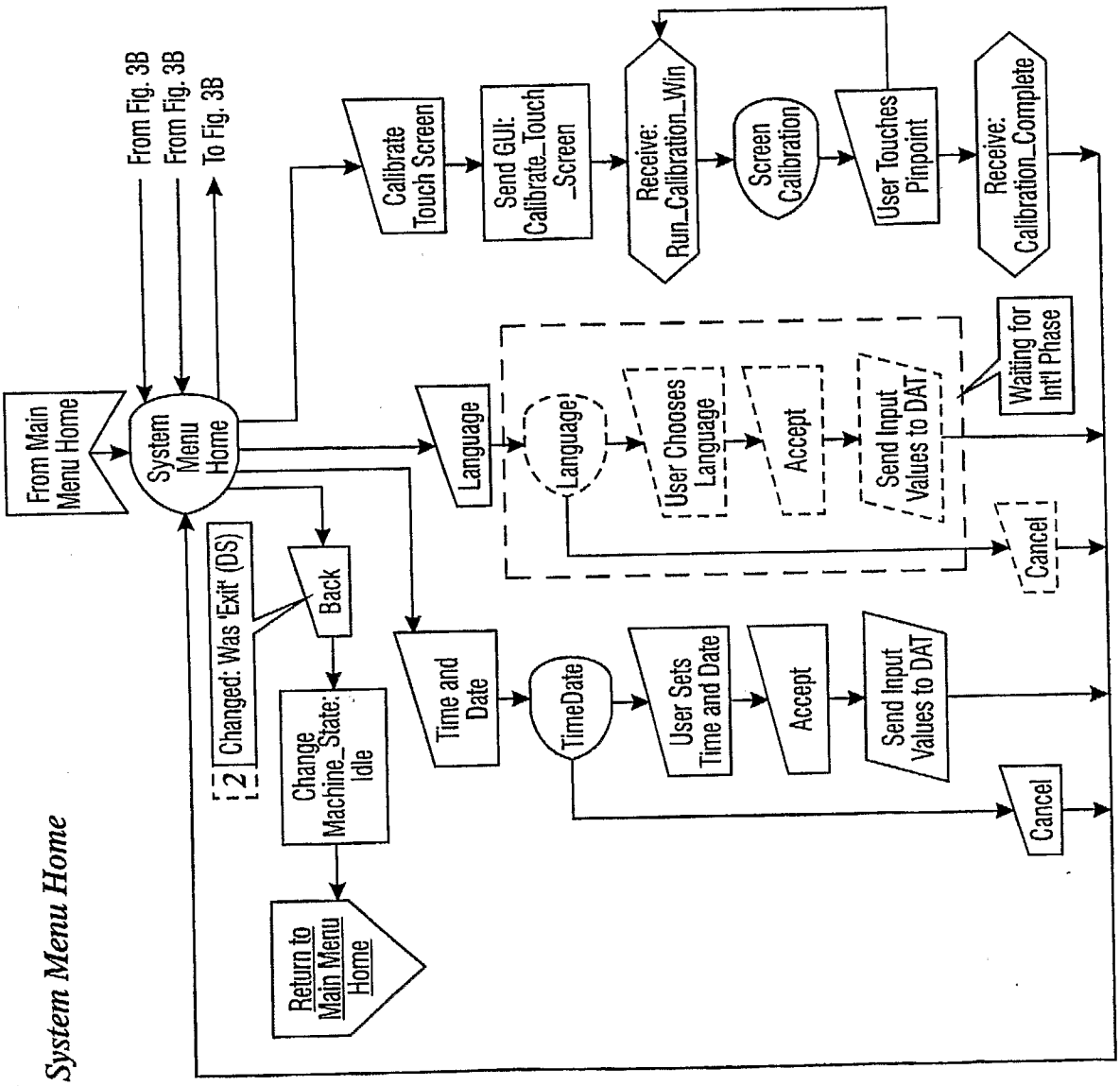

System Menu Home
From Main Menu Home
From Fig. 3B
From Fig. 3B
To Fig. 3B
System Menu Home
Calibrate Touch Screen
Send GUI: Calibrate_Touch _Screen
Receive: Run_Calibration_Win
Screen Calibration
User Touches Pinpoint
Receive: Calibration_Complete
Language
Language
User Chooses Language
Accept
Send Input Values to DAT
Waiting for Int'l Phase
Cancel
Time and Date
TimeDate
User Sets Time and Date
Accept
Send Input Values to DAT
Cancel
Back
2
Changed: Was 'Exit' (DS)
Change Machine_State: Idle
Return to Main Menu Home

Fig.3A

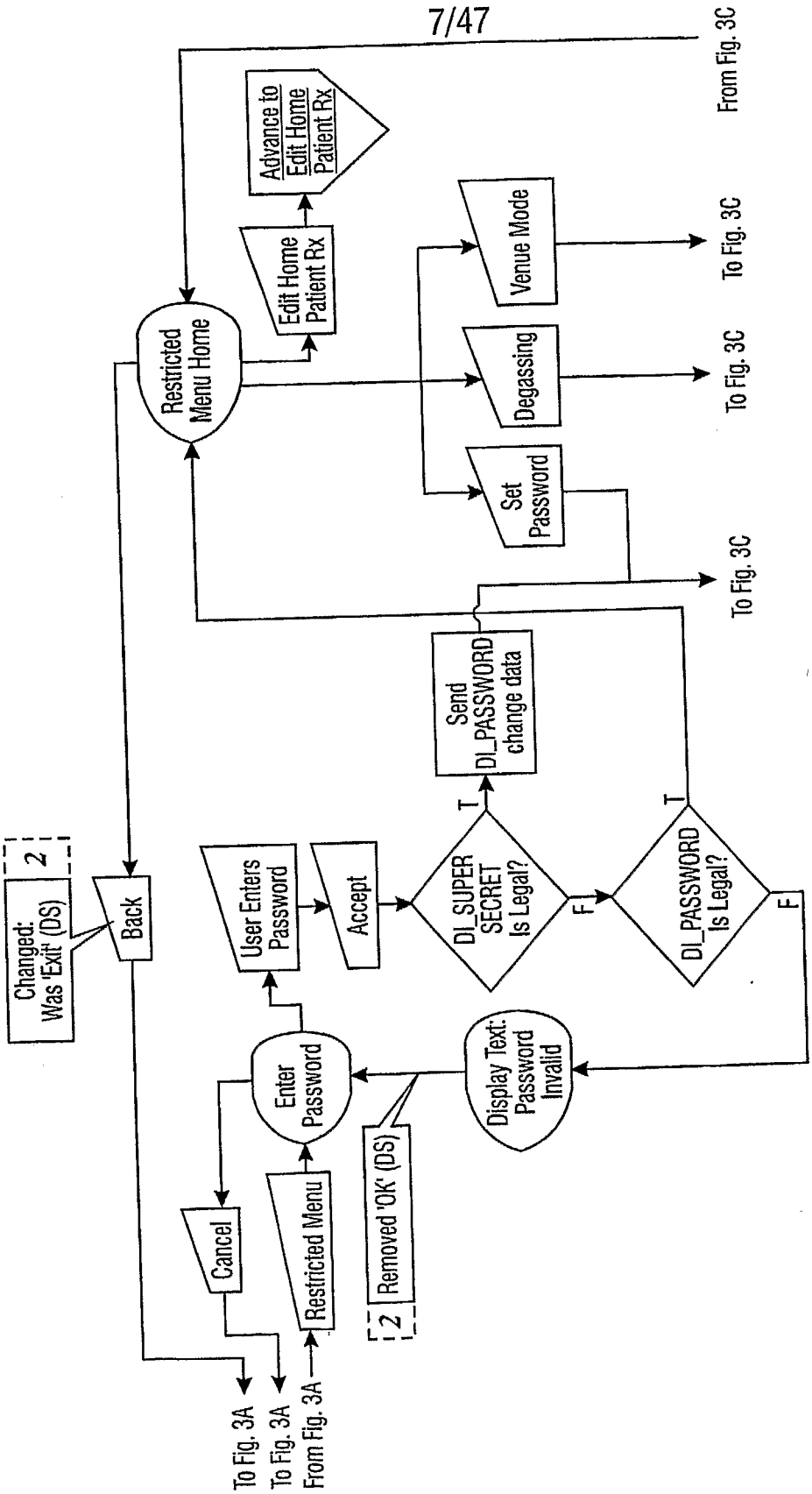

From Fig. 3C
Advance to Edit Home Patient Rx
Edit Home Patient Rx
Restricted Menu Home
Venue Mode
Degassing
Set Password
To Fig. 3C
To Fig. 3C
To Fig. 3C
Send DI_PASSWORD change data
T
DI_SUPER SECRET Is Legal?
F
T
DI_PASSWORD Is Legal?
F
User Enters Password
Accept
Changed: Was 'Exit' (DS)
2
Back
Enter Password
Display Text: Password Invalid
Cancel
Restricted Menu
2
Removed 'OK' (DS)
To Fig. 3A
To Fig. 3A
From Fig. 3A

Fig.3B

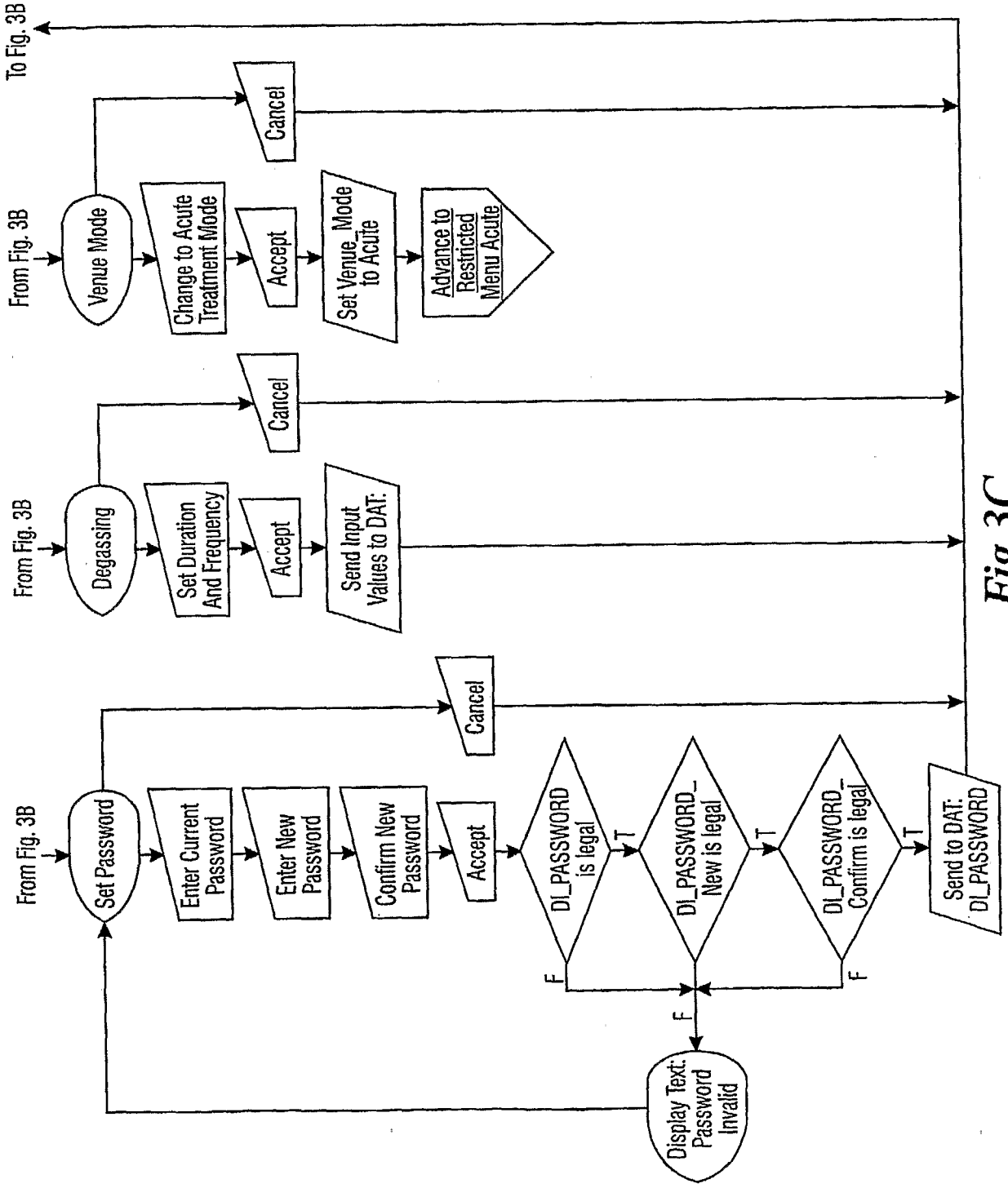

From Fig. 3B
Set Password
Enter Current Password
Enter New Password
Confirm New Password
Accept
DI_PASSWORD is legal
DI_PASSWORD_ New is legal
DI_PASSWORD_ Confirm is legal
Send to DAT: DI_PASSWORD
Cancel
Display Text: Password Invalid
T
F
From Fig. 3B
Degassing
Set Duration And Frequency
Accept
Send Input Values to DAT:
Cancel
From Fig. 3B
Venue Mode
Change to Acute Treatment Mode
Accept
Set Venue_Mode to Acute
Advance to Restricted Menu Acute
Cancel
To Fig. 3B

Fig.3C

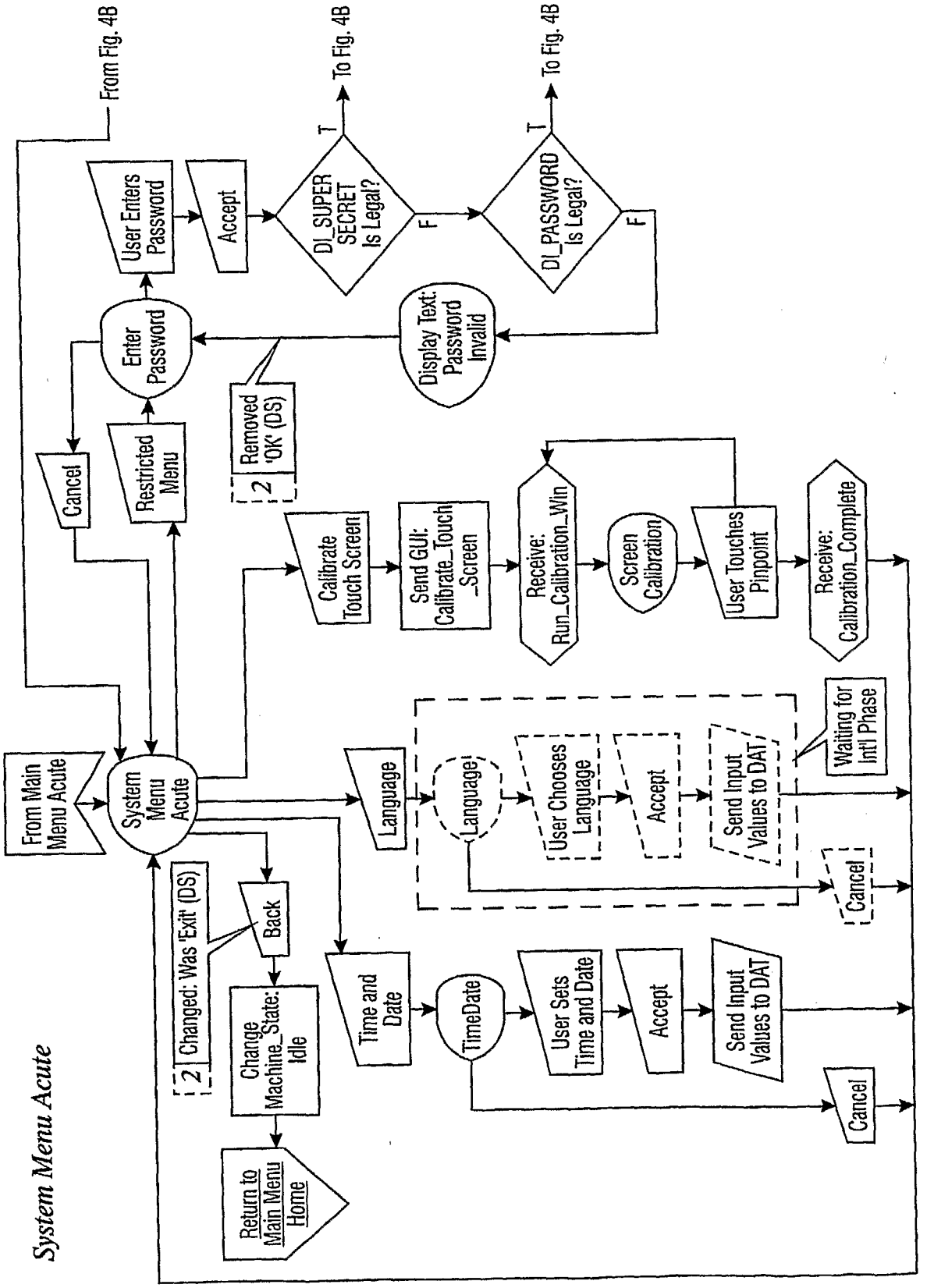

System Menu Acute
From Main Menu Acute
System Menu Acute
Return to Main Menu Home
2 Changed: Was 'Exit' (DS)
Back
Change Machine_State: Idle
Cancel
Restricted Menu
Enter Password
From Fig. 4B
User Enters Password
Accept
DI_SUPER SECRET Is Legal?
T
To Fig. 4B
F
DI_PASSWORD Is Legal?
T
To Fig. 4B
F
Display Text: Password Invalid
2 Removed 'OK' (DS)
Calibrate Touch Screen
Send GUI: Calibrate_Touch_Screen
Receive: Run_Calibration_Win
Screen Calibration
User Touches Pinpoint
Receive: Calibration_Complete
Language
Language
User Chooses Language
Accept
Send Input Values to DAT
Waiting for Int'l Phase
Cancel
Time and Date
TimeDate
User Sets Time and Date
Accept
Send Input Values to DAT
Cancel

Fig.4A

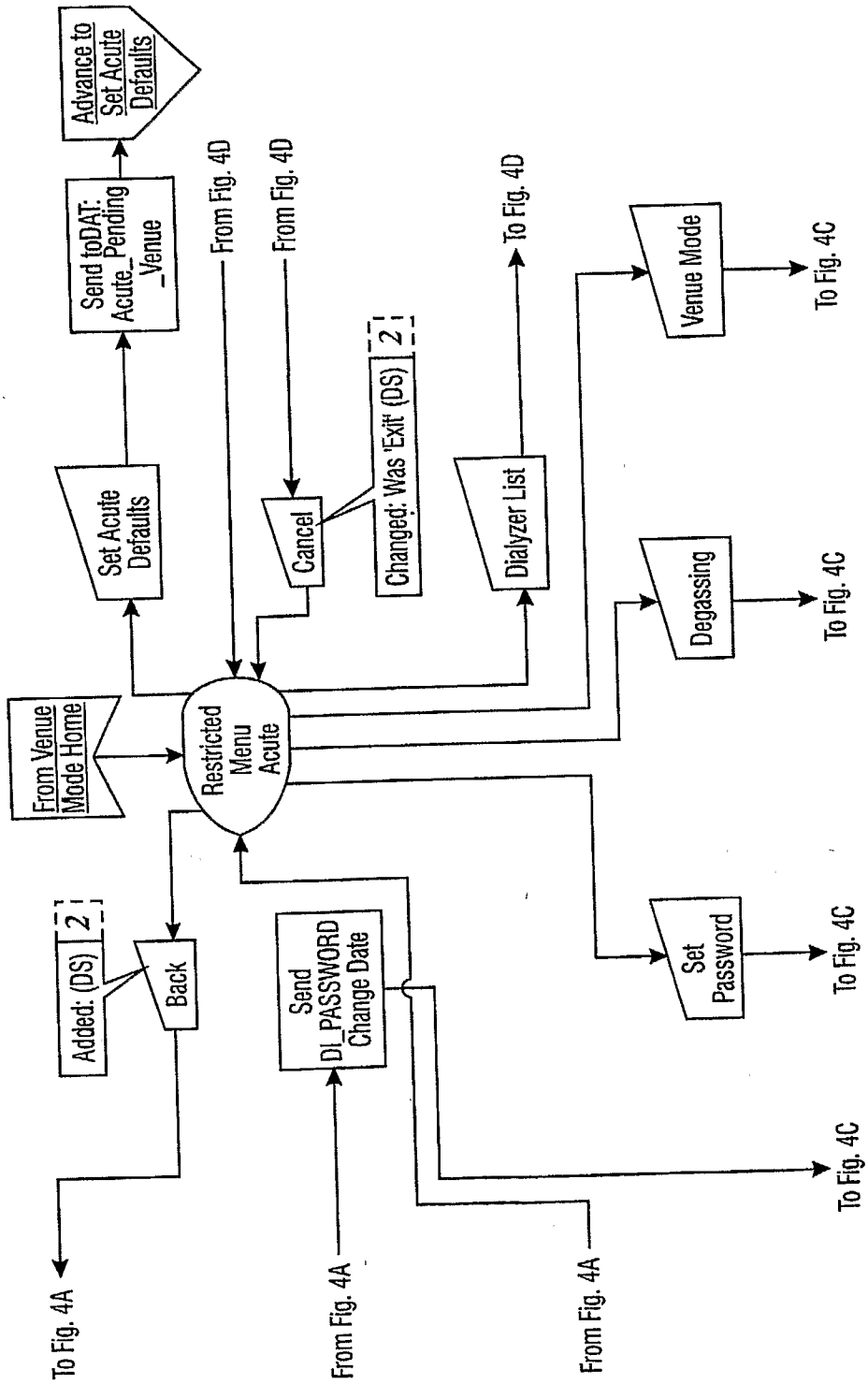

Advance to Set Acute Defaults
Send toDAT: Acute_Pending _Venue
From Fig. 4D
From Fig. 4D
To Fig. 4D
Venue Mode
To Fig. 4C
Set Acute Defaults
Cancel
Changed: Was "Exit" (DS) 2
Dialyzer List
Degassing
To Fig. 4C
From Venue Mode Home
Restricted Menu Acute
Added: (DS) 2
Back
Send DI_PASSWORD Change Date
Set Password
To Fig. 4C
To Fig. 4C
To Fig. 4A
From Fig. 4A
From Fig. 4A

