B BRAUN
SHARING EXPERTISE

Reverse Osmosis System

AQUAboss nX

Instructions for Use SW 1.0.0

CE 0123

CE marking according to Regulation (EU) 2017/745.

Technical alterations reserved.

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1 About these Instructions for Use

These instructions for use are an integral part of the reverse osmosis system. They describe how to properly and safely use the system in all operating stages.

NOTICE!

The reverse osmosis system should only be used, cleaned and transported in accordance with these instructions for use. Only then will the manufacturer assume liability for any effects on the safety, reliability and performance of the reverse osmosis system.
Always keep these instructions for use nearby wherever the reverse osmosis system is being used.
Give these instructions for use to any subsequent user of the reverse osmosis system.

Be sure also to follow the instructions for use and product information of any consumables.

Commissioning/decommissioning, and servicing of the system are only to be performed by service technicians authorized by the manufacturer. Information on calibration and connection to interfaces is only required by service technicians. Therefore, this information is not part of these instructions for use but is contained in the service manual.

These instructions for use and the service manual contain important information on how to install, operate, service and dispose of the reverse osmosis system in a safe, correct and environmentally friendly manner. Following these instructions helps avoid hazards, reduce repair costs and downtime, and minimize damage to the environment over the entire life cycle of the product.

These instructions for use are available on the B. Braun Avitum AG eIFU website.

1.1 Copyright

1.2 Terminology

Terms

Term	Definition
Permeate	Water for diluting concentrated hemodialysis solutions

Abbreviations

ADC	Analog to Digital Converter
CC	Cell constant
CD	Conductivity
CO	Control observer
conc.	Concentrate
DI	Disinfection
ext.	External
Fri	Friday
LC	Low conductivity
Mon	Monday
MV	Solenoid valve
P&ID	Piping and instrumentation diagram
Ph. Eur.	European Pharmacopoeia
REF	Reference number
RL	Ring piping
RO	Reverse osmosis
raw	Raw water
Sat	Saturday
SN	Serial number
Sun	Sunday
STK TSC	Technical safety check
SW	Software
Thu	Thursday
Tue	Tuesday
UPW	Ultra pure water
WCF	Water conversion factor
Wed	Wednesday

1.3 Validity

Reference Numbers

These instructions for use are valid for AQUAboss nX water treatment systems with the following reference numbers (REFs):

AQUAboss nX I

AQUAboss nX I 1000	REF	AQUAboss nX I 1500	REF
400 V/50-60 Hz	LA1140100	400 V/50-60 Hz	LA1140150
208–220 V/60 Hz	LA1140101	208–220 V/60 Hz	LA1140151
380 V/60 Hz	LA1140102	380 V/60 Hz	LA1140152

AQUAboss nX I 2000	REF	AQUAboss nX I 2500	REF
400 V/50-60 Hz	LA1140200	400 V/50-60 Hz	LA1140250
208–220 V/60 Hz	LA1140201	208–220 V/60 Hz	LA1140251
380 V/60 Hz	LA1140202	380 V/60 Hz	LA1140252

AQUAboss nX I 3000	REF	AQUAboss nX I 3500	REF
400 V/50-60 Hz	LA1140300	400 V/50-60 Hz	LA1140350
208–220 V/60 Hz	LA1140301	208–220 V/60 Hz	LA1140351
380 V/60 Hz	LA1140302	380 V/60 Hz	LA1140352

AQUAboss nX I 4000	REF
400 V/50-60 Hz	LA1140400
208–220 V/60 Hz	LA1140401
380 V/60 Hz	LA1140402

AQUAboss nX I HT

AQUAboss nX I 1000 HT	REF	AQUAboss nX I 1500 HT	REF
400 V/50-60 Hz	LA1160100	400 V/50-60 Hz	LA1160150
208–220 V/60 Hz	LA1160101	208–220 V/60 Hz	LA1160151
380 V/60 Hz	LA1160102	380 V/60 Hz	LA1160152

AQUAboss nX I 2000 HT	REF	AQUAboss nX I 2500 HT	REF
400 V/50-60 Hz	LA1160200	400 V/50-60 Hz	LA1160250
208–220 V/60 Hz	LA1160201	208–220 V/60 Hz	LA1160251
380 V/60 Hz	LA1160202	380 V/60 Hz	LA1160252

AQUAboss nX I 3000 HT	REF	AQUAboss nX I 3500 HT	REF
400 V/50-60 Hz	LA1160300	400 V/50-60 Hz	LA1160350
208–220 V/60 Hz	LA1160301	208–220 V/60 Hz	LA1160351
380 V/60 Hz	LA1160302	380 V/60 Hz	LA1160352

AQUAboss nX I 4000 HT	REF
400 V/50-60 Hz	LA1160400
208–220 V/60 Hz	LA1160401
380 V/60 Hz	LA1160402

AQUAboss nX II

AQUAboss nX II 500	REF	AQUAboss nX II 1000	REF
400 V/50-60 Hz	LA1150050	400 V/50-60 Hz	LA1150100
208–220 V/60 Hz	LA1150051	208–220 V/60 Hz	LA1150101
380 V/60 Hz	LA1150052	380 V/60 Hz	LA1150102

AQUAboss nX II 1500	REF	AQUAboss nX II 2000	REF
400 V/50-60 Hz	LA1150150	400 V/50-60 Hz	LA1150200
208–220 V/60 Hz	LA1150151	208–220 V/60 Hz	LA1150201
380 V/60 Hz	LA1150152	380 V/60 Hz	LA1150202

AQUAboss nX II 2500	REF	AQUAboss nX II 3000	REF
400 V/50-60 Hz	LA1150250	400 V/50-60 Hz	LA1150300
208–220 V/60 Hz	LA1150251	208–220 V/60 Hz	LA1150301
380 V/60 Hz	LA1150252	380 V/60 Hz	LA1150302

AQUAboss nX II 3500	REF	AQUAboss nX II 4000	REF
400 V/50-60 Hz	LA1150350	400 V/50-60 Hz	LA1150400
208–220 V/60 Hz	LA1150351	208–220 V/60 Hz	LA1150401
380 V/60 Hz	LA1150352	380 V/60 Hz	LA1150402

AQUAboss nX II HT

AQUAboss nX II 500 HT	REF	AQUAboss nX II 1000 HT	REF
400 V/50-60 Hz	LA1170050	400 V/50-60 Hz	LA1170100
208–220 V/60 Hz	LA1170051	208–220 V/60 Hz	LA1170101
380 V/60 Hz	LA1170052	380 V/60 Hz	LA1170102

AQUAboss nX II 1500 HT	REF	AQUAboss nX II 2000 HT	REF
400 V/50-60 Hz	LA1170150	400 V/50-60 Hz	LA1170200
208–220 V/60 Hz	LA1170151	208–220 V/60 Hz	LA1170201
380 V/60 Hz	LA1170152	380 V/60 Hz	LA1170202

AQUAboss nX II 2500 HT	REF	AQUAboss nX II 3000 HT	REF
400 V/50-60 Hz	LA1170250	400 V/50-60 Hz	LA1170300
208–220 V/60 Hz	LA1170251	208–220 V/60 Hz	LA1170301
380 V/60 Hz	LA1170252	380 V/60 Hz	LA1170302

AQUAboss nX II 3500 HT	REF	AQUAboss nX II 4000 HT	REF
400 V/50-60 Hz	LA1170350	400 V/50-60 Hz	LA1170400
208–220 V/60 Hz	LA1170351	208–220 V/60 Hz	LA1170401
380 V/60 Hz	LA1170352	380 V/60 Hz	LA1170402

Software Version

These instructions for use are valid for the following software version:

- AQUAboss nX SW 1.0.x
  (x = any)

Software updates should only be installed by trained and qualified technicians.

1.4 Target Group

These instructions for use are intended for the owner's trained personnel.

The reverse osmosis system should only be operated by persons who have been instructed on how to handle the product.

