AquaC UNO H
Water Purification System

Instructions for Use

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FRESENIUS
MEDICAL CARE

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1 Index

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2 Important information

2.1 How to use the Instructions for Use

Device name

The device name **AquaC UNO H** is referred to hereafter as "the device".

Identification

The document can be identified by the following information on the title page and on the labels, if any:
– Device software version
– Document edition
– Document part number

Footer

The footer contains the following information:
– Company name
– Device type
– The English abbreviation for the type of document and the international code for the language of the document, e.g., IFU-DE means Instructions for Use in the German language
– Edition information, e.g., 4A-2013 means edition 4A from the year 2013
– Page identification, e.g., 1-3 means Chapter 1, page 3

Organization of the chapters

To facilitate the use of documents from Fresenius Medical Care, the organization of the chapters has been standardized in all manuals. There may therefore be chapters within this document without any content. Chapters without content are identified.

Forms of notation found in the document

The following forms of notation may be used in the document:

Form of notation	Description
Name of key	Keys on the device are written in **bold**. Example: **Example** key.
Message text	Device messages are written in *italics*. Example: Message: *Example message*
➢ Instruction	Instructions are identified by an arrow ➢. The actions specified in instructions must be performed. Example: ➢ Perform action.
1. Numbered instruction 2. ... 3. ...	Long passages containing instructions can be represented by numbers. The actions specified in instructions must be performed. Example: 1. Perform action.

Illustrations

The illustrations used in the documents may differ from the original if this does not have any influence on the function.

Importance of the instructions

The Instructions for Use are part of the accompanying documents and are an essential part of the device. They include all information necessary for the use of the device.

The Instructions for Use must be carefully studied before operational qualification/startup of the device.

Before the responsible organization may begin operating the device, the individual responsible for operation must have been instructed by the manufacturer on how to use the device and must be thoroughly familiar with the contents of the Instructions for Use.

The device may only be operated by individuals certificated to have been instructed in the proper operation and handling of the device.

Changes

Changes to the technical document will be released as new editions or supplements. In general, these instructions are subject to change without notice.

Reproduction

2.2 Significance of warnings

Warning

Advises the operator that failure to observe this information can result in personal injury.

2.3 Significance of notes

Note

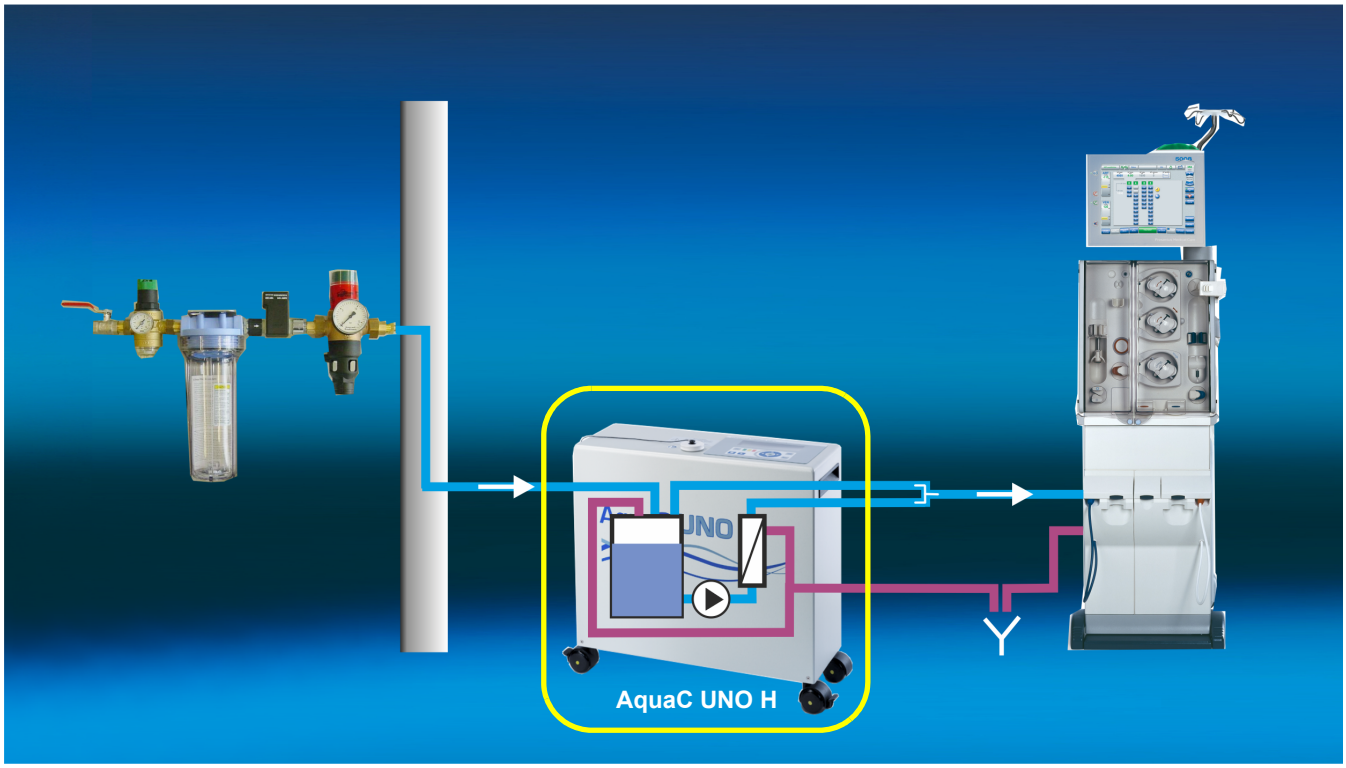
Advises the operator that failure to observe this information can
– cause damage to the equipment
– result in a specific function not being executed at all or not being executed correctly

2.4 Significance of tips

Tip

Information providing useful tips for easy handling.

2.5 Brief description



The **AquaC UNO H** is a single station reverse osmosis system with heat disinfection function for producing permeate in an economical and environmentally-friendly manner. The system can be extended by the responsible organization with additional components to form a complete water treatment system for use in a dialysis unit.

The **AquaC UNO H** reverse osmosis system provides the permeate required for the preparation of common dialysates.

The device belongs to device class 2 (21CFR 876.5665).

Note

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

2.6 Intended use

2.6.1 Intended purpose

The **AquaC UNO H** Portable Water Purification System is a reverse osmosis unit intended for use with hemodialysis systems to remove organic and inorganic substances and microbial contaminants from the water used for treating hemodialysis patients or related therapies.

The **AquaC UNO H** can be connected to hemodialysis equipment used in hospitals, clinics, and in home environments. This device is intended to be a component in a complete water purification system, and is not a complete water treatment system. The reverse osmosis unit must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well, to meet current AAMI/ANSI and FDA-recognized U.S. standards.

2.6.2 Use in the home environment

– All the instructions and regulations contained in these Instructions for Use apply to the home environment too.

– The device may only be used for the intended purpose, for dialysis treatment. Other types of use are not permitted.

– The particular requirements which pertain to the electrical supply in the home environment are described in Chapter 12.4 Electrical supply.

Warning

Take note where home applications are concerned:

➢ Only authorized persons may perform any installation, operational qualification or other maintenance procedures (including Technical Safety Checks).

➢ Use only consumables, accessories, etc., which have been approved by the manufacturer.

➢ Only treat the specific patient who has been marked out for this treatment by the responsible organization/the physician in charge.

➢ Only trained personnel may use the device.

➢ Keep unauthorized persons, infants, and pets away from the device.

2.6.3 Residual risks

Microbial contamination of feed water

The feed water must be of drinking water quality (in accordance with WHO Guidelines for Drinking-water Quality or with the EPA Safe Drinking Water Act).

In some countries, it is very difficult to achieve this quality. We recommend that the water therefore be checked continuously – at least quarterly – if the feed water quality is not stable or is unknown.

Microbiological monitoring

We strongly recommend that the entire device installation (in particular, the permeate and the permeate ring main) is monitored from a biological point of view at regular intervals and that appropriate cleaning and disinfection procedures are carried out.

Use of non-specified disinfectant

Use only the specified disinfectants. If other disinfectants are used, the desired disinfection effect and the appropriate safety are no longer ensured.

Checks for residue following disinfection

Meticulous checks for residue must be performed following disinfection. If mistakes are made, this could put patients at serious risk.

Negligence

When operating and servicing the systems, it is mandatory to properly and meticulously adopt the safety precautions described. For that reason, every responsible organization and every service technician should be familiar with and apply the safety rules and regulations.

2.6.4 Side effects

None

2.6.5 Contraindications

None

2.6.6 Target group

The device may only be installed, operated, and used by individuals with the appropriate training, knowledge, and experience.

Assembly, extensions, adjustments, modifications or repairs may only be carried out by the manufacturer or manufacturer-authorized persons.

2.6.7 When working on the device

Warning

Comply with authorization regulations

Start-up, expansions, adjustments, calibration, maintenance procedures, Technical Safety Checks (TSC), modifications or repairs may only be carried out by the manufacturer or manufacturer-authorized persons. This includes the installation of the protective earth conductor connection.

The Service Manual is reserved for this group of people.

Further information on installation (see Chapter 9 on page 9-1). Further information on Technical Safety Checks and maintenance procedures (see Chapter 11 on page 11-1).

Use only original spare parts.
For the identification and ordering of spare parts, test equipment, and accessories, always use the electronic spare parts catalog.

Transport and storage (see Chapter 10 on page 10-1).

When ready for operation, the **AquaC UNO H** should be considered a stationary device (as opposed to a mobile one). As such, the device may not be moved. It is only permitted to move the device into another room with the **AquaC CART US**/**AquaC CART Small** option or other approved portable RO cart.

2.6.8 Expected service life

The expected service life is 10 years.

If the Technical Safety Checks are performed as prescribed and at the defined intervals, the device will run safely between checks.
In addition, the manufacturer recommends performing maintenance procedures at the same intervals in order to prevent the device malfunctioning due to wear.

2.7 Duties of the responsible organization

The responsible organization must ensure
– compliance with the national or local installation, operation, use, and maintenance regulations
– compliance with the accident prevention regulations
– that the system is in a correct and safe condition
– that the Instructions for Use are available at all times

Warning

Scope of responsibility of the responsible organization

As defined by ISO 26722, the responsible organization is responsible for:

– The selection and composition of a water treatment system for dialysis

– A periodic check of the permeate used for dialysis

● **Further aspects of the responsible organization**

– The **AquaC UNO H** reverse osmosis system must be easily accessible from all sides. The responsible organization must ensure that its operators have been trained. Operators of the **AquaC UNO H** reverse osmosis system and operators of the hemodialysis devices must have received instructions on how to operate the system.

– The responsible organization must ensure that the design specifications of the **AquaC UNO H** reverse osmosis system comply with the requirements of the other components used. This affects in particular downstream system components such as the prefiltration unit and the hemodialysis device.

– As the complete system consists of separate, individual systems, the responsible organization is responsible for the complete system combination.

– The responsible organization should inform the local water supplier of the dialysis operation and insist on early provision of data regarding water composition, availability, etc. This measure does not relieve the responsible organization of its obligation to regularly check the feed water composition.

– Bacterial growth in the **AquaC UNO H** reverse osmosis system depends on the individual components, and the type and time of use. A sample for microbial testing must therefore be collected at the end of the permeate sampling port in accordance with a defined time schedule.

2.8 Operator responsibility

When entering parameters, the following must be observed:
– The parameters entered must be verified by the operator, i.e., the operator must check that the values entered are correct
– If the verification reveals a deviation between the desired parameters and the parameters displayed by the device, the setting must be corrected before activating the function
– The actual values displayed must be compared with the defined target values.

The device may only be operated under the operating conditions specified by the manufacturer.

● **Further aspects of the operator responsibility**

– The reverse osmosis system must be installed in a dry room.
– The reverse osmosis system must be easily accessible from all sides.

2.8.1 Use in the home environment

– All the instructions and regulations contained in these Instructions for Use apply to the home environment too.
– The device may only be used for the intended purpose, for dialysis treatment. Other types of use are not permitted.

2.9 Disclaimer of liability

Warning

Scope of responsibility of the responsible organization

The system has been approved for use with certain consumables and accessories (see Chapter 8, page 8-1). Should the responsible organization wish to use other consumables and accessories than those listed in this chapter, their suitability must be checked beforehand by gathering the appropriate manufacturer information, for example. The applicable legal regulations must be complied with.

The manufacturer does not assume any responsibility or liability for personal injury or other damage and the use of non-approved or unsuitable consumables or accessories resulting in damage to the system will void the warranty.

2.9.1 Membrane service life

Note

A different water quality may damage the membrane or may require the membrane to be replaced prematurely (see Chapter 12.8 on page 12-15).

2.10 Technical documentation

Upon request, circuit diagrams, descriptions, and other technical documents are made available by the manufacturer. These are intended to support trained personnel of the responsible organization in servicing and repairing the device.

2.11 Warnings

2.11.1 Basic warnings

Warning

Comply with authorization regulation

Cleaning and disinfection must be performed by personnel who have been trained in accordance with the latest cleaning and disinfection instructions.

Warning

Comply with authorization regulation

The **AquaC UNO H** reverse osmosis system may only be operated by authorized personnel/by an authorized operator.

Warning

Risk of tilting

- ➢ The system may only be operated on a horizontal, level surface.
- ➢ When moving the system across thresholds or other uneven surfaces, observe the risk of tilting or blocking.
- ➢ It is only permitted to move the device after completing operational qualification with the **AquaC CART US** or **AquaC CART Small** option or other approved portable RO cart. Without these options, the device is stationary.
- ➢ Do not push (from the side), pull or lift the **AquaC UNO H** (including options) when in operation.
- ➢ The operator must not lean against the system, use it as support, sit on it or step on it.
- ➢ Do not place any objects onto the system.

Warning

Danger of suffocation

When installing and operating the **AquaC UNO H**, it must be ensured that strangulation and suffocation of the patient or third parties caused by the presence of lines and small parts cannot occur.

Keep infants away from the reverse osmosis system!

Warning

Patient hazard

Cleaning procedures (decalcification, disinfection, and so on) or servicing and maintenance procedures must not be carried out while dialysis is in progress (**SUPPLY** program).

Warning

Comply with authorization regulations

Always keep the device in an upright position during storage, transport, and in all operating modes.

After installation:
The transport of the device is only possible with the optional equipment **AquaC CART US/AquaC CART Small** or ohter approved portable RO cart. Otherwise the device is not intended for moving between rooms.

Warning

Risk of injury caused by explosions

Do not use this device in explosive or flammable environments!

Warning

Risk of injury caused by heat

Do not touch the device or parts of the ring main while in Heat disinfection mode.

2.11.2 Warnings related to hygiene and biology

Warning

Risk of caustic burning when working with acidic substances (concentrated substance or disinfectant)

To prevent any skin contact with concentrated substances and disinfectants, wear appropriate protective gloves.

When working with acidic or alkaline substances:

➢ Wear goggles!

➢ Observe the safety precautions for the concentrated substance used!

➢ Observe the safety precautions for the disinfectant used!

In the event of contact with acid:

Eye: Immediately flush with running water for 15 minutes.
Skin: Use soap under running water for neutralization.
Ingestion: Do not induce vomiting, but have the victim drink plenty of non-carbonated water. Seek medical advice.

Warning

Comply with authorization regulation

The system may only be disinfected after consultation with the manufacturer of the device or by manufacturer-authorized persons.

➢ After a disinfection procedure, ensure that no residual disinfectant remains.

Warning

Risk of recontamination

➢ Connect the device drain to an available outlet, to prevent recontamination.

2.11.3 Electrical warnings

Warning

Risk of injury caused by electrical voltage

Touching live parts will cause an electric shock.

➢ Disconnect the power plug before opening the system. This will disconnect the system from the supply voltage.

➢ To prevent the risk of an electric shock, the **AquaC UNO H** may only be connected to a supply network with a protective conductor.

Note

Influence of other electromagnetic devices

– Do not install the device directly next to other electrical devices.

– Stacked device installation is not permitted.

If the system must be operated close to other electrical devices, it must be checked if the performance of a device is negatively affected by inadvertent electromagnetic coupling.

Warning

Patient hazard

➢ Never simultaneously touch the patient and accessible metallic parts of the device.

Warning

Comply with authorization regulations

The US regulatory standards and regulations must be observed when connecting the device to the power supply system. The use of additional extension cables or multiway sockets is prohibited.

Warning

Risk of injury caused by electrical voltage

Do not use multiway sockets or extension cables.

Warning

Risk of injury caused by electric current

Electric shock

➢ Lay connecting cables so they cannot be damaged by sharp-edged objects or by pets.

2.11.4 Chemical warnings

Warning

Patient hazard caused by residual disinfectant

Cleaning agents or disinfectants may enter the patient's bloodstream.

➢ No cleaning agent or disinfectant must enter the reverse osmosis system while dialysis is in progress.

➢ The responsible staff must be expressly informed of this by the responsible organization.

Warning

Comply with authorization regulation

The system may only be disinfected after consultation with the manufacturer of the device or by manufacturer-authorized persons.

After a disinfection procedure, ensure that no residual disinfectant remains.

2.11.5 Biological warnings

Warning

Not drinking water

The responsible organization must ensure that a warning sign bearing the words **Not drinking water** is permanently attached at the sampling ports of the device.

2.11.6 Warnings related to consumables and accessories

Note

The tubing materials must be food-grade, suitable for use with drinking water, and offer sufficient chemical resistance.

2.12 Addresses

Manufacturer

Vivonic GmbH
Kurfuerst-Eppstein-Ring 4
D-63877 Sailauf
Phone: +49 (0) 6093 9713-0
Fax: +49 (0) 6093 9713-15

International service

Vivonic GmbH
Technical Customer Service/Support
Kurfuerst-Eppstein-Ring 4
D-63877 Sailauf
Phone: +49 (0) 6093 9713-23
Fax: +49 (0) 6093 9713-214

Local service

3 Design

3.1 Views

3.1.1 Complete system

The illustration shows the device with **Hygiene option.**

Legend

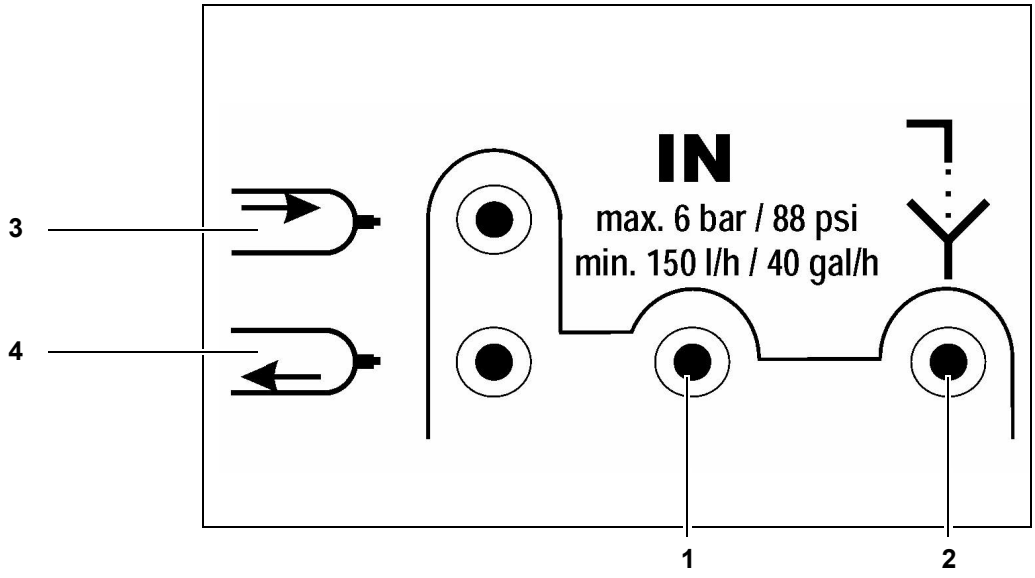
Pos.	Components
1	Fill port plug for decalcification, disinfection, and preservation
2	Display and keys to operate the system
3	Permeate connection for hemodialysis device with sampling port

3.1.2 Rear view

Legend

Pos.	Components
1	Hydraulic connections
2	RJ45 connection with protective plug
3	Potential equalization connection
4	Power cable
5	FMC interface 4008/5008S connection (not used)

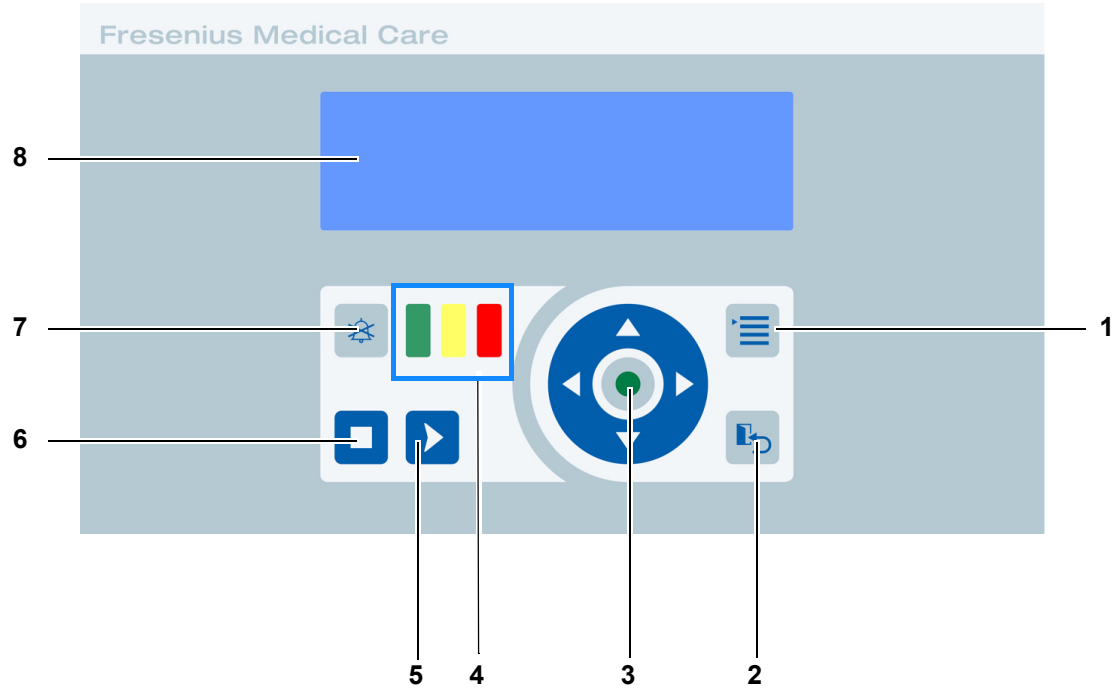
3.1.3 Sectional view of hydraulic connections and device labeling



Legend

Pos.	Components
1	Feed water inlet
2	Concentrate outlet
3	Permeate feed
4	Permeate return

3.2 User interface and display



Legend

Pos.	Components
1	**Menu** key
2	**Back/Escape** key
3	**Navigation/Enter** keys
4	Visual indicators **green/yellow/red**
5	**Start** key
6	**Stop** key
7	**Mute** key
8	Display

Menu key — Displays the main menu.

Back/Escape key — Exits the current menu.

Navigation/Enter Keys — The arrows are used to select different menu options, which are then confirmed with the **Enter** key.

Direction of arrow	Description
▲	**Navigates up**
▼	**Navigates down**
▶	**Navigates to the right**
◀	**Navigates to the left**
	**Enter** (Confirm) key

Visual indicators

The function of the visual indicator is to show the current condition of the system. Each color indicates a specific status.

Status of the visual indicator	Description
Off	The **AquaC UNO H** is in **Standby** mode and is performing a cleaning program or a disinfection.
Green	The system is in **SUPPLY** mode.
Yellow	– A warning is present. – T1 test is active.
Red, flashing	An alarm or a malfunction has occurred.

Start key

The quick access **Start** key is used to start the **SUPPLY** mode when the **AquaC UNO H** is in the **STANDBY** or **RINSE** mode.

Stop key

The quick access **Stop** key is used to stop the program currently in progress.

Mute key

The **Mute** key is used to silence an audible alarm for 2 minutes.

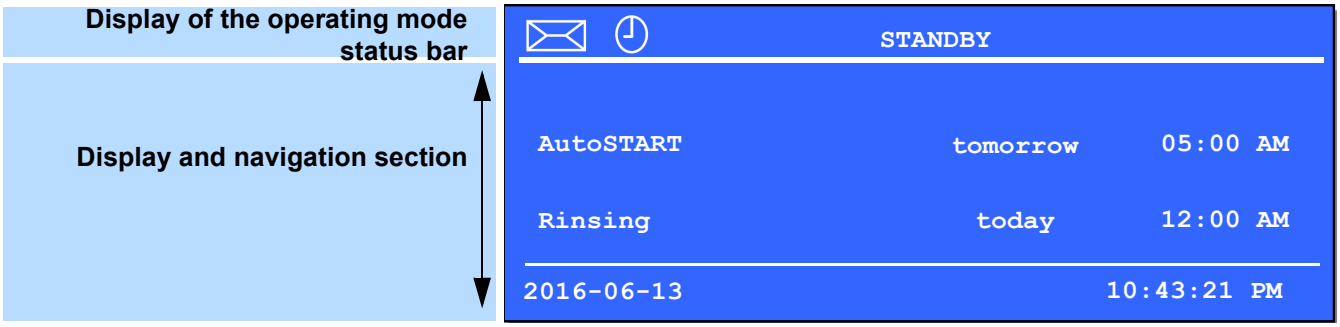
Display

The display is divided into the operating mode status bar and the display and navigation section.

Audible alarm

An audible alarm sounds in addition to the red status indicator.

3.2.1 Display of the operating mode status bar



Display of the operating mode status bar

The operating mode status bar shows the currently running program. Symbols provide additional information on the system status.

Symbol	Description
	Messages are available. The messages are displayed in the STATUS Messages menu (see Chapter 4.11.3 on page 4-12).
	This symbol indicates that an autostart timer is active. For more information on the timer programs (see Chapter 4.10 on page 4-9).

Display and navigation section

Standby information or the **AquaC UNO H** menu is shown in the display and navigation section.

4 Operation

4.1 Operating modes and display messages/overview

Operating modes
STANDBY
SUPPLY
RINSE
MODULE HEAT DISINFECTION
RING HEAT DISINFECTION
CHEMICAL DISINFECTION
DECALCIFICATION
ISOLATED STANDBY

4.2 STANDBY mode

4.2.1 Turning the system on/off

The system does not have a separate main power switch.

➢ When the power plug is connected, the **AquaC UNO H** is in **STANDBY** mode.

➢ To turn the **AquaC UNO H** completely off, disconnect the power plug. The system will no longer be supplied with power. Close the water supply (external stop valve) to the **AquaC UNO H**. The automatic programs are inactive.

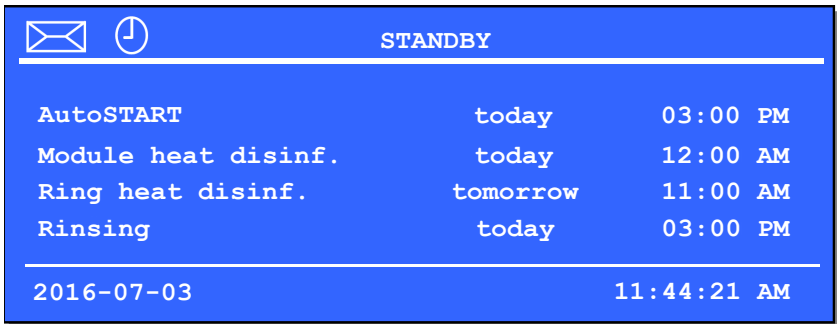
Home dialysis

A permanent electrical connection is needed for home dialysis unless local laws have other requirements.

➢ A two-pole power switch must be connected upstream of the device during installation, so the device can be disconnected from the supply. The device is then turned on/off at this external switch (not included in the scope of delivery).

4.2.2 STANDBY mode display

After connecting the power plug, the **AquaC UNO H** is always in **STANDBY** mode. The **STANDBY** mode is shown in the operating mode status bar.



This screen shows information on the automatic rinse procedure, on the next automatic start of the system, and on the next automatic heat disinfection (provided these functions have been activated).

4.3 SUPPLY mode

Warning

Patient safety

➢ Make sure that no decalcification agents or disinfectants are injected into the **AquaC UNO H** during dialysis hours.

Warning

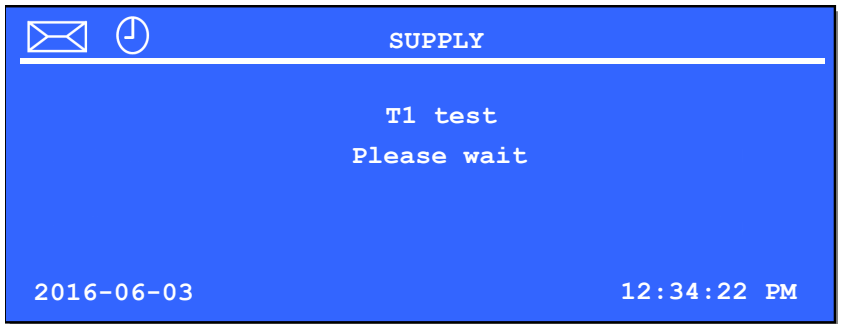
Use operating modes correctly

➢ Dialysis is only permitted when the system is in **SUPPLY** mode!

➢ Do not perform dialysis when the system is in **RINSE** mode!

4.3.1 T1 test/Device test

When starting the **SUPPLY** mode, a **T1 test** or a device test will be performed.



T1 tests

During the **T1 test**, only the safety-relevant components will be checked for correct function. The test takes approx. 2 minutes.

The **Rinse**, **Module heat disinfection**, **Ring heat disinfection**, **Chemical disinfection**, and **Decalcification** programs also start with a **T1 test**.

Device test

A complete **device test** is performed once a day. This test takes approx. 5 minutes. During the device test, all components are checked for correct function.

If the device has been disconnected from power for more than 24 hours, it will start with a **device test**.

Tip

If the **Automatic rinse** function has been activated, the device test will be performed once a day before the rinse program.

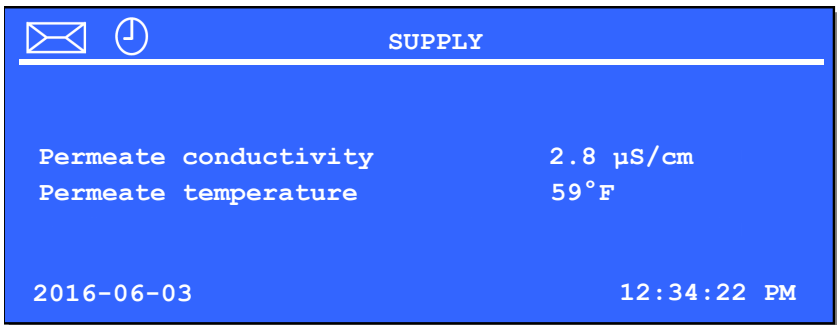
This prevents delays when programs are started manually (e.g., before **SUPPLY**).

Note

The **AquaC UNO H** is not designed for continuous supply. If the system is to operate in **SUPPLY** mode for > 24 hours, the system must be switched to **STANDBY** at least once a day. The system can then immediately be turned on again.

4.3.2 SUPPLY mode display

In **SUPPLY** mode, the **AquaC UNO H** reverse osmosis system produces permeate. During this mode, the system monitors all relevant parameters.



Tip

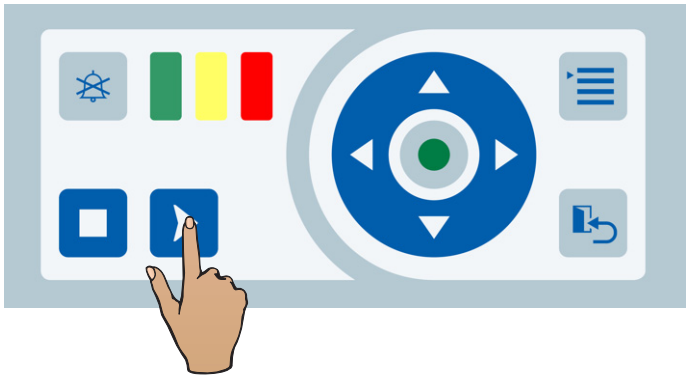
➢ When pressing the **Up** (▲) or **Down** (▼) navigation keys, the operating data screen will be displayed. This provides an overview of all parameters which can be displayed.

Permeate conductivity/ temperature monitoring

If the conductivity alarm limit is exceeded the permeate supply valve will close to stop the permeate supply. Permeate supply will be continued once the conductivity has dropped again below the alarm limit. If the permeate temperature alarm limit is exceeded, an alarm will be generated and the permeate outlet will be blocked as long as the alarm limit is exceeded.

4.3.2.1 Starting the SUPPLY mode

The **Start** key must be pressed for **approx. 3 seconds**. The system will then switch to the **SUPPLY** mode.

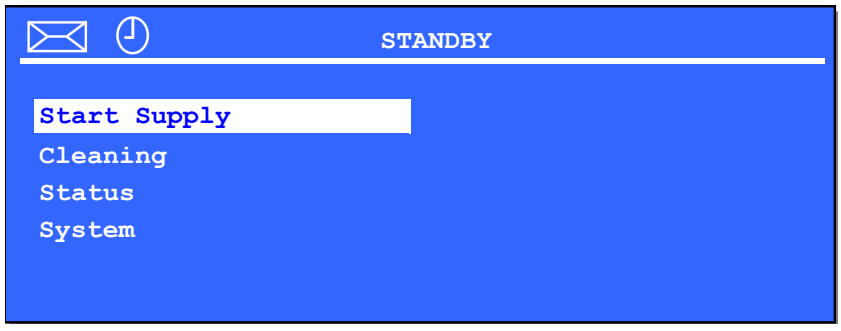


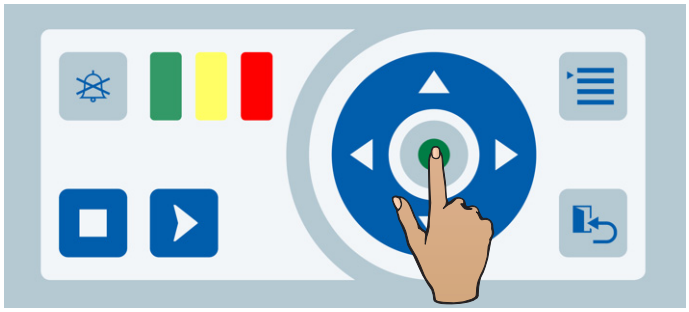
4.3.2.2 Stopping the SUPPLY mode

The **SUPPLY** mode can be stopped by pressing the **Stop** key.

4.3.2.3 Operation using the navigation keys

The **SUPPLY** mode can also be started and stopped from the main menu.





➢ Use the **navigation** keys to select the **Start Supply** program and press the **Enter** key for **3 seconds**.

The start is confirmed by an audible signal.

4.3.2.4 Automatic start of the SUPPLY mode

The system is able to switch automatically to **SUPPLY** mode if the **AutoSTART** function has been activated (see Chapter 4.11.7 on page 4-20).

Tip

When using the communication cable for the **AquaC UNO H**, the system will automatically be started in **SUPPLY** mode when dialysis starts. (This function is not available for all types of Dialysis machines. See your Technical Services department for more information.)
For part numbers (see Chapter 8.4 on page 8-4).

4.3.2.5 External control

Note

Connection of an external control is done by the technical service.

Tip

The communication cable is used for external control. For part numbers (see Chapter 8.4 on page 8-4).

4.3.2.6 Pressure switch option

If the Pressure switch option is activated and the pressure in the permeate ring drops below 1 bar/14.5 psi, the device switches from **STANDBY** to **SUPPLY** mode.

Note

If **SUPPLY** mode is started via the Pressure switch option, the **T1 test** is also performed before supply begins.

Furthermore, a T1 test is carried out if **SUPPLY** has been interrupted for more than 30 minutes. If the interruption is shorter than 30 minutes, no T1 test is performed.

Note

The Pressure switch option is only available with appropriately equipped devices.

Note

If the Pressure switch option is used, the AutoSTART/AutoSTOP function should be deactivated to prevent interruptions to the permeate supply.

4.4 RINSE mode

For detailed information (see Chapter 6.5 on page 6-10)

4.5 DECALCIFICATION mode

For detailed information (see Chapter 6.6 on page 6-12)

4.6 CHEMICAL DISINFECTION mode

For detailed information (see Chapter 6.7 on page 6-20)

4.7 MODULE HEAT DISINFECTION mode

For detailed information (see Chapter 6.8 on page 6-32)

4.8 RING HEAT DISINFECTION mode

For detailed information (see Chapter 6.9 on page 6-35)

4.9 ISOLATED STANDBY mode

For detailed information (see Chapter 6.10 on page 6-38)

4.10 Automatic program start (timer programs)

Tip

The **SUPPLY, RINSE, MODULE HEAT DISINFECTION**, and **RING HEAT DISINFECTION** modes can be started automatically by setting and activating the relevant timer.