Fig.4B

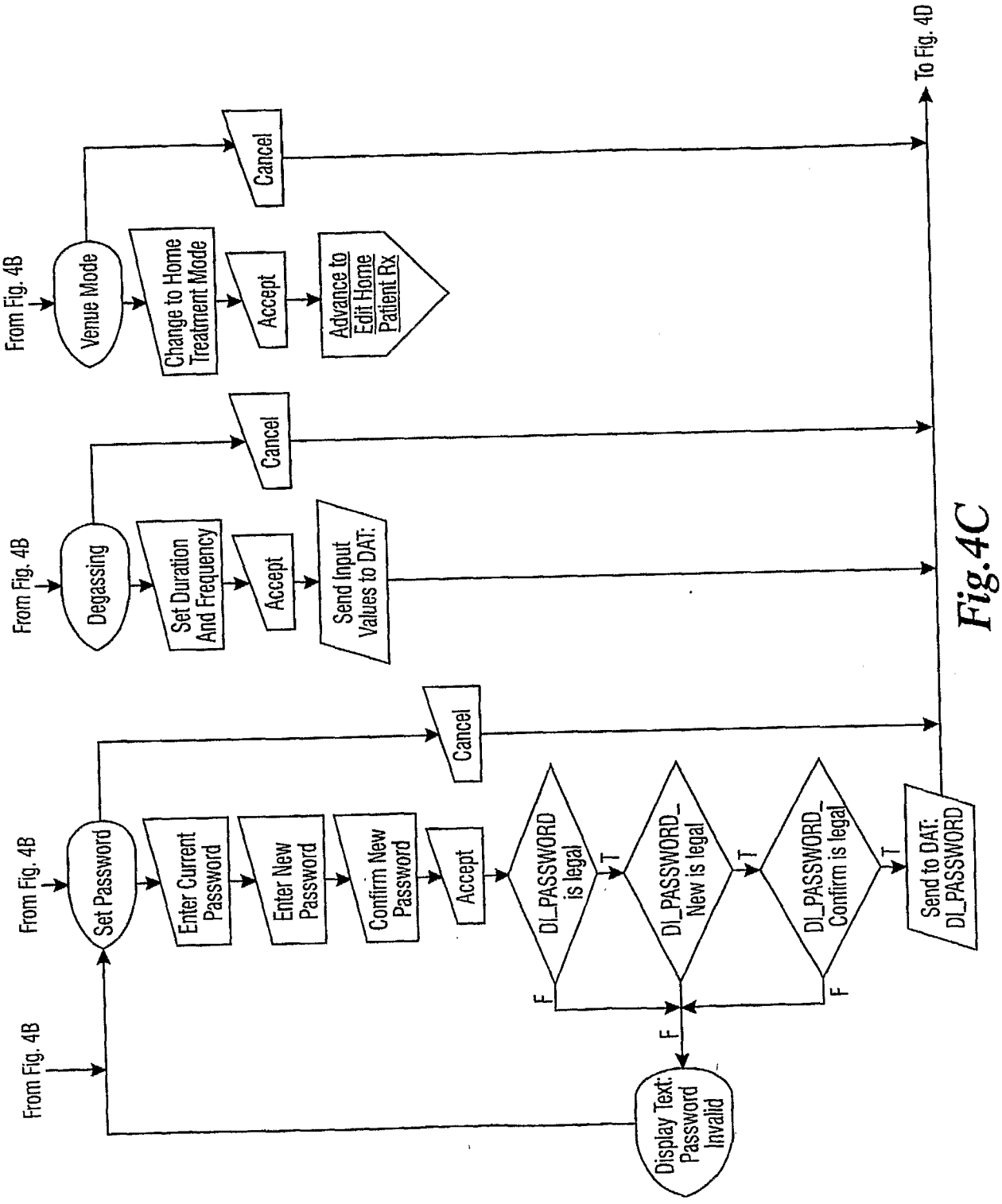

From Fig. 4B
Venue Mode
Change to Home Treatment Mode
Accept
Advance to Edit Home Patient Rx
Cancel
From Fig. 4B
Degassing
Set Duration And Frequency
Accept
Send Input Values to DAT:
Cancel
From Fig. 4B
Set Password
Enter Current Password
Enter New Password
Confirm New Password
Accept
DI_PASSWORD is legal
DI_PASSWORD_ New is legal
DI_PASSWORD_ Confirm is legal
Send to DAT: DI_PASSWORD
Cancel
From Fig. 4B
Display Text: Password Invalid
T
F
To Fig. 4D

Fig.4C

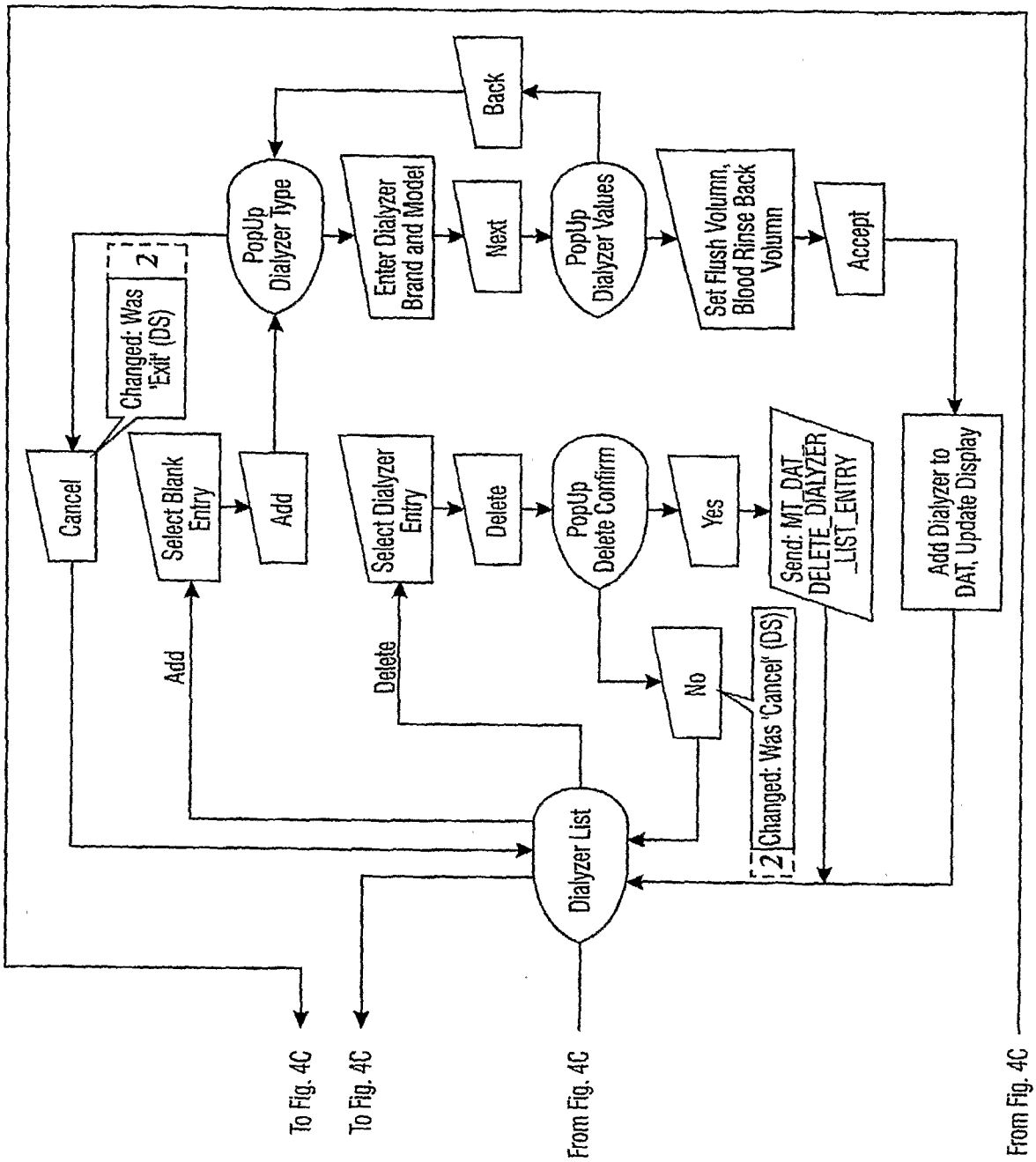

Back
PopUp Dialyzer Type
Enter Dialyzer Brand and Model
Next
PopUp Dialyzer Values
Set Flush Volumn, Blood Rinse Back Volumn
Accept
Changed: Was 'Exit' (DS)
2
Cancel
Select Blank Entry
Add
Select Dialyzer Entry
Delete
PopUp Delete Confirm
Yes
Send: MT_DAT_DELETE_DIALYZER_LIST_ENTRY
Add Dialyzer to DAT, Update Display
Add
Delete
No
Changed: Was 'Cancel' (DS)
2
Dialyzer List
To Fig. 4C
To Fig. 4C
From Fig. 4C
From Fig. 4C

Fig. 4D

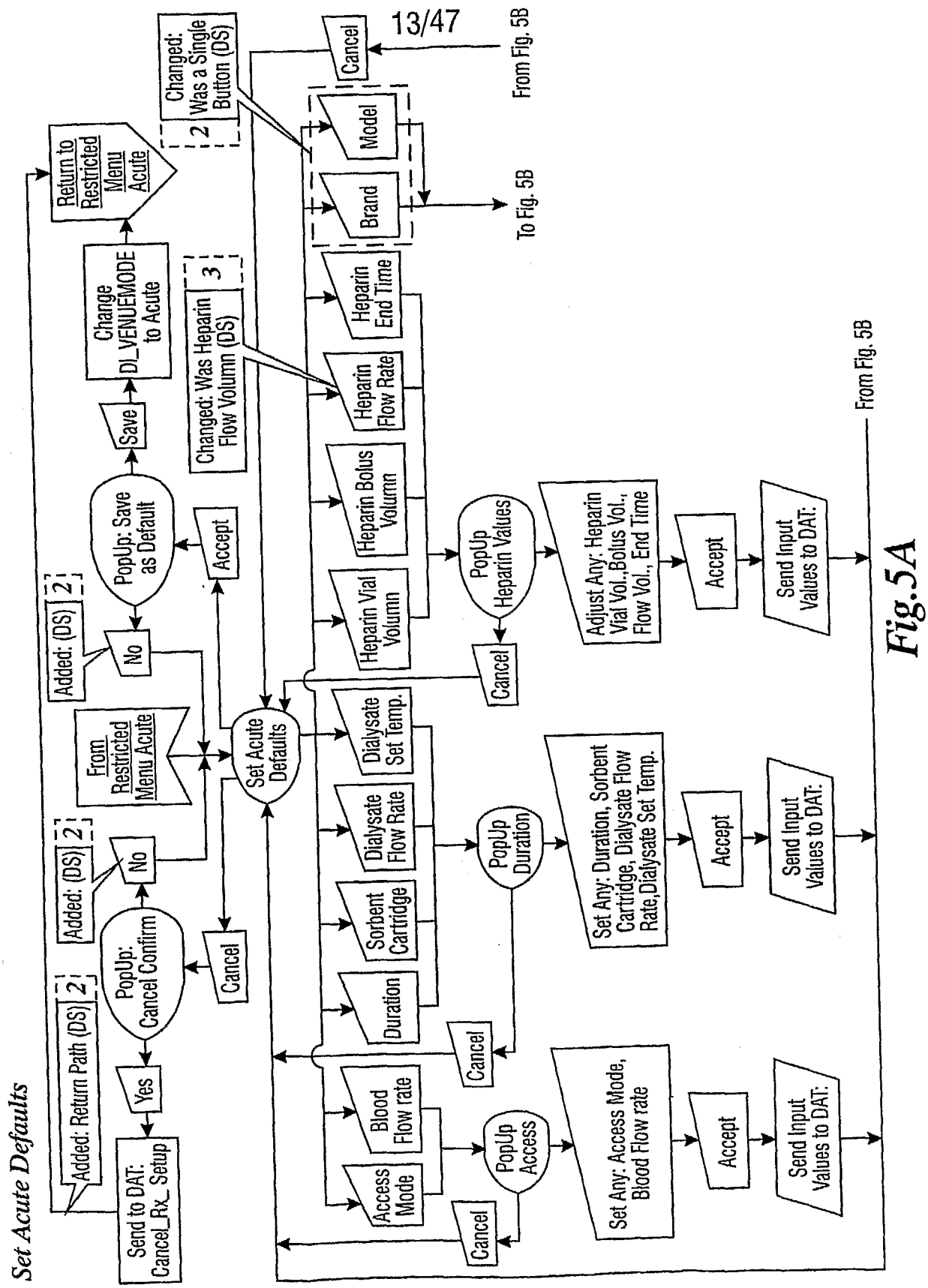

Set Acute Defaults
Added: Return Path (DS) 2
Send to DAT: Cancel_Rx_Setup
PopUp: Cancel Confirm
Yes
No
Added: (DS) 2
Cancel
From Restricted Menu Acute
Set Acute Defaults
Added: (DS) 2
PopUp: Save as Default
No
Accept
Save
Change DI_VENUEMODE to Acute
Return to Restricted Menu Acute
Changed: Was a Single Button (DS) 2
Changed: Was Heparin Flow Volumn (DS) 3
Access Mode
Blood Flow rate
Duration
Sorbent Cartridge
Dialysate Flow Rate
Dialysate Set Temp.
Heparin Vial Volumn
Heparin Bolus Volumn
Heparin Flow Rate
Heparin End Time
Brand
Model
Cancel
PopUp Access
PopUp Duration
PopUp Heparin Values
Cancel
Cancel
Cancel
Set Any: Access Mode, Blood Flow rate
Set Any: Duration, Sorbent Cartridge, Dialysate Flow Rate,Dialysate Set Temp.
Adjust Any: Heparin Vial Vol.,Bolus Vol., Flow Vol., End Time
Accept
Accept
Accept
Send Input Values to DAT:
Send Input Values to DAT:
Send Input Values to DAT:
13/47
From Fig. 5B
To Fig. 5B
From Fig. 5B

Fig.5A

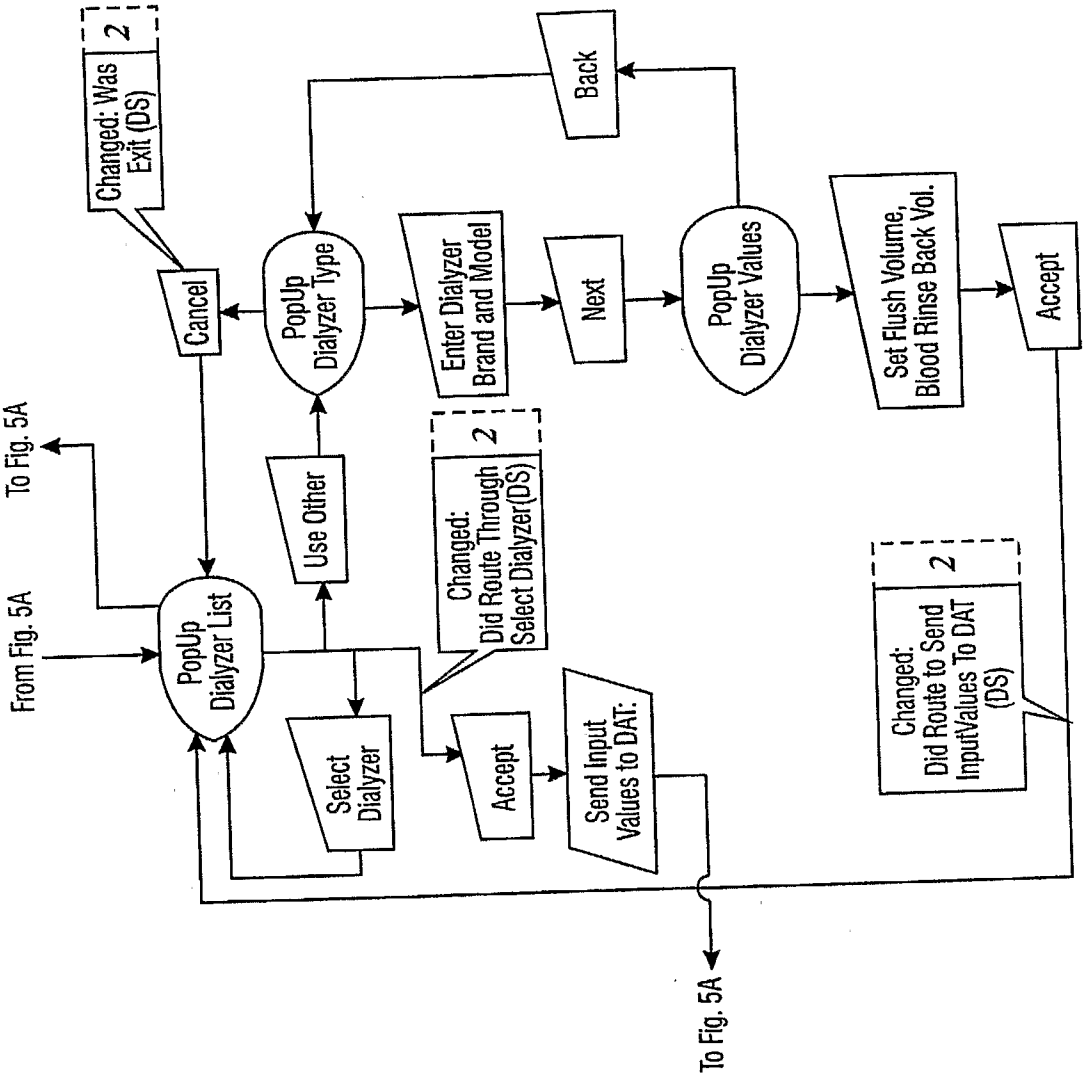

From Fig. 5A
To Fig. 5A
PopUp Dialyzer List
Use Other
Cancel
PopUp Dialyzer Type
Changed: Was Exit (DS)
2
Back
Enter Dialyzer Brand and Model
Next
PopUp Dialyzer Values
Set Flush Volume, Blood Rinse Back Vol.
Accept
Changed: Did Route Through Select Dialyzer(DS)
2
Select Dialyzer
Accept
Send Input Values to DAT:
Changed: Did Route to Send InputValues To DAT (DS)
2
To Fig. 5A

Fig.5B

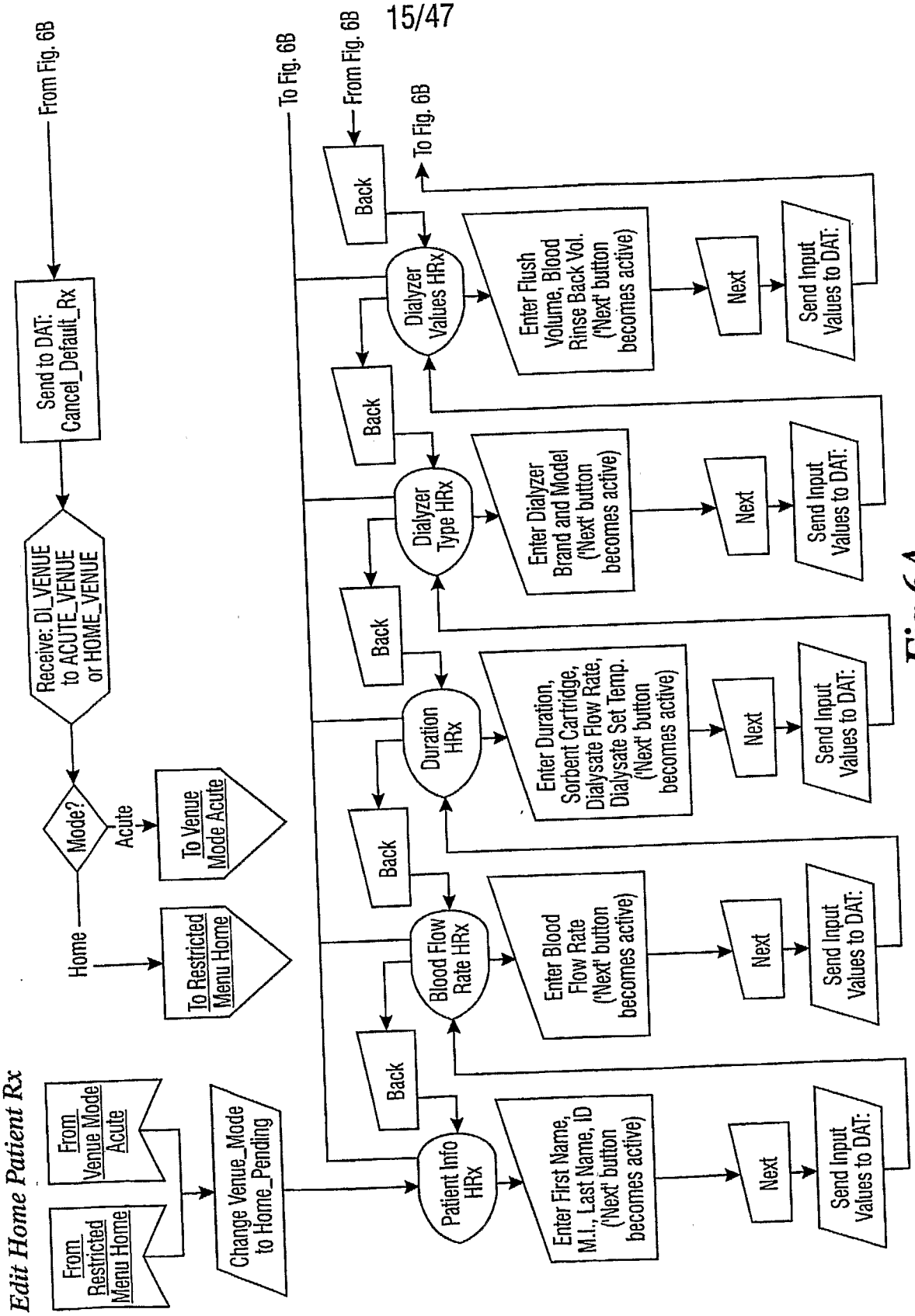

Edit Home Patient Rx
From Restricted Menu Home
From Venue Mode Acute
Change Venue_Mode to Home_Pending
Send to DAT: Cancel_Default_Rx
From Fig. 6B
Receive: DL_VENUE to ACUTE_VENUE or HOME_VENUE
Mode?
Acute
To Venue Mode Acute
Home
To Restricted Menu Home
To Fig. 6B
From Fig. 6B
To Fig. 6B
Patient Info HRx
Enter First Name, M.I., Last Name, ID ('Next' button becomes active)
Blood Flow Rate HRx
Enter Blood Flow Rate ('Next' button becomes active)
Duration HRx
Enter Duration, Sorbent Cartridge, Dialysate Flow Rate, Dialysate Set Temp. ('Next' button becomes active)
Dialyzer Type HRx
Enter Dialyzer Brand and Model ('Next' button becomes active)
Dialyzer Values HRx
Enter Flush Volume, Blood Rinse Back Vol. ('Next' button becomes active)
Back
Next
Send Input Values to DAT:

Fig. 6A

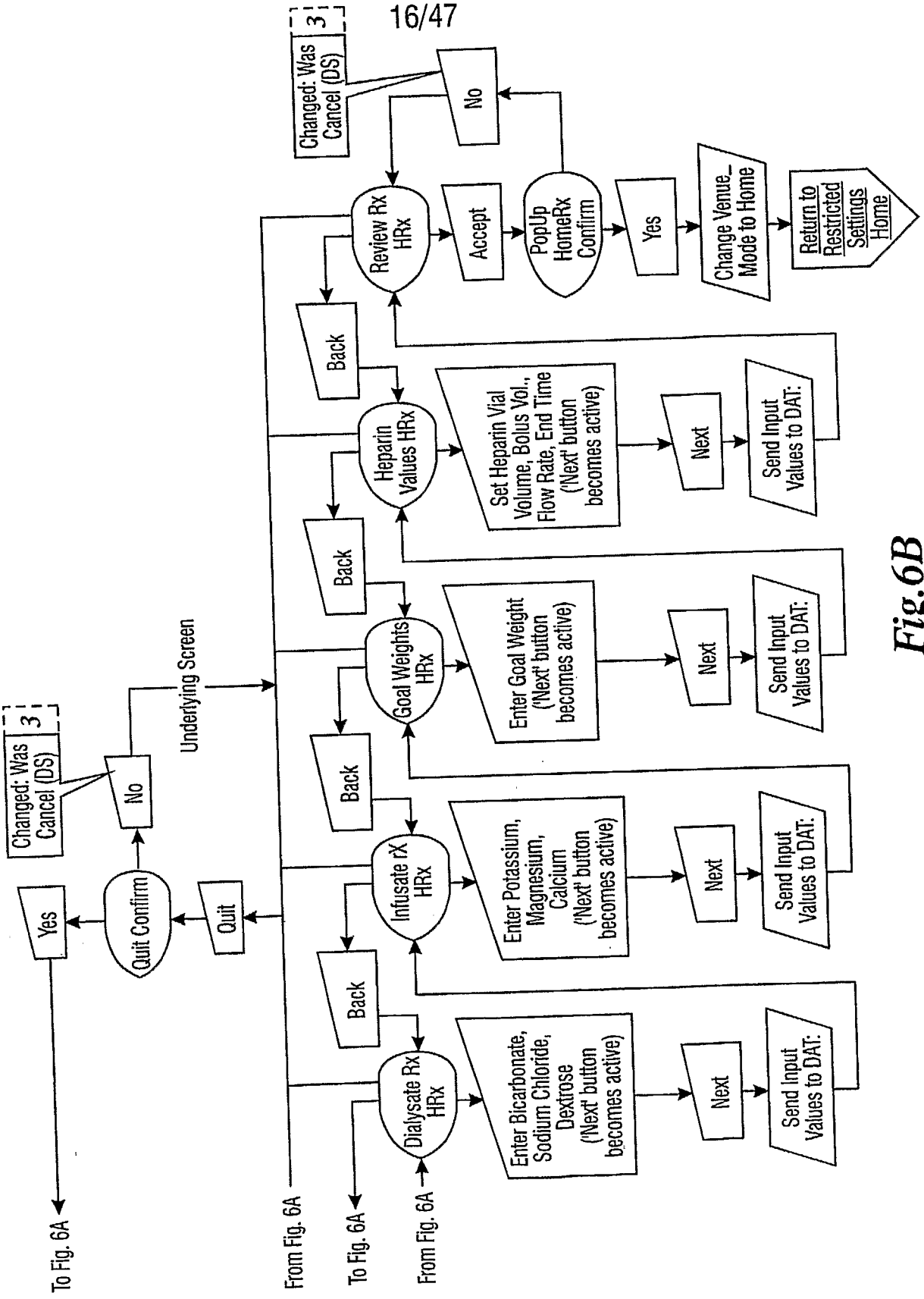

To Fig. 6A
Yes
Quit Confirm
Quit
No
Changed: Was Cancel (DS) 3
Underlying Screen
From Fig. 6A
To Fig. 6A
From Fig. 6A
Dialysate Rx HRx
Infusate rX HRx
Goal Weights HRx
Heparin Values HRx
Review Rx HRx
Back
Enter Bicarbonate, Sodium Chloride, Dextrose ('Next' button becomes active)
Enter Potassium, Magnesium, Calcium ('Next' button becomes active)
Enter Goal Weight ('Next' button becomes active)
Set Heparin Vial Volume, Bolus Vol., Flow Rate, End Time ('Next' button becomes active)
Next
Send Input Values to DAT:
Accept
PopUp HomeRx Confirm
Yes
No
Changed: Was Cancel (DS) 3
Change Venue_ Mode to Home
Return to Restricted Settings Home

