



versIPDTM

Cycler System

User's Guide



**FRESENIUS
MEDICAL CARE**

Versi™PD Cyclor System User's Guide

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This document is for software version 1.3 or later.

The VersiPD Cyclor is manufactured by:

*Fresenius USA Inc.
4040 Nelson Ave.
Concord, CA 94520
(800) 227-2572
fmcna.com*

*For:
Fresenius Medical Care, Renal Therapies Group, LLC
Waltham, MA*

Caution: *Federal (US) law restricts this device to sale by or on the order of a physician.*

Indications for Use: *The VersiPD Cyclor System is indicated for adult chronic peritoneal dialysis in home and clinical settings.*

Intended Use: *The VersiPD Cyclor System is intended for Automated Peritoneal Dialysis (APD) therapy for the treatment of end-stage renal disease (ESRD) in clinical and home settings. The supported peritoneal dialysis therapy types include: Continuous Cycling Peritoneal Dialysis (CCPD), Intermittent Peritoneal Dialysis (IPD), PD Plus™ Therapy (PD+), Tidal Peritoneal Dialysis (TPD), Nocturnal Intermittent Peritoneal Dialysis (NIPD) and adapted Automated Peritoneal Dialysis (aAPD).*

Important Information

Complete the following information and keep it in a safe place so you can refer to it if you need assistance.

Your Patient ID Number (PID) _____

Phone Numbers:

Home Therapy On-Call Nurse _____

Dialysis Clinic _____

FMCNA Customer Service (supplies) **1-800-323-5188**

Technical Support (cycler problems) **1-800-227-2572**
and follow the prompts for “Peritoneal Dialysis”

Serial Number _____

Patient Passcode (optional) _____

Pharmacy _____

Introduction to the VersiPD Peritoneal Dialysis Cyclers

The VersiPD Cyclers are small, lightweight peritoneal dialysis cyclers (machine). The cyclers were designed with input from patients, home therapy nurses, and nephrologists (kidney doctors).

The VersiPD Cyclers perform peritoneal dialysis in your home or when you are traveling and monitor many factors for safety and proper function. The cyclers have various features that will be explored throughout this guide.

Welcome to VersiPD.

Table of Contents

About the VersiPD Cycler System User's Guide.....	8
Before Your Treatment.....	9
VersiPD at a Glance.....	14
Getting Started	18
Front Panel	22
Touchscreen.....	23
General Warnings	24
Cautions	30
Notes	31
USB Drive.....	36
Bluetooth Pairing	40
Manual Exchanges.....	44
Vital Signs Entry (Pre-treatment).....	46
Vital Signs Entry (Pre-treatment).....	47
Weight	48
Blood Pressure	49
Pulse.....	50
Temperature	51
Blood Glucose	52
Program Selection.....	53
Program Review.....	54
Starting Treatment.....	57
Attach Line Holder	59
Place PIN Connector in Organizer	61
Insert Cartridge.....	63
Insert Warming Pouch	64
Close All Clamps	66
Gather Solution Bags	67
Connect Bags.....	69
Break Cones.....	71
Connect Drain Line or Bags	73
Open Patient Line with Blue Clamp.....	75
Prime the VersiPD Cycler Set	76
During Treatment	82
Stop Button.....	88
STAT Drain.....	89
Skip a Phase	91
Ending Treatment.....	93
Disconnection	94
Vital Signs (Post-treatment).....	99
Empty the Bags	100
Dispose of Materials	102

Data Transfer.....	103
PD+ Disconnection and Reconnection.....	104
Your Menu.....	108
Therapy Menu	110
Additional Drain Alert	112
Solution Temperature	114
Cycler Settings	115
Sound Volume	117
Night Screen	118
Time entry	119
Language Choice.....	120
Screen Brightness	121
History Menu	122
Treatment History	123
Data Transfer (History Menu)	125
Travel Tips.....	127
Accessories	128
Nurse Menu.....	133
Therapy Button	135
Program Button.....	136
Program Entry	139
New Programs	140
PD+ Option.....	141
Cycler Program	143
Last Fill Option	146
Manual Exchanges.....	148
Bags Configuration	149
Naming a Program.....	151
Additional Drain	153
Solution Temperature	154
Flow Rate.....	155
Fill Volume	156
Catheter Performance	157
Cycler Settings	158
Vital Signs	159
Units.....	161
New Patient Option.....	162
Patient Permissions.....	164
Alarms	169
Alarm Finder	170
Warning Alarms	179
List of Warning Alarms.....	181
Caution Alarms	192
List of Caution Alarms.....	193
Notice Alarms	210
Events	212
Power Failure	215

Cleaning the Cyclor	217
Battery Replacement.....	218
OptiDwell	223
Adapted Automated Peritoneal Dialysis.....	227
Machine Specifications.....	228
EMC Declaration	236
List of Terms.....	243
Screen Finder for Patients.....	250
Screen Finder for Home TherapyNurses	254
Index.....	259

Overview

About the VersiPD Cyclor System User's Guide

This User's Guide provides step-by-step instructions on how to set up the VersiPD Cyclor for your first home peritoneal dialysis (PD) treatment and future uses. It shows you how to use the cyclor's features and includes the information you need to maintain it.

Here are some useful pages to bookmark:

- The Table of Contents on page 4 directs you to topics quickly.
- The Index at the back of the guide helps you find information quickly and easily by searching for keywords and topics.
- The List of Terms on page 243 defines words used in this guide that might be unfamiliar to you.












As you set up and use your cyclor, the VersiPD hummingbird will appear on your screen as an indicator of what phase of treatment you are in.












Let's begin!







Before Your Treatment

Below is a list of symbols that are used in this guide or on the cycler, so it's important for you to become familiar with them.

Symbol	Description
	Warning: This symbol warns against an action or situation that could hurt you. If you do not follow these instructions, it can lead to serious injury or even death.
	Shock Hazard: This symbol means you could get a severe electrical shock if you use the equipment in the wrong way.
	Finger Pinch: This symbol reminds you to keep your fingers clear of any moving parts.
	MR (Magnetic Resonance) Unsafe: This symbol on your cycler means the cycler must not be placed in an MR environment.
	Caution: This symbol warns you about an action that could cause minor injury to you or damage your cycler.
	Note: This symbol points you to a note with helpful information.
	Class II: This symbol on your cycler means that it is double insulated.
	Degree of protection against electric shock: Type BF
	Symbol for Alternating Current (AC).
	Symbol for a Protective ground terminal.
	ON: This symbol, on the right part of the power switch on the back of the cycler, means the switch is in the ON position when pressed.

Symbol	Description
	OFF: This symbol, on the left part of the power switch on the back of the cyclor, means the switch is in the OFF position when pressed.
	This symbol means to consult the operating instructions for proper use of the equipment.
	This symbol indicates that radio-frequency interference may occur near the cyclor.
	This symbol appears next to the serial number of your cyclor.
	This symbol appears next to the product number of your cyclor.
	This symbol appears with your cyclor manufacturer's name and address.
	This symbol appears with your cyclor's date of manufacture.
IP21	This symbol indicates that the cyclor enclosure is protected against the entry of a solid object greater than 12.5 mm and vertically falling drops of water.
	This symbol indicates the temperature limits to which the medical device can be safely exposed.
	This symbol indicates that the cyclor uses a battery.
R_x only	This symbol, used on the cyclor or cyclor set, means that it must be prescribed by a physician.
	This symbol, used on the cyclor set, means that it cannot be reused.
	This symbol, used on the cyclor set, indicates that its fluid path is non-pyrogenic.

Symbol	Description
	This symbol, used on the cyclor set, means that it has been sterilized with ethylene oxide.
	This symbol, used on the cyclor set, means that it should not be used if the packaging is damaged.
	This symbol, used on the VersiPD Cart, warns against sitting on the cart.
	This symbol, used on the VersiPD Cart, warns against stepping on the cart.

Requirements for Users of the VersiPD Cyclor

Under the direction of a doctor, you will be trained by a nurse to perform peritoneal dialysis using the VersiPD Cyclor. When your training is complete, you will be:

- Familiar with peritoneal dialysis procedures and how they affect the body
- Well-practiced in aseptic techniques and other peritoneal dialysis procedures
- Trained in procedures to prevent contamination and infections
- Very familiar with the contents of this guide
- Fully trained to operate the cyclor. You will be able to tell the difference between normal and abnormal operation.

Contraindications

The following health problems may prevent you from using the VersiPD Cyclor:

- Leaks across the inside of your body's lining (Transdiaphragmatic leakage)
- A destructive metabolism (hypercatabolism)
- Too little peritoneal membrane surface area
- Clinically relevant scarring or fibrosis, for example from multiple abdominal surgeries

This is a guideline only. Your doctor must make the final decision whether any medical device is appropriate for you.

MR (Magnetic Resonance) Unsafe: the VersiPD Cycler must not to be used in an MR environment. The VersiPD Cycler may pose unacceptable risks to the patient, medical staff or other persons within the MR environment.

Peritoneal Dialysis Precautions

Your doctor has prescribed peritoneal dialysis for you. There are risks, but your doctor feels it is better to perform peritoneal dialysis than not. Here are some things your doctor should consider:

You must perform treatments according to the program given to you by your physician and the manufacturer's instructions. Not doing so may result in harm. Abdominal pain, bleeding, infected peritoneal membrane (peritonitis), and a blocked catheter extension set can cause problems with your treatment. Some dialysate solutions are stronger (higher percentage of dextrose) than others at removing fluids. It is important to use the right dialysate solution for your needs: the wrong dialysate solution may pull too much fluid (hypovolemia/dehydration) out of your body and cause low blood pressure (hypotension) or muscle cramping. Or it may pull too little fluid (hypervolemia/overhydration) and cause high blood pressure (hypertension) or swelling (edema). You must continue to correctly remove fluid from your body.

You and your home therapy nurse must work together to monitor your weight and blood chemistry levels. You must pay close attention to how you feel and report any changes to your home therapy nurse. This will help prevent such complications as congestive heart failure, volume depletion, overfill of solution, shock, and inadequate therapy. Follow your program and instructions to reduce the risk of these problems that could result in serious complications.

Care partners should carefully monitor patients for the above signs and symptoms.

About This User's Guide

This User's Guide is a reference for properly trained home users of the VersiPD Cycler—it does not replace formal

training by your PD Nurse. It cannot provide or replace clinical advice.

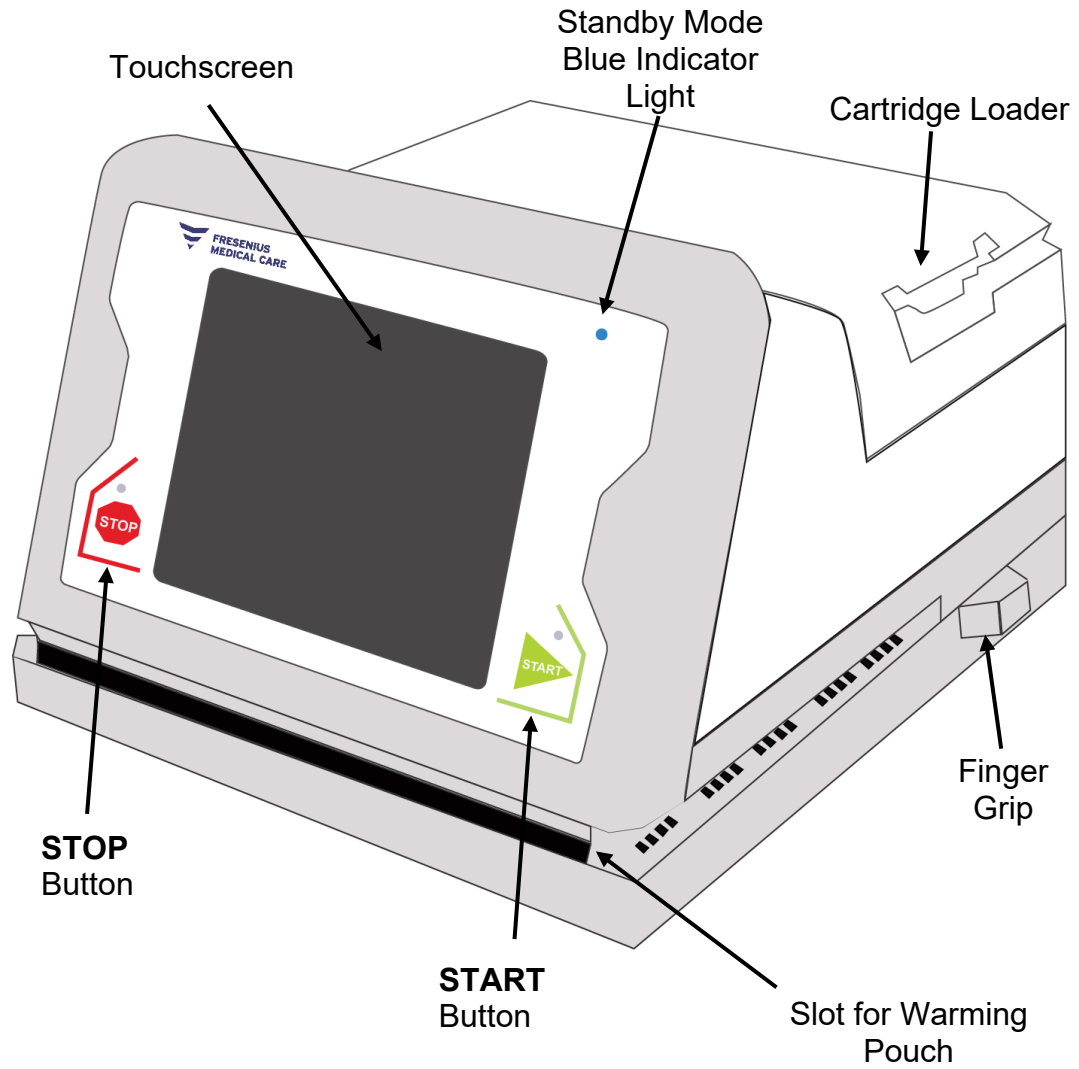
This User's Guide is specially designed for easy readability and understanding. It has illustrated procedures and step-by-step instructions.

Follow your cyclers' on-screen instructions. Use this User's Guide only as a guide for your cyclers' screens. You should read the entire User's Guide before beginning your treatment.

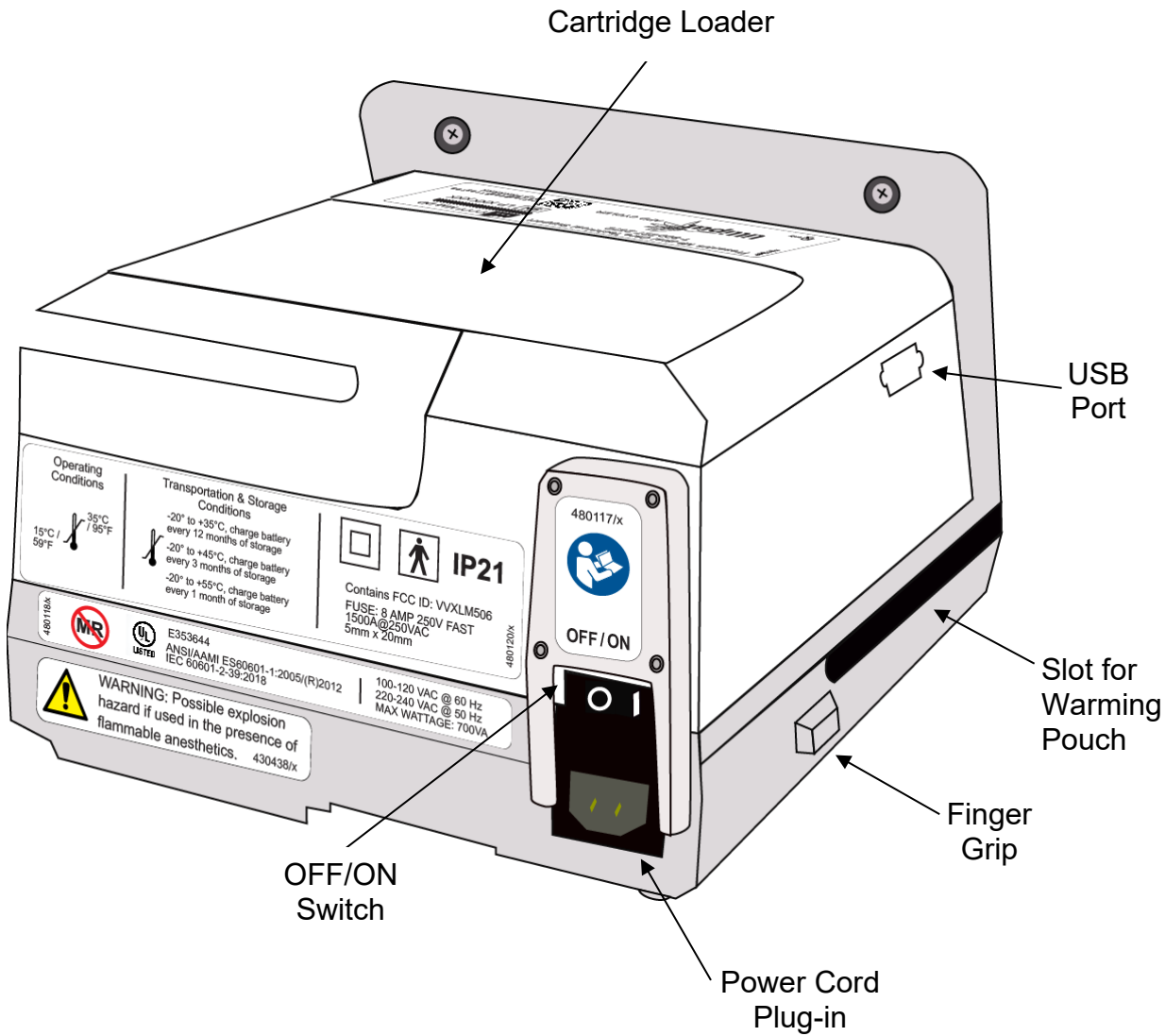
Training

Fresenius Medical Care provides written and virtual materials to train hospital staff and peritoneal dialysis nurses on the VersiPD Cycler.

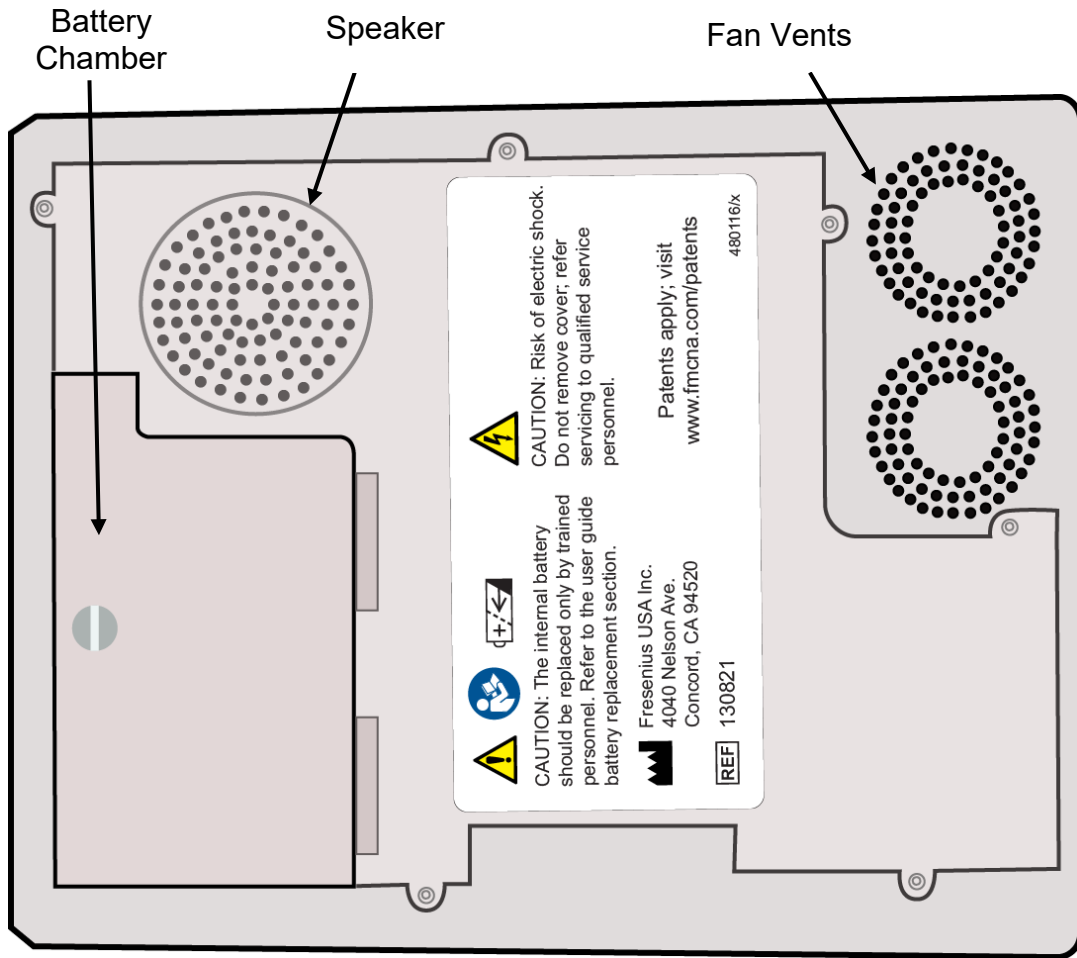
VersiPD at a Glance



This image shows the front and right-side view of the VersiPD Cycler



This image shows the back and left-side view of the VersiPD Cycler



Bottom side view of VersiPD Cycler

Treatment Setup

Getting Started

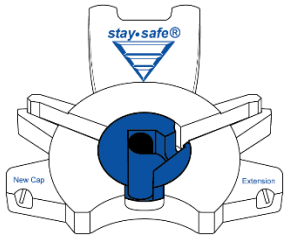
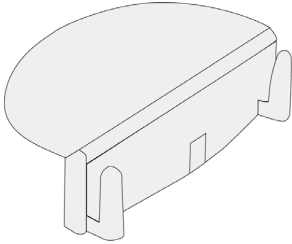
Find the best place in your home for the VersiPD Cyclor.



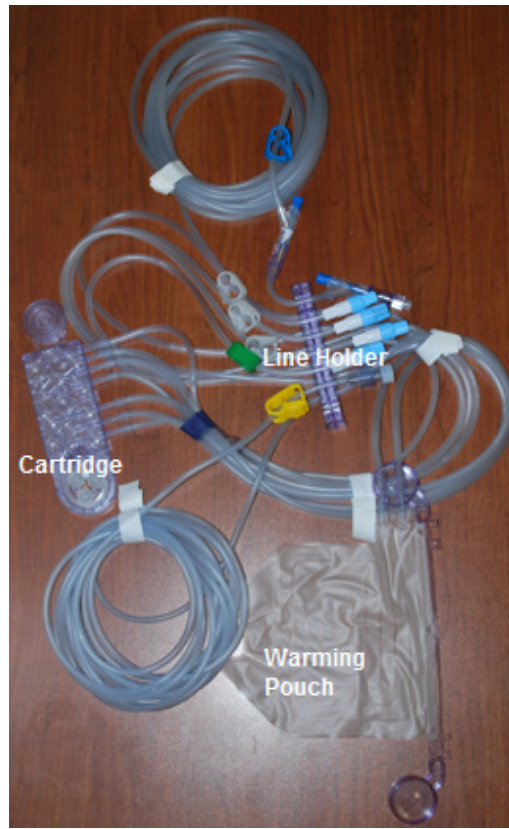
Caution: Do not place the cyclor or solution bags near heat or cold sources like heaters or air conditioners.

- Look for a space that is near your bed and an outlet to plug in the cyclor. You must use the power cord that came with the cyclor. Do not use a power strip, outlet adapter or extension cord—plug the cyclor directly into a wall outlet that is easily accessible for disconnection if needed. If you are using a GFI outlet, make sure it is reset.
- If you are using a drain line as your drain option (instead of drain bags), make sure you don't place the cyclor more than 20 feet from the drain. Your drain line should not be above the cyclor or more than 39 inches below it.
- Check the surface where the cyclor will sit. It should be a hard surface, clean and flat and not easily damaged. The top of the cyclor should be no more than 19 inches above or below your abdomen during treatment. Make sure you have a good light source nearby.
- Check for any damage to the cyclor, including cracks, sharp corners, or edges and rough surfaces. Report any damage to Technical Support immediately at 1-800-227-2572.
- When lifting and carrying the cyclor and its accessories, use both hands and lift with your knees, not your back.

Arrange the VersiPD Cyclers accessories that came with your order

	<p>1 Choose a place for the stay•safe® organizer within easy reach so that you can conveniently connect and disconnect your catheter extension set. If you are using the VersiPD Cart, there is a built-in prong to hold the organizer. If you are not using the cart, press down firmly on the stay•safe organizer until the suction cups grip the surface.</p>
	<p>2 Facing the cyclers, choose a place for the line holder nest near the front of the cyclers on the right-hand side. There should be enough room so that the lines can hang straight down without kinking.</p>
<p>3 The Instructions for Use contained in the packaging of the line holder nest will guide you through the installation process of the nest and the included anchor system. If you are using the VersiPD Cart, the nest is already built into it.</p>	

4 Remove the VersiPD Cycler Set from the box. Depending on the VersiPD Cycler Set selected for you by your home therapy nurse, you will find one of the examples below (a, b or c). Do not remove the VersiPD Cycler Set from the overwrap until ready to use it.



a VersiPD Cycler Set with 4 solution lines, 2 PIN connectors, a 20' VersiPD Cycler Drain Line, and a 20' patient line

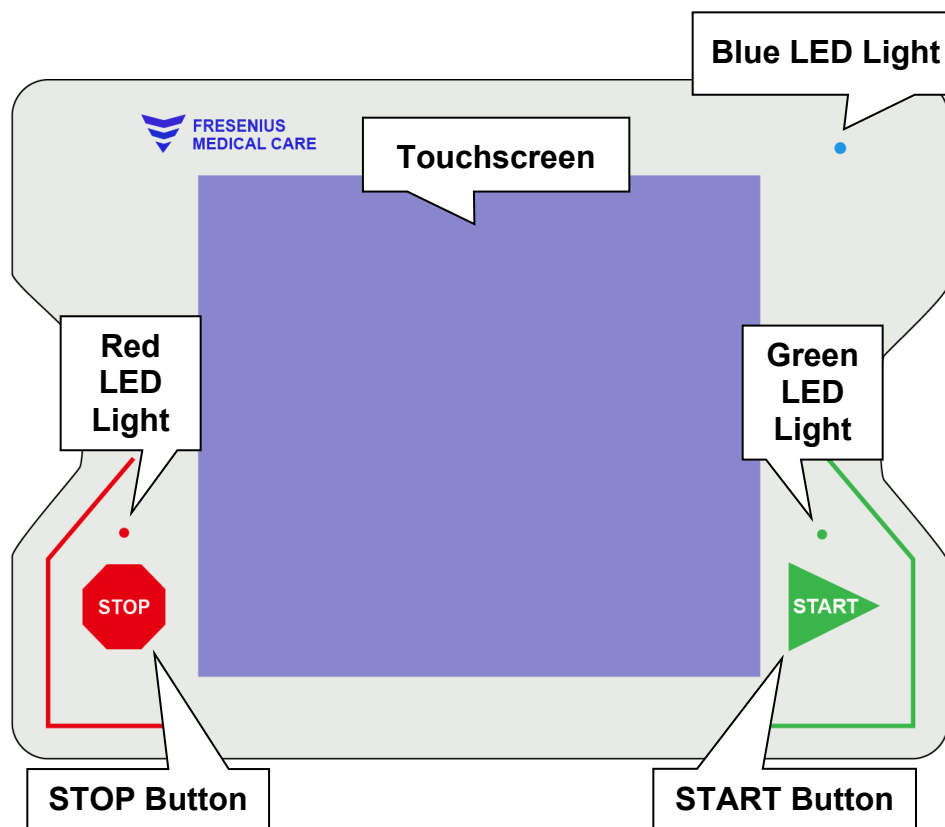
b VersiPD Cycler Set with 3 solution lines, 1 PIN connector, a 20' VersiPD Cycler Drain Line and a 20' patient line

c VersiPD Cycler Set with 3 solution lines, 1 PIN connector, a 4' VersiPD Cycler Drain Line, and a 10' patient line



5 Have your drain option ready (drain line or drain bags).

The Front Panel



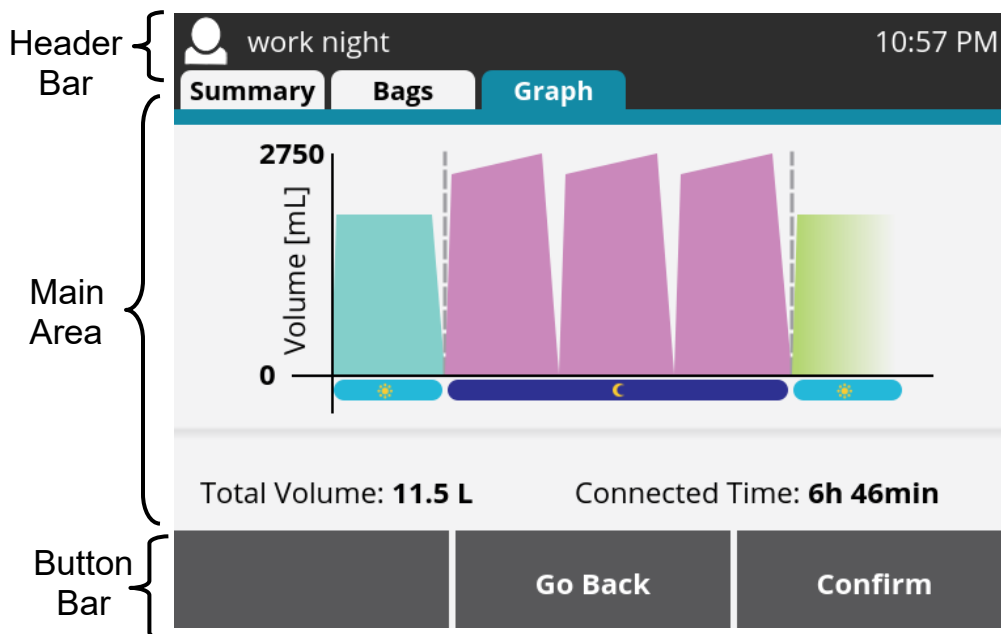
- **START Button:** This button on the lower right of the front panel takes VersiPD out of Standby Mode. This is also the button to use to start treatment or to resume treatment after a PD+ exchange.
- **STOP Button:** This button on the lower left of the front panel gives you the option of doing a STAT drain. It can also be used to end or pause treatment, or to bypass (skip) the current phase.
- **Touchscreen:** The area used to control and monitor your treatment. Buttons appear here that you activate by touching them. When you touch a button it turns orange to show that it has been selected. Once selected, you can change or confirm the value it displays.
- **LED Lights:** The *blue* LED light shines when the cycler is in Standby Mode. This means that power is supplied to the cycler and the **START** button will work. This is the normal mode between treatments.

The *red* LED light shines when the loudspeaker is active. It flashes when you press the **START** button because a beep sounds to test the sound system.

The *green* LED shines after the **START** button is pressed and then later when it is time to start treatment.

The Touchscreen

The VersiPD touchscreen display is divided into three parts: the header bar, the main area and the button bar.




Treatment
Setup

Header Bar: The *header bar* displays the screen name and the time as well as icons that show what menu is active and whether the cyclor is paired with other devices (icons are explained on page 253). In the example above, the screen name is “work night” and the icon shows that “Your Menu” is active.

Main Area: The *main area* is the space where information may be reviewed or changed. In the example above, clicking on one of the figures in the graph or on the tabs changes the view on the screen. (Patients may view the information. Nurses may view and edit).

Button Bar: The *button bar* is where you confirm, save, or cancel actions you have begun in the main area. A value entered in the main area is not saved unless you confirm it by touching a button in the button bar.

General Warnings

Any statement in this guide accompanied by the symbol  is a warning. Make sure to read all the warnings before beginning your treatment. The warnings shown here are not a complete list; other warnings will appear throughout this guide.



Warning: Increased Intraperitoneal Volume (IIPV), more commonly known as Overfill, is when you have too much fluid in your abdomen. This condition may cause injury or death. Patients and care partners should watch for the potential signs of IIPV. These include:

- Difficulty breathing
- Vomiting or spitting up
- Feeling full, bloated, or overfilled after treatment
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Chest pain
- Increased blood pressure
- Change in mental status
- Leakage of fluid from the PD catheter exit site

If you experience any of these symptoms or feel a large, painful build-up of pressure during your fill, do not finish your fill cycle. Press the red **STOP** button and immediately initiate a STAT drain as instructed by your home therapy nurse. See page 89 for more information on how to use the STAT drain feature. Once the fluid is completely drained from your abdomen, call your doctor or home therapy nurse.



Warning: A fill volume that is too high may cause an IIPV (Overfill) situation that could result in injury or death. Follow the physician's prescription when setting the fill volume.



Warning: The initial drain should be completed while you are awake. The fluid from your initial drain should have good clarity (not be cloudy), be free from fibrin strands and yellow or clear in color. If the fluid in the drain line appears cloudy, contact your home therapy nurse because this could be an early sign of infection.



Warning: Do not end the Initial Drain prematurely. This could result in an IIPV (Overfill) situation because the Initial Drain will be followed by a complete fill.



Warning: Always use aseptic technique when you connect or disconnect the tubing that goes to your catheter extension set or solution line. This means wearing a mask and cleaning your hands thoroughly as instructed by your doctor or home therapy nurse.



Warning: If any of the caps are not in place or any of the clamps are closed, discard the VersiPD Cyclor Set and replace it with a new one as there is a risk of contamination.



Warning: A new, sterile VersiPD Cyclor Set and drain line must be used for every treatment. Check that the VersiPD Cyclor Set is free from kinks or damage, and that it is not past its expiration date. Make sure all clamps are open and caps in place. A damaged VersiPD Cyclor Set can lead to leaks, contamination, and infection. If you notice damage, save your VersiPD Cyclor Set for pick up and immediately call Customer Service at 1-800-323-5188. You will be contacted about having the used tubing set picked up. Do not use this set!



Warning: Do not use the same VersiPD Cyclor Set (cartridge, warming pouch, tubing set) for more than one treatment, or continue to use a set that has been loaded in the cyclor for more than 24 hours.



Warning: Protective measures must be taken to prevent backup in the drain line. When connecting the drain line, ensure that an air gap is maintained between the end of the drain line and the drain. See page 74 for more information.



Warning: Position the power cord, VersiPD Cyclor Set and drain line so that they will not be tripped over by you or others living in your home.



Warning: Place solution bags and drain bags where punctures will be avoided. Punctures could occur from stepping on the bags, sharp edges of furniture, or pet damage. Fluid from the resulting spills could cause you to slip and fall.



Warning: Do not put the power cord, tubing set or drain line around your neck as they may pose a risk of strangulation. Special care must be taken in this regard with children or patients who cannot manage their own treatment.



Warning: The caps of the connectors present a risk of choking. Special caution must be exercised in the presence of children. These caps should be discarded safely as soon as they are removed from the tubing set.



Warning: Do not touch the inner part of the connectors (the part that will be in contact with fluid). If a connector falls on the floor, replace the set with a new one.



Warning: The number and type of solution bags must correspond to your program. Follow the guidance on the screen to ensure that the correct lines are connected to each bag.



Warning: The solution bags must be connected to the solution lines indicated on the screen. The connection of an incorrect solution bag could result in excessive or insufficient fluid volume in the blood (hypervolemia or hypovolemia).



Warning: If the Last Bag option is off, solution for the Last Fill will come from the same solution bag that was used for previous cycles.



Warning: Always inform your doctor or home therapy nurse if you have an incomplete treatment.



Warning: Check for proper functioning of your machine before beginning your treatment. Press the green **START** button. Make sure that you hear a beep and that the red LED light above the **STOP** button flashes. Alarm failure or unidentified problems could lead to serious health risks. If you do not hear a beep, call Technical Support at 1-800-227-2572 before proceeding.



Warning: Be careful to prevent the introduction of foreign matter into your cyclor. Possible sources of foreign matter are:

- Any kind of liquid spill on your cyclor;
- Pets or insects near your cyclor;
- Children touching or playing with your cyclor.

If you think foreign matter has been introduced, contact Technical Support immediately at 1-800-227-2572. Do not attempt to clean leaks inside your cyclor.



Warning: Always use a new PIN connector to connect to the cyclor. If you have to temporarily disconnect from the cyclor before the end of the scheduled treatment time, you must use a new PIN connector to reconnect and resume the treatment. You must use aseptic technique to disconnect the used PIN connector and then prepare the unused PIN connector for your reconnection. You must not connect yourself with the same PIN connector twice.



Warning: Use a new, sterile stay•safe cap each time you disconnect.



Warning: Care must be exercised when moving the cyclor. Allowing it to fall may cause an injury or damage the cyclor. If the cyclor falls or is dropped, call Technical Support at 1-800-227-2572.



Warning: Fluid may spill out of the tubing ends when priming is completed. Clean up any spills promptly as they may cause you to slip and fall. If any fluid gets inside your cyclor, call Technical Support immediately at 1-800-227-2572.



Warning: If fluid leakage is detected on bedding, clothing, or the outside surface of the VersiPD Cyclor Set during or at the end of treatment, report it to Technical Support and your home therapy nurse. Contamination may have occurred.



Warning: Follow local regulations concerning waste disposal.



Warning: There is a risk of biological contamination if a child or a pet bites or punctures the solution bags or VersiPD Cyclor Set.



Warning: There is a danger of explosion if the cyclor is used near flammable substances like anesthetics or oxygen or nitrous oxide rich environments. Keep all such materials away from your cyclor.



Warning: The VersiPD Cyclor is not meant to be shared between users. Do not attempt to loan or transfer your device to another person. Serious injury or death could occur if another person uses your cyclor and program.



Warning: Only trained and authorized personnel may repair or modify the VersiPD Cyclor. If modification or repair of the cyclor is carried out by an untrained or unauthorized person, patient injury or death may result.



Warning: If you use the optional accessories, such as the VersiPD Cart and Dialysate Solution Bag Case, do not modify or repair them. Refer all servicing to authorized personnel.



Warning: Do not connect your cyclor to any device that is not approved by Fresenius Medical Care for use with your cyclor.



Warning: Do not insert a USB drive that is not provided by your healthcare service provider or Fresenius Medical Care.



Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment may result in increased emissions or decreased immunity of the cyclor and result in improper operation.



Warning: Always verify that your program is correct before beginning treatment.



Warning: Failure to set expected ultrafiltration volume during Tidal treatment may lead to the accumulation of fluid in the peritoneal cavity.



Warning: Do not connect your catheter extension set to the VersiPD Cyclor Set until priming is complete.



Warning: No foreign matter may be inserted in the warming pouch gap on the cyclor due to the risk of fire and damage to cyclor's internal workings.



Warning: Do not remove or move the warming pouch after it is inserted, until prompted to do so post treatment.



Warning: Do not use devices emitting strong electromagnetic radiation such as portable phones, radio equipment (walkie-talkies, etc.), radio transmitters, and like equipment near your machine. Improper operation may result. Digital phones may be conditionally allowed. Discontinue use of any device if any interference is noted, such as false pressure readings that disappear when the external signal is removed.



Warning: Do not use this equipment in an EMC (Electromagnetic Compatible) environment, which includes, but is not limited to, placing it adjacent to or stacked with other equipment (e.g. cell phones and tablets). This will avoid interference with cyclor functionality.



Warning: Do not use any treatment values that are not prescribed by your physician. Values shown in illustrations are for example only.



Warning: Be careful to enter correct therapy parameters. Improper program entry may have severe consequences.



Warning: Setting the alarm sound volume too low can initially make the alarm difficult to hear. If you do not respond, the sound level of the alarm will increase to full volume.



Warning: Unplug the cyclor and call Technical Support at 1-800-227-2572 in the case of burnt plastic or electronics (metallic or burning smells).





Warning: Your cyclor must be plugged directly into an electrical outlet—do not use extension cords, outlet adaptors or power strips. Do not use power cords other than those provided with VersiPD. Do not use a power cord that is frayed or damaged.





Warning: Keep fingers clear of moving parts.


Cautions


Any statement in this guide accompanied by the symbol  is a caution. Observing these cautions will help minimize therapeutic and technical problems. The cautions shown here are not a complete list; other cautions will appear throughout this guide.


 **Caution:** Frequency, duration, and parameters of treatment are to be determined by the prescribing physician.


 **Caution:** If using the optional cart, apply the brakes to prevent movement during treatment and cleaning.


 **Caution:** Your VersiPD Cycler is a computer controlled electro-mechanical medical device. It should be installed in an appropriate environment (indoors) free from extremes of temperature and humidity and reasonably protected from dust and dirt contamination or liquid splashes. See page 228 for more information. Failure to install your VersiPD Cycler according to these guidelines may result in improper operation or early failure of the device or its parts.

 **Caution:** Do not place the cycler or solution bags near heat or cold sources like heaters or air conditioners.

 **Caution:** Use only your fingers on the touchscreen and cycler buttons. Use of other objects, such as pens, may result in damage or premature failure.

 **Caution:** Use only tubing sets intended for the VersiPD Cycler. The performance of tubing sets not manufactured by Fresenius Medical Care cannot be guaranteed by the company and are therefore the responsibility of the prescribing physician.

 **Caution:** Do not allow any fluid to drip into your cycler. If any fluid gets inside your cycler, you must contact a Fresenius Medical Care Technical Support Representative immediately at 1-800-227-2572. Your cycler should be placed on a water-tolerant surface, and spills should be cleaned up immediately.

 **Caution:** Follow the manufacturer's instructions for storage of all disposables. Unsuitable storage conditions may cause damage to the equipment.



Caution: In order to prevent potentially hazardous conditions and ensure the safe operation of the VersiPD Cycler, Radio Frequency Identification (RFID) Equipment or other RF emitting devices must be kept at least 3 meters from the system while in operation.



Caution: Only use the cleaning agents recommended in this User's Guide. Other cleaning agents have not been tested for compatibility and may lead to device damage.



Caution: Be careful of the sharp point at the back of the machine near the cartridge loader.



Caution: Risk of electric shock. Do not remove covers; refer service to qualified service personnel.

Notes

Notes accompanied by the symbol are distributed throughout the manual. They provide information to help you with your treatment. The notes here are not a complete list; other notes will appear throughout this guide.



Note: Pressing the part of the switch with the circle (○) on it will turn the cycler off.



Note: When first received, the cycler should be powered on and put into standby mode for four hours before being used. This is to make sure the battery is fully charged in case of power failures.














Note: Do not use any device in conjunction with your cycler that is not provided by Fresenius Medical Care or your home therapy nurse.



Note: If you are using the Bluetooth system, your blood pressure, pulse and weight will be sent to the cycler automatically when you use your scale and blood pressure cuff. You will have the choice to confirm or repeat the measurements. Verify the Kinexus[®] Gateway is powered on and paired to your cycler. For more information about the Kinexus Gateway, consult the *Kinexus Gateway User's Guide for VersiPD*.

Temperature and blood glucose values must be entered manually. Follow the instructions on page 46 for manual entry of vital signs.

-
-  **Note:** The package containing the VersiPD Cycler Set should be opened just before it is time to insert it in the cycler.
-
-  **Note:** Be careful not to push in the blue button on the PIN connector until prompted by your VersiPD Cycler. *If you do push in the blue button accidentally* and the PIN is released, this closed PIN connector will prevent fluid from moving through the tubing and cause an alarm to sound. You will need a new PIN connector to continue your treatment. If one is not available, you will need to restart your treatment with new supplies.
-
-  **Note:** Should the line holder become detached from the nest, or the nest from its fasteners, be sure to re-attach them promptly.
-
-  **Note:** If your tubing has two patient PIN connectors, use the one at the tip of the patient line first.
-
-  **Note:** Check your solution bags for S.C.A.L.E.: correct *solution*, proper *clarity*, correct *amount*, absence of *leaks*, and an *expiration date* that is still valid. If a bag fails inspection, open and inspect a new bag.
-
-  **Note:** The blue clamp is different from the blue button on the PIN connector. Close only the blue clamp when prompted.
-
-  **Note:** It is important to prevent blocking or kinking of the patient line when you turn in bed, to avoid Patient Line Blocked alarms.
-
-  **Note:** An additional drain is a planned drain. A Stat Drain is an unplanned drain.
-
-  **Note:** If you push in the button on the unused PIN connector instead of the used one, you will have to start over with a new VersiPD Cycler Set.
-
-  **Note:** Do not turn off the VersiPD Cycler using the switch on the back unless you need to move the cycler to a new location (for instance, when travelling). Leaving the power switch on with the cycler plugged in keeps the battery charged.
-
-  **Note:** Tips for travelling with medical devices can be found on the website of the Transportation Security Administration. Go to <https://www.tsa.gov/> to learn about this topic.
-



Note: You can find a list of warning alarms on page 179. Look there for information on the problems that cause specific alarms.



Note: If your storage area is very cold, you may need to move your solution bags into your treatment room several hours before starting treatment.



Note: When checking the patient line and catheter extension set for kinks, fibrin or clots, start at your abdomen and follow the line to the cyclor, checking for the problem.



Note: The U.S. Food and Drug Administration has published a booklet with tips on how to handle medical device power failures. It is available online at this address:
<https://www.fda.gov/media/80782/download>



Note: Your stay•safe organizer and line holder nest should be cleaned regularly. Refer to the product insert of each product for cleaning instructions.



Note: Under normal operating conditions, the expected useful life of the VersiPD Cyclor is six years. The maximum shelf life of the cyclor sets is six months.



Note: All warnings and cautions generated by the cyclor require user intervention.



Note: If the cyclor screen freezes and will not respond when buttons are touched, call Technical Support at 1-800-227-2572.



Note: The VersiPD Cyclor System incorporates safeguards designed to protect the security, integrity, and privacy of the Personally Identifiable Information it collects. Reasonable precautions are in place to protect information from loss, misuse, and alteration. For more information, consult the VersiPD Cybersecurity Statement that came with your cyclor.



Note: The VersiPD Cyclor System is not intended for acute care settings like Intensive Care Units (ICU) and Cardiac Care Units (CCU); it is strictly for use in chronic ESRD. Clinical settings include dialysis centers and other chronic care settings.

Maintenance

All Fresenius Medical Care peritoneal cyclers are designed to detect mechanical failures through an extensive self-check built into the cycler. This check is done each time cycler treatment is started and periodically during treatment.

If a failure does occur, in most cases Fresenius Medical Care will replace the cycler within one working day and, if applicable, pick up the used cycler. The replacement policy applies only to those cyclers that remain the property of Fresenius USA, Inc.

Return Instructions

If you need to return the cycler by mail, follow these instructions:

- 1 Locate the box the VersiPD Cycler was delivered in. If you no longer have this box, call Technical Support at 1-800-227-2572 to obtain a new box.
- 2 Remove all disposables (VersiPD Cycler Set, warming pouch and other tubing) from the VersiPD Cycler. If necessary, turn your VersiPD Cycler back on, press the **START** button and follow the instructions to remove the VersiPD Cycler Set.
- 3 Remove and keep your USB drive. Remove the power cord.
- 4 Place the foam piece with the rectangular open area in the bottom of the box. Place cycler in with the finger grips responding to the cut outs in the foam. Place the other foam piece over the cycler.
- 5 Wind the power cord and place it in the circular cut out.
- 6 Close the box and use packing tape to secure.

Questions

For medical or clinical questions: Call your home therapy or on-call nurse.

For technical questions: Call Technical Support 24 hours a day, seven days a week at **1-800-227-2572**. Follow the prompts for peritoneal dialysis.

Related Reading

Product Support Documentation is available on our website: fmcna.com.

Pre-Treatment Checklist

Before starting each treatment, check the following:

- ✓ Make sure that the power cord is plugged into an AC electrical outlet and the power switch on the back of the cyclor is in the ON (|) position.
- ✓ Make sure that your cyclor has been recently cleaned and is ready for treatment (see page 216 for more information).



Warning: If any of the conditions listed above have not been met, you must correct them before continuing with your treatment preparation. Failure to do so could result in complications that may be severe.

The USB Drive

If you have not done so already, locate the power switch on the back of the cyclor (see the photo on page 15). Turn on the power switch by pressing the part of the switch with the vertical line (|) on it. The **Blue LED Light** on the front panel of the cyclor will light up after a few seconds. Make sure the light is on before you proceed.



Note: Pressing the part of the switch with the circle (○) on it will turn the cyclor off.



Note: When first received, the cyclor should be plugged in and then put into standby mode for four hours before being used. This is to make sure the battery is fully charged in case of power failures.



Warning: Check for proper functioning of your machine before beginning your treatment. Press the green **START** button. Make sure that you hear a beep and that the red LED light above the **STOP** button flashes. Alarm failure or unidentified problems could lead to serious health risks. If you do not hear a beep, call Technical Support at 1-800-227-2572 before proceeding.

When prompted, insert the USB drive at an upward angle into the port on the left side of the cyclor as shown in the illustration below.

The USB may be left inserted between treatments.



The USB Drive (continued)



Warning: Do not insert a USB drive that is not provided by your healthcare service provider or Fresenius Medical Care.



Note: Do not use your USB drive in another device, as this can corrupt it and cause an alarm on the cyclor..



Note: The USB drive should be labelled with your name or other identifying information.



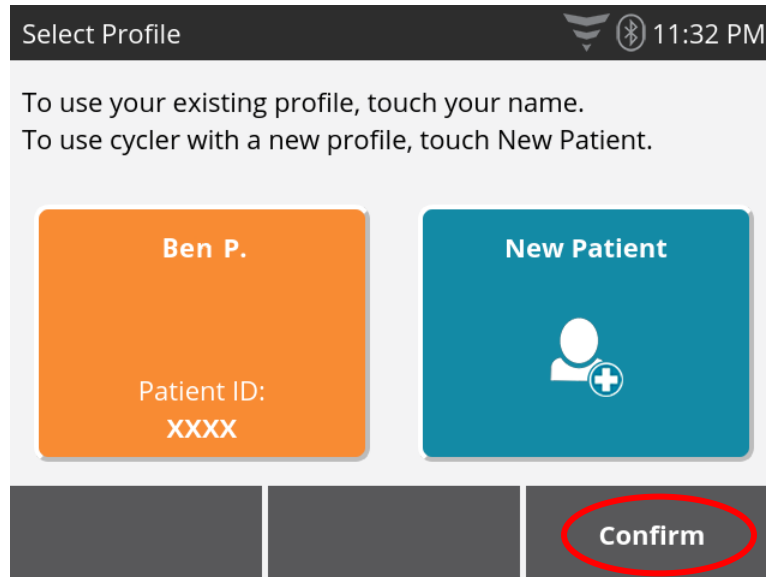
Touch this button on any screen to repeat a video from the beginning. If the audio is not repeated along with the video, touch the button again to enable it.

If you do not have a USB drive, or have been told not to use one for this treatment, touch the button **Proceed without USB-Drive** and follow the instructions on the next screen.

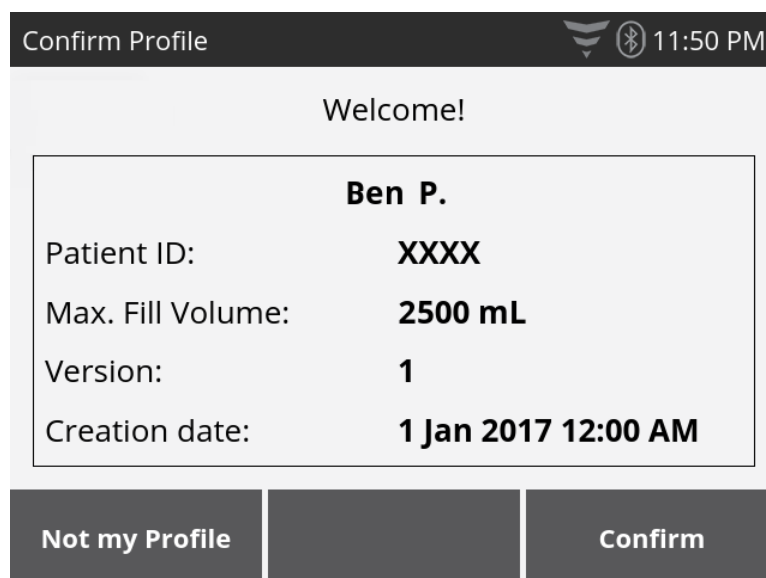
Confirm Your Profile

If the New Patient option is on, select your profile on the screen shown below. Touch the button showing your name and ID number. Once the button turns orange, touch the **Confirm** button. If you do not see your name, contact your home therapy nurse. If your USB drive contains a profile that matches the one on the cyclor, you will not see this screen.

Treatment
Setup



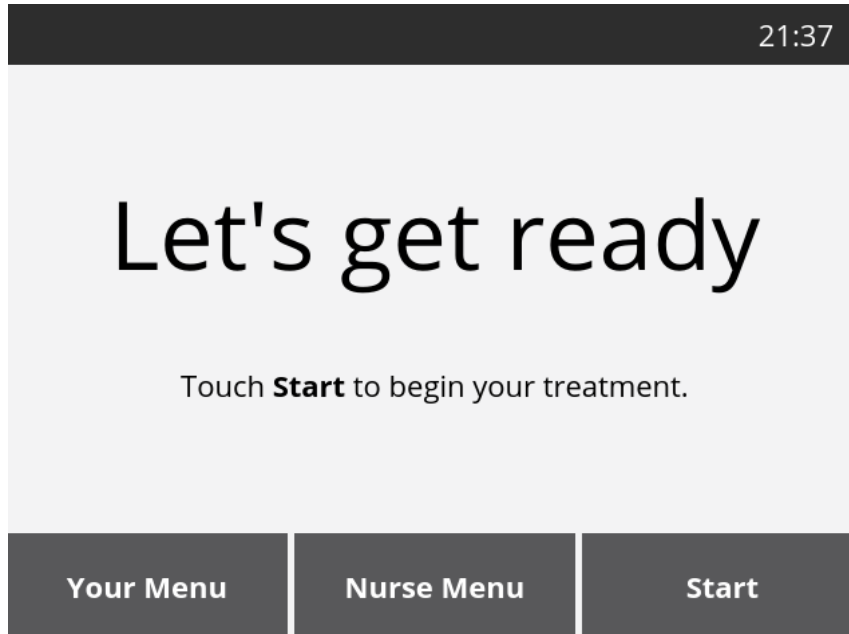
The screen below will appear. You will see your Patient ID, maximum fill volume, program version (if your home therapy nurse has sent more than one version of a program), and the date it was created. If the New Patient Option is off, this screen will appear first. If the information is correct, touch **Confirm**. If it is not correct, touch **Not my Profile** and contact your home therapy nurse.



After you have confirmed your profile, it is time to begin your treatment.



Warning: Always verify that your program is correct before beginning treatment.



Treatment
Setup

Button	Description
Your Menu	Touch this button to set your preferences for the cyclor settings, such as sound volume and screen brightness. You can also review the available therapy programs.
Nurse Menu	This menu is for the use of your home therapy nurse only.
Start	Touch this button when you are ready to start your treatment.

Bluetooth Pairing

If you are using a Bluetooth device to enter your weight and blood pressure automatically, you will need to connect a Kinexus Gateway to your cyclor. This process is called pairing. It must be done before you touch the **START** button on the “Let’s get ready” screen. This step only needs to be completed once, not before each treatment session.



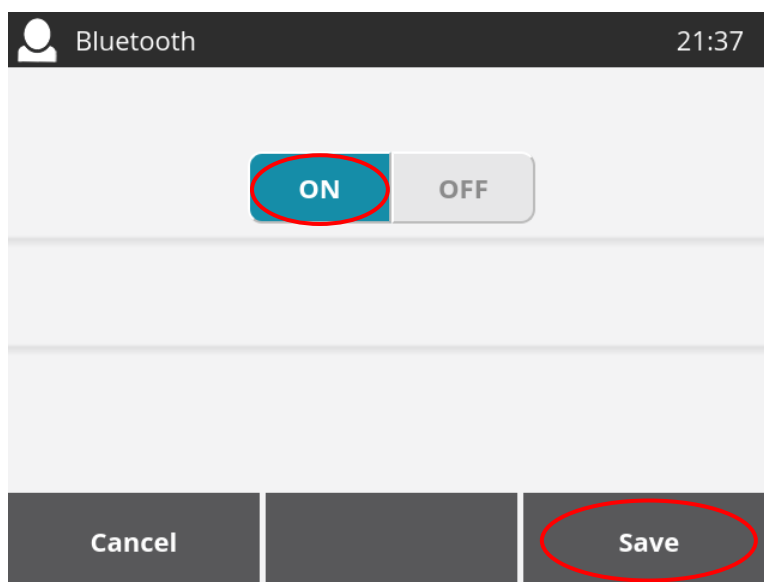
Note: Do not use any device in conjunction with your cyclor that is not provided by Fresenius Medical Care or your home therapy nurse.

- 1 Follow the instructions that have been provided by the manufacturer of your Kinexus Gateway to get it ready for pairing (the *Kinexus Gateway User’s Guide for VersiPD*).

- 2 Touch in sequence the buttons below:

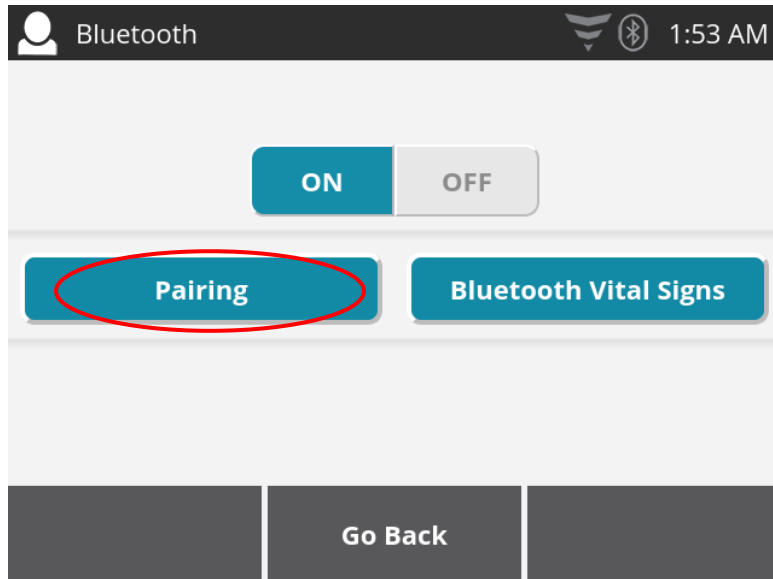


- 3 The screen below will appear. Touch **ON** and then touch **Save**.



