AmeriWater
The Water Purification Specialists

CENTURION 1500+

OPERATING MANUAL

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Revision C
December 2017

CENTURION 1500+/UF
OPERATING MANUAL
For L998374/5

DOCUMENT HISTORY

Revision	**Date of Change**
A	January 2013
B	January 2016
C	December 2017

CONTENTS

1.0 PREFACE

Note: The **Centurion 1500⁺** is an accessory in a **Medical Electrical (ME) System** in which the dialysis equipment comprises the **Medical Electrical Equipment.**

This **Operating Manual** provides all of the information and instructions needed to operate the ***Centurion 1500⁺*** single patient reverse osmosis unit.

Please read the instructions carefully and make sure that you fully understand the information given before operating the unit.

A detailed ***Service & Maintenance Manual*** is available and will be held by your Healthcare provider. The Service Manual provides all of the necessary information for a qualified technician to maintain and service the unit.

Details on how to install & commission the ***Centurion 1500⁺*** can be found in the ***Installation & Commissioning Guide***. Installation of the unit would always be carried out by your Healthcare provider or an approved trained technician.

Once trained and approved to do so by your Healthcare provider a detail step by step guide on how to chemically clean and carry out routine heat disinfection cycles can found in the ***Chemical Cleaning & Heat Disinfection Instructions*** document.

Warning:
Before operating the unit always check to see that the water and electrical connections are secure and not likely to cause a trip hazard. If you have concerns about the unit or are unsure of its operation contact your Healthcare provider for advice and assistance.

2.0 CONTACT US

Should you require any additional information relating to the servicing, maintenance, spares and consumables, simply contact your Healthcare provider or **AmeriWater** or refer to the relevant accompanying manuals and guides detailed in **Section 1.0 PREFACE**:

AmeriWater: Tel No. 800-535-5585

(Or your local authorized **AmeriWater** distributor dealer or Healthcare provider)

Useful Telephone Nos.

Healthcare Provider:

Tel No……Contact Name:……

Tel No……Contact Name:……

3.0 HEALTH AND SAFETY

3.1 Explanation of expressions

WARNING
This symbol is used to alert the user not to take a certain action, which if taken could cause a potential hazard and result in a serious adverse reaction, injury or even death. The warning symbol may also be used to alert the user to take a certain action to avoid a potential hazard.
In all cases within this document, where this symbol is used it is important that you familiarise yourself with the nature of the potential HAZARD and any action that needs to be taken. If in doubt ask your Healthcare provider.

Note:
A reminder or useful information that can be used to help explain a command or action or give guidance.

3.2 Explanation of labels

There are a number of labels applied to the outside of the ***Centurion 1500+*** unit which identify hazards, advise caution or instruct the operator to seek reference before proceeding with an action. These are identified below.

No Pushing: The unit has been designed as a stationary device during normal operation. Do not push the unit when in operation as this may cause the integral tilt detector to shut the unit down.

Refer to Manual: is used when reference should be made to the manual to obtain advice and or information before carrying out a task. Please read the information given in the operating instructions carefully before proceeding. If in doubt contact **AmeriWater** or your Healthcare provider

Trip Hazard: There are a number of water and electrical connections from the rear of the unit to the renal replacement equipment and general services. To warn anyone from inadvertently tripping over these service lines the label above is used as a visual warning.

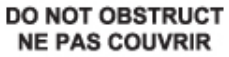
Hot Surface: This label is used to indicate that the surface labelled may be hot to touch under certain circumstances during the operation of the unit and in particular during the heat disinfection cycle. Avoid handling any part with this label during heat disinfection or take suitable measures to protect yourself from the heat.

Do Not Sit: Under no circumstances should the unit be sat on or objects placed on the top sloping cover as the stability of the unit may be affected.

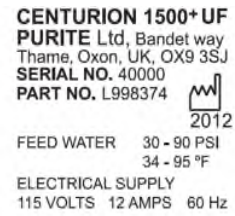
Do Not Step: The unit should under no circumstances be stood upon or used as step.

Note: The ***Centurion 1500***$^{+}$ unit is supplied with several detachable parts. Only use those parts that are identified with the following labels. **DO NOT** use alternative parts or this may invalidate the warranty or compromise the performance and or safety of the unit. Refer to **Section 3.7 " Unauthorized conversion and manufacturing replacement parts"**

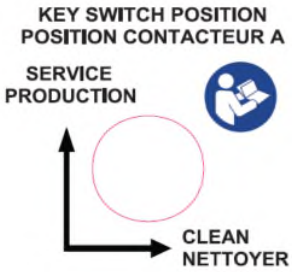
3.2.1 Rear panel labels



Placed above the main cooling fan, the label is used to warn user not to cover the vent which is essential for safe operation.



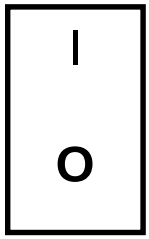
This label identifies the model of the unit, its part number, unique serial no.
year of manufacture, the original manufacturer's details, supply mains rating, feedwater pressure range and temperature.



For safety a key is provided to operate the unit and prevent the unit accidentally being placed into a clean. This label identifies the position of the key. When approved/trained to do so always refer to the "**Chemical cleaning and heat disinfection instructions**" if unsure about when and how to use this key.

External DIN socket connection. To be used by your Healthcare provider for connection to an external alarm device. **DO NOT** connect any unapproved devices to this point. Refer to **Section 11.1.4** for further details

The black cap provides protection of the USB outlet used for essential programming of the unit. **DO NOT** remove the cap or connect to any external device or mass storage device. To be used only by your Healthcare provider.

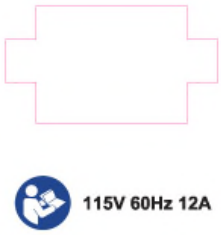


Supply mains **On/Off** isolating switch

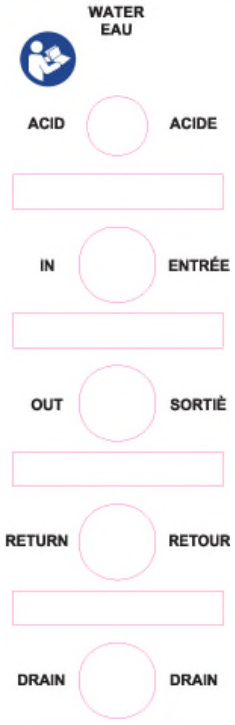
I = Power **On**

O = Power **Off**

This label identifies the position of the unit's two external fuses. **UNDER NO CIRCUMSTANCES** try to remove or replace these fuses, always refer to your Healthcare provider. Refer to **Section 11.1.2** for Fuse details



The supply mains electrical power lead is plugged in at this point. The label gives details of the electrical supply rating suitable to operate the unit. See **Section 11.1.1**.
The, **"Refer to the manual"** symbol will direct your Healthcare provider installer to the **Installation & Commissioning** guide.



This label provides details of all the water connections. If more details are required refer to the "**Installation and Commissioning guide**.

ACID/ACIDE	Cleaning chemical injection port.
IN/ENTREÉ	Mains feedwater connection.
OUT/SORTIÈ	Purified water outlet to dialysis machine.
RETURN/RETOUR	Purified water return from dialysis machine.
DRAIN/DRAIN	Waste water from unit to be connected to drain.

3.3 Safety considerations

Requirements, standards and regulations specific to the country in which the unit is used must be observed. Contact the local regulatory body for confirmation of these regulations and standards.

CAUTION: When used as a medical device Federal Law restricts this device to sale by or on the order of a physician as per 21CFR 801.109(b)(1)

Warning: To avoid risk of electric shock, this equipment must be connected to supply mains with protective earth. For permanent installations the mains supply must be provided with a Branch Circuit Breaker, refer to **Section 4.6.2** of the **Installation & Commissioning Guide** for details of rating and specification of Branch Circuit Breaker.`

Warning:

- The unit is not for use in explosive or oxygen rich atmospheres.
- The unit is for indoor use only and must not be washed down.
- The unit must not be allowed to freeze or be stored at temperatures below 41^0F or above 158^0F
- Always operate in a well ventilated area and ensure the cooling fan vents are not covered.
- **DO NOT SIT** on the unit, place items on top of it or use it as a step. Always operate the unit on a firm and level surface.
- **DO NOT DRINK** the purified water produced by the unit; it should only be used for the purposes intended as stated in **Section 3.4 "Intended Use"**
- Spillages from external equipment or other sources should be wiped off immediately, take the necessary precautions if the spillage contains bodily fluids. Refer to Section 8.3 "Cleaning external surfaces" when dealing with spillages.
- If the unit develops a leak follow the procedure in **Section 3.6.1**, DO NOT continue to operate the equipment.
- On no account must the unit be connected to the electrical supply when the side panels have been removed.
- If the unit's performance becomes impaired and any remedial work appears to be outside the scope of this manual, do not operate the unit and seek advice from **AmeriWater** or your Healthcare provider.
- The unit must only be serviced and maintained by **AmeriWater** or by your Healthcare provider.
- Failure to observe the instructions contained in this manual may compromise the safety, performance and reliability of the unit and may void any warranties.
- Under no circumstances try to service or repair the unit yourself; this will be the responsibility of your Healthcare provider.
- The unit must only be used as per it's "**Intended use"** to feed hemodialysis equipment as specified in **Section 3.4**

Note:

- It is possible that sensitive equipment/devices located in close proximity to the RO unit may be affected by electromagnetic or other interference generated from the RO unit. If this is so relocate the relevant equipment/device. **Refer to Sections 11.4, 11.5, 11.6 and 11.7 for further details.**
- Care must be taken not to place near the RO unit any source of RFI/EMI, which is liable to cause electromagnetic disturbance. If the RO is affected by such disturbance, the source must be suppressed or moved.