1.5 Warnings, Notices and Symbols

4 signal words are used in this document: DANGER, WARNING, CAUTION and NOTICE.

The signal words DANGER, WARNING and CAUTION point out particular hazardous situations for users and patients.

The signal word NOTICE points out information directly or indirectly related to prevention of damage and not to personal injury.

The signal word and the color of header indicate the degree or level of hazard:

⚠ DANGER!

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING!

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION!

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE!

Used to address practices not related to personal injury, i.e. information directly or indirectly related to prevention of damage.

Warning messages also suggest measures that shall be taken in order to avoid the respective hazardous situation. Thus, warning messages related to the risk of personal injury have the following structure:

Header with signal word

Here, the type of hazard is indicated!

Here, the source of hazardous situation is indicated and possible consequences if measures are not followed.

- This is the list of measures to prevent the hazard.

List of All Dangers

⚠ DANGER!

Risk of electric shock.

Dangerous voltage when control cabinet is open.

- Shut off the reverse osmosis system at the main switch and disconnect from power.

⚠ DANGER!

Danger of electric shock!

- Before working on the system, check that it is voltage-free.

⚠ DANGER!

Risk of electrocution

- Only authorized, trained and instructed electricians should perform electrical work.

⚠ DANGER!

Chemical disinfection

Risk of acute toxicity during chemical disinfection

- Only perform disinfection at times when dialysis is not taking place. Dialysis should not be possible at these times.
- Prior to starting disinfection, the permeate connection to the dialysis machines must be removed.
- If a softener is used: Softeners should only be operated with a Type BA backflow preventer.
- Take appropriate measures in the treatment rooms to indicate that the reverse osmosis system is being disinfected (see 12.2 Hazard Label (188)).
- There is a risk of acute toxicity if disinfectants or cleaning agents are taken or administered.
- Only clean and disinfect the system with the attending physician's approval.

List of All Warnings

⚠ WARNING!

Do not use the reverse osmosis system if the chemical or microbial quality of the raw water is unknown.

Do not use the reverse osmosis system if the raw water does not meet the requirements of Directive (EU) 2020/2184.

Do not use the reverse osmosis system if not all of the sampling points show no traces of disinfectant following chemical disinfection before hemodialysis.

⚠ WARNING!

In children and infants, hemodialysis treatment should be used with particular caution and under the close supervision of the responsible physician. The responsible physician has to assess potential risks for children and infants in the prescription. Clinical data on the use of this product in children and infants are not available.

Refer to instructions for use of the hemodialysis machine used, especially for children and infants.

Refer to the water quality requirements and consider for children and infants potential risks of concentration levels of individual water constituents in general and especially of molecules/organic and inorganic substances which pass through the reverse osmosis membrane.

Refer to microbial quality and consider potential risks for children and infants.

⚠ WARNING!

In pregnant women and nursing mothers hemodialysis treatment should be used with particular caution and under the close supervision of the responsible physician. The responsible physician has to assess potential risks for mother and fetus in the prescription. For the use of this device in pregnant women, including the risk for the fetus, and in nursing mothers clinical data are not available.

⚠ WARNING!

Only specialists authorized, trained and instructed by B. Braun Avitum AG should start up, operate, service and perform electrical work on the system.

⚠ WARNING!

The owner is responsible for ensuring the system is used as intended. The system as delivered is only safe during operation when used as intended. The values indicated in section 11 Technical Data (159) should never be exceeded.

⚠ WARNING!

Frequency Converter: Discharge Time

The frequency converter contains DC link capacitors that can be charged even when the frequency converter is switched off. Failure to observe the specified discharge time after disconnecting the power supply before maintenance or repair work can lead to serious or fatal injuries!

- Stop the motor.
- Disconnect the mains supply, the permanent magnet motors and the external DC link supplies, including the external battery, UPS and DC link connections to other frequency inverters.
- Only carry out maintenance or repair work after the capacitors have been completely discharged. The corresponding waiting time can be found in Tbl. 2-1 Discharge Time (29).

⚠ WARNING!

Risk to the patient in case of hypersensitivity reactions!

If severe hypersensitivity reactions occur:

- Dialysis must be discontinued and appropriate aggressive medical treatment for anaphylaxis must be initiated.
- The blood from the extracorporeal system must not be returned to the patient.

⚠ WARNING!

Risk to the patient in case of aluminum and nitrate passing through the reverse osmosis membrane.

Minor amounts of aluminum and nitrate can pass through the reverse osmosis membrane.

- Increased levels of aluminum in the permeate have been associated with anemia, neurological problems, encephalopathy, and changes in bone structure.
- Increased levels of nitrate have been associated with nausea and vomiting as well as hemolysis.
- Especially with increased levels of nitrate and aluminum in the raw water, it must be ensured that the permeate does not exceed the valid limits for water for diluting concentrated dialysates per Ph. Eur. or ISO 23500-3.

⚠ WARNING!

Failure to follow the safety instructions can put both the responsible organization and the patient at risk. This kind of failure can result in the following hazards:

- Failure of critical functions of the AQUAboss nX
- Danger to persons from electrical and mechanical activity
- Failure of prescribed maintenance and disinfection methods

⚠ WARNING!

Risk to patient in case of common contaminants in permeate:

- Increased levels of aluminum in the permeate have been associated with anemia, neurological problems, encephalopathy, and changes in bone structure.
- Increased levels of nitrate have been associated with nausea and vomiting, methemoglobinemia, as well as hemolysis.
- Increased levels of chlorine or chloramines in the permeate have been associated with haemolytic anemia.
- Increased levels of fluoride in the permeate have been associated with renal bone disease/changes in bone structure.
- Increased levels of calcium or magnesium in the permeate have been associated with hard water syndrome (nausea, vomiting, headache, muscle weakness).
- Increased levels of copper in the permeate have been associated with haemolytic anemia, nausea, vomiting and liver damage.
- Increased levels of zinc in the permeate have been associated with nausea, vomiting and fever.
- Increased levels of lead in the permeate have been associated with abdominal pain and muscle weakness.
- Increased levels of sulphate in the permeate have been associated with acidosis, nausea and vomiting.
- Increased levels of endotoxins in the permeate have been associated with pyrogenic reaction and chronic inflammation.
- Increased levels of microbial counts in the permeate have been associated with hypotension, nausea, vomiting, fever.

⚠ WARNING!

Risk of toxicity and pyrogenic reactions

The owner is responsible for selecting the water treatment system and checking the permeate against the Ph. Eur. and ISO 23500-3 once every year.

⚠ WARNING!

Risk of chemical, physical and/or microbial contamination

Permeate quality depends on feed water quality. If feed water quality is significantly reduced, changes in the permeate may result in acceptable limits being exceeded.

- The owner is responsible for regularly monitoring feed water limits.

⚠ WARNING!

Risk of toxicity and pyrogenic reactions

Even if the reverse osmosis system produces water of a quality that meets the requirements of the international standard DIN EN ISO 23500-2, the distribution of this water can degrade its quality to such a degree that it no longer meets the requirements of DIN EN ISO 23500-2 if the distribution system is not properly maintained.

- The reverse osmosis system and connected distribution system should be maintained/checked according to the manufacturer's instructions.

⚠ WARNING!

Risk of electric shock if the system is not properly grounded.

- To avoid the risk of electric shock, this system must only be connected to a power supply with a protective earth conductor.

⚠ WARNING!

This system provides a software comfort function for disinfection. Operator is obliged to monitor and record disinfection schedule, disinfection time and concentration and/or temperatures according to the parameters he has determined during validation according to ISO 23500-1 (Preparation and quality management of fluids for hemodialysis and related therapies - Part 1: General Requirements). Filling in the disinfection report for each disinfection is mandatory.

⚠ WARNING!

Risk of toxicity

- Ensure the permeate at each dialysis station is free of disinfectant after disinfecting and before starting dialysis.

⚠ WARNING!

Risk of toxicity from dissolved structural materials and destruction of components

- Only original materials resistant to up to 90 °C should be used.