Fig.6B

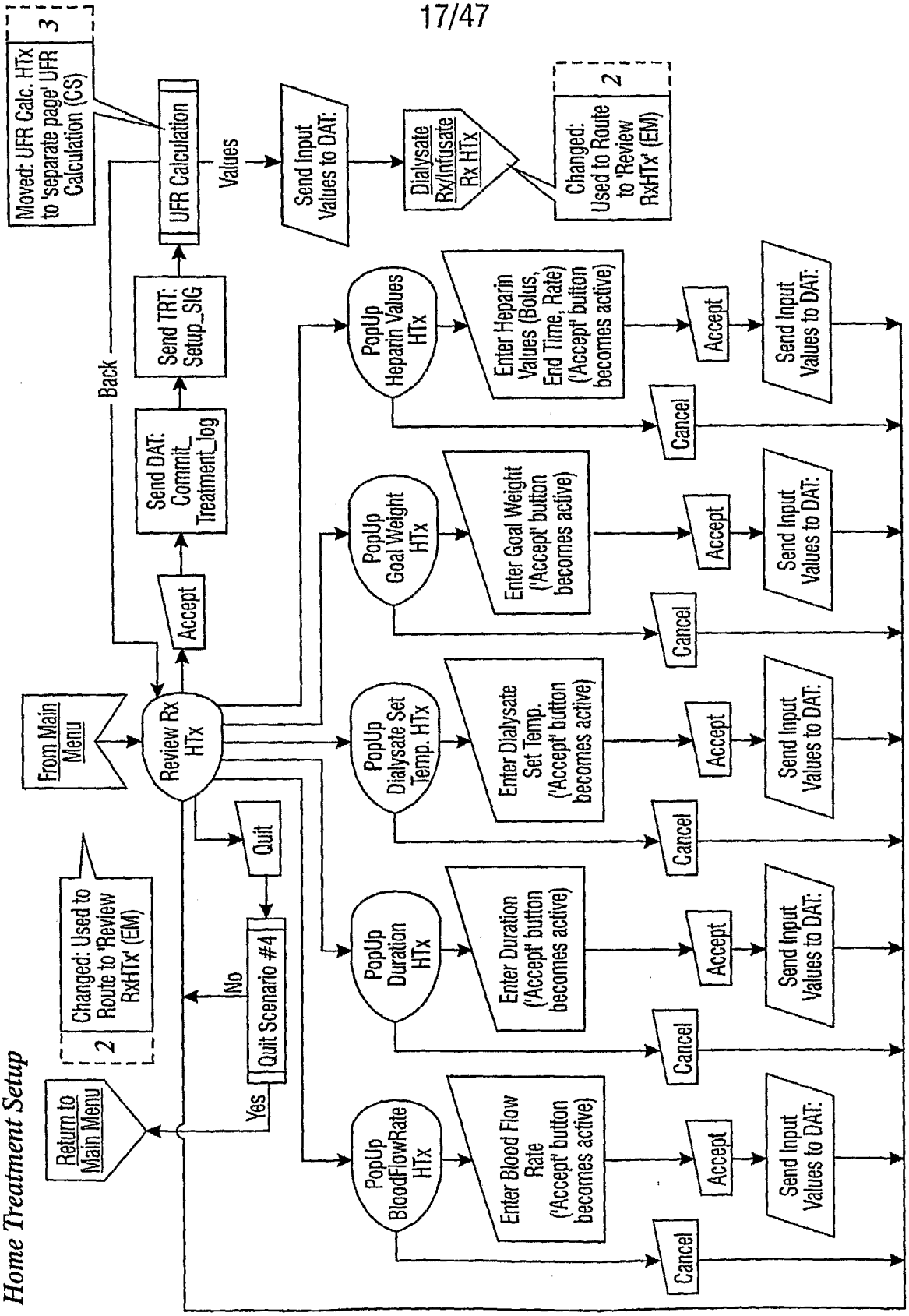

Home Treatment Setup
From Main Menu
Review Rx HTx
Return to Main Menu
Changed: Used to Route to 'Review RxHTx' (EM)
2
Quit
Quit Scenario #4
No
Yes
Back
Accept
Send DAT: Commit_ Treatment_log
Send TRT: Setup_SIG
UFR Calculation
Moved: UFR Calc. HTx to 'separate page' UFR Calculation (CS)
3
Values
Send Input Values to DAT:
Dialysate Rx/Infusate Rx HTx
Changed: Used to Route to 'Review RxHTx' (EM)
2
PopUp BloodFlowRate HTx
Enter Blood Flow Rate ('Accept' button becomes active)
PopUp Duration HTx
Enter Duration ('Accept' button becomes active)
PopUp Dialysate Set Temp. HTx
Enter Dialysate Set Temp. ('Accept' button becomes active)
PopUp Goal Weight HTx
Enter Goal Weight ('Accept' button becomes active)
PopUp Heparin Values HTx
Enter Heparin Values (Bolus, End Time, Rate) ('Accept' button becomes active)
Cancel
Accept
Send Input Values to DAT:

Fig.7

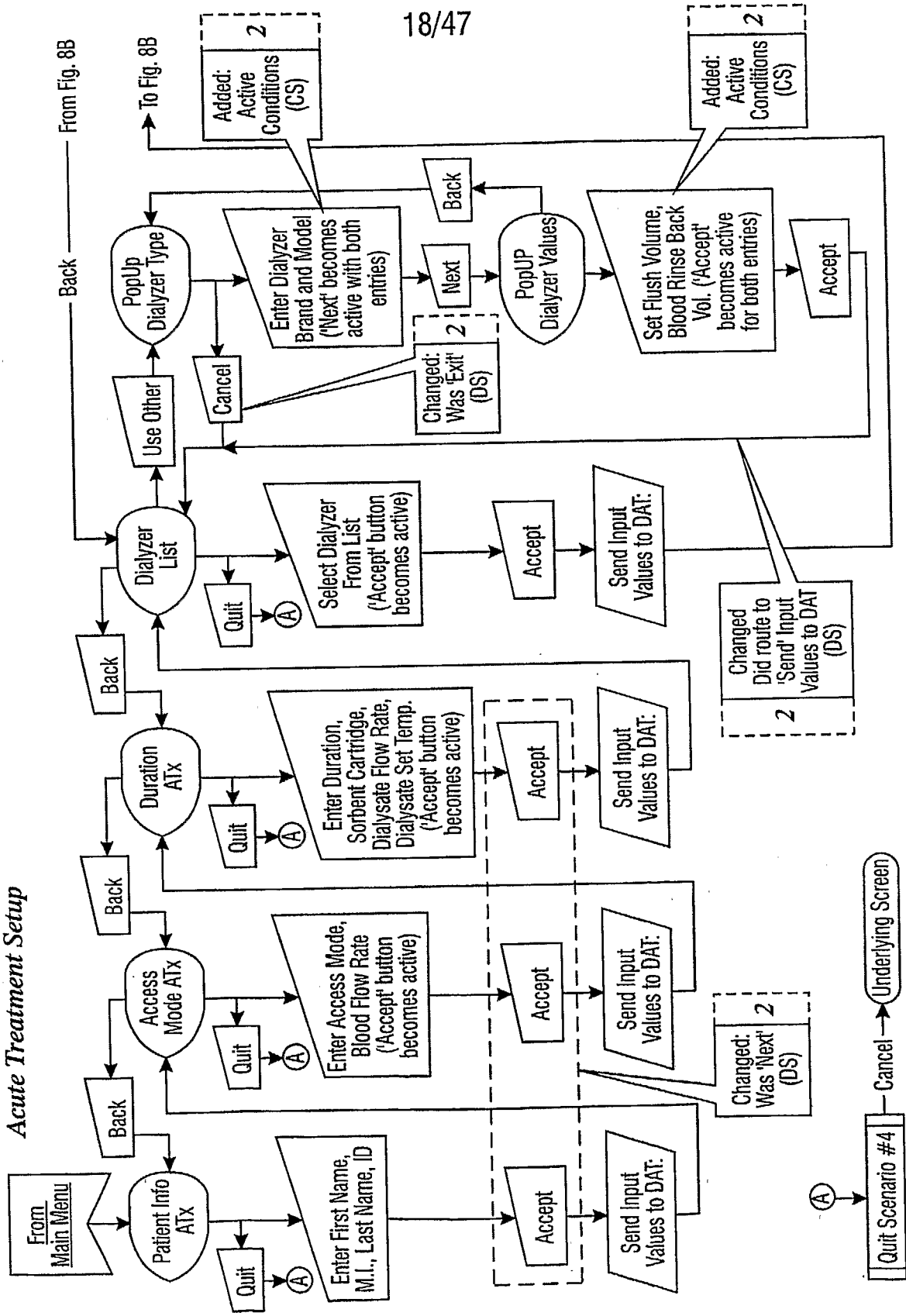

Acute Treatment Setup
From Main Menu
Patient Info ATx
Access Mode ATx
Duration ATx
Dialyzer List
PopUp Dialyzer Type
Use Other
Back
Quit
Cancel
Enter First Name, M.I., Last Name, ID
Enter Access Mode, Blood Flow Rate ('Accept' button becomes active)
Enter Duration, Sorbent Cartridge, Dialysate Flow Rate, Dialysate Set Temp. ('Accept' button becomes active)
Select Dialyzer From List ('Accept' button becomes active)
Enter Dialyzer Brand and Model ('Next' becomes active with both entries)
Next
PopUP Dialyzer Values
Set Flush Volume, Blood Rinse Back Vol. ('Accept' becomes active for both entries)
Accept
Send Input Values to DAT:
Changed: Was 'Next' (DS)
Changed: Was 'Exit' (DS)
Changed Did route to 'Send' Input Values to DAT (DS)
Added: Active Conditions (CS)
2
A
Quit Scenario #4
Underlying Screen
From Fig. 8B
To Fig. 8B

Fig. 8A

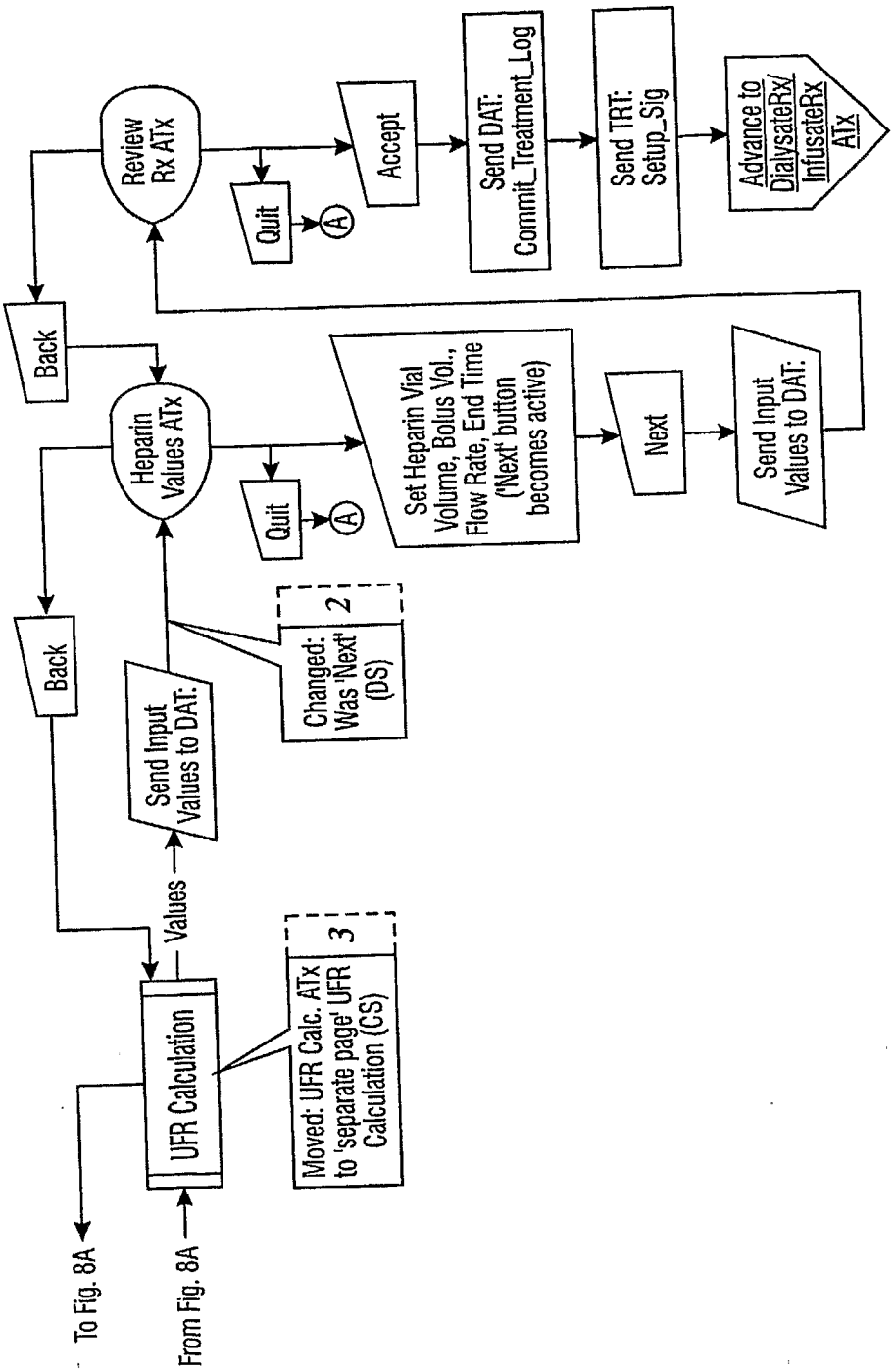

From Fig. 8A
To Fig. 8A
UFR Calculation
Values
Moved: UFR Calc. ATx to 'separate page' UFR Calculation (CS)
3
Send Input Values to DAT:
Changed: Was 'Next' (DS)
2
Back
Heparin Values ATx
Quit
A
Set Heparin Vial Volume, Bolus Vol., Flow Rate, End Time ('Next' button becomes active)
Next
Send Input Values to DAT:
Back
Review Rx ATx
Quit
A
Accept
Send DAT: Commit_Treatment_Log
Send TRT: Setup_Sig
Advance to DialysateRx/ InfusateRx ATx

Fig.8B

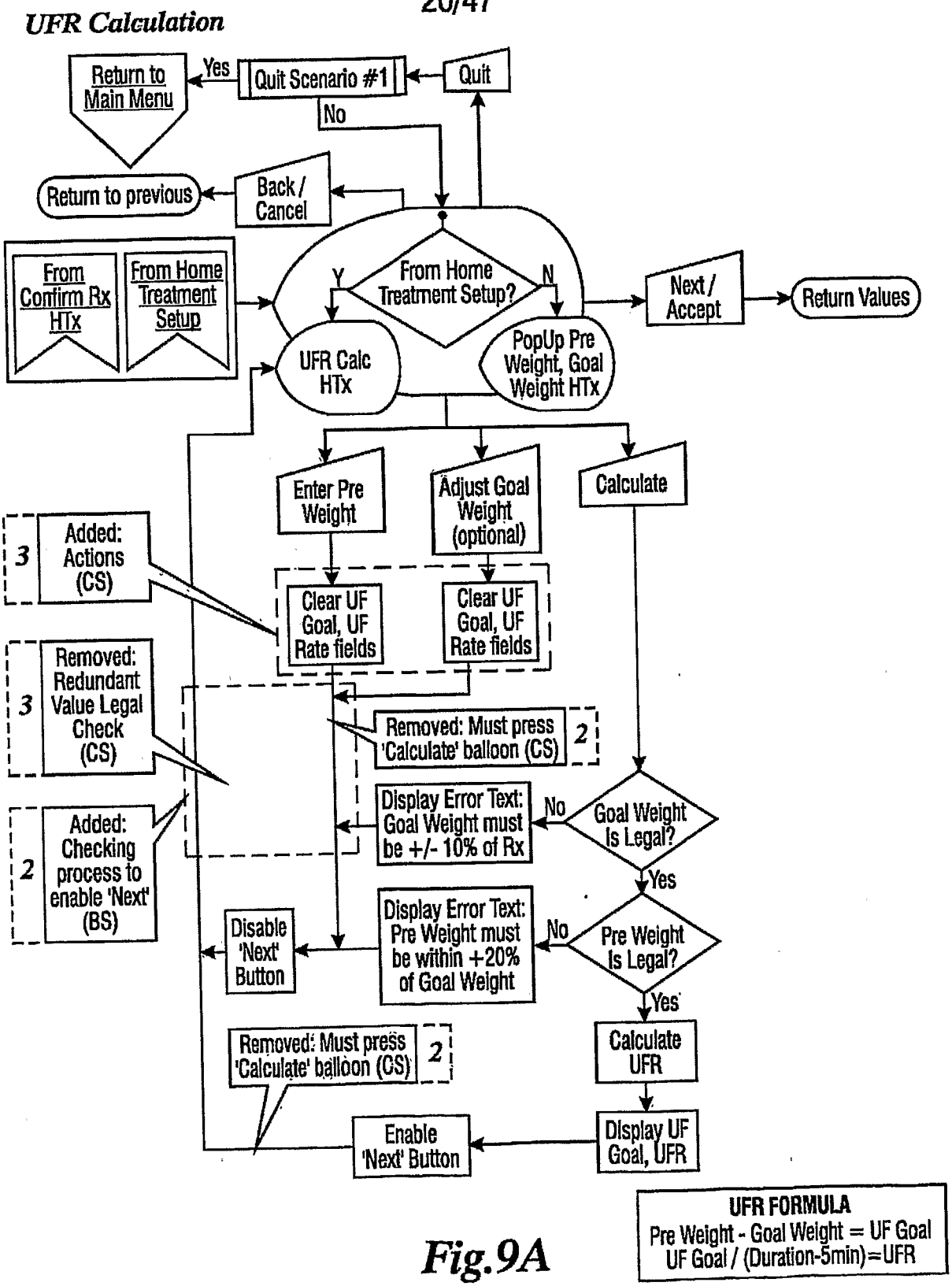

UFR Calculation
Return to Main Menu
Yes
Quit Scenario #1
Quit
No
Return to previous
Back / Cancel
From Confirm Rx HTx
From Home Treatment Setup
Y
From Home Treatment Setup?
N
Next / Accept
Return Values
UFR Calc HTx
PopUp Pre Weight, Goal Weight HTx
Enter Pre Weight
Adjust Goal Weight (optional)
Calculate
3
Added: Actions (CS)
Clear UF Goal, UF Rate fields
Clear UF Goal, UF Rate fields
3
Removed: Redundant Value Legal Check (CS)
Removed: Must press 'Calculate' balloon (CS)
2
Display Error Text: Goal Weight must be +/- 10% of Rx
No
Goal Weight Is Legal?
Yes
2
Added: Checking process to enable 'Next' (BS)
Disable 'Next' Button
Display Error Text: Pre Weight must be within +20% of Goal Weight
No
Pre Weight Is Legal?
Yes
Removed: Must press 'Calculate' balloon (CS)
2
Calculate UFR
Enable 'Next' Button
Display UF Goal, UFR
UFR FORMULA
Pre Weight - Goal Weight = UF Goal
UF Goal / (Duration-5min)=UFR