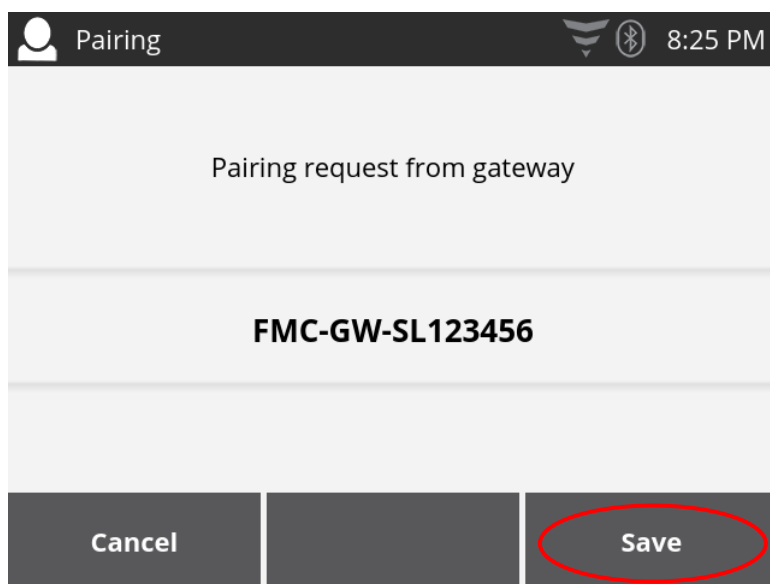
Bluetooth Pairing (continued)

4 Touch the **Pairing** button.



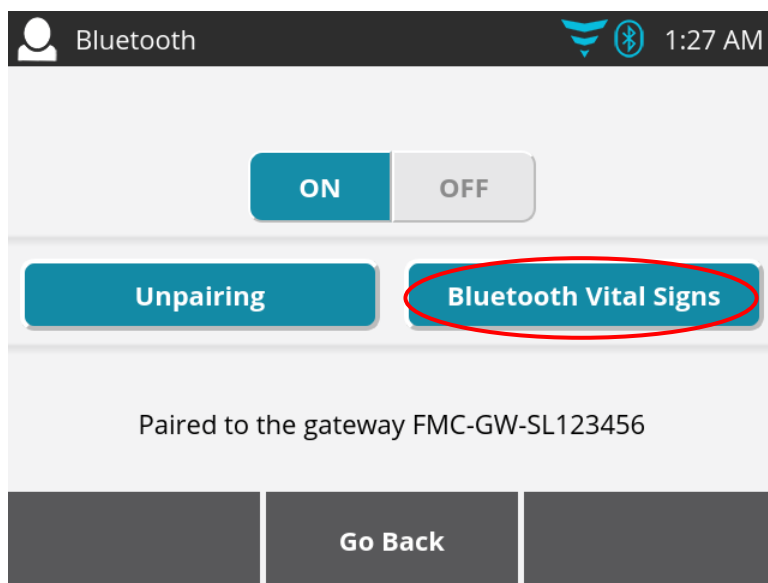
Treatment
Setup

5 When the screen displays the message “Pairing request from gateway”, touch the **Save** button.

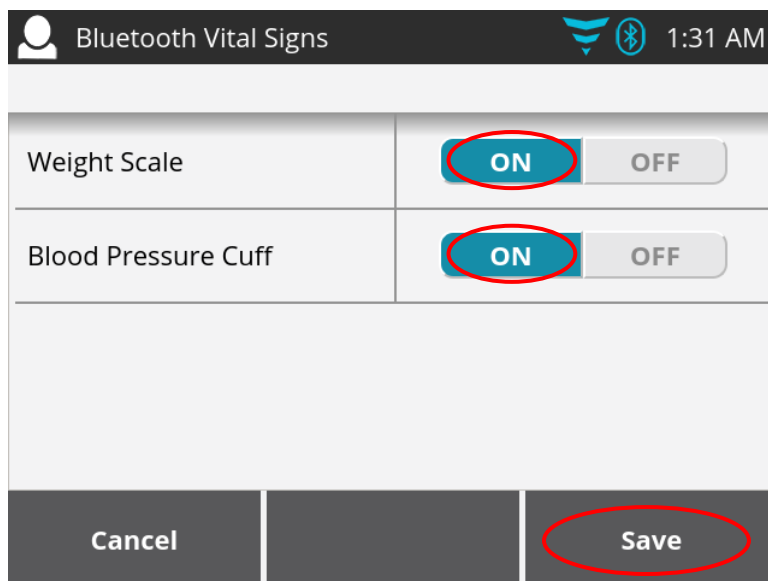


Bluetooth Pairing (continued)

- 6 If the pairing was successful, a message like the one shown below (“Paired to the gateway...”) will appear. Make sure the identification code is the same as the one on the bottom of your Kinexus Gateway. Next, touch the **Bluetooth Vital Signs** button.

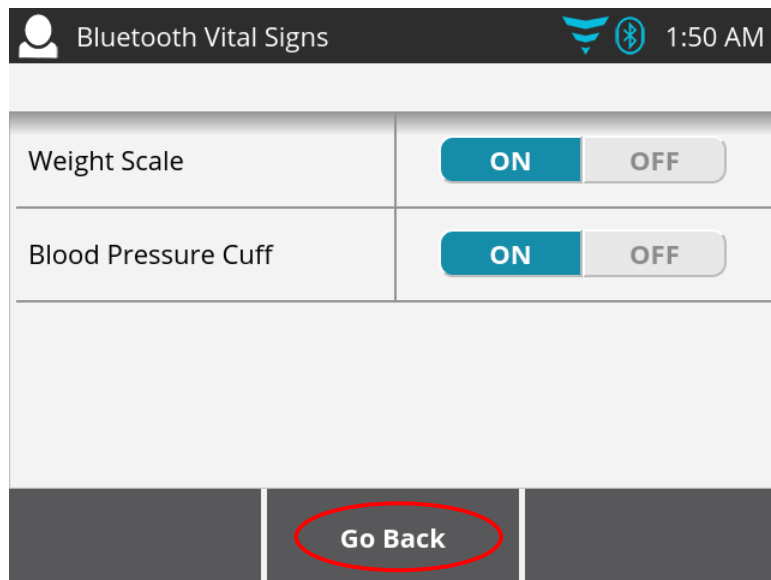


- 7 Turn on the **Weight Scale** and **Blood Pressure Cuff** by touching the **ON** buttons. If you do not have one of these items, leave it off. Touch **Save** to save your changes.



Bluetooth Pairing (continued)

- 8 Once you have saved these settings, the **Go Back** button will re-appear. Touch this button until you return to the “Let’s get ready” screen.



Treatment
Setup

- 9 Pair your blood pressure device and scale to the Kinexus Gateway. Use the instructions included with those devices. If pairing is not successful, contact Technical Support at 1-800-227-2572.

Manual Exchanges

Once you have touched **Start** on the “Let’s get ready” screen, you will be asked to enter information for manual exchanges you have done. One or two full or partial exchanges can be entered. Correct entry is important because all drain and fill volumes from the last fill of the previous treatment and manual exchanges affect the expected initial drain amount for your treatment. It is not required to fill in all fields; for example, if you only drained fluid after disconnecting from the previous treatment, enter only the drain volume.



Caution: The failure to enter the amount of any manual exchange you have done during the day can cause the cyclor to miscalculate the required initial drain volume. You must enter the amount into your cyclor if you have done a manual exchange before you begin your initial drain.

Manual Exchange(s) 21:10

I did a Manual Exchange

I did not do a Manual Exchange

Go Back Confirm

Edit Manual Exchange(s) 3:39 AM

Exchange 1 of 2

Fill 2500 mL Dextrose % 2.5% Drain 0 mL

0 0 0 0

Cancel Save

1 Select either **I did a Manual Exchange**, or **I did not do a Manual Exchange** from the screen. Once selected, the button will turn orange.

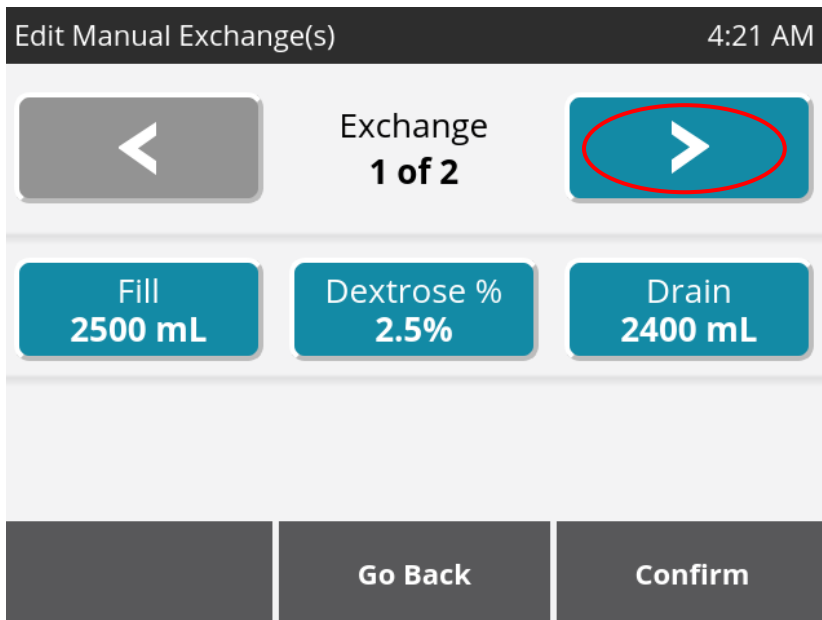
2 Touch the **Confirm** button.

3 If you selected **I did a Manual Exchange**, touch each button in turn (**Fill**, **Dextrose**, **Drain**).

4 When the button turns orange, use the **up** and **down** arrow buttons to enter the value.

5 Touch the **Save** button after entering your exchange values.

Manual Exchanges (continued)

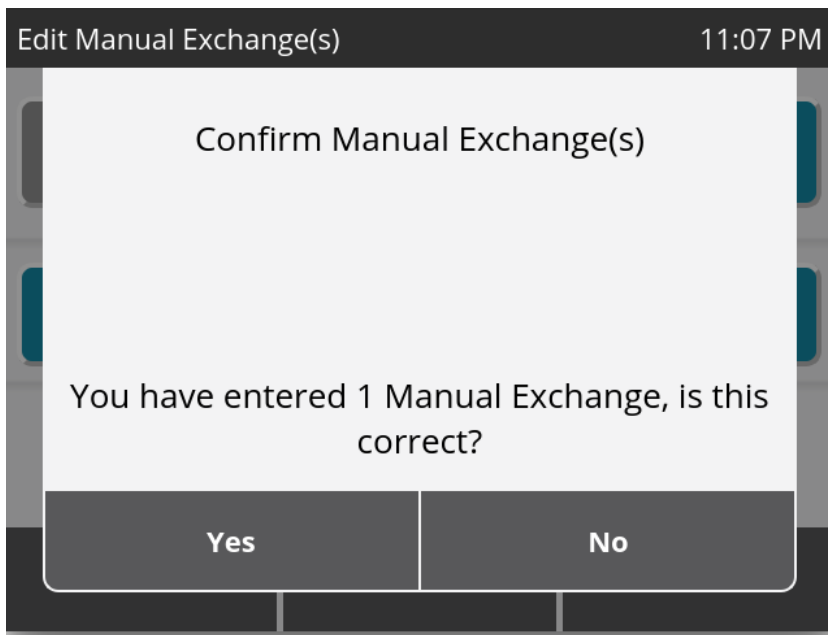


6 If you did a *second* manual exchange, touch the **right** arrow key to reach a screen where you can enter the information. Repeat steps **3-5** above.

7 Review the values you entered and touch the **Confirm** button to complete your entries.

Treatment Setup

When you confirm a manual exchange, the screen below will appear. If the number of manual exchanges is correct, touch **Yes**. If it is not correct (for instance, the screen says “1 Manual Exchange” but you did 2), touch **No**. You will then have to return to the screen shown above, touch the right arrow and enter values for the second exchange.

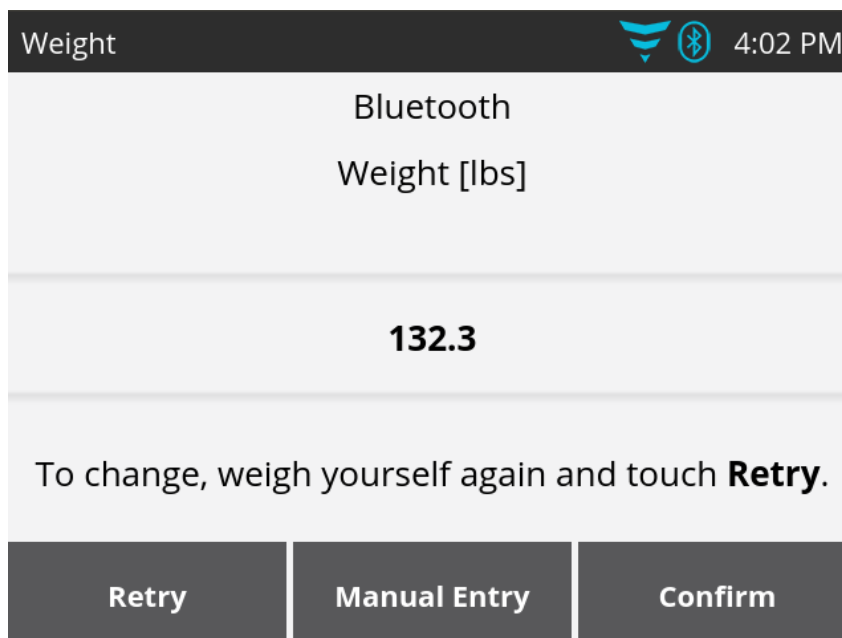


Vital Signs Entry (Pre-treatment)

If your home therapy nurse has programmed your cyclor for you to enter your vital signs before treatment, you will now see a series of screens that aid you to complete this task.

If you are using the Bluetooth system, your weight, blood pressure, and pulse will be sent to VersiPD automatically when you use your scale and blood pressure cuff. Verify the Kinexus Gateway is powered on and paired to your cyclor. For more information about Kinexus Gateway, consult the *Kinexus Gateway User's Guide for VersiPD*.

When you use your scale and the cyclor receives the information from the Kinexus Gateway, a screen like the one below will appear. To accept the weight shown, touch **Confirm**. To weigh again, touch **Retry**. To use a scale not connected to the cyclor and enter the values manually, touch **Manual Entry** and turn to the next page.



You will have the same choices when using the blood pressure cuff. Temperature and blood glucose values must be entered manually.

Follow the instructions on the next page for manual entry of vital signs.

Vital Signs Entry (Pre-treatment) (continued)

On the following pages, you will be instructed how to manually enter your:

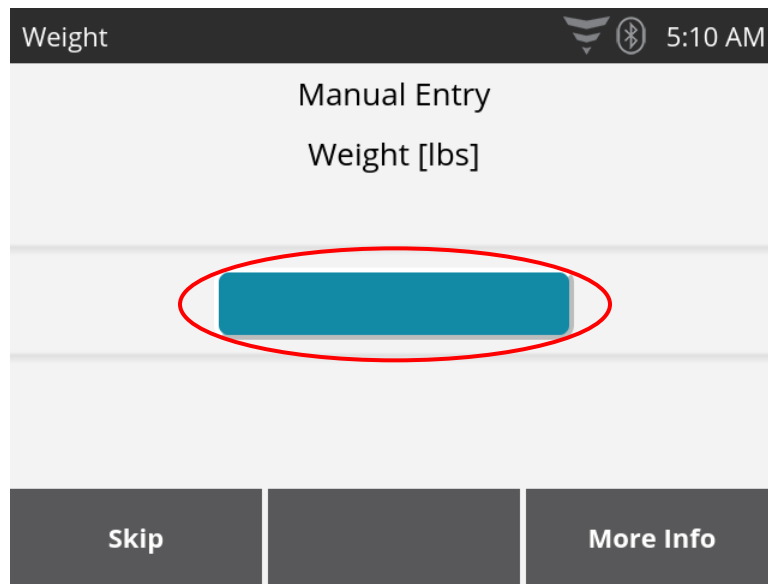
- Weight (see page 48)
- Blood Pressure (see page 49)
- Pulse (see page 50)
- Temperature (see page 51)
- Blood Glucose (see page 52)

If your values are out of the range that can be entered or the units of measure you use are different than those on the VersiPD Cycler, contact your home therapy nurse.

Weight

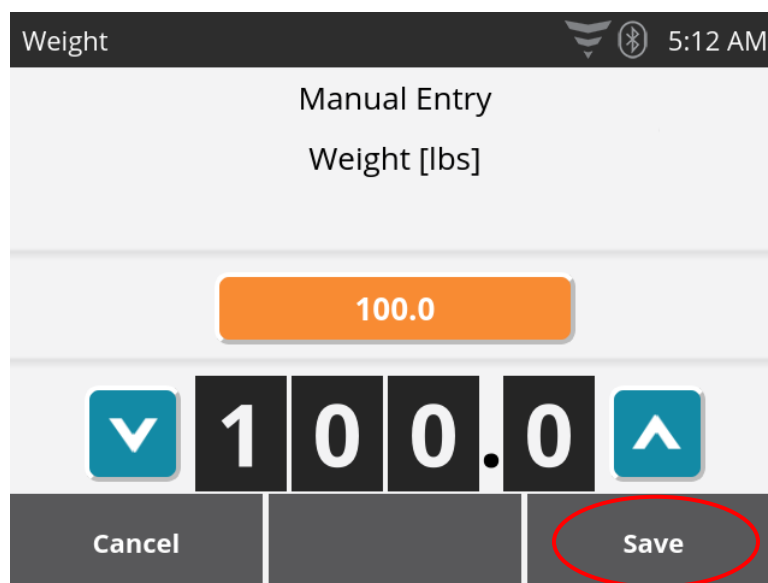
Enter your weight on this screen. If you cannot enter a value, touch **Skip** to leave the value blank.

- 1 Touch the blue rectangle to highlight it. It will turn orange and show the default value of 100 pounds or 45 kg.



Treatment
Setup

- 2 Use the **up** and **down** arrow buttons to enter your weight. Hold down the arrow button if you wish to move up or down quickly.

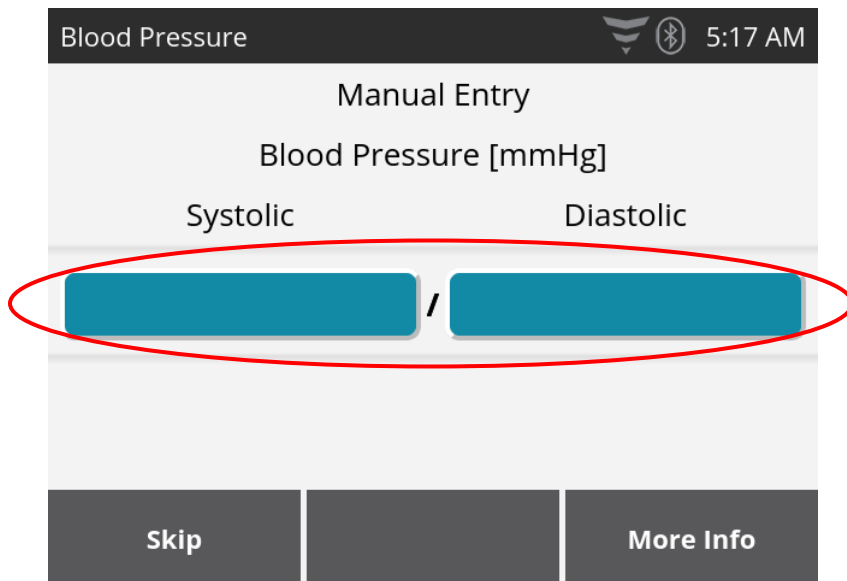


- 3 Touch the **Save** button to confirm your entry or the **Cancel** button to try again.
- 4 Touch the **Confirm** button to complete the entry.

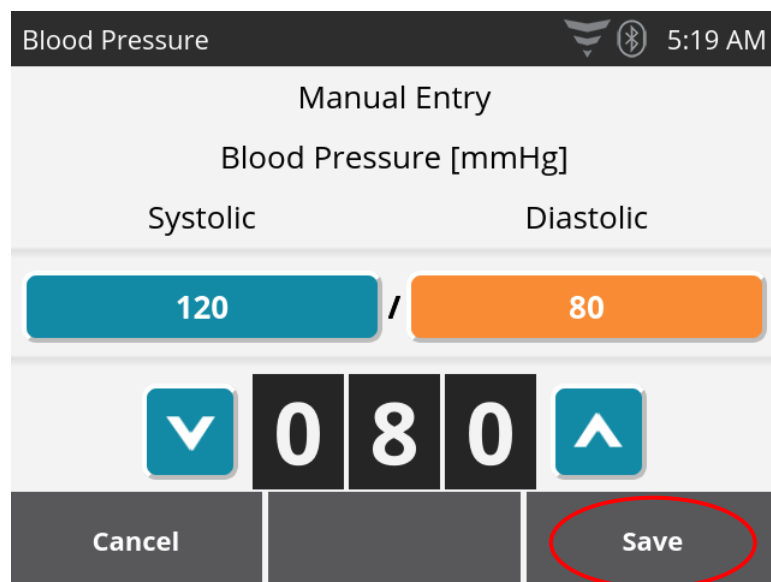
Blood Pressure

Next, you may be asked to enter your blood pressure. If you cannot enter a value, touch **Skip** to leave the value blank.

- 1 Touch a blue rectangle to highlight it. It will turn orange.



- 2 Use the **up** and **down** arrow buttons to enter your systolic (higher number) and diastolic (lower number) blood pressure.

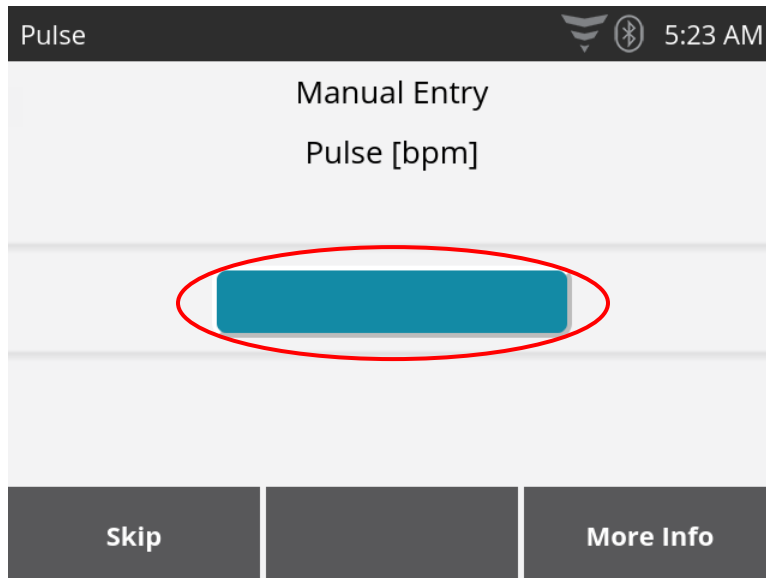


- 3 Touch the **Save** button to confirm your entry or the **Cancel** button to try again.
- 4 Touch the **Confirm** button to complete the entry.

Pulse

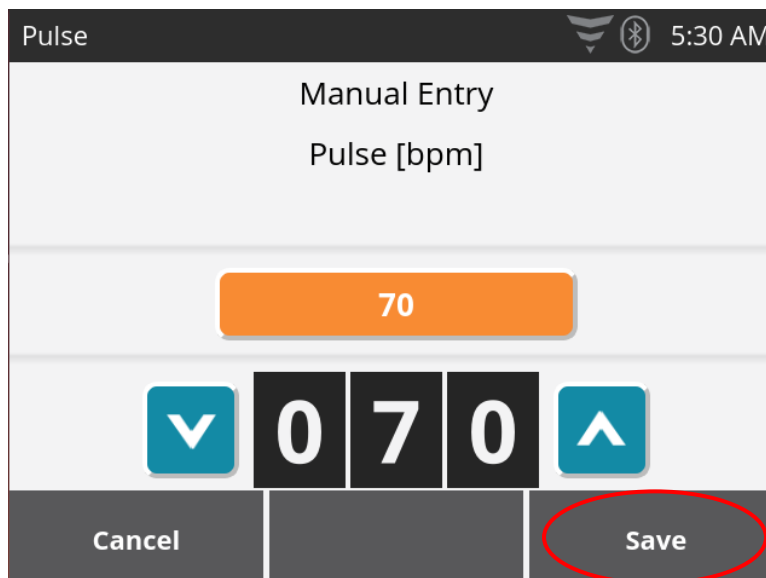
If you have been asked to enter your pulse, use this screen. If you cannot enter a value, touch **Skip** to leave the value blank.

- 1 Touch the blue rectangle to highlight it. It will turn orange.



Treatment
Setup

- 2 Use the **up** and **down** arrow buttons to enter your pulse.

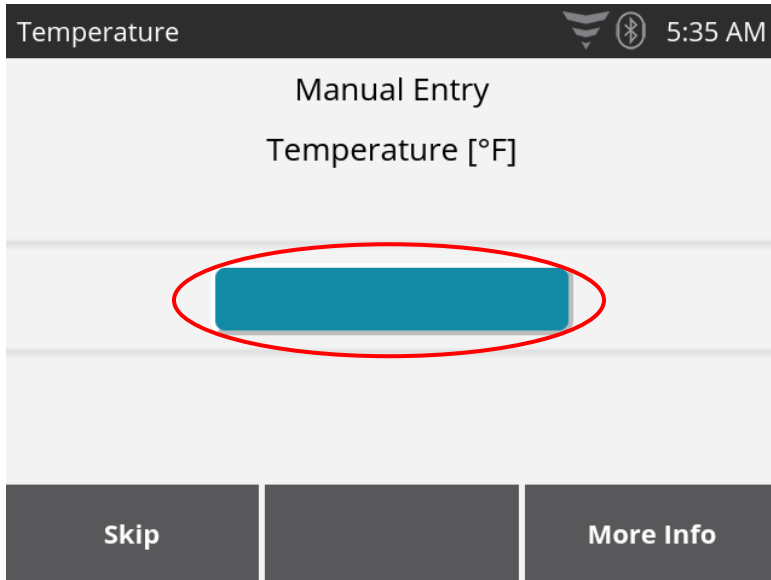


- 3 Touch the **Save** button to confirm your entry or the **Cancel** button to try again.
- 4 Touch the **Confirm** button to complete the entry.

Temperature

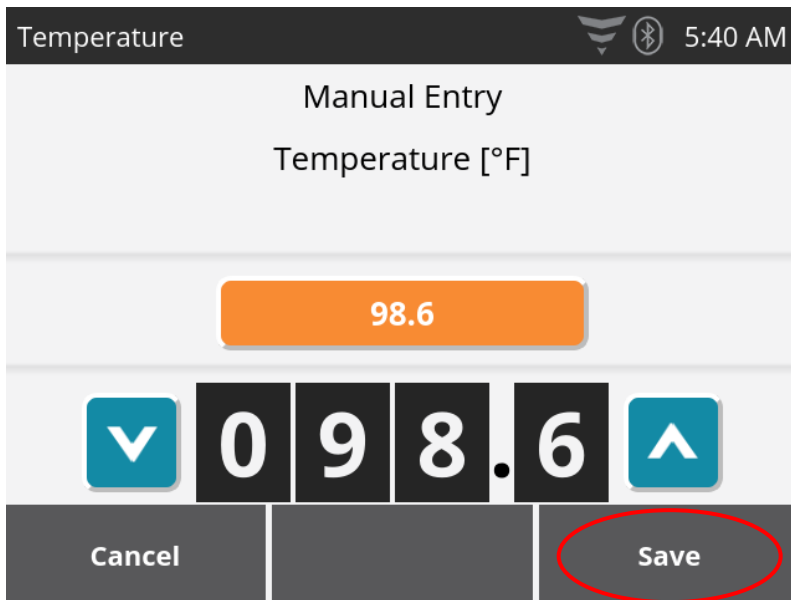
If you have been asked to record your body temperature, this screen will appear. If you cannot enter a value, touch **Skip** to leave the value blank.

- 1 Touch the blue rectangle to highlight it. It will turn orange.



Treatment Setup

- 2 Use the **up** and **down** arrow buttons to enter your body temperature.

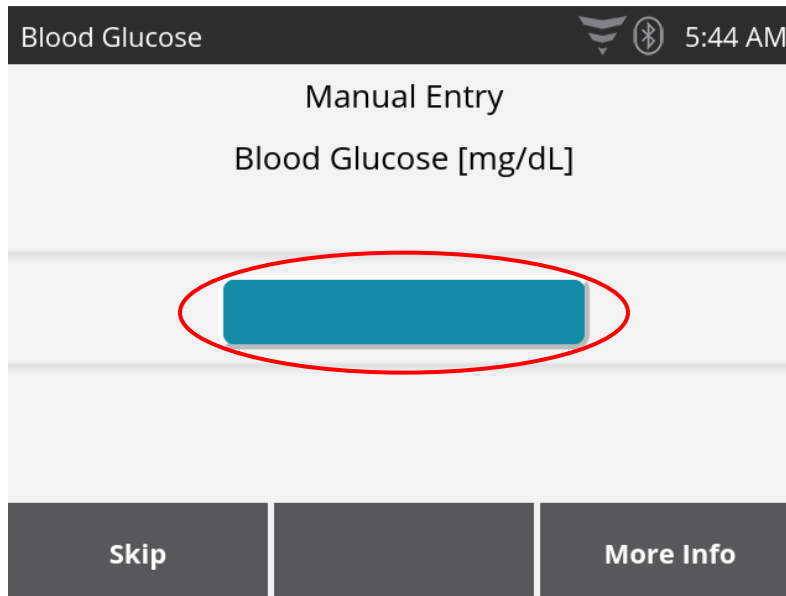


- 3 Touch the **Save** button to confirm your entry or the **Cancel** button to try again.
- 4 Touch the **Confirm** button to complete the entry.

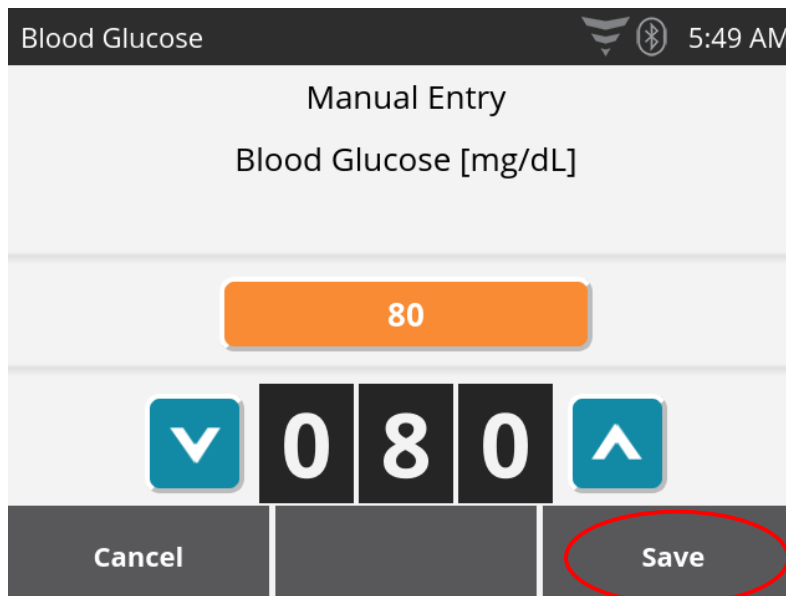
Blood Glucose

If you have been asked to record your blood glucose level, this screen will appear. If you cannot enter a value, touch **Skip** to leave the value blank.

- 1 Touch the blue rectangle to highlight it. It will turn orange.



- 2 Use the **up** and **down** arrow buttons to enter your blood glucose level.



- 3 Touch the **Save** button to confirm your entry or the **Cancel** button to try again.
- 4 Touch the **Confirm** button to complete the entry.

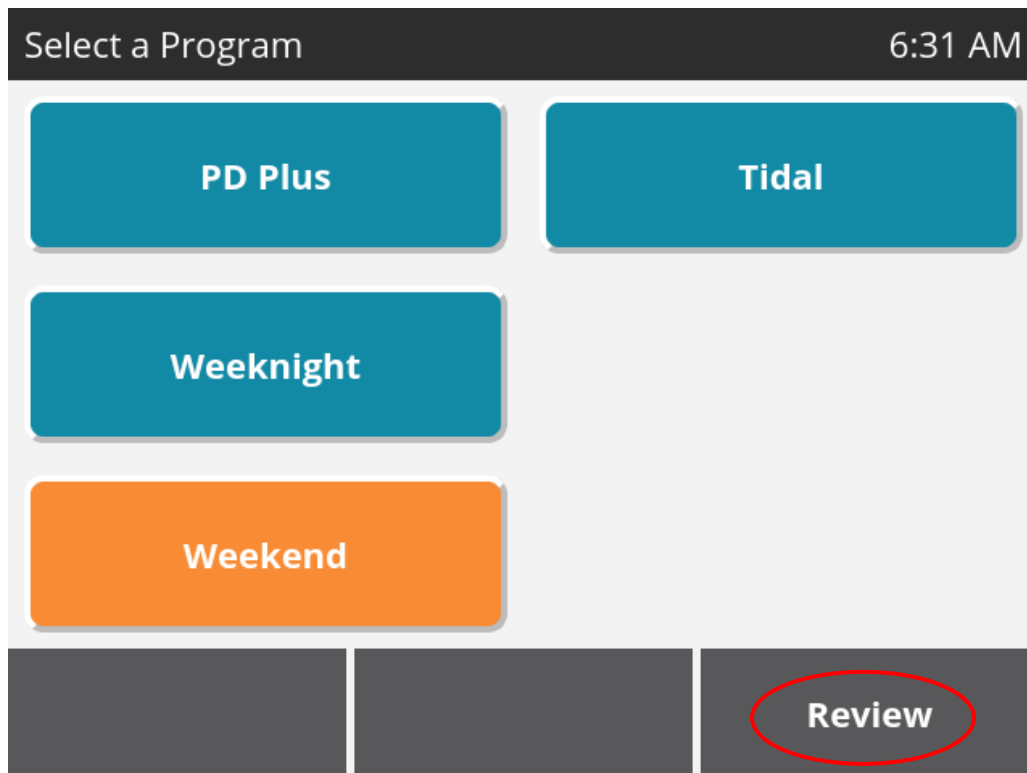
Program Selection

- 1 On the “Select a Program” screen, touch the blue button that displays the therapy program that you intend to use for this treatment. The button will turn orange.



Note: If only one program has been entered, this screen will not appear. The cyclor will proceed directly to the “Program Review” screen.

- 2 Touch the **Review** button.



Program Review

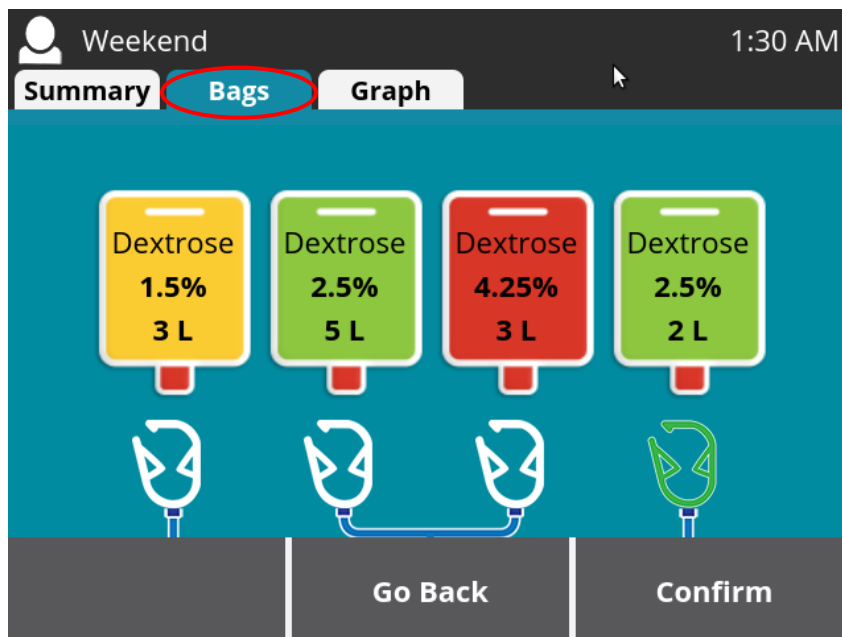
Review the selected program by touching each of the three tabs in turn. The selected tab will turn blue. The **Summary** tab screen has an overview of the treatment in numerical values.

Treatment Setup



Weekend		1:21 AM
Summary Bags Graph		
Cycler Total Volume [L]	12.5	
Connected Time [hh:mm]	08:25	
Total Cycles on Machine	4	
Cycler Total UF [mL]	300	
Manual Exchange Total Volume [L]	0.0	
Treatment Maximum Fill Volume [mL]	3500	
Nurse Menu		Confirm

The **Bags** tab screen shows an image of the bag amounts and dextrose concentrations and what color the clamps are on each line.

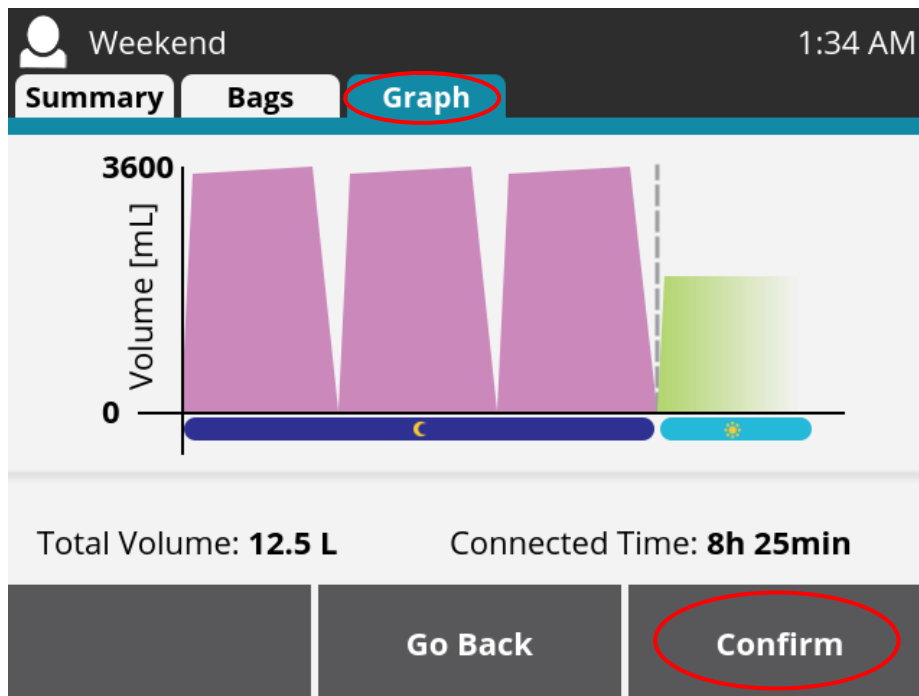


Program Review (continued)

The **Graph** tab screen shows the treatment in graphic form. Each colored column represents one cycle.

If this is the program you want to use, touch the **Confirm** button on any of the three screens to begin setup for treatment.

If you want to use a different program, touch the **Go Back** button and make another choice from the Program Menu. If you need assistance in selecting a program, contact your home therapy nurse for guidance.



Treatment
Setup

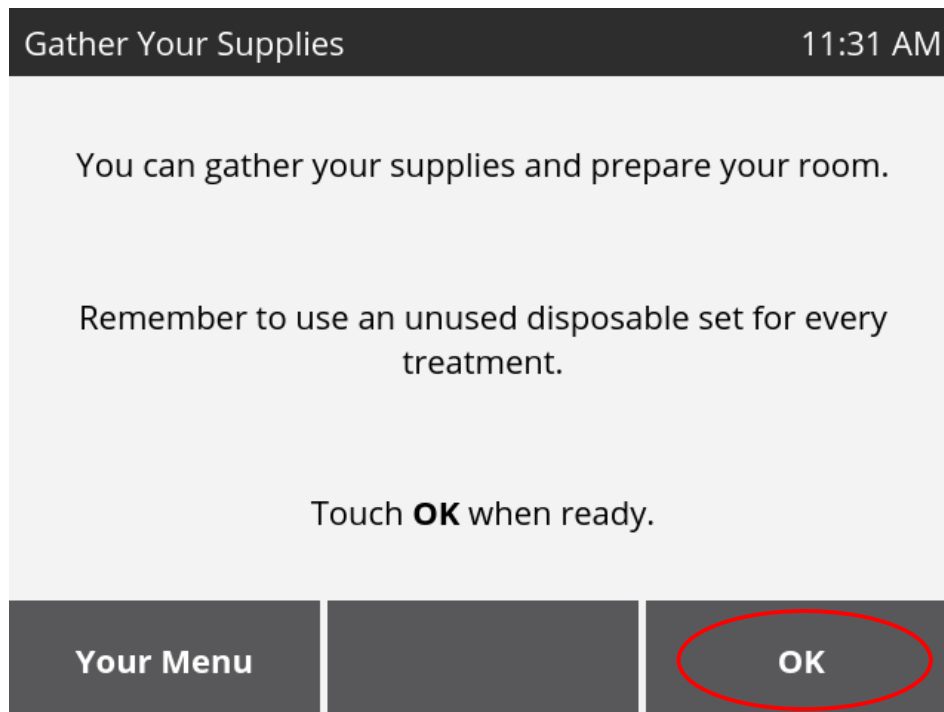


Warning: Do not use any treatment values that are not prescribed by your physician. Values shown in illustrations are for example only.

Starting Treatment

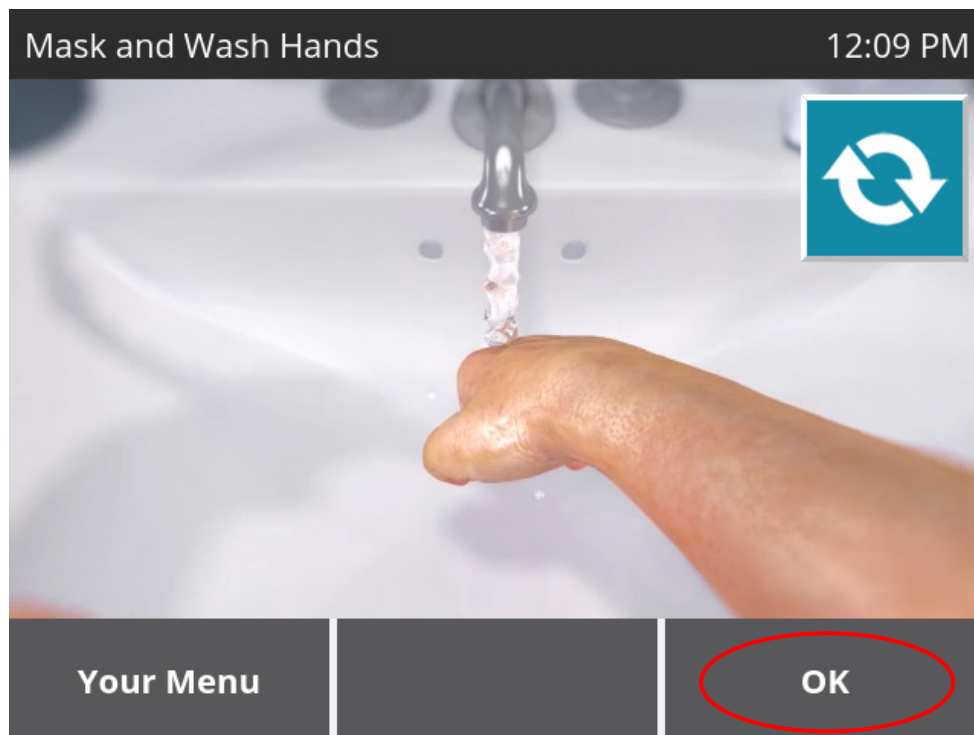
Starting Treatment

- 1 Gather the supplies you will need for your treatment:
 - a. VersiPD Cycler Set
 - b. Drain option (drain line or drain bags) if using one
 - c. stay•safe caps
 - d. Masks
 - e. Hand cleaning supplies
 - f. stay•safe organizer
 - g. Other supplies as instructed by your home therapy nurse
 - h. Optional VersiPD Cart (or line holder nest if not using the VersiPD Cart)
- 2 Touch the **OK** button when you are done.
- 3 Put on your mask.



Starting Treatment (continued)

- 3 Clean your hands thoroughly as instructed by your home therapy nurse.
Touch **OK**.



Warning: Do not use the same VersiPD Cyclor Set (cartridge, warming pouch, tubing set) for more than one treatment, or continue to use a set that has been loaded in the cyclor for more than 24 hours.



Note: The package containing the VersiPD Cyclor Set should be opened just before it is time to insert it in the cyclor.



Note: The VersiPD Cyclor Set is sterile when first removed from its packaging. There is no sterilization for the user to perform.

Attach Line Holder

- 1 Open and inspect the VersiPD Cyclers Set. Do not lay it down. Use a new set if any problems are found upon inspection.

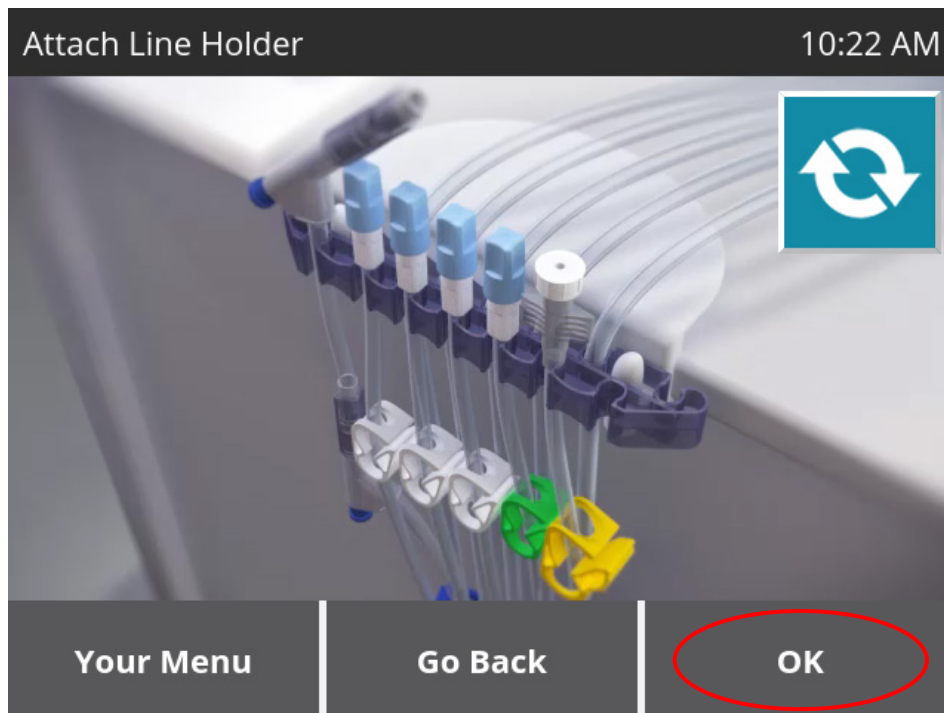


Warning: If any of the caps are not in place or any of the clamps are closed, discard the VersiPD Cyclers Set and replace it with a new one as there is a risk of contamination.



Warning: A new, sterile VersiPD Cyclers Set and drain line must be used for every treatment. Check that the VersiPD Cyclers Set is free from kinks or damage, and that it is not past its expiration date. Make sure all clamps are open and caps in place. A damaged VersiPD Cyclers Set can lead to leaks, contamination, and infection. If you notice damage, save your VersiPD Cyclers Set for pick up and immediately call Customer Service at 1-800-323-5188. You will be contacted about having the used tubing set picked up. Do not use this set!

- 2 Attach the line holder by aligning the holes in the line holder over the prongs on the nest and press down.
- 3 Check for bending or twisting in the lines that might block or slow the flow of fluid. Straighten these out before proceeding. Touch the **OK** button when you are ready to continue.



Attach Line Holder (continued)



Be careful not to push in the blue button on the PIN connector until prompted by your VersiPD Cycler. *If you do push in the blue button accidentally* and the PIN is released, this closed PIN connector will prevent fluid from moving through the tubing and cause an alarm to sound. You will need a new PIN connector to continue your treatment. If one is not available, you will need to restart your treatment with new supplies.



Note: Should the line holder become detached from the nest, or the nest from its fasteners, be sure to re-attach them promptly.



Note: Be careful to avoid a position for the tubing that causes any of the lines to kink or twist.

Place PIN Connector in Organizer

The next step is to place the PIN connector of the VersiPD Cyclor Set in the stay•safe organizer.

- 1 Remove the patient line (blue clamp) from the line holder by grasping it above the holder and pulling down.
- 2 Remove the white paper tab from the patient line.



If your tubing has two patient PIN connectors, use the one at the tip of the patient line first.

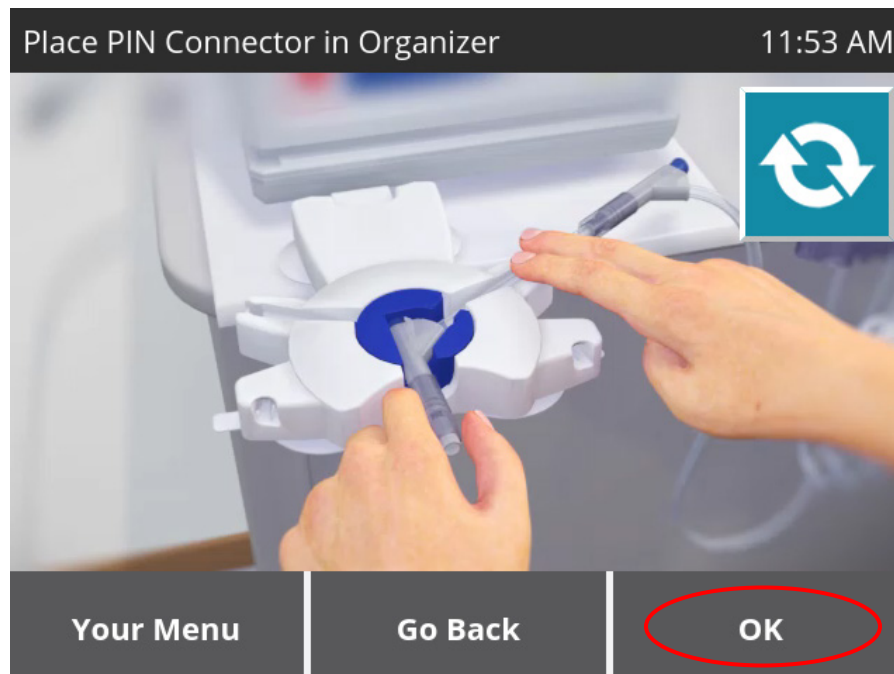
- 3 Grasp the PIN connector by the clear end (the other end from the blue button). Insert it carefully into the organizer as shown in the illustration below, fitting the blue button into the hole at the back of the channel.



Place PIN Connector in Organizer (continued)

- 4 Rotate the tubing to the right and press it firmly down into the channel on the upper right as shown in the illustration below.
- 5 Touch the **OK** button when you are done.

Starting
Treatment



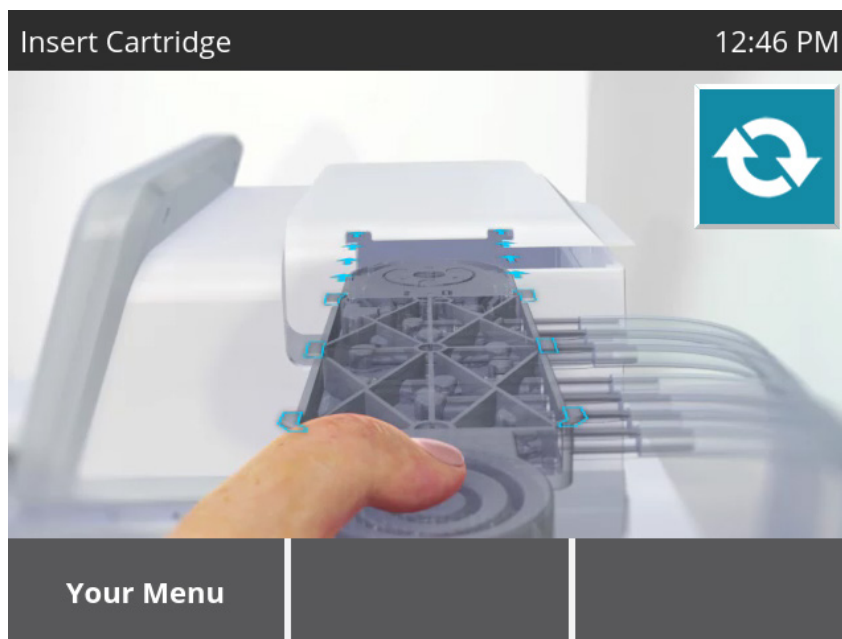
Insert the Cartridge

- 1 Wait for the cartridge loader to open automatically.



Warning: A new, sterile VersiPD Cycler Set and drain line must be used for every treatment. Check that the VersiPD Cycler Set is free from kinks or damage, and that it is not past its expiration date. Make sure all clamps are open and caps in place. A damaged VersiPD Cycler Set can lead to leaks, contamination, and infection. If you notice damage, save your VersiPD Cycler Set for pick up and immediately call Customer Service at 1-800-323-5188. You will be contacted about having the used tubing set picked up. Do not use this set!

- 2 With the cartridge tubing pointing toward the back of the cycler, grasp the round, rippled handle and insert the cartridge into the cartridge loader. Line up the tabs on the sides of the cartridge with the slots at the top of the cartridge loader.



Starting
Treatment

- 3 Move your hands away from the cartridge loader.



Warning: Keep fingers clear of moving parts.

- 4 Touch and hold the **Close Loader** button until the cartridge loader closes completely. An Integrity Test will run automatically to check the VersiPD Cycler Set after the cartridge loader closes.

Insert Warming Pouch

After the integrity check has been completed, you will be instructed to insert the warming pouch. The timer for warming pouch insertion starts as soon as the loader is closed. If it expires before you are finished, simply follow the Caution Alarm instructions on the screen to finish inserting the warming pouch.



Warning: If you notice any damage to the warming pouch, replace your VersiPD Cyclor Set. Do not use a damaged warming pouch for your treatment.



Warning: No foreign matter may be inserted in the warming pouch gap on the cyclor due to the risk of fire and damage to cyclor's internal workings



Note: Do not remove the warming pouch once it has been inserted for treatment.

- 1 Detach the warming pouch from the line holder. Loop the lines around the back of the cyclor.



Insert Warming Pouch (continued)

- 2 Grasp the warming pouch by the two handles. Make sure the tubing is on the left side. The left handle is labeled with an L and the right handle with an R.



- 3 Insert the warming pouch in the slot below the touchscreen and push toward the back of the cyclor. When it is almost fully inserted, use the finger grips to help you push it into place. You should feel or hear a click on both sides.

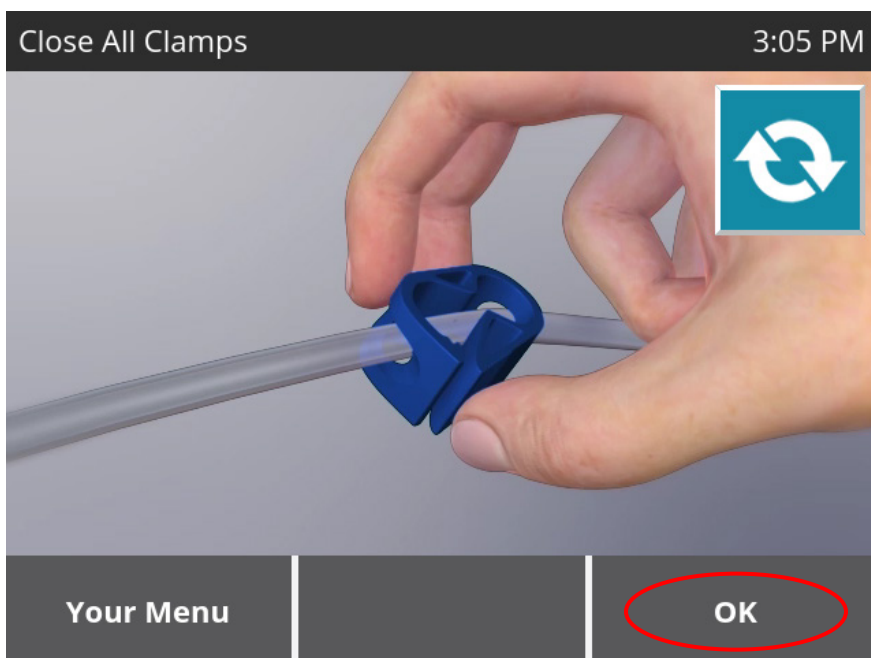
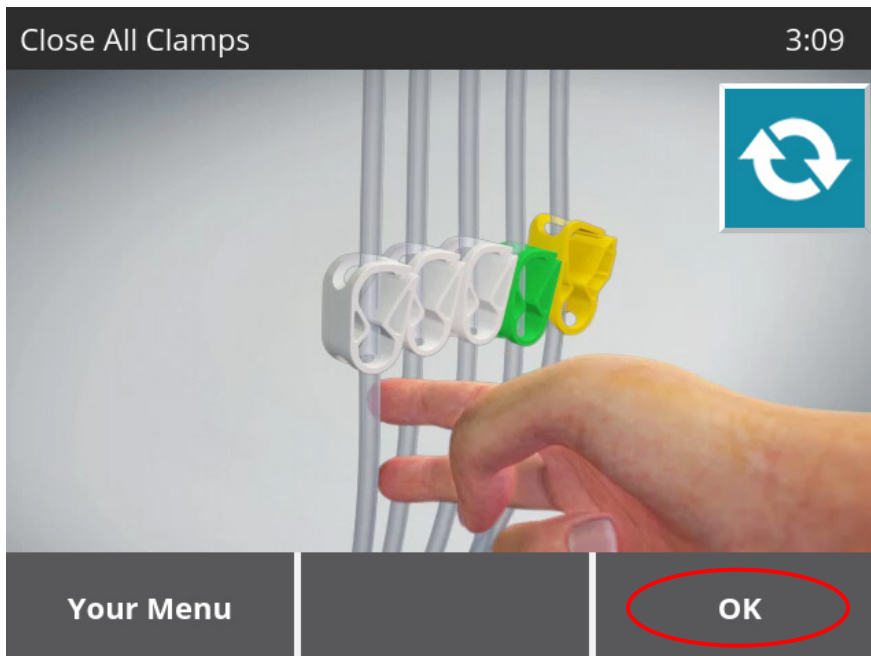


The cyclor will take you to the next screen automatically when the warming pouch is in the correct position.

