Renalyx

HEMODIALYSIS MACHINE

USER MANUAL

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Please verify latest document before each use.

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About the manual

The purpose of the RenalyxTreat Hemodialysis Machine Operator's Manual is to instruct qualified patient-care staff in the function, operation, and maintenance of the RenalyxTreat hemodialysis machine. It is not intended as a guide for performing hemodialysis, a medical treatment that should only be performed under the supervision of a licensed physician.

This manual is organized to systematically guide a patient-care specialist through the set-up, operation, and clean-up of the RenalyxTreat hemodialysis machine in daily use. The book begins with an overview that introduces the operator to the major components and describes how they are organized on the machine. Next, the operator is guided through a daily set-up procedure. Once the machine has been prepared for daily use, a step-by-step guide to prepare the machine for a patient-specific treatment is provided. The operator is then provided a tour of the various treatment screen functions useful in monitoring the treatment, followed by instruction in terminating treatment and post-treatment clean up. Also included are sections on troubleshooting, maintenance, and treatment options.

General requirement

Operators of the RenalyxTreat hemodialysis machine must be trained to administer hemodialysis at the direction of a physician. In addition, the operator should be:

- Knowledgeable of hemodialysis methodology and relevant physiology.
- Proficient in healthcare procedures regarding aseptic techniques.
- Thoroughly familiar with the contents of this manual.
- Fully trained and qualified to operate this machine, and able to distinguish between
- Normal and abnormal operation.

About Hemodialysis

Indications

Hemodialysis is prescribed by physicians for patients with acute or chronic renal failure, when conservative therapy is judged inadequate. Dialysis therapy may be intermittent or continuous.

Contraindications

There are no absolute contraindications to h the passing of a patient's blood through an extracorporeal circuit may require anticoagulation to prevent blood clotting. In addition, the parameters of dialysis should be optimized to avoid discomfort to the patient. Many patients are taking medicinal therapy prescribed by their physicians. Due to the dialysis treatment, some of the medication may be removed from the patient's blood thereby lowering the therapeutic level in the blood. In other cases, medications may not be excreted as quickly as expected with patients with renal insufficiency and the level may be higher than expect

Therefore, the prescribing physician should determine the appropriate dosage of the medicine to obtain the desired medicinal response in the patient.

Some Side Effects of Hemodialysis

Dialysis therapy occasionally causes hypovolemia, hypervolemia, hypertension, hypotension and related symptoms, headache, nausea, cramping or other muscular discomfort in some patients. Hypothermia, hyperthermia, itching, anxiety, convulsions, seizure, and other neurologic symptoms associated with dialysis dementia may also be manifested by the patient. These symptoms are thought to occur if the patient's blood volume or electrolyte balance is not maintained within acceptable limits. Other, more serious, complications arising from dialysis, such as hemorrhage, air embolism, or hemolysis, can cause serious patient injury or death. The prescribing physician must understand that prescribing insufficient bicarbonate may contribute to metabolic acidosis; excessive bicarbonate may contribute to metabolic alkalosis. Both conditions are associated with poor patient outcomes, including increased risk of mortality. Proper control of all elements of dialysis may prevent or control these physiological reactions or complications. Pyrogenic reactions may occur which can result in patient injury. Generally it is thought that these may be controlled by maintaining the dialysate solution within the chemical and bacteriologic limits (see Water Quality on the section 6.1.11 "Machine Specifications" section for more information). Failure to use these standards for water can also lead to accumulated toxic effects. A regular program for disinfection and testing of the water treatment system, piping, inlet lines, filters, concentrate feed containers or system, and the dialysate delivery machine must be established and followed. This program will vary from facility to facility. Infections or pyrogen reactions may also result from contamination of the extracorporeal circuit or inadequate procedures used to reuse dialyzers.

Allergic reactions to chemical disinfectants may occur if insufficient procedures are used to remove or maintain the residual disinfectant at acceptable levels. Chemical disinfectants are used for dialyzer disinfection, machine disinfection, or for disinfection of water treatment and distribution systems. All blood connections must be made using aseptic technique. All tubes and connections must be secured and closely monitored to prevent loss of blood or entry of air into the extracorporeal circuit or errors in the ultrafiltration control system. The patient may require blood transfusion or other medical intervention to prevent respiratory or cardiac disorders if these occur. The patient's blood pressure and general physical status must be closely monitored during dialysis in order to initiate appropriate remedial measures or therapy. Of particular importance is the control of the patient's serum potassium level to prevent cardiac dysrhythmia and the patient's blood clotting time to prevent clotting disorders.

These instructions are for the RenalyxTreat hemodialysis machine. The machine must only be operated in accordance with these instructions. All operators of this machine must be thoroughly trained and have read this entire manual and any applicable appendices before using the machine. Improper care/use of this device may result in serious patient injury or death.

General Warnings

This section contains general warnings statements regarding the use and maintenance of the RenalyxTreat hemodialysis machine. It is not a complete summary, and additional warning statements specific to pertinent topics can be found within this manual.

Water:

	**Warning!** Connect water inlet according to the specifications for the machine. For further information, see section 6.1.11, "Machine Specifications." The correct ionic concentration and bacterial quality can generally be achieved in the dialysate only with treated water that meets water quality standards. Be sure that all specifications are satisfied. The water source must be monitored periodically to detect fluctuations in water composition and quality that could have an adverse effect on the patient or dialysate delivery machine. Particular attention must be taken for chemicals such as aluminum, chlorine, and chloramine, as these chemicals can cause complications in dialysis patients.
	**Warning!** Comply with all local regulations in respect of separation of devices in the water supply in case of back siphonage; an air gap must be created between the machine's drain line and its drain.

Concentrates:

	**Warning!** The specific acid and bicarbonate concentrates, including the sodium, bicarbonate, and electrolyte compositions, must be prescribed by a physician.
	**Warning!** Many concentrate types are available for use in dialysate delivery machines. Concentrates contain various amounts of dextrose, potassium, calcium, sodium, chloride, magnesium, and other components. Most concentrates are designed as a two-part system of acid and bicarbonate solutions which are mixed in the machine with water. Even within the subgroup of bicarbonate type concentrates, there are at least four methods of compounding the solutions. Each of these methods requires special calibrations or setups. Certain methods are not supported. It is mandatory that the acid and bicarbonate types be matched to each other. Be sure to use compatible solutions, labeling, and setups. These setups include machine calibration, special adapters for

	certain concentrate types, correct setting of concentrate option, and labeling. Failure to use the properly matched solutions and machine Calibrations may allow improper dialysate to be delivered to the patient, resulting in patient injury or death. Verify composition, conductivity, and pH after converting to a different type of concentrate.
	**Warning!** Acid concentrate, bicarbonate concentrate, and water must be of the appropriate quality to ensure safety and performance of the final dialysate is met. (see Water Quality on the section 6.1.11 “Machine Specifications” section for more information)
	**Warning!** Incorrect composition will result if the acid concentrate probe is not connected to the appropriate acid concentrate or the bicarbonate concentrate probe is not connected to the appropriate bicarbonate solution. The acid and bicarbonate concentrates must match those selected in the “Dialysate” screen. Patient injury or death may occur if incorrect dialysate solution is used.
	**Warning!** Test the conductivity and approximate pH of the dialysate with an independent device before beginning treatment. Test it also when changing concentrates during treatment. The wrong conductivity or pH may cause serious injury or death. *Note: If alternative liquid bicarbonate concentrate sources are used (jugs or central delivery) the end user must ensure the bicarbonate is of appropriate quality and is prepared per manufacturer’s instructions.
	**Warning!** Use of an acid concentrate intended for a 1:44 mix ratio in any 1:34 proportioning dialysate delivery machine may result in a dialysate solution with a normal conductivity but without a physiological buffer. There may be no alarms in this event. Use of this improper dialysate solution may cause patient injury or death.
	**Warning!** The machine must be labeled to indicate the type of concentrate for which it is configured. Check the composition (i.e., Na, Cl, K, Ca, Mg, HCO_3) and pH of the dialysate solution after the machine is installed or after the machine is modified for different concentrate types. Check the conductivity and approximate pH of the dialysate solution with an independent device before initiating dialysis. Improper conductivity or pH could result in patient injury or death.

Machine:

	**Warning!** Failure to install, operates, and maintains this equipment according to the manufacturer's instructions may cause patient injury or death.
	**Warning!** Proper functioning of the machine must be verified prior to initiating treatment. Unidentified malfunctions or alarm failure could potentially expose a patient to a serious health risk. Alarm limits for temperature and conductivity are calculated for the dialysate composition and may be somewhat adjusted by the operator. These must be maintained within safe physiological limits as specified by the prescribing physician.
	**Warning!** Never perform maintenance when a patient is connected to the machine. If possible, remove the machine from the treatment area when it is being serviced. Label the machine to ensure it is not accidentally returned to clinical use before the service work is completed. Disinfect the machine and test the dialysate for acceptable conductivity and pH values before returning the machine to clinical use. Always test the machine when maintenance is completed.
	**Warning!** The electrical source must be single phase, three-conductor type provided with a hospital grade Power cord. The proper polarity and ground integrity must be initially checked and maintained. Failure to do so may result in electrical shock or burn to the operator or patient. The machine must be plugged directly into the electrical outlet; extension cords and power strips are prohibited.
	**Warning!** Shock hazard. Do not remove covers. Refer servicing to qualified personnel. Replace fuses only with the same type and rating.
	**Warning!** Do not use devices emitting strong electromagnetic radiation such as portable phones, radio equipment (walkie-talkies, etc.), radio transmitters, and like equipment near your machine. Improper operation may result. Cellular phones and Wi-Fi connected devices may be conditionally allowed. However, if any interference is noted, such as false pressure readings that disappear when the external signal is removed, it is recommended to move the cellular phone at least ten feet away from the RenalyxTreat hemodialysis machine when making or receiving phone calls. If a Wi-Fi-connected device (e.g. laptop computers, tablet devices, smartphones) is found to cause interference, it is recommended to use that device at least four feet away from the RenalyxTreat hemodialysis machine.

	**Warning!** Transducer protectors should be used between pressure ports and each pressure monitor line of the extracorporeal system to prevent the internal transducer protectors from getting wet. Wet transducer protectors must be replaced, as they will cause inaccurate pressure readings. If the external transducer protector and the internal transducer protector become contaminated with blood, the transducer protectors must be replaced and the transducer and associated parts must be disinfected or replaced.
	**Warning!** A new, sterile transducer protector should be placed on all the air connections from the drip chambers to the machine pressure monitor ports. This will prevent contamination of the machine and filters air that enters the chambers through the monitor lines. If the transducer protector should get wet and air is not able to pass, replace the transducer protector and clear the monitor line.
	**Warning!** To avoid damaging the equipment or personal injury, internal adjustments to the blood pressure module should only be made by a qualified technician.
	**Warning!** Possible Explosion Hazard if used in the presence of flammable anesthetics.
	**Warning!** Check all bloodlines for leaks after the treatment has started. Keep access sites uncovered and monitored. Improper bloodline connections or needle dislodgements can result in excessive blood loss, serious injury, and death. Machine alarms may not occur in every blood loss situation.
	**Warning!** The dialysate path is a closed fluidics system. Discontinue use immediately if a fluid leak is detected. Do not attempt to administer or continue dialysis treatment with a machine which has a fluid leak, this could result in excessive fluid removal from the patient leading to serious injury or death.
	**Caution:** System leaks may occur. Unattended operation of the machine (for example, during disinfection at night) may result in flooding and can cause property damage. Clean up spills immediately.
	**Caution:** Be careful not to tip the machine when rolling over uneven surfaces. Push the machine from the middle when moving it.

	**Caution:** You must follow all environmental regulations regarding waste disposal and eventual machine disposal. Contact your clinic for more information. Prior to the disposal of your machine, any possible risk of infection from blood borne pathogens must also be eliminated by appropriate disinfection.
	**Shock Hazard**: Ensure that no conductive electrical devices connected to or near the patient have leakage currents above the maximum CF applied parts limit of 10 µA DC and 50 µA DC in a single fault condition. Failure to follow these precautions may result in serious injury or death.

1. Over view Hemodialysis

The RenalyxTreat hemodialysis machine is designed to perform hemodialysis in hospitals and dialysis clinics. It can be used for patients suffering from chronic or acute renal failure.

1.1. Function of the RenalyxTreat Hemodialysis Machine:

The RenalyxTreat hemodialysis machine is designed to provide hemodialysis treatment by controlling and monitoring both the dialysate and extracorporeal blood circuits. In the extracorporeal blood circuit, the blood is continuously circulated from the patient through a dialyzer, where toxins are filtered out through a semi-permeable membrane, before being returned to the patient. During this process, the extracorporeal blood circuit is monitored for venous and arterial blood pressures, and for the presence of air and blood. The RenalyxTreat hemodialysis machine can also administer heparin evenly throughout the treatment. In the dialysate circuit, the dialysate concentrates are mixed with purified water, heated, degassed, and delivered to the dialyzer. Balancing chambers ensure that the incoming flow of the dialysate is volumetrically equal to the outgoing flow in order to control ultrafiltration from the patient.

1.2. Organization of the RenalyxTreat Hemodialysis Machine

The RenalyxTreat hemodialysis machine is designed for functional efficiency. The back of the machine houses the utility connections such as water source, drain, and electrical connections. By mounting them to the back, the water lines and power cord remain out of the way during treatment.

The front of the machine contains all of the controls the operator needs access to during hemodialysis. It can be broken down into three main sections. The **top section** contains the User Interface that runs the treatment program. The **middle section** contains the modules used for the safe transmission of the blood to and from the dialyzer. Dialysate is the primary concern of the **bottom section** of the RenalyxTreat hemodialysis machine. Here the concentrates used to make up the dialysate are mixed and pumped to the dialyzer.

Followings are different views of the RenalyxTreat hemodialysis machine:

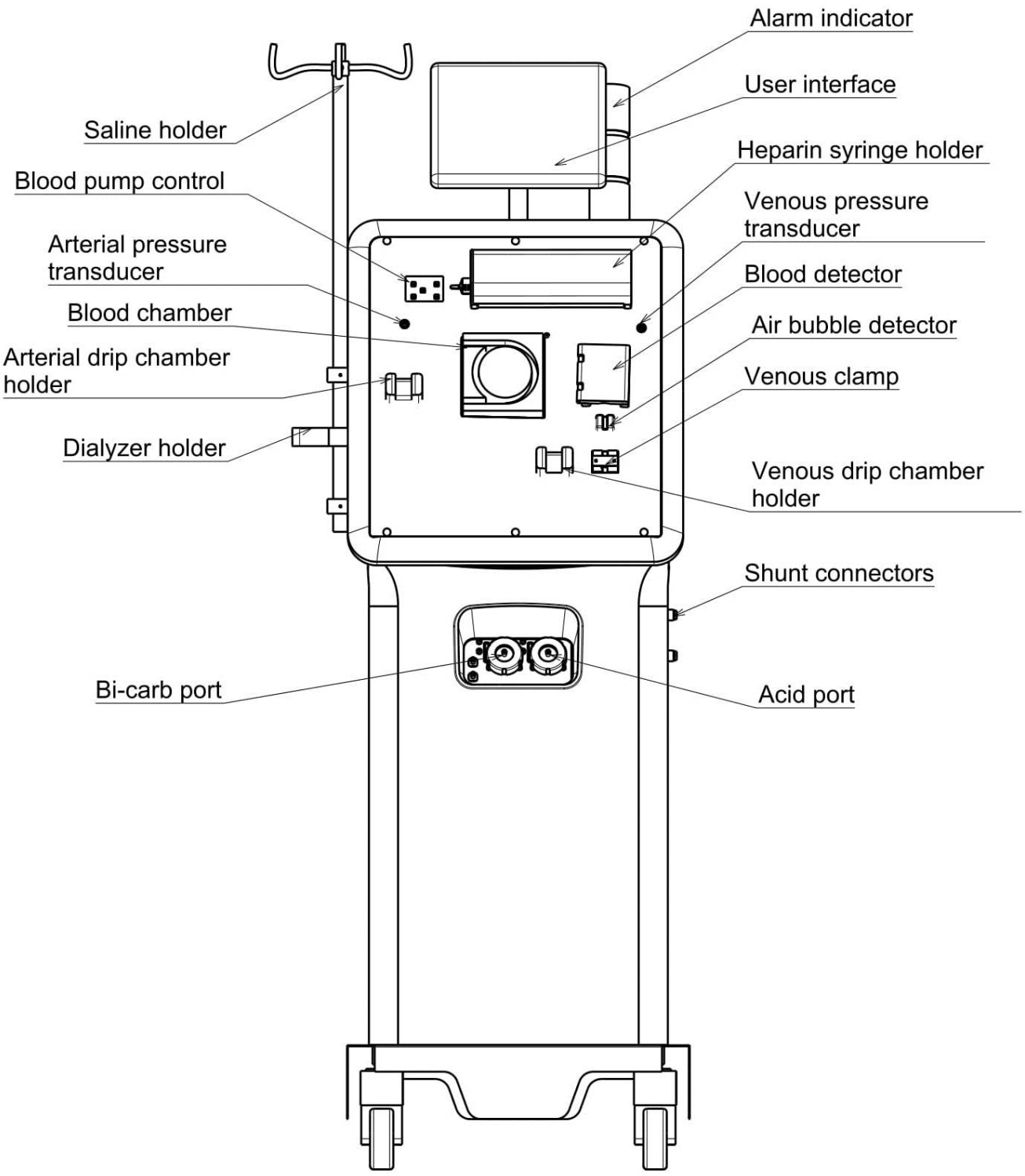

Figure 1: RenalyxTreat Hemodialysis machine front view

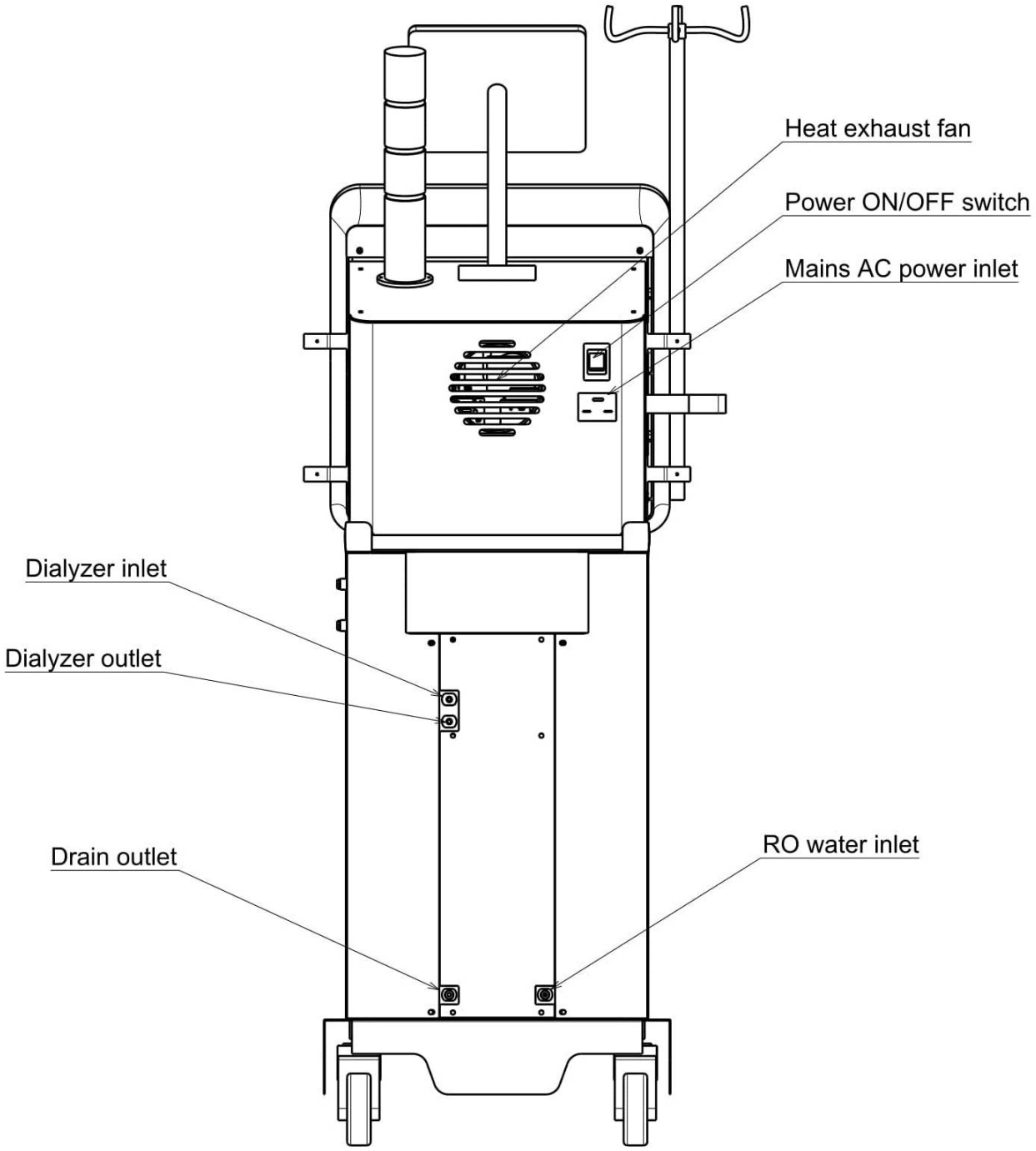

Figure 2: RenalyxTreat Hemodialysis machine Rear view

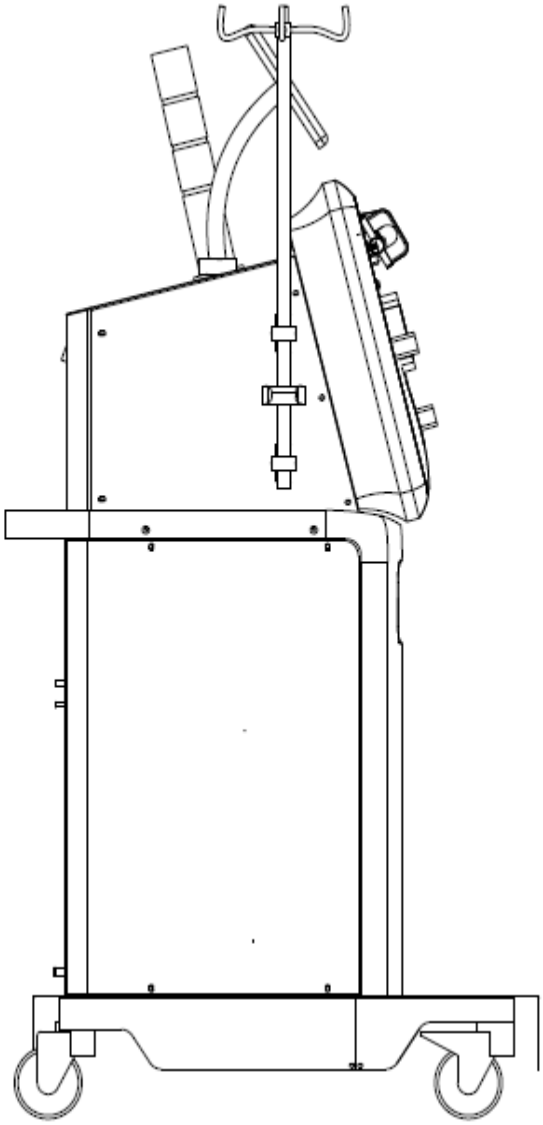

Figure 3: RenalyxTreat Hemodialysis machine Left view

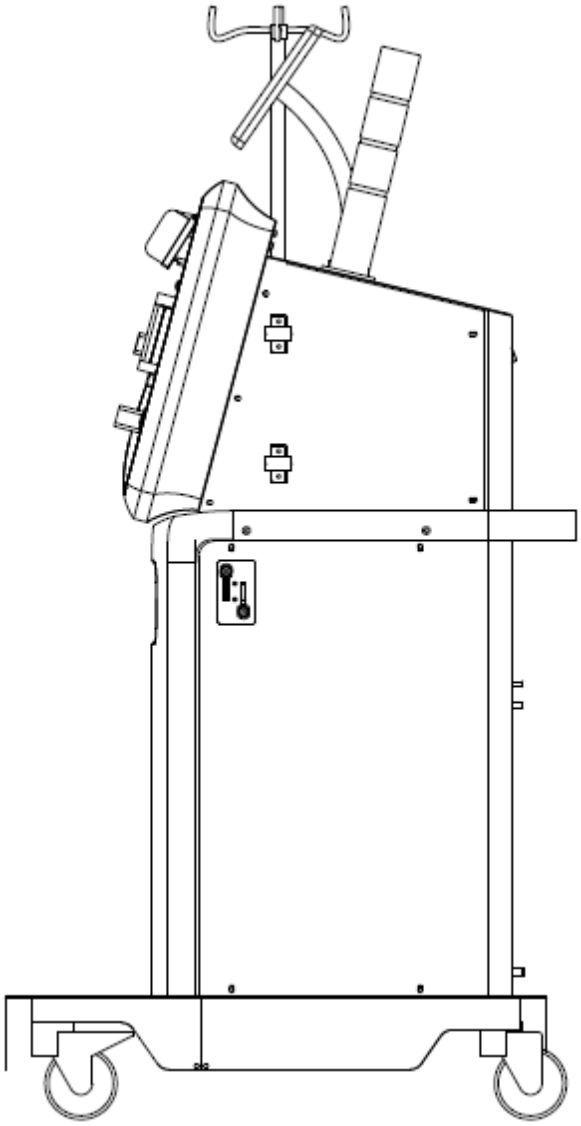

Figure 4: RenalyxTreat Hemodialysis machine Right view

1.3. User Interface

The tablet is required for user interface. HD machine functions are controlled via touch screen feature. The tablet will communicate with the machine through USB interface connections and controls (Figure 5).

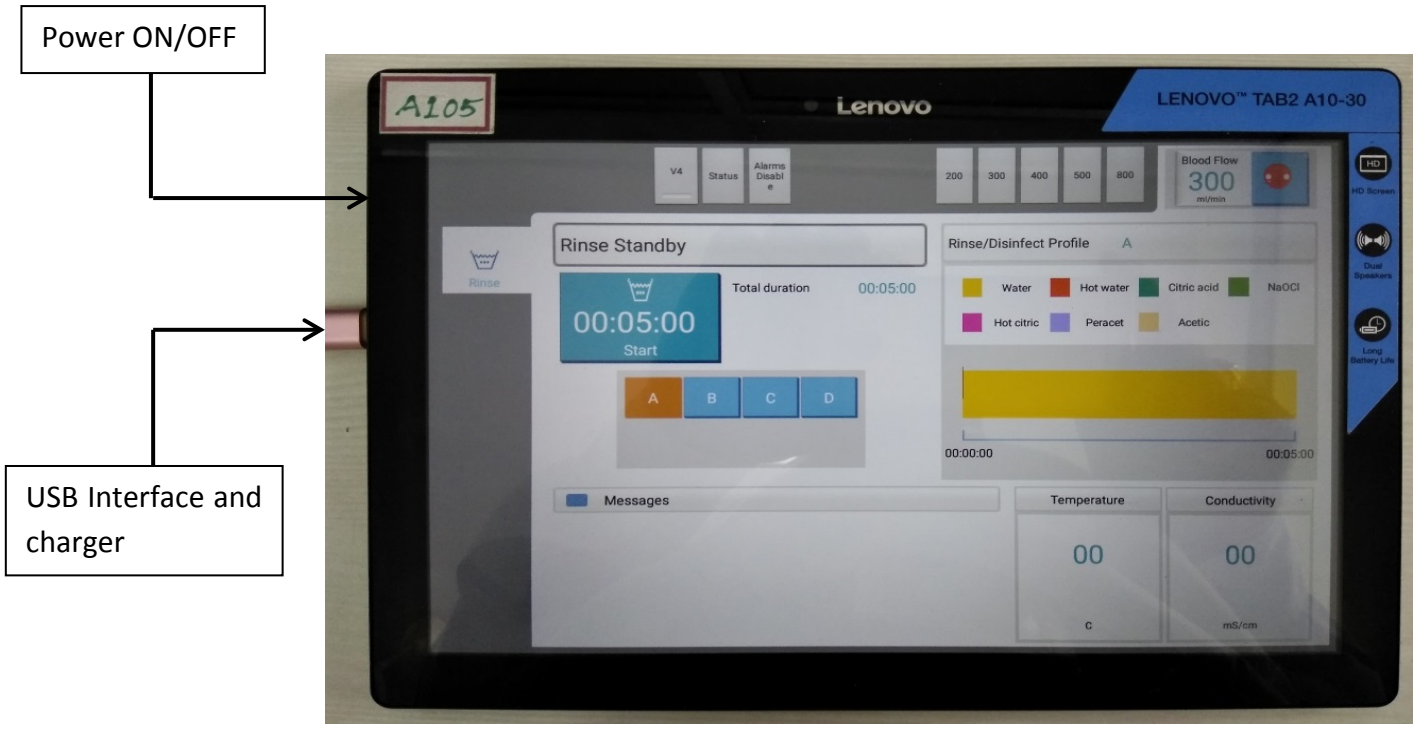

Figure 5: User interface connections and controls

1.4. User Interface Layout

The UI layout overview is depicted with the sample screen shot that provides an insight of common flow of user operation that can be carried out as shown (Figure 6).

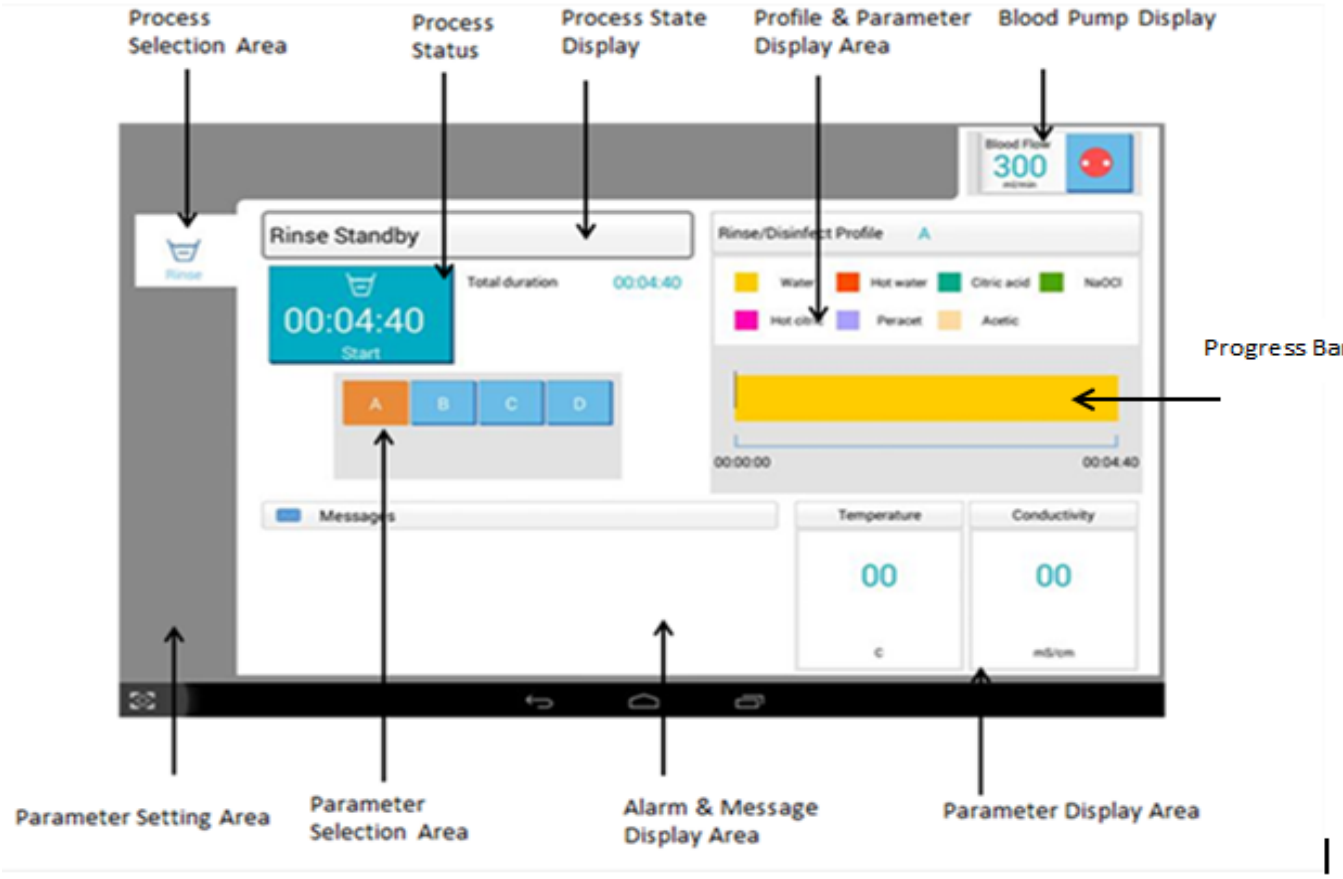

Figure 6: UI Layout Structure

2. Preparation for treatment

2.1. Machine Power ON

Power ON the mains power supply, heater and switch on the tablet. System will boot up and carries out self-test to check all the system vitals (Figure 7)

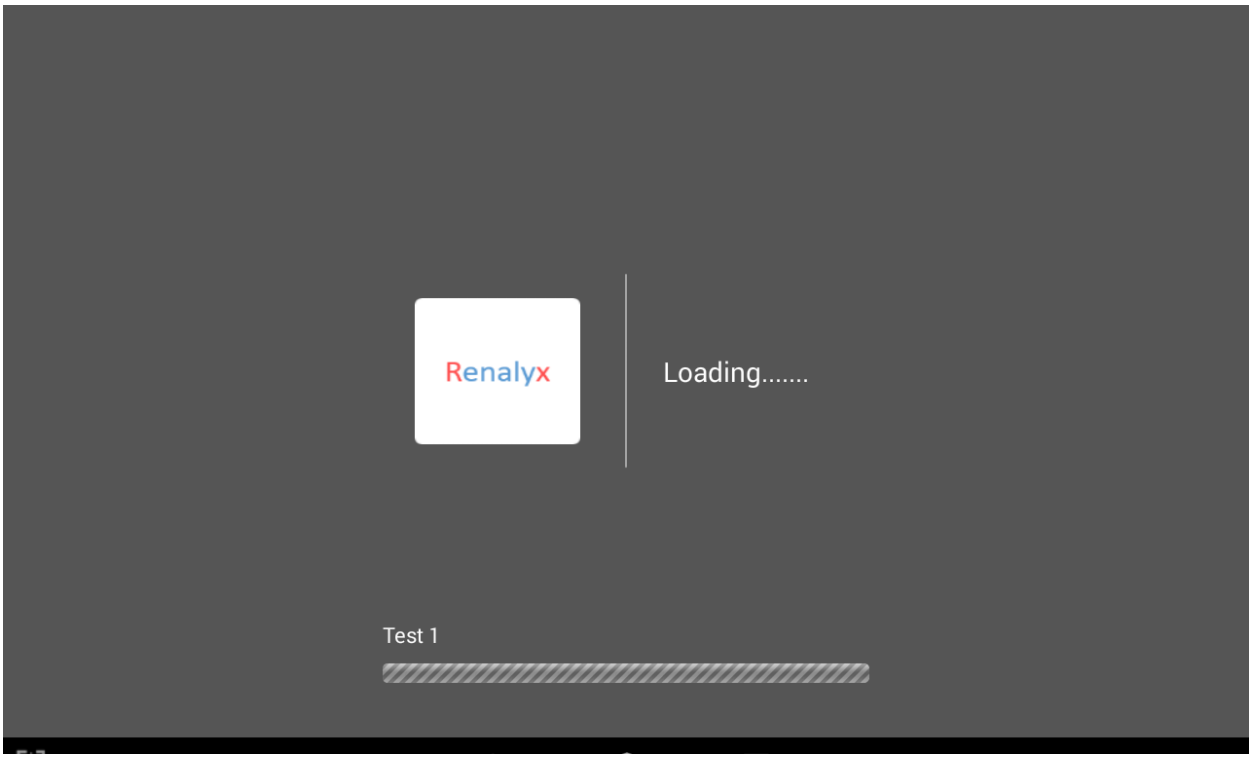

Figure 7: Boot up Screen

During the Self-test following tests are carried out internally:

- + 24 V test
- +/- 12 V test
- + 5 V test
- Display synchronization test
- Arterial pressure sensor test
- Venous pressure sensor test
- Blood leak detector test
- Air bubble detector test
- Blood detector test
- Venous clamp test
- Blood pump test
- Backup Battery test
- Ultra-filtration pump test

- Dialysate Conductivity sensor test
- Dialysate Temperature sensor test
- Alarm system (Sound + Display)

On the screen, the test in progress with name of the self-test along with bar indicating the action will be displayed as each self-test progress. Once all self-tests are completed the screen with self-test result will be displayed indicating which tests have passed and which tests have failed.