Note

If the start times of several programs coincide, the program with the highest priority will be started.

The priorities have been defined as follows:

- **(1) SUPPLY**
- **(2) RING HEAT DISINFECTION**
- **(3) MODULE HEAT DISINFECTION**
- **(4) RINSE**

Example

If the time for the start of the **RINSE** or the **RING HEAT DISINFECTION** program should coincide with the programmed start for **SUPPLY**, the **SUPPLY** program will automatically be started, as the **SUPPLY** program has the higher priority.

If the time for the start of the **RING HEAT DISINFECTION** program coincides with the start for **MODULE HEAT DISINFECTION**, the **RING HEAT DISINFECTION** program will have the higher priority.

Note

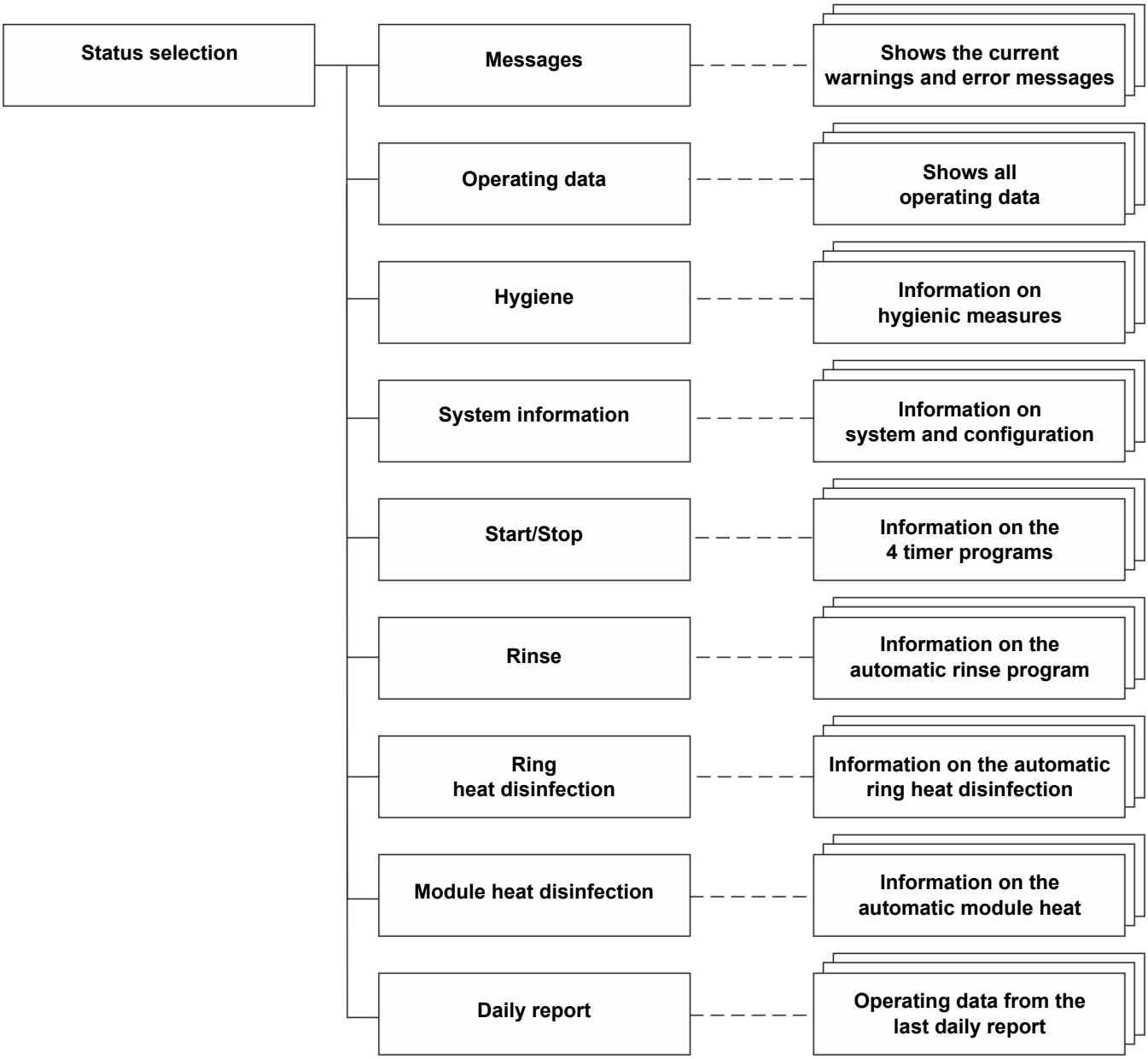
The timer for the **Module heat disinfection** program is only available if the water hardness is < 1 °dH / < 17.8 ppm $CaCO_3$.

The water hardness can be set in the Service section.

4.11 STATUS menu

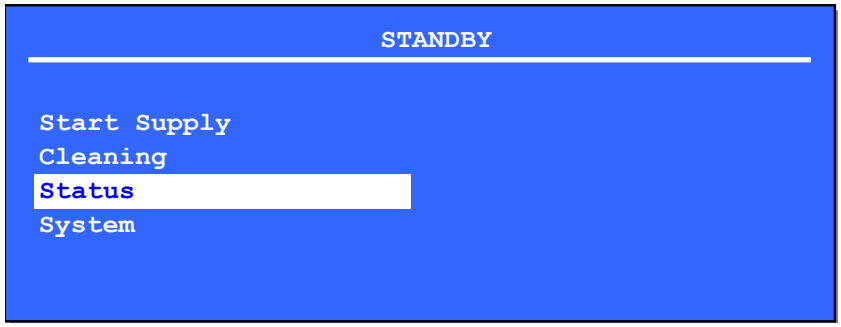
No settings can be made in the **Status menu**. This menu is only provided to display information.

4.11.1 Menu structures overview

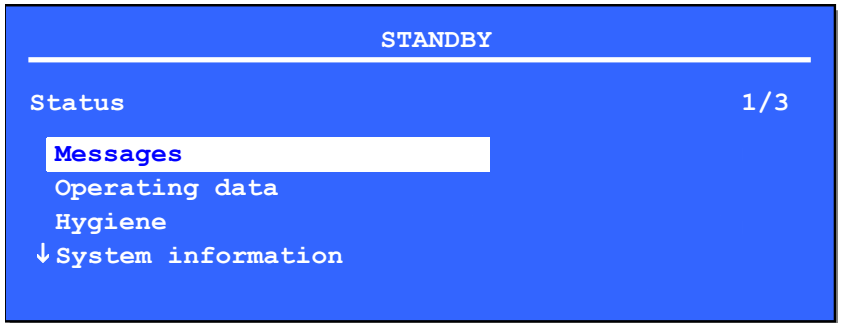


4.11.2 Opening the Status menu

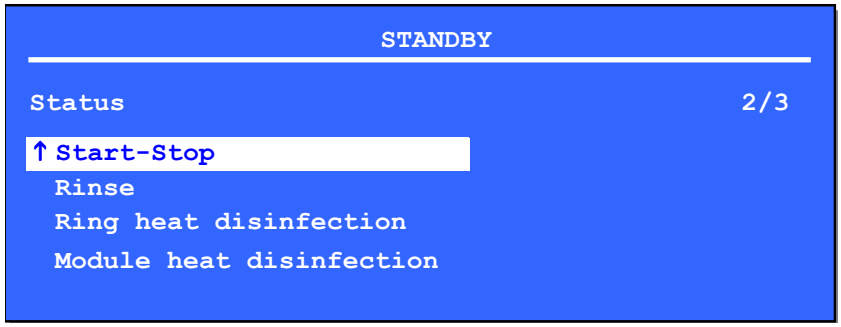
Pressing the **Menu key** will display the main menu. Selecting the menu option **Status** and confirming the selection with the **Enter** key will open the **Status menu**.



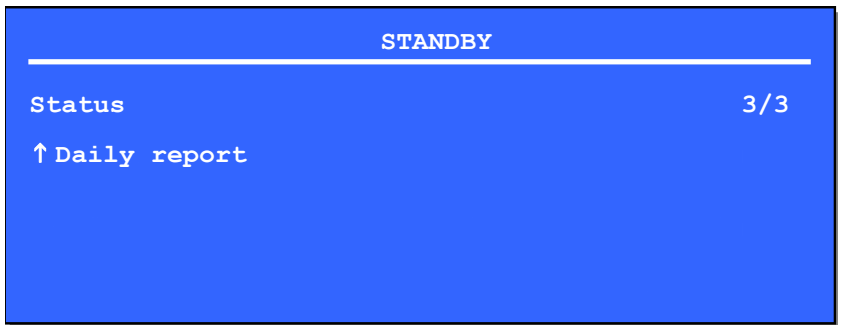
Page 1/3



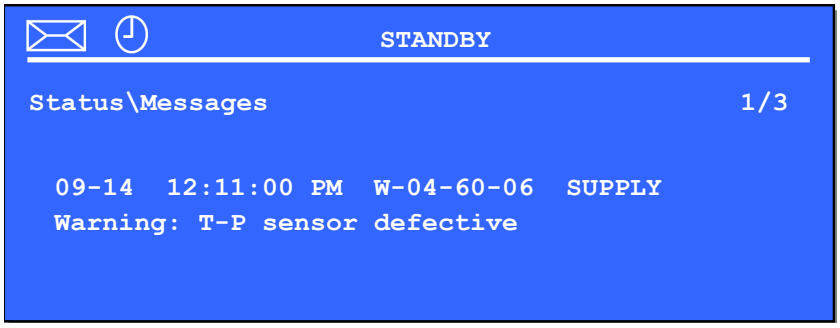
Page 2/3



Page 3/3

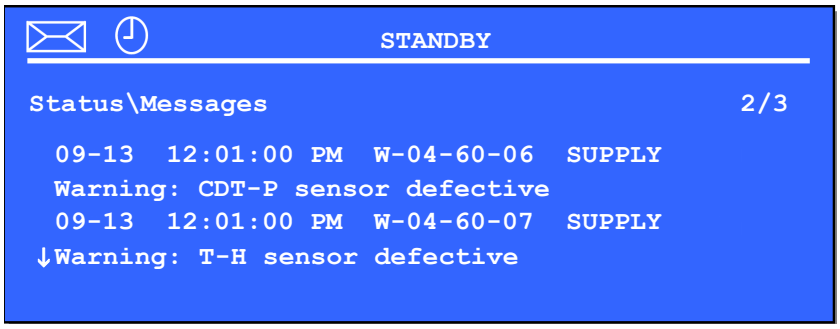


4.11.3 STATUS Messages



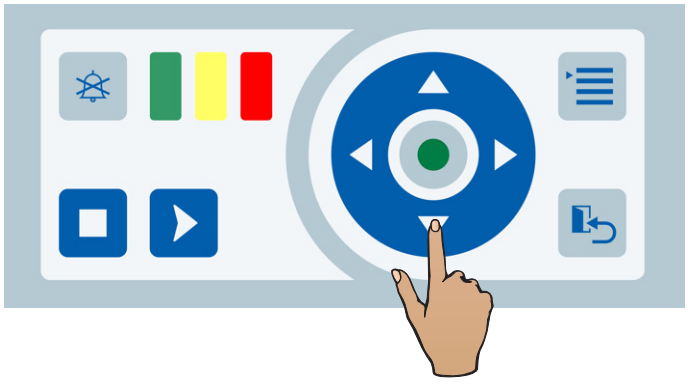
The messages that occur are displayed in chronological order.

For a description of the individual alarms, refer to Chapter 5 (Alarms).



In the **Status Messages** screen, only two messages will be displayed simultaneously.

If more than two messages are present, this will be indicated by an arrow (↓/↑) on the display.



➢ The **Down** (▼) navigation key can be used to scroll through the other pages.

Tip

➢ This menu can be exited at any time by pressing the **Back/Escape** key.

4.11.4 STATUS Operating data

Note

If the unit system has been configured in US format (in the **Service menu**), the operating data will be displayed in US units.

IS/US unit system

Operating data	Unit system SI	Unit system US
Conductivity	µS/cm	µS/cm
Temperature	°C	°F
Flow	L/min	gpm

4.11.4.1 Operating data overview table

Description page 1/3

Measured value	Sensor	Measuring range	Unit	Measuring accuracy (related to the actual value)
Permeate conductivity	CDT-P	0.0–2500	µS/cm	± 10%
Feed water conductivity	CDT-F	0.0–2500	µS/cm	± 10%
Permeate temperature	CDT-P	1.0–135 / 34–275	°C / °F	±1°C / ±1.8°F
Feed water temperature	CDT-F	1.0–135 / 34–275	°C / °F	±1°C / ±1.8°F

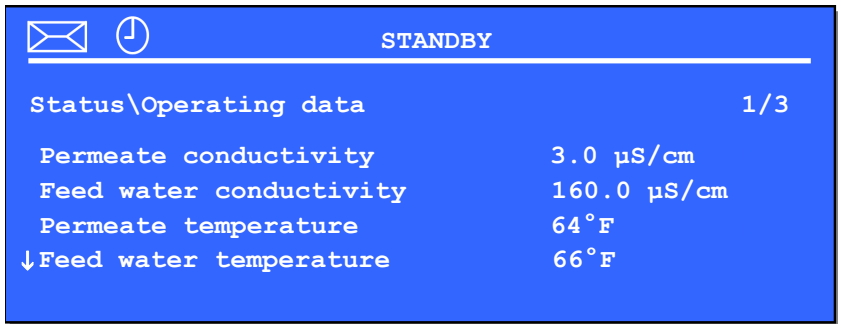
Description page 2/3

Measured value	Sensor	Measuring range	Unit	Measuring accuracy (related to the actual value)
Heater temperature	T-H	1.0–135 / 34–275	°C / °F	±1°C / ±1.8°F
Concentrate temperature	T-C	1.0–135 / 34–275	°C / °F	±1°C / ±1.8°F
Rejection rate		0.0–99	%	± 1%
Effective yield*		0.0–70	%	± 5%

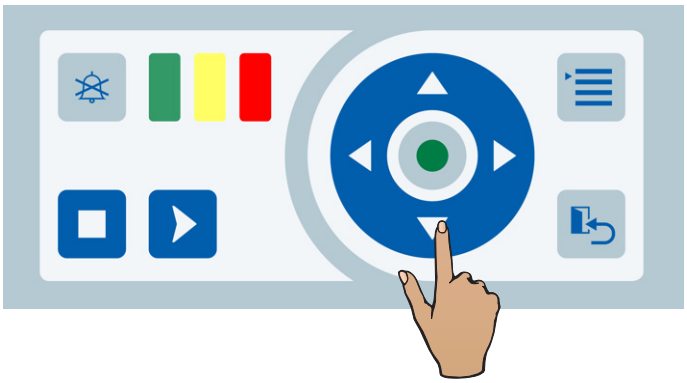
Description page 3/3

Measured value	Sensor	Measuring range	Unit	Measuring accuracy (related to the actual value)
Feed flow	FL-F	0.0–20 / 0.0-5.3	L/min / gpm	± 10%
Concentrate flow	FL-C	0.0–20 / 0.0-5.3	L/min / gpm	± 10%
Permeate consumption		0–6 / 0.0-1.6	L/min / gpm	± 10%

4.11.4.2 Viewing the operating data

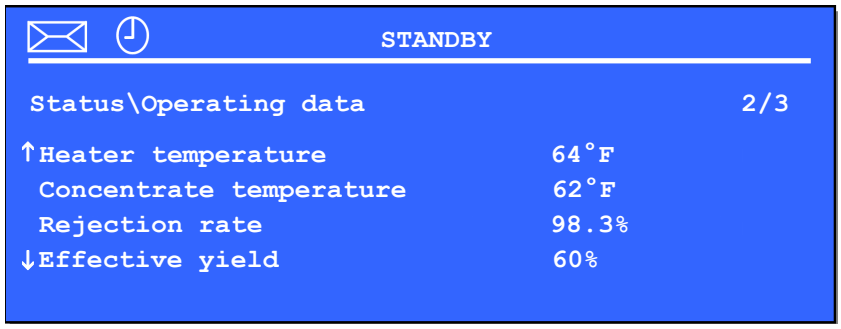


This screen shows the currently measured values of the system (see also Operating data overview table).



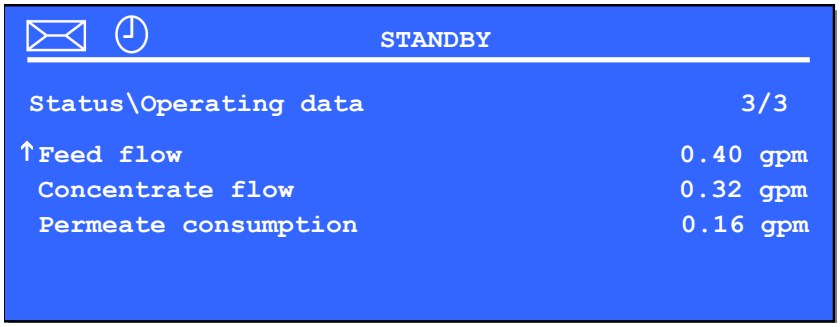
The operating data is shown over 3 consecutive screen pages. The different pages can be selected by pressing the **Up** (▲) or **Down** (▼) navigation keys.

Page 2/3



Page 3/3

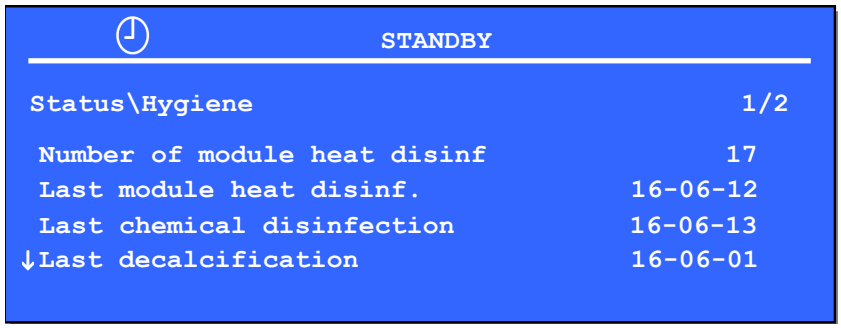
(Only displayed if the **Eco** option is installed)



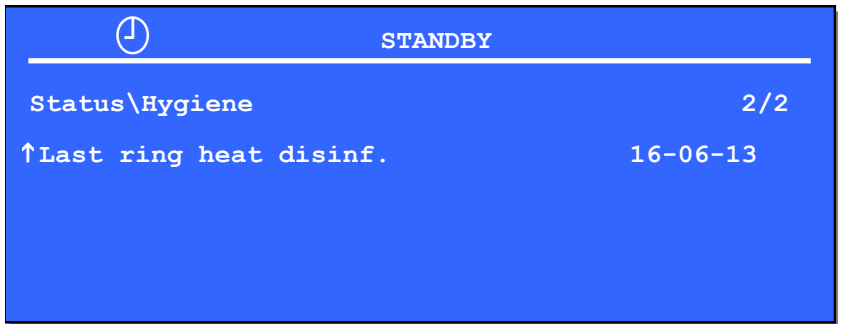
4.11.5 STATUS Hygiene

The **Status Hygiene** screen shows the total number of module heat disinfections, the date of the last chemical disinfection, of the last module heat disinfection, of the last ring heat disinfection, and of the last decalcification.

Page 1/2



Page 2/2

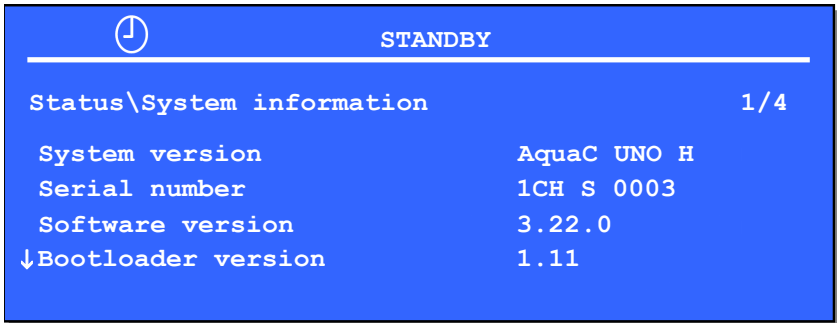


4.11.6 STATUS System information

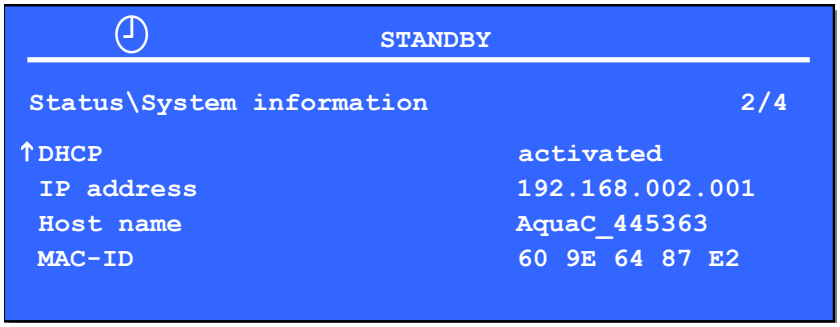
The menu option **Status System information** comprises three screen pages which provide basic information and show the configuration of the system.

The following system information is displayed:

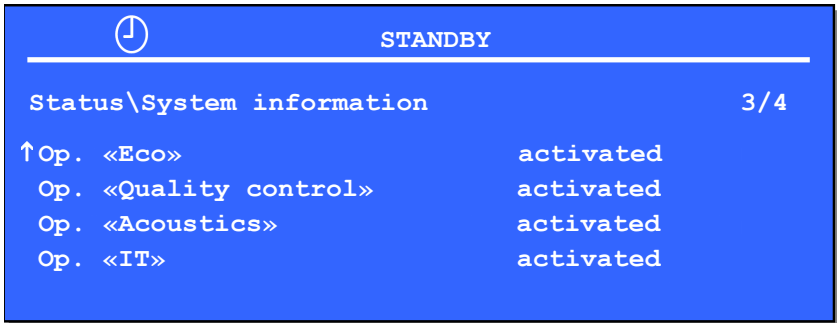
Page 1/4



Page 2/4

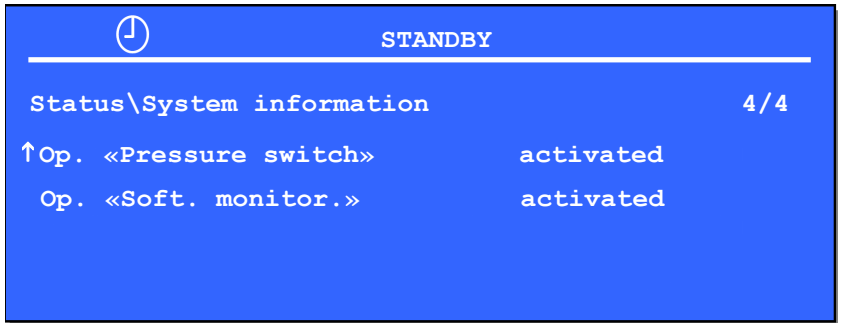


Page 3/4



The **Eco**, **Quality control**, **Acoustics,** and **IT** options are activated by default for US devices. If this is not the case, please contact the technical service.

Page 4/4

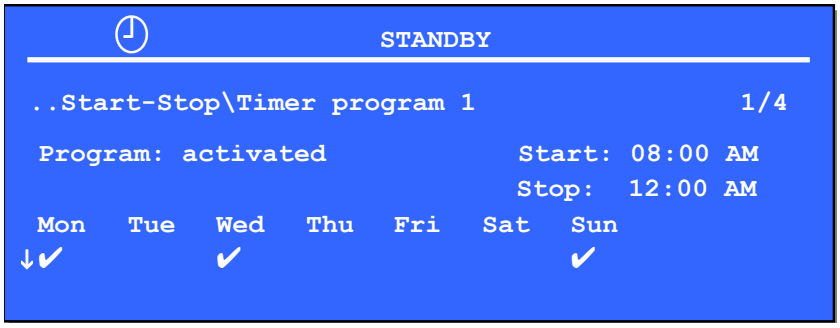

STANDBY
Status\System information 4/4
↑Op. «Pressure switch» activated
Op. «Soft. monitor.» activated

4.11.7 STATUS Start/Stop

Four timers for the SUPPLY mode

The **AquaC UNO H** has four timers for the Supply mode. All four timers work independently.

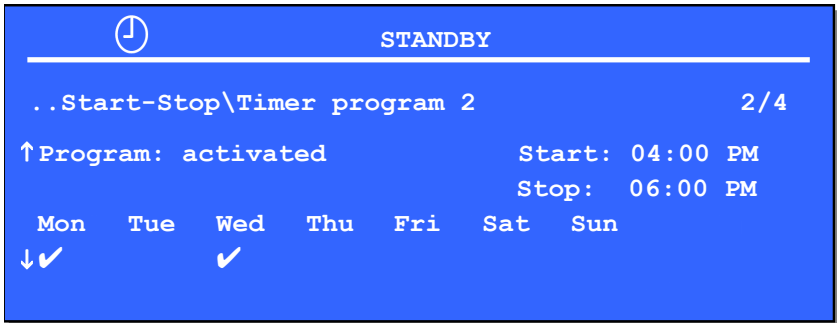
Page 1/4



The activation of the weekday is identified by the symbol ✔.

The other timer settings can be viewed using the **Up** (▲) or **Down** (▼) navigation keys.

Page 2/4

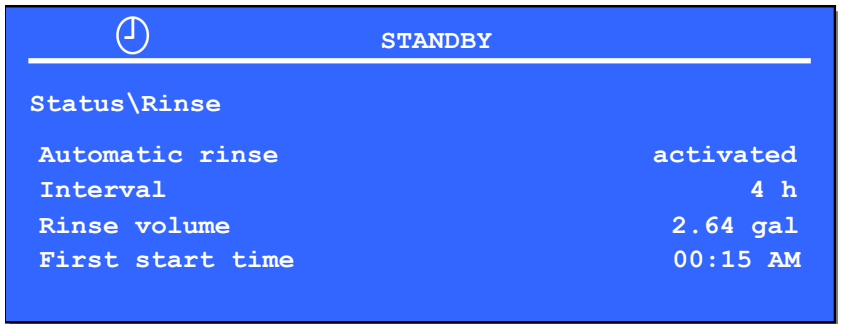


Next to the message **Program** it is indicated if the respective program has been **activated/deactivated**.

If the program status is shown as inactive, the system will not start at the defined times.

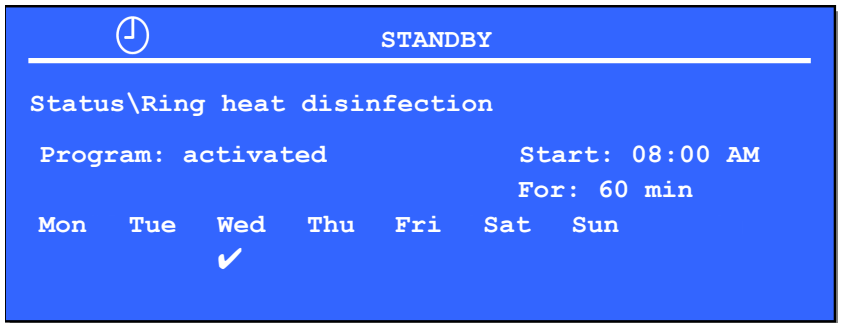
4.11.8 STATUS Rinse

The **Status Rinse** menu shows information on the automatic rinse program.



4.11.9 STATUS Ring heat disinfection

The **Status Ring heat disinfection** menu displays the settings programmed for the automatic ring heat disinfection.

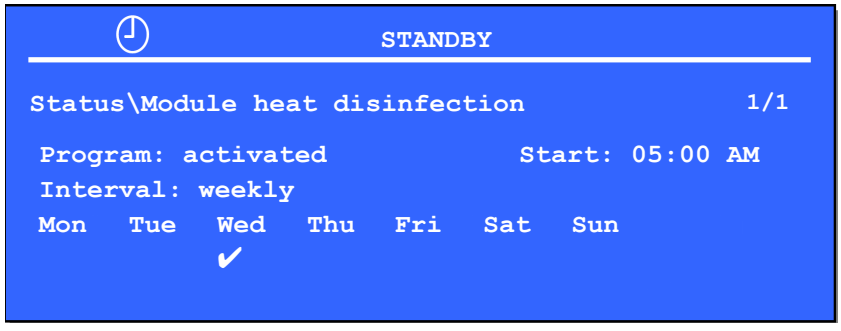


4.11.10 STATUS Module heat disinfection

Note

The menu option STATUS **Module heat disinfection** is only available if the water hardness is < 1 °dH / < 17.8 ppm $CaCO_3$.

The **Status Module heat disinfection** menu shows when the automatic disinfection of the module will be performed.

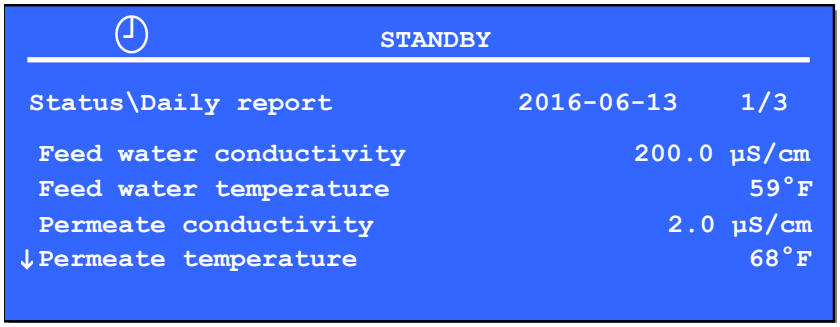


4.11.11 STATUS Daily report

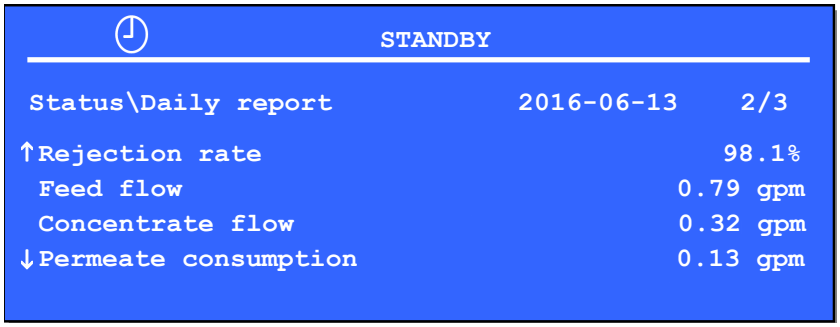
The operating data from the last recorded daily report is shown here.

The **Up** (▲) or **Down** (▼) navigation keys can be used to switch between the pages.

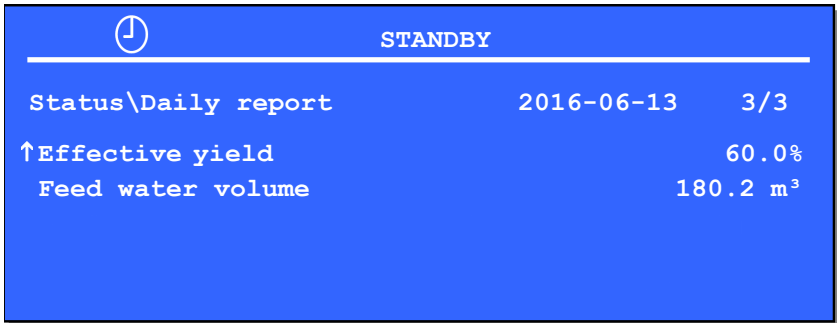
Daily report screens
Page 1/3



Page 2/3



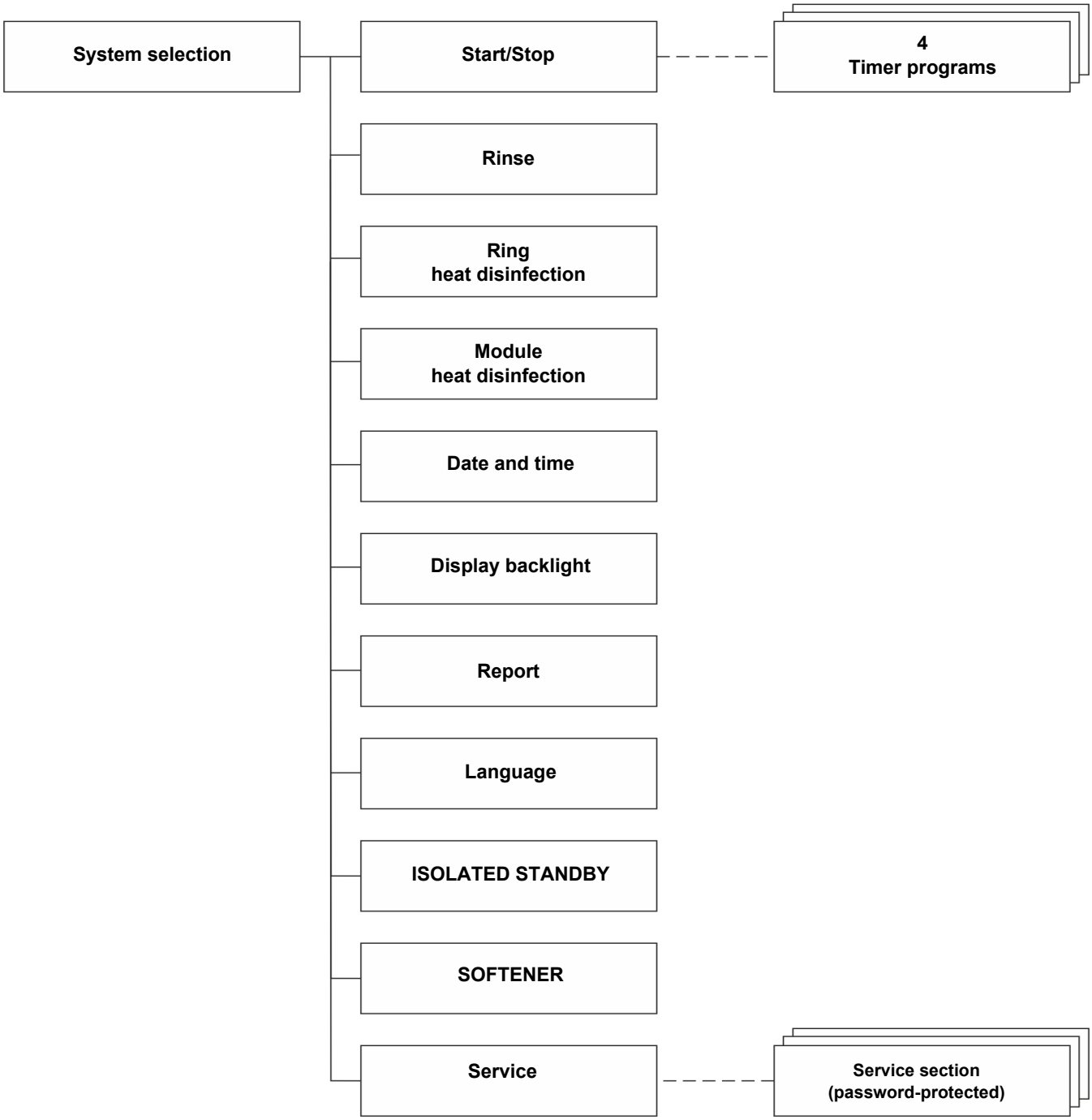
Page 3/3



4.12 SYSTEM menu

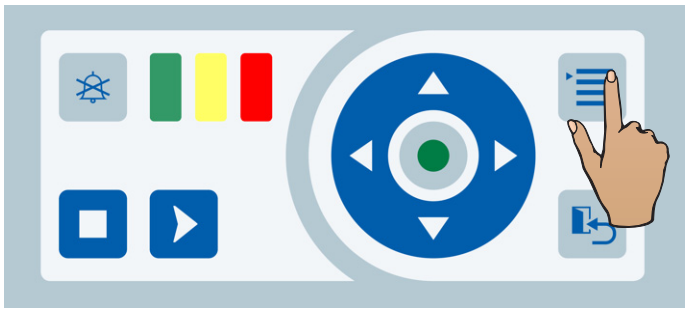
Settings can be defined in the **System menu**. This menu is used to set parameters.

