Tablo Hemodialysis System

User Manual

PN-0004205 Rev-05

℞Only Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The Tablo® System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription, with a trained individual available as needed who is considered competent in the use of the device by the prescribing physician.

CONTRAINDICATIONS

Prescribing physicians should consider the following contraindications for hemodialysis: shock, uncontrollable bleeding condition, or lack of vascular access. 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.

DRUG CLEARANCE

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

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. The patient may also manifest hypothermia, hyperthermia, itching, anxiety, convulsions, seizure, and other neurologic symptoms associated with dialysis dementia. These symptoms are thought to occur if the patients' blood volume or electrolyte balance is not maintained within acceptable limits. Other, more serious, complications arising from dialysis, such as hemorrhage, air embolism, acidosis, alkalosis or hemolysis, can cause serious patient injury or death. The embolism/foam detector is not able to be disarmed during treatment. The protective systems in the Tablo Console monitors the passages in the extracorporeal circuit and will notify the user via an alarm if a narrow passage is detected. 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 dialysis fluid within the chemical and bacteriologic limits, specified in the AAMI standards for water, concentrates and the dialysis fluid for dialysis.

Infections or pyrogenic reactions may also result from contamination of the extracorporeal circuit.

Allergic reactions to the chemical disinfectants may occur if insufficient procedures are used to remove or maintain the residual disinfectant at acceptable levels. Chemical disinfectants are used for machine disinfection, or for disinfection of water treatment and distribution systems.

All blood connections must be made using aseptic technique.

All tubing 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 complications if these occur.

Conventions Used in this Manual

Warnings:	Indicates a potentially hazardous situation, which if not avoided, could result in serious injury or death.
Caution:	Indicates a hazardous situation, which if not avoided, may result in minor or moderate injury, or result in product damage.
NOTE:	Extra information that may help the user complete/understand a task. No potential user harm, but the product or infrastructure could be impacted.

Table of Contents

General Warnings and Cautions

Warnings

1. The Tablo System is a prescribed device for use by adults.
2. Failure to install, operate, and maintain this equipment according to the manufacturer's instructions may cause patient injury or death.
3. The machine must be plugged directly into the electrical outlet; extension cords and power strips are prohibited.
4. To avoid damaging the equipment or personal injury, internal adjustments to the blood pressure module should only be made by a qualified technician.
5. This dialysis machine may be susceptible to electromagnetic interference (EMI) causing a false alarm and/or shutdown of the Hemodialysis delivery machine or components. Devices emitting strong electromagnetic radiation such as portable phones, radio equipment (walkie-talkies, etc.), radio transmitters, and like equipment, should not be used in the vicinity of this equipment. The use of digital cell phones can be conditionally allowed. Discontinue use of any device if any interference is noted, such as false pressure indications that disappear when external signal is removed.
6. 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 dialysis fluid before returning the machine to clinical use.
7. Unidentified malfunctions or alarm failures could potentially expose a patient to a serious health risk. Alarm limits for the arterial pressure monitor, venous pressure monitor, and transmembrane pressure (TMP) monitor are automatically set and delayed for pressure stabilization. Alarm limits for temperature and conductivity are calculated for the dialysis fluid composition. These must be maintained within safe physiological limits as specified by the prescribing physician.
8. Possible Explosion Hazard if used in the presence of flammable anesthetics.
9. The Tablo Hemodialysis System is equipped with one internal venous transducer protector and two external transducer protectors. The internal venous transducer protector is located inside the Tablo Console and cannot be accessed by the user. The external transducer protectors are located on the Tablo Cartridge. In the event the venous external transducer protector (Cartridge) is wetted, it should be inspected for blood and/or saline and the Cartridge should be immediately replaced. In the event blood and/or saline is observed on the Venous and/or Arterial Pressure Sensors, the Console should be wiped down with an appropriate cleaning agent, removed from service, and Outset personnel contacted.
10. 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.
11. The dialysis fluid 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. System leaks may also pose a slip-and-fall hazard. Clean up spills immediately.
12. 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.
13. Avoid placing the System, its power cord, and the water and drain lines in high traffic areas with poor visibility.
14. Keep the drain line outlet away from areas where food and beverages are prepared or consumed.
15. No modification of this equipment is allowed.

16. Should small parts become detached from the System, they may present a choking hazard.
17. Power cords and water lines can be a strangulation hazard, Keep small children away from the cords and lines when in use. When not in use, store cords and water lines as instructed.
18. Do not open any panel doors unless specifically instructed to do so as part of the use, cleaning, or maintenance instructions. There is a risk of electric shock or burns.
19. Ensure to test your incoming water per Federal and State Regulations.
20. Be sure to use compatible solutions. Failure to use properly matched solutions may allow improper dialysis fluid to be delivered to the patient, resulting in patient injury or death.

Cautions

1. Read these instructions before using the equipment.
2. Read all warnings, cautions, and instructions provided with this Hemodialysis System before using.
3. System leaks may occur. Unattended operation of the machine (for example, during disinfection) may result in flooding and can cause property damage. Clean up spills immediately.
4. Store the System in a clean, dry, indoor location with all doors and lids closed.

Blood Pressure Module Contraindications

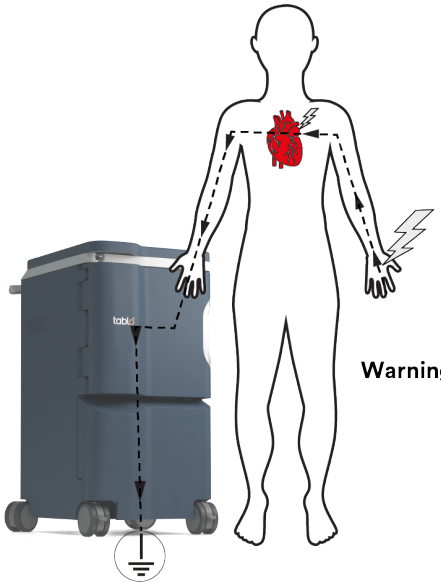
The following are generally accepted contraindications for using a timed automatic blood pressure instrument utilizing the Oscillometric principle:

- Use of a heart lung machine
- Peripheral circulation problems
- Severe arrhythmia
- Ectopic beats
- Convulsions
- Spasms
- Tremors
- Tachycardia

Use of incorrectly sized blood pressure cuffs may results in inaccurate blood pressure readings.

This is a guideline only. Final determination of the suitability of any medical instrument for use with any patient is the responsibility of the treating physician.

Using a Central Venous Catheter



Do not allow contact with additional electrically conductive devices with leakage currents greater than 10 µA DC or greater than 50 µA DC “single fault” condition.

Warning: Patient is electrically connected to ground via blood and dialysate. Leakage currents originating from other electrical equipment and medical electrical equipment set up in the patient environment can produce microshocks that could harm the patient. These leakage currents could flow through the body of the patient via the heart and the central venous catheter, whose tip is in the right atrium (and incorrectly in contact with the atrium wall,) to the earth via the Tablo.

Symbols on Packaging

The following symbols and equivalent English text appear on the packaging of the Tablo Console.

Symbol	Description
	Keep Dry
	Refer to User Manual
	Manufacturer and Date of Manufacture
	Serial Number
	Class I ME Equipment
	Temperature Limit
	Humidity Limit
	Atmospheric Pressure Limitation
	Caution
	Do Not Tip
	Do Not Step Upon
	Do Not Sit Upon
REF	Catalog Number
LOT	Lot Number

Introduction

Description

The Outset Tablo Hemodialysis System has a water purification system included inside the machine. The System's innovative design includes:

- The Console, a single module consisting of multiple fluidic systems that perform the activities of a Water Purification System (WPS) and a conventional Dialysis Delivery System.
- The Tablo Cartridge, a single-use blood tubing set attached to an Organizer. A disposable Cartridge is inserted onto the front panel of the Console for each dialysis treatment. For more information, see "*Front View of the Disposable Cartridge*" on page 15.

Accessories

Supplied by Outset:

- Tablo Cartridge
- Tablo Straws
- Tablo Acid concentrate (red-labeled jug)
- Tablo Bicarbonate concentrate (blue-labeled jug)
- Patient Key
- Non-invasive Blood Pressure Cuff (NIPB) kit, adult size medium. Small and large sizes are not shipped with the Console, but can be ordered from Outset Medical.
- Hand-Crank
- Locking Power Cord
- Drain Line
- Water Line
- Insert and straws for Minncare Cold Sterilant

Dialysis Treatment Accessories not Provided by Outset:

- High Flux Dialyzer (prescription required)
- Minncare Cold Sterilant
- Chlorine/Chloramine test kit
- Saline bags
- Heparin
- Syringes and needles
- Gloves and mask
- Biohazard container
- Disinfectant, gauze pads, and tape for access site

Overview

Figure 1. Front View of Tablo Console

NOTE: For transportability, there are lockable wheels in the front and swiveling casters in the rear.

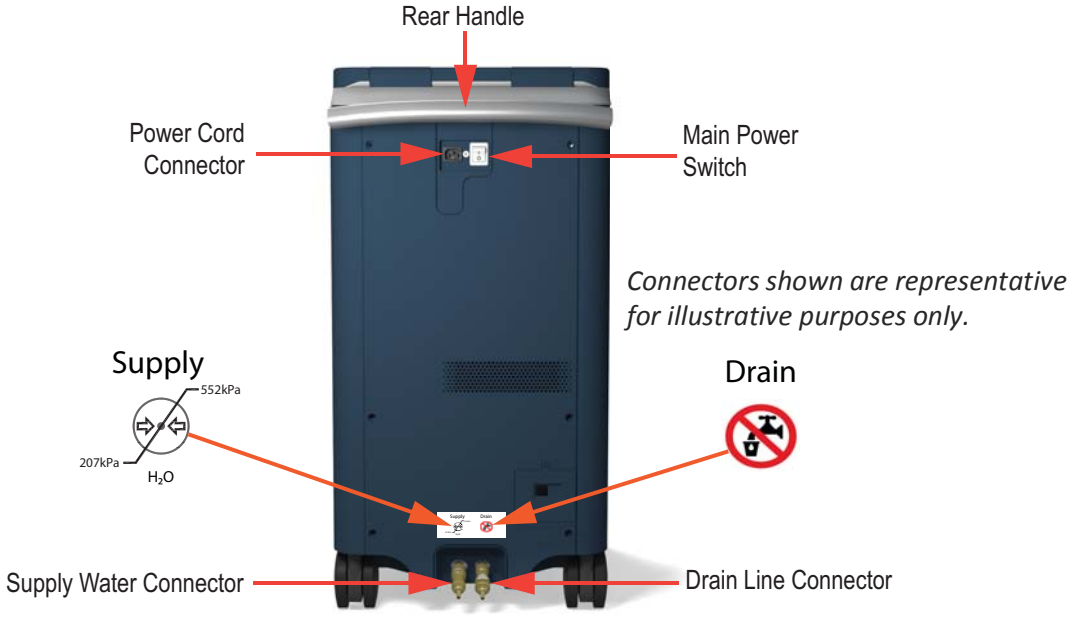


Figure 2. Back View of Tablo Console

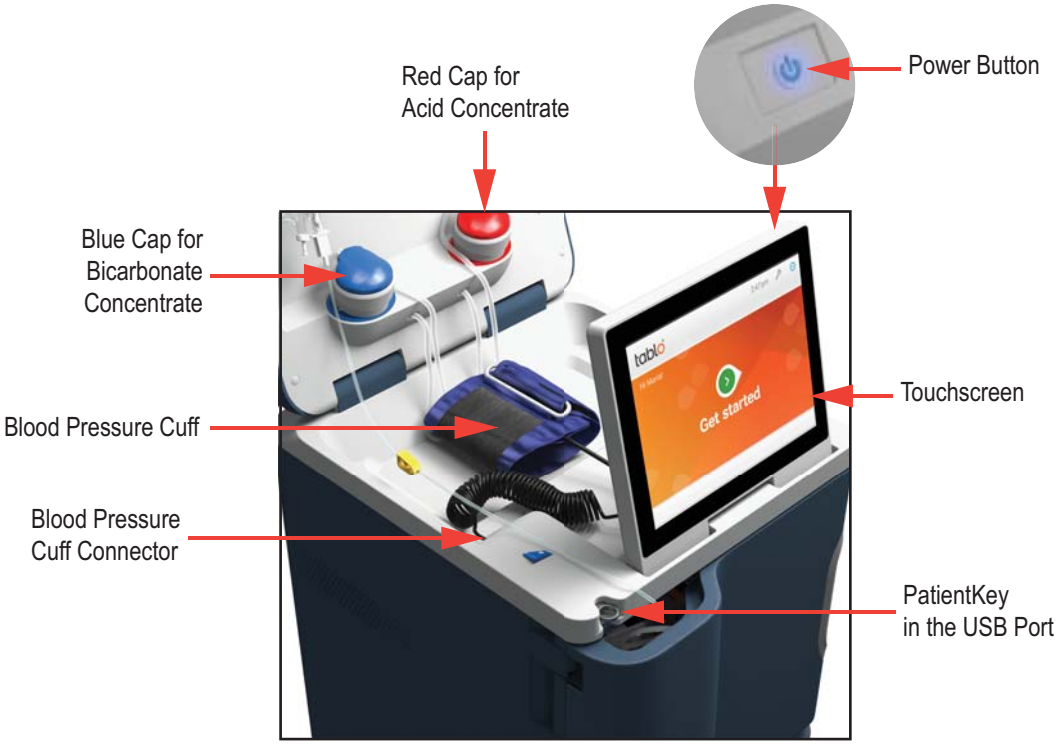


Figure 3. Top View of Tablo Console

Figure 4. Top View of Tablo with Accessories Installed

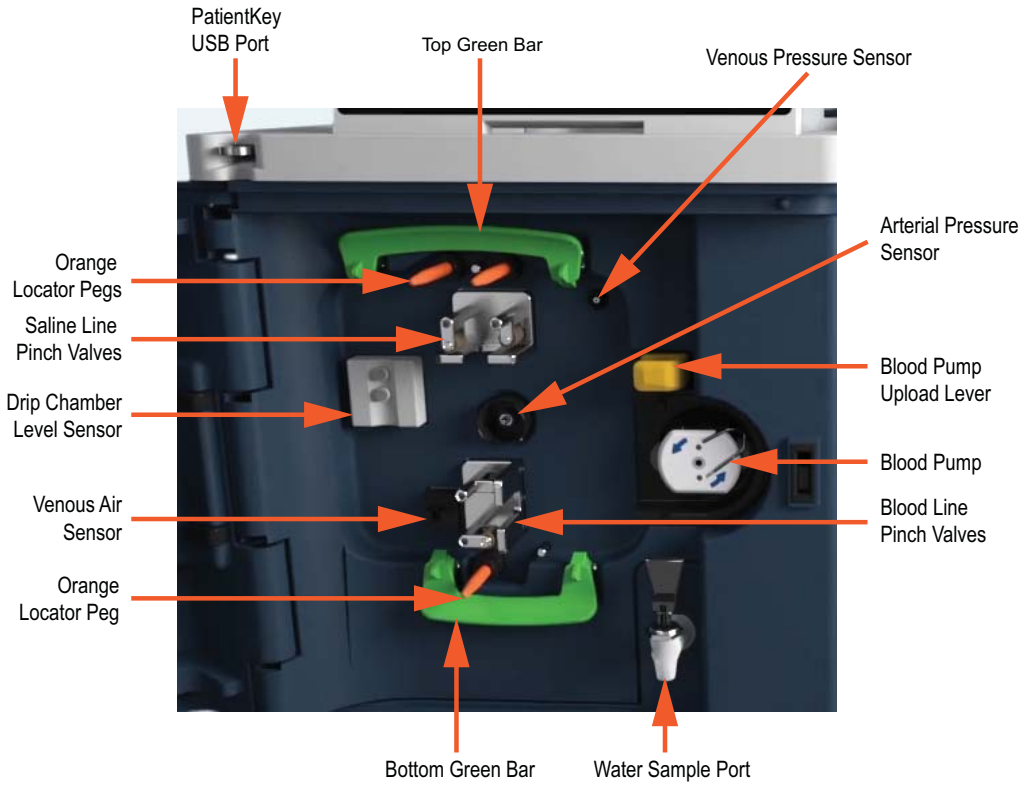


Figure 5. Inside Top Door without Cartridge Installed

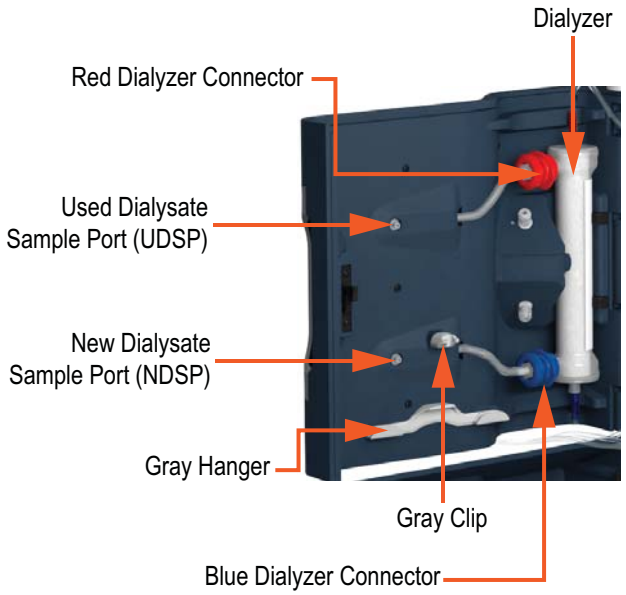


Figure 6. Tablo with Front Door Open

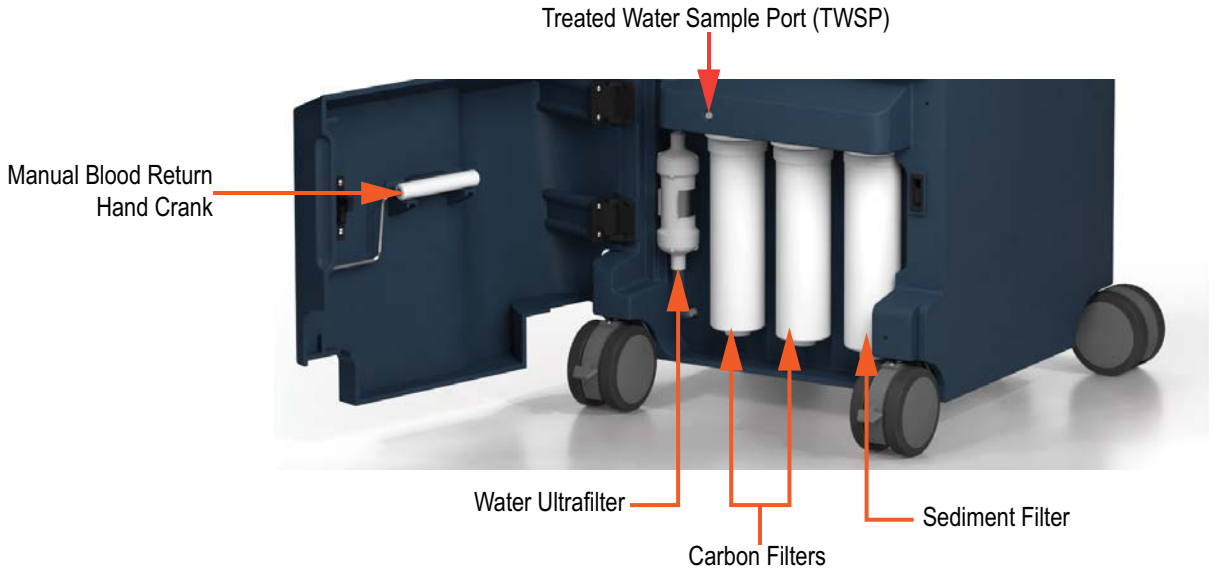


Figure 7. Tablo with Bottom Door Open

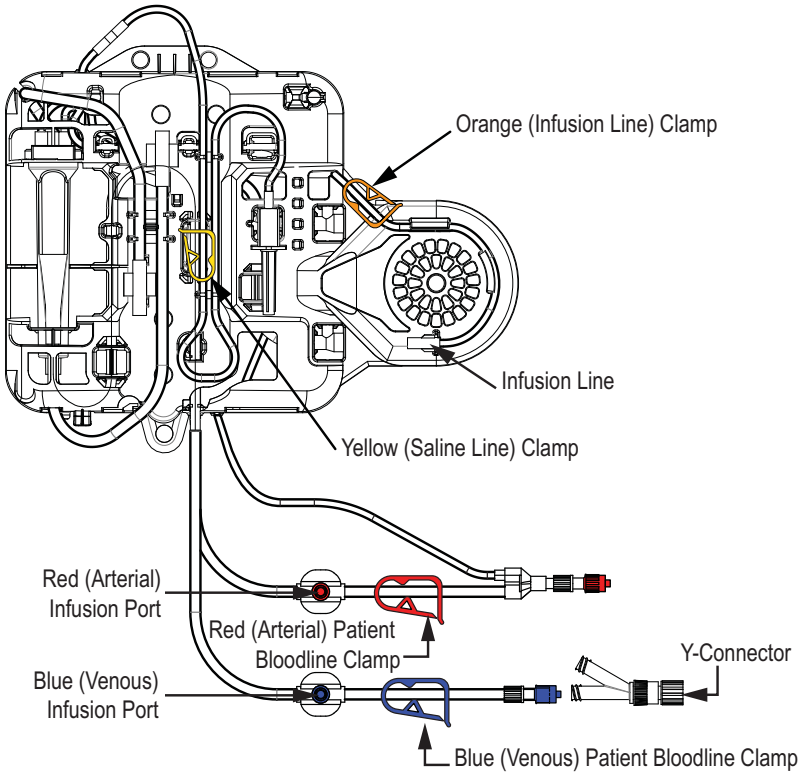


Figure 8. Front View of the Disposable Cartridge

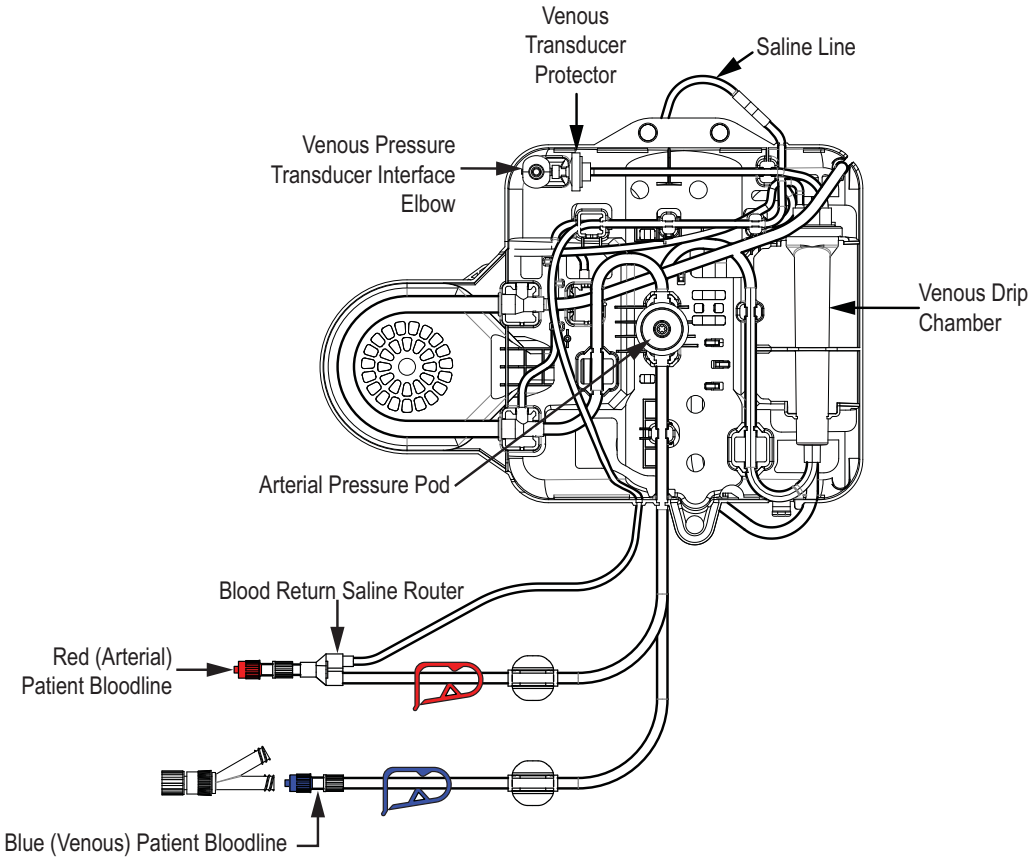


Figure 9. Back View of the Disposable Cartridge

System Setup

Cautions: Avoid placing the System, its power cord, and the water and drain lines in high traffic areas with poor visibility.