Close All Clamps

- 1 Close all clamps on the VersiPD Cycler Set, including the blue clamp on the patient line.
- 2 Touch **OK** when you are done.

Starting
Treatment



Gather Solution Bags

Gather, open and inspect the prescribed solution bags shown on the screen.



Note: Check your solution bags for S.C.A.L.E.: correct *solution*, proper *clarity*, correct *amount*, absence of *leaks*, and an *expiration date* that is still valid. If a bag fails inspection, open and inspect a new bag.



Warning: Do not use a dialysis solution bag that has expired. Discard it and connect a new bag using aseptic technique.

Your VersiPD Cycler uses solution one bag at a time, starting with the solution line on the far left of the line holder. Position the bags as described below to help avoid excess air infusion or occlusions.

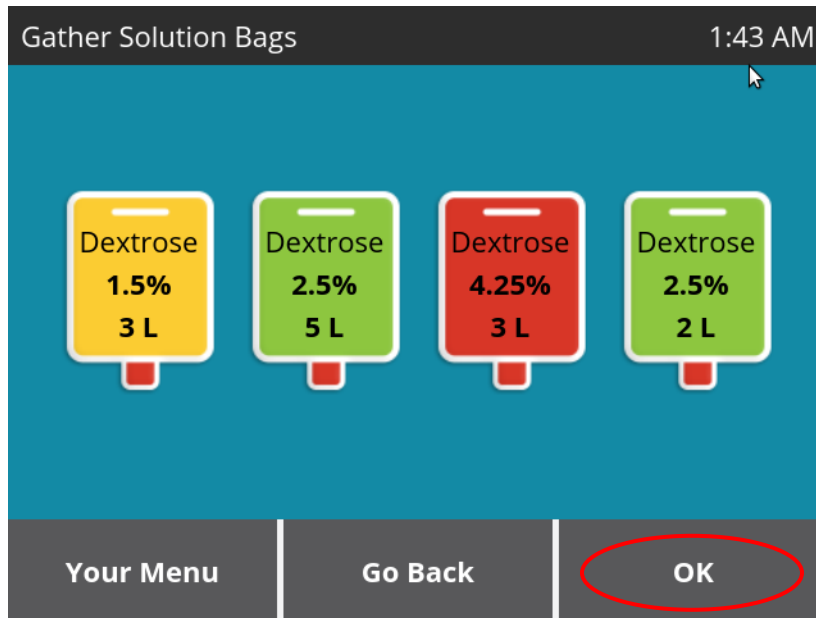
- If you are stacking the solution bags in the optional VersiPD Cart or Dialysate Solution Bag Case, carefully align the solution bags and place small bags on top of large bags. The port of the bag should be positioned at the front on the lower side of the sloped surface.
- If you are not using the cart or the case, do not stack the bags because they might fall over. It may be necessary to remove the solution line tubing from the back of the line holder for extra length if the bags are not placed on the right-hand side of the cycler.



Warning: Place solution bags and drain bags where punctures will be avoided. Punctures could occur from stepping on the bags, sharp edges of furniture, or pet damage. Fluid from the resulting spills could cause you to slip and fall.

Gather Solution Bags (continued)

- 1 When you are ready, touch **OK**.



Starting
Treatment

Connect Bags

While you inspect your solution bags, an integrity test will run in the background. If the test ends before all bags are opened and inspected, the integrity test screen won't be displayed and the screen shown below will appear.



Warning: The number and type of solution bags must correspond to your program. Follow the guidance on the screen to ensure that the correct lines are connected to each bag.

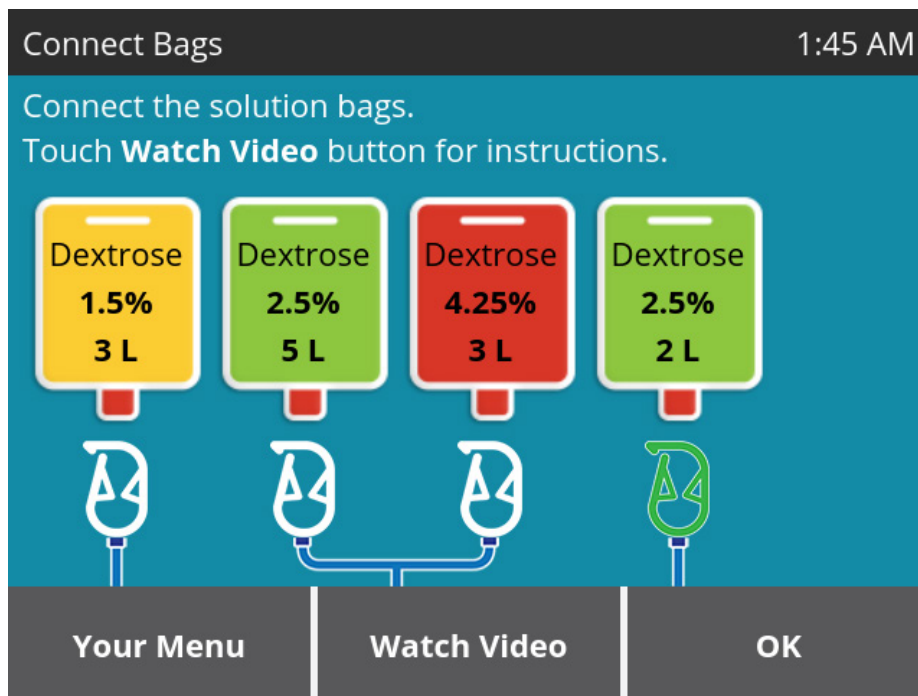


Warning: The solution bags must be connected to the solution lines indicated on the screen. The connection of an incorrect solution bag could result in excessive or insufficient fluid volume in the blood (hypervolemia or hypovolemia).



Caution: If using the optional cart, apply the brakes to prevent movement during treatment.

- 1 Make sure that your mask is still on. Clean your hands using the technique taught to you by your home therapy nurse.



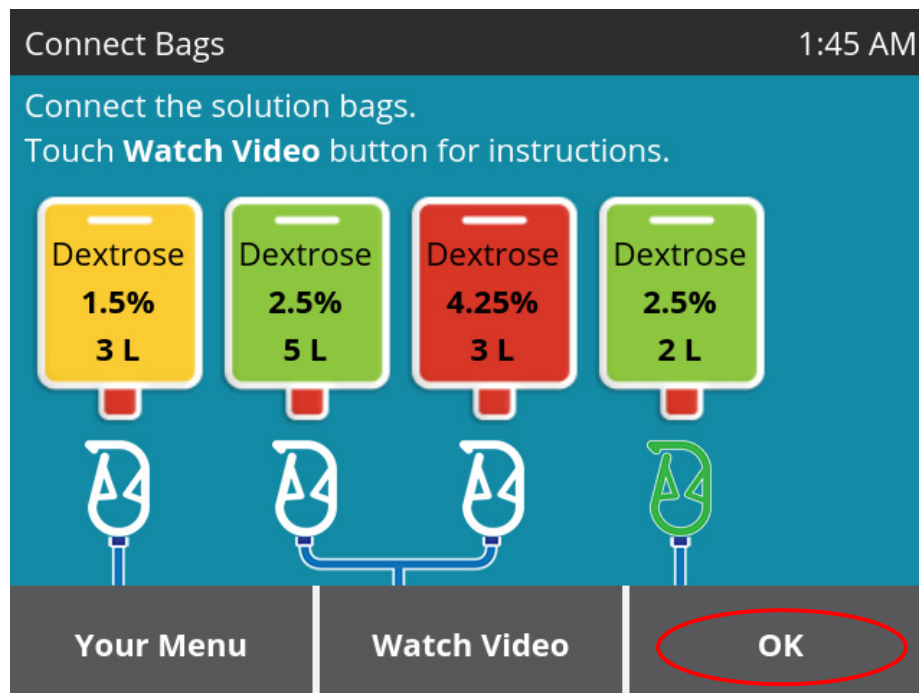
Connect Bags (continued)

- 2 Use aseptic technique, taught by your home therapy nurse, to attach each solution line to the port at the bottom of its bag. To remove the solution line from the line holder, grasp the white rectangular grip and pull down and towards you. Connect bags in the order they appear on the screen, moving from left to right.



Warning: Do not touch the inner part of the connectors (the part that will be in contact with fluid). If a connector falls on the floor, replace the set with a new one.

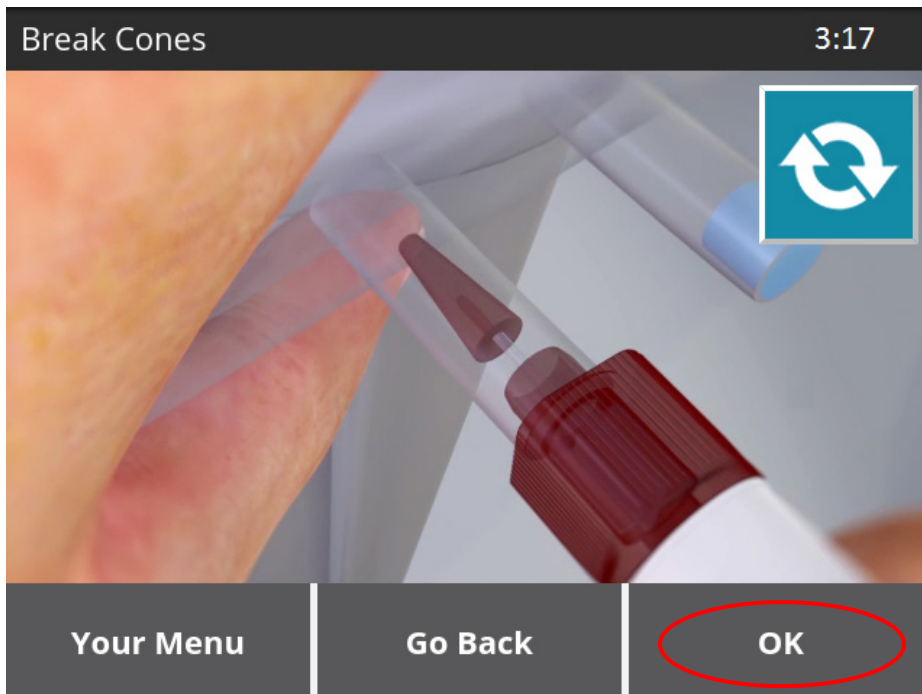
- 3 After connecting the indicated bags in the correct order, touch the **OK** button.



Note: If you are using a Cycler Set with 4 solution lines (see page 20, option 6a), mixing may occur between the contents of solution bags attached to lines 2 and 3. This is illustrated in the picture above by a line joining the second and third white clamps.

Break Cones

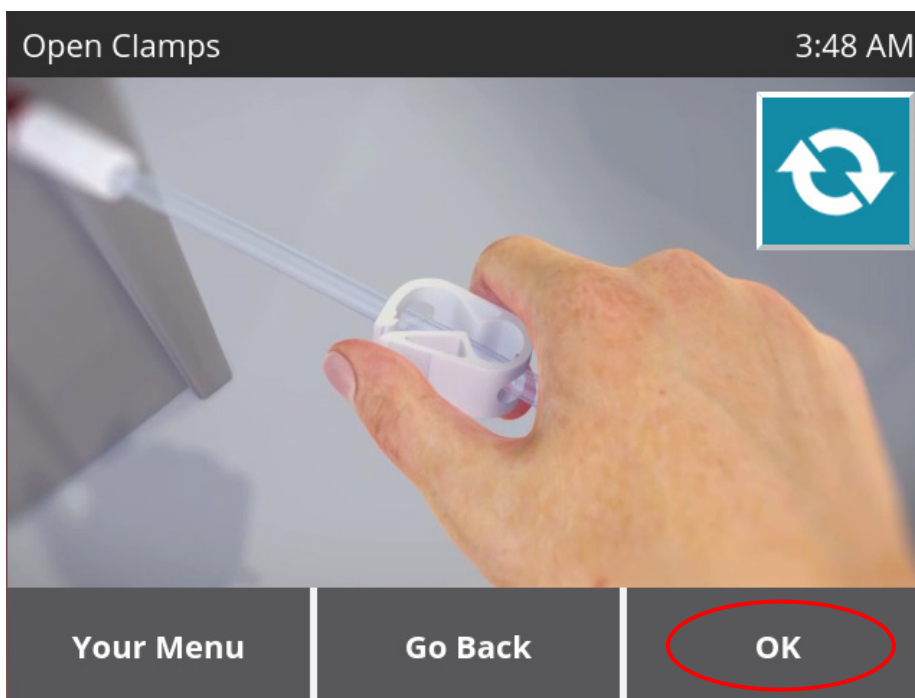
- 1 Break all the cones. Snap each cone front to back and side to side. The cone should be in two pieces after breaking. There is no need for the cones to float into the solution bag.
- 2 Touch **OK** when you are done.



Starting
Treatment

Open the Clamps

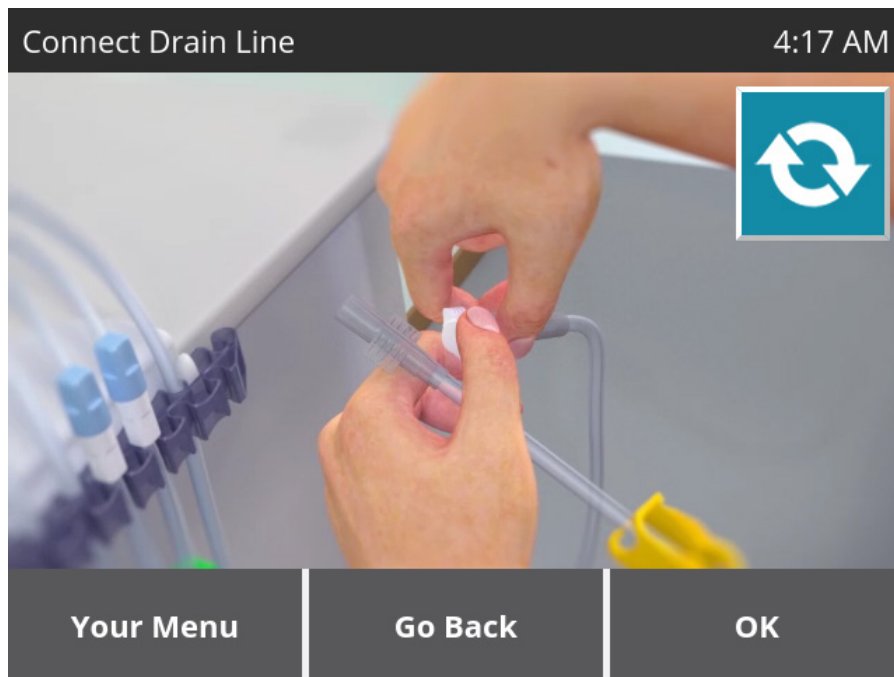
- 1 Open the clamp on each solution line that is connected to a bag.
- 2 Touch **OK** when you are done.



Starting
Treatment

Connect Drain Line or Bags

Once all the solution bags are connected, a drain option (if necessary) should be connected to the drain line of the Cyclor Set. A drain option is a drain line or drain bags.



Starting
Treatment

- 1 Remove the VersiPD Cyclor Drain Line (the line with the yellow clamp) from the line holder by grasping it above the holder and pulling down. Remove the cap from the line.
- 2 If you are using a drain option, open and inspect it. Do not use a drain option if damage is noted. Remove the cap and connect the drain option to the VersiPD Cyclor Drain Line.



Warning: Do not use a drain option if damage is noted.

- 3 Remove the white paper tab holding the VersiPD Cyclor Drain Line. This will help prevent the line from getting kinked.

Connect Drain Line or Bags (continued)

- 4 If you are using a *drain line* for your drain option, remove the end cap and position the end of the drain line as instructed by your home therapy nurse. Position it so as to avoid spills on your floor.



Warning: Protective measures must be taken to prevent backup in the drain line. When connecting the drain line, ensure that an air gap is maintained between the end of the drain line and the drain.



Warning: Position the power cord, VersiPD Cyclers Set and drain line so that they will not be tripped over by you or others living in your home.

If you are using *drain bags* for your drain option, fan them out to allow the fluid to flow freely into them.



Warning: Place solution bags and drain bags where punctures will be avoided. Punctures could occur from stepping on the bags, sharp edges of furniture, or pet damage. Fluid from the resulting spills could cause you to slip and fall.



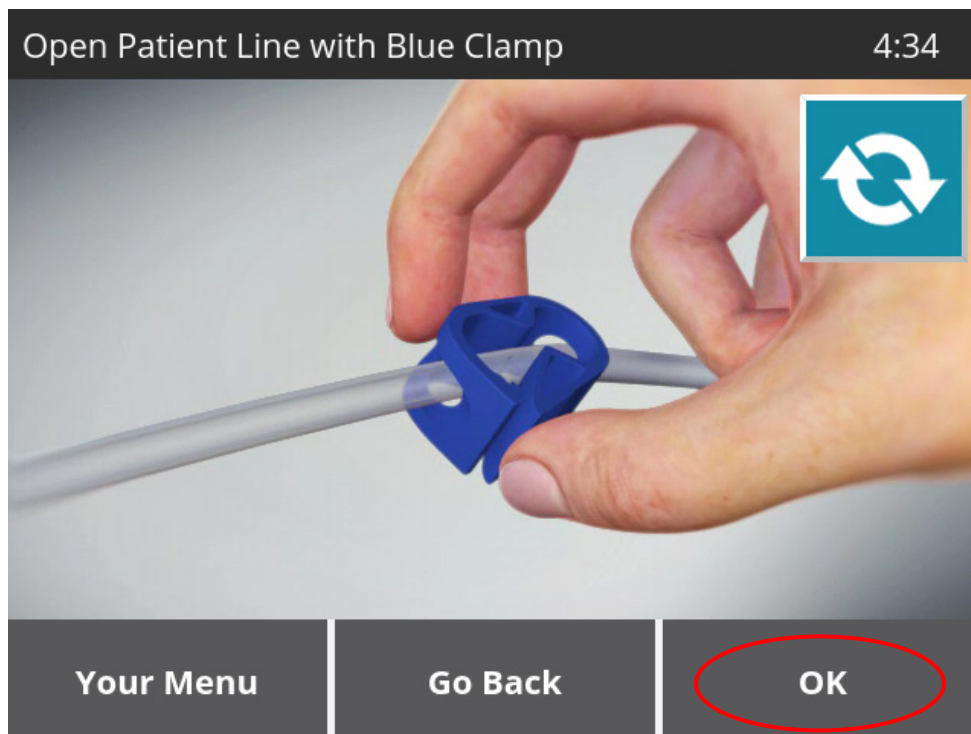
Warning: Do not place the drain bags on the floor where someone might trip on them.

- 5 Open the yellow clamp on the VersiPD Cyclers Set Drain Line.
- 6 When you are finished, touch **OK**. If you want to review the videos for breaking cones or closing clamps, touch **Go Back**.

Open Patient Line with Blue Clamp

The blue clamp must be open for the process of priming. This is the clamp for the patient line that brings fluid to and from your body.

- 1 Open the blue clamp.
- 2 Touch the **OK** button.



Starting
Treatment

Prime the VersiPD Cyclers Set

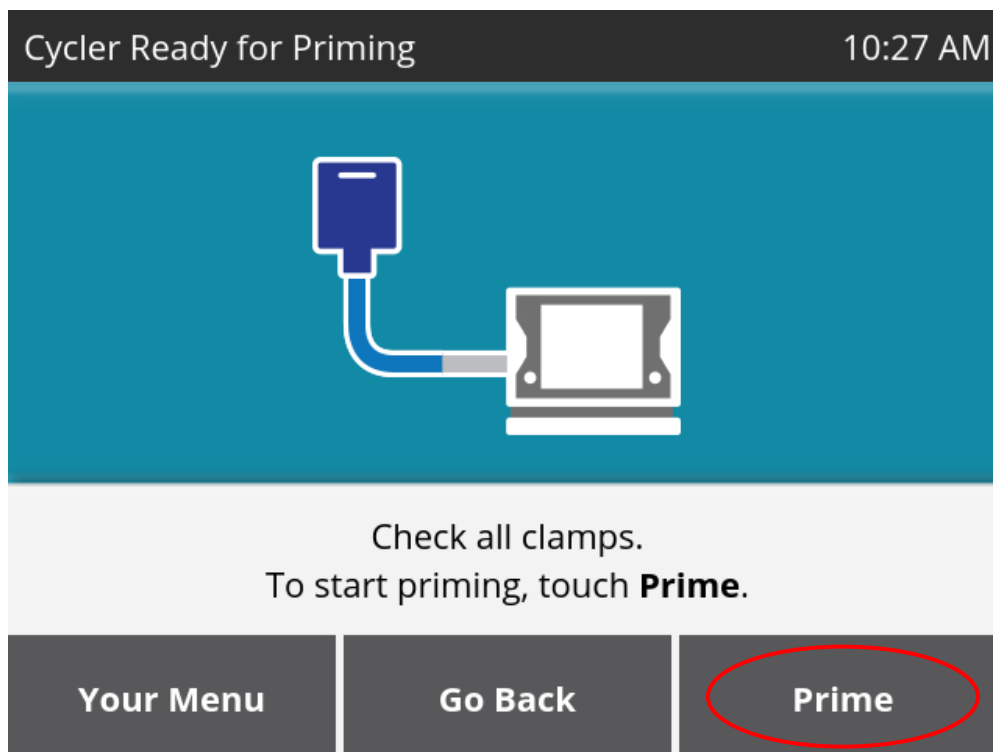
Priming pumps fluid through the tubing system to remove air in the lines.



Warning: Fluid may spill out of the tubing ends when priming is completed. Clean up any spills promptly as they may cause you to slip and fall. If any fluid gets inside your cycler, contact a Fresenius Medical Care Technical Support Representative immediately at 1 (800) 227-2572.

- 1 Make sure that the clamps on solution bag lines not in use remain closed. All other clamps should be open.
- 2 Touch the **Prime** button. Observe the flow in the patient line to make sure that there are no leaks and air bubbles are being pushed out.

Starting
Treatment



Finish Priming

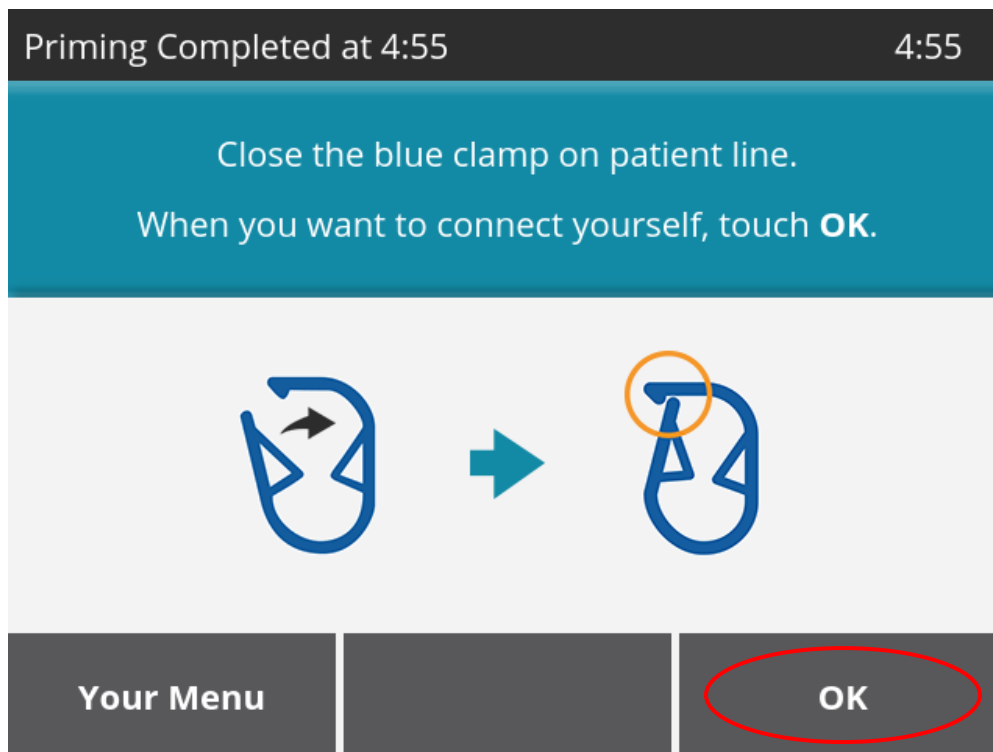
When the screen shown below appears, the VersiPD Cycler has completed the priming of the tubing set.

- 1 Close the blue clamp.



Note: The blue clamp is different from the blue button on the PIN connector. Close only the blue clamp when prompted.

- 2 When you are ready to connect yourself, touch the **OK** button.



Starting
Treatment

Connect to the Cyclor

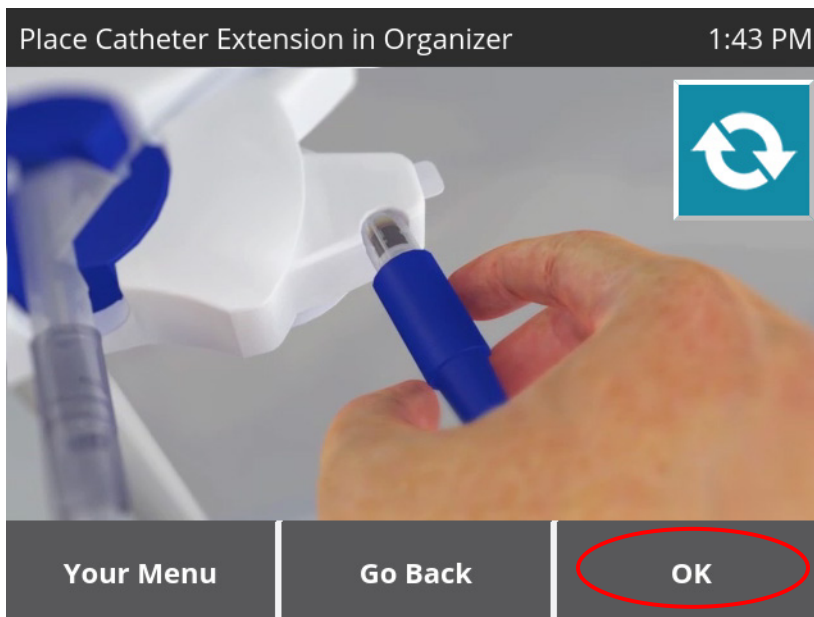
Follow the steps below to connect your patient line to your catheter extension set. Be careful to use aseptic technique as instructed by your home therapy nurse.



Warning: Do not connect your catheter extension set to the VersiPD Cyclor Set until priming is complete.

- 1 If you took your mask off during priming, put on a new mask now. Clean your hands as instructed by your home therapy nurse.
- 2 Place your catheter extension set line in the notch on the right side of the stay•safe organizer.
- 3 Touch **OK** when you are done.

Starting
Treatment



Connect to the Cyclor (continued)

- 4 Remove the cap from the PIN connector.



Warning: Always use aseptic technique when you connect or disconnect the tubing that goes to your catheter extension set or solution lines. This means wearing a mask and cleaning your hands thoroughly as instructed by your doctor or home therapy nurse.

- 5 Remove the catheter extension set line from the notch by unscrewing it to disconnect the stay•safe cap, leaving the cap in the notch.

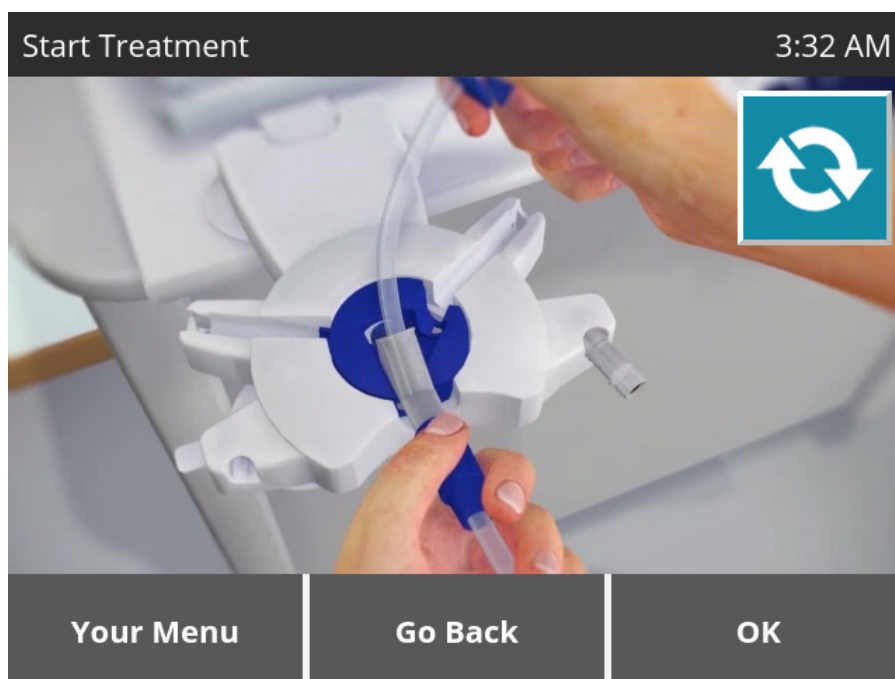


- 6 Connect the catheter extension set line to the PIN connector. Touch **OK** when you are done.



Connect to the Cyclor (continued)

- 7 Open the white clamp on your catheter extension set line.
- 8 Open the blue clamp on the VersiPD Cyclor Set patient line.
- 9 Remove the PIN connector from the stay•safe organizer as shown below.



Starting
Treatment

- 10 Press the green **START**  button to begin your treatment.
- 11 Discard the used stay•safe cap.



Warning: Use a new, sterile stay•safe cap each time you disconnect.

During Treatment

During
Treatment

During Treatment



Warning: The initial drain should be completed while you are awake. The fluid from your initial drain should have good clarity (not be cloudy), be free from fibrin strands and yellow or clear in color. If the fluid in the drain line appears cloudy, contact your home therapy nurse because this could be an early sign of infection.



Warning: If fluid leakage is detected on bedding, clothing, or the outside surface of the VersiPD Cycler Set during or at the end of treatment, report it to Technical Support and your home therapy nurse. Contamination may have occurred.

You will receive a **Risk of Overfill** warning or caution during each initial drain. Touch the **Mute** button. A screen like the one below will appear (for more information about warnings and cautions, see page 169).

! Initial Drain 4:46 AM

Initial Drain stopped, check Drain status:

Expected volume 50 mL	Drained volume 48 mL
--------------------------	-------------------------

Carefully consider your previous fill volume and your drained volume to determine if you should:

- Drain more, touch **Continue Drain** or
- End Initial Drain, touch **Start Fill 1**.

Continue Drain Start Fill 1

If you don't think you have drained enough, check to make sure that the blue patient line clamp and the white catheter extension set clamp are both open. If one is closed, open it and touch **Continue Drain**. The VersiPD Cycler cannot detect manual exchanges that have not been entered in the cycler. Compare the amount you have drained to your last fill or any manual exchanges you have done. If the amount is adequate, touch **Start Fill 1** to begin your first fill.

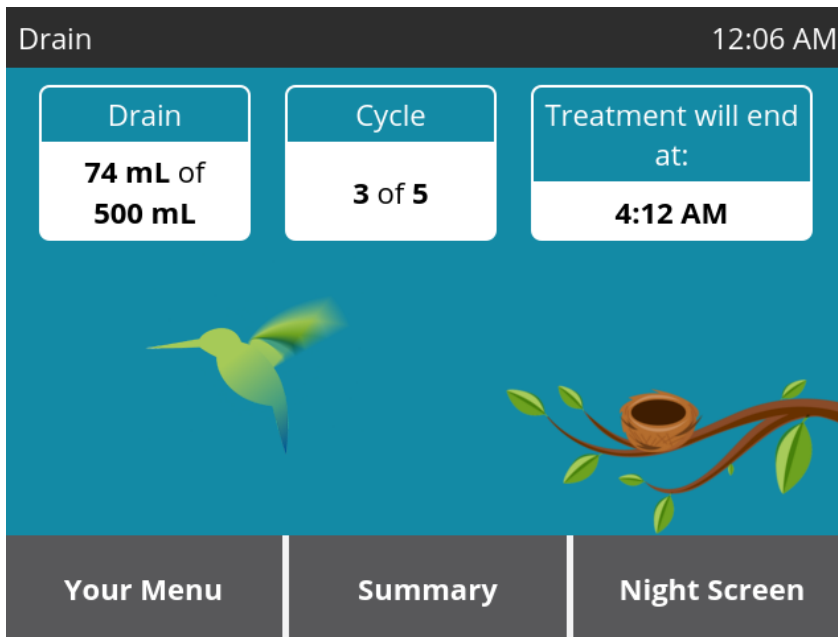


Warning: Do not end the Initial Drain prematurely. This could result in an IIPV (Overfill) situation because the Initial Drain will be followed by a complete fill.

It is normal to hear a humming sound and soft clicks during your treatment as the pump runs and valves open and close. As treatment continues, the VersiPD hummingbird changes position to indicate which phase (fill, dwell, or drain) is in progress. It flies toward the nest during a fill, sleeps in the nest during a dwell and moves from the nest back to the sky while you are doing a drain.



Note: It is important to prevent blocking or kinking of the patient line when you turn in bed, to avoid Patient Line Blocked alarms.



Button	Description
Your Menu	Some cyclor settings may be adjusted during treatment such as temperature, sound volume, screen brightness, night screen and treatment history. Menu options in gray are not available. Touch this button and then Cyclor Settings to make these adjustments.
Summary	This button is available during treatment if you want to check the details of your therapy.
Night Screen	During treatment, touch this button to darken the screen. To restore the screen display, touch the screen anywhere and the display will become visible again.

During Treatment

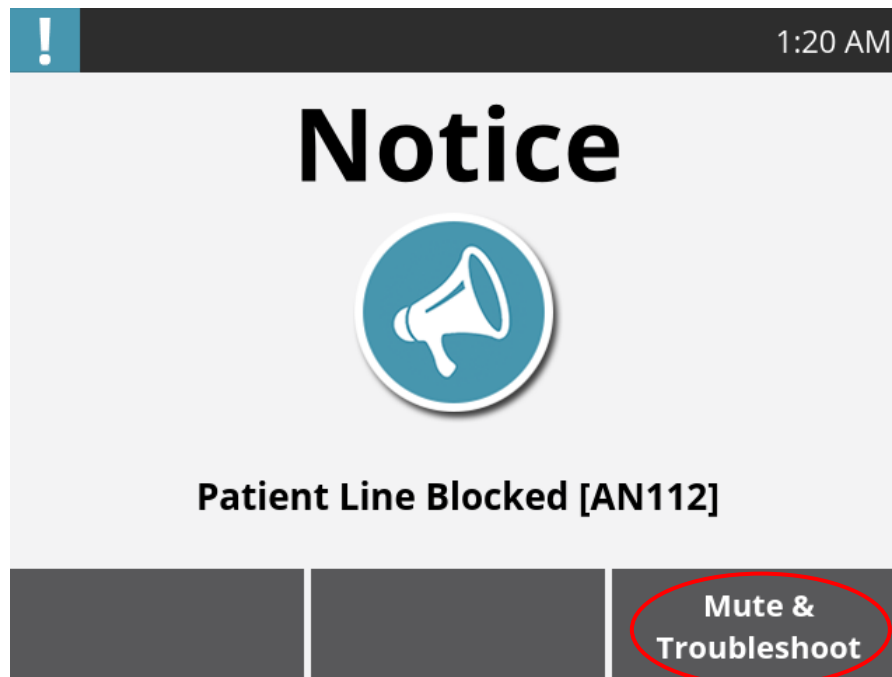
Patient Line Check

A normal function of the VersiPD Cycler is the Patient Line Check (PLC). If you are awake and not using the night screen, you may notice these during treatment. If your drain rate is too slow and you haven't drained enough fluid, a PLC sends you a maximum of 60 ml of fluid from the warming pouch to check if the tubing is blocked. Blocks may be caused by fibrin, kinks, accidentally closed clamps or the peritoneal dialysis catheter position in your body. Movement during the night may result in lying on the tubing; it may be necessary to straighten the tubing out to resolve or prevent alarms. The fluid used for a PLC is not added to the total volume or drain volume of the treatment because it has not dwelled long enough to be considered treatment volume. Your cycler makes sure the fluid used for a PLC is drained before continuing to register fill or drain treatment volume.

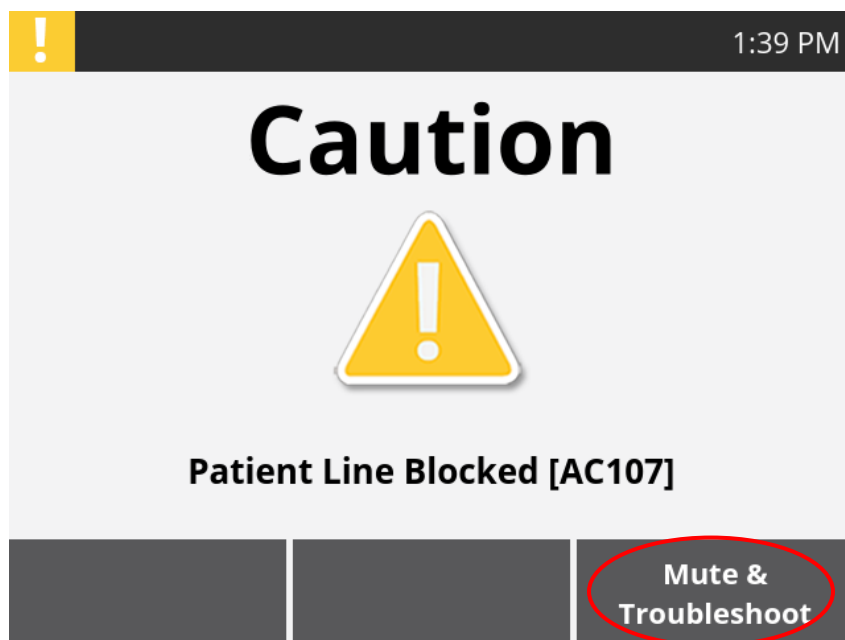
Patient Line Blocked

A series of self-resetting patient line blocked notices will sound if a blockage is found by the PLC. These notices are designed to make you move without fully waking you during the night. They are a series of guitar music sounds: the first notice is 25 percent of the full volume, the next is 50 percent, and the last is 75 percent. You do not need to touch the screen during these notices; when flow resumes they will stop. If you do wake up, however, a mute button is available as shown below.

During
Treatment



If the blockage is not resolved during the Patient Line Blocked notice, the cyclor will progress to a **Patient Line Blocked** caution. Touch **Mute and Troubleshoot** to address the blockage so you can continue your treatment.



Multiple patient line checks due to flow interruptions during drain or fill, may result in not having enough fluid for the treatment. If you frequently experience multiple flow interruptions causing PLCs, talk to your home therapy nurse about attaching extra solution during set-up.

The Blue Button

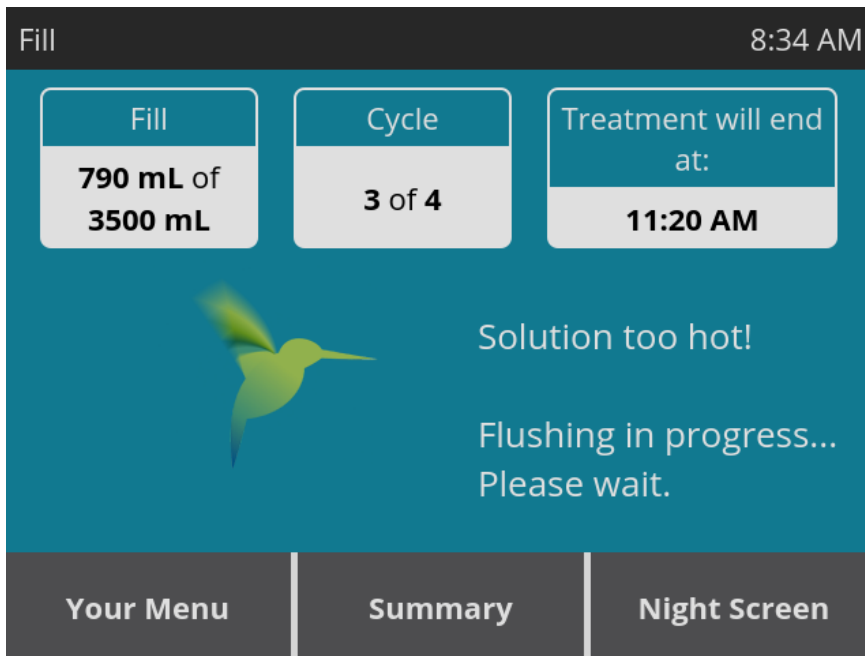
A blocked line may be caused by pushing the blue button on the PIN connector that inserts the PIN into the catheter extension set and closes the patient line. The PIN should only be inserted when you are ready to disconnect. If you inserted the PIN during treatment, you will need to disconnect and reconnect to the next PIN connector or end the treatment, disconnect and set up using a new VersiPD Cyclor Set.



During Treatment

Fluid Flush

A fluid flush can occur during a fill if the cyclor detects that the fluid is too hot. The screen will display without an alarm the message “Solution too hot! Flushing in progress...Please wait.” If you are using the night screen, the screen will not light up. The warm fluid is flushed down the drain while the cyclor continues to monitor the temperature. When the temperature is acceptable, your fill will resume. If the temperature cannot be brought down by flushing, an alarm will sound.

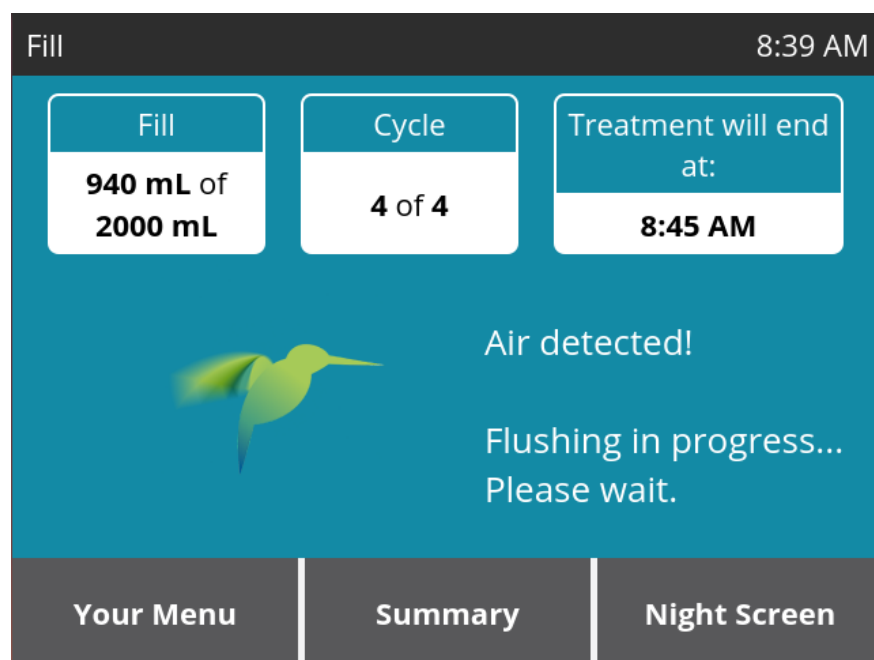


Integrity Checks

At various points during your treatment, the cyclor will run integrity tests to ensure proper function. During these tests, do not press the **STOP** button unless you need to do a STAT drain (see page 89 for instructions). For other **STOP** button actions, wait until the integrity test is over before touching **STOP**.

Air Flush

An air flush can occur during a fill when the cyclor detects air in the lines. The air is flushed down the drain while the cyclor continues to monitor for air. The screen will display without an alarm the message “Air detected! Flushing in progress...Please wait.” If you are using the night screen, the screen will not light up. When the air is gone, your fill will resume. If VersiPD cannot clear the air, an alarm will sound requiring your attention.



Safety Operating Mode

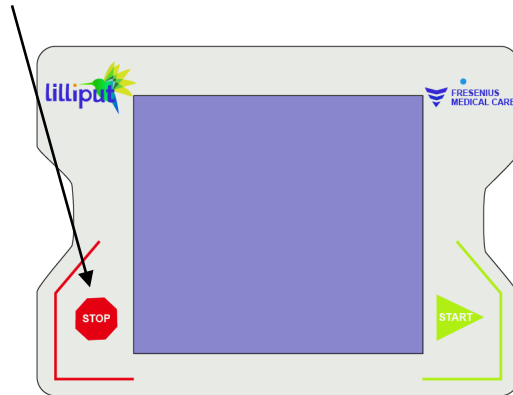
Your cyclor will go into safety operating mode if certain pressures are detected. The pump will run slower in safety operating mode. You will not receive an audible alarm and the screen will not light up if you are using the night screen. If you are awake, you may notice the pump running slower.

OptiDwell

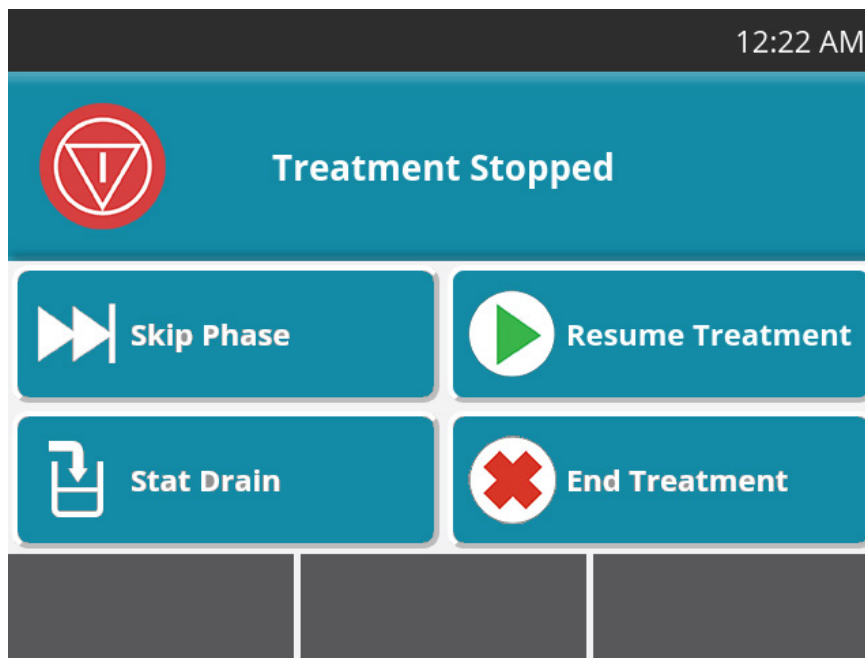
The VersiPD Cyclor technology maximizes the working time of peritoneal fluid (called dwell), by managing drain time and adjusting the next fill if necessary. These adjustments allow your treatment to continue with reduced sleep interruptions. The cyclor monitors drained volumes, rates, and pressures when making adjustments during standard drains. You may notice you receive more or fewer cycles than expected during a treatment because the cyclor adjusts to complete as much of your treatment as possible in the programmed time. You will be notified if less than 90 percent of the total volume is used during a treatment.

The STOP Button

If you need to stop your cyclor during your treatment, you can press the **STOP** button on the front panel of the cyclor.



Pressing **STOP** does not end your treatment, but brings up the screen below.



During
Treatment

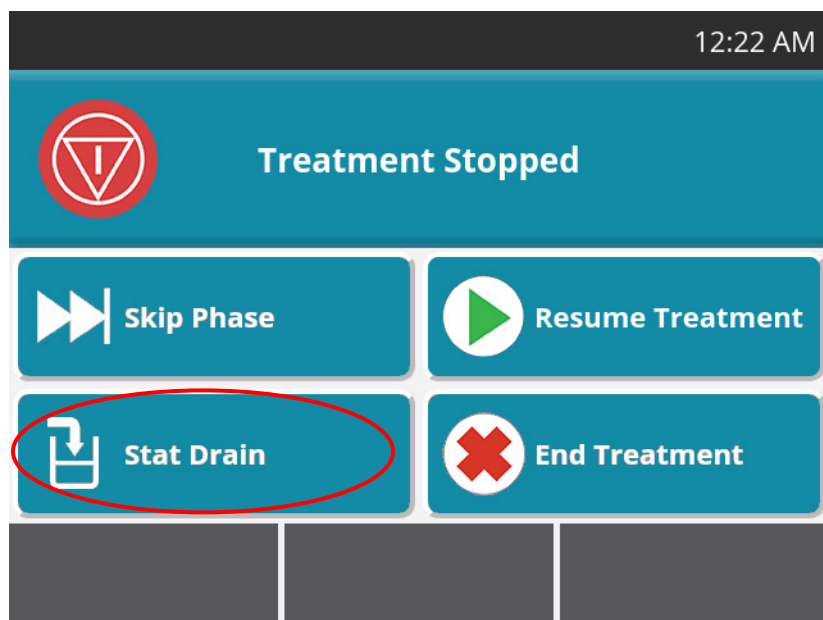
On this screen you have four options:

- To skip a phase of your treatment, turn to page 91.
- If you wish to resume your treatment, touch the **Resume Treatment** button.
- To end treatment, touch the **End Treatment** button.
- To perform a STAT drain, see the instructions on the next page.

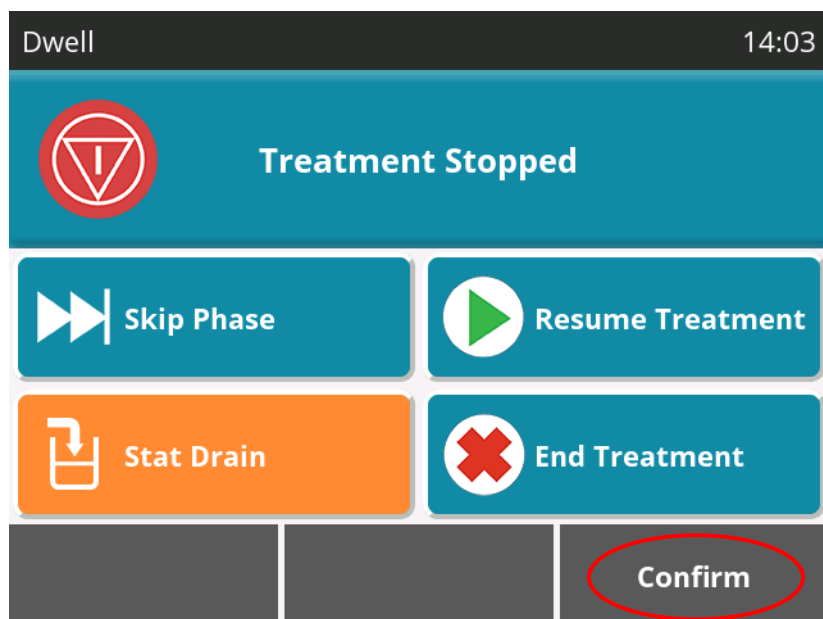
Stat Drain

If you feel overfilled or bloated at any point during treatment, you can do a “Stat”, or immediate, drain. Press the red **STOP button** in the lower left corner of the cyclor. The screen below will appear.

- 1 Touch the **Stat Drain** button to highlight it. It will turn orange.



- 2 Touch the **Confirm** button. Make sure that you drain completely. The phase after a Stat Drain will be a fill.



During
Treatment

Stat Drain (continued)



Note: If for any reason the cyclor does not execute a Stat Drain when you need one, touch **End Treatment** and perform a manual drain using the method taught to you by your home therapy nurse.



Warning: Increased Intraperitoneal Volume (IIPV), more commonly known as Overfill, is when you have too much fluid in your abdomen. This condition may cause injury or death. Patients and care partners should watch for the potential signs of IIPV.

These include:

- Difficulty breathing
- Vomiting or spitting up
- Feeling full, bloated, or overfilled after treatment
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Chest pain
- Increased blood pressure
- Change in mental status
- Leakage of fluid from the PD catheter exit site

If you experience any of these symptoms or feel a large, painful build-up of pressure during your fill, do not finish your fill cycle. Press the red **STOP** button and immediately initiate a STAT drain as instructed by your home therapy nurse. See page 89 for more information on how to use the STAT drain feature. Once the fluid is completely drained from your abdomen, call your doctor or home therapy nurse.

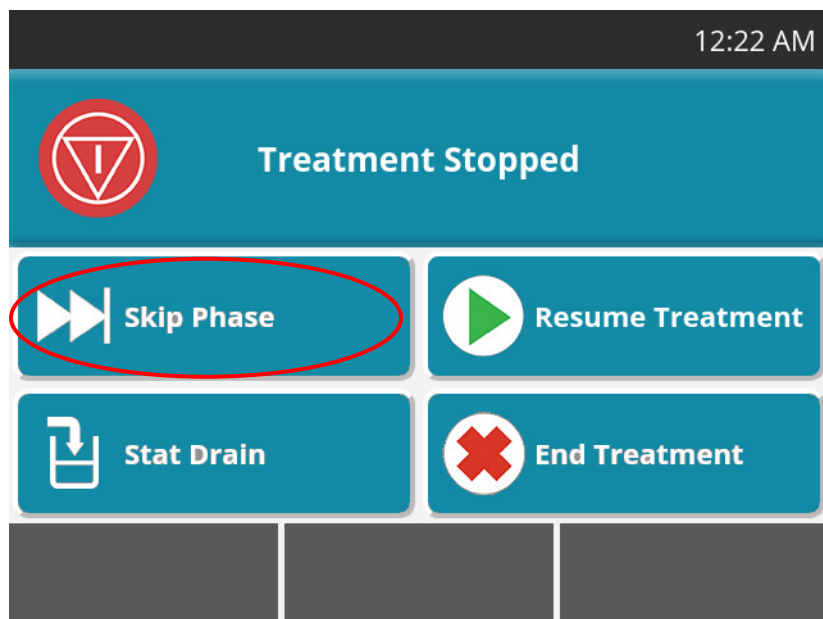


Note: An additional drain is a planned drain. A Stat Drain is an unplanned drain.

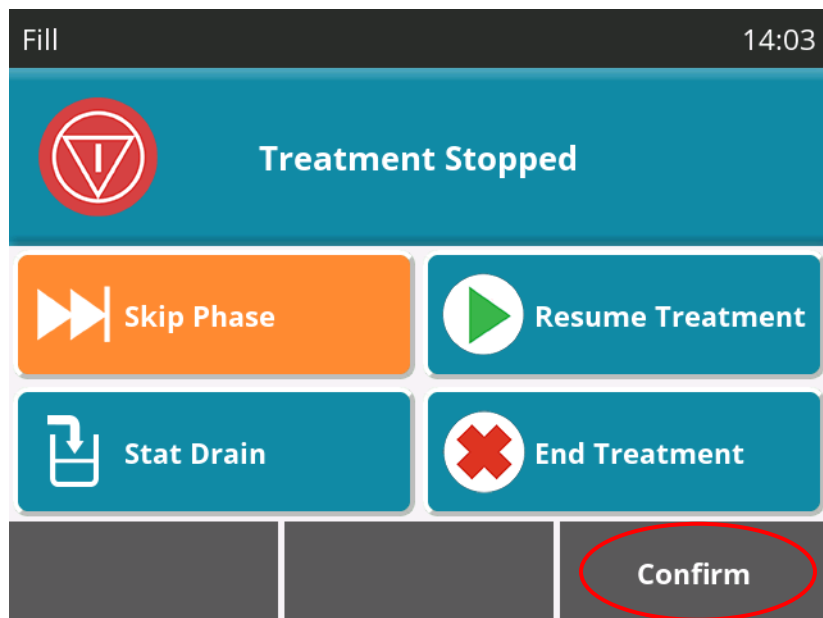
Skip a Phase

Any phase of an exchange, whether fill, dwell or drain, can be skipped (bypassed), with the exception of the Initial Drain. To skip a phase, press the red **STOP** button in the lower left corner of the cyclor. The screen below will appear. Remember to tell your doctor or home therapy nurse about any phase of treatment that you skipped.

- 1 Touch the **Skip Phase** button to highlight it. It will turn orange.



- 2 Touch the **Confirm** button.



During
Treatment

Ending Treatment

Ending Treatment



Note: If an additional drain is programmed, you will see a message saying that your treatment is nearly over. Follow your home therapy nurse's instructions for additional drain and touch **Start Drain**. If a wake-up alert is programmed, you will receive an alert with the message.

When your treatment is complete, a treatment summary screen will appear. Here you can compare your actual treatment results with the therapy program entered in the VersiPD Cycler. Five values are shown:

- *Cycler Total Volume* is the total fill volume for the whole therapy, including PD Plus™, Cycler, Last Fill and Manual Exchange.
- *Cycler Total UF* is the total ultrafiltration, meaning the amount of fluid beyond the fill volume that has been removed.
- *Connected Time* is your time connected to the cycler.
- *Total Cycles on Machine* is the number of complete cycles (fill, dwell and drain) that you have done in your treatment.
- *Number of Events and Alarms* is the total number of events (see page 212) and warning (page 181), caution (page 193) and notice (page 210) alarms you have received during your treatment. Events include cycler actions that are not visible during treatment and do not create an audible tone.