4.12.1 Menu structures overview

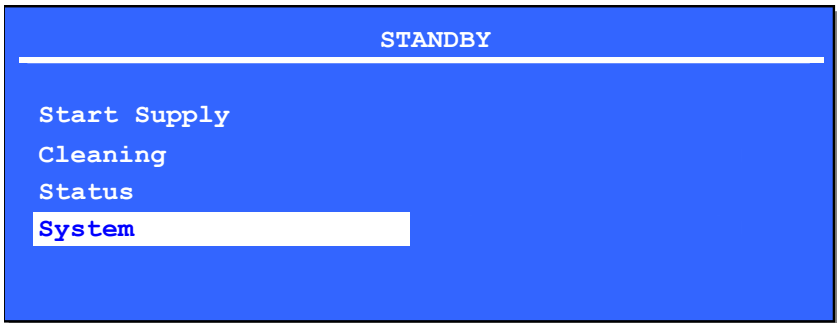


Switching to the main menu

Pressing the **Menu** key will switch to the main menu.

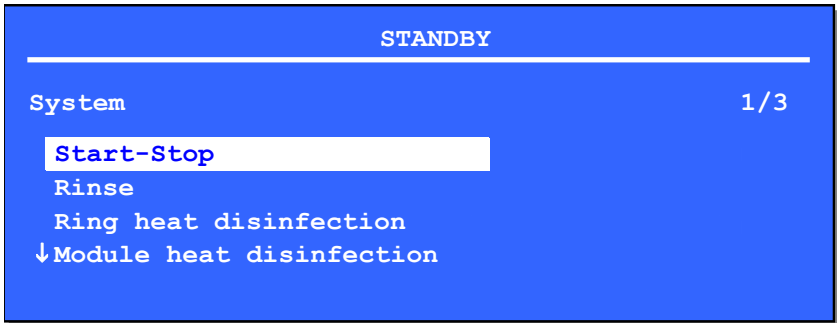


The following screen will be displayed:

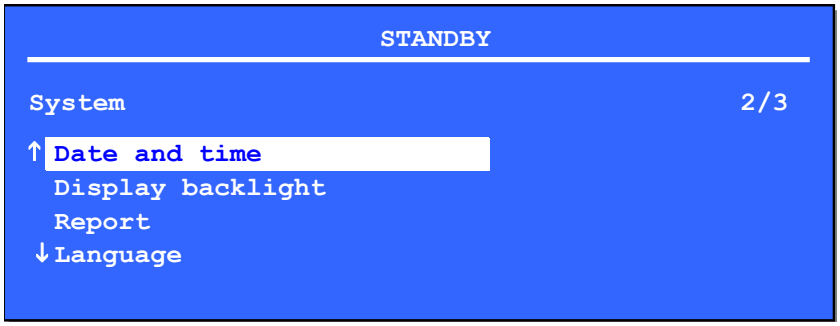


When selecting the menu option **System** and confirming the selection with the **Enter** key, the **System** menu will be opened.

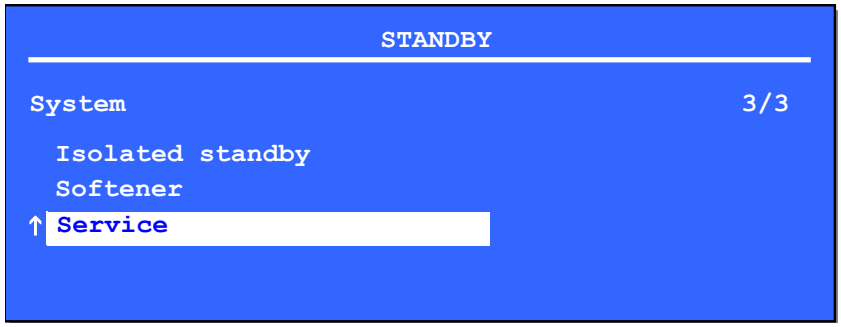
Page 1/3



Page 2/3



Page 3/3



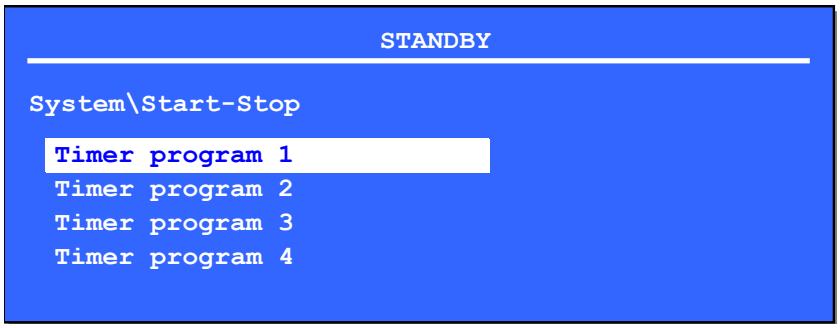
Note

If the water hardness is set to 1 °dH / 17.8 ppm $CaCO_3$ or higher in the **Service menu**, the "Module heat disinfection" line on page 1 is hidden.

4.12.2 Programming the SYSTEM Start/Stop

Setting the AutoSTART and AutoSTOP cycles

This menu is used to program the **AutoSTART** and **AutoSTOP** cycles (Supply timer programs).

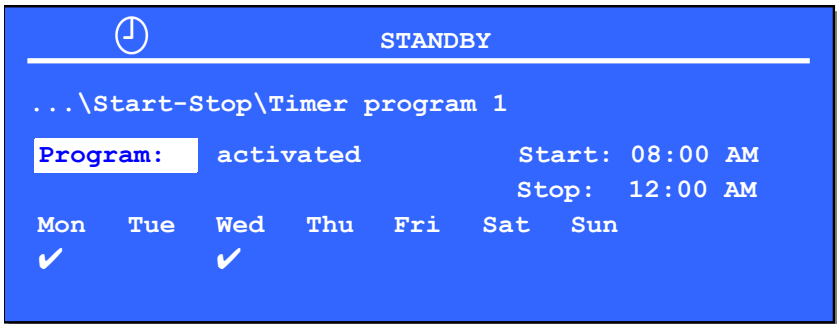


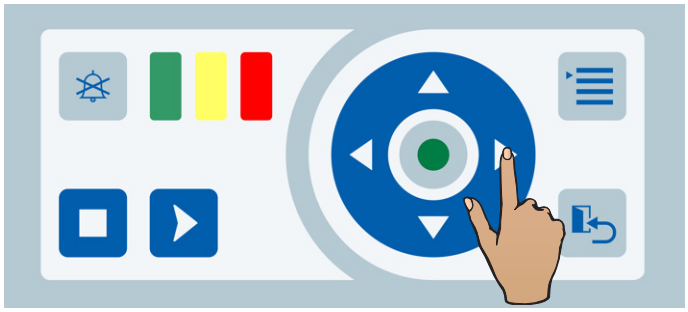
Four available timer programs

Four timer programs are available, which can be programmed independently.

Editing the timer program

➢ The selected timer program can be edited by pressing the **Enter** key.

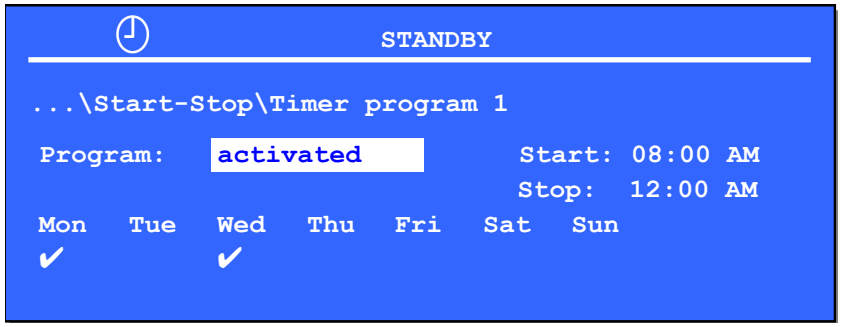


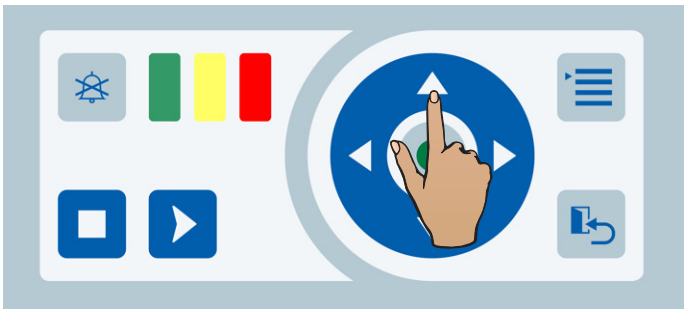


The **navigation** keys are used to select a parameter.

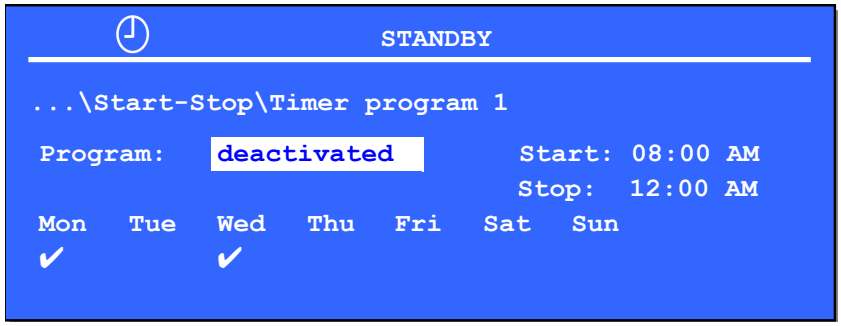
➢ After pressing the **Enter** key, the selected parameter can be changed.

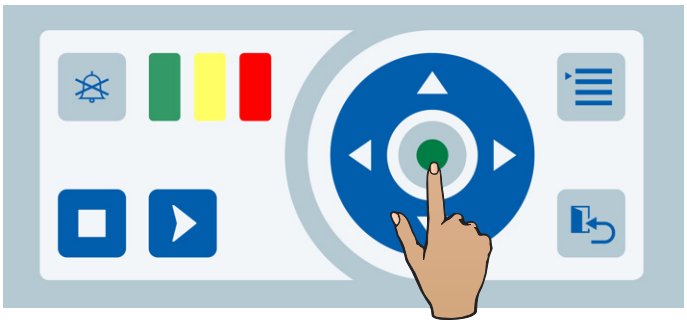
Activating or deactivating





The **Up** (▲) or **Down** (▼) navigation keys are used to switch between **activated/deactivated**.

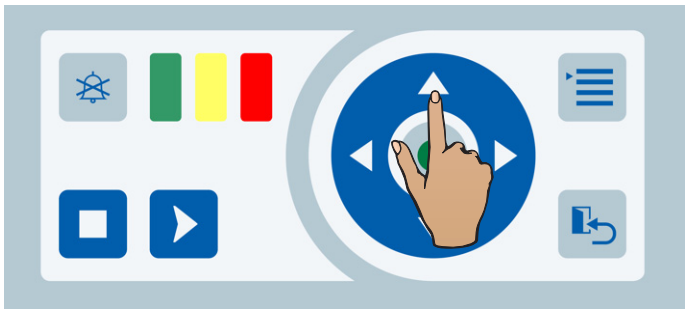




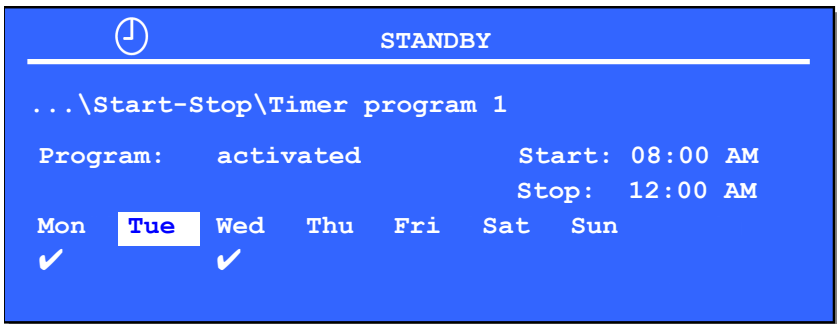
➢ The change of the parameter will not become effective before it has been confirmed with the **Enter** key.

➢ To exit the menu without saving the changes made, press the **Back/Escape** key.

Switching to the next menu option

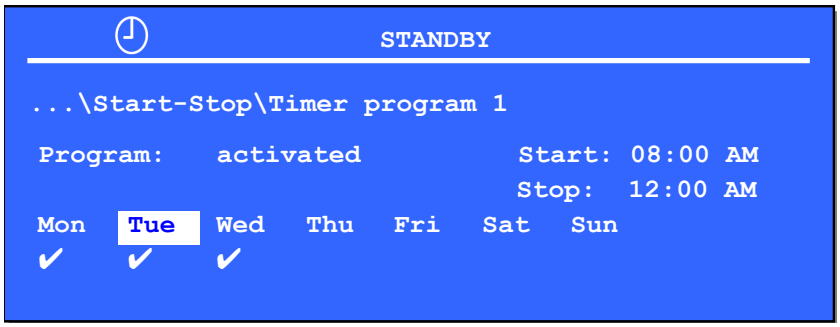


➢ The **Up** (▲) or **Down** (▼) navigation keys are used to move to the next line up or down.



➢ The change of the parameter will not become effective before it has been confirmed with the **Enter** key.

➢ To exit the menu without saving the changes made, press the **Back/Escape** key.

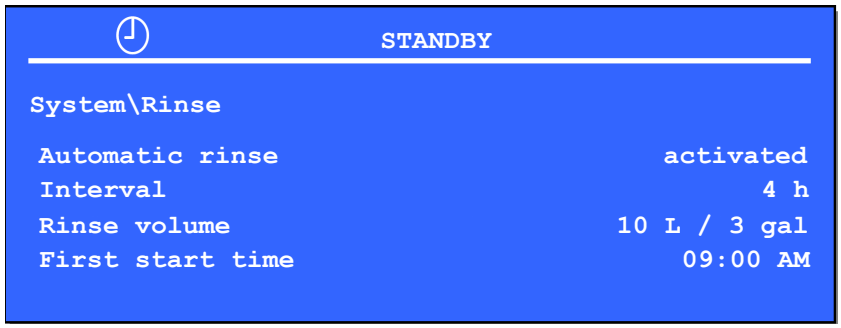


4.12.3 Programming SYSTEM Rinse

The parameters listed in the table below are available for programming the **SYSTEM Rinse**.

4.12.3.1 Programmable rinse parameters

Parameter	Adjustment range	Unit
Automatic rinse	[activated/deactivated]	- - -
Interval	[1, 2, 3, 4, 6, 8, 12]	h
Volume	5 ... 100 (in 1 L increments) 1 ... 26 (in 1 gal increments)	L gal
First start time	00:00 AM ... 11:45 PM	hh:mm



Automatic rinse program

This menu is used to define the settings for the **automatic rinse program**.

First start time (example)

First start time: 9:00 AM
Interval: 4 h

6 rinse cycles will be performed per day.

One is at 9:00 AM, then at 4-hour intervals after that (1:00 PM / 5:00 PM / 9:00 PM / 1:00 AM / 5:00 AM / 9:00 AM).

➢ By setting the first start time, the system can be programmed so that the rinse phase will only be performed at specified times.

➢ The rinse program will start at the programmed time and the following rinse procedure will then be performed at the programmed interval counted from this first time.

For more detailed information regarding rinse intervals (see Chapter 6.4.5 on page 6-9).

4.12.4 Programming SYSTEM Module heat disinfection

Note

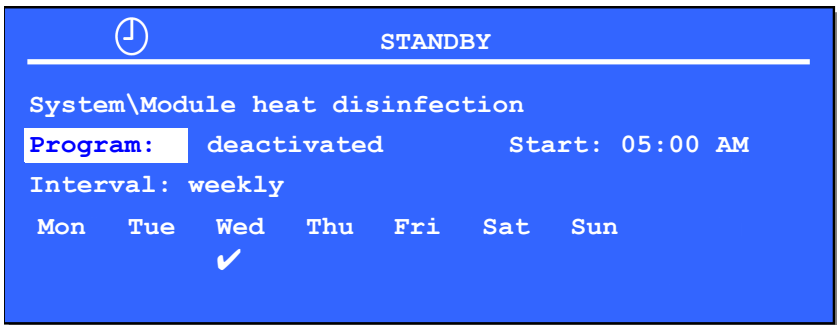
The menu option **SYSTEM Module heat disinfection** is only available if the water hardness is < 1 °dH / < 17.8 ppm $CaCO_3$.

This menu option is used to program the automatic module heat disinfection.

Programming the intervals

The module heat disinfection can only be programmed for **one weekday**.

The interval can also be programmed for once a week (weekly), every 2 weeks or once a month (monthly).



If the interval has been set to every 2 weeks or monthly, the module heat disinfection will be performed every 2 weeks or once a month on the programmed day of the week.

The first module heat disinfection will be performed on the next weekday selected for the disinfection, the next module heat disinfection will be performed on the following weekday of the programmed interval.

4.12.5 Programming SYSTEM Ring heat disinfection

This menu option is used to program the automatic ring heat disinfection.

Programming the intervals

Ring heat disinfection can be programmed for each day.

Programming the disinfection time

The duration of the ring heat disinfection can be programmed from 10 minutes to 100 minutes. During this time, the hemodialysis device can consume up to 200 ml/min / 0.05 gpm of hot permeate.

➢ The duration can be set with the **navigation** keys.

➢ Pressing the **Enter** key will save the setting.

➢ The **Up** (▲) or **Down** (▼) navigation keys are used to edit the value.

Note

The times of the reverse osmosis system and the hemodialysis device must be aligned.

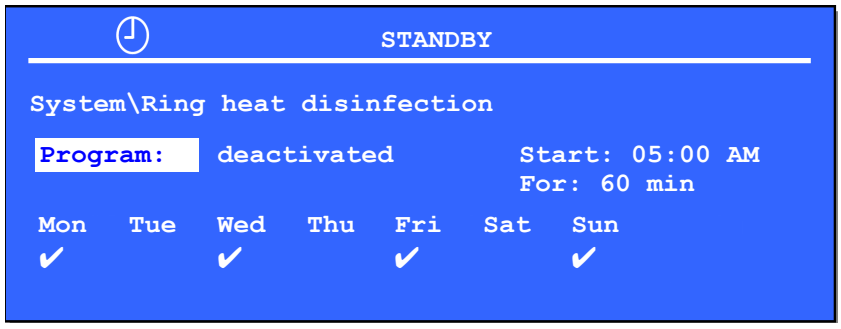
The following applies for a programmed automatic ring heat disinfection (AutoOn):

➢ The time for the start of the ring heat disinfection of the reverse osmosis system must be programmed so that it is **12 minutes** before that of the hemodialysis device.

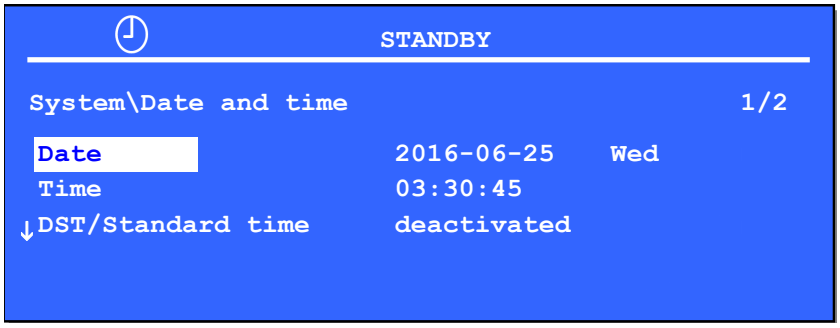
➢ The duration of the ring heat disinfection on the reverse osmosis system must be programmed so as to last **15 minutes** longer than the time in the Cleaning menu of the 5008/5008S.

The following applies for a manual start of the ring heat disinfection:

➢ The duration of the ring heat disinfection on the reverse osmosis system must be programmed so as to last **5 minutes** longer than the time in the Cleaning menu of the 5008/5008S.



4.12.6 Setting SYSTEM Date and SYSTEM Time

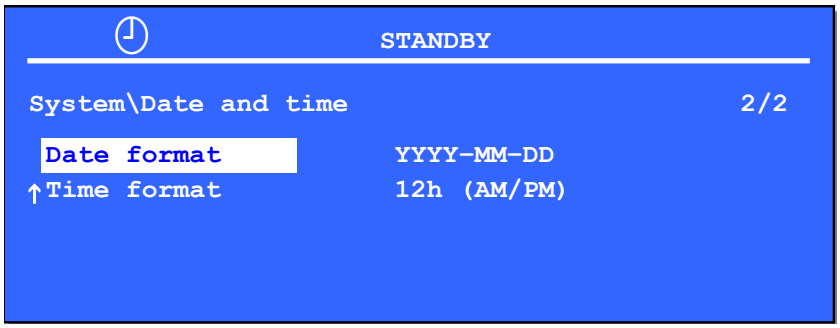


➢ Date and time can be set with the **navigation** keys.

➢ Pressing the **Enter** key will save the setting and advance to the next value.

➢ The **Up** (▲) or **Down** (▼) navigation keys are used to edit the value. The weekday will be automatically determined from the date.

The date and time format can be set on page 2.



Pressing the **Enter** key will select a value for setting. The format can be chosen with the **Up** (▲) or **Down** (▼) navigation keys. Pressing the **Enter** key will confirm the selected format.

Note

Configuration of time and date formats:

– The time format is configured in the **System\Date and time** menu.

– The unit system is configured in the **Service menu**.

Setting the date and time format

The display format can be individually adjusted, depending on the date and time format setting.

Possible formats for time, date:

– AM, PM

– 12:34:22, 12:34:22 PM

– 07.03.2016, 2016-07-03

Changing daylight savings/standard time

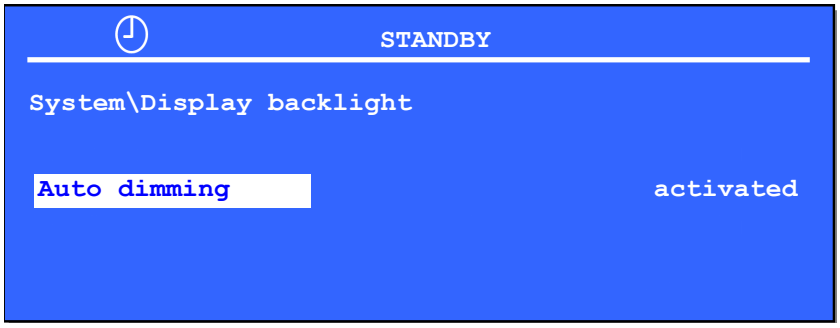
The automatic change from daylight savings time to standard time in line with the European standard can be activated or deactivated.

Note

The change from daylight savings time to standard time follows the Central European standard of directive 2000/84/EC.

The change from daylight savings time to standard time follows the Central European standard or Directive 2000/84/EC.

4.12.7 SYSTEM Display backlight



Activating the dimming function

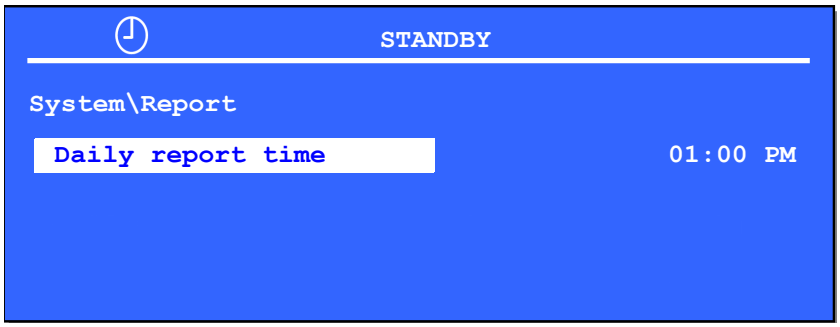
If the automatic dimming function has been activated, the display backlight will be turned off if no key is pressed for 1 minute.

When dimmed, the backlight will be turned on after pressing any key.

4.12.8 SYSTEM Report

Tip

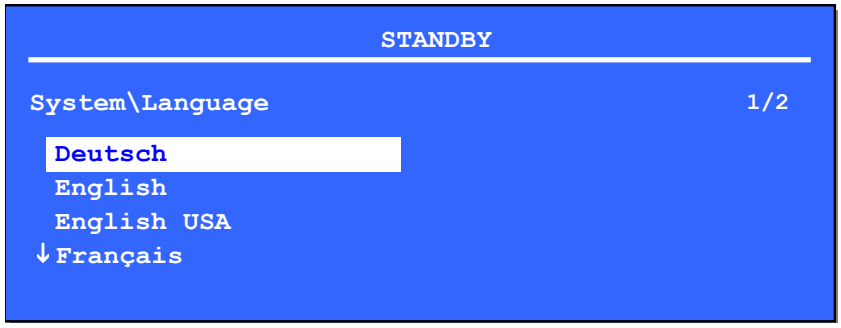
The time when the daily report values will be recorded and logged on a microSD card can be set in the Report menu.



Note

The daily report values are only recorded in **SUPPLY** mode.

4.12.9 Setting SYSTEM Language



After selecting the language and confirming the selection with the **Enter** key, the language will be activated.

Note

Possible formats for time, date:

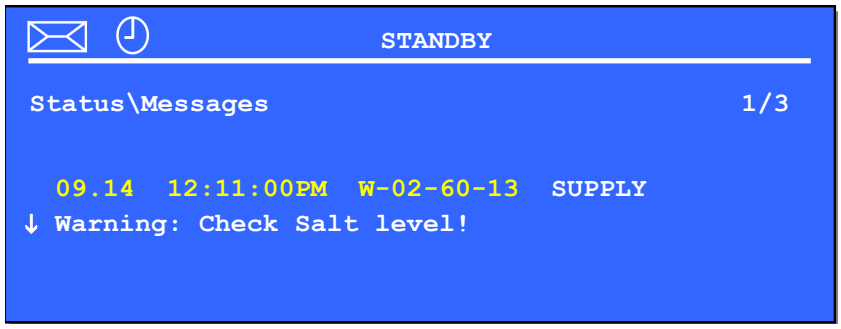
– AM, PM

– 12:34:22, 12:34:22 PM

– 07.03.2016, 2016-07-03

Setting the format (see Chapter 4.12.6 on page 4-32).

Example display for USA format YYYY.MM.DD and 12h



4.12.10 SYSTEM ISOLATED STANDBY

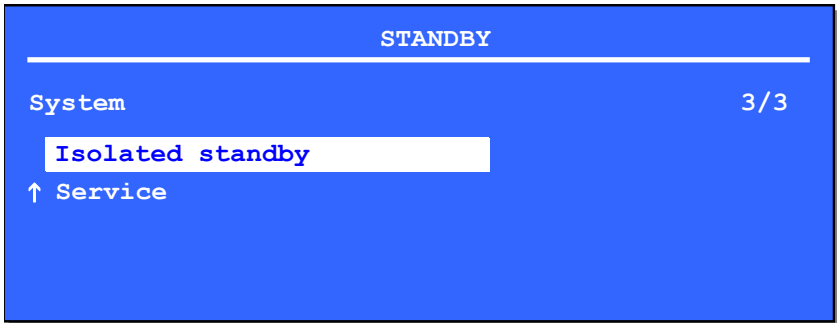
4.12.10.1 Starting in the System menu

Note

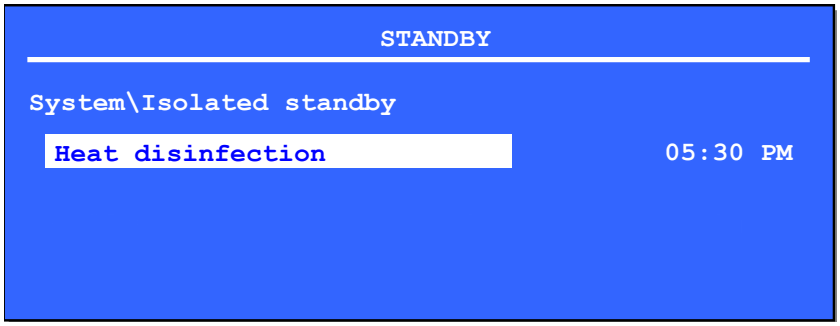
The **System Isolated standby** menu is available if the **Isolated standby** option has been activated with a license.

The **ISOLATED STANDBY (free option)** function can be started in the **System Isolated standby** menu.

Start isolated standby must be selected in the **System Isolated standby** menu. Pressing and holding the **Enter** key (for approx. 3 seconds) will start the preparation phase for the **ISOLATED STANDBY** program.

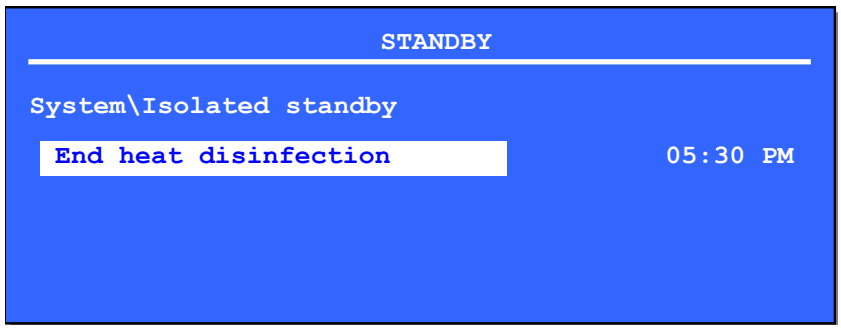


➢ Open the **System Isolated standby** menu.



➢ In the **System Isolated standby** menu, select and confirm the **Heat disinfection** option.

If **Heat disinfection** is active, the display in the **System Isolated standby** menu will change and **End heat disinfection** will appear.



➢ It is only possible to set the time.

➢ The program can now only be started in the **Cleaning** menu.

Note

Follow the full description of decalcification in Chapter 6 when performing the isolated standby. (Unless a Softener is installed and hardness is <1 degree german).
For further information (see Chapter 6.10 on page 6-38).

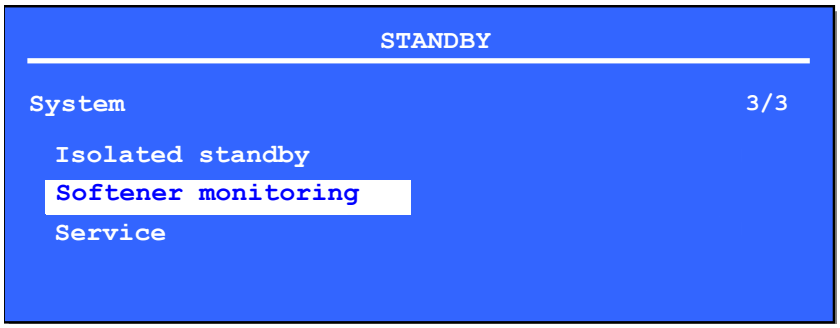
4.12.11 SYSTEM Softener

Note

Access to the **Service menu** is restricted to service technicians.

Note

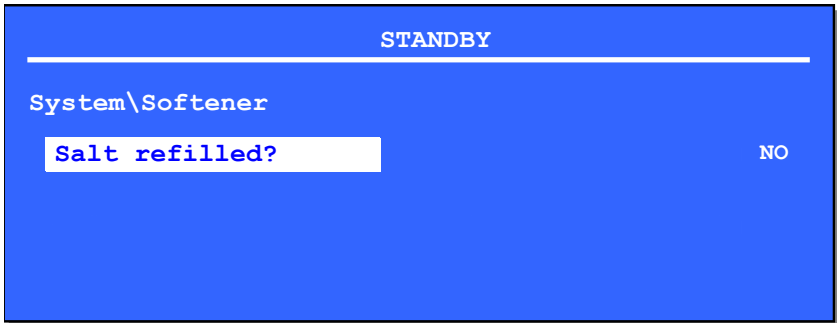
The **SYSTEM Softener** menu is only available if the **Softener** option has been activated in the **Service menu**.



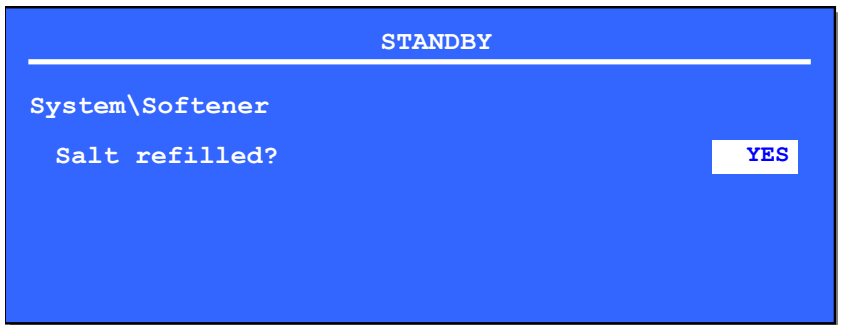
➢ The salt fill level for the softener can be confirmed in the **SYSTEM Softener monitoring** menu.

The **SYSTEM Softener monitoring** menu is opened automatically if message **W-02-60-13 Warning: Check Salt level!** is displayed and confirmed with the **Enter** key.

➢ The **SYSTEM Softener monitoring** menu can be opened at any time if the salt fill level is to be confirmed later.



➢ Change to **NO** by pressing the **Enter** key. Change **NO** to **YES** with the **Up** (▲) or **Down** (▼) navigation keys and confirm with the **Enter** key.


STANDBY
System\Softener
Salt refilled?
YES

4.12.12 SYSTEM Service (only with password)

Note

Access to the Service menu is restricted to service technicians.

Note

Configuration of time and date formats:

– The time format is configured in the System\Date and time menu.

– The unit system is configured in the Service menu.

4.13 Data processing

Network compatibility for remote access

The **AquaC UNO H** includes an electronics module for expanding the **AquaC UNO H** by adding network functions. Stored operating data and reports for remote maintenance can be accessed via the Ethernet interface using an existing network (Fast Ethernet 100BaseTX).

Possibility for operating data transfer

The operating data stored on the microSD card can be downloaded to the PC via an FTP connection. The network functions permit remote diagnostics of the system by the service technician.

4.14 Web server

Note

For the part numbers of the options, refer to Chapter 8.

Network compatibility for remote access

The **AquaC UNO H** includes an electronics module for expanding the **AquaC UNO H** with a network feature. Stored operating data and reports for remote maintenance can be accessed via the Ethernet interface using an existing network (Fast Ethernet 100BaseTX).

Possibility for operating data transfer

The operating data stored on the microSD card can be downloaded to the PC via an FTP connection. The network functions permit remote diagnostics of the system by the service technician.

Integrated web server

With the integrated web server, the most important operating data of the **AquaC UNO H** can be displayed on a PC (either locally or via a network). The integrated web server also enables the **AquaC UNO H** to be controlled remotely.

Note

A crossover cable must be used to establish a direct network connection between a PC and the **AquaC UNO H**. The PC is connected to the **AquaC UNO H** directly, without a network switch being inserted between the two.

The PC and the **AquaC UNO H** must have the same IP address range.

Note

If the **AquaC UNO H** and the PC are already integrated in an existing network, special settings may need to be made on the local network to enable remote access. These settings must be discussed with the network administrator.

Operating data can be displayed using a web browser, such as Microsoft Internet Explorer.

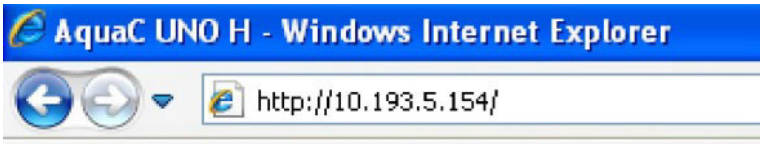
Connection setup

➢ Establish a network connection.

➢ Launch the web browser (e.g., Internet Explorer).

➢ In the web browser's address bar, enter the IP address of the **AquaC UNO H**, e.g., **10.193.5.154**. The IP address of the **AquaC UNO H** is shown in the Status/System information menu. The IP address can be modified in the System/Service/Settings/ Ethernet menu.

