

HEMODIALYSIS MACHINE USER MANUAL

Revision History

Author	Version	Date	Remarks
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1. Preparation for the treatment

1.1. Machine Overview

Hemodialysis (HD) machine is connected to the power supply (230 V AC \pm 10 %, 50Hz) with 3 pin power chord. The Renalix Hemodialysis Machine (Figure 1) is depicted to explain the parts of the equipment.

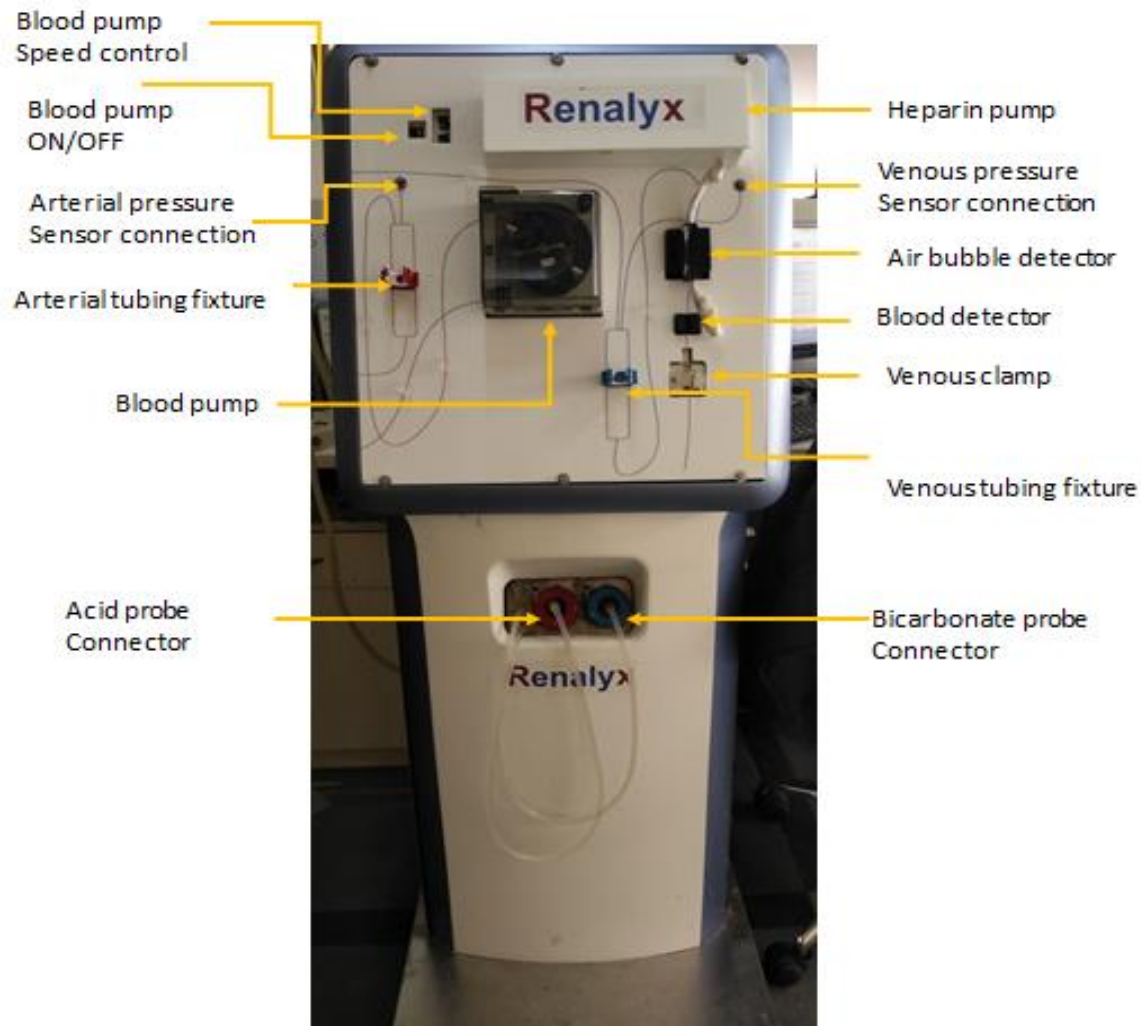
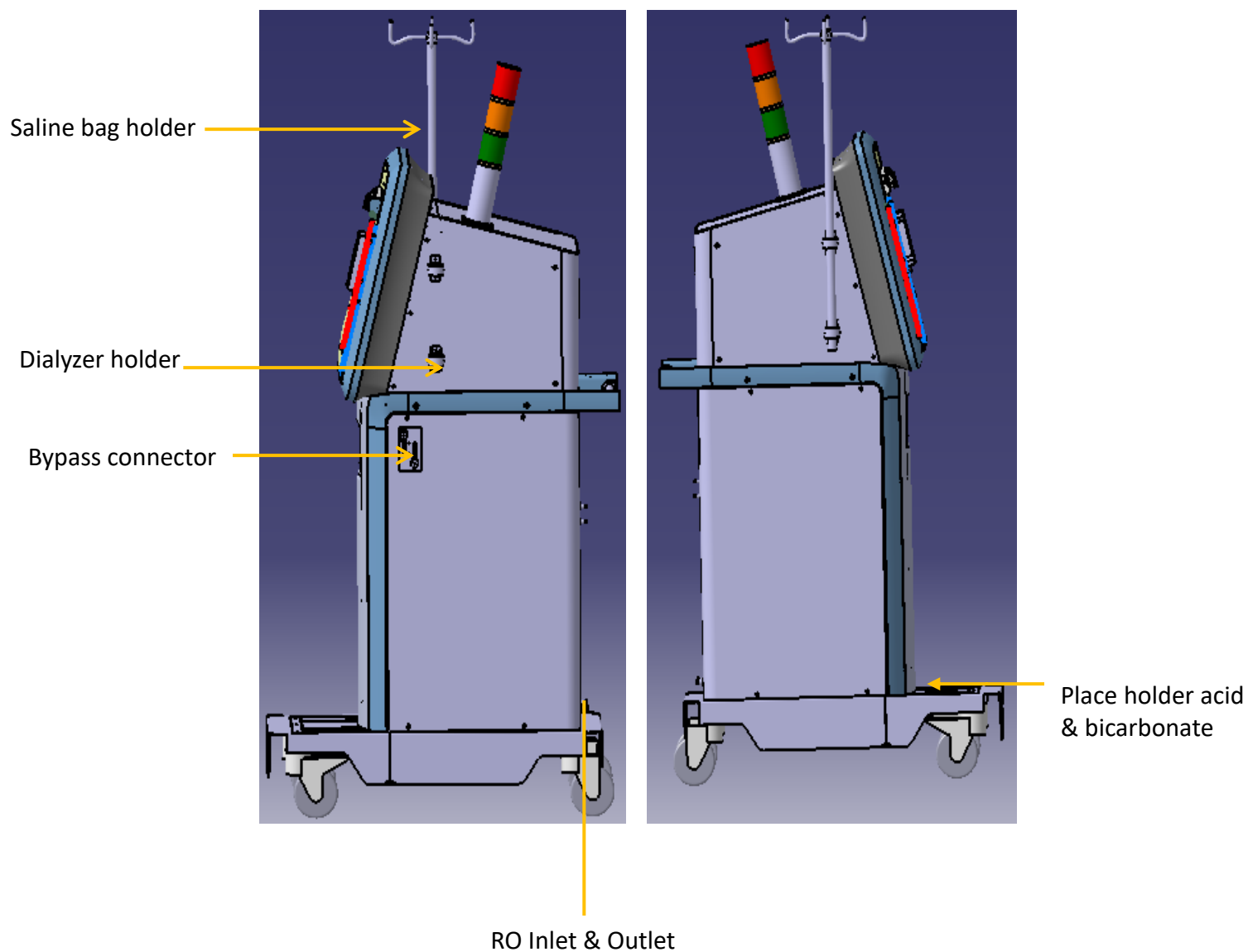


Figure 1: Renalix Hemodialysis (HD) Machine



1.2. User Interface

The tablet is used for user interface. HD machine functions are controlled via touch screen feature. The tablet will communicate with the machine through USB interface connection (Figure 2).



Figure 2: Display Screen

1.3. User Interface Layout

The UI layout overview is depicted with the sample screen shot that provide an insight of common flow of user operation can be carried out [Figure 3]

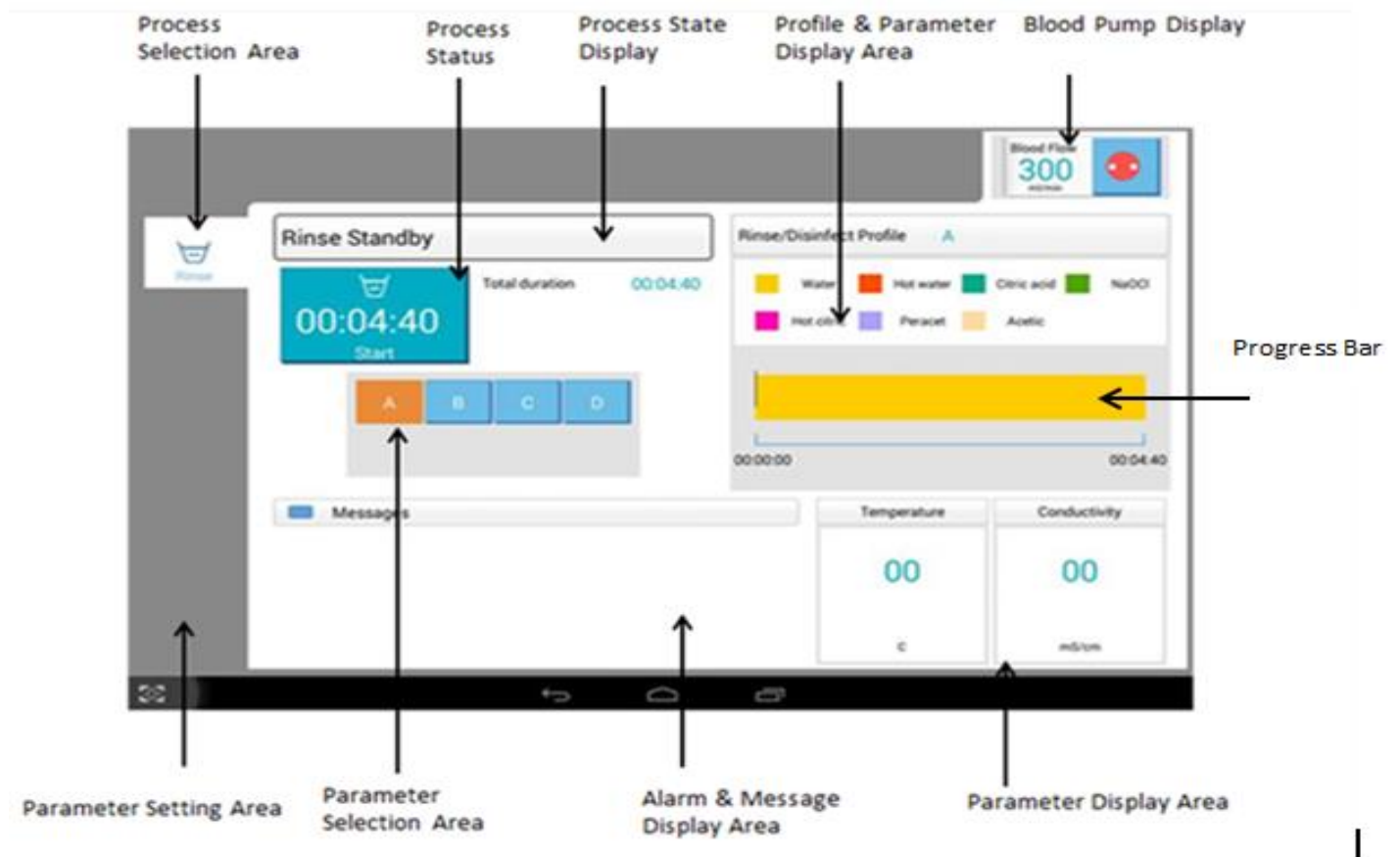


Figure 3: UI Layout Structure

1.4. 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 4)

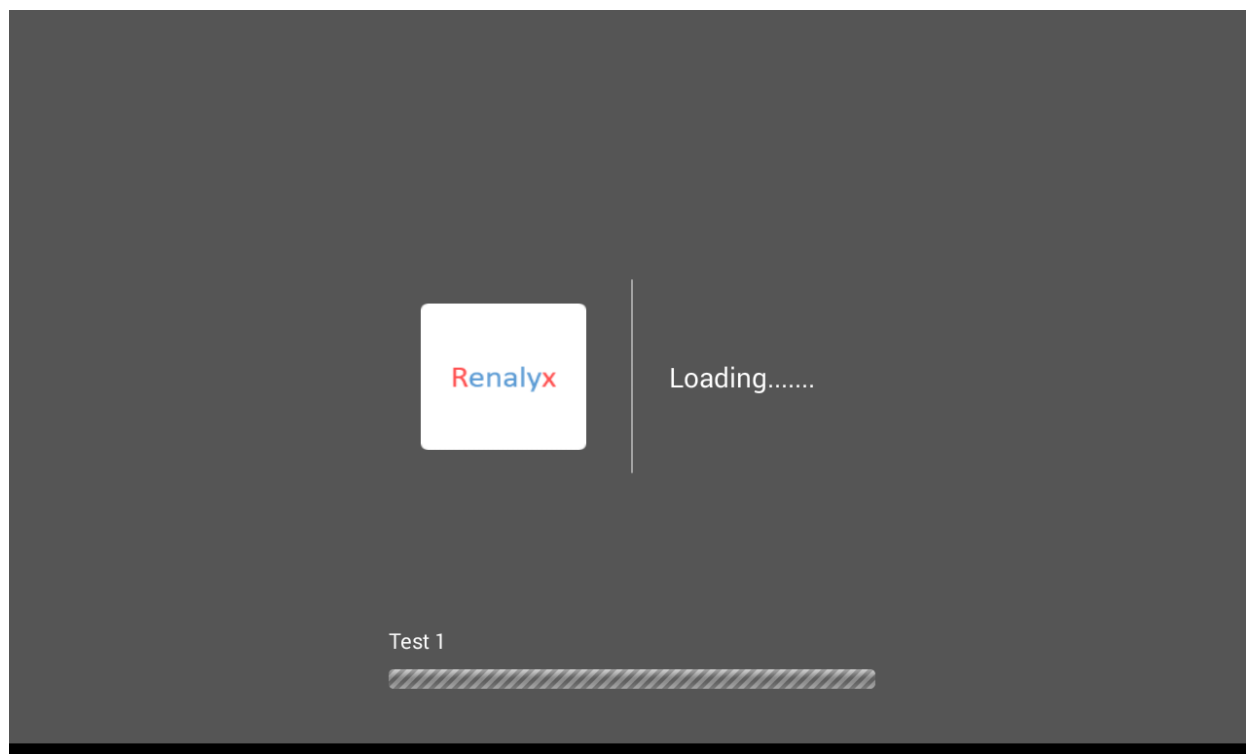


Figure 4: Boot up Screen

During loading following machine self-test is conducted:

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

User required action to be taken to fix the failure test results before user can be 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.