1 When you have finished this review, touch **OK**.

Treatment Completed at 2:42 PM		2:44 PM
	Programmed	Actual
Cycler Total Volume [L]	10.5	10.4
Cycler Total UF [mL]	300	301
Connected Time [hh:mm]	08:04	08:55
Total Cycles on Machine	3	3
Number of Events & Alarms	-	3

Your Menu
OK

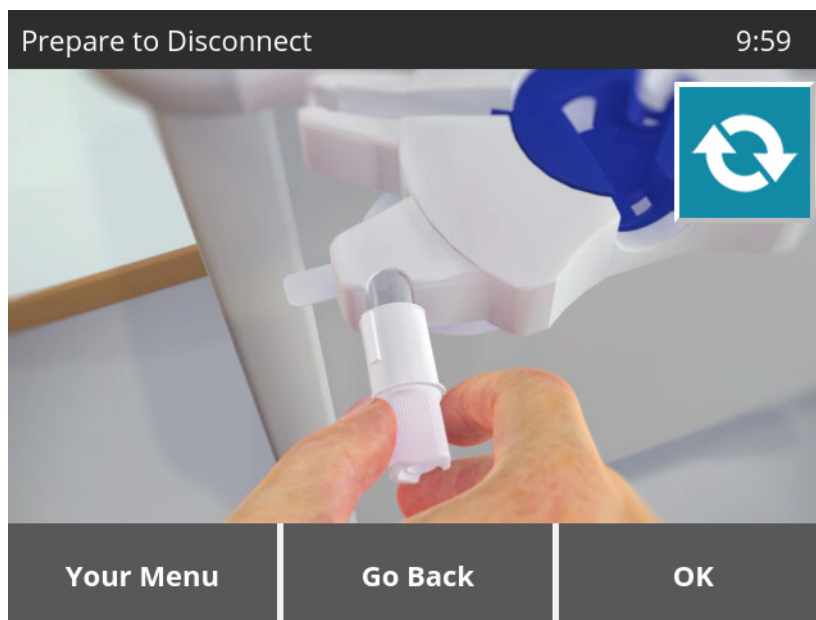
Ending Treatment

Disconnection



Warning: Always use aseptic technique when you connect or disconnect the tubing that goes to your catheter extension set or solution lines. This means wearing a mask and cleaning your hands thoroughly as instructed by your doctor or home therapy nurse.

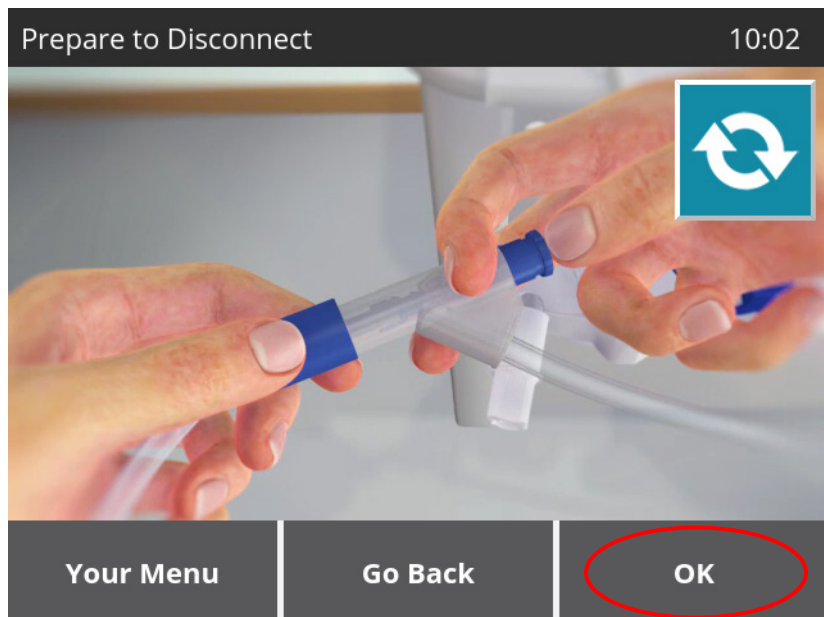
- 1 Put on a mask and clean your hands. Touch **OK**.
- 2 Place a new stay•safe connector cap in the notch on the left side of the stay•safe organizer as shown below.



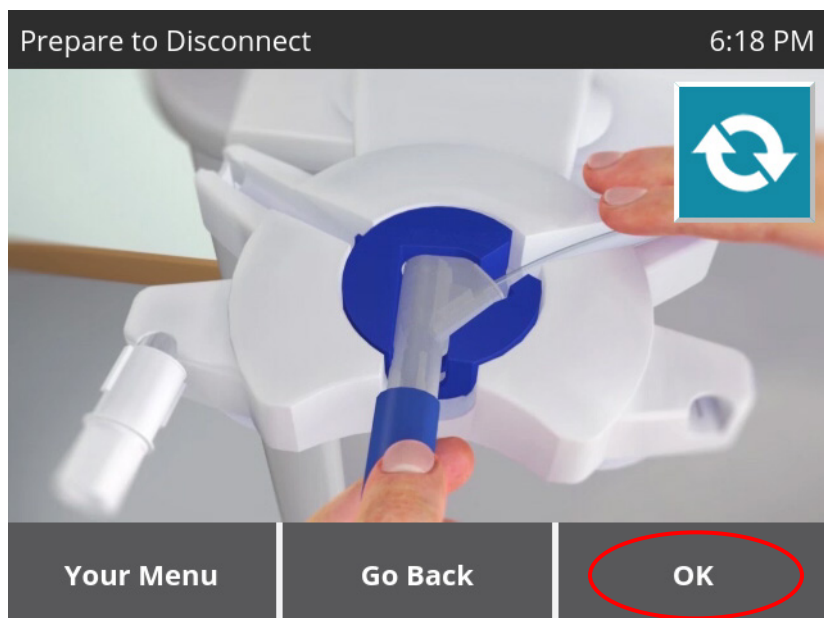
Warning: Use a new, sterile stay•safe cap each time you disconnect.

Disconnection (continued)

- 3 Make sure the blue clamp on the patient line and the white clamp on the catheter extension set are open. Turn the blue button on the PIN connector clockwise $\frac{1}{4}$ of a turn and push it in until it stops. Touch **OK**.



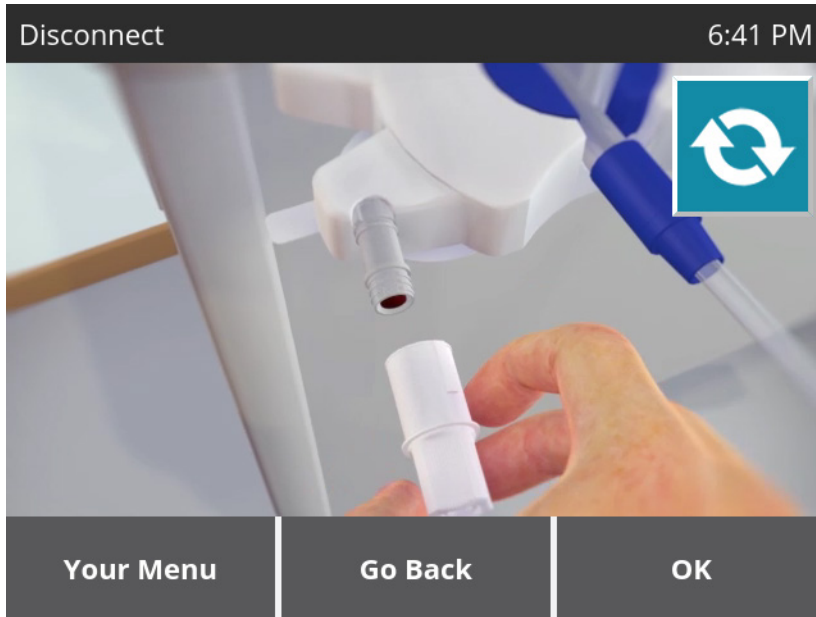
- 4 Close the blue clamp on the patient line and the white clamp on the catheter extension set.
- 5 Insert the PIN connector connected to the catheter extension set into the stay•safe organizer. Touch **OK**.



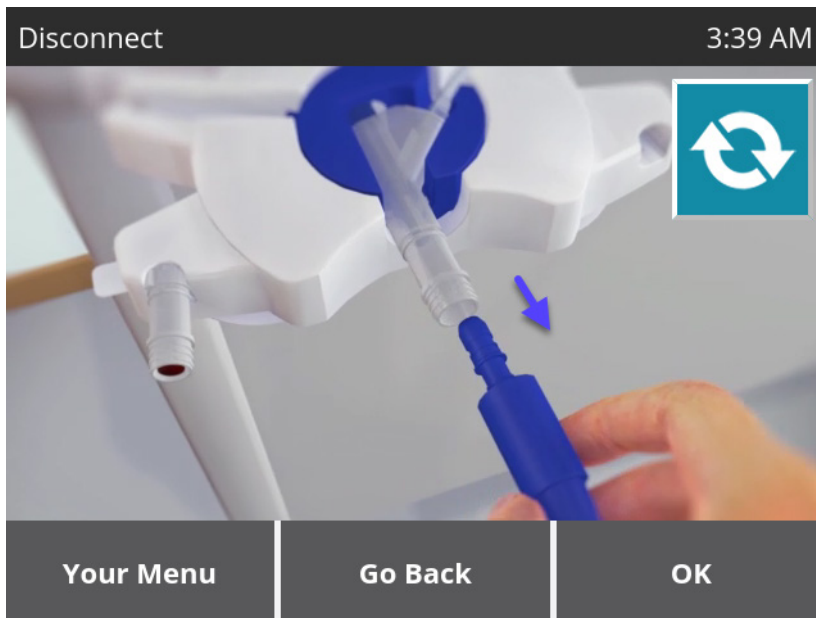
Ending
Treatment

Disconnection (continued)

- 6 Clean your hands. Unscrew the protective cover from the new stay•safe cap and set aside.



- 7 Unscrew your catheter extension set from the PIN connector.

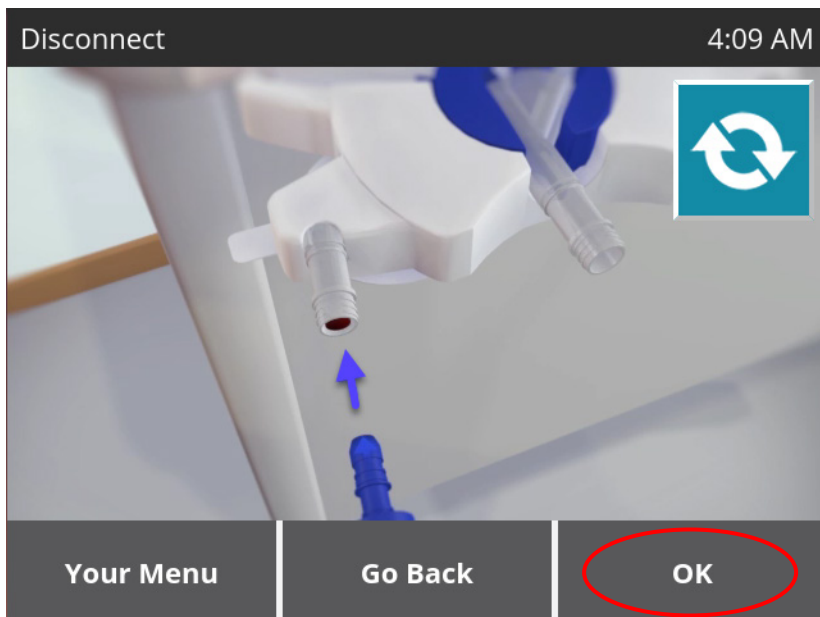


Disconnection (continued)

- 8 Carefully pull the catheter extension set away from the PIN connector without bending or twisting the PIN. Hold the catheter extension set up slightly—be sure the PIN is inserted. The illustration below shows an inserted PIN. If the PIN is not inserted, notify your home therapy nurse after you have finished the disconnection process.



- 9 Connect the catheter extension set to the new stay•safe cap. Press into the cap while turning the extension set clockwise. Remove the extension set from the notch and make sure the cap is tight. Touch **OK**.



Ending
Treatment

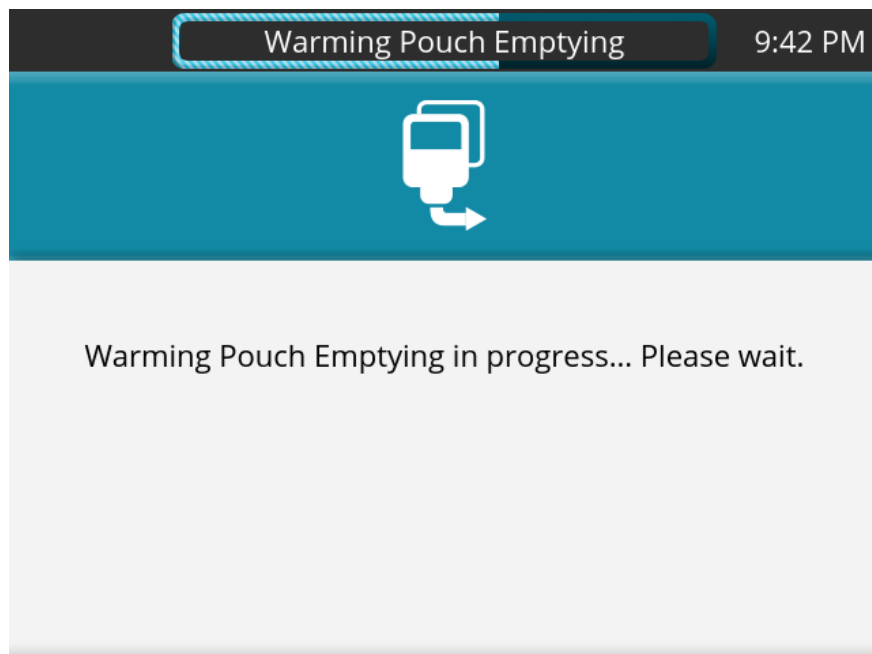
Disconnection (continued)



Warning: Even if the PIN in the PIN connector was not inserted, the stay•safe cap should be placed on your catheter extension set until a new PIN connector can be aseptically inserted.

- 10** Place the protective cover from the stay•safe cap on the PIN connector and set aside for later disposal.

Vital Signs (Post-treatment)



At this point the cycler will empty the warming pouch and display the screen shown above. When this is finished, you may be prompted to enter certain vital signs again, depending on how your cycler has been programmed by your home therapy nurse. The process is the same as at the start of treatment. If you need to look at the instructions again, see the following pages:

- *for Weight, page 48*
- *for Blood Pressure, page 49*
- *for Pulse, page 50*
- *for Temperature, page 51*
- *for Blood Glucose, page 52*



If you are using the Bluetooth system, your vital signs will be sent to the cycler automatically. You will have the choice to confirm them or repeat the measurements.

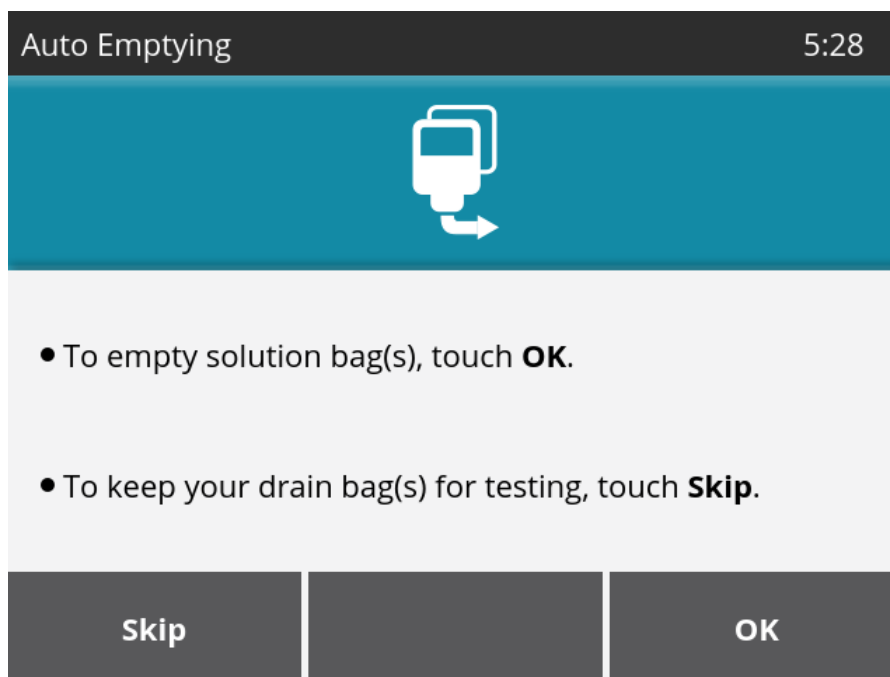
If you are not using Bluetooth, follow the instructions above to enter your vital signs.

Empty the Bags

The cyclor will ask you if you are keeping your drain bags for testing. If you are, you will have to drain the unused solution manually.

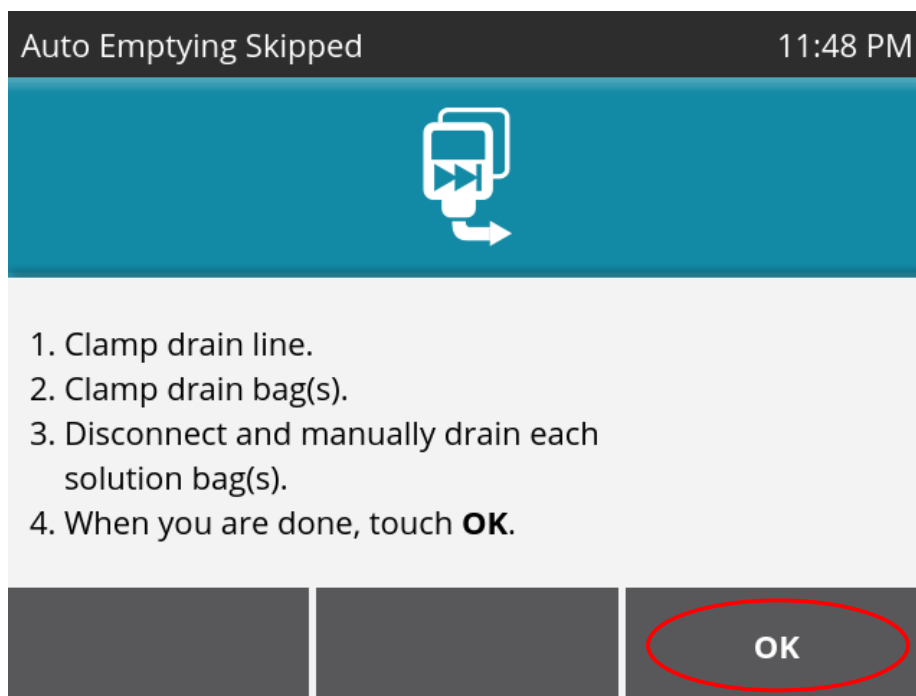
- 1 If your home therapy nurse has told you to keep the drain bags for testing, touch **Skip**. This will prevent the unused solution from flowing into the drain bags. Proceed to step 2 on the next page.

If you are *not* keeping the drain bags for testing, touch **OK** and allow the cyclor to empty any leftover solution. When this is finished, the “Auto Emptying Complete” screen will appear. Touch **OK** and proceed to page 102.



Empty the Bags (continued)

- 2 The next screen will ask, “Are you sure you want to keep your drain bag(s)?” Confirm your choice by touching the **YES** button. The screen shown below will appear.
- 3 Close the yellow clamp on the drain line and the clamps on the drain bags.
- 4 Disconnect the solution bags and manually drain the unused solution as instructed by your home therapy nurse.
- 5 When you are finished, touch **OK**.



Ending
Treatment

Dispose of Materials

The next step is to remove the used supplies and dispose of them.

- 1 When the screen prompts you, close all clamps and touch **OK**.
- 2 When prompted, grasp the tab on the front of the warming pouch and pull it slowly and firmly toward you.



- 3 When the cartridge loader opens, grasp the handle on the right and pull the cartridge out toward the right. Touch and hold the **Close Loader** button when you are done.



Warning: Keep your fingers clear of any moving parts.

- 4 Remove the line holder from the nest. Touch **OK**.
- 5 Remove the solution bags and tubing set as instructed by your home therapy nurse.
- 6 Dispose of the used supplies as instructed by your home therapy nurse. Touch **OK**.



Warning: Follow local regulations concerning waste disposal.

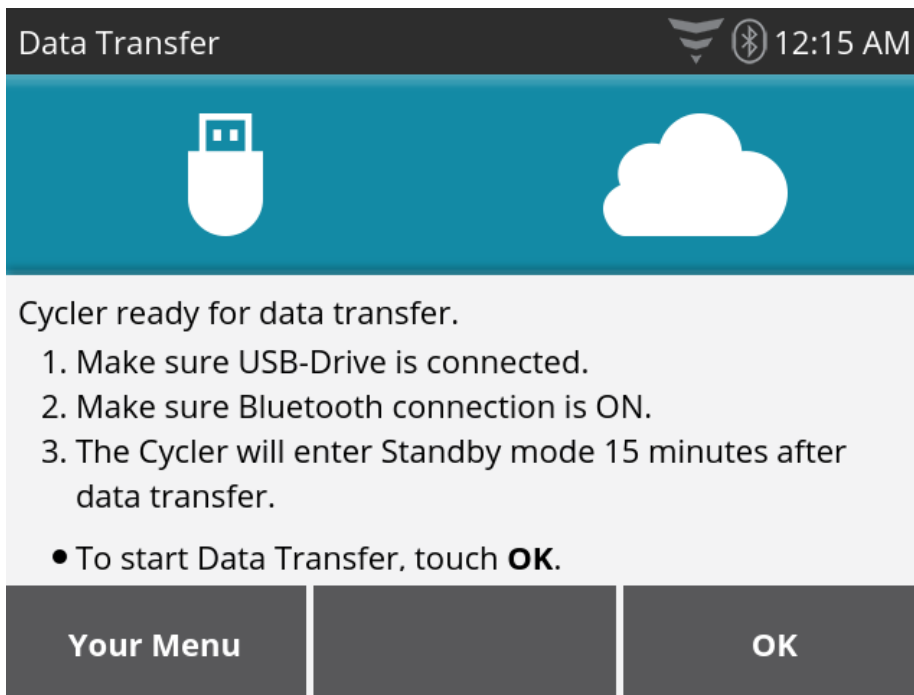
Data Transfer

This screen appears automatically when you have confirmed the removal of your VersiPD Cyclers Set and other disposables.

1 Touch the **OK** button to begin data transfer.

The data will be transferred to the USB drive. If you are using the Kinexus Gateway, the data will also be sent to your center.

It is not necessary to wait for the data to transfer. When the transfer is complete, the screen will prompt you to touch the **Standby** button. Even if you are not there, the cyclers will enter Standby Mode automatically after 15 minutes.



Note: Do not turn off the VersiPD Cyclers using the switch on the back unless you need to move the cyclers to a new location (for instance, when travelling). Leaving the power switch on with the cyclers plugged in keeps the battery charged.

PD+ Disconnection



Warning: Always use aseptic technique when you connect or disconnect the tubing that goes to your catheter extension set or solution lines. This means wearing a mask and cleaning your hands thoroughly as instructed by your doctor or home therapy nurse.

If you do a PD+ exchange, your steps to disconnect will be as follows:

- 1 Put on a mask and clean your hands. Touch **OK**.
- 2 Place a new stay•safe connector cap in the notch on the left side of the stay•safe organizer.



Warning: Use a new, sterile stay•safe cap each time you disconnect.

- 3 Make sure the blue clamp on the patient line and the white clamp on the catheter extension set are open. Turn the blue button on the PIN connector clockwise $\frac{1}{4}$ of a turn and push it in until it stops. Touch **OK**.
- 4 Close the blue clamp on the patient line and the white clamp on the catheter extension set.
- 5 Insert the PIN connector connected to the catheter extension set into the stay•safe organizer. Touch **OK**.
- 6 Clean your hands. Remove the protective cover from the stay•safe cap and set aside.
- 7 Unscrew your catheter extension set from the PIN connector.
- 8 Carefully pull the catheter extension set away from the PIN connector without bending or twisting the PIN. Hold the catheter extension set up slightly—be sure the PIN is inserted. If the PIN is not inserted, notify your home therapy nurse.



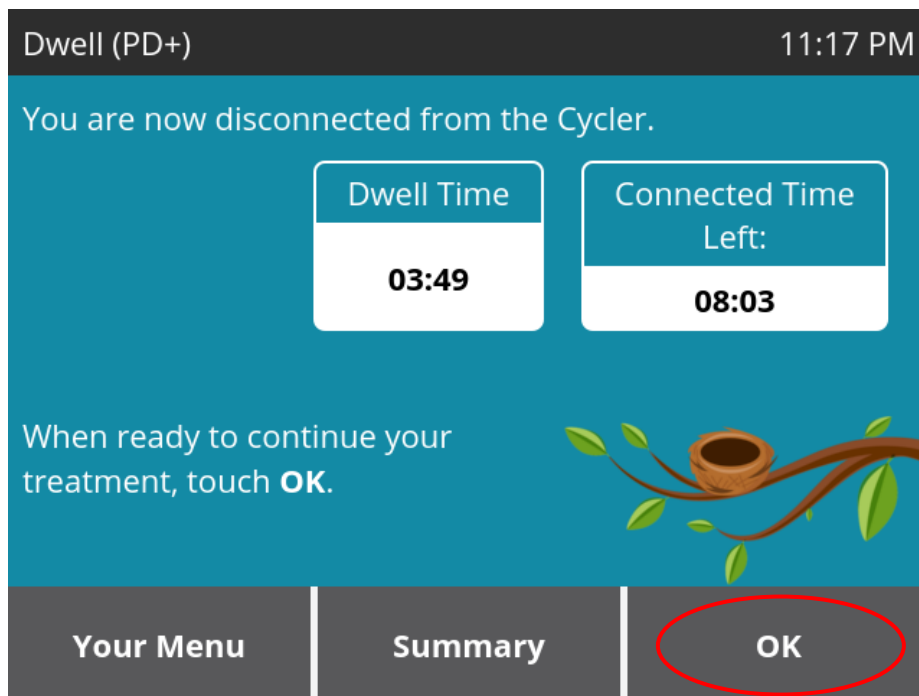
Warning: Even if the PIN in the PIN connector was not inserted, the stay•safe cap should be placed on your catheter extension set until a new PIN connector can be aseptically inserted.

- 9 Place the protective cover from the stay•safe cap on the PIN connector and set aside.

PD+ Reconnection

Follow the steps below to reconnect after a PD+ dwell.

- 1 When you are ready to continue your treatment, touch **OK** on the “Dwell (PD+)” screen.



- 2 Remove the used PIN connector from the stay•safe organizer.



Warning: Always use a new PIN connector to connect to the cyclor. If you have to temporarily disconnect from the cyclor before the end of the scheduled treatment time, you must use a new PIN connector to reconnect and resume the treatment. You must use aseptic technique to disconnect the used PIN connector and then prepare the unused PIN connector for your reconnection. You must not connect yourself with the same PIN connector twice.



Note: If you push in the button on the unused PIN connector instead of the used one, you will have to start over with a new VersiPD Cyclor Set.

PD+ Reconnection (continued)

- 3 Peel the cellophane from the second PIN connector. Place this unused PIN connector in the stay•safe organizer. Touch **OK**.
- 4 Put your mask on and clean your hands as instructed by your home therapy nurse. Touch **OK**.



Warning: Always use aseptic technique when you connect or disconnect the tubing that goes to your catheter extension set. This means wearing a mask and cleaning your hands thoroughly as instructed by your doctor or home therapy nurse.

- 5 Make sure the white clamp on the catheter extension set is closed. Place the catheter extension set line in the notch on the right side of the stay•safe organizer.
- 6 Unscrew the used PIN connector. Remove the catheter extension set line from the notch by unscrewing it to disconnect the stay•safe cap, leaving the cap in the notch.
- 7 Carefully connect your catheter extension set to the PIN connector. Touch **OK** when you are done.
- 8 Open the white clamp on your catheter extension set and the blue clamp on the patient line of the VersiPD Cycler Set. You may now remove the PIN connector from the stay•safe organizer.
- 9 Press the green **START** button to resume your treatment.

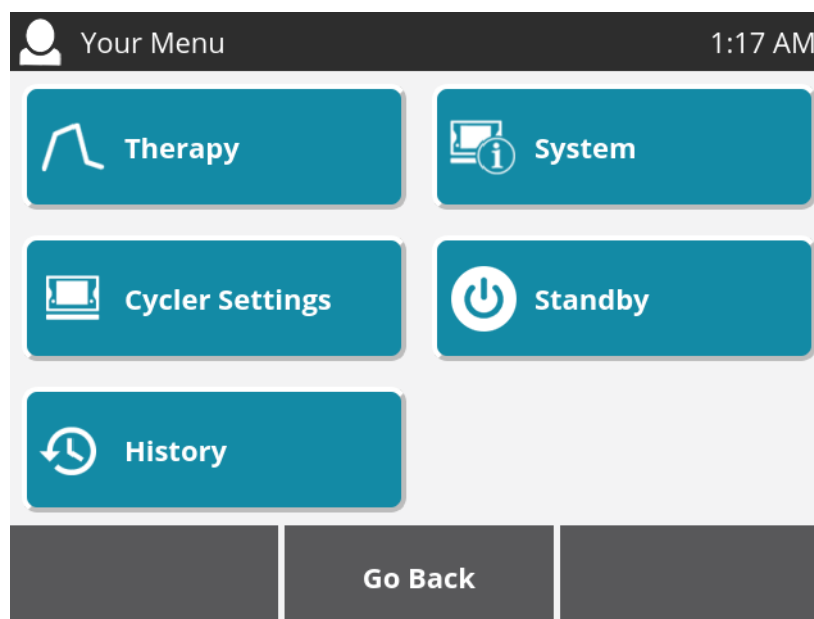
Your Menu



Your Menu




This menu is for you, the patient. Here you can do the following:

- Review therapy settings
- Set an additional drain for the end of your treatment
- Change cycler settings for comfort and convenience
- Monitor your treatment history
- Check the software version installed on your cyclor

To view this screen, touch the **Your Menu** button at the bottom left of the opening screen. It is also available during treatment.

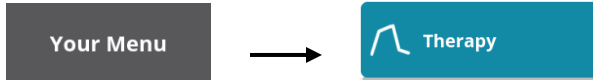


Button	Description
	Touch Therapy to review a program, set an additional drain and the alert for it, and set solution temperature. See page 110 for details.
	Touch Cycler Settings to set preferences: sound volume, screen lighting, and language (English or Spanish). Set the time here also. See page 115 for details.

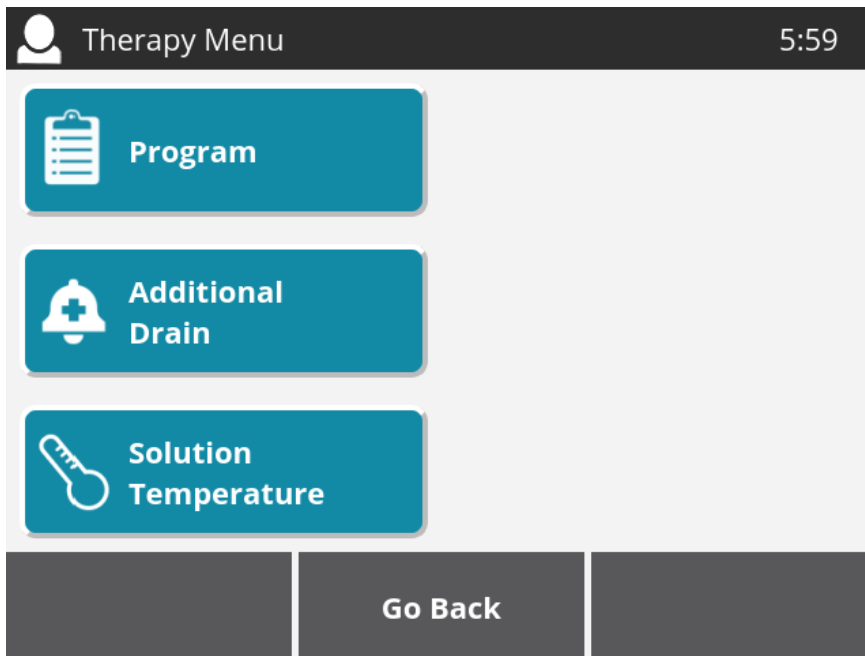
Button	Description
	<p>Touch History to transfer data or view your treatment history. See page 121 for details.</p>
	<p>Touch System to check the software version and access information about the cyclers' internal processes. See page 125 for details.</p>
	<p>In Your Menu, touch Standby before treatment to put the cyclers in Standby Mode (explained in the list of terms on page 243). The Standby button is not available during treatment and appears gray.</p>


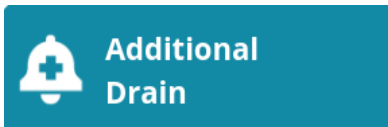

Therapy Menu

To reach this screen, touch in sequence the buttons:



Review your therapy programs in this menu. If you have permission from your home therapy nurse, you may set an additional drain and wake-up alert and change your solution temperature.



Therapy Menu Button	Description
	Touch Program to review existing programs. See the next page for more information.
	Touch Additional Drain to set an extra drain after the last scheduled drain and a wake up alarm for it if desired. See page 112 for details.
	Touch Solution Temperature to change the temperature of your dialysis solution. See page 114 for details.

Review Your Therapy Programs

If at any time you wish to review one or all of your therapy programs, press in sequence the buttons:



On the next screen, select a therapy program and then touch the **Review** button. The treatment values will be displayed in the format shown below.



Warning: Do not use any treatment values that are not prescribed by your physician. Values shown in illustrations are for example only.

Demo 3:45	
Summary Bags Graph	
Cycler Total Volume [L]	12.0
Connected Time [hh:mm]	05:17
Total Cycles on Machine	4
Total Expected UF [mL]	0
Manual Exchange Total Volume [L]	0.0
Treatment Maximum Fill Volume [mL]	3000
Go Back Confirm	

By touching the **Bags** tab, you can also see what solution concentrations are prescribed for this program. By touching the **Graph** tab, you can see the program values represented in graphical form.

Additional Drain

If your home therapy nurse has given you permission, you have the option of setting an additional drain after the last scheduled drain. You can also set a wake-up alert to sound when it is time for you to do the additional drain.

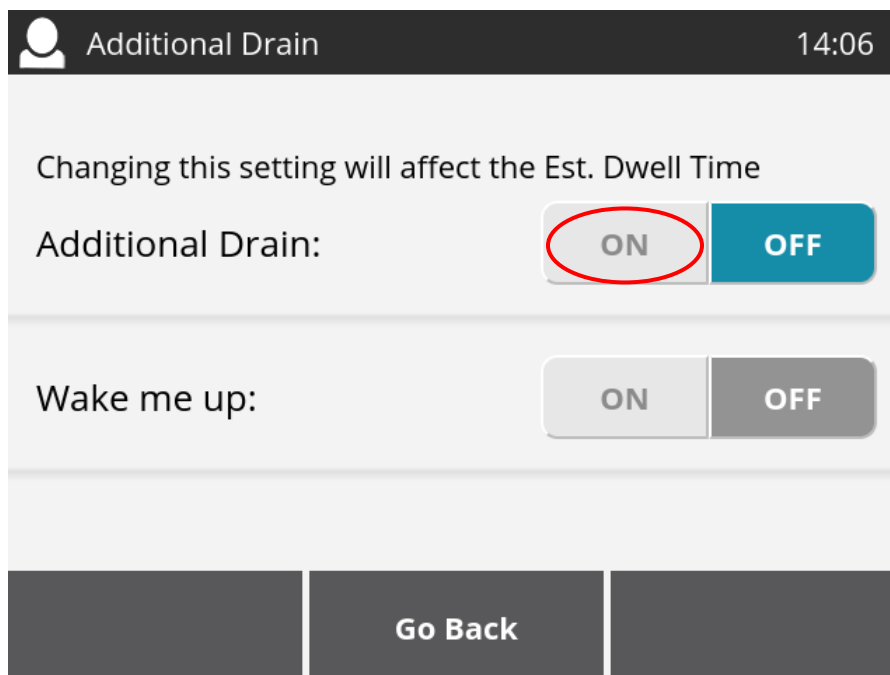
To reach this screen, touch these buttons in sequence:



If your home therapy nurse has not given you permission to set an additional drain, the Additional Drain button in the Therapy Menu will be gray (disabled).

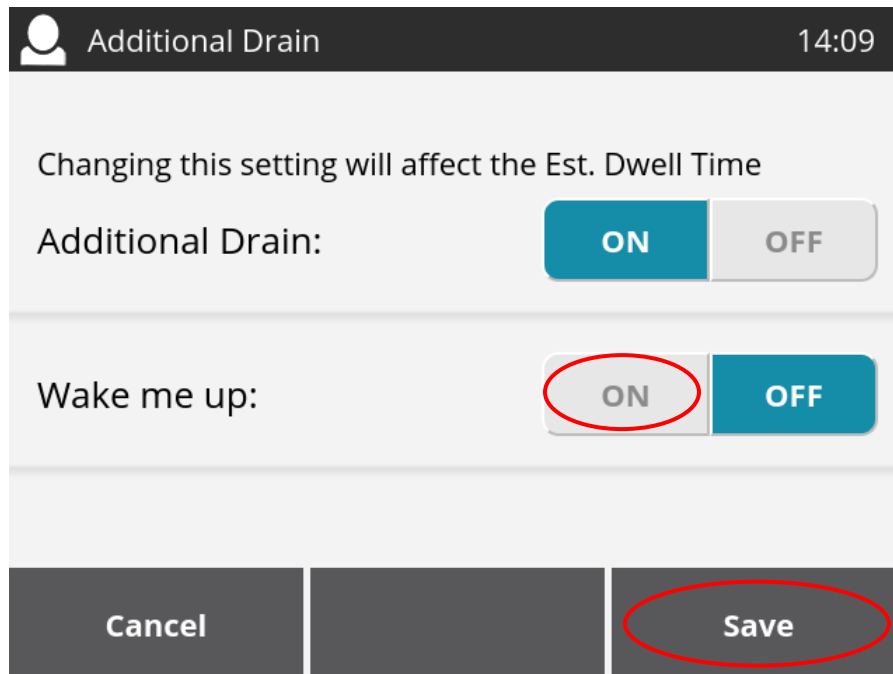
If you do have permission, you can set both an additional drain and a wake-up alert on the screen shown below.

- 1 Turn on the Additional Drain option by touching the **ON** button.



Additional Drain (continued)

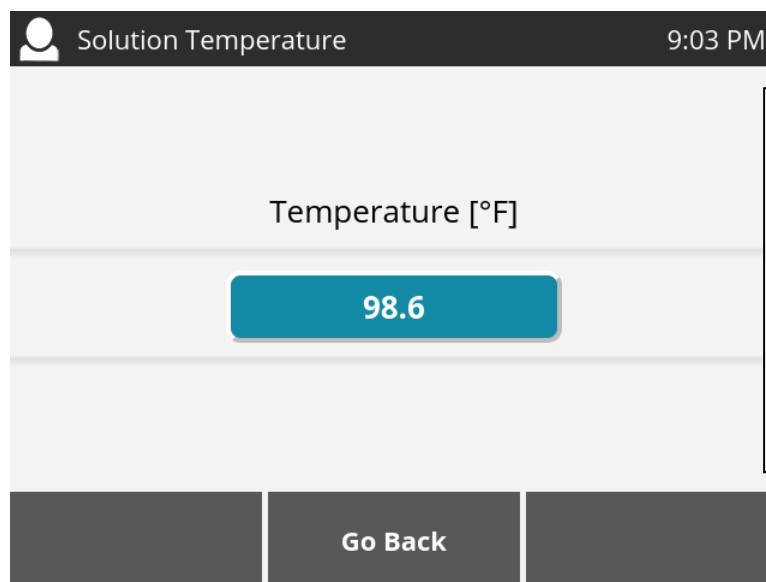
- 1 If you want an alert to wake you when it is time for your additional drain, touch the **ON** button next to **Wake me up**. If you choose not to have an alarm, you can do the Additional Drain when you wake up.
- 2 Touch the **Save** button to complete your selection.



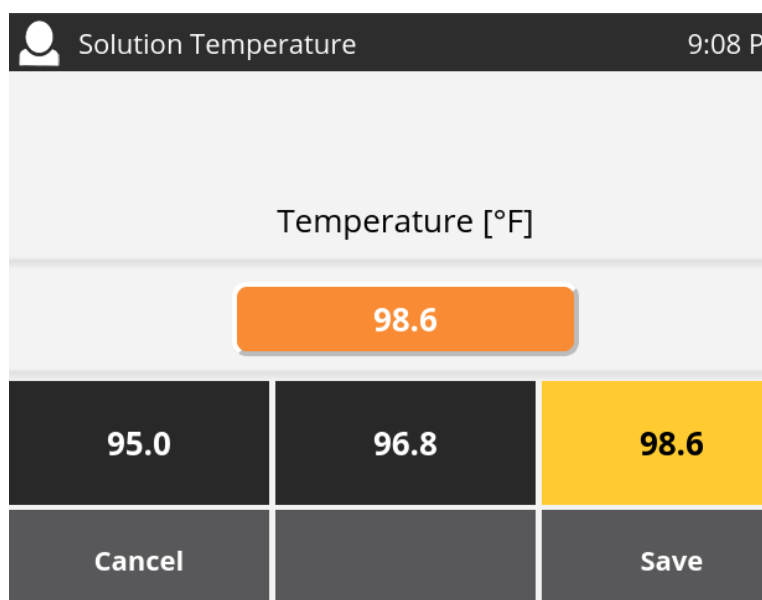
Solution Temperature

Sometimes the dialysis solution may feel too warm or too cold for your comfort. If your home therapy nurse has given you permission, you have the option of changing the solution temperature (if not, the button will be gray and not available). The default setting is 96.8°F (36°C).

To reach this screen, touch these buttons in sequence:



1 Touch the blue button to highlight it. It will turn orange. A new screen will appear like the one shown below.

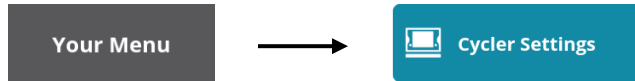


2 Touch the temperature you want and then touch **Save**. Your home therapy nurse will determine if the temperatures are displayed in Fahrenheit or Celsius.

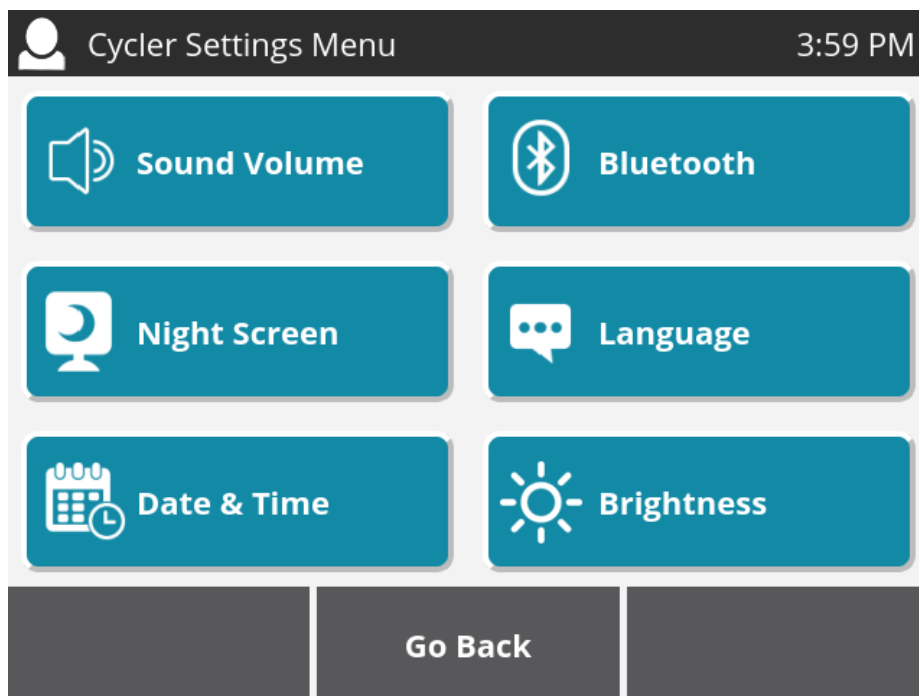
3 Touch **Go Back** to complete the entry.

Cycler Settings







To reach this screen, touch in sequence the buttons:



In this menu you can program various settings for your convenience and comfort on this screen.



- 1 Touch any blue button to view or change the setting associated with that button.

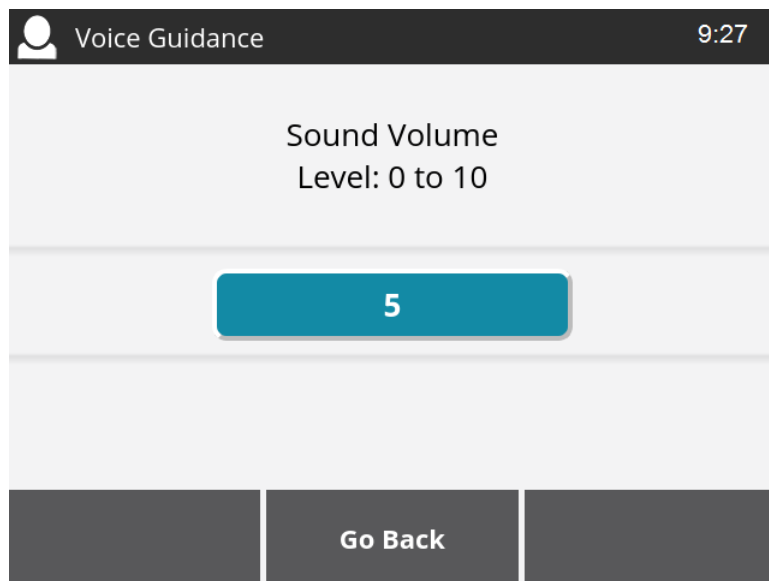
Cycler Settings Menu Button	Instructions
	<p>Touch Sound Volume to raise or lower the volume of the alarm tone and the voice guidance. Choose from a scale of 0 to 10 for voice guidance and 1 to 10 for alarms. Alarm volume cannot be turned off. See page 117 for more information.</p>
	<p>Touch Night Screen to tell the cycler how long to wait before darkening the screen when you go to bed. When the screen is dark you can “wake it up” by touching it. See page 118 for more information.</p>
	<p>Touch Date & Time to set the time. See page 119 for more information.</p>
	<p>A compatible Bluetooth scale and blood pressure monitor, in conjunction with the Kinexus Gateway, can be used to transmit readings to your center. Touch Bluetooth to enable pairing for the devices. See page 40 for more information.</p>
	<p>Touch Language to choose between English and Spanish. Messages on the screen as well as voice guidance will be in your chosen language. See page 120 for more information.</p>
	<p>Touch Brightness to set the brightness level for your screen display. See page 121 for more information.</p>

Set the Sound Volume

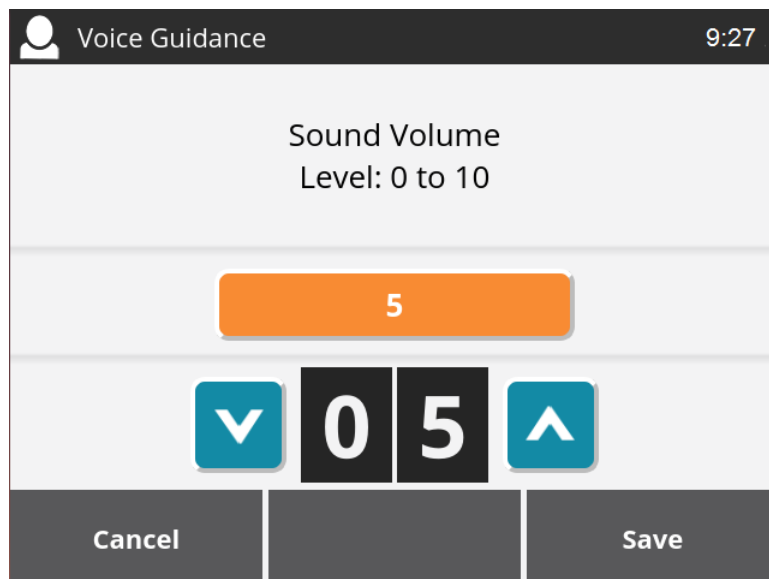
Use this screen to adjust the volume of the voice guidance and the alarm tones. To reach this screen, touch these buttons in sequence:



The screen will give you a choice between **Voice Guidance** and **Alarms**. Touch the button you want to change. The alarm volume cannot be turned off.



1 Touch the blue box to highlight it. It will turn orange.



2 Use the **down** arrow to lower the volume or the **up** arrow to increase it. A ping will indicate the new volume.

3 Touch **Save** to confirm your choice.

4 Touch **Go Back** to proceed.

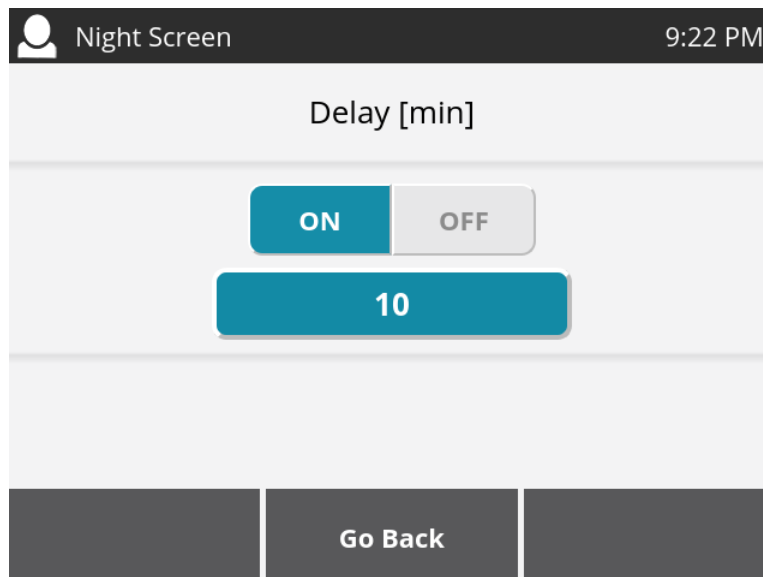
Night Screen

If the Night Screen option is set to **ON** and the screen has not been touched for a certain amount of time, the display will go dark to avoid disturbing your sleep. This option allows you to set the amount of time that the screen display will remain lit after being touched. The lowest setting possible is one minute and the highest is 60 minutes. If you want the screen to always remain lit, touch the **OFF** button on the screen shown below.

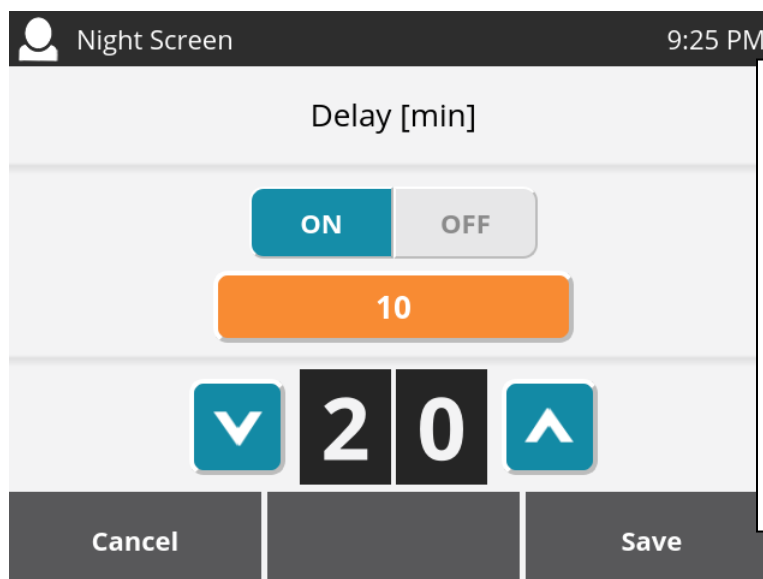
To reach this screen, touch these buttons in sequence:



The screen below appears:



1 Touch the blue box where the time value is displayed. It will turn orange.



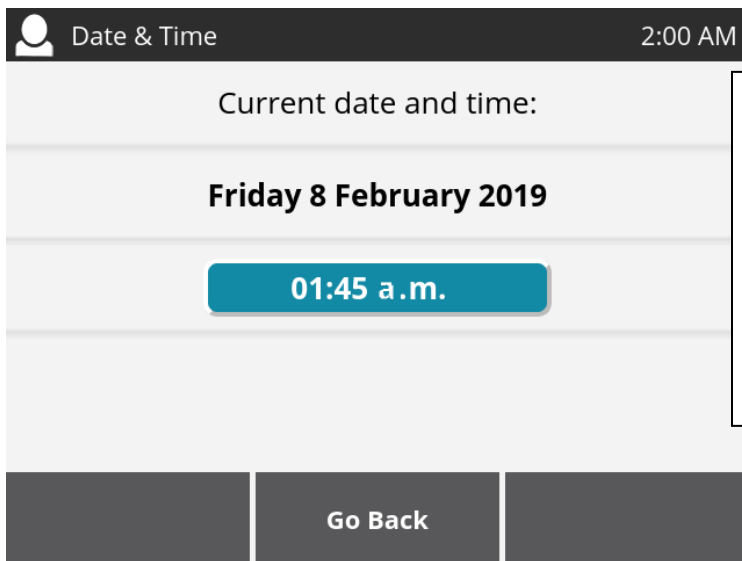
2 Use the **down** arrow to decrease the time delay or the **up** arrow to increase it.

3 Touch **Save** to confirm your choice.

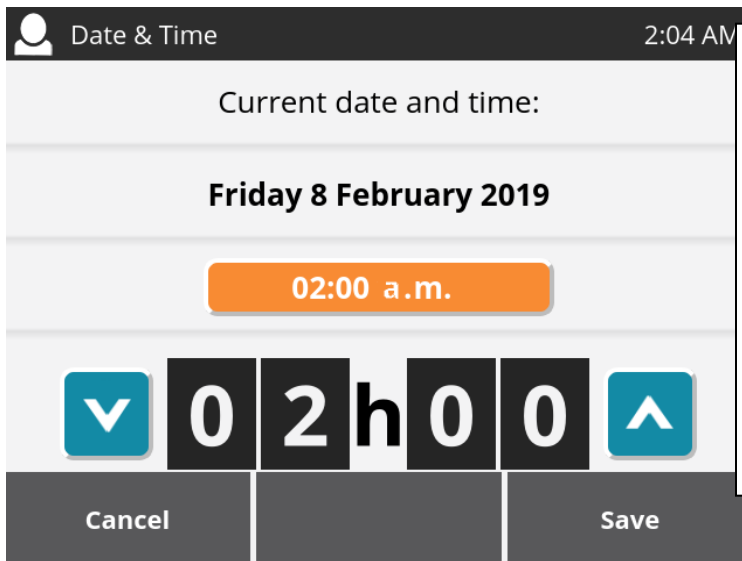
4 Touch **Go Back** to proceed.

Time Entry

You may need to set the time on your VersiPD Cycler when it first arrives or after changes from between daylight savings and standard time. The month, day and year will change automatically. The time cannot be set after starting treatment. To reach this screen, touch these buttons in sequence:



1 Touch the blue box where the time is displayed. It will turn orange and the screen shown below will appear.

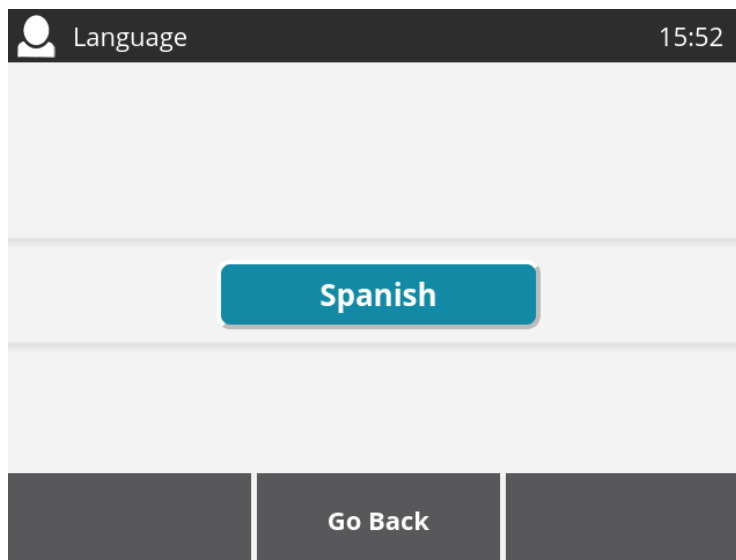


2 Use the **down** arrow to make the time earlier or the **up** arrow to make it later.
3 Touch **Save** to confirm your choice.
4 Touch **Go Back** to proceed.

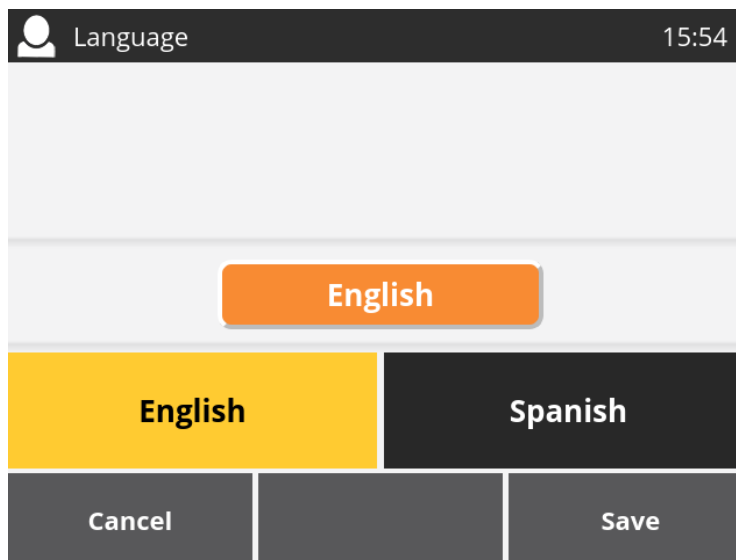
Language Choice

Your VersiPD Cyclor can speak and write to you in English or Spanish. Keep in mind that language cannot be changed after treatment has started.