Fig.9A

UFR Calculation

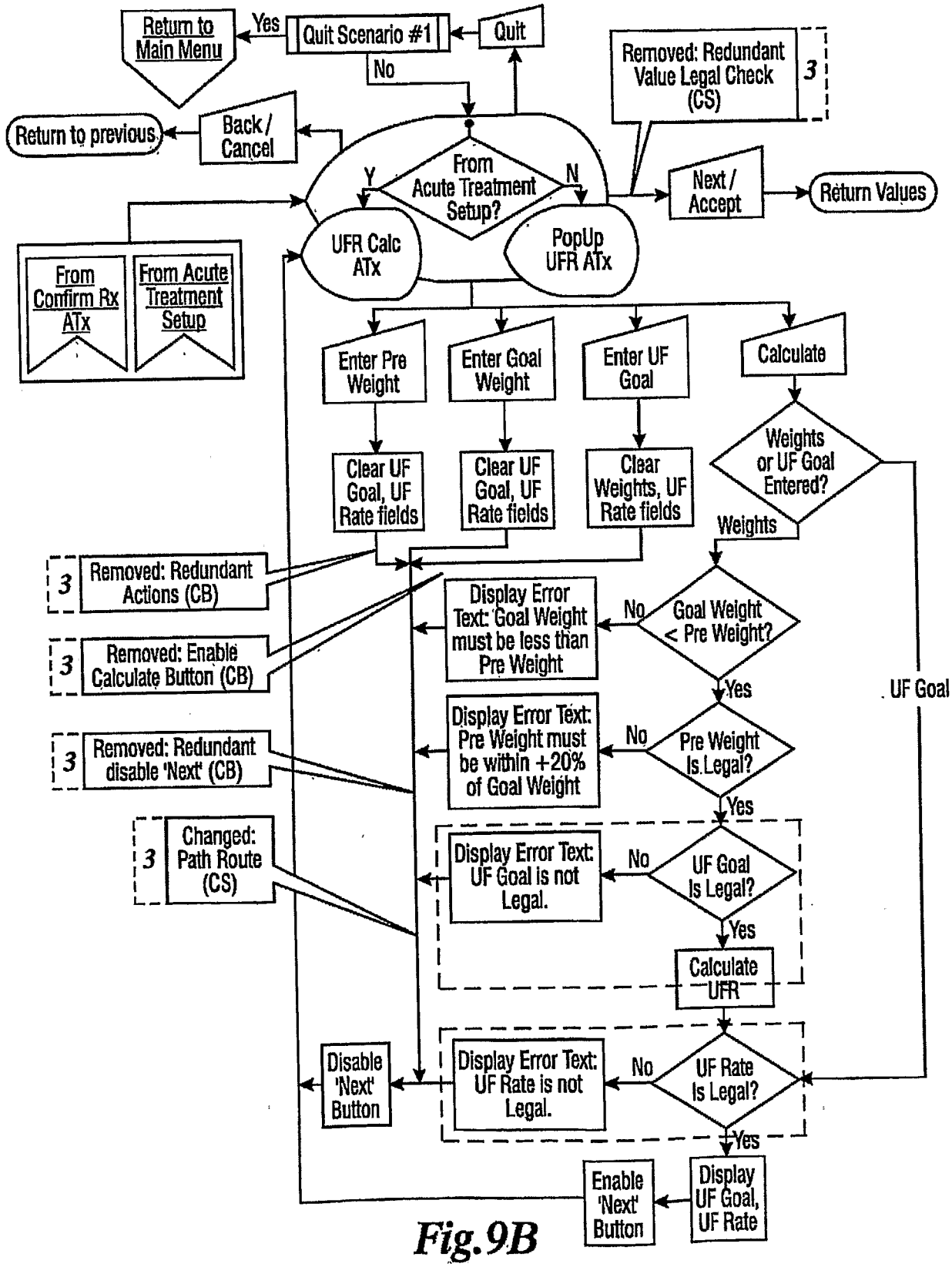


Fig.9B

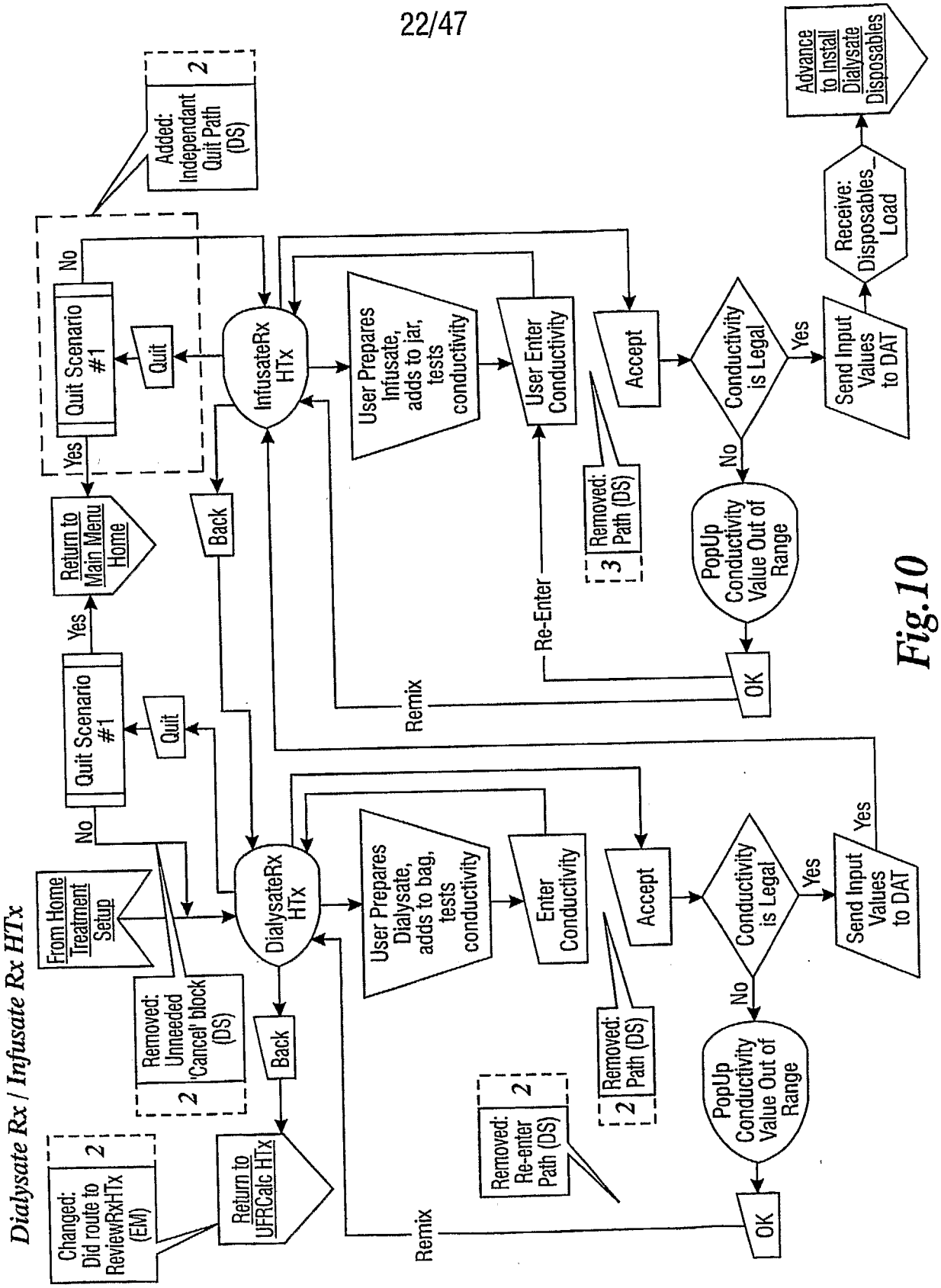

Dialysate Rx / Infusate Rx HTx
From Home Treatment Setup
DialysateRx HTx
Quit Scenario #1
Quit
No
Yes
Return to Main Menu Home
Back
Removed: Unneeded 'Cancel' block (DS)
2
Changed: Did route to ReviewRxHTx (EM)
2
Return to UFRCalc HTx
User Prepares Dialysate, adds to bag, tests conductivity
Enter Conductivity
Removed: Re-enter Path (DS)
2
Accept
Removed: Path (DS)
2
Conductivity is Legal
Yes
No
PopUp Conductivity Value Out of Range
OK
Remix
Send Input Values to DAT
Yes
Receive: Disposables_ Load
Advance to Install Dialysate Disposables
InfusateRx HTx
Quit Scenario #1
Quit
No
Yes
Return to Main Menu Home
Back
Added: Independant Quit Path (DS)
2
User Prepares Infusate, adds to jar, tests conductivity
User Enter Conductivity
Re-Enter
Removed: Path (DS)
3
Accept
Conductivity is Legal
Yes
No
PopUp Conductivity Value Out of Range
OK
Remix
Send Input Values to DAT
Yes
Receive: Disposables_ Load
Advance to Install Dialysate Disposables

Fig.10

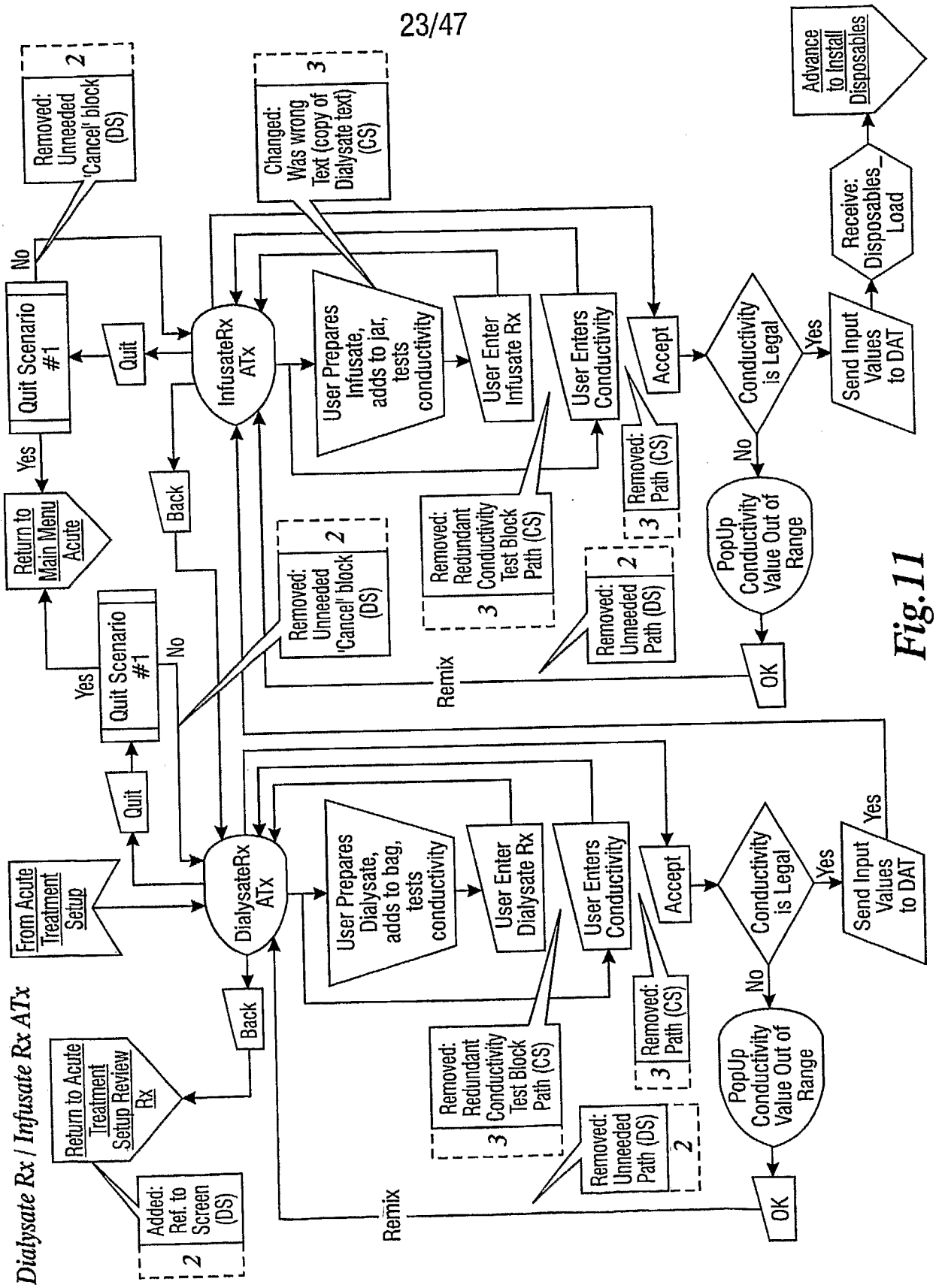

Dialysate Rx / Infusate Rx ATx
From Acute Treatment Setup
DialysateRx ATx
Quit
Quit Scenario #1
Yes
No
Return to Main Menu Acute
Back
Return to Acute Treatment Setup Review Rx
Added: Ref. to Screen (DS)
2
User Prepares Dialysate, adds to bag, tests conductivity
User Enter Dialysate Rx
User Enters Conductivity
Accept
Conductivity is Legal
Yes
No
Send Input Values to DAT
Yes
Advance to Install Disposables
Receive: Disposables_ Load
PopUp Conductivity Value Out of Range
OK
Remix
Removed: Redundant Conductivity Test Block Path (CS)
3
Removed: Unneeded Path (DS)
2
Removed: Path (CS)
3
InfusateRx ATx
User Prepares Infusate, adds to jar, tests conductivity
User Enter Infusate Rx
User Enters Conductivity
Accept
Conductivity is Legal
Yes
No
Send Input Values to DAT
Receive: Disposables_ Load
Advance to Install Disposables
PopUp Conductivity Value Out of Range
OK
Remix
Removed: Redundant Conductivity Test Block Path (CS)
3
Removed: Unneeded Path (DS)
2
Removed: Path (CS)
3
Quit
Quit Scenario #1
Yes
No
Return to Main Menu Acute
Back
Removed: Unneeded 'Cancel' block (DS)
2
Changed: Was wrong Text (copy of Dialysate text) (CS)
3
Removed: Unneeded 'Cancel' block (DS)
2

Fig.11

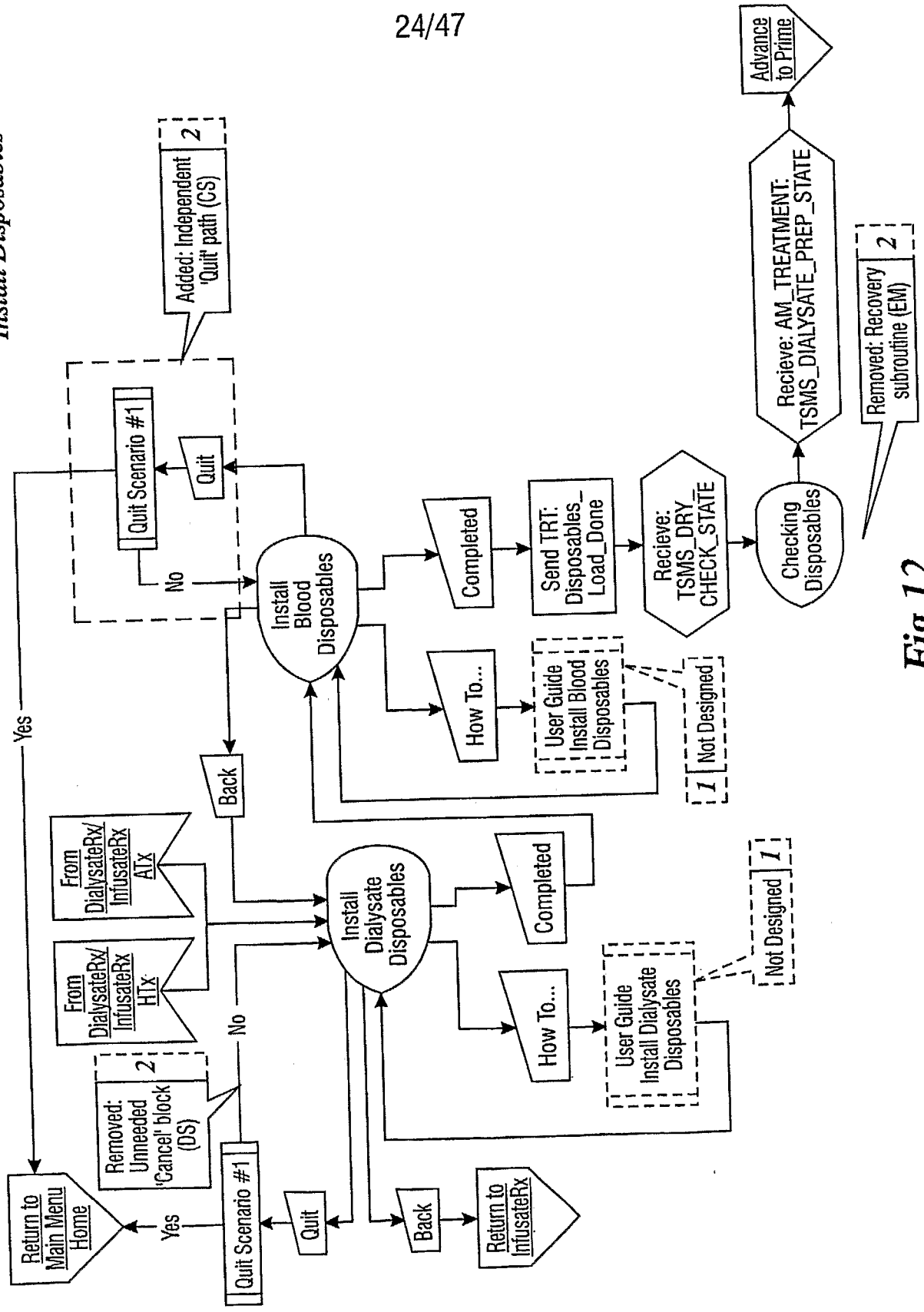

Install Disposables
Added: Independent 'Quit' path (CS) 2
Quit Scenario #1
Quit
No
Yes
Install Blood Disposables
Completed
Send TRT: Disposables_ Load_Done
Recieve: TSMS_DRY_ CHECK_STATE
Checking Disposables
Recieve: AM_TREATMENT: TSMS_DIALYSATE_PREP_STATE
Advance to Prime
Removed: Recovery subroutine (EM) 2
How To...
User Guide Install Blood Disposables
1 Not Designed
Back
From DialysateRx/ InfusateRx ATx
From DialysateRx/ InfusateRx HTx
Install Dialysate Disposables
Completed
How To...
User Guide Install Dialysate Disposables
Not Designed 1
Removed: Unneeded 'Cancel' block (DS) 2
Quit Scenario #1
Quit
Back
Return to InfusateRx
Return to Main Menu Home
Yes
No

Fig.12

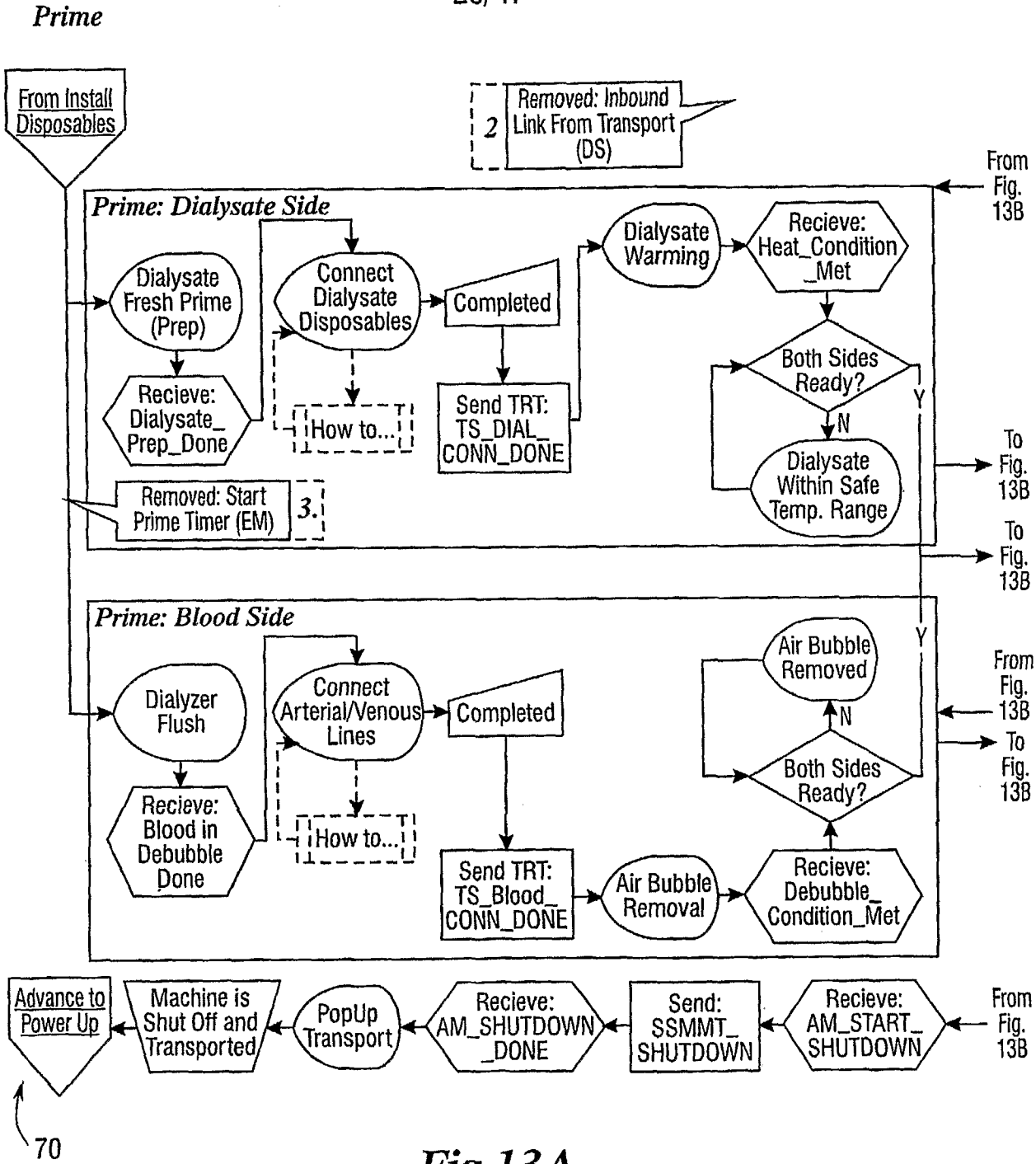

Prime
From Install Disposables
2
Removed: Inbound Link From Transport (DS)
From Fig. 13B
Prime: Dialysate Side
Dialysate Fresh Prime (Prep)
Connect Dialysate Disposables
Completed
Dialysate Warming
Recieve: Heat_Condition _Met
Recieve: Dialysate_ Prep_Done
How to...
Send TRT: TS_DIAL_ CONN_DONE
Both Sides Ready?
Y
N
Dialysate Within Safe Temp. Range
To Fig. 13B
Removed: Start Prime Timer (EM)
3.
To Fig. 13B
Prime: Blood Side
Dialyzer Flush
Connect Arterial/Venous Lines
Completed
Air Bubble Removed
Y
N
From Fig. 13B
To Fig. 13B
Recieve: Blood in Debubble Done
How to...
Both Sides Ready?
Send TRT: TS_Blood_ CONN_DONE
Air Bubble Removal
Recieve: Debubble_ Condition_Met
Advance to Power Up
Machine is Shut Off and Transported
PopUp Transport
Recieve: AM_SHUTDOWN _DONE
Send: SSMMT_ SHUTDOWN
Recieve: AM_START_ SHUTDOWN
From Fig. 13B
70

Fig.13A

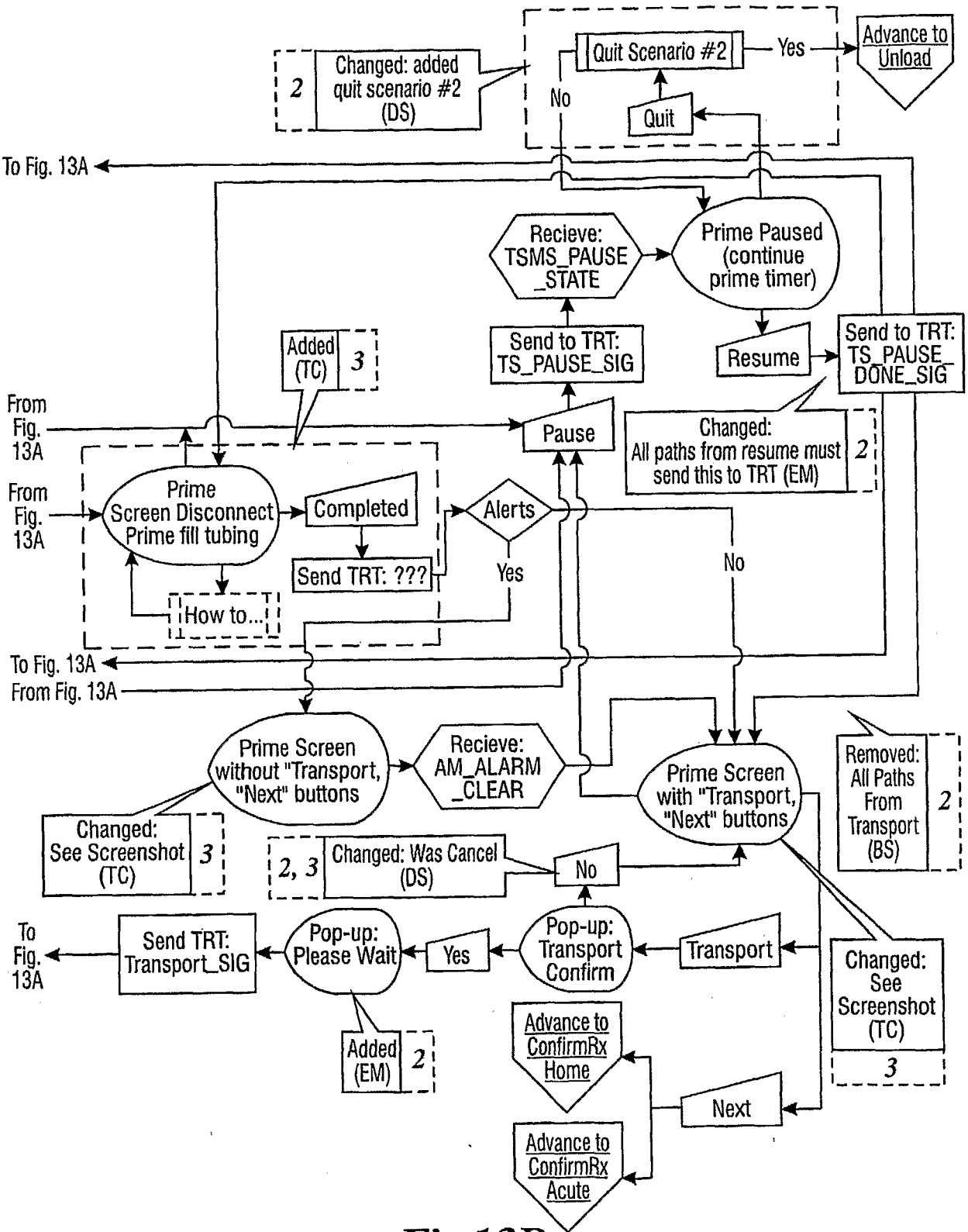

Quit Scenario #2
Yes
Advance to Unload
No
Quit
2
Changed: added quit scenario #2 (DS)
To Fig. 13A
Recieve: TSMS_PAUSE _STATE
Prime Paused (continue prime timer)
Send to TRT: TS_PAUSE_SIG
Resume
Send to TRT: TS_PAUSE_ DONE_SIG
Added (TC) 3
From Fig. 13A
Pause
Changed: All paths from resume must send this to TRT (EM) 2
From Fig. 13A
Prime Screen Disconnect Prime fill tubing
Completed
Alerts
Send TRT: ???
Yes
No
How to...
To Fig. 13A
From Fig. 13A
Prime Screen without "Transport, "Next" buttons
Recieve: AM_ALARM _CLEAR
Prime Screen with "Transport, "Next" buttons
Removed: All Paths From Transport (BS) 2
Changed: See Screenshot (TC) 3
2, 3
Changed: Was Cancel (DS)
No
To Fig. 13A
Send TRT: Transport_SIG
Pop-up: Please Wait
Yes
Pop-up: Transport Confirm
Transport
Changed: See Screenshot (TC) 3
Added (EM) 2
Advance to ConfirmRx Home
Next
Advance to ConfirmRx Acute

