AquaBplus
Water Purification System

Instructions for Use

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2 Important information

2.1 How to use the Instructions for Use

Identification

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

Footer

The footer contains the following information:
- Company name, e.g., Fresenius Medical Care
- 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, e.g., 4/03.11 means, 4th edition, March 2011
- 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.

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 information necessary for the use of the device.
The Instructions for Use must be carefully studied before operational qualification of the device.

Changes

Changes to documents will be released as new editions or supplements. In general, this manual is subject to change without notice.

Reproduction

2.2 Significance of warnings

Advises the operator that serious or even fatal personal injury can occur if the indicated measures for preventing the danger are not followed.

Warning

Type and cause of danger

Possible consequences when danger is present.

➢ Measures for preventing the danger.

The warnings may differ from the above model in the following cases:

– If a warning alerts the operator to multiple dangers.

– If it is not possible to link the warning to any specific dangers.

2.3 Significance of notes

Note

Advises the operator that failure to observe this information can result in the following:

– Damage to the system

– Specific functions not being executed or not being executed correctly

2.4 Significance of tips

Tip

Information providing useful tips for easy handling.

2.5 Brief description

The **AquaBplus** water purification system includes four models:

– **AquaBplus**

– **AquaBplus** + **AquaBplus B2**

– **AquaBplus** + **AquaBplus HF**

– **AquaBplus** + **AquaBplus B2** + **AquaBplus HF**

The main device is the **AquaBplus** reverse osmosis. The other modules **AquaBplus B2** and **AquaBplus HF** are described in chapter 14 Modules and Options.

The device reflects the latest state of technology. It is equipped with all safety systems required for its function and for patient safety. It complies with the requirements of IEC 60601-1:2005.

The device is classified as class IIb (MDD) equipment / device class 2 (21CFR 876.5665).

The **AquaBplus** is a reverse osmosis system which can be extended by the responsible organization with additional components to a complete system for the production and supply of permeate.

The reverse osmosis system uses pretreated soft water for the production of highly deionized water, also called permeate.

If necessary, additional modules can be connected downstream for improved quality. The product water can be used for dialysis treatments or for the production of concentrates.

Caution:

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

2.6 Intended use

2.6.1 Scope of application

The **AquaBplus** Water Purification Systems are reverse osmosis units intended for use with hemodialysis systems to remove organic and inorganic substances and microbial contaminants from the water used for treating hemodialysis patients or other related therapies. These devices are intended to be a component in a complete water purification system, and are not complete water treatment systems.

Each 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/ISO and Federal (U.S.) standards.

2.6.2 Residual risks

Operating the system

All instructions and operating steps in the Instructions for Use must be carried out completely and conscientiously. The system may only be operated by persons who have received the necessary training.

Use of non-specified disinfectant

Do not use other disinfectants than those described.

Recommended disinfectants:
Puristeril 340

Alternatives:
Appropriate peracetic acid solution for use on reverse osmosis membranes. (e.g. Minncare Cold Sterilant)

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

Microbiological monitoring

Monitoring of the complete system (especially the permeate and permeate ring main) for microbiological contamination at regular intervals is recommended. Appropriate cleaning and disinfection measures must be taken.

2.6.3 Target group

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

2.6.4 Repair, maintenance, transport

Operational qualification, expansions, adjustments, calibration, maintenance procedures, modifications or repairs may only be carried out by the manufacturer or manufacturer-authorized persons.

For performing the Technical Safety Checks and the maintenance procedures, contact the local service.

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

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

2.6.5 Expected service life

If the TSC are performed to the specified extend changes and at the specified intervals, safe operation of the device in the time between the TSC procedures is ensured.
In addition to these procedures, the manufacturer recommends to perform the maintenance procedures at the same intervals to prevent a malfunction of the device caused by wear.
The expected service life is 10 years.

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.
– correct and safe condition of the device.
– availability of the Instructions for Use at all times.

2.7.1 Further aspects of the responsible organization

- The system is a unit designed to improve permeate conductivity and can be extended by the responsible organization with additional components to form a complete water treatment system for use in a dialysis unit. The system must be installed in a dry room which is not used for medical procedures. The staff call feature should also be enabled.
- The responsible organization must ensure that the technical design of the system matches the requirements of the other components used to make up the complete system.
- The reverse osmosis system must be easily accessible from all sides. The responsible organization must prepare a plan for emergency operation of dialysis devices based on the available system components and must make this plan available to the operators of the system.
- The responsible organization must ensure that its operators have been trained. Operators of the reverse osmosis system and the dialysis devices must have received instructions on how to operate the system.
- The responsible organization should inform the local water supplier of the dialysis operation and insist on prior discussion with regards to 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 reverse osmosis system depends on the individual components, and the type and time of use. Bacterial growth in the system must be prevented by continuous operation of the system with a minimum of idle times and by preventive measures such as chemical disinfection or heat disinfection.
- Samples for microbial testing must therefore be collected from the system and from the individual parts of the system in accordance with the applicable regulations. As the complete system consists of a number of smaller systems, the responsible organization is responsible for the complete system.
- The key required to open the door to the control cabinet must be kept in a secure location, access to the key must be restricted to trained personal responsible for the system.

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, 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 specified operating conditions.

2.9 Disclaimer of liability

Warning

The device has been approved for use with certain consumables and accessories (see Chapter 8 on page 8-1). Should the responsible organization wish to use other consumables and accessories than those listed in this chapter, the suitability must be checked beforehand by gathering the appropriate manufacturer information.
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 device will void the warranty.

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

Adherence to required operating conditions

The **AquaBplus** may only be operated under the specified operating conditions:

- Appropriate water pretreatment in accordance with the specified inlet requirements is required.
- The control unit must be protected from humidity (water spray, condensation water, etc.) and moisture.
- In the event of a defect of the control unit, the type of problem (nature of the improper operation) should be recorded before disassembling the system. A disassembled system can only be repaired if a detailed description of the problem is available.
- The total output (rated output) of the reverse osmosis system must not be exceeded.
- The device may only be operated by individuals who have been instructed in the proper operation and handling of the device.
- Operational qualification of the device must be performed by a trained technician.
- Appropriate pipe fittings must be provided to ensure that the soft water inlet side is protected against a water inlet pressure of 10 bar.
- Use only the membranes installed by the manufacturer. Replacing the membrane unit by membrane units not expressly authorized by the manufacturer is not permitted.

Warning

Device safety

A system change / modification is not permitted and may cause patient / personal injury and damage to buildings.

Warning

Observe authorisation requirement

The system may only be operated and repaired by trained personnel!

Warning

Operator restrictions

Access to the **AquaBplus** reverse osmosis system must be restricted to authorized staff.

Warning

Responsible organization

The responsible organization must ensure that the Technical Safety Checks (TSC) are performed.

The selection of a water treatment system for dialysis is the operator's responsibility. The water produced must be regularly tested.

Warning

TSC procedure

The Technical Safety Checks / maintenance procedures (local service) for this device must be carried out at least once every **24 months**.

The measurements may only be performed by skilled technicians with electrical, system-related and medical/technical knowledge.

Warning

Regular checks

Damage / injury caused by leaking fluid

➢ It is recommended that regular visual inspections and checks for leaks be performed on all **AquaBplus** tubing, connectors, and piping that contain fluid. (Frequency to be determined by the facility)

➢ Tubing must be protected against possible mechanical damage.

Warning

Adherence to applicable laws and regulations

Observe the applicable local laws and regulations concerning the handling of laboratory equipment and reagents.

Warning

Risk of burning by hot surface

➢ **Do not touch** the system components while heat disinfection is in progress.

Warning

Risk of injury caused by explosions

Do not use this device in explosive or flammable environment!

Warning

To avoid severe damage to property:

– The room where the reverse osmosis system is operated must have a floor drain.

– A leakage detector must be installed.

– Use of a sealed floor covering, which is resistant to deionized water, is recommended.

Note

Materials to be used

The material used for the downstream tubing must be of food-grade quality, suitable for drinking water, and must be sufficiently resistant to deionized water.

Note

To prevent damage to the dialysis clinic of hours (unattended times without staff present) caused by water leaks, a leakage monitoring system such as the **AquaDETECTOR** with leakage sensors should be installed in all appropriate rooms with water connections.

If no leakage monitoring system is installed, it is recommended that all supply tubes be disconnected from the ring main of hours (unattended times without staff).

2.11.2 Warnings related to hygiene and biology

Warning

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

➢ Be careful when handling acidic fluids and do not spill any disinfectant concentrate.

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

➢ Wear protective 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 authorisation requirement

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

Warning

Risk of infection

Observe the applicable local laws and regulations concerning the handling of potentially infectious material.

Warning

Danger caused by return contamination

The device's drain must be connected to a free outlet in order to prevent the possibility of return contamination.

2.11.3 Electrical warning

Warning

Danger to life caused by electrical voltage

Touching live parts will cause an electric shock.

➢ Before opening the device, it must be disconnected from the power supply and Locked out to prevent the device from restarting. Operating the **ON / OFF** switch stops operation of the device, but does not disconnect the device from the supply voltage!

Warning

Guidelines for connecting to the power supply system

➢ The national standards and regulations must be observed when connecting the device to the power supply system.

➢ Do not use any additional extension cords, multiway plugs / connectors or multiway sockets.

2.12 Addresses

Manufacturer

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

International service

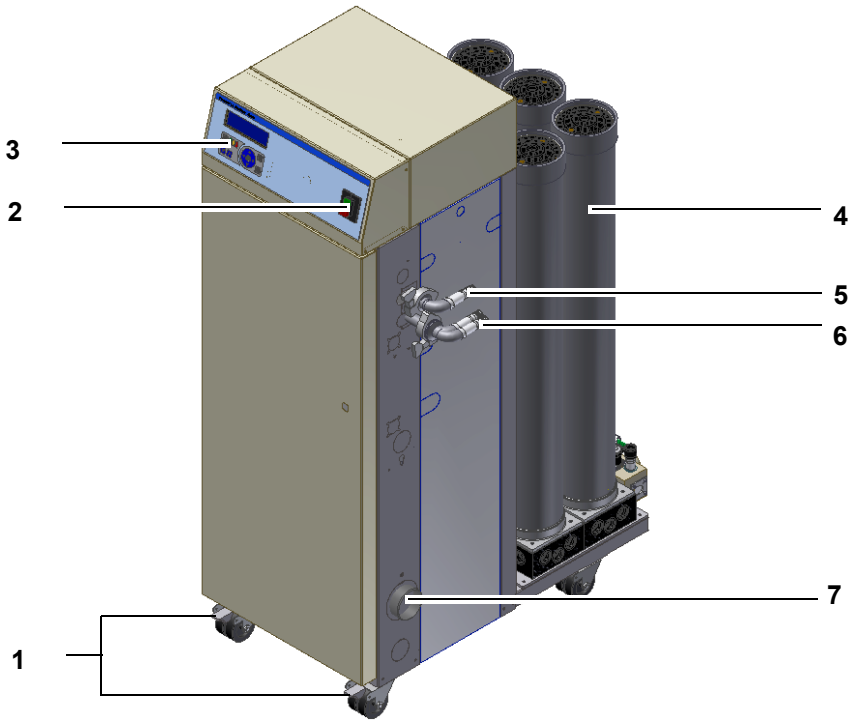
Vivonic GmbH
Technical Customer Service / Support
Kurfuerst-Eppstein-Ring 4
D-63877Sailauf
Phone: +49 (0)6093 9713-23
Fax: +49 (0)6093 9713-214

Local service

3 Design

3.1 Views

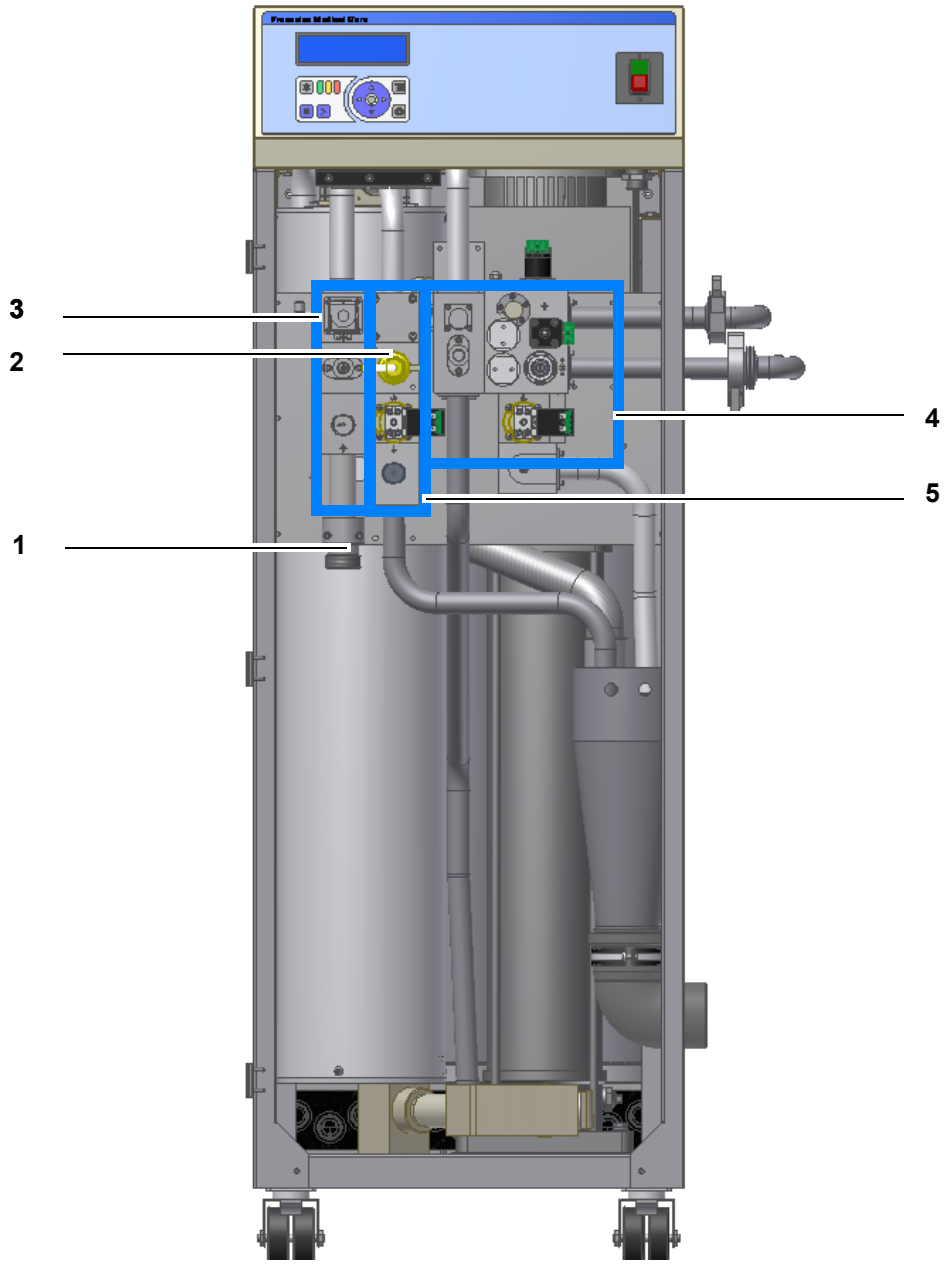
3.1.1 Complete system



Legend

Components	
1	Castor rollers with parking brake
2	Main power switch **ON / OFF**
3	User interface (display and control keys)
4	Pressure tubes
5	Ring return
6	Permeate Outlet to Ring
7	Drain

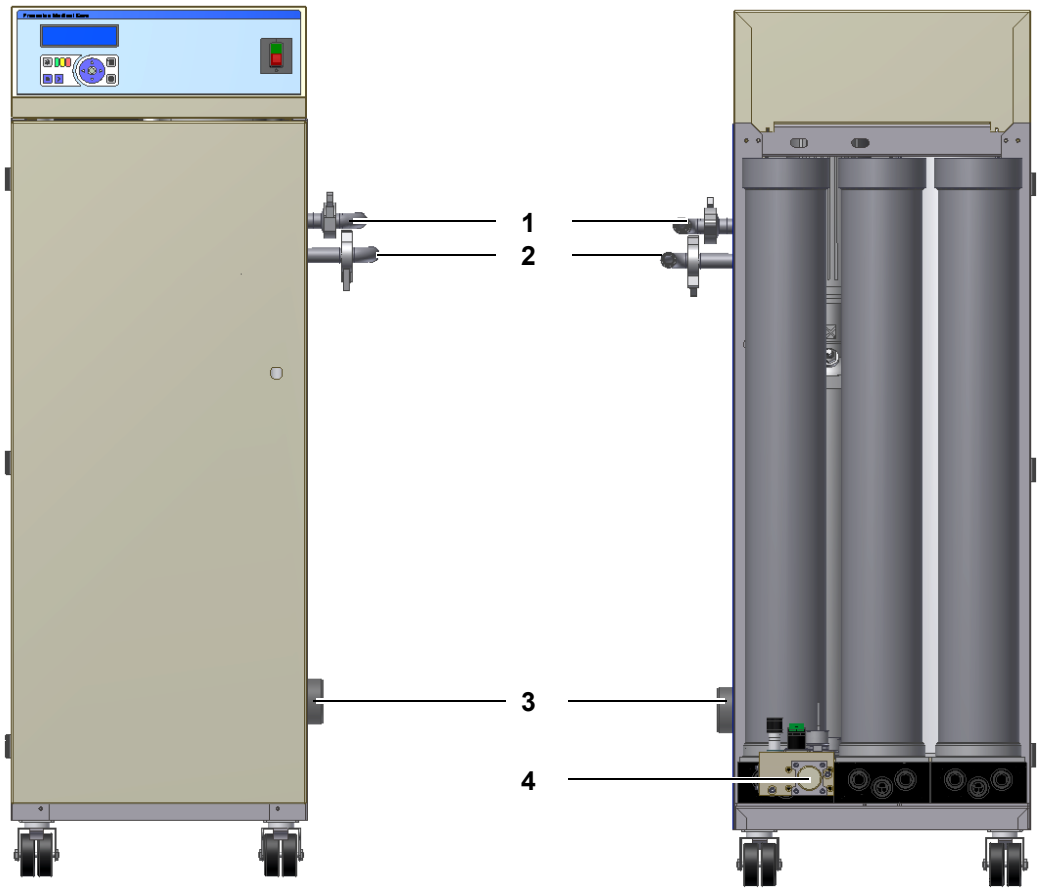
3.1.2 Interior (front)



Legend

Components	
1	Soft water inlet
2	Disinfection connector
3	Soft water inlet path
4	Permeate path
5	Concentrate path

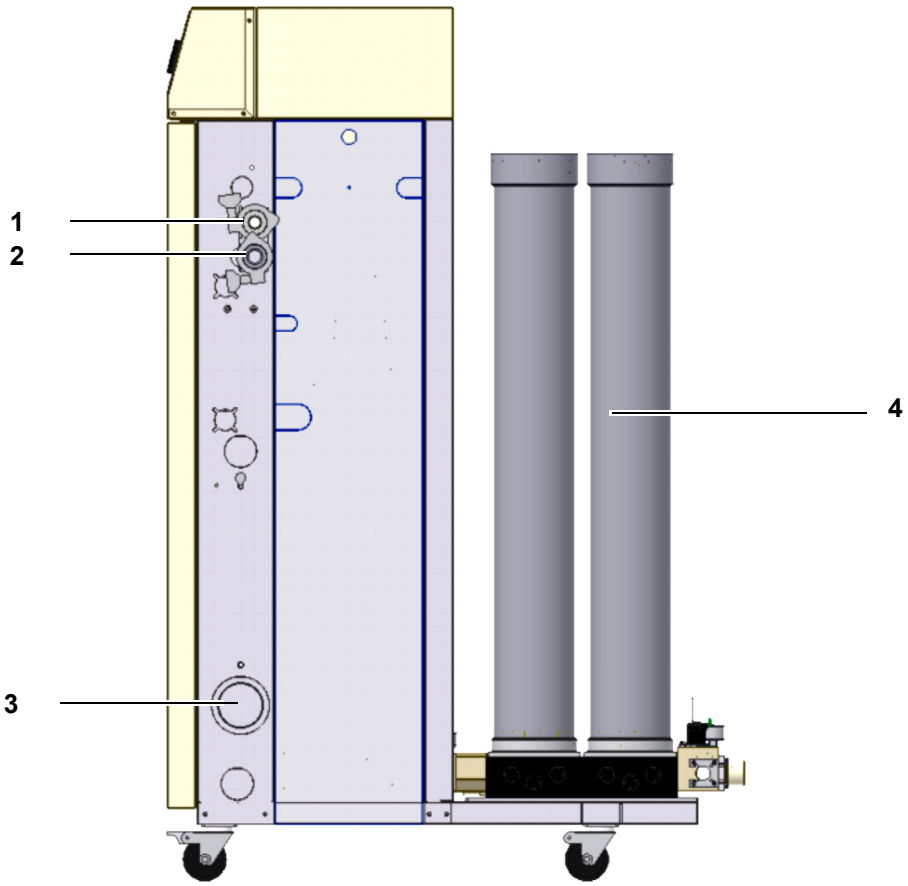
3.1.3 Front view / rear view



Legend

Components	
1	Ring Return
2	Permeate Outlet to Ring
3	Drain
4	Concentrate pressure valve

3.1.4 Side view

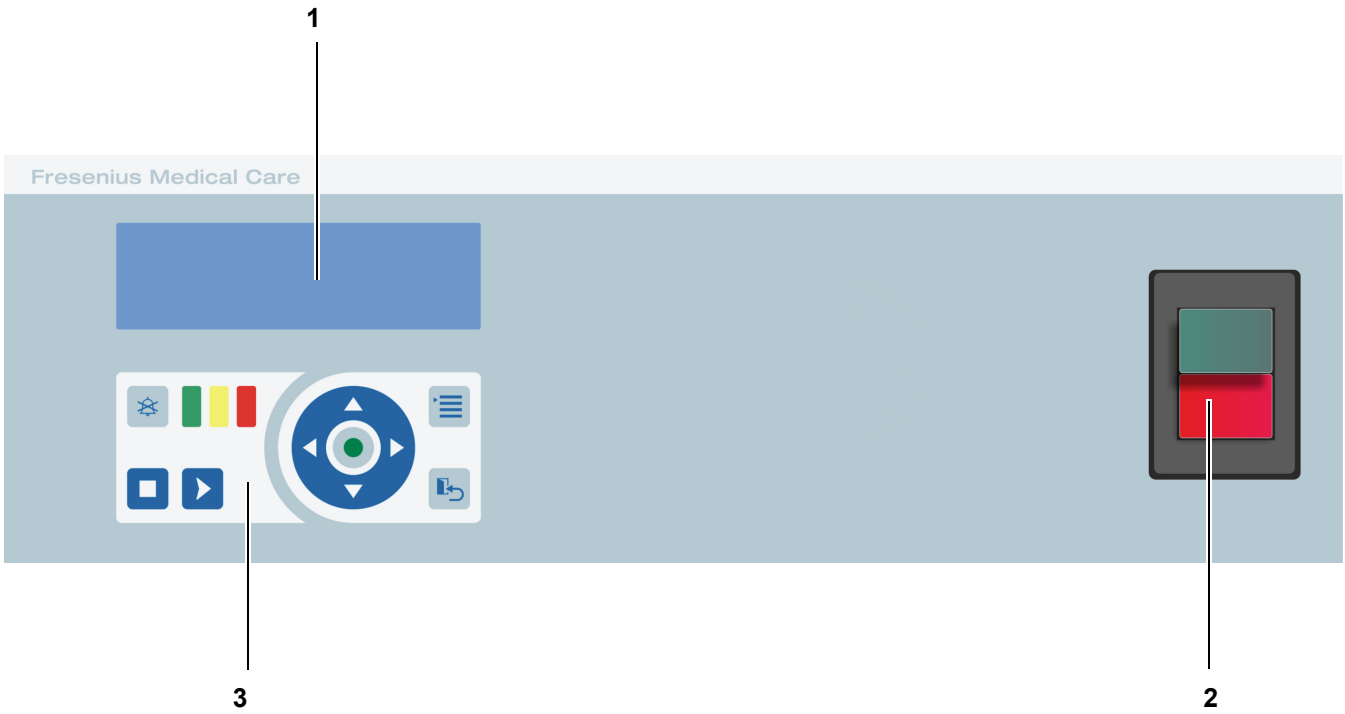


Legend

Components	
1	Ring Return
2	Permeate Outlet to Ring
3	Drain
4	Pressure tubes

3.2 Controls and indicators

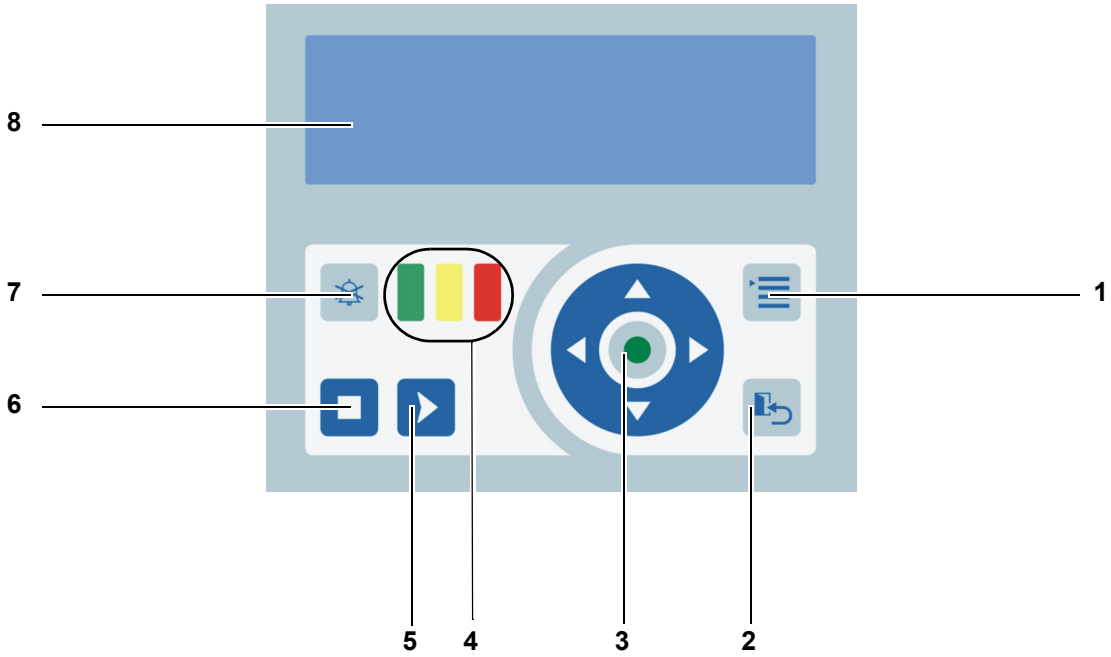
3.2.1 User interface and display



Legend

Pos.	Components
1	Display
2	Main power switch **ON / OFF**
3	Keys and visual indicators

3.2.2 Display / keys



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 indicate the current system status. Each color indicates a specific status:

Status Visual indicator	Description
Off	The **AquaBplus** is in **STANDBY** or is performing a cleaning / disinfection program.
Green	The system is in **SUPPLY** mode.
Yellow	A T1 test is in progress or a warning has occurred.
Red, flashing	An alarm or a malfunction has occurred.

Start key

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

Stop key

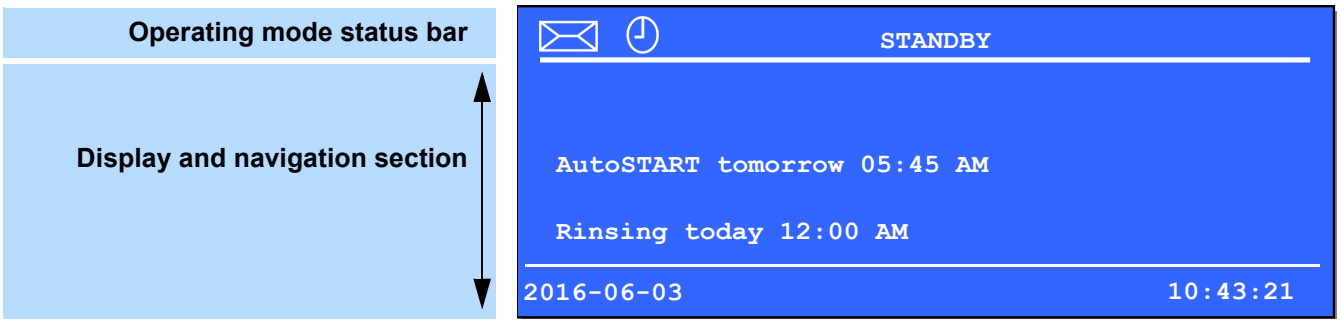
The quick access **Stop** key is used to terminate the program currently in progress.

Mute key

The quick access **Mute** key is used to silence an audible alarm for 3 minutes. After 3 minutes the audible signal will be reactivated.