1.5. 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 5)

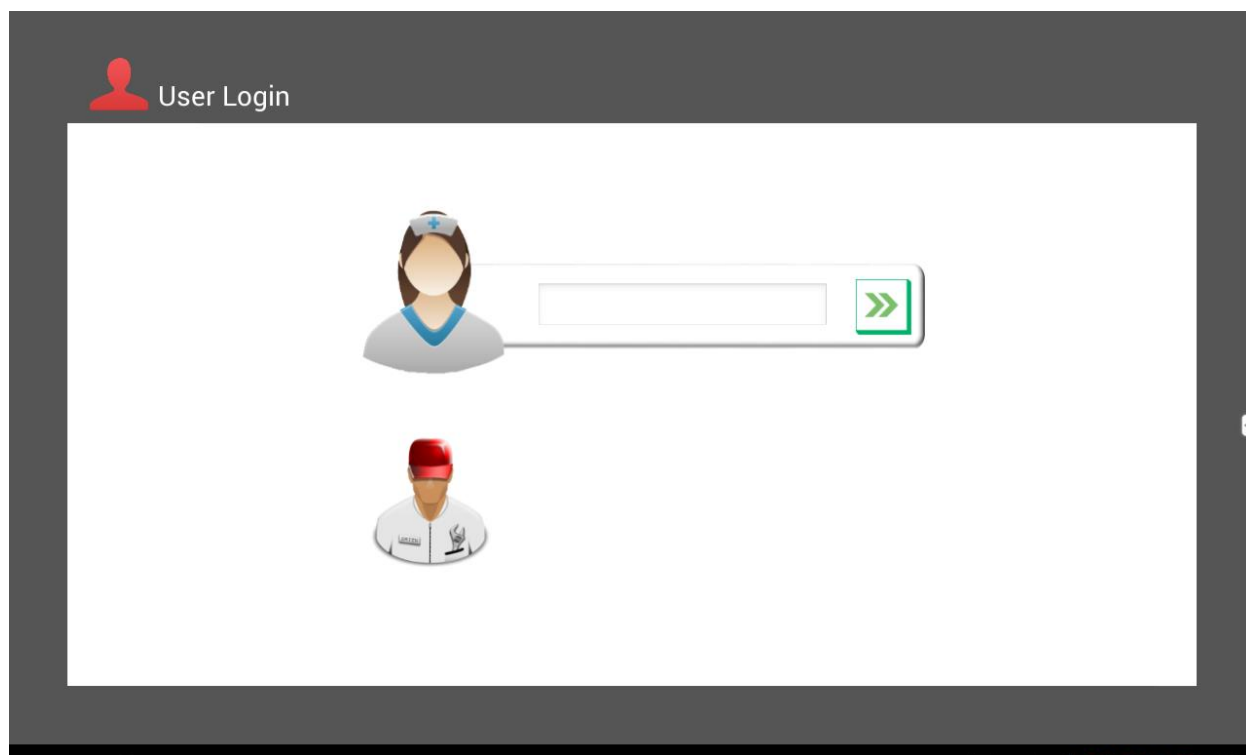




Figure 5: Login Screen

1.6. Program Mode Selection

After successful login, user enters in to program selection mode where option is provided to select Treatment Mode  or Calibration Mode  (Figure 6)

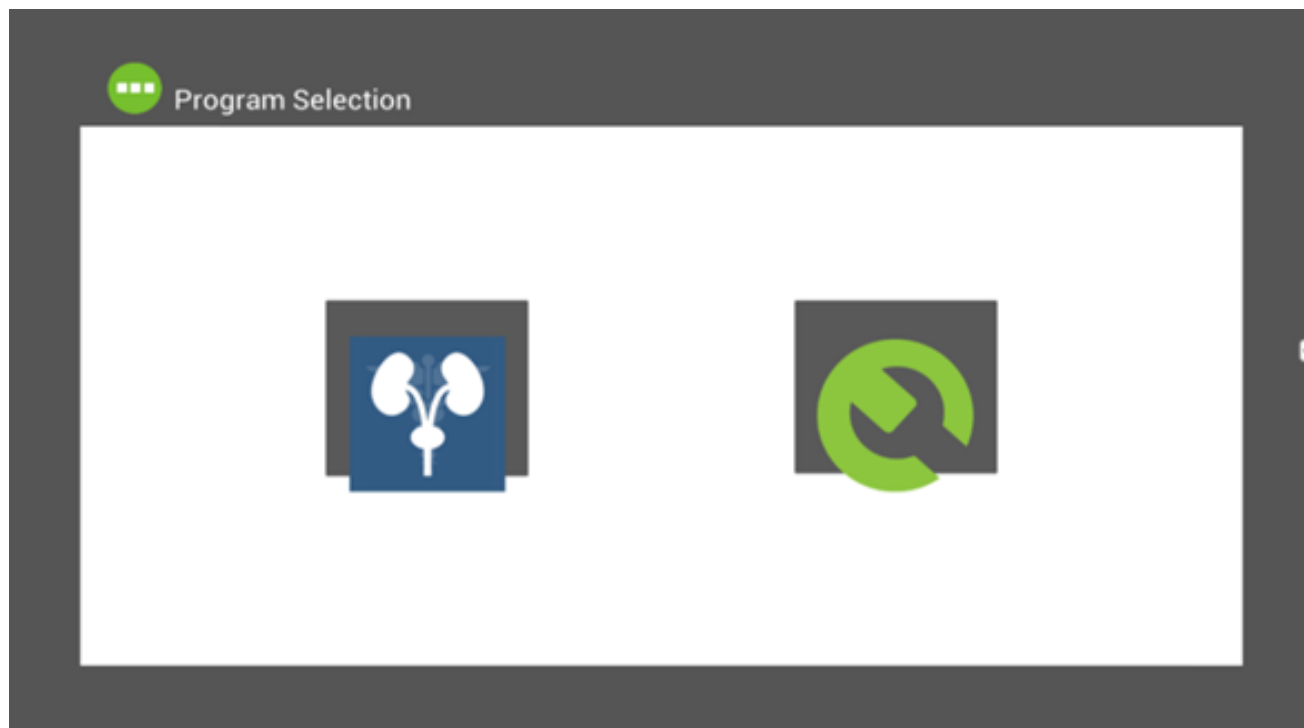


Figure 6: Program Selection

1.7. Accessories

The machine will be ready after user login to treatment mode. Once machine is ready then nurse will select the required accessories to carry out the treatment and keep it ready to have the connection to the machine.

The standard accessories required to carry out Hemodialysis treatment are:

- Saline bag
- Saline infusion set
- Transducer protector
- Venous tubing set
- Arterial tubing set
- Arterial Fistula needles
- Venous Fistula needles
- Dialyzer
- Heparin

- Syringe
- Needle.
- Acid Solution
- Bicarbonate Solution
- Disinfectants (Citric acid, Bleach)

The standard accessory description will help the user to understand the parts/terms used during treatment consistently and also to make the set-up correctly.

1.7.1. Saline bag

Saline bag will be used for priming purpose during the treatment and its connection is shown in (Figure 7).

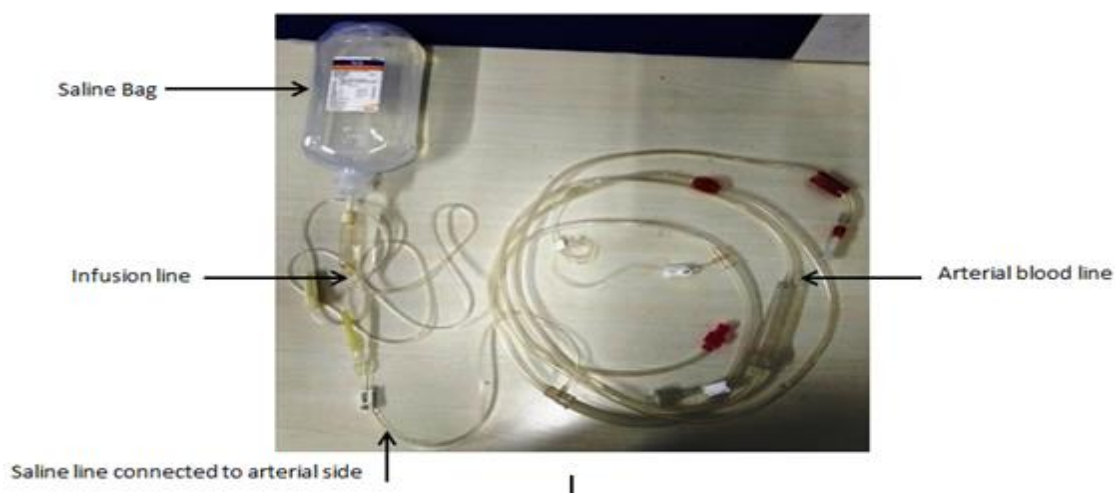


Figure 7: Saline bag connection

1.7.2. Arterial tubing set

Arterial tubing set is depicted in the Figure 8 to understand tubing set terms and to make arterial bloodline connection correctly

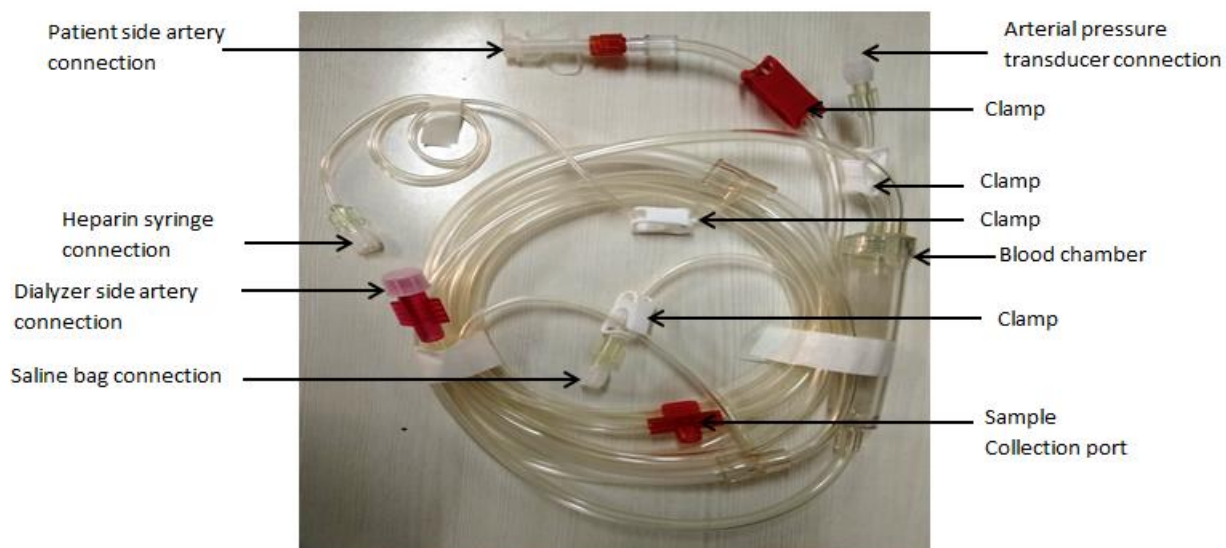


Figure 8: Standard Arterial blood tube set

1.7.3. Venous tubing set

Venous tubing set parts are depicted in the Figure 9 to understand the tubing set and helps to make arterial bloodline connection correctly.

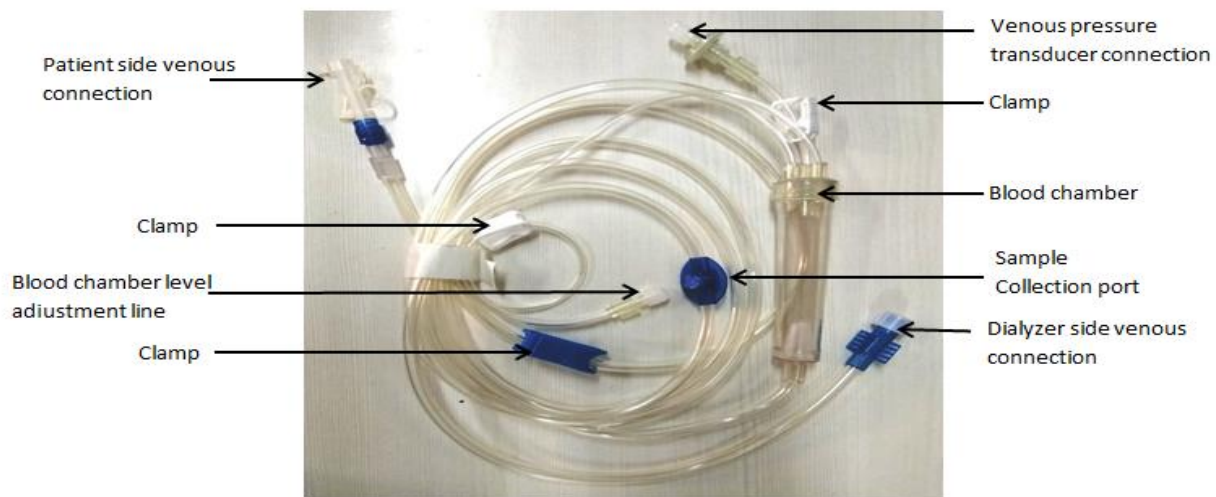


Figure 9: Standard Venous blood tube set

1.7.4. Dialyzer

Dialyzer connection to blood line tubing is depicted in the Figure 10 to make arterial bloodline connection correctly.