Fig.13B

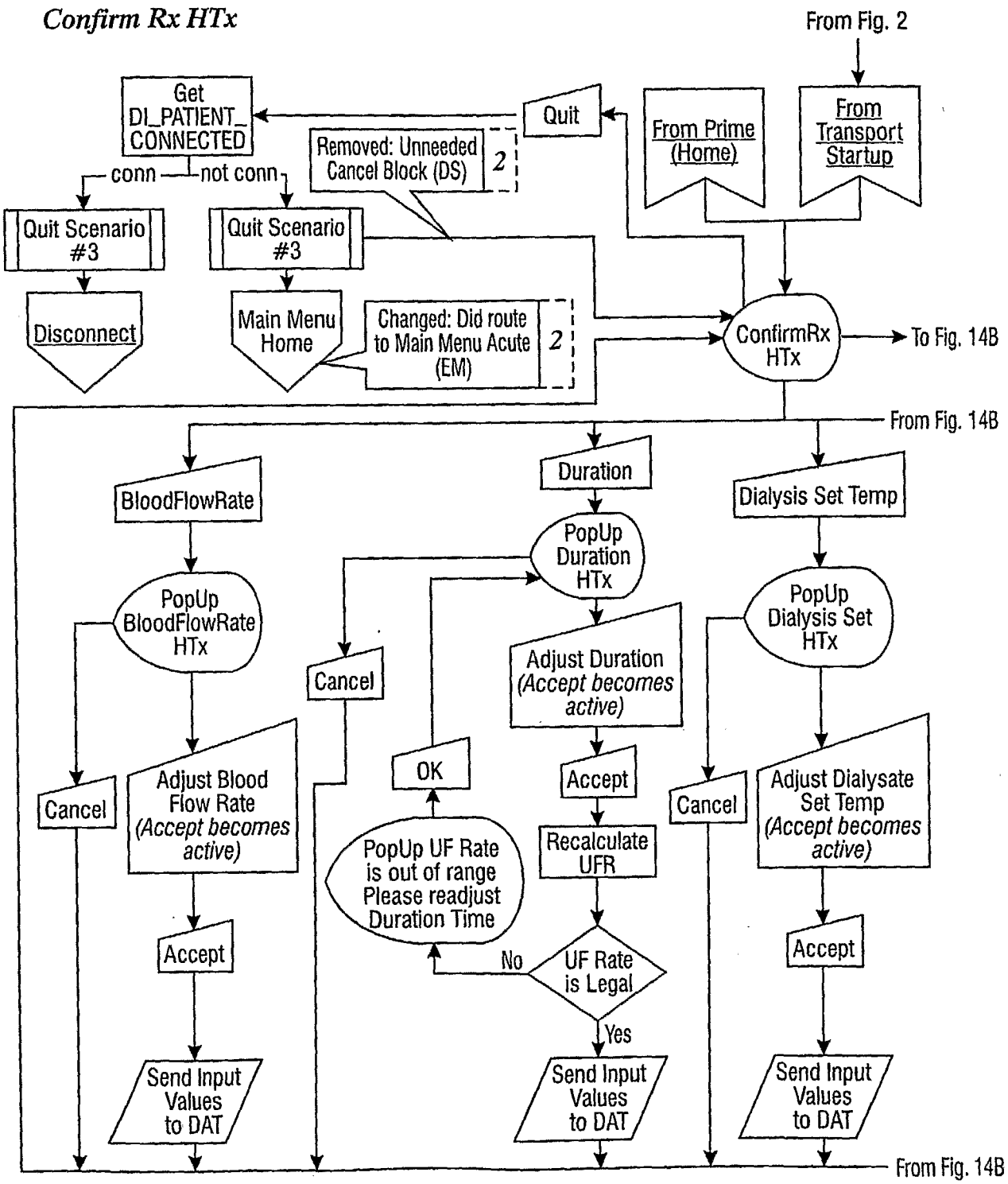

Confirm Rx HTx
From Fig. 2
Get DI_PATIENT_ CONNECTED
Quit
From Prime (Home)
From Transport Startup
Removed: Unneeded Cancel Block (DS)
2
conn
not conn
Quit Scenario #3
Quit Scenario #3
Disconnect
Main Menu Home
Changed: Did route to Main Menu Acute (EM)
2
ConfirmRx HTx
To Fig. 14B
From Fig. 14B
BloodFlowRate
Duration
Dialysis Set Temp
PopUp Duration HTx
PopUp BloodFlowRate HTx
PopUp Dialysis Set HTx
Cancel
Adjust Duration (Accept becomes active)
Cancel
Adjust Blood Flow Rate (Accept becomes active)
OK
Accept
Cancel
Adjust Dialysate Set Temp (Accept becomes active)
PopUp UF Rate is out of range Please readjust Duration Time
Recalculate UFR
Accept
No
UF Rate is Legal
Yes
Send Input Values to DAT
Send Input Values to DAT
Send Input Values to DAT
From Fig. 14B

Fig.14A

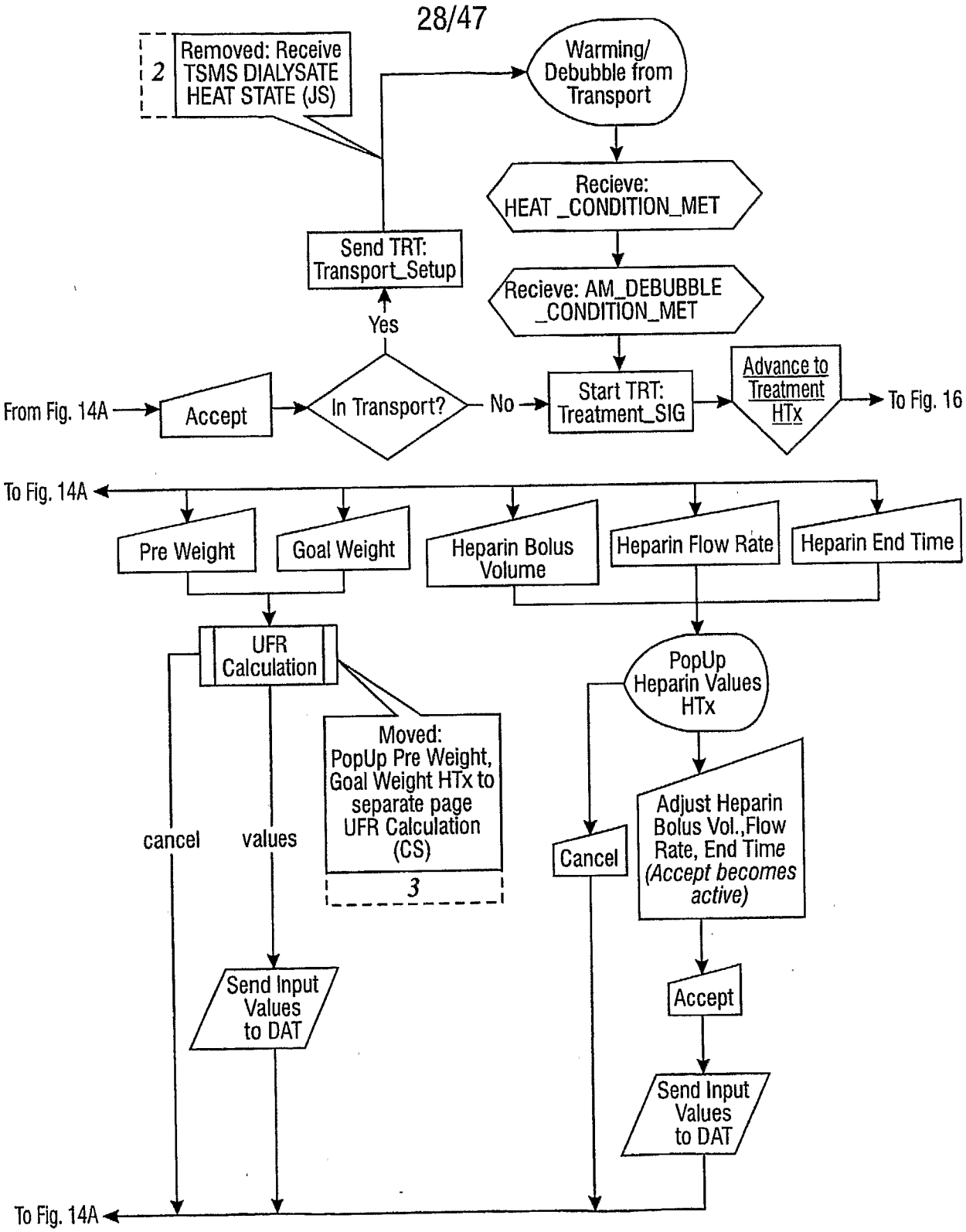

2
Removed: Receive TSMS DIALYSATE HEAT STATE (JS)
Warming/ Debubble from Transport
Recieve: HEAT _CONDITION_MET
Send TRT: Transport_Setup
Recieve: AM_DEBUBBLE _CONDITION_MET
Yes
From Fig. 14A
Accept
In Transport?
No
Start TRT: Treatment_SIG
Advance to Treatment HTx
To Fig. 16
To Fig. 14A
Pre Weight
Goal Weight
Heparin Bolus Volume
Heparin Flow Rate
Heparin End Time
UFR Calculation
PopUp Heparin Values HTx
Moved: PopUp Pre Weight, Goal Weight HTx to separate page UFR Calculation (CS)
3
cancel
values
Cancel
Adjust Heparin Bolus Vol.,Flow Rate, End Time (Accept becomes active)
Send Input Values to DAT
Accept
Send Input Values to DAT
To Fig. 14A

Fig.14B

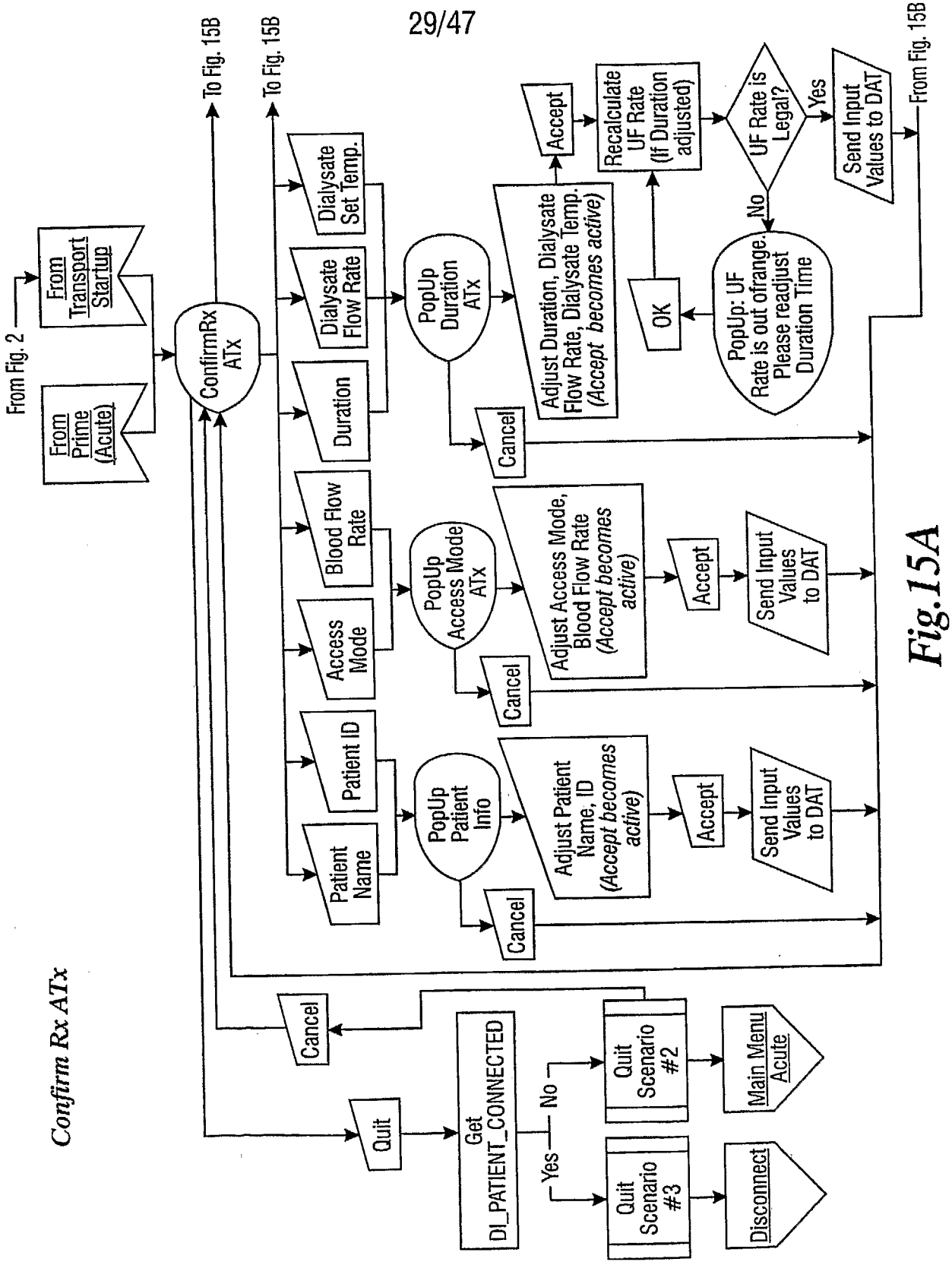

Confirm Rx ATx
From Fig. 2
From Transport Startup
From Prime (Acute)
ConfirmRx ATx
To Fig. 15B
To Fig. 15B
Dialysate Set Temp.
Dialysate Flow Rate
Duration
Blood Flow Rate
Access Mode
Patient ID
Patient Name
PopUp Duration ATx
PopUp Access Mode ATx
PopUp Patient Info
Cancel
Adjust Duration, Dialysate Flow Rate, Dialysate Temp. (Accept becomes active)
Adjust Access Mode, Blood Flow Rate (Accept becomes active)
Adjust Patient Name, ID (Accept becomes active)
Accept
Send Input Values to DAT
OK
Recalculate UF Rate (If Duration adjusted)
UF Rate is Legal?
No
Yes
PopUp: UF Rate is out ofrange. Please readjust Duration Time
Send Input Values to DAT
From Fig. 15B
Cancel
Quit
Get DI_PATIENT_CONNECTED
Yes
No
Quit Scenario #3
Quit Scenario #2
Disconnect
Main Menu Acute

Fig.15A

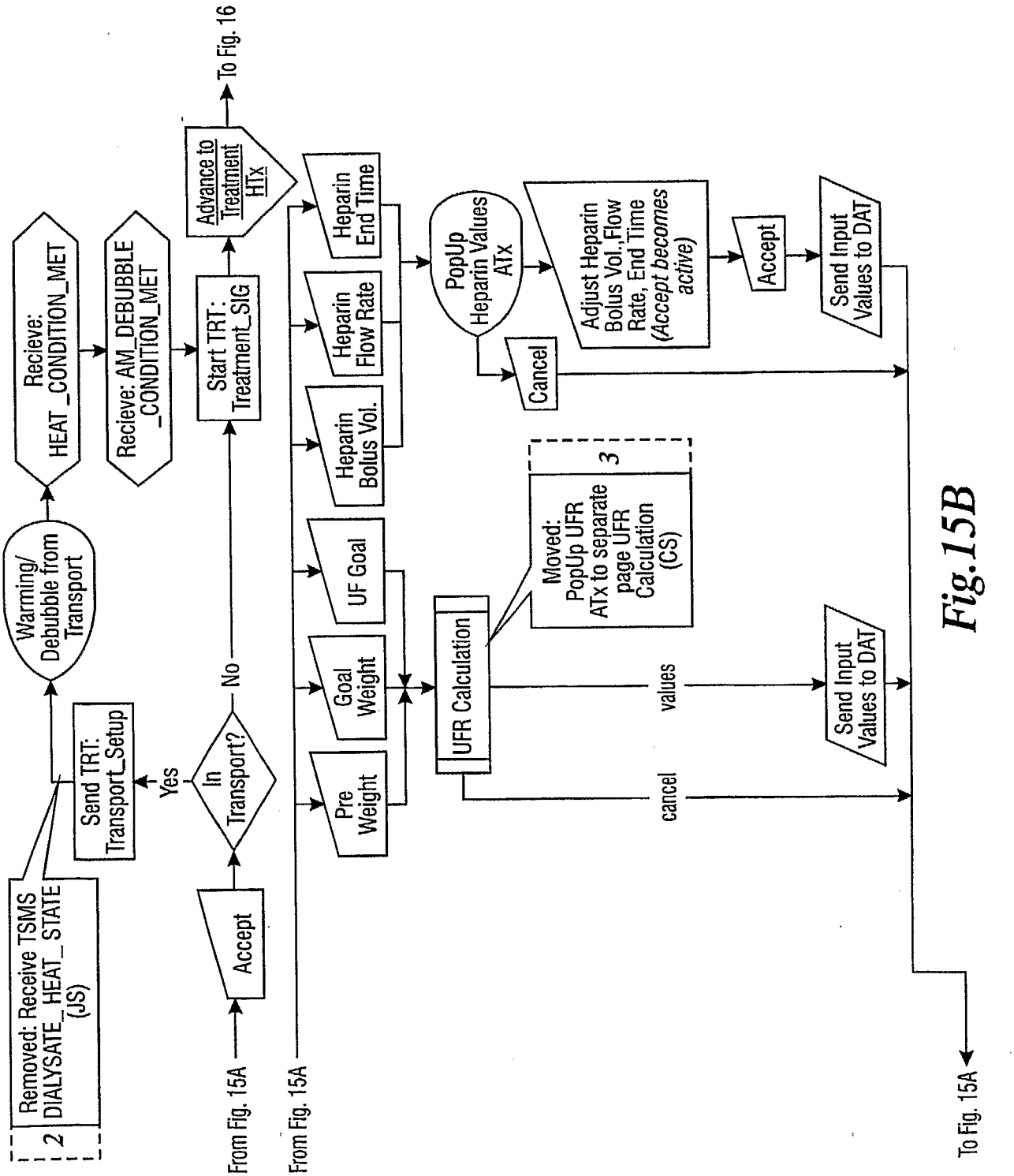

Removed: Receive TSMS DIALYSATE_HEAT_STATE (JS)
2
Warming/ Debubble from Transport
Recieve: HEAT _CONDITION_MET
Recieve: AM_DEBUBBLE _CONDITION_MET
Start TRT: Treatment_SIG
Advance to Treatment HTx
To Fig. 16
Send TRT: Transport_Setup
Yes
In Transport?
No
Accept
From Fig. 15A
From Fig. 15A
Pre Weight
Goal Weight
UF Goal
Heparin Bolus Vol.
Heparin Flow Rate
Heparin End Time
UFR Calculation
Moved: PopUp UFR ATx to separate page UFR Calculation (CS)
3
values
cancel
PopUp Heparin Values ATx
Cancel
Adjust Heparin Bolus Vol.,Flow Rate, End Time (Accept becomes active)
Accept
Send Input Values to DAT
Send Input Values to DAT
To Fig. 15A

Fig.15B

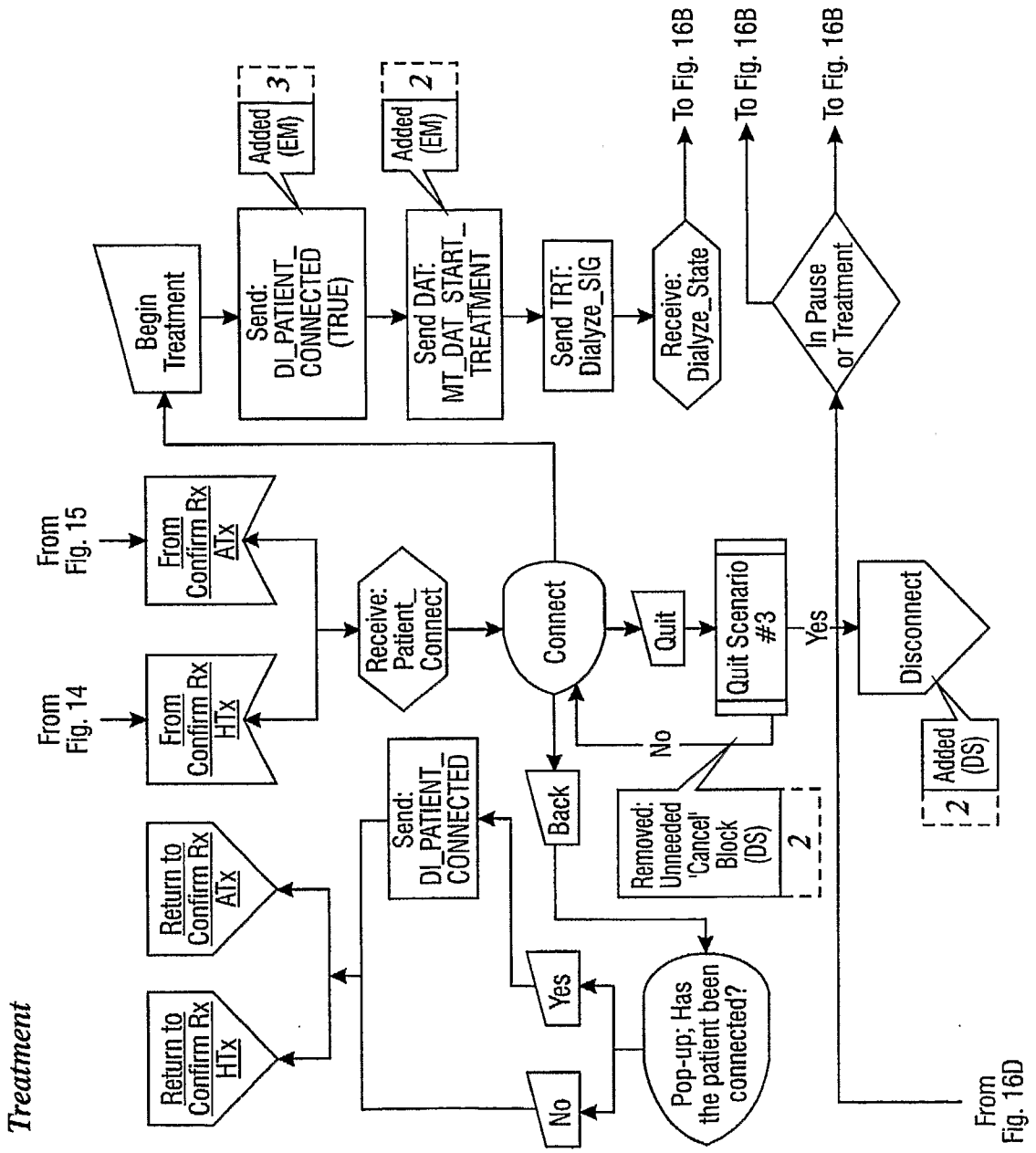

Treatment
From Fig. 15
From Fig. 14
From Confirm Rx ATx
From Confirm Rx HTx
Return to Confirm Rx ATx
Return to Confirm Rx HTx
Receive: Patient_ Connect
Connect
Quit
Quit Scenario #3
Yes
No
Back
Send: DI_PATIENT_ CONNECTED
Removed: Unneeded 'Cancel' Block (DS)
2
Pop-up; Has the patient been connected?
Yes
No
Begin Treatment
Send: DI_PATIENT_ CONNECTED (TRUE)
Added (EM) 3
Send DAT: MT_DAT_START_ TREATMENT
Added (EM) 2
Send TRT: Dialyze_SIG
Receive: Dialyze_State
To Fig. 16B
To Fig. 16B
In Pause or Treatment
To Fig. 16B
Disconnect
2 Added (DS)
From Fig. 16D