Display

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



Operating mode status bar

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

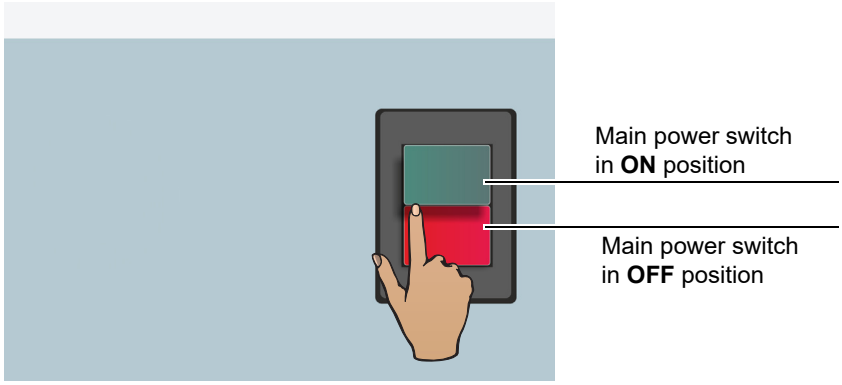
Symbol	Description
	Messages are available (see **STATUS – Messages** on page 4-14)
	This symbol indicates that an autostart timer is active.

4 Operation

4.1 System status STANDBY

4.1.1 Turning the system ON

➢ The system is turned on with the main power switch (**ON** position).



Note

Waiting period for turn on of the main power switch

To avoid thermal overload of the main power switch, the user has to wait of at least 120 seconds (2 minutes) until the **AquaBplus** is turned on again.

4.1.2 Turning the system OFF

➢ The system is turned of with the main power switch (**OFF** position).

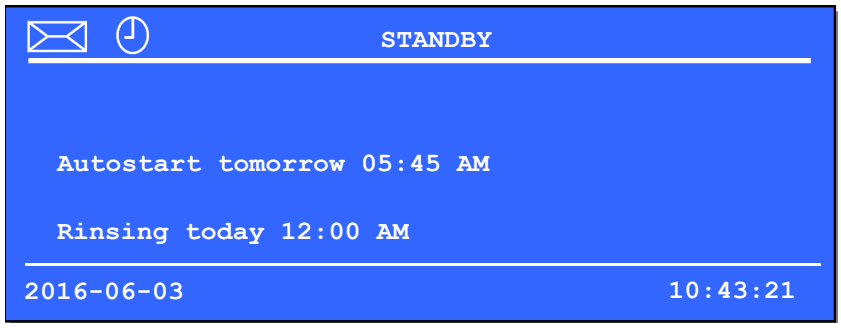
4.2 Operating modes and display messages / overview

The **AquaBplus** has the following operating modes:

Operating modes
STANDBY
SUPPLY
RINSE
DISINFECTION
EMERGENCY MODE (option)
HEAT DISINFECTION (option)

4.3 STANDBY mode

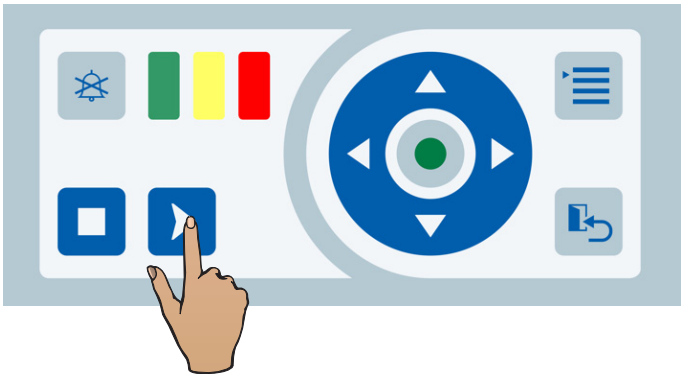
After turning the **AquaBplus** on, the display will switch to the **STANDBY** mode.



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).

4.4 SUPPLY mode

4.4.1 Starting the SUPPLY mode



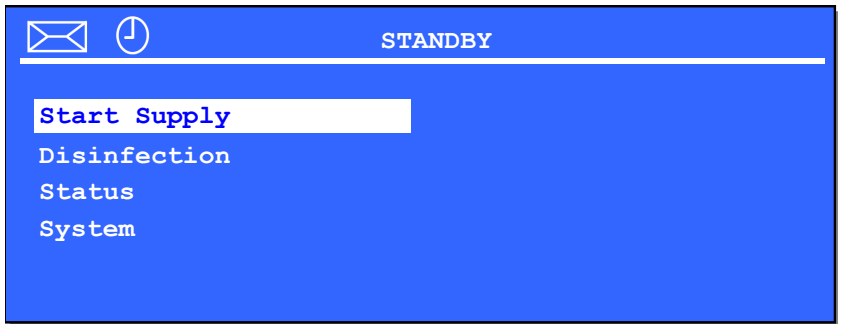
➢ Press and hold the **Start** key for **two seconds**.

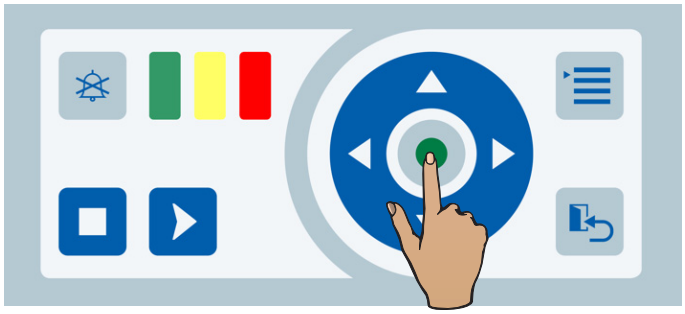
4.4.2 Terminating the SUPPLY mode

➢ Press and hold the **Stop** key for **two seconds**.

4.4.3 Operation using the Navigation keys

The **SUPPLY** mode can be started and stopped with the **Start** and **Stop** keys and also **from the main menu**.





➢ Use the **Navigation** keys to select the option **Start Supply** and press the **Enter** key for **two seconds**.

The start is confirmed by an audible signal.

➢ To stop the **SUPPLY** mode, use the **Navigation** keys to select the option **Terminate Supply** and press the **Enter** key for two seconds.

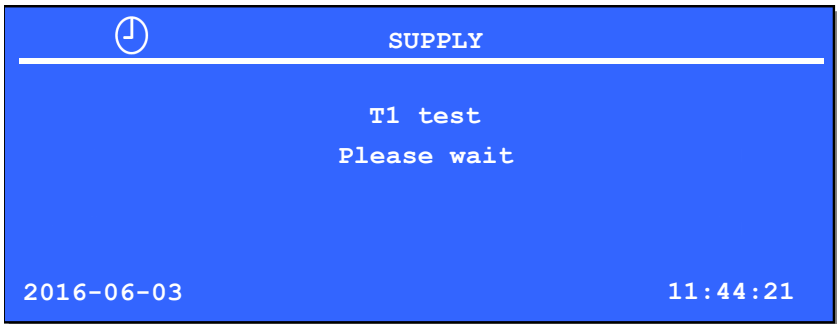
4.4.4 Automatic start of the SUPPLY mode

The system is able to switch automatically to the **SUPPLY** mode if one or more of the following functions has been activated.

- **Autostart**
- **Tank control**
- **HOTfeed**

4.4.5 T1 test

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

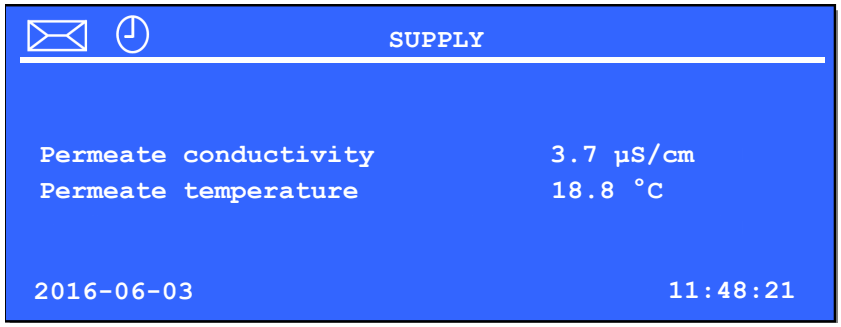


During the **T1 test**, safety-relevant components will be checked for correct function. Depending on the capacity and features of the **AquaBplus**, the test will take between 1 and 3 minutes.

The T1 test checks the safety-relevant components of the reverse osmosis system.

4.4.6 Permeate conductivity and temperature monitoring in SUPPLY

In **SUPPLY** mode, the **AquaBplus** reverse osmosis system produces permeate. In this mode the system controls the effective yield and monitors all relevant parameters.



Tip

➢ When pressing the **Up** (▲) or **Down** (▼) navigation keys, the operating data screen will be displayed.

It provides an overview of all important parameters which can be displayed.

- **Permeate conductivity and temperature monitoring**

If the conductivity or temperature alarm limit is exceeded, the permeate supply will be terminated by closing of the permeate flow valve. The permeate flow valve is part of the RingBase option.

If no RingBase is installed, an alarm will be generated. The effective yield control is deactivated during this time.

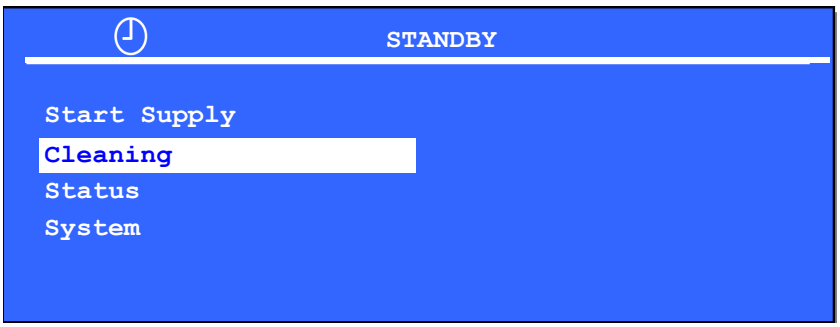
Note

➢ If the **AquaBplus** is operated continuously, it must be switched at least once a day from **SUPPLY** to **STANDBY** (and back) to run the T1 test.

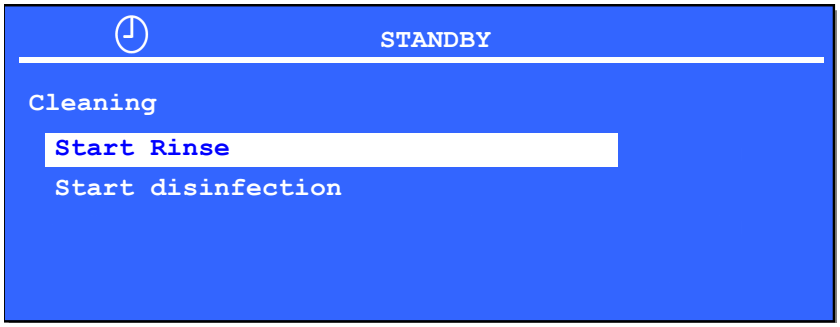
4.5 RINSE mode

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

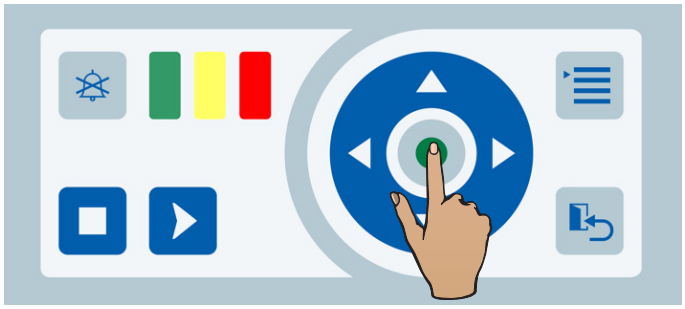
4.5.1 Manually starting the rinse program



➢ To access the **Cleaning** menu, press the **Menu** key, then confirm **Cleaning**.



➢ Select the **Start Rinse** program.



➢ Press the **Enter** key.

Rinse starts.

The system will switch to the **RINSE** mode. Prior to the rinse program, the system will perform a self-test (just as before **SUPPLY**).

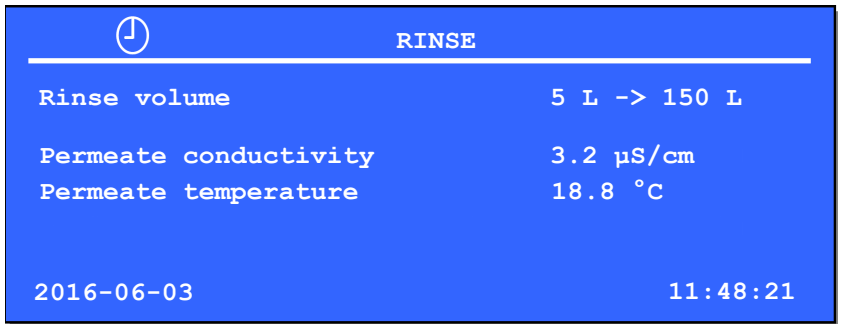
4.5.2 RINSE active

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 will be displayed:

- **the currently rinsed volume**
- **the target volume**
- **the permeate conductivity**
- **the permeate temperature**

The permeate to be discarded flows via the ring main drain valve (provided the RingBase option is installed) and the concentrate flows via the drain valve to the drain.



4.6 EMERGENCY MODE (option)

4.6.1 General information

Warning

Emergency mode (option) after a disinfection

The **EMERGENCY MODE** may not be started if there is still residual disinfectant in the system after a disinfection.

Note

The **EMERGENCY MODE** (option) can be started without any previous preparation and from any operating mode of the system.

4.6.2 Starting the emergency mode (option) on the AquaBplus

Note

The **EMERGENCY MODE** (option) in combination with the **AquaBplus B2** option is described in detail in Chapter 14 / Options (see Chapter 14.1.10 on page 14-6).

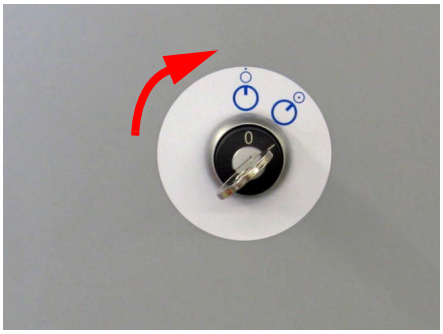
Tip

Using the emergency mode function by means of the key switch

If operation is impossible due to a defect, the emergency mode can be started with the key switch.

Key switch in original position

➢ The **key switch** is located on the front of the housing.



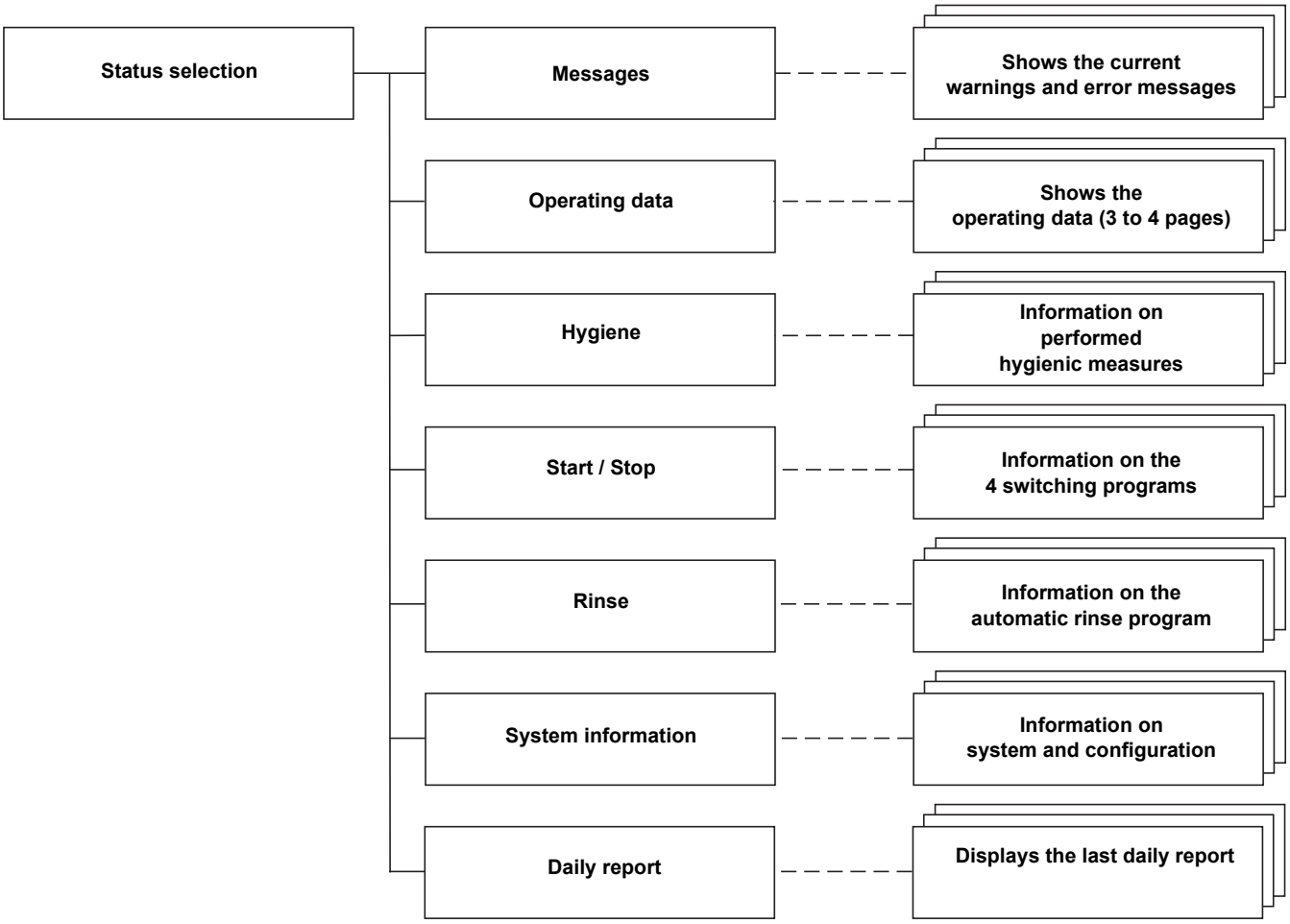
Key switch in emergency mode

➢ The **EMERGENCY MODE** can be started by turning the **key switch** clockwise.

4.7 STATUS – menu

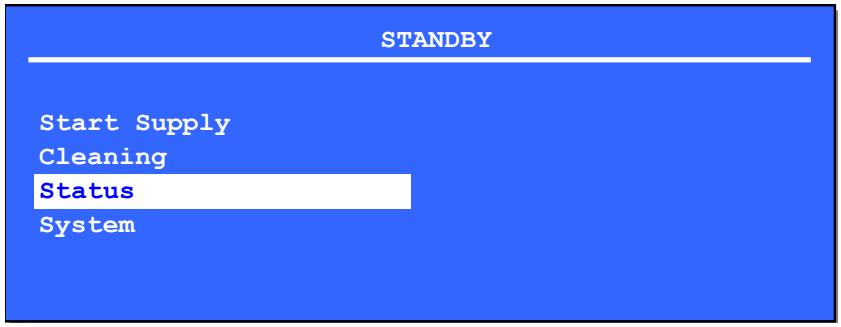
No settings can be made in the **Status – menu**. This menu is only provided to display information.

4.7.1 Menu structures overview

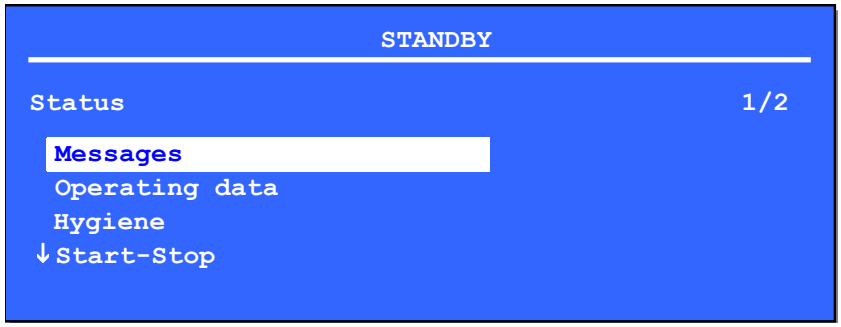


4.7.2 Opening the Status menu

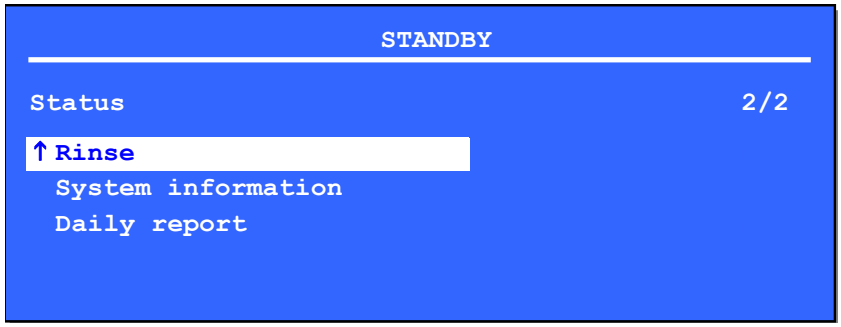
Pressing the **Menu** key will display the main menu. When selecting the menu option **Status** and confirming the selection with the **Enter** key, the **Status** menu will be opened.



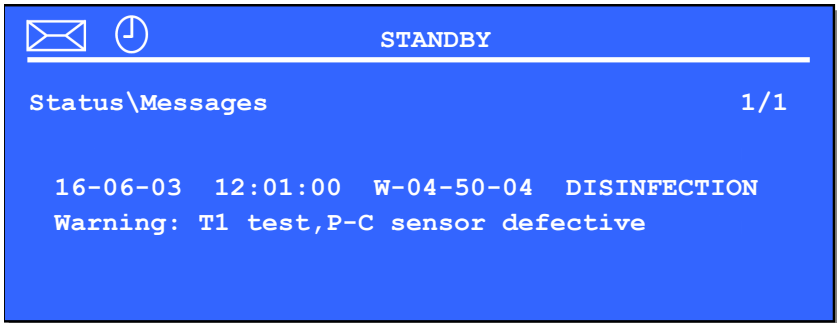
Page 1/2



Page 2/2

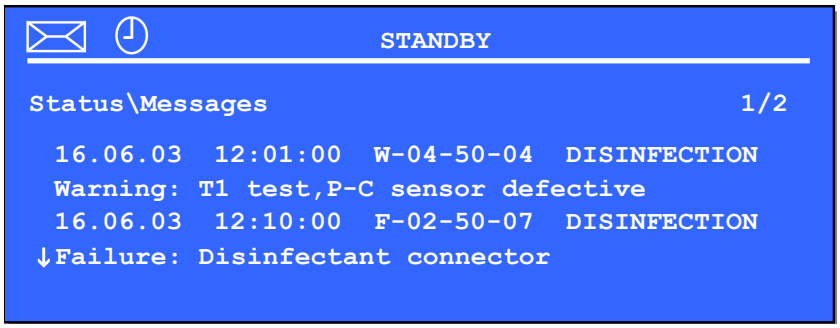


4.7.3 STATUS – Messages



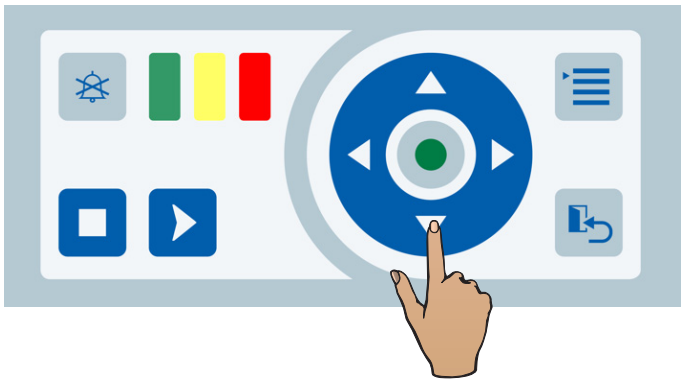
The occurring messages (failures, alarms) are displayed in chronological order.

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 existing pages.

Tip

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

4.7.4 STATUS – Operating data

Description page 1/3

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Permeate conductivity	CD-P	0.0 to 2500	µS/cm	±10 %
Permeate temperature	T-P	0.0 to 115.0	°C	±1°C
Soft water conductivity	CD-F	0.0 to 2500	µS/cm	±10 %
Soft water temperature	T-F	0.0 to 115.0	°C	±1°C

Description page 2/3

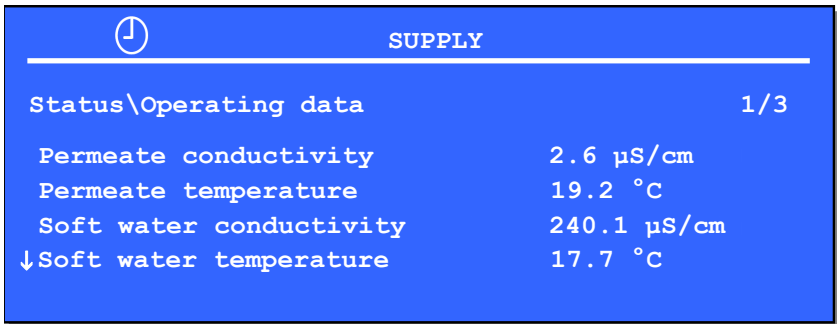
Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Soft water supply	FL-F	4.0 to 160	L/min	±10 %
Permeate consumption	FL-P	4.0 to 160	L/min	±10 %
Effective yield		55 to 75	%	±10 %
Rejection rate		0.0 to 99.9	%	- - -

Description page 3/3

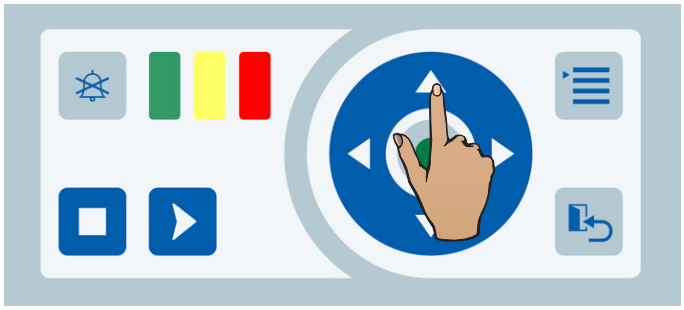
Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Concentrate pressure	P-C	0.0 to 20	bar	±10 %
Concentrate flow	FL-C	4.0 to 160	L/min	±10 %

4.7.4.1 Viewing the operating data

Page 1/3



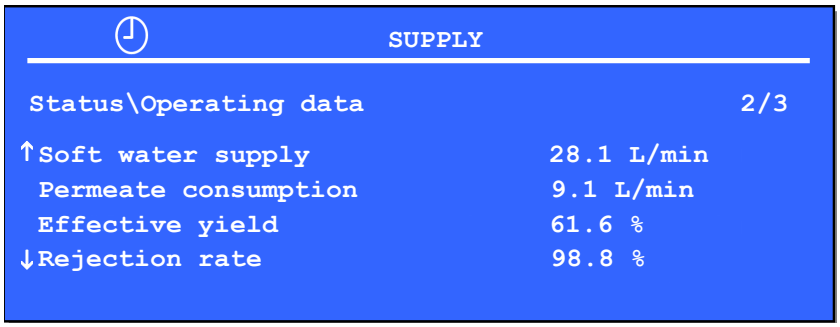
This screen shows the current system operating data (see Chapter 4.7.4 on page 4-15).



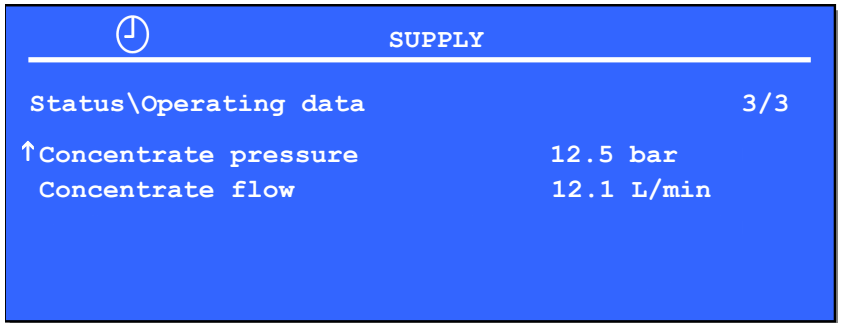
The operating data are shown over 3 consecutive screen pages.

➢ The different pages can be selected by pressing the **Up** (▲) or **Down** (▼) navigation keys.