3.4 Intended Use

The AmeriWater ***Centurion 1500+*** Reverse Osmosis Systems are water treatment systems intended for use in hemodialysis applications. They are designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. The Centurion 1500+ Reverse Osmosis System is intended for use in a hospital, clinic, dialysis center, or for home care for single patient use. The device includes an integrated heat sanitization process.

The ***Centurion 1500+*** unit is a **Class III (Health Canada) / Class II (USA) Medical Device** intended for use in hemodialysis applications. It should only be used to feed hemodialysis equipment that complies with the current IEC 60601-2-16 standard.

The unit has been designed to pre-treat and purify potable water for use in the preparation of dialysate solution suitable for hemodialysis and related therapies in accordance with current **AAMI/ANSI/ISO** and Federal (US and Canadian) standards.

The ***Centurion 1500+*** unit is intended as a stationary device for indoor use only in hospitals, clinics, dialysis centres or for home care for single patient use as part of a **Medical Electrical (ME) system**. The unit should not be stacked on top off or placed directly adjacent to other electrical/electronic equipment.

The ***Centurion 1500+*** water purifier works on the principle of reverse osmosis and Ultra-filtration to provide purified water suitable for both hemodialysis and Hemodiafiltration and has been designed for continuous operation.

CAUTION: When used as a medical device, Federal law restricts this device to sale by or on the order of a physician per 21CFR 801.109(b)(1).

3.4.1 Operating staff

Warning:
The unit must only be operated and installed by persons who have been suitably trained and have studied and understood the instructions within this manual and who are familiar and confident with the operation of the unit.

Maintenance is restricted to carrying out chemical cleans and heat disinfections, once approved and trained to do so by your Healthcare provider. There are no operator serviceable parts to be replaced.

It is essential that in the event of an emergency the location of the Circuit Breaker or other supply n mains isolation device protecting the equipment is known.

If at any time you are unsure about the electrical safety of the unit or have reason to believe that it is potentially unsafe to use you should switch the unit off, isolate it at the Circuit Breaker and seek advice from your Healthcare provider.

The supply mains isolation switch is located at the rear of the unit ensure that it is accessible at all times and remains clear from obstruction. Ensure that the wall plug is accessible at all times as this can be used as a method of isolation.

3.4.2 Residual dangers

Warning:

Electrical Shock.

Do Not remove the side covers or touch or interfere with any of the electrical components.

Mechanical force.

Some parts of the system can be under pressure of up to 215 psi (15 bar). Do Not remove the side covers and interfere with the water pipework or any water connections, as you could risk the possibility of injury to yourself or others or cause damage to surrounding equipment.

Hot Surfaces. During the heat disinfection cycle the external distribution pipework and connector to the dialysis machine will become hot to touch, avoid touching these components and warn others.

3.4.3 Handling

Warning:

The unit has been specifically designed as a stationary device. Should the unit need to be relocated it must be decommissioned before moving. Refer to **Section 4.14 "Decommissioning for relocation procedure"** in the **Installation & Commissioning Guide.** The dry weight of the unit is 86 pounds. A transport cart or other suitable device should be used when moving the unit. Precautions should be taken to secure the unit from toppling during relocation.

Do Not pick the unit up by the side covers; they are not designed to take the weight of the unit. Support the unit by holding the underside of the chassis while steadying the body.

When relocating the unit always ensure the unit has performed its full drain down routine. To do this switch the unit on, isolate the incoming mains water supply, press **"START"** and run the unit until it stops due to **'Low Tank Level'** then switch off.

Do Not move the unit while it is still in operation.

3.5 Bringing the unit to an immediate STOP

If you need to stop the unit immediately at any time, simply press the black rocker switch on the back of the unit to the **"O"** position. Then as a precaution, turn off the water supply at source. Alternatively press the red **"STOP"** button on the touch-screen twice.

Unless safe to do so **Do Not** restart the unit until you have spoken to **AmeriWater** or your Healthcare provider for advice or assistance, contact telephone numbers can be found in **Section 2.**

Warning:

The supply mains isolation switch is located at the rear of the unit ensure that it is accessible at all times and remains clear from obstruction.

Ensure that the wall plug is accessible at all times as this can be used as a method of isolation.

If the unit was stopped due to a leak, before reinstating the power to the unit carry out an electrical safety inspection as detailed in **Section 9.1.1** of the **"Service & Maintenance"** manual.

3.6 Disposal of consumables

The disposal of consumables will be the responsibility of either **AmeriWater** or your Healthcare provider.

3.6.1 Dealing with leaks from the unit

In the event of a leak from the unit, shut the unit down by following the procedure in **Section 3.5.**

If water has leaked from the unit follow in-house clinical practices that relate to the clearing up of spillages or leaks. If the leak cannot be cleared up immediately as a guide we recommend that the area affected is clearly identified and suitable warning signs erected to warn passers-by of a “potential slip hazard”.

3.7 Unauthorized conversion and manufacturing replacement parts

DO NOT under any circumstance, modify, remove or replace parts on the unit or attempt to change/alter its operation or functionality.

If the unit requires attention always contact **AmeriWater** or your Healthcare provider for assistance and advice.

Warning:
The ***Centurion 1500***$^{+}$ unit should only be used in accordance with its intended use and should be maintained and operated according to the instructions contained within this Operating manual and supporting documents. **AmeriWate**r/Healthcare provider will not accept any responsibility for any damage or injury resulting from improper use, maintenance, unauthorized repair or use of any un-approved parts.

3.8 Warranty claims and liability

This product has been manufactured in accordance with ISO 9001:2008 and ISO 13485:2012 procedures, after which it was subjected to a quality control process.

3.8.1 Product Warranty

This product has been manufactured in accordance with ISO 9001:2008 and ISO 13485:2012 procedures, after which it was subjected to a quality control process. If, however, you are unsatisfied with the unit, please contact **AmeriWater** or your Healthcare provider. Any warranties guaranteed by **AmeriWater**/Healthcare provider with respect to the ***Centurion 1500***$^{+}$ will be voided if the equipment is not installed/operated/serviced or maintained in accordance with the written instructions provided within the accompanying product manuals, or if the unit is serviced and maintained by a third party not approved or recognised by **AmeriWater** or the location of the unit is changed without notification to **AmeriWater**.

4.0 ABOUT YOUR CENTURION 1500+

4.1 General views of the Centurion 1500+ unit

Side view

Front view

Rear view

4.2 Overview

The ***Centurion 1500+*** water purification unit has been specifically designed as a single patient, reverse osmosis (RO) unit to supply purified water suitable for hemodialysis or renal replacement therapies.

The unit is capable of producing purified water up to 0.40 USGPM (1.5 litres per minute) based on a feedwater supply at 50ºF. (Refer to **Section 11.3.5** for more details relating to the performance of the unit)

The unit is fitted with an internal pump that pressurises the water supply and forces it through a membrane which then separates out all of the impurities from the feedwater. Purified water, termed “permeate” passing through the membrane feeds the dialysis machine whilst the rejected impurities are flushed to drain in the “Concentrate” stream.

4.3 Standard features

- Product water output up to 23.7 USgals/hr (0.40 USgals/min)
- Product water exceeding all recognised hemodialysis standards.
- Integrated hot water disinfection up to point of use.
- Multi-colored touch screen display for easy control.
- Instrumentation providing display of water quality, temperature, flow, pressure and salt rejection.
- Quiet running option for quiet operation.

- Audible alarm.
- Data logging facility.
- Internal leak and water loss detection system.
- Recirculation up to point of use.
- Ultra-filter
- Tilt detection.
- Built in backflow prevention.
- Semi-automatic chemical cleaning program.

4.4 Detailed features and process of operation

To reduce the risk of accidental damage all external water and electrical connections can be found at the back of the unit.
The feed water enters the unit, passes through the inlet solenoid valve and fills the internal feed water break-tank. The level in the tank is controlled by three level switches, one at the high water level and one at the mid water level. The mid-level switch controls the opening of the inlet solenoid and the high-level switch controls the closing of the inlet valve.

If the feed water stops for whatever reason, or there is insufficient flow, the third bottom level switch turns off the high-pressure Reverse Osmosis (RO) boost pump to protect it from running dry and damaging itself.

The (RO) pump takes water from the internal break tank and boosts the water pressure to the RO membrane. There is a pressure sensor situated immediately after the pump, which will display a warning message on the touch screen, should the maximum system pressure be exceeded.

The pressurized water is forced through the membrane which then separates out up to 98% of the impurities. The purified or “Permeate” water then goes on to feed the dialysis machine. The water containing the rejected impurities or “Concentrate” is flushed to drain.

The quality, temperature and flowrate of permeate water produced from the RO module is monitored and displayed on the touch screen.