Fig. 16A

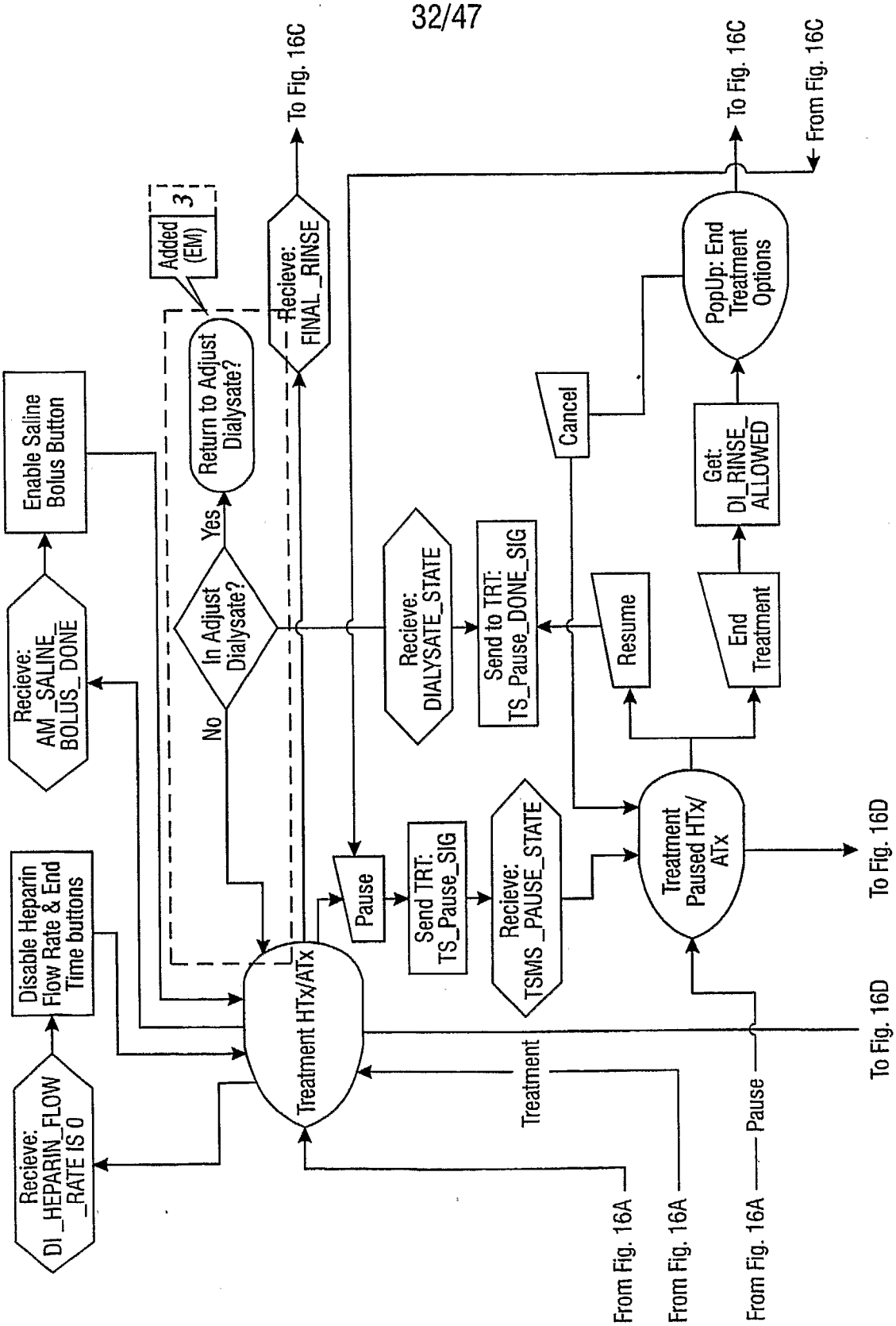

Recieve: DI _HEPARIN_FLOW _RATE IS 0
Disable Heparin Flow Rate & End Time buttons
Recieve: AM_SALINE_ BOLUS_ DONE
Enable Saline Bolus Button
Treatment HTx/ATx
In Adjust Dialysate?
Yes
No
Return to Adjust Dialysate?
Added (EM) 3
Recieve: FINAL_RINSE
To Fig. 16C
Pause
Send TRT: TS_Pause_SIG
Recieve: TSMS _PAUSE_STATE
Recieve: DIALYSATE_STATE
Send to TRT: TS_Pause_DONE_SIG
Cancel
Resume
End Treatment
Get: DI_RINSE_ ALLOWED
PopUp: End Treatment Options
To Fig. 16C
From Fig. 16C
Treatment Paused HTx/ ATx
To Fig. 16D
To Fig. 16D
From Fig. 16A
From Fig. 16A
From Fig. 16A
Treatment
Pause

Fig.16B

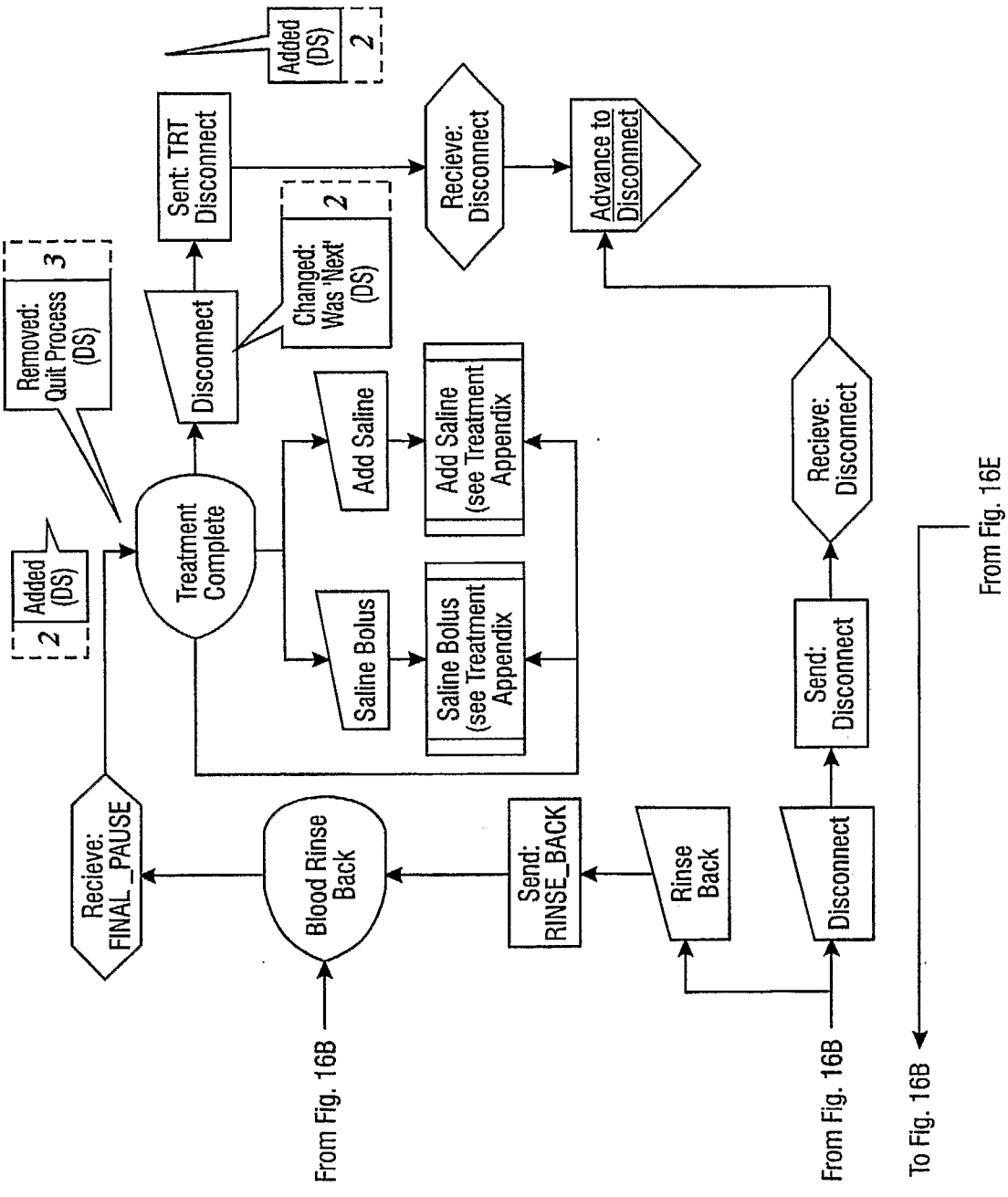

From Fig. 16B
From Fig. 16B
To Fig. 16B
From Fig. 16E
Recieve: FINAL_PAUSE
Blood Rinse Back
Send: RINSE_BACK
Rinse Back
Disconnect
Send: Disconnect
Recieve: Disconnect
Advance to Disconnect
Recieve: Disconnect
Sent: TRT Disconnect
Added (DS) 2
Changed: Was 'Next' (DS) 2
Disconnect
Removed: Quit Process (DS) 3
Added (DS) 2
Treatment Complete
Add Saline
Add Saline (see Treatment Appendix
Saline Bolus
Saline Bolus (see Treatment Appendix

Fig.16C

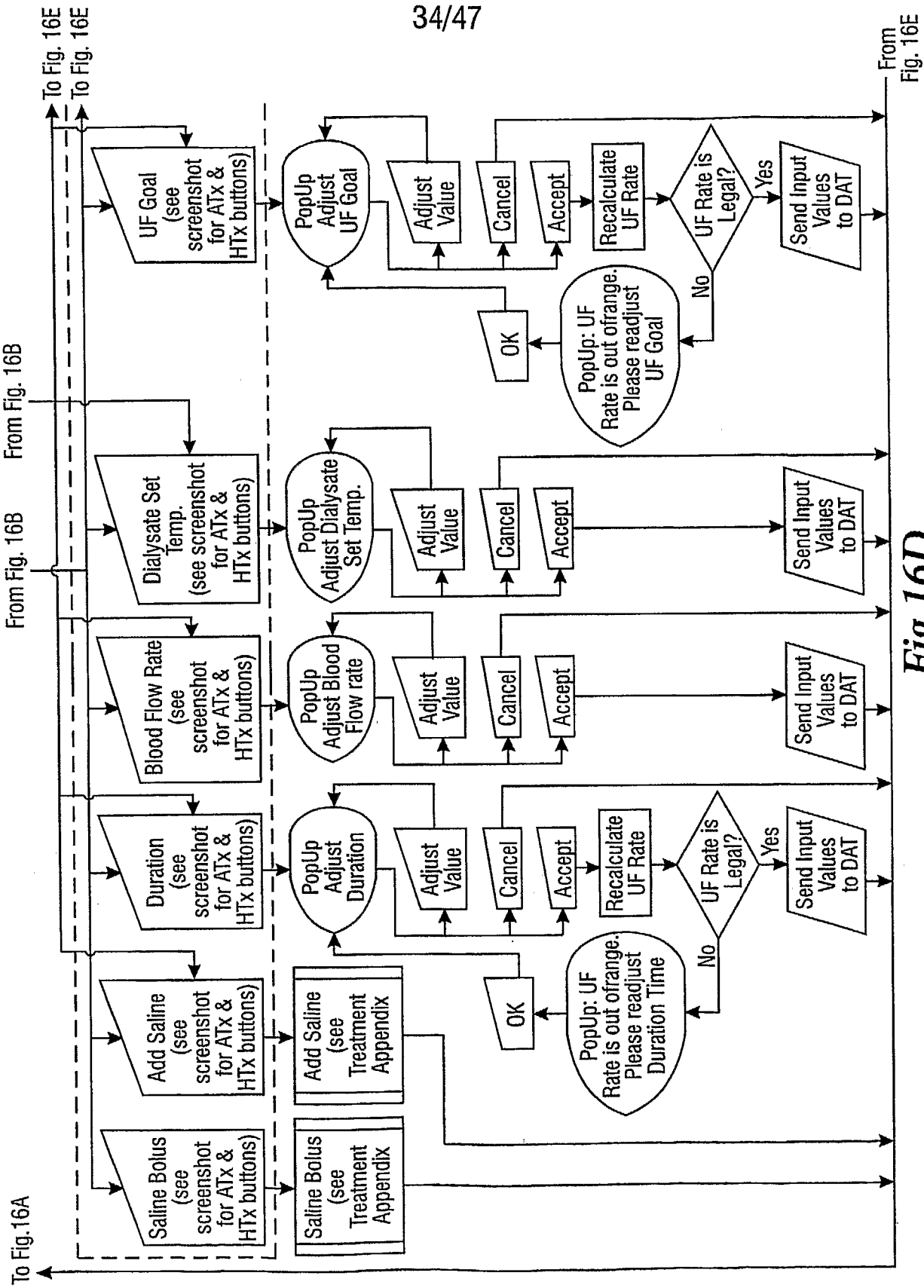

To Fig. 16A
From Fig. 16B
From Fig. 16B
To Fig. 16E
To Fig. 16E
From Fig. 16E
Saline Bolus (see screenshot for ATx & HTx buttons)
Add Saline (see screenshot for ATx & HTx buttons)
Duration (see screenshot for ATx & HTx buttons)
Blood Flow Rate (see screenshot for ATx & HTx buttons)
Dialysate Set Temp. (see screenshot for ATx & HTx buttons)
UF Goal (see screenshot for ATx & HTx buttons)
Saline Bolus (see Treatment Appendix
Add Saline (see Treatment Appendix
PopUp Adjust Duration
PopUp Adjust Blood Flow rate
PopUp Adjust Dialysate Set Temp.
PopUp Adjust UF Goal
Adjust Value
Cancel
Accept
Recalculate UF Rate
UF Rate is Legal?
Yes
No
Send Input Values to DAT
OK
PopUp: UF Rate is out ofrange. Please readjust Duration Time
PopUp: UF Rate is out ofrange. Please readjust UF Goal

Fig.16D

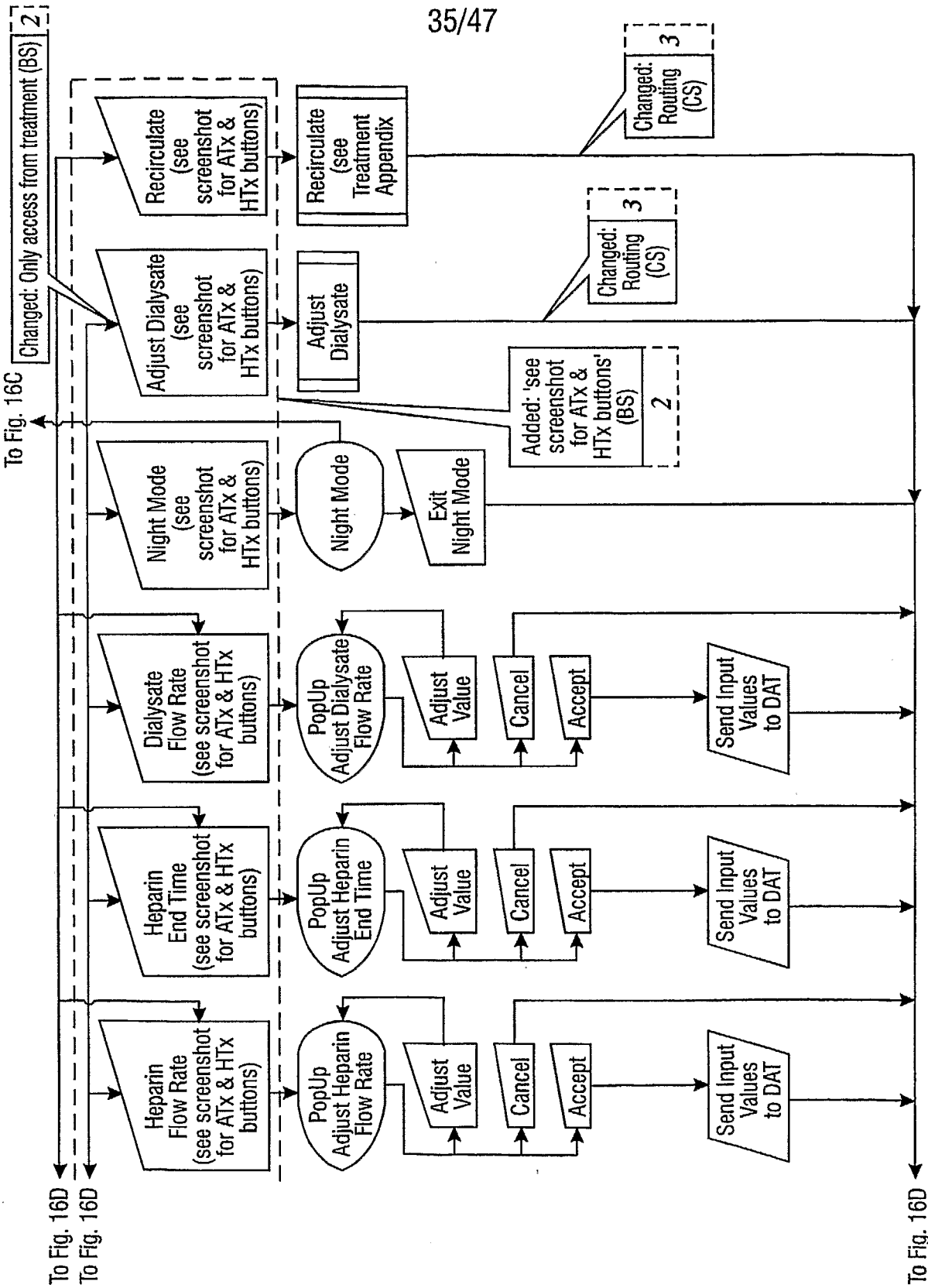

To Fig. 16C
Changed: Only access from treatment (BS) 2
Recirculate (see screenshot for ATx & HTx buttons)
Recirculate (see Treatment Appendix
Changed: Routing (CS) 3
Adjust Dialysate (see screenshot for ATx & HTx buttons)
Adjust Dialysate
Changed: Routing (CS) 3
Added: 'see screenshot for ATx & HTx buttons' (BS) 2
Night Mode (see screenshot for ATx & HTx buttons)
Night Mode
Exit Night Mode
Dialysate Flow Rate (see screenshot for ATx & HTx buttons)
PopUp Adjust Dialysate Flow Rate
Adjust Value
Cancel
Accept
Send Input Values to DAT
Heparin End Time (see screenshot for ATx & HTx buttons)
PopUp Adjust Heparin End Time
Adjust Value
Cancel
Accept
Send Input Values to DAT
Heparin Flow Rate (see screenshot for ATx & HTx buttons)
PopUp Adjust Heparin Flow Rate
Adjust Value
Cancel
Accept
Send Input Values to DAT
To Fig. 16D
To Fig. 16D
To Fig. 16D