Page 2/3

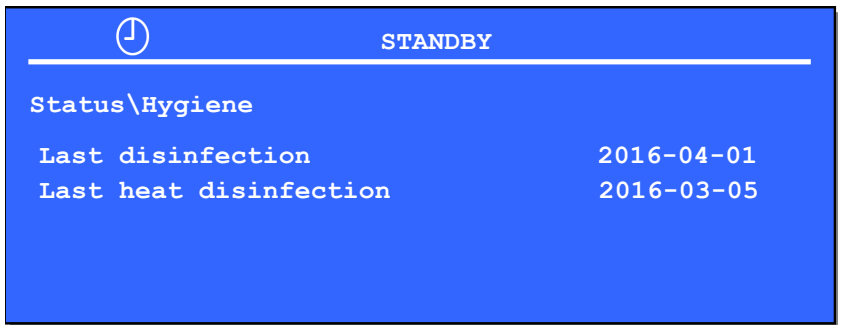


Page 3/3



4.7.5 STATUS – Hygiene

The **Status** – **Hygiene** screen shows the date of the last disinfection or ring heat disinfection (if the **AquaBplus HF** option is installed).

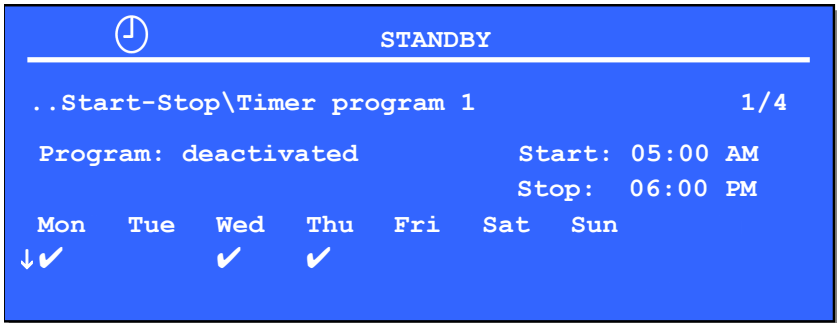


4.7.6 STATUS – Start / stop

Four timers for the SUPPLY mode

The **AquaBplus** has four timers for the **SUPPLY** mode. All four timers work independently.

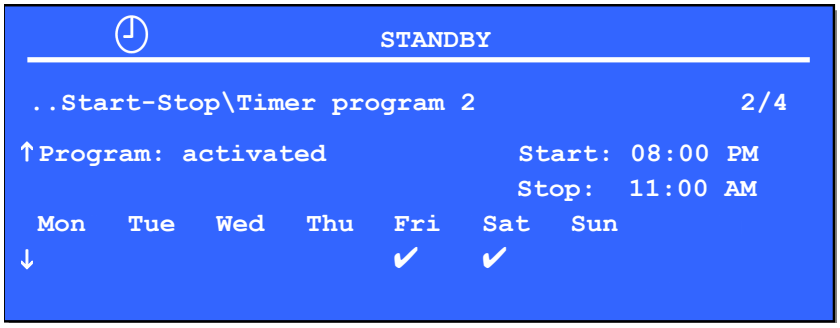
Page 1/4



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

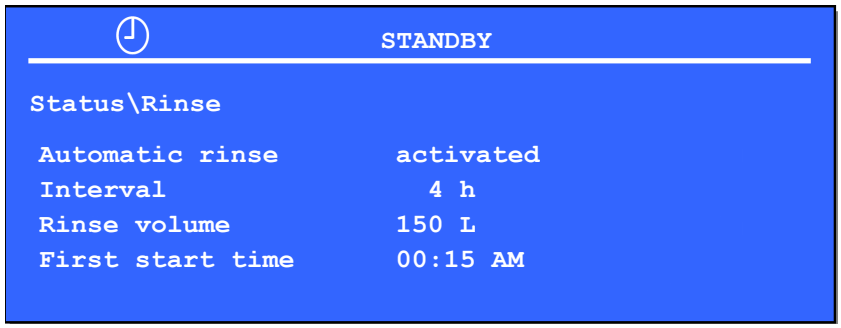


Next to the message **Program:** it is indicated if the respective program has been **activated / deactivated**.

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

4.7.7 STATUS – Rinse

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

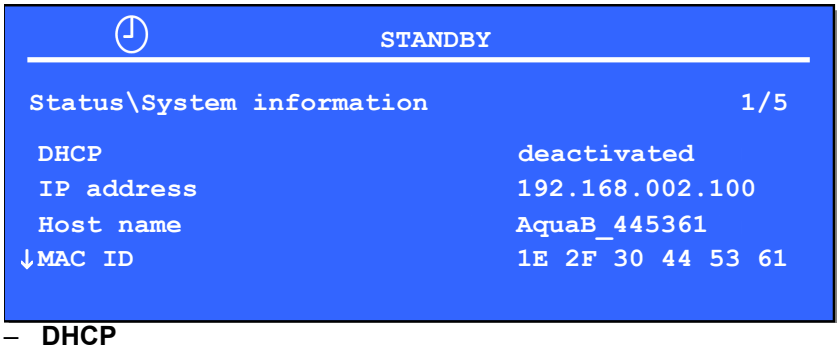


4.7.8 STATUS – System information

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

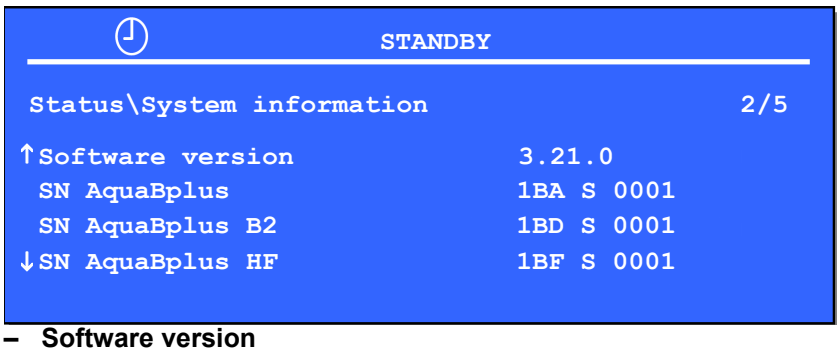
The following system information is displayed:

Page 1/5



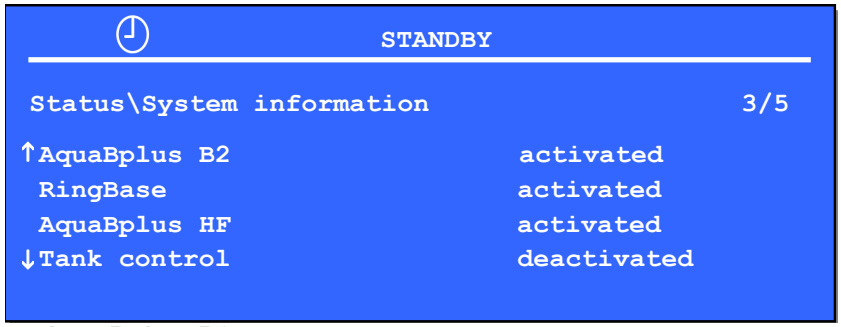
- **DHCP**
  [activated or deactivated]
- **IP address**
- **Host name**
- **MAC-ID**
  [The MAC address (Media Access Control address) is the hardware address for each network adapter which is used for unique identification of the system in a PC network.]

Page 2/5



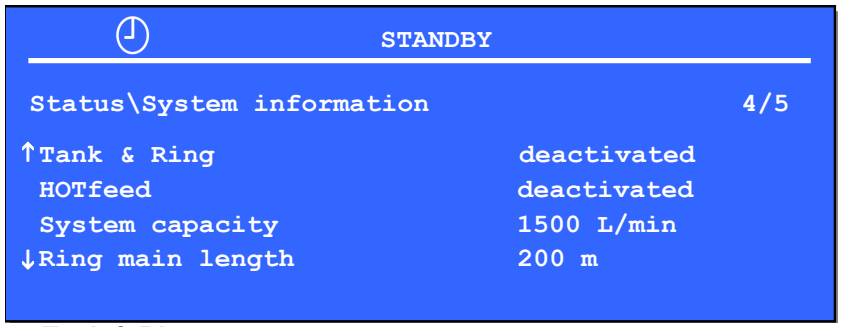
- **Software version**
- **AquaBplus serial number**
- **AquaBplus B2 serial number**
- **AquaBplus HF serial number**

Page 3/5



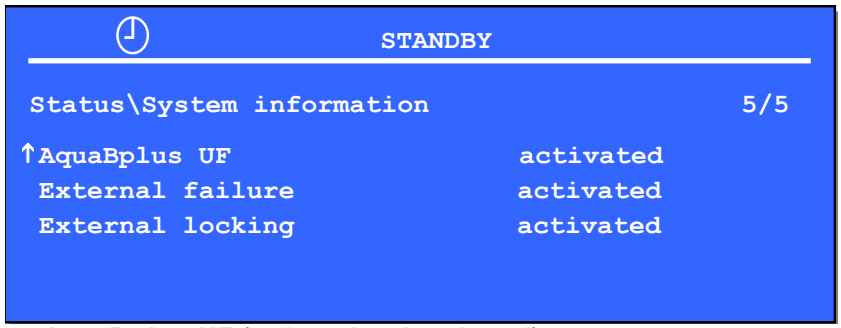
- **AquaBplus B2**
  [activated or deactivated]
- **RingBase**
  [activated or deactivated]
- **AquaBplus HF**
  [activated or deactivated]
- **Tank control**
  [activated or deactivated]

Page 4/5



- **Tank & Ring**
  [activated or deactivated]
- **HOTfeed**
  [activated or deactivated]
- **System capacity:** 500 to 3000 L/h
- **Ring main length:** 50 to 950 m

Page 5/5



- **AquaB*plus* UF** (activated or deactivated)
- **External failure** (activated or deactivated)
- **External locking** (activated or deactivated)

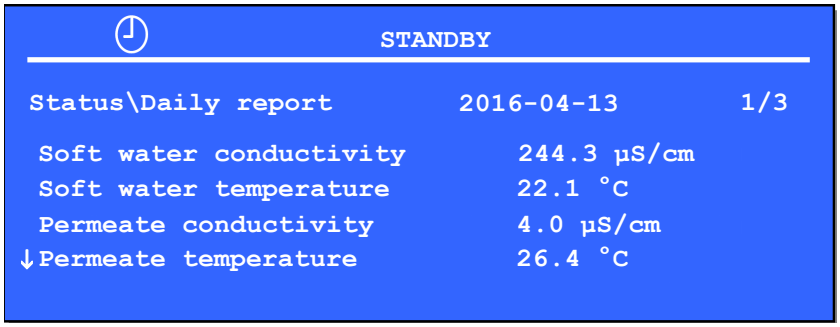
4.7.9 STATUS – Daily report

The **STATUS\Daily report** menu shows the last daily report that was saved.

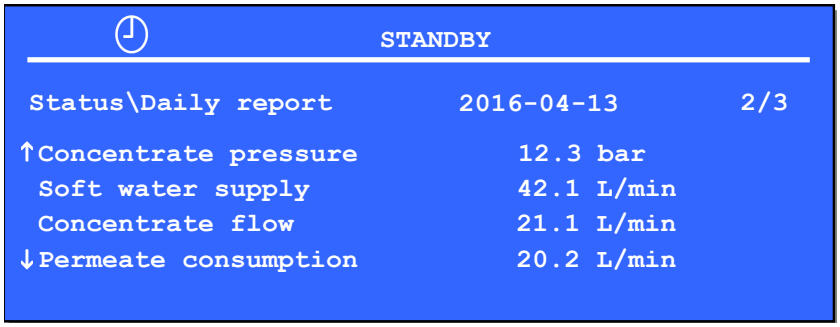
Tip

The time when the report is to be saved can be set in the **System\ Reports** menu.

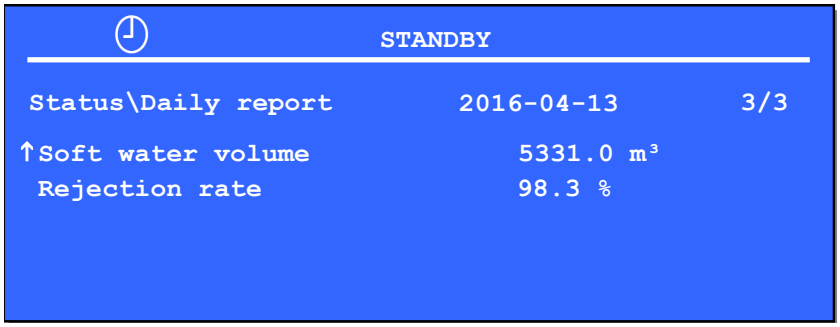
Page 1/3



Page 2/3

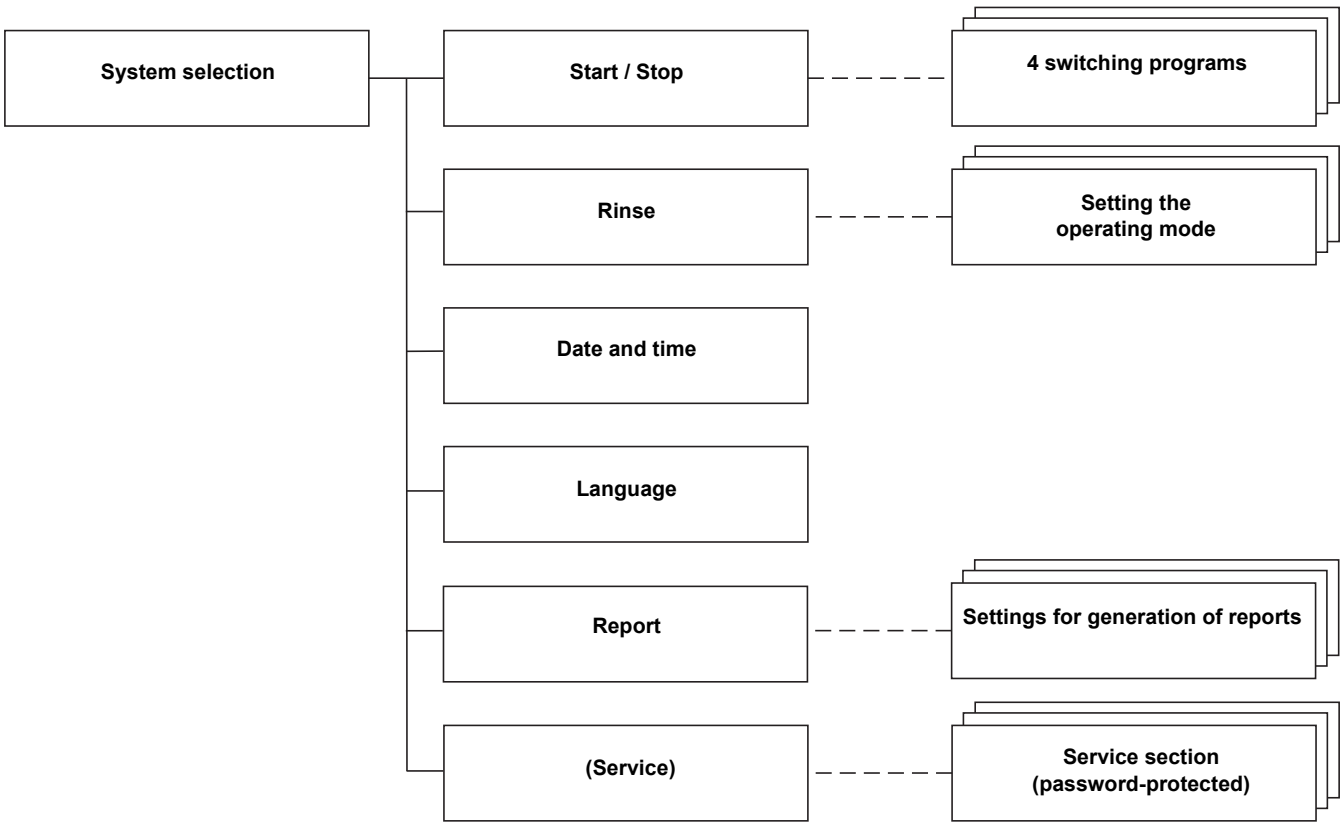


Page 3/3

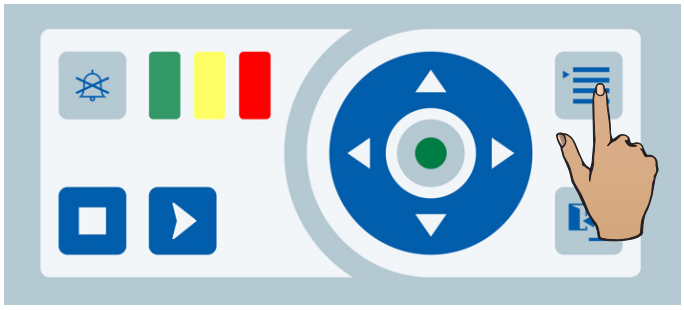


4.8 SYSTEM – Menu

4.8.1 Menu structures overview

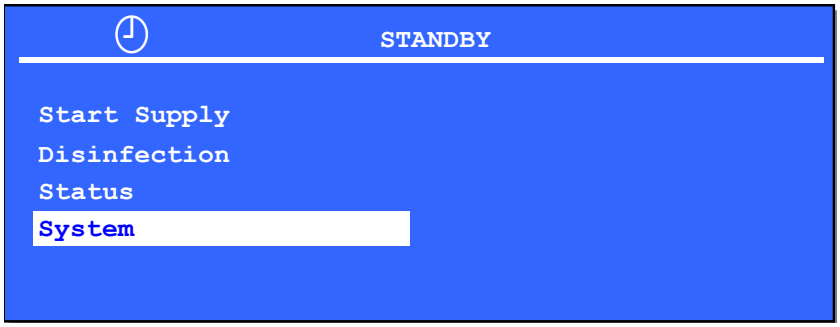


Switching to the main menu



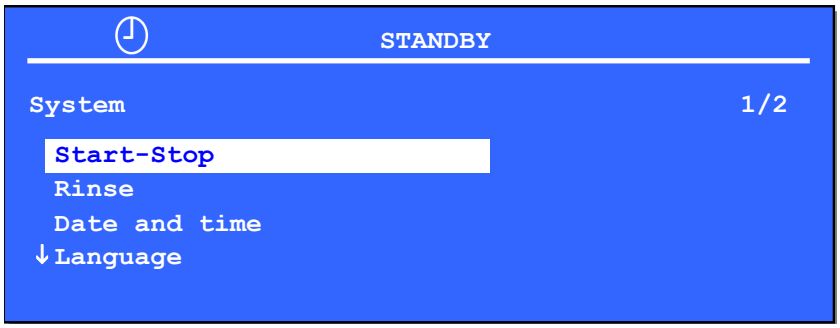
➢ Pressing the **Menu** key will switch to the main menu.

The following screen will be displayed:

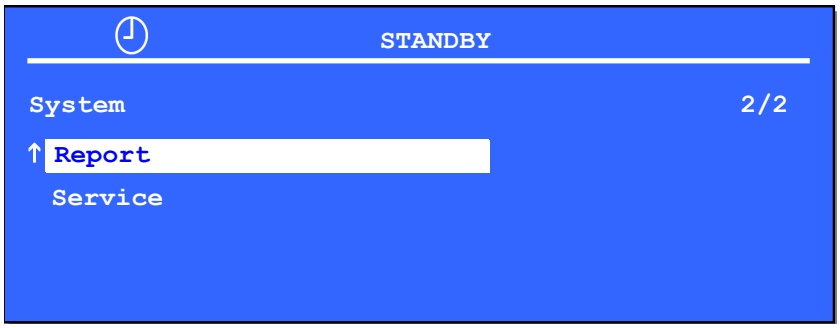


➢ When selecting the **System** menu option and confirming the selection with the **Enter** key, the **System** menu will be opened.

Page 1/2



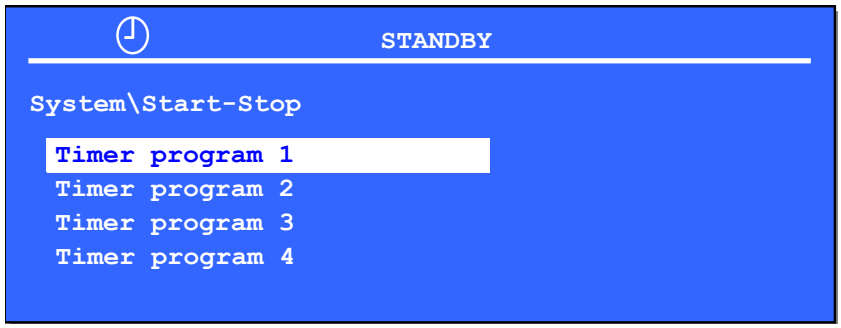
Page 2/2



4.8.2 SYSTEM – Programming the Start / Stop

Setting the autostart and autostop timer

This menu is used to program the **autostart** and **autostop** timers (Supply timer programs).

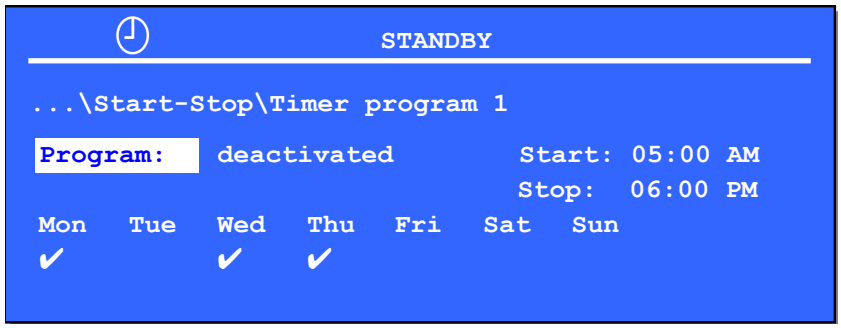


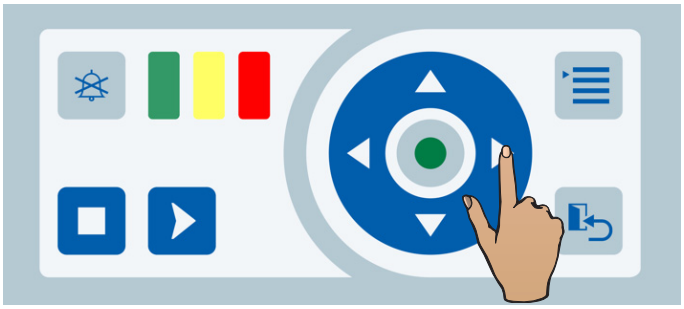
Four available switching programs

Four switching programs (timers) are available which can be programmed independently.

Editing the switching program

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

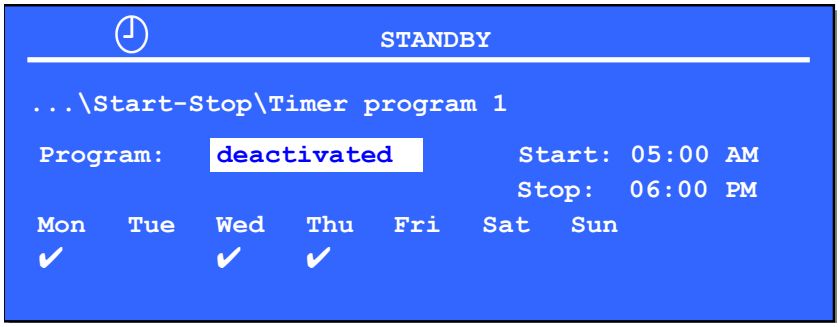


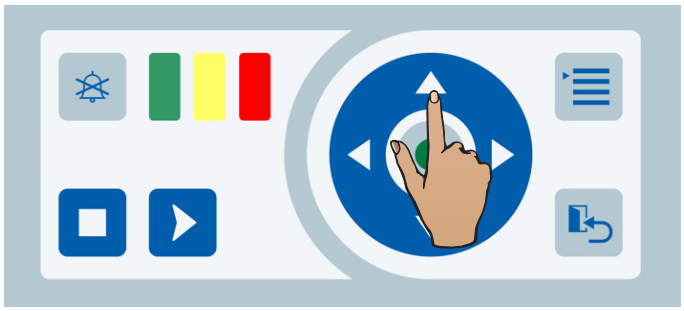


➢ The **Navigation** keys are used to select a parameter.

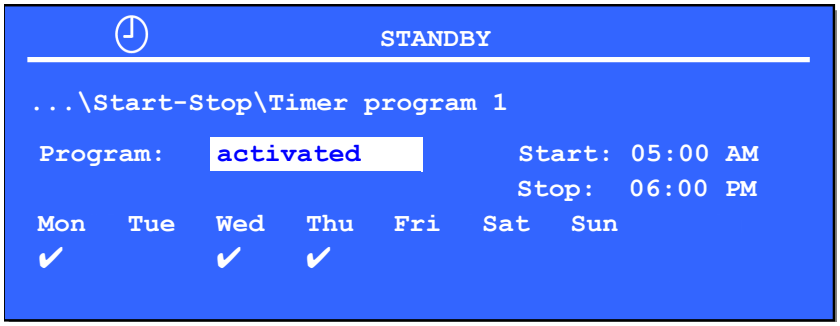
➢ After pressing the **Enter** key, the selected parameter can be changed.

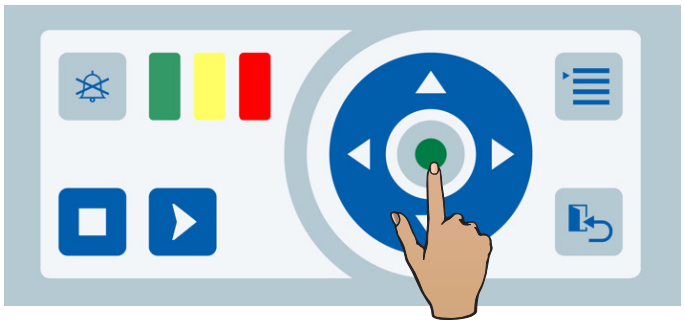
Activating or deactivating





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

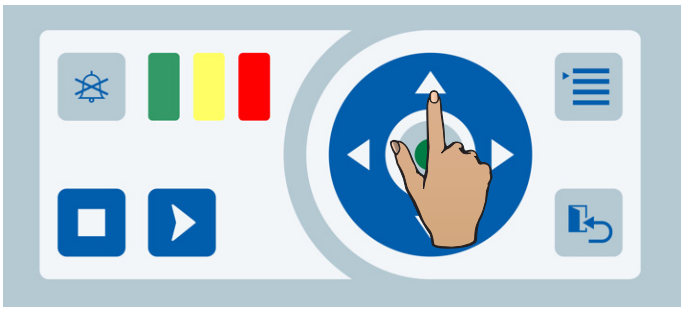




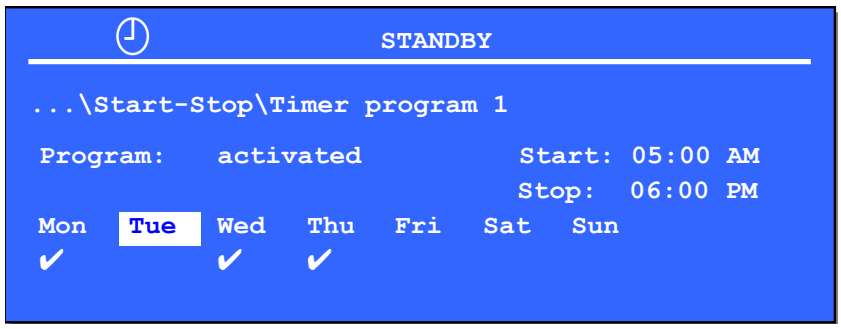
➢ The change of the parameter will not become effective before it has been confirmed with the **Enter** key.

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

Switching to the next menu option

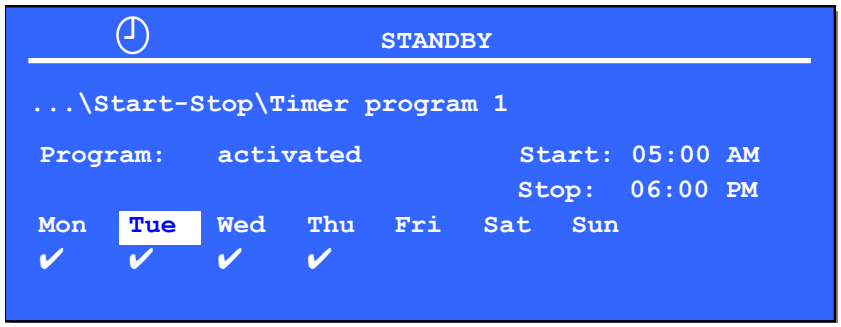


➢ The **Up** (▲) or **Down** (▼) navigation keys can be used to move to the next line up or down.



➢ 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.

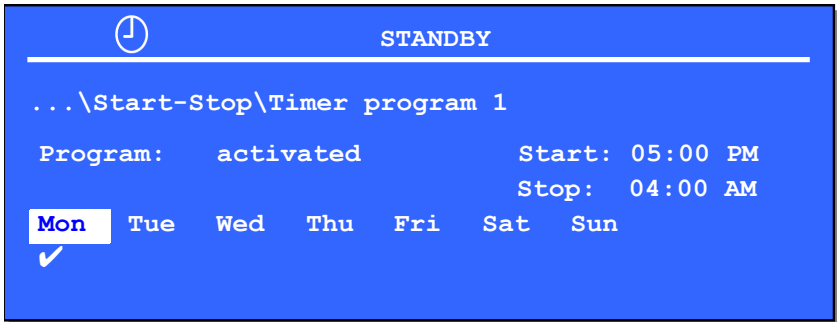


Programming extending to the next day

Tip

Programming extending to the next day

If a stop time preceding the start time is set, an Auto Stop will be performed the following day.