Do not place the System in a corner while in use. Ensure that the vents are not blocked.

NOTES: A smoke detector should be properly installed in the room used for dialysis. Follow the manufacturer's instructions. The alarm should be tested according to the manufacturer's instructions. Replace the battery as specified.

Always lock the front wheels after the System has been moved.

1. Position the System in an area with access to a water supply, drain, and a dedicated electrical outlet with input of 120 VAC ~ 60 Hz, 1440 watts. To move the System:
   a) Unlock the front wheels by pushing up on the wheel lock levers.
   b) Hold and pull on the handle located on the back of the Console and gently roll the System into position.

   NOTE: For safe transportation of the System, grab the rear handle from the back of the Console and pull gently without tipping the System.
2. Secure the System once it is in position by pushing down on the wheel lock levers.

Connect the Water and Drain Lines, and Power Cord

1. Unpack the water line and attach it to the Supply Water Connector on the back side of the Console. Insert the connector until it snaps into place.
2. Securely connect the other end of the water line to a water source.
3. Unpack the drain line and attach it to the Drain Line Connector on the back side of the Console. Insert the connector until it snaps into place.
4. Insert the other end of the drain line into a drain. There should be at least a 1-inch gap between the drain line and the drain to prevent contamination. The drain should not exceed 4 feet in height to allow for proper draining of fluids.

NOTE: The drain line must be positioned in a drain at all times when the System is in use.

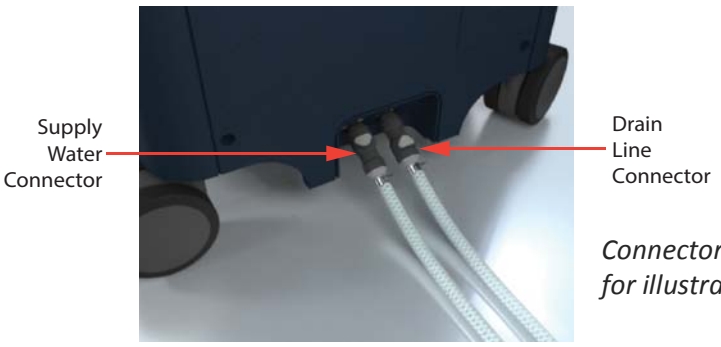


Figure 10. Water and Drain Connections

5. Plug the Outset supplied locking power cord into the Power Cord Connector located on the back of the Console.

Figure 11. Location of Power Cord Connector and Main Power Switch

6. Plug the other end of the power cord into a designated wall outlet with input of 120 VAC ~ 60 Hz, 1440 watts.
7. Turn On the Main Power Switch.

Warnings: Fire Hazard – Do not use extension cords.

Only the power cord provided by Outset Medical shall be used.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

How to Remove the Power Cord

NOTE: Connect the power cord to a wall outlet with input of 120 VAC ~ 60 Hz, 1440 watts. Otherwise, product damage may result.

Pull on the red tabs to release and remove the cord from the power cord connector.

Figure 12. Detaching Power Cord from System

Installing the Accessories

Caution: Read the instructions, warnings, and cautions provided with the System accessories before using. Specific instructions are not included in this manual.

1. Unpack the blood pressure cuff. Attach the blood pressure cuff to the system.
2. Ensure that the filters are installed and secure. For more information, see "*Filters Tab*" on page 90.

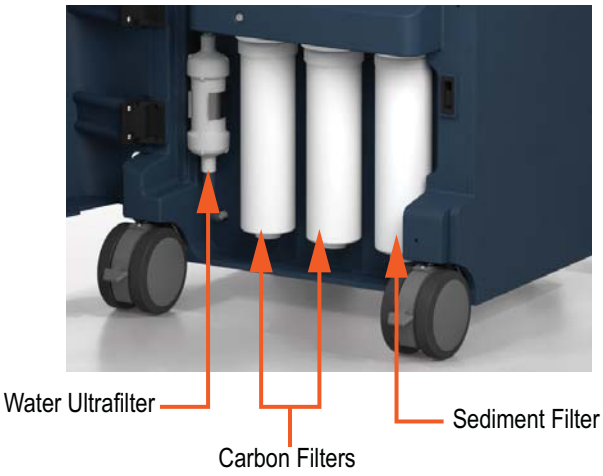


Figure 13. Check Filters

NOTE: The Tablo Console has seven filters installed: two reverse osmosis (RO) filters, two carbon filters, one water ultrafilter, one dialysate ultrafilter, and one sediment filter. Only four filters are accessible as shown in Figure 13.

Turn On the Power to the System

1. Turn on the Main Power Switch located on the back of the Console.

Figure 14. Location of Main Power Switch

2. Open the lid and lift the Touchscreen.

Caution: Keep fingers and other body parts away from hinges when opening or closing doors or when raising or lowering the Touchscreen and lid.

3. When the Power Button on the touchscreen fades the color blue on and off, press the Power Button to turn on the Console and bring up the Home Screen. The Power Button will be solid blue when the Console is on.

Figure 15. Power Button is located on the back of the Touchscreen

Powering the System

Use Case	Action
Turn on the System	1. Make sure the power cord is connected to the Console and a compatible power source. 2. Turn on the Main Power Switch on the back of the Console (if it is not already on). 3. When the Power Button on the touchscreen fades the color blue on and off, press the Power Button to turn on the System and bring up the Home Screen. The Power Button will be solid blue when the Console is on. ***NOTE:*** Screen will stay blank until the Power Button is pressed.
Power down the System while in home	Scenario 1: Press the Power Button if the user does not plan to move or unplug the System and plans to use it again. The Power Button will fade the color blue on and off while the Console is powered down into standby mode. Scenario 2: If the user plans to unplug, store or move the Console, they should do the following: 1. Press the Power Button. 2. When the Touchscreen goes blank, switch the Main Power Switch on the back of the Console off. 3. Finally, wait until the Power Button goes off before unplugging the Console. ***NOTE:*** When a rinse is occurring in the background, the System will display a RINSE INTERRUPTED alert before shutting down that instructs the user to turn the Console back on so it can complete the rinse.
Restart the System when a shutdown Error occurs during treatment and the blood clot timer has not expired	Press the Power Button. When the Touchscreen goes blank, press the Power Button again to restart the Console. If the Console recovers and the blood clot timer has not expired, it should resume the treatment.
Restart the System when a shutdown Error occurs during treatment and the blood clot timer has expired	Press the Power Button. When the Touchscreen goes blank, press the Power Button again to restart the Console. If the System recovers it will come back to the appropriate state.
Restart the System when a shutdown Error occurs when not in treatment	Press the Power Button. When the Touchscreen goes blank, press the Power Button again to restart the Console. If the System recovers it will come back to the appropriate state.

Wi-Fi and Ethernet

The System has Wi-Fi and Ethernet capabilities to send and receive data. The System transmits machine performance and treatment data to the Outset Tablo Cloud.

- Machine Performance Data – Used to diagnose machine performance issues to improve service time. Data is transmitted in real-time enabling real-time diagnostic of problems.
- Treatment Data – Used to create a treatment flow-sheet.
- The System transmits data to the Tablo Cloud. When Tablo Cloud or the network is not available data is queued on the Tablo System. When the connection is restored data is transmitted to the Cloud.

Establishing a Wi-Fi or Ethernet Connection

1. Navigate to the Home Screen, then touch and hold the button for 10 seconds.
2. Type in the Admin password in the Admin Password box, and then touch OK. For more information, see "*Admin Settings*" on page 27.

Figure 16. Admin Password Login Screen

3. Touch the Device tab.
4. Touch the “Connection type”, the “Choose Connection Type” screen is displayed.
5. Touch the and buttons and select the type of connection, Wi-Fi or Ethernet and then touch NEXT.
6. Touch the and buttons to select the Name of the Wi-Fi or Ethernet.
7. Type in the password for the Wi-Fi or Ethernet in the Password box and then touch NEXT.
8. Touch the and buttons to select the address type and then touch NEXT.
9. Touch JOIN to connect to the Wi-Fi or Ethernet.

Touchscreen Overview

The Touchscreen guides the user through the functions of the System.

NOTES: Do not use a pen, pencil, or other object on the Touchscreen as these may damage the display.

Do not spray the Touchscreen with liquid during Treatment.

Screen Icons

Icon	Name	Description
	Exit	Touch to exit the current mode.
	General Settings	Touch to open the General Settings Screen where the prescription (Rx), Patient, and Device settings can be viewed. Treatment (Tx) settings can also be viewed during treatment. When at the Home Screen, touch and hold the icon for 10 seconds to access the Admin Settings. Admin Settings are password protected.
	Blood Pressure	Touch to open the blood pressure fly out. All blood pressure readings taken using the  icon are logged on the History tab in the  section.
	Notes	Touch to open the notes screen and add notes. The notes section also includes a tab to view past events and details.
	Maintenance	Touch to open Maintenance and complete disinfect cycles, change filters, perform a rinse, and/or take samples.
	Information	Touch during treatment to view venous pressure, arterial pressure, and fluid removed.
	Tx Settings	Touch to view a select number of treatment settings that can be changed. There is also an option here to navigate to all Tx settings that can be changed.
	Mute Alarm	Touch to mute the alarm when allowed by system.
	Unmute Alarm	Touch to unmute the alarm when allowed by system.
	Box Unchecked	Touch to check the unchecked box or current task, once the task is complete and to proceed to the next task.
	Box Checked	Indicates a task has been completed.
	Step Bullet	Automatically lists all tasks and eliminates the need to check off task. The current task displayed by the visual on the screen will be darker than the other tasks to show the user how the written tasks link to the visual.

Home Screen

Use the Home Screen to start a treatment, start a maintenance procedure, access Admin Settings, or change general settings. Tablo will provide status updates and display actions that need to be taken.

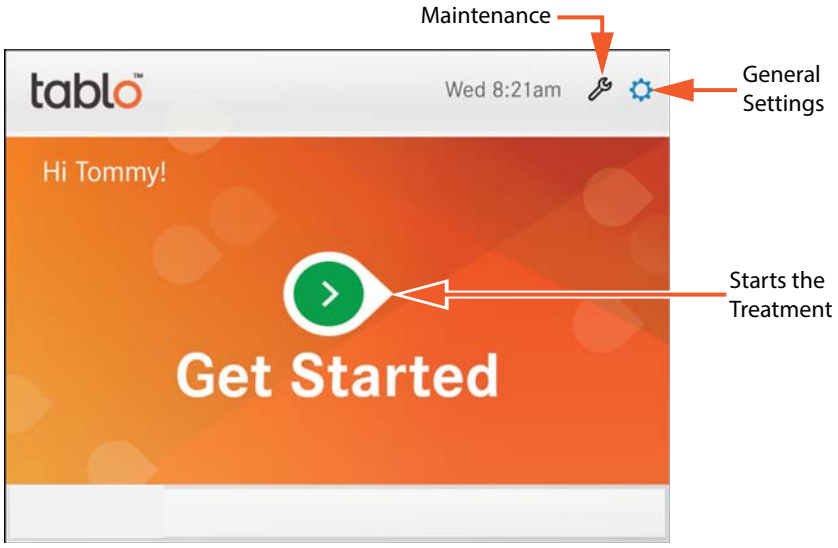


Figure 17. Home Screen

Settings Screen

NOTE: Insert the Patient Key to view and make changes to the patient settings if the RX Source for a patient prescription is set to Patient Key. For more information, see "*RX Source*" on page 28.

Use the General Settings screen to verify the patient's personal information, prescription details, and set the device settings, including the viewing mode.

Touch the ⚙ button to open the Settings screen.

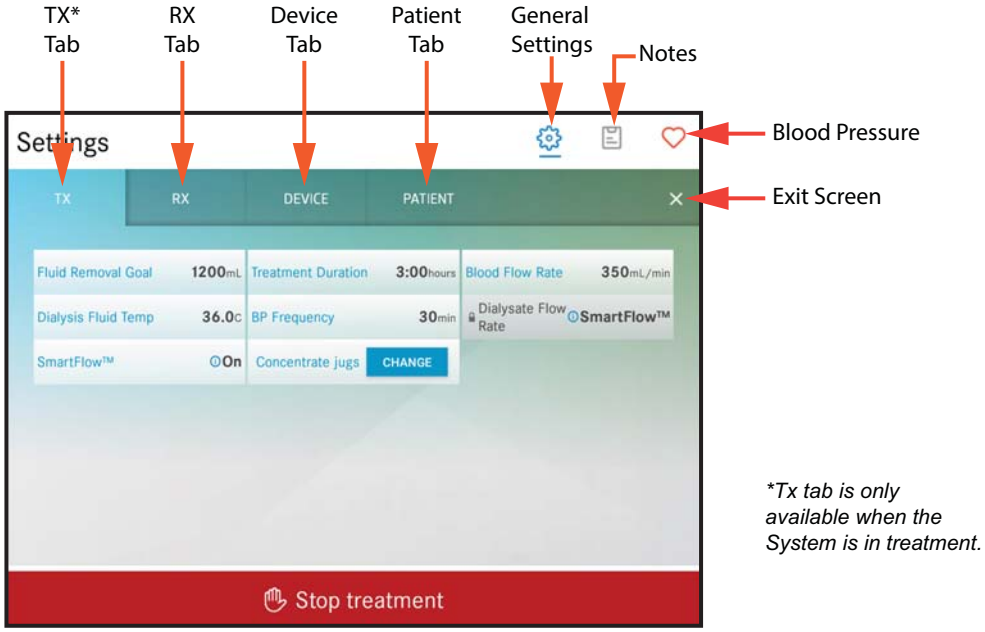


Figure 18. Settings Screen

Admin Settings Screen

Warning: When entering or changing data on the Touchscreen, always check to make sure the units of measurement are what you expect. Incorrect units may result in serious injury.

When on the Home Screen authorized users may touch and hold for 10 seconds to access Admin Settings. The user will be prompted to enter the password before entering Admin Settings. Only users with Admin permission will be able to access this screen.

Use this screen to review and/or edit patient information, patient prescription details, Tablo's System settings, and reminders. For more information, see "*Admin Settings*" on page 27.

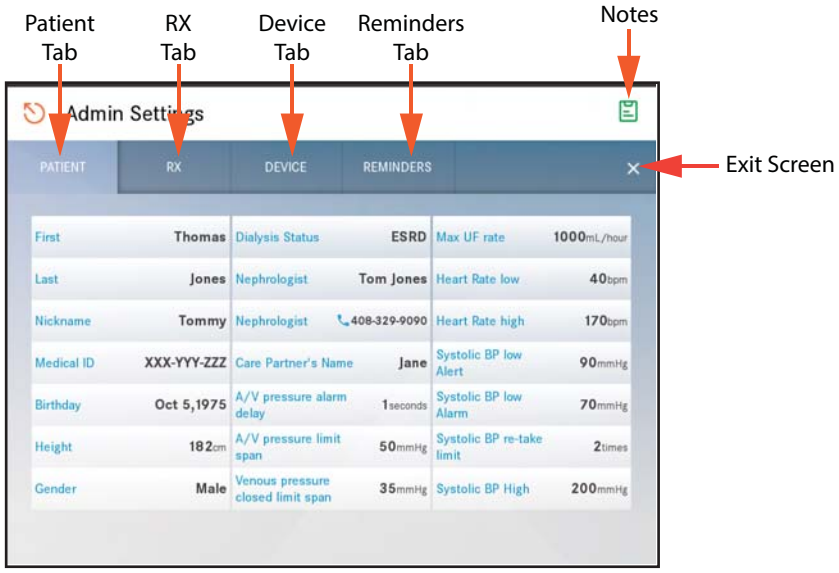


Figure 19. Admin Settings Screen

Maintenance Screen

Use the Maintenance section to perform internal disinfection cycles, change filters, perform a rinse, or take fluid samples.

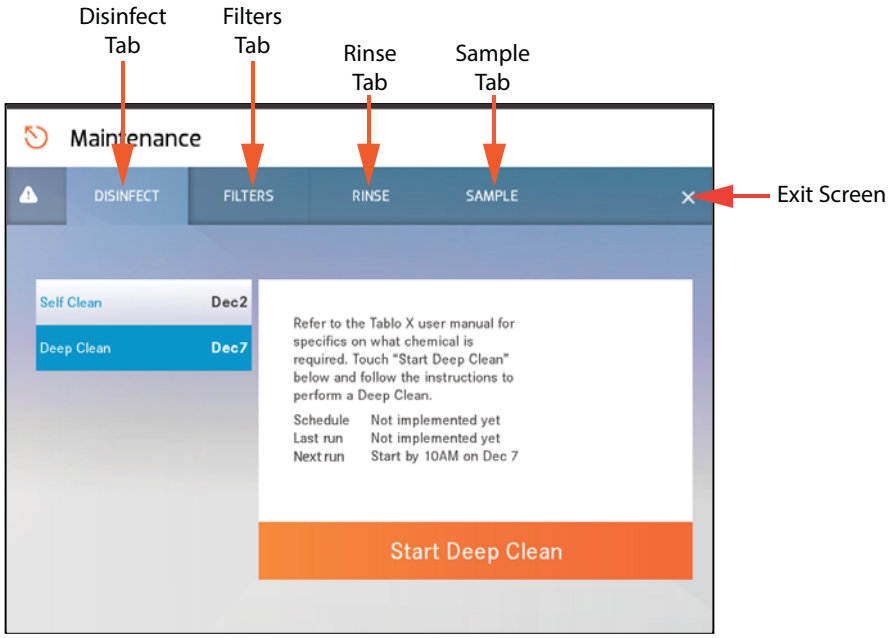


Figure 20. Maintenance Screen

Admin Settings

Warnings: Changing Admin Settings is intended to be performed only by clinicians.

NOTES: Admin Settings can only be accessed from the Home Screen.

Admin Settings are not available during pretreatment, treatment, and post-treatment.

Opening the Admin Settings Screen

1. Navigate to the Home Screen.
2. Touch and hold the ⚙ button for 10 seconds.
3. Type in the Admin Password in the Admin Password box.

NOTE: The password was provided by Outset when the System was installed. Refer to the Tablo Script User Manual to change the password. Call Outset Service if you forget the password.

4. Touch the Done key to close the keyboard.
5. Touch OK to open the Admin Settings screen.

NOTE: Blue text indicates that a setting can be changed.

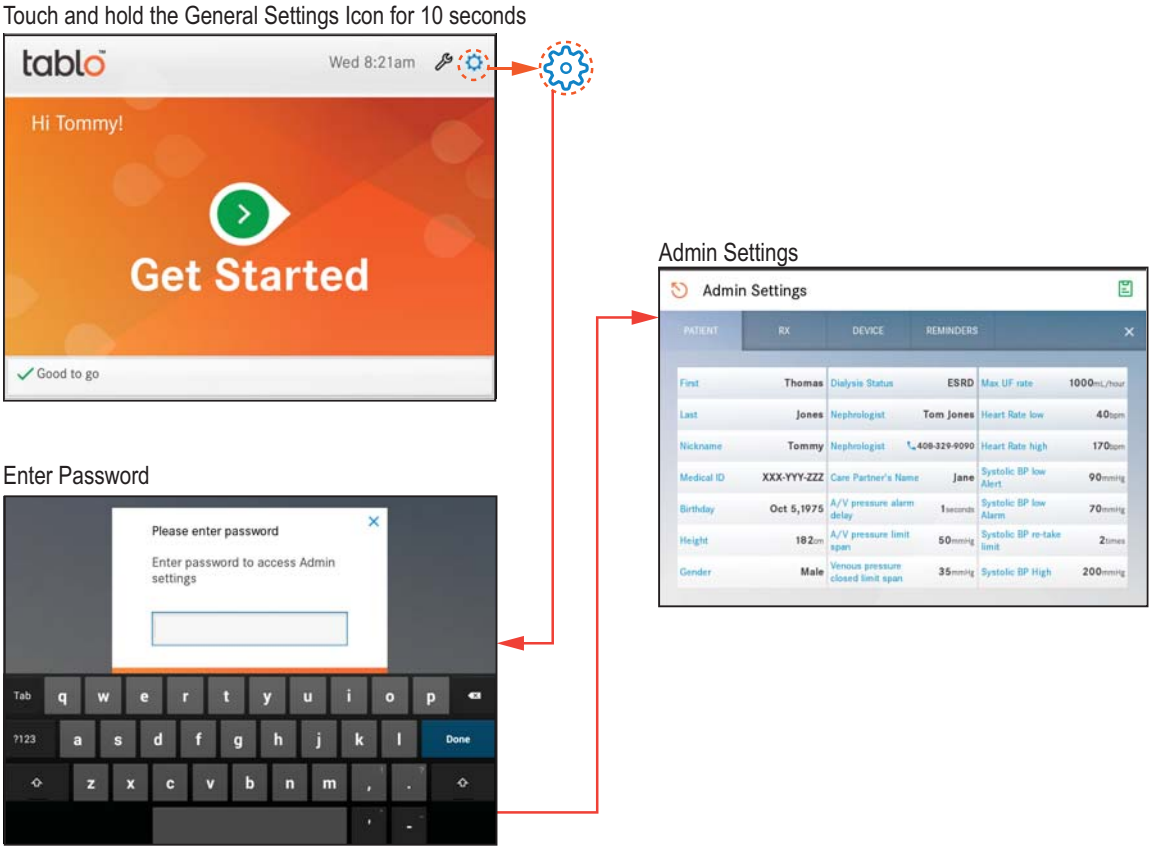


Figure 21. Navigating to the Admin Settings Screen

Dialysate Flow Rates

The Tablo System offers three Dialysate Flow Rates: 100mL/min, 200mL/min, and 300mL/min. The System also features SmartFlow.