To choose your language preference, touch these buttons in sequence:



1 Touch the blue box to highlight it. It will turn orange.



2 Touch the box with the language that you want to use. It will turn yellow.

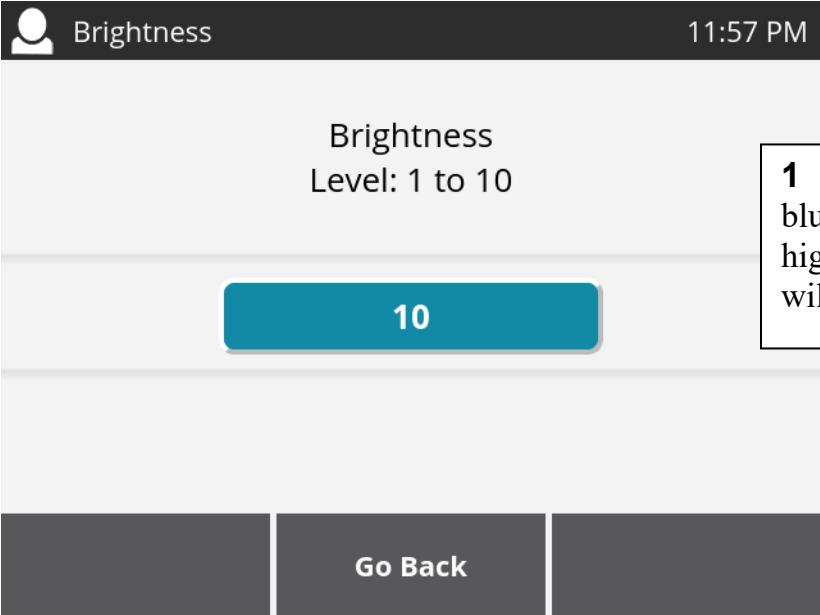
3 Touch **Save** to confirm your choice.

4 Touch **Go Back** to proceed.

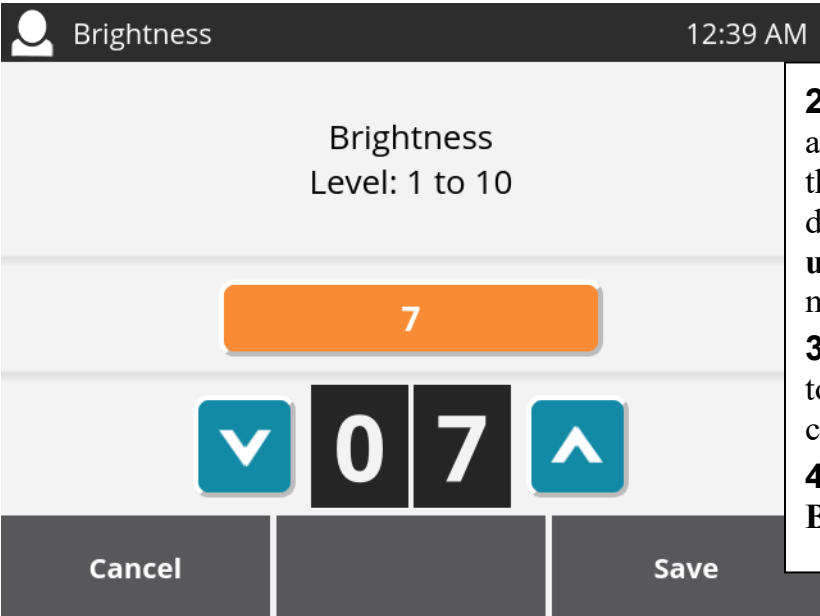
5 Touch the **Standby** button. The language change does not take effect until the cyclor is re-started.

Screen Brightness

You can adjust the brightness of the display screen to a level that is comfortable for you. To reach this screen, touch in sequence the buttons:



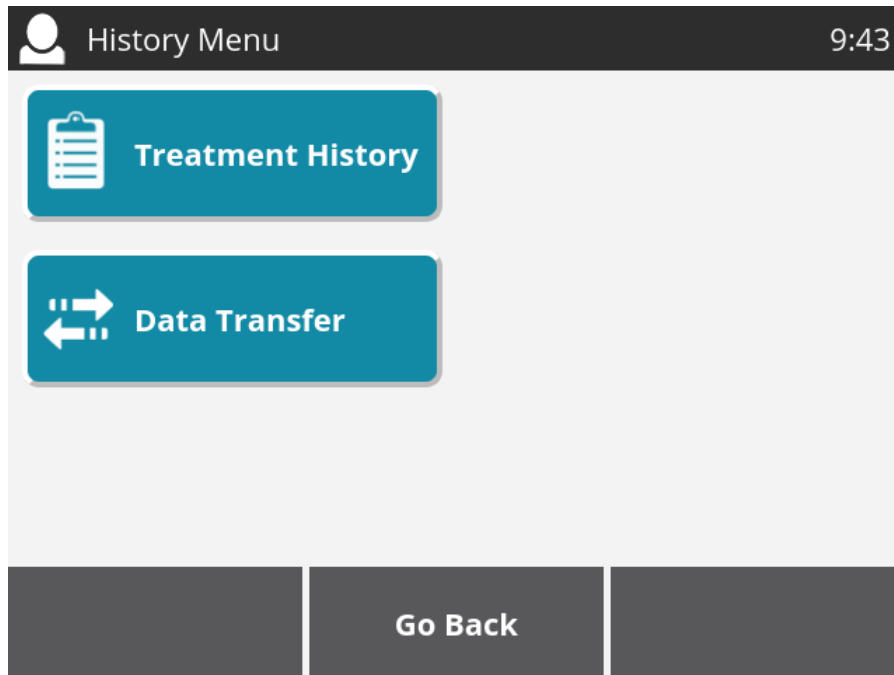
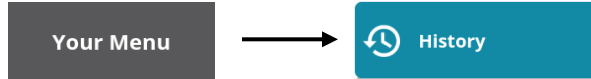
1 Touch the blue box to highlight it. It will turn orange.





2 Use the **down** arrow to make the screen dimmer and the **up** arrow to make it brighter.
3 Touch **Save** to confirm your choice.
4 Touch **Go Back** to proceed.

History Menu

To reach this screen, touch in sequence the buttons:



Button	Description
	Touch this button to review data from past treatments. The last 14 treatments are available for review. See the next page for more information.
	Touch this button to send data to your dialysis clinic using a USB drive. This button is not available during treatment. See page 125 for more information.

Treatment History

To reach this screen, touch in sequence the buttons:



This screen displays your treatments, beginning with the most recent. Grey buttons are inactive. Each line is not a separate treatment, but represents an instance when the cyclor was turned on and off. Touch a date to display treatment details.

Treatment Date	Delivered Vol. [mL]	UF [mL]	Events & Alarms	Total Time [hh:mm]
9 Feb 2019	0	0	1	00:00
9 Feb 2019	0	0	0	00:00
9 Feb 2019	0	0	0	00:00
9 Feb 2019	1900	1	1	07:54
9 Feb 2019	0	0	3	00:00

Go Back Page 2

A screen like the one below will appear. After reviewing, touch **Go Back**.

Treatment History: 9 Feb 2019 12:53 AM

Summary Bags Vitals Settings Cycles

	Programmed	Actual
Cycler Total Volume [L]	2.0	1.9
Cycler Total UF [mL]	0	1
Connected Time [hh:mm]	08:04	07:54
Total Cycles on Machine	4	4
Number of Events & Alarms	-	1

Go Back

Treatment History (continued)

Information about alarms and other treatment events is also available on the “Treatment History” screen.



Note: The number of alarms and events shown here may be less than the number shown on the **Cycler** tab on the next screen. The number shown there includes alarms outside of treatment.

To display details of alarm events, touch the blue box where the number of events is shown.

Treatment History					1:02 AM
Treatment Date	Delivered Vol. [mL]	UF [mL]	Events & Alarms	Total Time [hh:mm]	
9 Feb 2019	0	0	1	00:00	
9 Feb 2019	0	0	0	00:00	
9 Feb 2019	0	0	0	00:00	
9 Feb 2019	1900	1	1	07:54	
9 Feb 2019	0	0	3	00:00	
Page 1		Go Back			

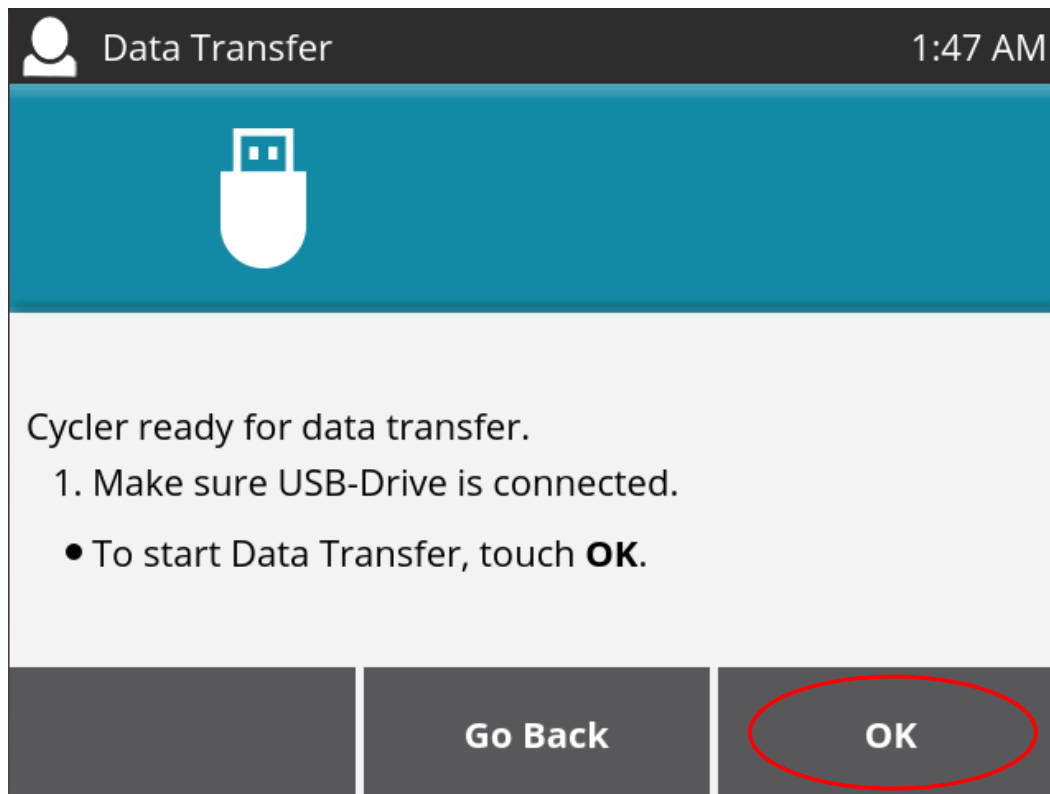
A screen like the one below will appear to help you track when these events occurred. The codes in the ID column (such as AW074 below) are explained in the Alarms section beginning on page 169.

Events & Alarms: 9 Feb 2019						1:12 AM
Occurred at [hh:mm]	Cleared at [hh:mm]	ID	Cycle	Phase	Info	
2:13 PM	2:13 PM	AW074	0	ID		
		Go Back				

Data Transfer (History Menu)

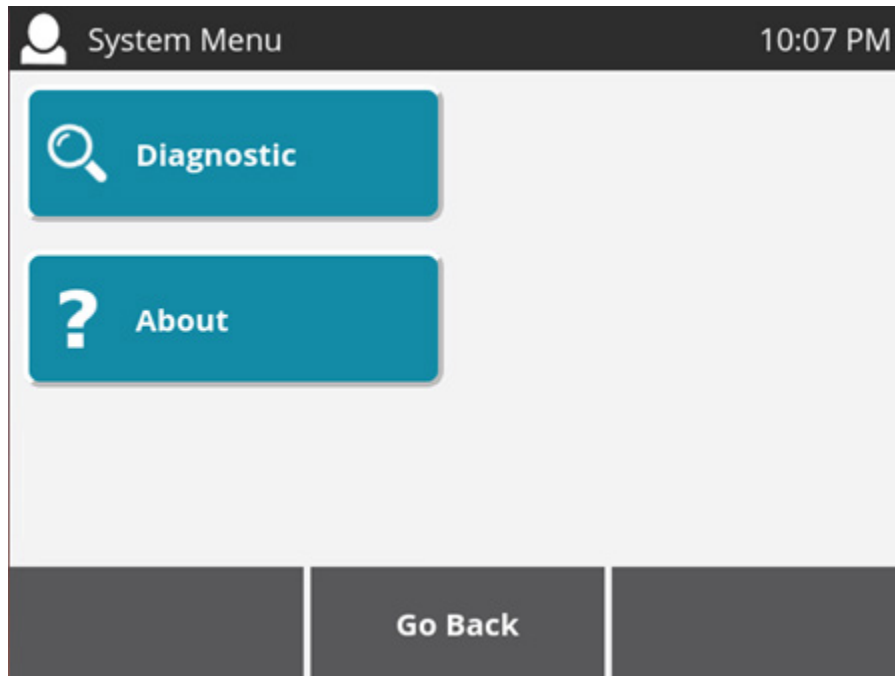
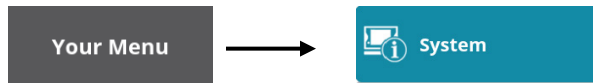
This screen allows you to send treatment information outside of the regular time for data transfer at the end of each treatment (that function is covered on page 103). This button is available after the cyclor is powered on until you touch the **START** button on the “Let’s get ready” screen. Then it becomes unavailable and remains so until the cyclor goes into Standby Mode and is turned on again.

- 1 Make sure that your USB drive is inserted in the USB port. See page 36 for a picture of how to do this.
- 2 Touch **OK**.





System Menu

During a call with Technical Support, you may be asked to access the “System Menu” screen. To reach it, touch these buttons in sequence:



The purpose of this screen is to store information that may be helpful in solving a problem that you are having with your cyclor.

Button	Description
	Touch this button to access information about your cyclor’s components or your current treatment.
	Touch this button to retrieve data about the cyclor, such as the software version and the Universal Device Identifier (UDI) numbers.

Travel Tips

The VersiPD Cycler is lightweight and easy to travel with. The VersiPD Travel Case (optional) will fit in the overhead compartment or under the seat of most commercial airplanes.

Things to consider when traveling with your cycler:

- Carry a medical necessity letter from your nephrologist.
- You cannot include the VersiPD Travel Case with your checked luggage. You must carry it on board an airplane, train or bus. If personnel want to check it, explain that it is a life-sustaining medical device and must be hand carried to avoid damage and loss.
- When using the VersiPD Travel Case, do not leave a USB drive in the cycler port. Remove it and place it in the case. Leaving the USB drive inserted could damage it or the cycler.
- Arrange to have solution, stay•safe caps, a drain option (a drain line or drain bags) and VersiPD Cycler Sets delivered to you at your destination (if needed).
- Remember that the cycler should not be more than 19 inches higher or lower than your abdomen during treatment. Most hotels have a table next to the bed that can be used for your cycler.
- Make a list of things you need, such as:
 - ✓ power cord
 - ✓ stay•safe organizer
 - ✓ extra stay•safe caps
 - ✓ line holder nest
 - ✓ masks
 - ✓ hand cleaner
 - ✓ thermometer
 - ✓ Kinexus Gateway
 - ✓ blood glucose monitor
 - ✓ blood pressure cuff
 - ✓ supplies to clean catheter exit site
 - ✓ extra adhesion strips for line holder nest



Note: Tips for travelling with medical devices can be found on the website of the Transportation Security Administration. Go to <https://www.tsa.gov/> to learn about this topic.



Note: The VersiPD Cycler does not use a lithium battery.

Accessories

VersiPD Cyclor accessories include:

1. VersiPD Cyclor Set containing a cartridge, a warming pouch, a line holder and tubing in one of the following three options:
 - 10 ft. patient line with 1 PIN Connector and 3 solution lines (2 white clamps, 1 green), and a 4 ft. drain line (P/N 050-087224)
 - 20 ft. patient line with 1 PIN Connector and 3 solution lines (2 white clamps, 1 green), and a 20 ft. drain line (P/N 050-087225)
 - 20 ft. patient line with 2 PIN Connectors and 4 solution lines (3 white clamps, 1 green), and a 20 ft. drain line (P/N 050-087226)
2. Line Holder Nest with Anchor (030-40000)
3. stay•safe Organizer (P/N 030-10807)
4. Sterile stay•safe Caps (P/N 050-95012) are protective caps for stay•safe extension sets.
5. USB Drive (P/N 130827) is a required device used to download new therapy and device settings to the cyclor and record treatment events and patient data.

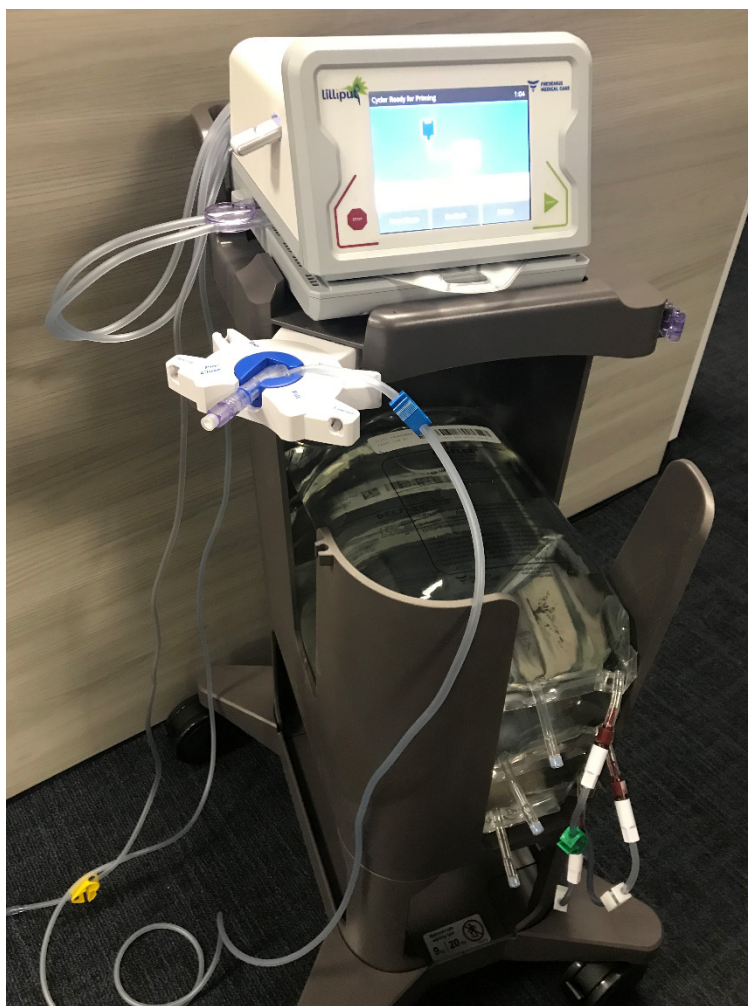
The following optional accessories are available:

6. VersiPD Travel Case (P/N 130828) is a custom case which allows the cyclor to be transported by hand and moderately protects the cyclor from damage during transport.
7. Kinexus Gateway (P/N VZ-ST) A device that allows the cyclor to receive information from Bluetooth devices such as a weighing scale or blood pressure monitor so that you don't have to enter the information manually. It also allows you to send information about your dialysis treatment to your health care team via the internet. An internet connection, or a cellular connection, is required to use the Kinexus Gateway.
8. Blood Pressure Cuff with Connected Blood Pressure Monitor (31-651B-0) (if using the Kinexus Gateway, you must use the blood pressure monitor that came with your order).

9. Bluetooth Weight Scale (P/N 36-352B-0) (if using the Kinexus Gateway, you must use the scale that came with your order). **Note:** this device has not been evaluated to ensure it meets the applicable IEC 60601-1 standards.
10. VersiPD Cart (P/N 130831) comes already assembled. Place the cyclor on the top shelf of the cart so that the line holder can fit on the notches designed for it. Make sure that the cyclor touchscreen is facing toward the opening for loading solution bags. Stack solution bags on the middle shelf with the smallest bag on top and the largest bag on the bottom. The VersiPD Cart is not intended to be moved when the cyclor is in use.

You may want to put frequently used supplies on the bottom shelf such as masks, stay•safe caps, and hand cleanser.

The photo below shows the VersiPD Cart fully loaded with solution bags.



11. Cleaning Pads
12. Dialysate Solution Bag Case (P/N 130832) is used to stack bags on a flat surface. Solution bags must not be more than 19 inches above or below the

cycler. The Dialysate Solution Bag Case is not intended to be moved when loaded.

The photo below shows the Dialysate Solution Bag Case fully loaded with solution bags.



13. Cyclor Drain Line (P/N 026-20036A): is used to extend the VersiPD Cyclor Drain Line.
14. Cyclor Drain Bag (P/N 026-20226A) FMC drain set includes three 7L drain collection bags. Drain bags feature sample ports and may be Snap[®] disconnected; bags frosted on one side and clear on the other to enhance visualization.
15. stay•safe Catheter Extension Set with Luer-Lock, 6-inch (P/N 050-95013).
16. stay•safe Catheter Extension Set with Luer-Lock, 12-inch (P/N 050-95004).
17. stay•safe Catheter Extension Set with Luer-Lock, 18-inch (P/N 050-95005)
18. stay•safe Catheter Extension Set with Safe-Lock, 12-inch (P/N 050-95001). Extension set used to connect Safe-Lock catheter adapter (co-pack) to systems with stay-safe PIN connectors.
19. Safe-Lock APD Luer Lock Connector (P/N 050-95018) is an adapter to solution containers with Luer-lock connectors. This single use device is designed to connect any VersiPD Cyclor Set with a Safe-Lock connector to a peritoneal dialysis solution bag equipped with a standard Luer-lock connector.

20. stay•safe Handi-tool (P/N 030-10810) is available for patients with limited dexterity to assist in turning the stay•safe CAPD disk, breaking cones, and loosening caps.
21. Super Klip (P/N 050-63297) holds disposable tubing to keep it from becoming kinked or dislodged.



Note: Do not share use of any of these accessories with other users of the VersiPD Cycler.



Note: Do not attempt to repair or modify these accessories. If you need a replacement item, call Customer Service at the number given below.

Ordering Supplies?

Call Customer Service at 1-800-323-5188 for information on how to order VersiPD Cycler Sets, solution bags, and optional accessories.

Nurse Menu

The Nurse Menu

The Nurse Menu is designed to help nurses arrange a customized therapy that works best for the patient’s health and lifestyle.

With this feature, nurses can allow patients to choose program options while closely monitoring their treatments. Requirements for pre- and post-treatment measurement of vital signs can be customized for each patient. Additional drain options and solution temperature can be managed through the Patient Permissions feature.

To access the Nurse Menu, touch the **Nurse Menu** button on the “Lets Get Ready” screen. The screen below will appear.



- 1 Enter the passcode provided by the clinic and touch **OK**.



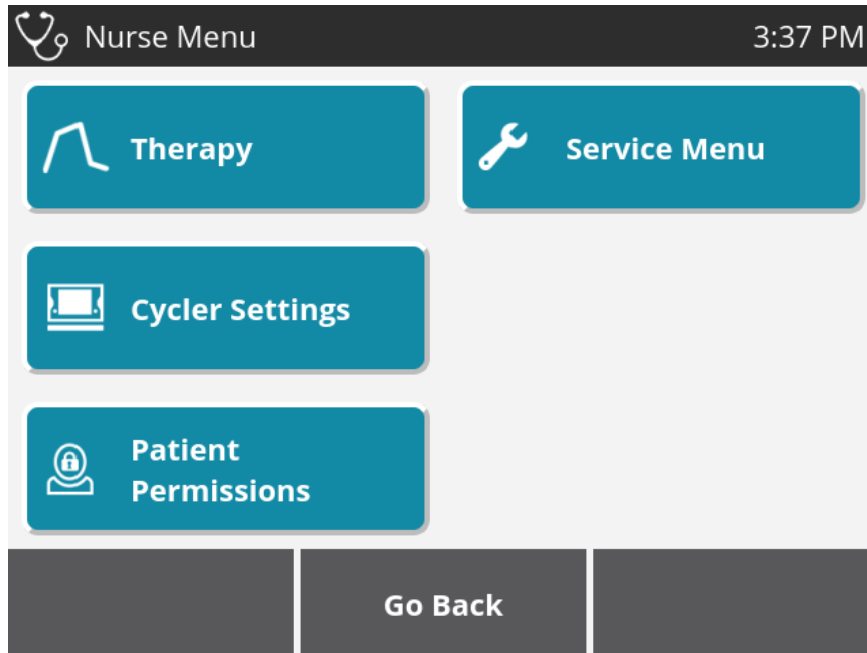
Warning: The cyclor should not be used by the patient while the Nurse Menu is active.



Note: The effect of changes made to the prescription should be evaluated using clinical and device data recorded during treatments.

Nurse Menu (continued)







The following screen with four options will appear after entry of the passcode:



- **Therapy**—This button is used to enter the patient’s program information. The nurse can also enter other settings for therapy, such as additional drain, last bag, solution temperature, flow rates, catheter performance and maximum fill volume. See page 135 for more information.
- **Cycler Settings**—This is where the nurse controls what vital signs the patient will be asked to enter, what units of measurement the dialysis clinic prefers, as well as set the New Patient and USB options. See page 158 for more information.
- **Patient Permissions**—This button enables the nurse to manage the patient’s ability to change solution temperature and additional drain options. See page 164 for more information.
- **Service Menu**— The service menu is used to upgrade the VersiPD Cycler software (see page 165) and reset the battery change date (see page 218) after changing the battery.

Therapy Button

The table below describes the secondary buttons that appear when the **Therapy** button is touched. It is recommended to set the patient's maximum flow rate, additional drain, fill volume, solution temperature and catheter performance before entering programs as some of these features affect estimated dwell time.

Button	Description
 Program	Enter the patient's program for the whole treatment. This process is described in detail on the following pages.
 Additional Drain	Enter whether the patient will have an additional drain after the last scheduled drain. This option also allows the setting of a wake-up sound to alert the patient when it is time for the additional drain. This option is described in detail on page 153.
 Solution Temperature	Enter the temperature the cyclor will use to heat the dialysis solution. See page 154 for more information.
 Flow Rate	Enter the maximum rate (in mL/min) above which the fill and drain volume should not flow. Changing these settings will affect the Estimated Dwell Time. See page 155 for more information.
 Fill Volume	Enter the patient's maximum fill volume limit. See page 156 for more information.
 Catheter Performance	Enter here whether the patient's catheter performance is low, medium, or high. For details see page 157.

Program Overview

This menu allows the nurse to store up to five programs for the patient. Programs on the VersiPD Cycler can be simple or customized to very specific patient needs and preferences.

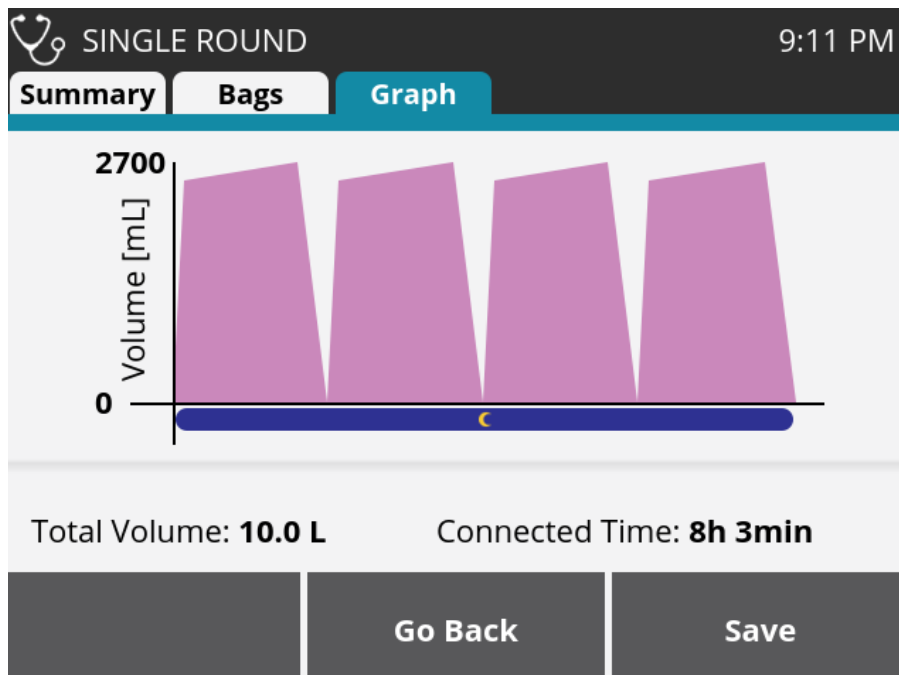
The Concept of Rounds

The round is a concept unique to the VersiPD Cycler. In most peritoneal dialysis cyclers, all cycles in the main (sleeping) portion of the treatment are identical. Only a PD+ cycle and the Last Fill cycle might be different (for an explanation of PD+, see page 246).

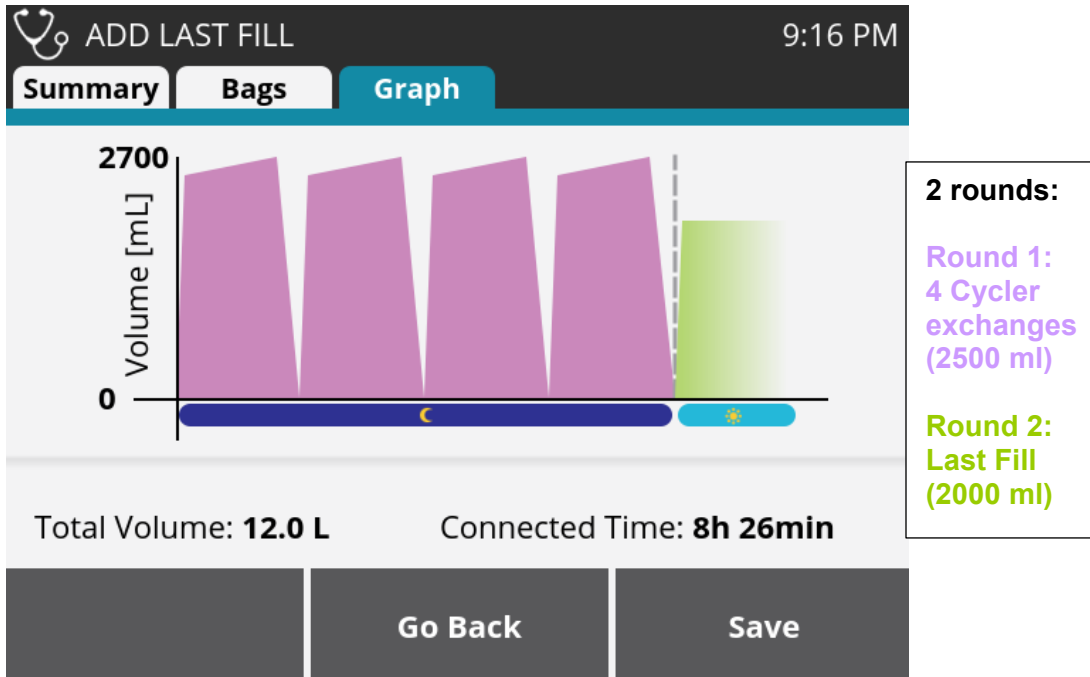
The VersiPD Cycler allows even the main portion of the treatment to be divided in such a way that each cycle, or any group of cycles, can be programmed separately. A cycle or group of identical cycles is called a round.

Programming by Rounds

A program can be simple, consisting of one round. An example of a single round program is shown below: 2500 ml fill for 4 cycles over 8 hours with 100% drain volume. Ultrafiltration is set at 200 ml per cycle, so the expected drain volume is 2700 ml (for an explanation of ultrafiltration, see page 248).

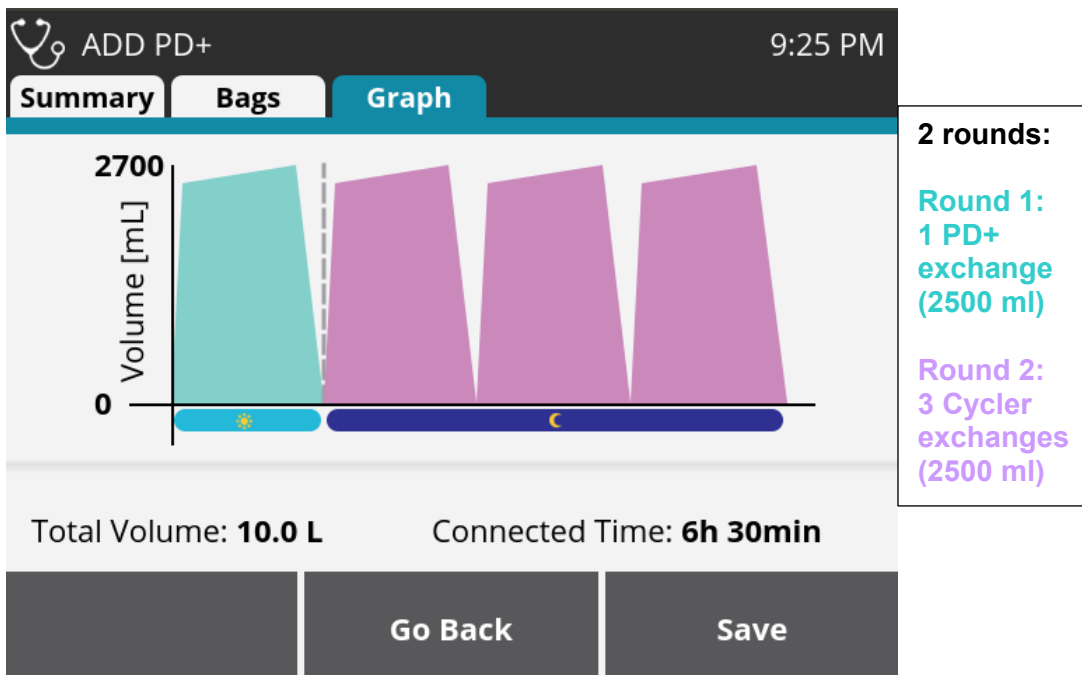


If a 2000 ml Last Fill is added to the Single Round program example above, it becomes a two-round program as shown below. The gray dashed line on the graph separates the two rounds.

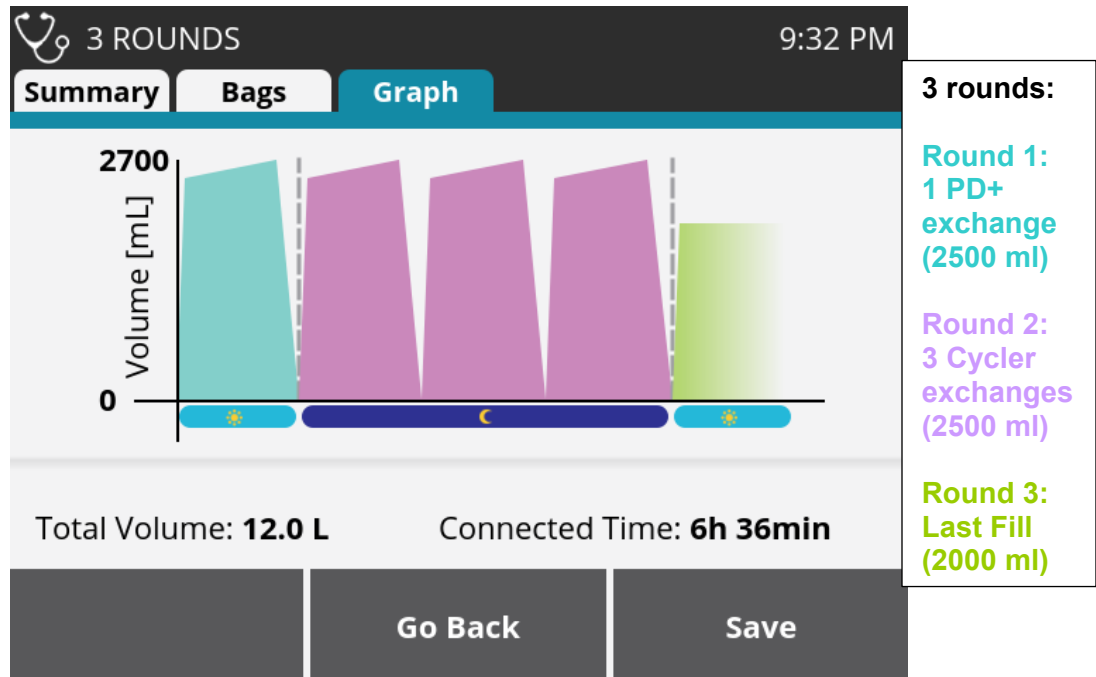


Nurse
Menu

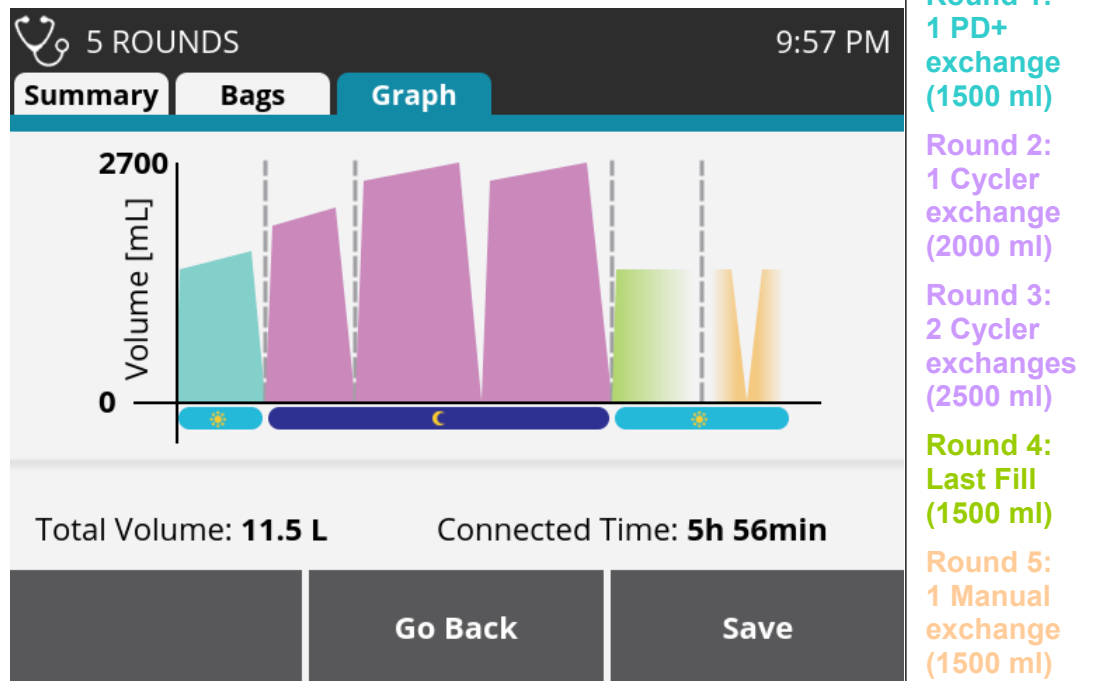
Maybe the patient in the first example (the Single Round program) does not stay in bed for 8 hours and the nurse wants to use PD+ to decrease the time he is on the cycler at night. That would also be a two-round program, decreasing the connected time to 6 hours and 30 minutes as shown below.



If this program is changed to use both PD+ and Last Fill, the new program will have three rounds as shown below.

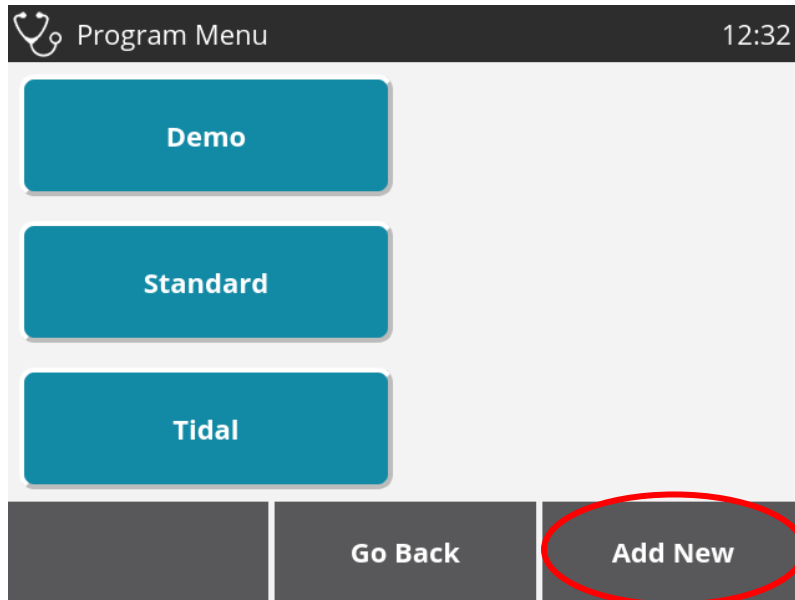


A program on the VersiPD Cycler may also use multiple rounds when customizing for a patient's needs or preferences. For instance, consider a patient who does not stay in bed for 8 hours and is also new and not comfortable with 2500 ml fills. His fill volume in PD+ and Last Fill can be decreased. The nurse can also make his first cycle a lower volume to allow him to get to sleep before increasing his volume to the desired 2500 ml, and even add a manual exchange until he is comfortable with larger fill volumes. This would result in the 5-round example below.



Program Entry

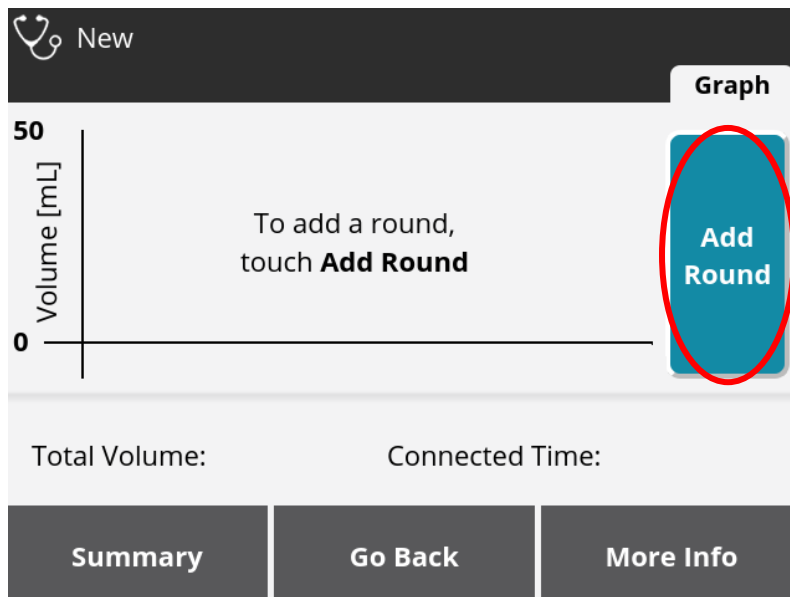
This menu allows the nurse to store up to five programs for the patient. Although sample names are given to the programs in the illustration below, nurses can give them any names they wish up to 14 digits.



To create a new program, touch the **Add New** button.



Warning: A fill volume that is too high may cause an IIPV (Overfill) situation that could result in injury or death. Follow the physician's prescription when setting the fill volume.

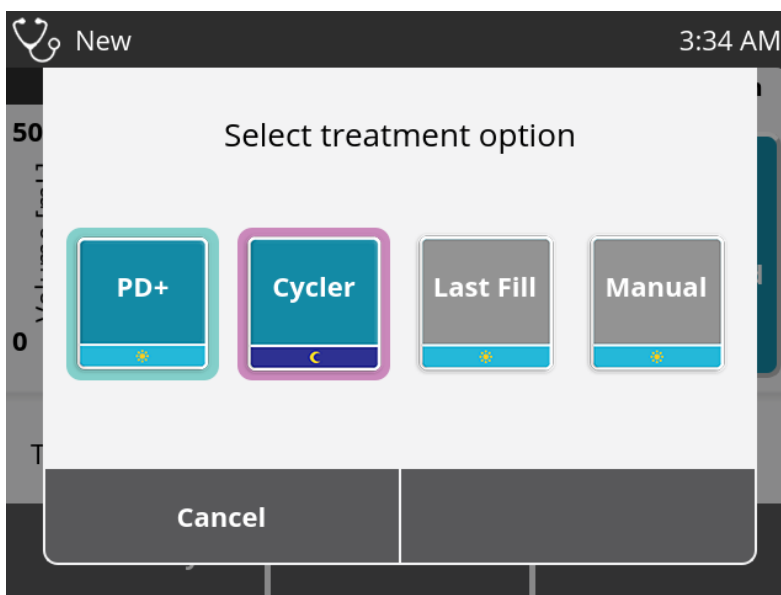




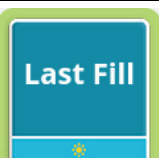

When the **Add New** button is touched, this screen appears. Next, touch **Add Round** to begin building a new program.

Select Treatment Option

Upon touching the **Add Round** button, the screen below appears. Use up to four buttons or only one to enter the therapy program. The **Cycler** button must be used for all programs.

Start with the **PD+** button and work from left to right through the others. If not entering a PD+ exchange, start with the **Cycler** button.



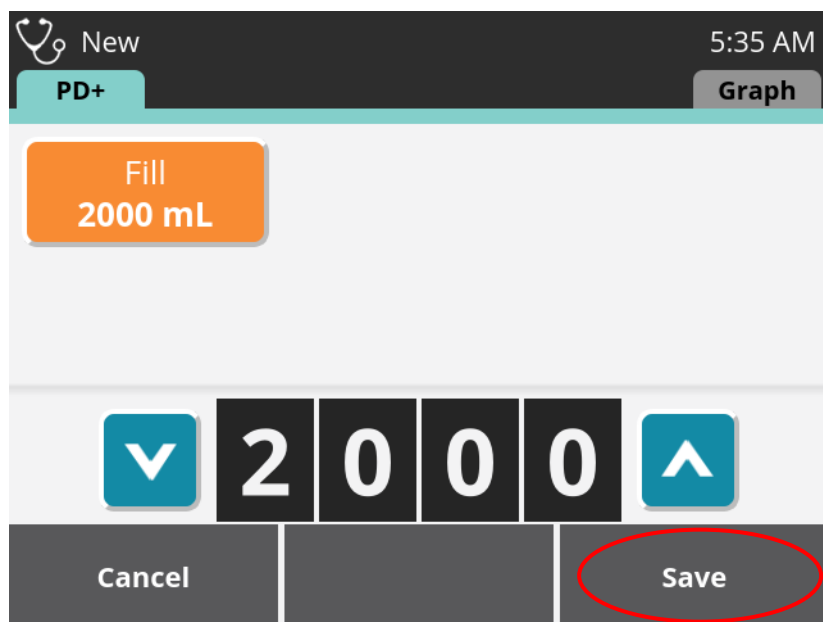
Button	Description
	Touch this button and then OK . Program an exchange that will be followed by a period of disconnection from the cycler before the main treatment begins. PD+ is one round only. See page 141 for details.
	Touch this button and then OK . Set parameters for the main portion of the treatment. A Cycler program can have one round or multiple rounds with one or more cycles each. Vary fill volumes and dwell times by using multiple rounds. See page 143 for details.
	Touch this button and then OK . Set the fill volume for the daytime dwell. Last Fill is one round only. See page 146 for details.
	Touch this button and then OK . Enter the prescribed manual exchanges the patient should complete before the treatment. A Manual program consists of one round with one or two exchanges (multiple rounds cannot be entered). See page 148 for details.

The PD+ option

The **PD+** option is designed for maximum flexibility in arranging the patient's schedule. It can be used to avoid a long daytime dwell or to shorten attached hours if the patient doesn't sleep the necessary amount for adequate therapy. Program the cyclers to do one exchange anytime during the day, then disconnect. Resume the treatment at bedtime. A PD+ program is one round only. It is optional and requires a VersiPD Cycler Set with two PIN connectors.



Warning: Always use a new PIN connector to connect to the cycler. If you have to temporarily disconnect from the cycler before the end of the scheduled treatment time, you must use a new PIN connector to reconnect and resume the treatment. You must use aseptic technique to disconnect the used PIN connector and then prepare the unused PIN connector for your reconnection. You must not connect yourself with the same PIN connector twice.

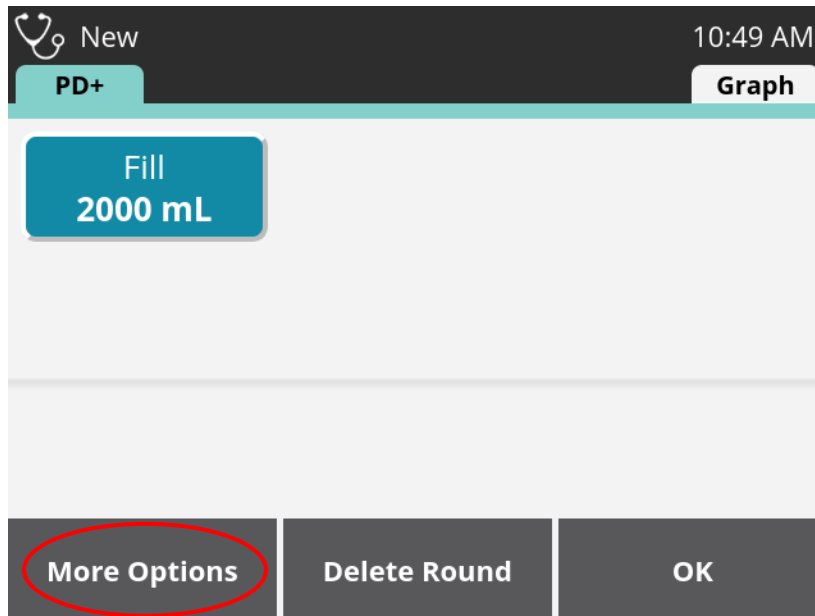


- 1 Touch the blue **Fill** button to highlight it. It will turn orange.
- 2 Touch the **up** button to increase the value or the **down** button to decrease it.
- 3 When the value is correct, touch **Save** to confirm the setting.

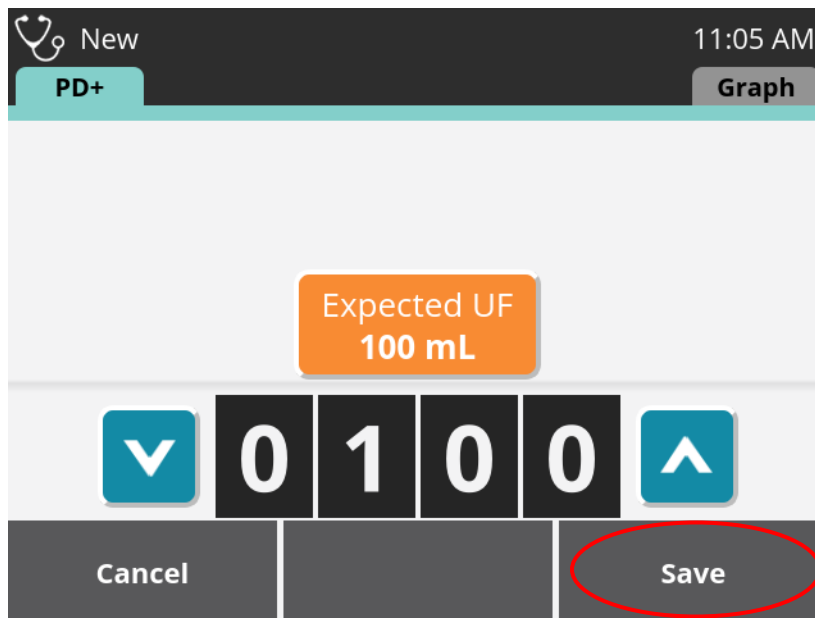


Note: The PD+ portion of the treatment must be entered first. Once the Cycler portion is entered, you cannot go back to PD+ except to edit the volume.

The PD+ option (continued)



- 4 To set the expected ultrafiltration for the PD+ round, touch the **More Options** button after saving the Fill Volume.



- 5 Touch the **Expected UF** button and then use the up and down arrows to set the desired amount. Touch **Save** and then **Back to Settings** to complete the entry.
- 6 Touch the **OK** button to go back to the Add Round screen.

Cycler Program

The **Cycler** screen is where the nurse enters the information for the main (typically sleeping) portion of the treatment program. The parameters for fill volume, number of cycles, and volume are linked so that when two of them are entered, the third is calculated automatically. Additional parameters are the time for the round and drain percentage. Estimated dwell time is calculated automatically.

The screenshot shows the 'Cycler' screen with the following parameters and controls:

- Top bar: 'New' (with a heart icon), '3:20 AM', and tabs for 'PD+', 'Cycler' (selected), and 'Graph'.
- Parameters (each in a button):
 - Fill: 1000 mL (orange button)
 - Cycles: 4 (teal button)
 - Volume: 4.0 L (teal button)
 - Time: 7h 0min (teal button)
 - Est. Dwell Time: 1h 31min (teal button)
 - Drain: 100% (teal button)
- Input area: A numeric keypad with a down arrow on the left and an up arrow on the right. The current value is 1000.
- Bottom bar: 'Cancel' and 'Save' buttons.

- 1 Touch a blue button to select it. It will turn orange.
- 2 Use the **up** arrow to increase the value and the **down** arrow to decrease it. Touch **Save** to confirm the new value. Repeat steps 1 and 2 for all the other values to be entered.
- 3 When all the new values have been saved, if there is no expected ultrafiltration value to be added, touch **Graph**. If desired, access the Last Fill or Manual screens by touching the **Add Round** button.
- 4 To add an expected ultrafiltration value for the Cycler round, touch the **More Options** button. On the next screen, touch the **Expected UF** button and use the up and down arrows to set the amount in the same way as for the Fill Volume. Touch **Save** and then **Back to Settings** to complete the entry.








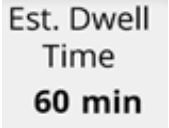
Warning: Failure to set expected ultrafiltration volume during Tidal treatment may lead to the accumulation of fluid in the peritoneal cavity.

Cycler Program (continued)

- Once all desired values have been entered, touch **OK** to return to the “Add Round” screen. If no more rounds are desired, touch **Continue** to move on to the Bags Configuration screen.

Therapy Program entry buttons

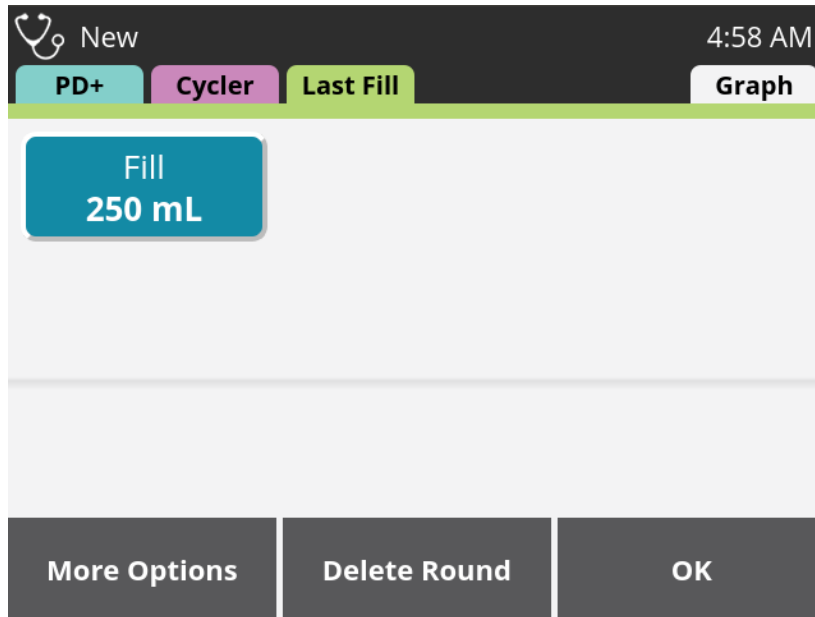
Button	Description
<div style="background-color: #0070C0; color: white; padding: 5px; text-align: center;"> Fill 2500 mL </div>	Enter the fill volume for the round here.  Warning: A fill volume that is too high may cause an IIPV (Overfill) situation that could result in injury or death. Follow the physician’s prescription when setting the fill volume.
<div style="background-color: #0070C0; color: white; padding: 5px; text-align: center;"> Cycles 2 </div>	Enter the number of cycles for the treatment here. A cycle is an exchange that includes a fill, dwell and drain.
<div style="background-color: #0070C0; color: white; padding: 5px; text-align: center;"> Volume 5.0 L </div>	The cycler will calculate the total volume for the round after the fill volume and number of cycles are entered. This is not the Total Volume for the treatment, which is accessed by touching the Summary button on the Add Round screen.
<div style="background-color: #0070C0; color: white; padding: 5px; text-align: center;"> Time 1h 30min </div>	Enter the total time for the round here.
<div style="background-color: #0070C0; color: white; padding: 5px; text-align: center;"> Drain 100 % </div> <div style="background-color: #0070C0; color: white; padding: 5px; text-align: center;"> Tidal 70 % </div>	Any reduction in the drain percentage below 100% constitutes Tidal Therapy. If a value less than 100 is entered, the Drain % button will change its name to Tidal and show the new drain percentage. The VersiPD Cycler automatically calculates the fills after the first cycle.  Warning: Failure to set expected ultrafiltration volume during Tidal treatment may lead to the accumulation of fluid in the peritoneal cavity.
<div style="background-color: #666; color: white; padding: 5px; text-align: center;"> More Options </div>	This button is available after the nurse has saved a value on the PD+, Cycler, Last Fill or Manual screens. It is located at the bottom left of the screen. Touch More Options to bring up a screen where the expected ultrafiltration for the round may be entered. For the Last Fill, this button also allows for selection of the Last Bag option.