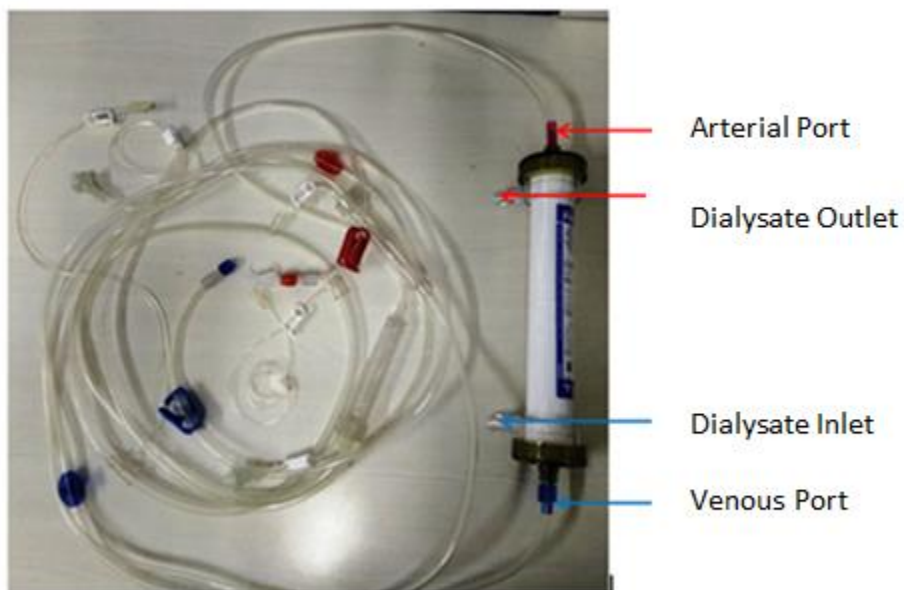


Figure 10: Dialyzer connection set-up to bloodline

1.7.5. Heparin syringe

Syringe connection to blood line tubing is depicted in the Figure 11 to make arterial bloodline connection correctly.

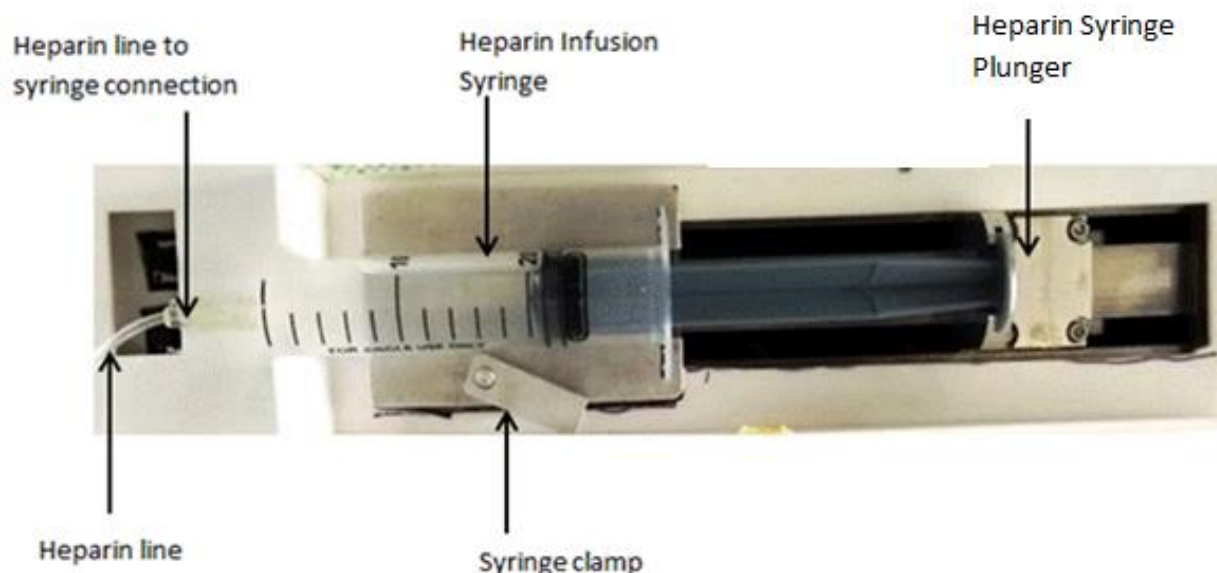


Figure 11: Heparin syringe set-up

1.8. Extracorporeal blood circuit

Hang the saline bag of 1 litre 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 down.

1.8.1. Arterial bloodline set-up

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 12].

After arterial blood line connection is completed, “NEXT” button on the screen is pressed to proceed.

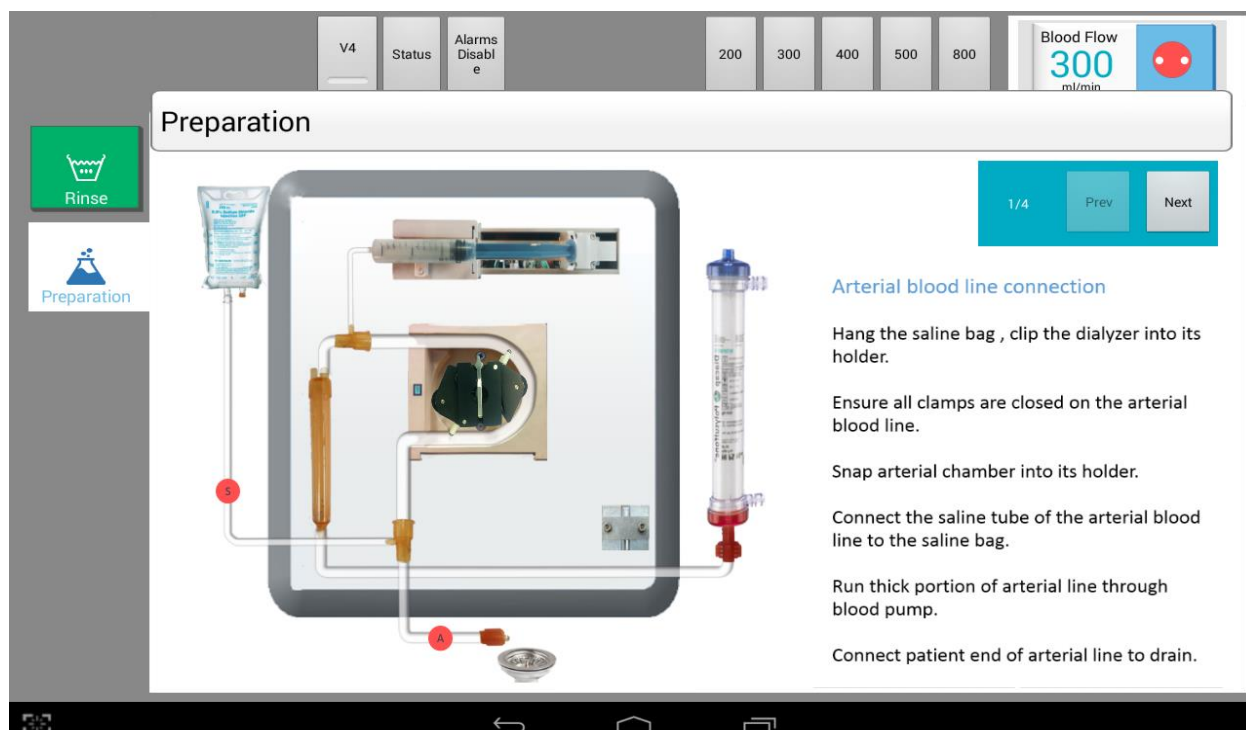


Figure 12: Arterial Blood Line Connection

Open the saline clamp and the arterial patient end 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 13]. NEXT is pressed to continue with priming.

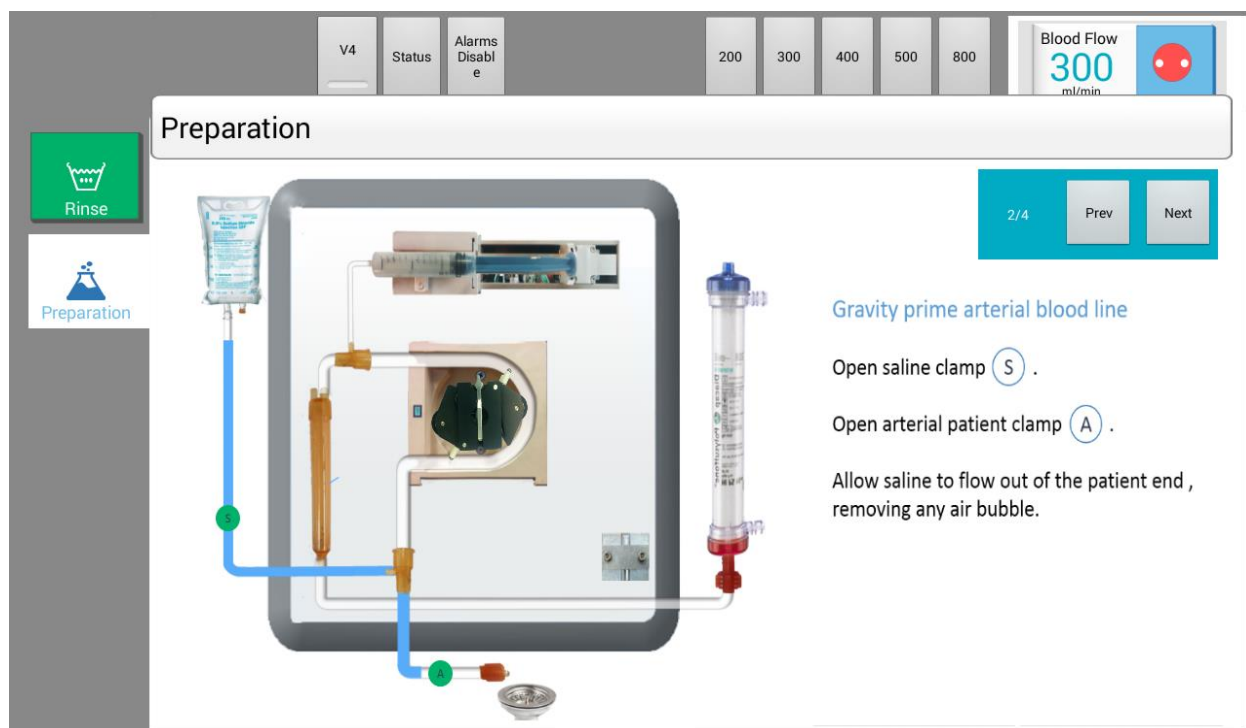


Figure 13: Arterial Bloodline Priming

Clamp the patient end of the arterial bloodline and open the dialyzer end of the tube. Start the blood pump and allow saline 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 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 [Figure 14].

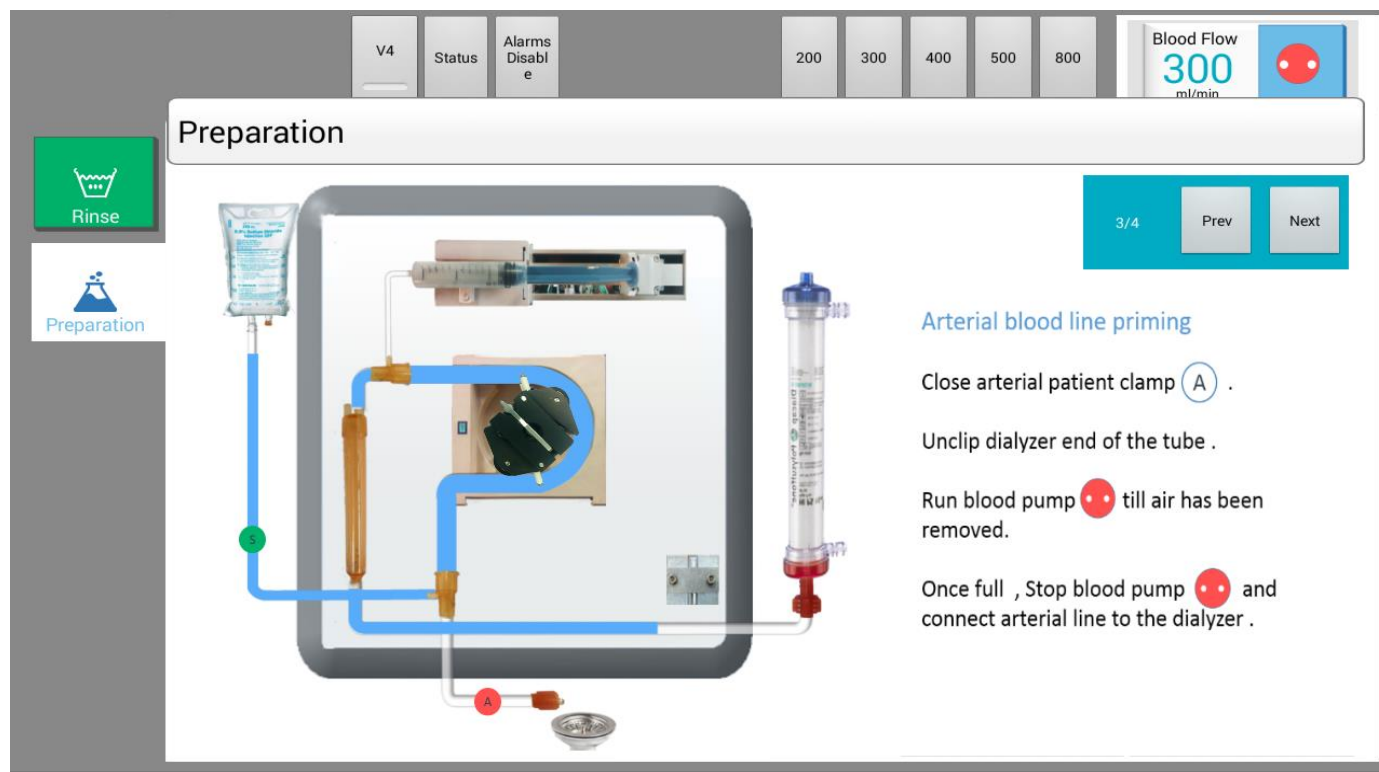


Figure 14: Arterial Blood Line Priming

1.8.2. 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 displayed [Figure 15].