SmartFlow will run at 300mL/min for as long as possible, and then automatically switch to 100mL/min to complete the treatment using a single set of concentrate jugs.

NOTE: Once SmartFlow is turned off it cannot be turned back on during treatment.

When SmartFlow is not used, the System may require the user to replace one or both concentrate jugs during treatment. Based on the dialysate flow rate and treatment duration, the concentrate jugs may need to be replaced multiple times during treatment.

RX Source

There are two patient prescription settings for a treatment, Patient Key or Console.

Patient Key

The Patient Key is a patient-specific secured USB storage device that contains encrypted treatment and prescription details. The System stores Electronic Medical Record (EMR) files on the Patient Key in a directory named "EMR".

Select the Patient Key option if the prescription data is on a Patient Key.

Console

A treatment can be performed without an installed Patient Key. A single prescription can be created and stored on the internal flash memory until it is cleared. The user will have the opportunity to clear an existing prescription during treatment complete and when entering Admin settings after a treatment. An existing prescription will also clear after a software update, when Service Mode is activated, and when the RX Source is changed to Patient Key.

Select the Console option if a Patient Key will not be used for treatment. The System stores Electronic Medical Record (EMR) files in Tablo Hub.

NOTE: The System will alarm if a Patient Key is inserted into the Console.

Setting the Rx Source

1. Navigate to the Home Screen.
2. Touch and hold the button for 10 seconds.
3. Type in the Admin Password.
4. Touch the Device tab.
5. Touch Rx Source.
6. Touch the and buttons and select Patient Key or Console.
7. Touch SAVE to save the setting.
8. Touch the icon to return to the Home Screen.

Source of Water

Intake water used for dialysis must meet EPA primary or secondary standards for drinking water with maximum total hardness level of 150 mg/L and with conductivity less than 2000 µS/cm.

NOTE: Changing the water source when a “Select Source of Water Alert” is triggered will permanently change the Source of Water setting in Admin Settings. For more information, see "*Source of Water Alert*" on page 71.

Tap

Select the Tap option if the System is connected to tap water that will be filtered by the built-in Water Purification system. The Reverse Osmosis (RO) rejection rate alarm will trigger if the System reaches the RO rejection rate alarm setting. This setting is located in the Admin Setting under the Device tab.

External RO

Select the External RO option if the System is connected to an external water purification equipment. The RO rejection rate alarm setting is automatically set to Off when an external RO is selected.

Setting the Source of Water

1. Navigate to the Home Screen.
2. Touch and hold the button for 10 seconds.
3. Type in the Admin Password.
4. Touch the Device tab.
5. Touch Rx Source.
6. Touch the and buttons and select Tap or External RO.
7. Touch SAVE to save the setting.
8. Touch the icon to return to the Home Screen.

Allow Skipping Patient Weight

The System can be set to skip the patient’s weight when entering pretreatment and post-treatment vitals. If the patient’s weight is not entered during pretreatment vitals, then the fluid removal goal will be required on the “Customizing today’s treatment” screen. For more information, see "*Enter the patient’s pretreatment vital signs.*" on page 43.

Setting the Console to Skip Patient Weight

1. Navigate to the Home Screen.
2. Touch and hold the button for 10 seconds.
3. Type in the Admin Password.
4. Touch the Device tab.
5. Touch Allow Skipping Patient Weight.
6. Touch the and buttons and select On or Off.
7. Touch SAVE to save the setting.
8. Touch the icon to return to the Home Screen.

Admin Settings That Can be Changed

Patient

Patient settings are patient specific values used for the documentation and administration of the patient's treatment. Like the Rx settings, these values are stored on the Patient Key or Device, based on the RX Source setting located under the Device tab.

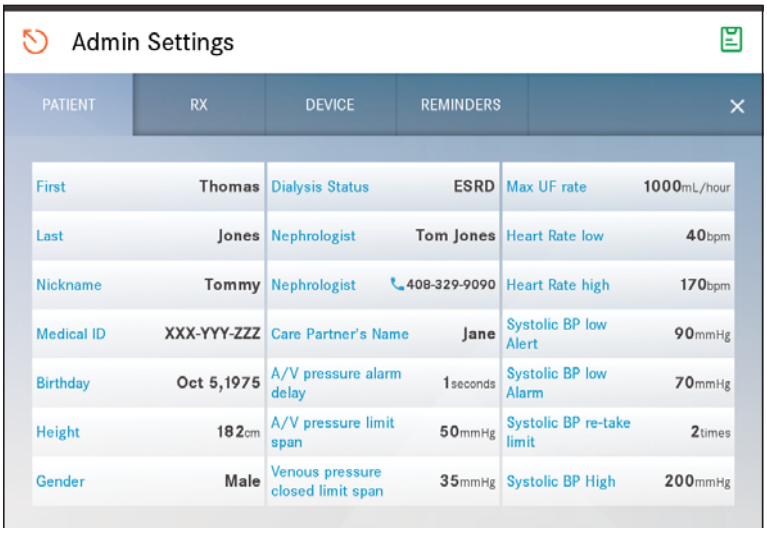


Figure 22. Admin Settings Patient Screen

Setting	Definition	Display Units	Interval/Limits
Medical ID	The patient's medical ID.	Alphanumeric	20 Characters Maximum
First	The patient's first name.	Alpha	N/A
Last	The patient's last name.	Alpha	N/A
Nickname	The name the patient prefers to be called.	Alpha	15 Characters Maximum
Birthday	The patient's date of birth.	Month/Day/Year	N/A
Height	The height of the patient.	Centimeters	N/A
Gender	The patient's gender.	Alpha	Female Male
Dialysis Status	Patient dialysis treatment status.	Alpha	ESRD, AKI, and New Start
Care Partner's Name	The name of the patient's caretaker.	Alpha	N/A
Nephrologist	The patient's doctor that specializes in kidney disorders.	Alpha	N/A
Nephrologist 	Phone number of the patient's Nephrologist.	Numeric	N/A

Setting	Definition	Display Units	Interval/Limits
Systolic BP Low Alert	The minimum systolic pressure limit that will trigger the Low Blood Pressure Alert.	mmHg	Minimum 70 mmHg Maximum 140 mmHg Interval 5 mmHg
Systolic BP Low Alarm	The minimum systolic pressure limit that will trigger the Low Blood Pressure Alarm.	mmHg	Minimum 60 mmHg Maximum 70 mmHg Interval 10 mmHg
Systolic BP High	The maximum systolic pressure limit that will trigger the High Blood Pressure Alert.	mmHg	Minimum 100 mmHg Maximum 260 mmHg Interval 5 mmHg
Systolic BP retake limit	The maximum number of Low Blood Pressure Alarms prior to ending treatment.	Numeric	Minimum: 1 Maximum: 5 Alternate: Off When set to Off the system will not end treatment based on the number of Low Blood Pressure Alarms
Heart Rate Low	The minimum heart rate limit for heart rate monitoring (blood pressure monitoring) and activation of the Low Heart Rate Alert.	bpm	Minimum 40 bpm Maximum 140 bpm Interval 5 bpm
Heart Rate High	The maximum heart rate limit used for heart rate monitoring (blood pressure monitoring) and activation of the High Heart Rate Alert.	bpm	Minimum 80 bpm Maximum 180 bpm Interval 5 bpm
Max UF rate	The maximum allowable ultrafiltration rate.	mL/hour	Minimum 1000 mL/hour Maximum 2000 mL/hour
A/V pressure alarm delay	The delay after either A/V pressure exceed a limit before A/V pressure alarm. Lowering this value makes the A/V pressure alarms more sensitive.	Seconds	Minimum 0 seconds Maximum 5 seconds
A/V pressure limit span	The pressure span to which the A/V pressure alarm limits are set around the current A/V pressure after stabilization. Lowering this value makes the A/V pressure alarms more sensitive.	mmHg	Minimum 50mmHg Maximum 100mmHg Interval 10mmHg

Setting	Definition	Display Units	Interval/Limits
Venous pressure closed limit span	The pressure limit to which the low venous pressure alarm limit is set below the current venous pressure after final pressure stabilization. This closing of the low venous pressure limit is designed to enhance the detection of venous access disconnection. Lowering this value makes the venous pressure alarm the more sensitive.	mmHg	Minimum 20mmHg Maximum 50mmHg Interval 5mmHg

Rx

Rx settings contain the patient's prescription. These values are used to initialize the System at the start of treatment. Like the Patient settings, these values are stored on the Patient Key or Device, based on the RX Source setting located under the Device tab.

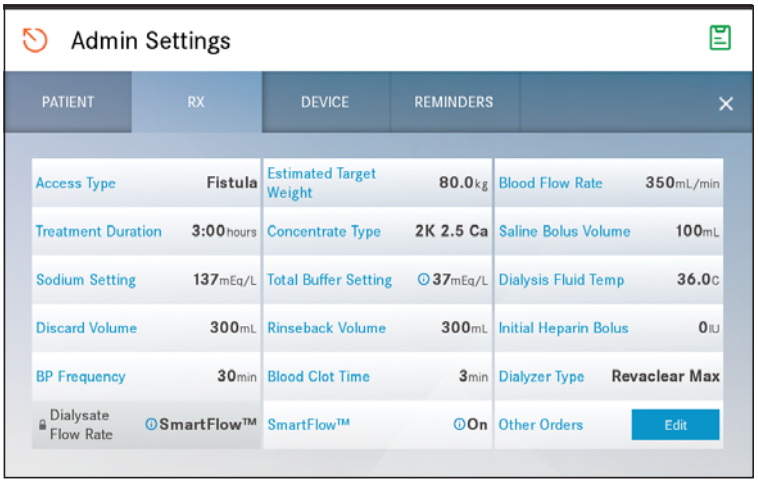


Figure 23. Admin Settings RX Screen

Setting	Definition	Display Units	Interval/Limits
Access Type	The patient's vascular access type.	Alphanumeric	Fistula/Graft Temp Catheter Perm Catheter
Estimated Target Weight	The patient's target weight at the end of treatment.	Kilograms	Minimum 34.0 kg Maximum 999.0 kg
Treatment Duration	The length of the treatment in hours.	Hours	Minimum 0:30 hours Maximum 12:00 hours
Concentrate Type	The potassium and calcium of the Outset acid concentrate.	-K -Ca	Minimum 1K 2.5 Ca Maximum 4K 2.5 Ca

Setting	Definition	Display Units	Interval/Limits
Saline Bolus Volume	The amount of saline delivered per saline bolus.	mL	Minimum 100.0 mL Maximum 200.0 mL
Sodium Setting	The desired concentration of sodium in the dialysis fluid.	mEq/L	Minimum 135 mEq/L Maximum 145 mEq/L
Total Buffer Setting	Total Buffer is the sum of Net Bicarbonate (currently 33 mEq/L based on the Total Buffer Setting entered) and 4 mEq/L of Acetate from the Acid Concentrate.	mEq/L	Minimum 30 mEq/L Maximum 40 mEq/L ***Note:*** *Total dialysis fluid buffer and patient predialysis bicarbonate levels should be considered when adjusting the total buffer dialysis fluid level.*
Dialysis Fluid Temp	The temperature setting for the dialysis fluid. The temperature can be adjusted during treatment.	Celsius	Minimum 35.0° C Maximum 38.0° C Interval 0.1° C Default 36.0° C
Discard Volume	The volume of saline discarded by the system during dialyzer priming. Select based on the dialyzer instructions for use.	mL	Minimum 300 mL Maximum 1000 mL
Rinseback Volume	The volume of saline to be used for blood return. This volume is removed by the system during treatment so that after blood return the patient's target weight is achieved.	mL	Minimum 300 mL Maximum 500 mL Interval 100 mL
BP Frequency	The interval at which the patient's blood pressure will be automatically taken during treatment (if On).	Minutes	Off, 5 min, 15 min, 30min, 45min, 60 min
Blood Clot Time	The time that blood can be stagnant before auto blood return is not allowed.	Minutes	Minimum 2 minutes Maximum 30 minutes
Dialyzer Type	Select or enter the high flux dialyzer used during treatment.	Alphanumeric	Select from the list of dialyzers or add a high flux dialyzer by typing in the name of the dialyzer (20 characters maximum) if it is not listed.
Blood Flow Rate	Enter the target blood flow rate for treatment.	mL/min	Minimum 50 mL/min Maximum 400 mL/min

Setting	Definition	Display Units	Interval/Limits
SmartFlow	This setting controls whether SmartFlow is enabled. For more information, see "*Dialysate Flow Rates*" on page 28.	Alpha	On Off
Dialysate Flow Rate	The dialysate rate when SmartFlow is turned off.	mL/min	Minimum 100 mL/min Maximum 300 mL/min Interval 100 mL/min
Initial Heparin Bolus	This value is the prescribed initial heparin dose to be manually administered at the start of treatment by the user	IU	Minimum 0 IU Maximum 10000 IU Interval 250 IU
Other Orders	This text field can be used to augment the prescription with any additional orders for the treatment.	Alphanumeric	200 Characters Maximum

Device

Device settings configure the System for use in its physical setting associated with things like water quality, disinfection schedule, and WiFi connection. These values are stored internally in the System.

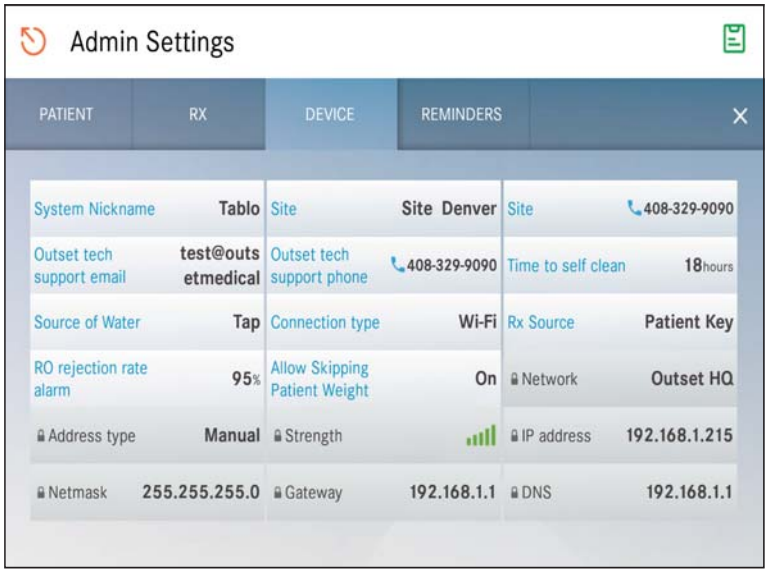


Figure 24. Admin Settings Device Screen

Setting	Definition	Display Units	Interval/Limits
System Nickname	Tablo system name.	Alphanumeric	N/A
Site	Name and/or location of the site where the Tablo is installed.	Alphanumeric	N/A
Site	Phone number to contact where the Tablo is installed.	Numeric	
Outset tech support email	Email to contact Outset technical support.	Alphanumeric	test@outsetmedical.com
Outset tech support	Phone number to contact Outset technical support.	Numeric	408-329-9090
Time to self clean	Time after treatment that the system will wait before automatically initiating the next Self Clean cycle.	Minutes and Hours	Minimum 5 minutes Maximum 18 hours Interval 5 minutes
Source of Water	Choose from External RO or Tap.	Alpha	External RO Tap
RO Rejection Rate Alarm	Choose from External RO or Tap.	Alpha	External RO Tap

Allow Skipping Patient Weight	Select On to allow users to skip entering the patient's weight. ***NOTE:*** The fluid removal goal is required if this setting is set to On.	Alpha	On Off
RX Source	Choose from Patient Key or Console.	Alpha	Patient Key Console
Connection Type	Choose from Wi-Fi or Ethernet.	Alphanumeric	Wi-Fi Ethernet

Reminders

Reminders allow users with Admin permission to add reminders to the System. To create a reminder:

1. Touch the grey text "Custom message #", the Custom Reminder screen opens.
2. Type a reminder in the Custom Reminder box.
3. Touch the Done key to close the keyboard.
4. Touch SAVE to add the reminder to the REMINDERS screen.
5. Touch "Day of the month", the Day of the month screen opens.
6. Touch the and buttons to select the date of the month.
7. Touch SAVE to add the date to the reminder.

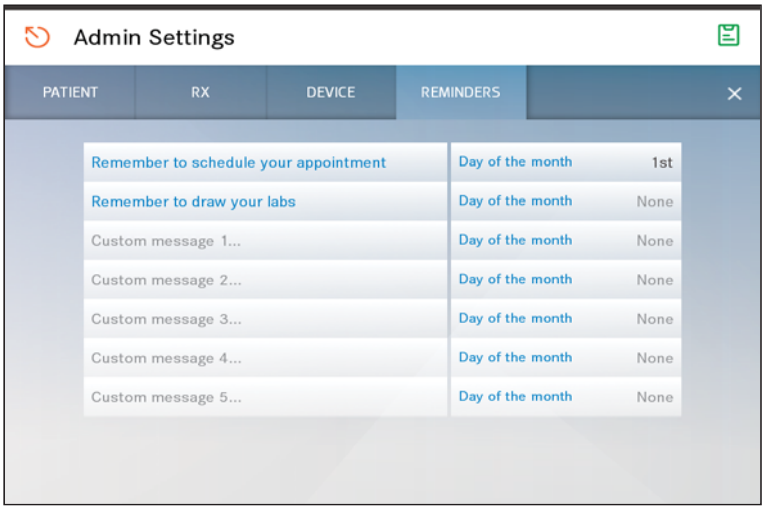


Figure 25. Admin Settings Reminders Screen

Pretreatment

Warnings: Do not use the System if the enclosure is cracked or broken. There is a risk of electric shock. Unplug the System from the wall and contact the Service Center for repair.

When entering or changing data on the Touchscreen, always check to make sure the units of measurement are correct. Incorrect units of measure may result in serious injury.

Cautions: Always check expiration dates on the disposable supplies. Disposable supplies include Tablo Cartridge, high flux dialyzer, concentrates, saline, cleaning solutions, and test strips. Never use supplies that are past their expiration date.

While the System is in use, visually inspect the System periodically for leaks. Terminate treatment if leaks cannot be resolved.

Viewing Modes

Tablo offers two different viewing modes for Pretreatment and Post-treatment; Training and Advanced modes.

Training Mode: Displays user instructions mainly in a step-by-step controlled navigation. Tasks are displayed with text, illustrations, and video guidance. One task is displayed at a time. The user must check-off each task, where applicable, before moving to the next task when check boxes are displayed.

Advanced Mode: Most checked boxes are replaced with bullets, but there are a few tasks that require the user to check-off. This reduces the number of tasks the user needs to physically check off. Additionally, the Next button is displayed when no additional user action is needed, enabling the user to navigate through the setup at their own pace.

The user can switch between Training and Advanced modes at anytime.

Changing the Viewing Mode

1. Touch the icon located at the top of a screen (you will be required to verify patient birthday when on the Home screen).
2. The General Settings screen opens.
3. Touch the Device tab to open Device settings.

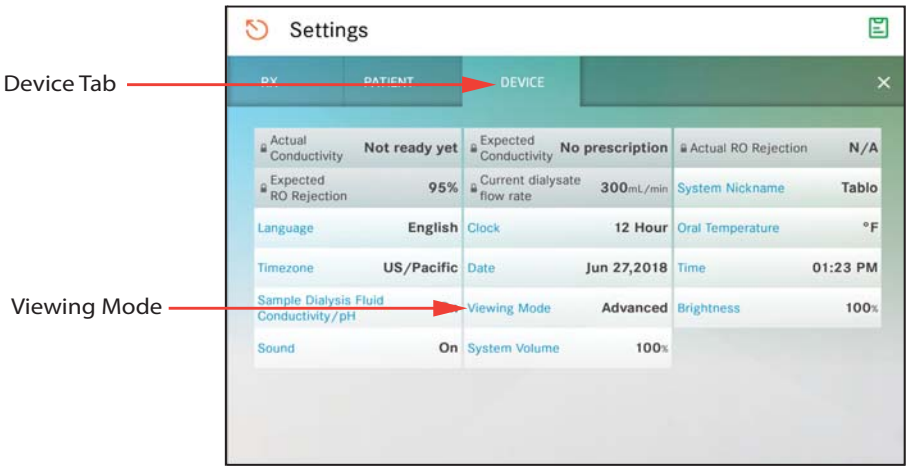


Figure 26. Location of the Viewing Mode Setting

4. Touch Viewing Mode, the Viewing setting screen opens.
5. Touch the ▲ and ▼ buttons to select Training or Advance mode.
6. Touch SAVE to save the selection.

Prepare the System for Treatment

Warning: Only insert the Patient Key into the Patient Key USB Port. No other USB connectors should be plugged into the USB port.

1. Open the lid and lift the Touchscreen.
2. Touch the Power button on the back of the Touchscreen to make sure the Console is on.
3. Enter the patient prescription using one of the following methods:
   - Patient Key – The RX source setting is set to Patient Key.
   - Console – The RX source setting is set to Console.
4. Confirm the patient's birthday.
   - Touch "YES>" if the patient's birthday is correct move to the next screen.
   - Touch "<NO" if the patient's birthday is incorrect, follow the instructions on the screen to enter the correct patient prescription.
5. Confirm the patient's Rx.
   - Touch "YES>" if the correct patient prescription is displayed on the screen.
   - Touch "<NO" if the Rx is wrong, follow the instructions on the screen to enter the correct patient prescription.

   NOTE: Make sure the correct access type is selected in the patient's Rx SETTING, so the touch-screen displays the correct instructions.
6. Review the Supplies Checklist.
7. Touch the orange droplet to begin a sound test. Confirm the user can hear the sound.
   - Touch "YES>" if the user can hear the sound to move to the next screen.
   - Touch "<NO" if the user can not hear the sound and then follow the instructions on the screen.

Caution: For the user's safety, Tablo will not perform a dialysis treatment if the audio alarm cannot be heard.

Get the Dialysis Fluid Ready

Warnings: Incorrect composition will result if the red acid concentrate cap is not connected to the appropriate acid concentrate or the blue bicarbonate concentrate cap is not connected to the appropriate bicarbonate concentrate. The acid and bicarbonate concentrates must match those selected in the Rx (prescription) screen. Patient injury or death may occur if incorrect dialysis fluid solution is used. The operator must use the concentrate jugs provided with the System and follow all instructions.

The System uses a 45X-proportioning ratio for mixing dialysis fluid. The use of other concentrates may result in serious patient harm.

A physician must prescribe the specific acid and bicarbonate concentrates, including the sodium, bicarbonate, and electrolyte compositions.

1. Prepare the red-labeled jug (Acid Concentrate):

   NOTE: Contact Outset for Safety Data Sheet (SDS).

   a) Set the red-labeled jug (Acid Concentrate) on the top deck of the Console, behind the Touchscreen.
   b) Unscrew and remove the cover of the red-labeled jug (Acid Concentrate).
   c) Remove the red cap from the Console by pulling it straight up.
   d) Insert the flat end of a straw into the red cap.
   e) Push the pointed end of the straw through the foil seal of the red-labeled jug (Acid Concentrate) until the red cap rests on the jug.