Button	Description
	<p>This button appears on the “More Options” screens at the bottom left. Touch Back to Settings after saving values to return to the PD+, Cyclor, Last Fill or Manual screens, as applicable.</p>
	<p>After saving the values for one round, use this tab to return to the Add Round screen where the nurse can enter more rounds or review the graph that displays the entries so far.</p>
	<p>This button is available after saving a value on the PD+, Cyclor, Last Fill or Manual screens. It is located in the middle of the button bar at the bottom of the screen. To delete the round being edited, touch this button.</p>
	<p>The Estimated Dwell Time is not an active button. It displays a time that is calculated based on the other entries. When a new entry is made, this time will change automatically.</p>

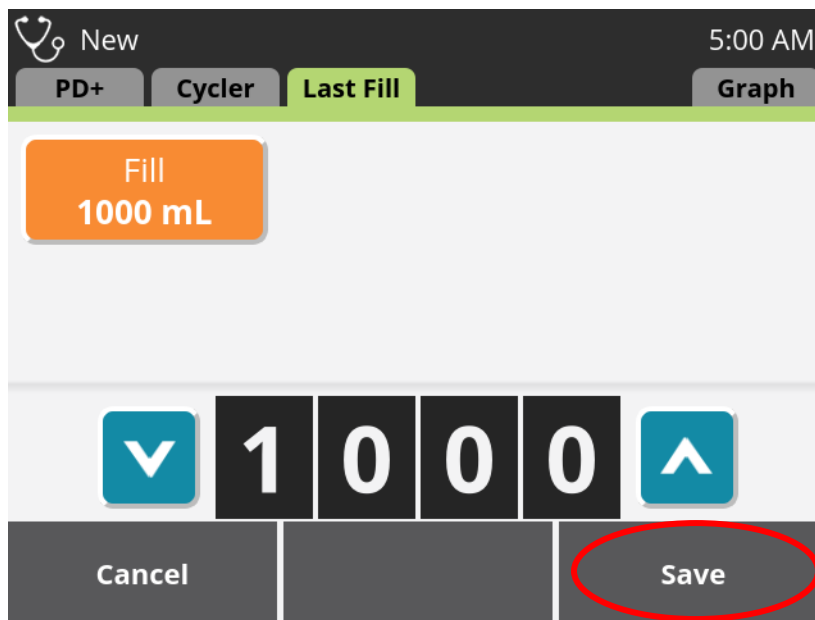
Last Fill Option

This is the place where the fill volume for a last fill for the patient's daytime dwell is entered.

Nurse
Menu



- 1 Touch the blue **Fill** button to select it. It will turn orange.



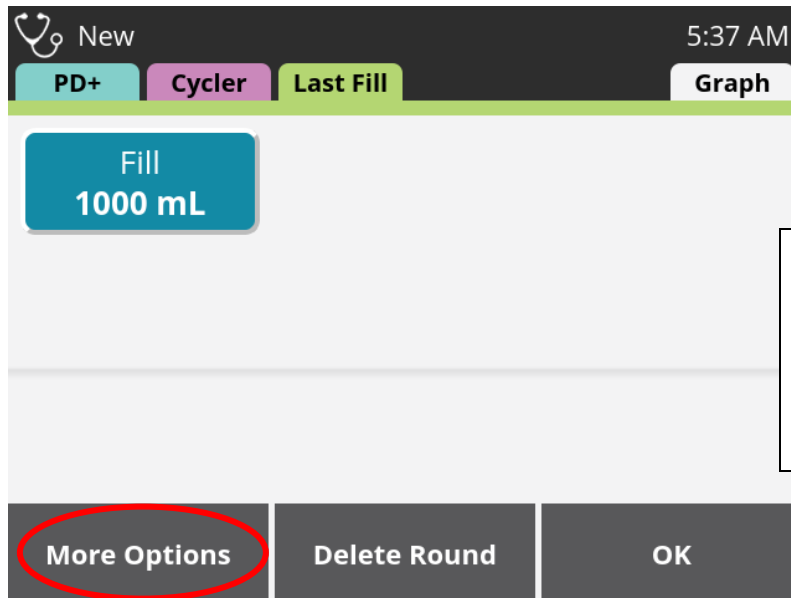
- 2 Use the **up** arrow to increase the value and the **down** arrow to decrease it.
- 3 Touch **Save** to confirm the entered value.

Last Fill Option (continued)

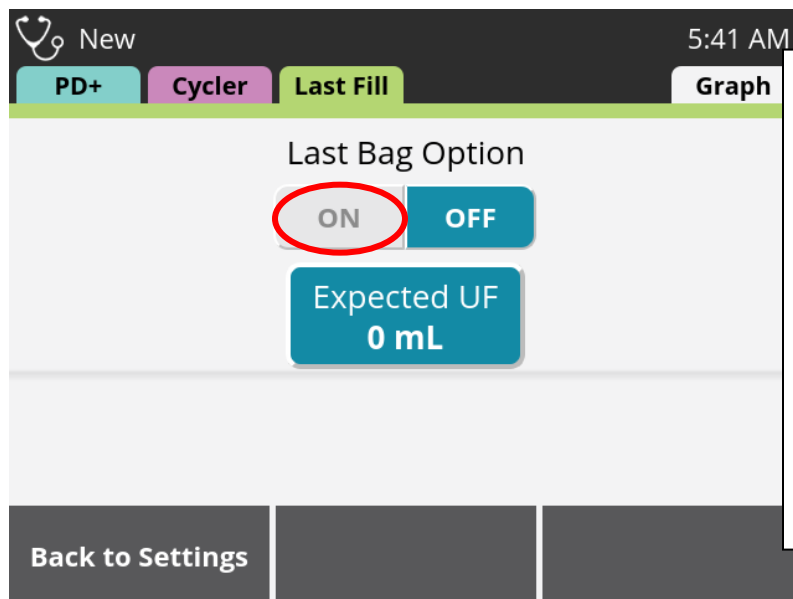
The Last Fill menu is also used to configure a Last Bag Option. Last Bag means that a separate bag will be attached to the line with the green clamp for use in the Last Fill.



Warning: If the Last Bag option is off, solution for the Last Fill will come from the same solution bag that was used for previous cycles.



4 Touch the **More Options** button. The screen below will appear.



5 Touch the **ON** button under the Last Bag Option text.

6 Touch **Save** to confirm the change.

7 Touch **Graph** to proceed.



To set the expected UF value for the Last Fill round, touch the **Expected UF** button and use the up and down arrows to set the amount just as for the Fill Volume. Touch **Save** and then **Back to Settings** buttons to complete the entry.

Manual Exchanges

If the patient's program includes a daytime manual exchange, it should be entered on this screen. One or two exchanges may be programmed. Even when no manual exchanges have been programmed in the cyclor, the patient will always be prompted at the start of treatment to enter any manual exchanges done during the day. All fill and drain volumes from the last fill and manual exchanges affect the initial drain expectation. When programmed, the expected ultrafiltration is also included in the initial drain expectation.

The screenshot shows the 'Manual Exchanges' screen. At the top, there is a status bar with a heart icon, the word 'New', and the time '5:59 AM'. Below this is a navigation bar with tabs: 'PD+', 'Cycler', 'Last Fill', 'Manual' (which is highlighted in orange), and 'Graph'. The main area contains three large buttons: 'Fill 1000 mL' (orange), 'Cycles 1' (teal), and 'Volume 1.0 L' (teal). Below these is a numeric keypad with a down arrow on the left, the digits '1', '0', '0', '0', and an up arrow on the right. At the bottom, there are three buttons: 'Cancel', a central button (partially obscured), and 'Save'.

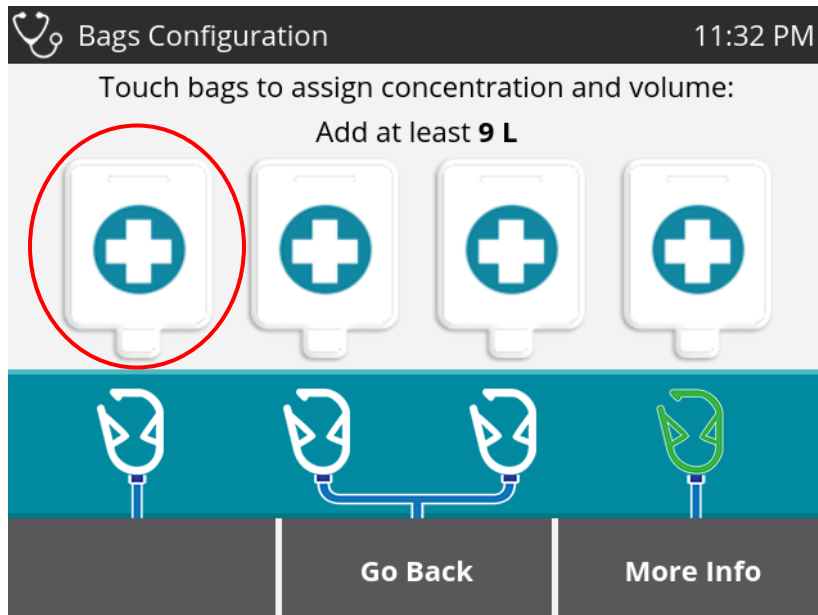
- 1 Touch a blue button to select it. It will turn orange.
- 2 Use the **up** arrow to increase the value and the **down** arrow to decrease it.
- 3 Touch **Save** to save the entered value. Follow the same process with any other values that need to be changed.
- 4 Touch **OK** to complete the entry.
- 5 Touch **Continue** to confirm all the changes and proceed to the Bags Configuration screen.



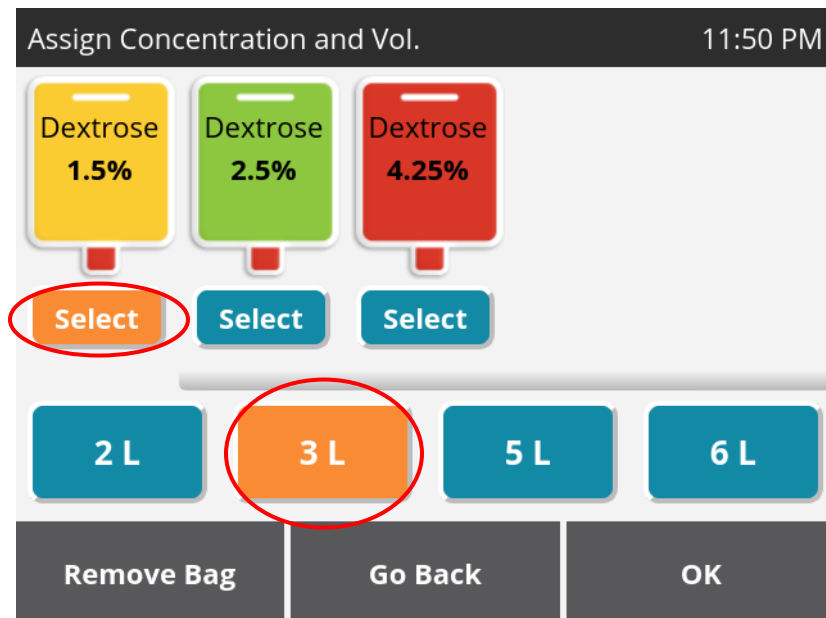
Note: To set the expected UF for the Manual Exchange, touch the **More Options** button after saving the treatment data. Then use the **up** and **down** arrows to set the amount in the same way as for the other values. Touch **Save** and then **Back to Settings** to complete the entry.

Bags Configuration

The next screen after program entry is the Bags Configuration screen. Here the volume and dextrose concentration of each solution bag is assigned.



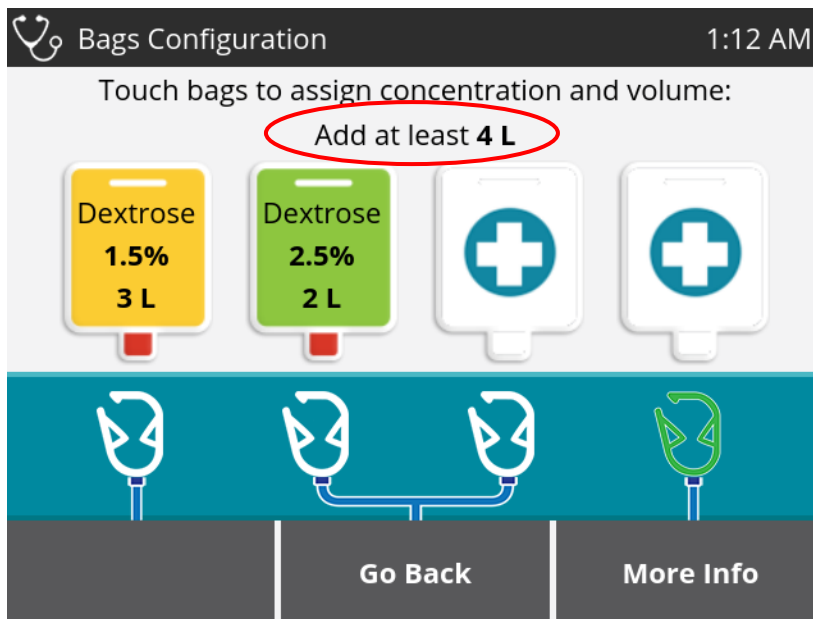
- 1 Touch one of the bags shown on the screen. A screen like the one below will appear.



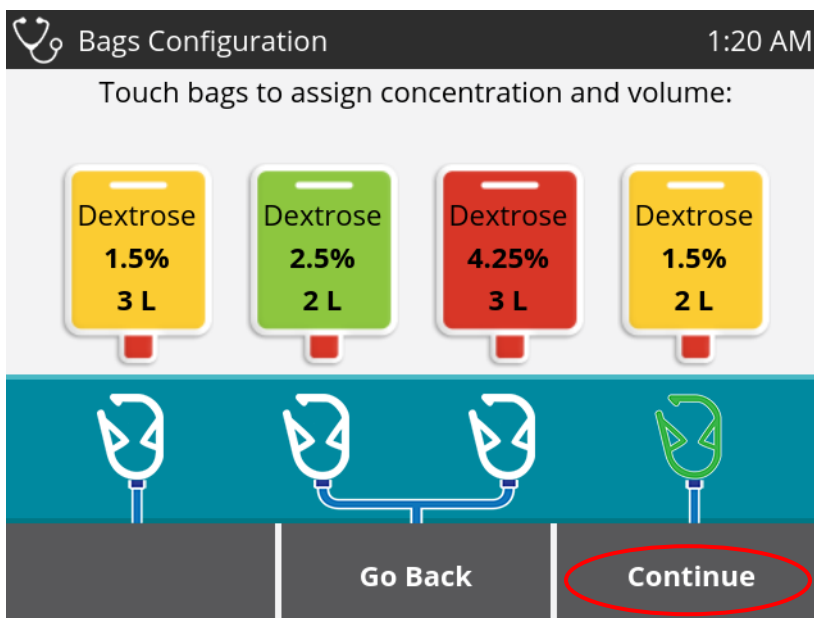
- 2 Touch a blue **Select** button to choose dextrose concentration and a blue liter (L) button to choose volume. The selected buttons will turn orange. When all the values are correct, touch **OK**.

Bags Configuration (continued)

- Follow the same procedure to configure the other bags needed to complete the patient's program. Be sure to set enough solution for the cyclor volume. The system will not let the nurse proceed until the patient's current volume is equal to or greater than total volume. In the example below, 5 liters have been added but 4 still need to be added.

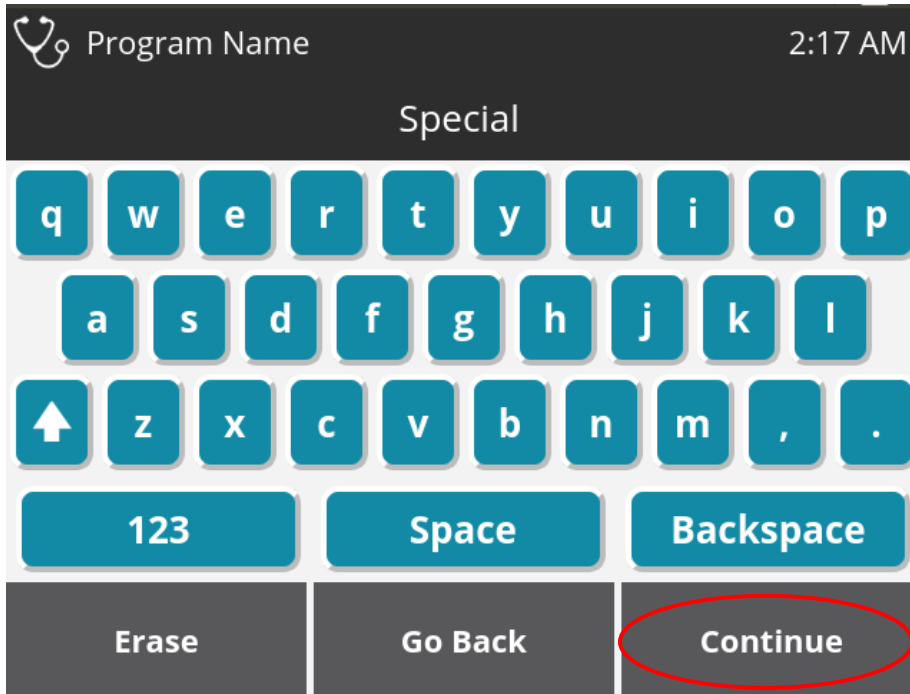


- When enough solution has been assigned to complete the therapy program, touch **Continue**. Remember that this screen is only for solution delivered by the cyclor, not that used in manual exchanges. If the Last Bag Option is on, indicate a solution bag for the green clamp line. This option must be on if a specific bag is desired for the last fill.



Naming a Program

Once the bags have been configured for a new program, the screen below will appear.



- 1 Touch the buttons to name the new program. Use the **up** arrow to display capital letters and the **123** button to display numbers. Up to 14 digits may be entered. Use the **Erase** button to delete a name and start over. This button will not delete the patient's program.
- 2 When the desired name has been entered, touch **Continue**.



Note: The patient cannot create or name a program. In Your Menu, the patient can add an additional drain if permission for it has been enabled in the Nurse Menu (the additional drain will be added to all programs). With this exception, the patient cannot edit an existing program.

Program Review

Now that the patient's program is named, review the values to make sure they are correct. Remember to review the information on the **Bags** and **Graph** tabs as well.

- 1 If the current settings are correct, touch **Save**. To make further changes, touch **Go Back** to return to the Bags Configuration or the Program screen.

Special 1:52 AM	
Summary Bags Graph	
Cyclor Total Volume [L]	9.0
Connected Time [hh:mm]	08:09
Total Cycles on Machine	5
Cyclor Total UF [mL]	400
Manual Exchange Total Volume [L]	0.0
Treatment Maximum Fill Volume [mL]	2000
Go Back Save	

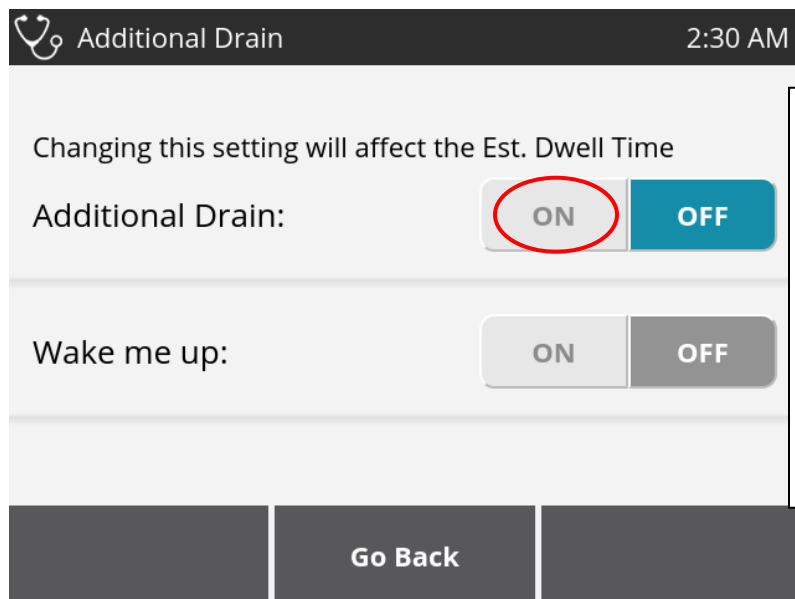
- 2 Once saved, the program will appear in the Program Menu. The nurse can still edit it by touching the **Edit/Review** button or delete it with the **Delete** button.

Program Menu 2:09 AM	
PD Plus	Tidal
Weeknight	Special
Weekend	
Edit/Review Go Back Delete	

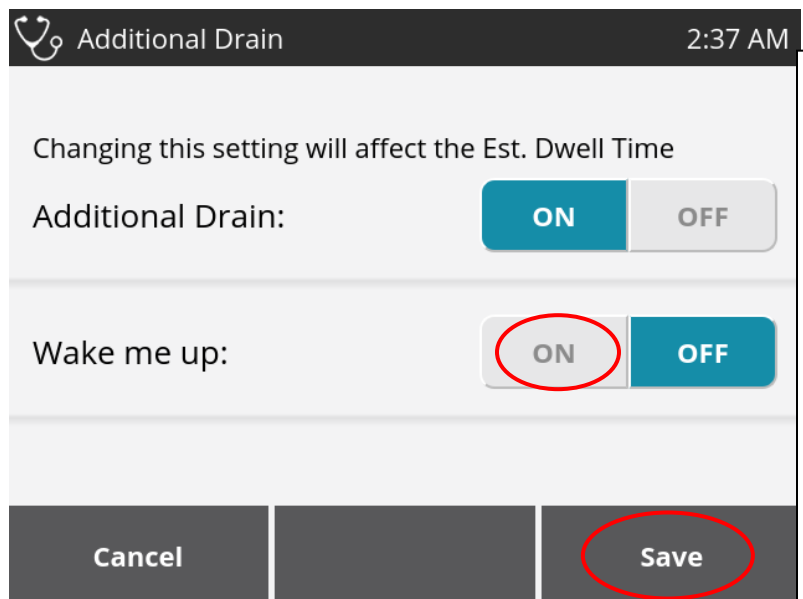
Additional Drain

To set an Additional Drain after the last scheduled drain, touch the **Additional Drain** button in the Nurse Menu. Remember that a change in this option will change the estimated dwell time of existing programs. To give the patient permission to set an additional drain, see page 164.

If the patient wants to be awakened by a pinging sound at the time when the drain is scheduled, that alert can be set on this screen.



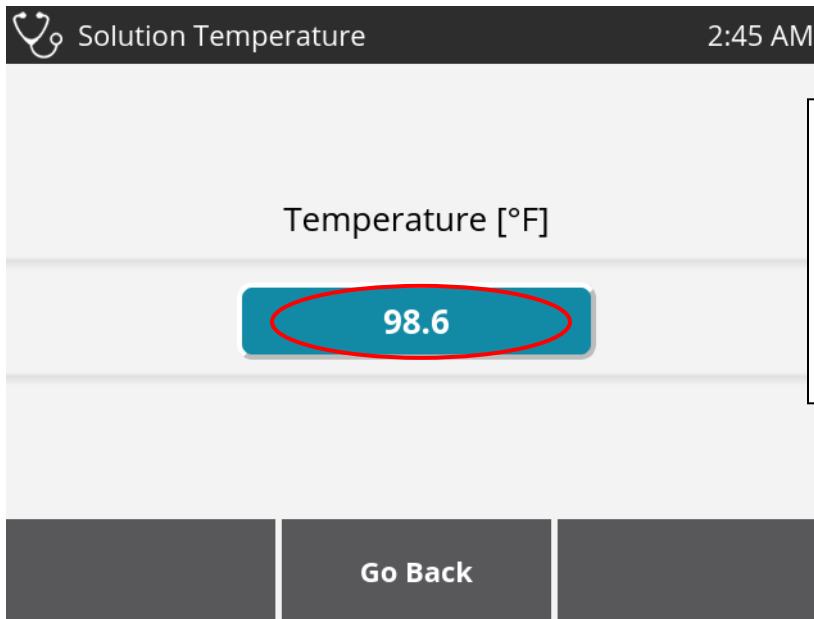
- 1** To activate the additional drain, touch the **ON** button to highlight it. It will turn blue.
- 2** Touch **Save** to confirm the change.



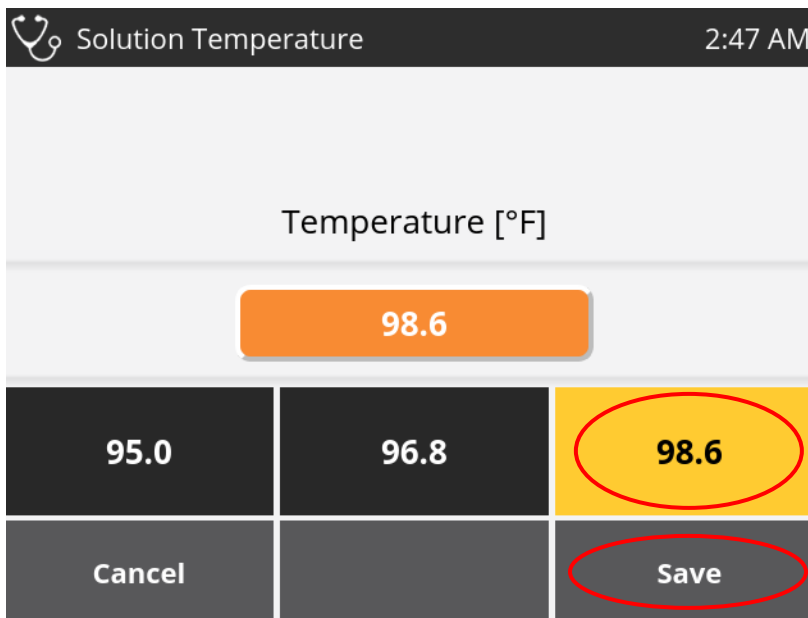
- 3** To activate the wake up alert, touch the **ON** button to highlight it. It will turn blue.
- 4** Touch **Save**.
- 5** To return to the Therapy Menu after saving, touch **Go Back**.

Solution Temperature

To set the solution temperature for the patient, go to this screen by touching the **Solution Temperature** button in the **Therapy** tab of the Nurse Menu. The default setting is 96.8°F (36°C). To give the patient permission to set solution temperature, see page 164 (if this is granted, the patient can override the program setting for this value).



1 Touch the blue **Temperature** button to highlight it. It will turn orange.



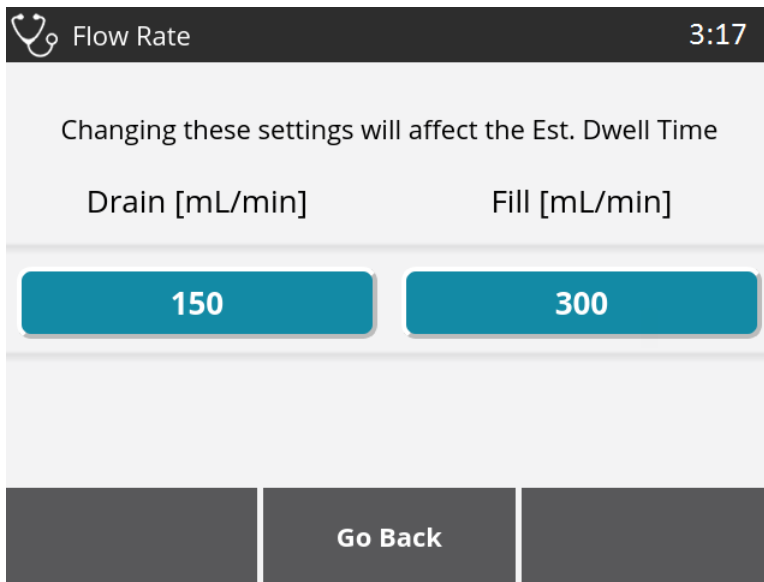
2 Touch one of the three options at the bottom of the screen. It will turn yellow.

3 Touch **Save**.

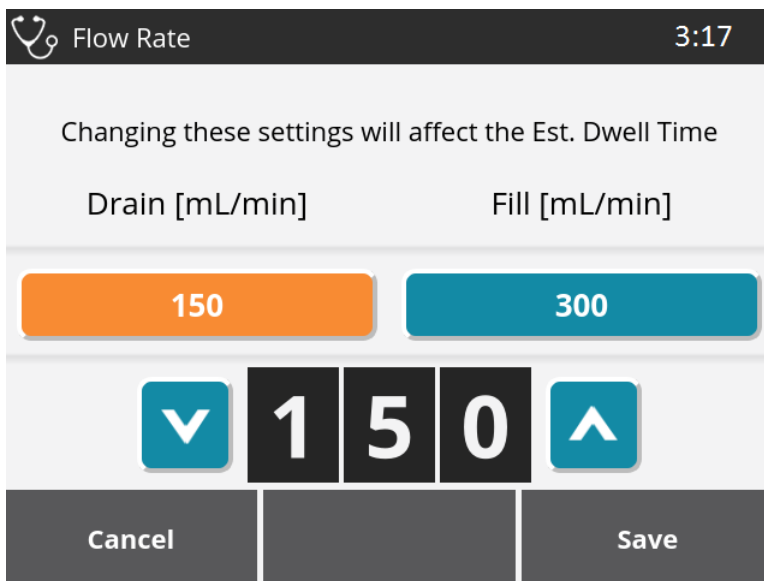
4 To return to the Therapy Menu after saving, touch **Go Back**.

Flow Rate

Navigate to this screen by touching the **Flow Rate** button in the **Therapy** tab of the Nurse Menu. This screen allows the nurse to set maximum limits for drain and fill rates in increments of 1 mL, which can be useful when setting a flow rate for patients who have drain or fill pain or a catheter with slow flow. The lowest allowable setting for drain flow rate is 100 ml/min and the highest is 250 ml/min. The lowest fill flow rate setting is 150 ml/min and the highest is 300 ml/min. Changing a maximum flow rate limit will affect the estimated dwell time of existing programs.



1 Touch a blue button. It will turn orange.



2 Use the up and down arrow buttons to set the desired value.

3 Touch **Save**.

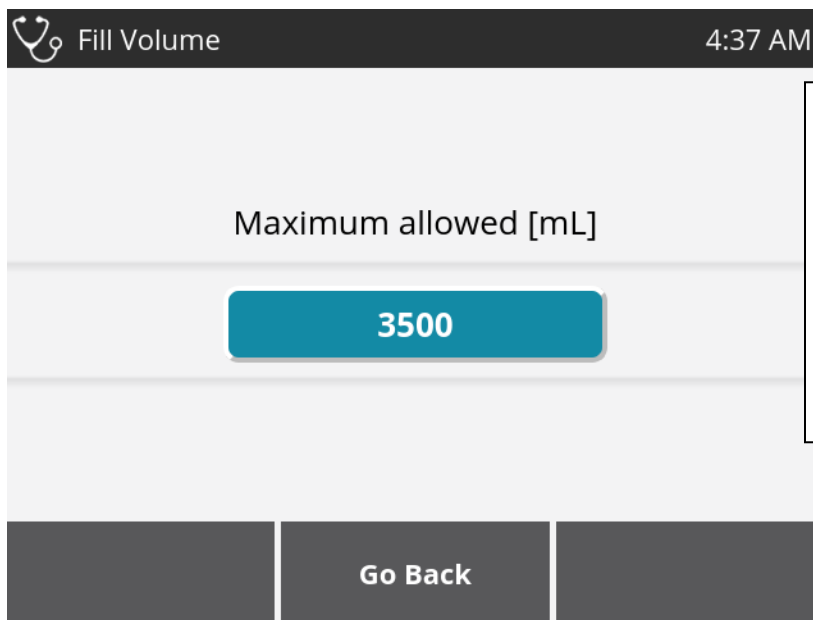
4 Touch **Go Back** to return to the Therapy Menu.

Fill Volume

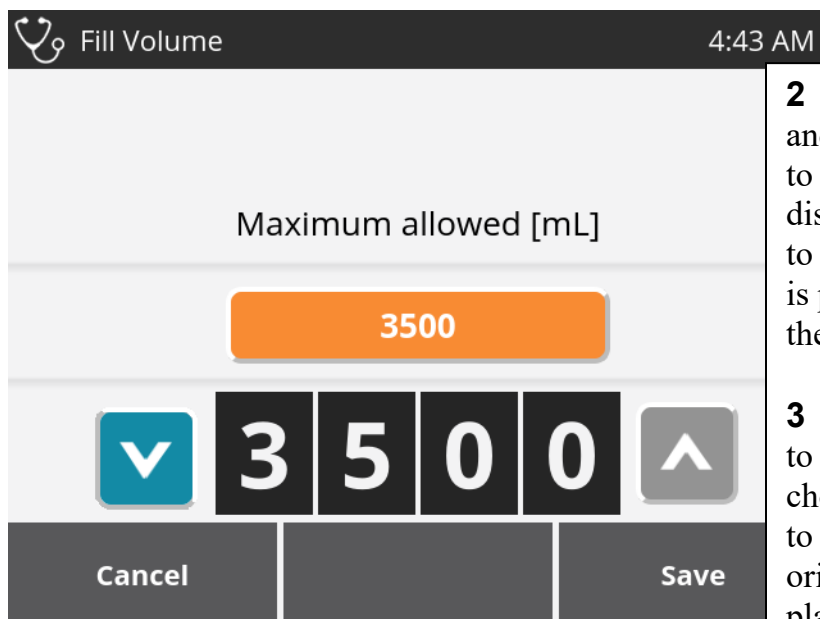
This screen is used to set a patient's maximum fill volume. A fill volume over this limit cannot be entered. This limit must be prescribed by a doctor. The maximum fill volume the cyclor will deliver is 3500 ml.



Warning: A fill volume that is too high may cause an IIPV (Overfill) situation that could result in injury or death.



1 Touch the **Max [mL]** button to highlight it. It will turn orange and the screen below will appear.

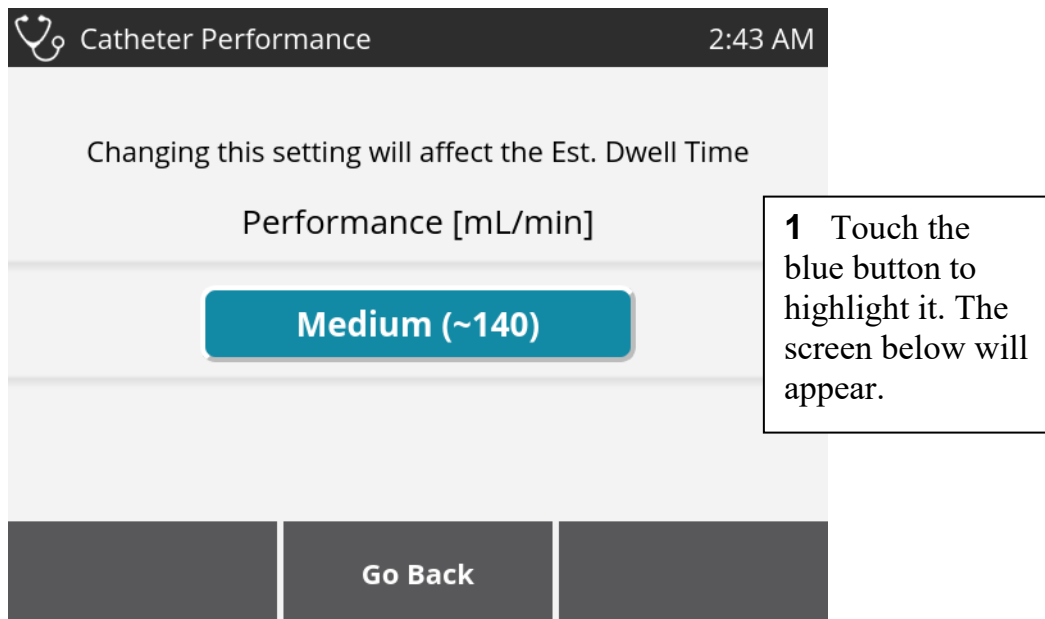


2 Use the up and down arrows to change the displayed number to the value that is prescribed for the patient.

3 Touch **Save** to confirm the choice or **Cancel** to leave the original value in place.

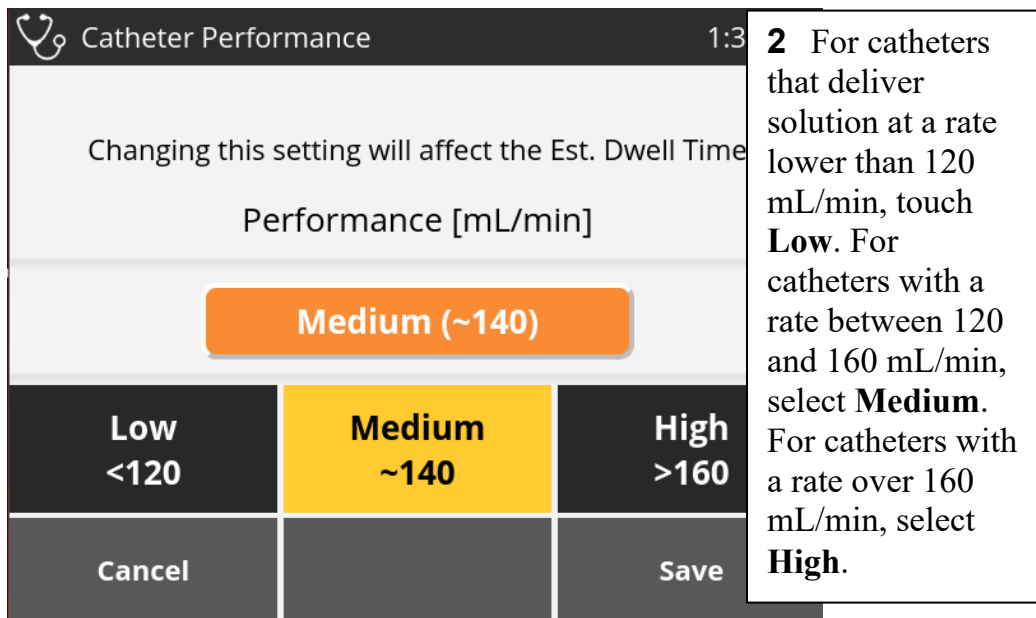
Catheter Performance

When the VersiPD Cycler calculates estimated dwell time and other values, it helps to know what level of performance the patient's catheter is capable of delivering. That information can be entered in the Therapy menu of the Nurse Menu by touching the **Catheter Performance** button. The screen shown below will appear. Setting catheter performance does not change flow rates, but does make estimated dwell time more accurate.



1 Touch the blue button to highlight it. The screen below will appear.

Nurse
Menu

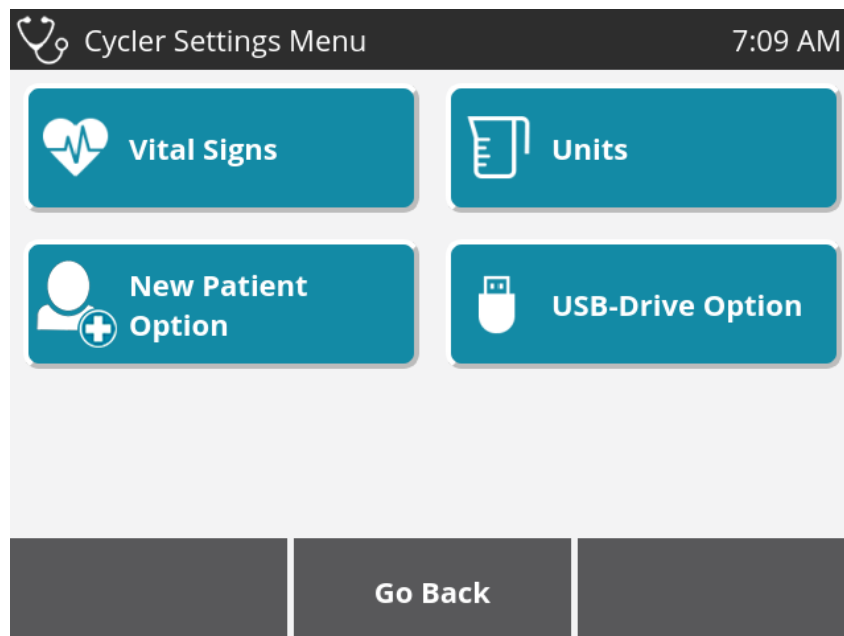






2 For catheters that deliver solution at a rate lower than 120 mL/min, touch **Low**. For catheters with a rate between 120 and 160 mL/min, select **Medium**. For catheters with a rate over 160 mL/min, select **High**.

3 Touch the **Save** button to confirm the choice or **Cancel** to leave the original setting in place.

Cycler Settings

The buttons on this screen allow the home therapy nurse to program various options related to patient therapy and convenience.



Button	Description
 Vital Signs	This button controls whether the patient is asked to enter information on vital signs like blood pressure, pulse and weight. See page 159 for details.
 Units	The system can use either standard American (Imperial) units or international (SI) units. See page 161 for details.
 New Patient Option	This option allows the nurse to enter a treatment program for a patient whose profile is not in the system. See page 162 for details.
 USB-Drive Option	This button allows the cycler to upload treatment information, download a new program and upgrade software via a USB device. See page 163 for details.

Vital Signs

Select on this screen the vital signs that the patient should record before and after treatment.


	Pre	Post
Weight	<input type="checkbox"/> ON <input type="checkbox"/> OFF	<input checked="" type="checkbox"/> ON <input type="checkbox"/> OFF
Blood Pressure	<input checked="" type="checkbox"/> ON <input type="checkbox"/> OFF	<input type="checkbox"/> ON <input checked="" type="checkbox"/> OFF
Pulse	<input type="checkbox"/> ON <input checked="" type="checkbox"/> OFF	<input type="checkbox"/> ON <input checked="" type="checkbox"/> OFF
Temperature	<input type="checkbox"/> ON <input checked="" type="checkbox"/> OFF	<input type="checkbox"/> ON <input checked="" type="checkbox"/> OFF
Blood Glucose	<input type="checkbox"/> ON <input checked="" type="checkbox"/> OFF	<input type="checkbox"/> ON <input checked="" type="checkbox"/> OFF

Cancel Save

- 1 Touch the **ON** buttons next to each vital sign to be recorded. In the example above, the patient will be prompted to record blood pressure before treatment and body weight after treatment.
- 2 Touch **Save** to confirm the setting.

Vital Signs (continued)

The table below provides the upper and lower limits, as well as the default values, for each vital sign. Imperial (U.S.) units of measure are shown first. Equivalent values in international units are in parentheses (if applicable). If the patient does not enter a vital sign, it will be reported as skipped.

 Lower Limit	Upper Limit	Default Value	
Weight	44.1 lbs. (20 kg)	881.8 lbs. (400 kg)	100 lbs. (45 kg)
Systolic Blood Pressure	20 mmHg	280 mmHg	120 mmHg
Diastolic Blood Pressure	20 mmHg	280 mmHg	80 mmHg
Pulse	30 bpm	200 bpm	70 bpm
Temperature	86°F (30°C)	113°F (45°C)	98.6°F (37°C)
Blood Glucose	20 mg/dl (1.2 Mmol/L)	700 mg/dl (38.8 Mmol/L)	80 mg/dl (4.4 Mmol/L)

Units

On this screen choose whether to display each value in standard American or international units of measurement.

Category	Unit 1	Unit 2
Time	24 h	am/pm
Weight	kg	lb
Temperature	°C	°F
Blood Glucose	mmol/L	mg/dL

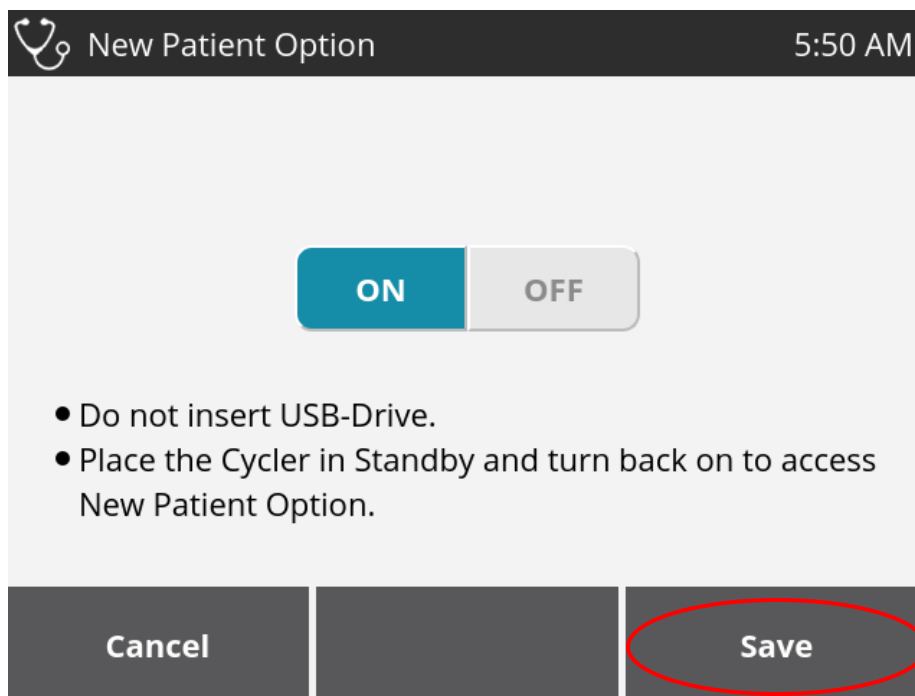
Buttons: Cancel, Save

- 1 Touch the button showing the unit of measurement that the patient will see for each value. In the above example, centigrade is chosen for temperature but standard values are chosen for time, weight and blood glucose.
- 2 Touch **Save** to confirm the choices.

New Patient Option

The New Patient Option removes the existing patient profile and programming from the VersiPD Cyclor. Treatments will be anonymous, meaning that patient identification and data will not be transmitted. Programs must be entered directly on the cyclor; a USB drive is not used in this case.

This option is intended for situations where a VersiPD Cyclor is not dedicated to one patient. For this reason, nurses treating home patients may wish to turn this option to **OFF** to prevent accidental removal of the patient profile.



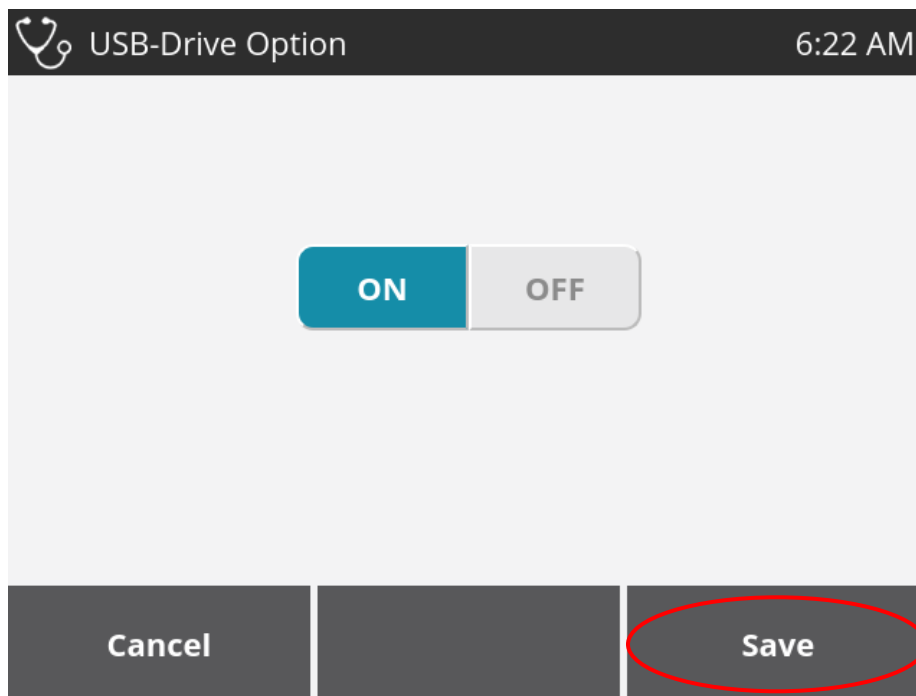
- 1 Touch the **ON** button to enable this option.
- 2 Touch **Save** to confirm the choice.

USB Drive Option

This option allows the use of a USB drive for software updates and the transmission of data between the patient and the clinic. Setting this option to ON sets up a reminder screen for the patient to insert a USB drive when the cyclor is activated (if the USB drive is not already inserted).



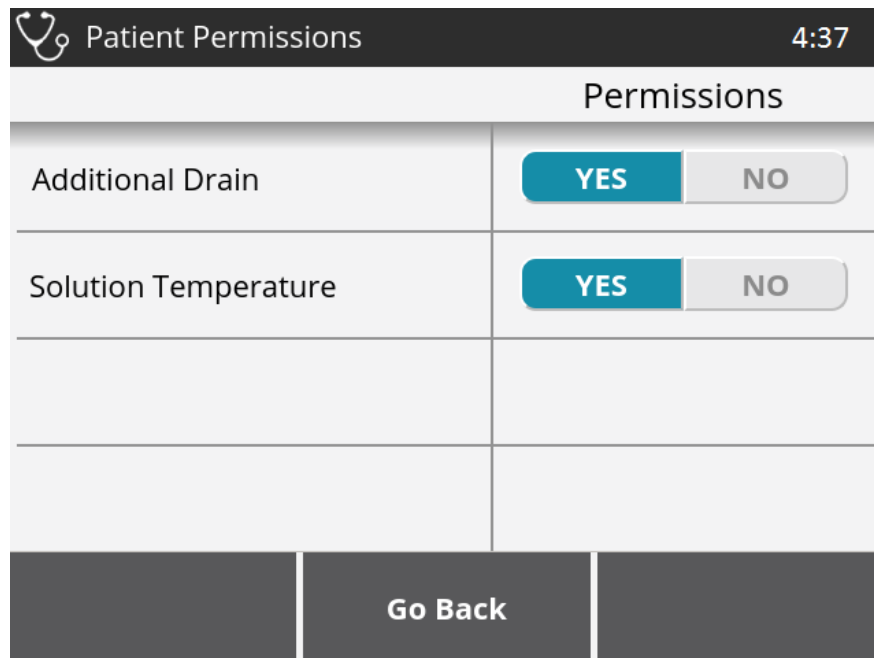
Note: Load only authorized Fresenius Medical Care software onto the VersiPD Cyclor.



- 1 Touch the **ON** button to enable this option.
- 2 Touch **Save** to confirm the choice.

Patient Permissions

On this screen the home therapy nurse may grant permission to the patient to set an additional drain or set a temperature for the dialysis solution. By default, these permissions are set to **No**.



The screenshot shows a mobile application interface titled "Patient Permissions" with a time of 4:37. The screen contains a table with two rows of permissions. The first row is "Additional Drain" with a "YES" button selected. The second row is "Solution Temperature" with a "YES" button selected. Below the table is a "Go Back" button.

Permissions	
Additional Drain	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Solution Temperature	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

Go Back

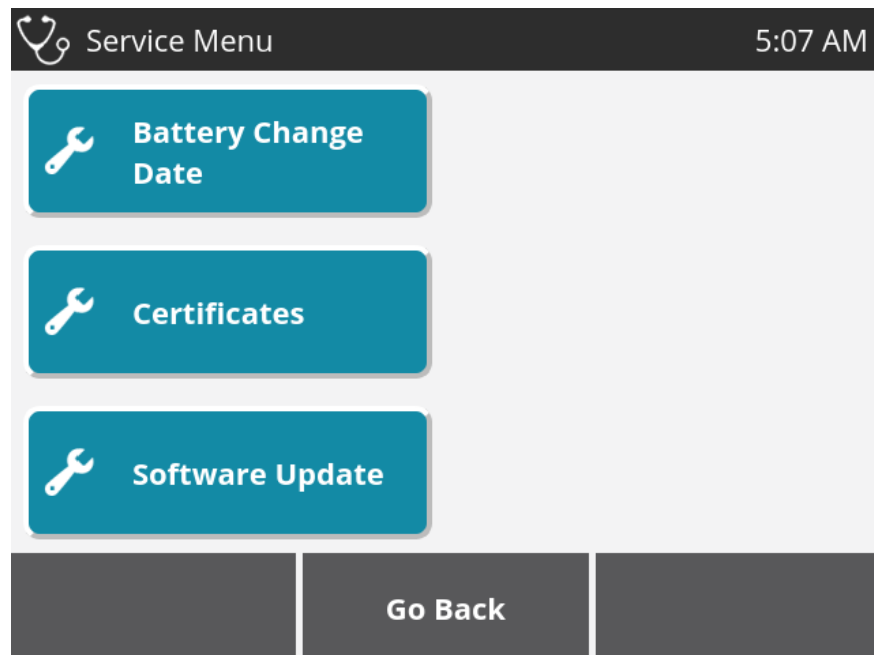
Nurse
Menu

Additional Drain—The home therapy nurse can give the patient permission to turn on or off the additional drain that has been established in the Nurse Menu.

Solution Temperature— The home therapy nurse can give the patient permission to change the temperature of the solution that has been established in the Nurse Menu.

Software Update

Touching the **Service Menu** button in the Nurse Menu brings up this screen.



- 1 If you have received a USB drive containing a software update from an authorized Fresenius Medical Care representative, touch **Software Update** to begin the process. The software version number will be at the lower right of the USB drive label.
- 2 Insert the USB drive in the USB port (see page 36 for a picture). The screen will display the message “Reading USB-Drive information...Please wait”. When the information has been read, the screen shown on the next page will appear.

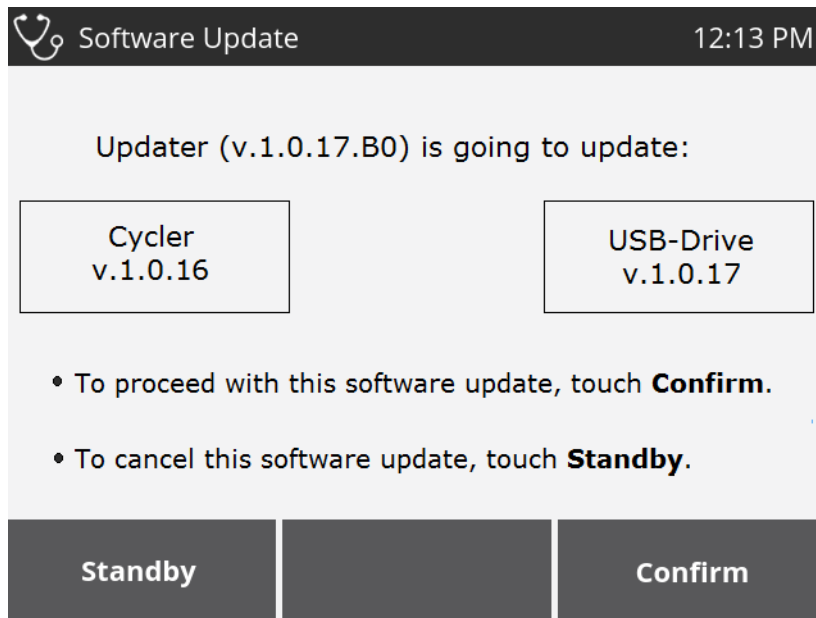


Note: The **Battery Change Date** button is explained on page 218.



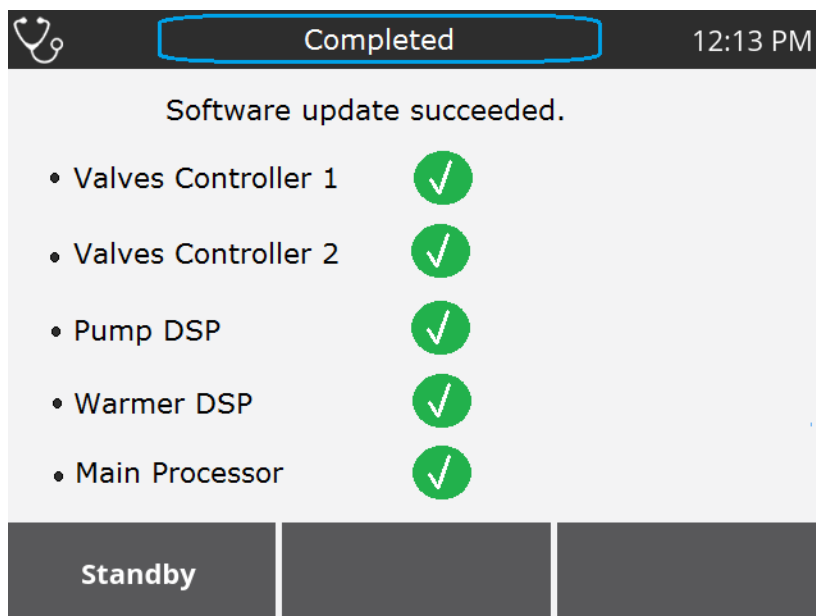
Note: The **Certificates** button is only to be used by service personnel.

Software Update (continued)



- 3 Verify that the software version number under “USB-Drive” (on the right in the illustration above) is higher than the number under “Cyclor” (shown on the left). The software version number is the last two numbers only. If the number is higher, press **Confirm**. The update should take about 15 minutes. As the update continues, check marks show progress as seen in the illustration below. It is not necessary to remain with the cyclor during the update.

If the “USB-Drive” version number is lower than the “Cyclor” version number, call Technical Services at 1-800-227-2572.



Software Update (continued)

- 4** If the update is successful, a screen message will appear saying “Software update succeeded”. All items will be checked and the **Standby** button will be displayed. Place the cyclor in standby mode and remove the USB drive. Keep it until all necessary updates have been completed.

If the update fails, a message will appear saying “Update failed”. Call Technical Services to report the failure.

- 5** Return the USB programmed with the software update and the list of cyclors updated in the return envelope.




Alarms and Troubleshooting

Alarms

The VersiPD Cycler features advanced technical support and patient troubleshooting capabilities. These resources enhance the ability to determine the cause of alarms and identify user corrective actions. Fresenius Medical Care Technical Support may request you enter the **Diagnostic Screen** during a telephone conversation with them. Double press the **START** button to enter the Diagnostic Screen. Technical Support will guide you to the information they need to help you. If you need to replace your cycler, Technical Support will make this decision at the end of the most recent treatment, after that all data is evaluated. Clinical evaluation of catheter function, review of program settings, or follow-up patient education may be requested to prevent an unnecessary swap of a cycler.

Alarm Types

There are three classifications of alarms in VersiPD.

- ❖ *Warning alarms* are identified with the color red  and an error code starting with the letters AW. Warnings require you to act and usually mean you will not be able to continue the current treatment. A warning alarm is an event that needs your immediate attention. They are identified by a red triangle containing an exclamation point. Continue to page 179 for more information.
- ❖ *Caution alarms* are signaled by the color yellow  and an error code starting with the letters AC. They require you to act to resolve the issue so that you can continue your treatment. See page 192 for more information.
- ❖ *Notice alarms* Notices are signaled by the color blue  and an error code starting with the letters AN. They inform you of a situation happening during your treatment and usually do not require you to interact with the cycler. See page 210 for more information.

Alarm Finder

In the sections that follow, you will see tables listing Warning, Caution and Notification Alarms by name, in alphabetical order. But each alarm also has a code number. If you wish to look up the alarm you're having by number, the tables below are provided for that purpose.