After venous bloodline and heparin line connection completion then press DONE. The Saline priming screen is displayed to the user [Figure 16].

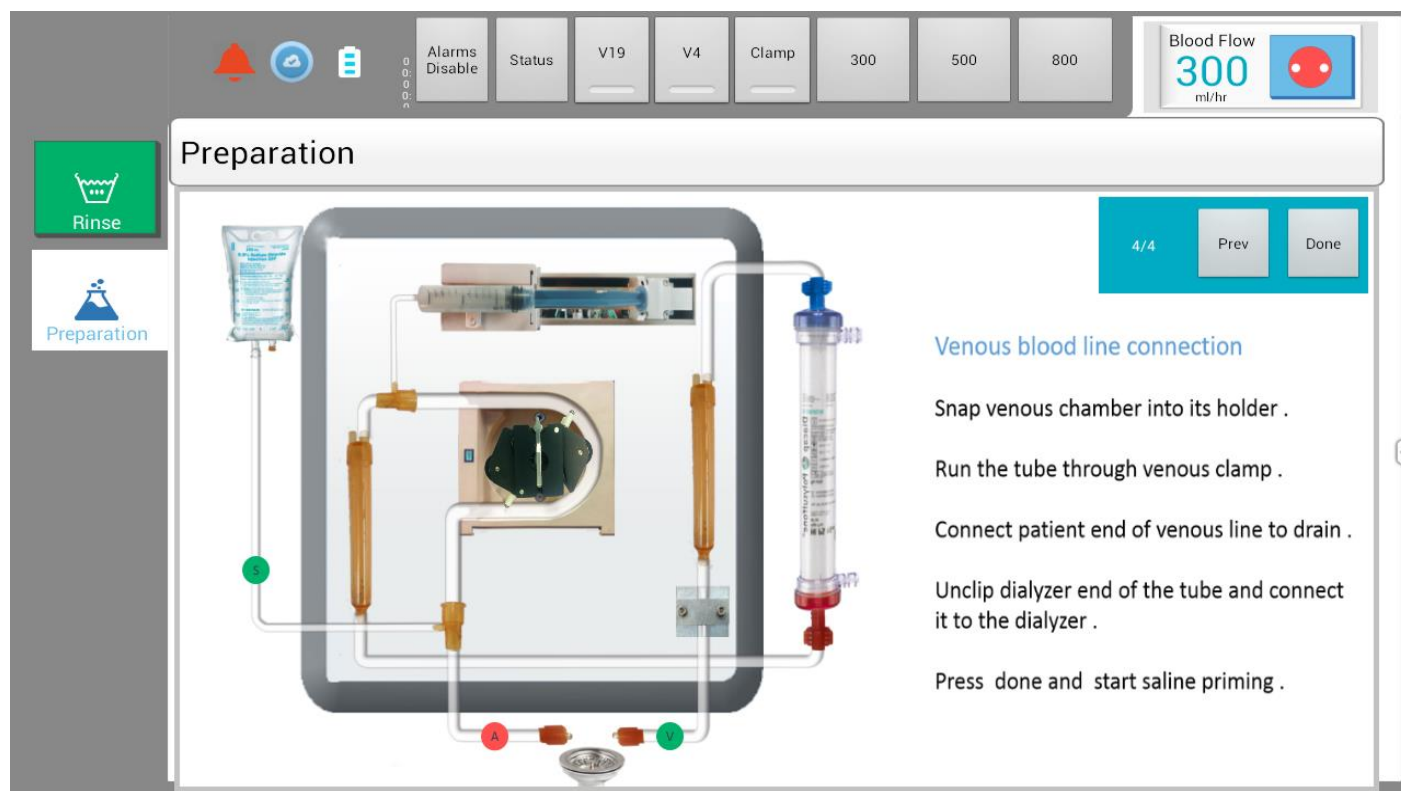


Figure 15: Venous Blood Line Connection

1.9.Saline Priming

Start the blood pump and allow saline drain 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.

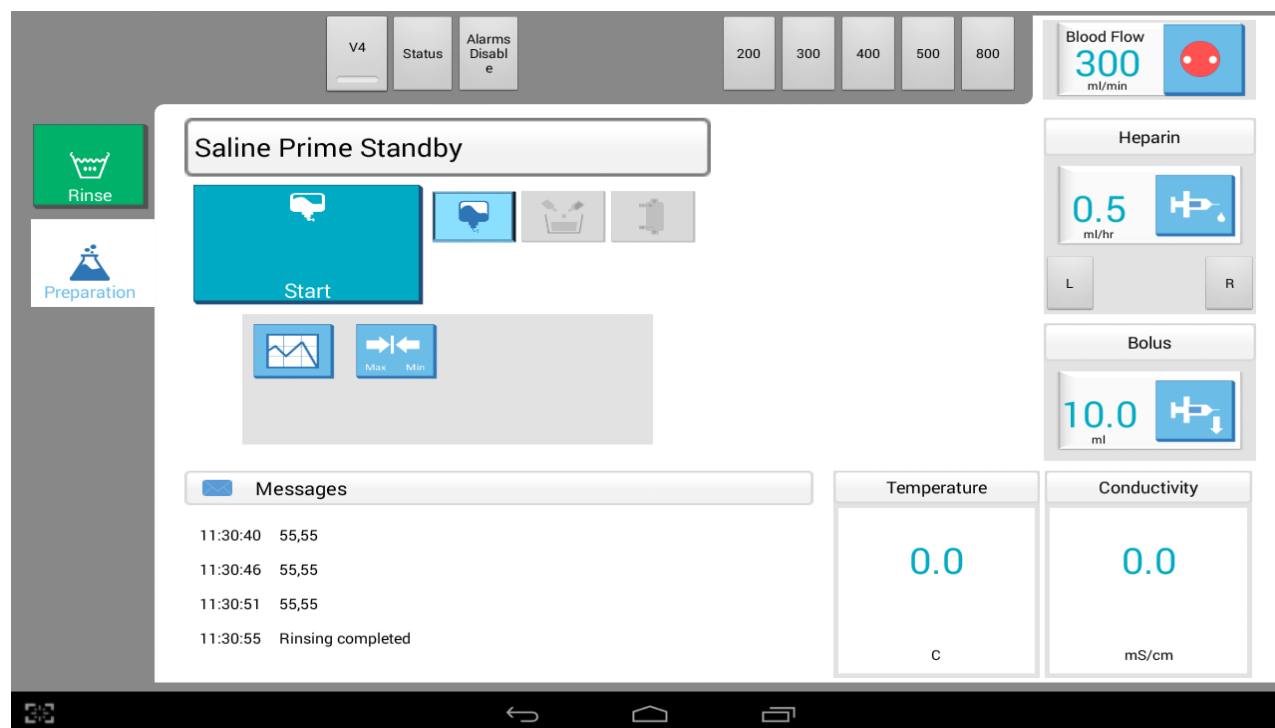


Figure 16: Saline Priming

1.10. Recirculation

After Completion of saline priming, automatically recirculation screen displayed [Figure 17].

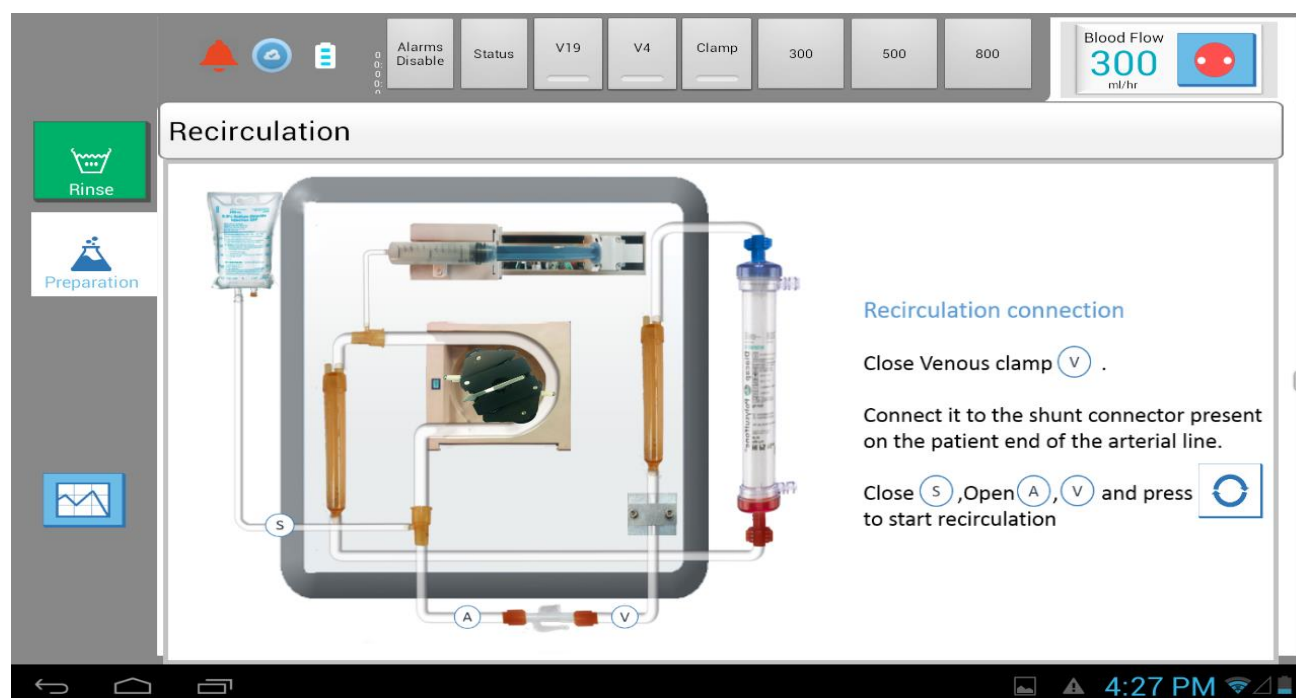


Figure 17: Recirculation

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

Dialysate preparation screen displayed [Figure 18]

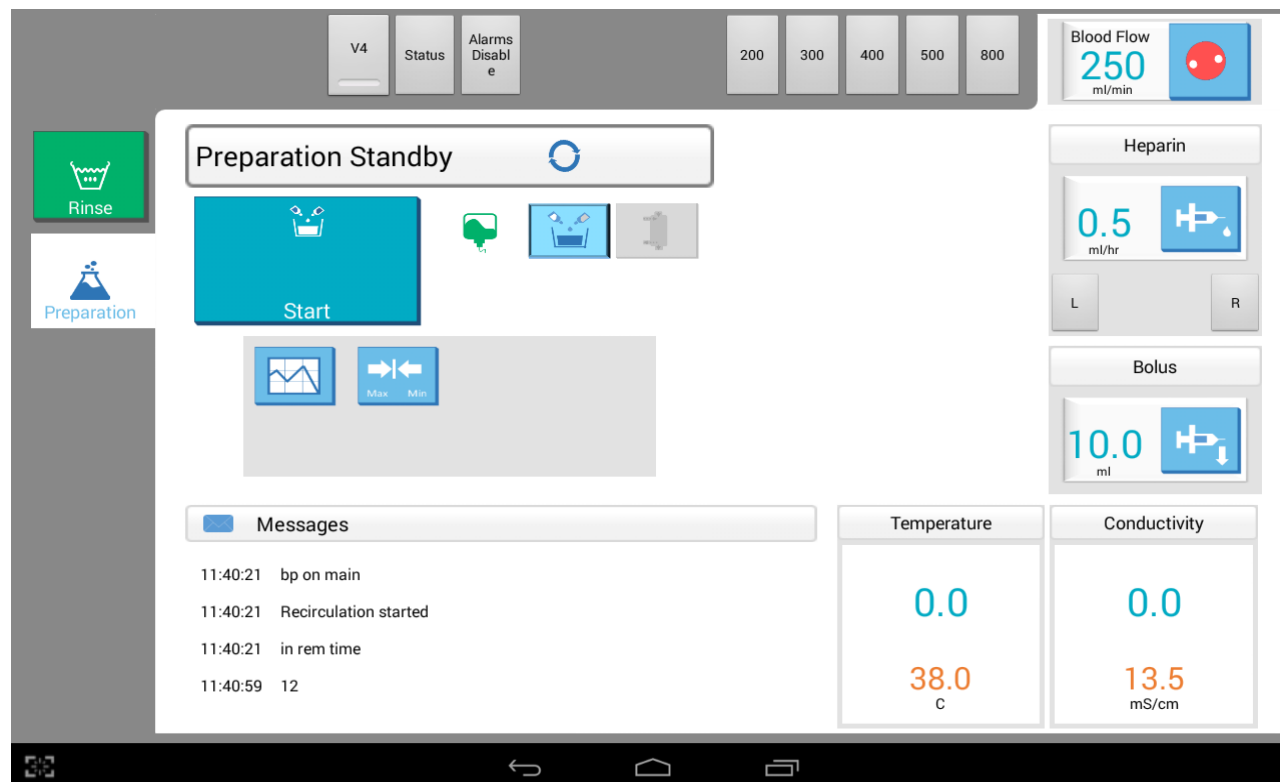


Figure 18: Start Dialysate Preparation

1.11. Dialysate Preparation

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

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; ± 0.1 mS/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, start the Dialysate Preparation.