User required action needs to be taken to fix the failed tests before user can access the **Login** in to treatment mode. User can Login to machine after successful completion of the self-test. User will select the treatment mode to carry out dialysis process.

2.2. User Login

Pop up screen appears when the entire self-test is successfully completed providing user with login option to choose Nurse Mode or Technician Mode with password entry (Figure 8)

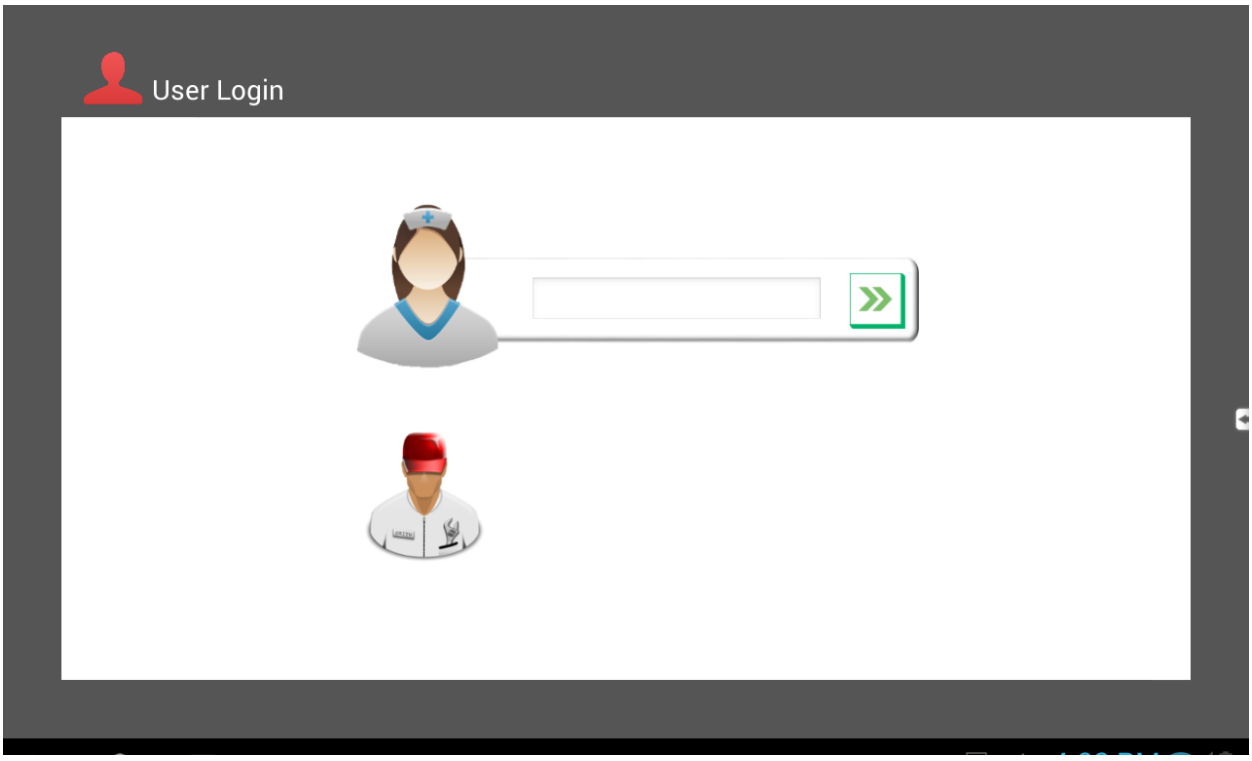

Figure 8: Login Screen

2.3. Program Mode Selection

After successful login, user enters in to program selection mode where option is provided to select either Treatment mode or the calibration mode. Press the  icon to enter in to the Rinse screen as shown in Figure 9.

Note: Calibration icon  is meant for Calibration of the machine and it is recommended to use this function by the service engineer during maintenance.

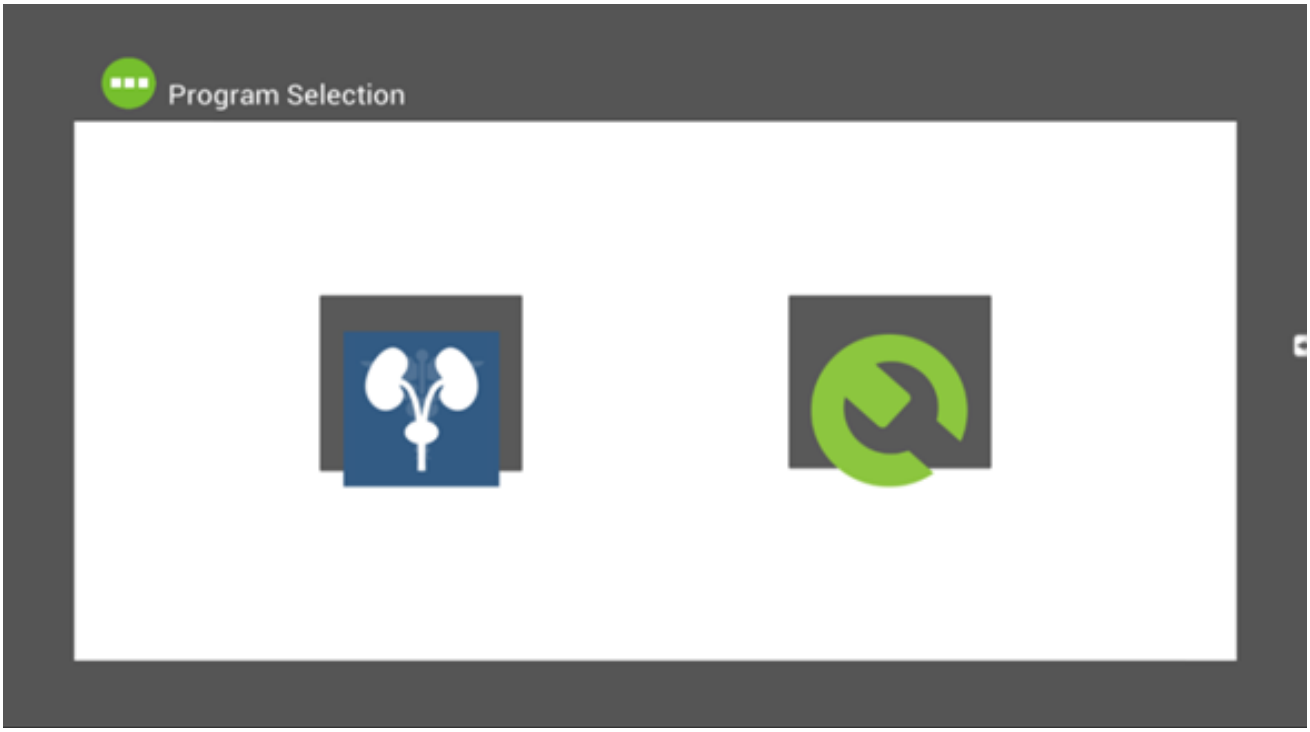

Figure 9: Program Selection

2.4. Rinse mode

Connect the acid and bicarbonate probes to the machine. Connect dialyzer inlet and outlet to the dialyzer shunt connection. Select profile A and Press “Start” Icon to start the RO water rinse.

Inlet permits RO water to flow through the dialysate path at 800ml/min for 15 minutes duration at an ambient temperature to remove the residuals of chemicals in the dialysate path.

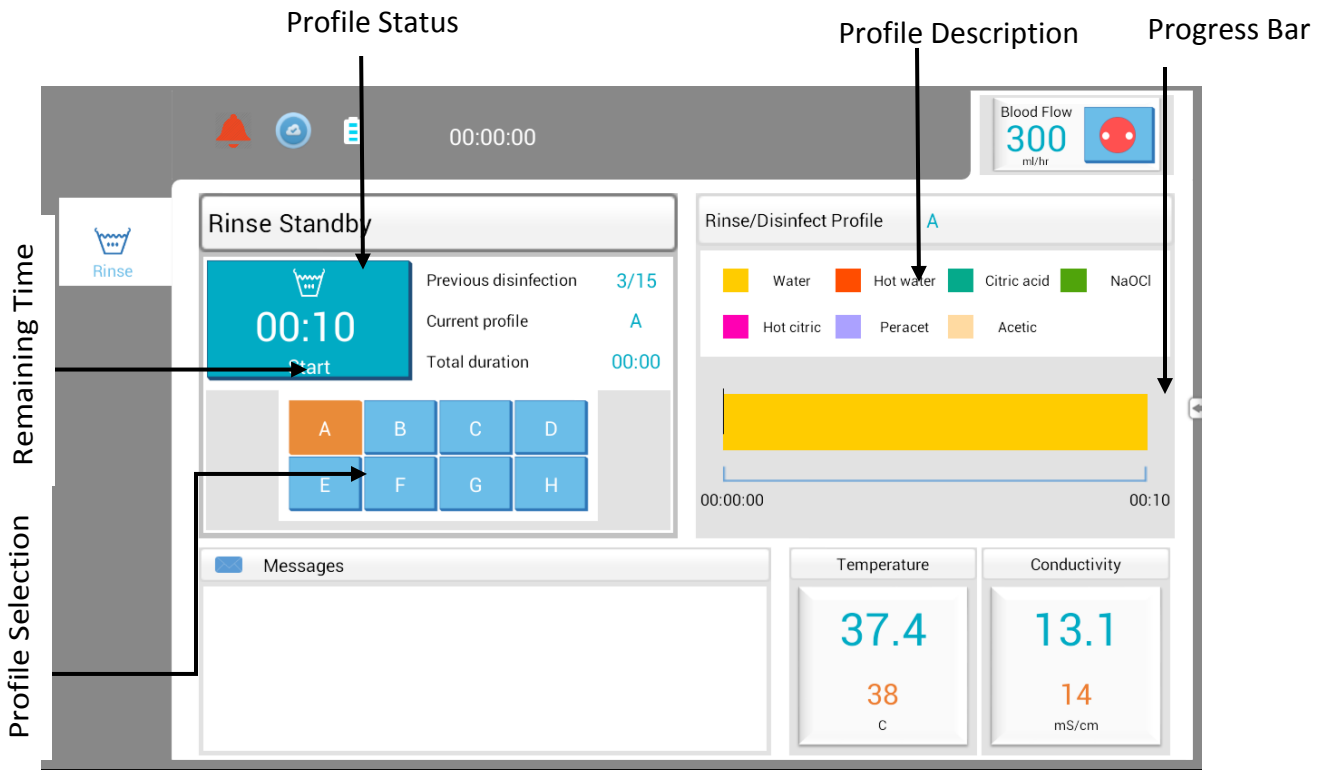

Figure 10: Rinse and Disinfection Selection Screen

2.5. Preparation mode

2.5.1. Extracorporeal blood circuit set-up

Hang the saline bag (1.0 L) on the saline holder. Using aseptic precautions spike the saline bag with the infusion set. Attach saline infusion line to the saline port of the arterial bloodline. Mount dialyzer onto its holder with arterial side facing down.

2.5.2. Arterial bloodline connection

Clamp medication port of the arterial bloodline. Place the arterial chamber of the line into its holder. Using the transducer protector connect the arterial line to the arterial pressure port. Verify that the monitoring line is unclamped.

Open the blood pump door and check the blood pump rotor for proper operation. Run the arterial segment of the blood pump (thick side) through the pump by manually rotating it, using the red guidelines shown on the machine.

Connect the saline line to the arterial blood line. Place the patient end of the arterial line into the disposable priming bag. Once connected, the arterial bloodline connection screen is displayed (Figure 11). After arterial blood line connection is completed, Press “NEXT” Icon to proceed to continue with gravity prime of arterial blood line.

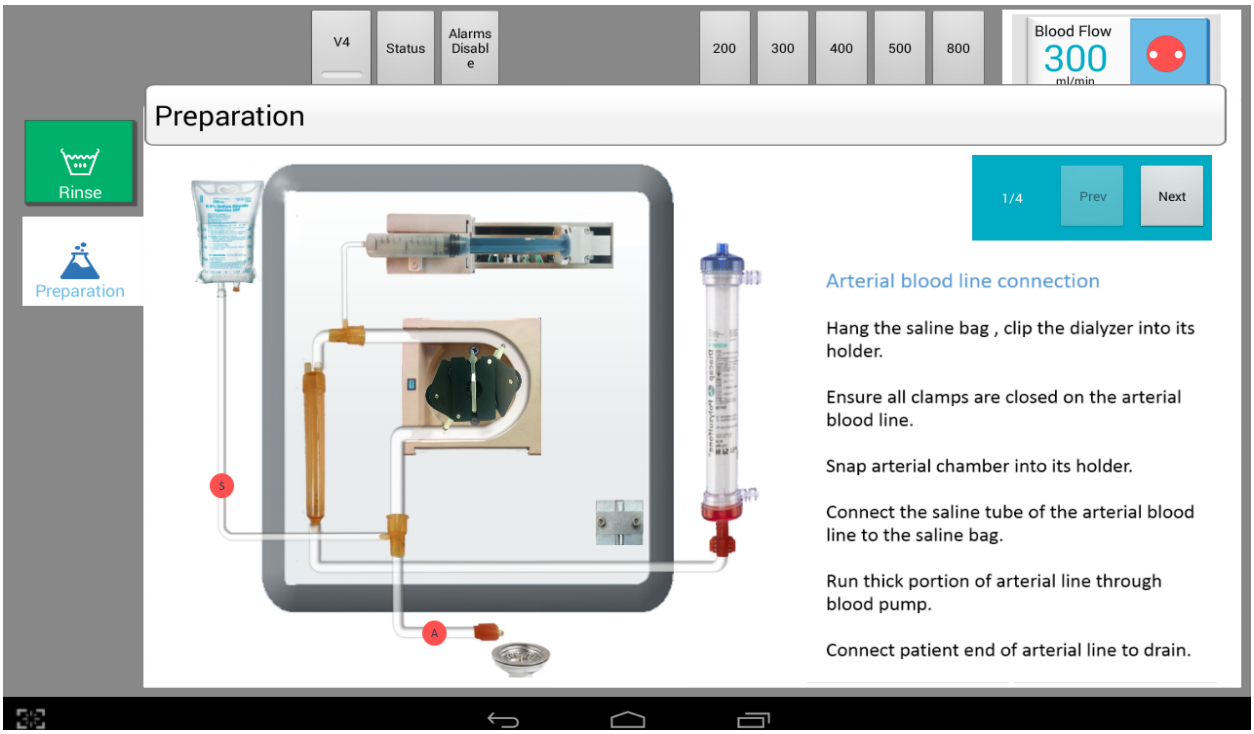

Figure 11: Arterial Blood Line Connection

Open the saline clamp and the arterial end patient clamp. Allow saline to flow out of the arterial bloodline, to ensure air bubbles are removed.

Fill the arterial drip chamber to acceptable level. Close the arterial pressure monitor line clamp and disconnect the line from the arterial pressure port so the port is open to atmosphere.

Priming instruction screen is displayed (Figure 12). Press NEXT Icon to continue with “arterial blood line priming”.

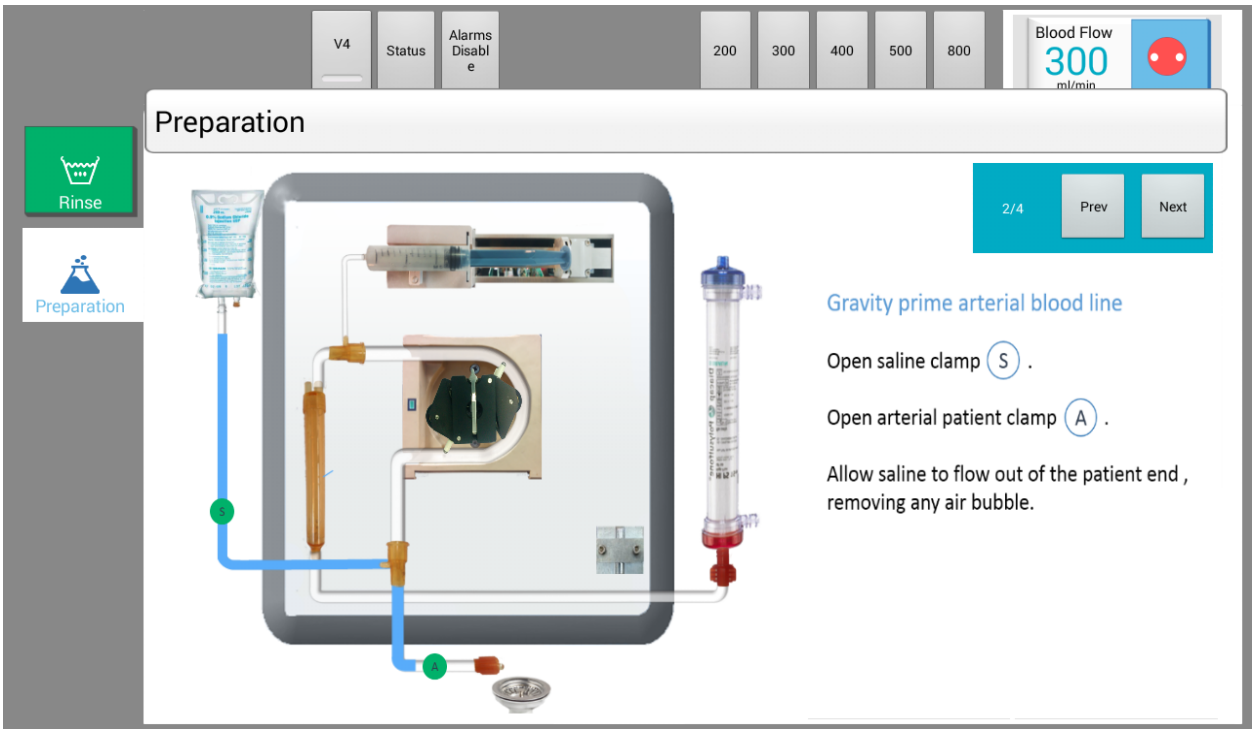

Figure 12: Gravity Priming of Arterial Bloodline

Clamp the patient end of the arterial bloodline and open the dialyzer end of the tube. Start the blood pump and allow saline to drain until the air bubbles are removed from the arterial line.

Prime to remove air from the heparin line using a saline filled syringe. Load the heparin syringe with heparin into the heparin pump.

After arterial bloodline is filled with saline, stop the blood pump. Connect the dialyzer end of the arterial bloodline to the arterial port of the dialyzer. Arterial bloodline priming instruction screen displayed on (Figure 13).Press next to continue with the venous blood line connection.