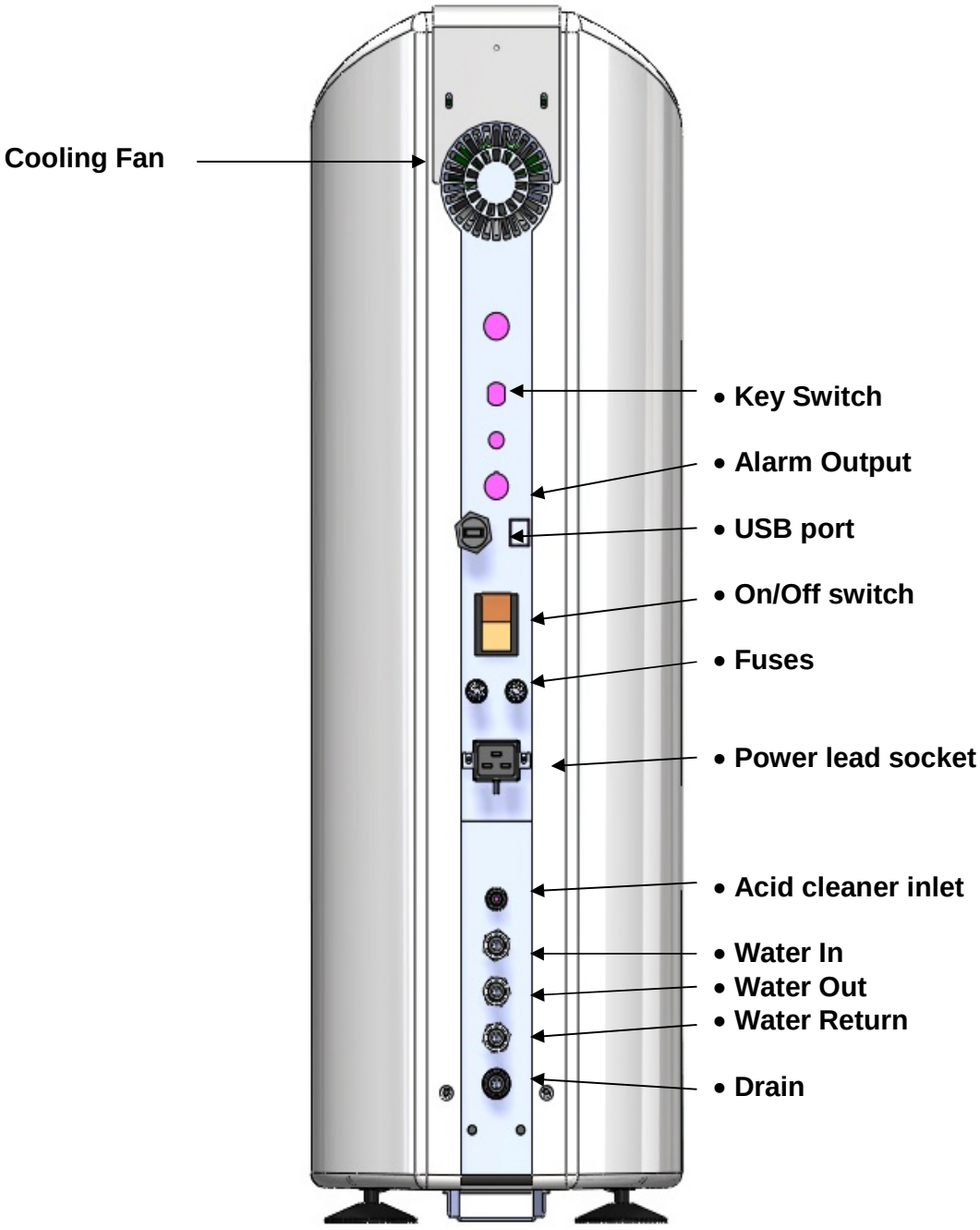
Ultra-filter used to reduce the endotoxin level to less than 0.03 EU/ml and the TVC to a level of <0.1cfu/ml.

To ensure the quality of water is maintained every time the unit starts up it carries out a flush to clear the unit of any standing water before producing fresh permeate water.

The microprocessor control system constantly monitors the unit’s performance and water quality. If any parameter is exceeded at any time the unit will respond with a warning or advisory message on the touch screen.

If the unit detects an unsafe condition it will automatically shut down in a safe and controlled manner.

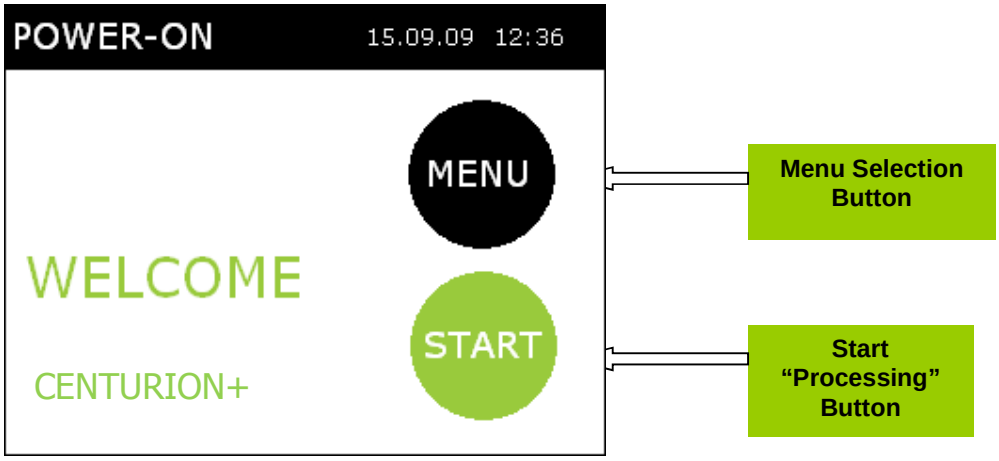
4.5 Explanation of rear connections



5.0 OPERATING THE TOUCHSCREEN

5.1 Explanation of Buttons

The operation of the ***Centurion 1500+*** is controlled via the touch screen display which can be found on the top of the unit. The picture below shows an interpretation of the display.



5.1.1 Using the screen

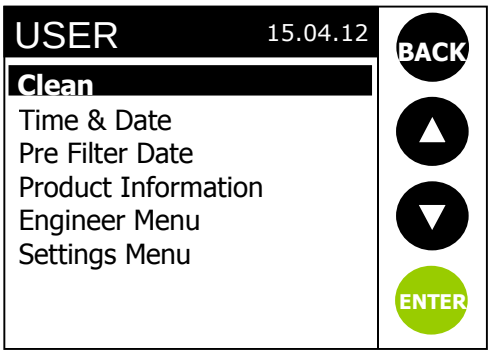
In normal operation the screen will display a diagram which mimics the flow path of the water purification along with any messages. **See Section 5.3** for more details.

To select an action simply touch the screen on the appropriate button once with your finger.

Note:
Do Not use sharp or pointed implements, such as pens, pencils etc... to operate the screen as this will damage the sensitive surface of the display, always operate the screen using your finger tips.
Do Not press more than one button at a time

5.1.2 "MENU" button

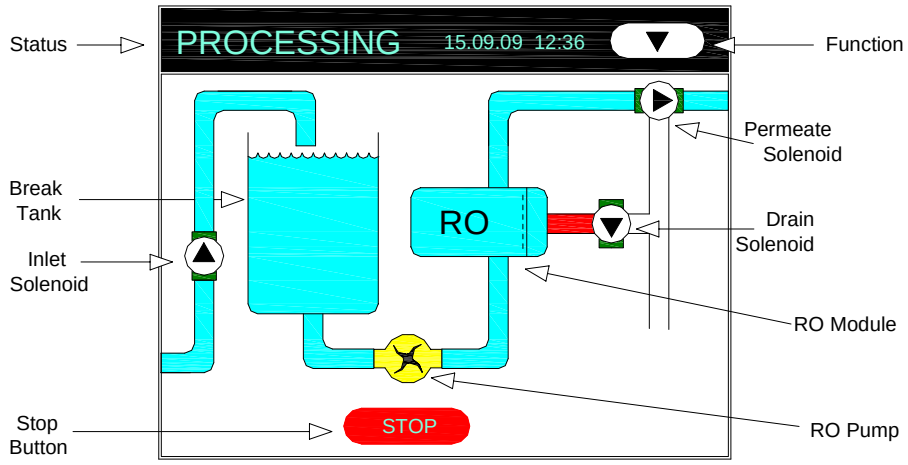
Pressing the **"MENU"** button will bring up the following **"USER MENU"** screen.



For details on each of the sub-menus and how to access them go to **Section 6**

5.1.3 "START" button

Pressing the **"START"** button the unit will go into **"PROCESSING"** mode and start to produce purified water and the screen below will be displayed.



Refer to **Section 5.3** for explanation of the mimic screen.

5.2 Operation

5.2.1 Initial Start up Procedure

Carryout the Pre-Dialysis checks listed in **Section 8.2.**

Once you have completed the above checks switch on the unit using the, **I/O** (on/off) switch at the rear of the unit. Switch to the **"I"** position.

When powered the unit's HMI screen will illuminate and display both text and a visual mimic of the units operation.

The touch screen will initially display **"Intialization"** for a few seconds before showing the **Power On** screen, which displays the current date, time, model type and any active messages.

During **"Intialization"**, two "bleeps" will sound indicating that the audible alarm is functioning correctly.

5.2.2 Starting the unit

To Start the unit select the "**START"** button, the screen will then change to the **"PROCESSING"** screen which will display a mimic of the unit's operation.

The unit will then carry out a high flow flush to drain, followed by an internal permeate rinse. After 90 seconds the permeate will automatically flow to the dialysis machine, if connected.

5.2.3 Stopping the unit during normal operation

To stop the unit at any time press the **"STOP"** button on the screen. If the unit has been running for two hours or more, the unit will perform a shut-down flush which directs a high concentrate flow across the membrane to the drain for 30 seconds. After the 30 second shut-down flush the screen will revert to the "**Power On"** display.

During the shut-down flush pressing the **"STOP"** button twice from the processing screen will stop the unit immediately terminating the flush. **(Refer to Section 3.5)**

⚠

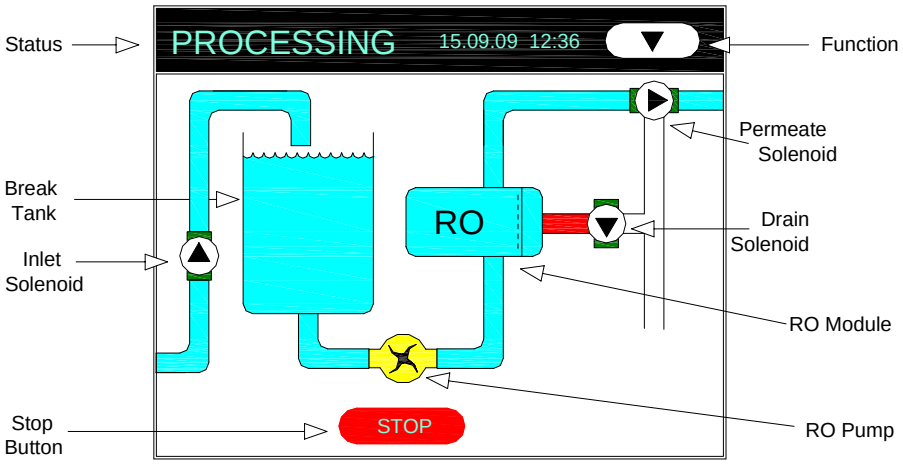
Warning: The supply mains isolation switch is located at the rear of the unit, ensure that is accessible at all times and remains free from obstruction.
Ensure that the wall plug is accessible at all times as this can be used as a method of isolation.