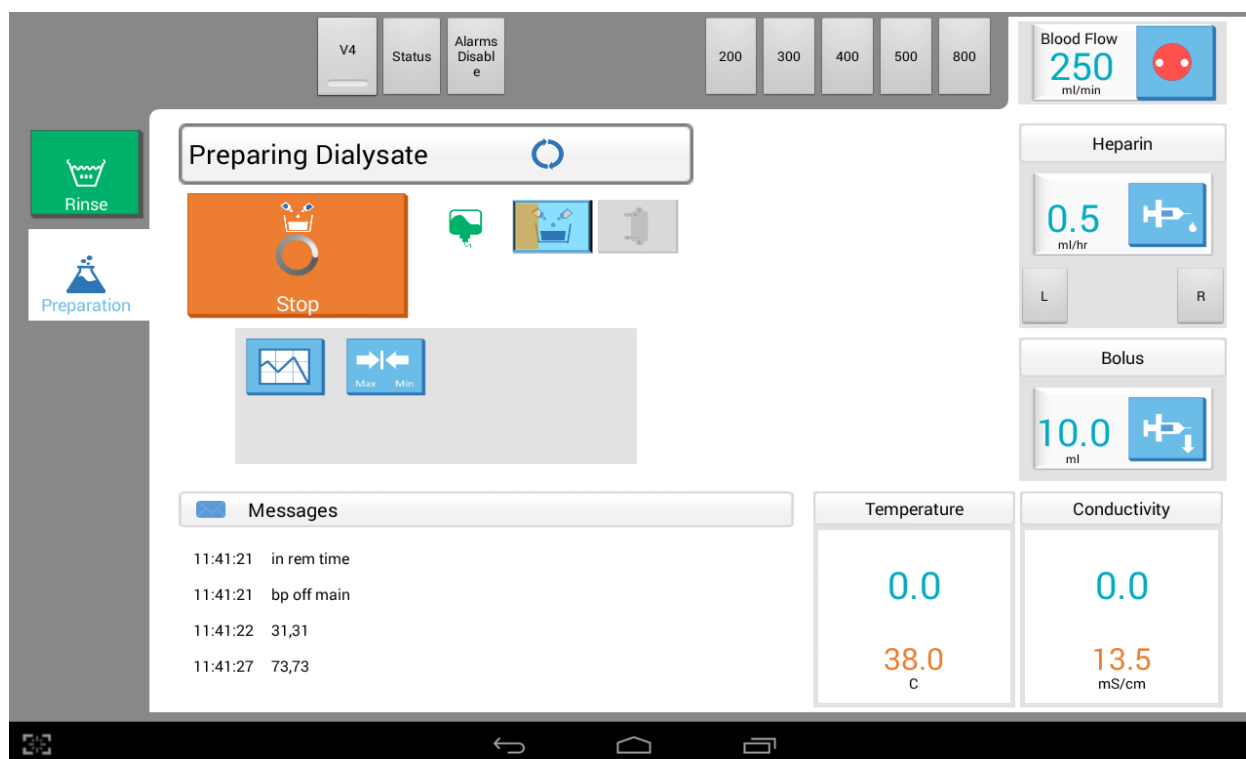


Figure 19: Dialysate Preparation

1.12. Dialysate flow

After dialysate is prepared, the Red and Blue Hansen connectors are removed from the machine. 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 flow can be adjusted to a flow rate 300 or 500 or 800ml/min.

Dialyzer connection screen is displayed [Figure 20].

After confirmation of the dialyzer connection then dialysate priming screen displayed [Figure 21].

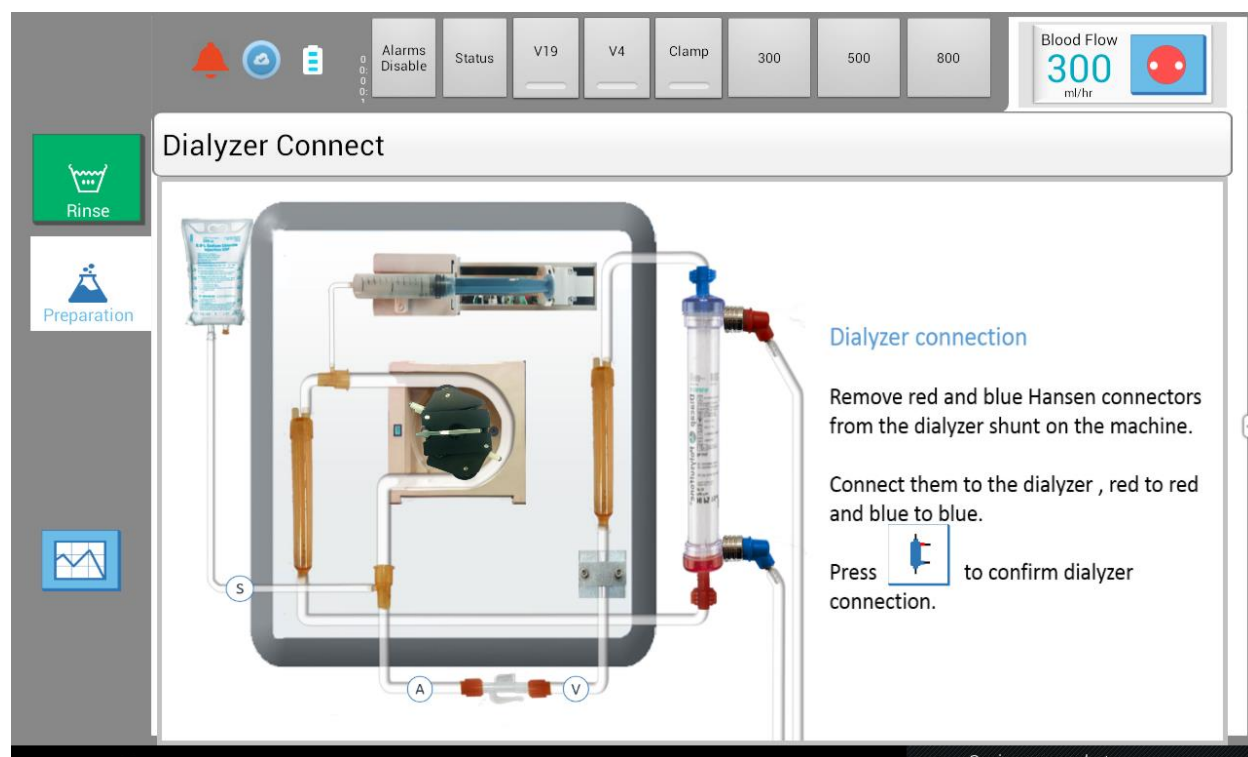


Figure 20: Dialyzer Connection

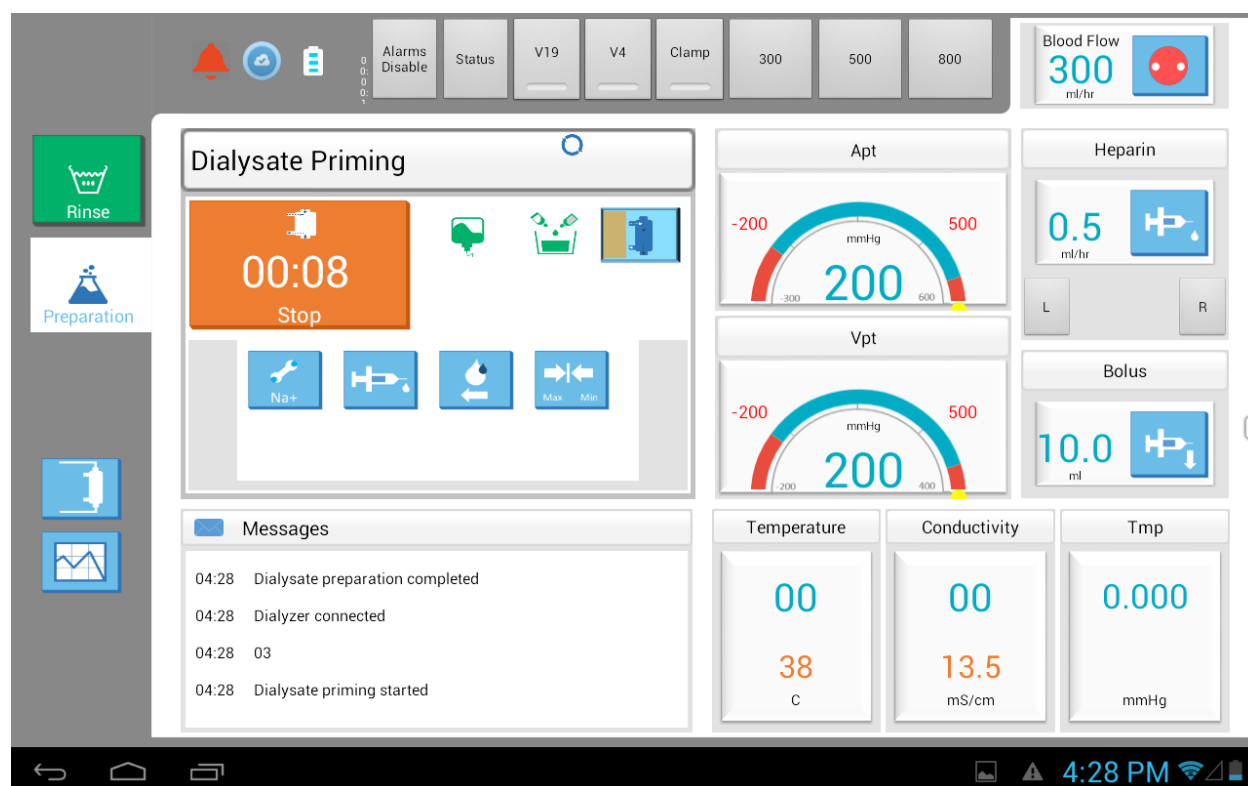


Figure 21: Dialysate Priming

2. Patient Connection

After dialysate priming is completed, Patient connect screen is displayed [Figure 22].

Self-test will be automatically initiated before patient is connected.

- Arterial pressure sensor test
- Venous pressure sensor test
- Blood detector test
- Venous clamp test
- Blood leak detector test
- Air bubble detector test
- Blood pump test
- Ultra-filtration pump test

After self-test completion, clamp both arterial and venous end of the bloodline. Remove shunt connector and connect the arterial line to the vascular access of the patient.

Open the arterial clamp. Run the blood pump at 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 to the target volume of patient.

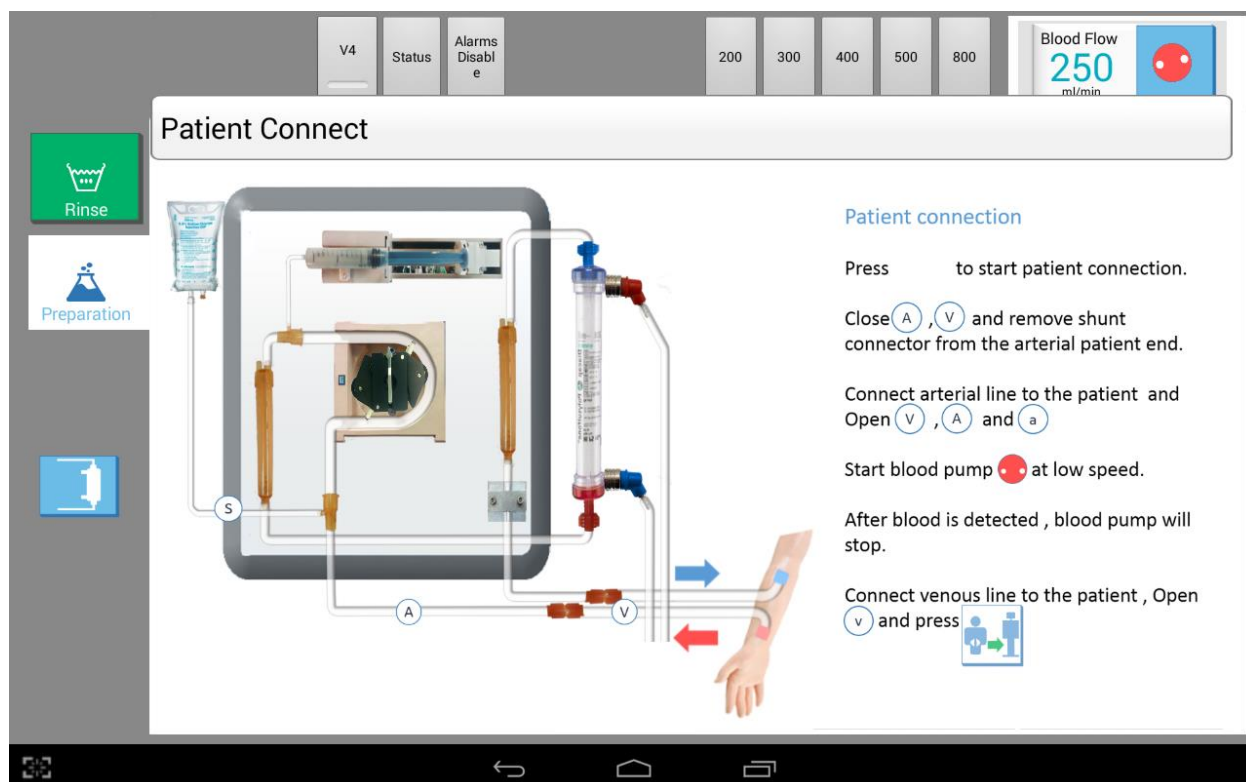


Figure 22: Patient Connection

3. Dialysis Session

Patient treatment parameters and alarm limits are set based on the dialysis prescription. Treatment parameters are set as below and dialysis began.