Note: Some alarm code numbers have more than one interpretation, depending on whether you are connected or not connected to the cyclor. Be sure to look up the right one.

Warnings

Alarm Code	Alarm Name	See page...
AW001	System Failure	191
AW002	System Failure	190
AW003	System Failure	190
AW004	System Failure	190
AW005	System Failure	190
AW006	System Failure	190
AW007	System Failure	190
AW008	System Failure	190
AW009	System Failure	190
AW012	System Failure	190
AW013	System Failure	190
AW016	System Failure	190
AW017	System Failure	190
AW018	System Failure	190
AW019	System Failure	190
AW020	System Failure	190
AW021	System Failure	190
AW025	System Failure	190
AW027	System Failure	190
AW039	System Failure	190
AW040	System Failure	190
AW043	System Failure	190
AW046	System Failure	190
AW048	System Failure	190
AW051	System Error	189
AW052	System Error	189
AW053	Cyclor Set Problem	187
AW054	Cyclor Set Problem	187
AW057	System Failure	190

Alarm Code	Alarm Name	See page...
AW060	System Error	189
AW061	Cycler Set Problem	187
AW062	Cycler Set Problem	187
AW063	Cycler Set Problem	187
AW064	Cycler Set Problem	187
AW065	System Error	189
AW067	Air Detected during Priming	187
AW070	Cycler Set Problem	187
AW073	Cycler Set Problem	187
AW074	Risk of overfill due to incomplete drainage	184
AW077	System Failure	186
AW078	System Failure	186
AW080	Cycler Set Problem	183
AW083	Cycler Set Problem	182
AW084	System Failure	186
AW085	Cycler Set Problem	182
AW089	System Failure	190
AW101	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW104	Cycler Set in Use More than 24 Hours	182
AW125	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW126	Cycler Set Problem—Patient Connected	182
	Cycler Set Problem—Patient Not Connected	187
AW128	Air Detected—Patient Connected	181
	Air Detected during priming—Patient Not Connected	187
AW129	Air Detected	181
AW130	Less than 90% of treatment delivered	188
AW131	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW132	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW133	Cycler Set Problem—Patient Connected	182
	Cycler Set Problem—Patient Not Connected	187
AW134	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW135	System Error	185

Alarm Code	Alarm Name	See page...
AW136	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW137	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW138	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW139	Warming Pouch removed during treatment	209
AW140	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW141	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW142	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW143	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW144	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW145	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW146	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW147	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW148	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW151	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW152	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW153	Fluid Leakage—Patient Connected	183
	Fluid Leakage—Patient Not Connected	187
AW154	Fluid Leakage	187
AW155	System Error	185
AW156	Cycler Set Problem	182
AW157	System Failure	186
AW158	Cycler Set Problem	182
AW159	System Failure	186
AW160	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW161	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW162	System Failure—Patient Connected	186

Alarm Code	Alarm Name	See page...
	System Failure—Patient Not Connected	190
AW163	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW164	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW165	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW166	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW167	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW168	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW169	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW170	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW171	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW172	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW173	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW174	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW175	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW176	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW177	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW181	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW182	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW183	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW184	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW185	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW186	System Error	185
AW191	System Error—Patient Connected	185

Alarm Code	Alarm Name	See page...
	System Error—Patient Not Connected	189
AW192	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW193	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW194	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW195	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW196	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW197	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW198	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW199	System Failure	190
AW203	System Failure	190
AW204	System Failure	190
AW207	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW208	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW209	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW210	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW211	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW213	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW214	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW215	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW216	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW217	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW218	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW219	System Error—Patient Connected	185
	System Error—Patient Not Connected	189

Alarm Code	Alarm Name	See page...
AW220	System Error	185
AW221	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW222	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW223	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW224	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW225	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW226	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW227	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW228	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW229	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW230	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW231	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW232	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW233	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW234	Fluid Leakage—Patient Connected	183
	Fluid Leakage—Patient Not Connected	187
AW235	Fluid Leakage	187
AW236	Air Detected—Patient Connected	181
	Air Detected during Priming—Patient Not Connected	187
AW237	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW238	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW239	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW240	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW241	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190

Alarm Code	Alarm Name	See page...
AW242	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW243	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW244	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW246	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW247	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW248	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW250	System Failure	190
AW258	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW261	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW262	System Error—Patient Connected	185
	System Error—Patient Not Connected	189
AW263	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW264	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190
AW265	System Error	185
AW266	System Error	185
AW999	System Failure—Patient Connected	186
	System Failure—Patient Not Connected	190

Cautions

Alarm Code	Alarm Name	See page...
AC011	Battery charge low	193
AC014	Invalid cyclor state at startup	198
AC023	Room Temperature too warm or too cold	205
AC024	Power Not Detected (at startup)	204
AC026	Warming Pouch found in the cyclor	208
AC028	USB-Drive reading failure	207
AC030	USB-Drive reading failure	207
AC041	Cartridge not inserted	194
AC042	Cartridge insertion error	193
AC044	Cartridge not fully inserted	194
AC045	Cartridge not fully inserted	194

Alarm Code	Alarm Name	See page...
AC047	Loader closing timed out	198
AC050	Object detected in loader	198
AC055	Error during cartridge loading	197
AC056	Error during cartridge loading	197
AC058	Warming Pouch not inserted	208
AC059	Warming Pouch not fully inserted	208
AC066	Solution bags' position is too high or too low	205
AC068	Solution bag temperature too cold	205
AC069	Solution bag temperature too warm	205
AC072	Drain line position too high or too low	196
AC075	Risk of overflow due to incomplete drainage	204
AC079	Solution bag temperature too cold	205
AC081	Solution bags' position is too high or too low	205
AC082	Patient's position too high or too low	201
AC086	Drain line position too high or too low	196
AC087	Patient's position too high or too low	201
AC088	The Patient Line Clamp is not closed	201
AC090	Warming Pouch not removed	208
AC093	Cartridge not removed	194
AC094	Foreign object detected	197
AC099	Data transfer to USB drive failed	195
AC100	Data transfer to USB drive failed	195
AC105	Patient Line Blocked (during set preparation)	199
AC107	Patient Line Blocked (during treatment)	200
AC111	Patient Line Blocked (during Initial Drain)	199
AC114	Patient Line Blocked (during treatment)	200
AC115	Drain line blocked	196
AC116	Drain line blocked	196
AC117	Drain line blocked	196
AC120	Solution Line Blocked	207
AC121	Patient Line or Warming Pouch Lines Blocked (during setup)	200
AC123	Patient Line or Warming Pouch Lines Blocked (during fill)	201
AC124	Drain Line or Warming Pouch Lines Blocked	197
AC127	Air Detected	193

Alarm Code	Alarm Name	See page...
AC149	Treatment Stopped: Time out. To continue, touch OK	207
AC150	Unauthorized USB Drive connected	207
AC179	Power Lost	201
AC200	Unauthorized USB Drive connected	207
AC201	USB-Drive reading failure	207
AC202	USB-Drive reading failure	207
AC205	Solution Line Blocked	207
AC206	Power Not Detected (at startup)	204
AC245	Power loss during previous session	203
AC252	Profile Lost	204
AC253	Cloud connection failure	195
AC254	Cloud settings reading failure	195
AC255	Cloud settings reading failure	195
AC256	Cloud settings reading failure	195
AC257	Cloud settings reading failure	195
AC260	Air Detected	193

Notifications

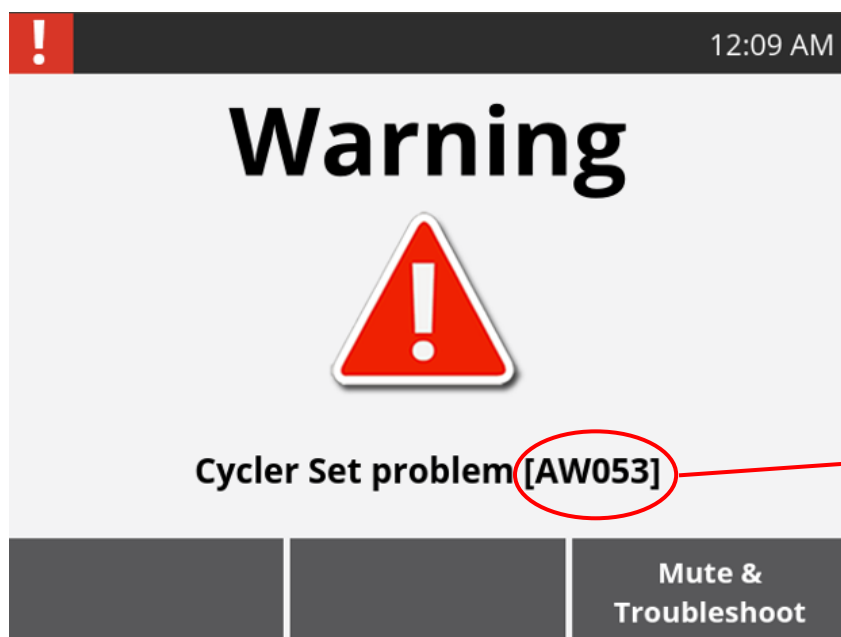
Alarm Code	Alarm Name	See page...
AN106	Patient Line Blocked	210
AN112	Patient Line Blocked	210
AN113	Patient Line Blocked	210
AN122	Patient Line Blocked	210
AN178	Power Lost since [time]	211
AN249	Battery replacement is due within [xx] days	210
AN251	Tidal Drain percentage not reached	211

Warning Alarms

There are three types of warning alarms on the VersiPD Cycler.

Recoverable Alarms

- The first type of warning alarm stops the treatment but allows you to resume dialysis with a new treatment. A message appears to identify the issue and provide an error code. Most of the messages say “System Error” but some are more specific, such as “Disposable Set Problem”. Write down the error code (see illustration below) in case you need to contact Fresenius Medical Care Technical Support for assistance. If you are connected to the VersiPD Cycler Set, touch **Disconnect** and follow the instructions. After placing your cycler in standby, press the green **START** button to remove the VersiPD Cycler Set. (If you have trouble removing the warming pouch, open the yellow clamp on the drain line, remove the pouch and then close the clamp). Set up for another treatment following the method your home therapy nurse taught you. Use only unused supplies for the new treatment.



Error
Code

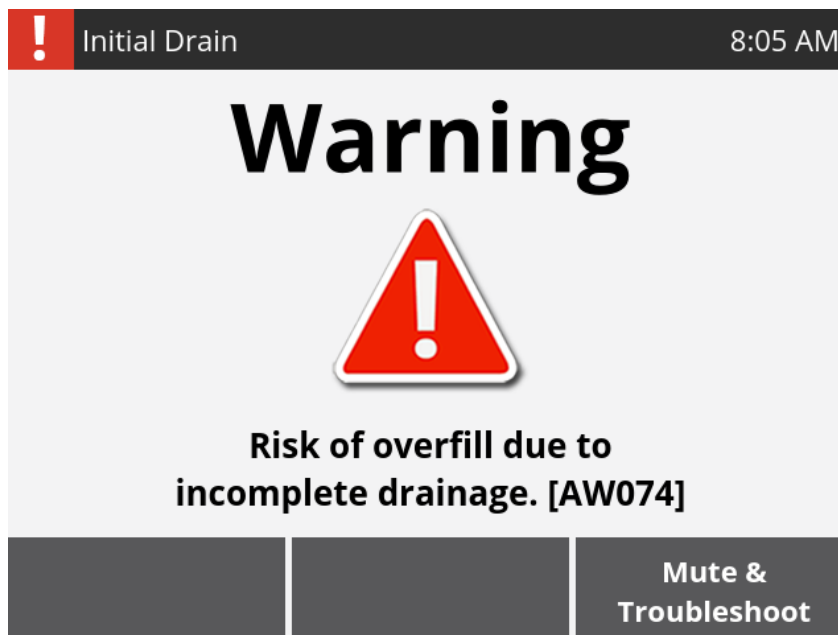
Unrecoverable Alarms (System Failure)

- The second type of warning alarm stops the treatment and does not allow you to resume it. This alarm will display the message “System Failure” or “Fluid Leakage” followed by the error code (see example on the next page). Write down the error code. If you are connected to the VersiPD Cycler Set, touch **Disconnect** and follow the instructions. After putting your cycler into standby, press the green **START** button to remove the VersiPD Cycler Set. Contact a Fresenius Medical Care Technical Support Representative at 1-800-227-2572.



Initial Drain (Risk of Overfill due to Incomplete Drainage)

- The third type of warning alarm is the *initial drain warning*. This warning can only happen during your initial drain. You will receive a warning during the initial drain if the minimum drain expected has not been met and the cyclor does not detect enough flow to continue draining. Always verify that the patient line clamp and catheter extension clamp are open and nothing is blocking the drain flow during your initial drain. It is important to consider any manual exchanges, fills, or drains done since your last treatment and evaluate if you have drained enough to safely start your first fill. You will be able to continue your treatment after this alarm.



List of Warning Alarms

This list of warning alarms on the VersiPD Cyclor is for your information only. You should always follow the directions on the cyclor screen, and in this guide, when trying to resolve alarm situations. The list is organized alphabetically by the name of the alarm.

The alarm codes are shown after the alarm names. Many alarms have more than one code to help Technical Support determine the exact nature of the problem when you call to consult them.

Two tables of warning alarms appear below:

- **Patient Connected:** the first table lists only those warnings that occur when you are connected to the cyclor. These are presented first because the consequences of ignoring them are more severe.
- **Patient Not Connected:** the second table lists the remaining warnings that occur only when you are not connected.

WARNING ALARMS—PATIENT CONNECTED

Name and Error ID (Patient Connected)	Explanation	What to Do
Air Detected AW128, AW129, AW236	Too much air has been detected during treatment and treatment has been stopped. Contamination may have occurred.	<ol style="list-style-type: none">1. Touch Mute and Troubleshoot.2. Write down and save Error ID number.3. To disconnect from the cyclor, touch Disconnect and follow the instructions on the screen.4. Call your home therapy nurse due to possible contamination.5. To shut down the cyclor, touch Standby.

Name and Error ID <i>(Patient Connected)</i>	Explanation	What to Do
Cyclor set in use more than 24 hours AW104	The VersiPD Cyclor Set was primed more than 24 hours ago. It cannot be used for your treatment.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Write down and save the Error ID number. 3. To disconnect from the cyclor, touch Disconnect and follow the instructions on the screen. 4. Call your home therapy nurse as instructed. 5. To shut down the cyclor, touch Standby.
Cyclor Set problem (risk of contamination) AW085, AW126	A problem has been detected with the current VersiPD Cyclor Set. It cannot be used for your treatment. Contamination may have occurred.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Write down and save Error ID number. 3. To disconnect from the cyclor, touch Disconnect and follow the instructions on the screen. 4. Call your home therapy nurse due to possible contamination. 5. Call Technical Support and follow phone prompts for PD support. 6. To shut down the cyclor, touch Standby.
Cyclor Set problem (no risk of contamination) AW083, AW133, AW156, AW158	A problem has been detected with the current VersiPD Cyclor Set. It cannot be used for your treatment.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. To disconnect from the cyclor, touch Disconnect and follow the instructions on the screen. 3. To set up with new supplies, touch Standby and restart the cyclor.

Name and Error ID (Patient Connected)	Explanation	What to Do
Cycler Set problem AW080	A problem has been detected with the current VersiPD Cycler Set. It cannot be used for your treatment.	<ol style="list-style-type: none"> 1. Write down and save Error ID number. 2. To disconnect from the cycler, touch Disconnect and follow the instructions on the screen. 3. Call Technical Support and follow phone prompts for PD support. 4. To set up with new supplies, touch Standby and restart the cycler. 5. Save VersiPD Cycler Set to return.
Fluid Leakage AW153, AW234	Fluid has been detected in the cycler. It could come from the VersiPD Cycler Set or from a splash or spill. Contamination may have occurred.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Write down and save the Error ID number. 3. To disconnect from the cycler, touch Disconnect and follow the instructions on the screen. 4. Call your home therapy nurse due to possible contamination. 5. Call Technical Support at 1-800-227-2572. Follow the prompts for PD support. 6. To shut down the cycler, touch Standby.

Name and Error ID <i>(Patient Connected)</i>	Explanation	What to Do
Risk of overflow due to incomplete drainage AW074	Because you may have done manual exchanges or fills, you are being asked to review the drain volume.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check your drain status by noting the expected volume and the actual drained volume shown on the screen. 3. Carefully consider if you feel empty and if the drain volume is what you should expect. 4. To resume draining, touch Continue Drain; to end the initial drain and start Fill 1, touch End Drain.

Name and Error ID (Patient Connected)	Explanation	What to Do
System Error AW101, AW125, AW134, AW135, AW143, AW144, AW145, AW146, AW147, AW155, AW183, AW184, AW185, AW186, AW191, AW192, AW193, AW194, AW195, AW196, AW197, AW198, AW207, AW208, AW209, AW210, AW211, AW213, AW214, AW215, AW216, AW217, AW218, AW219, AW220, AW221, AW222, AW223, AW225, AW226, AW227, AW228, AW230, AW231, AW237, AW239, AW242, AW244, AW247, AW258, AW262, AW265, AW266	A problem has been detected in the cyclor and you need to restart it.	<ol style="list-style-type: none"> 1. Write down and save Error ID number. 2. To disconnect from the cyclor, touch Disconnect and follow the instructions on the screen to disconnect yourself. 3. Follow your home therapy nurse’s instructions for restarting treatment with new supplies. 4. Touch Standby and restart the Cyclor by pressing the green START button. 5. If the error persists, call Technical Support at 1-800-227-2572 and follow the prompts for PD support.

Name and Error ID <i>(Patient Connected)</i>	Explanation	What to Do
System Failure AW077, AW078, AW084, AW131, AW132, AW136, AW137, AW138, AW140, AW141, AW142, AW148, AW151, AW152, AW157, AW159, AW160, AW161, AW162, AW163, AW164, AW165, AW166, AW167, AW168, AW169, AW170, AW171, AW172, AW173, AW174, AW175, AW176, AW177, AW181, AW182, AW224, AW229, AW232, AW233, AW238, AW240, AW241, AW243, AW246, AW248, AW261, AW263, AW264, AW999	The cyclor has detected a problem that may require replacing the cyclor.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Write down and save the Error ID number. 3. To disconnect from the cyclor, touch Disconnect and follow the instructions on the screen to disconnect yourself. 4. Call your home therapy nurse. 5. Call Technical Support at 1-800-227-2572. Follow the prompts for PD support. 6. Touch Standby to shut down the cyclor. 7. If you are told that your VersiPD Cyclor must be replaced, put it in the shipping box following the return instructions on page 34.

WARNING ALARMS—PATIENT NOT CONNECTED

Name and Error ID (<i>Patient Not Connected</i>)	Explanation	What to Do
Air Detected during priming AW067, AW128, AW236	Too much air has been detected during priming, indicating a possible leak or a connection that is not tight.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Call Technical Support at 1-800-227-2572. Follow the prompts for PD Support. 3. To set up with new supplies, touch Standby and then press the green START button on the front panel. You will be able to remove the VersiPD Cyclor Set after restarting.
Cyclor Set problem AW053, AW054, AW061, AW062, AW063, AW064, AW070, AW073, AW126, AW133	A problem has been detected with the current VersiPD Cyclor Set. It cannot be used for your treatment.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. To set up with new supplies, touch Standby and then press the green START button on the front panel. You will be able to remove the VersiPD Cyclor Set after restarting.
Fluid Leakage AW153, AW154, AW234, AW235	Fluid has been detected in the cyclor. It could come from the VersiPD Cyclor Set or from a splash or spill.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Write down and save Error ID number. 3. Close all clamps. 4. Call your home therapy nurse. 5. Call Technical Support at 1-800-227-2572. Follow the prompts for PD Support. 6. To shut down the cyclor, touch Standby.

Name and Error ID (<i>Patient Not Connected</i>)	Explanation	What to Do
Less than 90% of treatment delivered AW130	This warning appears at the conclusion of a treatment in which the completed volume was less than 90% of the prescribed amount.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Note how much treatment volume has been delivered in this treatment. 3. Notify your home therapy nurse. 4. Touch OK.

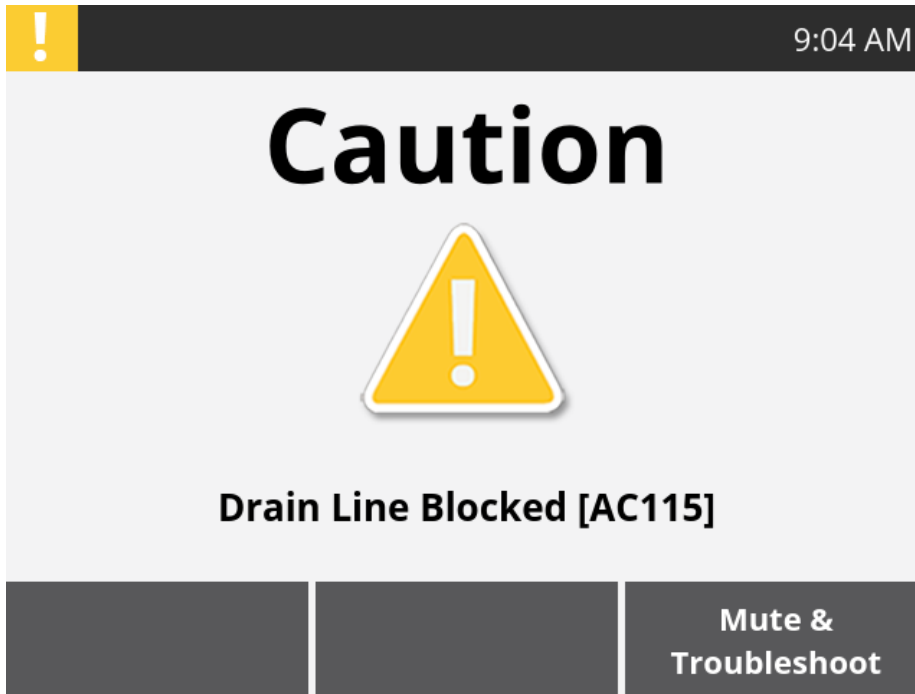
Name and Error ID (Patient Not Connected)	Explanation	What to Do
System Error AW051, AW052, AW060, AW065, AW101, AW125, AW134, AW143, AW144, AW145, AW146, AW147, AW183, AW184, AW185, AW191, AW192, AW193, AW194, AW195, AW196, AW197, AW198, AW207, AW208, AW209, AW210, AW211, AW213, AW214, AW215, AW216, AW217, AW218, AW219, AW221, AW222, AW223, AW225, AW226, AW227, AW228, AW230, AW231, AW237, AW239, AW242, AW244, AW247, AW258, AW262	A problem has been detected in the cyclor and you need to restart it.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Write down and save the Error ID number. 3. Touch Standby and restart the cyclor. 4. If the error persists, call Technical Support at 1-800-227-2572. Follow the prompts for PD Support.

Name and Error ID (Patient Not Connected)	Explanation	What to Do
<p>System Failure AW002, AW003, AW004, AW005, AW006, AW007, AW008, AW009, AW012, AW013, AW016, AW017, AW018, AW019, AW020, AW021, AW025, AW027, AW039, AW040, AW043, AW046, AW048, AW057, AW089, AW131, AW132, AW136, AW137, AW138, AW140, AW141, AW142, AW148, AW151, AW152, AW160, AW161, AW162, AW163, AW164, AW165, AW166, AW167, AW168, AW169, AW170, AW171, AW172, AW173, AW174, AW175, AW176, AW177, AW181, AW182, AW199, AW203, AW204, AW224, AW229, AW232, AW233, AW238, AW240, AW241, AW243, AW246, AW248, AW250, AW261, AW263, AW264, AW999</p>	<p>A problem has been detected in the cyclor and it may require replacement.</p>	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Write down and save the Error ID number. 3. Call your home therapy nurse. 4. Call Technical Support at 1-800-227-2572. Follow the prompts for PD support. 5. If necessary, touch Standby to shut down the cyclor. 6. If your VersiPD Cyclor must be replaced, put it in the shipping box following the return instructions on page 34.

Name and Error ID (Patient Not Connected)	Explanation	What to Do
System Failure AW001	A problem has been detected in the cyclor and it may require replacement.	<ol style="list-style-type: none"> 1. Call your home therapy nurse. 2. Call Technical Support at 1-800-227-2572. Follow the prompts for PD support. 3. If your VersiPD Cyclor must be replaced, put it in the shipping box following the return instructions on page 34.

Caution Alarms

A caution alarm is an event that does not end your treatment, but still requires user action to resolve. Some caution alarms (AC026, 044, 055, 056, 058, and 059), if not resolved after three attempts, will turn into warning alarms and stop your treatment. AC042 is elevated to a warning alarm after two failed attempts to resolve it.



Follow the directions on the screen to resolve the caution situation.



You can find a list of all the cautions on the next few pages. Look there for additional information the problems that cause specific cautions.

List of Caution Alarms

This list of caution alarms on VersiPD is for your information only. You should always follow the directions on the cyclor screen when trying to resolve caution situations.

Name and Error ID	Explanation	What to Do
Air Detected AC127, AC260	Air has entered the VersiPD Cyclor Set. It could come from a leak or loose connection. If you find damage to the catheter extension set, notify your home therapy nurse immediately.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check your VersiPD Cyclor Set for leaks, holes, loose connections, or damage. 3. To try to resume your treatment, touch Retry. <p>OR</p> <p>To end your treatment, touch End Treatment.</p>
Battery charge low AC011	The battery does not have enough charge to do your treatment. To keep the battery charged, leave the cyclor plugged in and in Standby between treatments.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Ensure the cyclor is properly plugged into power. 3. Touch Standby to charge battery. 4. Wait for the battery to charge (up to 4 hours).
Cartridge insertion error AC042	The cartridge is not correctly inserted in the cartridge loader.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Remove the cartridge. 3. Align and re-insert the cartridge. 4. Touch Retry.

Name and Error ID	Explanation	What to Do
Cartridge not fully inserted AC044, AC045	The cartridge is not fully inserted in the cartridge loader.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Make sure the cartridge is fully inserted in the cartridge loader. 3. Touch Retry.
Cartridge not inserted AC041	Too much time has passed with the cartridge loader open waiting for a cartridge to be inserted.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Insert the cartridge as shown in the video. Touch Watch Video if necessary. 3. To proceed, touch Retry. 4. If the cartridge is not detected after multiple tries, use a new VersiPD Cyclor Set.
Cartridge not removed AC093	Too much time has passed with the cartridge loader open waiting for the cartridge to be removed.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Remove the cartridge as shown in the video. Touch Watch Video if necessary. 3. To proceed, touch Retry. 4. If cartridge removal is not detected, insert and remove the cartridge again. 5. If the caution is still present, start over with a new VersiPD Cyclor Set. 6. If the problem persists, write down the error code and call Technical Support at 1-800-227-2572.

Name and Error ID	Explanation	What to Do
Cloud connection failure AC253	The connection between the cyclor and the data storage cloud has failed.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. To try to restore the connection, touch OK. 3. If the connection is not restored, call Technical Support at 1-800-227-2572.
Cloud settings reading failure AC254, AC255, AC256, AC257	The connection between the cyclor and the data storage cloud has failed.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. To try to restore the connection, touch OK. 3. If the connection is not restored, call Technical Support at 1-800-227-2572.
Data Transfer to USB Drive failed AC099, AC100	The cyclor could not perform data transfer to the USB drive.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Re-insert the USB drive in the USB port. 3. In the History Menu, touch Data Transfer and then OK. If this is not done, the data will be transferred after your next treatment. 4. To continue, touch OK.

Name and Error ID	Explanation	What to Do
Drain line blocked AC115, AC116, AC117	The cyclor is trying to drain, but fluid will not flow through the drain line.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check the drain line (yellow clamp) for closed clamps, cap, proper position and kinks. The drain line should not be submerged in a toilet bowl or inserted into a drain. 3. Check drain bags for closed clamps, kinks and proper position. Drain bags should be placed flat and not on top of each other. 4. To proceed, touch Retry. 5. If problem persists, call your home therapy nurse or Technical Support at 1-800-227-2572.
Drain line position too high or too low AC072, AC086	The drain line should not be above the cyclor or more than 39 inches below it.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Move the drain line so that it is not above the cyclor or more than 39 inches below it. 3. After repositioning, touch Retry.

Name and Error ID	Explanation	What to Do
Drain Line or Warming Pouch Lines Blocked AC124	An occlusion has been detected on the drain line or warming pouch lines.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check the drain line (yellow clamp) and drain bag lines for closed clamps, cap, kinks and proper position. The drain line should not be submerged in a toilet bowl or inserted into a drain. Drain bags should be placed flat and not on top of each other. 3. Check Warming Pouch lines for kinks. 4. To proceed, touch Retry. 5. If the problem is not resolved, call your home therapy nurse for further instructions.
Error during cartridge loading AC055, AC056	An error has occurred during cartridge loading.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Close the cartridge loader as shown in the video. Touch Watch Video if necessary. 3. To proceed, touch Retry. 4. If the cartridge loader does not close after the second attempt, use a new VersiPD Cycler Set.
Foreign Object Detected AC094	An object that does not appear to be the cartridge is in the cartridge loader.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Remove any object that is extending from the cartridge loader. Do not put your fingers or any object except the cartridge into the cartridge loader. 3. To proceed, touch Retry.

Name and Error ID	Explanation	What to Do
<p>Invalid Cyclor State at Startup AC014</p>	<p>The cyclor is not in a proper state to start treatment. The usual cause of this message is pressing the START button when the cartridge or warming pouch is inserted.</p>	<p>If a VersiPD Cyclor Set (cartridge and warming pouch) <i>is</i> inserted, follow these steps:</p> <ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Close all clamps except the yellow clamp on the drain line. When this is done, touch OK. 3. When the cyclor asks if there is a set in the cartridge loader, touch Yes. 4. Remove the used cartridge from the cartridge loader and touch OK. 5. Close the cartridge loader by touching the Close Loader button. 6. Remove the warming pouch and then touch OK. 7. Touch Standby to shut down the cyclor. <p>If a VersiPD Cyclor Set <i>is not</i> inserted, follow these steps:</p> <ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Touch OK. 3. When the cyclor asks if there is a set in the cartridge loader, touch No. 4. Touch Standby to shut down the cyclor.
<p>Loader closing timed out AC047</p>	<p>After insertion or removal of the cartridge, too much time has elapsed before closing the cartridge loader.</p>	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Keep your hands well away from the cartridge loader. 3. Touch Retry.

Name and Error ID	Explanation	What to Do
Object detected in loader AC050	An object has been detected in the cartridge loader.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Call Technical Support at 1-800-227-2572 and follow the prompts for PD support. 3. To try again, touch Retry.
Patient Line Blocked (during Initial Drain) AC111	The patient line is blocked during Initial Drain.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check patient line and catheter extension set for closed clamps, PIN insertion, kinks, fibrin or clots. 3. Change body position. 4. Either continue Initial Drain by touching Retry OR End Initial Drain and continue to Fill 1 by touching End Initial Drain
Patient Line Blocked (during set preparation) AC105	The patient line is blocked during priming.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check patient line for closed clamps, PIN insertion or kinks. 3. To proceed, touch Retry.


Name and Error ID	Explanation	What to Do
<p>Patient Line Blocked (during treatment) AC107, AC114</p>	<p>The patient line is blocked while treatment is underway.</p>	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check the patient line and the catheter extension set for closed clamps, PIN insertion or kinks, fibrin or clots. Start at your abdomen and follow the line to the cyclor, checking for the problem. 3. Change body position. 4. To proceed, touch Retry. 5. If the problem is not resolved, call your home therapy nurse for further instructions, or call Technical Support at 1-800-227-2572.
<p>Patient Line or Warming Pouch Lines Blocked (during setup) AC121</p>	<p>An occlusion has been detected on the patient line or the warming pouch lines during priming.</p>	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check the patient line for closed clamps, PIN insertion or kinks. 3. Check the warming pouch lines for kinks. 4. To proceed, touch Retry. 5. If problem persists, call your home therapy nurse or Technical Support at 1-800-227-2572.


Name and Error ID	Explanation	What to Do
Patient Line or Warming Pouch Lines Blocked (during fill) AC123	An occlusion has been detected on the patient line or the warming pouch lines during treatment.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Check the patient line (blue clamp), catheter extension set and warming pouch lines for closed clamps, PIN insertion or kinks. 3. Change body position. 4. To proceed, touch Retry. 5. If problem persists, call your home therapy nurse or Technical Support at 1-800-227-2572.
The Patient Line Clamp is not closed AC088	The blue clamp on the patient line must be closed in order to proceed.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Close blue clamp on the patient line. 3. To proceed, touch Retry.
Patient's position too high or too low AC082, AC087	Your abdomen is too far above or below the cyclor. Either change your position or the position of the cyclor.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. You must be no more than 19 inches above or below the cyclor. Move the cyclor or yourself to proper range. 3. After repositioning, touch Retry.

Name and Error ID	Explanation	What to Do
Power Lost AC179	VersiPD has not been receiving power for at least 25 minutes.	<p>Touch Mute and Troubleshoot.</p> <p>If you <i>are not</i> connected to the cyclor, touch Standby to shut it down.</p> <p>If you <i>are</i> connected, follow the instructions of your home therapy nurse for power failure. To disconnect yourself from the cyclor, touch Disconnect and follow these steps:</p> <ol style="list-style-type: none"> 1. Put on a mask and clean your hands. 2. Put a new stay•safe cap on the notch on the left side of the organizer. 3. On the PIN connector, turn the blue button a quarter turn and push in to insert the PIN. 4. Close the blue clamp on the patient line and the white clamp on your catheter extension line. 5. When you have placed the PIN connector in the organizer, remove the cover of the stay•safe cap. 6. Disconnect your catheter extension set from the VersiPD Cyclor Set and connect to the cap. 7. Touch OK when complete.

Name and Error ID	Explanation	What to Do
Power loss during previous session AC245	The cyclor has gone into Standby because of a power loss.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. To proceed, touch OK. The battery will need to be charged for at least four hours. 3. To end treatment, follow the steps for disconnection: <ol style="list-style-type: none"> a. Put on a mask and clean your hands. b. Put a new stay•safe cap on the notch on the left side of the organizer. c. On the PIN connector, turn the blue button a quarter turn and push in to insert the PIN. d. Close the blue clamp on the patient line and the white clamp on your catheter extension line. e. When you have placed the PIN connector in the organizer, remove the cover of the stay•safe cap. f. Disconnect your catheter extension set from the VersiPD Cyclor Set and connect to the cap. g. To shut down the cyclor, touch Standby.

Name and Error ID	Explanation	What to Do
Power Not Detected (at startup) AC024, AC206	Power to the cyclor is not detected. The cyclor will shut down in 5 minutes.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Make sure the cyclor is plugged in and the power switch on the back of the cyclor is on. 3. If the outlet is connected to a wall switch, make sure the switch is on. 4. If a GFI outlet is being used, check if it needs to be reset. 5. Touch the Standby button. When the blue light on the front panel of the cyclor lights up, press the green START button.
Profile Lost AC252	The patient profile has been lost.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. To recover your profile, insert your USB drive. If you do not have your USB drive, call your home therapy nurse. <p>To continue, touch OK.</p>
Risk of overflow due to incomplete drainage AC075	<p>The Initial Drain has been stopped. There is a risk of overflow if not enough fluid has been drained.</p> <p>The VersiPD Cyclor cannot detect manual exchanges that have not been entered in the cyclor. Compare the amount you have drained to your last fill or any manual exchanges you have done.</p>	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Carefully consider your previous fill volume and your drained volume to determine if you should drain more or start Fill 1. 3. To drain more, touch Continue Drain OR To end Initial Drain, touch Start Fill 1

Name and Error ID	Explanation	What to Do
Room Temperature too warm or too cold AC023	It is either too hot or too cold for the warmer to work properly during your treatment.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Change your room temperature. If you are unable to do this, call your home therapy nurse. 3. To proceed, touch Retry. OR To end treatment, follow the steps for disconnection: <ol style="list-style-type: none"> a. Put on a mask and clean your hands. b. Put a new stay•safe cap on the notch on the left side of the organizer. c. On the PIN connector, turn the blue button a quarter turn and push in to insert the PIN. d. Close the blue clamp on the patient line and the white clamp on your catheter extension line. e. When you have placed the PIN connector in the organizer, remove the cover of the stay•safe cap. f. Disconnect your catheter extension set from the VersiPD Cyclor Set and connect to the cap. g. To shut down the cyclor, touch Standby.
	 <p>Warning: Unplug the cyclor and call Technical Support at 1-800-227-2572 in the case of burnt plastic or electronics (metallic or burning smells).</p>	

Name and Error ID	Explanation	What to Do
Solution bag temperature too cold AC068, AC079	The solution is too cold for the warmer to properly heat it.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Make sure the solution bags and cyclor are not exposed to a cold source. 3. Give the solution time to warm up and then touch Retry. If the problem is not resolved after several attempts, touch End Treatment.
	 Note: If your storage area is very cold, you may need to move your bags into your treatment room several hours before starting treatment.	
Solution bag temperature too warm AC069	The temperature of the fluid in the solution bags is too warm.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Make sure the solution bags and cyclor are not exposed to a heat source. 3. Give the solution time to cool down and then touch Retry. If the problem is not resolved after several attempts, touch End Treatment.
Solution bags' position is too high or too low AC066, AC081	The solution bags are either too far above or too far below the cyclor.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Move solution bags to within the proper range. Solution bags must be no more than 19 inches above or below the cyclor. 3. After repositioning, touch Retry.

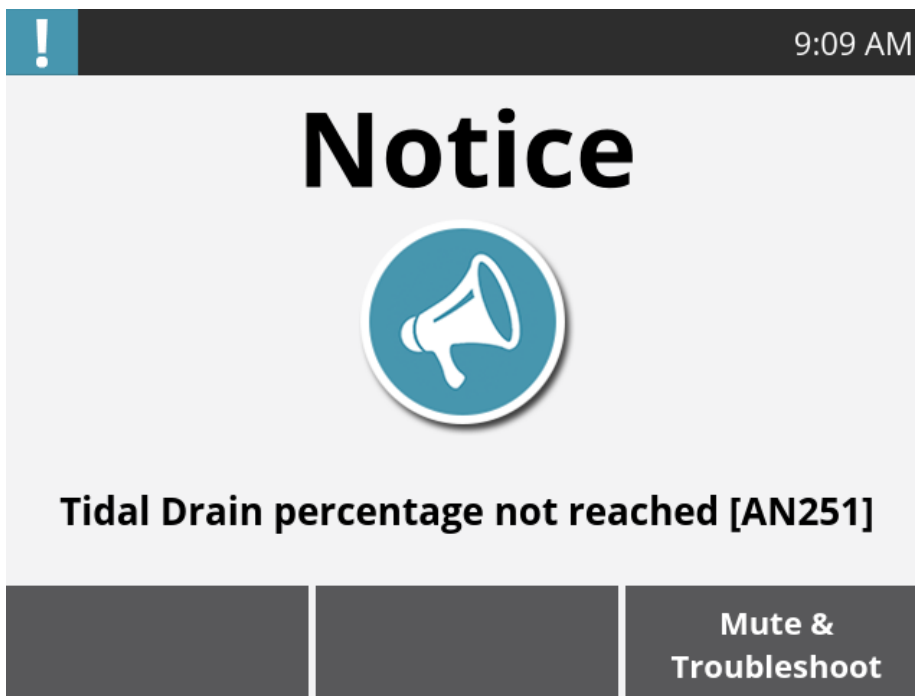
Name and Error ID	Explanation	What to Do
Solution Line Blocked AC120, AC205	An occlusion has been detected on a solution line.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Make sure solution line clamp is open, line is not kinked, bag is connected and cone is broken. 3. To proceed, touch Retry.
Treatment Stopped: Time out. To continue, touch OK AC149	You have pressed the STOP key and too much time has passed without choosing or confirming an option.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Touch the OK button to proceed. 3. Select an option from the screen.
Unauthorized USB Drive connected AC150, AC200	The USB you inserted is not an approved one. Use only an approved USB in the cyclor. Using your USB in another device can corrupt it and cause this alarm.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Remove unauthorized USB Drive from the cyclor. 3. Carefully insert approved USB Drive. The cyclor will automatically try again to read the USB Drive.
USB-Drive reading failure AC028, AC030, AC201, AC202	The cyclor failed to read data from the USB drive.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Remove the USB drive from the cyclor. 3. Carefully re-insert the USB drive. The cyclor will automatically try again to read data from the USB drive.


Name and Error ID	Explanation	What to Do
Warming Pouch found in the cyclor AC026	The Warming Pouch is in the cyclor when it should not be.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Remove the Warming Pouch and touch the Retry button. Remember that a new VersiPD Cyclor Set must be used for each treatment. 3. If you have tried multiple times to perform this action without success, call Technical Support at 1-800-227-2572.
Warming Pouch not fully inserted AC059	The cyclor has detected a warming pouch partially inserted.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Grasp the warming pouch handles and push it back to fully insert it as shown in the video. Touch Watch Video if necessary. 3. If the warming pouch is not detected after multiple tries, touch Retry and use a new VersiPD Cyclor Set.
Warming Pouch not inserted AC058	The cyclor is not detecting a warming pouch.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Insert the warming pouch as shown in the video. Touch Watch Video if necessary. 3. Touch Retry.
Warming Pouch not removed AC090	Too much time has passed without the Warming Pouch being removed.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. Remove the warming pouch by pulling on the front loop. 3. Touch Retry.

Name and Error ID	Explanation	What to Do
Warming Pouch removed during treatment AC139	The warming pouch is no longer in position.	<ol style="list-style-type: none"> 1. Touch Mute and Troubleshoot. 2. To correctly insert warming pouch, grasp handles and push warming pouch again. 3. To proceed, touch Retry. <p>OR</p> <p>To change VersiPD Cyclers Set, touch End Treatment.</p>

Notice Alarms

Notices are messages that do not require any response by the user. Some messages, however, will advise actions for the user to consider.



Name	Explanation	What to Do
Battery replacement is due within [xx] days AN249	The battery that operates the cyclor during power loss needs to be replaced.	<ol style="list-style-type: none"> 1. Call Customer Service to order a new battery. 2. Notify your home therapy nurse in the morning. 3. Bring your cyclor to your next clinic visit. 4. To continue, touch OK.
	 Caution: The battery pack may be changed only by trained personnel. Only battery packs supplied by Fresenius Medical Care may be used.	
Patient Line Blocked AN106, AN112, AN113, AN122	The cyclor is trying to pump solution through the patient line but there is a blockage.	<ol style="list-style-type: none"> 1. Check the patient line (blue clamp) and catheter extension set for closed clamps, PIN insertion or kinks. 2. Change your body position. Flow will resume automatically when the blockage is removed.

Name	Explanation	What to Do
Power Lost since [time] AN178	This notice appears when power is lost during initialization.	No action is required at this time. The cyclor will resume automatically when power is restored.
Tidal Drain percentage not reached AN251	You have not drained the expected amount in a tidal drain cycle or an OptiDwell drain.	<ol style="list-style-type: none"> 1. Call your home therapy nurse to review settings. 2. To continue, touch OK.

Events

Events are actions taken by the patient or the cyclor that usually do not cause an alarm tone or light the screen (if night screen is in use) but are reported in the treatment summary. Most events do not require any response by the patient. Events start with the code EV followed by three numeric digits. EV001 to EV099 are actions taken by the patient. EV100 to EV199 are triggered or handled by the cyclor. Not all numbers are in use.

The list below gives the code and the screen display for each event. The words (if any) displayed on the screen during the event are shown in the right hand column of the table.

Code	Description	Screen display
<i>Events triggered by Patient Actions</i>		
EV001	Pause Treatment	Pause
EV002	Resume Treatment	Resume
EV003	Skip Phase (Fill, Dwell, Drain, Auto-Emptying)	Skip
EV004	Stat Drain	Stat D.
EV005	End Treatment	End Tr.
EV006	Start Additional Drain Acknowledged	AD
<i>Events triggered or handled by Cyclor</i>		
EV100	Continuous Activation Interruption (Unloading Sequence)	-
EV101	Continuous Activation Interruption (Loading Sequence)	-
EV102	Flow Rate Reduction (Liquid Under-Heating)	-
EV103	Inlet Liquid Temperature Too High	-
EV104	Start of Additional Drain Requested	Req. AD
EV105	Cycle Suppressed	-
EV106	Bag Line Switching	-
EV107	Flow Rate Increase (Available Heating Power)	-
EV108	Prescribed Tidal Drain Volume Not Reached	-

Code	Description	Screen display
EV120	Flush: Air Flush Start	Air
<i>EV120^l</i>	<i>Flush: Air Flush End</i>	<i>xxx mL</i>
EV121	Flush: Hot Fluid Flush Start	Hot
<i>EV121^l</i>	<i>Flush: Hot Fluid Flush End</i>	<i>xxxx mL</i>
EV130	PLC: Initial Drain - Early End of Drain Start	PLC
<i>EV130^l</i>	<i>PLC: Initial Drain - Early End of Drain End</i>	<i>xx mL</i>
EV131	PLC: Slow Flow Start	PLC
<i>EV131^l</i>	<i>PLC: Slow Flow End</i>	<i>xx mL</i>
EV132	PLC: No Flow Start	PLC
<i>EV132^l</i>	<i>PLC: No Flow End</i>	<i>xx mL</i>
EV133	PLC: Occlusion PPS Start	PLC
<i>EV133^l</i>	<i>PLC: Occlusion PPS End</i>	<i>xx mL</i>
EV140	SOM: IPS Defective Coupling - Fill	SOM
EV141	SOM: OPS Defective Coupling - Fill	PSM
EV142	SOM: OPS or PPS Defective Coupling - Fill	PSM
EV143	SOM: OPS Defective Coupling - Drain	PSM
EV144	SOM: PPS/IPS Dynamic Pressure Check Failed - Drain	SOM
EV145	SOM: IPS or PPS Defective Coupling - Drain	SOM
EV146	SOM: IPS Pressure Control - Perform Retry	PSM
EV147	SOM: IPS Pressure Control - Retry Failed	SOM
EV148	SOM: IPS Pressure Control - Flow Rate Reduction	PSM
EV149	Minor SOM: IPS Pressure Control - Flow Rate Reduction Confirmed	SOM
EV150	PSM: IPS Pressure Control - Flow Rate Reduction Invalidated	PSM
EV161	Warmer Area Leak Detected	-
EV162	PFAS Defective	-
EV163	Final Pressure Test Failure (First Treatment)	-

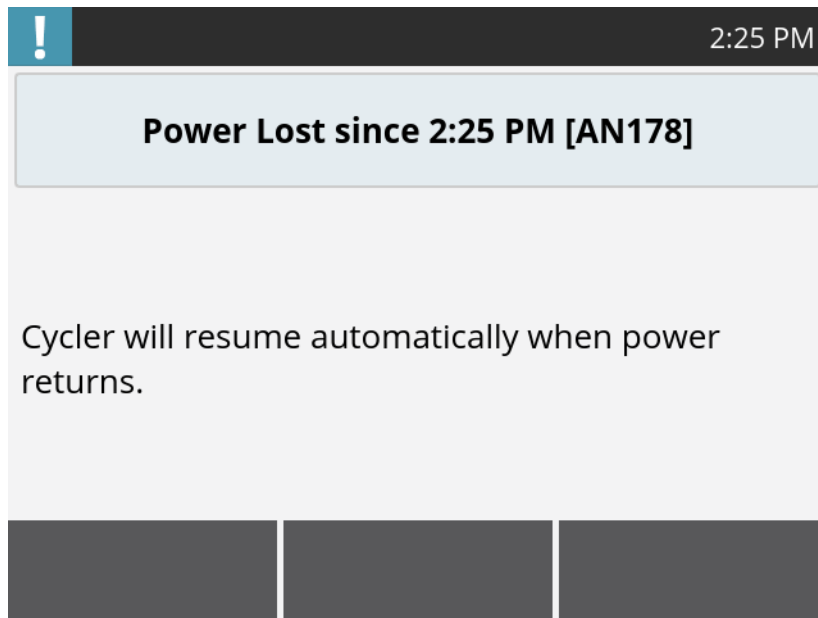
Code	Description	Screen display
EV164	Final Pressure Test Cancelled	-

Note¹: Event occurs right after the event above.

Abbreviation	Explanation
AD	Additional Drain
PLC	Patient Line Check
PSM	Pressure Sensor Monitoring
SOM	Safety Operating Mode

Power Failure

If there is a loss of power to your cyclor, it could be because the On/Off switch on the back panel has been turned to ‘Off’ (remember that the ‘O’ symbol means ‘Off’ and the vertical line means ‘On’). If you see a screen like the one below, check the On/Off switch as well as the outlet where your cyclor is plugged in to make sure the cord is connected.



During a power failure, your cyclor will save your treatment information for 25 minutes. During this time period, your treatment will resume automatically if power is restored.

When the power outage exceeds 25 minutes, the “Power Lost” caution [AC179] will be displayed. Your home therapy nurse will instruct you if you should disconnect during a power failure, or wait until power is restored or morning arrives.



Note: The U.S. Food and Drug Administration has published a booklet with tips on how to handle medical device power failures. It is available online at this address: <https://www.fda.gov/media/80782/download>

Cleaning and Specifications

Cleaning
and Specs

Cleaning the Cyclor

Your VersiPD Cyclor must be kept clean and dry to get the maximum efficiency and lifespan from the device. The external surface of the cyclor should be cleaned at least once a week, or more frequently if recommended by your home therapy nurse. The proper cleaning method is described below.

- 1 Take a soft, clean cloth and moisten it with one of the following: a diluted bleach solution (1 part bleach to 100 parts water); a mild detergent (soap); or household isopropyl alcohol (70%).
- 2 Wipe the outside of the cyclor gently, being careful not to let moisture drip into the inside of the cyclor. Do not apply cleaning solution in the slot for the warming pouch or the internal part of the cartridge loader (see page 14 for an illustration).



Warning: No foreign matter may be inserted in the warming pouch gap on the cyclor due to the risk of fire and damage to cyclor's internal workings.



Warning: Keep fingers clear of moving parts.



Caution: Do not allow any fluid to drip into your cyclor. If any fluid gets inside your cyclor, you must contact a Fresenius Medical Care Technical Support Representative immediately at 1 800 227-2572. Your cyclor should be placed on a water-tolerant surface, and spills should be cleaned up immediately.



Note: If you are using the optional VersiPD Cart, Dialysate Solution Bag Case, or VersiPD Travel Case, clean them at least once a week with one of the materials described in step 1 above.



Note: Clean the exterior surface of your Kinexus Gateway using a damp cloth and a diluted (1:100) bleach solution. Use surface cleaner in small amounts to prevent excess cleaner from entering the interior of your Kinexus Gateway. Rinse off cleaning solutions with a water-dampened cloth, especially if a corrosive cleaner such as bleach is used.

Battery Replacement

You will receive a notice that the nickel hydride battery must be changed within 30 days as well as a daily message with a countdown of the days left. Contact Technical Support at 1-800-227-2572 and they will send the new battery to your dialysis clinic. You will also be notified to contact your home therapy nurse to arrange the best date for bringing the cyclor to the clinic for the change.


Do not change the battery yourself. The instructions below are provided for the benefit of trained personnel who are responsible for changing the battery.

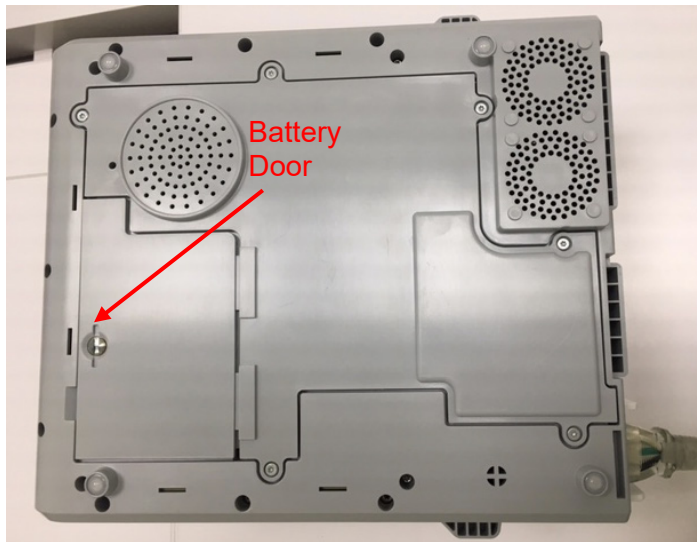


Caution: The battery pack may be changed only by trained personnel. Only battery packs supplied by Fresenius Medical Care may be used.



Note: The battery must be changed at least every two years even if the cyclor does not generate a notice to prompt the change.

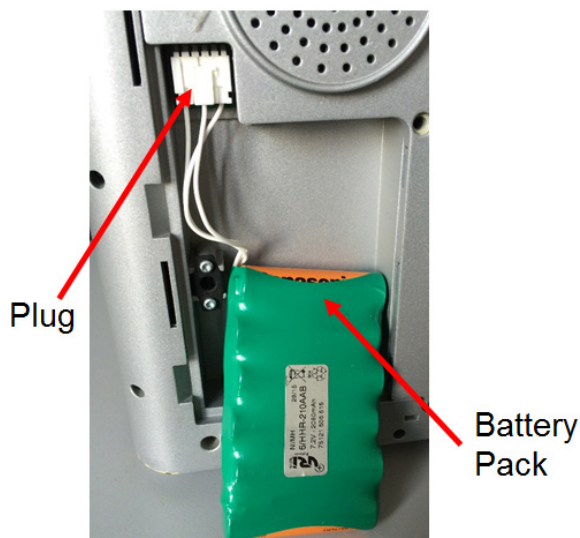
- 1 Turn the cyclor off by pressing the  symbol on the toggle switch on the back of the cyclor.
- 2 Disconnect the cyclor from its power cord.
- 3 Turn the cyclor on its side and find the battery door.



- 4 Using a coin or a screwdriver, turn the screw on the door $\frac{1}{4}$ turn counter-clockwise.

Battery Replacement (continued)

- 5 To unplug the battery pack, push down on the center of the white plug and pull it towards you. Remove the old battery pack.



- 6 Lay the new battery partially in the compartment with the battery cord towards the plug receptacle.
- 7 Plug the battery cord in and secure the battery completely in the compartment.
- 8 Replace the door and push it in until it closes. Turn the screw a quarter turn clockwise.



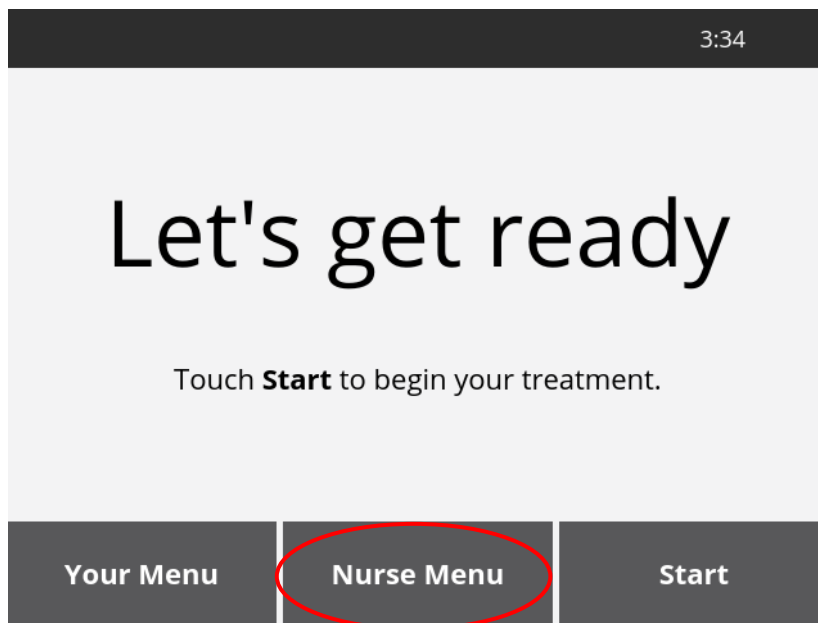
Note: The rubber seal that lines the battery chamber must be kept in place for the door to close properly and maintain a watertight seal.

- 9 Plug the power cord back into the cyclor.
- 10 Turn the cyclor on by pressing the **I** symbol on the toggle button on the back of the cyclor.
- 11 Press the green **START** button on the front of the cyclor.

- 12 Confirm the patient's profile.
VersiPD Cyclor System User's Guide

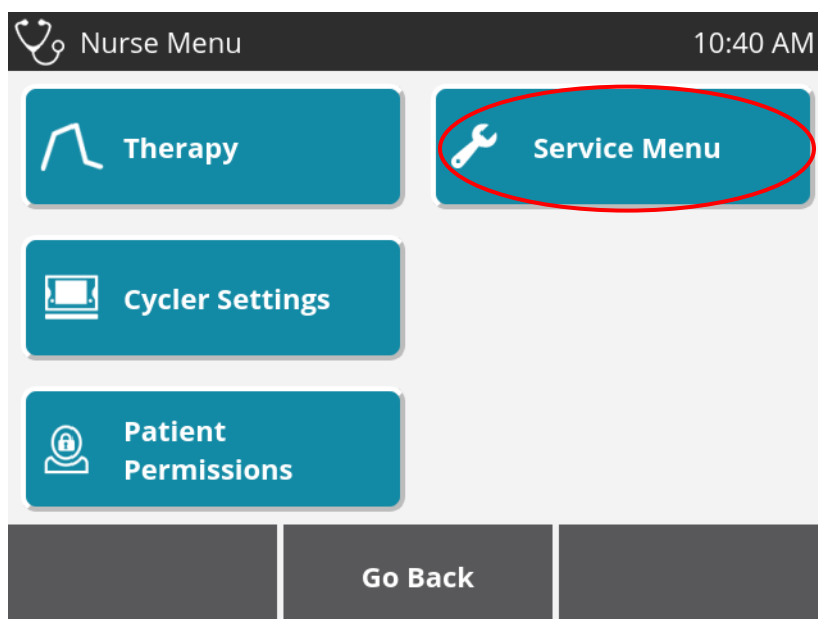
Battery Replacement (continued)

13 The screen shown below will appear. Touch the **Nurse Menu** button to continue.



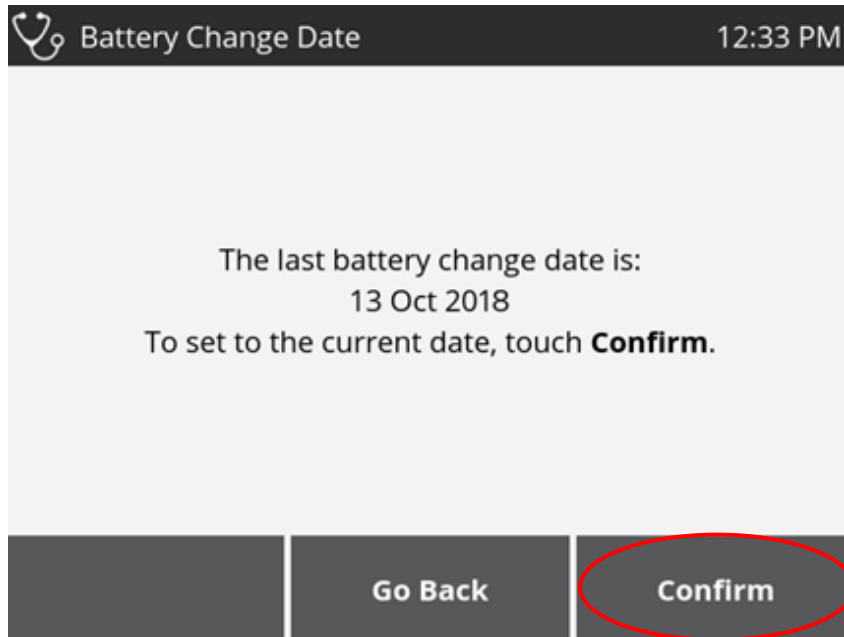
14 Enter the password for the Nurse Menu and touch **OK**. When you have entered the correct password, the screen shown below will appear.