⚠ WARNING!

During thermal disinfection the system can reach up to 85 °C. Some parts of the system can become hot. Do not touch any metal parts or any parts that are marked with the “Hot Surface” label.

⚠ WARNING!

Non-compliance with safety testing procedures can lead to serious injuries and functional failure of the system.

⚠ WARNING!

Risk of component failure from lack of maintenance and TSCs

The reverse osmosis system may become inoperable and result in permeate unavailability.

- An expert authorized by B. Braun Avitum AG will perform a TSC every second year.

⚠ WARNING!

Risk to patient due to system failure or failure to meet permeate requirements

- Following maintenance, repairs, replacement of components or other changes, the owner should provide documentation that the system conforms to the original specifications (permeate quality, material compatibility).

⚠ WARNING!

Risk of toxicity and pyrogenic reactions

Failure to comply with the manufacturer's maintenance and disinfection specifications can result in degraded permeate quality or reduced system function.

⚠ WARNING!

The pipes in the system are pressurized.

Opening fittings or valves can result in injury.

- Depressurize the pipes before working on the system.
- Use personal protective equipment.

⚠ WARNING!

Only operate the system with the control cabinet closed.

⚠ WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AQUAboss nX, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ WARNING!

Before the next dialysis treatment is carried out, ensure again that the test for residual disinfectant is negative.

List of All Cautions

⚠ CAUTION!

Improper Use

The water produced by reverse osmosis does not qualify as ultra pure water (UPW).

- UPW requires an additional process step and extensive validation of the entire system.

⚠ CAUTION!

Risk to the patient in case of hypersensitivity reactions!

Patients with a history of hypersensitivity reactions or patients who have a history of being highly sensitive and allergic to a variety of substances should be:

- carefully monitored during treatment.

⚠ CAUTION!

Electrical stroke or risk of burn if water enters system or plugs.

⚠ CAUTION!

Risk of skin burns or blindness

- The surface of the system should be regularly cleaned with a suitable cleaning agent.
- When working with liquid disinfectants, it is mandatory to take personal protective measures (gloves, apron, protective goggles).

⚠ CAUTION!

Risk of damage to system from liquid ingress

- Make sure liquid does not get inside the system.
- Do not use too much liquid to wipe down the surface.
- Only use suitable cleaning agents. Instructions and warnings of those cleaning agents must be adhered to.
- Liquids may not get into plugs, sockets or inside the cabinet as liquids may lead to electric shock.

⚠ CAUTION!

Electrical stroke or risk of burn if water enters system or plugs.

⚠ CAUTION!

Do not store the disinfectant on top of the reverse osmosis system. Follow the manufacturer's instructions for storing the disinfectant.

List of All Notices

NOTICE!

The reverse osmosis system should only be used, cleaned and transported in accordance with these instructions for use. Only then will the manufacturer assume liability for any effects on the safety, reliability and performance of the reverse osmosis system.
Always keep these instructions for use nearby wherever the reverse osmosis system is being used.
Give these instructions for use to any subsequent user of the reverse osmosis system.

NOTICE!

If membrane barrier is not integer, raw water salts can enter permeate side of the system. As a result permeate may not comply with chemical requirements of ISO 23500-3.

NOTICE!

Only experts may transport, install, use and repair the system.

NOTICE!

The owner is responsible for observing Ph. Eur. or ISO 23500-3 limits for microbial quality.

NOTICE!

The AQUAboss nX reverse osmosis system is designed to safely operate in conjunction with *Aquaboss*® products:

- Hot Rinse SMART
- CCS
- Soft Control
- Remote Control
- Water Monitor
- Double Ring Piping Set nX
- Ring Piping
- Eco Mix

NOTICE!

This device is professional medical electrical equipment. This means it is only for use by healthcare professionals and is not intended for sale to the general public.

NOTICE!

B. Braun Avitum AG is not liable for damages caused by the use of spare parts, accessories or consumables from other manufacturers.

NOTICE!

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

NOTICE!

Entry of incorrect values can impair the correct function of the control system or operational safety of the system.

NOTICE!

Changes may only be performed by trained personnel.

Manual switching of digital outputs can cause damage to the system.

NOTICE!

Only allow experienced transport experts to transport the device.

NOTICE!

The feed water upstream of the softener (ion exchanger) must meet the requirements of Directive (EU) 2020/2184 on the quality of water intended for human consumption. B. Braun Avitum AG-specific deviations from or addenda to the directives are listed in Section 2.13.3 Water Quality Requirements (32).

NOTICE!

Do not change the once installed final application due to EM DISTURBANCE. If the environment does not correspond to the conditions listed by the manufacturer, some actions are required to match those conditions. Please contact the manufacturer.

The climatic environmental conditions could affect the life of critical components of the AQUAboss nX. The presence of transmitters near the AQUAboss nX could affect its performance. The distances mentioned in the tables prepared by the manufacturer can help to prevent any disturbances of the equipment in normal operation.

NOTICE!

Permanent electrical connections should always be set up by authorized personnel in accordance with national rules and regulations.

NOTICE!

Irreversible damage to the pump, air in the pump body

Always bleed all pumps and the modules in the pressure pipes.

- Carefully open the bleed screw until the water flow is constant. Then close the bleed screw (see Fig. 4-1 Opening the bleed screw (112), Fig. 4-2 Water flow becomes constant (112) and Fig. 4-1 Opening the bleed screw (112)).

NOTICE!

During commissioning, the intervals for the microbial sampling are determined. According to ISO 23500-1, monthly sampling is advised.

NOTICE!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment should be observed to verify that it is operating normally.

NOTICE!

The AQUAboss nX is an electrical medical device. Special EMC safety measures are required and the system should always be installed in compliance with the EMC information provided here.

NOTICE!

EMC testing covers only the frequencies described in EN 60601-1-2.

NOTICE!

Disinfection cannot be performed during dialysis.

NOTICE!

During Standby mode, permeate cannot be extracted from the ring piping and dialysis is therefore not possible.

Tap the *Dialysis* button at any time to switch the machine back to Dialysis mode.

NOTICE!

Risk of leakage

Activating the temperature rinsing feature will cause the RO system to discard and take in raw water. The system will not monitor for leaks during this time.

NOTICE!

Do not use too much liquid to wipe down the display. If necessary, dry it off with a soft cloth.

NOTICE!

Record all disinfections in the designated log and in the medical devices log, see section 9.3.1 Medical Device Log (150).

NOTICE!

If total viable microbial counts in AQUAboss nX are monitored on a monthly basis, disinfection must be carried out whenever the action limit for the total viable microbial counts is exceeded but at least once a year (after citric acid cleaning). If the reverse osmosis system is monitored less frequently, preventive disinfection on a monthly basis is recommended.

NOTICE!

Contamination in the water treatment system can cause an unspecified disinfectant reaction that can greatly reduce the concentration of effective disinfectant. In certain cases, the amount of disinfectant needed can differ greatly from the calculated requirement.

NOTICE!

Discoloration of the test strips only indicates that the disinfectant concentration is above the test strip's limit of detection. It cannot be used to determine the concentration of active ingredient.

NOTICE!

The contents of the supply tank need to be mixed thoroughly, since different specific densities of disinfectant and permeate can lead to striations at the bottom of the tank.

NOTICE!

Drinking water contamination

- Before starting disinfection, make sure the softener and reverse osmosis system are only being operated with a Type BA backflow preventer.

NOTICE!

Only use the disinfectants approved by B. Braun Avitum AG.

NOTICE!

Make sure local discharge regulations for wastewater containing disinfectant are observed.

NOTICE!

ISO 15883-1 prescribes for an A0 value of 600 a dwell time of 10 min at a temperature of 80 °C. Lower temperatures require longer heating stages in order to kill off most vegetative bacteria, yeast, fungi and viruses (see ISO 15883-1 "Washer-disinfectors – Part 1: General requirements, terms and definitions, and tests").

NOTICE!