- 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)

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

Dialysis start screen is displayed {Figure 23}.

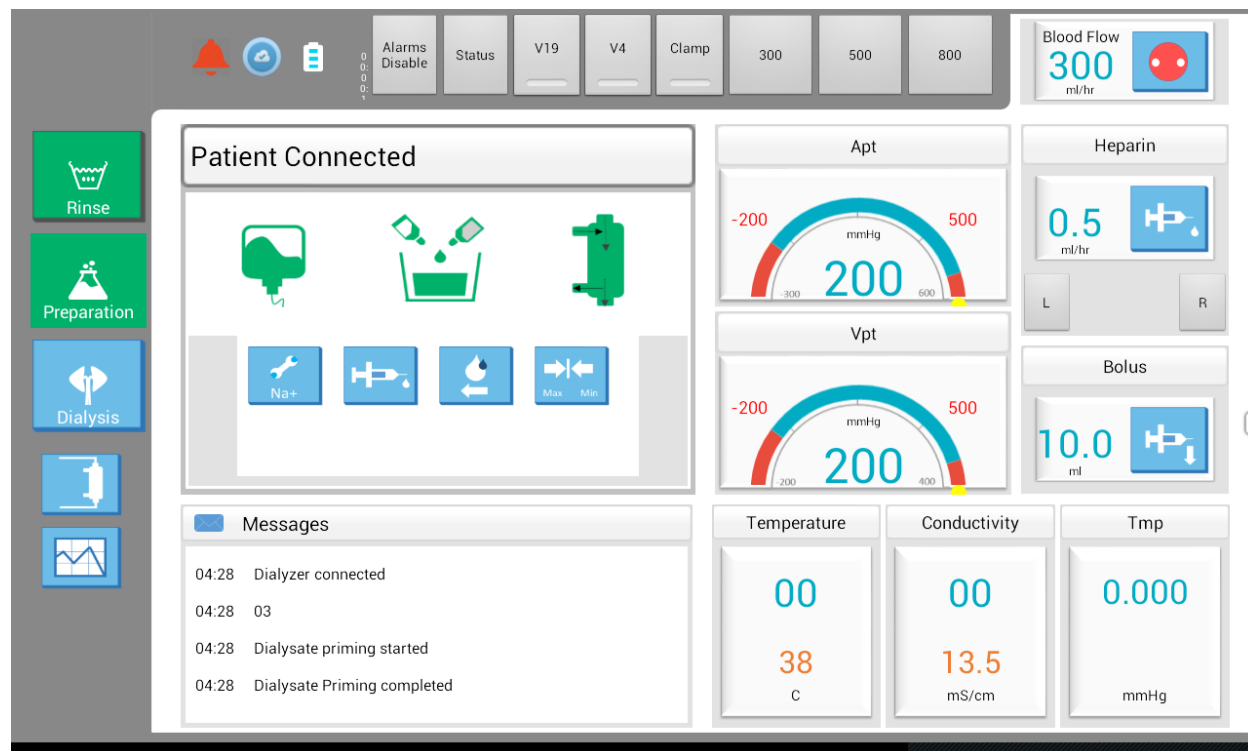


Figure 23: Dialysis Start Screen

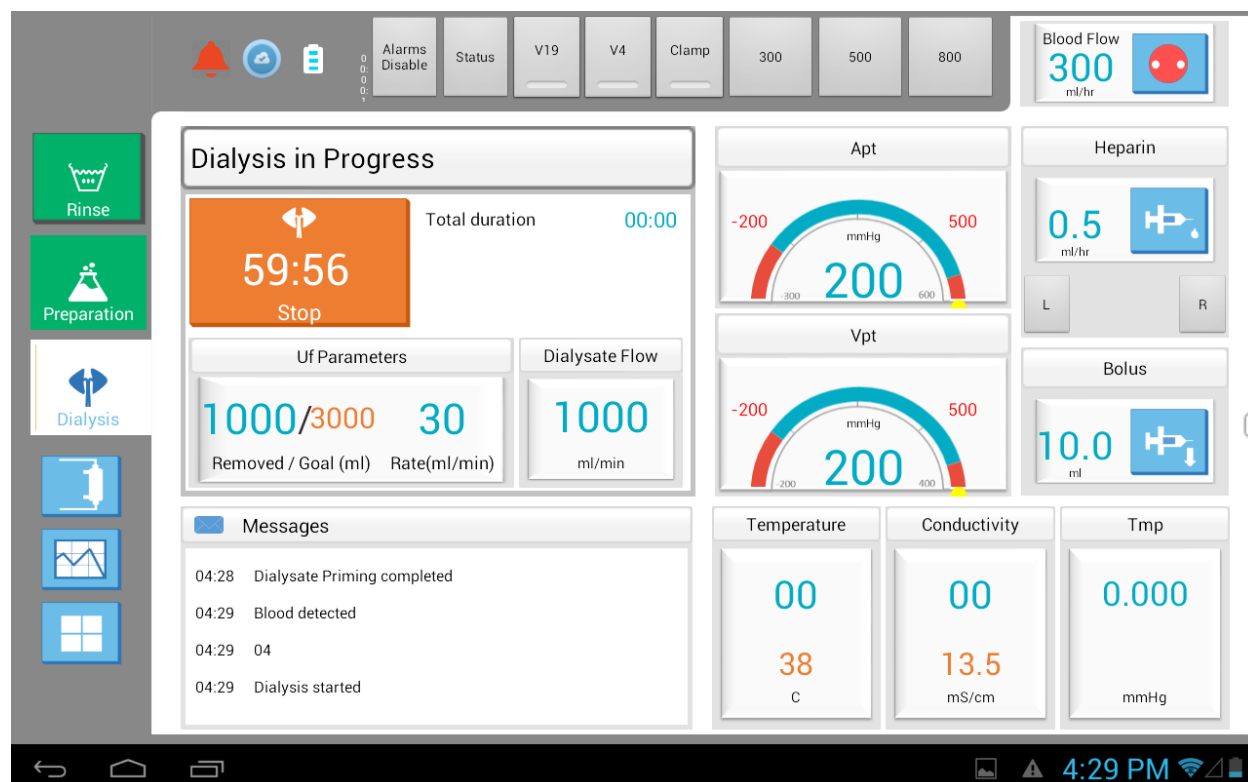


Figure 25: Dialysis monitoring screen

4. 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 bloodline.

Dialysis complete screen will be displayed [Figure 26]. The machine will display the Rinse and Disinfection profile screen to start cleaning and disinfection process for the next treatment.

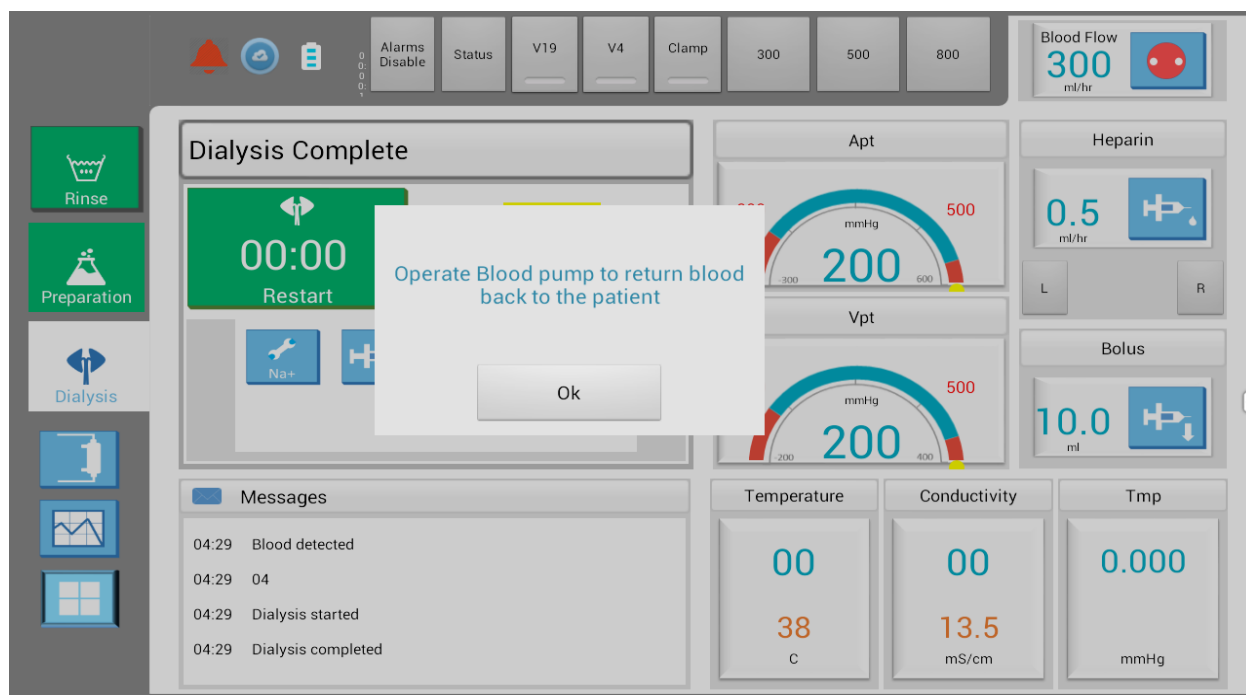


Figure 26: Dialysis Completion Screen

5. Rinse

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

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

Rinse and disinfection profile screen is displayed. Select “A” Water Rinse profile to start Rinse (Figure 27).

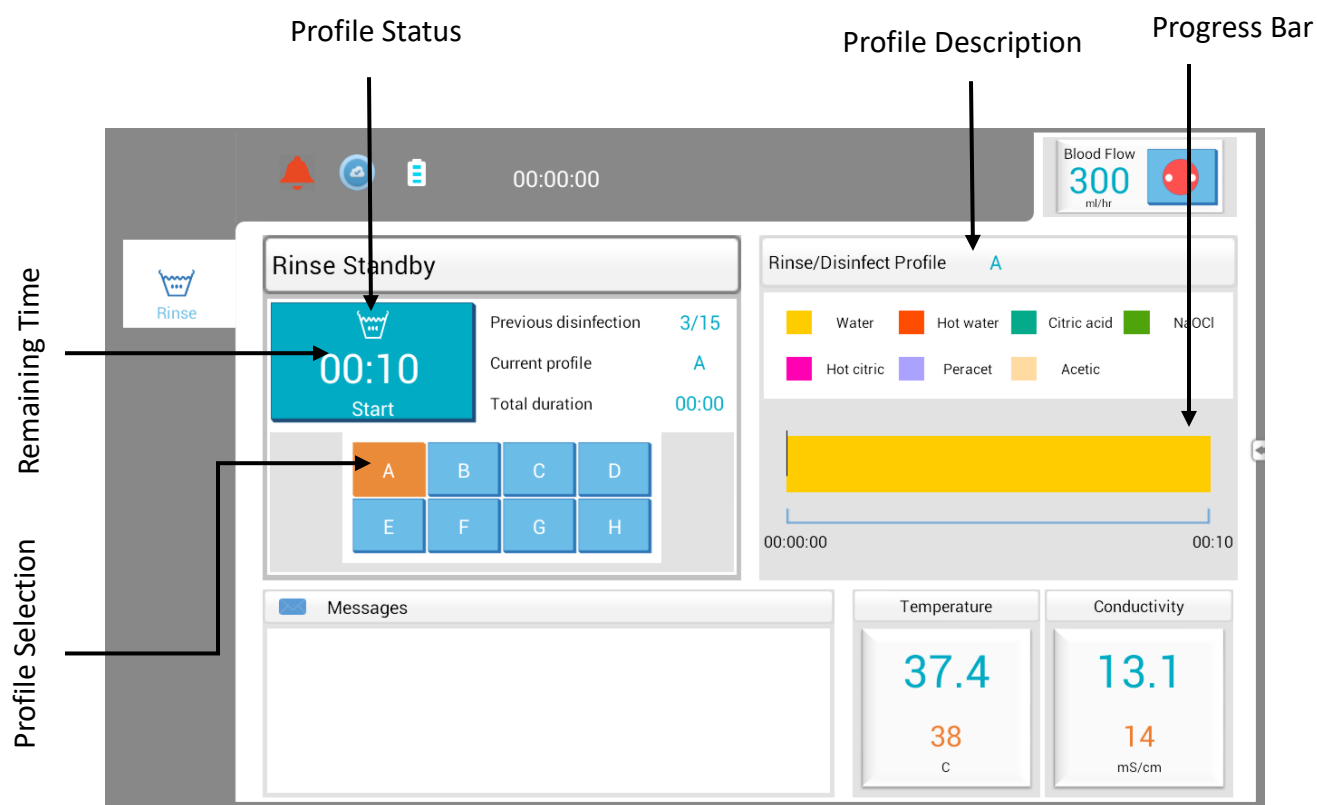


Figure 27: Rinse and Disinfection Selection Screen

6. Cleaning and Disinfection

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

6.1.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 provided for 15-30 minutes at 500ml/min. followed by cooling 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 27).