Example

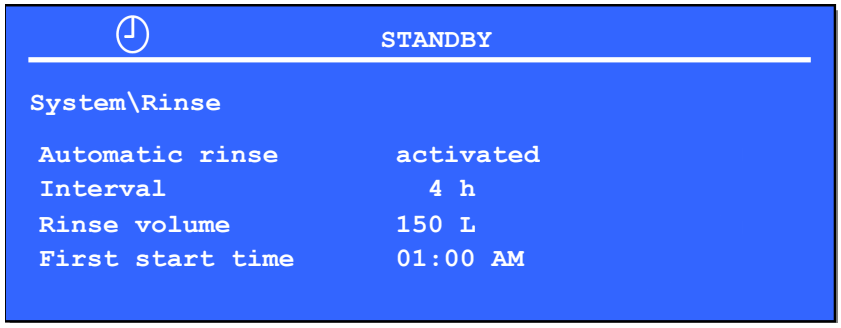
The system starts on Monday at 5:00 PM and stops on Tuesday at 4:00 AM.

4.8.3 SYSTEM – Programming the Rinse

4.8.3.1 Programmable rinse parameters

Description page 1/3

Parameter	Adjustment range	Unit
Rinsing	[activated / deactivated]	–
Interval	[1, 2, 3, 4, 6, 8, 12, 24]	h
Volume	100 to 1000	L
First start time	00:00 to 12:00	hh:mm



Automatic rinse program

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

First start time (example)

First start time: 9:00 AM

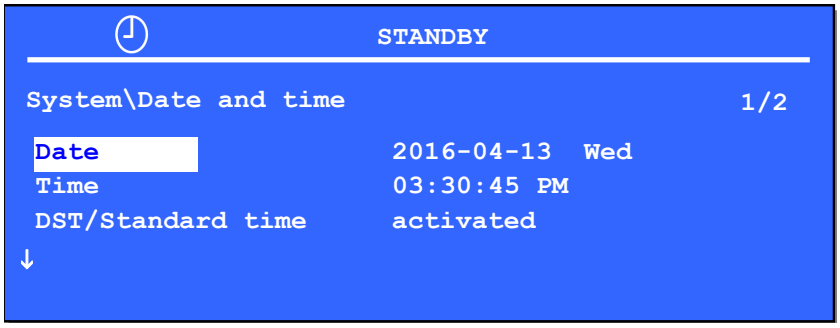
Interval: 4 h

6 rinse procedures per day will be performed at the following times:
– 1:00 AM, 5:00 AM, 9:00 AM, 1:00 PM, 5:00 PM, 9:00 PM

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

This allows, for example, rinsing of the **AquaBplus**, softener and activated carbon filter to be timed so that only one device will be rinsed at any given time.

4.8.4 SYSTEM – Setting the Date and time



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

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

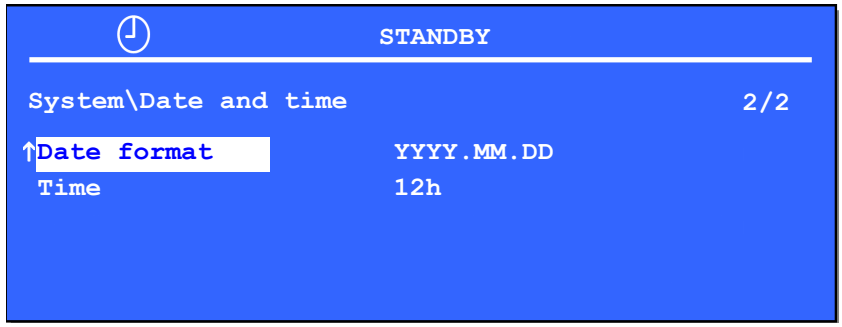
➢ Pressing the **Enter** key will save the setting and advance to the next value.

Change from daylight savings time to standard time

➢ It is possible to activate / deactivate the automatic change from daylight savings time to standard time and vice versa according to European standard.

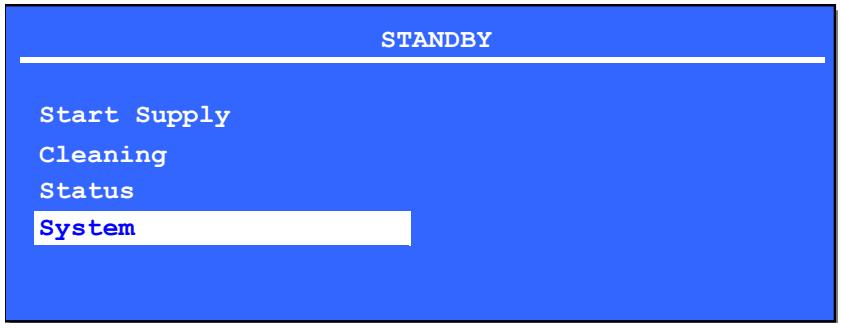
Note

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

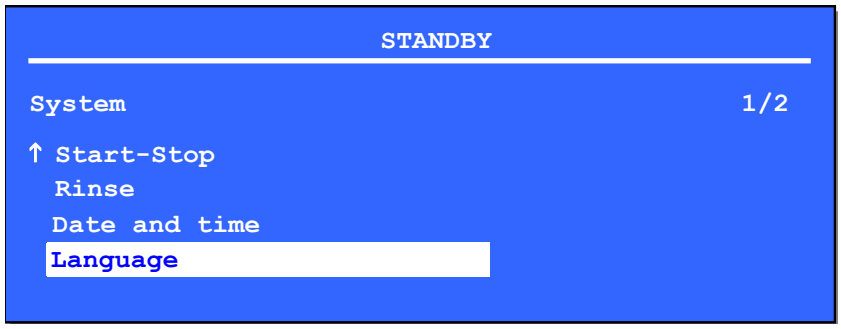


Parameter	Adjustment range
Date format	DD.MM.YYYY / JJJJ-MM-DD
Time	24 h / 12 h

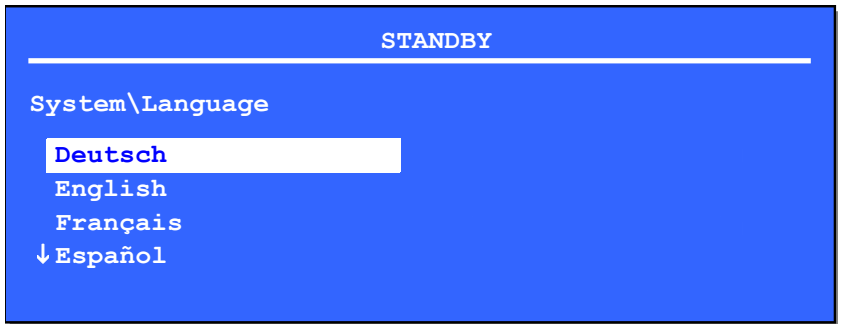
4.8.5 SYSTEM – Setting the Language



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



➢ On the first page of the **System** menu, select the menu option **Language**.

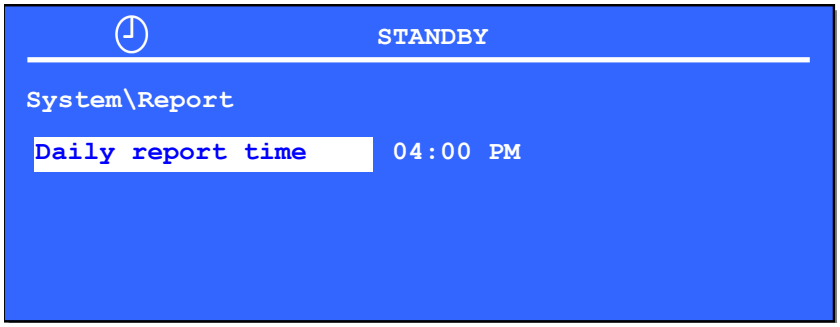


➢ Select the desired language and confirm with the **Enter** key.

The language is activated.

4.8.6 SYSTEM – Report

The **System\Report** menu is used to set the time for the automatic generation of the daily report. The values of the last recorded report can be viewed in the **Status\Daily report** menu.



4.8.7 SYSTEM – Service (only with password)

Note

The **Service** menu can only be accessed by an authorized technician.

4.9 Remote control via WEB browser

In addition to operation via the keypad, the **AquaBplus** can also be **remotely controlled** using a web browser. Internet Explorer, which is installed as a standard feature on Windows operating systems, could for instance be used as web browser.

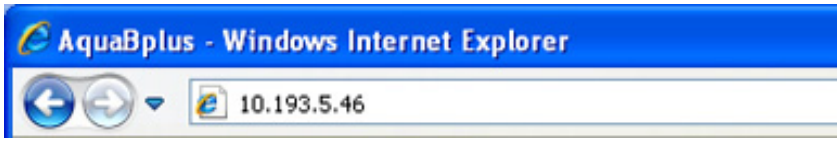
The remote control functions are restricted to starting and stopping **SUPPLY** and viewing all relevant operating data and information of the **AquaBplus**, **AquaBplus B2** and the **AquaBplus HF**.

Four views are available which are described on the following pages.

4.9.1 Connecting to the AquaBplus web server

Note

The **AquaBplus** must be located on the same network as the computer used to remotely control the **AquaBplus**.



➢ Enter the IP address of the **AquaBplus** in the web browser's address field.

Tip

The IP address can be found in the **Status/System information** menu of the **AquaBplus**.

➢ Confirm the entry with the **Return** key.

The following login screen will be displayed:

In the **User name** field enter:

In the **Password** field enter:

Note

➢ Observe case-sensitive spelling!

4.9.2 Overview of Web server view Overview

The **Overview** view displays system information. The **Start** and **Stop** buttons can be used to start or stop the **SUPPLY** mode of the **AquaBplus**.

4.9.3 Web server view Status

The **Status** view displays current warnings or malfunctions as well as information on programmed timers (AutoSTART, Rinse, Heat disinfection).

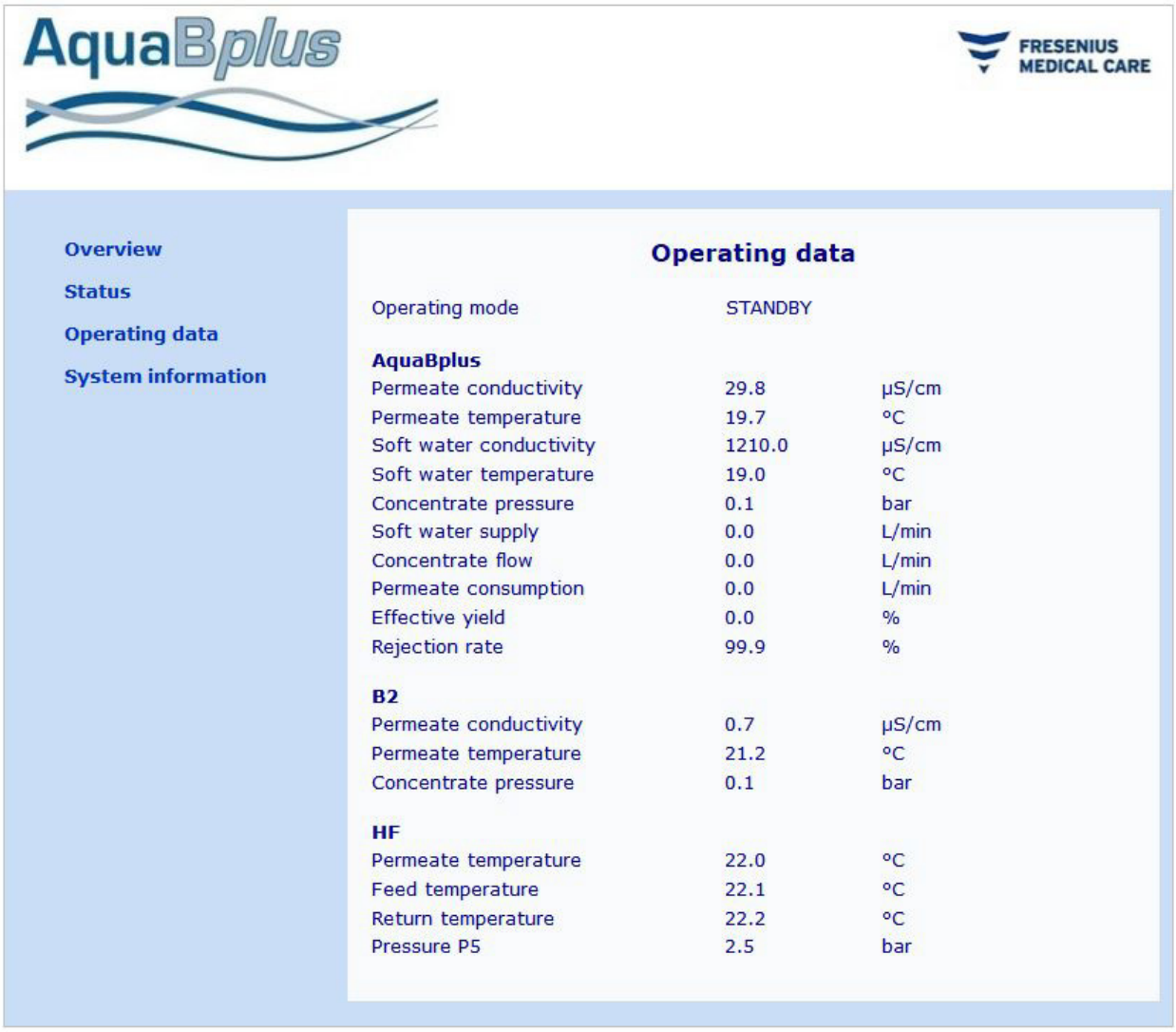
Further information on timers
- **AutoSTART** (see Chapter 4.8.2 on page 4-25)
- **Rinse** (see Chapter 4.7.7 on page 4-19)
- **Heat disinfection** (see Chapter 4.5 on page 4-8)

Further information on alarm messages (see Chapter 5.4 on page 5-4).

4.9.4 Web server view Operating data

The **Operating data** view displays the current operating data.

For information on operating data (see Chapter 4.7.4 on page 4-15).



4.9.5 Web server view System information

The **System information** view displays the configuration of the **AquaBplus**.

For information on the configuration (see Chapter 4.7.8 on page 4-20).

5 Alarms

5.1 General notes

The audible and visible alarm signals of the **AquaBplus** are programmed as follows in compliance with DIN EN 60601-1-8:

Higher-priority alarms: Failures that alert the operator to the following device behavior:

– The pump is switched off and the device interrupts operation. The permeate supply is interrupted during dialysis.

– The permeate quality during dialysis has exceeded the permissible values and the permeate supply may be interrupted at any time.

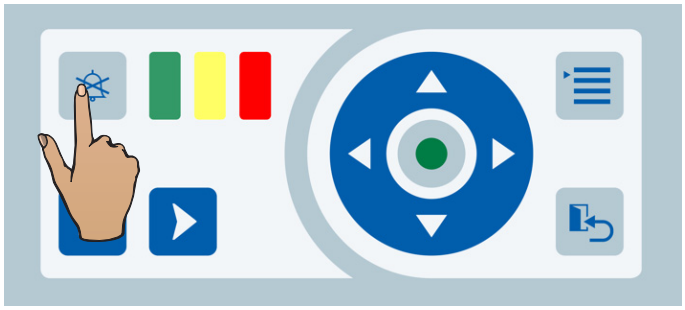
Medium-priority alarms: None

Low-priority alarms: Warnings alerting the operator to an error which impairs operation but does not cause the device to shut down.

In the event of an alarm condition, the device immediately indicates the alarm with acoustic and visual signals. All further operation of the alarms (alarm confirmation, muting) is performed directly on the device.

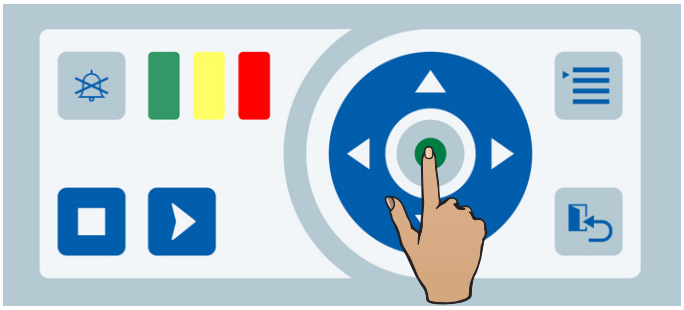
- **Alarm signal deactivation (muting)**

  When the mute key is pressed, the audible signal is stopped for 2 minutes. The signal is only completely deactivated once the alarm has been confirmed.



- **Alarm confirmation**

Alarms are confirmed by pressing the enter key. No further alarm will be signaled if the alarm condition persists.



Current messages are displayed in the Status Messages screen. Messages will not be automatically deleted until the individual message has been confirmed and the problem causing the message has been eliminated.

- **Alarm verification**

Verification of alarms by the operator is not required. Alarms are reviewed by the service technician during the TSC.

5.2 Contacting the service department

The phone numbers to contact Fresenius Medical Care or the international service of Vivonic are listed in the chapter Addresses. (Please contact your local Technical Services department first)

Should you make use of this service, please describe the error which occurred as precisely as possible (by telephone, if necessary) to help the technician analyze the problem. The following information should be available:

– Current operating data of the **AquaBplus** reverse osmosis system

– The 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
[yy.mm.dd], time [hh.mm.ss], error code [X-XX-XX-XX], operating mode [], message text

5.3 Messages

A new message will be displayed immediately. The message is confirmed by pressing the **Enter** key.

The current messages are displayed in the **Status \ Messages** screen. The messages will not be deleted automatically before the message has been corrected.

5.4 Alarm description

5.4.1 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) **03** – Preparation (e. g., start condition not fulfilled) **04** – T1 test and test routine
		50		**System** **50** – **AquaBplus** - (single pass system) or stage 1 **51** – **AquaBplus B2** - stage 2 **52** – **AquaBplus HF module** **53** – **Remote control**
			01	**Message number** Identification of the number (failure or warning)

5.4.2 Error categories overview

5.4.2.1 Category 01: System and hardware problem

Error code	Visual indica-tor	Error message text	Cause	Action required
F–01–50–01		Failure: CD-P sensor defective	Permeate conductivity sensor defective.	– Contact the service department.
F–01–50–02		Failure: T-P sensor defective	Permeate temperature sensor defective.	– Contact the service department.

Error code	Visual indica-tor	Error message text	Cause	Action required
W–01–50–01		Warning: CD-F sensor defective	Soft water conductivity sensor defective.	– Contact the service department.
W–01–50–02		Warning: T-F sensor defective	Soft water temperature sensor defective.	– Contact the service department.
W–01–50–03		Warning: P-C sensor defective	Concentrate pressure sensor defective.	– Contact the service department.

5.4.2.2 Category 02: Procedure

Error code	Visual indica-tor	Error message text	Cause	Action required
F–02–50–01		Failure: Permeate conductivity exceeded	The permeate conductivity has exceeded the specified alarm limit.	The permeate supply will be started immediately as soon as the conductivity is below the alarm limit. Confirm the message. – Contact the service department.
F–02–50–02		Failure: Permeate temp. exceeded	The permeate temperature has exceeded the specified alarm limit.	The permeate supply will be started immediately as soon as the temperature is below the alarm limit. Confirm the message. – Contact the service department.
F–02–50–03		Failure: Tank overflow	The external tank has reached level 4 (overflow).	– Contact the service department.
F–02–50–04		Failure: Concentrate pressure exceeded	The concentrate pressure has exceeded the specified alarm limit. P-C sensor defective.	– Contact the service department.

Error code	Visual indica-tor	Error message text	Cause	Action required
F–02–50–05		Failure: Run-dry protection	The level in the break tank has dropped to level 1. Water inlet pressure or flow too low.	Check water supply. The **AquaBplus** will continue to supply permeate as soon as level 3 has been reached again. This message will be displayed until it is confirmed. – Contact the service department.
F–02–50–06		Failure: Fill level dropped	Leakage or supply during disinfection	– Check that all hemodialysis devices are disconnected. – Check ring main for leakage.
F–02–50–07		Failure: Disinfectant connector	The disinfectant connector has been removed.	– Connect the connector to the appropriate connection port.
F–02–50–08		Failure: Leakage	Indication of water leakage from the connected leakage sensor.	Check all water-carrying lines and connections. – Contact the service department.
F–02–50–09		Failure: Leakage - ring main	Message signaling water leakage during a heat disinfection (only with **AquaBplus HF** option).	Check all water-carrying lines and connections. – Contact the service department.
F–02–50–10		Failure: External failure	This message is displayed if a signal is present at the external failure connection (X19.9).	– Check why there is a failure present at the externally connected system.
F–02–50–11		Failure: Supply volume not reached	Insufficient disinfectant volume.	– Connect new disinfectant containers. – Reconnect the disinfection connector.

Error code	Visual indica-tor	Error message text	Cause	Action required
W–02–50–01		Warning: Permeate conductivity exceeded	The permeate conductivity has exceeded 80 % of the specified alarm limit.	– Contact the service department.
W–02–50–02		Warning: Inlet temperature exceeded	The feed temperature has exceeded the specified alarm limit.	– Contact the service department.
W–02–50–03		Warning: Perm. cond close to limit	The feed temperature is close to the specified alarm limit.	– Contact the service department.
W–02–50–04		Warning: Inlet volume below limit	Water inlet pressure or pressure too low.	– Check water supply.
W–02–50–06		Warning: Temperature exceeded	A temperature of 45 °C was exceeded during the circulation phase of the chemical disinfection. Temperature during heat disinfection above 99 °C.	– Contact the service department.
W–02–50–08		Warning: Rinse volume not reached	Failure to reach the specified rinse volume within 30 minutes. Ring main drain valve V46 defective.	– Contact the service department.
W–02–50–14		Warning: Inlet conductivity exceeded	The feed conductivity has exceeded the specified alarm limit.	Check water supply. – Contact the service department.
W–02–50–16		Warning: Permeate temp. close to limit	The permeate temperature has exceeded 80 % of the specified alarm limit.	– Contact the service department.
W–02–50–17		Warning: Concentrate pressure too low	The concentrate pressure is below the specified alarm limit. V30 defective.	– Contact the service department.

5.4.2.3 Category 03: Start condition not fulfilled

Error code	Visual indica-tor	Error message text	Cause	Action required
F–03–50–01		Failure: Fill level cannot be lowered	The break tank could not be drained during the disinfection.	– Contact the service department.

5.4.2.4 Category 04: T1 test and test routines

Error code	Visual indicator	Error message text	Cause	Action required
F–04–50–02		Failure: T1 test, T-P sensor defective	Cable break. Permeate temperature sensor defective.	– Contact the service department.
F–04–50–04		Failure: T1 test, pump P1 defective	Pump defective. The motor protection switch has tripped.	– Contact the service department. **Note** After the motor protection switch has been tripped, wait for 2 minutes before the motor protection switch is switched on again.
F–04–50–06		Failure: T1 test, CD-P sensor defective	Cable break. Permeate conductivity sensor defective	– Contact the service department.
W–04–50–01		Warning: T1 test,FL-C sensor defective	Concentrate flow meter defective.	– Contact the service department.
W–04–50–02		Warning: T1 test,FL-F sensor defective	Flow meter in the water inlet defective.	– Contact the service department.
W–04–50–03		Warning: T1 test,CD-F sensor defective	Conductivity sensor in the water inlet defective.	– Contact the service department.
W–04–50–04		Warning: T1 test,P-C sensor defective	Concentrate pressure sensor defective.	– Contact the service department.
W–04–50–05		Warning: T1 test,valve V36 defective	Valve to concentrate diversion defective.	– Contact the service department.
W–04–50–06		Warning: T1 test,T-F sensor defective	Temperature sensor in the water inlet defective.	– Contact the service department.

5.4.2.5 Alarms and information messages – AquaBplus B2 (option)

Error code	Visual indica-tor	Error message text	Cause	Action required
W–01–50–04		Warning: CD-P sensor defective	Permeate conductivity sensor of stage 1 defective.	– Contact the service department.
W–01–50–05		Warning: T-P sensor defective	Permeate temperature sensor of stage 1 defective.	– Contact the service department.
F–01–51–01		Failure: CD-Ps sensor defective	Permeate conductivity sensor of stage 2 defective.	– Contact the service department.
F–01–51–02		Failure: T-Ps sensor defective	Permeate temperature sensor of stage 2 defective.	– Contact the service department.
W–01–51–03		Warning: P-Cs sensor defective	Concentrate pressure sensor of stage 2 defective.	– Contact the service department.
F–02–51–01		Failure: Permeate conductivity exceeded	The permeate conductivity after stage 2 has exceeded the specified alarm limit.	– Contact the service department.
F–02–51–02		Failure: Permeate temp. exceeded	The permeate temperature after stage 2 has exceeded the specified alarm limit.	– Contact the service department.
F–02–51–03		Failure: Concentrate pressure exceeded	The concentrate pressure in stage 2 has exceeded the specified alarm limit. Pressure sensor defective.	– Contact the service department.
F–02–51–04		Failure: Run-dry protection stage 2	The pressure upstream of pump P1s is too low. Pressure switch defective. Valve V27 defective.	– Contact the service department.
W–02–50–18		Warning: Stage1 temp. exceeded	The permeate temperature in stage 1 has exceeded the specified alarm limit.	– Contact the service department.

Error code	Visual indica-tor	Error message text	Cause	Action required
W–02–50–19		Warning: Stage1 cond. exceeded	The permeate conductivity in stage 1 has exceeded the specified alarm limit.	– Contact the service department.
W–02–50–20		Warning: Disinfection stopped	The chemical disinfection has been stopped by the operator or by a malfunction.	– Contact the service department.
W–02–51–01		Warning: Perm. cond close to limit	The permeate conductivity has exceeded 80 % of the specified alarm limit.	– Contact the service department.
W–02–51–02		Warning: Permeate temp. close to limit	The permeate temperature has exceeded 95 % of the specified alarm limit.	– Contact the service department.
W–02–51–03		Warning: Concentrate pressure too low	The concentrate pressure is below the specified alarm limit.	– Contact the service department.
F–04–51–01		Failure: T1 test,CD-Ps sensor defective	Cable break. Permeate conductivity sensor of stage 2 defective.	– Contact the service department.
F–04–51–02		Failure: T1 test,T-Ps sensor defective	Cable break. Permeate temperature sensor of stage 2 defective.	– Contact the service department.
F–04–51–03		Failure: T1 test,P-es switch defective	Pressure switch P-es downstream of pump P1s defective.	– Contact the service department.
F–04–51–04		Failure: T1 test,pump P1s defective	Booster pump of stage 2 defective. The motor protection switch has tripped. Stage 2 turned off	– Turn stage 2 on – Check the voltage supply of stage 2 – Contact the service department. **Note:** – After triggering the motor protection switch, wait 2 minutes until the motor protection switch is switched on again.

Error code	Visual indica-tor	Error message text	Cause	Action required
W–04–50–07		Warning: T1 test, CD-P sensor defective	Cable break. Permeate conductivity sensor of stage 1 defective.	– Contact the service department.
W–04–50–08		Warning: T1 test, T-P sensor defective	Cable break. Permeate temperature sensor of stage 1 defective.	– Contact the service department.
W–04–51–01		Warning: T1 test,P-Cs sensor defective	Concentrate pressure sensor of stage 2 defective.	– Contact the service department.
W–04–51–02		Warning: T1 test,valve V36s defective	Concentrate diversion valve of stage 1 defective.	– Contact the service department.
W–04–50–10		Warning: T1 test,valve V46 defective	No flow across V46 during the T1 test.	– Contact the service department.
W–04–50–11		Warning: T1 test,valve V10 defective	V10 does not close.	– Contact the service department.

5.4.2.6 Alarms and information messages – AquaBplus HF (option)

Error code	Visual indicator	Error message text	Cause	Action required
F–01–52–01		Failure: T-Hout sensor defective	Temperature sensor downstream of the heater in the HF module defective.	– Contact the service department.
F–01–52–02		Failure: T-Hin sensor defective	Temperature sensor upstream of the heater in the HF module defective.	– Contact the service department.
F–01–52–03		Failure: Pump P5 defective	Circulation pump in the HF module defective. The motor protection switch has tripped.	– Contact the service department. **Note:** – After triggering the motor protection switch, wait 2 minutes until the motor protection switch is switched on again.
F–01–52–04		Failure: Sensor P-5F defective	Pressure sensor upstream of pump P5 defective.	– Contact the service department.
F–01–52–05		Failure: T-sup sensor defective		– Contact the service department.
F–02–52–01		Failure: Temperature too high	Sensor T-Hout or T-Hin measure a temperature above 105 °C. Pump defective. Temperature sensor defective. Heater control defective.	– Contact the service department.
W–01–52–01		Warning: T-Hout sensor defective		– Contact the service department.
W–01–52–02		Warning: T-Hin sensor defective		– Contact the service department.
W–01–52–03		Warning: Sensor P-5F defective		– Contact the service department.