Fig.16E

Treatment Appendix

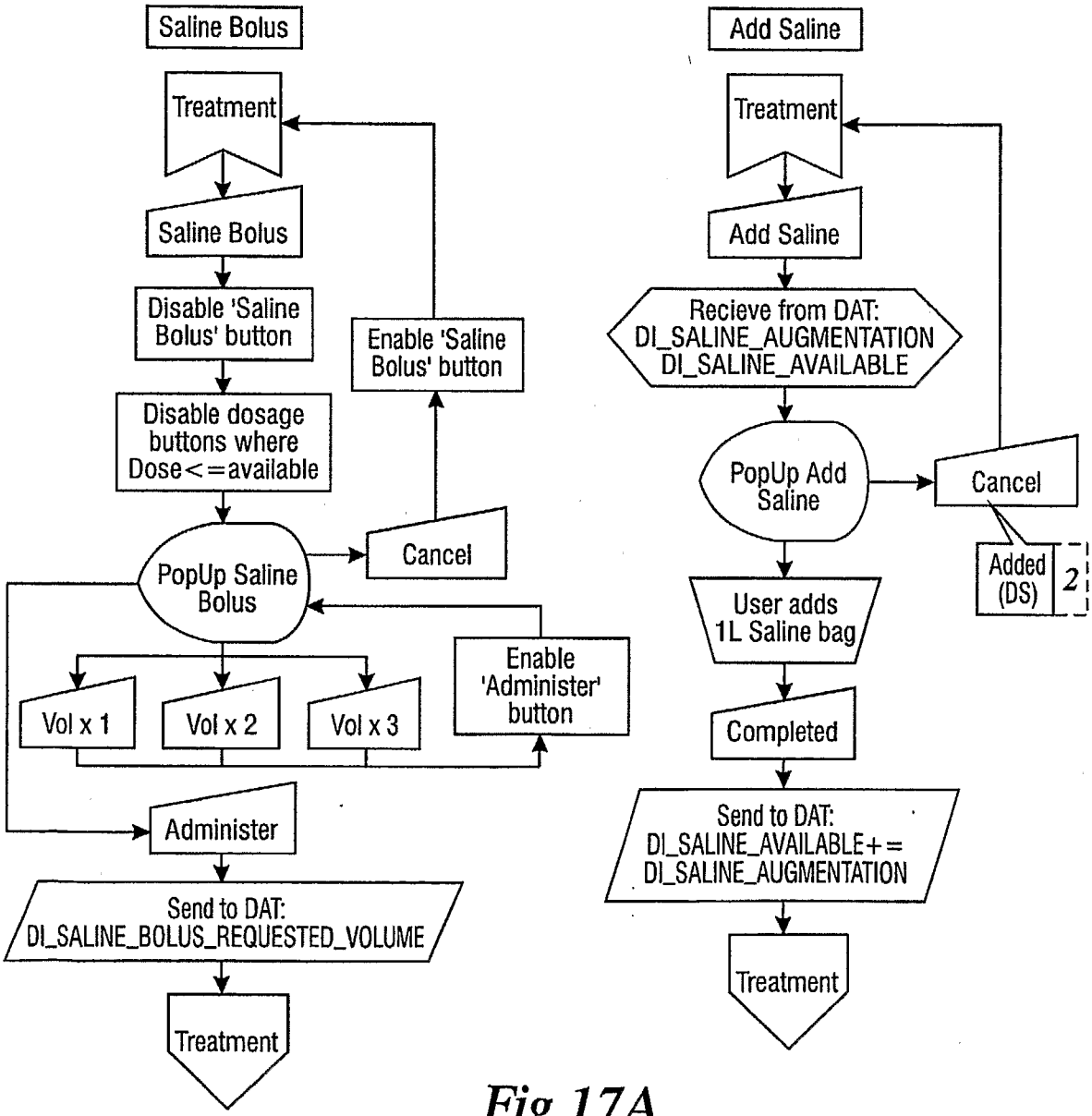


Fig.17A

Treatment Appendix

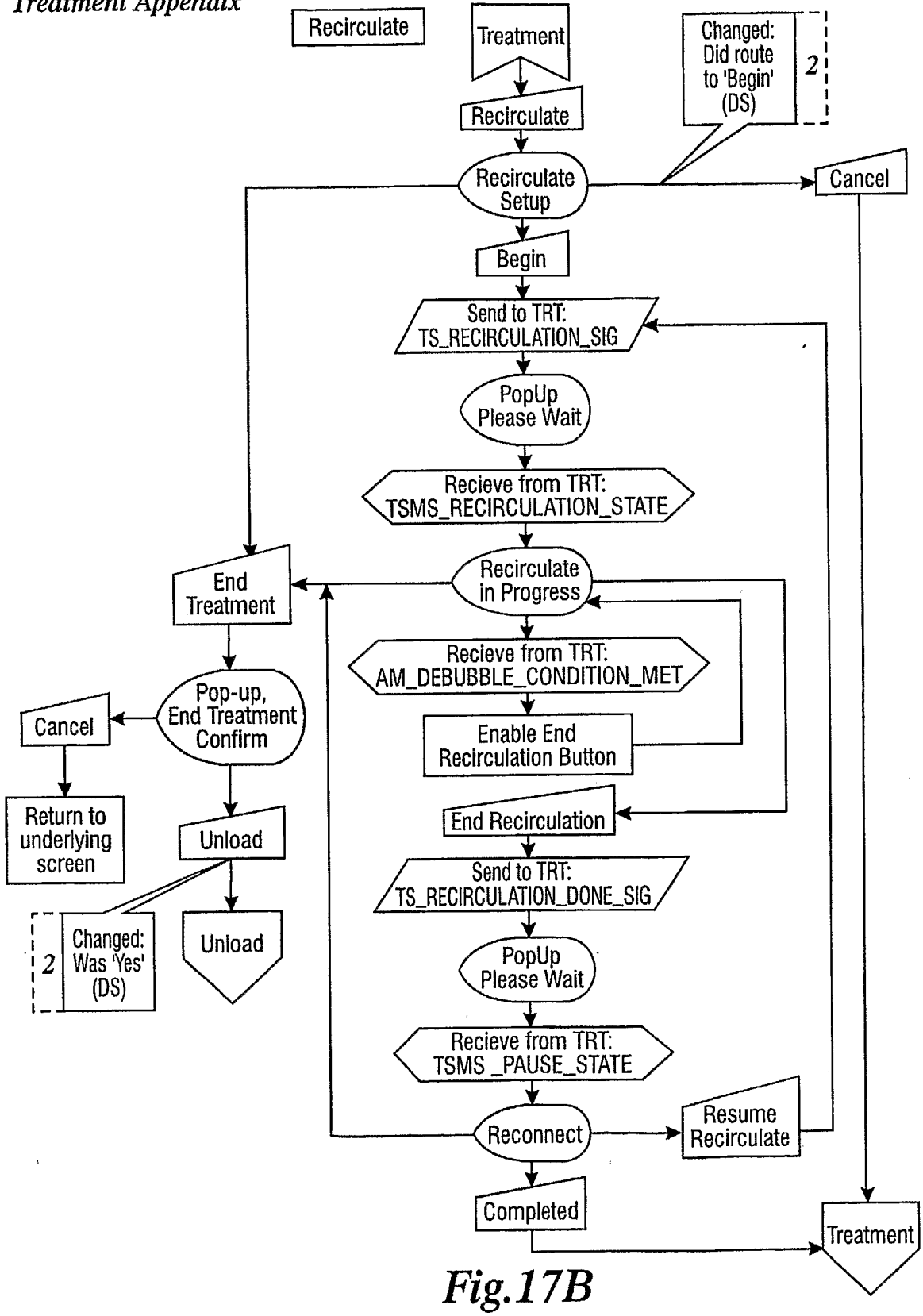


Fig.17B

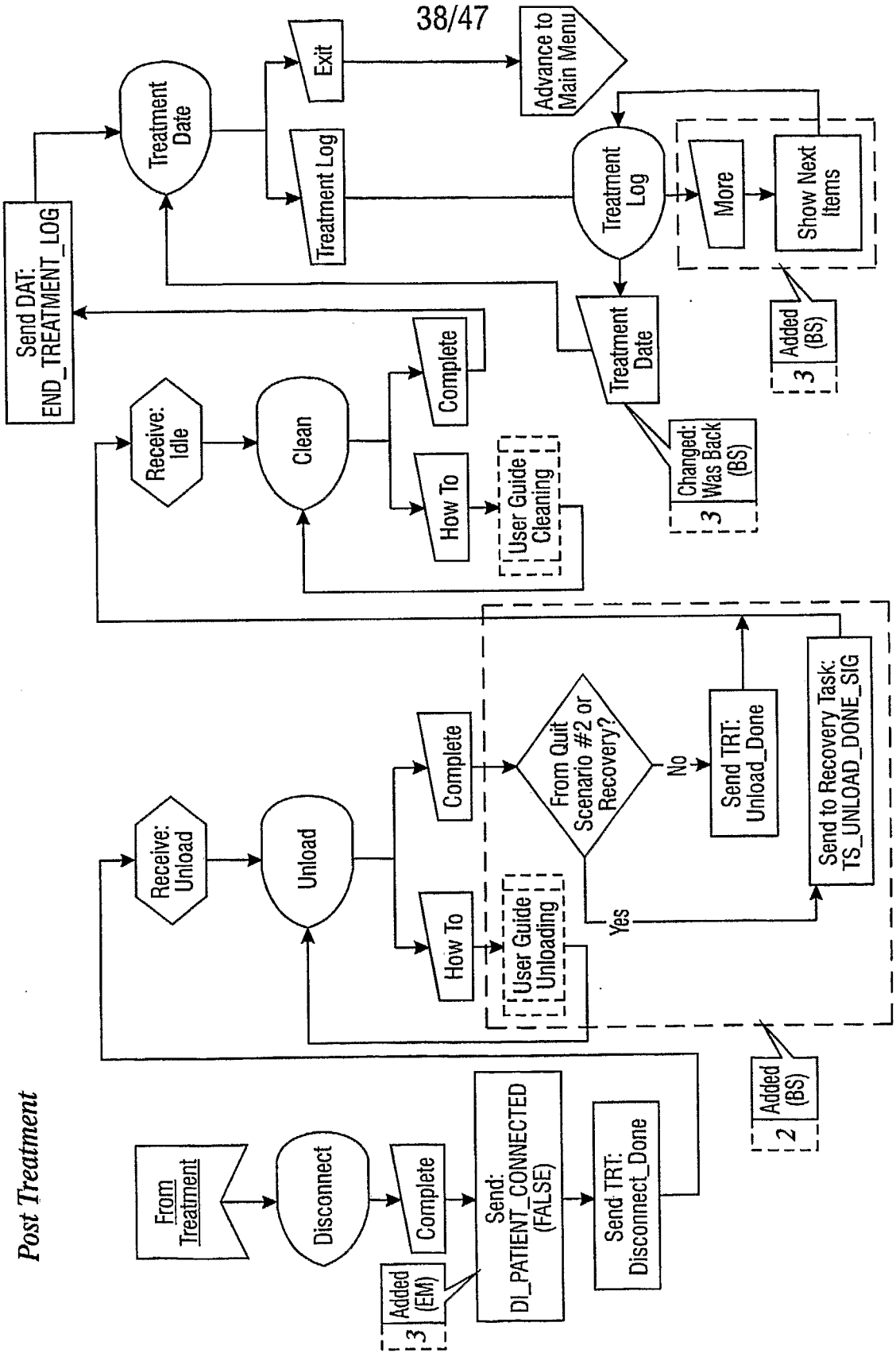

Post Treatment
From Treatment
Disconnect
Complete
Added (EM)
Send: DI_PATIENT_CONNECTED (FALSE)
Send TRT: Disconnect_Done
Receive: Unload
Unload
Complete
How To
User Guide Unloading
From Quit Scenario #2 or Recovery?
No
Yes
Send TRT: Unload_Done
Send to Recovery Task: TS_UNLOAD_DONE_SIG
Added (BS)
Receive: Idle
Clean
Complete
How To
User Guide Cleaning
Send DAT: END_TREATMENT_LOG
Treatment Date
Exit
Advance to Main Menu
Treatment Log
Changed: Was Back (BS)
Treatment Log
More
Show Next Items
Added (BS)

Fig.18

Alarms, Alerts 1

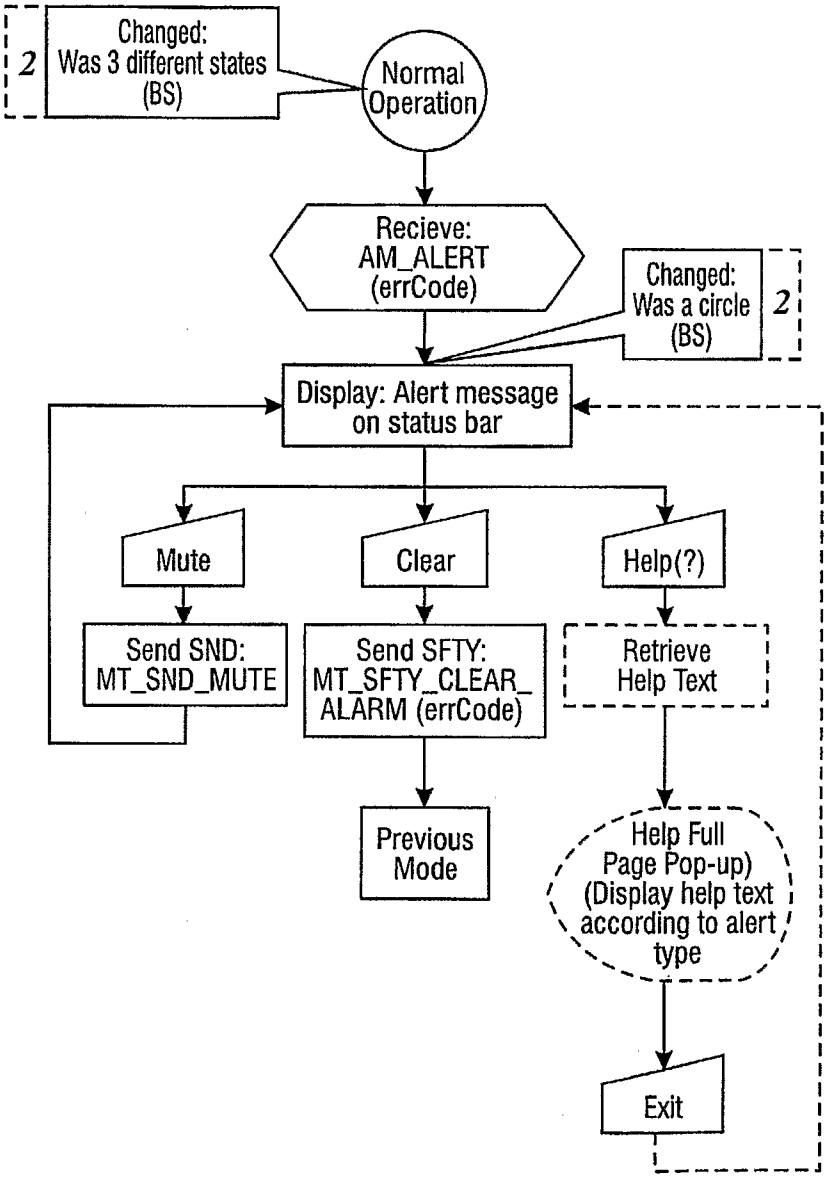


Fig.19A

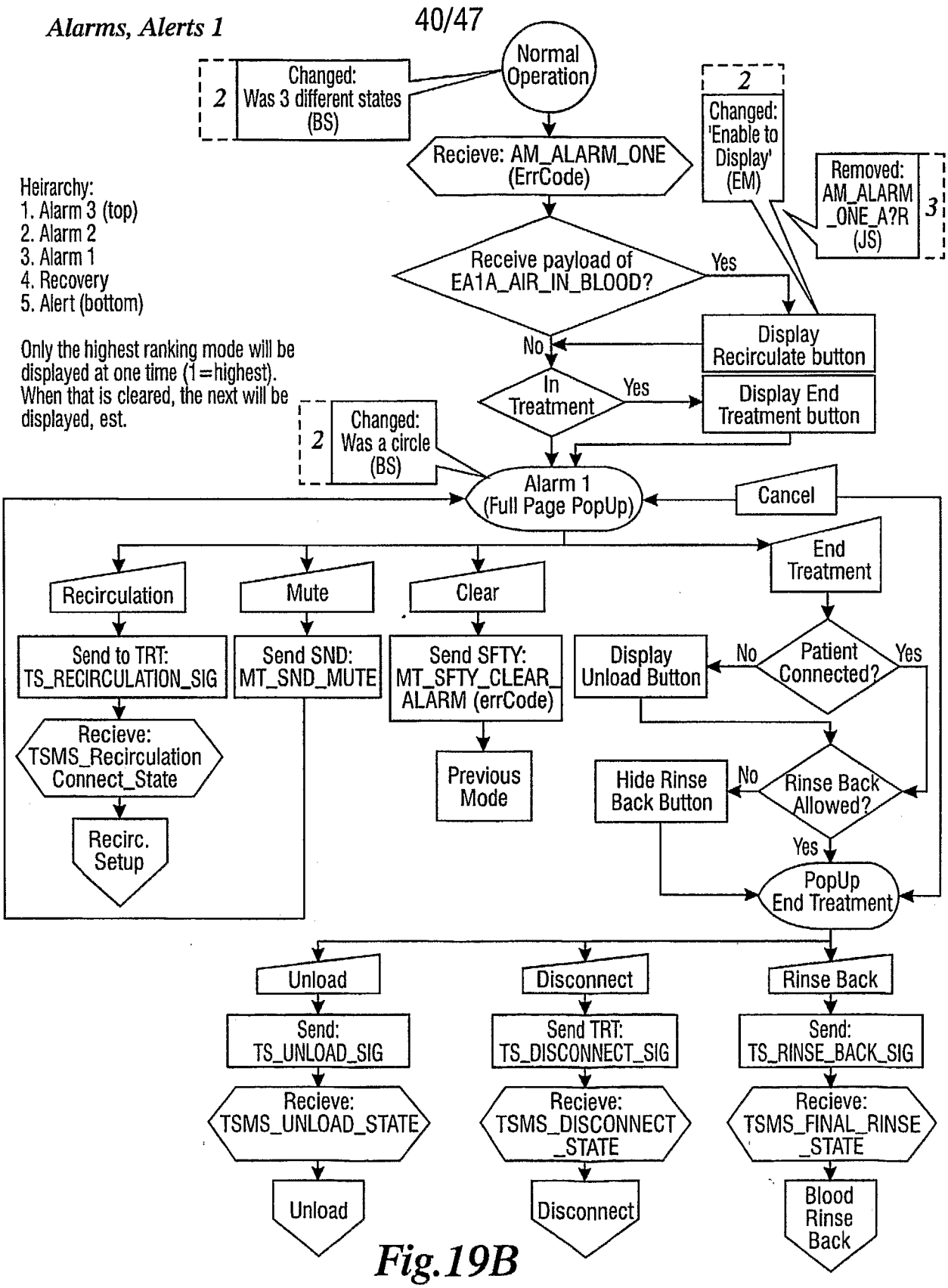

Alarms, Alerts 1
Heirarchy:
1. Alarm 3 (top)
2. Alarm 2
3. Alarm 1
4. Recovery
5. Alert (bottom)
Only the highest ranking mode will be displayed at one time (1=highest). When that is cleared, the next will be displayed, est.
Normal Operation
2
Changed: Was 3 different states (BS)
Recieve: AM_ALARM_ONE (ErrCode)
Receive payload of EA1A_AIR_IN_BLOOD?
Yes
No
2
Changed: 'Enable to Display' (EM)
Removed: AM_ALARM_ONE_A?R (JS)
3
Display Recirculate button
In Treatment
Yes
Display End Treatment button
2
Changed: Was a circle (BS)
Alarm 1 (Full Page PopUp)
Cancel
Recirculation
Mute
Clear
End Treatment
Send to TRT: TS_RECIRCULATION_SIG
Send SND: MT_SND_MUTE
Send SFTY: MT_SFTY_CLEAR_ALARM (errCode)
Display Unload Button
No
Patient Connected?
Yes
Recieve: TSMS_Recirculation Connect_State
Recirc. Setup
Previous Mode
Hide Rinse Back Button
No
Rinse Back Allowed?
Yes
PopUp End Treatment
Unload
Disconnect
Rinse Back
Send: TS_UNLOAD_SIG
Send TRT: TS_DISCONNECT_SIG
Send: TS_RINSE_BACK_SIG
Recieve: TSMS_UNLOAD_STATE
Recieve: TSMS_DISCONNECT_STATE
Recieve: TSMS_FINAL_RINSE_STATE
Unload
Disconnect
Blood Rinse Back