It is required to carry out a disinfection on the whole system after a cleaning. This includes the reverse osmosis system, the Hot Rinse SMART 10-50 and the whole ring piping, including secondary loops, etc.

NOTICE!

To prove effectiveness of the disinfection a bacterial test in the permeate is recommended within 5 – 7 days.

NOTICE!

Samples must be kept cool and be couriered to the lab within 6 hours.

1.6 Information and Activities

Information

This is additional useful information concerning procedures, background information and recommendations.

Activities

1. In this way instructions for an activity are listed.
   ↳ This symbol marks the result of an activity.

1.7 Typographic Conventions

Key and menu designations, button inscriptions as well as messages and prompts of the control software are represented in *italic* letters. In addition, they are written in uppercase and lowercase letters, exactly as they are displayed on the software interface.

Examples:

- Press *Enter* key to confirm.
- The *SETUP* screen appears.
- The message *System restored!* is displayed.

Cross references (hyperlinks) to other sections are not highlighted, but are indicated with the page number in brackets (xx) at the end of the reference.

Example: For detailed information, see section 1 About these Instructions for Use (7).

2 Safety

Carefully read all safety information in the following sections before using the device.

Refer also to the instructions for use of all medical devices/products that AQUAboss nX is used in combination with.

2.1 Intended Use

The intended use is the production of water for diluting hemodialysis concentrates according to the European Pharmacopoeia and ISO 23500-3.

2.2 Indication for Use

The device, producing water for diluting hemodialysis concentrates, is indicated for patients who need hemodialysis treatments due to renal insufficiency in chronic kidney disease and/or acute kidney injury and/or intoxication.

2.3 Contraindication

Contraindications are:

- Unknown chemical or microbial quality of the raw water
- Unmet requirements of Directive (EU) 2020/2184
- Sampling points show traces of disinfectant following chemical disinfection before hemodialysis

⚠ WARNING!

Do not use the reverse osmosis system if the chemical or microbial quality of the raw water is unknown.

Do not use the reverse osmosis system if the raw water does not meet the requirements of Directive (EU) 2020/2184.

Do not use the reverse osmosis system if not all of the sampling points show no traces of disinfectant following chemical disinfection before hemodialysis.

Contraindication for AQUAboss nX

Contraindications for AQUAboss nX are known hypersensitivity to any material used in the device (see 11.2 Design Data (181)).

Contraindication for a hemodialysis treatment

Contraindications for a hemodialysis treatment are known hypersensitivity to any material used and/or the patient condition (clinical aspects, uncontrollable coagulation anomalies and other treatment relevant conditions).

The responsible physician must define contraindications for a hemodialysis treatment based on patient characteristics and conditions (cardiovascular status, hemodynamic stability, comorbidities, therapy tolerance of extracorporeal blood volume, bleeding risk and other treatment relevant conditions according to state of the art medical knowledge).

2.4 Intended Use Environment

The reverse osmosis system is intended to be used in hospitals, health care or limited-care facilities. The installations are located in a separate osmosis room.

Emergency medication for the management of possible side effects of treatment must be readily available.

2.5 Patient Population

Patient population shall be chosen according to the most critical and limiting weight and age group considering the hemodialysis treatment performed.

Refer also to the instructions for use of all medical devices/products that AQUAboss nX is used in combination with.

The physician shall prescribe the treatment based on patient's characteristics and conditions (cardiovascular status, hemodynamic stability, comorbidities, therapy tolerance, body size, weight, fluid, and blood volume status, bleeding risk, vascular access and other treatment relevant conditions according to state of the art medical knowledge) and clinical requirements.

⚠ WARNING!

In children and infants, hemodialysis treatment should be used with particular caution and under the close supervision of the responsible physician. The responsible physician has to assess potential risks for children and infants in the prescription. Clinical data on the use of this product in children and infants are not available.

Refer to instructions for use of the hemodialysis machine used, especially for children and infants.

Refer to the water quality requirements and consider for children and infants potential risks of concentration levels of individual water constituents in general and especially of molecules/organic and inorganic substances which pass through the reverse osmosis membrane.

Refer to microbial quality and consider potential risks for children and infants.

⚠ WARNING!

In pregnant women and nursing mothers hemodialysis treatment should be used with particular caution and under the close supervision of the responsible physician. The responsible physician has to assess potential risks for mother and fetus in the prescription. For the use of this device in pregnant women, including the risk for the fetus, and in nursing mothers clinical data are not available.

2.6 Intended User

Intended user of the device are service technicians, specialists and healthcare professionals who are trained and instructed for its appropriate use according to these instructions for use and who can prove that they have been trained and instructed.

⚠ WARNING!

Only specialists authorized, trained and instructed by B. Braun Avitum AG should start up, operate, service and perform electrical work on the system.

2.7 Number of Uses and Duration of Use

The device is designed for continuous operation. Number of uses and duration of uses are not limited. For expected service life see section 2.15.8 Expected Service Life (42).

2.8 Essential Performance

- The system produces filtered water according to ISO 23500-3.
- The salt rejection according to ISO 23500-3 shall be greater than 90%.

2.9 General Safety Advice

⚠ WARNING!

The owner is responsible for ensuring the system is used as intended. The system as delivered is only safe during operation when used as intended. The values indicated in section 11 Technical Data (159) should never be exceeded.

⚠ CAUTION!

Improper Use

The water produced by reverse osmosis does not qualify as ultra pure water (UPW).

- UPW requires an additional process step and extensive validation of the entire system.

The AQUAboss nX reverse osmosis system is state-of-the-art and safe to operate. This device is professional medical electrical equipment by means of IEC 60601-1-2. This means it is only for use by healthcare professionals and is not intended for sale to the general public.

NOTICE!

If membrane barrier is not integer, raw water salts can enter permeate side of the system. As a result permeate may not comply with chemical requirements of ISO 23500-3.

Improper or unintended use can put operating personnel at risk. For this reason:

- Keep these instructions for use close to the reverse osmosis system.
- Only specialists authorized, trained and instructed by B. Braun Avitum AG should start up, operate, service and perform electrical work on the system.
- All local safety and accident prevention regulations apply to operating the system and must be observed at all times.
- Observe posted information and warning signs.
- Seek immediate medical attention in the event of injuries, accidents or skin irritation.
- Permeate is unsuitable as drinking water.
- Disinfect the system after prolonged periods of disuse (over 72 h) and at least once every year (7 Disinfection and Cleaning (123)).
- Depending on the type, the system's output is 500–4000 L/h. A feed water temperature below 10 °C reduces hydraulic performance. This device is designed for continuous operation.
- Portable and mobile HF communication equipment can affect electrical medical devices.
- The AQUAboss nX and AQUAboss nX HT series systems are electrical medical devices subject to special EMC precautions that must be installed and started up in accordance with the information in Section 4.10 Electromagnetic Compatibility (EMC) (116).

2.10 Residual Risks

Despite all precautions taken, there remain residual risks. These residual risks concern the user of the device, not the patient.

Residual Risks of the Device – AQUAboss nX

Residual risks associated with the device are:

- Hazards that can arise from the product or medium, such as allergies, irritation or burns
- Hazards from a malfunction in the control system
- Hazards from operator error

Electric Shock

The AQUAboss nX reverse osmosis system is operated at a voltage of, for example, 400 V (AC). Improper opening of the control cabinet or damage to the electrical wiring can cause electric shock (risk of death!).

Only perform work involving the opening of the control cabinet or touching the power cables when the system is off (main switch at “0”) and the power line is secured against unintended reconnection.

The reverse osmosis system has a permanent electrical connection and the system must be completely disconnected from power through an upstream disconnect device. Power cables, connection terminals and mains filters against electromagnetic interference are connected upstream of the main switch (1) of the system (IEC 60601-1/8.11.1).

⚠ WARNING!

Frequency Converter: Discharge Time

The frequency converter contains DC link capacitors that can be charged even when the frequency converter is switched off. Failure to observe the specified discharge time after disconnecting the power supply before maintenance or repair work can lead to serious or fatal injuries!