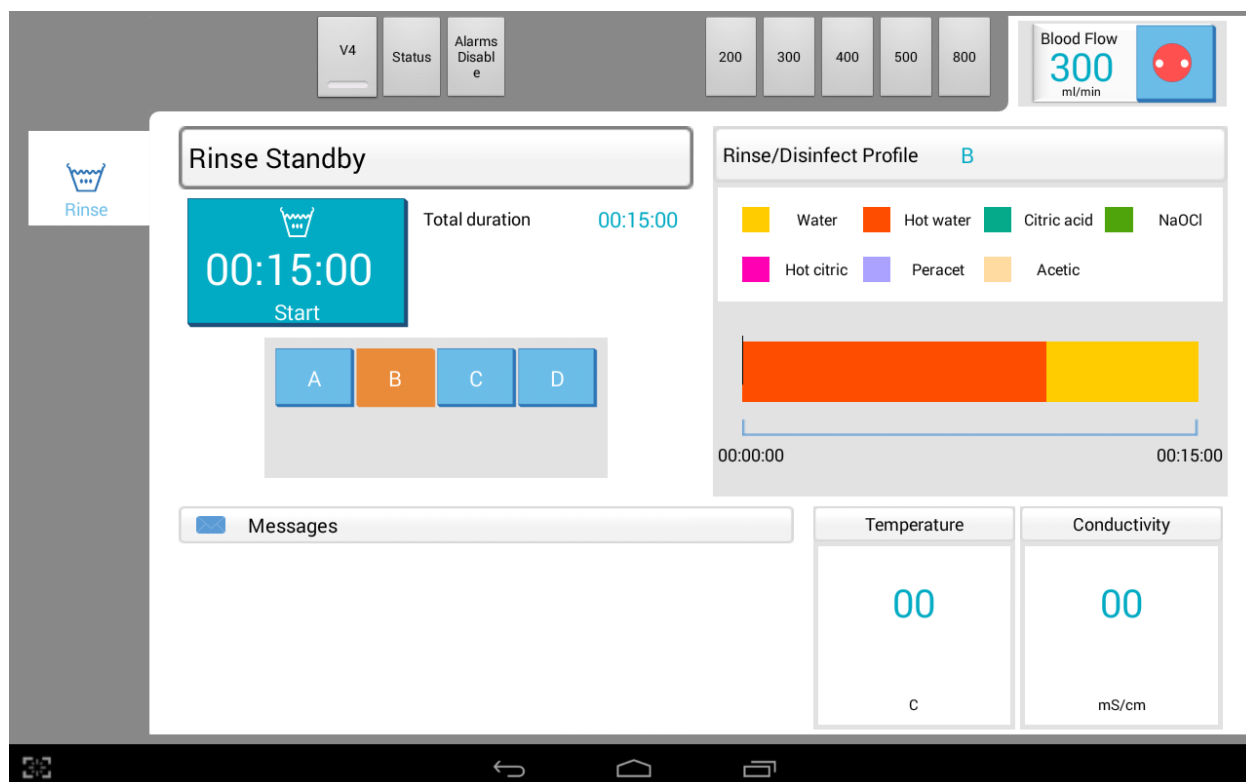


Figure 27: Heat Disinfection Screen

6.2. 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 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 28).

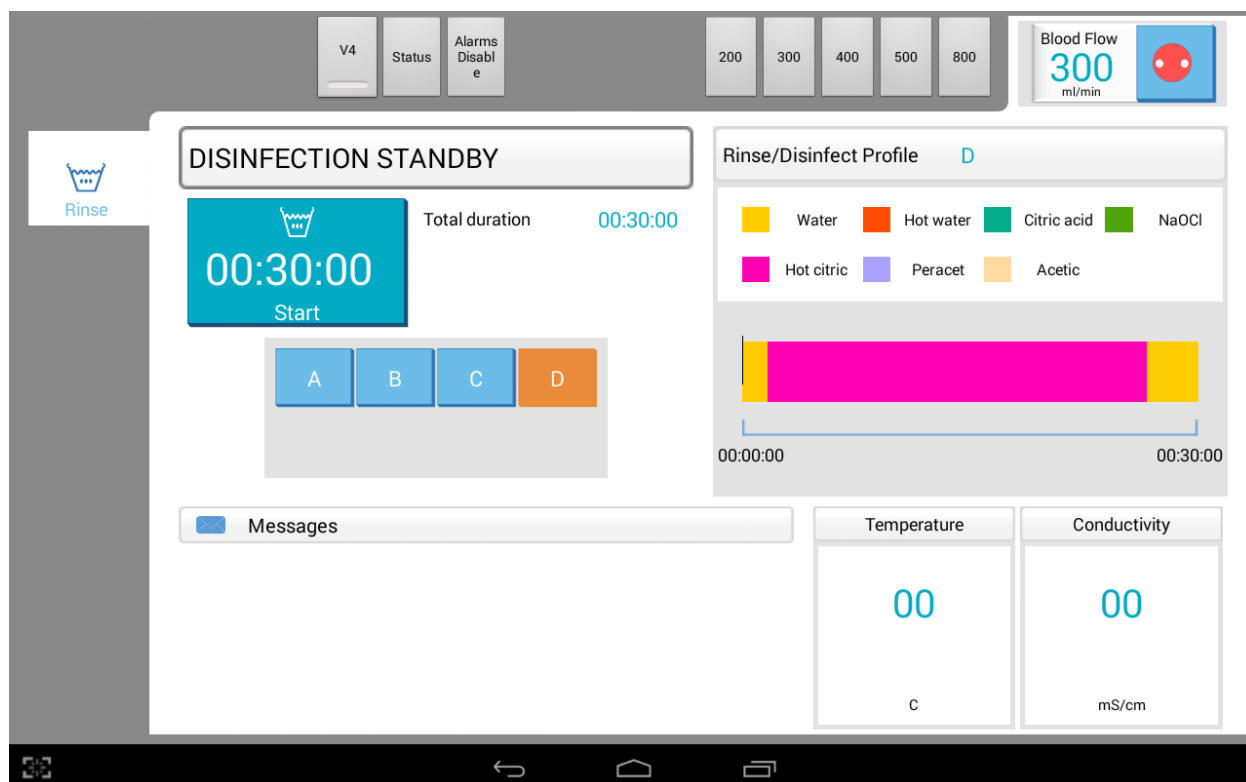


Figure 28: Citric acid Disinfection Screen

6.3. 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 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.

Rinse and disinfection profile screen is displayed (Figure 29). Select "D" NaOCl (Bleach) profile and start bleach chemical disinfection.

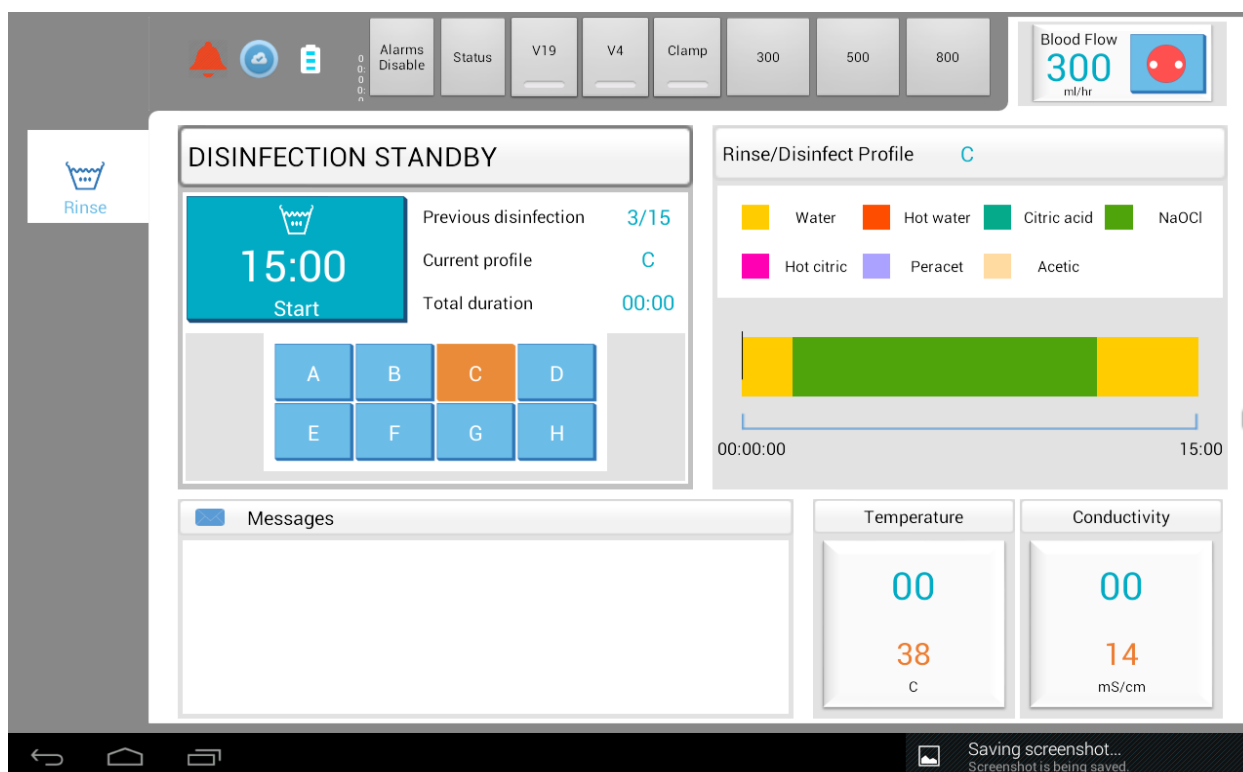


Figure 29: Bleach Disinfection Screen

6.4. 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 75°C - 85°C, citric acid heat disinfection 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 30). The progress bar on the screen will indicate the different phases of the heat chemical disinfection.

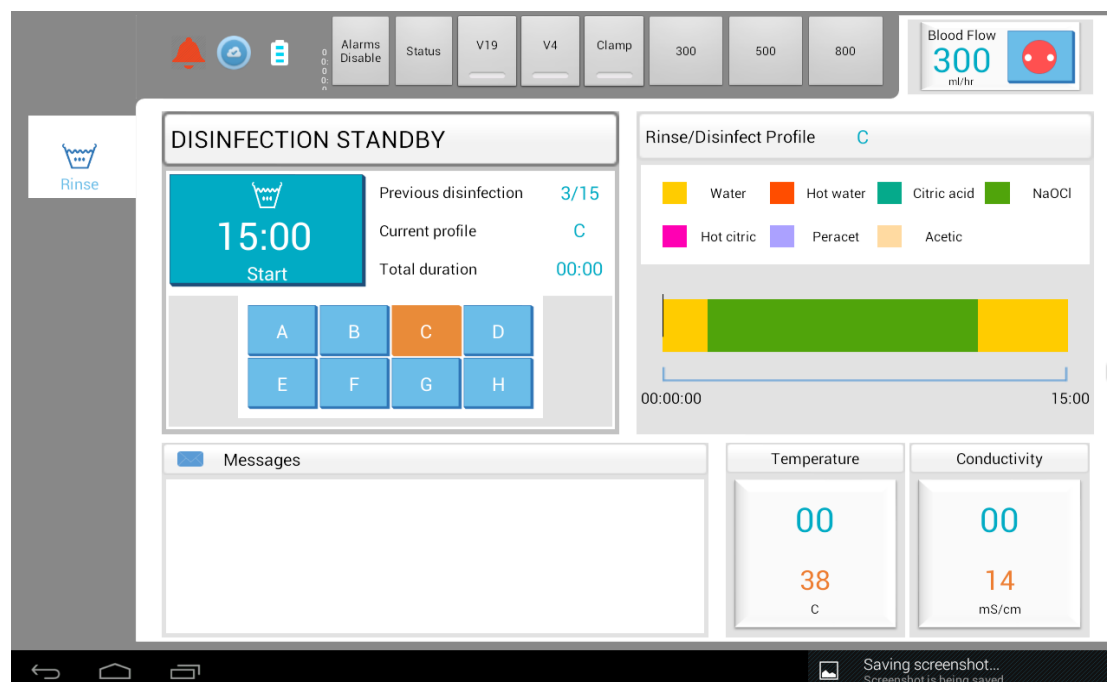


Figure 30: Bleach Disinfection Screen

6.5. 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.

7. Alarms Generated

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 31.

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.

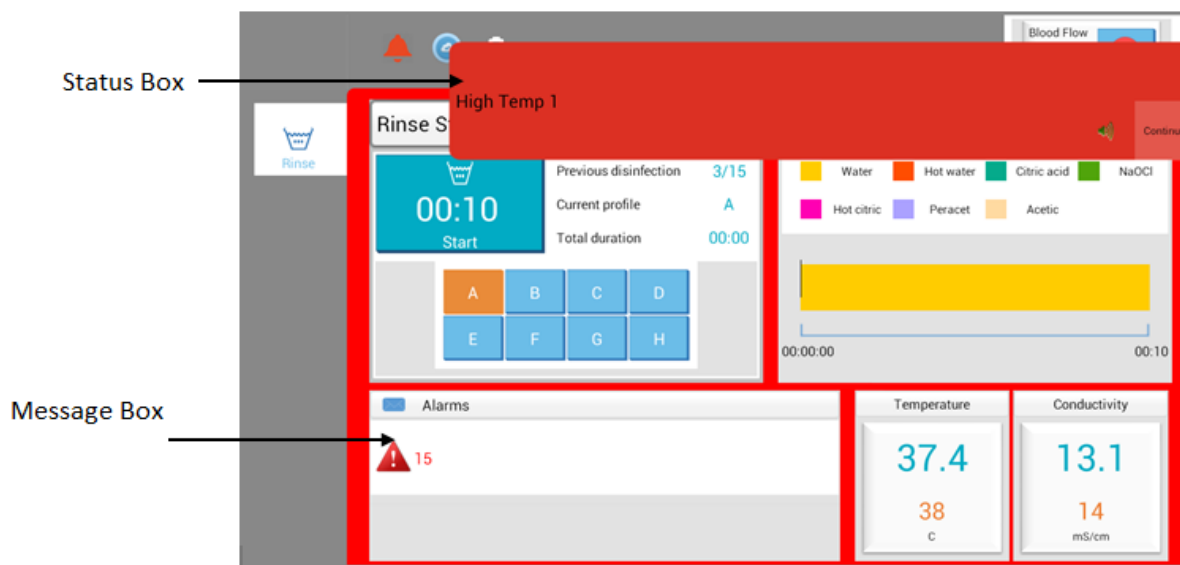


Figure 31: Alarm Screen

The operational statuses may be 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 pop up with RED background, RED light and an audible alarm.