➢ After the IP address has been entered in the web browser's address bar and confirmed with the Enter key, a request for access data appears. The following data must be entered here:



Example: IP address

User name: **aquacunoh**

Password: **fmeuser**

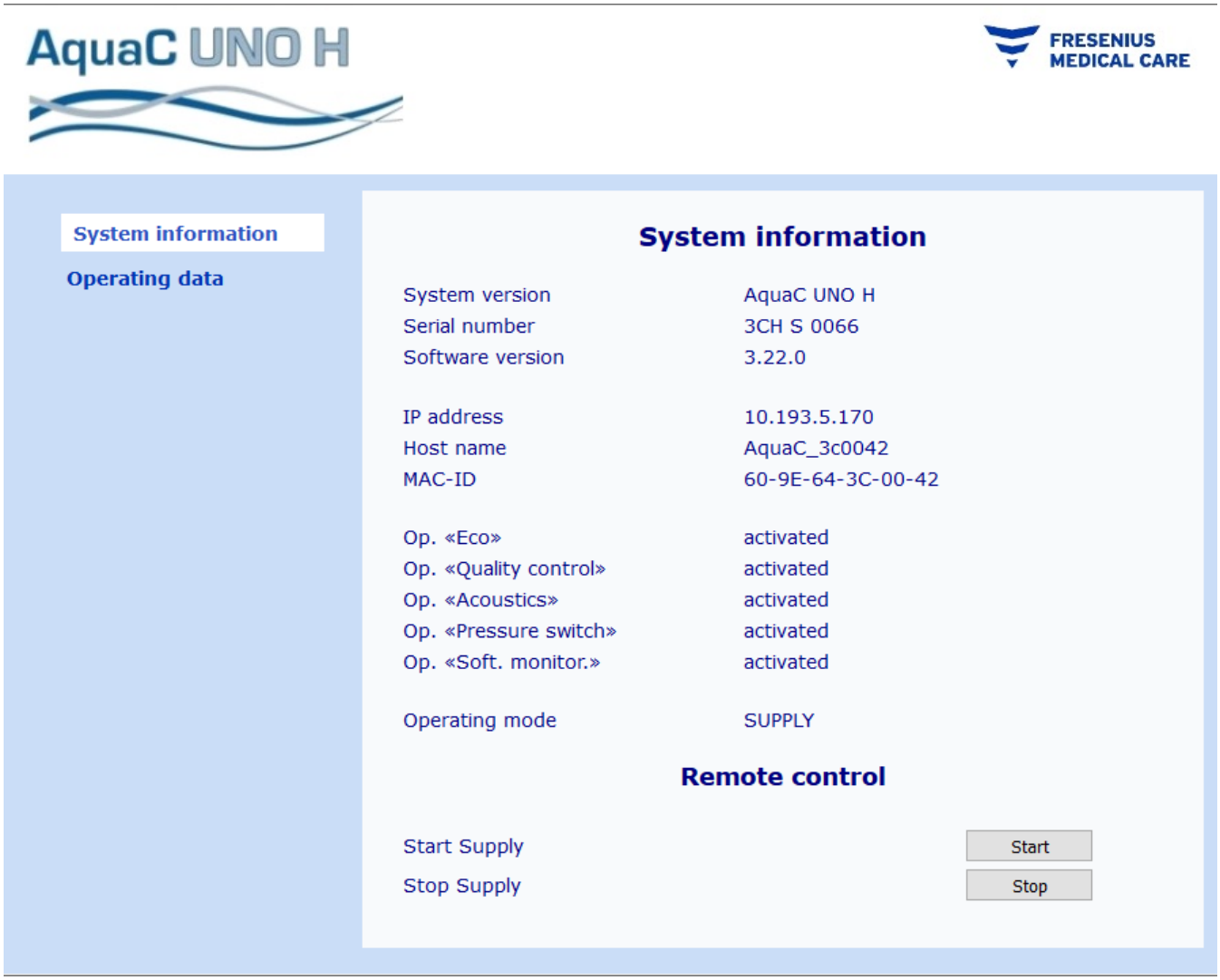
➢ These entries are case-sensitive.

➢ Press the **OK/Log on?** button.

You can display two screens with the **AquaC UNO H** web server: **System information** and **Operating data**.

Required system information

An overview of system information is displayed. The data shown corresponds to the status display.



Remote control Start/Stop

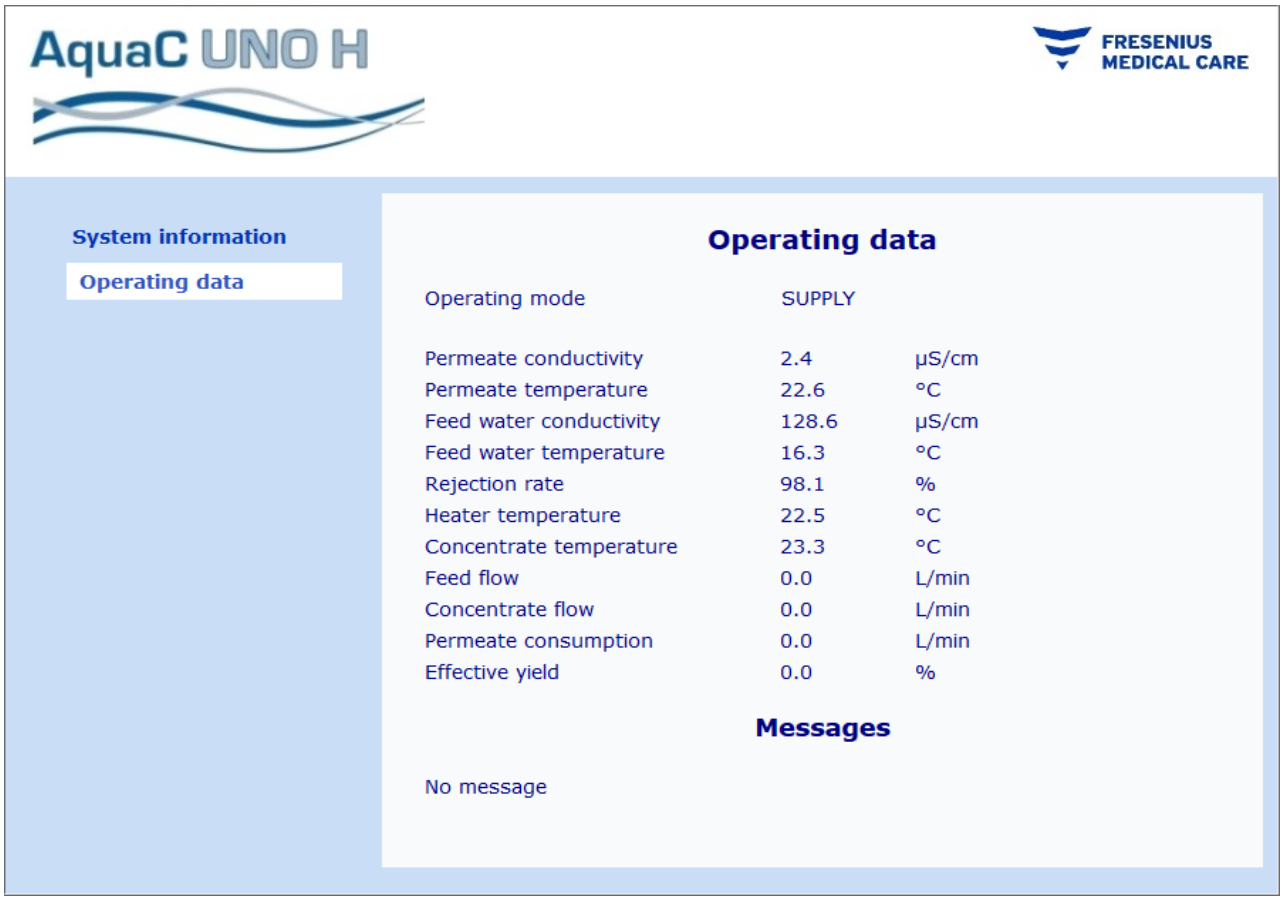
The **Supply** program can be started and stopped in the **Remote control** section.

➢ To start **Supply** mode, press the **Start** button.

➢ To stop **Supply** mode, press the **Stop** button.

Operating data

Click **Operating data** on the left. A window containing the most important operating data appears.



5 Alarms

5.1 General notes

Audible and visual alarms of the **AquaC UNO H** are coded according to their priority as follows:

High-priority alarms

Failure alarms which illicit the following system response:

The pump is turned off and the system will stop operation. Permeate supply during dialysis will be interrupted.

The permeate quality for dialysis exceeds the permitted values and permeate supply can be interrupted at any time.

Medium-priority alarms

None

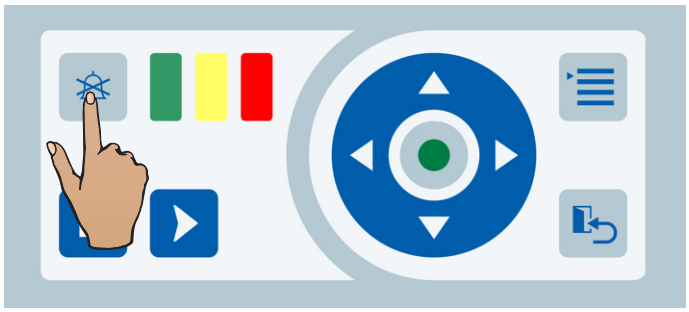
Low-priority alarms

Warnings which indicate an error and restrict operation but do not stop operation of the system.

These alarms are indicated by an audible signal and are displayed visually without any delay if an alarm condition occurs. Further alarm handling (confirmation and silencing of the alarm) is done directly on the system.

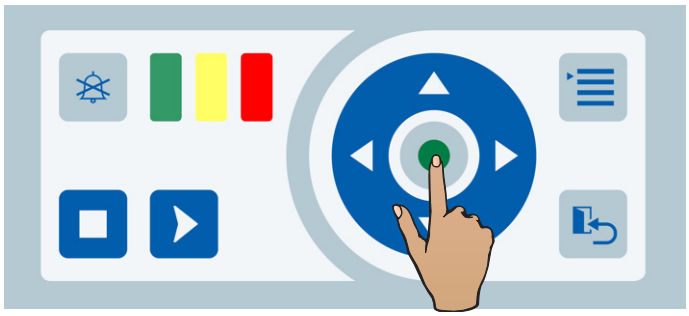
5.1.1 Silencing the audible alarm (mute)

If the Mute key is pressed, the audible signal will be silenced for just 2 minutes. The audible signal will not be completely silenced before the alarm message has been confirmed.



5.1.2 Confirming alarms

An alarm is confirmed by pressing the Enter key. The alarm will not be indicated again even if the alarm condition persists.



The current messages are displayed in the Status **Messages** screen. The messages will be deleted automatically after the message has been confirmed and the problem causing the message has been corrected.

5.1.3 Verifying alarms

A verification of the alarms by the operator is not required. The alarms will be verified by the service technician as part of the TSC.

5.2 Contacting the service department

The following information should be available when contacting the service department:

- Daily reports of the previous week
- Current values of the **AquaC UNO H** reverse osmosis system
- Number, kind, and type of components connected upstream and downstream
- The error code of the control unit with date and time
  Format of the message: [dd.mm.yy], time [hh.mm.ss], error code [X-XX-XX-XX], operating mode [], message text
- In the event of malfunctions or if alarm limits are exceeded, the system must be restarted after checking the cause of the problem and correcting the problem.

5.3 Alarm description

5.3.1 Identification of the error code

F	01	01	01	Definition
F				**Identifier** **F** – Failure, malfunction **W** – Warning, warning condition
	01			**Category** **01** – System and hardware problem **02** – Procedure (e.g., violation of alarm limits)
		60		**System** **60** – **AquaC UNO H**
			01	**Message number** Identification of the number (failure or warning)

5.3.2 Error categories overview

- **Category 01: System and hardware problem**

Error code	visual indicator	Error message text	Action required
F–01–60–01		Failure: *CDT-P sensor defective*	➢ Contact the service department.
W–01–60–05		Warning: *Heater relay defective*	➢ Contact the service department.
W–01–60–01		Warning: *Level sensor defective*	➢ Contact the service department.
W–01–60–02		Warning: *T-C sensor defective*	➢ Contact the service department.
W–01–60–03		Warning: *T-H sensor defective*	➢ Contact the service department.
W–01–60–04		Warning: *CDT-F sensor defective*	➢ Contact the service department.

Error code	visual indicator	Error message text	Action required
W–01–60–06		Warning: *Inlet valve leakage*	➢ Contact the service department.
W–01–60–07		Warning: *FL-F sensor defective*	➢ Contact the service department.
W–01–60–08		Warning: *FL-C sensor defective*	➢ Contact the service department.
W–01–60–09		Warning: *Valve V30 defective*	➢ Contact the service department.
W–01–60–10		Warning: *Heater defective*	➢ Contact the service department.
W–01–60–11		Warning: *Pump P2 defective*	➢ Contact the service department.
W–01–60–12		Warning: *Valve V42 defective*	➢ Contact the service department.

- **Category 02: Procedure**

Error code	visual indicator	Error message text	Action required
F–02–60–01		Failure: *Leakage*	➢ Correct the leakage. ➢ Dry the sensors.
F–02–60–02		Failure: *Fill level dropped*	➢ Check if water was removed during the disinfection. ➢ Contact the service department.
F–02–60–03		Failure: *Run-dry protection*	➢ Check water supply. ➢ Contact the service department.
F–02–60–04		Failure: *Permeate temp. exceeded*	➢ Start rinse. If the temperature does not drop, contact the service department.
F–02–60–05		Failure: *Permeate conductivity exceeded*	➢ If the conductivity does not improve, start the rinse program. ➢ Contact the service department.
F–02–60–06		Failure: *Fill level cannot be lowered*	➢ Contact the service department.

Error code	visual indicator	Error message text	Action required
F–02–60–07		Failure: *Break tank cannot be filled*	➢ Check water supply. ➢ Contact the service department.
W–02–60–01		Warning: *Temperature too high*	➢ Contact the service department.
W–02–60–02		Warning: *Cool-down problem*	➢ Check water supply. ➢ Contact the service department.
W–02–60–03		Warning: *Temperature not reached*	➢ Contact the service department.
W–02–60–04		Warning: *Temperature heat dis.* *< 80°C/< 176°F*	➢ The heat disinfection program started was not successful. The program must be restarted.
W–02–60–05		Warning: *Cleaning has been stopped*	➢ Start rinse. ➢ Repeat the disinfection program.
W–02–60–06		Warning: *Rinse volume not reached*	➢ Check water supply. ➢ Contact the service department.
W–02–60–07		Warning: *Insufficient feed flow*	➢ Check water supply. ➢ Contact the service department.
W–02–60–08		Warning: *Inlet conductivity exceeded*	➢ Water inlet conductivity too high. ➢ Check the softener. ➢ Contact the service department.
W–02–60–09		Warning: *Inlet temperature exceeded*	➢ Alarm limit set too low. ➢ Water inlet temperature too high. ➢ Contact the service department.
W–02–60–10		Warning: *T-P measuring problem*	➢ Contact the service department.
W–02–60–11		Warning: *Perform Decalcification!*	➢ Decalcify
W–02–60–13		Warning: *Check Salt level!*	➢ Confirm warning and salt fill level (in the **System/Softener**) menu. ➢ Refill salt. ➢ Confirm **Salt refilled?** message with **YES**. ➢ If the warning is confirmed, the **System/ Softener** menu will open automatically. The **Salt refilled?** message here can be confirmed with **NO** or **YES**.

6 Cleaning, disinfection, preservation

6.1 Generally applicable regulations for cleaning, disinfection, and preservation

Warning

Operator restrictions

Decalcification, chemical disinfection, heat disinfection, and the preservation of the system may only be performed by persons who have been instructed in the proper handling.

The operator must observe and follow the general safety precautions.

Warning

Operator restrictions

Cleaning and disinfection must be performed by personnel who have been trained in accordance with the latest cleaning and disinfection instructions.

Warning

Contact contamination

When connecting the system, always disinfect the connectors.

It is imperative to avoid contamination of the connectors through contact with skin or non-sterile objects.

)

Note

The manufacturer recommends the use of a peracetic acid-based disinfectant e.g., **Puristeril 340** (**Minncare** or other approved peracetic acid solution) for a chemical disinfection.

Note

Performing a module heat disinfection at least once a week is recommended.

The interval can be increased, depending on the results of the microbiological analysis.

Note

If the system has been continuously idle (time when the system is neither running in **SUPPLY** nor **RINSE** mode) for more than 72 hours, a chemical disinfection or a module heat disinfection is recommended. In case of longer idle times, the system should be preserved.

6.2 Precautions

6.2.1 Patient safety

Warning

Patient hazard caused by decalcification agents and disinfectants

Disconnect the systems!

Ensure that no hemodialysis device is connected during the entire decalcification/chemical disinfection procedure.

➢ Prior to decalcification/chemical disinfection, all hemodialysis devices connected to the ring main must be disconnected.

Warning

Patient hazard caused by residual disinfectant

➢ When using disinfectants, perform a suitable test to ensure the absence of residual disinfectant.

➢ If the test shows a residual concentration of disinfectant, the rinse program must be repeated until all residual disinfectant has been completely removed.

6.2.2 Operator safety

Warning

Risk of caustic burning when working with acidic substances (concentrated substance or disinfectant)

➢ Always handle acidic fluids with care and do not spill any disinfectant concentrate.

➢ Rubber gloves (acrylonitrile latex, cotton-lined) should be worn to avoid contact with the skin.

➢ Wear goggles!

➢ Observe the safety precautions for the concentrated substance/disinfectant used!

In the event of contact with acid:
Eye: Immediately flush with running water for 15 minutes.
Skin: Use soap under running water for neutralization.
Ingestion: Do not induce vomiting, but have the victim drink plenty of non-carbonated water. Seek medical advice.

Warning

Observe the safety data sheet!

When handling disinfectants, observe the latest safety data sheet of the disinfectant.

6.2.3 Protection of buildings

Warning

Safe handling of disinfectants

When using disinfectants, observe the following manufacturer's instructions for use:

– The expiration date printed on the container

– The storage conditions for the disinfectant concentrates

– The disinfectant must match the respective disinfection program

– Different disinfectants may not be mixed

Incorrect use of disinfectants (regarding concentration, temperature range, dwell time) may damage the system.

Warning

Leakage caused by improper handling

Improper handling of the reverse osmosis system may cause leakage which, in the event of uncontrolled spillage, may result in damage to equipment, installation or buildings.

– Tubing must be protected from possible mechanical damage (puncturing, crimping).

– Regular visual inspection of all tubing, connectors, and piping containing fluid is required.

Note

Damage due to leakages

In rooms without floor drainage, it is recommended to install a leakage detector (e.g., **AquaSTOP**).

6.3 Cleaning functions overview

Setting in System menu	Function	On the AquaC UNO H	On the hemodialysis device
MODULE HEAT DISINFECTION	**Temperature: min. 81°C/min. 177.8°F** Disinfection of the reverse osmosis system incl. module and ring main.	➢ Start of the **MODULE HEAT DISINFECTION** program in the menu **Cleaning.**	➢ Switch the HD device to **STANDBY** or disconnect the HD device.
RING/ RING HEAT DISINFECTION	**Temperature: min. 82°C/min. 179.6°F** Disinfection of the reverse osmosis system with ring main (without module).	➢ Start of the **RING HEAT DISINFECTION** program in the menu **Cleaning.**	➢ Switch the HD device to **STANDBY** or disconnect the HD device.
	Temperature: min. 82°C/min. 179.6°F Disinfection of the reverse osmosis system with ring main (without module) and the water inlet unit of the HD device.	➢ Start of the **RING HEAT DISINFECTION** program in the menu **Cleaning.**	➢ Start of the **RING HEAT DISINFECTION** on the HD device after the audible signal has been sounded.
CHEMICAL DISINFECTION	Chemical disinfection of the reverse osmosis system.	➢ Start of the **CHEMICAL DISINFECTION** program in the menu **Cleaning.** ➢ Add disinfectant after prompt.	➢ The HD device must be disconnected!
DECALCIFICATION	Decalcification of the reverse osmosis system.	➢ Start of the **DECALCIFICATION** program in the menu **Cleaning.** ➢ Add decalcification agent after prompt.	➢ The HD device must be disconnected!
RINSE	Rinsing of the reverse osmosis system.	➢ Start of the **RINSE** program in the menu **Cleaning.**	➢ No action required on the HD device.
ISOLATED STANDBY	Hot cleaning and rinsing of the reverse osmosis system without feed or drain.	➢ Start of the **Isolated standby** program in the menu **Cleaning.**	➢ The HD device must be disconnected!

6.4 Rinse, decalcification, chemical disinfection, and preservation intervals

6.4.1 Criteria for a disinfection

Disinfection is required if the microbiological purity of the permeate is no longer ensured, or if the scheduled time for a disinfection has been reached.

This happens by way of different procedures:

– **Chemical disinfection** (with a disinfectant)
– **Module heat disinfection** (with hot permeate)
– **Ring heat disinfection** (disinfection incorporating the supply lines of the hemodialysis device)

Other criteria for a disinfection are, e.g.:

Criteria for a disinfection
– If the system has been continuously idle (time when the system is neither running in **SUPPLY** nor **RINSE** mode) for more than **72 hours**, a module heat disinfection or a chemical disinfection is recommended. In case of longer idle times, the system should be preserved.
– If the microbiological test reveals an elevated microbial count in the permeate.
– In the event of a service intervention in the permeate circuit.

6.4.2 Module heat disinfection intervals (recommended)

Interval

System menu settings	Intervals
Module heat disinfection	Once a week

During module heat disinfection, the connected ring is disinfected too. Separate ring heat disinfection is not required, therefore.

6.4.3 Ring heat disinfection intervals

Interval

System menu settings	Intervals
Ring heat disinfection	Once a week (if module heat disinfection has not been performed)

Note

A shorter interval will also improve the microbiological quality.

6.4.4 Decalcification intervals

- **Automatic decalcification prompt**

Interval

In case of an automatic decalcification prompt, which depends on the set water hardness, a **decalcification** of the system as specified in the following table is required.

Water hardness range	Decalcification interval
< 1 °dH / < 17.8 ppm	No decalcification required
1–5 °dH / >17.8–89 ppm	Every 100 operating hours
6–15 °dH / 89–267 ppm	Every 50 operating hours
16–25 °dH / 267-445 ppm	Every 20 operating hours
> 25 °dH / > 445 ppm	Softener required

Note

The interval will be reset, if:

– A preventive decalcification has been performed before the prompt is displayed

– A decalcification has been performed after the prompt is displayed

– A decalcification has been performed during the module heat disinfection

The interval will be reset after the decalcification program has been performed without any problems.

The interval will not be reset after a chemical disinfection.

- **Recommended decalcification agent**

The manufacturer recommends a solution of approx. 20% citric acid to decalcify the system.

6.4.5 Rinse intervals (recommended)

Interval

System menu settings	Operating hours intervals (with Eco option)	Operating hours intervals (without Eco option)
Rinse	4 hours/rinse volume 10 L/3 gal	4 hours/rinse time 10 minutes

Note

A shorter rinse interval will also improve the microbiological quality.

6.5 Rinse

The **RINSE** mode can be started manually or with the rinsing timer. The time of the next interval rinse is shown on the display.

Tip

➢ If the **Start** key is pressed for **3 seconds** during the **RINSE** mode, the **Supply** program will be started.

Warning

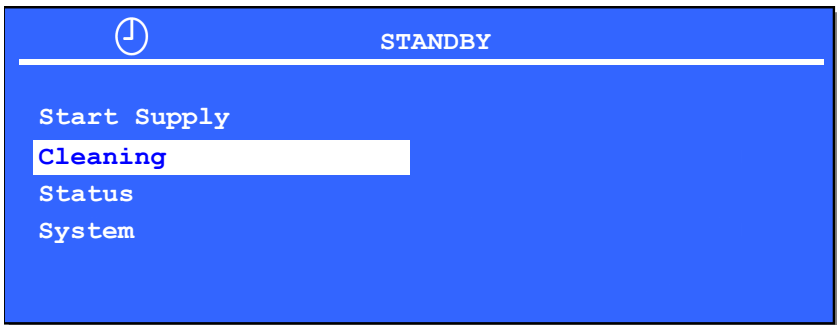
Use operating modes correctly

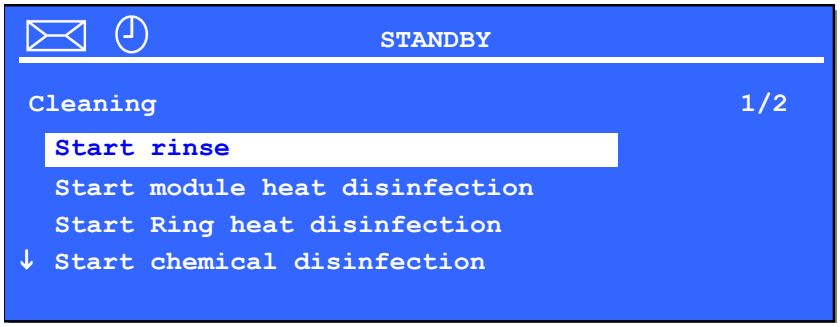
➢ Dialysis is only permitted when the system is in **SUPPLY** mode!

➢ Do not perform dialysis when the system is in **RINSE** mode!

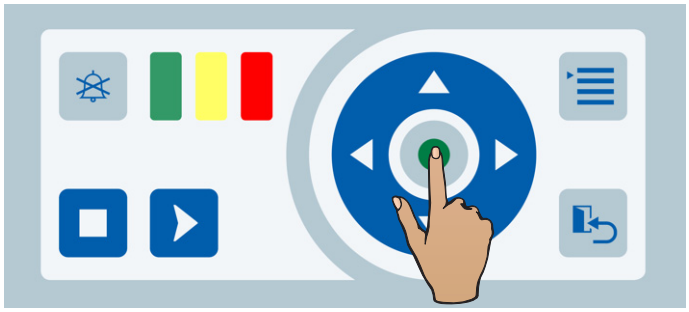
6.5.1 Manually starting the Rinse program

The **Rinse** program can be started from the **Cleaning** menu. The **Cleaning** menu can only be selected when the system is in **STANDBY** mode.





➢ **Rinse** is started by selecting the **Start rinse** program and by pressing the **Enter** key.



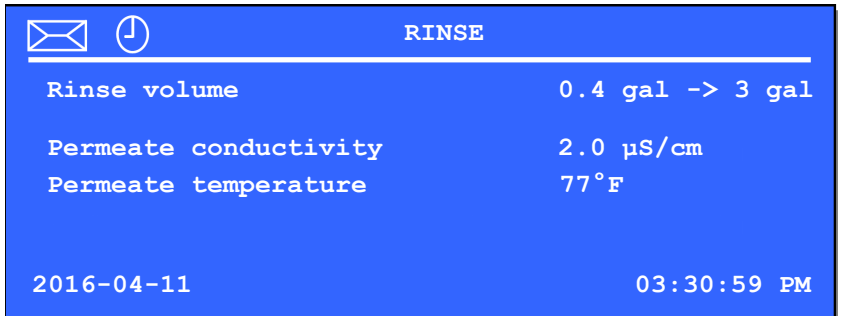
➢ The **Enter** key must be pressed for **approx. 3 seconds**. The system will switch to the **Rinse** mode.

The system will perform a self-test before the selected program is started.

6.5.2 Rinse active

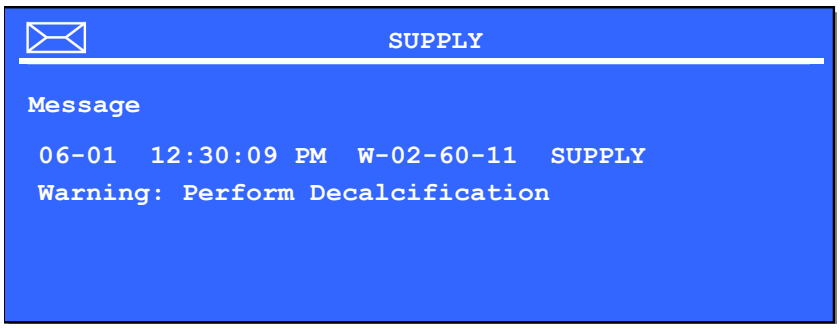
During the **RINSE** program, all paths will be rinsed and the water volume in the system will be exchanged.

While rinsing is in progress, the following parameters are displayed:
– The currently rinsed volume
– The target volume
– The permeate conductivity
and
– The permeate temperature



6.6 Decalcification

When the respective number of operating hours has been reached (see Chapter 6.4.4 on page 6-8), the message **Perform decalcification** will be displayed.



Tip

There is no need to interrupt a dialysis treatment in progress when this message is displayed.

A decalcification should however be performed as soon as possible.

6.6.1 Preparing for decalcification

Note

➢ Prior to each decalcification, the conductivity of the permeate must be determined and must be documented in the decalcification report.

Required equipment

The following equipment is recommended by the manufacturer:

Recommended equipment
– Goggles
– Rubber gloves
– Disinfectant
– Decalcification agent: 250 ml/0.066 gal of a ~20% **citric acid solution**

6.6.2 Performing a decalcification (when using any of the ring mains in the table below)

General notes

Warning

Patient hazard caused by cleaning agent

Disconnect the systems!

Ensure that no hemodialysis devices are connected during the entire decalcification procedure!

➢ **Prior to decalcification, the system must be disconnected from the hemodialysis device!**

Cleaning duration

Note

A decalcification using default values (rinse volume 50 L) takes approx. 2 hours. The time depends on the programmed rinse volume and the number of rinse cycles performed.

Volumes of cleaning agents

Note

The following description of decalcification relates to the use of any of the ring mains in the table below.

Ring main lengths that deviate from the standard are listed in the chapter Extended ring main option (see Chapter 14.6 on page 14-11).

Ring main length:	Amount of Citric acid:
2 x 1.5 m/2 x 4.92 ft (standard)	**250 ml/0.066 gal**
2 x 3 m/2 x 9.84 ft	**250 ml/0.066 gal**
2 x 5.0 m/2 x 16.40 ft	**250 ml/0.066 gal**
2 x 10.0 m/2 x 32.80 ft	**250 ml/0.066 gal**

6.6.2.1 STEP 1/PROVIDING THE DECALCIFICATION AGENT

Preparing the decalcification agents

➢ Prepare the funnel (funnel for disinfection) and 200 ml/0.05 gal (300 ml/0.08 gal) of an approx. 20% citric acid solution in a suitable container.

Note

The general rules for operator safety for cleaning agents and disinfectants apply when decalcifying the system.

Volume

The reverse osmosis module is decalcified with a citric acid solution of 20% citric acid.

For more detailed information regarding the decalcification agent, refer to the information provided by the manufacturer of said decalcification agent.

6.6.2.2 STEP 2/PREPARING FOR AUTOMATIC DECALCIFICATION

Preparing for decalcification

Warning

Comply with the obligation to provide documentation!

➢ Prior to each decalcification, the conductivity of the permeate must be checked on the display and documented in the decalcification report.

➢ Switch the **AquaC UNO H** to **SUPPLY** mode.

➢ Read and note down the permeate conductivity after 3 minutes.

Stopping SUPPLY mode

➢ When stopping, the system will switch to **STANDBY** mode.

➢ Remove the permeate coupling from the hemodialysis device.

➢ Provide the decalcification agent (citric acid solution).

6.6.2.3 STEP 3/STARTING DECALCIFICATION

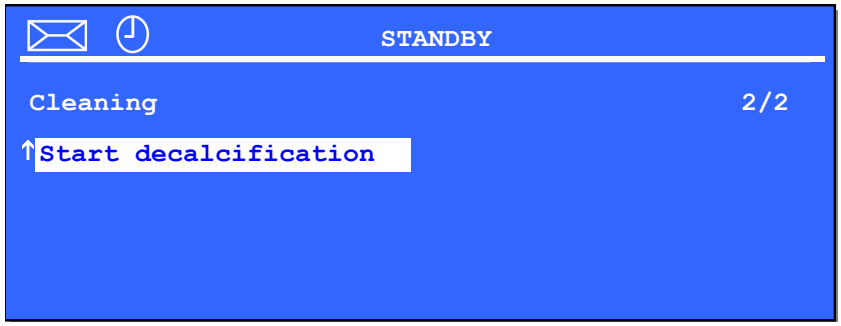
➢ After the decalcification has been started, the decalcification program can be stopped until the message **Please add decalcifier!** is displayed.

➢ After the program step **Please add decalcifier!**, the **Supply** program is disabled. It will not be enabled before the decalcification is complete.

➢ In case of an interruption of the power supply, the **Supply** program will also remain disabled until the decalcification is complete.

➢ The **Decalcification** program can be started from the **Cleaning** menu. The decalcification is started by selecting the menu option **Start decalcification** and pressing the **Enter** key.

➢ The **Enter** key is pressed for **approx. 3 seconds**.



- **Decalcification/confirming the message Disconnect dialysis machine!**

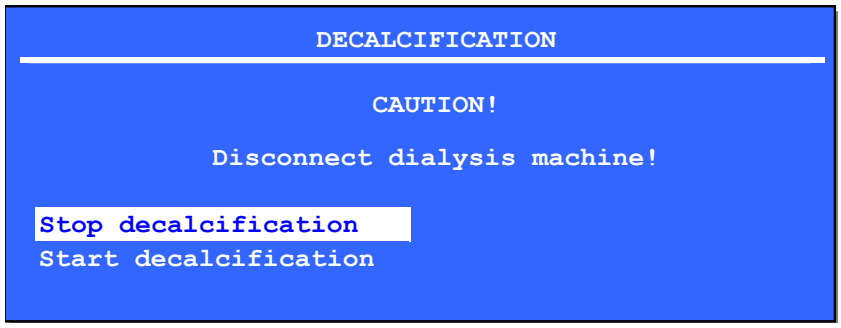
Warning

Patient hazard caused by cleaning agent

The following applies to module decalcification:

Cleaning agents present a hazard for the patient.

➢ **Prior to decalcification, the system must be disconnected from the hemodialysis device!**



➢ **Start decalcification** must be selected with the **navigation** keys and must be confirmed with the **Enter** key.

➢ To stop the decalcification, confirm **Stop decalcification**.

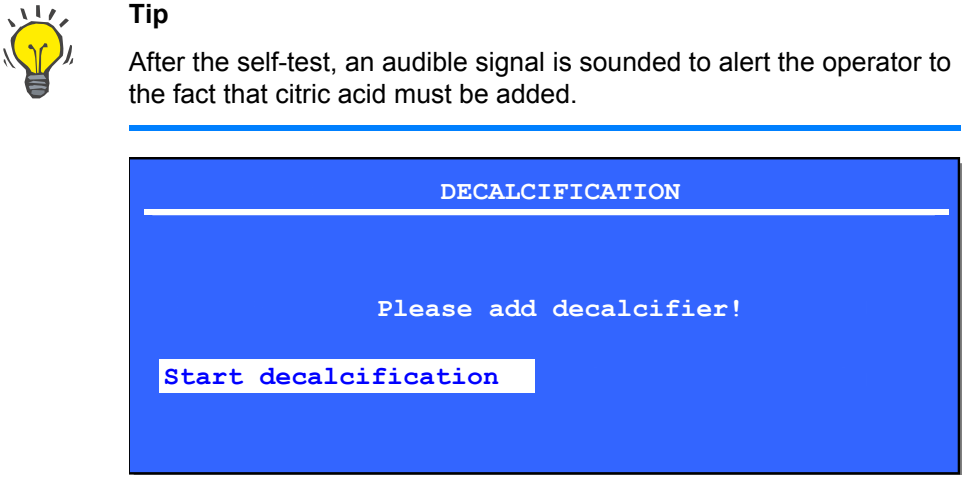
- **Decalcification/start test**

The decalcification program starts with a start test to check all components which are relevant for the decalcification.

- **Decalcification/adding decalcifier**

Tip

After the self-test, an audible signal is sounded to alert the operator to the fact that citric acid must be added.

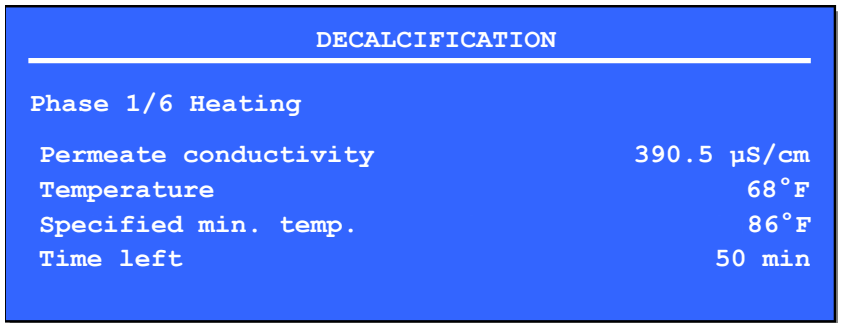


➢ As soon as the message **Please add decalcifier!** is displayed, the 250 ml/0.066 gal of 20% citric acid solution provided (when using a any of the ring mains in the table) must be poured into the funnel for the disinfectant.

➢ After confirming the selection **Start decalcification**, the program will advance to the next step.