- Stop the motor.
- Disconnect the mains supply, the permanent magnet motors and the external DC link supplies, including the external battery, UPS and DC link connections to other frequency inverters.
- Only carry out maintenance or repair work after the capacitors have been completely discharged. The corresponding waiting time can be found in Tbl. 2-1 Discharge Time (29).

Voltage [V]	Minimum waiting time (in minutes)		
	4	7	15
200-240	0.25-3.7 kW	-	5.5-37 kW
280-500	0.25-7.5 kW	-	11-75 kW
525-600	0.75-7.5 kW	-	11-75 kW
525-690	-	1.5-7.5 kW	11-75 kW

Tbl. 2-1 Discharge Time

Even if the Alarm LED is lit up there can be high voltage!

Noise

The noise level of the system is under 80 dB (A) at a distance of up to 0.5 m. The law does not require any hearing protection measures for background noise up to 80 dB (A).

However, the sound level can increase in areas with multiple sources of noise and require hearing protection. If there are multiple devices in one room, an additional sound level measurement and notification of all affected persons (cleaning personnel, owner, etc.) about individual hearing protection measures are recommended.

Heat

The hot water-cleanable AQUAboss nX HT reverse osmosis system can radiate heat during hot cleaning. Parts of the system (e.g., piping and membrane modules under flow) can reach temperatures of up to 90 °C, which can cause burns.

The system has the symbol for "Attention: Hot Surfaces" on it.

2.11 Side Effects

Side Effects Related to the Device – AQUAboss nX

In rare cases hypersensitivity reactions including anaphylactic (with possible shock and death) or anaphylactoid reactions to the device (e.g. materials in the hydraulic circuit, molecules/organic and inorganic substances which pass through the reverse osmosis membrane, refer to chapter 2.13.3 Water Quality Requirements (32)) may occur during hemodialysis. Hypersensitivity reactions may cause mild to severe signs and symptoms including: malaise, nausea, headache, itching, flushing, hives, peripheral and facial swelling, erythema, contact dermatitis, ocular hyperemia, tingling sensations of the mouth and jaw, fever, leukopenia, hemolysis, anemia, hypotension, hypertension, tachycardia, arrhythmias, shortness of breath (dyspnea), wheezing, asthmatic reactions, bronchospasm, chest congestion, intradialytic pulmonary hypertension, reduced oxygen concentration and/or respiratory arrest, hemoconcentration, convulsion, unconciousness, chronic low grade systemic inflammation, complement activation, immune dysregulation.

⚠ WARNING!

Risk to the patient in case of hypersensitivity reactions!

If severe hypersensitivity reactions occur:

- Dialysis must be discontinued and appropriate aggressive medical treatment for anaphylaxis must be initiated.
- The blood from the extracorporeal system must not be returned to the patient.

⚠ CAUTION!

Risk to the patient in case of hypersensitivity reactions!

Patients with a history of hypersensitivity reactions or patients who have a history of being highly sensitive and allergic to a variety of substances should be:

- carefully monitored during treatment.

⚠ WARNING!

Risk to the patient in case of aluminum and nitrate passing through the reverse osmosis membrane.

Minor amounts of aluminum and nitrate can pass through the reverse osmosis membrane.

- Increased levels of aluminum in the permeate have been associated with anemia, neurological problems, encephalopathy, and changes in bone structure.
- Increased levels of nitrate have been associated with nausea and vomiting as well as hemolysis.
- Especially with increased levels of nitrate and aluminum in the raw water, it must be ensured that the permeate does not exceed the valid limits for water for diluting concentrated dialysates per Ph. Eur. or ISO 23500-3.

It must be ensured that the permeate does not exceed the valid limits for water for diluting concentrated dialysates per Ph. Eur. or ISO 23500-3.

Side Effects Related to Therapy – Hemodialysis Treatment

Patients with renal insufficiency treated with hemodialysis can experience side effects associated with the hemodialysis treatment. These side effects include:

- hypotension, hypovolemia, dizziness, muscle cramps, nausea, vomiting, hypertension, fluid overload, hypervolemia,
- arrythmias, myocardial stunning, sudden death, myocardial infarction, pericarditis, pericardial effusion/tamponade,
- acid-base disturbances, electrolyte disorders and shifts (sodium, chloride, potassium, calcium, magnesium, phosphate, acetate glucose, others (according to the used concentrates), bone disease,
- anxiety, stress, frustration, depression, fatigue, cognitive impairment, uremic pruritus,
- microinflammation, fever, infections, sepsis, access site complications, pain,
- anticoagulation dosing: increased bleeding risk, prolonged cannulation closure, thrombus formation/clotting due to insufficient anticoagulation resulting in decreased dialysis efficacy, blood loss, heparin-induced thrombocytopenia (HIT).

Adverse reactions such as hypertension, hypotension, palpitations, headache, dizziness and nausea may be associated with hypovolemia or hypervolemia and can usually be diminished or avoided with careful management of patient fluid, electrolyte and acid-base balance, blood flow rate and ultrafiltration rate.

2.12 Clinical Benefits

Hemodialysis provides a life-saving treatment and includes the following clinical benefits:

- Removal of excess fluid
- Removal of uremic retention solutes and molecules
- Electrolyte removal and control
- Acid-base adjustment

This device contributes indirectly in combination with an acid and alkaline concentrate to the removal of uremic retention solutes and molecules, electrolyte removal and control and acid-base adjustment based on production of water for diluting hemodialysis concentrates according to the European Pharmacopoeia and ISO 23500-3.

2.13 Special Hazards and Precautions

2.13.1 Risks from Disregarding Safety Instructions

⚠ WARNING!

Failure to follow the safety instructions can put both the responsible organization and the patient at risk. This kind of failure can result in the following hazards:

- Failure of critical functions of the AQUAboss nX
- Danger to persons from electrical and mechanical activity
- Failure of prescribed maintenance and disinfection methods

2.13.2 Application Guidelines

Never process products/media that, when exposed to pressure and temperature changes, tend to react uncontrollably, such as increased viscosity, increased temperature, precipitation, foaming or gas separation, and in doing so could cause the system limits to be exceeded even temporarily.

The raw water must be treated by an expertly designed pre-treatment stage.

Any pretreatment stage requires a water analysis or validation from the municipal water utility. Check and log the levels in the raw water feed every year.

The owner of the system must request a water analysis once every year.

Consult the municipal water utility regarding water quality/chlorination of the drinking water. A useful letter template can be found in 12.1 Sample letter to municipal water utility (187).

Follow local discharge regulations for connecting the concentrate outlet (including on the discharge of disinfectants).

Water supply and waste water connections must be properly installed per DIN 1988-100 and DIN EN 1717 or other national regulations.

Consult the manufacturer on using the system for other purposes.

NOTICE!

Only experts may transport, install, use and repair the system.

Only authorized, trained and instructed experts may start up, operate and maintain the system.

Any other use is considered improper and the manufacturer is not liable for any resulting damages.

2.13.3 Water Quality Requirements

In order not to endanger patient health and depending on the application, the quality of raw water and clean water must meet the guidelines for their respective use.

Feed/Raw Water Requirements

AQUAboss nX reverse osmosis systems are designed to be generally able to operate with a feed water quality meeting the standard of "water intended for human consumption" per (EU) 2020/2184 in addition to appropriate pretreatment.

The service life of a reverse osmosis membrane and the permeate quality as the product flow of the reverse osmosis system depend directly on the concentration of the individual water constituents and need to be optimized through suitable pretreatment processes.

ISO 23500-1 recommends the daily logging of process parameters (9.3.1 Medical Device Log (150)).