Error code	Visual indica-tor	Error message text	Cause	Action required
W–02–52–01		Warning: Temperature not reached	Failure to reach an A0 value of 600 at the end of the heat disinfection (calculated according to ISO 23500).	– Contact the service department.
W–02–52–02		Warning: Heating phase complete	The heating phase lasted longer than the programmed time.	– Contact the service department.
W–02–52–03		Warning: Heat disinfection stopped	Heat disinfection was prematurely terminated. This message is displayed if the heat disinfection program has been stopped by the operator or by a failure. The system must be cooled down.	– Confirm the message and start the cool-down. – Contact the service department.
F–04–52–01		Failure: T1 test, T-Hout sensor defect.	Temperature sensor at the heater outlet side defective.	– Contact the service department.
F–04–52–02		Failure: T1 test,T-Hin sensor defective	Temperature sensor at the heater inlet side defective.	– Contact the service department.
F–04–52–04		Failure: T1 test,P-5F sensor defective	Pressure sensor upstream of pump P5 defective.	– Contact the service department.
F–04–52–05		Failure: T1 test,T-sup sensor defective		– Contact the service department.
F–04–52–06		Failure: T1 test,pump P5 defective		– Contact the service department.
F–04–52–07		Failure: T1 test, sensor VR-P5 defective		– Contact the service department.
W–04–52–01		Warning: T1 test, heater H1 defective	Heater H1 is defective. The automatic circuit breaker of H1 has tripped.	– Contact the service department.

Error code	Visual indica-tor	Error message text	Cause	Action required
W–04–52–02		Warning: T1 test, heater H2 defective	Heater H2 is defective. The automatic circuit breaker of H2 has tripped.	– Contact the service department.
W–04–52–03		Warning: T1 test, T-Hout sensor defect.		– Contact the service department.
W–04–52–04		Warning: T1 test,T-Hin sensor defective		– Contact the service department.
W–04–52–05		Warning: T1 test,sensor P-5F defective		– Contact the service department.

6 Cleaning, disinfection, preservation

6.1 Generally applicable rules for cleaning, disinfection and preservation

Warning

Operator restrictions

The system may only be cleaned, disinfected and preserved by persons who have been instructed on the proper handling of the system.

➢ The operator must observe and follow the general safety precautions.

Warning

Operator restrictions

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

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.

6.2 Precautions

6.2.1 Patient safety

Warning

Disconnect the system!

Ensure that no dialysis devices are connected during the entire cleaning, disinfection and preservation procedure.

➢ Prior to cleaning, disinfection and preservation, all dialysis devices connected to the ring main must be disconnected.

Warning

Test for the absence of residual disinfectant

When using disinfectants, an appropriate test for the absence of residual disinfectant must be performed.

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)

➢ Be careful when handling acidic fluids and do not spill any disinfectant concentrate.

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

➢ Wear protective 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

Safe handling of disinfectants

When using disinfectants, observe the 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 cleaning and disinfection program.

– different cleaning agents and disinfectants may not be mixed.

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

6.2.3 Protection of buildings

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, installations or buildings.

- ➢ Tubing must be protected from possible mechanical damage (pinching / kinking).
- ➢ It is recommended that regular visual inspections be performed on all **AquaBplus** tubing, connectors, and piping that contain fluid. (Frequency to be determined by the facility)
- ➢ If a storage tank is used, a spill protection must be installed.

6.3 Disinfection

● **General information for disinfection**

Operating principle

The disinfection procedure is program-controlled.

Reason for a disinfection

– If a water supply as specified by the applicable regulations can no longer be ensured:
– After **repair** in the permeate circuit.
– If the system has been **idle** for more than **72 hours**. In case of longer times of no use, preservation of the system is recommended.
– ISO 23500 "Guidance for the preparation and quality management of fluids for haemodialysis and related therapies" recommends a regular (e.g., monthly) **preventive disinfection** to avoid significant biofilm formation (Biofouling).

Recommended disinfectant

– **Puristeril 340**
– **Or other appropriate peracetic acid solution for use on reverse osmosis membranes (~3–5 % peracetic acid). (e.g. Minncare cold sterilant)**

Note

– The manufacturer recommends a peracetic acid-based disinfectant for use with the reverse osmosis membrane.
– The manufacturer recommends **Puristeril 340** or another corresponding peracetic acid solution for use with a reverse osmosis membrane.
– The disinfectant volume depends on the concentration of the disinfectant.
– For effective peracetic acid concentration in the effective disinfection mixture the amount to approx. 0,2 % is recommended.

6.3.1 Disinfecting the system

Warning

Authorization requirement

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

Note

If the microbiological tests reveal a constant microbial count in the permeate, the disinfection interval must be reduced.

6.4 Preservation

Note

Reasons for preservation

Preservation is necessary to prevent clogging / bacterial growth in the module unit when the system is decommissioned for a prolonged period.

For preservation of the system, contact the manufacturer.

6.5 Surface cleaning and disinfection

Note

Surface cleaning and disinfection should only be performed on housing parts.

➢ Do not use the surface cleaner/disinfectant on any parts located inside the device.

6.5.1 Surface cleaning

- **General information for service cleaning**

➢ The housing surface must be cleaned if dust and dirt are present on the surface.

Warning

Disconnect the system from the power

➢ Disconnect the device from the power supply before cleaning the surface.

Note

To be observed for surface cleaning

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 **AquaBplus** may only be cleaned by a service technician.

➢ Do not use any cleaning agents which contain acetone.

➢ Do not use solvents, diluting agents or chemical cleaning sprays.

➢ Do not use any aggressive cleaning agents and solvents or abrasives.

➢ Do not use rough cleaning tools (e.g., scouring pad or similar) to clean the system.

6.5.2 Cleaning the surface

➢ When performing a surface cleaning, use a disposable cloth to remove dust and dirt from the housing surface.

6.5.3 Surface disinfection

● **General information for surface disinfection**

Note

The manufacturer recommends the surface disinfectants indicated in the chart below.

➢ When performing surface disinfecting follow the disinfectants manufactures instructions for use.

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

Recommended Surface disinfectants

Surface disinfectants
Alcohol-based surface disinfectants: **Surface disinfectants with ethanol (~ 80 % ethanol)**
Chlorine-based surface disinfectants: **Chlorine bleach, in solution, max. 5 % bleach**
Peroxide-based surface disinfectants: **Oxivir Tb / Oxivir Tb Wipes** (ready-to-use wipes) **Oxivir Tb five 16 concentrate** (concentrate)

6.5.4 Disinfecting the surface

➢ The housing surface can also be disinfected if a surface disinfectant is used during cleaning.

7 Functional description

This chapter provides a brief description of how the **AquaBplus** reverse osmosis functions.

7.1 Description of the procedure

7.1.1 Functions

The **AquaBplus** is a microcontroller-driven, fully automatic reverse osmosis system, which processes pretreated soft water into deionized purified water, also known as permeate.

The system consists of a water inlet section where the inflowing volume of water is volumetrically measured and controlled in relation to the flow.

The water is stored in a break tank. The pump which is connected downstream generates the high pressure and transports the water to the membranes. If the conductivity exceeds the programmed maximum permissible value, the permeate will be discarded in the (optional) downstream **RingBase**.

Based on the set effective yield, the concentrate is discarded into the drain via the drain valve.

7.1.2 Operating modes

The **AquaBplus** has the following operating modes:

Operating modes
STANDBY
SUPPLY
RINSE
DISINFECTION
EMERGENCY MODE (option)
HEAT DISINFECTION - RING MAIN (option)

7.1.3 Flow diagrams

Note

For flow diagrams, please contact the technical service.

8 Consumables, accessories, additional equipment

Warning

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

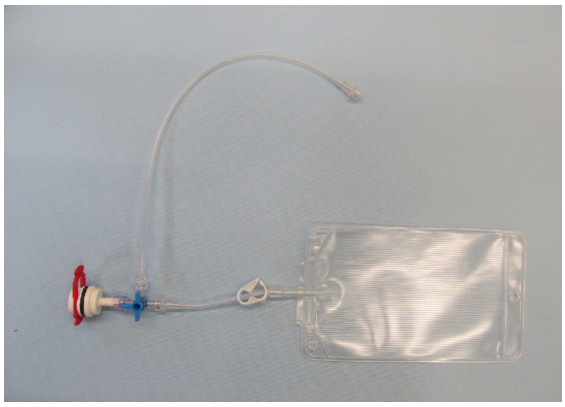
Should the responsible organization wish to use other consumables and accessories than those listed in this chapter, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with.

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.

8.1 Consumables

No content

8.2 Accessories

	Accessories	Description	Part no.
1	**Sampling set** for **insulated ring main**	Permeate sampling set for Fresenius sampling valve 	G03000836

8.3 Additional equipment

For further information (see Chapter 14 on page 14-1).

9 Installation

9.1 Important information for operational qualification

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.

Environmental conditions

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.

Tester's qualification

Operational qualification must be performed by a trained technician.

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.

Test equipment and accessories

The activities described in this document require the availability of the necessary technical test equipment and accessories.

Specifications

Observe the information on the specifications.

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 of.

ESD precautions

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

TSC / MA intervals

The TSC / MA procedures are to be performed on this system after 24 months.

9.2 Operational Qualification

9.2.1 To be observed before operational qualification

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 manufacturer-authorized person.

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.

Warning

If the reverse osmosis system is decommissioned after operational qualification, the following must be observed:

➢ In case of an operational requalification, check that the pressure of the water supply complies with the prescribed minimum pressure.

9.2.2 Electrical installation

Connection to the power supply system

The national requirments of the US regulatory standards and regulations must be observed when connecting the device to the power supply system.

Protective earth

When using protection class I devices, the quality of the protective conductor of the installation is of particular importance. It must be taken into consideration that in many countries regulations have been enacted by the national authorities.

9.3 Operational qualification procedure

9.3.1 General information

Authorized persons

Note

Operational qualification may only be performed by persons qualified to properly perform an operational qualification based on their educational background, training, knowledge and experience.

Operational qualification after the initial operational qualification

Note

When the device is supplied, an operational qualification has already been performed.

When the system is installed this is actually an operational requalification of the system which is treated like an operational qualification.

9.4 Decommissioning / shutdown / operational requalification

9.4.1 Decommissioning

Note

➢ For information regarding decommissioning of the device, contact your local technical services department.

9.4.2 Shutdown

Note

➢ For information regarding shutdown of the device, contact your local Technical Services department.

9.4.3 Operational requalification

Note

➢ Operational requalification and instruction may only be performed by authorized personnel.

10 Transport / storage

10.1 Transport and storage conditions

Warning

Efficacy of the preservation solution

Storage time in the preserved state: maximum **12 months**.

– The **AquaBplus** must be stored in a well-ventilated room with little variation in temperature.

– To prevent bacterial growth, the **AquaBplus** must undergo another preservation procedure in case of prolonged storage times and, particularly, in case of increased storage temperatures.

Position

Note

➢ Store upright!

Temperature range +5 to +40 °C

Note

➢ Protect the device from freezing!

Relative air humidity Up to 80 % at 20 °C, non-condensing

Atmospheric pressure 500 to 1150 hPa

Note

Protection from exposure to UV light

Do not expose the device to direct sunlight (UV rays may cause faster aging of the materials).

➢ Do not store outdoors!

10.2 Transport

10.2.1 General information

Note

For further information regarding transport, please contact the manufacturer.

Note

➢ Do not tilt or topple!

➢ Do not push or pull the **AquaBplus** across uneven surfaces!

10.2.2 Inside buildings

➢ Before transporting the systems, the connecting tubes of the system must be disconnected.

➢ To prevent the systems from being damaged or tipping over, the **AquaBplus** should be pushed slowly across expansion joints in the floor, uneven surfaces and passages into or out of elevators.

10.2.3 Outside of buildings

➢ Do not move the **AquaBplus** across uneven surfaces (e.g., cobblestone pavement).

➢ The system parts of the **AquaBplus** 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 packing).

➢ Moreover, the permissible operating temperatures must be observed when transporting the system outside of buildings.

10.3 Environmental compatibility / disposal

In EU Member States, the system can be returned in accordance with the "Directive on Waste Electrical and Electronic Equipment" (WEEE Directive) when no longer in use. Please also observe the applicable local legal regulations.

Before returning or disposing of the system, the responsible organization must ensure that all consumables attached to the device are removed, and that the system has been disinfected according to the manufacturer's instructions (see Chapter 6, page 6-1).

The responsible organization must also notify the disposal company responsible for dismantling and disposing of the system of the following before any disposal measures are taken:

– The device may be contaminated upon return. Suitable precautions (e.g. use of personal protective equipment) must therefore be observed when dismantling the system.

– All batteries must be properly disposed of in accordance with local legal provisions.

– Disposal companies can obtain additional information from the manufacture on request.

● **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 and maintenance

11.1 Important procedural information

Testing

Technical Safety Checks must be performed every 24 months.

Tester's qualification

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

Tests 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 tests must not be bound by any directives when performing this activity.

Specifications

Observe the information on the specifications.

Documents

The local service department must be contacted if Technical Safety Checks and maintenance procedures are to be performed!

Reports are available on request.

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

11.2 Maintenance procedures

There are no maintenance procedures defined for the operator.

12 Specifications

12.1 Specifications AquaBplus

12.1.1 Dimensions and weight

Dimensions of control units, including membranes, each

Parameter	AquaBplus (500–3000)
Height	1500 mm
Width	550 mm
Depth	951 mm

Weight

Values	AquaBplus 500	AquaBplus 1000	AquaBplus 1500
Empty	120 kg	150 kg	180 kg
Filled	160 kg	200 kg	240 kg
1 kg = 2.20462 lb			

Values	AquaBplus 2000	AquaBplus 2500	AquaBplus 3000
Empty	200 kg	220 kg	240 kg
Filled	280 kg	320 kg	360 kg

Break tank fill volume

Component	Volume
Break tank	20 L

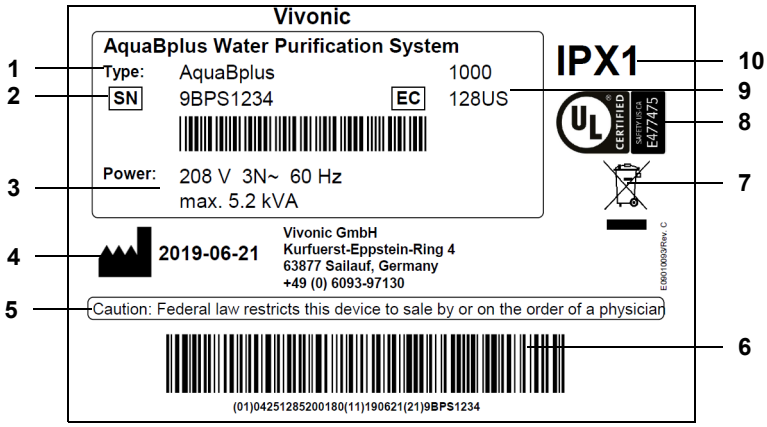
12.1.2 System data

Parameter	Values
Permeate output	500 to 3000 L/h for 15 °C and a counter-pressure of 2 bar 500 L/h (per pressure tube)*
Effective Yield	55 to 75 % adjustable
Rejection rate (membrane)	> 99 % for bacteria and endotoxins > 96 % for dissolved salts (average)
Concentrate pressure	Operating range: 9–13 bar Max. 25 bar (maximum pump pressure)

* The indicated rated output applies for water temperatures of 15 °C. With lower temperatures, an output of 3 % less per degree must be expected. With higher temperatures the permeate output increases accordingly.

12.1.3 Identification label (system identification)

The identification label shown is only an example. The decisive criteria is the data specified on the identification label of the device.



1. Type identification
2. Serial number
3. Power requirements
4. Manufacturer (year of manufacture, 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. UL Safety and Identity Mark
9. Equipment code (EC: Equipment Code)
10. Protection against ingress of liquids: Drip-proof

12.1.4 Electrical safety

Classification according to IEC 60601-1:2005

Type of protection against electric shock — Protection class I

Degree of protection against electric shock — Type B

Degree of protection against ingress of liquids — Drip-proof

Leakage currents — According to EN 60601-1:2005

Additional parameters

Parameter	Values
Installation altitude	Up to 3000 m above sea level
Atmospheric pressure	700 to 1150 hPa
Relative air humidity	Up to 80 % at 20 °C, non-condensing
Overvoltage category	II
Pollution severity	II
Material group	III b
Operating mode	Continuous operation (standby)

Note

Continuous operation mode refers to the switched-on state (STANDBY). The **SUPPLY** program may only be operated periodically.

12.1.5 Electrical supply

12.1.5.1 Electrical connection of the reverse osmosis system

Line voltage	Frequency	Soft water temperature	Power consumption	Protection	Tripping characteristic
208 V 3/N/PE	60 Hz	Standard	Up to 5.2 kVA	3 x 20 A	D or K or similar recommended (due to high starting currents) Fuses according UL 248-8, Class J
		Always above 15 °C			
		Always above 25 °C			

RCD fault current circuit breaker
The manufacturer recommends using an RCD 30 mA type A or better (i.e. according to the locally applicable directives).
For the exclusive fuses of an approved medical device, residual-current devices with a lower triggering residual current (RCD 5 mA type A or better) may be used.
Residual-current devices must be used in accordance with the locally applicable directives and laws.

12.1.6 Fuses

Fuse	Protection of the component	Fuse rating
Power supply cable		
F2	Power supply	3.15 AT
F3	Power supply	3.15 AT

12.1.7 Guidance and manufacturer's declaration for EMC (IEC 60601-1-2:2007)

12.1.7.1 General specifications for IEC 60601-1-2

Note

EMC directive for medical electrical equipment

Medical electrical equipment is 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

System installation

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

If the device must be operated close to other electrical devices, check whether the performance of the device is negatively affected by inadvertent electromagnetic coupling.

Electromagnetic radiation

Do not use devices that emitt electromagnetic radiation (e.g., walkie-talkies, mobile phones, radio transmitters) in the vicinity of an **AquaBplus** in operation. (If these devices must be used take note of the recommended seperation distances) This may cause a malfunction of the device.

12.1.7.2 Electromagnetic emissions

Guidance and manufacturer's declaration – Electromagnetic emissions		
The **AquaBplus** system is intended for use in an environment as specified below. The customer or the user of the **AquaBplus** system should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The **AquaBplus** system only uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic devices.
RF emissions CISPR 11	Class A	The **AquaBplus** system is suitable for use in establishments other than domestic establishments and those directly connected to the public power grid that supplies buildings used for domestic purposes, provided that the following warning is heeded.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Warning

This device system is only intended for use by health professionals. This is an item of class A equipment as defined by CISPR 11. In domestic establishments this system may cause radio interference so that it may be necessary to take appropriate measures such as reorientation, relocation or shielding of the **AquaBplus** or filtering of the connection to the place of installation.

12.1.7.3 Electromagnetic immunity

Guidance and manufacturer's declaration – Electromagnetic immunity			
The **AquaBplus** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AquaBplus** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the **AquaBplus** requires continued operation during power interruptions to the power supply network, powering of the **AquaBplus** from an uninterruptible power supply or a battery is recommended.
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level			

			Portable and mobile RF communications equipment should be used no closer to any part of the **AquaBplus**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	d = 0.35 $\sqrt{P}$ for 150 kHz to < 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 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 maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b]  Interference may occur in the vicinity of equipment marked with the following symbol.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **AquaBplus** is used exceeds the applicable RF compliance level above, the **AquaBplus** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **AquaBplus**.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

12.1.7.4 Recommended separation distances between portable and mobile RF communication equipment and the AquaBplus

Recommended separation distances between portable and mobile RF communication equipment and the AquaBplus

The **AquaBplus** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **AquaBplus** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **AquaBplus** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to < 80 MHz $d = 0.35 \sqrt{P}$	80 MHz to < 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meter (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12.1.8 Operating conditions

Operating temperature range

+5 to +35 °C

Radiated heat / losses

Rated output* in L/h	500 – 1000 L/h	1500 – 3000
Radiated heat	500 W	650 W

* The indicated rated output applies for water temperatures of 15 °C. With lower temperatures, an output of 3 % less per degree must be expected. With higher temperatures the permeate output increases accordingly.

Noise level

In **SUPPLY** mode; max. 62 to 73 dB (A) at a distance of 1 m (depending on system capacity and features)

Atmospheric pressure

700 to 1150 hPa

Relative air humidity

Up to 80 % at 20 °C, non-condensing

Water inlet temperature

+5 to max. +35 °C*

Soft water inlet pressure AquaBplus

2.0 to 6.0 bar; dynamic

Inlet volume AquaBplus

Capacity	Feed flow*
500 L/h	Min. 1000 L/h
1000 L/h	Min. 2000 L/h
1500 L/h	Min. 3000 L/h
2000 L/h	Min. 4000 L/h
2500 L/h	Min. 5000 L/h
3000 L/h	Min. 6000 L/h
The actual water volume required depends on the yield. The water required for water pretreatment must also be considered.	

Feed water quality

Warning

Patient hazard caused by different feed water qualities

➢ The design of the water pretreatment system must ensure that the required parameters are fulfilled.

Required parameters

Parameter	Values	Unit
Water hardness	< 1 / < 17.86	°dH / ppm $CaCO_3$
Total Chlorine	< 0.1	mg/L / ppm
Iron*	< 0.1	mg/L / ppm
Manganese*	< 0.1	mg/L / ppm
Silicate*	< 25	mg/L / ppm
Max. conductivity	2500	µS/cm
SDI* (**S**ilt-**D**ensity **I**ndex or colloid index)	< 3	- - -

* The feed water quality parameters for iron, manganese, silicate and SDI are intended to be checked initially for the dimensioning of the pretreatment components.
If the concentrations of these parameters are known from a pre-installation water analysis there is no need to check these values continuously accompanying the dialysis operation.

Warning

Patient hazard caused by a destroyed membrane

A change in water quality can adversely affect the membrane life, potentially requiring the membrane to be replaced prematurely.

➢ Make sure that the required parameters are complied with.

Water pretreatment

Pretreatment of the water is determined after previous water analysis.

Maximum ring main length

– Per ring main: max. 250 m
– Total for 3 ring mains: max. 600 m

For the **Fluid Fly Loop** option

The maximum ring main length in conjunction with the **Fluid Fly Loop** option is reduced by 0.5 m for each **Fluid Fly Loop** option installed.

12.1.9 Transport and storage conditions

Warning

Risk of contamination due to a preservation solution which has become ineffective

Storage time in the preserved state: maximum **12 months**.

➢ An operational requalification must be performed after 12 months at the latest.

➢ Alternatively, extend the storage time by another 12 months by carrying out preservation again.

– The **AquaBplus** must be stored in a well-ventilated room with little variation in temperature.

– To prevent bacterial growth, the **AquaBplus** must undergo another preservation procedure in case of prolonged storage times and, particularly, in case of increased storage temperatures.

Position

Note

Store upright!

Temperature range +5 to +40 °C

Note

Protect the device from freezing!

Relative air humidity Up to 80 % at 20 °C, non-condensing

Atmospheric pressure 500 to 1150 hPa

Note

Protection from exposure to UV light

Do not expose the device to direct sunlight (UV rays may cause faster aging of the materials).

Do not store outdoors!

12.1.10 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 must comply with the requirements for medical electrical systems (see Chapter 16 and Annex I to IEC 60601-1:2005).

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 IEC 60601-1:2005.

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

– 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.

- **System connections**

LAN	Electrically isolated interface for the exchange of data. The system can be connected to a domestic network. Port: RJ 45.
Tank control	See Tank control
External start / stop	Electrically isolated inputs to start the **AquaBplus** in **SUPPLY** mode or to stop all operating modes.
External failure	Electrically isolated input as "collective alarm" from external equipment.
Floating contacts for warning, alarm, supply	Floating contacts to provide information about the status of the **AquaBplus**, e.g., for connection of a visual indicator unit. The contacts have a load capacity of 24 V / 1 A.

12.1.11 Materials used

According to ISO 10993-1:2009, components coming into contact with permeate must be biocompatible.

12.2 Specifications for AquaBplus B2 (option)

- **Dimensions and weight**

Dimensions of control units, including membranes, each

Parameter	AquaBplus B2 (500 – 2500)
Height	1500 mm
Width	550 mm
Depth	951 mm

Parameter	AquaBplus +AquaBplus B2 as complete system
Height	1500 mm
Width	1250 mm
Depth	951 mm
Gap	200 mm

Weight

Values	AquaBplus B2 500	AquaBplus B2 1000	AquaBplus B2 1500	AquaBplus B2 2000	AquaBplus B2 2500
Empty	110 kg	140 kg	170 kg	190 kg	210 kg
Filled	130 kg	170 kg	210 kg	250 kg	290 kg

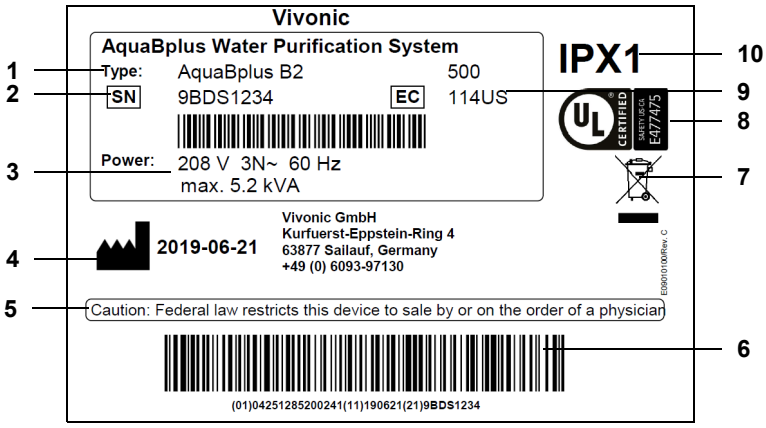
- **System data**

Parameter	Values
Permeate output	500 - 2500 L/h for 15 °C and a counter-pressure of 2 bar 500 L/h per pressure tube*
Effective Yield	55–75 %, adjustable (to save water)
Rejection rate	> 99 % for bacteria and endotoxins > 96 % for dissolved salts (average)
Concentrate pressure	max. 25 bar

* The indicated rated output applies for water temperatures of 15 °C. With temperatures below 15 °C, an output of 3 % less per degree must be expected. With higher temperatures the permeate output increases accordingly.

● Identification label (system identification)

The identification label shown is only an example. The decisive criteria is the data specified on the identification label of the device.



1. Type identification
2. Serial number
3. Power requirements
4. Manufacturer (year of manufacture, 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. UL Safety and Identity Mark
9. Equipment code (EC: Equipment Code)
10. Protection against ingress of liquids: Drip-proof

- **Electrical safety**

  Classification according to IEC 60601-1:2005

Type of protection against electric shock	Protection class I
Type of applied part (degree of patient protection)	Type B
Degree of protection against ingress of liquids	Drip-proof
Leakage currents	According to 60601-1

- **Electrical supply**

  Electrical connection

Line voltage	Frequency	Power consumption	Protection	Tripping characteristic
208 V 3/N/PE (North America option)	60 Hz	Up to 5.2 kVA	3 x 20 A	D or K or similar recommended (due to high starting currents) Fuses according UL 248-8, Class J

- **Fuses**

  None

- **Guidance and manufacturer's declaration on EMC (IEC 60601-1-2)**

  The system has undergone and passed the EMC tests.

Tip

The technical specifications are identical to the specifications for the **AquaBplus**.

- **Electromagnetic emissions**

Tip

The technical specifications are identical to the specifications for the **AquaBplus**.

- **Electromagnetic immunity**

Tip

The technical specifications are identical to the specifications for the **AquaBplus**.

Recommended separation distances between portable and mobile RF communication equipment and the **AquaBplus B2**.

Tip

The technical specifications are identical to the specifications for the **AquaBplus**.

- **Operating conditions**

Operating temperature range

+5 to +35 °C

Radiated heat / losses

Rated output* in L/h	500 – 1000 L/h	1500 – 3000
Radiated heat	500 W	650 W

* The indicated rated output applies for water temperatures of 15 °C. With lower temperatures, an output of 3 % less per degree must be expected. With higher temperatures the permeate output increases accordingly.

Noise level

In **SUPPLY** mode; max. 62 to 73 dB (A) at a distance of 1 m (depending on system capacity and features)

Atmospheric pressure

700 to 1150 hPa

Relative humidity

Up to 80 % at 20 °C, non-condensing

Water inlet temperature

+5 to +35 °C

Soft water inlet pressure

2 to 6 bar; dynamic

Maximum ring main length

General information

– Per ring main: max. 250 m
– Total for 3 ring mains: max. 600 m
– The ring mains must also be thermally isolated.

For the **Fluid Fly Loop** option

The maximum ring main length in conjunction with the **Fluid Fly Loop** option is reduced by 0.5 m for each **Fluid Fly Loop** option installed.

● Transport and storage conditions

Warning

Risk of contamination due to a preservation solution which has become ineffective

Storage time in the preserved state: maximum **12 months**.

➢ An operational requalification must be performed after 12 months at the latest.