Fig.19B

Alerts 2, 3

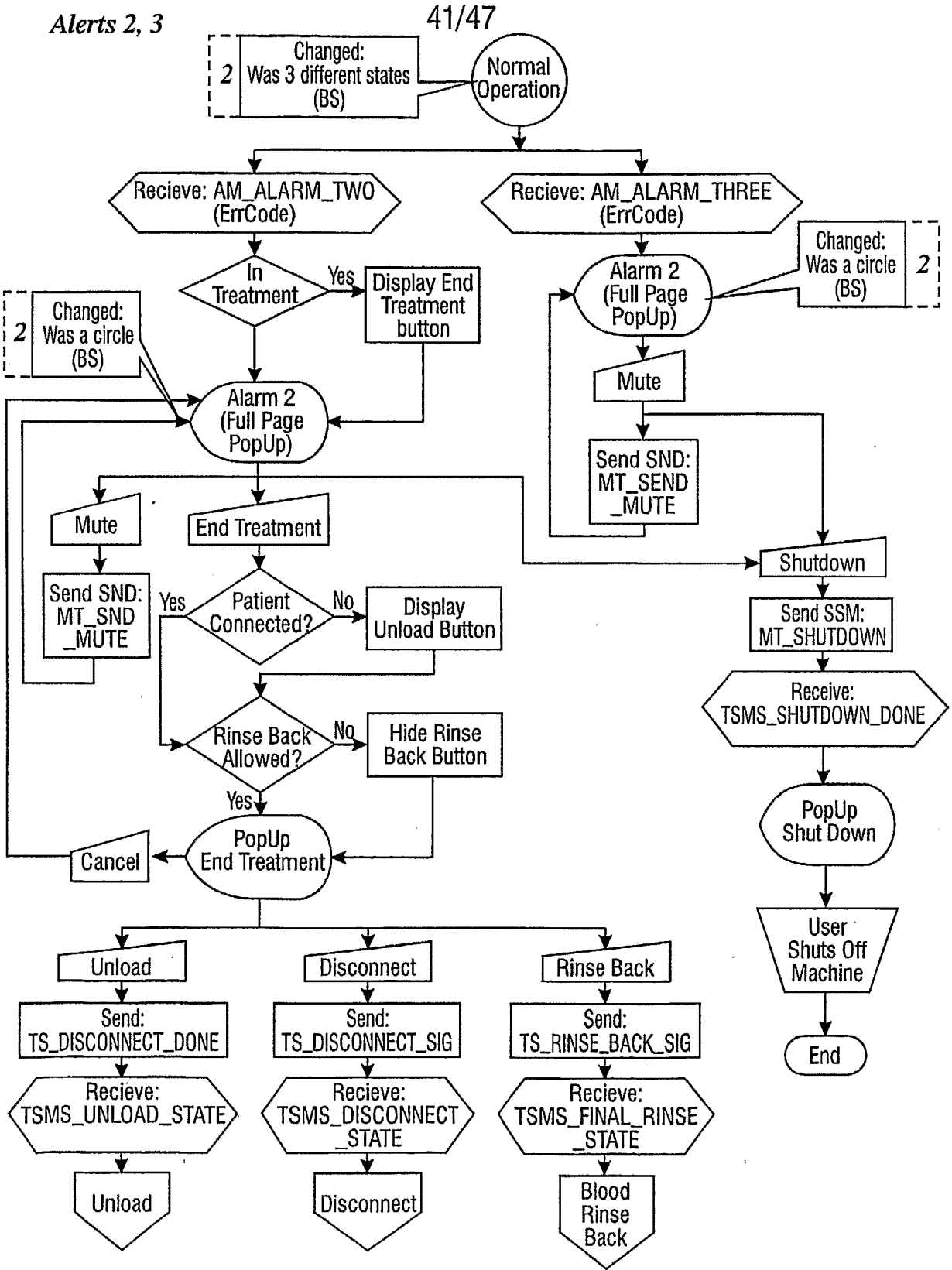


Fig.20

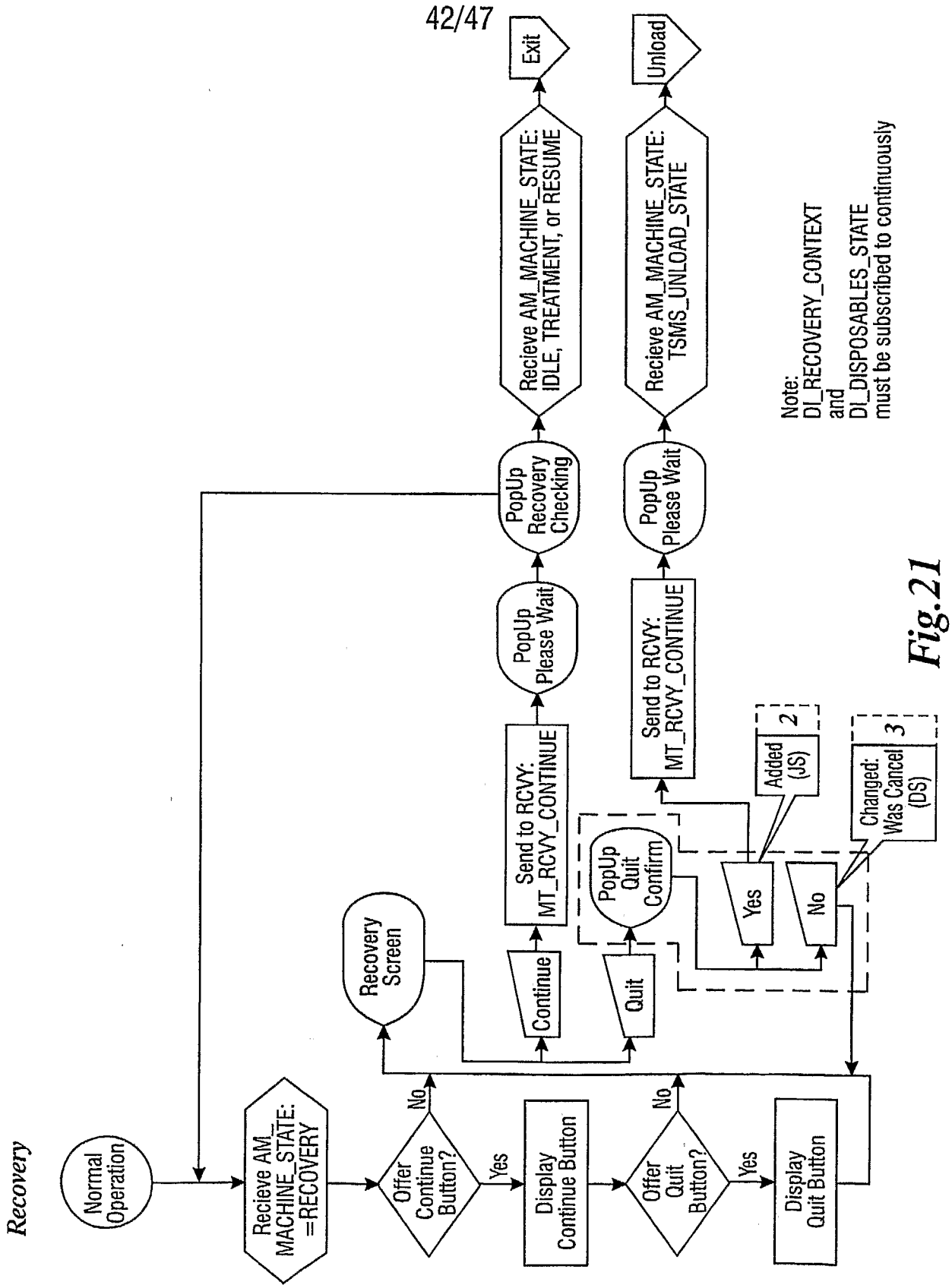
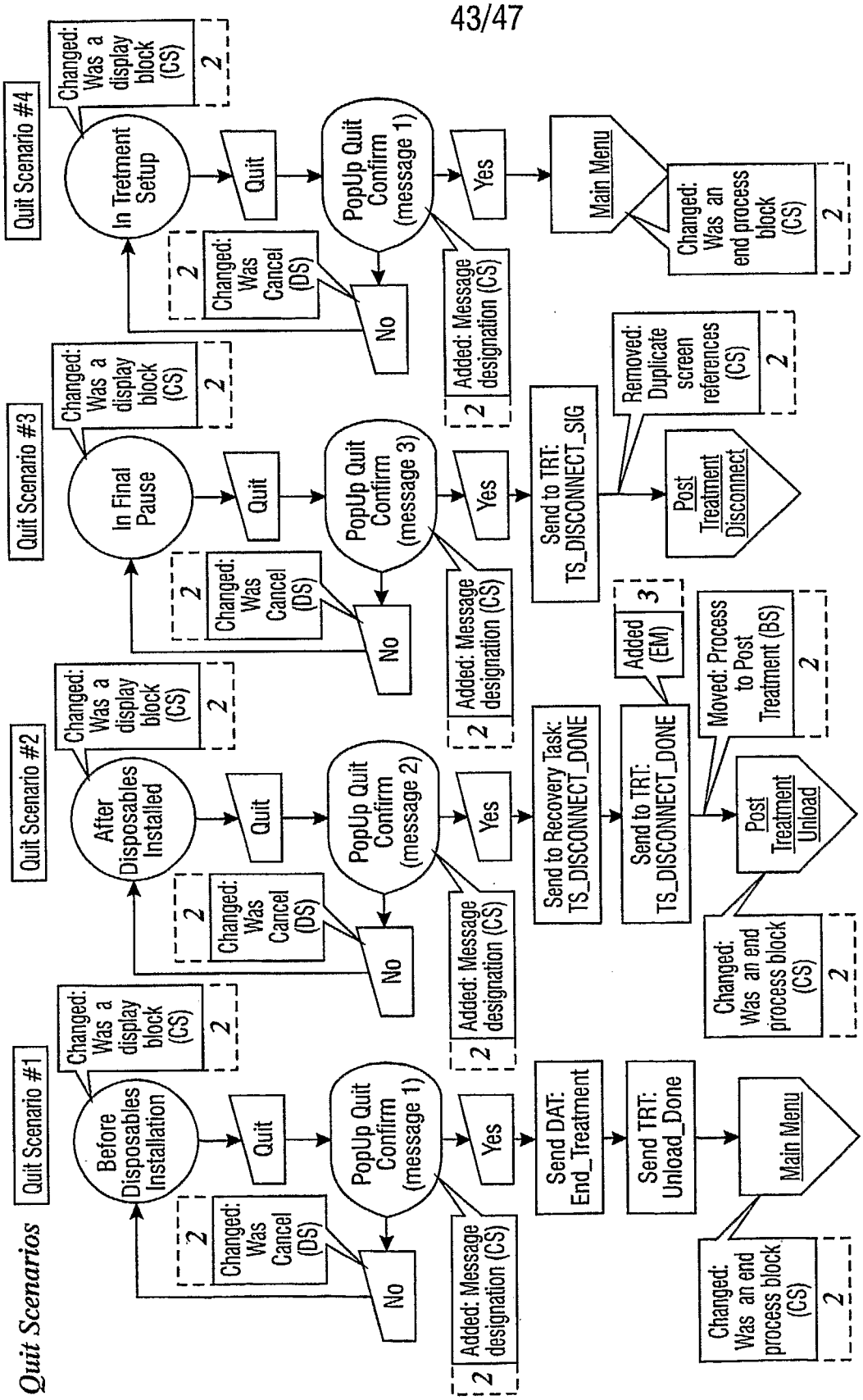

Recovery
Normal Operation
Recieve AM_ MACHINE_STATE: =RECOVERY
Offer Continue Button?
No
Yes
Display Continue Button
Offer Quit Button?
No
Yes
Display Quit Button
Recovery Screen
Continue
Quit
Send to RCVY: MT_RCVY_CONTINUE
PopUp Quit Confirm
Yes
No
Added (JS) 2
Changed: Was Cancel (DS) 3
PopUp Please Wait
PopUp Recovery Checking
Recieve AM_MACHINE_STATE: IDLE, TREATMENT, or RESUME
Exit
Send to RCVY: MT_RCVY_CONTINUE
PopUp Please Wait
Recieve AM_MACHINE_STATE: TSMS_UNLOAD_STATE
Unload
Note:
DI_RECOVERY_CONTEXT
and
DI_DISPOSABLES_STATE
must be subscribed to continuously

Fig.21



Quit Message Texts: Message 1- Are you sure that you want to quit?
Message 2- Are you sure that you want to quit? If you select yes, you will be directed to unload the disposables to complete the process.
Message 3- Are you sure that you want to quit? If you select yes, you will be directed to disconnect the patient to complete the process.

Fig.22

Adjust Dialysate 44/47

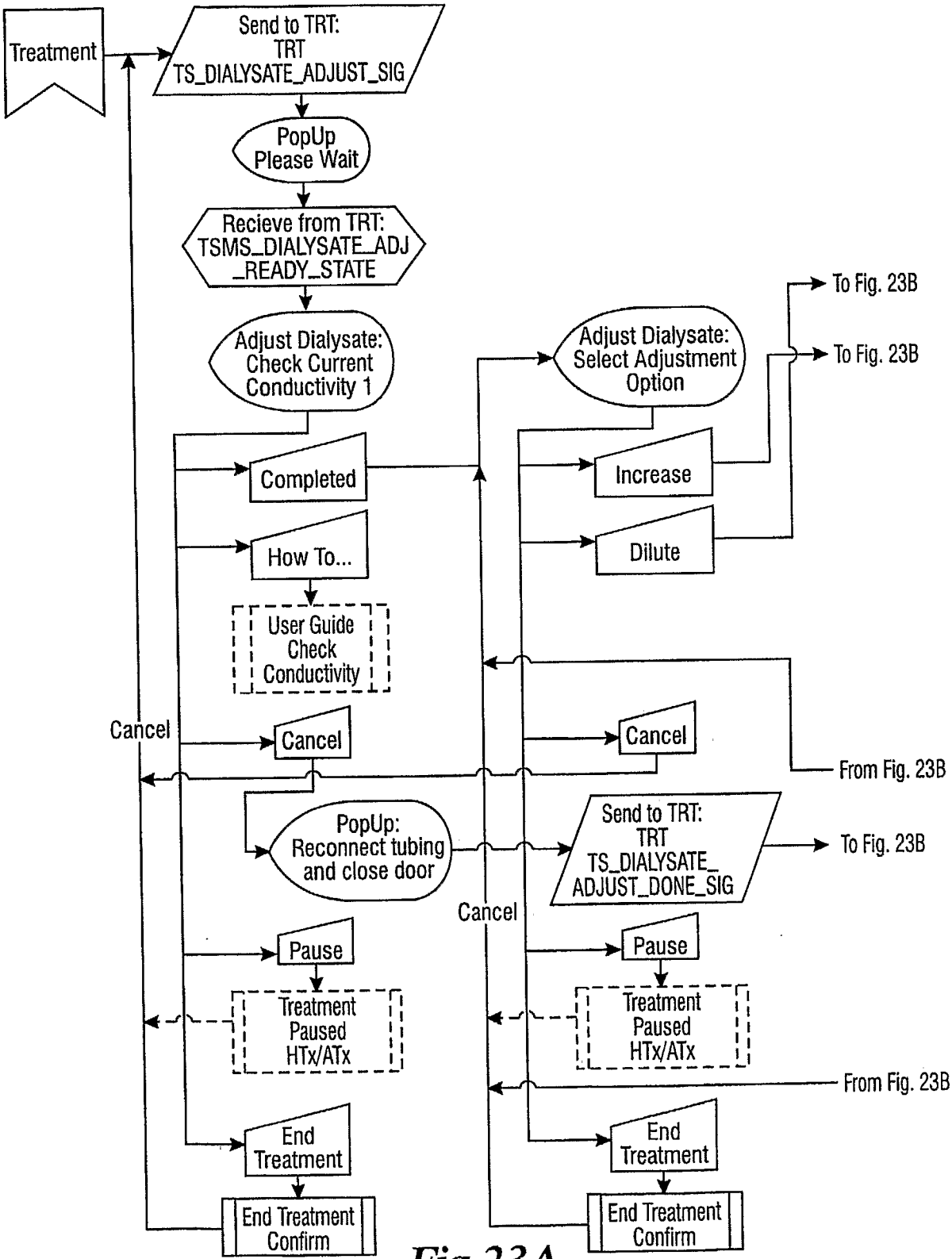


Fig.23A

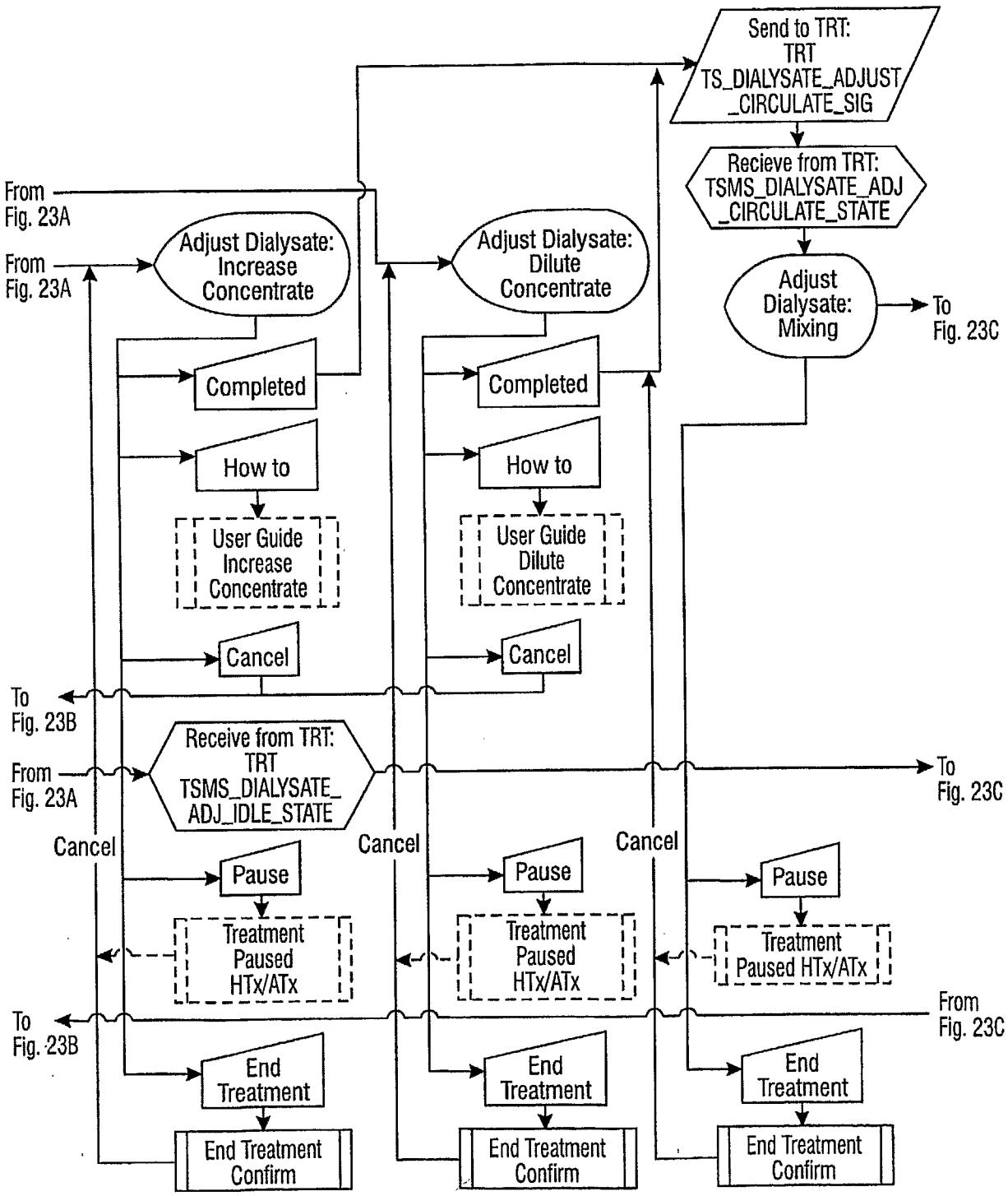

Send to TRT:
TRT
TS_DIALYSATE_ADJUST
_CIRCULATE_SIG
Recieve from TRT:
TSMS_DIALYSATE_ADJ
_CIRCULATE_STATE
From
Fig. 23A
From
Fig. 23A
Adjust Dialysate:
Increase
Concentrate
Adjust Dialysate:
Dilute
Concentrate
Adjust
Dialysate:
Mixing
To
Fig. 23C
Completed
Completed
How to
How to
User Guide
Increase
Concentrate
User Guide
Dilute
Concentrate
Cancel
Cancel
To
Fig. 23B
From
Fig. 23A
Receive from TRT:
TRT
TSMS_DIALYSATE_
ADJ_IDLE_STATE
To
Fig. 23C
Cancel
Cancel
Cancel
Pause
Pause
Pause
Treatment
Paused
HTx/ATx
Treatment
Paused
HTx/ATx
Treatment
Paused HTx/ATx
From
Fig. 23C
To
Fig. 23B
End
Treatment
End
Treatment
End
Treatment
End Treatment
Confirm
End Treatment
Confirm
End Treatment
Confirm

Fig.23B

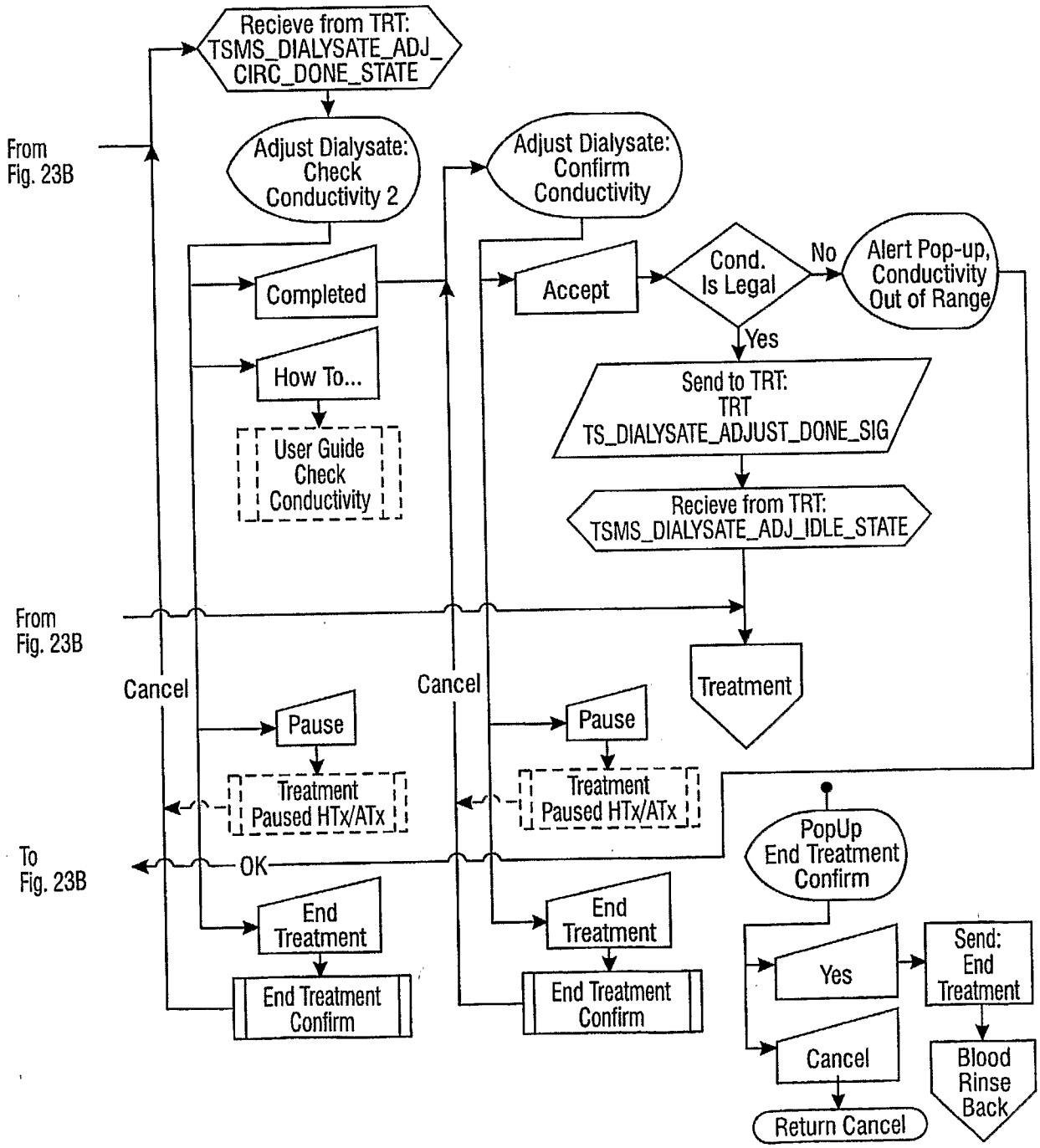

Recieve from TRT: TSMS_DIALYSATE_ADJ_ CIRC_DONE_STATE
From Fig. 23B
Adjust Dialysate: Check Conductivity 2
Adjust Dialysate: Confirm Conductivity
Completed
Accept
Cond. Is Legal
No
Alert Pop-up, Conductivity Out of Range
Yes
How To...
Send to TRT: TRT TS_DIALYSATE_ADJUST_DONE_SIG
User Guide Check Conductivity
Recieve from TRT: TSMS_DIALYSATE_ADJ_IDLE_STATE
From Fig. 23B
Treatment
Cancel
Cancel
Pause
Pause
Treatment Paused HTx/ATx
Treatment Paused HTx/ATx
PopUp End Treatment Confirm
To Fig. 23B
OK
End Treatment
End Treatment
Yes
Send: End Treatment
End Treatment Confirm
End Treatment Confirm
Cancel
Blood Rinse Back
Return Cancel

Fig.23C

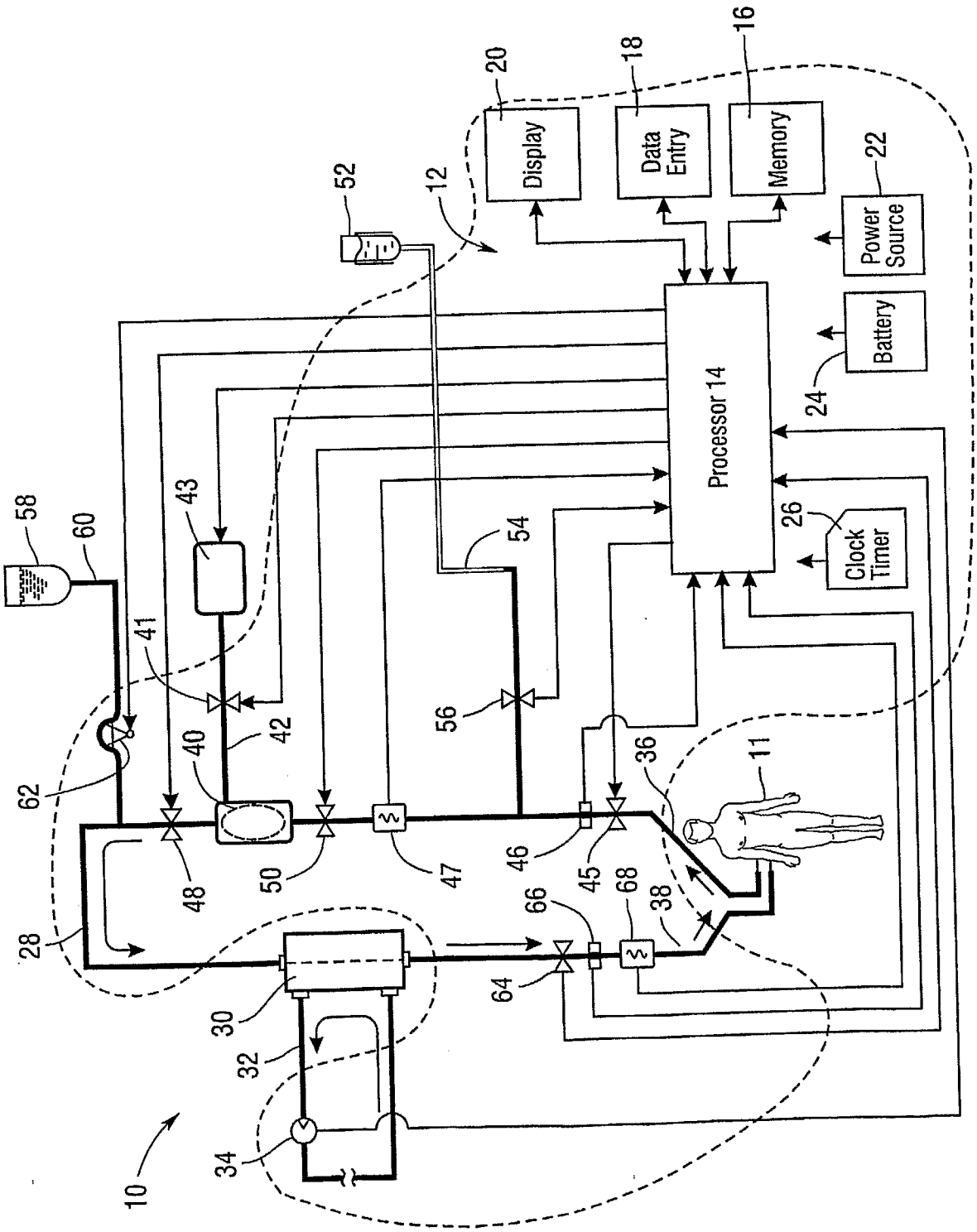

Display
Data Entry
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Power Source
Battery
Processor 14
Clock Timer
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Fig.24

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/021055

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06F A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 310 602 A (* AKSYS LTD) 3 September 1997 (1997-09-03) page 1, line 1 - page 15, line 28 page 68, line 36 - page 76, line 6	1-13
A	EP 0 597 817 A (ALTHIN CD MEDICAL, INC; ALTHIN CD MEDICAL INC; BAXTER INTERNATIONAL IN) 18 May 1994 (1994-05-18) page 9, line 6 - page 11, line 19; figure 7 page 22, line 20 - page 23, line 3	1-17
A	US 6 468 242 B1 (WILSON LARRY ET AL) 22 October 2002 (2002-10-22) column 6, line 15 - line 46 column 8, line 8 - column 12, line 41 column 13, line 58 - column 15, line 47	

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 September 2006	05/10/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	SANANDRES LEDESMA, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/021055

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