Raw Water Requirements	
Feed water (raw water)	Min. 2x clean water output (if pretreating, add the water consumption of that system to the min. volume)
Min. dynamic pressure (extraction only)	2.5 bar
Max. static pressure	6 bar
pH range	5.0–9.0
Free chlorine (constant load)	Max. 0.0 ppm
5 µm fine filter silt density index (SDI)	≤ 3
Raw water TDS benchmark (as NaCl)	500 ppm
Temperature range	10–30 °C

Definition/ Water Quality	Drinking Water (Water Intended for Human Consumption)	Feed Water for AQUAboss nX Reverse Osmosis AQUAboss nX	Dialysis Water/Permeate (Water for Diluting Concentrated Hemodialysis Solutions)		
Directive	(EU) 2020/2184	(EU) 2020/2184 + Process Limits	ISO 23500-3	Ph. Eur.	Applied Hygiene Recommendation[a]
Chemical/Physical Parameters [ppm]					
Sodium (Na)	200	200	70	50	50
Potassium (K)	N/A	N/A	8	2	2
Calcium (Ca)	N/A	Total hardness < 1 °dH or < 1.79 °f	2	2	2
Magnesium (Mg)	N/A		4	2	4
Boron (B)	1.0	1	N/A	N/A	N/A
Barium (Ba)	N/A	0.7	0.1	N/A	0.1

Definition/ Water Quality	Drinking Water (Water Intended for Human Consumption)	Feed Water for AQUAboss nX Reverse Osmosis AQUAboss nX	Dialysis Water/Permeate (Water for Diluting Concentrated Hemodialysis Solutions)		
Directive	(EU) 2020/2184	(EU) 2020/2184 + Process Limits	ISO 23500-3	Ph. Eur.	Applied Hygiene Recommendation[a]
Beryllium (Be)	N/A	0.004	0.0004	N/A	0.0004
Ammonium (NH_4)	0.5	0.1	N/A	0.2	0.2
Aluminum (Al)	0.2	< 0.01	0.01	0.01	0.01
Metals	N/A	N/A	N/A	N/A	N/A
Copper (Cu)	2	1	0.1	0.1	0.1
Arsenic (As)	0.01	0.01	0.005	N/A	0.005
Lead (Pb)	0.01	0.01	0.005	N/A	0.005
Silver (Ag)	N/A	0.1	0.005	N/A	0.005
Chrome (Cr)	0.05	0.05	0.014	N/A	0.014
Selenium (Se)	0.01	0.01	0.09	N/A	0.01
Antimony (Sb)	0.005	0.005	0.006	N/A	0.005
Quicksilver (Hg)	0.001	0.001	0.0002	0.001	0.0002
Nickel (Ni)	0.02	0.02	N/A	N/A	N/A
Tin (Sn)	N/A	N/A	N/A	N/A	N/A
Iron (Fe)	0.2	< 0.1	N/A	N/A	N/A
Cadmium (Cd)	0.003	0.003	0.001	N/A	0.001
Zinc (Zn)	N/A	5.0	0.1	0.1	0.1
Manganese (Mn)	0.05	< 0.01	N/A	N/A	N/A
Uranium (U)	0.010	0.01	N/A	N/A	N/A
Or total heavy metals	N/A	N/A	0.1	0.1	N/A
Cyanide (CN)	0.05	0.05	N/A	N/A	N/A
Chlorine (Cl_2)	N/A	**Total chlorine: 0.0**	0.1	0.1	0.1
1,2-dichloroethane	0.0030		N/A	N/A	N/A
Chloramine	N/A		0.1	N/A	N/A
Chloride (Cl)	250	250	N/A	50	N/A
Fluoride (F)	1.5	1.5	0.2	0.2	0.2
Sulfate (SO_4)	250	240	100	50	50
Nitrate (NO_3)	50	10	2 (as N)	2	2

Definition/ Water Quality	Drinking Water (Water Intended for Human Consumption)	Feed Water for AQUAboss nX Reverse Osmosis AQUAboss nX	Dialysis Water/Permeate (Water for Diluting Concentrated Hemodialysis Solutions)		
Directive	**(EU) 2020/2184**	**(EU) 2020/2184 + Process Limits**	**ISO 23500-3**	**Ph. Eur.**	**Applied Hygiene Recommendation[a]**
Nitrite (NO_2)	0.5	0.5	N/A	N/A	N/A
Polycyclic aromatic hydrocarbons	0.00010	0.0001	N/A	N/A	N/A
Benzole	0.0010	0.001	N/A	N/A	N/A
Bromate	0.010	0.01	N/A	N/A	N/A
Tetrachloroethane and trichloroethane	0.010	0.005	N/A	N/A	N/A
Trihalomethane	0.050	0.05	N/A	N/A	N/A
Vinyl chloride	0.00050	0.0005	N/A	N/A	N/A
Silicon dioxide (SiO_2)	N/A	< 10	N/A	N/A	N/A
pH level	6.5–9.5	6.5–9.0	N/A	N/A	N/A
Temperature	N/A	6–30 °C	N/A	N/A	N/A
Conductivity	2,500 µS/cm at 20 °C	< 1,000 µS/cm at 20 °C	N/A	N/A	N/A
SDI (15) Turbidity (NTU)	NTU < 1	SDI (15 min) < 3 per ASTM 4189	N/A	N/A	N/A
Microbiological Parameters					
Total viable count [CFU/mL]	< 100 (22 ± 2 °C, 44 ± 4 h) < 100 (36 ± 1 °C, 44 ± 4 h)	< 100 (22 °C) < 100 (36 °C)	< 100 (action at 50%) (17–23 °C, 7 d)	< 10^2 (30–35 °C, 5 d)	< 100 per RKI (22 ± 2 °C, 3–7 d)
Enterococcus	0 CFU/100 mL	0 CFU/100 mL	N/A	N/A	N/A
E. coli/coliforms	0 CFU/100 mL	0 CFU/100 mL	N/A	N/A	N/A
Endotoxins [EU/mL]	N/A	N/A	< 0.25 (action at 50%)	< 0.25	0.25

a. Leitlinie für angewandte Hygiene in der Dialyse. Hrsg. Deutsche Gesellschaft für angewandte Hygiene in der Dialyse (DGAHD) e.V. (ISBN 978-3-00-073337-6; 2022)

⚠ WARNING!

Risk to patient in case of common contaminants in permeate:

- Increased levels of aluminum in the permeate have been associated with anemia, neurological problems, encephalopathy, and changes in bone structure.
- Increased levels of nitrate have been associated with nausea and vomiting, methemoglobinemia, as well as hemolysis.
- Increased levels of chlorine or chloramines in the permeate have been associated with haemolytic anemia.
- Increased levels of fluoride in the permeate have been associated with renal bone disease/changes in bone structure.
- Increased levels of calcium or magnesium in the permeate have been associated with hard water syndrome (nausea, vomiting, headache, muscle weakness).
- Increased levels of copper in the permeate have been associated with haemolytic anemia, nausea, vomiting and liver damage.
- Increased levels of zinc in the permeate have been associated with nausea, vomiting and fever.
- Increased levels of lead in the permeate have been associated with abdominal pain and muscle weakness.
- Increased levels of sulphate in the permeate have been associated with acidosis, nausea and vomiting.
- Increased levels of endotoxins in the permeate have been associated with pyrogenic reaction and chronic inflammation.
- Increased levels of microbial counts in the permeate have been associated with hypotension, nausea, vomiting, fever.

Lead has been shown to be elevated in long-term hemodialysis and patients show sensitivity towards lead, even if lead concentrations in the permeate are according to the standards. The responsible physician should be aware of lead specific clinical symptoms and react accordingly.

Directive (EU) 2020/2184 and ISO 23500-3 specify limits for rare substances that are not listed here and can be found in the original publications. Compared to earlier releases, they do not provide any information on phosphates.

NOTICE!

If membrane barrier is not integer, raw water salts can enter permeate side of the system. As a result permeate may not comply with chemical requirements of ISO 23500-3.

⚠ WARNING!

Risk of toxicity and pyrogenic reactions

The owner is responsible for selecting the water treatment system and checking the permeate against the Ph. Eur. and ISO 23500-3 once every year.

⚠ WARNING!