➢ Alternatively, extend the storage time by another 12 months by carrying out preservation again.

– The **AquaBplus HF** must be stored in a well-ventilated room with little variation in temperature.

– To prevent bacterial growth, the **AquaBplus HF** must undergo another preservation procedure in case of prolonged storage times and, particularly, in case of increased storage temperatures.

Position

Note

Store upright!

Temperature range +5 to +40 °C

Note

Protect the device from freezing!

Relative air humidity Up to 80 % at 20 °C, non-condensing

Atmospheric pressure 500 to 1150 hPa

Note

Protection from exposure to UV light

Do not expose the device to direct sunlight (UV rays may cause faster aging of the materials).

Do not store outdoors!

● Materials used

According to ISO 10993-1:2009, components coming into contact with permeate must be biocompatible.

12.3 Specifications for AquaBplus HF (option)

Dimensions

Parameter	Values
Height	1500 mm
Width	220 mm
Depth	610 mm

Parameter	AquaBplus + AquaBplus HF
Height	1500 mm
Width	990 mm
Depth	951 mm

Parameter	Complete system AquaBplus + AquaBplus B2 + AquaBplus HF
Height	1500 mm
Width	1670 mm
Depth	951 mm

Weight

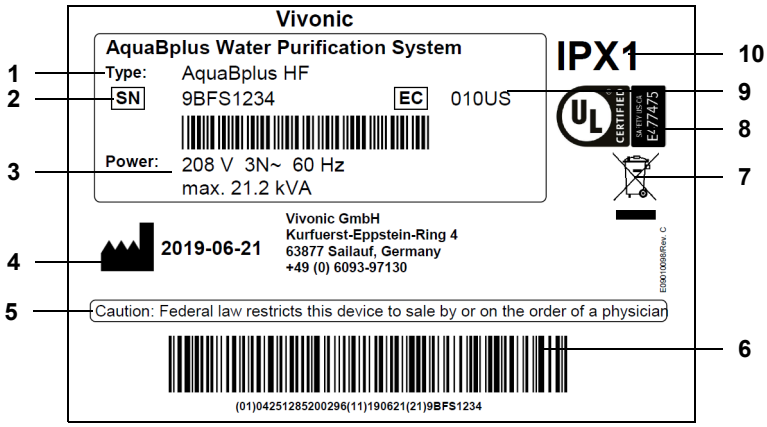
Parameter	Empty	In operation
Weight	70 kg	75 kg

System data

Parameter	Values
Permeate output	Distributes the permeate of the **AquaBplus** or **AquaBplus B2**.
Heater output	max. 19.5 KVA
Maximum pressure	6 bar
Temperature Heat disinfection	70 – 92 °C (adjustable) /

Identification label (system identification)

The identification label shown is only an example. The decisive criteria is the data specified on the identification label of the device.



1. Type identification
2. Serial number
3. Power requirements
4. Manufacturer (year of manufacture, 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. UL Safety and Identity Mark
9. Equipment code (EC: Equipment Code)
10. Protection against ingress of liquids: Drip-proof

Electrical safety

Electrical safety (classification according to IEC 60601-1:2005)

Type of protection against electric shock	Protection class I
Degree of protection against electric shock	Type B
Degree of protection against ingress of liquids	Drip-proof
Leakage currents	According to EN 60601-1:2005

- **Electrical supply**

  Electrical connection

Line voltage	Frequency	Power consumption	Protection	Tripping characteristic
208 V 3/N/PE	60 Hz	Up to 21.2 kVA	3 x 80 A	D or K or similar recommended (due to high starting currents) Fuses according UL 248-8, Class J

- **Fuses**

  none

- **Guidance and manufacturer's declaration on EMC (IEC 60601-1-2)**

  The system has undergone and passed the EMC tests.

- **Electromagnetic emissions**

Tip

The technical specifications are identical to the specifications for the **AquaBplus**.

- **Electromagnetic immunity**

Tip

The technical specifications are identical to the specifications for the **AquaBplus**.

- **Recommended separation distances between portable and mobile RF communication equipment and the AquaBplus HF option**

Tip

The technical specifications are identical to the specifications for the **AquaBplus**.

- **Operating conditions**

  Operating temperature range +5 to +35 °C

Feed water	See operating conditions for **AquaBplus** (see Chapter 12.1.8 on page 12-11)

13 Definitions

13.1 Terms and definitions

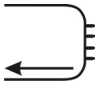
Operational Qualification	Commissioning the system
Operational requalification	Recommissioning the system

13.2 Abbreviations

CD	Conductivity
Fig.	Figure (diagram)
RO	Reverse osmosis
TSC	Technical Safety Checks

13.3 Icons

IPX1	Protection against ingress of liquids: Drip-proof (IPX1)
	UL Safety and Identity Mark
	Alternating current
	Protective earth connection
	Dangerous electrical voltage
I/O	ON / OFF (supply voltage)
	Identification of electrical and electronic devices
	Manufacturer
	Serial number
	Equipment code (EC code)
	Observe instructions for use!
	Disconnect the power plug before opening the housing
	General warning
	Caution: Hot surface
	Caution: Dangerous electrical voltage
	Permeate feed



Permeate return

IN

Soft water inlet

Drain

13.4 Certificates

On request, the local service department can provide the current version of the required certificates.

14 Module and options

14.1 AquaBplus B2 module (double pass reverse osmosis system)

14.1.1 Preface

The following overview shows where to find the required information in the document.

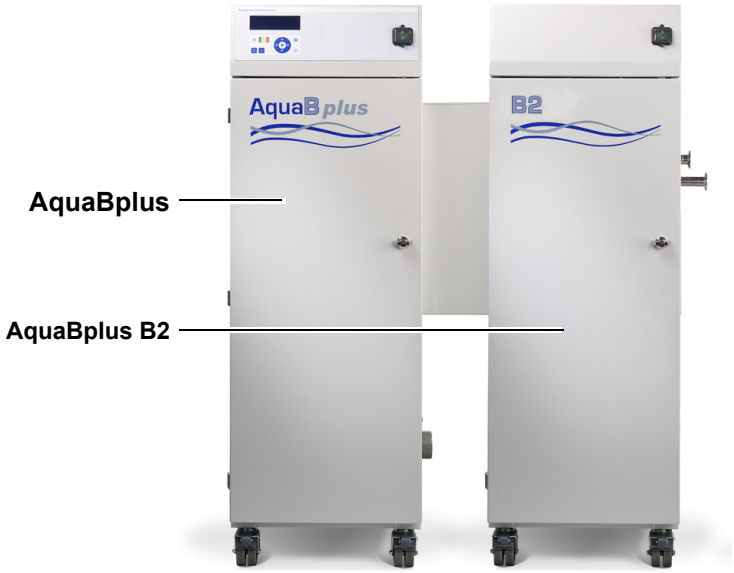
Generally applicable chapters which apply to both the main system and the options will only be described once in the documentation of the main system.

14.1.2 Contents overview

Subject, contents of the AquaBplus B2	refer to
– **Index**	➢ (see **chapter 1** of the **AquaBplus**)
– **Important information** – **Target group** – **Responsible organization** – **Operator responsibility** – **Disclaimer of liability** – **Technical documentation** – **Warnings** – **Residual risks** – **Addresses**	➢ (see **chapter 2** of the **AquaBplus**)
– **Alarms**	➢ (see **chapter 5** of the **AquaBplus**)
– **Installation**	➢ (see **chapter 9** of the **AquaBplus**)
– **Transport / storage**	➢ (see **chapter 10** of the **AquaBplus**)
– **Technical Safety Checks / maintenance**	➢ (see **chapter 11** of the **AquaBplus**)

14.1.3 Functional description – AquaBplus B2

- **Brief description AquaBplus B2**



The **AquaBplus** and **AquaBplus B2** form a double pass reverse osmosis system.
The **AquaBplus B2** is completely controlled by the **AquaBplus** (stage 1).
All operating steps (except for turning the system on) are performed on the **AquaBplus**.

- **Intended use AquaBplus B2**

  – (see Chapter 2.6 on page 2-4).

- **Restrictions AquaBplus B2**

  – As for the **AquaBplus** or the possible options.

14.1.4 System design – AquaBplus B2

- **Front view**

Legend:

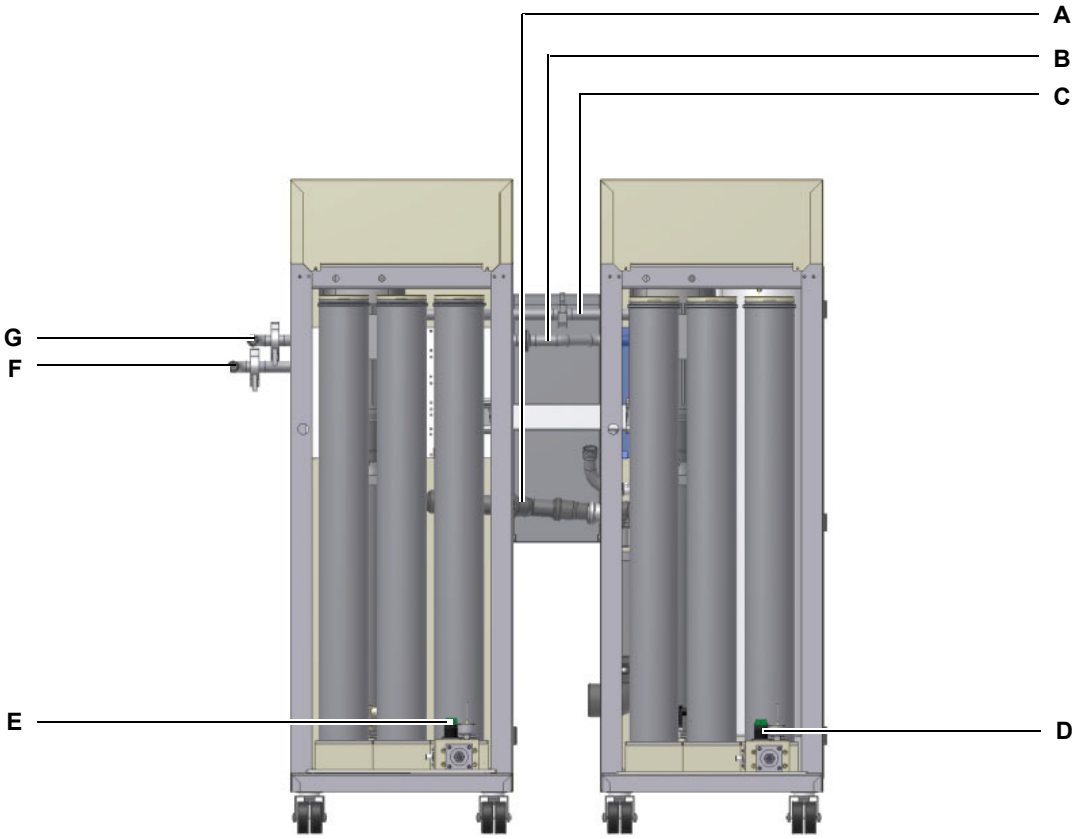
A User interface (keys and display)

B Drain

C Permeate outlet, from ring main

D Permeate outlet, to ring

- **Rear view**



Legend:

A Drain (**AquaBplus B2**)

B Permeate feed (**AquaBplus B2**)

C Permeate return (**AquaBplus B2**)

D Membrane rinse valve V30 (**AquaBplus**)

E Membrane rinse valve V30s (**AquaBplus B2**)

F From ring main

G Permeate outlet, to ring main

14.1.5 Operating modes – AquaBplus B2

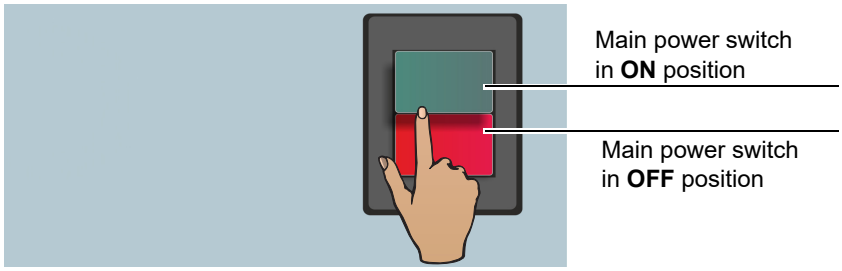
Tip

The **AquaBplus B2** is completely integrated into the operating modes of the **AquaBplus** and therefore has no individual operating modes.

Any deviations during the start phases are described in the respective chapters.

14.1.6 System status STANDBY – AquaBplus B2

The system is turned on with the main power switch (**ON** position).



Turning the system on

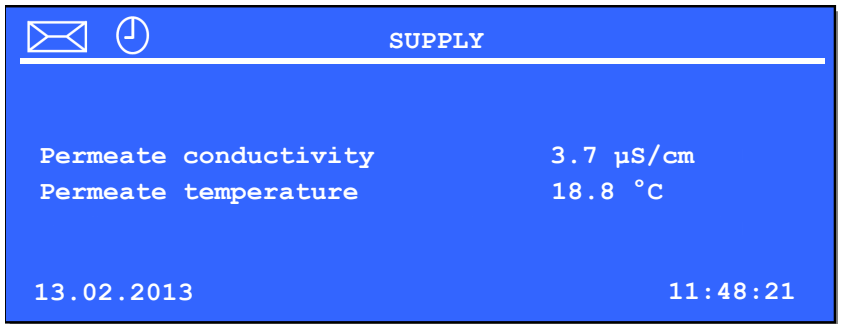
– Use the main power switch to turn the **AquaBplus** on.
– Use the main power switch to turn the **AquaBplus B2** on.

The **AquaBplus B2** has no operating controls for the operator. The system is operated from the **AquaBplus**. After turning the system power on, the **STANDBY** screen will be displayed.

14.1.7 SUPPLY mode – AquaBplus B2

Switch the **AquaBplus** + **AquaBplus B2** system to **SUPPLY** (see Chapter 4.4 on page 4-4).

Before the **SUPPLY** mode is started, the system will perform a T1 test.



The conductivity and the temperature displayed in **SUPPLY** mode refer to the permeate outlet of the **AquaBplus B2**. The parameters of the **AquaBplus** can be viewed in the **Status - Operating data** menu.

Tip

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

14.1.8 RINSE mode – AquaBplus B2

(see Chapter 4.5 on page 4-8).

14.1.9 DISINFECTION mode – AquaBplus B2

(see Chapter 6 on page 6-1)

14.1.10 EMERGENCY MODE (option)

14.1.10.1 General information

Warning

Emergency mode after a disinfection

The **EMERGENCY MODE** may not be started if there is still residual disinfectant in the system after a disinfection.

Note

After turning the emergency switch, a disinfection is required!

Note

EMERGENCY MODE can be started without any previous preparation and from any operating mode of the system.

Note

The service time of the emergency operation must be reduced to a necessary minimum until a repair is possible.

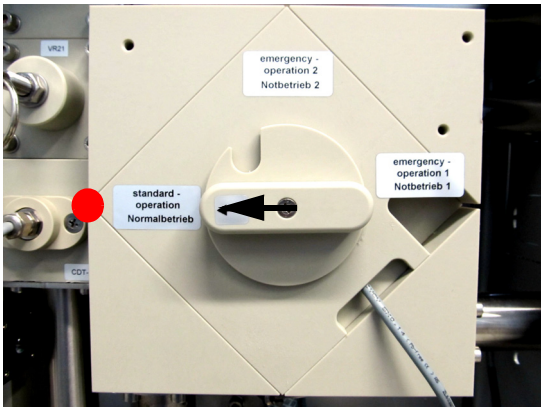
This period between the first use of the emergency operation and the repair of the device should not exceed 120 hours.

14.1.10.2 Starting the emergency mode on the AquaBplus B2

Tip

Using the emergency mode function

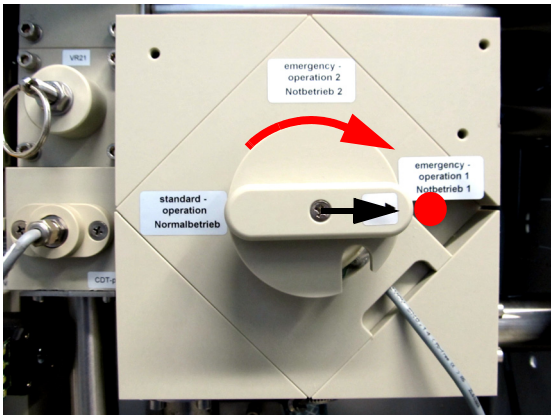
If double pass operation is impossible due to a defect on one of the two systems, emergency supply can be ensured by single pass operation of the first or second system.



Switch position for normal operation

➢ The emergency switch can be accessed by opening the door of the first system.

➢ For **normal operation** the switch is in its **left** position.



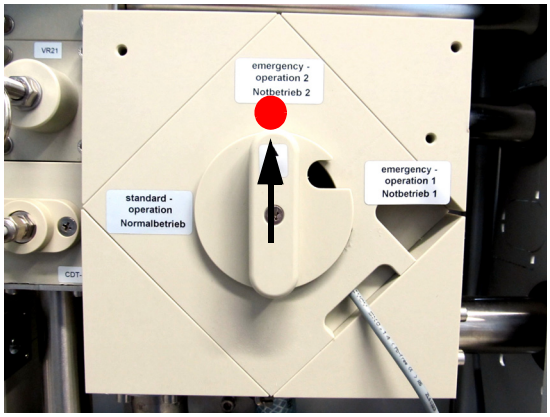
Switch position for Emergency mode, Stage 1

➢ **Emergency mode, Stage 1** is started by turning the **Emergency switch** to the **right** position.

Tip

For **Emergency Mode Stage 1** it states that conductivity and Temperature monitoring is active.

It does not state that in **Emergency mode Stage 2**, conductivity and temperature monitoring is active.



Switch position for Emergency mode, Stage 2

➢ **Emergency mode, Stage 2**, is started by turning the **Emergency switch** to the **up** position.

14.1.11 STATUS – Information – AquaBplus B2

Tip

The menu structure of the **STATUS Information** for the **AquaBplus B2** is identical to the menu structure of the **AquaBplus** and is operated via the display of the **AquaBplus**.

14.1.12 STATUS – Operating data for AquaBplus B2

Description page 1/4

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Permeate conductivity	CD-Ps	0.0 to 2500	µS/cm	±10 %
Permeate temperature	T-Ps	0.0 to 115.0	°C	±1 °C
Soft water conductivity	CD-F	0.0 to 2500	µS/cm	±10 %
Soft water temperature	T-F	0.0 to 115.0	°C	±1 °C

Description page 2/4

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Soft water supply	FL-F	4.0 to 160	L/min	±10 %
Permeate consumption	–	4.0 to 160	L/min	±10 %
Effective yield	–	55 to 75	%	±10 %
Rejection rate	–	0.0 to 99.9	%	–

Description page 3/4

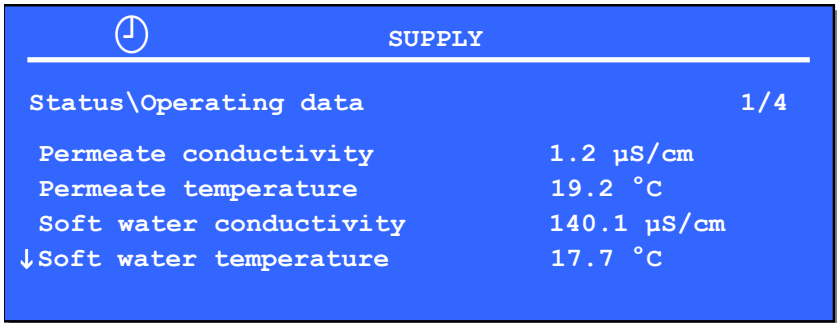
Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Concentrate pressure stage 1	P-C	0.0 to 20	bar	±10 %
Concentrate flow stage 1	FL-C	4.0 to 160	L/min	±10 %
Permeate conductivity stage 1	CD-P	0.0 to 2500	µS/cm	±10 %
Permeate temperature stage 1	T-Ps	0.0 to 115.0	°C	±1 °C

Description page 4/4

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Concentrate pressure stage 2	P-Cs	0.0 to 20	bar	±10 %
Rejection rate stage 1	–	0.0 to 99.9	%	–

14.1.12.1 Viewing the operating data

Page 1/4



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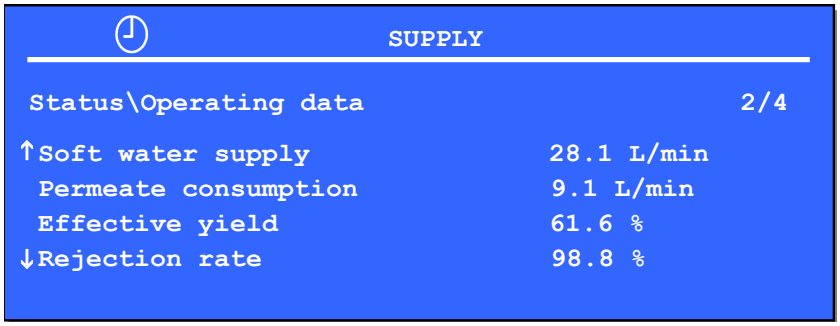

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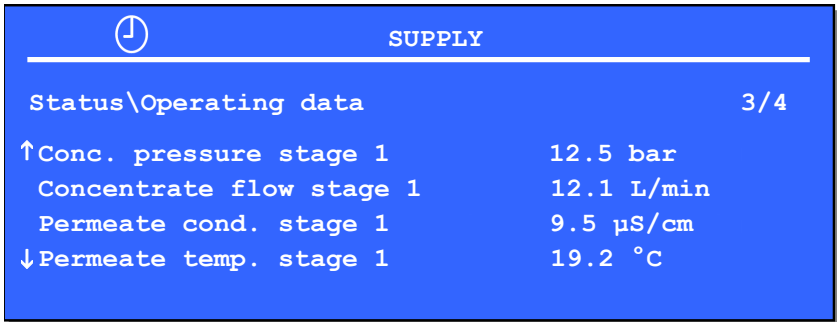

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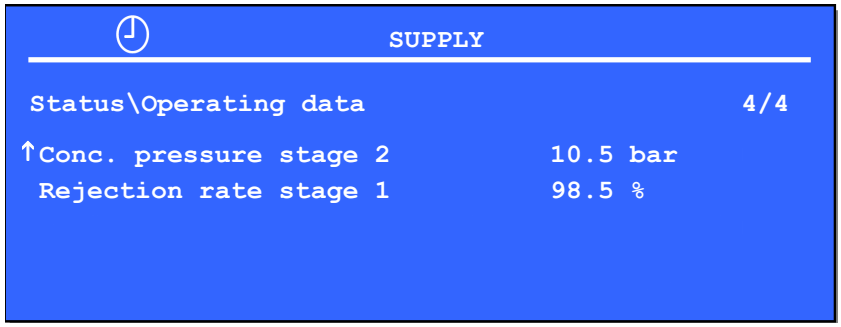


14.1.13 Specifications – AquaBplus B2

Tip

The specifications for the **AquaBplus HF** are located in the main specifications chapter (see Chapter 12.2 on page 12-15).

14.2 Module AquaBplus HF (ring heat disinfection module)

14.2.1 Preface

The following overview shows where to find the required information in the document.

Generally applicable chapters which apply to both the main system and the options will only be described once in the documentation of the main system.

14.2.2 Contents overview

Subject, contents of the AquaBplus HF	refer to
– **Index**	➢ (see **chapter 1** of the **AquaBplus**)
– **Important information** – **Target group** – **Responsible organization** – **Operator responsibility** – **Disclaimer of liability** – **Technical documentation** – **Warnings** – **Residual risks** – **Addresses**	➢ (see **chapter 2** of the **AquaBplus**)
– **Alarms**	➢ (see **chapter 5** of the **AquaBplus**)
– **Installation**	➢ (see **chapter 9** of the **AquaBplus**)
– **Transport / storage**	➢ (see **chapter 10** of the **AquaBplus**)
– **Technical Safety Checks / maintenance**	➢ (see **chapter 11** of the **AquaBplus**)

14.2.3 Functional description – AquaBplus HF

The **AquaBplus HF** is an extension module for the **AquaBplus** or **AquaBplus B2** reverse osmosis system to permit heat disinfection of the permeate production and permeate supply equipment.

The module does not alter the existing functions or operating phases of the **AquaBplus** and the **AquaBplus B2**, but rather is a supplement to them.

Additional functions and operating phases are as follows:

- **Heat disinfection of the permeate ring main**
- **Integrated heat disinfection** (e.g., dialysis devices draw in hot permeate after the phase for which the temperature is maintained)

● **Intended use – AquaBplus HF**

Restrictions

- **Heat disinfection of the ring main** is restricted to ring mains with a maximum length of 3 x 250 m.
- Depending on the insulation of the ring main, the **integrated heat disinfection** is restricted to a maximum of 5 dialysis devices at a time.

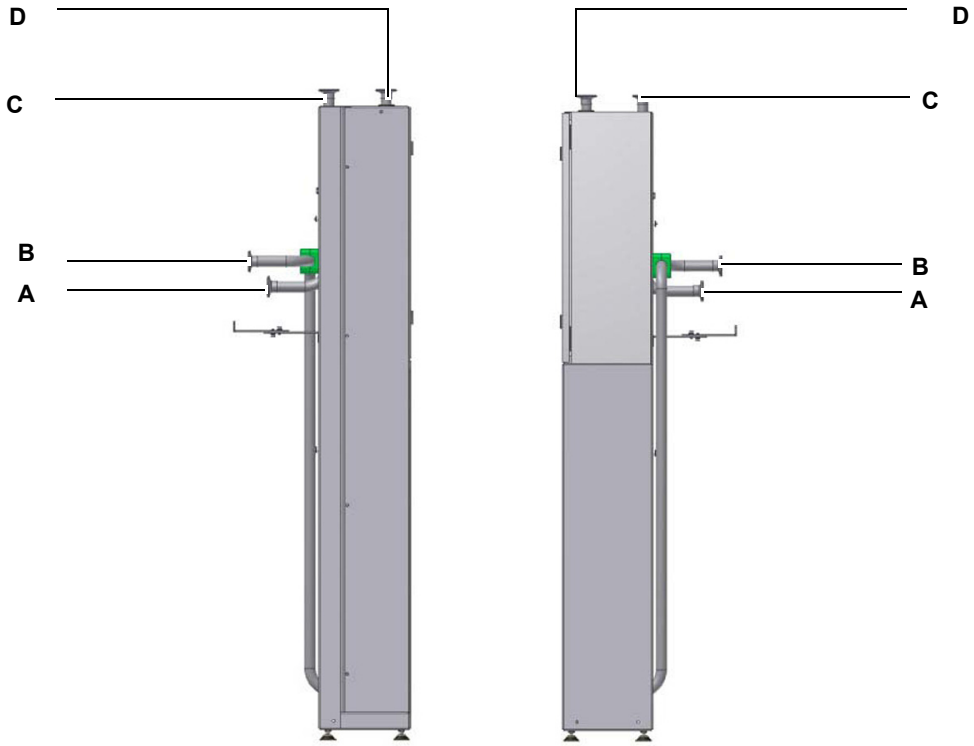
Note

The manufacturer recommends running a **heat disinfection once a week**.

This is a recomendation not a requirement. The actual heat disinfection interval is determined by the operator by **regular sampling**. The disinfection intervals may be extended or single measures may be omitted if the results of the microbiological monitoring show no considerable growth in excess of the allowed limit.