2. Prepare the blue-labeled jug (Bicarbonate Concentrate):

   NOTE: Contact Outset for Safety Data Sheet (SDS).

   a) Set the blue-labeled jug (Bicarbonate Concentrate) on the top deck of the Console, behind the Touchscreen.
   b) Unscrew and remove the cover of the blue-labeled jug (Bicarbonate Concentrate).
   c) Remove the blue cap from the Console by pulling it straight up.
   d) Insert the flat end of a straw into the blue cap.
   e) Push the pointed end of the straw through the foil seal of the blue-labeled jug (Bicarbonate Concentrate) until the blue cap rests on the jug.

Figure 27. Acid Jug and Bicarb Jug

Place the Cartridge

Warnings: Do not touch the Cartridge line connectors or allow them to touch dirty surfaces. Contaminating the connectors increases the risk of serious infection.

Do not apply any coagulum or ultrasound gel to the Cartridge or Cartridge interface area of the Console as this could prevent the air detectors from functioning properly thereby creating a potential for a hazardous situation (air infusion).

When removing the Cartridge from the bag do not disturb the bloodlines within the cartridge as the position of these lines is important for proper operation when mounted on the Console.

1. Remove the Cartridge from the Cartridge bag carefully.

NOTE: Do not throw away the bag. It will be used during pretreatment for prime discard.

2. Open the upper, front door of the Console.
3. Place the Cartridge on the three orange pegs.
4. Push the Cartridge into the top and bottom green bars until the latches engage with the Cartridge.

NOTE: Make sure to push the Cartridge fully into place. There are two latch points on each green bar. All four latch points need to be latched to the cartridge.

Figure 28. Installing the Cartridge

5. Hang the Cartridge bag onto the gray Prime Discard Holder inside the door. The Cartridge bag has two slits cut into the bag and the gray hanger has two connection points to hang the bag.

NOTE: Ensure the bag is hanging securely on both connection points. Also, ensure the clear portion of the bag is facing forward.

6. Tighten the patient bloodlines to the Y-connector and tighten its cap.

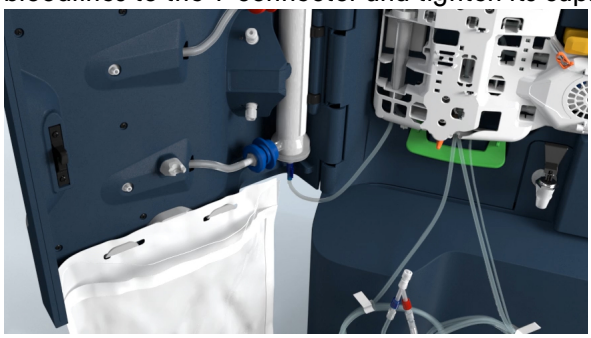


Figure 29. Cartridge Bag Installed and Y-Connector Attached to Patient Bloodlines

Connect the Saline Bag

Warning: Never touch the saline spike.

Caution: Keep concentrates, saline bags, and disinfectants away from scissors and other sharp objects.

1. Close the yellow clamp on the saline line.
2. Close the orange clamp on the infusion line.
3. Pull the saline line off of the Cartridge.
4. Remove the cap from the saline line and spike the saline bag.
5. Hang the saline bag on the top yellow hook located on the top lid of the system.

Figure 30. Hanging the Saline Bag

Set Up the High Flux Dialyzer

Warnings: Do not use the high flux dialyzer if the package is damaged, has been dropped, or if blood port cap seals are not in place.

Avoid touching the connection points on the high flux dialyzer. Touching the connection points may increase the risk of infection.

The System shall be labeled for use only with commercially available high flux dialyzer. Follow the instructions for use, supplied with the high flux dialyzer.

1. Grab the blue dialyzer bloodline from the Cartridge and remove the cap.
2. Twist the blue dialyzer bloodline onto the bottom of the dialyzer.

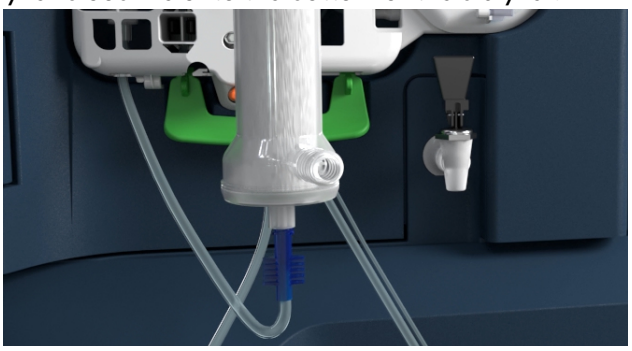


Figure 31. Blue Dialyzer Bloodline Attached to Dialyzer

3. Grab the red dialyzer bloodline from the Cartridge and remove the cap.
4. Twist the red dialyzer bloodline to the top of the dialyzer.

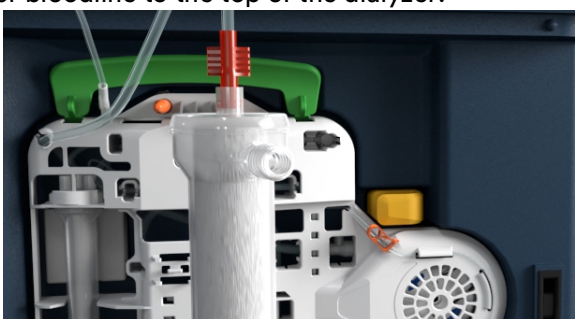


Figure 32. Red Dialyzer Bloodline Attached to Dialyzer

5. Remove the blue dialysate connector from the door and attach it to the bottom of the dialyzer.
6. Remove the red dialysate connector from the door and attach it to the top of the dialyzer.
7. Clip the dialyzer into the door.

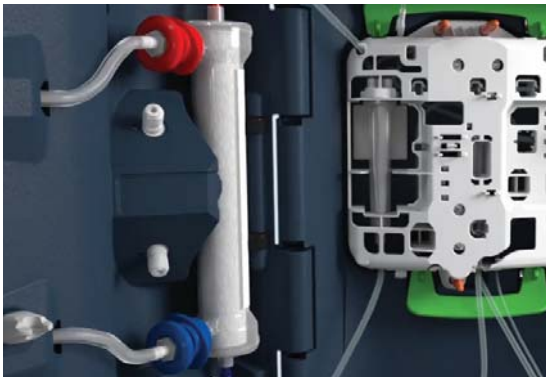


Figure 33. Installed High Flux Dialyzer

Prime Tablo

1. Open the yellow clamp on the saline line.

Figure 34. Yellow Clamp on the Saline Line

2. Touch “Begin prime” on the touch screen.

NOTE: During the PRIME cycle, Tablo uses the pressure sensors and air detectors to ensure that saline is filling the bloodlines and high flux dialyzer as expected. In the event that this does not occur, Tablo will let you know that there is a problem. At the end of the priming procedure, Tablo performs a pressure holding test of the blood set to make sure that all connections are tight and that there are no leaks in the blood tubing.

3. Enter the patient’s pretreatment vital signs.

Figure 35. Pretreatment Vital Signs Screen

NOTE: If it is not possible to obtain the pretreatment patient’s weight, check the “Unable to obtain” box.

4. Touch Continue, the “Customize today’s treatment?” screen opens. Make any treatment changes in accordance with your site’s policies.

Figure 36. Customize Today’s Treatment

NOTE: If the patient’s weight is skipped manually enter the patient’s Fluid Removal Goal. These settings will be used only for the current treatment and will not affect future treatments.

Test the Water for Chlorine/Chloramines

Tablo instructs the user to test the water per your site's policies to verify that the Chlorine/Chloramine level is low enough to safely perform a treatment. If the sample does not pass, both carbon filters need to be replaced.

1. Collect a water sample using the spout on the front of the System.

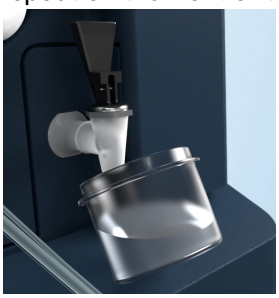


Figure 37. Taking a Water Sample

2. Test the sample per your site's polices.
3. Confirm the results by touching PASS or FAIL.
4. Take action as indicated by the results.

NOTE: If the water test does not pass, a Chloramine Test Error alarm screen activates, and ends treatment setup transitioning to post-treatment state. The user will be instructed to replace the Carbon filters.

Testing the Dialysis Fluid

NOTE: This is only available if "Sample Dialysis Fluid Conductivity/pH" is set to On in General Settings under the Device tab.

1. Clean the bottom port on the door with alcohol and allow it to dry completely.
2. Take a dialysis fluid sample.

Figure 38. Taking a Dialysis Fluid Sample

3. Test the sample per your site's polices.
4. Take action as indicated by the results.

Discard the Prime Fluid

NOTE: Tablo keeps track of the amount of saline needed to complete prime discard and will alert the user to change the saline bag if there is not enough left to complete this step.

1. Remove the hole punched tape near the Y-connector from the patient bloodlines. Do not remove the other three pieces of tape at this time.
2. Insert the patient bloodlines into the grey clip on the inside upper door. Ensure the patient's bloodlines are inserted into the clip correctly, see image below and the animation on the Touchscreen for visual guidance on the correct placement.
3. Unscrew the cap from the Y-connector and ensure the Cartridge bag is open.
4. Check the box next to "Begin Prime Discard".
5. Touch Continue.

Figure 39. Discard Prime Fluid

Prepare the Access

1. Use proper aseptic techniques.
2. Wash your hands and use personal protective equipment.
3. Establish vascular access following your site's policies.
4. If prescribed, give a heparin dose as instructed.

Get Connected - Catheter

1. Close the clamps on the red and blue patient bloodlines.
2. Remove the red patient bloodline from the Y-connector and attach it to arterial catheter port.
3. Remove the blue patient bloodline from the Y-connector and attach it to the venous catheter port. Touch continue to move to the next screen.
4. Open the clamps on the patient bloodlines and catheter ports. Touch continue to move to the next screen.
5. Touch "Begin treatment".

Get Connected - Fistula/Graft Needle

1. Close the clamps on the red and blue patient bloodlines.
2. Remove the red patient bloodline from the Y-connector and attach it to arterial fistula needle.
3. Remove the blue patient bloodline from the Y-connector and attach it to the venous fistula needle. Touch Continue to move to the next screen.
4. Open the clamps on the patient bloodlines and fistula needles. Touch Continue to move to the next screen.
5. Touch "Begin treatment".

Start Treatment

Warnings: The low venous pressure alarm may not occur with every disconnection or needle dislodgement. Check all bloodlines for leaks after the treatment has started. Keep access sites uncovered and monitored. Improper bloodline connections or needle dislodgement can result in excessive blood loss, serious injury, and death. Machine alarms may not occur in every blood loss situation.

Blood Flow, and thus treatment efficacy, may be reduced when the Arterial Pressure pre-blood pump is extremely negative. Tablo is designed to compensate for this scenario by modulating the blood pump flow based on the arterial pressure thereby reducing this scenario's probability of occurrence.

Before starting dialysis treatment, verify the line connections are secure to the patient's fistula needles or catheter ports.

While the System is in use, inspect all tubing and fluid connections for leaks. This includes water lines; drain lines, dialysis fluid connections, and blood tubing.

Blood and used dialysis fluid are potentially infectious. Follow the "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings" found on the CDC Website as well as your facility's practices when providing care to all patients.

If a patient has known allergies, monitor for reactions.

During the dialysis treatment, monitor the lines and check for leaks.

When establishing blood flow, ensure that air will not be infused into the patient. This can occur at connection points downstream of the air detector. As always, when connecting to the patient's access, if air is detected in the lines via visual inspection, re-clamp and disconnect the lines.

Cautions: Always check the accuracy of the prescription before beginning treatment.

Make sure that venous and arterial patient line connections are securely connected before beginning treatment.

Reducing treatment time below the physician's prescription will reduce the effectiveness of the Hemodialysis treatment.

Make sure that venous and arterial patient line connections are always visible for inspection and are not covered by sheets, blankets, or tape.

Make sure air has been properly flushed out of the venous needle line or the venous catheter line.

Using Infusion Devices with the System

- Refer to the Instructions for Use provided by the infusion device manufacturer.
- Follow all standard procedures to prevent air from being introduced during infusion.
- The recommended maximum infusion rate into the System is 600mL/hr. An infusion volume of up to 100mL may be infused within 2 minutes.
- Ensure the occlusion pressure of the infusion device is set appropriately.
- In the event of a System alarm which stops the blood pump, ensure the infusion device stops delivery until the alarm is resolved and the blood pump resumes.

Treatment Screens

Tablo allows the blood pump to be manually stopped and started during therapy. Examples of when this may become necessary include when needle position is being adjusted, if clots are suspected in the line, or during an incident of catheter malfunction.

If the patient is susceptible to periods of excessively high or low blood pressure, consult with the attending physician.

Main Treatment Screen

The user can monitor the treatment using the Treatment screen. This screen displays the patient's name, the remaining treatment time, and a tree graphic which will fill in with color as the treatment progresses. The user can also use the Main Treatment screen to stop fluid removal, administer a Saline Bolus, or Stop Treatment.

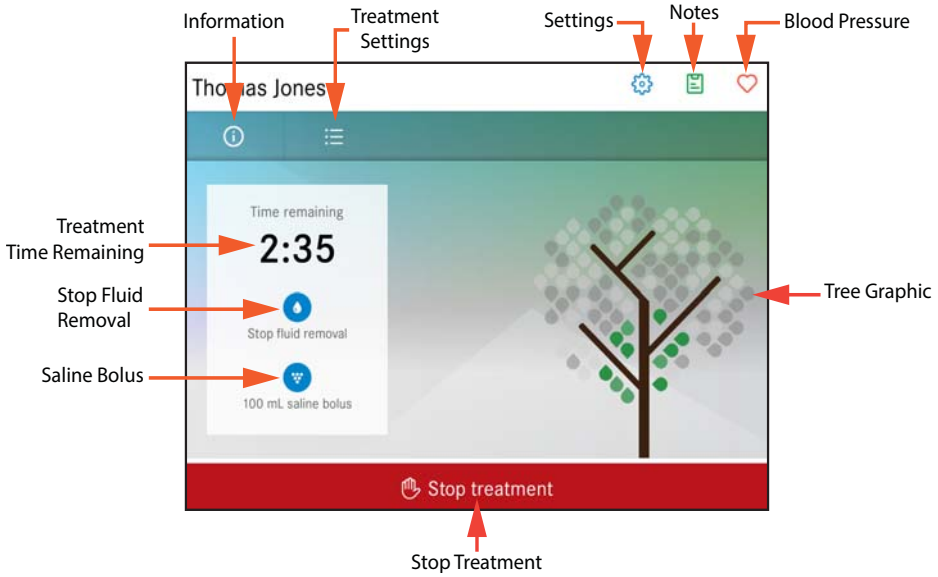


Figure 40. Main Treatment Screen

Information Treatment Screen

Touch the ⓘ icon to open the Information Treatment screen to view the venous pressure, arterial pressure, and the amount of fluid removed.

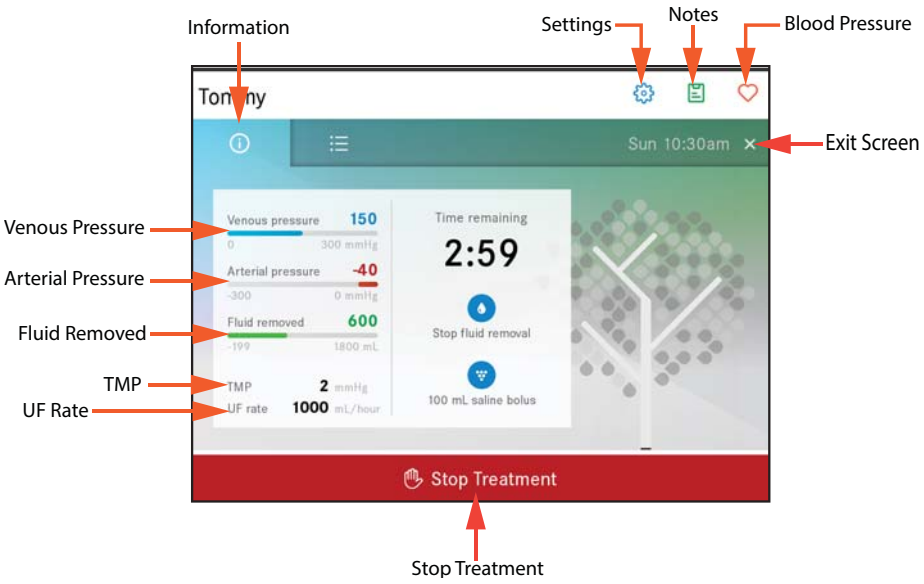


Figure 41. Information Treatment Screen

Treatment Settings Screen

Touch the ☰ icon to open the Treatment Settings screen. Touch the blue text to open and change a treatment setting. For example to change the treatment duration from 3 hours to 4 hours, touch the blue Treatment Duration text and then change the setting in the Treatment Duration screen. To keep the change touch Save or touch Cancel to cancel the setting.

To access all treatment settings that can be modified, touch the More settings icon.

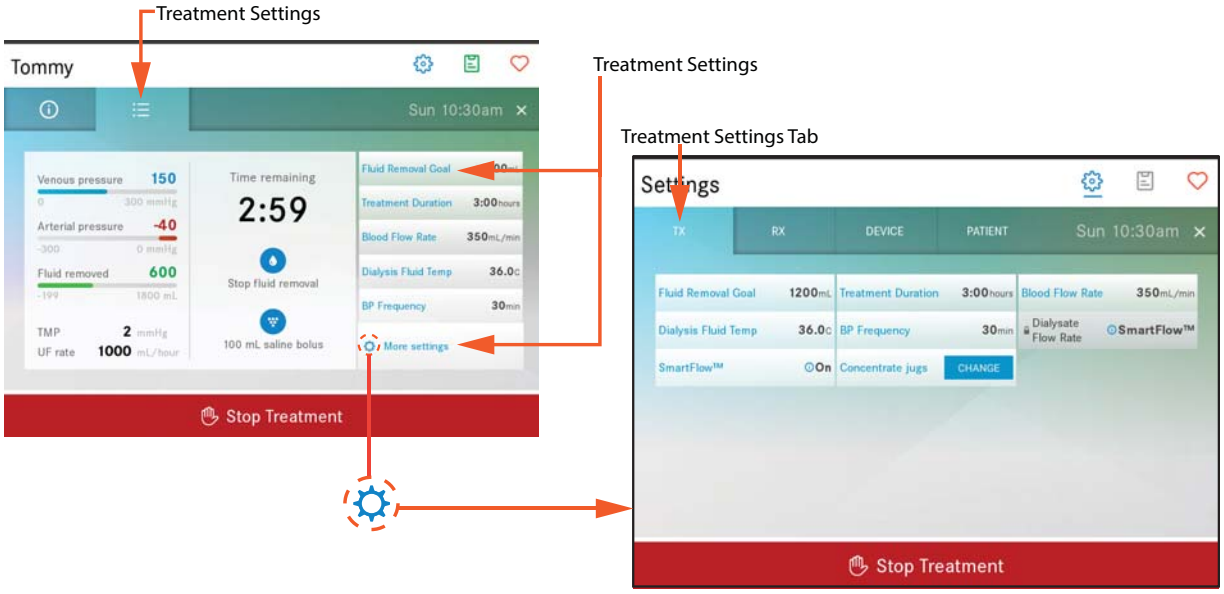


Figure 42. Treatment Settings Screen

Treatment Settings that can be Changed During Treatment

Setting	Definition	Display Units	Interval/Limits
Fluid Removal Goal	For more information, see "*Fluid Removal Goal*" on page 51.	Alphanumeric	Minimum 0mL Maximum 24000mL
Treatment Duration	The length of the treatment in hours.	Hours	Minimum 0:30 hours Maximum 12:00 hours
Blood Flow Rate	Enter the target blood flow rate for treatment.	Alpha	Minimum 50mL/min Maximum 400mL/min
Dialysis Fluid Temp	The temperature setting for the dialysis fluid. The temperature can be adjusted during treatment.	Celsius	Minimum 35.0° C Maximum 38.0° C Interval 0.1° C Default 36.0° C
BP Frequency	The interval at which the patient's blood pressure will be automatically taken during treatment.	Minutes	Maximum 60 min ***NOTE:*** *The BP frequency cannot be set to Off during treatment.*

Warning: Follow the physician's prescription for monitoring blood pressure during treatment. Skipping blood pressure measurements during dialysis increases the risk that blood pressure can become dangerously low or high during treatment.

Dialysate Flow Rate	The set blood pump rate when SmartFlow is turned off.	mL/min	Minimum 50 mL/min Maximum 300 mL/min
SmartFlow	This setting controls whether SmartFlow is enabled. See "Dialysis Fluid Flow Rates" above.	Alpha	On Off
Change concentrate jugs	Touch the "Change concentrate jug" button if the Acid or the Bicarbonate jug needs to be changed.		

If any treatment settings are changed during Treatment, the text of the setting will change to orange.

Figure 43. Orange Text Indicates the Setting was Changed During Treatment

Fluid Removal Goal

Tablo will automatically calculate the amount of fluid needed to be removed based on the patient's target weight and the weight entered during Pretreatment. The System removes extra fluid during treatment to compensate for the saline used during blood return so that the patient ends treatment at the correct weight.

If the treatment time is modified, the fluid removal goal will not be changed. However, the ultrafiltration rate will be changed such that the fluid removal goal will be met in the now-modified treatment time. If the fluid removal goal for the treatment time exceeds the maximum ultrafiltration rate, Tablo will set the fluid goal to the maximum setting and inform the user that the fluid goal cannot be reached.

Tablo delivers a minimum of 54 liters of dialysate for a 3 hour treatment when the dialysis fluid flow rate is set to either 300mL/min or SmartFlow. Tablo continues to make dialysis fluid even when the System is in bypass.

Tablo also calculates the fluid removal rate in relation to the blood flow rate, and will not remove more than the prescribed fraction of the blood flow rate to prevent over-concentration of the blood. In some instances, the blood flow rate will need to be increased to achieve the desired fluid removal goal.