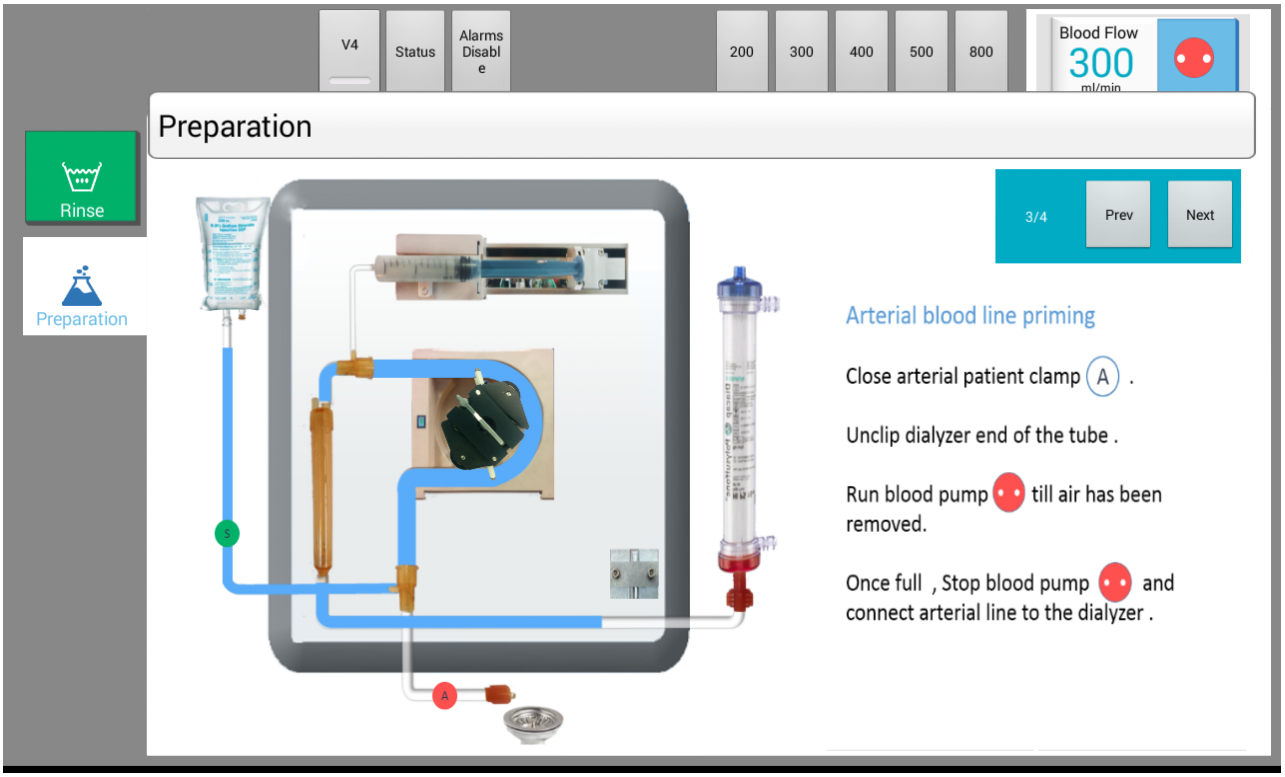

Figure 13: Arterial Blood Line Priming

2.5.3. Venous bloodline set-up

Close the medication port of the venous bloodline. Place the venous drip chamber into its holder. Connect the venous pressure monitor line to the pressure port through the transducer protector with the monitoring line kept open. Place venous tubing along the blue guidelines as shown on the machine. Place the patient end of the venous line to the disposable priming bag. Venous bloodline connection instruction screen is displayed on Figure 14.

After venous bloodline and heparin line connection completion then press on “DONE” Icon to start the saline priming.

The Saline priming screen is displayed on the (Figure 15).

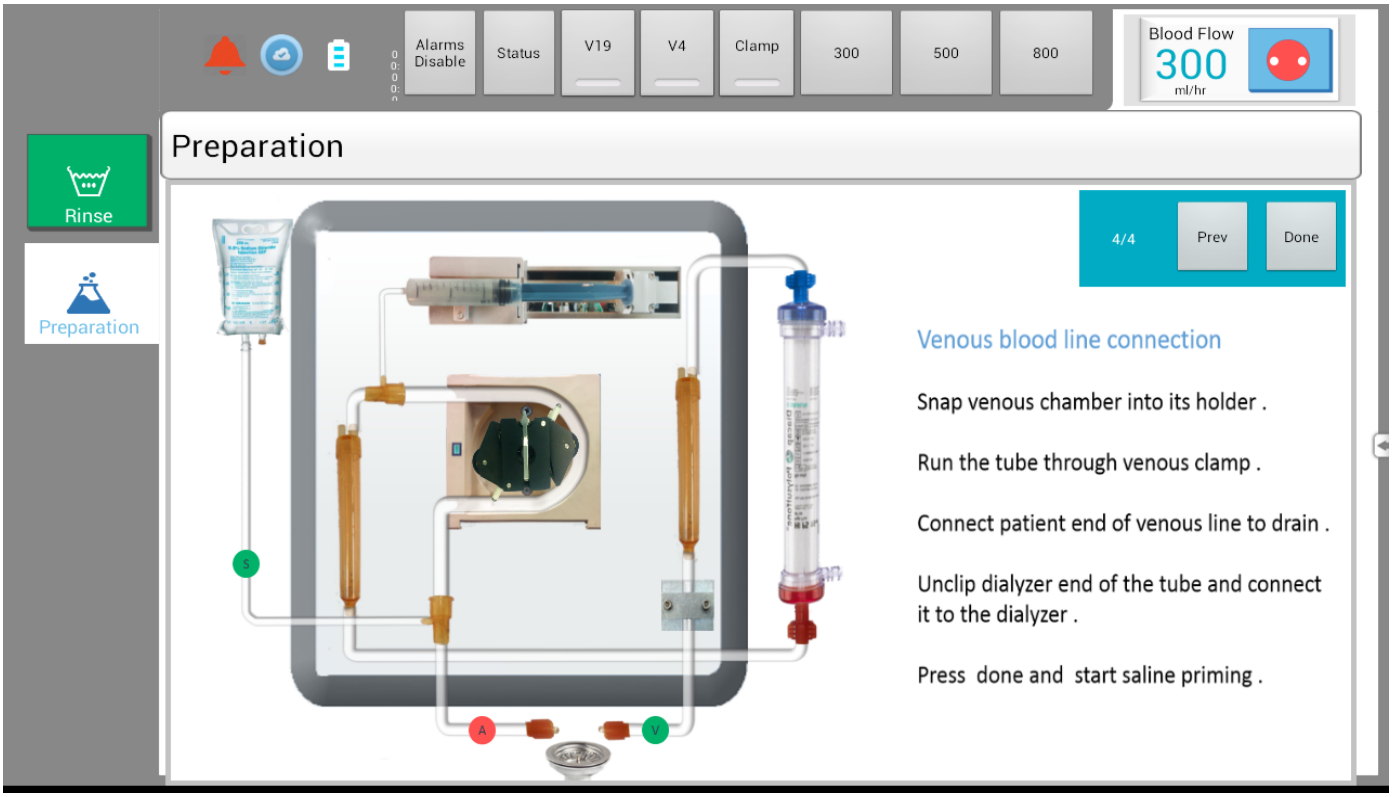

Figure 14: Venous Blood Line Connection

2.5.4. Saline Priming

After the arterial and venous blood line connections are done start the saline priming by pressing the start Icon as shown in Figure 15.

After “start” icon is pressed, blood pump allows to circulate the saline and drain out until the air bubbles are removed from the venous line. In case of air trapping dialyzer can be inverted and tapped to remove the air bubbles completely from the system.

Fill the venous drip chamber up to required level. Close the venous pressure monitor line clamp and disconnect the monitor line from the venous pressure port so the port is open to atmosphere.

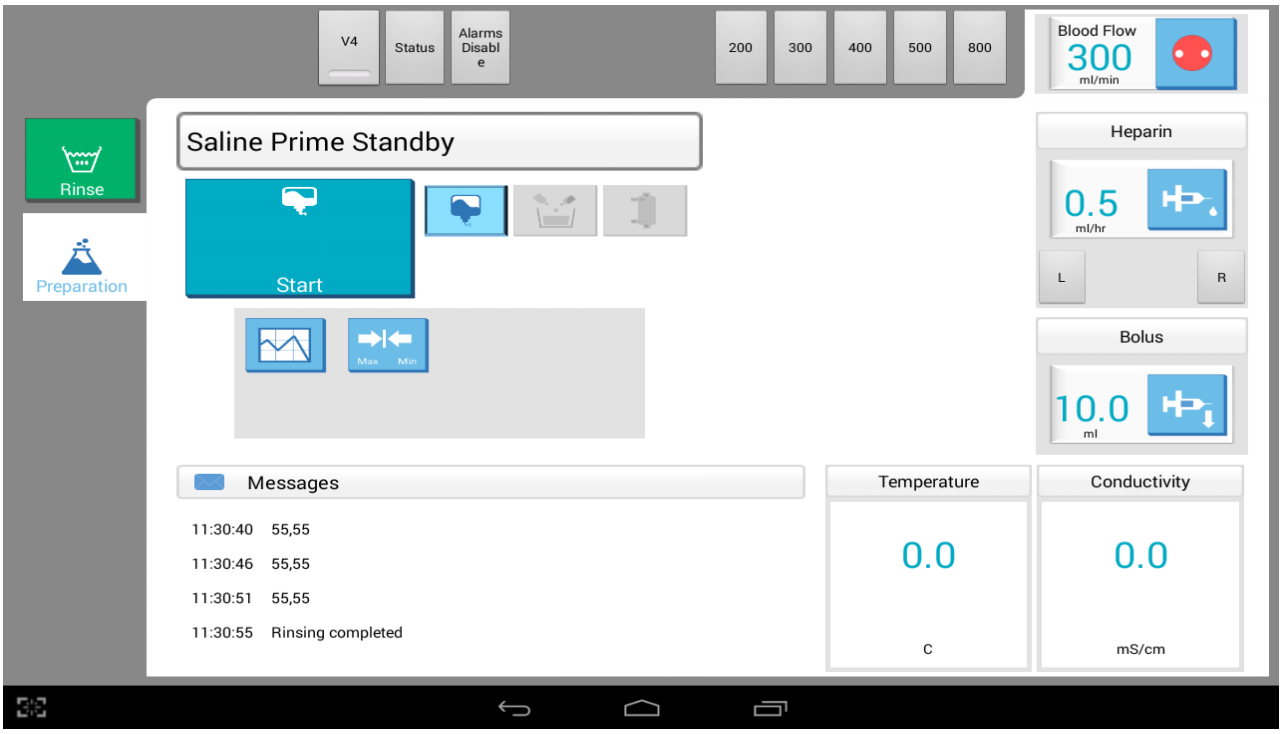

Figure 15: Saline Priming

2.5.5. Recirculation

After Completion of saline priming, automatically recirculation screen displayed (Figure 16).

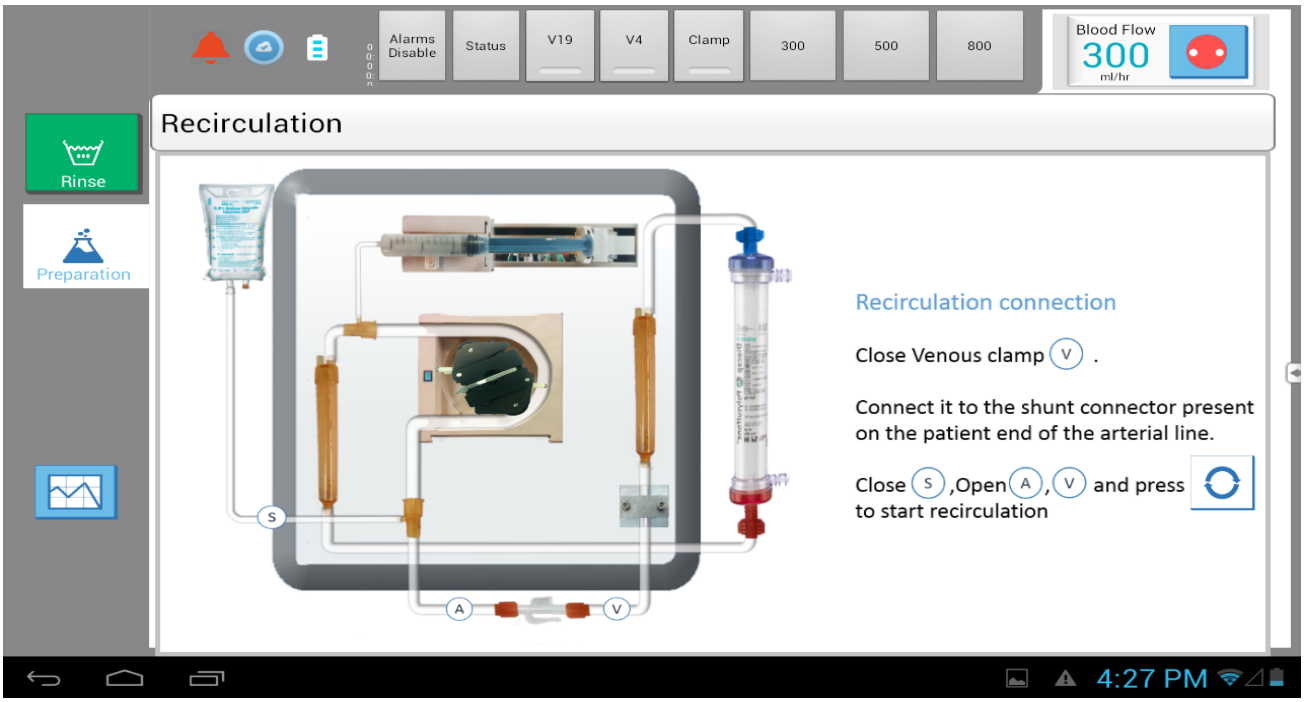

Figure 16: Recirculation

Connect the arterial and venous ends of the tubing using recirculation tube. Open arterial and venous patient side clamp and start recirculation.

2.5.6. Dialysate Preparation

After successful completion of saline recirculation UI displays the dialysate preparation screen.

User will ensure Acid probes (RED) and Bicarbonate (BLUE) probes are dipped into respective solution containers.

The base mix ratio of Acid: Bicarbonate: Water = 1:1.83:34 is used to prepare the dialysate solution. User will set the values based on doctor prescription:

- Blood flow range (100 ml/min – 400 ml/min)
- Dialysate Conductivity range (13 – 14.5mS/cm; ±0.1mS/cm);
- Dialysate Temperature range (35.5 – 37.5°C; ±0.5 °C accuracy);
- Dialysate Flow rates (300 - 500 - 800 ml/min, ±5 % of set value accuracy).

After confirmation of the set parameters, Press “Start” Icon to start the dialysate Preparation icon as shown in the Figure 17.

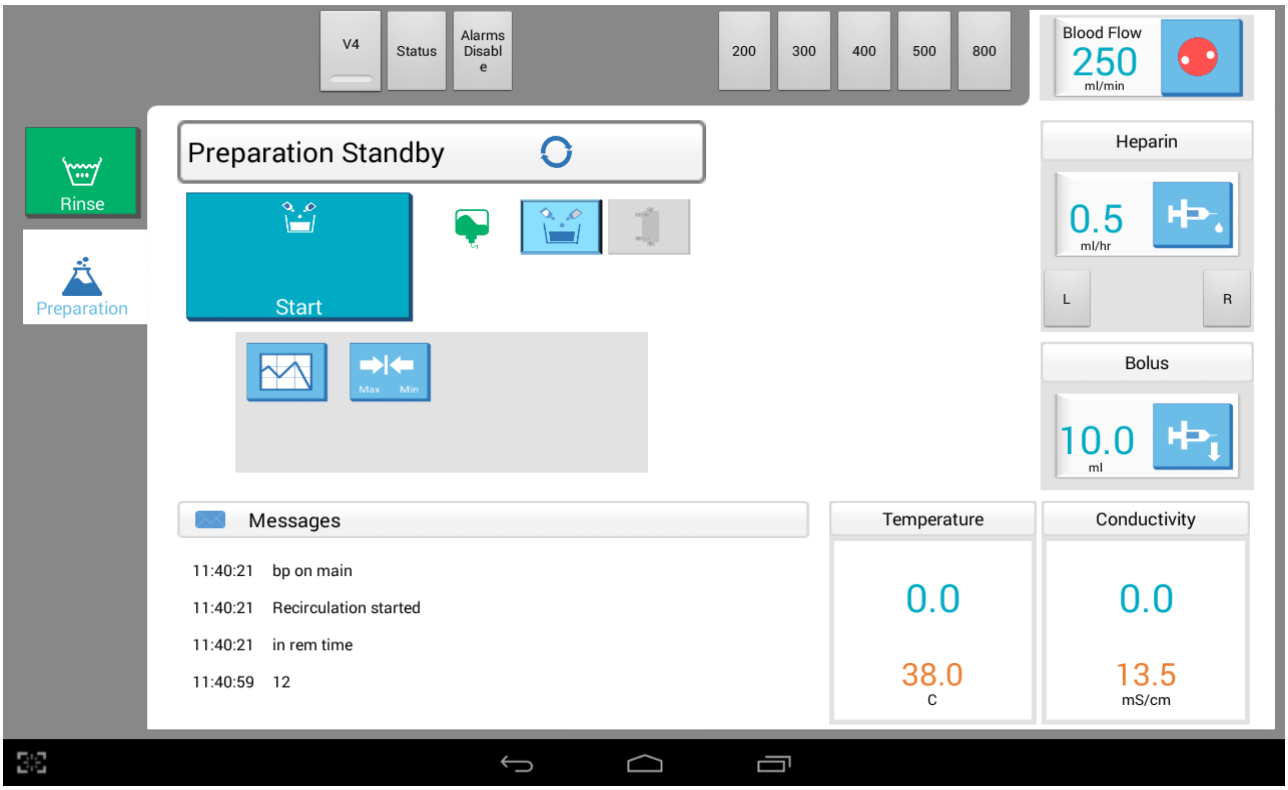

Figure 17: Start Dialysate Preparation

Once the dialysate preparation is started the UI screen is shown as in Figure 18.