Risk of chemical, physical and/or microbial contamination

Permeate quality depends on feed water quality. If feed water quality is significantly reduced, changes in the permeate may result in acceptable limits being exceeded.

- The owner is responsible for regularly monitoring feed water limits.

The water quality in the permeate is reflected online by conductivity (sum parameters of most water constituents). It depends on pretreatment, supply water quality and temperature.

2.13.4 Microbiological Safety

When used as intended, the reverse osmosis system produces water for diluting concentrated dialysates.
Permeate quality per ISO 23500-3 and the Ph. Eur. is affected by:

- Raw water quality (Directive (EU) 2020/2184 must be observed)
- Pretreatment (hardness, chlorine, heavy metals, etc.)
- Ring piping (sizing, material)
- Cleaning and disinfection cycles

After initial startup, the system is handed over in proper working condition (incl. microbial quality).

NOTICE!

The owner is responsible for observing Ph. Eur. or ISO 23500-3 limits for microbial quality.

- After a period of disuse (over 72 h), disinfection is recommended.
- If not used for a prolonged period, the entire water treatment system is at risk of microbial contamination. This also applies to the connected piping if it is not automatically flushed.
- Check the microbial quality of the permeate at least once every 6 months (see Section 2.13.3 Water Quality Requirements (32)).
- If the alarm limit for the total bacteria count (50 CFU/mL) and endotoxins (0.125 IU/mL) is exceeded, disinfect the system.
- Constant bacterial exposure can lead to the formation of biofilm. Biofilm usually can only be removed by a combination of mechanical and chemical cleaning.
- If Ph. Eur. or ISO 23500-3 limits are exceeded (see Section 2.13.3 Water Quality Requirements (32)), the system must be cleaned and disinfected immediately (alarm limit).

2.13.5 Usage with other Equipment

Combining the AQUAboss nX with other medical devices (e.g., ring pipings, heat disinfection or dialysis machines) is at the owner's discretion. The AQUAboss nX and other medical devices can be operated independently of one another. B. Braun Avitum AG does not sell any standard combination of medical devices.

The manufacturer, B. Braun Avitum AG, has established the following guidelines for combining the reverse osmosis system with other devices. Equipment for pre-treating the feed water (e.g., softeners, activated carbon filters, etc.) and systems for accumulating or distributing the clean water must meet DIN EN ISO 23500-2 requirements.

When using with permeate ring pipings, they must be designed in accordance with EN ISO 11197 (electrical medical devices, particular requirements for the safety of medical supply units). Pressure loss at the end of the ring piping at max. throughput must not exceed 3 bar. The feed and return of the ring piping must have a mechanical shutoff feature.

When using with media supply units, permeate sampling points per EN ISO 11197 must be included.

When using with dialysis machines (Medical Device Class IIb), these machines must comply with the standard IEC/TR 62653 (Guidelines for the safe use of medical products in dialysis treatment).

AQUAboss nX is an accessory to a medical device (hemodialysis machine) and does not include an applied part itself. The applied part of the hemodialysis machine is further defined in IEC 60601-2-16.

They must also comply with the standard IEC 60601-2-16 (Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment).

For water pretreatment, a Type BA backflow preventer is only adequate when the connected dialysis machines guarantee a free inlet.

The user is responsible for establishing the functional safety and proper working condition any devices used in conjunction with the system.

Add-on equipment connected to the analog and digital interfaces of the device must have documented compliance with their corresponding EN specifications (e.g., DIN EN 62368-1 for data-processing equipment, DIN EN 61010-1 for measurement, test and laboratory equipment, and DIN EN 60601-1 for electrical medical devices). Any configuration must also meet the valid version of system standard DIN EN 60601-1-1. Any person who connects additional devices to the signal input or output section of a system is considered a system configurator and is therefore responsible for complying with the valid version of system standard DIN EN 60601-1-1. If you have any questions, please contact your distributor or technical service.

NOTICE!

The AQUAboss nX reverse osmosis system is designed to safely operate in conjunction with *Aquaboss*® products:

- Hot Rinse SMART
- CCS
- Soft Control
- Remote Control
- Water Monitor
- Double Ring Piping Set nX
- Ring Piping
- Eco Mix

No compatibility against HF surgical equipment.

⚠ WARNING!

Risk of toxicity and pyrogenic reactions

Even if the reverse osmosis system produces water of a quality that meets the requirements of the international standard DIN EN ISO 23500-3, the distribution of this water can degrade its quality to such a degree that it no longer meets the requirements of DIN EN ISO 23500-3 if the distribution system is not properly maintained.

- The reverse osmosis system and connected distribution system must be maintained/inspected according to the manufacturer's instructions.

2.14 Notice to the User

If any serious incident occurs in relation to the system this incident should be reported to B. Braun Avitum AG and to the responsible competent authority.

2.15 Information for the Responsible Organization

2.15.1 Conformity

The system and options meet the requirements of the following relevant standards in their valid national versions:

- IEC 60601-1 Electrical medical devices
- IEC 60601-1-2 Electromagnetic compatibility
- ISO 23500-2 Functional safety

The system is delivered to countries in which it is registered and classified in accordance to local regulations. The space where the AQUAboss nX is operated should be secured against unauthorized access.

2.15.2 Training by Manufacturer prior to Commissioning

The liable organization should ensure that only trained personnel operate the system. This training should only be provided by personnel authorized by the manufacturer. Contact your local B. Braun Avitum AG representative or your distributor for more information on training courses.

2.15.3 Requirements on the User

Any information provided by the software is only a comfort function.

The user is responsible for establishing the functionality and proper working condition of a medical device before use.

The system should only be operated by experts who are properly trained in and instructed on its use in accordance with these instructions for use.

The liable organization should ensure that the instructions for use have been read and understood by all users entrusted with any kind of work on or with the system. The instructions for use should be available to the user.

This medical device should only be operated for its intended use and in accordance with national law.

The system should not be operated or used if it is defective in a way that puts patients, employees or third parties at risk. The user is responsible for establishing the functionality and proper working condition of the system before use.

The user is also responsible for reporting any changes to the system affecting safety to a supervisor/the owner and for following all safety instructions.

The owner is responsible for providing instructions and performing checks to ensure the cleanliness and orderliness of the space where the system is used.

The owner is responsible for clearly regulating who is responsible for startup, operation and maintenance so this work is performed by everyone involved without any misunderstandings as to who has authority with regard to safety aspects.

If flexible hoses are used for supplying liquids (e.g. for dialysis) in an operator-adjustable system (e.g. a ceiling pendant), the following test shall be carried out following modification or replacement of the flexible hose:

- test for leakage.
- test for cross connections between pipelines for different liquids.

NOTICE!

This device is professional medical electrical equipment. This means it is only for use by healthcare professionals and is not intended for sale to the general public.

2.15.4 Manufacturer's Responsibility

The manufacturer is only liable for changes in the safety, reliability and performance of the system when installations, enhancements, readjustments, modifications or repairs are made by authorized persons.

The system should only be operated when:

- The manufacturer or an authorized person acting on behalf of the manufacturer has performed a functional test at the place of operation (initial startup).
- The persons tasked by the liable organization with using the system have been instructed in the proper handling, use and operation of the medical device based on these instructions for use, the enclosed information and servicing information.
- The quality of the water used with the reverse osmosis system meets the requirements of Directive (EU) 2020/2184 "Water intended for human consumption".
- The functional safety and proper working condition of the system have been verified.

2.15.5 Modifications to the System

Do not make modifications to the system.

2.15.6 Preventive Maintenance and Technical Safety Inspection

Regular preventive maintenance should be performed every second year per the checklist and the instructions for use.

The system should be inspected by properly trained persons who do not require any instructions to perform such an inspection.

The results of the TSC should be documented, e.g., by attaching a test badge or on the "History of Maintenance" sticker on the system.

The liable organization should keep TSC documentation with the system's documentation.

A service manual will only be provided as part of technical training.

Safety During Repairs, Maintenance and Servicing

⚠ DANGER!