5.2.4 Operation of screen function button

To access different performance values, while the mimic screen is displayed, press the function button "▼" at the top right of the screen. This will in turn, display **"Permeate Quality", "Temperature", "Flow Rate", "Pump Pressure"**, **"Feed Quality** and **" Salt Rejection".**

5.3 Explanation of the mimic screen

This screen is displayed during normal processing.



Mimic screen

5.3.1 Mimic symbols

The symbols are presented on the screen below the “status bar”. The text indicates the current operation and the stage reached within that operation. This text will alternate with any warning or advisory messages that may be present.

The symbols represent the main components within the unit. Anything coloured red indicates that it is closed or stopped. If the symbol is moving or flashing it indicates it is powered.

5.3.2 Explanation of displayed functions

Each time you press the Function button, “▼”, at the top right hand edge of the screen you will be able to display information relating to the performance of the unit. The information will be in the form of numbers and text and displayed on the “status bar”. This information may be required by your Healthcare provider when diagnosing a possible fault.

There are 6 selectable function values, an explanation of each is given in the table below.

Displayed Function	Explanation
Flow Rate	This is the volume of permeate the unit is producing and is measured in “**gallons/min**”
Permeate Quality	This value indicates the quality of the permeate water and is measured in **microsiemens/cm** or **µS/cm**.
Temperature	This tells you the temperature of the water being produced and is displayed in, “**^{0}F”**.
Pump Pressure	The unit contains a pump to process the water and this displays the pressure the pump is running at in **“psi”.**
Feed Quality	If enabled the unit will constantly measure the quality of the incoming water supply and display the reading in **microsiemens/cm** or **µS/cm**.
Salt Rejection	Again if enabled the **“Salt Rejection**” compares the quality of the purified water to the feed water and expresses it as a “%”. This will be used by your Healthcare provider to check the performance of the unit.

Note:
When diagnosing a fault on the unit your Healthcare provider may ask you for some of the readings above. Make sure that you are familiar with the operation of the **“Function”** button and how to obtain the information.
Always refer to **Section 9.1 “Troubleshooting guide”** when speaking to your Healthcare provider regarding any fault.

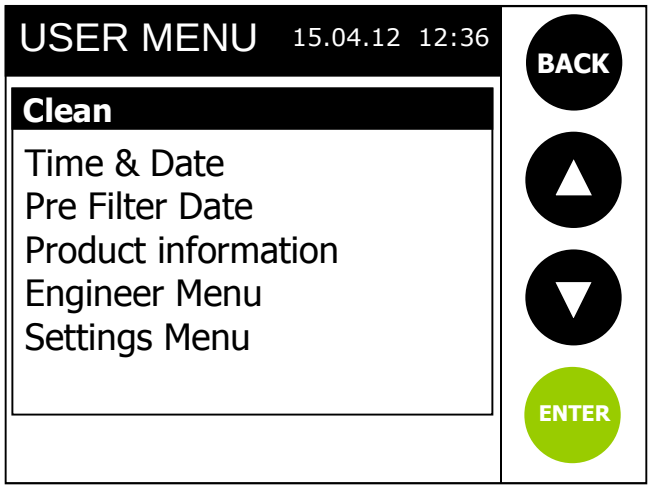
Warning:
It is recommended that the key used to select CLEAN/SERVICE positions is removed to prevent anyone from accidentally switching the unit to the wrong mode during use. The key is only required for use during either Heat disinfection or Chemical clean.
Having the key switch in the wrong position could interrupt dialysis or the cleaning/disinfection of the unit.

6.0 MENUS AND SETTINGS

6.1 User menu

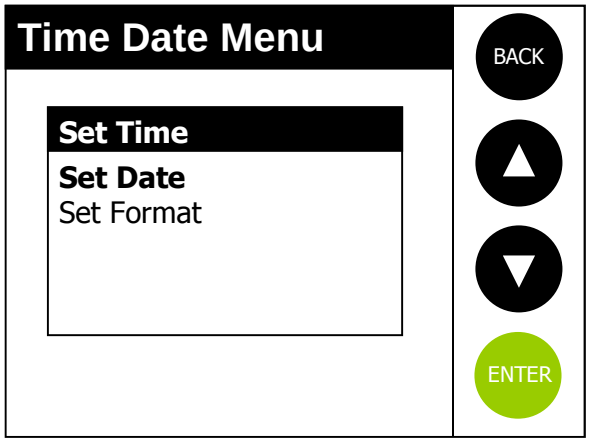
Pressing the "**MENU"** button from the **POWER-ON** screen will reveal the "**USER MENU"**.

There are six sub menus which will allow you to adjust the **"Time & Date" (see Section 6.1.1)**, start a **"Clean" (see Section 7)**, reset the internal Ultra-filter replacement date **(see Section 6.1.2)**, for **"Product Information"** refer to **Section 6.1.3** and for the **"Engineer Menu" and "Settings Menu (see Section 6.1.4),** which are only provided for use by your Healthcare provider. The various sub menu options can be selected by pressing the ▲/ ▼buttons followed by **"ENTER"**



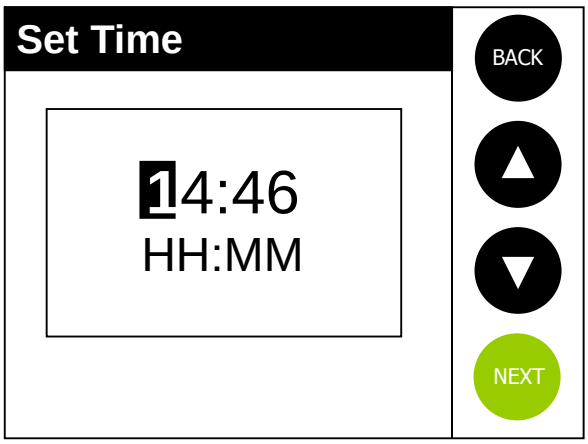
6.1.1 Set Time and Date

From the USER MENU and by using the ▲/ ▼buttons select **"Time & Date"**, then press the **"ENTER"** button. The first screen below will be displayed.



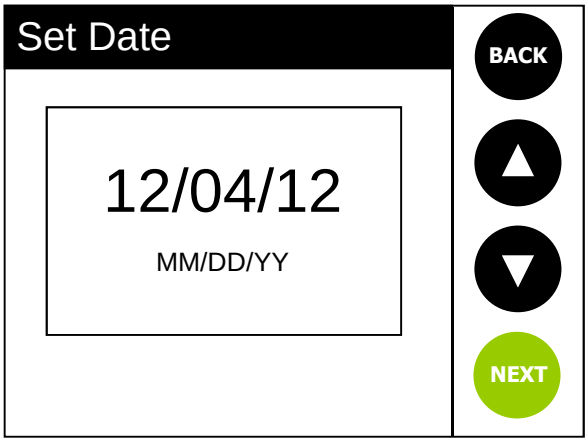
Again by using the ▲/ ▼buttons select from one of the entries listed and press **"ENTER"**

To return to the main "USER MENU" simply press the **"BACK"** button



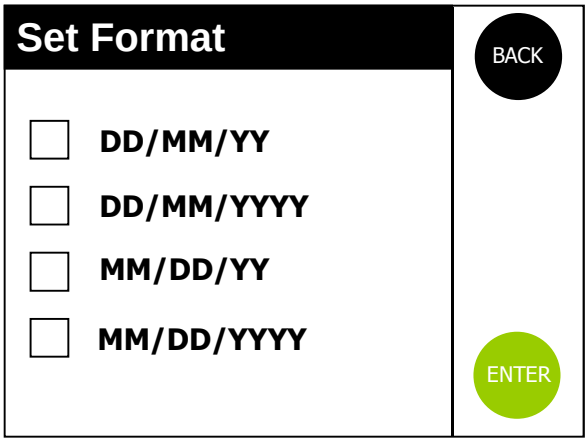
If you select **"Set Time"** the screen opposite will be displayed. The flashing cursor identifies which digit you can adjust.

By using the ▲/▼buttons you can either increase or decrease the number value. Once the correct number has been selected, press **"NEXT"** to move to the next number. **On pressing "NEXT"** on the final number a confirmation screen will pop up, stating **"Done"** and after a few seconds the screen will revert back to the **"Time Date Menu"**



To select "**Set Date**" from the menu use the ▲/▼ buttons and press **"ENTER".** The date will be displayed and the cursor will flash on the first number.