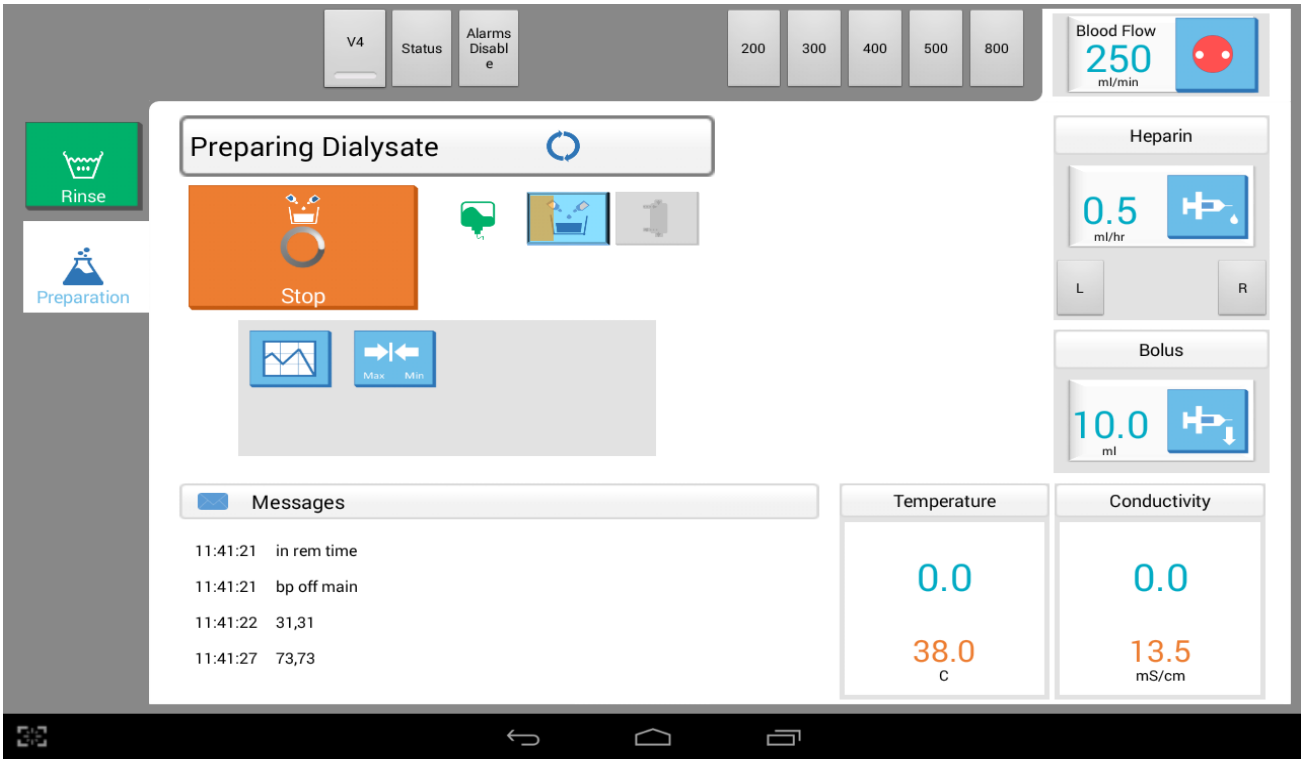

Figure 18: Dialysate Preparation

2.5.7. Dialysate priming

After dialysate is prepared, remove the Red and Blue Hansen connectors from the machine and connect the Red Hansen connector to the Red side of the dialysate port and Blue Hansen connector to blue side of the dialysate port. Priming of the dialysate system with dialysate is then begun. Dialysate flows can be adjusted to a flow rate of either 300 or 500 or 800ml/min.

Dialyzer connection screen is displayed (Figure 19).

After confirmation of the dialyzer connection then dialysate priming screen displayed (Figure 20).

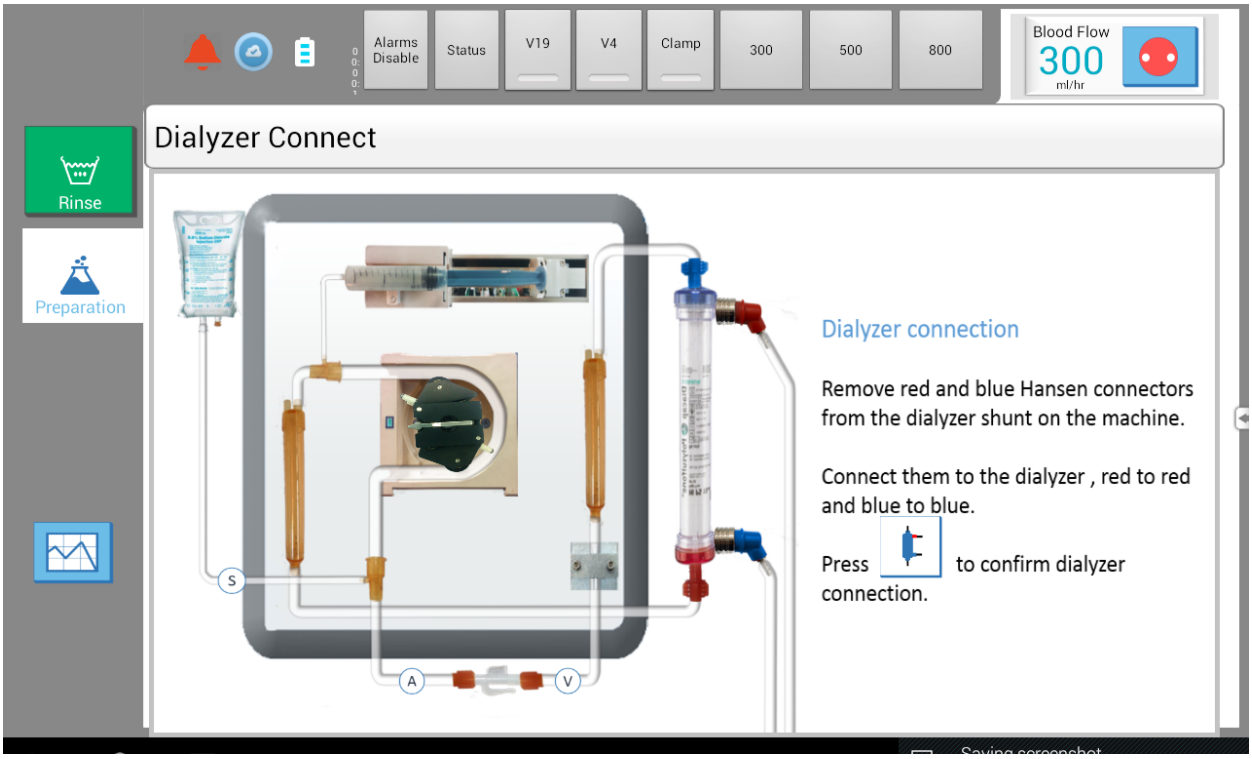

Figure 19: Dialyzer Connection

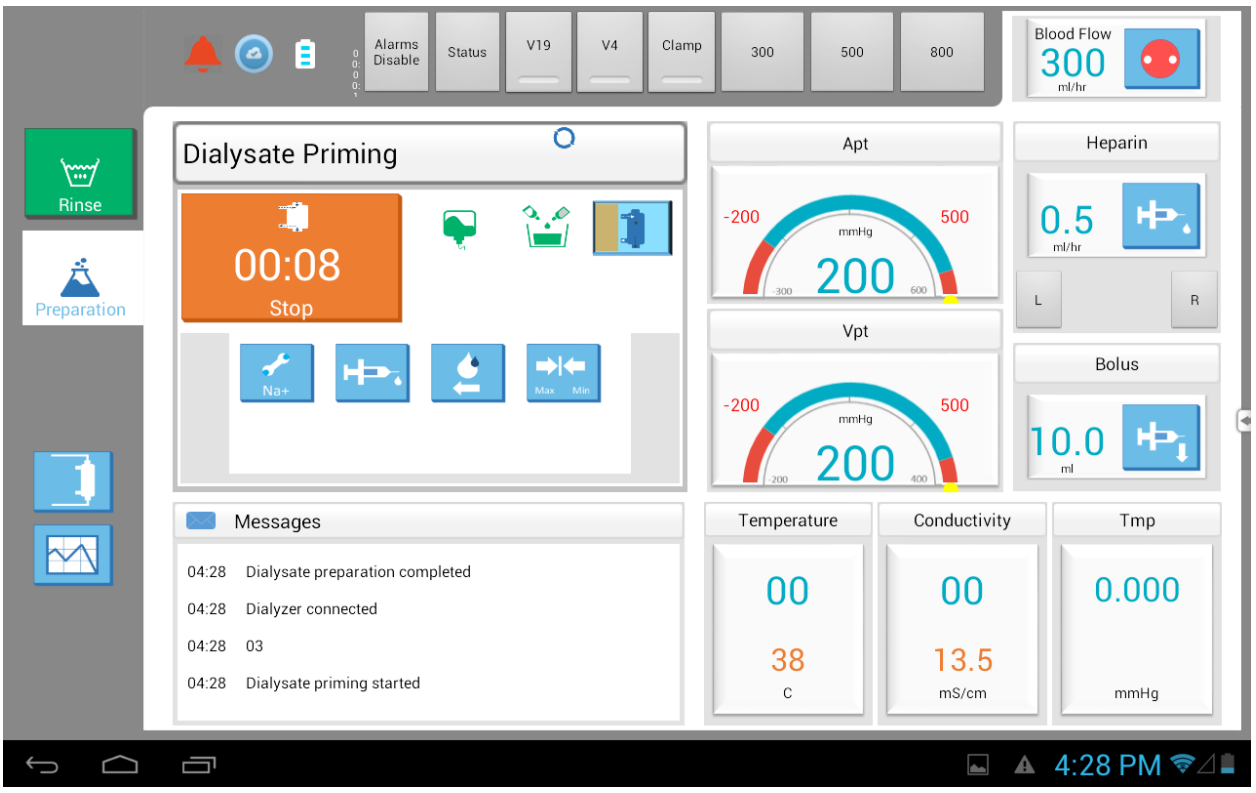

Figure 20: Dialysate Priming

2.5.8. Patient Connection

After dialysate priming is completed, Patient connection screen is displayed (Figure 21).

Clamp the both arterial and venous end of the bloodline remove shunt connectors and connect the arterial line to the vascular access of the patient.

Open the arterial clamp. Run the blood pump at a low speed. Once blood is detected by the blood detector the blood pump will stop. Next, connect the venous end of the blood line to the vascular access of the patient. Open venous end clamp. Run the blood pump and gradually increase the blood flow rate to reach the target volume of patient.

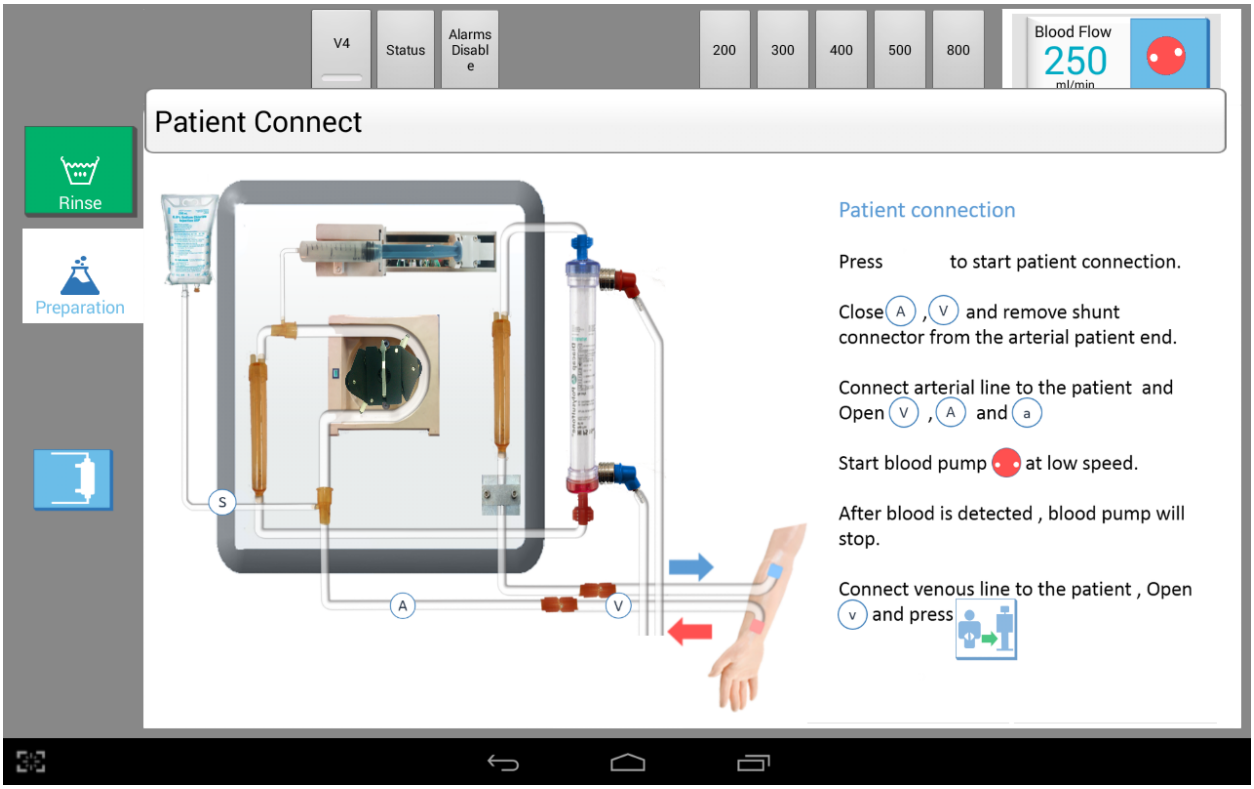

Figure 21: Patient Connection

3. Dialysis

3.1. Start Dialysis

After successful patient connection the UI displays the screen as shown in the Figure 22. Press on "Dialysis" icon to start the Dialysis treatment.

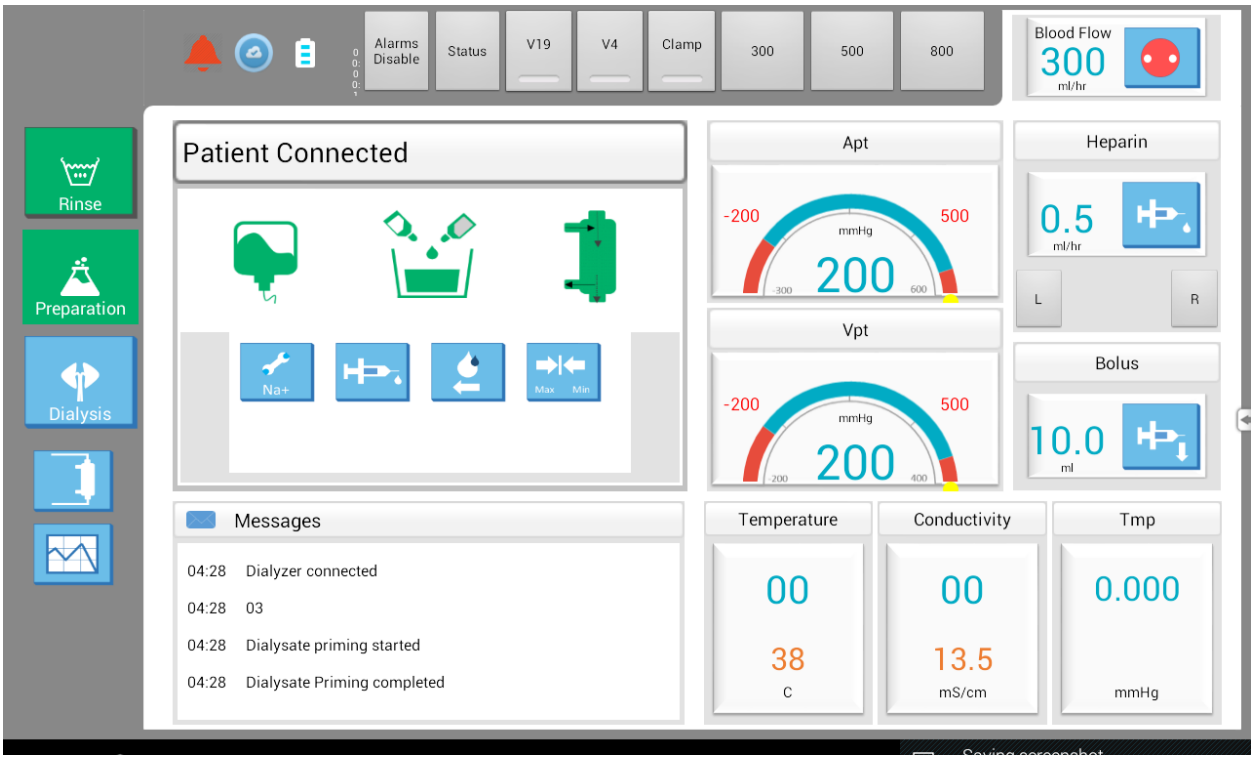

Figure 22: Dialysis Start Screen

Patient treatment parameters and alarm limits are set according to the dialysis prescription. Treatment parameters are set as below before the dialysis begins.

- Dialysis duration
- Blood flow
- Dialysate flow
- Dialysate temperature
- Dialysate conductivity
- UF goal (UF goal set to Zero means UF=OFF)
- UF time
- Heparin bolus volume
- Heparin rate.

Alarm limit parameters set for the following:

- Arterial pressure
- Venous pressure

- Dialysate Temperature
- Dialysate Conductivity
- Trans Membrane Pressure (TMP)

Press on “Start” icon to start the dialysis as shown in the Figure 23.