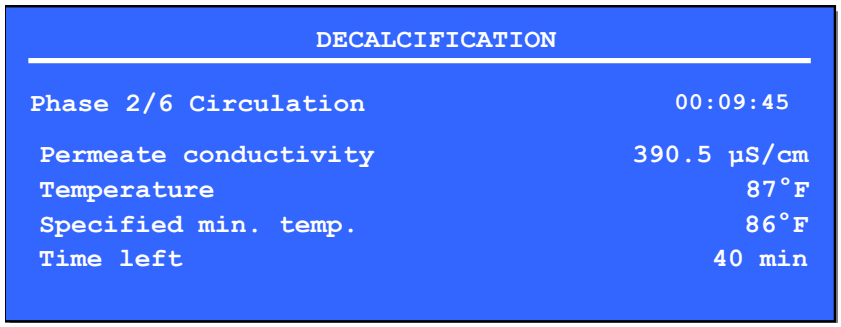
- **Decalcification/Heating**

During the heating phase, the decalcification agent is distributed in the system. The system is heated to 30°C/86°F to increase the efficiency of the decalcification agent.



- **Decalcification/circulation**

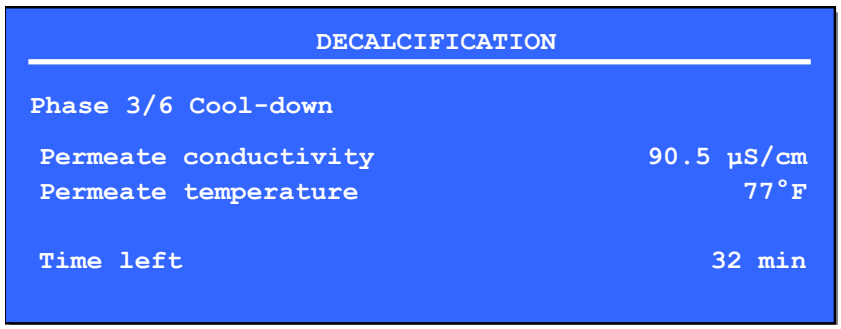
When the specified temperature has been reached, circulation continues.



During the circulation phase, the decalcification agent is circulated for the programmed time.

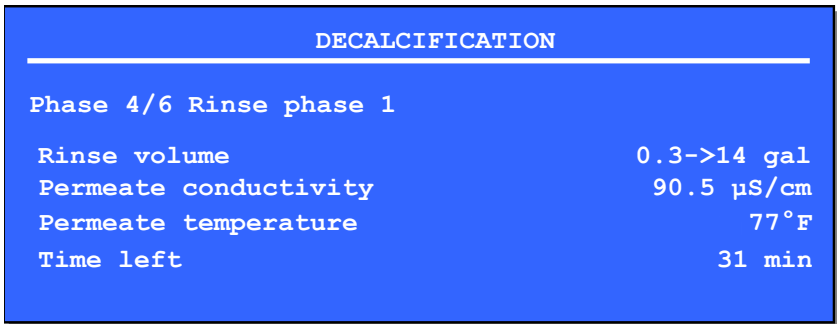
➢ The circulation time can be programmed in the **Service/Settings/ Disinfection** menu.

- **Decalcification/cool-down**



During the cool-down phase, the system is cooled down by fresh water until the temperature is below the permeate temperature alarm limit.

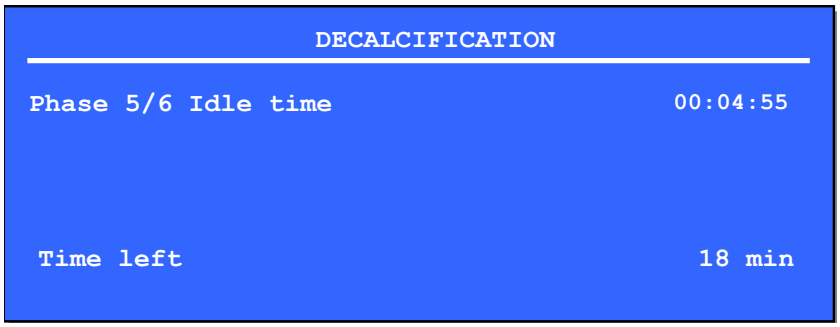
- **Decalcification/rinse phase 1**



During the rinse phase, the decalcification agent is directed to the drain by flushing with fresh water. Then all hydraulic paths will be rinsed.

➢ The rinse volume can be programmed in the **Service/Settings/ Disinfection** menu. The default value is 14 gal.

- **Decalcification/Idle time**



The idle time lasts 5 minutes.

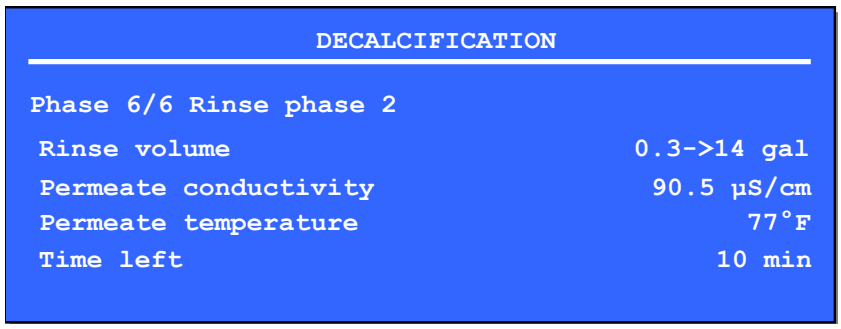
Note

If decalcification was selected when starting the module heat disinfection, the module heat disinfection will start after the idle time.

● Decalcification/rinse phase 2

During rinse phase 2, the programmed rinse volume is rinsed from the system and the ring main just as during the first rinse phase.

➢ The rinse volume can be programmed in the **Service/Settings/ Disinfection** menu. The default value is 14 gal.



Documenting the test for the absence of decalcification agent

Warning

Comply with the obligation to provide documentation

➢ On completion of a decalcification, the **conductivity** must be checked **again** on the display and must be compared with the original conductivity. The permeate conductivity after decalcification must be the same or lower than the conductivity measured prior to the decalcification.

➢ In case of a significant deviation of the conductivities, the system must be rinsed again.

➢ The final conductivity must then be documented again in the decalcification report in the column **PERMEATE CONDUCTIVITY** (after decalcification).

➢ Report master copy – see chapter Appendix (15).

Warning

Observe the notes on disinfection!

➢ Before reconnection, disinfect coupling and nipple.

6.7 Chemical disinfection

6.7.1 General notes

➢ During a chemical disinfection, appropriate chemicals are used to destroy microorganisms.

➢ A chemical disinfection is required if regular heat disinfection no longer produces the desired effect (e.g., presence of heat-resistant bacteria).

Warning

Operator restrictions

A chemical disinfection of the system may only be performed by persons who have been instructed on the proper handling.

The operator must observe and follow the general safety precautions.

Warning

Comply with authorization regulation

Cleaning and disinfection must be performed by personnel who have been trained in accordance with the latest cleaning and disinfection instructions.

Warning

The following must be considered when performing a chemical disinfection of the modules:

Disinfectants present a hazard for the patient.

➢ **Prior to chemical disinfection, the system must be disconnected from the hemodialysis device!**

Warning

Safe handling of disinfectants

When handling disinfectants, care must be taken not to spill any disinfectant concentrate. To prevent acid burns, these fluids must always be handled with care!

Operating principle

The chemical disinfection is a program-controlled disinfection procedure.

Reason for a chemical disinfection

If a water supply as specified by the applicable regulations is no longer ensured:

– After repairs in the permeate circuit (alternatively a module heat disinfection can be performed)

– If the system has been continuously idle (time when the system is neither running in **SUPPLY** nor **RINSE** mode) for more than 72 hours

– After an operational requalification of a preserved system

Recommended disinfectant

Puristeril 340 (Minncare or other approved peracetic acid solution)

We recommend a peracetic acid-based disinfectant for use on reverse osmosis membranes.

200 ml / 0.05 gal of **Puristeril 340 (Minncare** or other approved peracetic acid solution for use on reverse osmosis membranes).

If other disinfectant agents are used, then the volume must be adapted to the peracetic acid concentration:

– 200 ml/0.05 gal of a ~3–5% peracetic acid solution

or

– 50 ml/0.013 gal of a ~15–20% peracetic acid solution

The effective peracetic acid concentration in the final disinfectant solution within the **AquaC UNO H** should be (at least) ~0.2% peracetic acid.

AquaC UNO H volume: 2.5 L/0.66 gal

Warning

➢ Disinfectant agents that are based on other chemical formula than peracetic acid (e.g., formaldehyde-based agents) must not be used!

Disinfection duration

Note

A disinfection using default values (rinse volume 50 L) takes approx. 2 hours. The time depends on the programmed rinse volume and the number of rinse cycles performed.

Volumes of disinfectants

Note

The following description of disinfection relates to the use of any of the ring mains in the table below.

Ring main lengths that deviate from the standard are listed in the chapter Extended ring main option (see Chapter 14.6 on page 14-11).

If the Extended ring main option is used, different amounts of **Puristeril 340** (**Minncare** or other peracetic acid solution) stated below are needed.

Tip

It is possible to install other, optional ring main lengths with software 3.20.x.

This results in additional specifications for the amounts of **Puristeril 340** (**Minncare** or other peracetic acid solution) cleaning agent required as per the table below:

Ring main length:	Amount of Puristeril 340 (Minncare or other approved peracetic acid solution
2 x 1.5 m/2 x 4.92 ft (standard)	**200 ml/0.05 gal**
2 x 3.0 m/2 x 9.84 ft	**200 ml/0.05 gal**
2 x 5.0 m/2 x 16.40 ft	**400 ml/0.11 gal**
2 x 10.0 m/2 x 32.80 ft	**400 ml/0.11 gal**

6.7.2 Preparing for a chemical disinfection

Note

Prior to each disinfection, the conductivity of the permeate must be determined and documented in the disinfection report.

Required equipment

The following equipment is recommended by the manufacturer:

Recommended equipment
– Goggles
– Rubber gloves
– Alcohol-based disinfectant
– Disinfectant funnel
– **Puristeril 340** disinfectant agent (**Minncare** or other approved peracetic acid solution).
– Test for absence of residual disinfectant: **peracetic acid test**

Disinfectant funnel

Part no.:	Description
See local catalog number	**Disinfectant funnel** 

Disinfectant

We recommend a peracetic acid solution that is intended for disinfection of water treatment systems for hemodialysis:

200 ml/0.05 gal of Puristeril 340 (**Minncare** or other appropriate peracetic acid solution for use on reverse osmosis membranes).

Test for the absence of residual disinfectant: **peracetic acid test**

Part no.:	Description
See local catalog number	Test for the absence of residual disinfectant **Peracetic acid test: DiaQuant peracetic acid** Alternative: **QUANTOFIX peracetic acid 50 test strips or other vendor approved peracetic acid strips**

6.7.3 Performing a chemical disinfection

General notes

Warning

Patient hazard caused by disinfectant

Disconnect the systems!

Ensure that no hemodialysis devices are connected during the entire chemical disinfection procedure.

➢ **Prior to chemical disinfection, the system must be disconnected from the hemodialysis device!**

6.7.3.1 STEP 1/PROVIDING THE DISINFECTANT

Preparing the disinfectant

Note

The general rules for operator safety for disinfectants apply when performing a chemical disinfection.

Volume

For more detailed information regarding the disinfection agent, refer to the information provided by the manufacturer of the disinfection agent.

200 ml/0.05 gal of a ~3–5% peracetic acid solution are required for the disinfection of the standard configuration (2 x 1.5 m/2 x 4.92 ft ring main)!

For other optional ring main lengths, the following volumes are needed for a disinfection:

2 x 3 m/2 x 9.84 ft ring main >>>
200 ml/0.05 gal of a 3–5% peracetic acid solution

2 x 5.0 m/2 x 16.40 ft ring main >>>
400 ml/0.11 gal of a 3–5% peracetic acid solution

2 x 10.0 m/2 x 32.80 ft ring main >>>
400 ml/0.11 gal of a 3–5% peracetic acid solution

6.7.3.2 STEP 2/PREPARING FOR CHEMICAL DISINFECTION

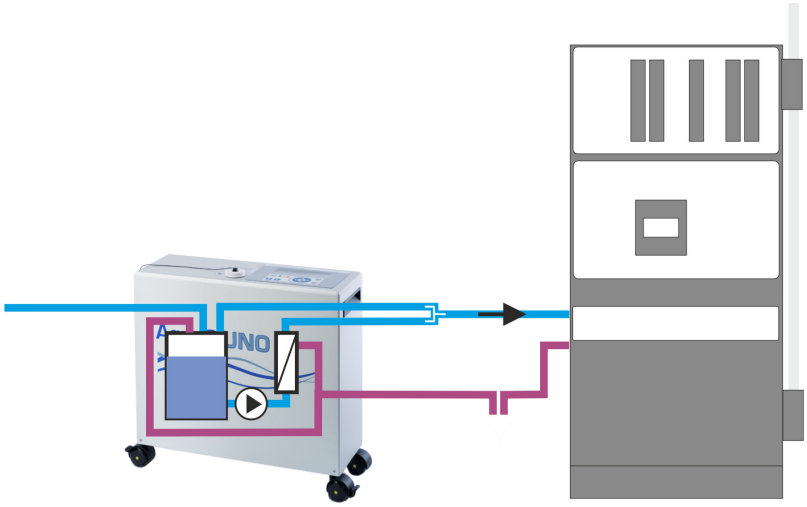
Preparing for chemical disinfection

Note

Prior to each chemical disinfection, the conductivity of the permeate must be determined and must be documented in the disinfection report.

➢ Switch the **AquaC UNO H** to **SUPPLY** mode.

➢ Determine and note down the permeate conductivity.



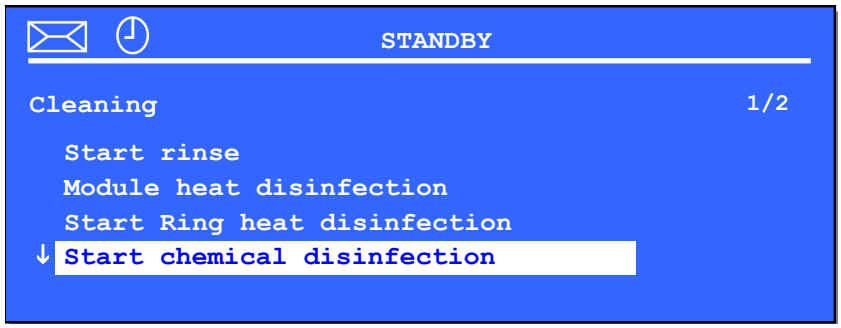
➢ Remove the permeate coupling from the hemodialysis device.

➢ Provide the disinfectant agent.

6.7.3.3 STEP 3/STARTING THE CHEMICAL DISINFECTION

The **Chemical disinfection** program can be started from the **Cleaning** menu. The disinfection is started by selecting the menu option **Start chemical disinfection** and pressing the **Enter** key.

➢ The **Enter** key must be pressed for **approx. 3 seconds**.



- **Chemical disinfection/confirming the message Disconnect dialysis machine!**

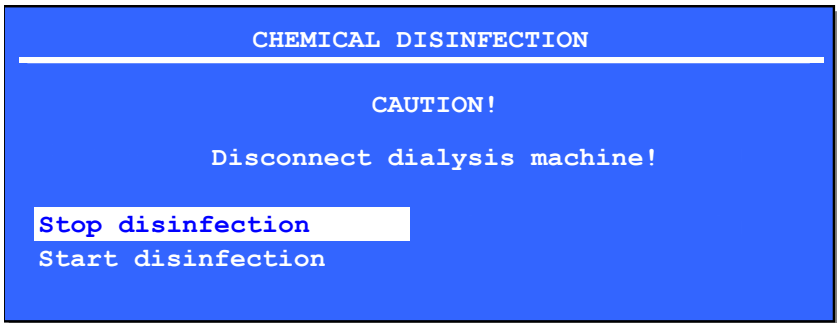
Warning

Patient hazard caused by disinfectant

The following must be considered when performing a chemical disinfection of the modules:
Disinfectants present a hazard for the patient.

➢ **Prior to chemical disinfection, the system must be disconnected from the hemodialysis device!**

➢ **The chemical disinfection must be performed by personnel who have been trained in accordance with the disinfection instructions.**

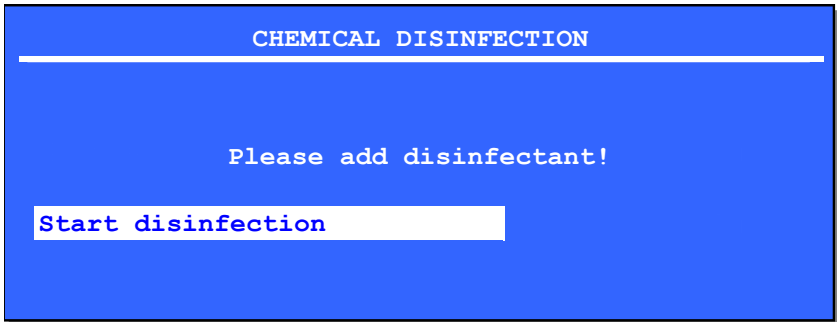


➢ After selecting **Start disinfection**, the selection must be confirmed with the **Enter** key.

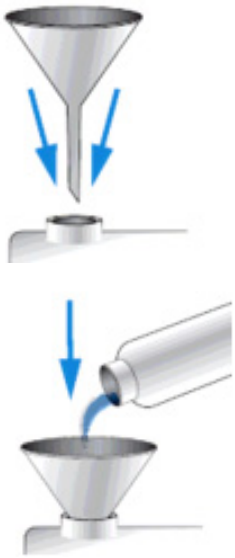
- **Chemical disinfection/start test**

The **Chemical disinfection** program starts with a **start test** to check all components which are relevant for the chemical disinfection.

- **Chemical disinfection/adding the disinfectant**



➢ As soon as the message **Please add disinfectant!** is displayed, the disinfectant must be added.



After confirming the selection **Start disinfection**, the program will move to the next step.

- **Chemical disinfection/heating**

During the heating phase, the disinfectant is distributed in the system. The system is heated to 86°F to increase the efficiency of the disinfectant.

CHEMICAL DISINFECTION	
Phase 1/6 Heating	
Permeate conductivity	90.5 µS/cm
Temperature	60°F
Specified min. temp.	86°F
Time left	70 min

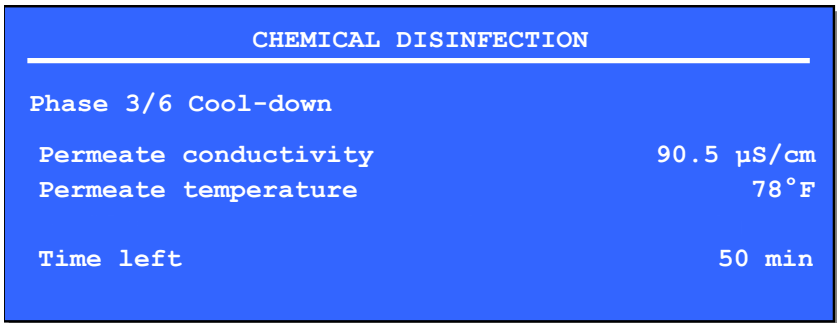
- **Chemical disinfection/circulation**

CHEMICAL DISINFECTION	
Phase 2/6 Circulation	
Permeate conductivity	90.5 µS/cm
Temperature	87°F
Specified min. temp.	86°F
Time left	60 min

During the circulation phase, the disinfectant is circulated for the programmed time.

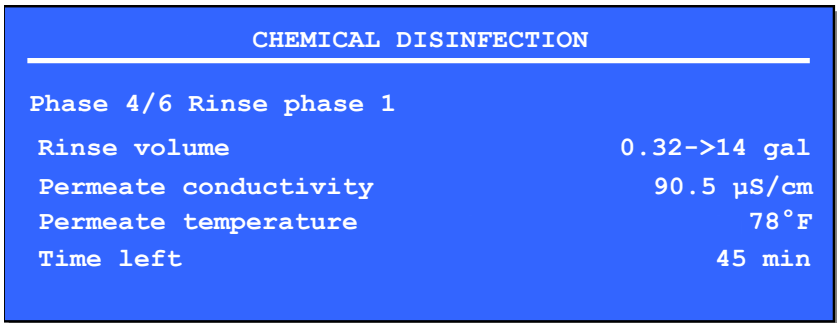
➢ The circulation time can be programmed in the **Service/Settings/ Disinfection** menu.

- **Chemical disinfection/cool-down**



During the cool-down phase, the disinfectant is cooled down until the temperature is below the permeate temperature alarm limit.

- **Chemical disinfection/rinse phase 1**

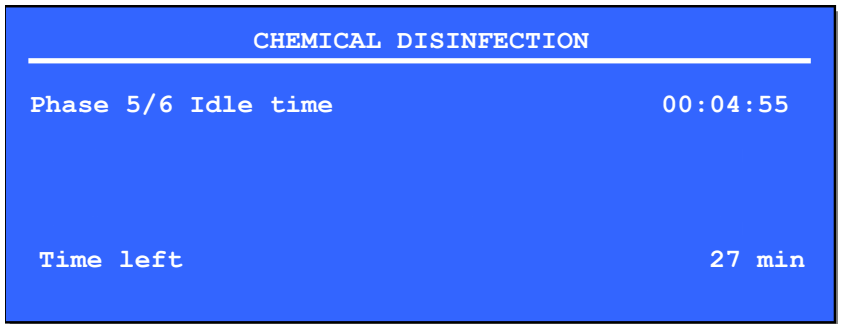


During the rinse phase, the disinfectant is directed to the drain by flushing with fresh water.

Then all hydraulic paths will be rinsed.

➢ The rinse volume can be programmed in the **Service/Settings/ Disinfection** menu. The default value is 50 L/14 gal.

- **Chemical disinfection/Idle time**



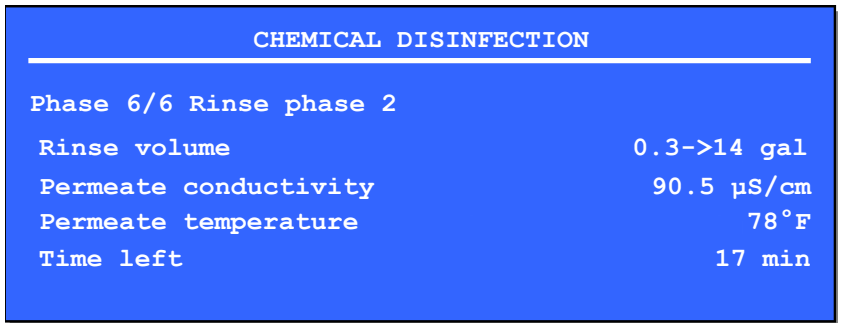
During the idle time, all actuators are switched off. The idle time lasts 5 minutes.

- **Chemical disinfection/rinse phase 2 – check for residual disinfectant**

During rinse phase 2, the programmed rinse volume is rinsed from the system and the ring main just as during the first rinse phase.

➢ The rinse volume can be programmed in the **Service/Settings/ Disinfection** menu. The default value is 50 L/14 gal.

Rinse phase 2 can be repeated as often as required by selecting the menu option **Repeat rinse**.

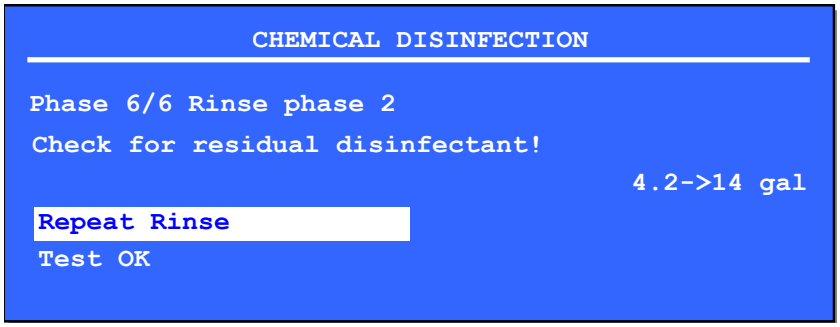


When 90% of the programmed rinse volume has been reached, a prompt to check for residual disinfectant and to confirm absence of residual disinfectant will be displayed.

Collecting a sample **/STEP 4** (see Chapter 6.7.3.4 on page 6-30).

An audible signal will be sounded.

➢ If there is still disinfectant in the system or the ring main, the rinse procedure must be repeated.



When the rinse volume has been reached and there is no input, the **AquaC UNO H** will perform a rinse at regular intervals. The interval is defined by the **Rinsing/Rinse/Interval** setting.

If **Rinsing** has been deactivated, this interval will be four hours. The remaining time until the next rinse is displayed next to the menu option **Repeat Rinse**.

6.7.3.4 STEP 4/ON COMPLETION OF THE CHEMICAL DISINFECTION

Warning

Test for the absence of residual disinfectant:

On completion of the chemical disinfection, the device must be checked for the absence of residual disinfectant,

Puristeril 340 (Minncare or other approved peracetic acid solution)

➢ Observe the expiration dates of the residual disinfectant test

➢ If the test shows a residual concentration, the rinse program must be restarted

➢ On completion of the rinse program, the system must be checked again for absence of residual disinfectant

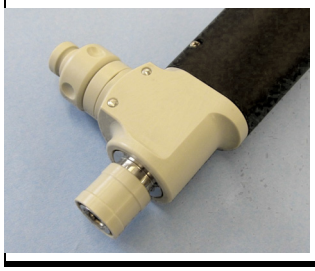
- **Sampling port (AquaC UNO H system connection)**

The **AquaC UNO H** must be in the **RINSE** phase of the disinfection program. Otherwise, start **SUPPLY** (or **RINSE**) mode manually.

➢ Collect a water sample via the sampling port.

Tip

For a description of the sampling procedure (see Chapter 15.7 on page 15-19).

Check with option Hygiene	
	**The sampling valve is opened by turning.**

- **Checking for absence of residual disinfectant**

➢ Check the permeate which flows from the coupling for absence of residual disinfectant.

Test for the absence of residual disinfectant:
peracetic acid test

Part no.:	Description
See local catalog number	Test for the absence of residual disinfectant **Peracetic acid test:** **DiaQuant peracetic acid** Alternative: **QUANTOFIX peracetic acid 50 test strips or other vendor approved peracetic acid strips**

Procedure

➢ Observe the expiration dates of the residual disinfectant test. Expired residual disinfectant tests must not be used!

➢ Follow the instructions for use of the residual disinfectant test to find the correct concentrations.

➢ The result must be 0 mg/L / ppm.
If the test shows a residual concentration (> 0 ppm peracetic acid), the rinse program must be restarted. On completion of the rinse program, the system must be checked again for absence of residual disinfectant.

Final steps

➢ After the absence of residual disinfectant has been ensured, the permeate tube can be reconnected to the hemodialysis device.

Warning

Observe the disinfection instructions!

➢ Before reconnection, disinfect coupling and nipple.

6.8 Module heat disinfection

6.8.1 Function

A heat disinfection is a thermal disinfection with hot permeate without adding any additional chemicals.

– The complete system and the permeate ring main are heated to > 80 C/> 176°F. It must be ensured that no permeate is removed while module heat disinfection is in progress.

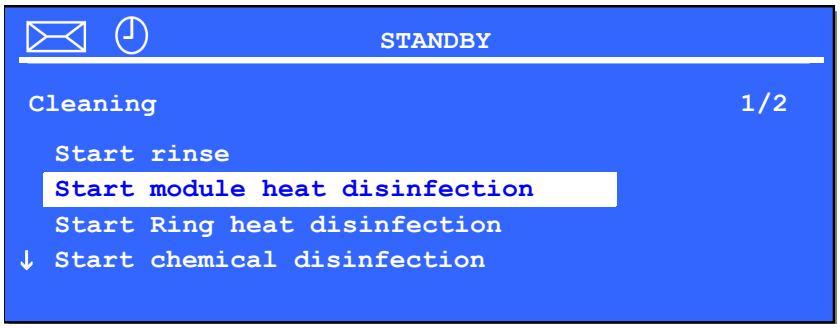
– During the module heat disinfection, all system components, the module, and the ring main are thermally disinfected.

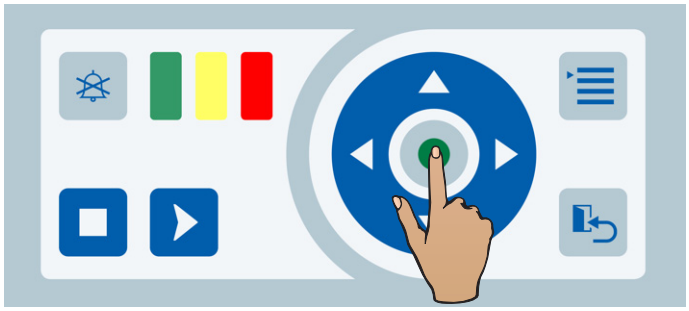
Note

At the end of the module heat disinfection, an automatic rinse procedure will be started after 45 minutes to rinse away the water which has been heated by the residual heat of the system.

6.8.2 Starting the module heat disinfection

The **Module heat disinfection** program can be started in the **Cleaning** menu by confirming the selection **Start module heat disinfection**.





➢ After selecting the menu option **Module heat disinfection**, press and hold the **Enter** key for **approx. 3 seconds**.

6.8.2.1 Recommended decalcification before module heat disinfection

Warning

Comply with the decalcification instructions!

If the feed water hardness is > 17.8 ppm $CaCO_3$, the module heat disinfection must be preceded by a decalcification to prevent damage to the membrane.

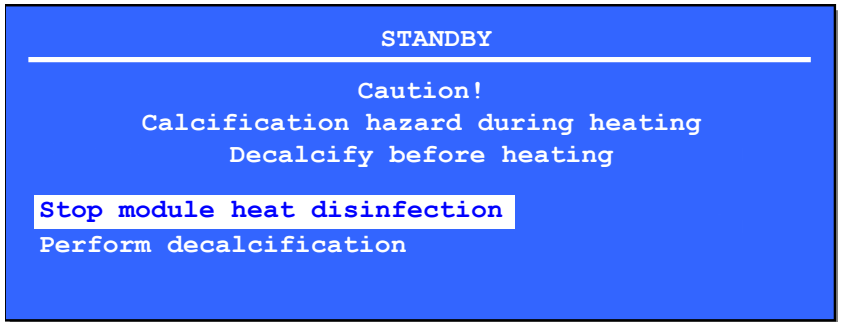
Warning

Comply with the obligation to provide documentation!

➢ If a decalcification has been selected, the **conductivity before the decalcification** is shown on the display and must be documented in the disinfection/decalcification report in the column **PERMEATE CONDUCTIVITY (prior to decalcification)**.

➢ Report master copy, see also Chapter 15.

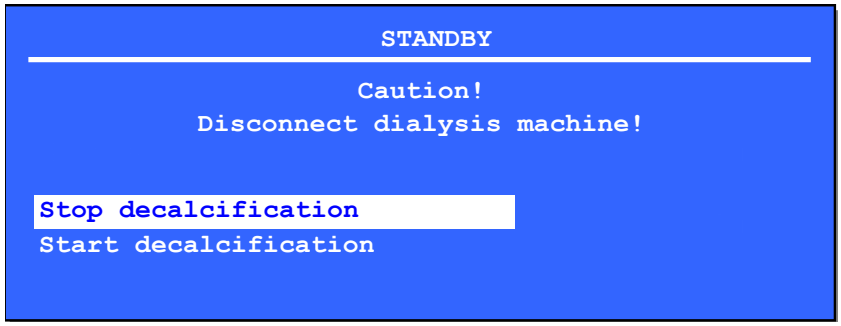
➢ The following message will only be displayed if the water hardness is ≥ 17.8 ppm $CaCO_3$. If the water hardness is < 17.8 ppm $CaCO_3$, no decalcification is required before the heat disinfection.

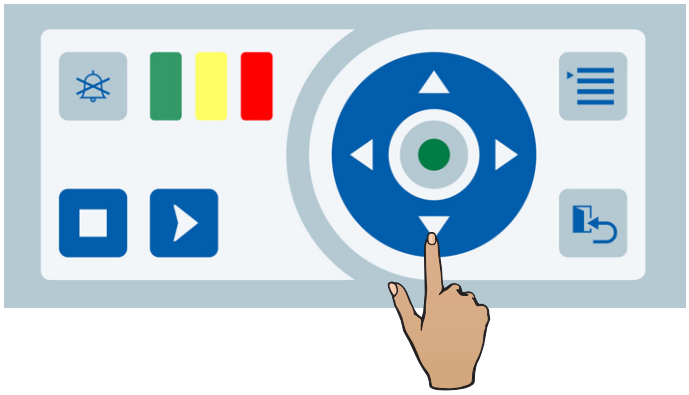


➢ The water hardness can be set in the Service section.

➢ If the water hardness is ≥ 17.8 ppm $CaCO_3$, the following message will be displayed after starting the module heat disinfection.

➢ If the water hardness is < 17.8 ppm $CaCO_3$, this message will not be displayed and module heat disinfection will start immediately.





➢ The decalcification can be started by confirming the selection **Start decalcification** or can be stopped by selecting **Stop decalcification**. If decalcification was stopped, the module heat disinfection will not start.

➢ If the option **Start decalcification** has been selected, a decalcification will be run before the **module heat disinfection** (see Chapter 6.6 on page 6-12). The module heat disinfection will then start automatically.

Test for the absence of decalcification agent

Warning

Comply with the obligation to provide documentation!

➢ On completion of a decalcification, the **conductivity** must be checked **again** on the display and must be compared with the original conductivity.

➢ In case of significant deviations of the conductivities, the system must be rinsed again.

➢ The final conductivity must then be documented again in the disinfection/decalcification report in the column **PERMEATE CONDUCTIVITY (after decalcification)**.

Report master copy – see also Chapter 15.

Continuing with the heat disinfection

Module heat disinfection will be started automatically after the idle phase of the decalcification.

Note

At the end of the module heat disinfection, an automatic rinse procedure will be started after 45 minutes to rinse away the water which has been heated by the residual heat of the system.

6.9 Ring heat disinfection

6.9.1 Function

– In the **Ring heat disinfection** program, the entire internal permeate path, the permeate ring main, and the permeate sampling port are thermally disinfected.

– In addition, the hemodialysis device can use up to **200 ml/min / 0.05 gpm** of hot permeate during the consumption phase and the permeate inlet of the hemodialysis device is therefore also thermally disinfected.

Warning

Comply with the disinfection instructions!

A heat disinfection of the permeate inlet of the hemodialysis device in the ring heat disinfection program may only be performed with hemodialysis systems designed and released for this type of disinfection.

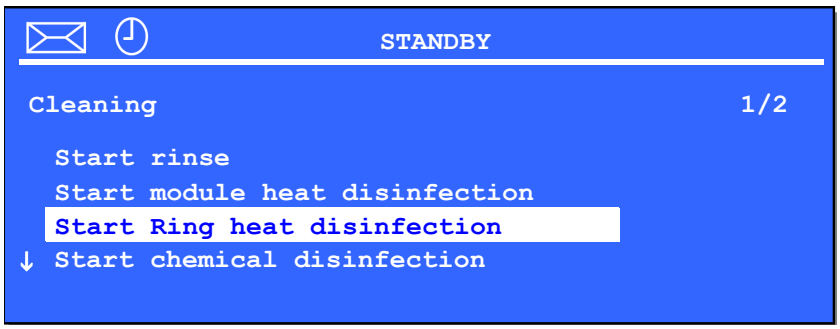
➢ Please contact the technical service for more information.

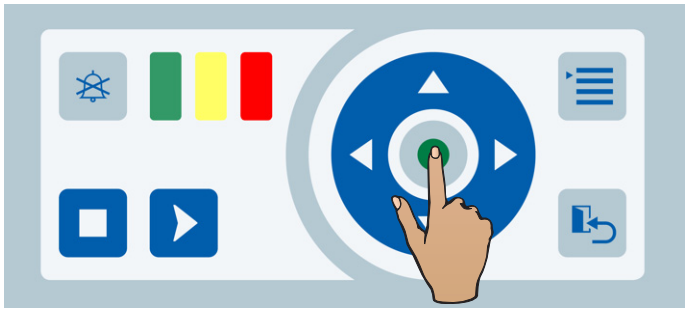
6.9.2 Starting the ring heat disinfection

The **Ring heat disinfection** program can be started automatically using the timer programs, or can be started manually by selecting **Start Ring heat disinfection** in the **Cleaning** menu.

Note

Before a manual start of the ring heat disinfection, the disinfection time must be set/checked (see Chapter 4.12.5 on page 4-31).





➢ The **Enter** key must be pressed for **approx. 3 seconds**.

After the start, the **Ring heat disinfection** program will be performed fully automatically. After a manual start of the ring heat disinfection, an audible signal will be sounded as soon as the **AquaC UNO H** can supply hot permeate.

➢ As soon as this signal is sounded, the ring heat disinfection can be started on the hemodialysis device.

If the ring heat disinfection has been started automatically, e.g., via a timer, no audible signal will be sounded.

Note

If a water supply problem or a power failure occurs during the ring heat disinfection, the ring heat disinfection will be stopped and the device will be cooled down.