14.2.4 Design – AquaBplus HF

- **Front view / rear view – AquaBplus HF**



Legend:

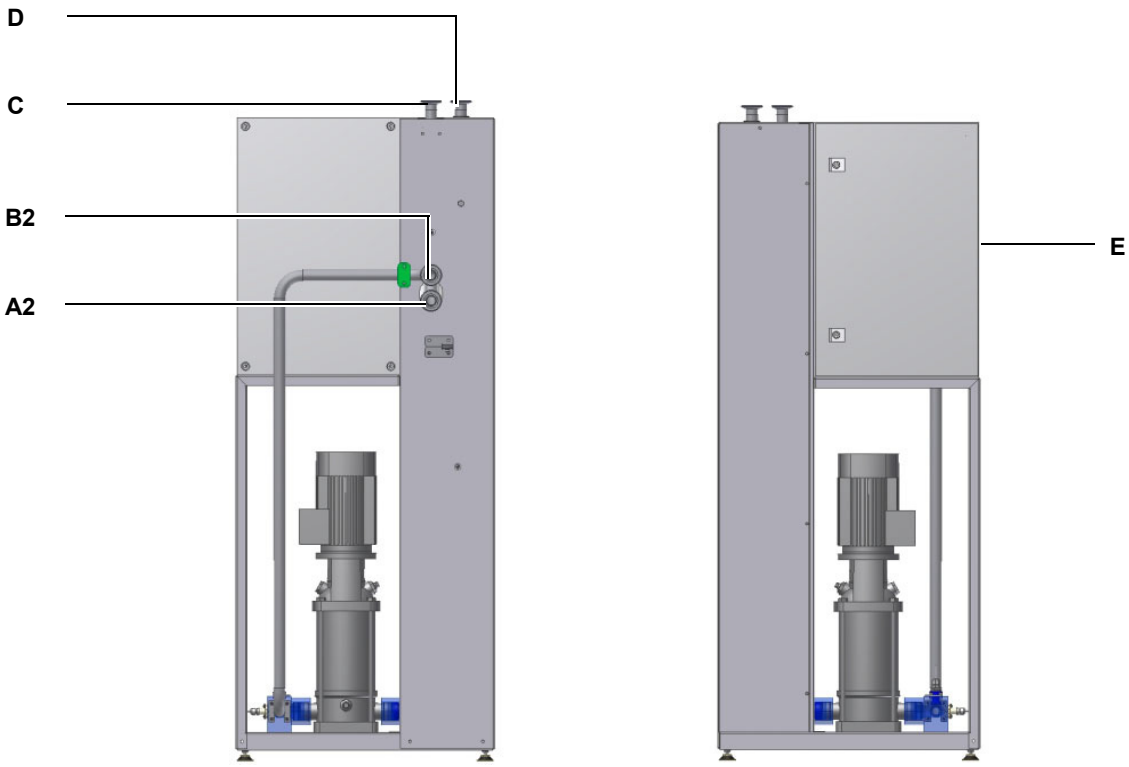
A Return

B Feed

C From ring main

D To ring main

- **Side view – from left / from right**



Legend:

A2 Return

B2 Feed

C From ring main

D To ring main

E Control cabinet door

14.2.5 HEAT DISINFECTION mode – AquaBplus HF

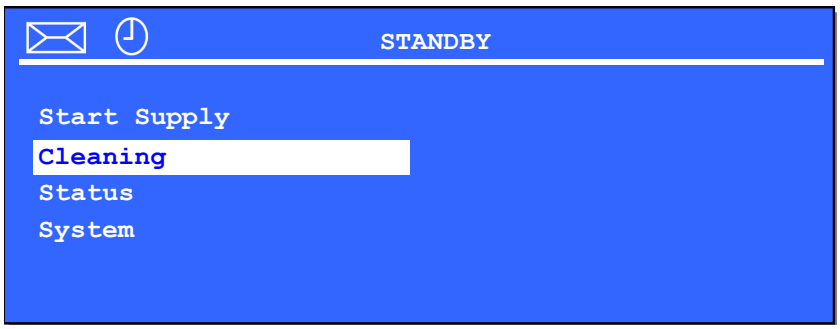
Prior to the first start of a heat disinfection, the **HEAT DISINFECTION** program must be configured in the System **–** Settings menu.

Tip

For the configuration of the heat disinfection parameters
(see Chapter 14.2.12 on page 14-25).

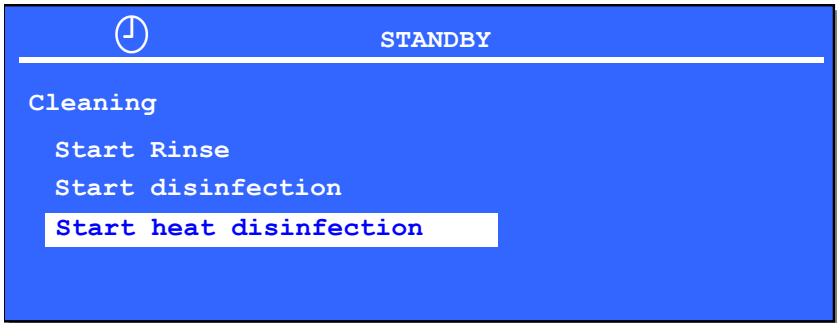
- **Manually starting the heat disinfection**

Select the menu option **Cleaning** and confirm with the **Enter** key.



Then select the menu option **Start heat disinfection** and confirm with the **Enter** key.

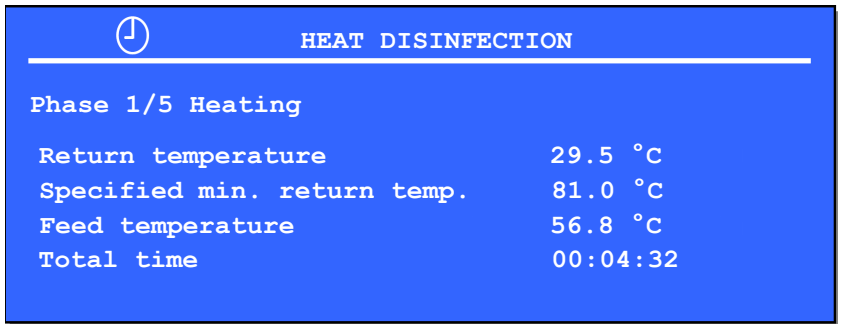
The system will switch to the **Heat disinfection** mode.



A **start test** is performed before heating of the permeate ring main.

Phase 1/5 Heating

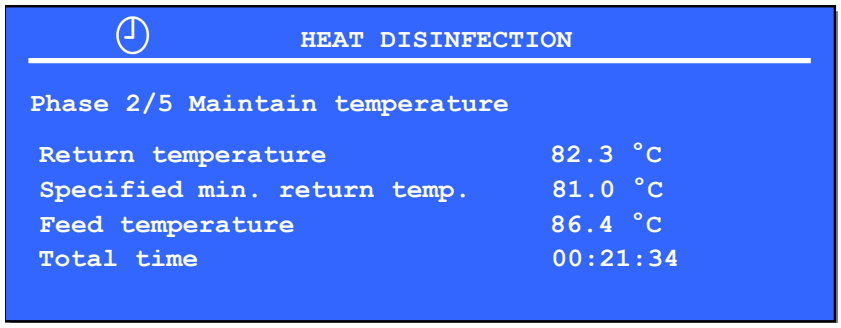
During this phase, the permeate in the ring main is heated to the specified temperature.



When the specified value has been reached, the next phase of the heat disinfection will be started.

Phase 2/5 Maintain temperature

During this phase, the temperature in the ring main is maintained at the specified value.



Warning

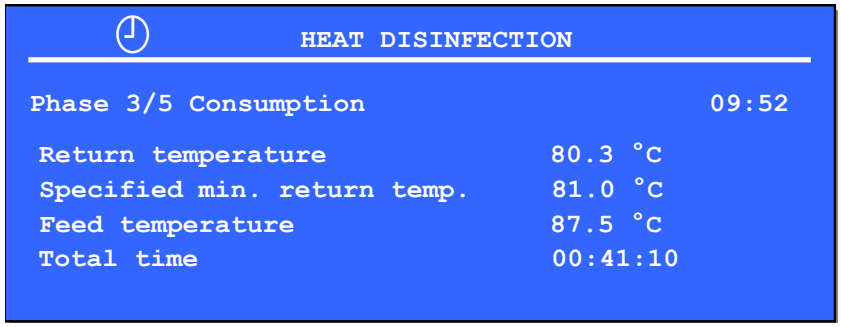
Consumption prohibited

➢ No permeate may be used during **Phase 2/5 Maintain temperature** to ensure that the efficacy of the heat disinfection is not negatively affected.

The temperature in the ring main is maintained for the programmed time. After this phase, consumption starts.

Phase 3/5 Consumption

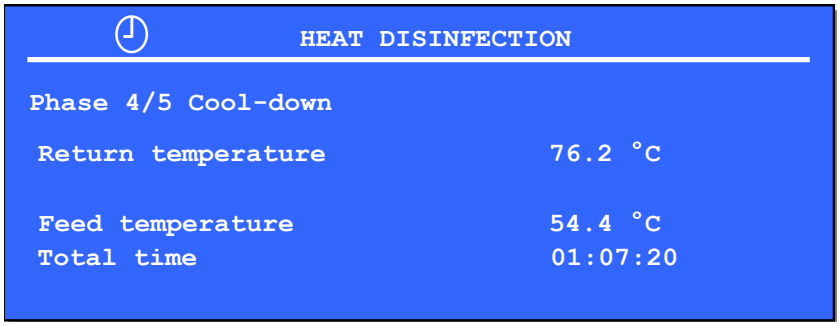
Depending on the insulation of the ring main and the ambient conditions, up to 5 dialysis devices can be supplied simultaneously with hot permeate from the ring main during the consumption phase.



The **AquaBplus HF** provides hot permeate for the supply of the dialysis systems for the programmed time. This phase is followed by the cool-down phase.

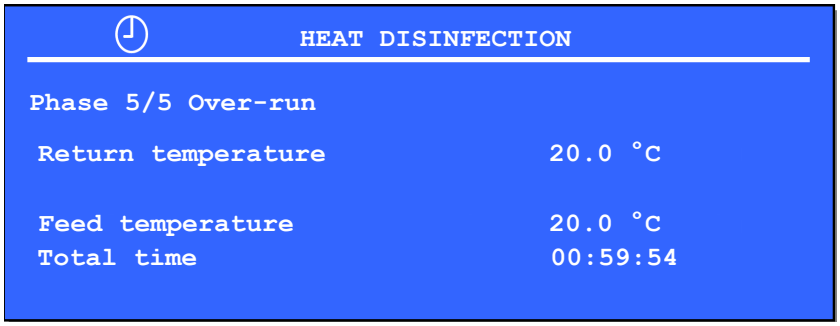
Phase 4/5 Cool-down

During this phase, the ring main is cooled down to a temperature below the specified alarm limit of the permeate temperature by discarding the preset volume on the **RingBase**.



Phase 5/5 Over-run

During the time of the over-run, permeate is discarded to the drain via the RingBase for the programmed time.



On completion of the heat disinfection, the **AquaBplus** will automatically switch to **STANDBY**.

14.2.6 SUPPLY mode – AquaBplus HF

During **SUPPLY**, the **AquaBplus HF** is inactive. The permeate flows through the module into the ring main.

All control and monitoring functions of the **AquaBplus** and the **AquaBplus B2** remain unchanged.

14.2.7 RINSE mode – AquaBplus HF

The system rinses all flow paths.

14.2.8 DISINFECTION mode – AquaBplus HF

The **AquaBplus HF** module is included in the disinfection and subsequent rinsing.

14.2.9 STATUS – Information – AquaBplus HF

Tip

The structure of the **STATUS – Information** menu of the **AquaBplus HF** is identical to the menu structure of the **AquaBplus** and is operated via the display of the **AquaBplus**.

14.2.10 STATUS – AquaBplus + AquaBplus HF operating data

Description page 1/4

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Permeate conductivity	CD-P	0.0 to 2500	µS/cm	±10 %
Permeate temperature	T-P	0.0 to 115.0	°C	±1 °C
Soft water conductivity	CD-F	0.0 to 2500	µS/cm	±10 %
Soft water temperature	T-F	0.0 to 115.0	°C	±1 °C

Description page 2/4

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Soft water supply	FL-F	4.0 to 160	L/min / gpm	±10 %
Permeate consumption		4.0 to 160	L/min	±10 %
Effective yield		55 to 75	%	±5 %
Rejection rate		0.0 to 99.9	%	- - -

Description page 3/4

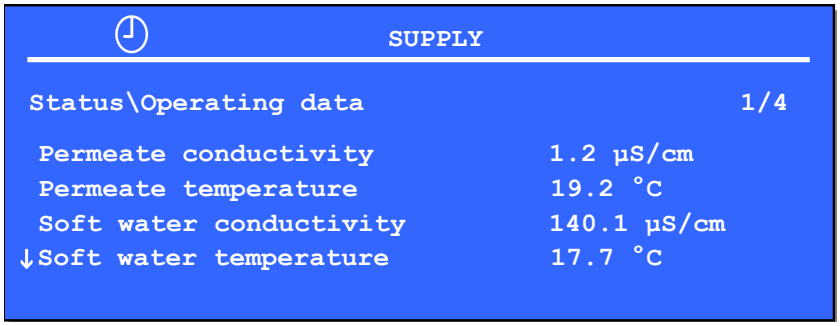
Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Concentrate pressure	P-C	0.0 to 20	bar	±10 %
Concentrate flow	FL-C	4.0 to 160	L/min	±10 %
Feed temperature	T-Hout	0.0 to 135.0	°C	±1 °C
Return temperature	T-Hin	0.0 to 135.0	°C	±1 °C

Description page 4/4

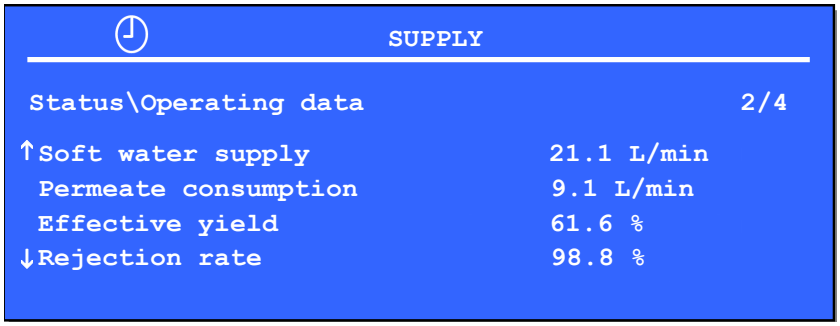
Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Pressure P5	P-5F	0.0 to 10	bar	±10 %

14.2.10.1 Viewing the operating data

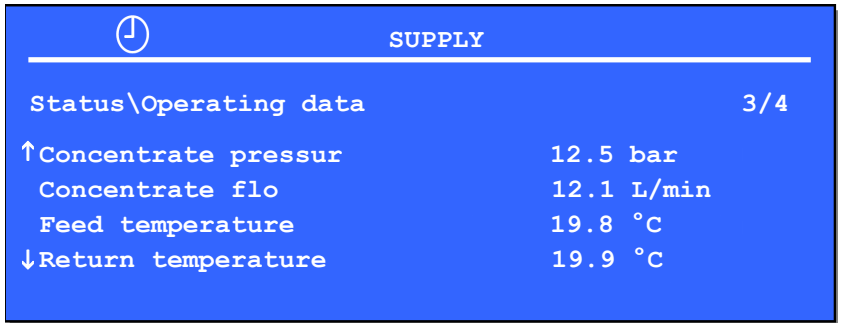
Page 1/4



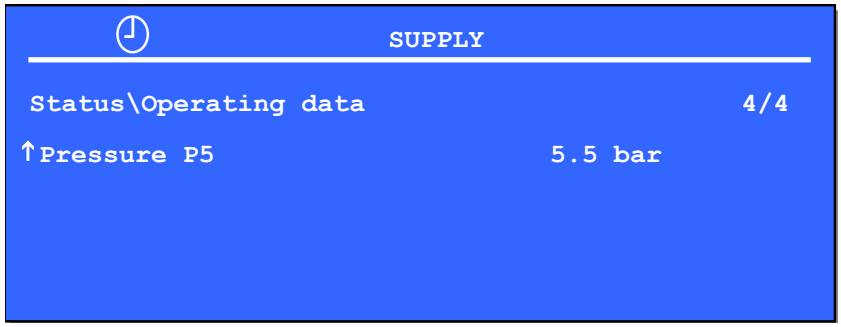
Page 2/4



Page 3/4



Page 4/4



14.2.11 STATUS – AquaBplus + AquaBplus B2 + AquaBplus HF operating data

Description page 1/5

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Permeate conductivity	CD-Ps	0.0 to 2500	µS/cm	±10 %
Permeate temperature	T-Ps	0.0 to 115.0	°C	±1 °C
Soft water conductivity	CD-F	0.0 to 2500	µS/cm	±10 %
Soft water temperature	T-F	0.0 to 115.0	°C	±1 °C

Description page 2/5

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Soft water supply	FL-F	4.0 to 160	L/min	±10 %
Permeate consumption		4.0 to 160	L/min	±10 %
Effective yield		55 to 75	%	±5 %
Rejection rate		0.0 to 99.9	%	- - -

Description page 3/5

Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Conc. pressure stage 1	P-C	0.0 to 20	bar	±10 %
Concentrate flow stage 1	FL-C	4.0 to 160	L/min	±10 %
Permeate conductivity stage 1	CD-P	0.0 to 2500	µS/cm	±10 %
Permeate temperature stage 1	T-P	0.0 to 115.0	°C	±1 °C / ±1.8 °F

Description page 4/5

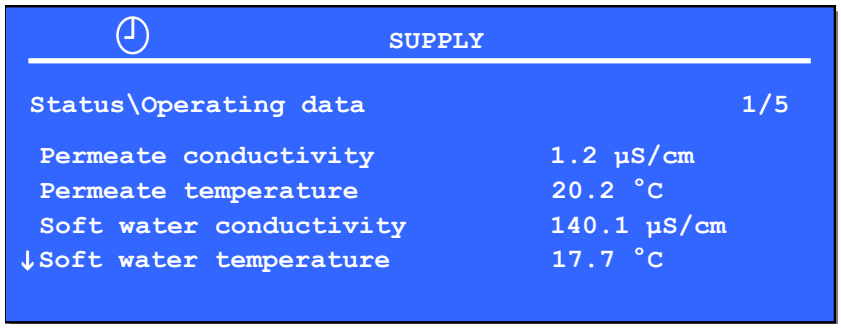
Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Conc. pressure stage 2	P-Cs	0.0 to 20	bar	±10 %
Feed temperature	T-Hout	0.0 to 135.0	°C	±1 °C
Return temperature	T-Hin	0.0 to 135.0	°C	±1 °C
Pressure P5	P-5F	0.0 to 10	bar	±10 %

Description page 5/5

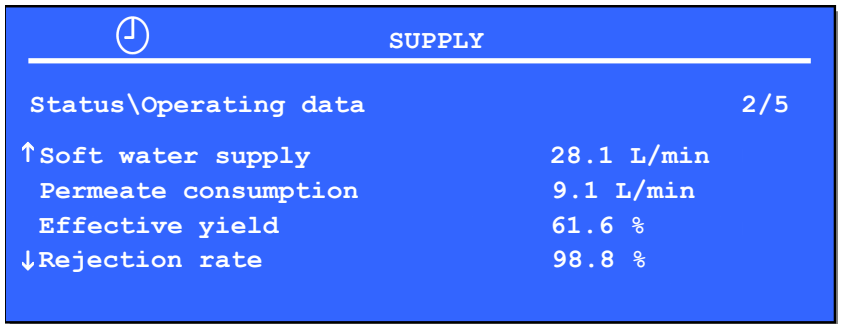
Measured value	Sensor	Measuring range	Unit	Measuring accuracy
Rejection rate stage 1		0.0 to 99.9	%	- - -

14.2.11.1 Viewing the operating data

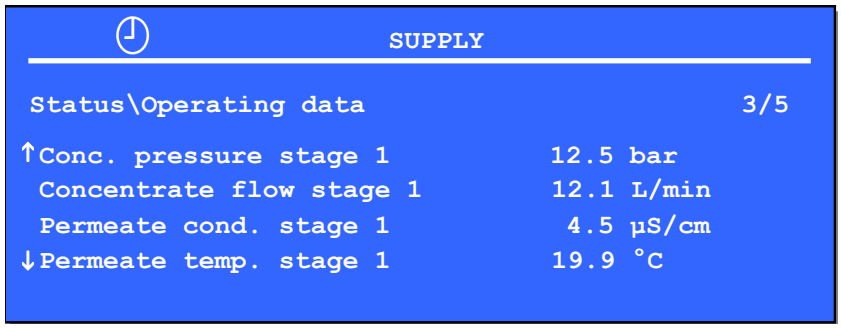
Page 1/5



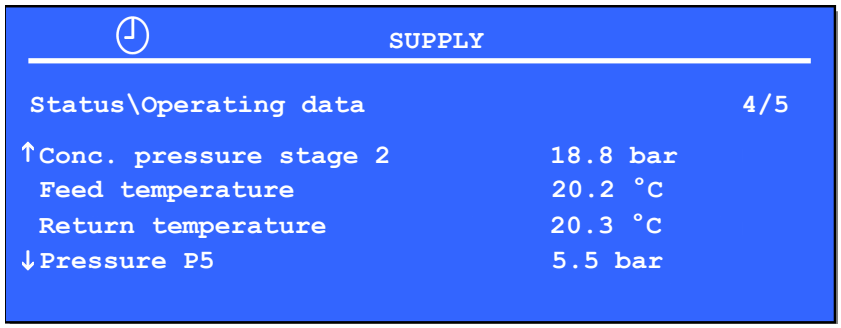
Page 2/5



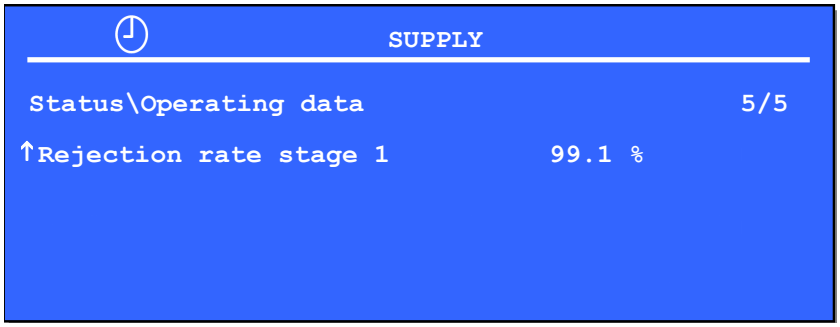
Page 3/5



Page 4/5

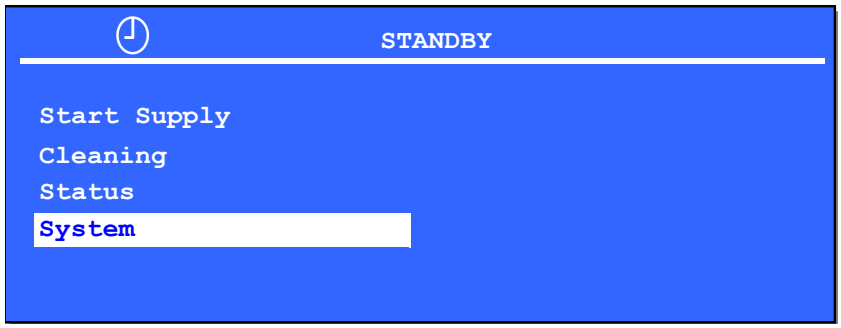


Page 5/5



14.2.12 SYSTEM –Settings

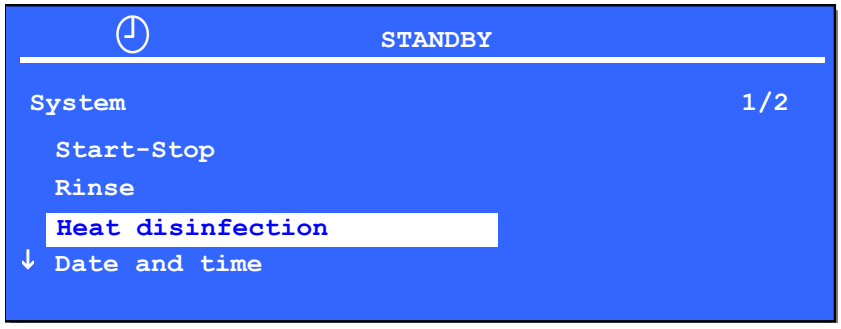
This menu is provided for the operator to set different parameters. The main menu can be displayed by pressing the **Menu** key.



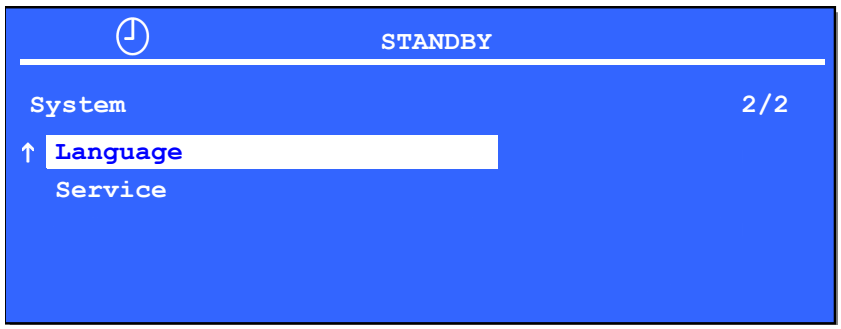
First confirm the menu option System with the **Enter** key. The **System** menu will be displayed:

If the **AquaBplus HF** option is installed, the additional menu option **Heat disinfection** will be displayed in the **System** menu.

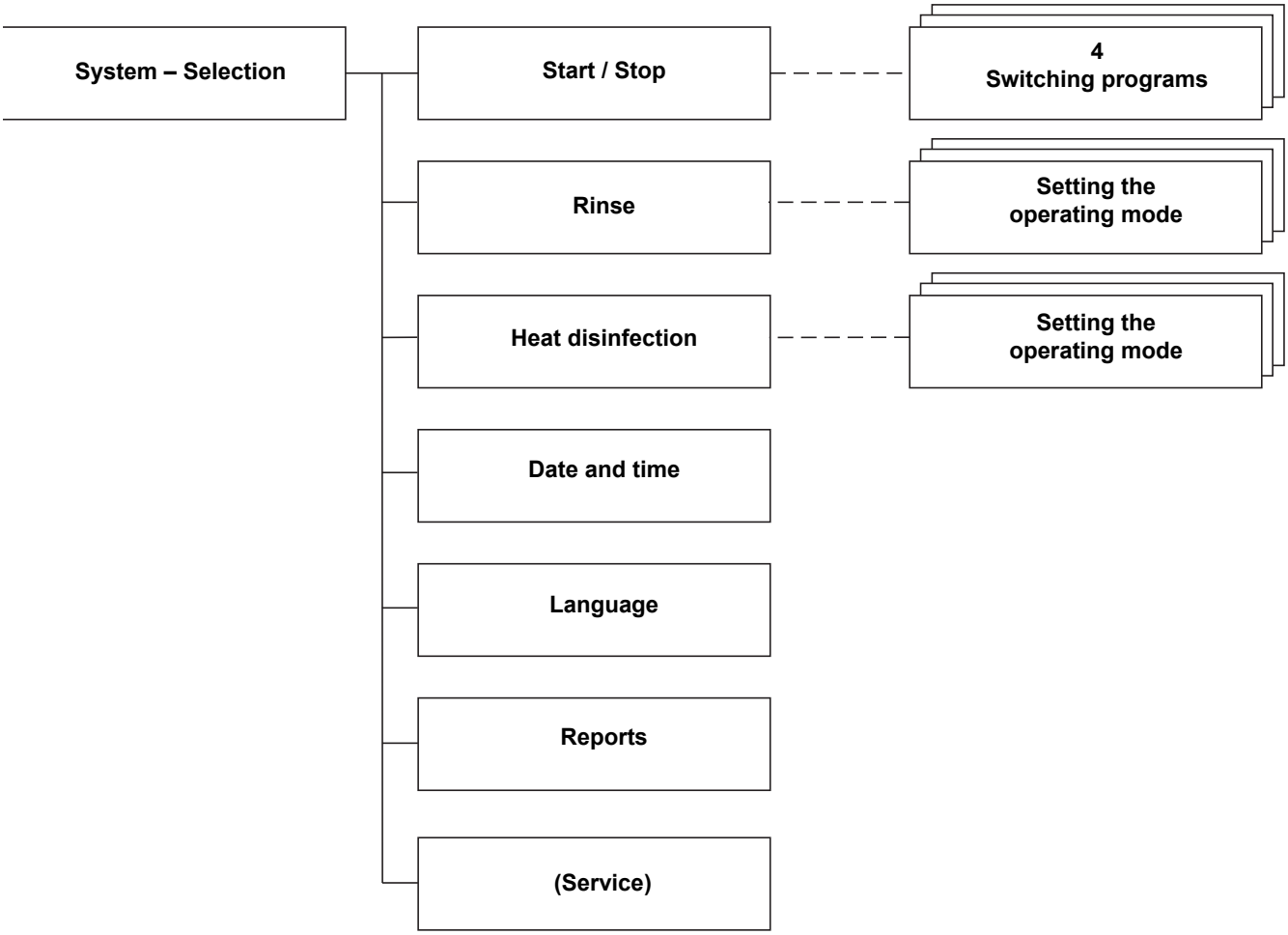
Page 1



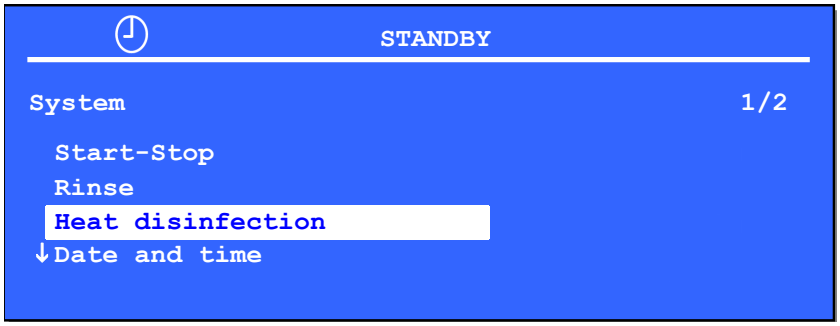
Page 2



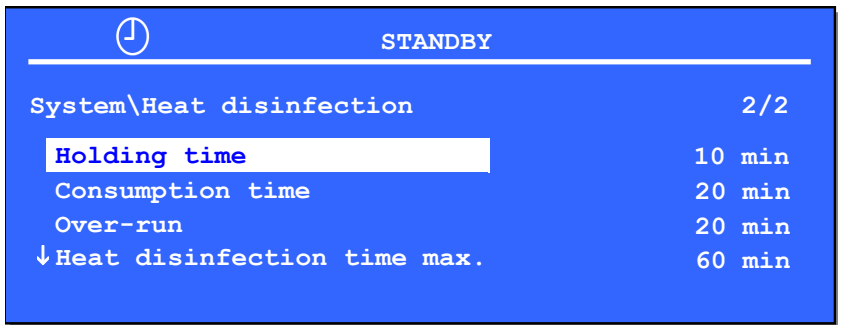
14.2.13 Menu structures overview – AquaBplus HF



- **Setting the HEAT DISINFECTION mode**



To define the settings, first select the menu option **Heat disinfection**.