Use the ▲/▼ buttons to change the number to the correct value, then press **"NEXT"** to move to the next one. On pressing **"NEXT"** on the final number a confirmation screen will pop up and after a few seconds the screen will revert back to the **"Time Date Menu"**



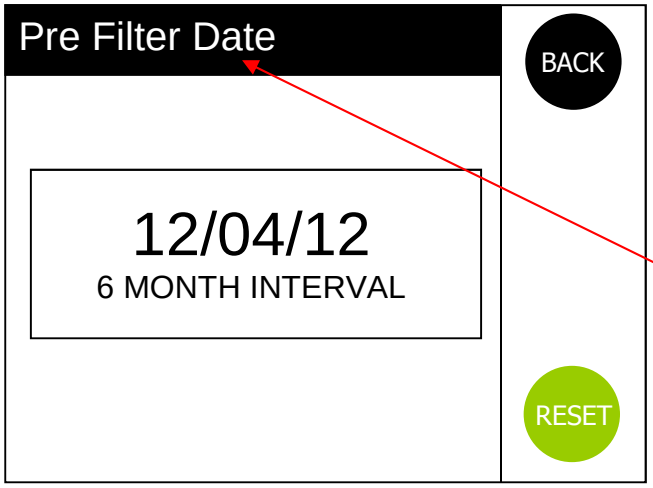
Should the format of the date be wrong, by selecting the "Set Format" menu and by pressing **"ENTER"** the **"Set Format"** menu will be displayed. Touch the box that matches the correct format. A tick will appear to confirm your selection. Press **"ENTER"** a confirmation screen will pop up and after a few seconds the screen will revert back to the **"Time Date Menu"**

Note: Pressing the "**BACK"** button prior to pressing the "**ENTER"** button will cancel changes currently being made and return you to the **"USER MENU"**

6.1.2 Pre-Filter replacement date

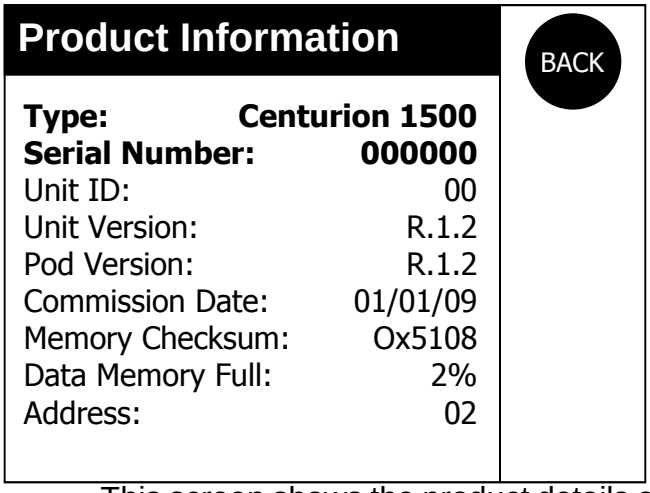
(Centurion 1500^{+}UF variant L998374 only)

The Pre filter replacement date should be reset when the Ultra-filter is replaced during maintenance. This would normally be carried out by your Healthcare provider and will ensure that the Centurion unit will provide a prompt message when the next filter change becomes due.



Pre Filter Date will be used to provide users with a reminder to replace the Ultra-filter inside of the Centurion. The reminder shall be set to a 6 month interval

6.1.3 Product Information



This screen shows the product details and software version numbers and is for information only.

6.1.4 Engineer & Settings menu

Warning:
The ‘Engineer and Settings Menus’ are only accessible for use by trained and authorized personnel. If any data held within these menus is altered the performance/safety of the unit and/or water quality may be seriously affected. An access PIN number is required to enter this menu.

7.0 CHEMICAL CLEANING AND HEAT DISINFECTION

7.1 Chemical cleaning

To maximize the life and maintain the performance of the unit's reverse osmosis membrane and to ensure the permeate quality meets the requirements for hemodialysis, chemical cleaning of the unit is recommended.

Note:
You will not be able start a chemical clean or heat disinfection unless you have been provided with a key, the key allows you to switch the unit from normal processing "Service" to the "Clean" position. Once you have been trained and approved to carry out chemical cleans and heat disinfection by your Healthcare provider you will then be given a key. Always keep the key in a safe place when the unit is in normal operation and DO NOT leave the key in the switch, to avoid someone inadvertently turning it during dialysis.

A separate **"Chemical Cleaning & Heat Disinfection Instructions"** document contains all the necessary information required to carry out cleaning/disinfection of the unit. When approved to do so ensure that the procedures detailed within this document are followed.

Warning:
Chemical cleaning of the unit **MUST** only be carried by an approved or person trained by **AmeriWater** or your Healthcare provider. **DO NOT** attempt to clean the unit if you have not been trained.

DO NOT use any other household cleaner to clean the unit, only use those cleaners supplied by **AmeriWater**, or your Healthcare provider or you may risk causing severe damage to the unit and its components and pose a serious risk to yourself or the person on dialysis.

If You wish to clean the unit and carry heat disinfections yourself please contact **AmeriWater** or your Healthcare provider who will provide all the necessary instructional training, approved cleaning chemicals, instruction leaflet and security key to enable the cleans to take place.

Your Healthcare provider will provide a cleaning program based on your specific requirements and frequency of dialysis.

We advise that chemical cleans should be carried out within the confines of the Technician's area and not on the ward.

7.2 Heat disinfection

As a guide refer to **Section 8.1** for recommendations as to when to carry out heat disinfection on the unit.

Warning:
Heat disinfection should only be carried out if you have been trained by **AmeriWater** or by your Healthcare provider. For security a key is provided once you have been trained which will enable you to activate the heat disinfection cycle. **DO NOT** attempt to clean the unit if you have not been trained.

If you wish to clean the unit and carry heat disinfections yourself please contact **AmeriWater** or your Healthcare provider who will provide all the necessary instructional training, instruction leaflet and security key to enable the heat disinfection to take place.

Failure to heat disinfect the unit or carry out recommended chemical cleans could result in a deterioration of the water quality provided by the unit making it unsuitable for hemodialysis.

During heat disinfection of the unit there is a potential for water exceeding 176^0F to be discharged to drain, ensure the drain pipework is made of suitable material to tolerate this water temperature

8.0 MAINTENANCE AND CHECKS

8.1 Maintenance

Your Centurion unit will be maintained and serviced regularly by your Healthcare provider. The unit does not contain any serviceable parts that require replacement on a regular basis but will require servicing at set intervals in order to ensure the unit's performance. Refer to the **Service & Maintenance manual** for details

As part of the servicing program for the unit certain components will require replacing. Your Healthcare provider will be responsible for replacing these parts.

It is recommended that regular checks are carried out on the unit and its performance to ensure safe and uninterrupted operation. Refer to table below for details.

8.1.1 Schedule of regular checks & tasks

Task detail	Typical range of values	Typical frequency	Comments
Pre-Dialysis checks	Refer to Section 8.2	Before each dialysis session	Refer to Healthcare provider if results are unacceptable
Dialysis water quality: Chemical contaminants	Maximums as listed in Tables 1 & 2 of ANSI/AAMI/ISO 13959:2009	Yearly	To be sampled by your Healthcare provider. Refer to Section 9.1.3 if limits unacceptable
Bacterial growth and Endotoxin concentration in dialysis water	<100 cfu/ml Bacteria <0.25 EU/ml Endotoxin (as per ANSI/AAMI/ISO 13959:2009)	Monthly	To be sampled by your Healthcare provider. Refer to Section 9.1.3 is levels are unacceptable.
Purified water output	Min 0.40 USgals/min @ 50^0F	Monthly	Check to be carried out by Healthcare provider.
Hot water disinfection	Min temp 176^0F Min hold time 10 mins	Once per week (min)*	Record of last heat disinfection cycle can be viewed. Ref to Section 4.3.1, step 13 "Chemical cleaning & heat disinfection instructions" manual.
Chemical clean	N/A	Monthly**	Refer to Section 7.1
Electrical safety inspection	Refer to Section 9.1.1 Service & maintenance manual	Yearly or following a leak or electrical repair	To be carried out by approved trained technician or your Healthcare provider
Labels	Refer to Section 3.2	yearly	Ensure all labels are present and legible.

* Based on dialysing 3-4 times per week for 4-5 hours at a time.

** Based on an acid descale cleaning cycle, the choice of cleaning chemical will be determined by your Healthcare provider and will depend on the quality of the mains feedwater.

8.2 Pre-Dialysis checks

It is always recommended to carry out the following checks before starting dialysis:

- Check that the electrical mains lead is securely clipped in place on the unit and at the wall socket and that the lead is not damaged or likely to cause anyone to trip over it.
- All the water connections are in place, not kinked and show no signs of leaks.
- The **"Blue"** water tubing is connected to the **"In/Entreé",** port; the **"Black"** water tubing is connected to the **"Drain"** port.
- The water supply is turned on.
- There are no warning messages displayed on the touch-screen. (Refer to **Section 9**, **"Troubleshooting"** if any messages are displayed.
- If the unit sounds unusually noisy or you are concerned about its operation call you Healthcare provider for advice.
- There are no signs of water loss or leaks in or around the unit.
- Verify the conductivity on the Centurion display is below the alarm set point.

Note: **Do Not** start dialysing if the unit appears to have a fault or the water quality is in doubt, contact your Healthcare provider for advice and assistance.

8.3 Cleaning external surfaces

Clear up spillages from external equipment or other sources immediately.
Use a clean damp cloth to wipe up spillages from the exterior surface of the unit. Take care not to get excess liquid on the control panel areas.

Do not use any solvent-based cleaners on the covers or front display. To remove more persistent marks and to disinfect surfaces, you should be provided with suitable surface disinfectant or surface cleaner by your Healthcare provider. If unsure ask, or contact **AmeriWater** for advice.

Take the necessary precautions when wiping up any bodily fluids, your Healthcare provider should be consulted if unsure.

Note: The unit has an IP rating =21, refer to **Section 11.1.3** for details

8.4 Storage and preservation recommendations

Use the guide below to determine the best method to store your unit if it is not be used for any length of time.

Time not in use		Recommendations
Up to 1 month	**Short term storage**	Ideally the unit should be left in **Power-On Standby** mode such that it will run for 10 minutes every 2 hours. If the unit is to be left ensure the room temperature does not fall below freezing point, 32^0F. On starting the unit up after standing run for 10 minutes disconnected from the dialysis machine and carryout a heat disinfection. Your Healthcare provider will advise you on the best method of maintaining your unit during periods of non-use.
>1 month up to 3 months	**Medium**	For extended periods of non-use if the unit cannot be left in "Standby" mode it is recommended that the unit is either returned to your Healthcare provider for them to look after the unit or alternatively the unit should be left in preservative solution. Contact your Healthcare provider to discuss the best option.
>3 months- 6 months+	**Long Term**	1. As above .