Device Settings that can be Changed During Treatment

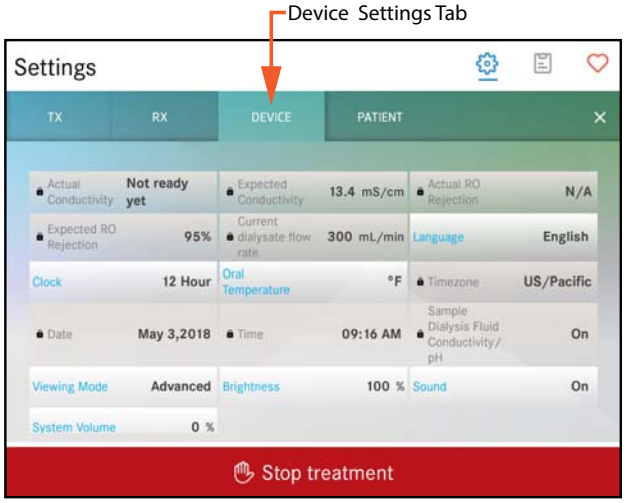


Figure 44. Device Settings Screen

Setting	Definition	Display Units	Interval/Limits
Clock	Displays the time of day.	Alphanumeric	Available settings are 12 hour A.M./P.M., or 24 hour military time.
Viewing Mode	Available settings are Training and Advanced modes. For more information, see "*Viewing Modes*" on page 28.		
System Volume	Controls the volume of the Touchscreen clicks. Does not control alarm sounds.	Alpha	Minimum 0% (off) Maximum up to 100%
Oral Temperature	Set the temperature to display Fahrenheit or Celsius.	Alphanumeric	Fahrenheit Celsius

Brightness	Brightness setting of the Touchscreen.	Percentage	0% (dark) up to 100%
Language	Language displayed on the Touchscreen.	Alpha	English
Sound	Turns off the sound of the Touchscreen clicks. Does not control alarm sounds.	Alpha	ON OFF

The user must touch SAVE to keep the treatment changes, or CANCEL to discard them.

Treatment Notes

Users can document patient symptoms by touching the treatment notes icon during Pretreatment, Treatment and/or Post-treatment.

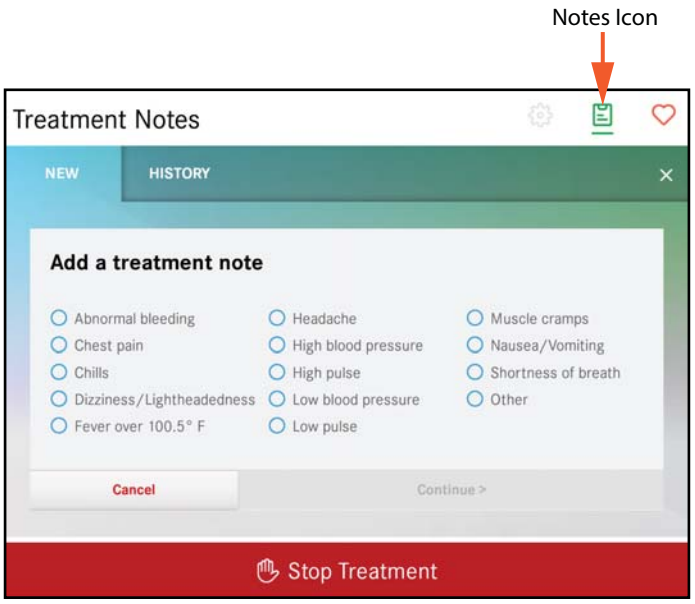


Figure 45. Treatment Notes Screen

To add treatment notes:

1. Touch the button, a screen will appear listing common dialysis symptoms.
2. Touch a symptom the patient is experiencing or select other to document a symptom not listed or to enter a general note.
3. Touch Continue, a new screen is displayed requesting the actions taken.
4. Enter the actions taken and include the note and add initials. Initials are optional and do not have to be included.
5. Touch SAVE to save the note or Cancel.
6. Repeat steps 1 through 5 to add more patient symptoms or general notes.

Stop Fluid Removal (Ultrafiltration)

Warning: If the patient is prone to specific potential adverse events such as, lightheadedness, low blood pressure, increasing heart rate, chest pain, worsening headache or any others that may be exacerbated by a change in ultrafiltration rate, please consult with the attending physician prior to changing the UF rate.

The System allows ultrafiltration to be stopped and started during treatment.

To stop fluid removal touch the Stop Fluid Removal button, a confirmation screen will appear:

- Touch YES to confirm and stop of fluid removal. The button will change to START FLUID REMOVAL, as a reminder to resume ultrafiltration when ready.
- Touch NO to cancel and continue with fluid removal.

Saline Bolus

During dialysis therapy, a patient may need to deliver a bolus of saline to help stabilize low blood pressure, or relieve lightheadedness, cramps, or palpitations.

NOTES: Repeated infusions of saline may warrant re-evaluation by the attending physician.

The volume of the saline bolus administered to the user is not removed by Tablo as part of ultrafiltration. Therefore, the administration of a saline bolus either during treatment or after blood return will result in the user completing dialysis without achieving the target fluid removal goal.

To administer a saline bolus, touch the Saline Bolus button, a confirmation screen appears:

- Touch YES to confirm the saline bolus delivery. A volume of either 100mL, or 200mL (set under RX Settings) of saline will be delivered at the same rate as the blood flow rate. During the saline bolus delivery, the button will change to DELIVERING SALINE and the treatment clock will stop until after the bolus is delivered.
- Touch NO to cancel and continue treatment without delivering a saline bolus.

Stop Treatment

Tablo allows the blood pump to be stopped and started during therapy. Examples of when this may become necessary include when the needle position is being adjusted, if clots are suspected in the line, or during an incident of catheter malfunction.

If the patient is susceptible to periods of excessively high or low blood pressure, consult with the attending physician.

Tablo allows a treatment to be manually stopped and started during treatment.

1. Touch Stop Treatment on the screen, “Are you sure you want to stop?” is displayed.
2. Select one of the following options:

Figure 46. Stop Treatment Options

   - Touch Resume to continue treatment.
   - Touch Pause to pause treatment. For more information, see "*Pause Treatment*" on page 55.
   - Touch Stop to stop treatment. The “End treatment options” screen is displayed.
3. Select one of the “End treatment options”:

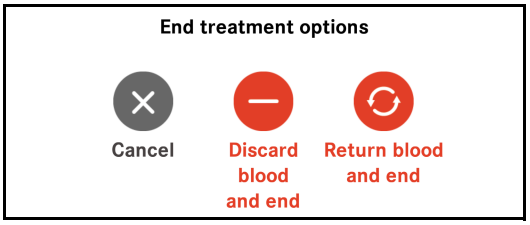


Figure 47. End Treatment Options

   - Touch Cancel the, “Are you sure you want to stop?” screen opens.
   - Touch “Discard blood and end”. If this option is selected follow the instructions on the screen to discard blood and end treatment.
   - Touch “Return blood and end”. If this option is selected follow the instructions on the screen for blood return and end treatment.

Pause Treatment

Tablo allows treatment to be paused in order to temporarily disconnect the patient from the System. When treatment is paused, the System will return the patient's blood and circulate saline in the patient bloodlines until the patient is ready to reconnect and resume treatment.

Tablo does not have a maximum treatment pause time. Refer to your site's policy for guidelines on pausing a treatment.

NOTES: After Treatment Pause, the System will adjust its internal fluid removal goal to remove the saline delivered to the patient when blood was returned prior to recirculation. Therefore, there is no need to adjust the fluid removal goal after treatment is paused in order to achieve the patient's fluid removal goal.

Saline boluses are not automatically removed by the system, therefore the administration of saline boluses during TREATMENT PAUSE will cause the patient to complete treatment without achieving their fluid removal goal.

1. Touch Stop Treatment.
2. Touch Pause to pause treatment.
3. Select one of the following options:
   - Touch Cancel to resume treatment.
   - Touch Pause to pause treatment. If this option is selected, follow the instructions on the screen.

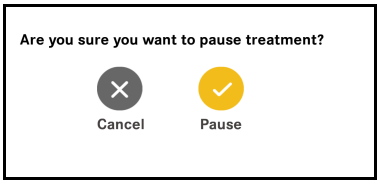


Figure 48. Pause Treatment Screen

End Treatment

Select one of the end treatment options:

- Touch “Discard blood and end treatment”. If this option is selected follow the instructions on the screen to discard blood and end treatment.
- Touch “Return blood and end treatment”. If this option is selected follow the instructions on the screen for blood return and to end treatment. When Blood Return is complete, the screen will prompt the user to take blood pressures readings and deliver saline as needed before disconnecting the patient lines.

When the user is ready, they may begin disconnecting by touching the DISCONNECT button and following the instructions displayed on the screen. For more information, see "*Get Disconnected – Blood Return*" on page 62.

Warning: The internal fluid pathway of the Hemodialysis System must be disinfected at a minimum, once every 72 hours between treatments. If a treatment is conducted following a self clean, Tablo must undergo a subsequent self clean within 24 hours of the treatment. Regular cultures of the dialysis fluid should be taken to ensure that the bacteria and endotoxin levels in the dialysis fluid are acceptable. Also, chemical disinfection will be performed on a weekly basis.

Post-Treatment

Power Failure Recovery

Warnings: In the event of a power failure, the System will not perform a treatment using the internal battery. The battery is not designed to support a dialysis treatment.

NOTES: If an alarm condition occurs during or before interruption of the power supply, the alarm settings are stored and recovered automatically when the power is restored, regardless of the duration of the period, when power is interrupted.

If the power returns before the patient's prescribed blood clot time expires resume normal use of the System.

In case of a power failure a built- in battery will continue to power the Touchscreen for up to 30 minutes. Disconnect the patient from the System during the power failure by following the instructions displayed on the screen. For more information, see "*Get Disconnected – Blood Return*" on page 62.

When the power resumes, follow the Touchscreen instructions for removing the supplies and preparing the System for another treatment.

Manual Blood Return

If you lose power for 30 seconds or more and the blood clot time has not expired, touch "SHOW ME HOW" on the alarm screen and follow the instructions to manually return blood. Once the blood is returned the patient can be disconnected.

To manually return blood do the following:

1. Remove the Hand-Crank located on the inside of the bottom front door of the System.

Figure 49. Location of Hand-Crank

2. Insert the Hand-Crank into the TOP LEFT hole of the Cartridge. Rotate the crank COUNTER CLOCKWISE until it stops.

NOTE: If the Hand-Crank does not rotate COUNTER CLOCKWISE, the System is already in position. Proceed to the next step.

Figure 50. Place Hand-Crank in Top Left Hole of Cartridge

3. Insert the Hand-Crank into the BOTTOM MOST hole of the Cartridge. Rotate the crank CLOCKWISE until it stops.

NOTE: If the Hand-Crank does not rotate counter CLOCKWISE, the System is already in position. Proceed to the next step.

Figure 51. Place Hand-Crank in Bottom Hole of Cartridge

4. Insert the Hand-Crank into the TOP RIGHT hole of the Cartridge. Rotate the crank COUNTER CLOCKWISE until it stops.

NOTE: If the Hand-Crank does not rotate COUNTER CLOCKWISE, the System is already in position. Proceed to the next step.

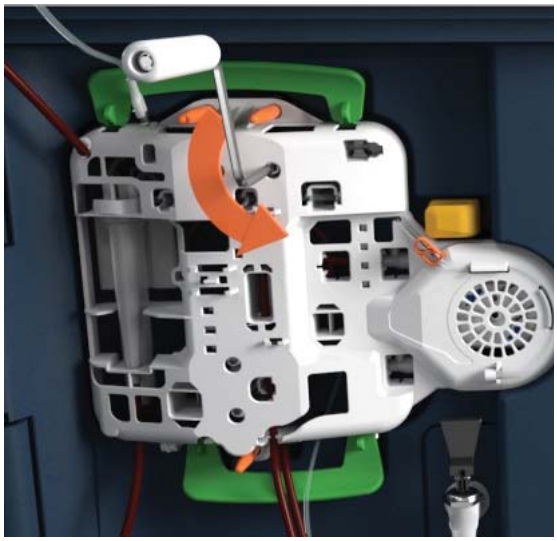


Figure 52. Place Hand-Crank in Top Right Hole of Cartridge

5. Insert the Hand-Crank into second to BOTTOM hole of the Cartridge. Rotate the crank COUNTER CLOCKWISE until it stops.

NOTE: If the Hand-Crank does not rotate COUNTER CLOCKWISE, the System is already in position. Proceed to the next step.

Figure 53. Place Hand-Crank in Second to Bottom Hole of Cartridge

6. Ensure the yellow saline clamp is OPEN.

Figure 54. Open Yellow Saline Clamp

7. Ensure patient bloodlines and venous access line clamps are open.

Figure 55. Opened Patient Bloodlines and Venous Access Line Clamps

8. Close the arterial access line clamp.

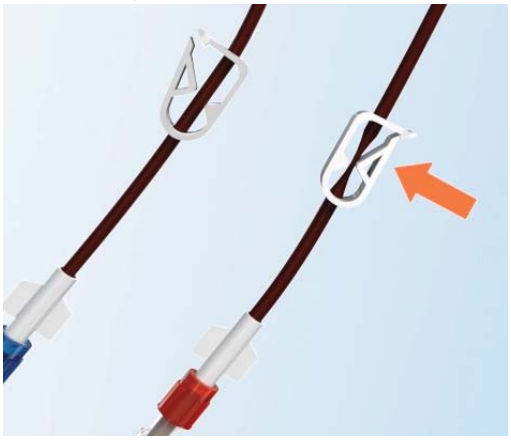


Figure 56. Closed Arterial Access Line Clamp

9. Insert the crank into the RIGHT MOST hole of the Cartridge. Rotate the crank COUNTER CLOCKWISE until the patient bloodlines are light pink.

Figure 57. Place Hand-Crank in Far Right Hole of Cartridge

10. Close the patient bloodline clamps and access line clamps.
11. Disconnect the patient. For more information, see "*Get Disconnected – Blood Return*" on page 62.

Removing the Cartridge After Manual Blood Return

NOTE: Do not pull or force the removal of the Cartridge, potential damage to the Console may occur.

The Cartridge may be difficult to remove after manual blood return.

1. Insert the Hand-Crank into the TOP LEFT hole of the Cartridge. Rotate the crank COUNTER CLOCKWISE until it stops.
2. Insert the Hand-Crank into the RIGHT MOST hole of the Cartridge.
3. Pull and hold on the yellow lever while turning the crank COUNTER CLOCKWISE two revolutions.
4. Release the yellow lever.
5. Press the top and bottom green bars and remove the Cartridge.

Get Disconnected – Blood Return

Catheter

1. Close the clamp on the arterial catheter port.
2. Touch Continue, “Sending blood back” timer is displayed.
3. Take the patient’s blood pressure readings.
4. Touch Disconnect.
5. Close the clamps on the Venous catheter port and patient bloodlines.
6. Clean the catheter ports per your site’s policies.
7. Touch Continue.
8. Disconnect the red patient bloodline from the arterial catheter port and attach it to the Y-connector.
9. Prepare the arterial catheter port per your site’s policies.
10. Disconnect the blue patient bloodline from the venous catheter port and attach it to the Y-connector.
11. Prepare the venous catheter port per your site’s policies.

Fistula/Graft Needle

1. Close the clamp on the arterial fistula needle.
2. Touch Continue, “Sending blood back” timer is displayed.
3. Take the patient’s blood pressure readings.
4. Touch Disconnect.
5. Close the clamps on the venous fistula needle and patient bloodlines.
6. Touch Continue when the clamps are closed.
7. Disconnect the red patient bloodline from the fistula needle and attach it to the Y-connector.
8. Disconnect the blue patient bloodline from the fistula needle and attach it to the Y-connector.
9. Take out each fistula needle and hold pressure on the needle sites.

Get Disconnected – Discard Blood

Catheter

1. Take the patient’s blood pressure readings.
2. Close the clamps on the catheter ports and patient bloodlines.
3. Clean the catheter connection ports per your site’s policies
4. Touch Continue
5. Disconnect the red patient bloodline from the arterial catheter port and attach it to the Y-connector.
6. Prepare the arterial catheter port per your site’s policies.
7. Disconnect the blue patient bloodline from the venous catheter port and attach it to the Y-connector.
8. Prepare the venous catheter port per your site’s policies.

Fistula/Graft Needle

1. Take the patient’s blood pressure readings.
2. Close the clamps on the fistula needles and patient bloodlines.
3. Touch Continue.
4. Disconnect the red patient bloodline from the fistula needle and attach it to the Y-connector.
5. Disconnect the blue patient bloodline from the fistula needle and attach it to the Y-connector.
6. Take out each fistula needle and hold pressure on the needle sites.

Discard the Jugs

1. Lift the blue cap, drop the straw into the jug, and press the cap onto its port.
2. Lift the red cap, drop the straw into the jug, and press the cap onto its port.
3. Discard the jugs. It is safe to pour any remaining liquid down the sink and discard the jugs per your site's policies.

Disconnect the High Flux Dialyzer

1. Open the front door.
2. Remove the red dialyzer connector from the dialyzer and push it onto the red port.

Figure 58. Disconnect the Red Dialyzer Connector

3. Touch the check box next to Drain Dialyzer to drain the Dialyzer.
4. Remove the blue dialyzer connector from the dialyzer and push it onto the blue port.
5. Close the yellow clamp on the saline line.

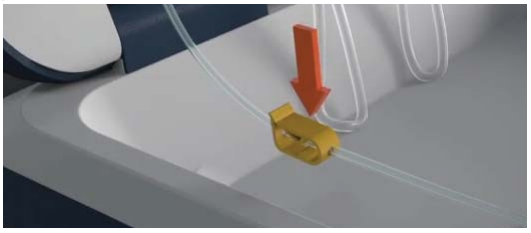


Figure 59. Close the Yellow Clamp to the Saline

Disconnect the Supplies

Warnings: Dispose of all used dialysis supplies immediately, using containers and methods approved by your site. Improper disposal increases the risk of serious infection.

Comply with your site's procedures when disposing of the used Tablo Cartridge.

Clean all blood spills per your site's policies.

1. Pull and hold the yellow lever for 5 seconds and then release.
2. Press the top and bottom green bars and remove the Cartridge.

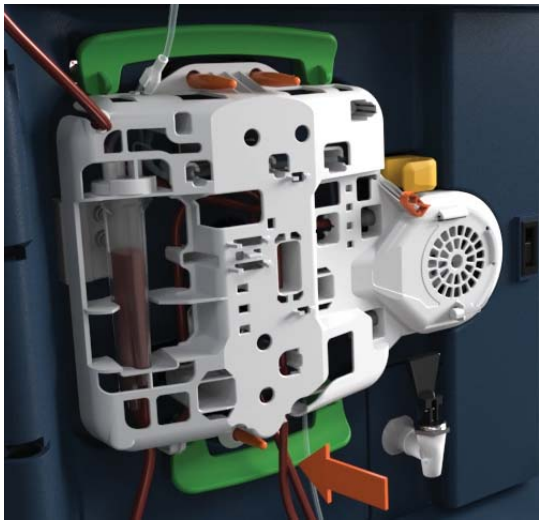


Figure 60. Disconnect the Cartridge

3. Remove and discard the saline bag, the high flux dialyzer, and the Cartridge.

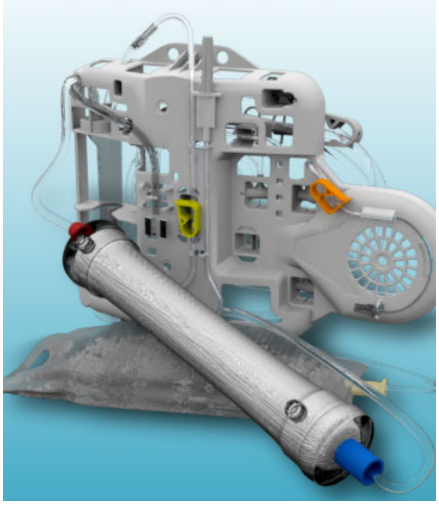


Figure 61. Discard the Saline Bag, the High Flux Dialyzer, and Cartridge

4. Enter the post-treatment vitals.

Post-Treatment Rinse

The Console will default to initiate an optional rinse cycle between treatments.

The user may skip this rinse cycle if they wish to proceed with the next treatment by touching “Get Started” on the Home Screen. Complete the Rinse Cycle prior to powering off the system.

General Cleaning

Caution: After each treatment the external surfaces of the System, including the Touchscreen, must be disinfected.

After every treatment, thoroughly wipe all exposed surfaces of the System including the Touchscreen and Blood Pressure Cuff per your site’s policies.

Outset has tested the following chemicals on the System and its accessories:

- 70% Isopropyl Alcohol
- 10% bleach (0.3% - 0.6% hypochlorite)
- PDI Super Sani Cloth Germicidal Wipes
- CaviWipes
- CaviWipes1 Disinfecting Wipe
- Oxivir 5
- Oxivir TB Wipes

Alarms and Alerts

All alarms include on-screen instructions for the user to follow. The information below is intended to supplement the alarm screen instructions.

Warnings: Unidentified malfunctions or alarm failures could potentially expose a patient to a serious health risk. Alarm limits for the arterial pressure monitor, venous pressure monitor, and trans-membrane pressure (TMP) monitor are automatically set and delayed for pressure stabilization. Alarm limits for temperature and conductivity are calculated for the dialysis fluid composition. These must be maintained within safe physiological limits as specified by the prescribing physician.

All alarms require prompt attention. Failure to respond to alarms can result in serious injury.

NOTE: The System detects Alarm conditions that persist even after clearing an Alarm and promptly terminates treatment if a Hazardous situation is presented. Please follow all instructions as described on the Alarm screen to ensure underlying causes for the condition are promptly and appropriately responded to as described on the individual Alarm Screens.

Alarm Priority

Alarms/Alerts are categorized into three priority levels as described in the following table. The color of the screen and System's sound depend on the priority.

When an alarm of higher priority occurs at the same time as a lower priority alarm/alert is active, the higher priority alarm screen will replace the lower priority screen. The user will be required to acknowledge all alarms before the System will resume.

Priority	Icon	Sound	Description
High	Red 	Rapid	Requires an immediate user response. These alarms will stop the blood pump and may end treatment based on the alarm. These alarms stop all other modes. The button on the alarm screen will indicate the alarm response as either Continue, End Treatment, or Show Me How. Outside of treatment, the End Treatment button ends the current mode.
Medium	Yellow 	Slow	Requires a prompt user response. During treatment, these alarms stop treatment time accumulation, but do not stop the blood pump. In other modes, these alarms stop time accumulation in the mode.
Alert	Gray 	Intermit-tent	Alerts indicate the presence of a condition that may or may not require user response. Alerts are intended to prevent higher priority alarms from occurring. The user must touch the Con-tinue button to clear an alert.

Alarm Response

When the System detects an alarm or alert condition, an alarm tone will sound and an error will appear on the screen with a flashing title bar. The user must take action by acknowledging or responding to the alarm or alert.

All error screens have a MUTE button to allow the user to temporarily silence the alarm for 90 seconds. The tone will sound again if the error has not been addressed during that time.

NOTE: The System detects Alarm conditions that persist even after clearing an Alarm and promptly terminates treatment if a Hazardous situation is presented. Please follow all instructions as described on the Alarm screen to ensure underlying causes for the condition are promptly and appropriately responded to as described on the individual Alarm screens.

Alarms that Stop Blood Flow

Alarms that stop the blood flow are high priority alarms displayed with a Continue button and a red background, indicating that prompt user attention is required.

These alarms include a blood clot timer that limits the amount of time that the blood pump can be stopped. Before the blood clot timer expires, the treatment can be resumed by touching the Continue Button.

An example Alarm that Stops Blood Flow is shown below.