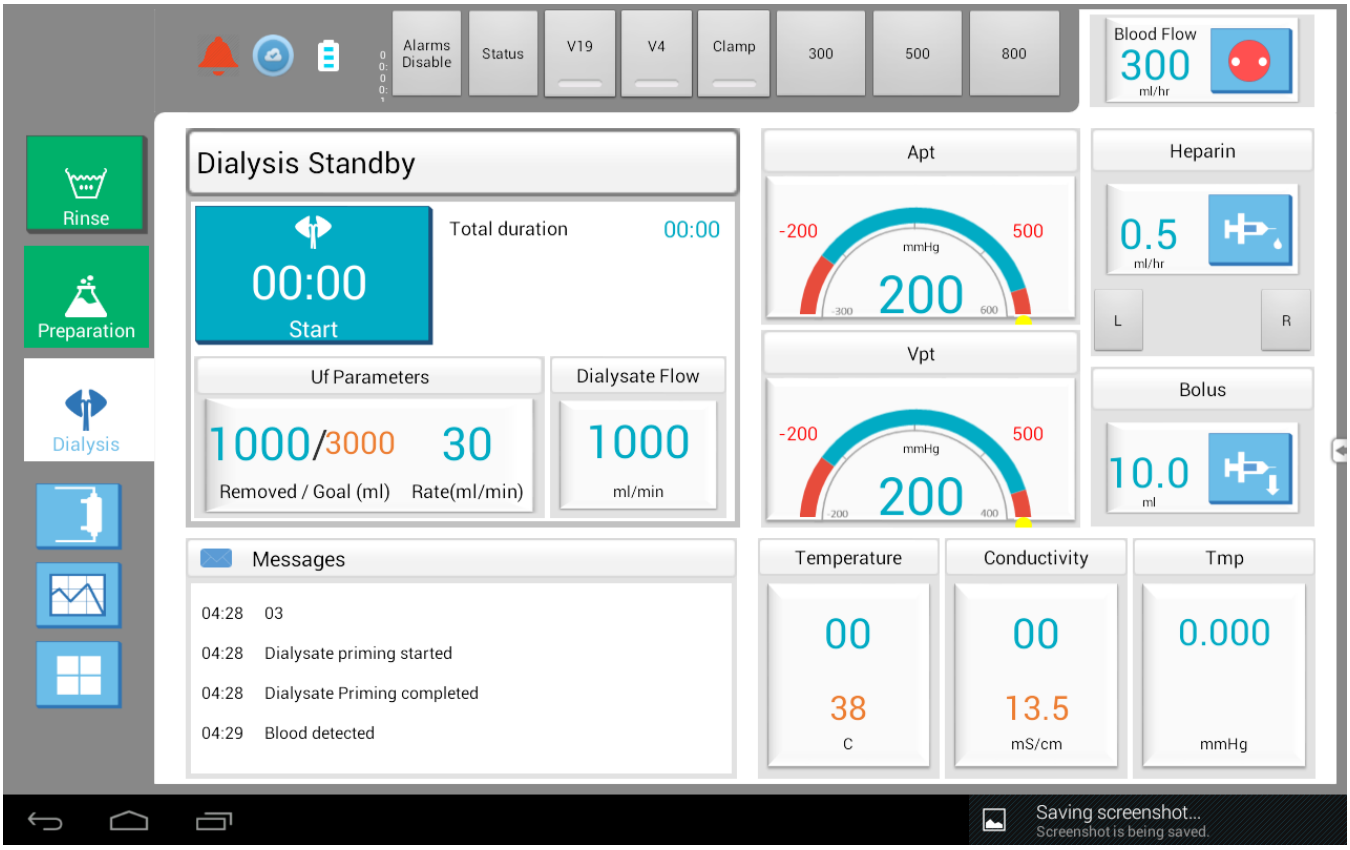

Figure 23: Dialysis standby screen

3.2. Treatment parameters monitoring

After the dialysis is started the UI screen displays the screen as shown in the Figure 24 with patient treatment parameters.

The patient treatment parameters are continuously monitored and documented at predetermined intervals during the entire dialysis session.

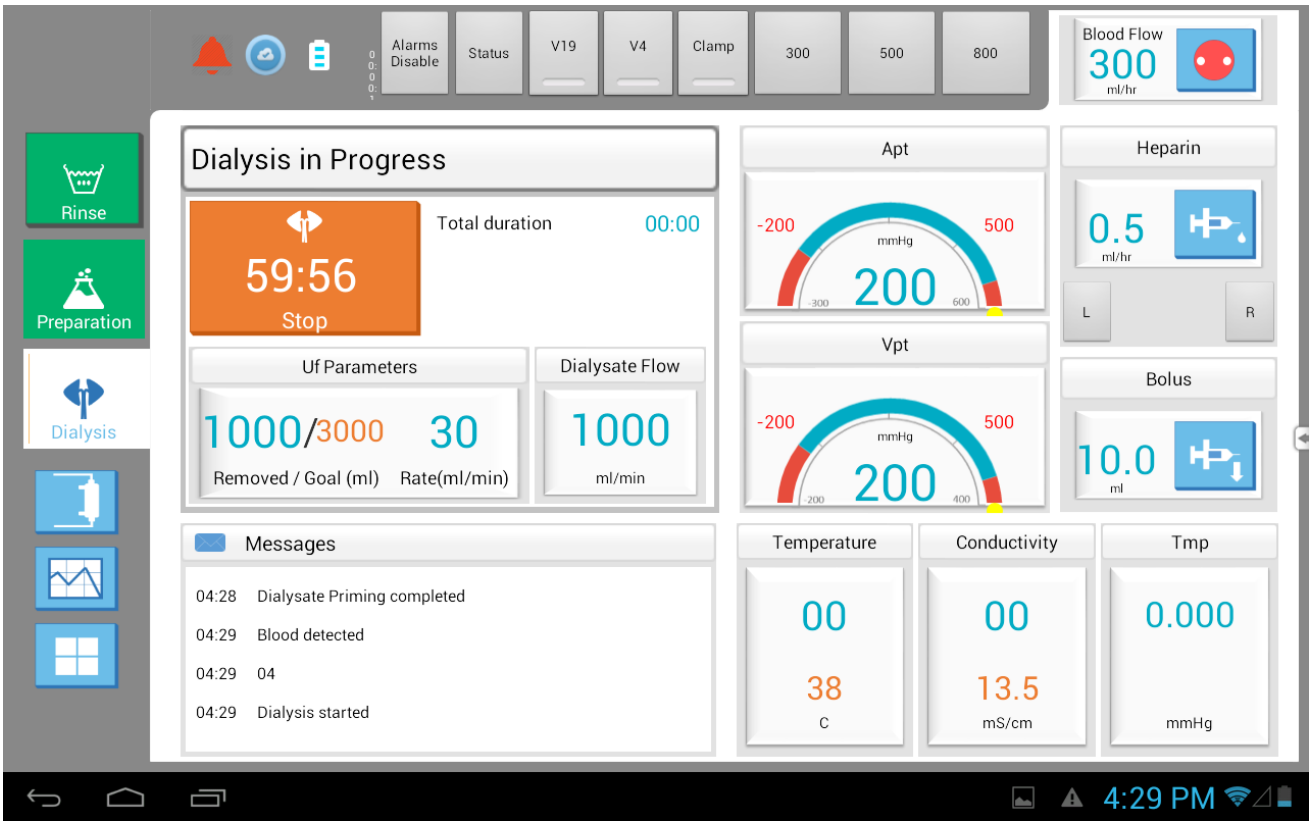

Figure 24: Dialysis monitoring screen with patient treatment parameters

3.3. Dialysis Termination

At termination, clamp the arterial end of the bloodline and release the saline clamp. Start the blood pump to return the blood. Stop blood pump once the blood is returned and saline fills the tube.
Clamp the venous line. Disconnect arterial and venous line from arterial and venous pressure ports. Open the blood pump cover and remove the pump segment by manually turning the pump. Disconnect and discard the dialyzer and bloodlines.
Dialysis complete screen will be displayed (Figure 25). The machine will display the Rinse and Disinfection profile screen to start cleaning and disinfection process for the next treatment.

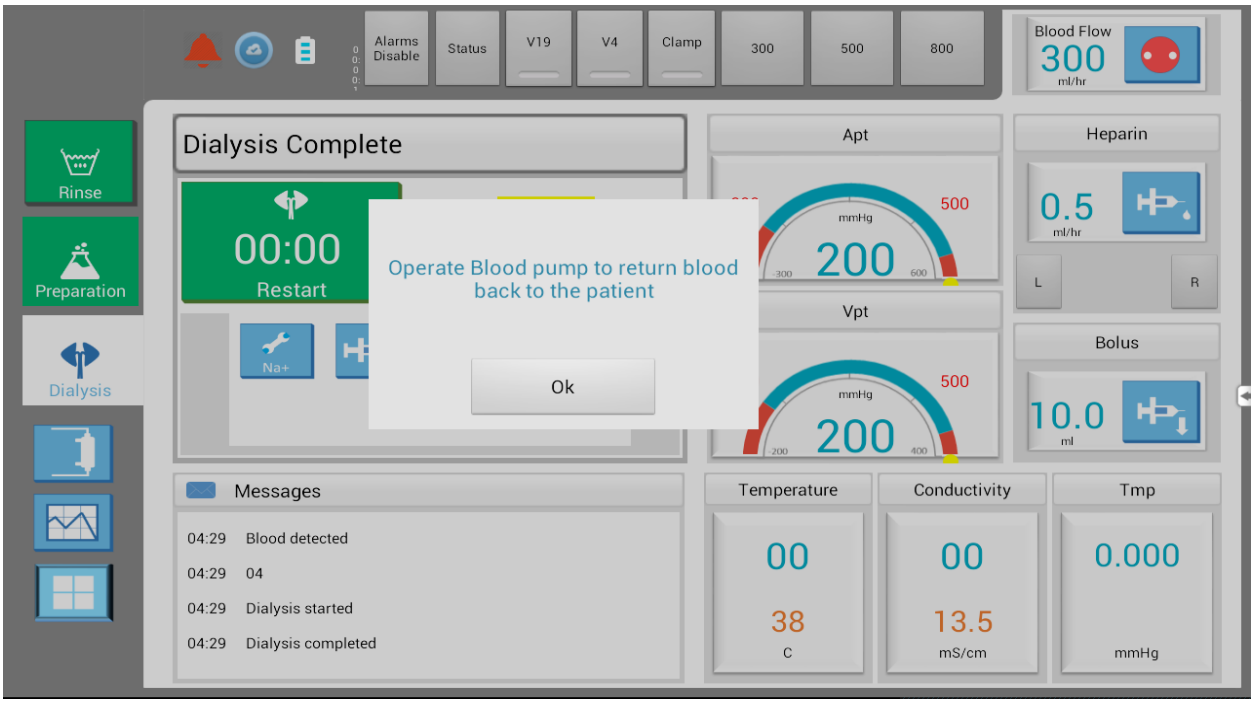

Figure 25: Dialysis Completion Screen

3.4. Power failure during dialysis

In case of a power failure, the blood pump stops and the venous line clamp closes. The dialysate flow pump, heater, blood leak detector, and level detector are non-functional. All function lights go out. A steady, audible alarm will immediately sound for seven minutes that cannot be silenced with the **Mute** key. It can be silenced manually, however, by removing the 12-volt battery from the back of the machine. The back-up of the battery lasts for 20 minutes that backs the blood pump and alarm. The blood can be either returned to the patient and we can stop the dialysis or resume dialysis once connected to a power source or return of power within the 10 minutes.

4. Disinfection and Maintenance

Disinfection and or decalcification is carried by heat, chemical or a combination.

4.1. Heat Disinfection

Connect the acid probe and bicarbonate probe to the machine. Connect arterial and venous port of the dialyzer with the connector.

Heat disinfection program draws water to rinse the system for first 5 minutes. The water is gradually heated over 10 minutes to 80°C - 90°C, heat disinfection is provided for 15-30 minutes at 500ml/min. followed by cooling time of over 10 minutes. The progress bar on the screen will indicate the different phases of the heat disinfection.

Rinse and disinfection profile screen is displayed. Select “B” Hot Water profile and start the heat disinfection (Figure 26).

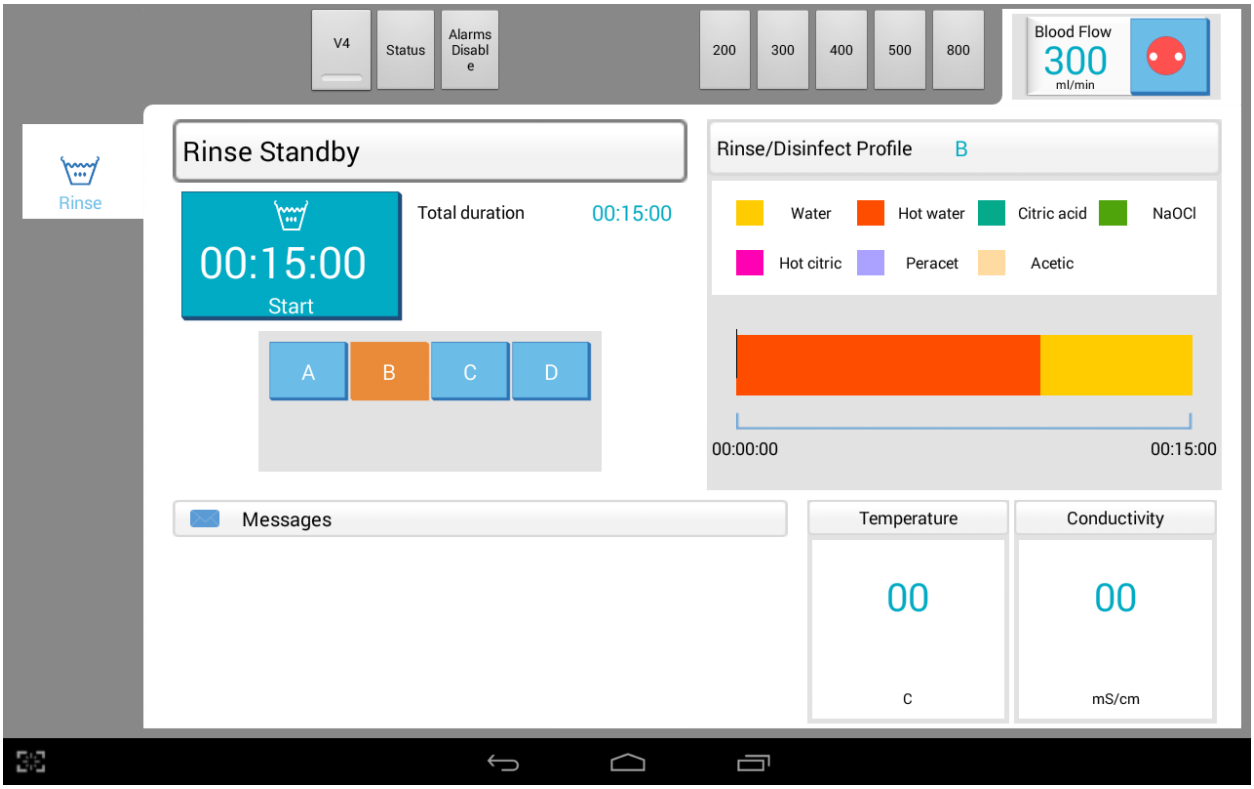

Figure 26: Heat Disinfection Screen

4.2. Citric Acid Decalcification

Citric acid decalcification will remove build-up of bicarbonate precipitate in the hydraulics of the machine.

Connect the acid and bicarbonate probe to the machine. Connect arterial and venous port of the dialyzer with the connector.

The citric acid program draws water to rinse the system for first 5 minutes until a message pops up on the screen to remove the bicarbonate probe.
Remove Bicarbonate probe from the machine and dip into citric acid (5%) container to draw citric acid into the machine. Chemical disinfection at 500ml/min for 10 to 20 minutes occurs until a message pops up again on the screen to reconnect the bicarbonate probe to the machine. Water rinse is carried out for 15-30 minutes to clear the chemicals.
Rinse and disinfection profile screen is displayed. Select “C” Citric Acid profile and start the citric acid chemical disinfection (Figure 27).

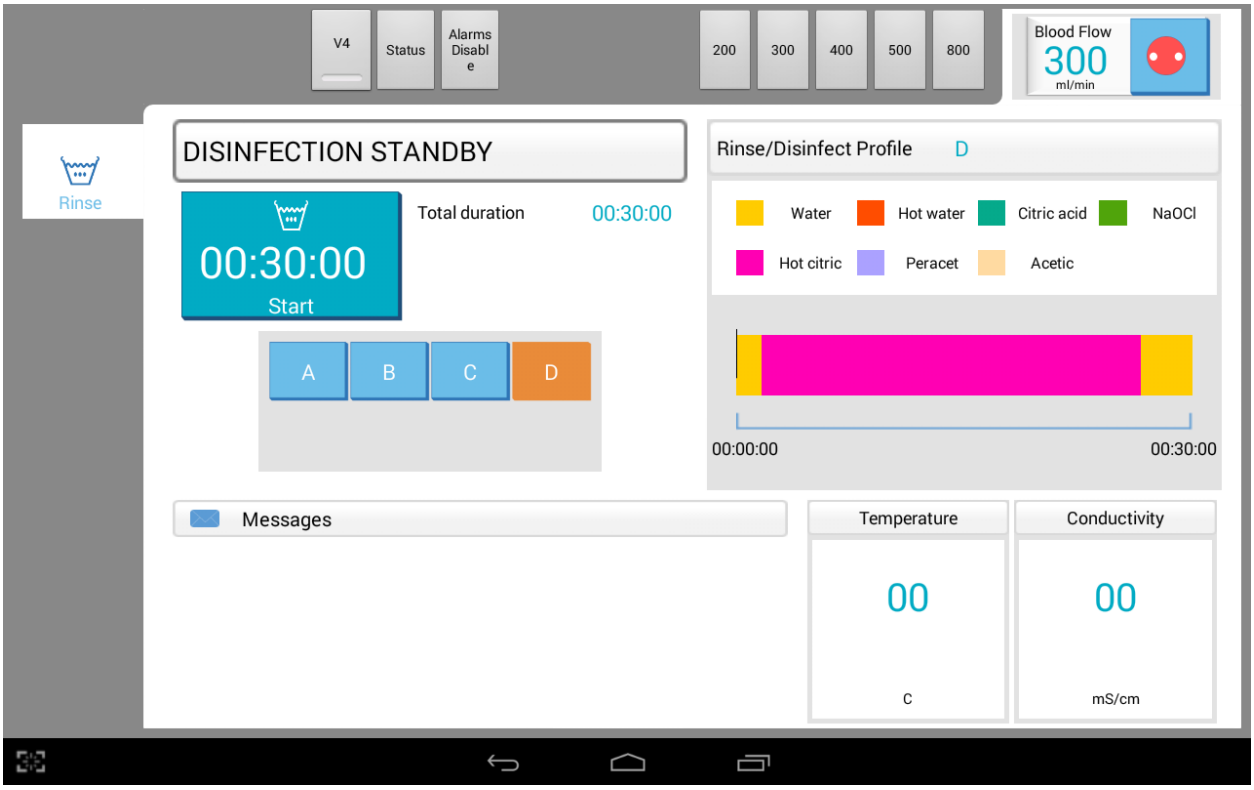

Figure 27: Citric acid Disinfection Screen

4.3. Bleach Disinfection

Bleach is used to disinfect the dialysate system.
Connect the acid and bicarbonate probe to the machine. Connect arterial and venous port of the dialyzer with the connector.
The bleach program draws water to rinse the system for first 5 minutes until a message pops up on the screen to remove the acid probe.
Remove acid probe from the machine and dip into bleach (5%) container to draw bleach into the machine. Chemical disinfection at 500ml/min for 10 to 20 minutes is run until a message pops up again on the screen to reconnect the acid probe to the machine. Water rinse is carried out for 15-30 minutes to clear the chemicals. A chlorine strip test will ensure for the presence of residue at the end of this cycle.
Rinse and disinfection profile screen is displayed (Figure 28). Select “D” NaOCl (Bleach) profile and start bleach chemical disinfection.