The following message will be displayed:

Warning:
Temperature heat dis. < 80°C/< 176°F

The disinfection was therefore not successful and must be repeated (if required by the type of application).

Note

At the end of the ring heat disinfection, an automatic rinse procedure will be started after 45 minutes to rinse away the water which has been heated by the residual heat of the system.

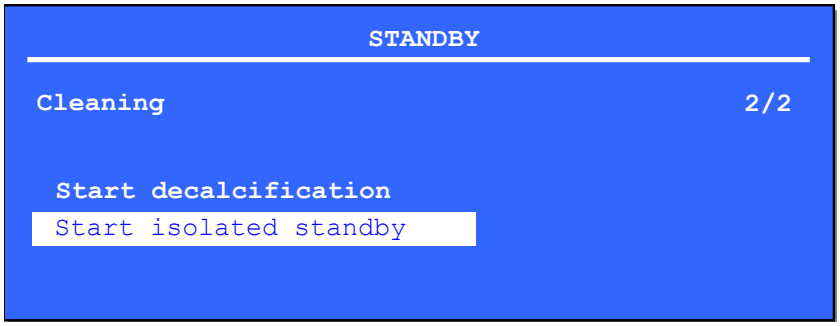
Note

If the voltage fluctuation is more than –10% (up to –15% possible in home care) and the feed water temperature is below < 10°C (< 50°F), then the target temperature for the hot water for a ring heat disinfection may not be reached at a hot water flow of 200 ml/min / 0.05 gpm.

6.10 Isolated standby

If Isolated standby has been activated, Isolated standby can be started in the Cleaning menu.

➢ **Isolated standby** is started by selecting the **Start isolated standby** menu line and pressing the **Enter** key.



6.10.1 Preparation phase for the ISOLATED STANDBY program

The **Isolated standby** program is made up of several phases. During the start and preparation phase, the **PREPARE ISOLATED STANDBY** mode is active.

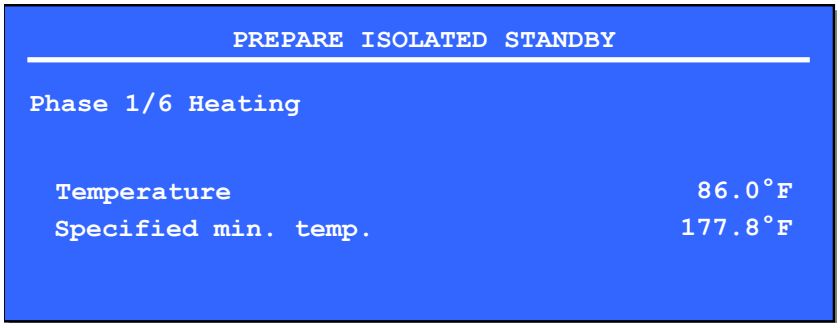
A device test is performed as soon as the **ISOLATED STANDBY** mode has been started.

Module heat disinfection is carried out after the device test. Decalcification is performed prior to heat disinfection in the preparation phase, depending on the water hardness which has been set.

Water hardness
< 17.8 ppm $CaCO_3$

➢ Module heat disinfection is performed without decalcification.

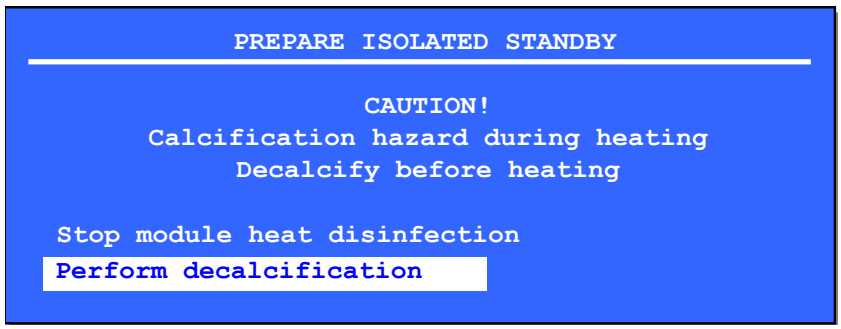
➢ Module heat disinfection is started after the device test.



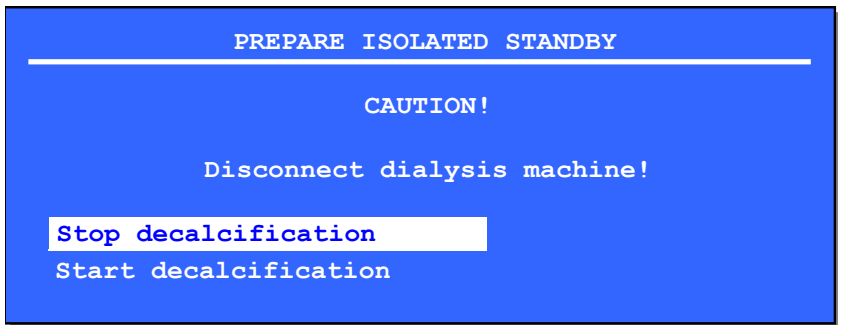
Water hardness
17.8–445 ppm $CaCO_3$

Note

➢ If the water hardness is ≥ **17.8 ppm $CaCO_3$**, decalcification must be performed prior to heat disinfection.



➢ After selecting **Perform decalcification**, the selection must be confirmed with the **Enter** key.



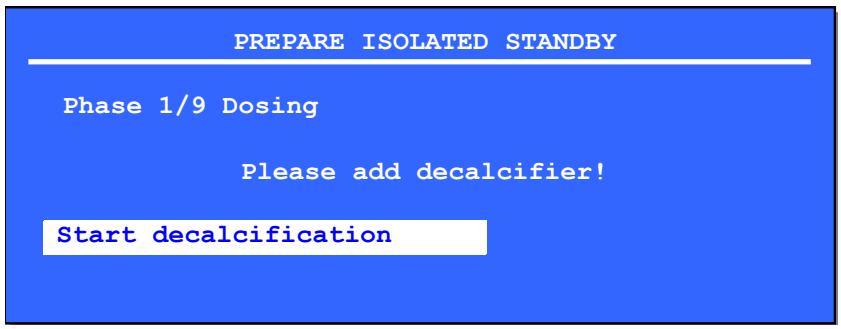
➢ After selecting **Start decalcification**, the selection must be confirmed with the **Enter** key.

– The device test is run.
– Decalcification is started after the device test.

Note

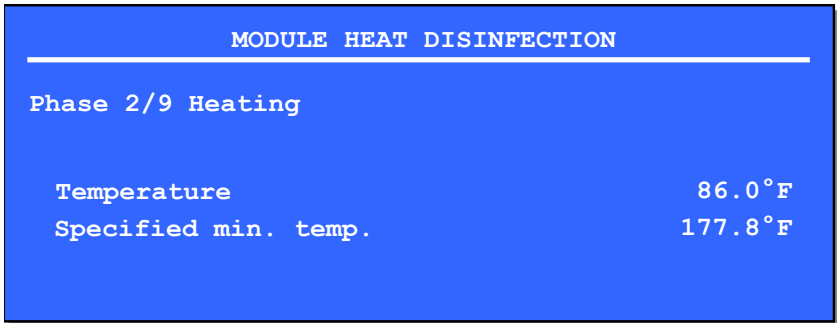
Follow the full description of decalcification in Chapter 6 (Cleaning, disinfection, preservation) when performing the decalcification (see Chapter 6.6 on page 6-12).

➢ Add the **citric acid** when prompted to add the decalcification agent.

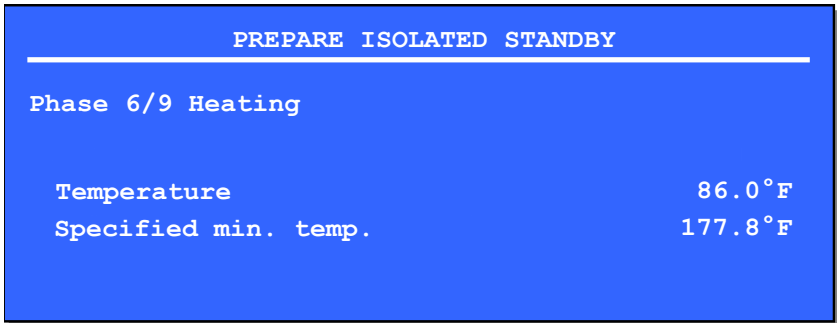


➢ After selecting **Start decalcification**, the selection must be confirmed with the **Enter** key.

Decalcification starts.



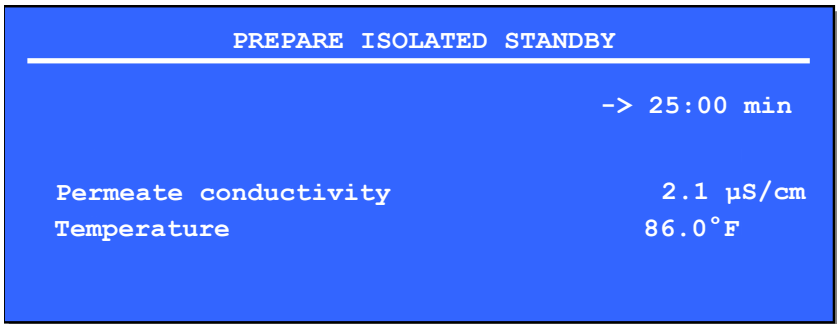
Module heat disinfection will be started after the idle phase of the decalcification.



6.10.2 Rinsing before ISOLATED STANDBY

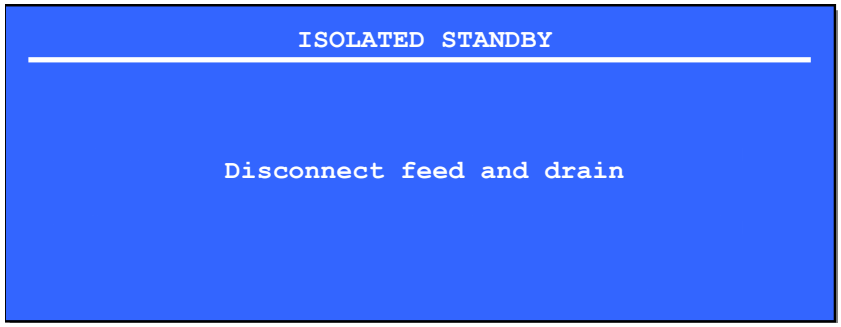
Once the **module heat disinfection** and any **decalcification** is complete, an **additional rinse phase** is started. This lasts around 25 minutes.

The display is the same as in the **Rinse** program, without the **Eco** option:



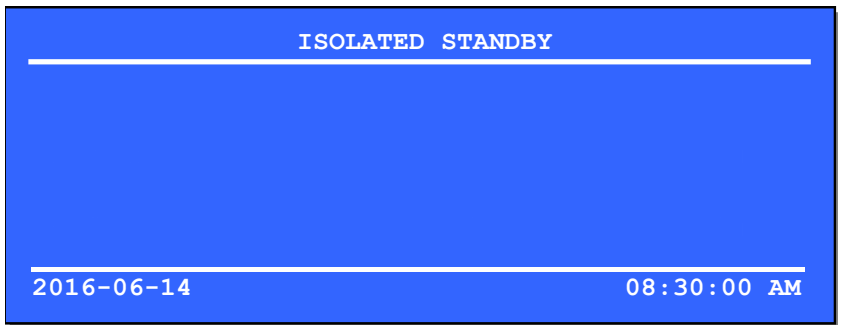
Once the rinse time of 25 minutes has elapsed, **ISOLATED STANDBY** is started.

The message **Disconnect feed and drain** is displayed:



When this message appears, the **AquaC UNO H** is already in **ISOLATED STANDBY** mode.

➢ The message **Disconnect feed and drain** can be confirmed with the **Enter** key.

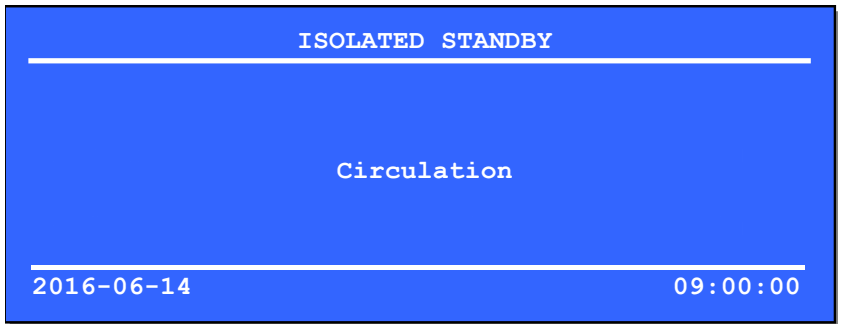


6.10.3 ISOLATED STANDBY mode

Circulation in 4-hour intervals

During **ISOLATED STANDBY** mode, the water is circulated in the device every 4 hours, with neither fresh water nor drainage being required. The 4-hour intervals are always calculated from the heat disinfection time set in the System**ISOLATED STANDBY** menu.

Display during circulation:

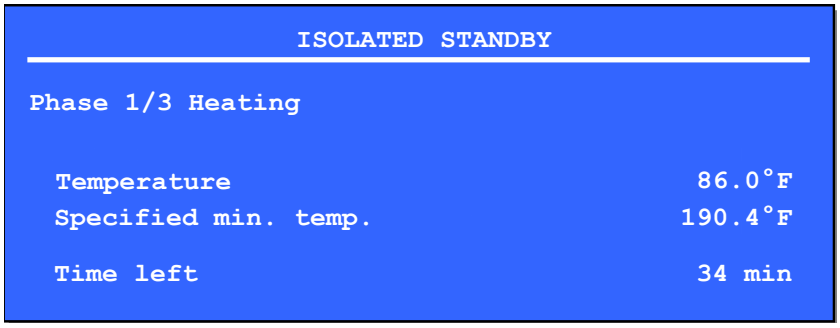


During circulation, the fluid is circulated in the device for 5 minutes.

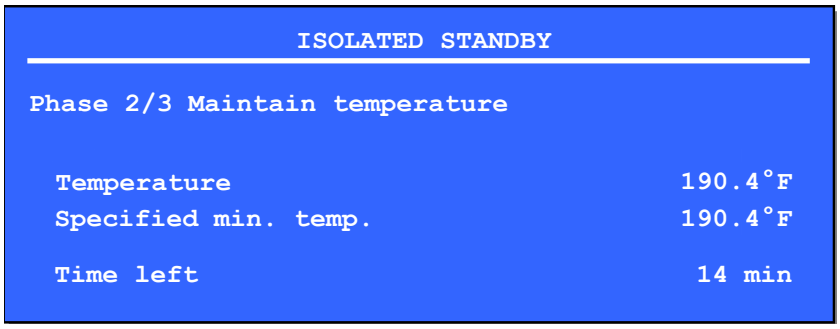
6.10.4 Heat disinfection during ISOLATED STANDBY

Once the set heat disinfection time has been reached, heat disinfection is performed after one circulation.

Phase 1 – Heating

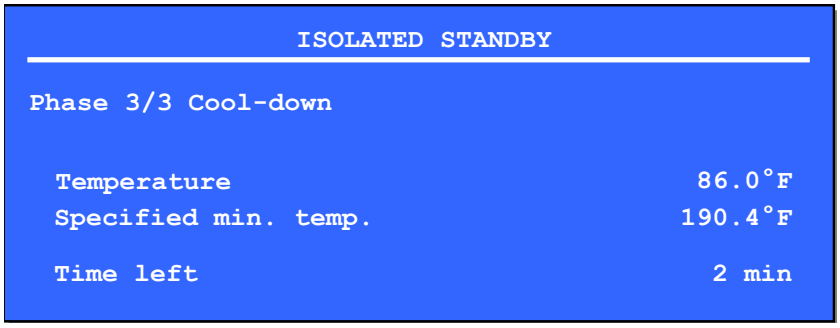


Phase 2 – Maintain temperature

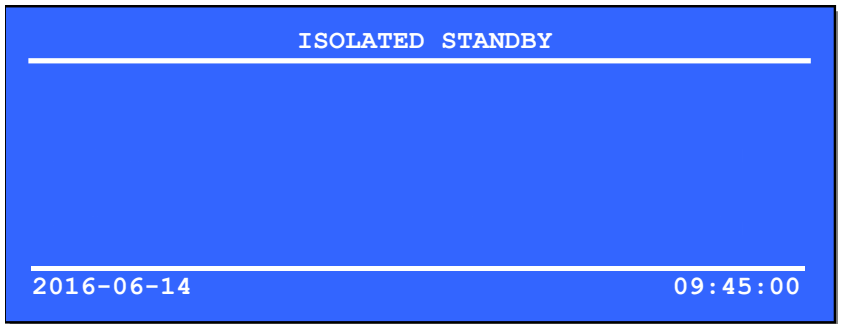


The permeate temperature is maintained at 88°C/190.4°F for 12 minutes.

Phase 3 – Cool-down



In the cool-down phase, the permeate is circulated for 2 minutes. When this phase is complete, the default screen for this mode is displayed:



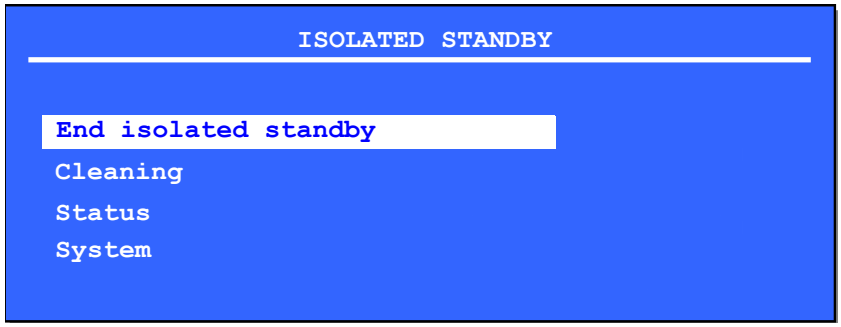
6.10.5 End ISOLATED STANDBY

Note

➢ In the main menu, using **End ISOLATED STANDBY**.

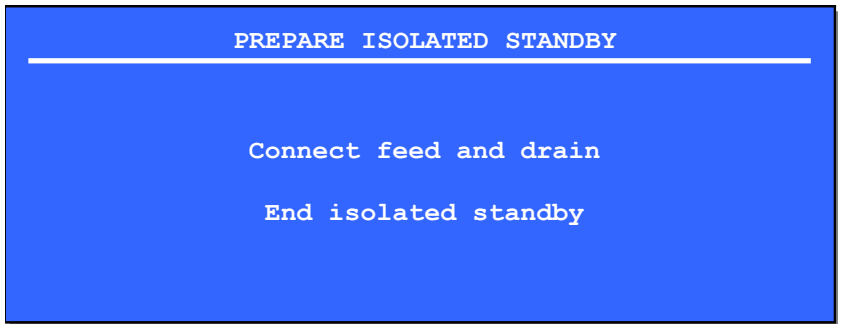
End ISOLATED STANDBY in the main menu

The selection of **End isolated standby** must be confirmed.



– If the **ISOLATED STANDBY** program has been active for 30 days, a prompt to end the program appears.

The message **Connect feed and drain**, **End isolated standby** is displayed:



– An audible signal will be sounded.

– The device remains in the **Isolated standby** program until the message is confirmed.

– The message is displayed again following a circulation or ring heat disinfection.

Ending due to a malfunction or warning.

The heating phase is stopped if one of the following messages appears:

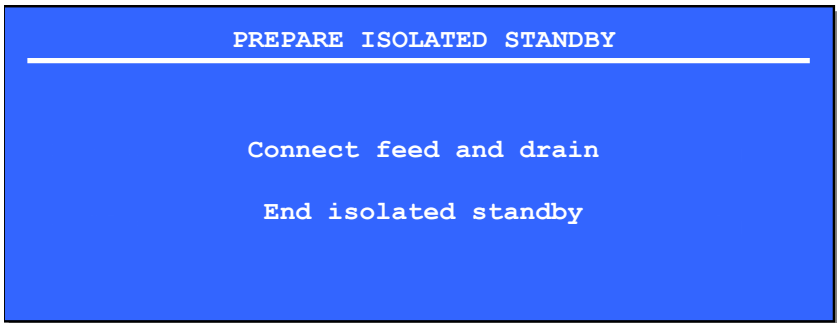
– Warning: *T-H sensor defective*

– Warning: *T-C sensor defective*

– Warning: *Pump P2 defective*

– Warning: *Temperature too high*

After cool-down, the message **Connect feed and drain**, **End isolated standby** is displayed:



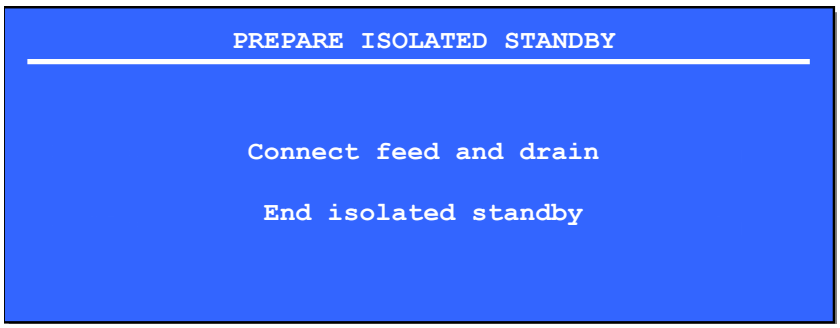
– An audible signal will be sounded.

– The device remains in the Isolated standby program until the message is confirmed.

– Ring heat disinfection will not be started after the circulation if one of the warnings listed is still active.

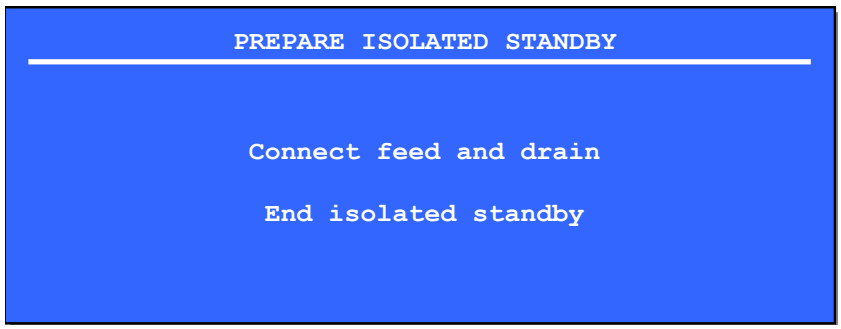
– The **ISOLATED STANDBY** program will be ended if fault messages are issued.

The message **Connect feed and drain**, **End isolated standby** is displayed.



Confirming an end

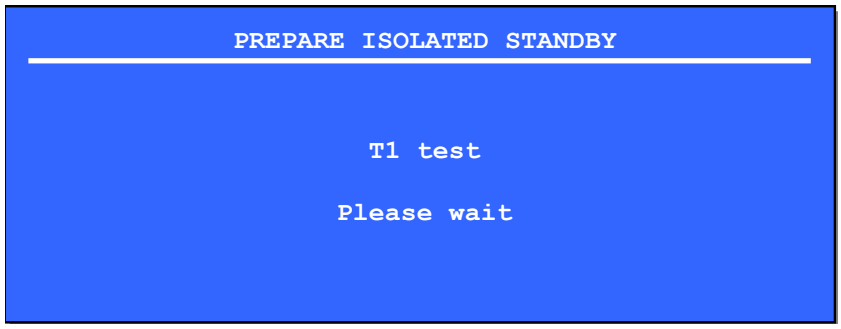
Only once the message **Connect feed and drain**, **End isolated standby** is confirmed with the **Enter** key will the **ISOLATED STANDBY** program be ended and the **RINSE** program started.



➢ Confirm with the **Enter** key.

Starting **Rinse**

Rinse is started with T1 test (not Device test). The following display appears:



– Rinsing is performed for 50 minutes or with 50 liters/13.2 gal (with the **Eco** option).
– Once **RINSE** is ended, the device will be in the **STANDBY** mode.

Tip

SUPPLY can be started before the T1 test or the **RINSE** program is complete.

6.11 Preservation

Note

Preservation of the system is required if the system is decommissioned. The preservation must be performed by the technical service.

6.12 Surface cleaning and disinfection

General notes

- The housing surface must be cleaned if dust and dirt are present on the surface. Use a clean, single-use wipe to remove dust and dirt from the housing surface.
- The housing surface can be disinfected in addition to the surface cleaning. The cleaning of the housing can be combined with a disinfection procedure by using surface disinfectants.
- The surface cleaning and disinfection is restricted to the housing surface. Do not disinfect the parts inside of the device with the surface disinfectant cleaners.

Warning

Risk of injury caused by electrical voltage

Touching live parts will cause an electric shock.

➢ Disconnect the device from power before carrying out surface cleaning.

Warning

Surface cleaning agents

Do not use any abrasive or aggressive cleaning agents and solvents.

➢ If the housing is extremely dirty, wipe the affected sections with a damp cloth.

➢ Use a soft cloth or a brush to remove dust and dirt from the housing surface.

➢ The interior of the **AquaC UNO H** may only be cleaned by a service technician.

6.12.1 Surface disinfectants

Disinfectant

Note

The manufacturer recommends using the disinfectant cleaners in the table below for the surface cleaning of the **AquaC UNO H**.

➢ Follow the instructions of the manufacturer of the disinfectant to disinfect the surface.

➢ The manufacturer does not assume any liability for potential damage to the surface if a different disinfectant than the one recommended is used.

Surface disinfectant
Alcohol-based surface disinfectants: – Surface disinfectants with ethanol (≤ 80% ethanol)
Chlorine-based surface disinfectants: – Bleach, diluted, max. 5% bleach
Hydrogen peroxide-based surface disinfectants: – **Oxivir Tb/Oxivir Tb wipes** (ready-to-use wipes) – **Oxivir Tb Five 16 concentrate**

7 Functional description

This chapter briefly describes the function of the **AquaC UNO H** reverse osmosis system.

7.1 Description of the procedure

7.1.1 Brief description

The **AquaC UNO H** is a microcontroller-controlled, fully automatic reverse osmosis system with heat disinfection function which uses pretreated soft water for the production of highly deionized water, also called permeate.

The system consists of a water inlet section where the inflowing volume of water is volumetrically measured.

The servo valve in the water supply ensures continuous supply thus avoiding pressure peaks and noise in the supply line (domestic installation).

It also compensates minor supply variations in the inlet section.

The water is stored in a break tank and is used by the pump to generate high pressure. The pump generates the high pressure and transports the water to the membrane.

The permeate flows from the membrane through the conductivity cell to the permeate outlet.

The concentrate is discarded via the drain valve to the drain.

The yield control is done by the two flow meters. In combination with an upstream softener or a feed water hardness < 1° dH (< 17.8 ppm CaCO3), a yield of up to 70% can be achieved. Without softener, the yield is reduced to 60%.

No water is discarded if the system is not suppled with permeate.

Water hardness	Yield
< 1° dH (< 17.8 ppm $CaCO_3$)	70%
> 1° dH (< 17.8 ppm $CaCO_3$)	60%

The valve V22 stops the permeate feed if the permeate alarm limits (conductivity or temperature) are exceeded. When the value has dropped below the alarm limit, permeate supply will automatically be started again. An operator action is not required.

Restrictions

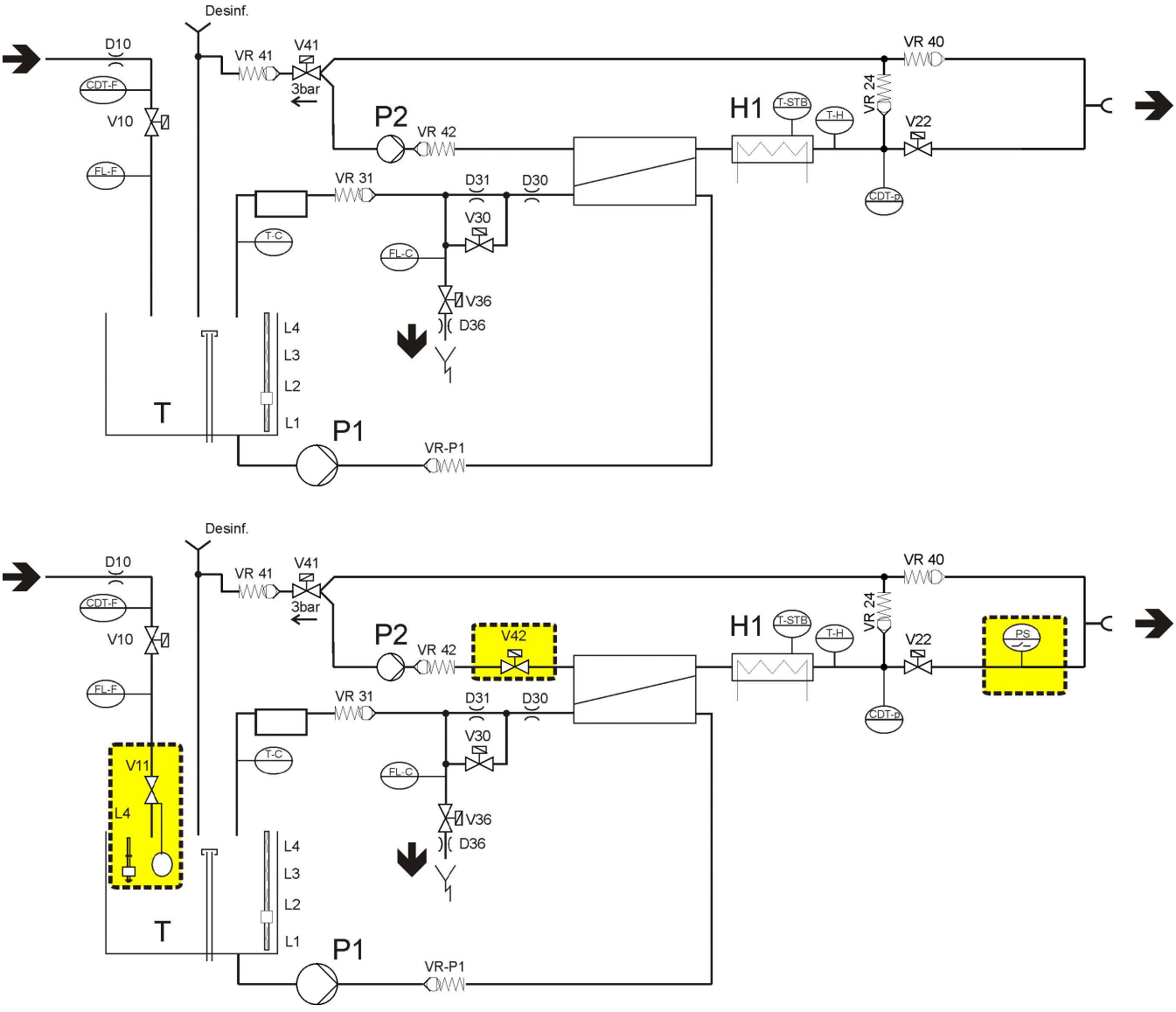
The ring heat disinfection in combination with a hemodialysis device for the disinfection of the water inlet section on the hemodialysis device may only be performed on hemodialysis devices approved for this function.

Note

The membrane life is primarily determined by the number of heat disinfection cycles. The minimum expected membrane life is 120 heat disinfection cycles.

(The warranty for the membranes refers to the number of module heat disinfection cycles performed.)

7.1.2 Flow diagram



8 Consumables, accessories, additional equipment

Warning

Scope of responsibility of the responsible organization

The device has been approved for use with certain consumables and accessories.

Should the responsible organization wish to use other consumables and accessories than those listed in this chapter, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with.

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the device resulting from the use of non-approved or unsuitable consumables or accessories.

Upon request the local service will provide information about further accessories, consumables, and other additional equipment.

8.1 Consumables for the reverse osmosis system (Please see your local catalogs for local Part numbers for all consumables)

	Consumables	Information	Part no.
1	Peracetic acid test	Test for peracetic acid	**see local catalog number**
2	Test kit for determination of iron	Iron test kit	**E07001264**
3	Test kit for determination of the hardness	Total hardness test kit	**E07001265**
4	Test kit for determination of chlorine	Chlorine test kit	**E07000154**

8.2 Consumables for the AquaC CART US option (Please see your local catalogs for Part numbers for all consumables)

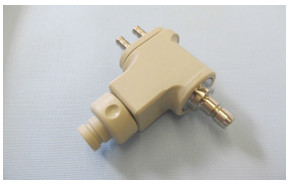
	Consumables	Information	Part no.
1	Filter element 20"	50 µm filter for **AquaC CART US**	**E06000141**
2	Filter element 20"	20 µm filter for **AquaC CART US**	**E06000149**
3	Filter element 20"	5 µm filter for **AquaC CART US**	**E06000131**
4	Filter element 20"	1 µm filter for **AquaC CART US**	**E06000130**
5	Activated carbon filter tank 8 × 35"	Activated carbon tank for **AquaC CART US**	**E06000182**
6	Filter element, particle filter 9 ¾"	1 µm filter for **AquaC CART Small**	**E06000110**
7	Filter element, particle filter 9 ¾"	5 µm filter for **AquaC CART Small**	**E06000133**
8	Filter element, particle filter 9 ¾"	20 µm filter for **AquaC CART Small**	**E06000098**
9	Activated carbon filter element 9 ¾"	5 µm activated carbon filter for **AquaC CART Small**	**E06000246**
10	Regeneration salt: block salt	Regeneration salt (2 × 4 kg/2 x 8.82 lb) for softener **Aqua-Kinetic** and **AquaC CART US** with automatic softener	**E06000053**

8.3 Accessories

	Accessories	Information	Part no.
1	Funnel	Disinfectant funnel	**E08000981**
2	Sampling set	Permeate sampling set for Fresenius sampling valve	**G03000836**

8.4 Additional equipment/options

	Additional equipment/options	Information	Part no.
1	OPTION **Pressure switch**	The optional pressure switch enables the **AquaC UNO H** to be started automatically in SUPPLY mode. (Only for initial order, not for refitting!)	**G04001142FMC**
2	Drain connection	Additional drain connection for home hemodialysis installation kit	**G03000374**
3	OPTION **AquaSTOP** US plug (100–240 V) (optional)	Leakage sensor and stop valve	**G04000628**
4	OPTION **AquaC CART US**	Transport cart for **AquaC UNO H**	**G03000519**
5	OPTION **AquaC CART Advanced US**	Transport cart for AquaC UNO H with adapted equipment (pre-assembled) Possible configuration: – Automatic softener – 20" particle filter 20 µm – 20" fine filter 5 µm – 2 × activated carbon tank (8 × 35") – Booster pump – UV lamp – Pipe disconnector – Coupling for HD device – Driving gear	**- On request -**
6	OPTION **AquaC CART Small**	Small transport cart for **AquaC UNO H** (without prefilter)	**G02000276**
7	OPTION **Single prefilter** – 9 3/4" for **AquaC CART Small** (without filter insert)	Prefilter for **AquaC CART Small**	**G03002150**
8	OPTION **Dual prefilter** – 9 3/4" for **AquaC CART Small** (without filter insert)	Prefilter for **AquaC CART Small**	**G03002154**
9	Wrench for filter housing 9 3/4"	Additional mounting wrench for **AquaC CART Small**	**E06000177**
10	OPTION **Tubing holder**	Holder for tubing and cable management	**G03000616**

	Additional equipment/options	Information	Part no.
11	OPTION **Long permeate ring main**	Permeate ring main **2 x 3 m/2 x 9.84 ft** Permeate ring main **2 x 5.0 m/2 x 16.40 ft** Permeate ring main **2 x 10.0 m/2 x 32.80 ft**	**G03000656** **G03000657** **G03000658**
12	Softener **AquaKinetic**	Softener with adapter for water hardness up to 25°dH (445 ppm $CaCO_3$) and higher	**G06000457FMC**
13	**Connection set** for softener	For the operation of the softener upstream of a small osmosis system	**G03000710**
14	**Hydraulic connector with coupling and sampling port** 	Standard permeate connection for **AquaC UNO H**	**G03000588**
15	**Hydraulic connector with nipple and sampling port** 	Alternative permeate connection for **AquaC UNO H**	**G03000589**

9 Installation

9.1 Connection conditions

- **Follow the applicable installation guidelines**

  The applicable installation guidelines must be followed for first installations.

- **To be observed before operational qualification**

  – Installation of the water pretreatment system must be completed before operational qualification of the reverse osmosis system.

  – Fresenius Water Technology can plan and carry out this work.

- **Observe national and local regulations**

  The national or local installation, operation, use, and maintenance regulations must be complied with.

9.1.1 Spatial environment

- **Observe on-site conditions**

  – The installation location must be level and free of frost and dust. The ground must be capable of bearing the weight of the components to be installed.