9.0 TROUBLESHOOTING

Warning:
There are several safety features built into the controls of the unit and they are designed to protect the unit from damage and to warn of any malfunction.

The operator should pay attention to warning messages and follow the instructions, warnings, cautions and notes given in this manual

If the unit develops a fault, follow the instructions in **Section 5.2.3** to shut the unit down safely and in a controlled manner.

In the event of an emergency follow the instructions in **Section 3.5** to shut the unit down quickly.

Once the unit has been safely shut down and the water supply turned off, make a note of any messages that were displayed on the screen as these will be needed to assist your Healthcare provider in diagnosing the fault.

Contact your Healthcare provider or **AmeriWater** and provide them with the details of the fault.

Warning:
DO NOT attempt to fix the fault yourself.
DO NOT remove the covers.
DO NOT attempt to run the unit with the side covers off.
DO NOT continue to run the unit with a warning message displayed unless the Operating manual or Healthcare provider says that it is safe to do so.
IF IN DOUBT ASK.

9.1 Troubleshooting Guide

9.1.1 Warning & alarm messages

Displayed Message or notification	Reason	Checks	Proposed Actions
"Tank Low Level"	The internal water break tank has insufficient water to run the unit.	**1.** Make sure the feedwater supply is turned on and flowing. Check other taps to confirm.	**1.** If the feedwater supply is not a problem and the unit still does not run and this message is frequently seen contact your Healthcare provider. **2.** If the water supply has stopped contact your water utility company.
"High Pressure"	The unit has detected an unsafe operating pressure.	**1.** There are no checks to made, simply switch the unit off using the switch at the rear and turn off the water supply.	**1. DO NOT** try to run the unit in this condition, contact your Healthcare provider for assistance.
"Low Pressure"	The unit has detected insufficient pressure to operate.	**1.** Check that the feedwater is still flowing. **2.** Check that there are no leaks. **3.** Check for any other messages on the display.	**1.** If the checks do not show any problems, press the "START" button. After a few minutes, if the pressure in unit has returned to normal the unit will run. If the message returns then switch the unit off, turn off the water supply and contact your Healthcare provider for advice.
"Perm-Line Cell Error"	The unit has detected a fault with the sensor measuring the water quality.	**1.** There are no checks to be made.	**1.** For safety the unit will have stopped running as the quality of water being produced cannot be monitored accurately. Contact your Healthcare provider to resolve the problem.

"Temperature High"	The water being produced has a temperature above the entered set point of 95 Deg F	**1.** Check the temperature of the incoming water supply. **2.** Check that the unit is not next to a source of heat, eg, radiator or room heater. **3.** Check that the unit is in "Processing" mode.	**1.** If the feedwater has a high temperature, investigate or change supply. **2.** Remove any local external heat source. **3.** If the problem persists call your Healthcare provider to investigate.
"Temperature Sensor Error"	There is a fault with the temperature sensor.	**1.** Make a note of any other messages displayed on the screen.	**1.** The unit can still be operated but if the fault persists contact your Healthcare provider before you next dialyse or carryout a heat disinfection.
"Level Switch Error"	The unit has detected a problem with the level sensors in the internal water break tank.	**1.** Ensure the unit has no other displayed messages. **2.** Check the unit is level and not tilted over.	**1.** To prevent the possibility of water leakage due to the internal tank overflowing for safety it will have stopped running. **2.** No other warning messages are displayed and the unit appears to be as normal but the problem persists, call your local Healthcare provider for assistance.
"Water leak" 	The leak detector in the bottom of the unit has detected water. The unit will stop running and the buzzer will sound.	**1.** The unit has developed an internal leak, check that the unit is upright and level and has not been recently toppled or knocked. **2.** Check to see if water is leaking from the unit at a constant rate. **3.** Check for excessive feedwater pressure causing splashing.	**1.** If the unit has been toppled some water may have overflowed from the internal water break tank. Drain the water off from the unit. At the front underside of the unit is a black drain plug, unscrew the plug and let any water drain from the unit Then press **"START".** **2.** If draining the unit does not clear the message call your Healthcare provider. **3.** If the unit is losing a lot of water turn of the water supply and call you Healthcare provider immediately.

“Tilt” 	The unit has been moved or knocked whilst running to such an extent that the internal tilt switch has been activated.	**1.** Check that the unit is upright and standing on a firm flat surface. **2.** Make sure that there is nothing located near the unit that might knock it . **3.** Check that the unit is not placed next to a door or could be knocked over by children or pets.	**1.** At the front underside of the unit is a black drain plug, unscrew the plug and let any water drain from the unit, then with the unit upright and all potential hazards removed, switch the unit off and on using the on/off power switch at the back of the unit, the unit should now run. If not and the message remains call your Healthcare provider for advice.
“Reset Error”	The unit has switched on and off more than 3 times in one minute.	**1.** Make sure the mains electrical lead is secure at the connection to the unit at the wall socket. **2.** Check that you’re household circuit breaker has not tripped out or has a fault. **3.** Are you experiencing power cuts to your property? **4**. Is the unit being serviced and the Engineer has switched the unit off many times to repair a fault.	**1.** Ensure that the mains electrical lead is secure and fixed. **2.** Check the condition of your circuit breaker and any other household appliances being used. This may have to be carried out you’re your Healthcare provider. **3.** Check with your local power company if they are experiencing any power losses in your area. **4.** If the problem persist and none of the above are the cause then contact your Healthcare provider for assistance.
“Feed-Line Cell Error”	The unit has detected a fault with the line cell used to measure the quality of the incoming feedwater supply.	**1.** Check that there are no other displayed alarm messages, if there are make a note of them.	**1.** Contact your Healthcare provider and give them the details of all messages displayed in order for them to diagnose the problem and advise you if the unit can be operated with this fault.
“Clean Due”	The time period set by your Healthcare provider for the next chemical clean has expired and the unit now requires a chemical clean.	No checks required.	If you are trained and approved to do so carryout a chemical clean on the unit at the next convenient time. If you are not authorized to clean the unit then contact your Healthcare provider to clean the unit.

“HeatSan Due”	The time period set by your Healthcare provider for the next Heat disinfection has expired and the unit now requires full heat disinfection.	No checks required.	If you are trained and approved to do so carryout a heat disinfection on the unit at the next convenient time. If you are not authorized to clean the unit then contact your Healthcare provider to heat disinfect the unit.
“Service Due” 	The unit has detected that the quality of the water being produced by the unit has exceeded the set limit.	**1**. Using the touch screen check the water conductivity reading. **2.** Check that the feedwater complies with the requirements in **Section 11.1.6**	**1.** If the water quality does not recover contact your Healthcare provider for advice.
“Poor Water Quality” 	The unit has detected that the quality of the permeate water is above 200µS/cm	Refer to “Service Due” message previously detailed. **Note:** Should the permeate quality reach a value of 200 µS/cm for a period of more than 20 seconds, the flow will be interrupted and returned to the integral tank.	If the water quality does not recover contact your Healthcare provider for advice.
Poor Permeate Quality” 	The unit has failed to recover the water quality back to acceptable limits and has as a matter of safety shut down.	Refer to “Poor Water quality”. If after 10 minutes the quality does not improve and remains above 100 µS/cm the unit will shut down and display the ‘Quality Alarm’. Should the quality fall below 100 µS/cm, within 10 minutes the unit will return to normal operation.	If the water quality does not recover contact your Healthcare provider for advice.

. **Over Temperature**	During heat disinfection the unit has detected a temperature of the circulating water that is above the maximum limit and has aborted the cycle for safety	1. The fault may lie with the heater, circulating pump or one of the temperature sensors. Only your Healthcare provider can check these items. 2. To help check to make sure that the unit's ventilation fan is not obstructed or the unit covered by anything and placed in a well ventilated area at ambient temperature away from any heat sources.	1. Advise your Healthcare Provider immediately, do not try to carry out another heat disinfection cycle
Pump fault	The unit has detected a fault with the internal boost pump.	1. Switch the unit off and isolate from the mains electrical supply and turn the water supply off.	1. Do not try to restart the unit, contact your Healthcare provider immediately for advice and assistance.

 indicates that a buzzer will sound

9.1.2 Electrical & mechanical faults

Observed Fault	Reason/s	Checks	Proposed Actions
The unit will not switch on and the screen is blank.	1. The mains incoming power supply has been disconnected. 2. The circuit breaker or other isolation device in your house has tripped out. 3. The power cord on the unit has become disconnected from either the unit or the wall socket. 4. The unit has developed a fault that requires assistance from your Healthcare provider. 5. The external fuses that protect the supply mains may have "blown"	1. Check that your area is not experiencing power cuts. 2. Check to see if the circuit breaker or other isolating device in your house has tripped and check other household appliances being used as they may e responsible for interrupting the power supply. 3. Check that the power cord is secure at both ends and check that it has not been damaged or cut. 4. Arrange for a qualified electrical engineer or your Healthcare provider to check the condition of the external fuses.	1. If checks 1 – 3 have not proved to be the cause then contact your Healthcare provider. **DO NOT** attempt to fix the fault or remove the side covers. 2. Replace the external fuses. (Only to be carried out by HCP or trained /qualified electrical engineer that is familiar with this equipment.
There is insufficient flow to run the dialysis machine.	1. A fault has occurred with the unit that has either stopped the unit or intermittently interrupts the production of purified water. 2. The incoming mains water supply has been cut off or has reduced pressure. 3. If fitted an external pre-treatment filter may have become blocked. 4. The reverse osmosis membrane may have become blocked or fouled. 5. The incoming feedwater supply	1. Check for any displayed warning or alarm messages. Make a note of any displayed and refer to Section 9.1.2 for details. 2. Check your tap water to see if it is still running at a rate that seems to be normal and at an expected pressure. 3. If any pre-treatment filters or devices are fitted check to see if there are any leaks or faults. By disconnecting the feed water to the unit, there should be a flow after the pre-treatment equipment.	1. If the unit is not showing any displayed messages but the problem persists carryout the checks 2-5. If any of the checks reveal a fault or you are not sure of what you have seen or feel the unit should be cleaned then contact your Healthcare provider with all the details and they will assist you. 2. If the fault is not related to items 1-5 then it may be due to the internal pressure sustaining valves, contact your Healthcare provider for assistance.

	temperature has dropped significantly. 6. One of the internal pressure sustaining valves may be incorrectly set or at fault. 7. Check all hydraulic connections are in their correction positions.	4. Check the last time the unit was chemically cleaned and make a note of the date. 5. Only during extreme winter months would reduced water temperature be an issue.	
The unit will not run when pressing the "START" button	1. The key switch at the rear of the unit is in the "CLEAN" position or there is a fault with the key switch itself.	1. Check the position of the key at the rear of the unit.	1. If the key is not in the "SERVICE" position, then turn the key to the "SERVICE" position. If the key is in the correct position and the unit still does not run then contact your Healthcare provider.