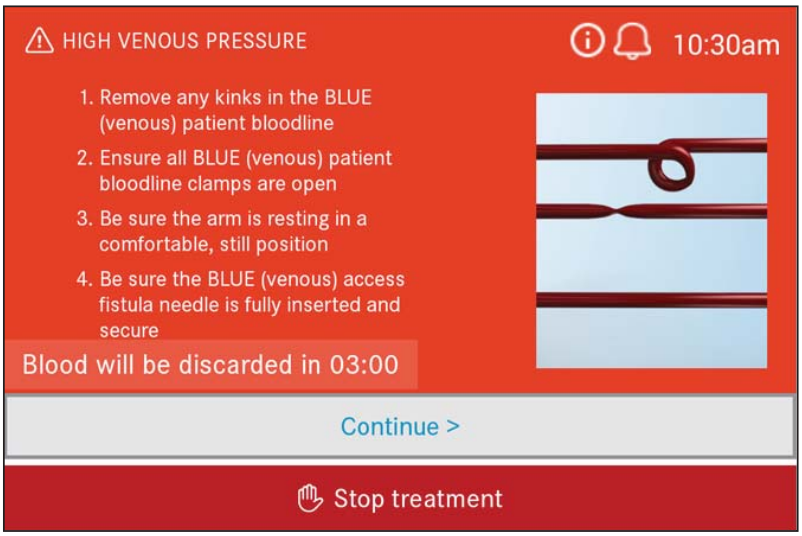


Figure 62. High Venous Pressure Alarm

Other Alarms that Stop Blood Flow

- Low Venous Pressure
- High Arterial Pressure
- Low Arterial Pressure
- Air in Blue Line
- Blood in Dialysis Fluid
- Blood Pump Error
- Clamp Failure
- Cartridge Not Loaded
- Arterial Access Line Clamp Error
- Saline Clamp Error

Blood Clot Time

When an alarm that stops the blood pump occurs, the “Blood Clot Time” begins counting down to the prescription setting. While the blood clot time continues to count down, the Continue button is displayed on the alarm screen. When the timer expires, the Continue button is replaced by the End Treatment button (as shown below), indicating that treatment must end and blood return is no longer allowed.

Figure 63. Blood Clot Time

Caution: If the countdown timer reaches zero before the blood pump is restarted, Tablo will end the treatment without returning the blood. These alarms include: Arterial Pressure (high and low), Venous Pressure (high and low), Blood Leak, Air in Blood (venous).

Blood can be manually returned before the blood clot timer reaches zero. For more information, see "*Manual Blood Return*" on page 57.

Alarms that End Treatment

NOTE: End Treatment alarms are conditions that are not recoverable. Tablo will end the treatment.

Alarms that End Treatment are high priority alarms displayed with an End Treatment Button. The user must touch this button to clear the alarm and end the treatment.

An example Alarm that Ends Treatment is shown below.

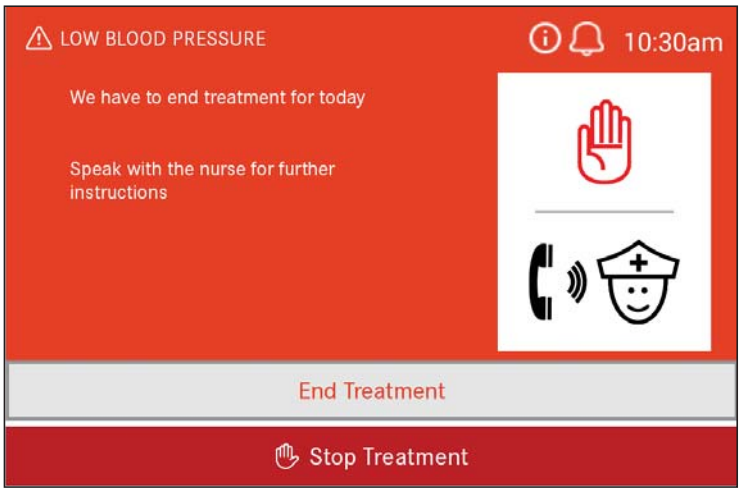


Figure 64. Low Blood Pressure

Other Alarms that End Treatment

- Degas Level Error
- Pressure too High for Water Purification
- Degas Temperature Low
- Conductivity Sensor Failure
- Dialysis Fluid Pressure too High
- Temperature Sensor Failure
- Drip Chamber Level Out of Range
- Flow Balance Failure
- System Device Error
- Bad Water Supply
- Water too Hot
- Low Water Pressure
- Low Blood Pressure
- Transmembrane Pressure Alarm
- Bypass Error
- Water Purification Sensor Failure
- RO Feed Pressure
- RO Filter Failure
- RO Filter Water Sensor Failure
- Saline Deliver Error
- Water Pressure Error
- Fluid Removal Rate Error
- Venous Drip Chamber Level
- Unable to Clear Blood in Dialysis Fluid
- Unable to Clear Dialysis Fluid Conductivity
- Unable to Clear Dialysis Fluid Temperature
- Internal Drain Blocked.

Alarms that End Treatment Preparation

Alarms that occur during treatment preparation require the user to touch the End Treatment button and end System treatment preparation.

Figure 65. Transmembrane Pressure Alarm

Other Alarms that End Treatment

- Chloramine Test Error
- RO Rejection Limit Not Set
- Alarm Not Heard

Source of Water Alert

The Source of Water Alert gives the user a chance to recover if Tablo is set to the wrong Source of Water in Admin Settings.

Users are not able to edit the RO Rejection Rate alarm during this alert. When switching from External RO to Tap, the RO rejection rate alarm will revert back to the value it was previously set at in Admin Settings or the default value if the setting has never been changed. When switching from Tap to External RO, the RO rejection rate alarm automatically switches to Off and locks.

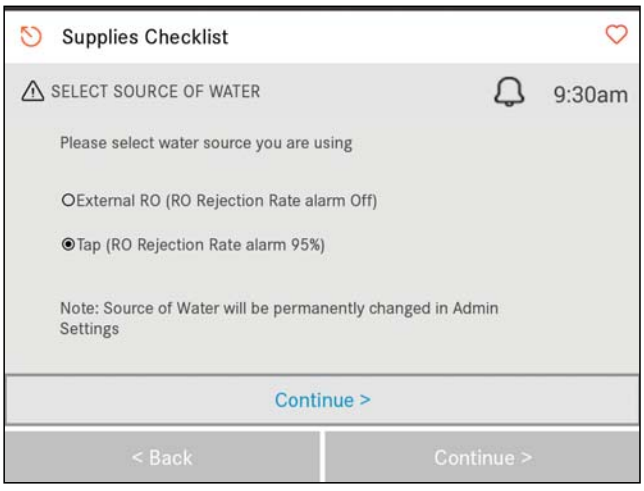


Figure 66. Select Source of Water Alert

Concentrate Alarms and Alerts

Concentrate Alarms/Alerts instruct the user when the concentrate bottles, for both acid and bicarbonate, need to be replaced or are nearing the time for replacement. These notifications begin as an alert, telling the user that within the next 15 minutes the associated concentrate bottle will need to be replaced, see below.

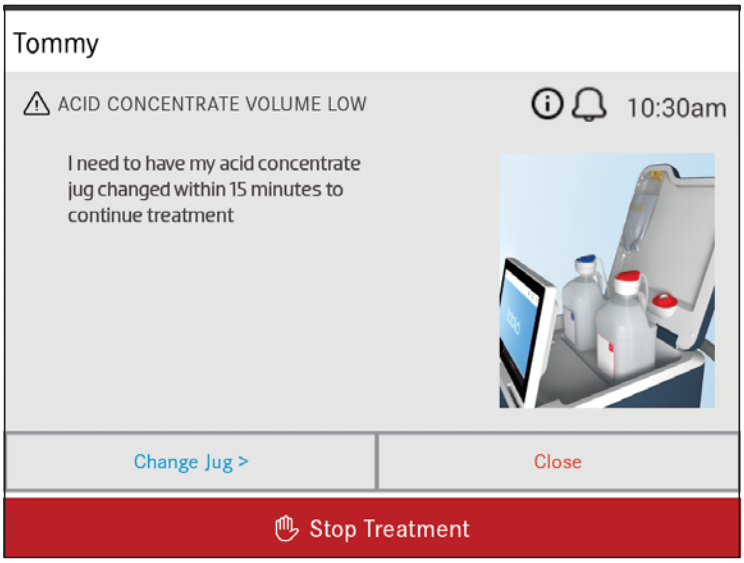


Figure 67. Bicarb Concentrate Volume Low

The user can change the concentrate jug when the alert is displayed or they can close the alert and wait until the subsequent alarm becomes active, as shown below.

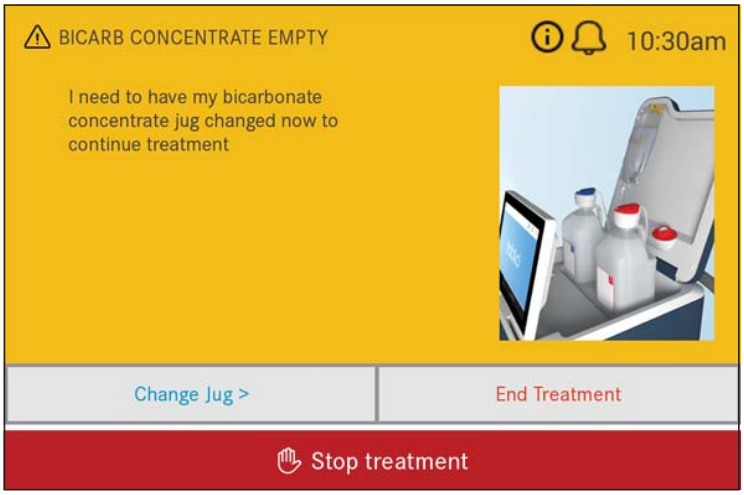


Figure 68. Bicarb Concentrate Empty

Once the concentrate alarm has been activated, the user has only two options, either replace the jug or end treatment.

Alarms that Bypass Dialysate Flow

Alarms that bypass dialysate flow are medium priority alarms and stop treatment time accumulation. They are displayed with a yellow background and include a Continue button.

Bypass alarms will allow treatment to resume once the alarm is cleared. An example of an alarm that bypasses dialysate flow is shown below.

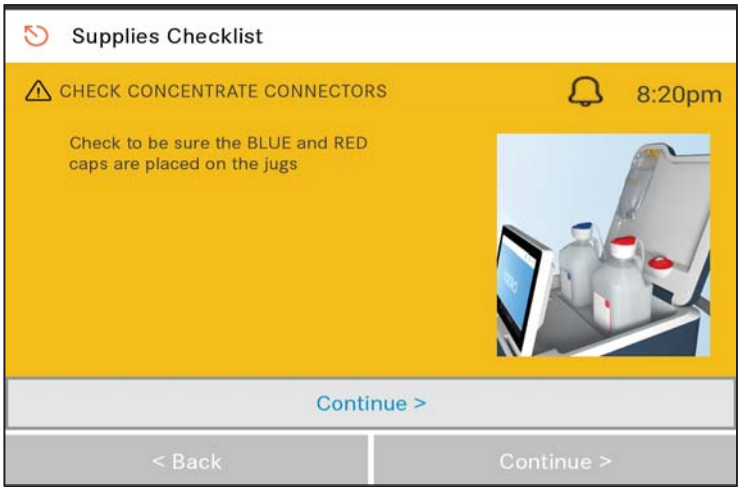


Figure 69. Check Concentrate Connectors

If treatment time is stopped for more than 15 minutes, the System displays an alert indicating that treatment time has been extended.

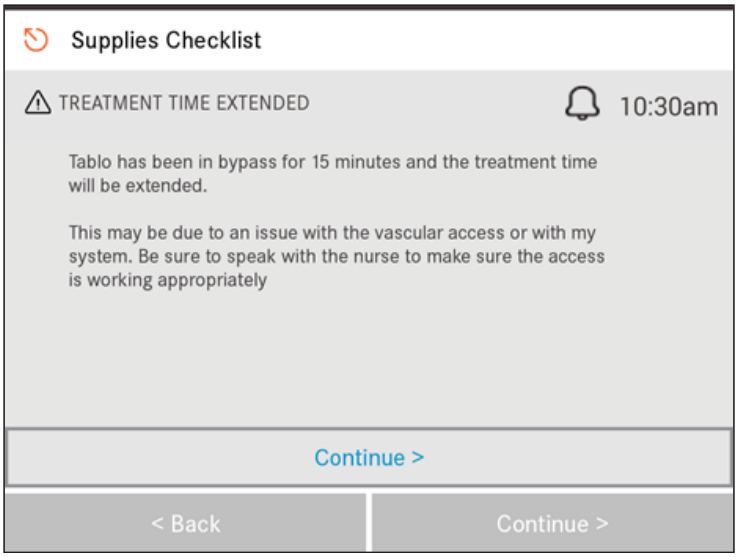


Figure 70. Treatment Time Extended

Other Alarms that Bypass Dialysate Flow

- System in Bypass
- Dialyzer Connection
- Water too Hot
- Low Water Pressure

Saline Alarm

Treatments may require more than one bag of saline. In those cases, the following alarm will instruct the user on how to replace the saline bag.

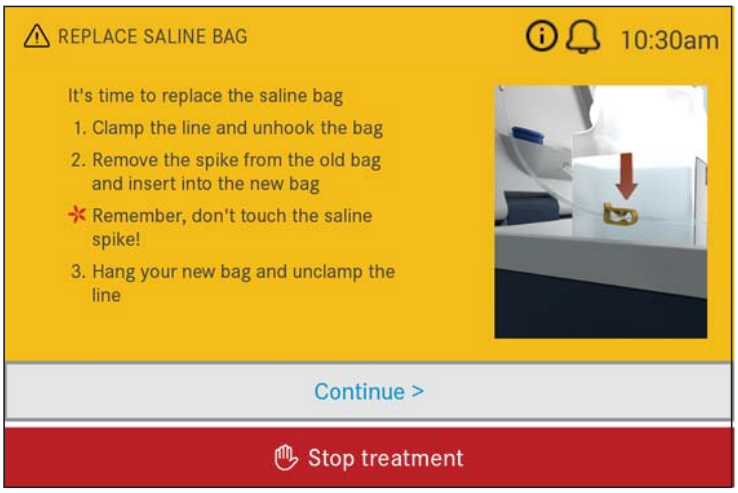


Figure 71. Replace Saline Bag

When the Continue button is touched, the System confirms whether the user has replaced the saline bag with a second alarm screen. This screen accounts for the saline volume during the remainder of treatment.

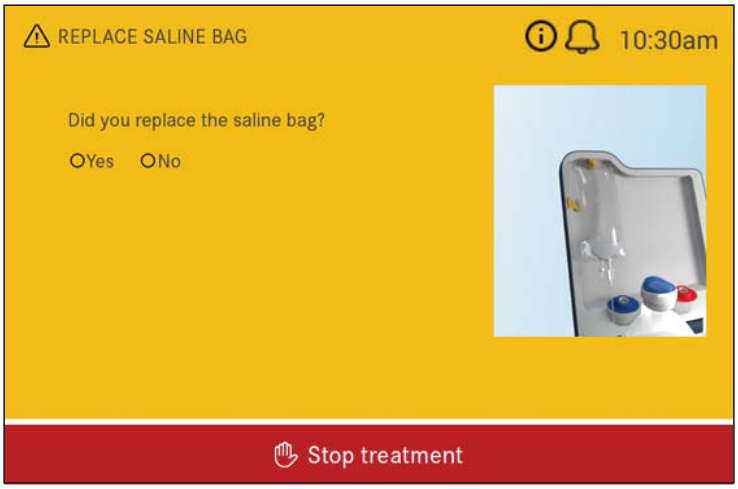


Figure 72. Did You Replace the Saline Bag

Blood Pressure Alerts/Alarms

Blood Pressure Alerts and Alarms are activated based on the following Patient Admin Settings.

- Systolic BP Low
- Systolic BP High
- Systolic BP re-takes
- Pulse low
- Pulse high

After the alarm is cleared the System will retake the patient's blood pressure in five minutes. After the blood pressure is retaken, the System will revert to the timed interval setting, BP Frequency. This setting is located in Admin Settings under the Device tab.

Below is an example of a blood pressure alert based on the Blood Pressure Patient Admin Settings.

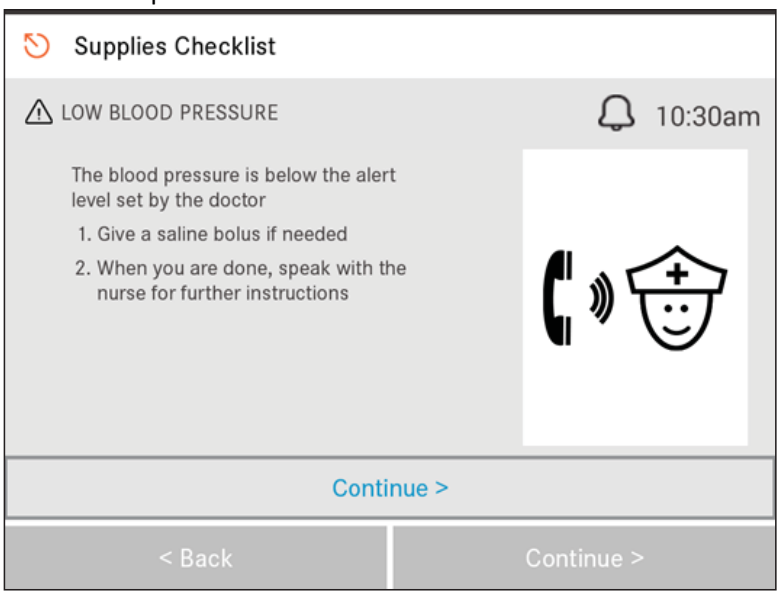


Figure 73. Low Blood Pressure Alert

When the blood pressure cuff is unable to obtain a reading, other alerts will be displayed instructing the user to check the cuff and its position as shown below.

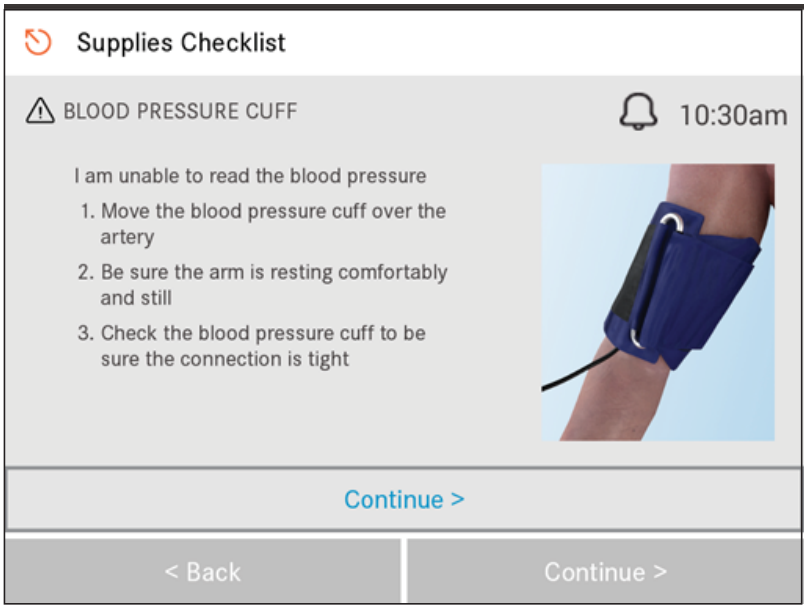


Figure 74. Blood Pressure Cuff Checklist

The System also includes a lower Systolic blood pressure limit that can be set between values of 60mmHg and 70mmHg, named "Systolic BP Low Alarm" and is initialized as part of the Patient Data in Admin Settings. When the systolic blood pressure measured by the cuff is below this limit the System activates the following alarm and schedules another blood pressure measurement (re-take).

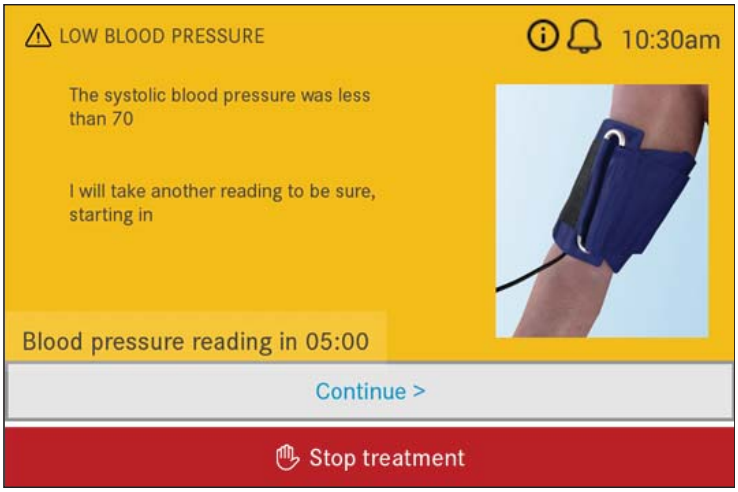


Figure 75. Retake Blood Pressure

The System includes an option to escalate low Systolic Blood Pressure Alarm to an End Treatment Alarm based on the Patient Admin Settings, “Systolic BP re-take limit”. When this value is set to “Off” the End Treatment alarm is disabled and the System will re-take blood pressure readings as long as the measured Systolic blood pressure remains below the low Systolic pressure limit. When the re-take limit is set (not “Off”) and the number of Low Systolic alarms exceeds the maximum re-take limit, then the following End Treatment alarm is activated, forcing the end of treatment and the return of the patient’s blood.

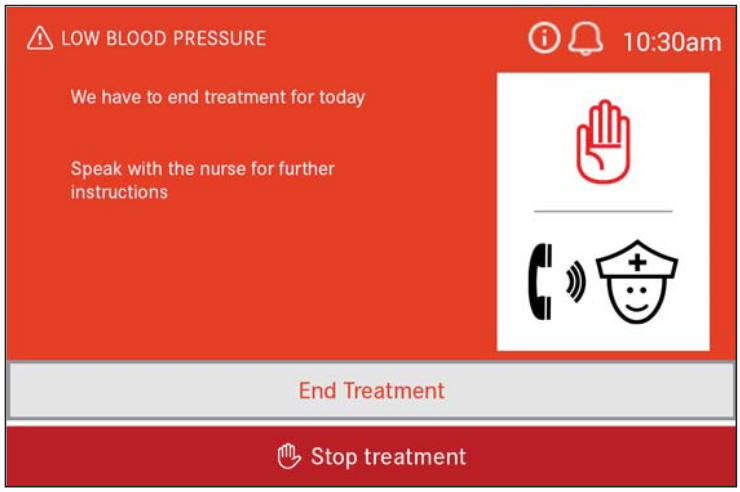


Figure 76. Low Pressure End Treatment

Procedural Alarms

Procedural Alarms are medium priority alarms that stop time accumulation in the current mode. These alarms can occur during treatment preparation, but also during maintenance and disinfection modes. They are displayed with a yellow background and a Continue button. These alarms inform the user when the System is not configured correctly and instruct the user on how to resolve the situation. Generally, these alarms relate to connectors, clamps, or the treatment cartridge being in the incorrect position for the current mode. Other configuration alarms are based on the water supply or drain line connections.