  – The components must not be exposed to direct sunlight on an ongoing basis.

  – The system's control electronics must be protected against moisture.

- **Variations in temperature**

  Variations in temperature during transport may cause condensation leading to water developing on live parts. In the event of major variations in temperature, allow sufficient time for the system to adjust to the ambient temperature before operational qualification.

9.1.2 Supply network (electrical)

9.1.2.1 General requirements

When connecting the system to a power supply, the relevant national standards and regulations must be observed.

Residual-current device

Warning

Install a residual-current device

➢ The power socket to which the single-station reverse osmosis system is connected must be protected by a residual-current device, residual current of 30 mA or lower.

Potential equalization

Potential equalization must be connected at the rear of the system if the statutory regulations of the installation location so prescribe.

Power cable

If the power cable is replaced, only the original power cable listed in the spare parts catalog may be used.

Warning

The system may only be used in accordance with the accompanying documents.

Only then will the manufacturer consider himself liable for the safety, reliability, and performance of the system.

➢ Operational qualification must be performed by the technical service of the manufacturer or a person authorized by them.

➢ In case of a first installation of the reverse osmosis system, observe the Specifications.

➢ When bringing the reverse osmosis system from a cooler to a warmer room, allow approx. 2 hours for the system to adjust to the ambient temperature before turning it on.

Protective ground

When using class I devices, the quality of the protective ground of the installation is of particular importance. Please note that national authorities specify standards and regulations in many countries.

Observe for a basic electrical installation

Basic electrical installations must be performed by a specialist electrical company in accordance with DIN VDE 0100.

Using potential equalization

– If potential equalization is used, it must be connected in accordance with the national statutory regulations, e.g., in Germany as per DIN VDE 0100.

– Potential equalization must be connected at the rear of the system if the statutory regulations of the installation location so prescribe.

9.1.2.2 Additional requirements for operation in the home environment

Installation of the system

– The system should not be installed directly next to other electrical devices. Stacked installation is not permitted.

– If the system must be operated close to other electrical devices, it must be checked if the performance of a device is negatively affected by inadvertent electromagnetic coupling.

– When installing the system, it must be ensured that all controls and indicators are easily accessible and that the labels on the system are legible.

9.2 Installation and operational qualification requirements

9.2.1 General notes

Note

Installation of the water pretreatment system must be completed before operational qualification of the device. Planning and implementation are to be performed by skilled personnel.

Operational qualification may only be carried out by the responsible skilled personnel or by a specialist in compliance with the regulations for this device!

9.2.2 System-specific requirements

Warning

Observe the operating conditions!

The **AquaC UNO H** single-station reverse osmosis system may only be operated under the conditions specified in the following:

If the quality of the feed water is insufficient, the required water pretreatment components must be installed after consulting the Fresenius project planning department. In this event it is necessary to perform an analysis of the local feed water.

Note

The power plug of the **AquaC UNO H** must be easily accessible.

Note

When installing the system it must be ensured that all controls and indicators are easily accessible and that the labels on the device are legible.

Note

Electromagnetic radiation

Do not use devices emitting electromagnetic radiation (e.g., walkie-talkies, cell phones, radio transmitters) in the vicinity of the device in operation. See separation distances if you must. This may cause a malfunction of the device.

Note

The device should not be installed directly next to other electrical devices. Stacked installation is not permitted.

If the device must be operated close to other electrical devices, it must be checked if the performance of a device is negatively affected by inadvertent electromagnetic coupling.

Note

The device must not be installed directly in patient environments and must not be accessible by the patient during treatment.
Protocolls should be in place to prevent unauthorized use of the device.

9.2.3 Hydraulic connection requirements

Optional components for water pretreatment

Note

Use of a leakage sensor with stop valve (AquaStop/optional) is recommended.

For more detailed information on the AquaStop option
(see Chapter 14.5 on page 14-10).

Note

An optional prefilter (complete filtration unit with filter element) is recommended. If the silt density index SDI is > 3, this prefilter is compulsory.

For more detailed information on the prefilter option
(see Chapter 11.3.2 on page 11-3).

The following special installation requirements must be checked:

➢ A softener is installed if the water hardness is > 25 °dH (445 ppm).

➢ All tubing and piping connections must be checked for leakage.

➢ A drain connection for concentrate diversion to drain DN 6 is installed.

Warning

Observe the operating conditions!

➢ Make sure that the drain line is never placed directly into the drain.

– A drain pipe in DN 40 with a free fall of 20–30 mm/0.79–1.18 inch to the drain must be present to prevent back-contamination.

– The drain of the system must not be connected with the drain of the hemodialysis device.

Warning

Observe the operating conditions!

– The material of the drain must be resistant to hot water.

9.2.4 To be observed before operational qualification

Tester's qualification

Operational qualification must be performed by the technical service of Fresenius Medical Care or a person authorized by them.

The operational qualification may only be performed by persons qualified to properly perform the specified checks based on their educational background, training, knowledge, and experience. Furthermore, the persons performing the checks must not be bound by any directives when performing this activity.

For operational qualification only

The following information is only intended for operational qualification. It is not applicable for operational requalification of systems that have been removed from service or temporarily shut down.

Specifications

– Observe the information on the specifications.
– Refer to the chapter Specifications for particular connection and performance data.

Electromagnetic radiation

Do not use devices emitting electromagnetic radiation (e.g., walkie-talkies, mobile phones, radio transmitters) in the vicinity of the device in operation. See separation distances if you must. This may cause a malfunction of the system.

Power plug

The power plug must be easily accessible.

Use of spare parts

Any installation, modification or repair work requiring the system to be opened may only be performed by manufacturer-authorized persons and is permitted only when using original spare parts.

Test equipment and accessories

The activities described in this document require the necessary technical test equipment and accessories to be available.

Precautions

Before turning power on, repair any visible damage.

Prior to opening the device and when working on the open device, the following precautions must be observed:

➢ Protect the components against the ingress of fluids

➢ Do not touch live parts

➢ Disconnect and connect all jacks, connectors, and components only when the device is turned off

ESD precautions

When repairing the system and when replacing spare parts, observe the applicable ESD precautions.

9.2.5 Performing an operational qualification

The operational qualification may only be performed using the startup report. An up-to-date startup report can be found in the Service Manual.

9.3 Shutdown, operational requalification, decommissioning

9.3.1 Shutdown

Note

➢ For information regarding shutdown of the device, contact the local service.

9.3.2 Operational requalification

Note

When delivered, the device has already undergone operational qualification.

Strictly speaking, when the device is installed it is an operational requalification which is performed, although this is nevertheless treated as an operational qualification.

Note

➢ For information regarding operational requalification of the device, contact the local service.

9.3.3 Decommissioning

Note

For information regarding decommissioning of the device, contact the local service.

Warning

Observe for operational requalification!

If the reverse osmosis system is decommissioned following operational qualification, observe the following:

➢ On operational requalification, the water supply pressure must be checked against the prescribed minimum pressure

10 Transport/storage

10.1 Transport

Note

It is only permitted to transport the **AquaC UNO H** in conjunction with the optional **AquaC CART US** or **AquaC CART Small** or other vendor approved portable RO cart.

Without these options, the **AquaC UNO H** is a stationary device.

Warning

Risk of tilting

- ➢ The system may only be operated on a horizontal, level surface.
- ➢ When moving the system across thresholds or other uneven surfaces, observe the risk of tilting or blocking.
- ➢ Do not push (from the side), pull or lift the **AquaC UNO H** (including options) when in operation.
- ➢ The operator must not lean against the system, use it as support, sit on it or step on it.
- ➢ Do not place any objects on the system.

Note

If the **AquaC CART US**/**AquaC CART Small** is to be transported across a threshold (max. 20 mm), it must be pulled.

10.1.1 Inside buildings

Transport inside buildings

Before transporting the system, the connecting tubes of the system must be disconnected. To prevent the system from being damaged or falling over, the **AquaC UNO H** should be pushed slowly across expansion joints in the floor, uneven surfaces, and passages into or out of elevators.

When ready for operation, the **AquaC UNO H** should be considered a stationary device (as opposed to a mobile one). As such, the device may not be moved. The device, with permanently attached rollers, may only be moved within a room when in **STANDBY** or when turned off (e.g., for cleaning purposes). It is only permitted to move the device into another room with the **AquaC CART US**/**AquaC CART Small** option or other approved portable RO cart.

10.1.2 Outside of buildings

Transport outside of buildings

Do not move the **AquaC UNO H** across uneven surfaces (e.g., cobblestone pavement). The system parts of the **AquaC UNO H** must always be transported in an upright position. When transported in vehicles, the housing must be appropriately protected against damage (if possible using the manufacturer's original transport packaging). Moreover, the permissible ambient temperatures must be observed when transporting the system outside of buildings.

10.2 Storage

10.2.1 Storage conditions/system

Note

Store upright.

Temperature range +5 to +40°C/41 to 104°F

Note

Protect the device from frost.

Relative air humidity Up to 80% at 20°C/68°F (non-condensing)

Atmospheric pressure 500 hPa to 1150 hPa

10.2.2 Storage of preserved systems

Warning

Efficacy of the preservation solution

Storage time when preserved: **maximum 12 months**.

To prevent bacterial growth, the **AquaC UNO H** must be subjected to another preservation procedure in case of prolonged storage times and, particularly, in case of increased storage temperatures.

10.3 Environmental compatibility/disposal

10.3.1 Information for the responsible organization

In EU member states, the device can be returned in accordance with the "Directive on waste electrical and electronic equipment" (WEEE Directive). Please also observe the applicable local legal regulations. Please also observe the applicable local legal regulations (e.g., OSHA regulations).

Before returning or disposing of the device, all the consumables within it must be removed and the device must be disinfected as per the manufacturer's specifications (see Chapter 6.2 on page 6-1).

10.3.2 Information for recycling and disposal companies

Recycling and disposal companies must observe the following information regarding the dismantling and disposal process.

It is possible that the device may be contaminated when returned. It must be handled accordingly and disinfected as per the manufacturer's specifications before it is dismantled (see Chapter 6.2 on page 6-1).

Information on the materials used can be found in the following chapter (see Chapter 12.10 on page 12-5).

Batteries and rechargeable batteries must be disposed of correctly in accordance with local statutory regulations.

Further information will be provided if requested by disposal companies.

10.3.3 Handling of disinfectants

It is absolutely essential to observe the manufacturer's specifications of the disinfectants used (e.g,. protective clothing, storage, dosing, expiration date).

The local regulations with regards to the disposal of waste water, if defined, must be clarified and observed before using disinfectants.

11 Technical Safety Checks/maintenance

11.1 Important information on Technical Safety Checks/ maintenance procedures

Technical Safety Checks (TSCs)

The first TSCs must be performed at the latest by the end of the 24th month after initial startup following delivery. All other TSCs must be performed at the latest by the end of the 24th month after the last TSCs.

Maintenance procedures

Maintenance procedures are recommended by the manufacturer. They serve to prevent malfunctions and the first ones should be performed at the latest by the end of the 12th month after initial startup following delivery. All other maintenance procedures must be performed at the latest by the end of the 12th month after the last maintenance procedures.

Tester's qualification

The checks must be performed by the manufacturer's service department or a person authorized by them.

The checks may only be performed by persons qualified to properly perform the specified checks based on their educational background, training, knowledge, and experience. Furthermore, the persons performing the checks must not be bound by any directives when performing this activity.

Specifications

Observe the information on the specifications.

Documents

The Technical Safety Checks, maintenance points, and other explanations regarding the procedure can be found in the Service Manual.

Reports can be supplied on request.

Performance of the Technical Safety Checks must be entered in the Medical Device Register.

- **Responsible organization and intervals**

Warning

Scope of responsibility of the responsible organization

The responsible organization must ensure that the TSC are performed.

Note

The Technical Safety Checks (TSC) must be carried out every **24 months**.

11.2 TSC/MA test report

For further details, refer to the latest **AquaC UNO H** Service Manual.

11.2.1 TSC procedure

- **Generally applicable according to EN 60601-1**

  Interval

  Note

  The Technical Safety Checks (TSC) in accordance with the manufacturer's requirements must be carried out every 2 years (24 months).

  Authorized persons

  Note

  The checks may only be performed by persons qualified to properly perform the specified checks based on their educational background, training, knowledge, and experience.

11.3 Maintenance procedures

11.3.1 Quality assurance and maintenance measures

The measures described below must be performed:

Component/to be checked	Equipment/desired condition/action to be taken	Interval	Comment
Hygienic condition of the system			See Chapter 5
Check softener (if installed)	➢ Refill salt.	**Daily**	
Check optional prefilter (if installed)	Desired condition: Pressure drop < 1 bar/< 14.5 psi ➢ If pressure drop > 1 bar/> 14.5 psi, replace the filter!	**Recommendation:** **Weekly**	
Connecting tubes	➢ Check for leak tightness.	**Recommendation:** **Weekly**	

11.3.2 Replacing the filter element on the optional prefilter

Procedure

To replace the filter element, proceed as follows:

➢ Close the water inlet valve/stop valve.

➢ Set the **AquaC UNO H** to the dialysis mode to depressurize the filter.

➢ Confirm the following alarm message:

Failure: Run-dry protection

➢ Disconnect the power plug.

➢ Place a collection jug under the prefilter housing.

➢ Drain the water.

➢ Unscrew and remove the filter housing.

➢ Remove the filter element and discard it with the domestic refuse.

➢ Insert a new filter element.

➢ Screw on the filter housing.

➢ Open the water inlet valve/stop valve again and watch the water inlet tube (check for leakage).

➢ Connect the power plug.

➢ Start the **AquaC UNO H**.

➢ Rinse for 5 – 10 minutes.

Note

Replacement of the filter must be entered in the Medical Device Register. The Medical Device Register is enclosed with the **AquaC UNO H**.

12 Specifications

12.1 Dimensions and weight

Dimensions	Height: 500 mm/1.64 ft Width: 520 mm/1.71 ft Depth: 195 mm/0.64 ft
Weight	Empty: approx. 35 kg/77.2 lb Full: approx. 37.5 kg/82.7 lb

12.2 System data

Permeate output	85 ±10% L/h at 15°C/59°F water inlet temperature
Yield	Up to 70% with <1 °dH (< 17.8 ppm CaCO3) water hardness Up to 60% with >1 °dH (> 17.8 ppm CaCO3) water hardness The yield is adjusted by the service technician during the course of the operational qualification.
Membrane rejection rate	> 99% for bacteria and endotoxins > 96% for dissolved salts (average)
Concentrate pressure	Max. 290.1 psi
Noise level	Noise level in **SUPPLY**: 44–46 dB (A) at a distance of 1 m.

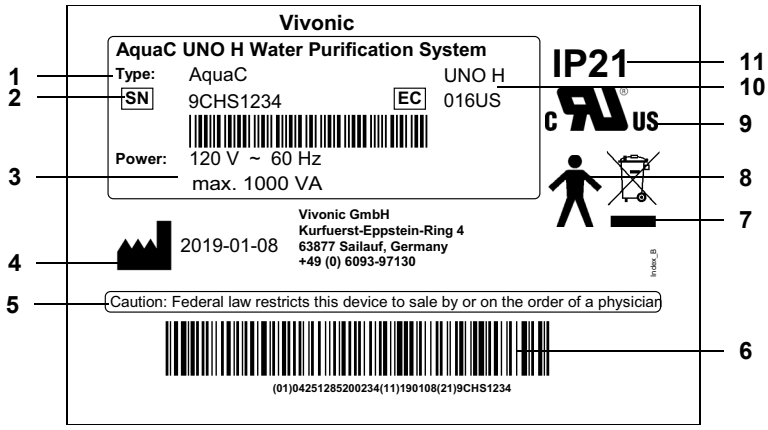
Note

The permeate output depends on the temperature of the feed water, the operating differential pressure, and the condition of the module used (silt density).

Cleaning/disinfection	
Permeate output	12 L/h ±10% during ring heat disinfection
Temperature	– Ring heat disinfection up to 90°C/194°F – Module heat disinfection up to 82°C/179.6°F
Membrane life	The minimum expected life is 120 heat disinfection cycles.
Hydraulic connections	
Permeate connection	Permeate nipple, optional permeate coupling

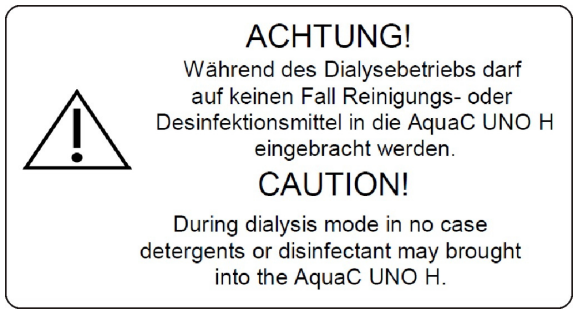
12.3 Identification label (system identification)

The identification label shown is only an example. The actual data is the data specified on the identification label of the system.



1. Type designation
2. Serial number
3. Power ratings
4. Manufacturer: year of manufacture and manufacturer's address
5. Regulatory note in accordance with 21 CFR 801.109(b)(1)
6. UDI - Unique Device Identifier
7. Identification of electrical and electronic devices
8. Applied part type (level of patient safety): Type B
9. UL-recognized component
10. Equipment code
11. Protection against ingress of solid particles = 12.5 mm/0.49 inch and liquids: drip-proof

- **Device labeling – disinfectant injection port**



CAUTION!
Make sure that no cleaning agents or disinfectants are injected into the **AquaC UNO H** during dialysis hours.

WARNING!
Safety instructions
Do not remove any warning / label or other description from the device.

12.4 Electrical safety

Warning

Risk of injury caused by electrical voltage

Touching live parts will cause an electric shock.

➢ To prevent the risk of an electric shock, this system may only be connected to a supply network with a protective conductor.

Note

If the device is to be connected to potential equalization, the potential equalization cable included in the scope of delivery must be used. Connect it to the potential equalization port on the rear of the device.

Warning

Multiway sockets or other electrical connections which do not offer appropriate protection against splashwater and water jets must not be used in the vicinity of the **AquaC UNO H** and the **AquaC Cart US**.

Classification in accordance with EN 60601-1:2006 + A1:2013, IEC 60601-1:2005 + A1:2012

Type of protection against electric shock	Protection class I
Degree of protection against electric shock: Applied part classification	Type B
Degree of protection against ingress of liquids	Drip-proof
Atmospheric pressure	700–1150 hPa (10.2–16.7 psi)
Relative air humidity	15–93% at 20°C (68°F), non-condensing
Installation altitude	Up to 9842 ft
Leakage currents	In accordance with IEC 60601-1:2005 + A1:2012
Overvoltage category	II
Pollution severity	II
Material group	IIIb

Operating mode	Continuous operation (Standby)

Note

Continuous operation refers to the mode in which the system is turned on (**STANDBY** or **SUPPLY**). The **SUPPLY** program may only be used periodically.

12.5 Electrical supply

Note

A fixed connection is needed to operate the device in the home environment. The power cable is prepared for such home applications and equipped with wire end ferrules.

A two-pole power switch must be connected upstream of the device, so it can be disconnected from power.

National requirements relating to the design of the power supply for medical products and rooms used for medical purposes must be observed.

A tested electrical connection is required. This connection must be established by a qualified electrician. The line voltage, operating current, and frequency data is specified on the device identification label.

Warning

Risk of injury caused by electrical voltage!

➢ The device must only be operated via tested power connections.

12.5.1 Voltage variants AquaC UNO H

The actual data is the line voltage, the current consumption, and the frequency specified on the identification label of the system.

	US standard configuration	Available as an option
Voltage	120 V	120 V
Frequency	60 Hz	60 Hz
Power	1000 VA	1700 VA
Current consump-tion	8.4 A	14.2 A

Heat output

– Supply/Rinse/Standby / < 0.1 kW

– Ring disinfection without hemodialysis device / < 0.19 kW

– Module heat disinfection and integrated heat disinfection at a consumption of 200 ml/min / 0.05 gpm / < 0.85 kW

12.5.2 System data

Number of hemodialysis devices	1 device
Permeate output	85 ±10% L/h / 22.5 ±10% gph at 15°C/59°F water inlet temperature
Yield	Up to 70% with < 1 °dH (< 17.8 ppm $CaCO_3$) water hardness Up to 60% with > 1 °dH (> 17.8 ppm $CaCO_3$) water hardness The yield will be adjusted by the service technician during initial startup.
Concentrate pressure	Max. 20 bar/290.1 psi (maximum pump pressure)
Noise level	Noise level in "Supply" mode: 44–46 dB (A) at a distance of 1 m.

- **Cleaning and disinfection**

Permeate output	12 L/h / 3.2 gph ±10 % during ring heat disinfection
Temperature	– Ring heat disinfection up to 90°C/194°F – Module heat disinfection up to 82°C/179.6°F

- **Membrane**

Rejection rate	– > 99% for bacteria and endotoxins – > 96% for dissolved salts (average)
Structure	Spirally-wound membrane

Note

The permeate output depends on the temperature of the feed water, the operating differential pressure, and the condition of the module used (silt density).

12.6 Fuses

Note

Fuses in the **AquaC UNO H** may only be replaced by trained personnel.

Fuse	Protection of component	Fuse rating	Fuse rating
		120 V–1000 VA	120 V–1700 VA
F1	Voltages, +5 V/–5 V/ 3.3 V/1.8 V	0.315 A slow-blow	0.315 A slow-blow
F2	Actuators	4 A slow-blow	4 A slow-blow
F3	Voltages, +5 V/–5 V/ +12 V	0.315 A slow-blow	0.315 A slow-blow
F4	Pump L	5 A H slow-blow	5 A H slow-blow
F5	Pump N	5 A H slow-blow	5 A H slow-blow
F6	Heater L	5 A H slow-blow	20 A H slow-blow
F7	Heater N	5 A H slow-blow	20 A H slow-blow

12.7 Information on electromagnetic compatibility

12.7.1 Minimum distances between radiation source and device

General specifications for IEC 60601-1-2

Note

EMC guidelines for medical electrical equipment

Medical electrical devices are subject to special EMC precautions. Therefore all notes and any information regarding EMC described in this manual must be observed during installation, operational qualification, and operation of the system.

Note

Installation of the system

The system should not be installed directly next to other electrical devices. Stacked installation is not permitted. If the system must be operated close to other electrical devices, it must be checked if the performance of a device is negatively affected by inadvertent electromagnetic coupling.

Electromagnetic radiation

Do not use devices emitting electromagnetic radiation, e.g., walkie-talkies, mobile phones, radio transmitters, in the vicinity of an **AquaC UNO H** in operation. See separation distances if you must. This may cause a malfunction of the system.

Medical electrical devices are subject to special precautions with respect to electromagnetic compatibility (EMC).

Portable and mobile communication equipment with a high-frequency transmitting power (radiation sources which emit electromagnetic waves) can affect medical electrical devices. This may cause medical electrical devices to malfunction.

Therefore, radiation sources must always be kept a certain minimum distance away from medical electrical devices when they are operating.

Warning

Patient hazard caused by a possible device malfunction

High-frequency radiation (radiation source) can cause the device to malfunction.

➢ Observe the minimum distances from radiation sources.

Radiation sources	Minimum distance from electrical medical equipment, including all connecting cables
Cell phones	325 cm (128 inch)
DECT phones (cordless phones)	115 cm (45.3 inch)
Bluetooth devices (laptops, cell phones)	23 cm (9.1 inch)
Radio remote controls	85 cm (33.5 inch)
WLAN devices **(e.g., laptops, repeaters, access points, printer servers)**	73 cm (28.7 inch)

12.7.2 Guidelines and manufacturer's declaration on EMC

This information relates to the specifications of IEC 60601-1-2:2007.

- **Electromagnetic emissions**

Guidelines and manufacturer's declaration – electromagnetic emissions		
The **AquaC UNO H** is intended for operation in an environment as specified below. The purchaser or operator of the **AquaC UNO H** should ensure that it is operated in such an environment.		
Emitted interference measurements	**Compliance**	**Electromagnetic environment – guide**
HF emissions according to CISPR 11	Group 1	The **AquaC UNO H** uses HF energy solely to perform its internal function. Therefore, its HF emissions are very low and it is unlikely to interfere with adjacent electronic devices.
HF emissions according to CISPR 11	Class B	The **AquaC UNO H** is suitable for use in all equipment, including that in the home environment, which is directly connected to a public supply network that also supplies residential buildings with power.
Emissions from harmonics according to IEC 61000-3-2	Class A	
Emissions from voltage fluctuations/flickers according to IEC 61000-3-3	Complies	

- **Noise immunity**

Guidelines and manufacturer's declaration – noise immunity			
The **AquaC UNO H** is intended for operation in the electromagnetic environment specified below. The customer or operator of the **AquaC UNO H** should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Discharge of static electricity (ESD) According to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or concrete, or fitted with ceramic tiles. If the floor is fitted with synthetic material, relative humidity must be at least 30%.
Rapid electrical transients/bursts according to IEC 61000-4-4	±2 kV for power cables ±1 kV for input and output cables	±2 kV for power cables Not applicable	The power supply should be of the same quality as that found in a typical commercial and/or hospital environment.
Surges according to IEC 61000-4-5	±1 kV normal-mode voltage ±2 kV common-mode voltage	±1 kV normal-mode voltage ±2 kV common-mode voltage	The power supply should be of the same quality as that found in a typical commercial and/or hospital environment.

Voltage dips, short-term interruptions, and fluctuations in the power supply according to IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for 0.5 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for 0.5 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	If the power supply is interrupted, the **AquaC UNO H** rechargeable battery takes over the supply without delay.
Magnetic field at supply frequencies (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at line frequency should correspond to the typical values found in a commercial and hospital environment.
Comment: U_T is the AC line voltage before the test level is applied.			
Conducted HF disturbances according to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile radio equipment should not be used any closer to the **AquaC UNO H**, including cables, than the recommended safety distance, which is calculated using the equation that applies to the transmitting frequency. **Recommended safety distance:** $d = 1.17 \sqrt{P}$ for 150 kHz to < 80 MHz
Radiated HF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35 \sqrt{P}$ for 80 MHz to < 800 MHz $d = 0.7 \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d is the recommended safety distance in meters (m). According to an on-site investigation[a] , the field strength of fixed radio transmitters should be lower than the compliance level at all frequencies.[b]  Interference is possible in the vicinity of devices bearing this symbol.

Comment: These guidelines may not apply in all cases. Electromagnetic radiation is affected by absorption and reflection from structures, objects, and people.

a The field strength of fixed transmitters, e.g., base stations for cordless phones and mobile land radios, ham radios, AM and FM radio broadcasters, and TV stations cannot be theoretically predicted with any degree of accuracy. The site should be surveyed in order to assess the electromagnetic environment in terms of fixed transmitters. If the field strength measured at the site where the **AquaC UNO H** is used exceeds the compliance level stated above, the **AquaC UNO H** should be monitored to ensure it is performing as intended. If unusual performance characteristics are observed, additional measures may be necessary, such as changing the alignment or using the **AquaC UNO H** at a different site.

b The field strength should be lower than 3 V/m over the frequency range of 150 kHz to 80 MHz.

- **Recommended safety distances between portable and mobile HF telecommunications equipment and the device**

Recommended safety distances between portable and mobile HF telecommunications equipment and the AquaC UNO H

The **AquaC UNO H** is intended for operation in an electromagnetic environment where HF disturbances are controlled. The customer or operator of the **AquaC UNO H** can help to avoid electromagnetic interference by complying with the minimum distance between portable and mobile HF telecommunications equipment (transmitters) and the **AquaC UNO H** – depending on the output power of the communication equipment, as specified below.

Rated power of the transmitter W	**Safety distance depending on the transmitting frequency m**		
	150 kHz to < 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to < 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.11	0.035	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.7	1.10	2.21
100	11.7	3.5	7.0

For transmitters whose maximum rated power is not stated in the table above, the recommended safety distance d in meters (m) can be determined using the equation belonging to the corresponding column, where P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer's specifications.

Comment: These guidelines may not apply in all cases. Electromagnetic radiation is affected by absorption and reflection from structures, objects, and people.

12.8 Operating conditions

Inlet volume	150 L/h / 39.6 gph
Feed water temperature	Min. 5°C/max. 30°C/ min. 41°F/max. 86°F
Ambient temperature range	+5°C to +40°C/ 41°F to 104°F
Atmospheric pressure	700–1,150 hPa
Relative air humidity	Up to 80% at 20°C/68°F (non-condensing)

- **Installation requirements**

Feed water inlet pressure max.	6 bar/87.0 psi
Feed water inlet pressure min.	– 1.5 bar/21.8 psi dynamic at 150 L/h / 39.6 gph feed and max. 50 L/h / 13.2 gph permeate consumption – 2.0 bar/29.0 psi dynamic at 150 L/h / 39.6 gph feed and more than 50 L/h / 13.2 gph permeate consumption
Permeate connection	Nipple (standard) or coupling
Inlet connection	G 3/4" union nut
Drain connection	DN6 hose connector
Installation altitude	Max. 3000 m/max. 9842 ft above sea level
Permeate ring main	– Standard: 2 x 1.5 m/4.92 ft Option: – 2 x 3 m/2 x 9.84 ft – 2 x 5 m/2 x 16.40 ft – 2 x 10 m/2 x 32.80 ft

- **Feed water quality**

Warning

Water pretreatment system design

The design of the water treatment system must ensure that the following parameters are fulfilled:

Water pretreatment	Pretreatment of the water is determined after previous water analysis.

Parameter	Desired value	Unit
Water hardness	< 25/ < 445	°dH/ ppm $CaCO_3$
Chlorine	< 0.1	mg/L / ppm
Iron*	< 0.1	mg/L / ppm
Manganese*	< 0.05	mg/L / ppm
Silicate*	< 25	mg/L / ppm
Max. conductivity	< 2,000	µS/cm
pH*	6–8	
SDI* (SDI: silt density index or colloid index)	< 3	
* The water hardness and the total chlorine should be checked daily according to ISO 23500 recommendations. All other water parameters in the table do not need to be checked continuously accompanying the dialysis operation if a secure and consistent water supply is ensured.		

Note

If the water hardness is ≥ 1 °dH/≥ 17.8 ppm $CaCO_3$, a decalcification must be performed prior to each heat disinfection of the membrane.

Warning

Membrane life

A different water quality may damage the membrane or may require the membrane to be replaced prematurely.

Warning

Ensure that the feed water is of a suitable quality!

The single-station reverse osmosis system **AquaC UNO H** may only be operated under the conditions specified below:

If the quality of the feed water is insufficient, the required water pretreatment components must be installed after consulting the Fresenius project planning department. In this event an analysis of the local feed water is required.

Warning

Scope of responsibility of the responsible organization

The product water quality depends on the feed water quality. Any change in the feed water quality will change the quality of the produced dialysis permeate. The user is responsible for monitoring the feed water quality.

12.9 Transport/storage

For further information (see Chapter 10 on page 10-1).

12.10 External connection options

Other, additional equipment connected to this device must comply with the applicable IEC or ISO standards (e.g., IEC 60950-1 for information technology equipment).

Furthermore, all device configurations shall comply with the requirements for medical electrical systems; see Chapter 16 and Annex I to EN 60601-1:2006.

Connecting the device to an IT network that contains components not installed and validated by the manufacturer can introduce unknown risks for patients, operators or third parties.

These risks must be identified, analyzed, evaluated, and monitored by the responsible organization. For assistance, consult IEC 80001-1:2010 and Annexes H5 and H6 to EN 60601-1:2006.

Any modification to an IT network that has been installed and validated by the device manufacturer can introduce new risks and therefore requires a repeat analysis. Especially problematic activities include:

- Modifications to the IT network configuration
- Connection of additional components and devices to the IT network
- Removal of components and devices from the IT network
- Updates or upgrades of components and devices in the IT network

Note that local laws take priority over the above-mentioned requirements. If in doubt, contact the local service.

LAN

Interface for data exchange.
Electrically isolated by transformer.
Port: RJ 45

Only devices complying with the regulations of IEC 60950 may be connected to the LAN ports.

Fresenius interface:

Interface for connection to Fresenius hemodialysis devices.

12.11 Materials used

Materials comply with DIN EN ISO 10993–1:2010–04.
The materials on a gray background are used in conjunction with dialysis water, dialysate or dialysate concentrate.

According to DIN EN ISO 10993-1, components coming into contact with permeate must be biocompatible.

Material	
Tubes/pipes	FEP/silicone/stainless steel
Sensors	Ti, Al_2O3, PBT
Module tube	V4A stainless steel
Membrane	PSU/PA
Hydraulic blocks	PP
Valves	IPP, PVDF, Noryl GTX
Seals	EPDM

13 Definitions

13.1 Definitions and terms

Dialysate	The exchange fluid used in dialysis.

13.2 Abbreviations

AC	Alternating current
CD	Conductivity
DC	Direct current
Dialysate	The exchange fluid used in dialysis.
Fig.	Figure (diagram)
LED	Light-emitting diode
MA	Maintenance
RO	Reverse osmosis system
TSC	Technical Safety Checks

13.3 Symbols


Permeate feed


Permeate return

IN
Feed water inlet


Drain

Network connection (RJ 45)


Potential equalization

IP21
Protection against ingress of dripping liquids and solid objects ≥ 50 mm


Degree of protection against electric shock:
Type B


Alternating current


Protective conductor terminal


Identification of electrical and electronic devices

Manufacturer

SN
Serial number

EC
Equipment code


Disconnect the power plug before opening.


Follow Instructions for Use!

UL-recognized component

Danger: Electricity

Caution: Hot surface

Do not push

13.4 Certificates

Upon request the local service will provide the currently valid versions of the certificates.

14 Options

14.1 Free option (isolated standby)

Brief description

The **free option** brings the **AquaC UNO H** into a state where reverse osmosis runs under the following conditions:

– No water consumption

– No drainage needed

– Freedom from bacteria and endotoxins without chemicals

This means that the **AquaC UNO H** can be set aside in a way that saves resources during long idle times (recommended from 72 hours). The **AquaC UNO H** only needs a power connection in order to circulate the fluid inside the device four times a day.

In addition, heat disinfection of the internal circuits will be started once a day, to ensure that the microbiological and chemical requirements of the dialysis water can be met.

This operating mode can be maintained for a maximum of 30 days. If a longer period is needed, the operator must reconnect the feed and drain of the **AquaC UNO H** so the internal circuits can be rinsed. The system can then be disconnected from the feed and drain again for another 30 days.

14.2 AquaC CART US option

Note

For the part numbers of the options, refer to Chapter 8.

14.2.1 AquaC CART Advanced US brief description

The **AquaC CART Advanced US** water pretreatment system is a portable unit for the pretreatment of drinking water to operate a reverse osmosis system type **AquaC UNO H** or **AquaUNO**.

14.2.2 General operating conditions for the AquaC CART Advanced US

Note

The system may only be pushed (pulled) using the handle provided for this purpose.

Warning

Comply with the installation regulations!

– Multiway sockets must not be used within 1.5 m/4.92 ft of the **AquaC UNO H** and the **AquaC CART Advanced US** in all directions.

Warning

Comply with the installation regulations!

➢ To prevent major damage to buildings in the event of damage, **the room where the water pretreatment system is operated must have a floor drain.**

➢ An additional **leakage detector** must be installed.

➢ A pipe disconnector must be installed upstream of the **AquaC CART US** in accordance with national requirements for protecting drinking water.

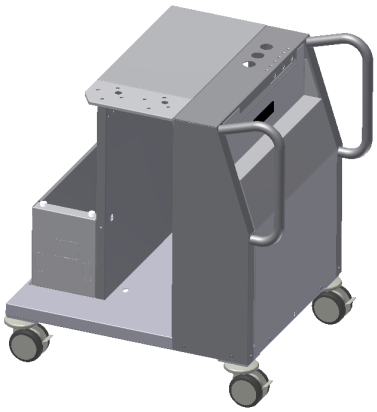
➢ Use of a **sealed floor covering**, which is resistant to ingress of liquids, is recommended.

Warning

Ensure protection against moisture and the effects of humidity

➢ The control electronics of the systems must be protected against humidity (splash water, condensation water, etc.) and moisture.

14.2.3 Specifications for the AquaC CART US option



Dimensions

Parameter	Function/specifications
Height*	944 mm (371.7 inch)
Width*	730 mm (287.5 inch)
Depth*	856 mm (337.0 inch)
Weight (empty*)	50 kg (110.2 lb)
* empty/without filters	

Electrical connection

Only if a booster pump is installed: 120 V/60 Hz

Configuration options

The **AquaC CART US** may be adapted with prefiltration components to make the water reach the specified feed water quality.