9.1.3 Water quality non-compliance

Non-compliance	Possible causes	Checks	Proposed actions
Bacterial count and/or Endotoxin levels in dialysis water exceed recommended guidelines	1. Fault with Heat disinfection cycle 2. Period between Heat disinfections too long. 3. Increase in bacterial levels in feedwater. 4. Unit left for long periods idle. 5. RO membrane damaged. 6. Contaminated sample or poor sampling technique.	1. Monitor full Heat disinfection cycle, ensure unit completes successfully and displays "Pass". Refer to Section 4.1.3 Chemical cleaning & heat disinfection Instructions" manual. 2. Refer to Section 8.1.1 for recommendations regarding sanitisation frequency. 3. Obtain samples of feedwater for analysis and/or contact local water supplier for updates on water quality. 4. Refer to Section 8.4 "Storage and preservation" for	1. It will be the responsibility of your healthcare provider to carry out these checks and diagnose the problem/s and rectify any faults founds. DO NOT use the unit if the water quality is unacceptable until you are told to do so by your Healthcare provider.

		guidance when not using the unit. 5. Refer to section 8.2 “Pre-dialysis checks” to assess RO membrane performance. 6. Repeat analysis to confirm result.	
Dialysis water quality: One or more of the Chemical contaminants exceed their permitted maximum concentration	1. Excessive increase in concentration of contaminant/s in feedwater. 2. RO membrane damaged 3. Contaminated sample or poor sampling technique. 4. Malfunction of pre-treatment system 5. Recommended Chemical clean frequency not being followed or change in chemical cleaner required.	1. Obtain sample of feedwater to assess level of contaminants. Contact local water authority if outside standards for drinking water. 2. Refer to section 8.2 Pre-dialysis checks to assess performance of RO membrane. 3. Repeat samples to confirm levels. 4. Check pre-treatment is functioning correctly. 5. Refer to Section 8.1.1 for detail of chemical clean frequency.	1. It will be the responsibility of your healthcare provider to carry out these checks and diagnose the problem/s and rectify any faults founds. DO NOT use the unit if the water quality is unacceptable until you are told to do so by your Healthcare provider.

10.0 CONSUMABLES AND SPARES

Note: The unit does not contain any user replaceable spares or consumables items. Your Healthcare provider will be responsible for replacing any components or consumable item and maintaining and servicing the unit, this will include the internal Ultra-filter device. For more information on Ultra-filter replacement interval, see the **Service and Maintenance manual**.

11.0 Technical specification

11.1 Services/ connections and physical properties

11.1.1 Electrical specifications/connections

Mains supply

Electrical supply	Operation	Max Power consumption (Watts)
Single phase 115V 60Hz plus earth	Standby	10
	Normal operation	160
	During heat disinfection	1000

Warning: To avoid risk of electric shock, this equipment must be connected to a supply main with protective earth.
For permanent installations the mains supply must be provided with a Branch Circuit Breaker, refer to **Section 4.6.2** of the **Installation & Commissioning Guide** for details of rating and specification of Branch Circuit Breaker.`

11.1.2 Fuse rating/type

External: (Located at the rear of the unit)
Type: 2 off 12 Amp**T12AH115V**- 5mm x 20mm, Ceramic, time delay
Internal: (Located in main electrical tray)
Type: 2 off 5 Amp **T5AH115V** – 5mm x 20mm, Ceramic, time delay

Note: Fuses must only be replaced with those approved and supplied by the manufacturer, refer to Service and Maintenance Manual for details.

11.1.3 IP Rating

The unit has an **IP21** rating.

2 = Protected against solid objects greater than 0.492" (12.5mm)
1= Protected from vertically dripping water

11.1.4 Alarm port connection details

Type:	Volt free/dry changeover contacts
Minimum applied Voltage:	34Vdc/24Vac
Maximum applied current:	1 Amp

Details of this connection shall be provided upon request, contact **AmeriWater** or your Healthcare provider.

11.1.5 Water quality and performance

Max drain flow-rate @ 10°C USgals/min	Permeate output @ 10°C USgals/min	Recovery %	Output water quality
0.29	0.4	60%	Will meet the requirements of current AAMI/ANSI/ISO:13959 standard for ***"water for hemodialysis and related therapies"***

11.1.6 Feed water requirements

Pre-filtration	Filtered to 5 microns
Total Hardness	Maximum 400 ppm as $CaCO_3$
Temperature	34 – 95°F (1-35°C)
Chlorine (Total)	<0.1 ppm free Cl_2
Total dissolved solids (max)	1500 mg/l
Fouling index	<5
Feed water pressure	2-6 bar (30-90 psi)
Feed water flowrate	1-1.5USgals/min (3.8-5.7ltrs/min)

11.1.7 Water services connections

Connection	Description	Size	Type
Drain	Unit waste water-out	8mm	Push fit
In	Feedwater supply-in	8mm	Push fit
Out	Permeate-out	8mm	Push fit
Return	Returned permeate-in	8mm	Push fit
Acid	Chemical disinfectant-in	4mm	Push fit

11.1.8 Raw water break tank

Working volume: 0.092USgals (350 mls)
Classification: 20mm air gap to provide backflow prevention
Material: 316 Stainless steel

11.1.9 Weights and dimensions

Weight (Lbs)	Height (inches)	Width (inches)	Depth (inches)
86 (Dry) 99 (Working)	34	11	19

11.1.10 Main PCB battery

Voltage: 3V
Type: Lithium, CR2032

11.1.11 USB mass storage device

Specification: FAT 16 formatted USB memory stick
Memory size: Must be less than 2GB

11.2 Environmental data

Parameter	Normal Operation	Storage	Transport
Temperature range	50-104^{0}F (10 to 40^{0}C)	41 ^{0}F-158^{0}F (5 to 70^{0}C)	23^{0}F -158^{0}F (-5 to +70^{0}C)
Relative humidity	30 to 75%	10-100%	10-100%
Atmospheric pressure range (altitude)	80 to 106 KPa (sea level-2000m or 0-6,562 ft)	50 to 106 KPa (sea level-5000m or 0-16,404 ft)	50 to 106 KPa (sea level-5000m or 0-16,404 ft)

11.3 Guidance on electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Centurion 1500^{+} is intended for use in the electromagnetic environment specified below. AmeriWater or Healthcare Provider should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Centurion 1500^{+} uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Centurion 1500^{+} is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

11.4 Guidance on electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The **Centurion 1500+** is intended for use in the electromagnetic environment specified below. AmeriWater or your Healthcare Provider 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	± 6 kV contact ± 8 kV air	B A	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input / output lines	A N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	A A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T) (>95% dip in U_T) For 5s	B B B B	Mains power quality should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the Centurion be powered from an uninterruptable power supply.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

11.5 Guidance on electromagnetic immunity for non-life supporting equipment

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The Centurion 1500+ is intended for use in the electromagnetic environment specified below. AmeriWater or your Healthcare Provider should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance Level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF

IEC 61000-4-6

Radiated RF

IEC 61000-4-3</td><td>3 Vrms

150 kHz to 80 MHz

3 V/m

80 MHz to 2.5 GHz</td><td>3V

3V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Centurion, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = [1.17]\ \sqrt{P}$

$d = [1.17]\ \sqrt{P}$ 80 MHz to 800 MHz

$d = [2.33]\ \sqrt{P}$ 800 MHz to 2.3 GHz

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).
Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance lever in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency applies.</td></tr>
<tr><td colspan="4">NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">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 Centurion is used exceeds the applicable RF compliance level above, the Centurion should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Centurion unit.</td></tr>
<tr><td colspan="4">b
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

11.6 Separation distances for RF devices and Centurion

Recommended separation distances between portable and mobile RF communications equipment and the Centurion 1500⁺.			
The Centurion 1500⁺ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. AmeriWater or your Healthcare Provider will help prevent electromagnetic interference by calculating and maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Centurion unit as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = [1.17]\sqrt{P}$	80 MHz to 800 MHz $d = [1.17]\sqrt{P}$	800 MHz to 2.5 GHz $d = [2.33]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
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.			

11.7 Classification and standards applied

Electrical	Class I Equipment (see Note1)
Overvoltage category – Fixed installation	Category II
Overvoltage category – Permanently installed	Category III
Pollution degree classification	Degree 2
IP Classification	IP21
Medical class - USA	Class II
Medical class - Canada	Class III
Radio Performance - USA	To FCC Part 18 (industrial, Scientific and Medical)
Radio Performance - Canada	To ICES-001 (Industrial, Scientific and Medical (ISM) Radio Frequency Generators.
Designed in general accordance with the requirements of BS EN 60601-1-2 :2007 Medical Electrical Equipment – Part 1-2: general requirements for basic safety and essential performance	

Warning: Note 1, To avoid risk of electric shock, this equipment must be connected to a supply main with protective earth.