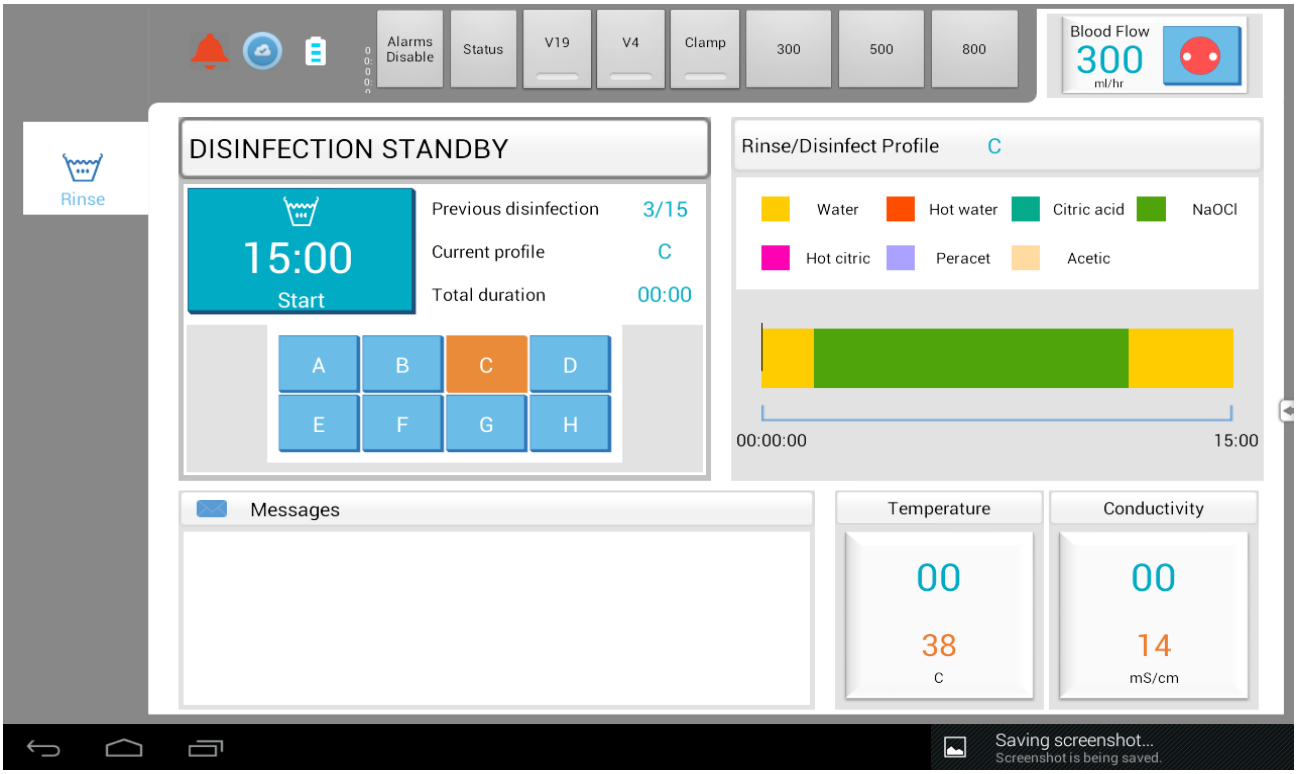

Figure 28: Bleach Disinfection Screen

4.4. Heat Chemical Disinfection

Connect the acid and bicarbonate probe to the machine. Connect arterial and venous port of the dialyzer with the connector.

The citric acid program draws water to rinse the system for first 5 minutes until a message pops up on the screen to remove the bicarbonate probe.

Remove Bicarbonate probe from the machine and dip into citric acid (5%) container to draw citric acid into the machine. The citric acid solution is gradually heated over 10 minutes to 75ºC - 85ºC, citric acid heat disinfection is provided for 15-30 minutes at 500ml/min followed by cooling over 10 minutes.

Rinse and disinfection profile screen is displayed. Select “E” Citric Acid profile and start the hot citric acid disinfection (Figure 29). The progress bar on the screen will indicate the different phases of the heat chemical disinfection.

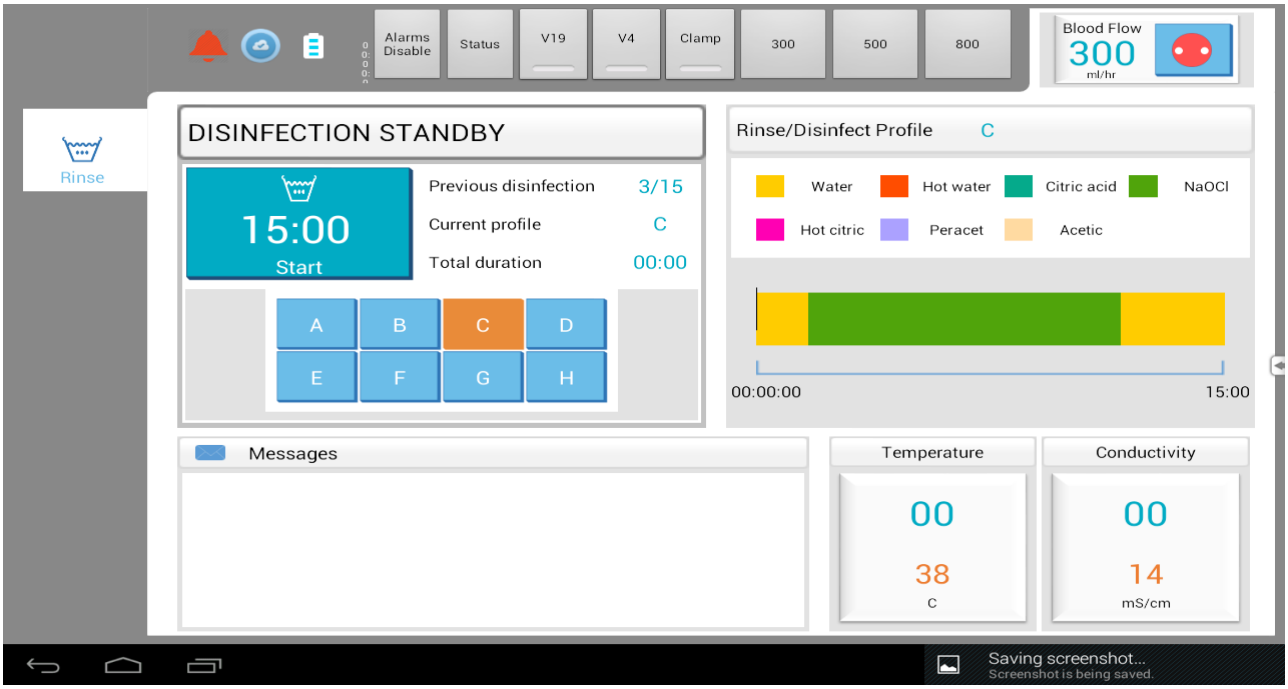

Figure 29: Bleach Disinfection Screen

4.5. Exterior surface cleaning and disinfection

Carry out machine surface cleaning and disinfection by wiping down using Bleach (1%) with a smooth cloth. The machine surface cleaning should be rinsed off with a water-damped cloth, especially if a corrosive, cleaning agent such as bleach is used.

5. Alarm and Troubleshooting

Informational messages are displayed during the dialysis treatment to the operator when potential problems are detected. Operator is alerted by pop up message, illuminated beacon and audible alarms as needed.

The information message is displayed on the screen Figure 30.

The background colour of the status box changes the colour to accentuate the operational status Green, Yellow and Red. The message prompts an action or update to the operator.

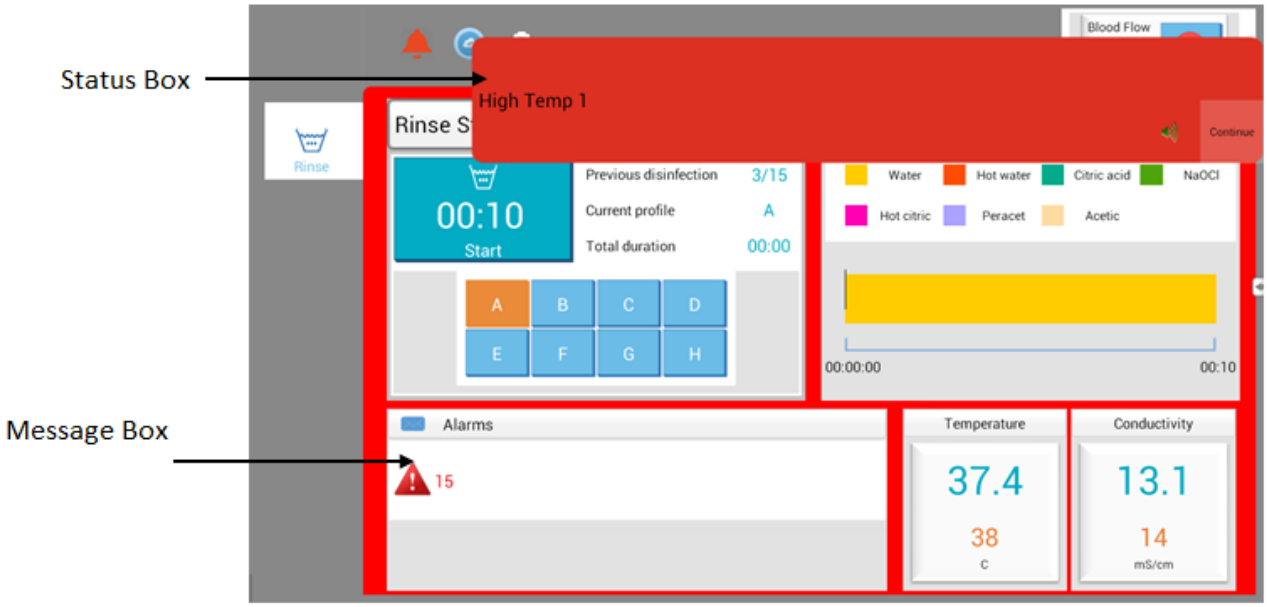

Figure 30: Alarm Screen

The operational statuses may be either Normal or Warning or Alarm.

Normal Status:

The status box turns to a GREEN background under normal operation at successful completion of process or operation. Status beacon will illuminate with GREEN light to alert the operator with no audible alarm.

Warning Status:

The status box turns to a YELLOW background under warning condition potentially serious does not pose an immediate threat to the patient. An error requiring remedial action is alerted by warning with Yellow light and an audible alarm.

Alarm Status:

Alarm situations need an immediate attention of the operator. Failure to do so may cause serious or fatal injury to the patient. Alarm message is a pop up with RED background, RED light and an audible alarm.

SI No	Alarm Message	Machine Alert	Purpose of Message	Machine Safety Action	User Action
1.	Arterial pressure is low	• Acoustic alarm • Red light	Measured arterial pressure exceeds the lower limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check blood line for disconnection and leakages • Adjust blood lines • Check if any water content is trucked in the APT connector. • Correct position of Cannula • Increase blood pump speed • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
2.	Arterial pressure is high	• Acoustic alarm • Red light	Measured arterial pressure exceeds the upper limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check blood line for disconnection and leakages • Adjust blood lines • Correct position of Cannula • Decrease the blood pump speed • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
3.	Venous pressure is low	• Acoustic alarm • Red light	Measured Venous pressure exceeds the lower limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check blood line for disconnection and leakages • Adjust blood lines • Check if any water content is trucked in the APT connector. • Correct position of Cannula • Increase blood pump speed • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.

4.	Venous pressure high	• Acoustic alarm • Red light	Measured Venous pressure exceeds the upper limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check blood line for disconnection and leakages • Adjust blood lines • Correct position of Cannula • Decrease the blood pump speed • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
5.	Blood pump stopped	• Acoustic alarm • Red light	Blood pump stops working during • saline priming • Saline recirculation • dialysate priming	• Machine generates alarm "Blood pump stops "	• Open the blood pump door then, try to rotate it manually. • If blood pump not starts running and alarm will not reset or alarm continues intermittently contact a qualified technician.
6.	Blood pump stopped	• Acoustic alarm • Red light	Blood pump stops working during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Open the blood pump door then, try to rotate it manually. • If blood pump not starts running and alarm will not reset or alarm continues intermittently contact a qualified technician.
7.	Blood pump door open	• Acoustic alarm • Red light	During the blood pump running ,blood pump door opened during • saline priming • saline recirculation • dialysate priming • dialysis	• Machine generates the alarm " Blood pump door open " • Blood pump stops	• Close the Blood pump door • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
8.	Blood pump over or under run	• Acoustic alarm • Red light	During the blood pump running ,blood pump speed mismatch with set speed during	• Machine generates the alarm Blood pump over or under run "	• Check the blood pump and proper tubing connection.

			• saline priming • saline recirculation • dialysate priming • dialysis	• Blood pump stops	• If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
9.	Blood not detected	• Acoustic alarm • Red light	Blood not detected during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check the venous blood line connection to the blood detector • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
10.	Air bubble detected	• Acoustic alarm • Red light	Air bubble detected in blood line more than 10 µL air bubble size during dialysis	• Venous clamp closes • Blood pump stop • Heparin pump stops • UF stops • Bypass mode	• Check blood line for presence of air bubbles • Follow the instructions of the alarm window
11.	Heparin pump stopped	• Acoustic alarm • Red light	The Heparin pump is encountering resistance during heparin infusion in dialysis	• Venous clamp closes • Blood pump stop • Heparin pump stops • UF stops • Bypass mode	• Check correct type of syringe is loaded and locked in place properly. • Check the heparin line for clamps or kinks and correct. • Check the heparin syringe for adequate amount of heparin and correctness. • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
12.	Blood leak detected	• Acoustic alarm • Red light	Blood detects in dialysate lines at the rate of (blood flow 0.35 mL/min at Hct 0.25) during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops	• Check dialyzer and dialyzer lines for blood leak • If blood is detected change dialyzer

				• Machine Standby	• If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
13.	Dialysate temperature high	• Acoustic alarm • Red light	Measured dialysate temperature exceeds upper limit during dialysate priming	• Bypass mode	• Check water supply to machine for excess temperature and correct if necessary. • If heat disinfection was recently performed, place machine in rinse cycle to decrease temperature. • Check the Temperature value set in the screen. Re-enter it if necessary and allow five minutes for the temperature to stabilize. • If unable to reach prescribed temperature, discontinue treatment and contact qualified technician.
14.	Dialysate temperature high	• Acoustic alarm • Red light	Measured dialysate temperature exceeds upper limit during dialysis	• Venous clamp close • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• If unable to attain prescribed temperature, discontinue treatment and alert a qualified technician.
15.	Dialysate temperature low	• Acoustic alarm • Red light	Measured dialysate temperature exceeds lower limit during dialysate priming	• Bypass mode	• Check water supply to machine for excess temperature and correct if necessary. • If heat disinfection was recently performed, place machine in rinse cycle to decrease temperature. • Check the Temperature value set in the screen. Re-enter it if necessary and allow

					five minutes for the temperature to stabilize. • If unable to reach prescribed temperature, discontinue treatment and contact qualified technician.
16.	Dialysate temperature low	• Acoustic alarm • Red light	Measured dialysate temperature exceeds lower limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• If unable to attain prescribed temperature, discontinue treatment and alert a qualified technician.
17.	Dialysate preparation failed – low temperature	• Acoustic alarm • Red light	Measured temperature exceeds the lower limit during dialysate preparation	• Machine Standby	• Check that the concentrates are properly mixed and in their proper containers. • Remix concentrates as needed. • Allow fixed default duration for conductivity to reach the prescribed level and adjust the conductivity alarm limit window if necessary. • Verify that there is flow out of the drain. • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
18.	Dialysate preparation failed – high temperature	• Acoustic alarm • Red light	Measured temperature exceeds the upper limit during dialysate preparation	• Machine Standby	• Check that the concentrates are properly mixed and in their proper containers. • Remix concentrates as needed. • Allow fixed default duration for conductivity to reach the prescribed level and adjust the conductivity alarm limit window if necessary.

					• Verify that there is flow out of the drain. • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
19.	Dialysate conductivity high	• Acoustic alarm • Red light	Measured conductivity exceeds the upper limit during dialysate priming	• Bypass mode	• Check that the concentrates are properly mixed and in their proper containers. • Remix concentrates as needed. • Allow fixed default duration for conductivity to reach the prescribed level and adjust the conductivity alarm limit window if necessary. • Verify that there is flow out of the drain. • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
20.	Dialysate conductivity high	• Acoustic alarm • Red light	Measured conductivity exceeds the upper limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
21.	Dialysate conductivity low	• Acoustic alarm • Red light	Measured conductivity exceeds the lower limit during dialysate priming	• Bypass mode	• Check that the concentrates are properly mixed and in their proper containers. • Remix concentrates as needed. • Allow fixed default duration for conductivity to reach the prescribed level and adjust the conductivity alarm limit window if necessary. • Verify that there is flow out of the drain.

					• If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
22.	Dialysate conductivity low	• Acoustic alarm • Red light	Measured conductivity exceeds the lower limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
23.	Dialysate preparation failed – low conductivity	• Acoustic alarm • Red light	Measured conductivity exceeds the lower limit during dialysate preparation	• Machine Standby	• Check that the concentrates are properly mixed and in their proper containers. • Remix concentrates as needed. • Allow fixed default duration for conductivity to reach the prescribed level and adjust the conductivity alarm limit window if necessary. • Verify that there is flow out of the drain. • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
24.	Dialysate preparation failed – high conductivity	• Acoustic alarm • Red light	Measured conductivity exceeds the higher limit during dialysate preparation	• Machine Standby	• Check that the concentrates are properly mixed and in their proper containers. • Remix concentrates as needed. • Allow fixed default duration for conductivity to reach the prescribed level and adjust the conductivity alarm limit window if necessary. • Verify that there is flow out of the drain.