The possible configurations of the **AquaC CART US** option are:

– Softener
– Particle filter
– Fine filter
– Activated carbon filter
– Booster pump
– Backflow preventer

Note

The configuration should be adapted to the local feed water quality so that the complete water treatment system (including the **AquaC UNO H**) produces water that meets the AAMI/ANSI and FDA-recognized U.S. standards.

14.2.3.1 Problem-free softener regeneration

Note

After the reverse osmosis system is turned off, the softener may still be in regeneration mode. Therefore, after the **AquaUNO/AquaC UNO H** is turned off, the water inlet should remain open for at least 11 minutes to enable regeneration to finish without any problems.

14.2.3.2 Softener performance values

Parameter	Specifications
Flow range	Up to 18 L/min (4.75 gal/min)
Minimum flow	0.4 L/min (0.04 gal/min)
Salt consumption	Approx. 0.23 kg/regeneration (0.51 lb/regeneration)
Regeneration time	11 minutes

Note

Damage due to leakages

In rooms without floor drainage, it is recommended to install a leakage detector (e.g., AquaSTOP).

14.2.3.3 Hardness range

Softener disks	2	3	4	5	6	7	8
Up to hardness °dH/ ppm CaCO3	6/ 107	9/ 160	12/ 214	15/ 267	18/ 320	22/ 392	24/ 427
Liter (gal)/regeneration	1154 L/ 304.9 gal	768 L/ 202.9 gal	575 L/ 151.9 gal	461 L/ 121.8 gal	386 L/ 102 gal	329 L/ 86.9 gal	287 L/ 75.8 gal

14.2.3.4 Softener monitoring

– The Softener option can only be activated in the Service menu.
– The Softener option is only available in conjunction with the **Eco** option (flow meter).

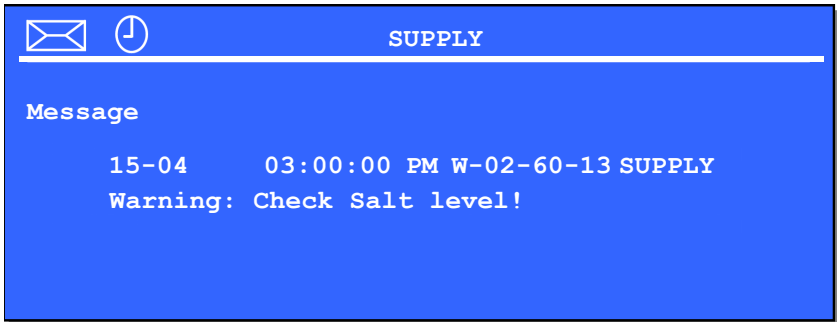
If the **AquaC UNO H** is consuming water, the volume consumed if measured.

➢ After a certain volume of water has been consumed, the salt for the softener will need to be refilled.

➢ The softener capacity amount can only be set in the Service menu.

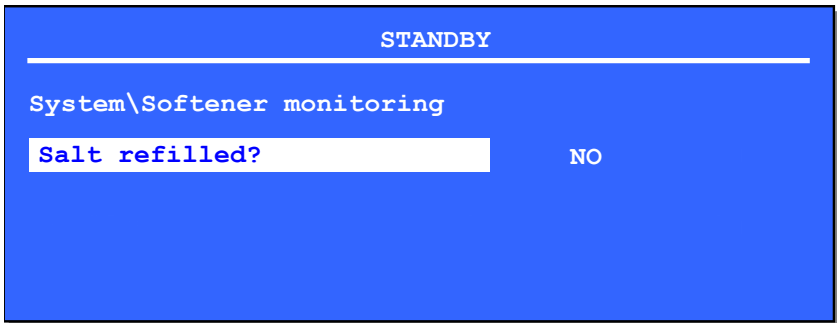
If the maximum set water volume is reached, the following message appears on the display:

W-02-60-13 Warning: Check Salt level!



➢ As soon as this message is confirmed with the **Enter** key, the System\Softener menu opens.

➢ The salt fill level can be confirmed in the System\Softener menu.



➢ Change to **NO** by pressing the **Enter** key. Change **NO** to **YES** with the **Up** (▲) or **Down** (▼) navigation keys and confirm with the **Enter** key.

The volume of water consumed is reset to 0 liters.

If **Salt refilled?** is confirmed with **NO** or if the System\Softener menu is exited without any confirmation, the message **Warning: Check Salt level!** appears again the next time the program starts.

➢ If the salt is to be refilled and the salt fill level to be confirmed later, the **System\Softener** menu can also be opened manually.

➢ The salt fill level can be confirmed at any time.

14.2.4 Overview of maintenance intervals

Component	Equipment/desired condition/action to be taken	Interval/comment
Tubes and connectors	Check for leak tightness	– **Weekly**
Pressure drop	Desired condition: Pressure drop < 1 bar/< 14.5 psi	– **Weekly** If applicable, replace filter inserts/manually rinse externally
Filter inserts	Replace/backwash	– **At least every 3 months** (depending on the pollution severity)
Softener function	Check water hardness; desired: < 1 °dH/ < 17.8 ppm $CaCO_3$	– **Daily**
Softener resin	Regenerate	– **As required** (rinse manually with saline solution)
Activated carbon filter	Check chlorine content; desired: < 0.1 mg/L (ppm)	– **Daily/prior to each shift**
Activated carbon filter granulate	Replace	– **As required** **Recommendation:** After 48 months at the latest

14.3 AquaC CART Small option

Note

For a description of the articles and the part numbers of the required consumables, accessories, and options, refer to Chapter 8.

*Fig.: **AquaC CART Small** with attached 9 3/4" single prefilter option for **AquaC CART Small***

Space requirements/ weight

Parameter	Function/specifications
Height*	Handle retracted: 550 mm (216.5 inch) Handle extended: 860 mm (338.6 inch)
Width*	270 mm (106.3 inch)
Depth*	570 mm (224.4 inch)
Empty weight	7.4 kg (16.31 lb)

Filter

Parameter	Function/specifications
Weight of single filter, empty	2.5 kg (5.51 lb)
Weight of dual filter, empty	3.5 kg (7.72 lb)

14.3.0.1 Configuration options

TYPE/description of options
Single prefilter – 9 3/4" for AquaC CART Small (without filter insert)
Dual prefilter – 9 3/4" for AquaC CART Small (without filter insert)

- **Assembly**

➢ The **AquaC CART Small** pretreatment system is screwed onto the front of the **AquaC CART Small** using the screws supplied with the unit.

➢ Reduce the **AquaUNO** or **AquaC UNO H** feed water tube to the required length and connect it directly to the filter outlet. The length of tubing which was cut off is connected to the filter inlet.

- **Consumables/accessories**

Description of options
Filter element, particle filter 9 3/4"; 1 µm
Filter element, particle filter 9 3/4"; 5 µm
Filter element, particle filter 9 3/4"; 20 µm
Filter element, activated carbon block 9 ¾"; 5 µm

Note

For a description of the articles and the part numbers of the required consumables, accessories, and options, refer to Chapter 8.

14.4 Pressure switch option

Note

For the part numbers of the options, refer to Chapter 8.

The Pressure switch option includes a pressure switch (1.0–3.0 bar/14.5–43.5 psi) and an additional valve.

Automatic start

The device switches from **STANDBY** to **SUPPLY** mode if the Pressure switch option is activated and the pressure in the permeate tube falls below 1 bar/14.5 psi.

Supply mode is stopped automatically if the Pressure switch option is activated and no permeate is consumed for 5 minutes.

Note

If a heat cleaning program has been stopped manually, the **AquaC UNO H** will not start in **SUPPLY** mode automatically.

The **AquaC UNO H** then has to be started manually so the device can cool down. Automatic operation is thus set to active again.

14.5 AquaStop option

Note

For a description of the articles and the part numbers of the required consumables, accessories, and options, refer to Chapter 8.

Description	Usage
AquaStop (optional) Consisting of: Leakage sensor and stop valve	Stopping the water supply and US plug (100–240 V)

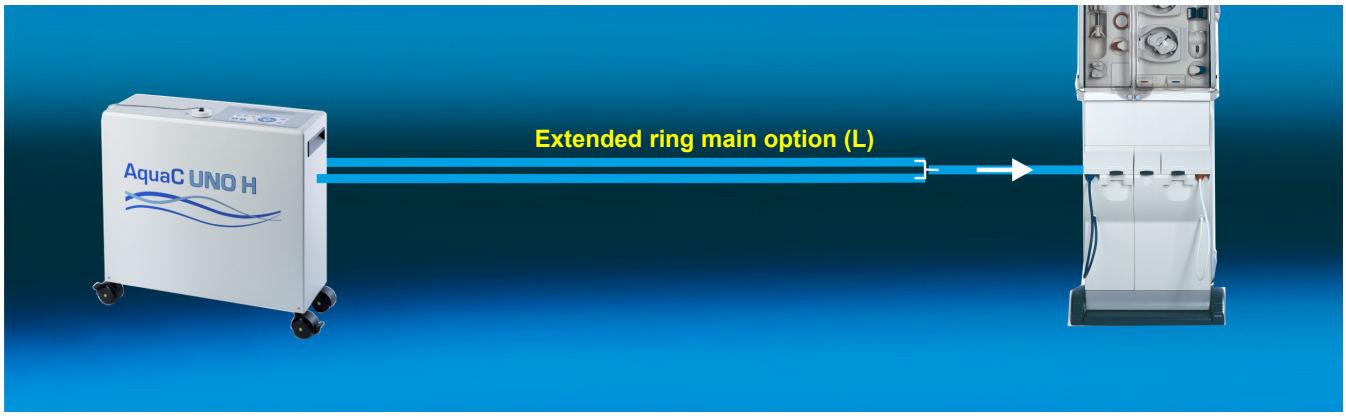
14.6 Extended ring main option

Advantage

The **AquaC UNO H** can be installed in a different location or room to the hemodialysis device.

Note

The ring main length does not depend on the system connection (nipple, coupling, with/without sampling port).



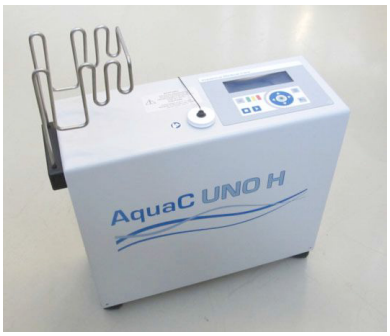
Description	Configuration
Standard ring main version	L = 2 x 1.5 m/4.92 ft
Extended ring main option	L = 2 x 3 m/9.84 ft
	L = 2 x 5 m/16.40 ft
	L = 2 x 10 m/32.80 ft

14.6.1 Tube holder option

The Tube holder option stands alone and is independent of the Extended ring main option.

Advantage

– Tubes are hung up tidily.
– Tubes do not become dirty.



Description	Usage
Tube holder	Hanging up tubes

15 Appendix

15.1 Medical Device Register AquaC UNO H

15.1.1 Address of the responsible organization and identification

The following page shows the master template for the address of the responsible organization and the identification.

AquaC UNO H	Address of the responsible organization & identification	FRESENIUS MEDICAL CARE

Address of the responsible organization
Name:
Address:
City:
Phone:
Site of installation:

Internal medical consultant
Name, phone:
Name, phone:
Name, phone:
Name, phone:
Name, phone:

Identification		
System: AquaC UNO H		
Type: Water treatment system, reverse osmosis system		
Serial number:		
Manufacturer: Fresenius Medical Care & Co. KGaA 61346 Bad Homburg, Germany		
Options installed:		
AquaC CART US		❑
AquaC CART Small		❑
AquaSTOP		❑
Pressure switch		❑
Tube holder		❑

Tests/checks	
Type	**Intervals**
Technical Safety Check (TSC)	Every 24 months
_____	Every _____ months
_____	Every _____ months

Contracts regarding tests and checks:
Technical Safety Checks:
Company name:
Address:
Phone:

15.1.2 Contents of the AquaC UNO H Medical Device Register

The following pages show the contents of the Medical Device Register of the **AquaC UNO H**.

AquaC UNO H **Contents of the Medical Device Register** FRESENIUS MEDICAL CARE

1	**Instructions for Use**
Monitoring	
2	**System monitoring** – Operational data acquisition reports
3	**Microbiological and chemical monitoring** – Results of the microbiological analysis – Results of the chemical analysis – Sample collection plans
4	**Disinfection** – Disinfection reports – Disinfection plans
5	**Settings reports**
6	**Service reports/training records/malfunctions** – Training records – Service reports and documentation of modifications to the system options – Reporting of incidents – Documentation of malfunctions and repeated, identical operating errors
7	**Technical Safety Checks (TSC)/revalidation**
Validation phase	
8	**Installation qualification (IQ)** – Installation report – Validation plan
9	**Operational qualification (OQ)** – Disinfection report OQ – Settings report OQ – Training record OQ – Sample collection plan OQ – Disinfection plan OQ – Operational qualification report OQ
10	**Performance qualification (PQ)** – Operational data acquisition report PQ – Results of the microbiological analysis PQ – Results of the chemical analysis PQ

15.2 AquaC UNO H Training Record

The following page shows the master template for the **AquaC UNO H** Training Record.

AquaC UNO H	Training Record	FRESENIUS MEDICAL CARE

Training location
Center/clinic:
Address:
Town/city / ZIP code:
Phone:
Fax:

Training period
From:
Until:

❑ Person(s) assigned by the responsible organization
❑ Operator
❑ Others
Names:

Reverse osmosis system:
❑ **AquaC UNO H**
Serial no.:
Equipment code:
Software version:

Document	✓
AquaC UNO H Instructions for Use, edition: _____	❑
Training documentation	❑
Operational data acquisition report (daily report)	❑

Comments:

Note

Observe index, important information, and all warnings in the IFU!

Training subjects			Filed in	✓
Basics				
A	Connection conditions during installation (see Chapter 9.1 on page 9-1)	– The feed water must be of drinking water quality – Free fall of waste water 20–30 mm – Floor drain installed – Leakage sensor installed	IFU	❑
B	Intended use (see Chapter 2.6 on page 2-4)	– Supply of the hemodialysis device (see IFU Chapter 2.6)	IFU	❑
Design				
A	Top view (see Chapter 3.2 on page 3-4)	– Display control panel – visual indicator	IFU	❑
B	Rear view (see Chapter 3.1 on page 3-1)	– Permeate feed – Permeate return – Concentrate outlet – Feed water inlet – Potential equalization connection – Identification label – Network connection (RJ 45 connection with protective cap) (if the **IT** option is installed) – Power plug (electrical connection)	IFU	❑
C	Left and right side view (see Chapter 3.1 on page 3-1)	– Handles	IFU	❑
User interface and display				
A	User interface: Layout and function (see Chapter 3.2 on page 3-4)	– Status bar with current operating mode and information menu: Timer, letter, and clock symbols Status menu – Display area – Operating modes and menu structure: Selection of programs System menu: Settings and service Password protection	IFU	❑
Operating modes and functions				
A	Quick guide (see Chapter 4 on page 4-1)	– The operator should be shown the available operating modes and how to start them by pressing the Enter key (for 3 seconds). – Available operating modes are: Standby, Supply, Chemical disinfection, Decalcification, Module heat disinfection, and Ring heat disinfection.	IFU	❑
B	Operating programs (see Chapter 4 on page 4-1)	The following operating modes must be demonstrated: – Standby – Supply – Rinse (Cleaning) It must also be shown how to start and stop **Supply** with the "Start" and "Stop" keys.	IFU	❑
C		– Chemical disinfection (demonstrate in full)	IFU	❑
D		– Decalcification (only if no softener is installed) – Only start and completion required (operator actions); does not have to be run in full.	IFU	❑
E	Status and system menu (no password required) (see Chapter 4.11 on page 4-10)	– Messages: Current messages Confirm messages – AutoStart/AutoStop: Timer settings for Supply and Rinse – System information: Configuration and system values – Operating data (current operating data)	IFU	❑

Training subjects			Filed in	✓
Alarms				
A	visual indicator (see Chapter 3.1 on page 3-1)	– Red – an alarm or a malfunction has occurred or has not yet been confirmed – Yellow – a warning has occurred or has not yet been confirmed – Green – Supply mode active	IFU	❑
B	Alarms (see Chapter 5 on page 5-1)	– Are displayed directly if an alarm occurs – Refer to Chapter 5 "Alarms" in the Instructions for Use – Refer to Chapter 2 "Addresses" (Water Technology hotline)	IFU	❑
Home dialysis				
A	**AquaC UNO H** voltage variants (see Chapter 12.5.1 on page 12-7)	– Do not connect any other device to the power socket.	IFU	❑
B	**AquaC UNO H** voltage variants (see Chapter 12.5.1 on page 12-7)	– Only connect the device to the tested power socket.	IFU	❑
Documentation/maintenance				
A	Daily report (see Chapter 15.3 on page 15-10)	– Date and time when the data was collected – Feed water conductivity – Feed water temperature – Permeate conductivity – Permeate temperature – Total chlorine – Water hardness	IFU/ ODR	❑
B	Maintenance (staff) (see Chapter 11.3 on page 11-3)	– Decalcification on demand as specified (by message) – Refill softener salt (if softener is installed) – Check for leak tightness – Soft water sample (if softener is installed) – Replacement of filter cartridges (if present)	IFU	❑
Options				
	AquaC CART US	– Functional description, operation, maintenance (see Chapter 14.2 on page 14-2)	IFU/ TD	❑
	AquaC CART Small	– Functional description, operation, maintenance (see Chapter 14.3 on page 14-8)	IFU/ TD	❑
	AquaStop	– Functional description, operation, maintenance (see Chapter 14.5 on page 14-10)	IFU/ TD	❑
	Prefilter	– Functional description, operation, maintenance (see Chapter 11.3.2 on page 11-3)	IFU/ TD	❑
Miscellaneous				
A	Various items (see Chapter 15.7 on page 15-19); (see Chapter 15.7 on page 15-19)	– Collection of microbiological samples (sampling ports) – Ordering accessories (filter, salt) – Medical Device Register – Intervals for Technical Safety Checks	IFU/ TD	❑
IFU = Instructions for Use ODR = Operational data acquisition report TD = Training documentation				
Reference to the Instructions for Use: The device has been approved for use with the consumables and accessories listed in the Instructions for Use. Should the responsible organization wish to use other consumables and accessories than those listed in the Instructions for Use, the responsibility to ensure the correct function of the device lies exclusively with the responsible organization.				

Trainer	
Name	**Date, signature**

Participant	
Name	**Date, signature**

15.3 Operational data acquisition

GENERAL NOTES
Monitoring of the operating parameters is indispensable to ensure safe and continuous operation of the reverse osmosis system. Meticulous recording of the data is also an absolute requirement for potential warranty claims. If values deviate, inform the technical service so that they can take appropriate action before a malfunction occurs.

General notes

Note

➢ According to ISO 23500 the operating data must be monitored daily.

Tip

➢ The daily operating data of the **AquaC UNO H** can be displayed in the **Status** menu and the submenu **Operating data** (see Chapter 4.11.4.1 on page 4-13).

Note

➢ Manually measure the value **Hardness in feed water** downstream of the prefiltration unit. The measured value must be identical with the value set in the system.
Without softener, max. 25 °dH/445 ppm $CaCO_3$ is permitted.

➢ Manually measure the value **Total chlorine in feed water** downstream of the prefiltration unit.
The maximum permissible value is 0.1 mg/L (ppm).

➢ Do not operate the **AquaC UNO H** if the alarm limits for hardness or total chlorine have been exceeded!

15.3.1 Manual operational data acquisition report

The following page shows the master template for the **AquaC UNO H** operational data acquisition report.

Operational data acquisition/daily report AquaC UNO H	**Year:** _____ **Calendar week:** _____

Procedure								
Weekday	Mon	Tue	Wed	Thu	Fri	Sat	Sun	–
Time	_____	_____	_____	_____	_____	_____	_____	

	Entries (operator)							**Unit**
AquaC UNO H								
Serial number: _____								
Rejection rate	_____	_____	_____	_____	_____	_____	_____	
Permeate conductivity CDT-P	_____	_____	_____	_____	_____	_____	_____	µS/cm
Feed water conductivity CDT-F	_____	_____	_____	_____	_____	_____	_____	µS/cm
Feed water temperature CDT-T	_____	_____	_____	_____	_____	_____	_____	°C/°F
Hardness in feed water	_____	_____	_____	_____	_____	_____	_____	°dH/ ppm $CaCO_3$
Total chlorine in feed water**	_____	_____	_____	_____	_____	_____	_____	mg/L / ppm

** The chlorine in the feed water does not have to be measured if it has been ensured that the water does not contain any chlorine (e.g., by confirmation from the water supplier).

	Entries (operator)							Unit
Disinfection								
Heat disinfection								
Ring heat disinfection: Completed without error?	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	–
Module heat disinfection: Completed without error?	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	–
Initials								
–	_____	_____	_____	_____	_____	_____	_____	–

Note

➢ If the conductivity changes by more than 100% compared with the previous average value for a significant length of time, it is essential to contact the responsible technician or the manufacturer.

15.4 Disinfection report

The following page shows the master template for the **AquaC UNO H** disinfection report.

AquaC UNO H	Disinfection report	FRESENIUS MEDICAL CARE

Responsible organization:	**Serial number:**	**Disinfectant:**
Address:	**Equipment code (see identification label):**	**Type/manufacturer:**
City:	**Date:**	**Batch number:**
Phone:	–	**Storage life:**

Procedure	Unit	Entries (operator)
START DISINFECTION (time)	h	
PERMEATE CONDUCTIVITY (prior to disinfection)	µS/cm	
Disinfectant used	(brand/name)	
VOLUME of disinfectant	ml/gal	
PERMEATE CONDUCTIVITY REACHED	µS/cm	
NUMBER OF RINSE CYCLES	Number	
PROGRAMMED RINSE VOLUME	liter/gal	
ABSENCE OF RESIDUAL DISINFECTANT	Yes/no	
PERMEATE CONDUCTIVITY (after the disinfection)	µS/cm	
PERMEATE CONDUCTIVITY (the value must be the same or lower than before disinfection)	Yes/no	
END DISINFECTION (time)	h	

Comments:		
Date:	**Signature:**	**Stamp:**

15.5 Decalcification report

The following page shows the master template for the **AquaC UNO H** decalcification report.

AquaC UNO H	Decalcification report	FRESENIUS MEDICAL CARE

Responsible organization:	**Serial number:**	**Decalcification agent:**
Address:	**Equipment code (see identification label):**	**Type/manufacturer:**
City:	**Date:**	**Batch number:**
Phone:	–	**Storage life:**

Procedure	Unit	Entries (operator)
PERMEATE CONDUCTIVITY (prior to decalcification)	µS/cm	
VOLUME of 20% citric acid (200 ml/0.05 gal)	ml/gal	
PERMEATE CONDUCTIVITY REACHED	µS/cm	
PERMEATE CONDUCTIVITY (after decalcification)	µS/cm	
PERMEATE CONDUCTIVITY (the value must be the same or lower than before decalcification)	Yes/no	

Comments:		
Date:	**Signature:**	**Stamp:**

15.6 Quality of dialysis water

The microbiological and chemical purity of the dialysate prepared in the dialysis center is of critical importance for the quality of the patient's treatment.
The quality of the dialysis water (permeate) should comply with local regulations. If no local regulations apply, the requirements of ISO 13959:2014 - "Water for haemodialysis and related therapies" must be observed.

15.6.1 Microbiological quality standards

	Medium	Alarm limits	
		Total microbial counts CFU/ml	Endotoxin concentration EU/ml
ISO 13959 Water for haemodialysis and related therapies	Dialysis water	< 100 (AL* 50)	< 0.25 (AL* 0.125)
*AL = action level. ISO 13959:2014: From this concentration on, steps must be taken to stop the trend to higher, unacceptable values. The value usually is about 50% of the alarm limit.			

15.6.2 Chemical quality standards

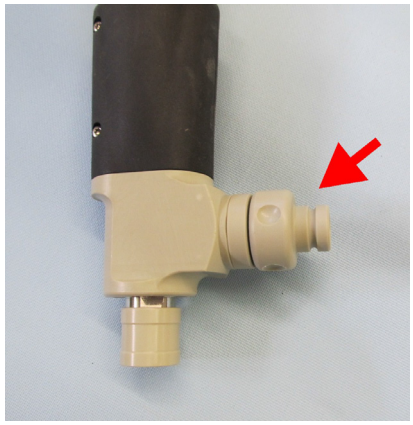
	Parameters with proven toxicity in dialysis	Alarm limit [mg/L, ppm]	Electrolytes	Alarm limit [mg/L, ppm]	Trace elements	Alarm limit [mg/L, ppm]
ISO 13959	Aluminum	0.01	Calcium	2	Antimony	0.006
	Lead	0.005	Potassium	8	Arsenic	0.005
	Fluoride	0.2	Magnesium	4	Barium	0.1
	Total chlorine	0.1	Sodium	70	Beryllium	0.0004
	Copper	0.1			Cadmium	0.001
	Nitrate as (N)	2			Chrome	0.014
	Sulfate	100			Mercury	0.0002
	Zinc	0.1			Selenium	0.09
					Silver	0.005
					Thallium	0.002

To ensure permanent optimum water quality, regular checks and, if necessary, disinfection/cleaning cycles of the water supply system must be performed.

ISO 23500:2014 "Guidance for the preparation and quality management of fluids for haemodialysis and related therapies" recommends a regular preventive disinfection to avoid significant biofilm formation (biofouling). Microbiological analyses of the dialysis water should be performed once a month, although the monitoring interval can be increased or decreased, depending on the results of the microbiological analysis. In addition, a chemical analysis of the dialysis water according to ISO 23500 should be performed every year.

15.7 Sampling port for microbiological analysis

15.7.1 Standard configuration



Configuration
Hygiene option with sampling port

The sample is collected from the **AquaC UNO H** at the permeate outlet with the Fresenius sampling port, which can be opened by turning.

15.7.2 Preparation

➢ Permeate can only be collected if the reverse osmosis system is in **SUPPLY** mode.

➢ Before collecting the sample, the reverse osmosis system must have been in **SUPPLY** mode for at least 15 minutes.

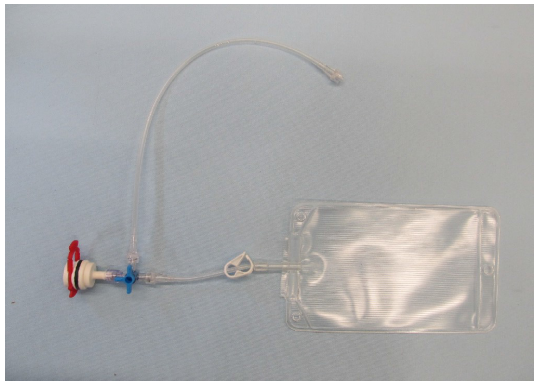
15.7.3 Accessories/equipment

The following equipment is recommended by the manufacturer:

– Rubber gloves

– Alcohol-based disinfectant

– **Permeate sampling set for Hygiene option** (This is an option not a requirement)
(part no.: G03000836):



15.7.4 Brief description

➢ Place a pre-cooled transport box with cooling packs nearby.

➢ Before collecting the sample, the reverse osmosis system must be operated in **SUPPLY** mode for at least 15 minutes.

➢ While collecting the sample, the reverse osmosis system must run in the **SUPPLY** program.

➢ Disconnect the permeate connection from the hemodialysis device and collect the sample as specified in the following description.

15.7.5 Sample collection procedure

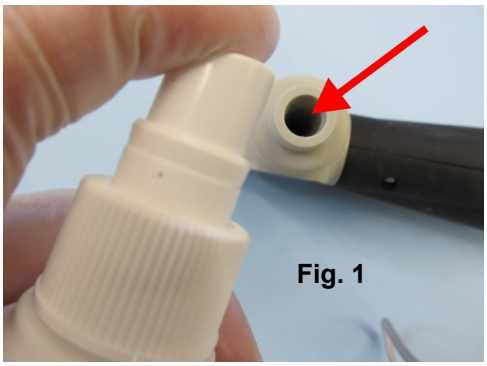
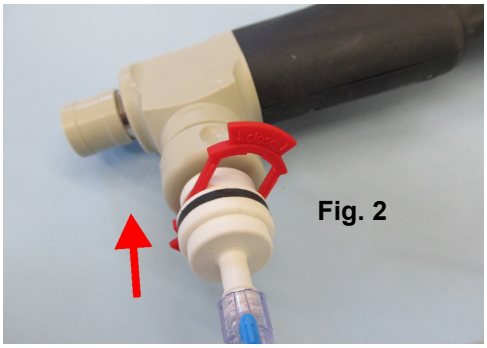
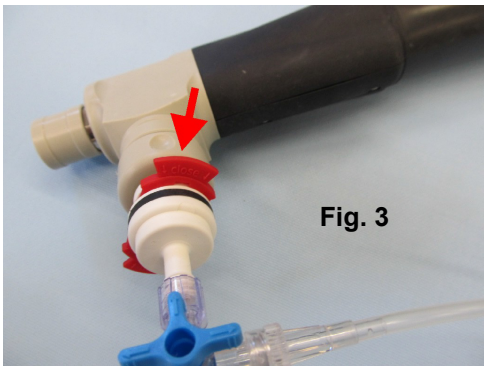
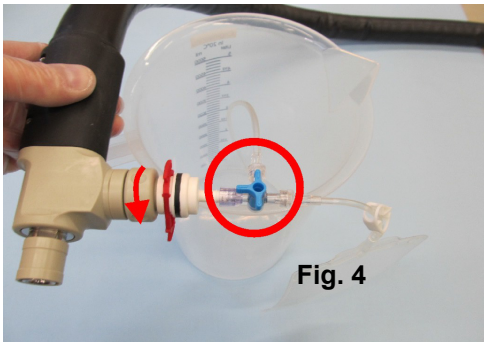
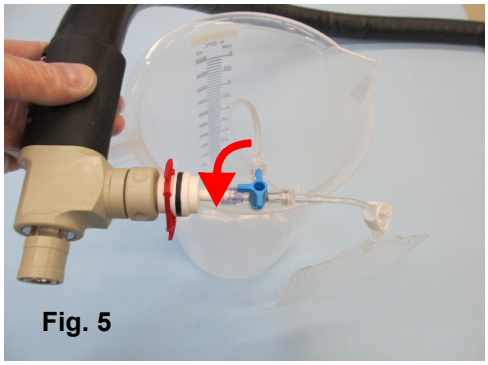
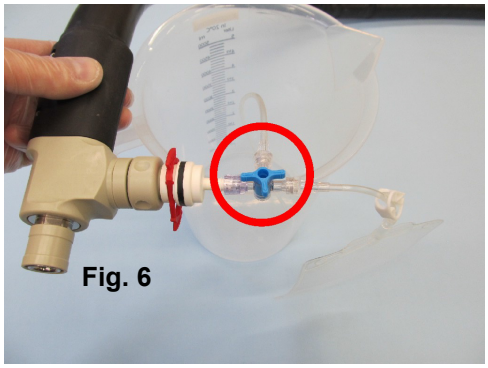
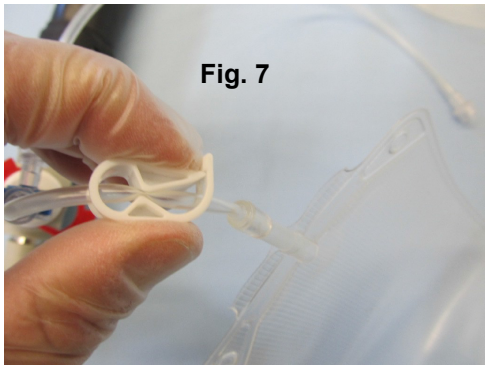
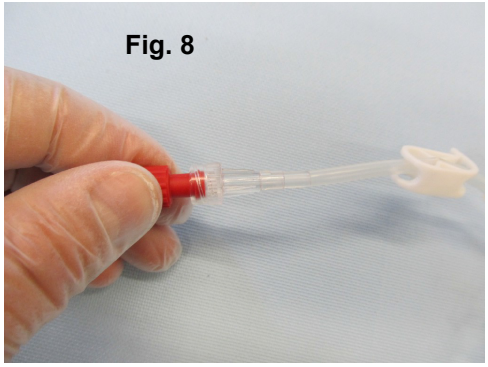
Image	Description
 Fig. 1	**Fig. 1 – disinfection:** ➢ Disinfect the sampling port with an alcohol-based disinfectant and, if necessary, remove any contamination with a sterile swab. ➢ Then repeat the disinfection procedure. **Caution:** **Ensure sufficient acting time of the disinfectant!**
 Fig. 2  Fig. 3	**Fig. 2 and 3:** ➢ Attach the sampling adapter (Fig. 2) and lock it with the clip (Fig. 3).
 Fig. 4	**Fig. 4:** ➢ Turn to open the sampling port. In this valve position, rinse the sampling port for at least 60 seconds.

Image	Description
 Fig. 5  Fig. 6	**Fig. 5 and 6:** ➢ Turn the multiway valve 90° (Fig. 5) and fill the bag in the position shown (Fig. 6). **Caution:** **Make sure to return the multiway valve in time to its original position to prevent bursting of the bag!**
 Fig. 7  Fig. 8	**Fig. 7 and 8:** ➢ Close the bag by pressing the clip together (Fig. 7) and screw on the end plug (Fig. 8). ➢ Gently squeeze the bag to check for any leaks. ➢ Affix the completed label on the bag and place it into the prepared transport box.

15.8 Determining total hardness and total chlorine

Warning

➢ Observe the Instructions for Use!

➢ Also observe the original instructions from the manufacturer of the test kits.

15.8.1 Determination of the total hardness

For determining the total hardness, the manufacturer recommends using:

Part no.	Description/illustration
	Hach Stericheck LR sens hardness strips (other hardness tests may also be used if a reliable result can be achieved)

Conversion table

°dH/ ppm $CaCO_3$	°e	°f	mg/L CaO	mg/L CaO_3	mmol/L
1/ 17.8	1.3	1.8	10	18	0.18
2/ 35.6	2.5	3.6	20	36	0.36
3/ 53.4	2.8	5.4	30	54	0.54
4/ 71.2	5.0	7.1	40	71	0.71
5/ 89.0	6.3	8.9	50	89	0.89
6/ 107	7.5	10.7	60	107	1.07
7/ 125	8.8	12.5	70	125	1.25
8/ 142	10.0	14.3	80	143	1.43
9/ 160	11.3	16.1	90	161	1.61
10/ 178	12.5	17.8	100	178	1.78

15.8.2 Total chlorine concentration

For determining the total chlorine concentration, the manufacturer recommends using:

Part no.	Description/illustration
	RPC k100?0118F test strips

15.8.2.1 Sampling ports for water hardness and total chlorine

The sample is collected to determine the water hardness and/or the total chlorine.

Image	Description
Figure: AquaC CART US sampling port  Figure: AquaC CART Small sampling port 	**Collecting the sample:** ➢ Place a collection jug under the sampling port. ➢ The sample is collected at the sampling port upstream of the filter. ➢ Open the sampling port and discard the fluid flowing from the port for **approx. 5 seconds**. ➢ Follow the measuring procedure as described in the instructions included with the test kits. ➢ After filling the jug, close the sampling port.

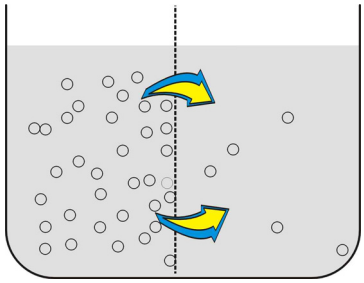
15.9 Physical background – diffusion/osmosis

Diffusion and osmosis are purely physical processes taking place in every living cell.

If identical solutions with different concentration are separated by a semipermeable membrane, the concentrations of the solutions have the tendency to equalize. This happens by way of two different processes:

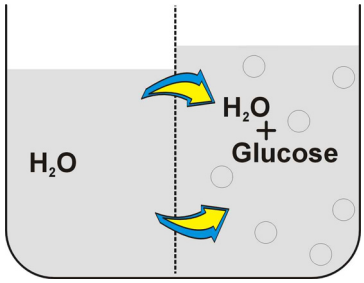
1. Diffusion

Solutes in a fluid move from the area of higher concentration to the area of lower concentration.



2. Osmosis

The solvent moves from the area of lower concentration to the area of higher concentration until equilibrium is reached. The fluid level in the compartment of the solution with the higher concentration rises. The difference between these levels corresponds to a static pressure, which is called osmotic pressure.



The phenomenon of osmosis can be reversed by applying a pressure, which is higher than the osmotic pressure, to the solution with the higher concentration. This action causes water molecules to pass through the membrane to the area of lower concentration. This increases the concentration in the area of higher concentration and further dilutes the solution in the area of lower concentration. Reverse osmosis is based on this principle.

There are numerous applications for reverse osmosis. In dialysis it permits environmentally compatible and economical production of deionized water – known as permeate.