11.8 Classification mark

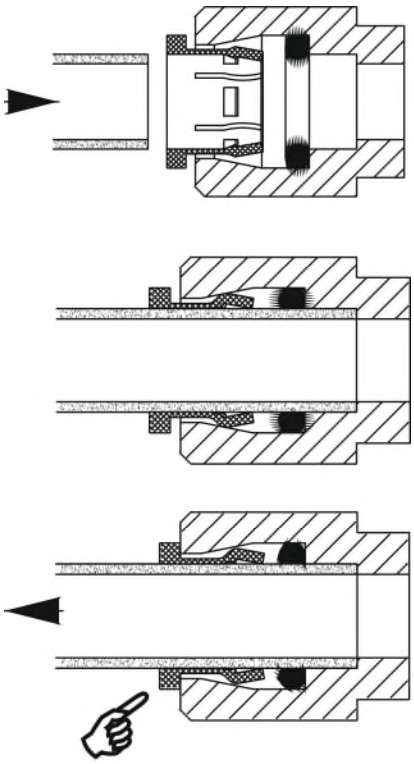
The device bears the following UL mark:

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRIC SHOCK, FIRE,
MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005, 3rd ed.)
and CAN/CSA-C22.2 No. 60601-1
E351652

12.0 APPENDICES

12.1 How to use the push-fit connectors

To make a connection, simply push to tube in by hand; the pushfit collet locking system then holds the tube firmly in place without deforming it or restricting flow

Push the tube into the connector until the tube stops. Ensure the tube is pushed in as far as the tube stop; pull on the tube slightly to check that it is secured. To remove the tubing, push the collet against the body of the connector, as shown in the diagram opposite and slide the tube out of its fitting. A release tool may be required to do this.	

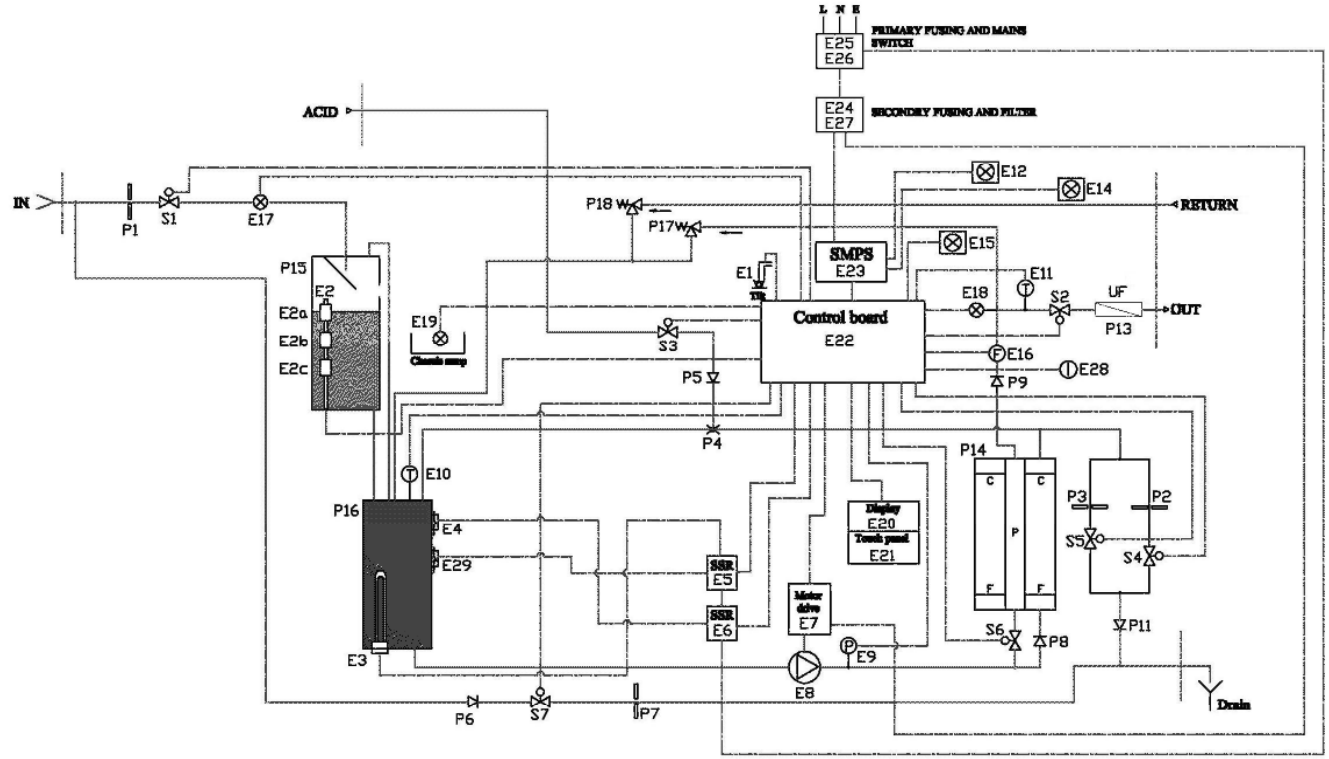
12.2 E-Waste

Disposal of the unit or any electrical component from the unit must be in accordance with local requirements in your province or state for the disposal of electrical waste (E-Waste).

Your Healthcare provider will be responsible for the disposal of any such items and for the disposal of the unit if required.

12.3 Flow schematic

SOLENOID VALVES	
ITEM No	DESCRIPTION
S1	INLET
S2	PERMEATE
S3	CHEM. DRAW
S4	DRAIN 1
S5	DRAIN 2
S6	EQUALISE
S7	BLEND
ELECTRICAL ITEMS	
ITEM No	DESCRIPTION
E1	TILT SWITCH
E2	FLOAT SWITCH ASSEMBLY
E2a	FLOAT SWITCH HIGH LEVEL
E2b	FLOAT SWITCH MID LEVEL
E2c	FLOAT SWITCH LOW LEVEL
E3	HEATER
E4	TEMPERATURE CUT OUT
E5	HEATER CUT OUT RELAY
E6	HEATER CONTROL RELAY
E7	PUMP INVERTER CONTROLLER
E8	MOTOR/PUMP
E9	PRESSURE TRANSMITTER
E10	THERMISTOR TANK
E11	THERMISTOR RING
E12	FAN ELECTRICAL ENC. TOP
E13	NO ITEM FITTED
E14	FAN INVERTER ENC.
E15	FAN MAIN
E16	FLOW SENSOR
E17	LIME CELL FEED QUALITY
E18	LIME CELL PERMEATE QUALITY
E19	LIME CELL LEAK DETECTION
E20	DISPLAY COLOUR TFT SCREEN
E21	TOUCH PANEL
E22	CONTROL BOARD
E23	POWER SUPPLY (SMPS)
E24	MAINS FILTER
E25	PRIMARY MAINS FUSING
E26	MAINS SWITCH
E27	SECONDARY MAIN FUSING
E28	KEY SWITCH
E29	TEMPERATURE CUT OUT
PROCESS ITEMS	
ITEM No	DESCRIPTION
P1	FLOW RESTRICTOR INLET
P2	FLOW RESTRICTOR DRAIN 1
P3	FLOW RESTRICTOR DRAIN 2
P4	CHEMICAL EDUCTOR
P5	NON RETURN VALVE CHEM DRAW
P6	NON RETURN VALVE BLEND 1
P7	FLOW RESTRICTOR FLAMIN
P8	NON RETURN VALVE RO FEED
P9	NON RETURN VALVE PERMEATE
P10	NO ITEM FITTED
P11	NON RETURN VALVE DRAIN
P12	NO ITEM FITTED
P13	ULTRA FILTER
P14	RO MODULE
P15	WATER BREAK TANK
P16	HEATER TANK
P17	PRESSURE REG VALVE PERMEATE
P18	PRESSURE REG VALVE PERMEATE RETURN



KEY:

- WATER FLOW PATH
- ELECTRICAL CONNECTIONS
- EXTERNAL BOUNDARY

12.4 Certificate of conformity

CERTIFICATE OF COMPLIANCE

Certificate Number	20131031-E351652
Report Reference	E351652-A1-UL
Issue Date	2013-OCTOBER-31
Issued to:	PURITE LTD Bandet Way, Thame OX9 3SJ UNITED KINGDOM
This is to certify that representative samples of	GENERAL MEDICAL EQUIPMENT Reverse Osmosis Device – Model Centurion 1500+ / 1500+ UF
	Have been investigated by UL in accordance with the Standard(s) indicated on this Certificate.
Standard(s) for Safety:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Additional Information:	See the UL Online Certifications Directory at www.ul.com/database for additional information

Only those products bearing the UL Classification Mark for the U.S. and Canada should be considered as being covered by UL's Classification and Follow-Up Service and meeting the appropriate U.S. and Canadian requirements.

The UL Classification Mark includes: the UL in a circle symbol: with the word "CLASSIFIED" (as shown); a control number (may be alphanumeric) assigned by UL; a statement to indicate the extent of UL's evaluation of the product; and the product category name (product identity) as indicated in the appropriate UL Directory. The UL Classification Mark for Canada includes: the UL Classification Mark for Canada: with the word "CLASSIFIED" (as shown); a control number (may be alphanumeric) assigned by UL; a statement to indicate the extent of UL's evaluation of the product; and the product category name (product identity) in English, French, or English/French as indicated in the appropriate UL Directory.

Look for the UL Classification Mark on the product.

William R. Carney, Director, North American Certification Programs

UL LLC

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