Alarm numbering:

Alarm will be numbered as per below format:

Category	Event Type	Sequence Number
N – Normal Condition	B – Blood Side Related	3 Digit Number starting from

W -Warning Condition A - Alarm Condition	D – Dialysate Related T – Self Test S – Service Related O – Other	001
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Example: AB001, AD025, WO100

SI No	Alarm Message	Machine Alert	Purpose of Message	Machine Safety Action	User Action
1.	Arterial pressure is low	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured arterial pressure exceeds the lower limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured arterial pressure exceeds the upper limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured Venous pressure exceeds the lower limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured Venous pressure exceeds the upper limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Blood pump stops working during <ul style="list-style-type: none"> • saline priming • Saline recirculation • dialysate priming 	<ul style="list-style-type: none"> • Machine generates alarm “Blood pump stops “ 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Blood pump stops working during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	During the blood pump running ,blood pump door opened during <ul style="list-style-type: none"> • saline priming • saline recirculation • dialysate priming • dialysis 	<ul style="list-style-type: none"> • Machine generates the alarm “ Blood pump door open “ • Blood pump stops 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	During the blood pump running ,blood pump speed mismatch with set speed during	<ul style="list-style-type: none"> • Machine generates the alarm Blood pump over or under run “ 	<ul style="list-style-type: none"> • Check the blood pump and proper tubing connection. • If the alarm will not reset or continues

			<ul style="list-style-type: none"> • saline priming • saline recirculation • dialysate priming • dialysis 	<ul style="list-style-type: none"> • Blood pump stops 	to alarm intermittently, alert a qualified technician.
9.	Blood not detected	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Blood not detected during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Air bubble detected in blood line more than 10 μ L air bubble size during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stop • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • Check blood line for presence of air bubbles • Follow the instructions of the alarm window
11.	Heparin pump stopped	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The Heparin pump is encountering resistance during heparin infusion in dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stop • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops 	<ul style="list-style-type: none"> • Check dialyzer and dialyzer lines for blood leak • If blood is detected change dialyzer • If the alarm will not reset or continues

				<ul style="list-style-type: none"> Machine Standby 	to alarm intermittently, alert a qualified technician.
13.	Dialysate temperature high	<ul style="list-style-type: none"> Acoustic alarm Red light 	Measured dialysate temperature exceeds upper limit during dialysate priming	<ul style="list-style-type: none"> Bypass mode 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Acoustic alarm Red light 	Measured dialysate temperature exceeds upper limit during dialysis	<ul style="list-style-type: none"> Venous clamp close Blood pump stops Heparin pump stops UF stops Bypass mode 	<ul style="list-style-type: none"> If unable to attain prescribed temperature, discontinue treatment and alert a qualified technician.
15.	Dialysate temperature low	<ul style="list-style-type: none"> Acoustic alarm Red light 	Measured dialysate temperature exceeds lower limit during dialysate priming	<ul style="list-style-type: none"> Bypass mode 	<ul style="list-style-type: none"> 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.

					<ul style="list-style-type: none"> • If unable to reach prescribed temperature, discontinue treatment and contact qualified technician.
16.	Dialysate temperature low	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured dialysate temperature exceeds lower limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • If unable to attain prescribed temperature, discontinue treatment and alert a qualified technician.
17.	Dialysate preparation failed – low temperature	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured temperature exceeds the lower limit during dialysate preparation	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured temperature exceeds the upper limit during dialysate preparation	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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

					<p>drain.</p> <ul style="list-style-type: none"> • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
19.	Dialysate conductivity high	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured conductivity exceeds the upper limit during dialysate priming	<ul style="list-style-type: none"> • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured conductivity exceeds the upper limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
21.	Dialysate conductivity low	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured conductivity exceeds the lower limit during dialysate priming	<ul style="list-style-type: none"> • Bypass mode 	<ul style="list-style-type: none"> • 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

					<p>drain.</p> <ul style="list-style-type: none"> • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
22.	Dialysate conductivity low	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured conductivity exceeds the lower limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • If unable to attain prescribed conductivity, discontinue treatment and alert a qualified technician.
23.	Dialysate preparation failed – low conductivity	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured conductivity exceeds the lower limit during dialysate preparation	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured conductivity exceeds the higher limit during dialysate preparation	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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.

					<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured UF volume removed more than the set UF volume during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • If unable to attain prescribed UF volume, discontinue treatment and alert a qualified technician.
26.	UF volume removed -low	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Measured UF volume removed less than the set UF volume during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • If unable to attain prescribed UF volume, discontinue treatment and alert a qualified technician.
27.	Trans membrane pressure high	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Trans membrane pressure exceeds upper limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Trans membrane pressure exceeds lower limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The inlet dialyzer pressure exceeds the upper limit during dialysate priming	<ul style="list-style-type: none"> • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The inlet dialyzer pressure exceeds the upper limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The inlet dialyzer pressure exceeds the lower limit during dialysate priming	<ul style="list-style-type: none"> • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The inlet dialyzer pressure exceeds the lower limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The outlet dialyzer pressure exceeds the upper limit during dialysate priming	<ul style="list-style-type: none"> • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm 	The outlet dialyzer pressure exceeds the upper limit	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops 	<ul style="list-style-type: none"> • Check dialyzer for clotting and leakage dialysate

		<ul style="list-style-type: none"> • Red light 	during dialysis	<ul style="list-style-type: none"> • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • Check dialyzer tubing system for kinking • If the alarm will not reset or continues to alarm intermittently, alert a qualified technician.
35.	Dialyzer out let pressure low	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The outlet dialyzer pressure exceeds the lower limit during dialysate priming	<ul style="list-style-type: none"> • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The outlet dialyzer pressure exceeds the lower limit during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The machine is not receiving RO water during <ul style="list-style-type: none"> • rinse • dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection 	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The machine is not receiving RO water during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm 	The machine is not receiving enough RO water	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • Inspect the RO water source supplying to the machine. Correct as required.

		<ul style="list-style-type: none"> • Red light 	during <ul style="list-style-type: none"> • rinse • dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection 		<ul style="list-style-type: none"> • If the alarm does not clear, take the machine out of service and contact qualified technician.
40.	Low inlet flow	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The machine is not receiving enough RO water during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The machine is receiving high RO water flow during <ul style="list-style-type: none"> • rinse • dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection 	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	The machine is receiving high RO water flow during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	TS1 detects the inlet RO Water temperature $\geq 30^{\circ}\text{C}$ during <ul style="list-style-type: none"> • rinse • dialysate preparation 	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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

			<ul style="list-style-type: none"> • dialysate priming 		machine out of service and contact qualified technician.
44.	Inlet RO water temperature high	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	TS1 detects the inlet RO Water temperature $\geq 30^{\circ}\text{C}$ during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Acid probe not connected to the machine during rinse	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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.	Bicorb Probe OUT	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Bicorb probe not connected to the machine during rinse	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • Check the connection of Bicorb 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Acid probe is connected to the machine during <ul style="list-style-type: none"> • dialysate preparation • dialysate priming • bleach disinfection 	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Acid probe is connected to the machine during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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.	Bicorb Probe IN	<ul style="list-style-type: none"> • Acoustic 	Bicorb probe is connected	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • Check the connection of Bicorb probe

		alarm <ul style="list-style-type: none"> • Red light 	to the machine during <ul style="list-style-type: none"> • dialysate preparation • dialysate priming • bleach disinfection 		(BLUE) connector. Correct as required. <ul style="list-style-type: none"> • If the alarm does not clear, take the machine out of service and contact qualified technician.
50.	Bicorb Probe IN	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Bicorb probe is connected to the machine during dialysis	<ul style="list-style-type: none"> • Venous clamp closes • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • Check the connection of Bicorb 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	<ul style="list-style-type: none"> • Venous clamp closes unintentionally during • saline priming • dialysate priming • dialysate preparation 	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	<ul style="list-style-type: none"> • Venous clamp unintentionally closes during -dialysis 	<ul style="list-style-type: none"> • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Venous clamp not closes during Alarm condition	<ul style="list-style-type: none"> • Blood pump stops • Heparin pump stops • UF stops • Bypass mode 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic 	Dialyzer inlet-outlet connectors are not	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • Connects the Dialyzer inlet-outlet

		alarm <ul style="list-style-type: none"> • Red light 	connected to machine during rinse <ul style="list-style-type: none"> • rinse • dialysate preparation • heat disinfection • citric acid disinfection • bleach disinfection 		connectors to bypass shunt connections <ul style="list-style-type: none"> • Alarm persists, contact qualified technician
55.	Shunt connectors IN	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Dialyzer inlet-outlet connectors are not connected to dialyzer during dialysate priming	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • Connects the Dialyzer inlet-outlet connectors to bypass shunt connections • Alarm persists, contact qualified technician
56.	Shunt connectors IN	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Dialyzer inlet-outlet connectors are not connected to dialyzer during dialysis	<ul style="list-style-type: none"> • Machine Standby 	<ul style="list-style-type: none"> • Connects the Dialyzer inlet-outlet connectors to bypass shunt connections • Alarm persists, contact qualified technician
57.	Main AC power supply failure	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Main AC power supply failure during <ul style="list-style-type: none"> • rinse • dialysate preparation • dialysate priming • heat disinfection • citric acid disinfection • bleach disinfection 	<ul style="list-style-type: none"> • Battery Backup • Machine Standby 	<ul style="list-style-type: none"> • Re-establish power mains supply and system recovery • Alarm persists, contact qualified technician
58.	Main AC power supply failure	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	Main AC power supply failure during dialysis	<ul style="list-style-type: none"> • Battery Backup 	<ul style="list-style-type: none"> • Machine running by battery backup. • Blood pump stops • Venous clamp closes • Dialysate flow pump stops • Heater is OFF

					<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Yellow light 	Battery charge is less than desired threshold voltage (< 12 V 7 ah) during <ul style="list-style-type: none"> • rinse • dialysate preparation • dialysate priming • dialysis • heat disinfection • citric acid disinfection • bleach disinfection 	<ul style="list-style-type: none"> • Machine displays the alarm “Low battery voltage” 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic signal • Yellow light 	Missing supply of Bicarbonate concentrate during rinse	<ul style="list-style-type: none"> • Machine displays the alarm “Bicarbonate solution volume low” 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic signal • Yellow light 	Missing supply of Bicarbonate concentrate during dialysis	<ul style="list-style-type: none"> • Machine displays the alarm “Bicarbonate solution volume low” 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Acoustic alarm • Red light 	CPU goes to dead lock state during <ul style="list-style-type: none"> • rinse • dialysate preparation • dialysate priming • dialysis • heat disinfection • citric acid disinfection • bleach disinfection 	<ul style="list-style-type: none"> • Machine rebooted 	<ul style="list-style-type: none"> • If alarm persists, contact qualified technician
63.	UF goal reached	<ul style="list-style-type: none"> • Yellow light 	This message is to alert the operator that set ultrafiltration goal has been reached during dialysis	<ul style="list-style-type: none"> • No response 	<ul style="list-style-type: none"> • No response
64.	Dialysis time reached	<ul style="list-style-type: none"> • Yellow light 	This message is to alert the operator that set dialysis time has been reached during dialysis	<ul style="list-style-type: none"> • No response 	<ul style="list-style-type: none"> • No response

8. Technical specifications

8.1.General

8.1.1. 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)

8.1.2. Medical device classification

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

8.1.3. 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

8.1.4. Fuses

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

8.1.5. Electrical safety

Parameter	Specification
Protection against electrical shock (Safety classification as per IEC 60601-1)	Class 1
Degree of protection (As per IEC 60601-1)	Type B
Protection class (Protection against penetration of fluid)	IPX1
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 μ A or less
Patient Leakage current (Single fault condition)	50 μ A or less

8.1.6. EMC and EMI

Parameter	Specification
EMC	IEC60601-1-2, Compliance Certificate (4th Edition)
EMI	IEC60601-1-2, Compliance Certificate (4th Edition)

8.1.7. 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

8.1.8. External connection

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

8.1.9. Storage

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

8.1.10. Transportation

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

8.1.11. Operating condition

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

8.1.12. 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

8.1.13. Heater

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

8.2.Dialysate system

8.2.1. Dialysate temperature

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

8.2.2. 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

8.2.3. Dialysate flow

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

8.2.4. Transmembrane pressure

Parameter	Specification
Transmembrane Pressure range (TMP)	Calculation: $TMP = \frac{1}{2}[(APT + VPT) - (PS1 + PS2)] - 25 \text{ mmHg}$ 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

8.2.5. Dialyzer inlet pressure

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

8.2.6. Dialyzer outlet pressure

Parameter	Specification
Measurement range	-400 mmHg to + 330 mmHg
Accuracy	±10mmHg
Alarm Limit	-400 mmHg to + 330 mmHg

8.2.7. Ultrafiltration (UF)

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

8.2.8. 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

8.2.9. Blood leak detector

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

8.3.Extracorporeal circuit

8.3.1. 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

8.3.2. Venous pressure

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

8.3.3. Blood pump

Parameter	Specification
Blood Pump	2-roller unidirectional peristaltic 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.

8.3.4. 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

8.3.5. Venous clamp

Parameter	Specification
Venous Clamp	Closes with critical alarm for patient safety

8.3.6. Blood detector

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

8.3.7. 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

8.4. Rinse and Disinfection

8.4.1. Rinse

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

8.4.2. 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

8.4.3. 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%
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8.4.4. 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%

8.4.5. 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%

8.4.6. Surface disinfection

Parameter	Specification
Surface Disinfection	Surface cleaning and disinfection by wiping down using bleach

Concentration	Bleach 1 %
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8.5.Alarm sound pressure level

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

8.6.Materials used for dialysate line

Following materials are coming in direct contact with water, dialysate, dialysis concentrate and/or disinfectants.

Material Name	Specification
Metal	Stainless steel, SS304, SS316
Plastic	PEEK (Polyetheretherketone)
Plastic	PEI (Polyetherimide)
Plastic	PVDF (Poly vinylidene fluoride)
Plastic	PTFE (Polytetrafluoroethylene)
Plastic	Acrylic (ABS Plastic)
Tubing	Silicone
Rubber	Fluorocarbon rubber (FKM)
Others	Alumina