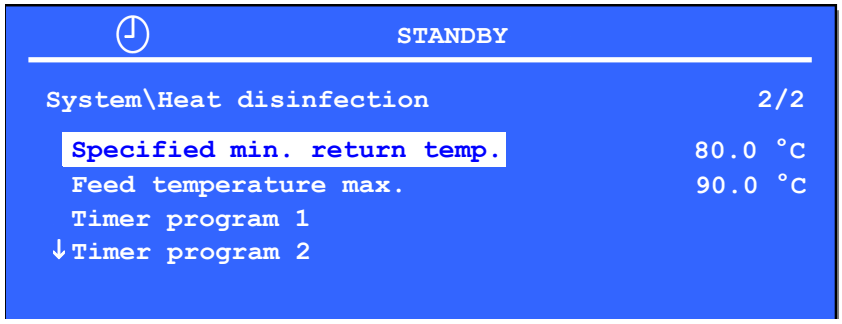


Holding time [10 to 60 min] Duration of the **2/5 Maintain temperature** phase

Consumption time [0 to 600 min] Duration of the **3/5 Consumption** phase

Over-run [0 to 120 min] The over-run is started after the cool-down phase. During this time permeate is discarded via the RingBase.

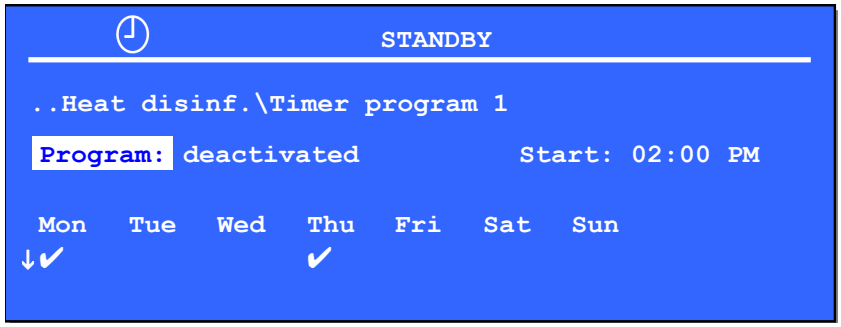
Max. heat disinfection time [0 to 750 min] Maximum duration of the heat disinfection. A cool-down will follow after the programmed time irrespective of the actual progress of the heat disinfection.



Specified min. return temp. [70 to 92 °C] Specified temperature for **Phase 2/5 Maintain temperature** and for **Phase 3/5 Consumption**.

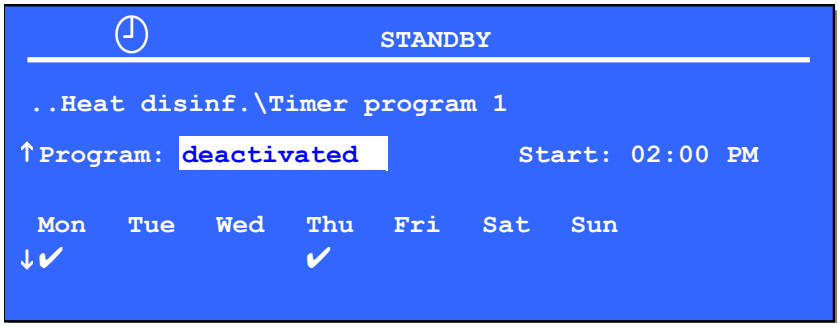
Feed temperature max. [70 to 95 °C] Maximum feed temperature permitted during heat disinfection.

Heat disinfection of the ring main can also be initiated automatically. For an automatic start at least one switching program must be configured and activated.

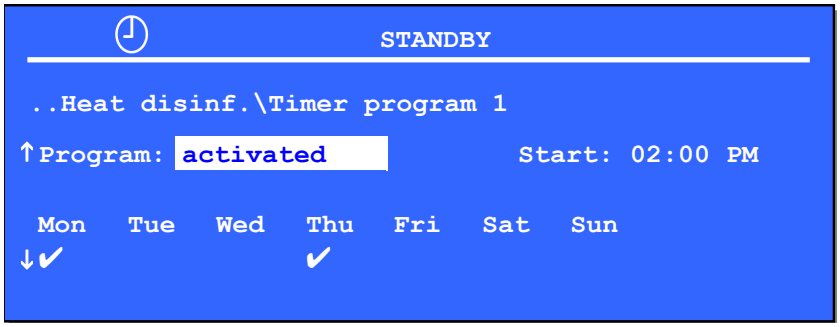


The activation of the weekday is identified by the symbol ✔.

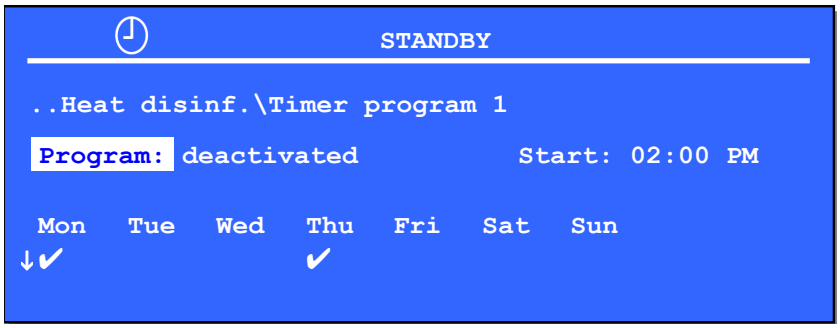
After pressing the **Enter** key, the selected program can be changed.



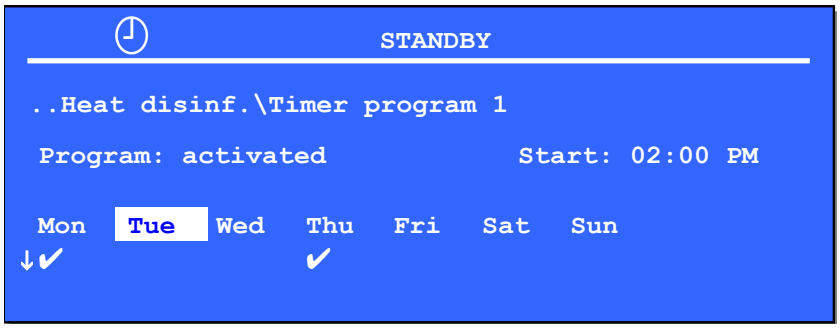
The other parameters can be changed using the **Up** (▲) or **Down** (▼) navigation keys.



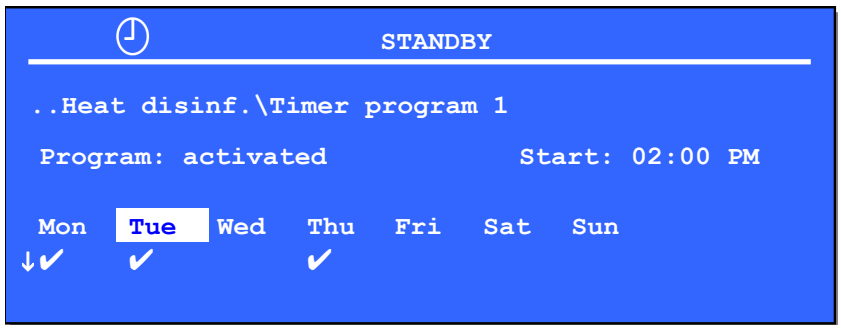
The change of the parameter will not become effective before it has been confirmed with the **Enter** key. To exit the menu without saving the changes, press the **Back / Escape** key.



Use the **Up** (▲) or **Down** (▼) and **Right / Left** (▶) / (◀) navigation keys to navigate to the next menu option and to make the desired settings.



The switching program is active if the selection was set to Program: activated.



14.2.14 Specifications – AquaBplus HF

Tip

The specifications for the **AquaBplus HF** are located in the main specifications chapter (see Chapter 12.3 on page 12-20).

14.3 Other options

The options listed in the following table are available for the **AquaBplus**.

Part no.	Option description	Usage
G03040107FMC	Filtration unit ¾	**AquaBplus** / **AquaBplus B2**
G03040106FMC	Filtration unit 1 ½“	**AquaBplus** / **AquaBplus B2**
G03040139FMC	Housing	**AquaBplus** / **AquaBplus B2**
G04040154FMC	Emergency mode	**AquaBplus**
G04040165FMC	RingBase	**AquaBplus** / **AquaBplus B2**
G03040160	Wall-mounted inlet unit, 1 ring main	**AquaBplus** / **AquaBplus B2** / **AquaBplus HF**
G03040161	Wall-mounted inlet unit, 2 ring mains	**AquaBplus** / **AquaBplus B2** / **AquaBplus HF**
G03040162	Wall-mounted inlet unit, 3 ring mains	**AquaBplus** / **AquaBplus B2** / **AquaBplus HF**
G05000504ET	Additional buzzer	**AquaBplus** / **AquaBplus B2**
G05000500ET	External rotating signal light	**AquaBplus** / **AquaBplus B2**
G04002036	Tank control	**AquaBplus** / **AquaBplus B2**
6365361	LED signal lamp with buzzer	**AquaBplus** / **AquaBplus B2** / **AquaBplus HF**
6341121	**AquaDETECTOR** standard central unit, complete	**AquaBplus** / **AquaBplus B2** / **AquaBplus HF**
6341131	(standard leakage sensor unit)	**AquaBplus** / **AquaBplus B2** / **AquaBplus HF**
6363751	3-phase line voltage monitoring / 400 V	**AquaBplus** / **AquaBplus B2** / **AquaBplus HF**
F00006911	Basic remote control	**AquaBplus / B2 / HF**

15 Appendix

15.1 Medical Device Register AquaBplus

15.1.1 Responsible organization and identification

The following page shows the master copy of the address of the responsible organization and the identification.

AquaBplus	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: **AquaBplus**
Type: Water purification system, reverse osmosis system
Registration number:
Serial number:
Equipment code:
Manufacturer: Vivonic GmbH Germany / 63877 Sailauf

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 AquaBplus Medical Device Register

The following pages show the contents of the Medical Device Register of the **AquaBplus**.

AquaBplus	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 / Malfunctions – Training records – Service reports and documentation of modifications to the system options – Reporting of incidences – 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 – Sampling plan OQ – Disinfection plan OQ – Operational Qualification report
10	Performance Qualification (PQ) – Operational data acquisition report PQ – Results of the microbiological analysis PQ – Results of the chemical analysis PQ

15.2 AquaBplus training record

The following page shows the training record for the **AquaBplus**.

AquaBplus **Training record** FRESENIUS MEDICAL CARE

Place where instructions were given
Center / clinic:
Address:
Zip code / city:
Phone:
Fax:

Training period
From:
Until:

❑ Person(s) assigned by the responsible organization
❑ Operator
❑ Others
Names:

Reverse osmosis system:
❑ **AquaBplus**
❑ **AquaBplus B2**
❑ **AquaBplus HF**
❑ **Emergency mode**
Serial no.:
Equipment code:
Software version:
Operating hours:
Permeate capacity:
❑ 500 L/h
❑ 1000 L/h
❑ 1500 L/h
❑ 2000 L/h
❑ 2500 L/h
❑ 3000 L/h

Document	✓
AquaBplus Instructions for Use, version: _____	❑
Training documentation	❑
Operational data acquisition log (daily report)	❑

Comments:

Note

Observe the index, important information and all warnings in the Instructions for Use!

Training subjects			Filed in	✓
Basics				
A	Functional description	– Principle of reverse osmosis – Physical background – Osmosis – Diffusion – Principle of the softener – Water hardness	IFU	❑
B	Installation requirements	– The feed water must be of drinking water quality – Free fall of waste water 20 – 30 mm – Floor drain installed – Leakage sensor installed	IFU	❑
C	Intended use	– Supply of dialysis devices – The total output of the dialysis device may not be exceeded.	IFU	❑
Design				
A	Front view	– Main power switch (including 120 seconds waiting period after tripping) – Display – Emergency operation switch – Pumps – Visual indicator	IFU	❑
B	Rear view	– Hydraulic connections – Electrical connection	IFU	❑
C	Side view	– Break tank – RingBase – Concentrate restrictor	IFU	❑
Controls and indicators				
A	Controls: Keys, layout and function	– Status bar with current operating mode and information menu: Timer, letter symbol Status menu – Display area – Key function – Access to Status menu and System menu	IFU	❑
Operating modes and functions				
A	Quick Guide	– Select program (**STANDBY**, **SUPPLY**) – Press and hold key for two seconds	IFU	❑
B	Operating programs	– **STANDBY** – **SUPPLY** – **RINSE** – Emergency mode	IFU	❑
C		– Heat disinfection	IFU	❑
D	Status menu	– Messages: current messages confirming messages – Report – Start / Stop: Timer settings for **SUPPLY** and **RINSE** – System information: Configuration and system values – Operating data (current operating data)	IFU	❑
E	Emergency mode	– No emergency supply with soft water – Activating the emergency mode – Deactivating the emergency mode	IFU	❑
Alarms				
A	Visual indicator	– Allocation of status indicator colors to alarms and operating modes.	IFU	❑
B	Error messages	– Are displayed directly if an alarm occurs (see Chapter 5 on page 5-1) (see Chapter 2.12 on page 2-13)	IFU	❑

Training subjects			Filed in	✓
Documentation / maintenance				
A	Operational data acquisition	**AquaBplus** – Date and time when the data was collected – Permeate conductivity CD–P (CD–P's) – Permeate temperature T–P (T–P's) – Soft water conductivity CD–F – Soft water temperature T–F – Soft water supply FL–F – Permeate consumption FL-P – Effective yield – Rejection rate – Concentrate pressure stage 1 – Concentrate flow stage 1 incl. **AquaBplus B2** option: – Permeate conductivity stage 1 CD–P – Permeate temperature stage 1 – Concentrate pressure stage 2 – Rejection rate stage 1 incl. **AquaBplus HF** option: – Pressure P5 – Heat disinfection	IFU / ODR	❑
B	Maintenance (staff)	– Refilling softener salt – Check for leakage – Soft water test – Replacing the filter cartridges	IFU	❑
Miscellaneous				
A	Various items	– Collection of microbiological samples – 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 suitability must be checked beforehand by gathering the appropriate manufacturer information.

Trainer	
Name	**Date, signature**

Participant	
Name	**Date, signature**

15.3 Operational data acquisition

General notes

Tip

The operating data of the **AquaBplus** can be displayed in the **Status/Operating data** menu (see Chapter 4.7.4 on page 4-15).

Note

Check the water hardness and the Total chlorine concentration at least once **every day before treatments**.

15.3.1 Title page - Operational data acquisition

The following page shows the cover page of the operational data acquisition for the **AquaBplus**.

AquaBplus	Operational data acquisition Daily report	FRESENIUS MEDICAL CARE

Serial number:
System capacity (L/h / gph):
Software:
Equipment code (EC):
Site of installation:
Address:
ZIP code:
City:
Responsible technician:
Phone:

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.

International service

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

Local service

15.3.2 Manual operational data acquisition report

The following pages show the operational data acquisition report for the **AquaBplus**.

Operational data acquisition / daily report AquaBplus	**Year: _____ Calendar week: _____**

Procedure								
Weekday	**Mon**	**Tue**	**Wed**	**Thu**	**Fri**	**Sat**	**Sun**	–
Time								

	Entries (operator)							**Unit**
AquaBplus								
Permeate conductivity CD-P (CD-P's)								µS/cm
Permeate temperature T-P (T-P's)								°C
Soft water conductivity CD-F								µS/cm
Soft water temperature T-F								°C
Soft water supply FL-F								L/min
Permeate consumption FL-P								L/min
Effective yield								%
Rejection rate								%
Conc. pressure stage 1								bar
Concentrate flow stage 1								L/min
incl. AquaBplus B2 option:								
Permeate conductivity stage 1								µS/cm
Permeate temperature stage 1								°C
Conc. pressure stage 2								bar
Rejection rate stage 1								%
AquaBplus HF								
Pressure								bar
Heat disinfection of the ring main: performed without any problems?	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	–
Initials								
–								–

15.4 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.

15.4.1 Microbiological quality standards

	Medium	**Alarm limits**	
		Total microbial counts CFU/ml	**Endotoxin concentration EU/ml**
ISO 13959: 2014 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.			

15.4.2 Chemical quality standards

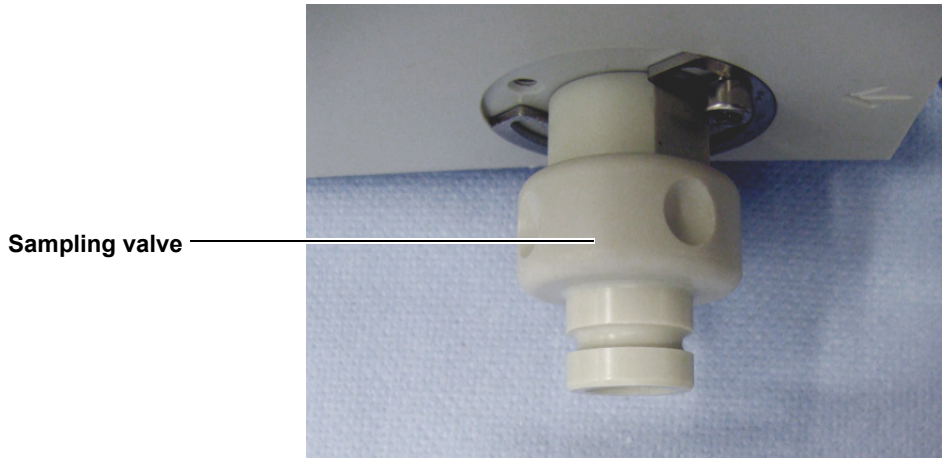
	Parameters with proven toxicity in dialysis	Alarm limit [mg/L]	Electrolytes	Alarm limit [mg/L]	Trace elements	Alarm limit [mg/L]
ISO13959:2014	Aluminum	0.01	Calcium	2	Antimony	0.006
	Lead	0.005	Potassium	8	Arsenic	0.005
	Fluoride	0.2	Magnesium	4	Barium	0.1
	Total chlorine	0.1	Sodium	70	Beryllium	0.0004
	Copper	0.1			Cadmium	0.001
	Nitrate as (N)	2			Chromium	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- "Guidance for the preparation and quality management of fluids for haemodialysis and related therapies" recommends a regular (e.g., monthly) preventive disinfection to avoid significant biofilm formation (Biofouling). Microbiological analyses of the dialysis water should be performed once a month, whereas 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.

15.5 Collecting a sample on the AquaBplus for microbiological analysis

The sampling port of the **AquaBplus** is the sampling valve which can be opened by turning the valve.



15.5.1 Preparation

– Have a cooled shipping box available.

– Before collecting the sample, the reverse osmosis system must be operated in **SUPPLY** mode for at least 20 minutes.

– While collecting the sample, the reverse osmosis system must be in the **SUPPLY** program.

15.5.2 Accessories / tools

The following equipment is recommended by the manufacturer:

– Rubber gloves

– Alcohol-based hand disinfectant

For the microbiological sampling of the permeate, the sampling set for the Fresenius sampling valve (part no.: **G03000836**) can be used.

15.5.3 Collecting a sample on the AquaBplus

Illustration	Description
 **Fig. 1**	**Fig. 1 - disinfecting the sampling valve:** ➢ Disinfect the sampling valve using an alcohol-based skin disinfectant (without lipid replenisher). ➢ Remove any contamination with a swab. ➢ Then repeat the disinfection procedure. (**Fig. 1**) **Caution:** **Observe the acting time of the disinfectant!**
  **Fig. 2+3**	**Fig. 3 - connecting and locking the adapter:** ➢ Place the adapter of the sampling bag onto the sampling valve. (**Fig. 2**) ➢ Then lock the adapter. (**Fig. 3**) The multiway valve on the sampling set must be set so as to ensure that no fluid can flow.
 **Fig. 4**	**Fig. 4 - opening the sampling valve** ➢ Turn the sampling valve counter-clockwise to open it. (**Fig. 4**)

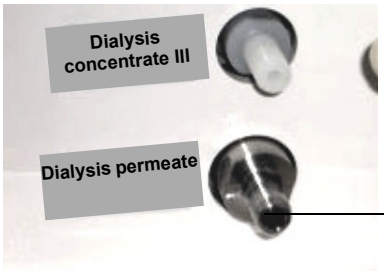
Illustration	Description
 **Fig. 5**	**Fig. 5 - rinsing the sampling valve** ➢ Turn the multiway valve 90° clockwise. ➢ Rinse the sampling valve for approx. 60 seconds via the rinse tubing. (**Fig. 5**)
 **Fig. 6**	**Fig. 6 - filling the bag** ➢ Then turn the multiway valve again 90° clockwise to fill the bag. (**Fig. 6**) ➢ **Caution:** Make sure to return the multiway valve in time to its original position (**Fig. 4**) to prevent bursting of the bag!
	Completing the sampling procedure ➢ The sampling valve is now closed again by turning it clockwise. ➢ Clamp of the disposable parts after the multiway valve and **immediately** close the bag with the enclosed plug. ➢ Gently squeeze the bag to check for any leaks. ➢ Affix the completed label on the bag and place it into the prepared transport box.

Note

Local policy and procedures may supersede the manufacturers sampling methods.

15.6 Collecting a sample on the MSC for microbiological analysis

The sampling port is the permeate coupling on the media supply center.



15.6.1 Preparation

➢ Have a cooled shipping box available.

➢ Before collecting the sample, the reverse osmosis system must be operated in **RINSE** or **SUPPLY** mode for at least 20 minutes.

➢ While collecting the sample, the reverse osmosis system must be in the **RINSE** or **SUPPLY** program.

➢ Disconnect the permeate connection from the dialysis system and collect the sample as specified (see Chapter 15.6.3 on page 15-18).

15.6.2 Accessories / tools

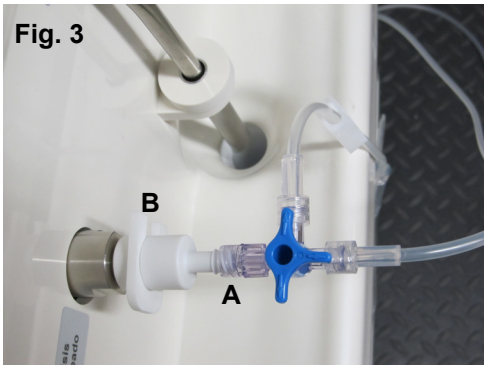
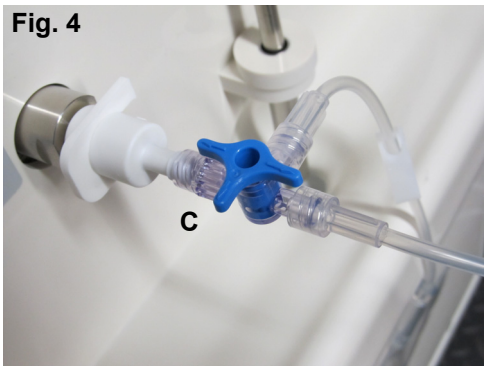
The following equipment is recommended by the manufacturer:

– Rubber gloves

– Alcohol-based hand disinfectant

For the microbiological sampling of the permeate, the **adapter (part no.: G03000832)** can be used.

15.6.3 Collecting a sample on the MSC

Illustration	Description
 Fig. 1  Fig. 2	**Fig. 1 and 2 - disinfecting the permeate coupling:** ➢ Use an alcohol-based skin disinfectant (e.g., SEPTODERM®) to disinfect the permeate coupling (**Fig. 1**). **Caution:** **Observe the acting time of the disinfectant!** ➢ Remove any contamination with a swab (**Fig. 2**). ➢ Then repeat the disinfection process (**Fig. 1**).
Fig. 3  Fig. 4 	**Fig. 3 and 4 - collecting the sample:** ➢ Set the multiway valve on the sampling set (**A**) so as to ensure that no fluid can flow (**Fig. 3**). ➢ Place the adapter of the sampling bag on the coupling and lock it (**B) (Fig. 3**). ➢ Then turn the multiway valve 90° clockwise (**C**) and "rinse" the coupling for approx. 60 seconds via the rinse tubing (**Fig 3**). ➢ Then turn the multiway valve again 90° clockwise to fill the bag (**Fig. 4**). – **Danger! Make sure to return the multiway valve in time to its original position (A) (Fig. 3) to prevent bursting of the bag!** ➢ Disconnect the disposable parts after the multiway valve and immediately close the bag with the enclosed plug. ➢ Gently squeeze the bag to check for any leaks. – Affix a completed label on the bag and place it **immediately** into the prepared shipping box.

15.7 Collecting a sample for chemical analysis

15.7.1 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 operation for at least 20 minutes.

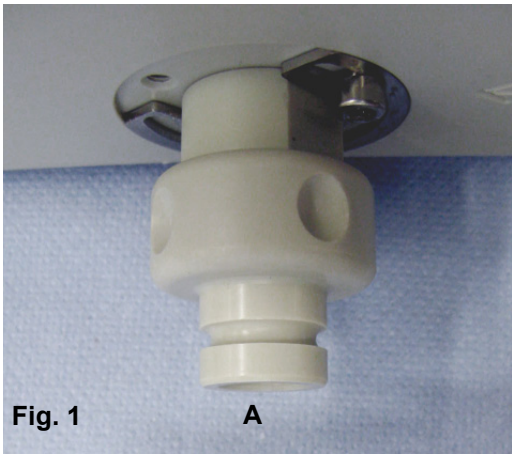
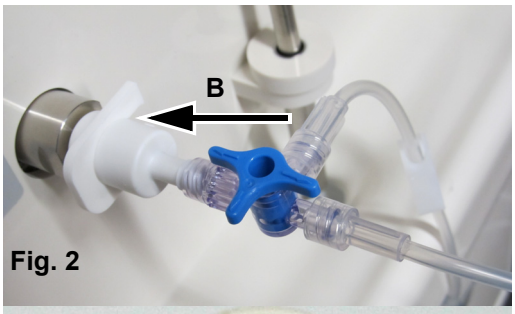
15.7.2 Accessories / tools

The following equipment is recommended by the manufacturer:

– Rubber gloves

For the chemical sampling, use the sample containers provided by the laboratory. As a tool for the microbiological sampling of the permeate, the **adapter** (**part no.: G03000832**) can be used.

15.7.3 Collecting a sample for chemical analysis

Illustration	Description
 Fig. 1	➢ The permeate must be collected while the system is in operation (during dialysis) or after extensive rinsing of the system (see above). Before collecting the sample, rinse the sampling valve **(A or B) (approx. 2-10 L)**. **Caution:** **To avoid contamination of the sample by dirty sample containers, use only the containers supplied by the laboratory!** ➢ When collecting the sample, do not open the sample containers until directly before collecting the sample and make sure to close the containers immediately after taking the sample to prevent contamination. ➢ The sample containers must be filled up to the top. ➢ When collecting a sample the valve must first be sufficiently rinsed **(approx. 5 L)**. Then the sample containers must be filled from the free flowing jet of water.
 Fig. 2 	➢ When collecting the sample on the media supply column attach the bag / adapter to the coupling and fix it in place with the latch (Fig. 2 – B). ➢ Then thoroughly rinse the coupling (**approx. 2 L**) via the rinse tube. ➢ Fill the sample container via the rinse tube. **Caution:** **When collecting a sample at the media supply column coupling, do not use the bag (with adapter) as a sample container.** **Use the bottles supplied by the laboratory as sample containers!**

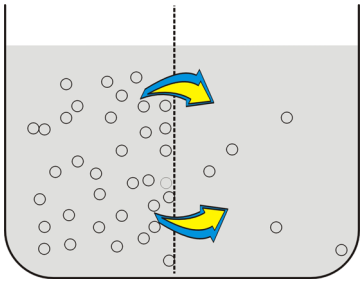
15.8 Physical background – diffusion / osmosis

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:

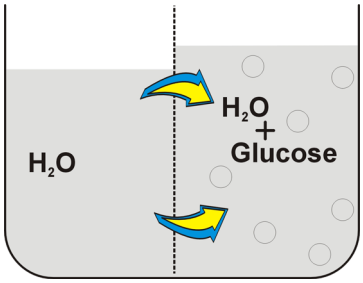
1. Diffusion

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 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.