					• If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
25.	UF volume removed -high	• Acoustic alarm • Red light	Measured UF volume removed more than the set UF volume during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• If unable to attain prescribed UF volume, discontinue treatment and alert a qualified technician.
26.	UF volume removed -low	• Acoustic alarm • Red light	Measured UF volume removed less than the set UF volume during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• If unable to attain prescribed UF volume, discontinue treatment and alert a qualified technician.
27.	Trans membrane pressure high	• Acoustic alarm • Red light	Trans membrane pressure exceeds upper limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check dialyzer for clotting, if necessary change dialyzer • Decrease UF volume if needed. • Decrease blood pump speed if needed. • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
28.	Trans membrane pressure low	• Acoustic alarm • Red light	Trans membrane pressure exceeds lower limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check dialyzer for clotting, if necessary change dialyzer • Increase UF volume if needed. • Increase blood pump speed if needed. • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.

29.	Dialyzer inlet pressure high	• Acoustic alarm • Red light	The inlet dialyzer pressure exceeds the upper limit during dialysate priming	• Bypass mode	• Check dialyzer for leakage dialysate • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
30.	Dialyzer inlet pressure high	• Acoustic alarm • Red light	The inlet dialyzer pressure exceeds the upper limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check dialyzer for clotting and leakage dialysate • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
31.	Dialyzer inlet pressure low	• Acoustic alarm • Red light	The inlet dialyzer pressure exceeds the lower limit during dialysate priming	• Bypass mode	• Check dialyzer for leakage dialysate • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
32.	Dialyzer inlet pressure low	• Acoustic alarm • Red light	The inlet dialyzer pressure exceeds the lower limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check dialyzer for clotting and leakage dialysate • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
33.	Dialyzer outlet pressure high	• Acoustic alarm • Red light	The outlet dialyzer pressure exceeds the upper limit during dialysate priming	• Bypass mode	• Check dialyzer for leakage dialysate • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
34.	Dialyzer outlet pressure high	• Acoustic alarm • Red light	The outlet dialyzer pressure exceeds the upper limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops	• Check dialyzer for clotting and leakage dialysate • Check dialyzer tubing system for kinking

				• UF stops • Bypass mode	• If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
35.	Dialyzer out let pressure low	• Acoustic alarm • Red light	The outlet dialyzer pressure exceeds the lower limit during dialysate priming	• Bypass mode	• Check dialyzer for leakage dialysate • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
36.	Dialyzer out let pressure low	• Acoustic alarm • Red light	The outlet dialyzer pressure exceeds the lower limit during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check dialyzer for clotting and leakage dialysate • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
37.	No RO Water	• Acoustic alarm • Red light	The machine is not receiving RO water during • rinse • dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection	• Machine Standby	• Inspect the RO water source supplying to the machine. Correct as required. • If the alarm does not clear, take the machine out of service and contact a qualified technician.
38.	No RO Water	• Acoustic alarm • Red light	The machine is not receiving RO water during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Inspect the RO water source supplying to the machine. Correct as required. • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
39.	Low inlet flow	• Acoustic alarm • Red light	The machine is not receiving enough RO water during • rinse	• Machine Standby	• Inspect the RO water source supplying to the machine. Correct as required.

			• dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection		• If the alarm does not clear, take the machine out of service and contact qualified technician.
40.	Low inlet flow	• Acoustic alarm • Red light	The machine is not receiving enough RO water during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Inspect the RO water source supplying to the machine. Correct as required. • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
41.	High inlet flow	• Acoustic alarm • Red light	The machine is receiving high RO water flow during • rinse • dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection	• Machine Standby	• Inspect the RO water source supplying to the machine. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
42.	High inlet flow	• Acoustic alarm • Red light	The machine is receiving high RO water flow during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Inspect the RO water source supplying to the machine. Correct as required. • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
43.	Inlet RO water temperature high	• Acoustic alarm • Red light	TS1 detects the inlet RO Water temperature > = 30 °C during • rinse • dialysate preparation • dialysate priming	• Machine Standby	• Check the temperature of inlet RO water. Correct & keep water temperature less than 30 °C degree set value as required • If the alarm does not clear, take the machine out of service and contact qualified technician.

44.	Inlet RO water temperature high	• Acoustic alarm • Red light	TS1 detects the inlet RO Water temperature >= 30 °C during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check the temperature of inlet RO water. Correct & keep water temperature less than 30 °C degree set value as required • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
45.	Acid Probe OUT	• Acoustic alarm • Red light	Acid probe not connected to the machine during rinse	• Machine Standby	• Check the connection of acid probe (RED) connector. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
46.	Bicarb Probe OUT	• Acoustic alarm • Red light	Bicarb probe not connected to the machine during rinse	• Machine Standby	• Check the connection of Bicarb probe (BLUE) connector. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
47.	Acid Probe IN	• Acoustic alarm • Red light	Acid probe is connected to the machine during • dialysate preparation • dialysate priming • bleach disinfection	• Machine Standby	• Check the connection of acid probe (RED) connector. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
48.	Acid Probe IN	• Acoustic alarm • Red light	Acid probe is connected to the machine during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check the connection of acid probe (RED) connector. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
49.	Bicarb Probe IN	• Acoustic alarm • Red light	Bicarb probe is connected to the machine during • dialysate preparation • dialysate priming	• Machine Standby	• Check the connection of Bicarb probe (BLUE) connector. Correct as required.

			• bleach disinfection		• If the alarm does not clear, take the machine out of service and contact qualified technician.
50.	Bicarb Probe IN	• Acoustic alarm • Red light	Bicarb probe is connected to the machine during dialysis	• Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check the connection of Bicarb probe (BLUE) connector. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
51.	Venous clamp failure	• Acoustic alarm • Red light	• Venous clamp closes unintentionally during • saline priming • dialysate priming • dialysate preparation	• Machine Standby	• Check the venous clamp. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
52.	Venous clamp failure	• Acoustic alarm • Red light	• Venous clamp unintentionally closes during -dialysis	• Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check the venous clamp. Correct as required. If not return manually blood to the patient using blood pump hand crank and disconnect the patient. • If the alarm does not clear, take the machine out of service and contact qualified technician.
53.	Venous clamp failure	• Acoustic alarm • Red light	Venous clamp not closes during Alarm condition	• Blood pump stops • Heparin pump stops • UF stops • Bypass mode	• Check the venous clamp. Correct as required. If not return manually blood to the patient using blood pump hand crank and disconnect the patient. • If the alarm does not clear, take the machine out of service and contact qualified technician.
54.	Shunt connectors OUT	• Acoustic alarm • Red light	Dialyzer inlet-outlet connectors are not	• Machine Standby	• Connects the Dialyzer inlet-outlet connectors to bypass shunt connections

			connected to machine during rinse • rinse • dialysate preparation • heat disinfection • citric acid disinfection • bleach disinfection		• Alarm persists, contact qualified technician
55.	Shunt connectors IN	• Acoustic alarm • Red light	Dialyzer inlet-outlet connectors are not connected to dialyzer during dialysate priming	• Machine Standby	• Connects the Dialyzer inlet-outlet connectors to bypass shunt connections • Alarm persists, contact qualified technician
56.	Shunt connectors IN	• Acoustic alarm • Red light	Dialyzer inlet-outlet connectors are not connected to dialyzer during dialysis	• Machine Standby	• Connects the Dialyzer inlet-outlet connectors to bypass shunt connections • Alarm persists, contact qualified technician
57.	Main AC power supply failure	• Acoustic alarm • Red light	Main AC power supply failure during • rinse • dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection	• Battery Backup • Machine Standby	• Re-establish power mains supply and system recovery • Alarm persists, contact qualified technician
58.	Main AC power supply failure	• Acoustic alarm • Red light	Main AC power supply failure during dialysis	• Battery Backup	• Machine running by battery backup. • Blood pump stops • Venous clamp closes • Dialysate flow pump stops • Heater is OFF

					• Blood leak detector stops • Manually Return the blood to the patient and disconnect the patient. • Re-establish power mains supply • Alarm persists, contact qualified technician
59.	Low battery voltage	• Yellow light	Battery charge is less than desired threshold voltage (< 12 V 7 ah) during • rinse • dialysate preparation • dialysate priming • dialysis • heat disinfection • citric acid disinfection • bleach disinfection	• Machine displays the alarm "Low battery voltage"	• Inspect the Battery source supplying to the machine. Correct as required. • If the alarm does not clear, take the machine out of service and contact qualified technician.
60.	Bicarbonate solution volume low	• Acoustic signal • Yellow light	Missing supply of Bicarbonate concentrate during rinse	• Machine displays the alarm "Bicarbonate solution volume low"	• Check position of bicarbonate probe in the container • Check suction line • Check bicarbonate availability in the container • If alarm persists, contact qualified technician
61.	Acid solution volume low	• Acoustic signal • Yellow light	Missing supply of Bicarbonate concentrate during dialysis	• Machine displays the alarm "Bicarbonate solution volume low"	• Check position of acid probe in the container • Check suction line • Check bicarbonate availability in the container

					• If alarm persists, contact qualified technician
62.	Watch dog timer error	• Acoustic alarm • Red light	CPU goes to dead lock state during • rinse • dialysate preparation • dialysate priming • dialysis • heat disinfection • citric acid disinfection • bleach disinfection	• Machine rebooted	• If alarm persists, contact qualified technician
63.	UF goal reached	• Yellow light	This message is to alert the operator that set ultrafiltration goal has been reached during dialysis	• No response	• No response
64.	Dialysis time reached	• Yellow light	This message is to alert the operator that set dialysis time has been reached during dialysis	• No response	• No response

6. Machine specifications

6.1. General

6.1.1. Dimension and Weight

Parameter	Specification
Dimensions (Length × Breadth × Width)	1200 x 470 x 752 mm Approx. (Taken from the model).
Housing Material	Plastic, corrosion-proof
Total weight	85 kg Approx.
Height	1200 mm (without saline holder and alarm post)

6.1.2. Medical device classification

Parameter	Specification
Medical device classification	Class II b according to EC Directive for Medical Devices 93/42/EEC.

6.1.3. Electrical supply

Parameter	Specification
Nominal voltage	230 VAC ± 10 %
Nominal frequency	50 HZ
Nominal current	Typical 7 A ± 10 %
Power consumption	Less than 2 kW

6.1.4. Fuses

Parameter	Specification
Circuit Breaker	8 A, Single medium blow fuse
Heater Control Unit	Fuse 250 VAC, 7 A

6.1.5. Electrical safety

Parameter	Specification
Protection against electrical shock (Safety classification as per IEC 60601-1)	Class 1
Earth Leakage current (Normal condition)	5 mA or less
Earth Leakage current (Single fault condition)	10 mA or less
Enclosure Leakage current (Normal condition)	0.1 mA or less
Enclosure Leakage current (Single fault condition)	0.5 mA or less
Patient Leakage current (Normal condition)	10 µA or less
Patient Leakage current (Single fault condition)	50 µA or less

6.1.6. Battery specification

Parameter	Specification
Type	Lead Acid
Capacity	12 V, 7AH
Charging time	10 hours
Continuous operation time (Only Blood pump & Alarm operation)	20 minutes

6.1.7. External connection

Parameter	Specification
USB	Interface for serial communication with display.
Wireless	Interface for wireless connection to the network

6.1.8. Storage

Parameter	Specification
Storage Temperature	5 - 40 °C
Storage Relative Humidity	10 % – 90 %, non-condensing
Storage Pressure	70 – 106 kPa

6.1.9. Transportation

Parameter	Specification
Transportation Temperature	5 - 40 °C
Transportation Relative Humidity	10 % – 90 %, non-condensing

Transportation Pressure	70 – 106 kPa

6.1.10. Operating condition

Parameter	Specification
Temperature	5 - 40 °C
Relative Humidity	35 % – 90 %, non-condensing
Atmospheric Pressure	70 – 106 kPa

6.1.11. Inlet RO water supply

Parameter	Specification
Water Inlet Pressure range	1.5 to 6 bar
Water Inlet Flow	More than 1100 ml/min
Water Inlet Temperature range	5 - 30 °C 5 °C lower than dialysate set temperature
Water Drain	Drain Height – Maximum 30cm above the ground. No less than 5cm free fall.
Norms of Water Quality	As per: AAMI Standard, RD52:2004 (RD52) Water for hemodialysis - ANSI/AAMI 13959:2014

6.1.12. Heater

Parameter	Specification
Heating Power	1500 W
Voltage	230 VAC ± 10 %
Frequency	50Hz
Protection system	DPDT switch, Fuse

6.2. Dialysate system

6.2.1. Dialysate temperature

Parameter	Specification
Dialysate Temperature range	35.5 – 37.5 °C
Tolerance	± 0.5 °C of set value
Alarms Limit	±1 °C

6.2.2. Dialysate conductivity

Parameter	Specification
Dialysate Conductivity range	13 – 14.5 mS/cm
Tolerance	±0.1 mS/cm of set value
Measurement	Temperature-Compensated (Reference temperature 25 °C)
Alarm Limit	±0.5 mS/cm of set value

6.2.3. Dialysate flow

Parameter	Specification
Dialysate Flow rate	300, 500, 800 mL/min
Tolerance	±5 % of set value

6.2.4. Transmembrane pressure

Parameter	Specification
Transmembrane Pressure range (TMP)	Calculation: TMP = ½[(APT + VPT) - (PS1 + PS2)] – 25 mmHg APT – Arterial Pressure VPT – Venous Pressure PS1 – Dialyzer Inlet Pressure PS2 – Dialyzer Outlet Pressure
Measurement range	-100 mmHg to +500 mmHg
Tolerance	±20mmHg
Alarm Limit	-100 mmHg to +500 mmHg

6.2.5. Dialyzer inlet pressure

Parameter	Specification
Measurement range (PS1)	-275 mmHg to + 375 mmHg
Accuracy	±10mmHg
Alarm limit range	-275 mmHg to + 375 mmHg

6.2.6. Dialyzer outlet pressure

Parameter	Specification
Measurement range	-400 mmHg to + 330 mmHg

Accuracy	±10mmHg
Alarm Limit	-400 mmHg to + 330 mmHg

6.2.7. Ultrafiltration (UF)

Parameter	**Specification**
Ultrafiltration Rate range	0 – 4,000 mL/h
Tolerance	± 10% of set value OR ± 400ml per treatment whichever is largest

6.2.8. Degassing

Parameter	**Specification**
Deaeration method	Negative pressure deaeration method
Dissolved gas in dialysate	Max: 140 mmHg, partial pressure of oxygen When water temperature at deaeration is 37 °C

6.2.9. Blood leak detector

Parameter	**Specification**
Blood Leak Detector	Optical sensor
Sensitivity	>= 0.35 mL/min of blood (Hematocrit of 25%)
Alarm	>=0.45ml/min of blood (Hematocrit=25%)

6.3. Extracorporeal circuit

6.3.1. Arterial pressure

Parameter	**Specification**
Arterial pressure display range	+ 100 to + 400 mmHg Post pump arterial dip chamber measurement
Tolerance	± 10 mmHg
Alarm Limit	+100 mmHg to +400 mmHg

6.3.2. Venous pressure

Parameter	Specifications
Venous pressure display range	+ 50 to + 200 mmHg
Tolerance	± 10 mmHg
Alarm Limit	+ 50 to + 200 mmHg

6.3.3. Blood pump

Parameter	Specification
Blood Pump	2-roller unidirectional peristatic pump with automatic motor switch-off when lid is opened.
Blood Flow rate	60 - 400 mL/min, Adjustable in 10 mL steps For tube size ID 6.35 x OD 9.75 mm
Tolerance	± 10 % of set value
Power outage use	Blood pump can be operated by Battery for maximum 15 minutes Pump can be manually operated with hand crank.

6.3.4. Air bubble detector

Parameter	Specification
Air bubble Detector	<Single bubble> Outputs alarm when a bubble of 10µL or more is detected. Note: Flow rate: 200 mL/min, Fluid temp: 37±1.0°C. Detecting sensitivity differs depending on flow rate of the bubble that passes bubble sensor.
Sensor type	Ultrasonic sensor

6.3.5. Venous clamp

Parameter	Specification
Venous Clamp	Closes with critical alarm for patient safety

6.3.6. Blood detector

Parameter	Specification
Blood Detector	Detects blood in the tubing system
Sensor type	Optical based colour sensor

6.3.7. Heparin

Parameter	Specification

Heparin pump	10 or 20 mL of disposable syringe
Pumping rate	0.1 – 10 mL/h
Tolerance	± 5 %
Bolus	0.1 to 5 mL volume

6.4. Rinse and Disinfection

6.4.1. Rinse

Parameter	**Specification**
Rinse	Water Rinse
Flow rate	800 ml/min
Duration	15 minutes

6.4.2. Heat disinfection

Parameter	**Specification**
Heat Disinfection (Hot Water)	Pre-Rinse – Hot Water – Post Rinse
Temperature	80oC - 90oC
Flow rate	500 ml/min
Duration	40 minutes - 55 minutes

6.4.3. Bleach chemical disinfection

Parameter	**Specification**
Bleach Disinfection	Pre-Rinse –Bleach – Post Rinse
Flow rate	500 ml/min
Duration	30 minutes – 55 minutes
Concentration	Bleach 5%

6.4.4. Hot citric acid disinfection

Parameter	**Specification**
Hot Citric Acid Disinfection	Pre-Rinse –Hot Citric Acid – Post Rinse
Temperature °C	75 to 85°C
Flow rate	500 ml/min

Duration	30 minutes - 55 minutes
Concentration	Citric acid 5%

6.4.5. Citric acid disinfection

Parameter	**Specification**
Citric Acid Decalcification	Pre-Rinse – Citric Acid – Post Rinse
Flow rate	500 ml/min
Duration	30 minutes - 55 minutes
Concentration	Citric acid 5%

6.4.6. Surface disinfection

Parameter	**Specification**
Surface Disinfection	Surface cleaning and disinfection by wiping down using bleach
Concentration	Bleach 1 %

6.5. Alarm sound pressure level

Parameter	**Specification**
Sound Pressure Range	65 dB or more at a distance 1 m

Revision history

Author	Description	Rev No.	Date	Remarks
Ravi Dixit	Initial Version of the document · Initial draft prepared by 28-12-16 · Reviewed with Kishin on 29-12-16 · Reviewed with Ravi Maniyal on 30-12-16. · Reviewed with Doctor Lloyd on 2-1-2017 · Reviewed with Kishin (Alarm section) on 9-1-2017 · Hot citric acid disinfection Reviewed with Dr. Shyam Vasudeva Rao on 20-2-2017 · Updated with machine technical specification based on Doctor Lloyd inputs as per bench trial results, reviewed with Kishin, Ravi Maniyal and Sanjeer on 22-2-2017.	0	01-Jun-17	
Umesh & Ajay	Realigned to specs of Fresenius for JSS_CDSA-CCRE randomized crossover study	1	10-Jul-2017	