An example of a Procedural Alarm is shown below.

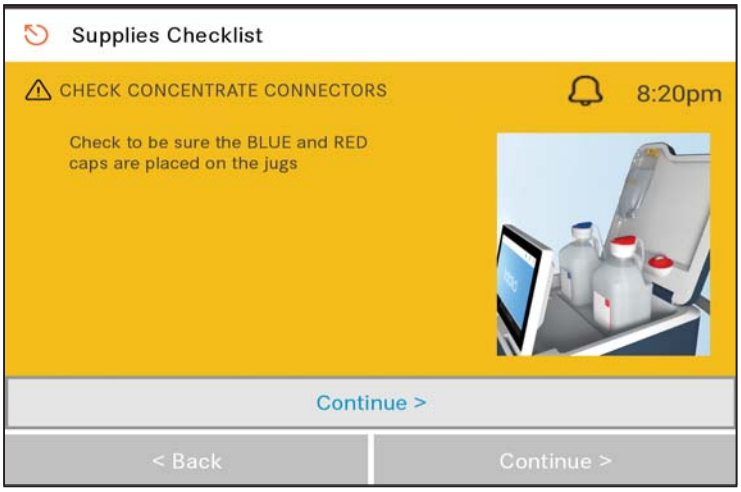


Figure 77. Procedural Alarm

Other Procedural Alarms include:

- Check Red Cap
- Connectors Not On Rinse Ports
- Expired Concentrate Formula
- Blue Cap Not On Rinse Port
- Cartridge Loaded
- Dialyzer Connection
- Water Too Hot
- Low Water Pressure
- Patient Key Removed
- Wrong Patient Key
- Check Clamps and Connections
- Prime Failure
- Saline Clamp Error
- Y-Connector Closed
- Drain Restricted
- Wrong Concentrate Formula

Disinfection Alarms

The Console monitors the disinfection cycles to ensure that they function correctly. When a disinfection failure is detected, the System activates the associated alarm and then requires that the disinfection, or rinse, be performed again. Below is an example of a disinfection alarm.

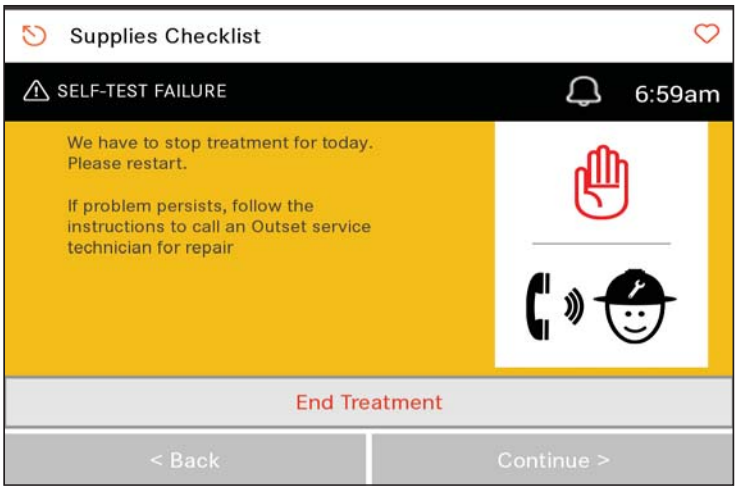


Figure 78. Self-Test Failure

Other disinfection alarms include:

- Disinfectant Conductivity Error
- Deep Clean Failure
- Water Test Failure
- Ultrafilter Failure

Shutdown Alarms

The System is constantly monitoring itself for integrity issues. These issues can occur anytime, and when one does, the System ends what it is doing. The cause of these issues include things like component or connection failures. Depending on the situation and the status of the System, the Touchscreen will display one of the following three screens (see below). Follow the instructions on the alarm screen that appears.

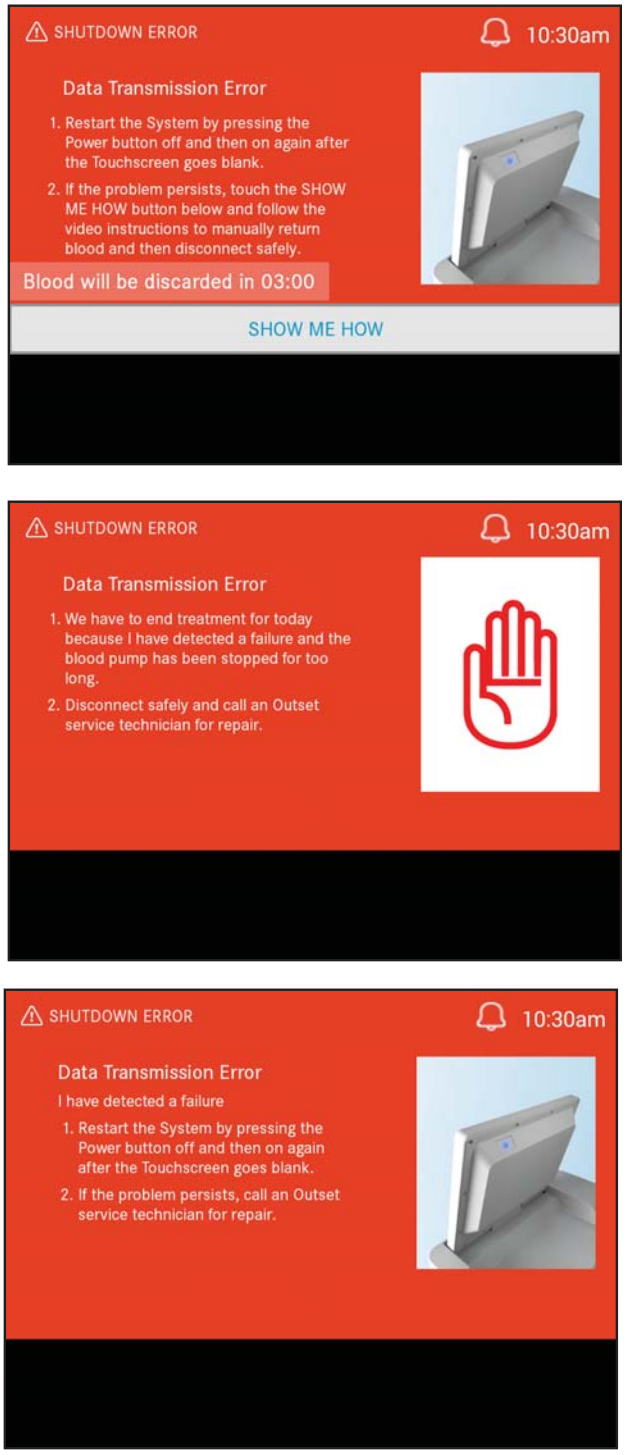


Figure 79. Examples of Shutdown Error Screens

Other Shutdown Alarms include:

- Dialysis Monitor Alarm Failure
- Wrong Blood Pump Direction
- Incorrect Blood Pump Rate
- Bypass Valve Failure
- Calibration Error
- Unable to Clear Clamp Failure
- Timer Not Working
- System Device Error
- Dialysis Fluid Pressure High
- Dialysis Fluid Supply Valve Failure
- Dialysis Module Too Hot
- Feed Heater Failure
- General Internal Error
- Heater Over Temperature
- State Transition Error
- Internal USB Error
- Water Module Failure
- Data Transmission Error
- Software Failure
- Venous Air Detector Failure
- Venous Pressure Sensor Failure
- Water Module Too Hot

Home Screen Messages

While at the Home Screen, the System will inform the user of any pending or required maintenance or other notifications that need attention. Some Home Screen Messages block the System from entering treatment or maintenance modes, others provide information only. The user can clear these messages by following the instructions on the screen.

Below is an example Home Screen Message, “Water Ultrafilter Replacement Pending”. It informs the user that the water ultrafilter will need to be replaced within the next several days. This message provides a 14 day notice.

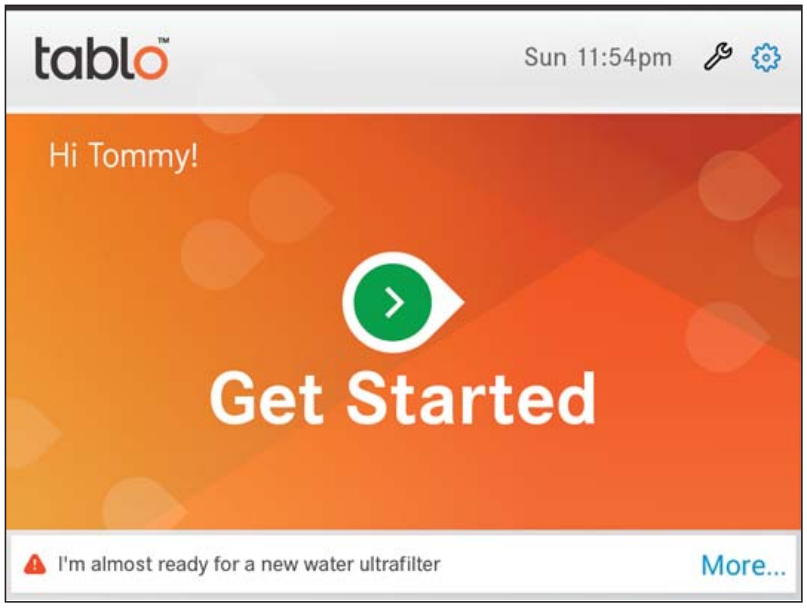


Figure 80. Water Ultrafilter Replacement Pending

To clear the message, the user must touch “More”. This will open the message as displayed below. It offers the user the option to replace the filter or wait for another time.

If “Replace later” is selected the message is cleared. If “Replace now” is selected, the System will start the filter replacement process in Maintenance.

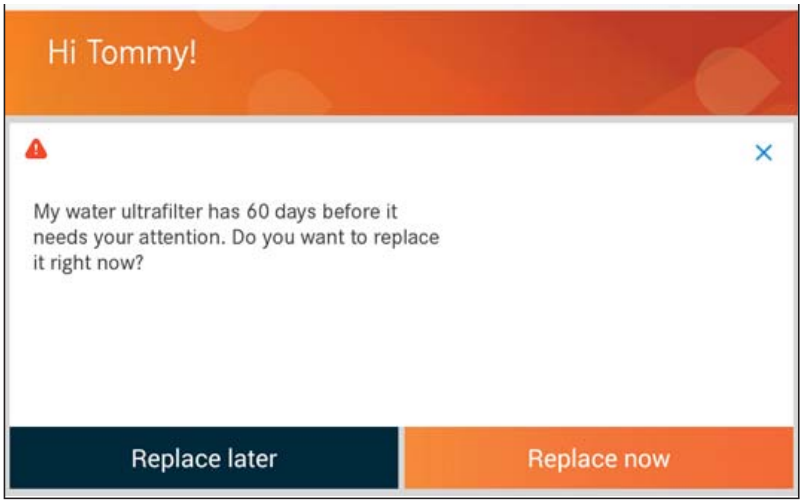


Figure 81. Water Ultrafilter 60 Day Notice

Once the water ultrafilter has completely expired, the user will no longer be given the option to clear the Home Screen Message and start a treatment, instead the following message “Water Ultrafilter Replacement Required” will be displayed and the Begin button will be disabled.

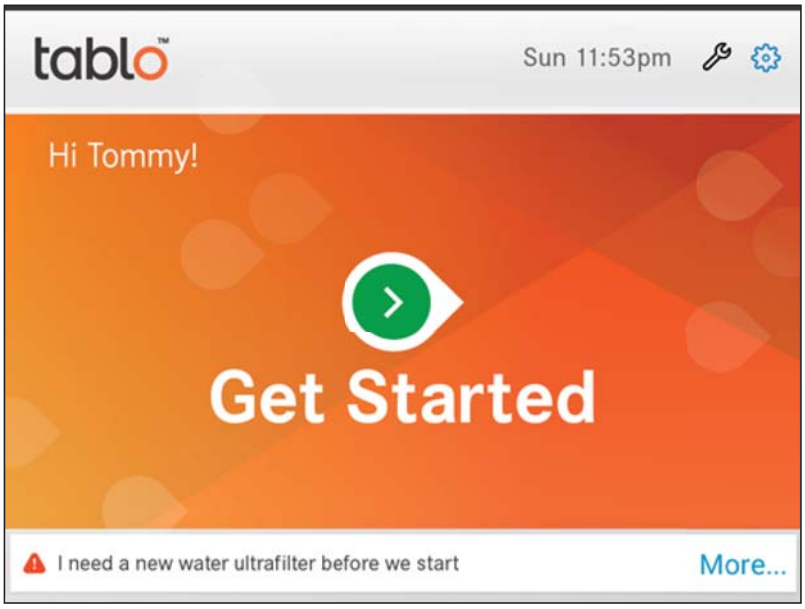


Figure 82. Water Ultrafilter Replacement Required

When opened, this message offers the user the option to replace the ultrafilter or wait for another time, but treatment will not be allowed until the after the filter has been replaced.

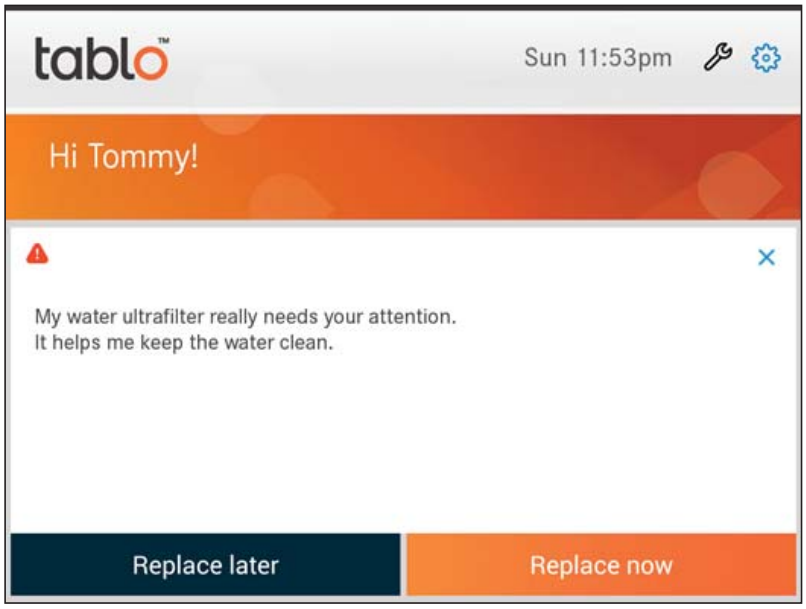


Figure 83. Water Ultrafilter Replacement Required to Complete Treatment

Other Home Screen Messages include the following:

Reminders

Title	Description
Dialysate Ultrafilter Replacement Pending	Like the water ultrafilter HSM described above, this message informs the user that the filter will need to be replaced soon, starting when 14 days remain.
Dialysate Ultrafilter Replacement Required	This message is displayed after the dialysate ultrafilter has expired, or when a test of the ultrafilter has detected a blockage or breach. It disables “Get Started” until the Dialysate Ultrafilter is replaced.
Carbon Filter Replacement Required	This message is displayed when a test of the filter has detected a blockage or the water test prior to the start of treatment fails. It disables “Get Started” until the Carbon Filters are replaced.
Sediment Filter Replacement Required	This message is displayed when a test of the filter has detected a blockage. It disables “Get Started” until the Sediment Filter is replaced.
Self Clean Required	This message is displayed when Self Clean is required prior to treatment, either after 72hr of idle time since the last Self Clean or after 24 hours since treatment (without Self Clean). It disables “Get Started” until successful Self Clean is completed.
Automatic Self Clean Starting Soon Notification	This message is displayed for 5 minutes prior to the System initiating a Self Clean cycle based on the Admin Device Setting “Time to self clean”. The user can snooze the disinfection cycle initiate by touching the SNOOZE button on the message screen.

Title	Description
Deep Clean Pending	This notification is displayed when Deep Clean is required within the next two days. It gives the user the opportunity to schedule the pending Deep Clean without being forced to perform it.
Deep Clean Required	This message is display when Deep Clean is required. It disables “Get Started” until Deep Clean is performed.
System Too Hot to Start	This message is displayed after a Self or Deep Clean cycle while the System is cooling. It disables “Get Started” until the System has cooled sufficiently.
Low Battery	Displayed when the battery needs charging and disables “Get Started” until then.
Technical Service Required	Displayed after an alarm has occurred on the System that requires technical service before the System is returned to service. It is disables “Get Started” and is cleared after the message is acknowledged and the System is serviced.
WiFi Needs	Displayed after the WiFi connection has been down for over 24 hours.

The System offers several Reminder Home Screen Messages, including five custom Reminders that can be used for any purpose. In the example below, the System is displaying the Monthly Lab Reminder. All Reminders are informational only and don’t block or control any System function.

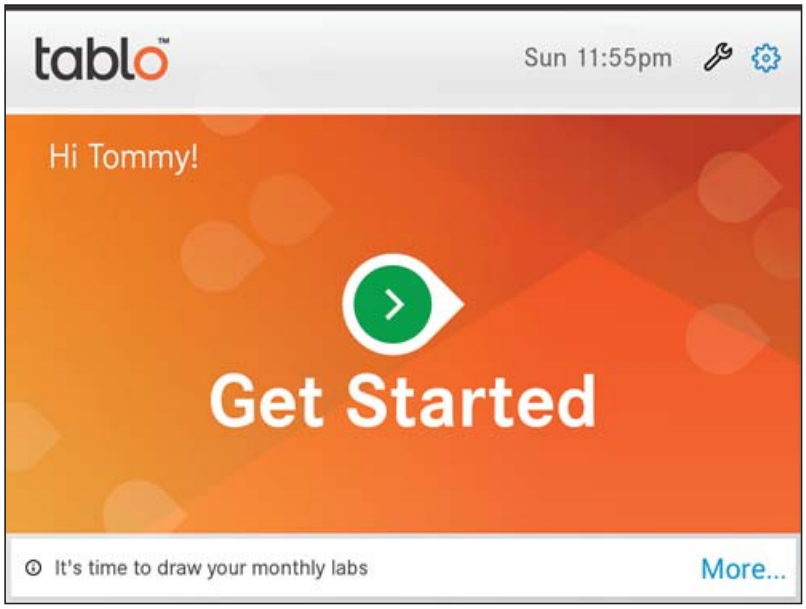


Figure 84. Reminder to Draw Monthly Labs

The Reminder is cleared when “OK” is touched.

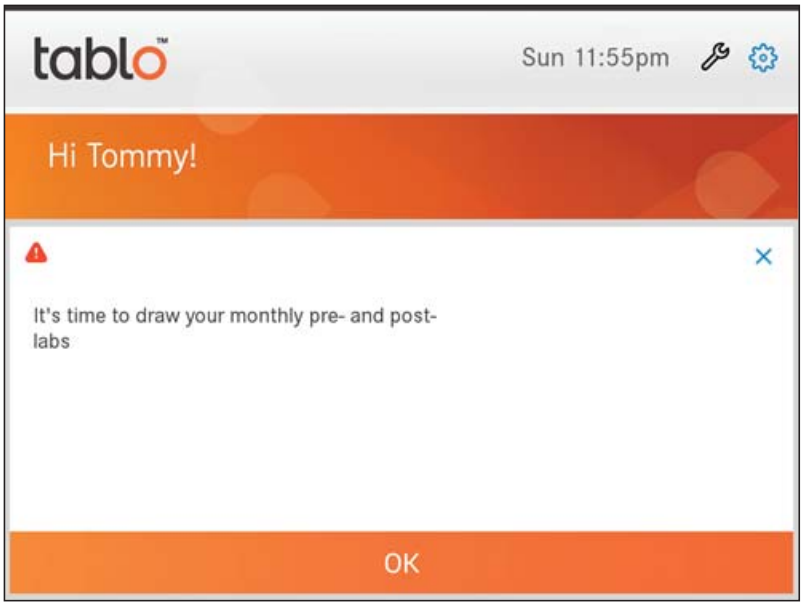


Figure 85. Click OK to Clear Reminder

Other HSM Reminders include the following:

Title	Description
Monthly Clinic Appointment	Like the Monthly Labs Reminder, described above, this Reminder provides the user the option to be reminded every month by System that it’s time to draw labs.
Custom Message 1 - 5	Up to five Custom Reminders that can be used for any purpose.

Maintenance

Warnings: Wear personal protective equipment according to the chemical manufacturer's specification prior to initiating a deep clean.

Follow the cleaning and disinfection procedures exactly as described in the instructions. Skipping a cleaning, skipping steps, or using different cleaning agents could lead to serious infections or damage to the equipment.

Blood and used dialysis fluid are potentially infectious. Follow the "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings" found on the CDC Website as well as your facility's practices when providing care to all patients.

Always replace filters according to the defined schedule. Failure to replace filters can increase the risk of serious infection or exposure to toxic chemicals during dialysis.

Do not transfer the chemical disinfectant into another container.

Never skip a heat disinfection or a chemical disinfection. Failure to disinfect the dialysis machine can cause serious infections or adverse reactions.

Caution: Keep the drain line outlet away from areas where food and beverages are prepared or consumed.

General Cleaning

Caution: After each treatment, the external surfaces of the System, including the Touchscreen, must be disinfected.

After every treatment, thoroughly wipe all exposed surfaces of the System including the Touchscreen and Blood Pressure Cuff per your site's policies.

Outset has tested the following chemicals on the System and its accessories:

- 70% Isopropyl Alcohol
- 10% bleach (0.3% - 0.6% hypochlorite)
- PDI Super Sani Cloth Germicidal Wipes
- CaviWipes
- CaviWipes1 Disinfecting Wipe
- Oxivir 5
- Oxivir TB Wipes

Maintenance Screen

Use the Maintenance screen to perform internal disinfection of the Console, replace filters, perform a rinse, and/or take samples.

The Maintenance screen displays the date and time when cleanings are due, and the number of days remaining until a filter needs to be replaced, where applicable.

Opening the Maintenance Screen

1. Touch the located on the Home Screen to open the Maintenance screen.
2. Touch one of the tabs displayed on the Maintenance screen to disinfect the system, change a filter, preform a rinse, or take a sample.

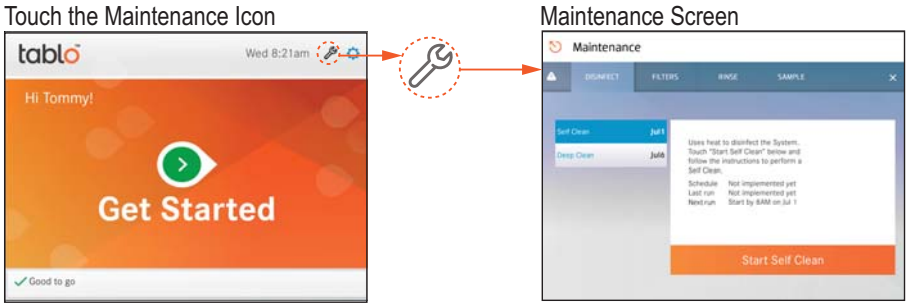


Figure 86. Maintenance Screen

Cleaning Errors

During Self Clean (heat disinfection) or Deep Clean (chemical disinfection), the Console monitors itself to ensure adequate disinfection. Parameters that are monitored include system temperatures during Self Clean and proper instillation of chemical during Deep Clean. After a Deep Clean, the system will guide the user to test for the absence of disinfectant before it is used again for a dialysis treatment.