15 Touch the **Service Menu** button and enter the password when prompted.

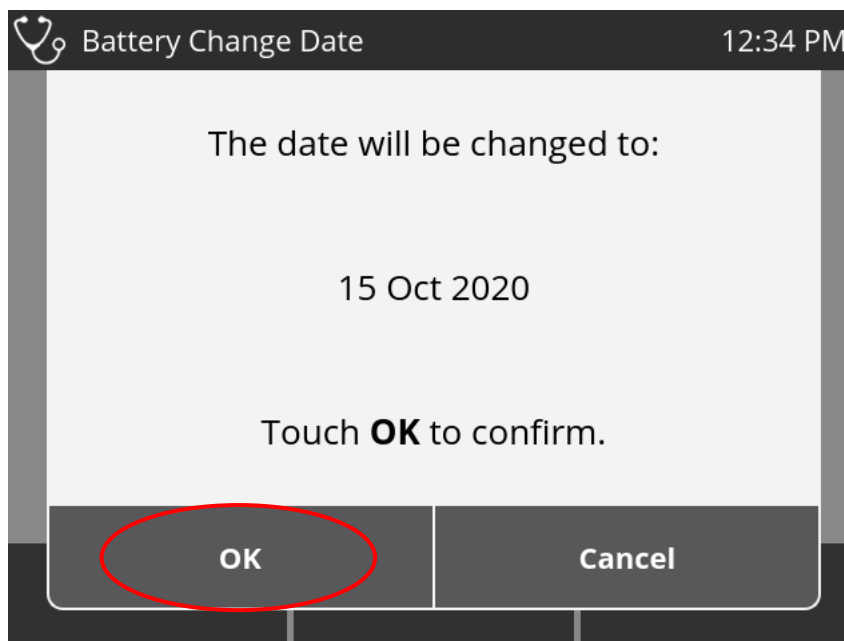


Battery Replacement (continued)

16 On the next screen, touch the **Battery Change Date** button. The screen shown below will appear.

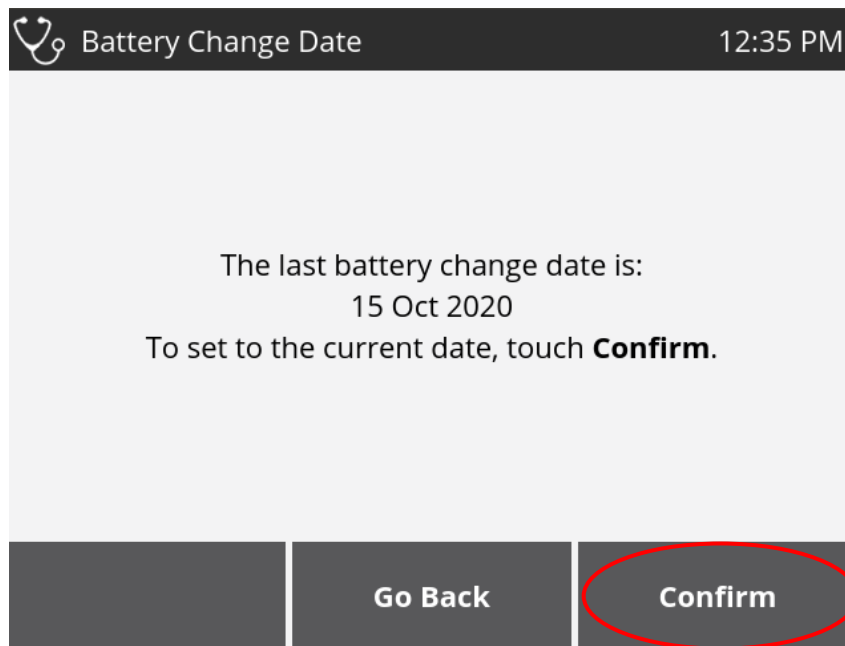


17 To set the battery change date to today's date, touch **Confirm**.



18 If the date shown is correct, touch **OK**. To return to the Nurse Menu, touch **Cancel**. The screen shown on the next page will appear.

Battery Replacement (continued)



- 19** To accept the new date, press **Confirm**.
- 20** Place the cyclor in standby, turn it off, and unplug to send home with the patient.
- 21** Tell the patient to leave the cyclor plugged in with the power switch on for four hours before using it in a treatment.



Note: Dispose of the used battery in accordance with local regulations. Improperly discarded batteries may pose a hazard to the environment.

OptiDwell

Peritoneal dialysis requires that dialysate be in contact with the peritoneal membrane. The VersiPD Cycler technology maximizes the time that dialysate is in contact with the peritoneal membrane by managing drain time. During the drain phase the cycler considers expected ultrafiltration (UF), the previous fill volume, pressure, and the drain rate. If drain issues are encountered, the cycler may adjust the next fill volume and continue the treatment. In this way prolonged drain times are reduced and dialysate contact time with the peritoneal membrane is optimized. The cycler is also monitoring the estimated volume in the peritoneum to make sure it does not exceed 150% of the programmed fill volume. In addition, adjusting the next fill volume and allowing the treatment to continue will reduce sleep interruptions for the patient.

Another aspect of OptiDwell is the patient line check. Any time a patient line check detects a blocked patient line, a series of three patient line blocked notice sounds will occur, with increasing volume. The sound is music instead of an alarm tone and the volume is not adjustable. It is not resolved like a caution or warning alarm. The notices promote patient movement to resolve the occlusion, without disturbing the patient's sleep by requiring interaction with the cycler. If flow is not established during the series of notices, an alarm will occur requiring the patient to interact with the cycler. Patient Line Blocked notices and alarms are detailed in the alarm section of this User's Guide.

A complete drain occurs during the initial drain and the last drain of each cycler treatment. In Tidal Therapy, a complete drain is inserted to prevent more than eight consecutive tidal cycles.

Initial Drain: the cycler continues to drain until the flow rate is less than or equal to 30 ml/minute for greater than 2 minutes.

If the drained volume is less than 70% of the previous fill plus 100% of expected UF, or 35 ml if there was no previous fill, a patient line check of up to 60 ml is performed. If the line is occluded, a Patient Line Blocked caution alarm will occur. If no occlusion is found an overflow warning will occur and the user will choose to end the drain or continue drain. The next fill volume will be the programmed volume.

If the drain volume is greater than 70% plus 100% of expected UF or 35 ml if there was no previous fill, an overflow caution will occur and the user will need to confirm drain is complete or continue draining. The next fill volume will be 100% of the programmed fill volume.

Last Drain: the cyclor continues to drain until the flow rate is less than or equal to 30 ml/minute for greater than 2 minutes. A patient line check will then be performed. If an occlusion is found, a Patient Line Blocked Notice and (if necessary) an Alarm will occur.

If the drained volume is 70% or more of the previous fill plus 100% of expected UF and no occlusion is found, the treatment will proceed. If a last fill is programmed the cyclor will adjust it if necessary. If a last fill is not programmed the treatment will end.

If the drained volume is less than 70% of the previous fill plus 100% of expected UF, and no occlusion was found, the drain will continue.

The table below summarizes the conditions that will trigger a patient line check during the initial and last drains and shows the next fill volume for each scenario.

Initial Drain				
UF	Previous Fill Volume	Rate and Time	Patient Line Check	Next Fill Volume
100%	>70% or ≥ 35 ml if no previous fill	≤ 30 ml/min for > 2 minutes	no	100% if End Drain is selected after overfill caution alarm
100%	< 70% or ≤ 35 ml if no previous fill	≤ 30 ml/min for > 2 minutes	yes	100% if End Drain is selected after overfill warning alarm and pop-up
Last Drain				
100%	> 70%	≤ 30 ml/min for > 2 minutes	yes	Adjust last fill volume if necessary and if last fill is programmed
100%	< 70%	≤ 50 ml/min for > 5 minutes or ≤ 12 ml/min for > 3 minutes	yes	Continue draining

Standard drain: active after the initial drain and before the last drain in treatment (excluding tidal therapy). When a drain volume is less than 70% of the previous fill volume plus 100% of the expected UF and the flow rate is less than or equal to 50 ml/minute for greater than 5 minutes, or flow rate is less than or equal to 12ml/min for more than 3 minutes, a patient line check is

done. If the patient line is occluded a series of Patient Line Blocked notices will be initiated. If the patient line is not occluded the drain will continue.

When drain volume is greater than 70% of the previous fill volume plus 100% of expected UF and less than 100% of the previous fill volume plus 100% of the expected UF, and flow rate is less than or equal to 30 ml/min for greater than 30 seconds, the cyclor will move to the next fill phase. The next fill volume will be adjusted to reach the prescribed fill volume.

When the drain volume is 100% or more of the previous fill volume plus expected UF and flow rate less than or equal to 30 ml/min for greater than 30 seconds the next fill is 100% of the programmed fill.

The table below summarizes the conditions that will trigger a patient line check during a standard drain (not initial or last drain or tidal therapy) and shows the next fill volume for each scenario.

Standard Drain				
UF	Previous Fill Volume	Rate & Time	Patient Line Check	Next Fill Volume
100%	$\geq 100\%$	≤ 30 ml/min for > 30 seconds	no	100%
100%	$> 70\%$	≤ 30 ml/min for > 30 seconds	no	Adjust fill volume to reach programmed volume
100%	$< 70\%$	≤ 50 ml/min for > 5 minutes or ≤ 12 ml/min for > 3 minutes	yes	Continue draining

Tidal treatment: the drain phase is complete when 100% of UF plus the prescribed tidal volume are achieved. Complete drains occur in the initial and last drains, and to avoid eight consecutive tidal cycles. Tidal drains are a percentage of the initial fill volume plus expected UF. If the flow rate is ≤ 50 ml/min for > 5 minutes or ≤ 12 ml/min for > 3 minutes, and tidal volume plus 100% of UF has not been reached, a patient line check is performed. If the line is occluded, a series of Patient Line Blocked notices initiates. If the line is not occluded, drain continues. If the drain is more than 70% of the tidal volume plus 100% of expected UF, the cyclor proceeds to the next fill. The next fill volume will be adjusted to reach the prescribed fill volume.

The table below summarizes the conditions that will trigger a patient line check during tidal drains and shows the next fill volume for each scenario.

Tidal Drains Excluding Initial, Last and Added Complete Drains				
UF	Programmed Tidal %	Rate & Time	Patient Line Check	Next Fill Volume
100%	100%		no	The programmed volume
100%	> 70%	≤ 30 ml/min for > 30 seconds	no	Adjust fill volume to reach programmed volume
100%	< 70%	≤ 50 ml/min for > 5 minutes or ≤ 12 ml/min for > 3 minutes	yes	Continue draining

Added and suppressed cycles: If 100% of the total programmed volume has not been delivered in a treatment, the cycler will compensate by adding one or more cycles using time saved by avoiding prolonged drains. If slow drain and or fill times are experienced during much of a treatment, one or more cycles may not be delivered. The cycler will deliver as much of the total volume as possible within the treatment time. The user will be notified if less than 90% of the total volume is used during a treatment.

Adapted Automated Peritoneal Dialysis (aAPD)

The adapted automated peritoneal dialysis (aAPD) approach combines sequences of short dwells and small fill volumes with long dwells and large fill volumes to promote ultrafiltration (UF) and clearance within one PD session.

An aAPD approach to patient therapy is programmable on the VersiPD Cyclor by a clinician using the Nurse Menu. Access to this menu requires a password. The effect of changes made to the prescription should be evaluated using clinical and device data recorded during treatments.

Machine Specifications

Overall

Dimensions	Fits within a rectangle of height 20cm, width 30cm and depth 30cm
Weight	5.44 kg (12 lbs.) excluding power cord

Operating Conditions

Ambient Temperature	15 °C to 35 °C
Inlet Dialysate Solution Temperature	15 °C to 35 °C
Intended Position of Operator	No more than 19 inches higher or lower than the cyclor during treatment. No more than 80 centimeters from the cyclor when reading labels on its surface.
Rel. Humidity	15% to 90% (non-condensing)
Atmospheric Pressure Range	700 hPa to 1060 hPa (equivalent to an altitude range of 3,000m to -1,200m)
Noise Level	Does not exceed 37 dBA at a distance of 1m and a flow rate of 200 ml/min.

Transportation and Storage Conditions

Temperature	From -20° to +35°C, after every 12 months of storage the battery must be recharged. From -20° to +45°C, after every 3 months of storage the battery must be recharged. From -20° to +55°C, after every 1 month of storage the battery must be recharged.
Rel. Humidity	5% to 95% (non-condensing)
Atmospheric Pressure Range	500 hPa to 1060 hPa (equivalent to an altitude range of 5,500m to -1,200m)



Note: If the cyclor has been stored outside of these conditions, it must be powered in standby mode for at least four hours before use.



Note: When removed from storage under these conditions, the VersiPD Cyclor does not need time to warm up or cool down before being operational.

Electrical Power

Power Supply	AC 100 – 120 VAC at 60 Hz and 220 – 240 AC at 50 Hz
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Power Consumption	Maximum AC power of 700 VA
Patient Leakage Current	Does not exceed 100 μ A AC / 10 μ A DC in normal condition Does not exceed 500 μ A AC / 50 μ A DC in single fault condition
Circuit Breaker	Fuse contained in Power Entry Module fast-acting, non-resettable 8A, 250VAC, 5 x 20 mm Breaking Capacity 1500A @250VAC
External Connections	USB Port, Class II Isolation IEC 60601-1:2012, Edition 3.1 Clause 7.2.4 (Accessories, SIP/SOP connections)
Electromagnetic compatibility	See EMC Declaration on page 236.

Electrical Safety

Protection against electric shock	Class II equipment, Type BF Applied Part per IEC 60601-1
Ingress Protection Rating	IP21
Mode of Operation	Continuous Operation
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	

User Interface


Language	The operating screens may be set to display text in English or Spanish.
Touchscreen	LCD display reacts to fingertip pressure
Buttons	Stop, Start

Hardware Settings

Alarm Loudness	1 to 10 (10 being the default value) that correspond to 39 dBA – 74 dBA at 1m distance
Voice Guidance Loudness	0 to 10
Screen Blanking Delay	1 to 60 minutes
Screen Brightness	1 to 10

Solution

Bag Sizes	2000, 3000, 5000, 6000 mL
Solution Types	1.5, 2.5, 4.25% Dextrose, NpH
Initial Fill Volume Range	250 to 3500 mL

Temperature Adjustable by User	35 to 37°C Resolution: 1°C
Temperature Set Point	Three set points (35°C, 36°C, and 37°C).
Total Volume	500 to 24,000 mL
Dwell Time Accuracy	± 1 minute for the calculated dwell time
Fill Volume	250 to 3500 mL
PD Plus Volume	250 to 3500 mL
Last Fill Volume	250 to 3500 mL
Flow Rate	Fill: programmable from 150 to 300 mL/min Drain: programmable from 100 to 250 mL/min
Fill Flow Rate Accuracy	Less than or equal to ± 15% versus the programmed flow rate of 150 to 300 mL/min, accounting for ramp period and excluding phases with automatic flow reduction or any flow interruption
Drain Flow Rate Accuracy	Less than or equal to ± 15% versus the programmed flow rate of 100 to 250 mL/min, accounting for ramp period and excluding phases with automatic flow reduction or any flow interruption
	 Note: If the patient is located 50 cm or more below the cycler, the drain flow rate accuracy specification may not be met.
Volume Accuracy (Fill and Drain)	At 2 standard deviations, less than or equal to ±15 mL or ±5%, whichever is larger
Symmetric Volume Accuracy (Fill Volume minus Drain Volume)	At 2 standard deviations, less than or equal to ±12 mL or ±2%, whichever is larger
Pump Pressures Generated	The average pressure (over a peristaltic cycle) at the patient connection point (catheter) must be not outside ±100 mbar (75 mmHg) with the patient at the same level as the cartridge under normal condition (±150 mbar (112.5 mmHg) under single fault condition).

Therapy

Total Therapy Time	10 minutes to 24 hours
Number of Fills	1 to 99
Pauses	PD+ cycles allowed: 1

Safety Systems

Air Infusion Protection	<p>Warning level alarm triggered if more than 1% of the total treatment volume (cyclor assisted) of air per treatment is detected by system.</p> <p>Two infrared sensors:</p> <p>Advanced Multi-Sensor Array sensor detects bubbles near solution bags.</p> <p>Patient Air Sensor detects bubbles in patient line (both outbound and inbound). If bubble is detected, the system will try to push it to the drain; for priming, fill, and PLC, if more than 18 mL of air is detected, caution alarm AC127 is generated. If more than 1% of the total treatment volume (cyclor assisted) of air per treatment is detected, warning alarm AW128 is generated. For drain, if more than 18 mL of air is detected, AC260 is generated; If more than 1% of the total treatment volume (cyclor assisted) or 100 mL of air (whichever is larger) per treatment is detected, AW129 is generated.</p>
Dialysate Solution Overfill Protection	<p>Peritoneal volume limited to 150% of the prescribed fill volume Initial Drain Warning requires user to acknowledge risk of IIPV.</p> <p>During fill: Pump revolutions are counted. Using the known volume of each revolution, the cyclor determines the fill volume.</p> <p>During drain: Pump revolutions are counted. Using the known volume of each revolution, the cyclor determines the drain volume.</p> <p>Symmetric accuracy between fill and drain volume is within 2% of target volume.</p>
Dialysate Solution Over Temperature Protection	<p>Dialysate shutoff if two independent outlet fluid temperature sensors do not each read lower than 39 °C.</p>
Alarm Priority	<p>Alarms of equal priority are resolved on a “first in, first out” basis, i.e. the alarm that occurs first is resolved first.</p> <p>If another alarm occurs during troubleshooting of the first alarm:</p> <ul style="list-style-type: none">- With higher priority: the system will alarm- With equal priority: the system will sound and visually present the alarms at the end of the troubleshooting of the first alarm.- With lower priority: the system will sound and visually present the alarms at the end of the troubleshooting of the first alarm.

Alarm Signal	<p>AC026, AC044, AC055, AC056, AC058, and AC059 are elevated to warning status if the user tries three times to resolve them and fails. AC042 is elevated to warning status after two failed attempts to resolve it.</p> <p>Audio alarm signal is elevated to the maximum loudness after two minutes if the user fails to intervene.</p> <p>Generation of AC179 [Power Lost] signal is delayed for 25 minutes from the time power is lost.</p> <p>Audio alarm signal may be paused. The audio pause is limited to 10 min in accordance with IEC 60601-2-39 §208.6.3.3.101.</p> <p>Auditory information signals are limited to the voice guidance for cyclers usage. The volume for this signal type can be changed from a range of 0 to 10 (setting it to 0 turns it off). The sound pressure level for this is the following:</p> <p style="padding-left: 40px;">0 volume: 0dBA 1-10 volume: 39 dBA-74 dBA at 1m distance</p>
Alarm Log	<p>Auditory alarm signals: caution alarms and warning alarms are accompanied by a repetitive siren-like noise, and they are distinguishable from each other thanks to a difference in sound frequency; both alarms have the same sound pressure level range (39 dBA to 74 dBA). The Patient Line Blocked Notice alarm generates a musical sound that is distinguishable from the other alarms. The volume of alarm signals cannot be turned off. The volume range is from 1 to 10 only.</p> <p>The last 14 treatments are viewable in the History Menu. All clinically relevant treatment data is saved for 180 treatments. Data older than that is overwritten.</p>
Protective System Failure Safeguard	<p>Air Infusion Protection: in case of failure, variations in pressure cause pressure failure alarms.</p> <p>Over Temperature Protection: in case of failure, disagreement of two independent sensors will cause temperature alarms.</p>

Options

Last bag	USB enabled	Drain %
Language	Bluetooth pairing	Additional drain alert
SI Units	Additional drain	

Applied Parts

Kinexus Gateway	Drain bags	stay•safe caps
VersiPD Cart	Solution bags	stay•safe catheter extension set
USB drive	stay•safe organizer	Drain lines
	VersiPD Cyclers Set	

VersiPD Cyclers Set

Storage Conditions	0 °C to 40 °C
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USB Drive

Memory Size	8GB
LED	Built-in, indicates data receiving or transmitting
Safety Compliance	FCC Class B and CE
Power Supply	USB-bus powered
Interface	USB specification 2.0 High Speed Device, Mass Storage Class, USB-IF and WHQL certified
Power Consumption	Sleep <650 uA; Read/Write <150 mA
Temperature	Operating: 0° C to 45° C Storage: -20° C to 60° C
Humidity	Operating–non-condensing: 10% to 90% RH (0° C to 45° C) Storage–non-condensing: 5% to 90% RH (-10° C to 60° C)
Vibration	Operating: 2 G, 10 to 500 Hz, 1.0/min. sweep rate Storage: 4 G, 10 to 500 Hz, 1.0/min. sweep rate
Shock	Operating: All six surfaces – 40 G for 11 ms, three shocks per surface Storage: All six surfaces – 80 G for 11 ms, three shocks per surface
Maximum Altitude	Operating: 3,048 m Storage: 12,192 m
Lifetime Endurance	100 K, under typical conditions
Data Retention	10 years

Kinexus Gateway

Network connection	Cyclers communications with the Cloud and Kinexus Gateway are secured via mutual authentication with TLS 1.2.
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Operating Conditions	The Kinexus Gateway must be at least 1.5 meters (5 ft.) away from cyclers when in use.
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Bluetooth Dongle FCC Interference Statement

FCC Identifier	VVXLM506
Name of Grantee	LM Technologies Ltd.
Equipment Class	Part 15 Digital Transmission System
Notes	Bluetooth V4.0 Dual-Mode Dongle
FCC Rule Parts	15C
Frequency Range (MHZ)	2402.0 – 2480.0
Output Watts	0.0029

Cloud Connection

Logs sent to cloud	<p>Cycler configuration settings, clinic ID, prescription set;</p> <p>Language of the cycler user interface, screen darkening preferences, sound volume, screen brightness;</p> <p>Treatment ID, treatment date and time, patient ID, UDI of the cycler, SW and HW information of cycler, prescription ID, vital signs measurements, manual exchanges, list of treatment phases, list of alarms, cassette type, user preferences on cycler at treatment start;</p> <p>Treatment date and time, UDI of cycler, SW and HW version information, fill, drain, patient line checks and flushes volume profile samples;</p> <p>USB events, Gateway, IoT;</p> <p>Cockpit information items;</p> <p>List of programs and settings changes;</p> <p>Certificates</p>
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VersiPD Cart

Maximum Safe Working Load	<p>Top Tray: 20 lbs.</p> <p>Bin: 27 lbs.</p> <p>Base: 20 lbs.</p>
Operating Conditions	<p>Temperature: 15-35°C (59-95°F)</p> <p>Humidity: 15-90% humidity</p>

Dialysate Solution Bag Case

Maximum Safe Working Load	60 lbs.
Operating Conditions	<p>Temperature: 15-35°C (59-95°F)</p> <p>Humidity: 15-90% humidity</p>



UL FILE NUMBER E353644
VERSIPD CYCLER
MEDICAL – GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
IEC60601-1-11: 2015
IEC60601-1-8: 2006
IEC60601-1-6: 2010
IEC60601-2-39: 2018

Manufacturer's EMC Declaration

The VersiPD Cyclor has been certified to the requirements of IEC 60601-1-2:2014 within the scope of equipment intended to be used in the home and institutional environments, such as hospitals.


Emissions testing of the machine was performed using the limits for CISPR 11:2019, Group 1, Class B which are specified for equipment intended to be used in homes. However, use of the VersiPD Cyclor in residential environments may result in interference with some types of broadcast receivers such as televisions and radios. Should such interference occur, it will not permanently affect those receivers and can be reduced or eliminated by repositioning of the receiver or the VersiPD Cyclor.

In order to assure the safety of the VersiPD Cyclor as well as other medical devices when used with the VersiPD Cyclor in the home environment, a detailed technical analysis was performed. This analysis has shown that the emissions levels of the VersiPD Cyclor are significantly below the immunity requirements of IEC 60601-1-2:2014 and therefore are not likely to impact the safe operation of other medical devices used within the proximity.

Likewise, immunity of the VersiPD Cyclor has been tested at the maximum levels of electromagnetic disturbances foreseeable in the environments of intended use, namely at patients' homes and professional healthcare facilities. However, the VersiPD Cyclor is not intended for use in "special environments" such as military areas, heavy industrial areas, or medical treatment areas with high-powered ME equipment (HF surgical equipment, short-wave therapy equipment, inside the RF shielded room of an ME system for magnetic resonance imaging).

Guidance and manufacturer's declaration – electromagnetic emissions		
The VersiPD Cyclor is intended for use in the electromagnetic environment specified below. The customer or user of the VersiPD Cyclor should assure it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11:2019	Group 1	The VersiPD Cyclor uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11:2019	Class B	
Harmonic emissions IEC 61000-3-2: 2005	With input current $\leq 16A$ per phase Class A (EUT connected), harmonic ratios of test voltage shall not exceed: <u>Limits Harmonic Order</u> 0 9% 3 0 4% 5 0 3% 7 0 2% 9 0, 2% even, from 2 to 10 0, 1% from 11 to 40 Voltage drop on input impedance ZM shall not exceed 0.15V peak.	The VersiPD Cyclor is suitable for use in all establishments including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3: 2013	With rated current $\leq 16A$ per phase and not subject to conditional connection Short Term Flicker Limit: 1.00 Long Term Flicker: 0.65 Max. Relative Voltage Change: 4.00% Relative Steady-State Voltage Change: 3.00% Maximum Interval Exceeding 3.00% Limit: 500msec	

Guidance and manufacturer's declaration – electromagnetic immunity			
The VersiPD Cyclor is intended for use in the electromagnetic environment specified below. The customer or the user of the VersiPD Cyclor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	Level contact discharge ± 8 kV Level air discharge ± 15 kV	± 8 kV contact ± 15 kV air	Can be used in a dry location (minimum 15% relative humidity)
Electrical fast transient/burst IEC 61000-4-4:2012	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical low-voltage power supply network that supplies hospitals or buildings used for commercial or domestic purposes.
Surge IEC 61000-4-5:2017	± 1 kV line to line	± 1 kV line to line	Mains power quality should be that of a typical low-voltage power supply network that supplies hospitals or buildings used for commercial or domestic purposes.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11:2017	0% U_T dip, duration 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T dip, duration 1 cycle 70% U_T dip, duration 25/30 cycles	0% U_T , duration 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T , duration 1 cycle 70% U_T , duration 25/30 cycles	Mains power quality should be that of a typical low-voltage power supply network that supplies hospitals or buildings used for commercial or domestic purposes. If you require continued operation during power mains interruptions, it is recommended that the VersiPD Cyclor be powered from an uninterruptible power supply.
Power-Frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	30 A/m at 50/60Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies hospitals or buildings used for commercial or domestic purposes.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The VersiPD Cyclor is intended for use in the electromagnetic environment specified below. The customer or the user of the VersiPD Cyclor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6:2013</p> <p>Radiated RF IEC 61000-4-3:2006 +A1:2007 +A2:2010</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>10 V/m 80 MHz to 2.7 GHz</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>10 V/m 80 MHz to 2.7 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the VersiPD Cyclor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = [3.5 / 3] \sqrt{P}$ $d = [3.5 / 3] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [7 / 3] \sqrt{P} \text{ 800 MHz to 2.7 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
NOTE 1	At 80 MHz and 800 MHz, the higher frequency applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		
^a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VersiPD Cyclor is used exceeds the applicable RF compliance level above, the VersiPD Cyclor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VersiPD Cyclor.		
^b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.		

Product Improvement Policy

Your VersiPD Cycler machine was designed and built to comply with these product specifications. It is the intention of Fresenius Medical Care to continuously improve products, a process that may result in modifications to specifications or equipment produced in the future. Such product improvements shall not incur any obligation to make similar changes or improvements to equipment previously produced. Where possible, improvements will be made available at reasonable prices. Any such improvement shall not be construed as corrections of any deficiency in previously produced equipment.

Warranty

REFURBISHMENT POLICY

It is the policy of Fresenius USA, Inc. to refurbish medical devices so that they meet the same performance specification as new products. Controlled procedures are used and the refurbishment is carried out at the same manufacturing location under the same quality management system as new medical devices. Refurbished units are excluded from the UL/cUL certification.

REPLACEMENT

The Fresenius USA, Inc. business model is to rent cyclers in order to maintain and ensure product quality. Refurbished medical devices meet the same performance specification as new medical devices (see above) and either may be supplied by the company as warranty replacements.

PERITONEAL CYCLERS

VersiPD Cyclers that are rented or leased may be either new or refurbished units. History files on new and refurbished medical devices are maintained by Fresenius USA, Inc. at its Concord, CA manufacturing facility.

Preventive maintenance of peritoneal cyclers is not required. Service is performed at the factory only. Cyclers requiring service or investigation are replaced, generally with refurbished equipment, so that investigation and/or service can be performed at the factory. No user service records are required.

In cases where the VersiPD Cycler requires service, replacement of the machine or parts described or referenced herein is expressly conditioned upon the terms and conditions set forth below. Any additional or different terms or conditions set forth by the Customer to Fresenius Medical Care, Inc., (herein called

“the Company”) shall not be effective or binding, and the terms set forth herein shall not be modified or amended, unless assented to in writing by an authorized official of the Company located in Waltham, Massachusetts.

LIMITED WARRANTY: *The Company warrants to the Purchaser that the equipment delivered is free from defects in material or workmanship for the periods specified below, provided the equipment is used and maintained in accordance with the original manufacturer’s operating instructions:*

A. Mainframe chassis, and electronic components, lamps, etc. shall be warranted for ninety (90) days from the date of initial installation or one hundred and eighty (180) days from the shipment, whichever occurs first.

B. Consumables shall not be warranted.

The Company will repair or replace, at its option, using new or reconditioned parts and/or assemblies, any parts subject to this warranty which are proven defective in materials or workmanship. Such repair and replacement will be made without cost to the Purchaser, and the Company reserves the right to determine the location at which the repair or replacement will be accomplished. The Warranty does not apply to any equipment which is misused, abused, neglected, tampered with, damaged by accident, flood, fire, or other hazard, subjected to abnormal or unusual electric or fluid stress, improperly installed or operated, or not maintained in accordance with the routine maintenance schedule set forth in the operating manual for the equipment.

Routine maintenance is not covered under warranty.

Modifications, alterations, installation, and service by other than a FRESSENIUS MEDICAL CARE authorized representative may void the warranty.

WARRANTIES APPLICABLE TO EQUIPMENT EXTEND ONLY TO THE PURCHASER, AND ARE NOT ASSIGNABLE OR TRANSFERABLE, AND SHALL NOT APPLY TO AUXILIARY EQUIPMENT, DISPOSABLE ACCESSORIES, OR LIGHT SOURCES. THE FOREGOING WARRANTY SHALL BE IN LIEU OF ANY OTHER WARRANTIES, EXPRESSED, IMPLIED, OR STATUTORY, RESPECTING THE EQUIPMENT OR ANY PARTS OR COMPONENTS THEREOF, AND THE COMPANY MAKES NO IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE PURCHASER’S SOLE AND EXCLUSIVE REMEDY IN


CONTRACT, TORT, OR UNDER ANY OTHER THEORY AGAINST THE COMPANY RESPECTING THE EQUIPMENT AND ITS USE SHALL BE THE REPLACEMENT OR REPAIR OF THE EQUIPMENT AND ITS PARTS AS DESCRIBED ABOVE, AND NO OTHER REMEDY (INCLUDING, WITHOUT LIMITATION, CONSEQUENTIAL DAMAGES) SHALL BE AVAILABLE TO THE PURCHASER. The Company shall have no further obligation or liability with respect to the equipment or its sale, operation and use, and the Company neither assumes, nor authorizes the assumption of, any obligation or liability in connection with such equipment.

TERMS: *Net 30 days, FOB shipping point plus sales and similar taxes. The Company's prices do not include sales, use, excise, or similar taxes. Consequently, in addition to the prices specified herein, the amount of any present or future sales, use, excise, or other similar tax applicable to the or use of the equipment hereunder shall be paid by the Purchaser, or in lieu thereof, the Purchaser shall provide the Company with a tax exemption certificate acceptable to the taxing authorities. Purchase price will include operation training of Purchaser's personnel when a complete system is purchased. Installation for replacement parts will be charged to the Purchaser on a time, material, and expense basis unless covered under the limited warranty or a service contract.*

SHIPPING: *The Company will use its own judgment in determining the most effective method of shipping unless otherwise specified by the purchaser.*

List of Terms

Term	Definition
Abdomen	Area of your body below the chest and above the hips, also called the belly.
Adapted Automated Peritoneal Dialysis (aAPD)	A type of therapy using a cyclor to vary dwell times and fill volumes so as to improve clearance of wastes while reducing glucose absorption. A fuller explanation of this feature is given on page 227.
Additional Drain	An optional drain after the last scheduled drain that is programmed by the user before treatment begins.
Aseptic Technique	A series of steps used to keep an area as germ free as possible, including putting on a mask, thoroughly cleaning and drying your hands, and remembering which parts of your supplies are sterile.
Automated Peritoneal Dialysis (APD)	Dialysis that is performed by a cyclor.
Button	An area on the touchscreen that, when touched, causes a specific action.
Catheter Extension Set	The tubing that connects your body with the cyclor's tubing set.
Clean	You have removed most, but not all of the germs. Good hand washing makes your hands clean, not sterile. Your work surface is clean, not sterile. See also <i>Sterile</i> .
Cone	Plug at the inside end of a solution bag. Breaking the cone allows the flow of solution to the connected tubing.
Connected Time	Your total expected time to be connected to the cyclor and receiving dialysis in a particular program.

Term	Definition
Continuous Ambulatory Peritoneal Dialysis (CAPD)	A type of therapy that consists of manual exchanges without the use of a cycler.
Continuous Cycling Peritoneal Dialysis (CCPD)	A type of therapy using a cycler where exchanges occur throughout the night and sometimes during the day.
Cycle	This is the basic unit of a treatment program. It consists of three phases: Fill, Dwell, and Drain.
Dextrose	A type of sugar used in dialysis solution.
Dialysate	Another word for dialysis solution. See <i>Dialysis Solution</i> .
Dialysis Solution	A mixture of sugar and water used to draw waste fluid out of your bloodstream and into your abdomen.
Diastolic Pressure	The lower blood pressure number, it represents the blood's pressure on arteries just before the next heartbeat.
Disposables	Supplies like the VersiPD Cycler Set that are not to be used more than once.
Drain	The phase of treatment where waste fluid is removed from your body. The Drain Time is the time used to drain this fluid.
Drain Percentage	This is the percentage of the fill volume to be removed by the Drain. The default setting is 100%. Any setting less than 100% introduces a Tidal Therapy. See also <i>Tidal Therapy</i> . 
Dry Day	Term for having very little fluid left in your abdomen as a result of no programmed Last Fill for your treatment.
Dwell	The phase of treatment in which the dialysis solution remains in your abdomen for a specified amount of time. The Dwell Time is the time allowed for actual dialysis to take place during each cycle.

Term	Definition
EMC	Abbreviation for Electromagnetic Compatibility. A device is compatible with its electromagnetic environment if it does not emit levels of electromagnetic energy that cause interference with other devices in the vicinity.
Exchange	Another name for Cycle. See <i>Cycle</i> .
Fill	Process of filling your abdomen with fresh dialysis solution. The Fill Time is the amount of time used for this process.
Fill Volume	The prescribed amount of dialysis solution to enter your abdomen during a cycle.
Gateway	See <i>Kinexus Gateway</i> .
GFI	Ground Fault Interrupter; a protective device designed to break the circuit every time there is an imbalance between incoming and outgoing current.
IIPV	Stands for Increased Intraperitoneal Volume, commonly known as Overfill. This condition occurs when you have too much fluid in your abdomen. IIPV may result in serious injury or death. Patients and care partners should watch for the potential signs of overfill. These include: difficulty breathing; vomiting or spitting up; feeling full, bloated, or overfilled after treatment; abdominal pain or discomfort; expanded or tense abdomen; chest pain, increased blood pressure, change in mental status, and leakage of fluid from the catheter exit site.
Intermittent Peritoneal Dialysis (IPD)	A type of therapy using a cycler where exchanges are not continuous, usually occurring at night. The patient will have a dry day.
Kinexus Gateway	A device that allows the cycler to receive information from other devices like scales and blood pressure cuffs without your having to enter it manually. It also allows you to send information about your dialysis treatment to your health care team via the internet. An internet connection, or a cellular connection, is required to use the Kinexus Gateway.

Term	Definition
Last Bag	This option enables the cyclor to deliver the last fill of the treatment from a separate bag connected to the green clamped line of the VersiPD Cyclor Set. It is used to prevent mixing of this fill with solution from other connected bags and may be used if a solution with a different dextrose is needed or if a medication is necessary in the last fill.
Last Fill	This is an option that allows dialysis solution to dwell in your abdomen during the day. If there is no Last Fill you will have a dry day.
MR	Refers to MRI, Magnetic Resonance Imaging.
Nocturnal Intermittent Peritoneal Dialysis (NIPD)	An <i>Intermittent Peritoneal Dialysis</i> (see above) treatment that takes place at night.
Occlusion	Something that blocks the free flow of fluid.
Overfill	See <i>IIPV</i> .
PD	See <i>Peritoneal Dialysis</i> .
PD+ (PD plus)	This option allows you to program a break in your treatment so you can let dialysis solution dwell in your abdomen while you are disconnected from the cyclor. A typical PD+ treatment would begin in the early evening, followed by a break and then the beginning of regular treatment at bedtime.
Peritoneal Dialysis	Also called ‘PD’. This is the process by which waste products are drawn from your blood across the peritoneum, a semi-permeable membrane in your abdomen.
Phase	One part of a cycle. A Fill is one phase of a cycle, and so is a Dwell or a Drain.
Prime	A procedure to remove air from the tubing line that connects to the catheter extension set.
Profile	Your name and treatment information that are remembered by the VersiPD Cyclor for the purpose of delivering consistent care to you.

Term	Definition
Program	A course of dialysis care using the VersiPD Cyclor that your doctor has prescribed for you.
Pyrogenic	Causing fever.
Round	A section of a treatment consisting of one cycle or more than one identical cycles.
SI Units	SI is an abbreviation for ‘System, International.’ This is a set of measuring standards that uses the metric system including kilograms (kg), Celsius degrees (°C), and millimole per liter (mmol/L). VersiPD can display values in either SI units or US standard units (lbs., °F, or mg/dL).
Standby Mode	This is the condition when the screen is turned off but the cyclor is still plugged in and the On/Off switch on the back panel is On (I). When the cyclor is in Standby Mode, the blue LED light at the top right of the front panel will be illuminated. Press the green START button to exit Standby Mode.
STAT Drain	An unplanned drain initiated by the user.
Sterile	Sterile means completely free of germs. Some of the supplies are packaged to keep them sterile. Some parts of the supplies must remain sterile after opening the package. See also <i>Clean</i> .
Systolic pressure	The higher blood pressure number, it represents the blood’s pressure on arteries during a heartbeat.
Tidal Peritoneal Dialysis (TPD)	The same thing as <i>Tidal Therapy</i> (see below).
Tidal Therapy	This term covers any therapy where the Drain Percentage is set at less than 100 percent. See also <i>Drain Percentage</i> .
Total Volume	This is the total Fill Volume for the whole therapy, including PD Plus, Cyclor, Last Fill and Manual Exchange.
UF	<i>See Ultrafiltration</i>

Term	Definition
Ultrafiltration (UF)	The amount of fluid beyond the fill volume to be removed from the patient. If a patient has a fill volume of 2500 ml and an expected drain volume of 2550 ml, the extra 50 ml is expected UF volume for that cycle.
USB	Abbreviation for ‘Universal Serial Bus.’ This is a device used to transfer data. The USB drive connects to the USB port on the left side of your cyclor.

Screen Finders and Index

Screen Finder
and Index

Screen Finder for Patients

Touch the buttons shown below in sequence to find the feature that is mentioned in the title of each row. Page references are added in case more information is needed.

Additional Drain and Wake Me Up Alert (page 112)



Alarm History (page 123)



Bluetooth (page 40)



Bypass → See Skip Phase

Data Transfer (History Menu) (page 125)



Event History (page 123)



Language Setting (English or Spanish) (page 120)



Night Screen Delay (page 118)



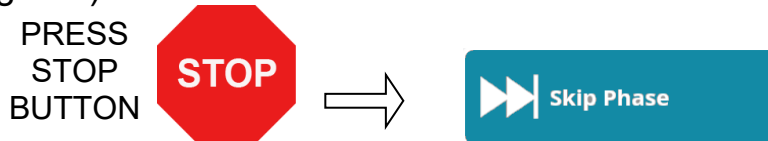
Program Menu (page 111)



Screen Brightness (page 121)



Skip Phase (page 91)



Solution Temperature (page 114)

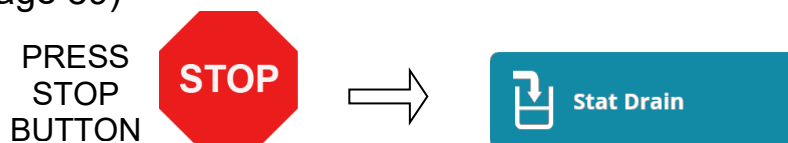


Sound Volume (page 117)



Spanish Language → See Language Setting

STAT Drain (page 89)



Time Entry (page 119)






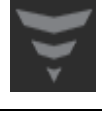









Treatment History (page 123)



Icons Used on VersiPD

Not all icons are represented here. If an icon is accompanied by text that explains its meaning, it is not explained here.

	This icon appears at the top left of screens in Your Menu (the menu for the patient).
	This icon appears at the top left of screens in the Nurse Menu.
 	This icon appears at the top right of the screen when the cyclor has been paired with the Kinexus Gateway using Bluetooth. The Kinexus Gateway device allows data from your scale and blood pressure monitor to be recorded by your cyclor without your having to enter it manually. The icon is blue when the cyclor is connected to the Kinexus Gateway, gray when it is not.
 	This icon appears at the top right of the screen when a cloud computing connection has been established for wireless communication between the cyclor and a clinic. The icon appears blue when the cloud connection is active, gray when it is not.
	This icon represents a white clamp for a solution line.
	This icon represents a green clamp for the Last Fill solution line.
	This icon represents a blue clamp for the Patient Line.
	The icon appears on the top left of Warning screens.
	The icon appears on the top left of Caution screens.
	The icon appears on the top left of Notice screens.
	This arrow will revolve while data transfer is taking place. There is no need to wait for this process to finish. The cyclor will shut off automatically 15 minutes after the completion of data transfer.

Screen Finder for Home Therapy Nurses

Touch the buttons shown below in sequence to find the feature that is mentioned in the title of each row. Page references are added in case more information is needed.

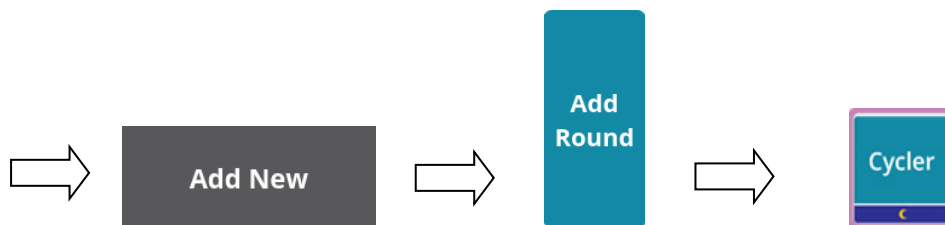
Additional Drain (page 153)



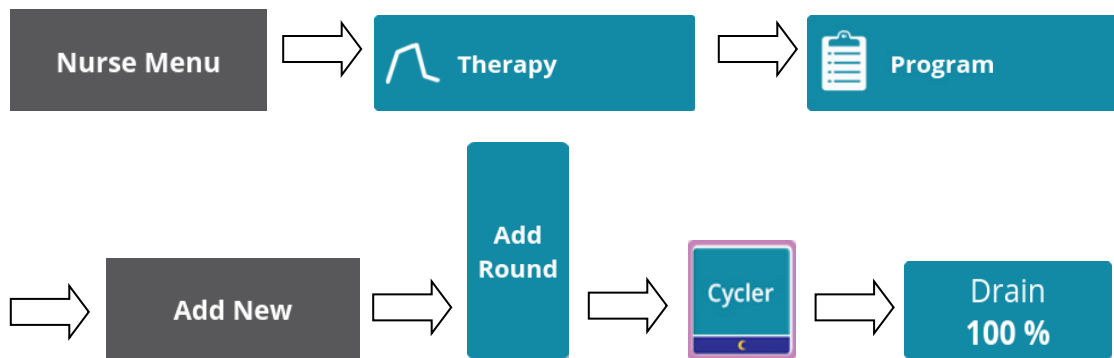
Catheter Performance (page 157)



Cycler Program (page 143)



Drain Percentage (page 144)



Drain Rate ➡ See *Flow Rate*

Expected UF ➡ See *UF Entry*

Fill Rate ➡ See *Flow Rate*

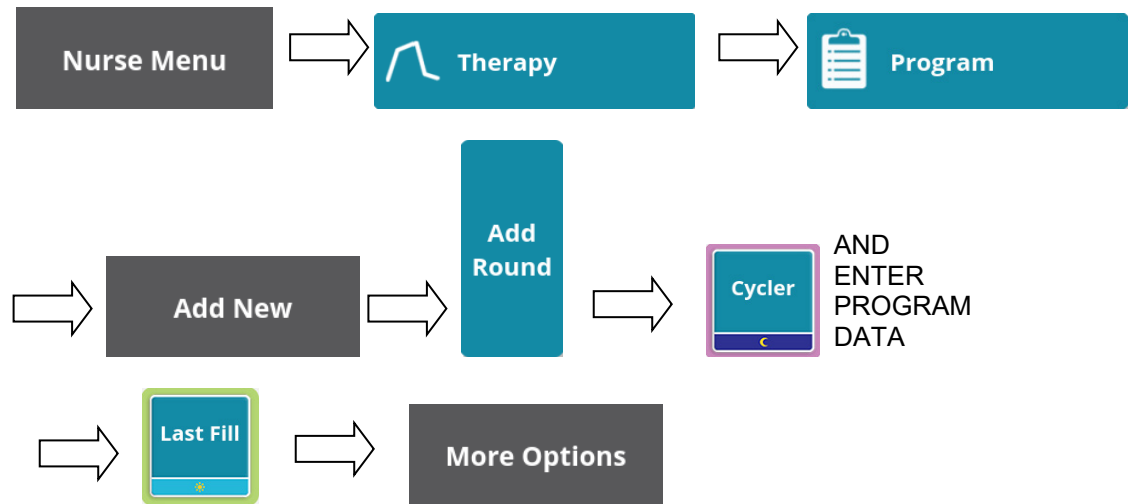
Fill Volume Limits (page 156)



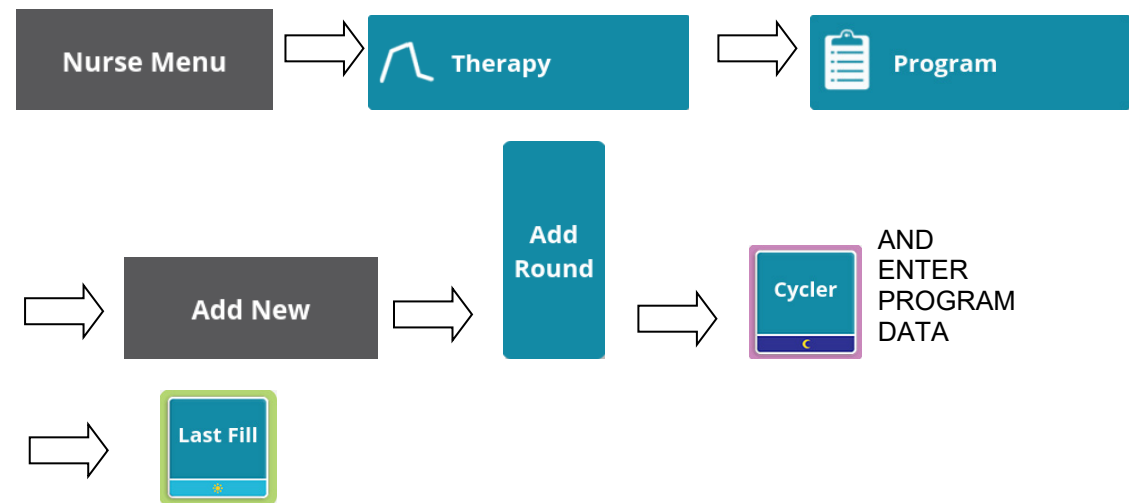
Flow Rate (page 155)



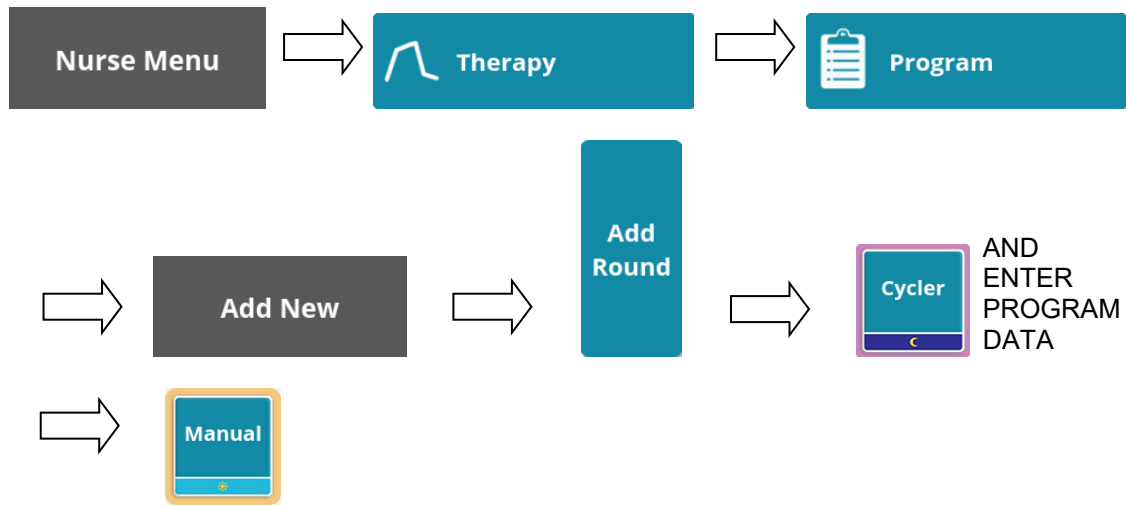
Last Bag Option (page 147)



Last Fill Option (page 146)



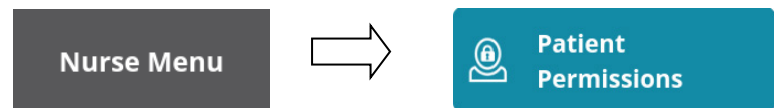
Manual Exchange (programmed) (page 148)



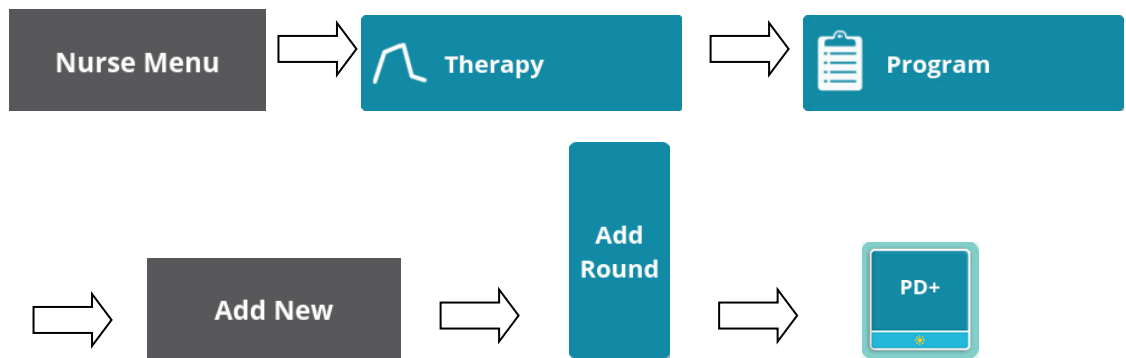
New Patient Option (page 162)



Patient Permissions (page 164)



PD Plus Option (page 141)



Program Entry (page 139)

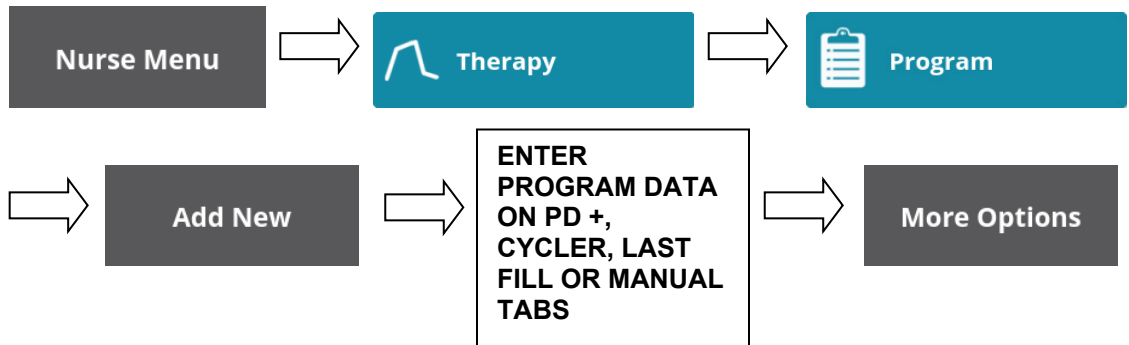


Solution Temperature (page 154)



Tidal Therapy → See Drain Percentage

UF Entry (page 142)



Units of Measure (American or International) (page 161)



Vital Signs (to program what the patient should measure) (page 159)



Index

A

Additional Drain.....243

Alarms

 Finder (search tool)..... 170

 List.....181

Aseptic Technique243

B

Back Panel.....15

Blood Glucose Entry52

Blood Pressure49

Brightness See Screen Brightness

Bypass See Skip a Phase

C

Cartridge Loader 14, 15

Catheter Performance.....157

Cautions.....192

 List.....193

Cleaning the Cyclor.....217

Cycle244

Cyclor Settings

 Nurse Menu158

 Your Menu115

D

Daytime Exchange.....See Manual Exchange

Diastolic Pressure244

Drain244

Drain Line.....73

Drain Percentage255

Drain Rate..... See Flow Rate

Dry Day244

Dwell244

E

Electric Shock29

EMC236, 245

Exchange See Cycle

F

Fill245

Fill Rate..... See Flow Rate

Fill Volume

 Maximum156

Finger Grip 14

Flow Alerts..... 84

Flow Rate 155

G

Gateway See Kinexus

Glossary See List of Terms

Green Button See Start Button

I

IIPV..... See Overfill, See Overfill

Increased Intraperitoneal VolumeSee Overfill, See Overfill

K

Kinexus Gateway plug in..... 15

L

Language Choice 120

Last Bag246

Last Fill246

Last Fill Option 146

List of Terms.....243

M

Machine Specifications..... 228

Manual Exchanges..... 148

MR Label 9, 246

N

Night Screen..... 118

Nurse Menu 133

O

On/Off Switch See Power Switch

Overfill 24, 90, 231, 246

P

Patient Line Check 84

Patient Menu See Your Menu

Patient Permissions..... 164

PD+ option..... 141

Phase246

PIN connector..... 27, 105, 141

Power Failure 215

Power Switch..... 15

Preventive Maintenance	34
Priming	76, 246
Product improvement policy	240
Pulse Entry	50

R

Red Button	See Stop Button
Round	247

S

Screen Brightness	121
Screen Finder	
Home Therapy Nurses	254
Patients	250
Shock	See Electric Shock
Skip a Phase	91
Slot for Warming Pouch	14
Solution Bags	
Cone	243
Connecting	67
Sizes	229
Solution Temperature	114
Spanish Language Setting	See Language Choice
Start Button	22
Start Key	14
STAT Drain	89
Stop Key	14
Systolic pressure	247

T

Temperature Entry	51
Temperature of Solution	See Solution Temperature
Terms, List of	See List of Terms
Tidal Therapy	247
Touchscreen	14, 23

U

UF	See Ultrafiltration
Ultrafiltration	258
Units of Measure	247, 258
USB	248
Drive	36
Ports	15

V

Vital Signs	
Nurse Settings	158
Patient Entry	46, 47

W

Warming Pouch	64
Slot	14
Warnings	24
Warranty	240
Weight Entry	48

Y

Your Menu	108
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INDICATIONS FOR USE: The VersiPD Cyclor System is indicated for adult chronic peritoneal dialysis in home and clinical settings.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

NOTE: Read the Instructions for Use for safe and proper use of this device. For a complete description of hazards, contraindications, side effects, and precautions, see full package labeling at fmcna.com.

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