Disinfect Tab

Self Clean

The user may start a Self Clean cycle at any time by touching on the Maintenance icon located on the Home Screen.

Warnings: The red and blue caps, and dialyzer connectors must be securely in place during heat disinfection in order to prevent the possibility of serious burns.

The internal fluid pathway of the hemodialysis System must be disinfected at a minimum of once every 72 hours between treatments. If a treatment is conducted following a Self Clean, Tablo must undergo a subsequent Self Clean within 24 hours of the treatment. Regular cultures will be taken of the dialysis fluid to ensure that the bacteria and endotoxin levels in the dialysis fluid are acceptable. Also, chemical disinfection will be performed on a weekly basis.

The red and blue caps and the dialyzer connector ports may become very hot during heat disinfection.

Cautions: Take care when handling the post-disinfection water sample. The water may still be hot.

Avoid contact with the fluid exiting the drain lines. The fluid may include infectious materials, irritating chemicals, and/or hot water.

The Self Clean cycle uses heat to disinfect the System and will display a progress graphic so the user can see the progress. Cleaning takes about one hour to complete. A message will be displayed on the Touchscreen informing the user when the Self Clean is complete. Tablo will power itself off when the Self Clean is complete.

A Self Clean must be completed at a minimum every 72 hours if no treatments are performed. If a treatment is conducted following a Self Clean, Table must undergo a subsequent Self Clean within 24 hours of the treatment.

NOTES: Perform a Self Clean within 24 hours if the red and/or blue caps, or the red and/or blue dialysate connectors are lifted from their position when the system is turned off.

A Self Clean is also required whenever the user confirms the presence of blood in the dialysis fluid.

Automating Self Clean

The System can be automated to initiate Self Clean after treatment. To customize the TIME TO SELF CLEAN setting, do the following:

1. Navigate to the Home Screen.
2. Touch and hold the button for 10 seconds.
3. Type in the Admin password in the Admin Password box.
4. Touch the DEVICE tab.
5. Touch “Time to self clean”.
6. Touch the and buttons and select setting for the automated Self Clean.
7. Touch SAVE to save the setting or Cancel to return to previous screen.

NOTE: Ensure that the System is connected to the water source and drain during its scheduled Self Clean time.

Deep Clean

Warnings: Wear personal protective equipment according to the chemical manufacturer’s specifications prior to initiating a deep clean.

The fluid exiting the drain line can exceed temperatures of 85°C during Heat Disinfection Mode. Please do not touch the drain line when the instrument is in treatment or post-treatment modes.

Tablo requires a weekly Deep Clean to disinfect the System using Minncare Cold Sterilant. Contact the supplier for Safety Data Sheet (SDS).

Follow the Chemical Disinfection preparation instructions below for a new container of chemical disinfectant.

Prepare a Minncare Cold Sterilant Bottle for Deep Clean

1. Place the new chemical bottle on a flat surface and remove and discard the chemical bottle cap.
2. Place the insert with the straw onto bottle. Only use an insert with straw provided by Outset.
3. Screw the insert with straw tightly onto bottle for storage or for immediate use.

NOTES: Once the insert and straw are in place, do not remove them, as the bottle of disinfectant with the insert and straw can be used for multiple chemical disinfection cycles. When the chemical bottle is empty, dispose of the chemical bottle with the insert and straw intact according to the chemical manufacturer's instructions.

Only an insert with a straw provided by Outset should be used with the chemical bottle to conduct chemical disinfection of the Tablo Console.

Start Deep Clean

1. Touch the Deep Clean button on the Maintenance screen located on the DISINFECT tab.
2. Put on protective equipment as required by the labeling on the chemical disinfectant.
3. Set the disinfectant behind the Touchscreen and unscrew the top.
4. Remove the red cap from the Console by pulling it straight up.
5. Press the red cap onto the disinfectant.

Figure 87. Chemical Bottle

Testing Water After Deep Clean

After the Deep Clean cycle is done, complete a water test to confirm the System is free of residual chemicals. The water sample must be drawn from the Bottom port on the door. Test the sample by placing a water sample on a Minncare Residual Test Strip.

Figure 88. Bottom Port with Syringe Installed

Complete a water test by following the instructions on the screen. If the water test fails, perform a Tablo Rinse before repeating the water test again.

NOTE: The user will not be able to continue with another treatment until the System is free of residual chemicals and the water test passes. If the water test has not been successfully completed before the start of the next treatment, the touchscreen will display a Residual Water Test to prompt a retest of the water.

Filters Tab

Warning: Always replace filters according to the defined schedule. Failure to replace filters can increase the risk of serious infection or exposure to toxic chemicals during dialysis.

The System contains four types of filters. Two carbon filters, a sediment filter, two RO filters, and two ultrafilters. With the exception of the upper dialysate ultrafilter and RO filters, filters are replaceable by the user. Filters must be replaced according to their performance, as monitored by the System, or a predetermined schedule displayed on the Maintenance screen. The upper dialysate ultrafilter and RO filter are replaced by Outset Service personnel during maintenance checks.

Sediment Filter Replacement

1. To change the sediment filter, touch the icon.
2. Navigate to Sediment Filter in the Filters section in Maintenance.
3. Follow the instructions on the screens to remove the old sediment filter and install the new one.
4. After the sediment filter is replaced, the System needs to complete a flush cycle. Following the flush cycle, the System will reset the filter replacement schedule.

Carbon Filter Replacement

1. To change the carbon filters, touch the icon.
2. Navigate to Carbon Filter in the Filters section in Maintenance.
3. Follow the instructions on the screen to replace both carbon filters.
4. After the carbon filters are replaced, the System needs to complete a flush cycle. The System flush can be viewed on the screen. When the carbon filters flush is complete, Tablo will notify the user. If no action is taken the System will automatically power down.

Water Ultrafilter Replacement

1. To change the water ultrafilter, touch the icon.
2. Navigate to Water Ultrafilter in the Filters section in Maintenance.
3. Follow the instructions on the screen to replace water ultrafilter.
4. After the water ultrafilter is replaced, the System needs to complete a flush cycle. The System flush can be viewed on the screen. Following the flush cycle, the System will reset the filter replacement schedule.

Rinse Tab

The user may initiate a rinse cycle of the system (Tablo Rinse) by touching on the Rinse tab located on the Maintenance screen.

During the rinse cycle, a progress graphic is displayed so the user can see progress to completion. The rinse cycle may be initiated by the user in response to an interruption during the Post-treatment rinse. The duration of the rinse cycle is determined by Tablo. When the rinse cycle is complete, Tablo will transition back to the Home Screen.

NOTE: When changing the water source from a water treatment system to tap water or from tap water to a water treatment system, perform a Tablo Rinse immediately after connecting to the new water source.

Sample Tab

Warning: Water samples should be periodically tested per your sites policies to ensure they continue to meet ANSI/AAMI/ISO 13959 or other appropriate quality standards.

The Take Culture Samples option on the Maintenance Screen gives the user two options:

- Take Water Culture Sample
- Take Dialysis Fluid Culture Sample

Take Water Culture Sample

Touch the Take Water Culture Sample button. Follow the instructions on the screen to take a water culture sample.

NOTE: If after both Carbon filters have been replaced, the water sample fails, stop what you're doing and call an Outset service technician for further instructions.

Take Dialysis Fluid Culture Sample

When the Take Dialysis Fluid Culture Sample button is selected, a Supplies Checklist is displayed on the screen. Follow the instructions on the screen to take a dialysis fluid culture sample.

Specifications

Caution: The Tablo System must be installed and put into service in accordance with the outlined specifications.

Essential Performance

Blood Flow	Range: 50 – 400 mL/min Accuracy: larger of ±10% or ±10 mL/min
Dialysis Fluid Flow	Low Dialysis Fluid Flow = 100 mL/min ±10% Medium Dialysis Fluid Flow = 200 mL/min ±10% High Dialysis Fluid Flow = 300 mL/min ±10%
Fluid Removal Rate (UF Rate)	(Fluid Removal Goal + (1 + Number of Treatment Pauses) * Rinse-back Volume – Fluid Removed)/(Remaining Treatment Time) Range Minimum: 0 Maximum: The lesser of (Maximum UF Rate or 25% x blood pump flow rate) Where Fluid Removal Goal = Today's weight – Estimated Target Weight
Length of Treatment (Treatment Duration)	Range: 0 – 12 hours Accuracy: ± 5 minutes
Dialysis Fluid Composition	Dialysate Conductivity= 13700 µS/cm (TYPICAL) Range: 13015 - 14385 µS/cm
Dialysis Fluid Temperature	Dialysis Fluid Temp Setting ± 0.5°C when the environmental temperature is within 20°C to 25°C

Machine Specifications

Physical Specifications

Floor Space	19" x 17.5"
Height	33.5"
Dry Weight	195 lbs
Ingress Protection Rating	IP21

Operating Conditions Specs

Temperature	15 - 38°C
Relative Humidity	30 - 75%
Ambient Pressure Range	700 hPA to 1060 hPA

Transport and Storage Conditions Specs

Temperature	5 - 40°C
Relative Humidity	10 - 90%
Atmospheric Pressure	700 hPA to 980 hPA

Electrical Specs

Voltage & Frequency	120 VAC, 60 Hz
Power Rating	1440 watts max. Avoid using other appliances on the same circuit.
Fuses	15A breaker
External Connections	Power Cord, 15A, C13 Locking USB Port, 1500V Isolated, Patient Prescription Ethernet Port, 1500V Isolated, Diagnostic
Ethernet Connection	CAT-5 / CAT-6
Wi-Fi Connection	Wi-Fi module supports IEEE 802.11 a/b/g/n protocol and uses IEEE 2.4GHz (2412-2462 MHz) or 5GHz (5180-5805 MHz) bands for the connection. The provider may set up a secured WiFi network using WEP, WPA, or WPA2 security protocols.
Ethernet/Wi-Fi Bandwidth	3KB/second bandwidth per Tablo device. Lower bandwidth will not cause any issue other than a delay in transmission of data.
Heat Dissipation to Room	600 - 700 BTU/hr
Electromagnetic compatibility	IEC 60601-1-2 EMI/EMC Compatible RF Compatible per IEC-60601-1 safety requirements

Electrical Safety Specs

Protection against electric shock	Protection in Power Input Type: Safety Class I Tablo Cartridge: Type B Applied Part (with CF current leakage limits)
Alarm Characteristics	Audible alarms occur at around 65 – 75 dB(A)
Leakage currents	[According to IEC 60601-1]

Water Specs

Water Pressure	Min: 30 PSI; Max: 80 PSI
Water Temperature	Min: 5°C Max: 32°C
Incoming Quality	EPA primary and secondary standards for drinking water
Total Hardness	≤150 mg/L
Conductivity	<2000 µS/cm
Out coming Quality	ISO / AAMI 13959:2014, Water for Hemodialysis and Related Therapies
Drain	4 ft maximum height. Must meet local codes and maintain a minimum 1" air gap between drain hose and building drain. 40 feet maximum drain hose length. Warning: The fluid exiting the drain line can exceed temperatures of 85°C during Heat Disinfection Mode. Please do not touch the drain line when the System is in treatment or post-treatment modes.

Dialysate Specs

Dialysis Fluid Flow	Three modes: 100 mL/min, 200 mL/min, and 300 mL/min Accuracy: ± 10%

Proportional Mixing System Specs

Acid and Bicarbonate Concentrate Identification	As part of the Supplies Checklist, the patient / user is requested to confirm the Acid Type and confirm that the bicarbonate has not expired in order to ensure proper concentrates are used for treatment. The System is designed to alarm if the Acid Type is incorrect or if the bicarbonate has been noted to have expired.
Sodium Proportioning	Default: 137 mEq/L (standard ratio) Minimum: 135 mEq/ L Maximum: 145 mEq/ L Interval: 1 mEq/L
Bicarbonate Proportioning	Default: 37 mEq/L (standard ratio) Minimum: 30 mEq/ L Maximum: 40 mEq/ L Interval: 1 mEq/L
Monitoring Conductivity	The System monitors the dialysis fluid conductivity to be ±5% of the nominal expected value. If the conductivity is out of range, the user is notified with a bypass alarm to check the connection to the dialysate concentrates. If the alarm is not resolved within 10 minutes an alarm is activated that ends treatment.
Dialysis Fluid Heating	Minimum: 35°C Maximum: 38°C Interval: 0.1°C Default: 36°C
Monitoring Dialysis Fluid Temperature	The System monitors dialysis fluid temperature to be ± 2 °C of the Dialysis Fluid Temperature Setpoint. If the temperature is out of range, the user is notified that the System is bypass. If the alarm is not resolved within 10 minutes and alarm is activated that ends treatment.

Heat Disinfection Specs

Description	The System heats the water in the fluid path while it is being recirculated until the disinfection temperatures are achieved for greater than 20 minutes, at which point the System transitions to standby.
Temperature	>80°C for 20 minutes

Chemical Disinfection Specs

Description	The System infuses chemical into the fluid path using the Acid pump to achieve a 1% final dilution. The System then recirculates the mixture throughout the water and dialysis modules to achieve the required contact time before rinsing. After rinsing, the System performs a heat disinfection. The user is required to verify the absence of chemical disinfectant prior to the System allowing initiation of treatment.
Type	Minncare with the following composition: Hydrogen Peroxide 10-30% Acetic Acid 9% Peroxyacetic Acid 3-7% Stabilizer 0.5-1.5%

Blood Pump Specs

Flow rate	Minimum: 50 mL/min Maximum: 400 mL/min Interval: 10 mL/min Default: Rx Value Accuracy: ± 10%
Blood Pump Protective Systems	The System generates an Alarm if the Blood Pump Rate or Direction is different than expected within the accuracy described above. NOTE: The Blood Pump Alarms will protect the patient from hazard if there is extra-corporeal blood loss due to coagulation.

Saline Infusion System Specs

Saline Bolus Delivery	Saline Bag Volume: 1000 mL Minimum Bolus: 100 mL Maximum Bolus: 200 mL Accuracy: ±10% Alarm: System alarms when: • A sufficient volume of requested saline is not available for delivery or • When the volume of saline remaining at the end of treatment is less than the preset Rinseback volume

Blood Circuit Monitoring Elements Specs

Arterial Pressure Monitor	Minimum: -300 mmHg Maximum: 100 mmHg Interval: 10 mmHg Accuracy: ±20mmHg, ±10% (greater of)
Arterial Pressure Alarm	Fixed Alarm Limits: -300 mmHg to 100 mmHg Dynamic Alarm Limits: Alarm limits set to ± "Adjustable Alarm Limit Setting Span" around current arterial pressure measurement 8 seconds after stabilization Adjustable Alarm Limit Setting Span possible values include: 50mmHg, 75mmHg, 100mmHg Maximum high limit = 0 mmHg Minimum low limit = -300 mmHg

Warning: Blood Flow and thus treatment efficacy may be reduced when the Arterial Pressure pre-blood pump is extremely negative. Tablo is designed to compensate for this scenario by modulating the blood pump flow based on the arterial pressure and time into treatment.

Venous Pressure Monitor	Minimum: -100 mmHg Maximum: 400 mmHg Interval: 10 mmHg Accuracy: ±20mmHg, ±10% (greater of)

Venous Pressure Alarm	Fixed Alarm Limits: -100 mmHg to 400 mmHg Dynamic Alarm Limits: Alarm limits set to ± "Adjustable Alarm Limit Setting Span" around current venous pressure measurement 15 seconds after stabilization. Adjustable Alarm Limit Setting Span possible values include: 50 mmHg, 75 mmHg, 100 mmHg. Low Venous Limit sets to "Venous Closed Alarm Limit Setting" below the current venous pressure measurement 60 seconds after stabilization. Closed Alarm Limit Setting range: 20 mmHg – 35 mmHg Maximum high limit = 400 mmHg Minimum low limit = 20 mmHg
Air Detection	The System monitors Air in the Venous Bloodline and produces an alarm if the following trigger conditions are met: - Air volume of single bubble >60 uL - Air volume over 30 sec > 150 uL The System also monitors for air during Automated Blood Return to ensure patient safety. The blood return process is unidirectional and returns the blood through the Venous Bloodline.
Blood Leak Monitor	Blood Leaks are detected at the High Flux Dialyzer membrane in case of a hole or tear causing blood to leak into the dialysis fluid flow path at a rate greater than 0.35 mL/min. If the blood leak cannot be cleared the System provides an alarm indication "Unable to Clear Blood Leak" and transitions to end treatment.
TMP Monitor	TMP (Trans-membrane Pressure) is calculated as the difference between venous pressure (VENPr) and post dialyzer dialysis fluid pressure (PODPr). TMP = VENPr - PODPr ● Alarm: VENPr - PODPr > 200mmHg OR VENPr - PODPr < -100mmHg for 10 seconds ● Alert: VENPr - PODPr > 100mmHg for 10 seconds
Venous Drip Chamber Level Monitor	The System uses two ultrasonic level sensors (VUL, VLL) to control the level in the Venous Drip Chamber. The System alarms in the case when the Venous Drip Chamber level cannot be maintained.
Clamp	Closes with any blood/Extra-corporeal Cartridge alarm

Ultra-Filtration Control Specs

UF Accuracy	±100 mL/hour
Fluid Removal Rate (UF Rate)	Minimum: 0 mL/hr Maximum: Maximum UF Rate Setting in Patient Admin Settings between values of 1000 and 2000 mL/hr in 100mL/hr interval increments Interval: < 1 mL/hr

Monitoring Fluid Removal	The System alarms during Treatment if the UF Rate differs from the set value by > 10 mL/hr. The System alerts the user if it is unable to meet the Fluid Removal Goal as specified by the user in Pretreatment or Treatment due to inadequate treatment time or blood flow rate. The System automatically updates the Fluid Removal Goal to the maximum possible value based on the Blood Flow Rate and Treatment Time.

Treatment Time Specs

Length of Treatment Duration	Minimum: 0:30 hr:mins Maximum: 12:00 hr:mins Interval: 0:05 hr:mins

Functional Options Specs

Auto-Features	Self clean must be completed at a minimum every 72 hours. If a treatment is conducted following a self clean, Tablo must undergo a subsequent self clean within 24 hours of the treatment.

Treatment Administration Specs

Patient Prescription	The RX source setting controls the patient prescription. Settings include Console or Patient Key.

User Interface Specs

Language	English

Blood Pressure Measurement Specs

Technique	Blood Pressure Cuff
Cuff Deflation	Interactive computer controlled
Cuff Inflation	Typically 5 - 10 seconds from 0 - 250 mmHg
Interval Settings	Interval times: 5, 15, 30, 45 and 60 minutes
Cuff pressure Range	10 - 325 mmHg
Initial Cuff Inflation	180 mmHg or adjusted by host
Systolic Determination Range	80 - 260 mmHg
MAP Determination Range	35 - 220 mmHg
Diastolic Determination Range	30 - 200 mmHg
Pulse Rate Determination Range	40 - 180 BPM
Cuff Inflation Rate	5 seconds
Determination Time Normal	145 seconds
Overpressure Cut Off	325 mmHg
Transducer Drift	Auto Zeroing
Leakage Rate (Max)	3 mmHg in 3 minutes
Pressure Rate Offset	Auto Zeroing
Alarm Preset Values (Internal Alarm values preset to provide alarm limits in the event individual values are not entered)	Internal Alarm Values preset to provide alarm limits in the event individual values are not entered
Systolic	High systolic alarm limit: 100 – 260 Low systolic alarm limit: 70-140
Pulse	170/40
Inflation Pressure	Auto

Manufacturer's EMC Declaration

Guidance and Manufacturer's Declaration – Emissions

All ME Equipment and ME Systems

The Tablo is intended for use in the electromagnetic environment specified below. The customer or user of the Tablo should ensure that it is used in such an environment.10

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The Tablo does not use RF energy for any of its functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Tablo is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Manufacturer's EMC Declaration

Guidance and Manufacturer's Declaration – Immunity

All ME Equipment and ME Systems

The Tablo is intended for use in the electromagnetic environment specified below. The customer or user of the Tablo should ensure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
ESD IEC 61000-4-2	± 6kV Contact ± 8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	± 2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV Differential ± 2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Tablo requires continued operation during power mains interruptions, it is recommended that the Tablo be powered from an interruptible power supply or battery.
Power Frequency 50/ 60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 **Radiated RF IEC 61000-4-3**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 Ghz	(V1) = 3Vrms (E1) = 3V/m	Portable and mobile communications equipment should be separated from the Tablo by no less than the distances calculated/listed below: D = (3.5/V1)(Sqrt P) 150kHz to 80MHz D = (3.5/E1)(Sqrt P) 80 to 800 MHz D = (7/E1)(SqrtP) 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by and electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Regulatory and Compliance

FCC, Class A

Federal Communication Commission Interference Statement:

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device is restricted to indoor use when operated in the 5.15 to 5.25 GHz frequency range.

FCC requires this product to be used indoors for the frequency range 5.15 to 5.25 GHz to reduce the potential for harmful interference to co-channel Mobile Satellite systems.

This device does not permit operations on channels 116-128 (5580 – 5640 MHz) for 11na and 120-128 (5600- 5640 MHz) for 11a which overlap the 5600 -5650 MHz band.

IMPORTANT NOTE: FCC Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

EC Statement

This device complies with the essential requirements of the R&TTE Directive 1999/5/EC. The following test methods have been applied in order to prove presumption of conformity with the essential requirements of the R&TTE Directive 1999/5/EC:

- EN60950-1:2001 A11:2004 Safety of Information Technology Equipment
- EN 300 328 V1.8.1: (2006-10) Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive
- EN 301 489-1 V1.6.1: (2005-09) Electromagnetic compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- EN 301 489-17 V1.2.1 (2002-08) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2,4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment
- EN 301 893 V1.5.1 (2008-12) Electromagnetic compatibility and Radio spectrum Matters (ERM); Broadband Radio Access Networks (BRAN); Specific conditions for 5 GHz high performance RLAN equipment
- EU 2002/95/EC (RoHS) Declaration of Compliance – EU Directive 2003/95/EC; Reduction of Hazardous Substances (RoHS)

This device is a 2.4 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in France and Italy where restrictive use applies. In Italy the end-user should apply for a license at the national spectrum authorities in order to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services. This device may not be used for setting up outdoor radio links in France and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz. For detailed information the end-user should contact the national spectrum authority in France.

Wireless Quality of Service

The System with Wireless Capability allows for data transfer on a Wireless WiFi (IEEE 802.11) network when available. The Wireless Communication system, has multiple layers of data transmission control to ensure no loss of data during transfer. In the case of WiFi or Cellular interference, the Console will notify the user that the MICS connection is unavailable.

In the event that a wireless network is unavailable or the data transmission was not complete, the user is advised to complete the data transfer via manual means or patient USB. Software updates are managed through Outset Medical field service engineers and technical support staff.

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