Risk of electric shock.

Dangerous voltage when control cabinet is open.

- Shut off the reverse osmosis system at the main switch and disconnect from power.

⚠ WARNING!

Frequency Converter: Discharge Time

The frequency converter contains DC link capacitors that can be charged even when the frequency converter is switched off. Failure to observe the specified discharge time after disconnecting the power supply before maintenance or repair work can lead to serious or fatal injuries!

- Stop the motor.
- Disconnect the mains supply, the permanent magnet motors and the external DC link supplies, including the external battery, UPS and DC link connections to other frequency inverters.
- Only carry out maintenance or repair work after the capacitors have been completely discharged. The corresponding waiting time can be found in Tbl. 2-2 Discharge Time (41).

Voltage [V]	Minimum waiting time (in minutes)		
	4	7	15
200-240	0.25-3.7 kW	-	5.5-37 kW
280-500	0.25-7.5 kW	-	11-75 kW
525-600	0.75-7.5 kW	-	11-75 kW
525-690	-	1.5-7.5 kW	11-75 kW

Tbl. 2-2 Discharge Time

Even if the Alarm LED is lit up there can be high voltage!

When the control cabinet is open:

- The reverse osmosis system should have been shut off at the main switch (1) (see Section 3.3 Front View ROI (47)) and disconnected from power before starting maintenance and repairs.
- Damaged or removed notices, warning signs and safety labels should be replaced immediately.
- All removed safeguards should be properly reinstalled after servicing.
- Unauthorized modifications or changes to the system can jeopardize the safety of persons and the system and should therefore be avoided.
- The system has a permanent electrical connection, it must be completely disconnected from power through an upstream disconnect device. Power cables, connection terminals and mains filters against electromagnetic interference are connected upstream of the main switch (1) of the system (IEC 60601-1/8.11.1).

2.15.7 Accessories, Spare Parts and Consumables

Only B. Braun original spare parts, accessories and consumables should be used; see 10 Items used in combination with AQUAboss nX (157). A detailed spare parts list can be found in the B. Braun Service Portal.

NOTICE!

B. Braun Avitum AG is not liable for damages caused by the use of spare parts, accessories or consumables from other manufacturers.

NOTICE!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment can result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

2.15.8 Expected Service Life

The AQUAboss nX is designed for a service life of 10 years.

2.15.9 Safe Switch-Off

1. Set system to operating mode “System off”.
2. Switch off system at main switch (set to “0”).
3. Disconnect power upwards of the permanent connection.
4. According to the mains filter and frequency converter recommendation, wait until capacitors are discharged but at least 5 minutes, whichever is longer.

⚠ DANGER!

Danger of electric shock!

- Before working on the system, check that it is voltage-free.

Switching off at the main switch does not disconnect the mains voltage from all internal parts of the unit (e.g. mains filter). To disconnect the system completely from the mains, always disconnect the system from power before working on it.

Before switching off the system, check to make sure that the system is not in dialysis mode or running a disinfection. If disinfection is aborted, it is recommended to run it again.

After power failure or reset, the reverse osmosis is operational within 120 seconds after restart. The system restarts in the operating mode that was pending before power cut off.

Exit Point	Re-Entry Point
System Off	System Off
Dialysis	Dialysis
Standby	Standby
Chemical Disinfection	Chemical Disinfection (Flushing Phase)
Thermal Disinfection	Thermal Disinfection (Cooling Phase)
Emergency Mode (first and second stage)	System Off
Emergency Mode (without display)	System Off
Blocking State	Blocking State

2.15.10 Decommissioning

If the system is to be taken out of operation for a longer period of time, it is recommended to preserve the system. In order to preserve the system, please contact the Technical Service for information about preservation.

If the system is to be left idle for a longer period of time, softener must be monitored for microbial contamination. It must also be put back into operation according to chapter 4.7 Initial Startup Preparations (113).

In order to exclude any risk to patients, disinfection must be carried out in accordance with chapter 7.2 Disinfection (124) after preservation. Preservation is recorded in a separate protocol intended for this purpose and noted in the medical devices book (see chapter 9.3.1 Medical Device Log (150)).

If the AQUAboss nX is taken out of service, remove the batteries to prevent leakage. Observe the battery change interval as per section 9 Preventive Maintenance and Technical Safety Inspection (145).

2.15.11 Disposal

The system should be disposed of per local regulations and the liable organization's internal procedures. Do not dispose of the system with ordinary waste.

Spare parts should be disposed in accordance with the law and local regulations (e.g., Directive 2012/19/EU).

This medical device contains batteries. Used batteries should be recycled. The batteries are on the back side of the display and on the main board in the control cabinet and can be removed from the circuit board with a screwdriver.

Follow these steps

1. Turn the main switch to "0".
2. Replace or remove the battery.

B. Braun Avitum AG will accept and properly dispose of the systems it delivers in accordance with the law. B. Braun Avitum AG guarantees the acceptance of spare parts as well as old devices and systems.

The materials used meet the requirements of Directive 2015/863 of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Preservation

If the system will not be used for a prolonged period, please contact the technical service for information on preservation.

2.15.12 Technical Changes

B. Braun Avitum AG reserves the right to change the products in line with further technical developments.

3 Product Description

3.1 Features

The AQUAboss nX systems have the following features:

- Produces water for diluting concentrated dialysate.
- Modular design
  - Variable system performance by changing out pumps and membranes
- Standby mode
  - In addition to Dialysis mode (permeate operation), the system regularly switches to a flushing mode to prevent microbial growth.
- Unauthorized operation that could put connected medical devices and, ultimately, the patient at risk is prevented by measuring devices and associated control measures (alarm and error functions).
- Semiautomatic chemical disinfection and cleaning
  - Chemical disinfection available as an alternative to hot cleaning (thermal disinfection).
- "HT" option
  - Automatic hot water-cleanable reverse osmosis with supply tank

3.2 Brief Description

The AQUAboss nX is a consumption-controlled, single or dual stage reverse osmosis system. A 15" graphical touchscreen allows access and monitoring of all operating parameters at any time. Various languages are available for the display.

Customized parameters make a high water yield possible, even under poor raw water conditions. Raw water consumption is based solely on the end user's permeate needs.

The touchscreen makes it possible for the user to monitor all production parameters as well as customize some system functions, including disinfection mode, individually and reproducibly.

3.2.1 Mode of Operation

Treating water with a reverse osmosis system will produce purified water with a very low concentration of chemical solutes. More than 95% of unwanted water constituents are eliminated. The quality of water for diluting concentrated dialysate is defined in the Ph. Eur or ISO 23500-3.

AQUAboss nX operates on the reverse osmosis principle. This principle corresponds to pressure-driven crossflow filtration where water flows at high pressure tangentially through a semipermeable membrane. As with normal filtration, the solvent (in this case, water) passes through the membrane virtually unhindered while all other water constituents (dissolved and undissolved substances) are more or less stopped by the membrane and carried away with the concentrate.

This is a purely physical process at the molecular level that does not chemically, biologically or thermally alter the separate substances. The membrane is spiral-wound polyamide. How material is transported through

this kind of membrane can be best described by the solution-diffusion model. This model views the polymer membrane as a real fluid into which the solvent (water) is dissolved and diffused along the density gradient.

3.2.2 Design Features

The system has the following design features:

- Disconnection from mains/free water intake per EN 1717
- User-friendly touchscreen control
- Password protection of configurable device data
- Compact design
- Designed to reduce power consumption
- Single pipe construction
  - The single pipe construction is designed for a long service life of the membrane. The membrane pipe is made of stainless steel (1.4571/ 1.4404).
- AQUAboss nX HT hot water-disinfectable elements
  - All hot-cleanable reverse osmosis systems in the AQUAboss nX HT series come with special reverse osmosis membrane elements whose external, high precision-manufactured, knurled polypropylene texture makes them especially suitable for use in microbially sensitive water treatment systems.
- Low dead-space, stainless steel piping
  - The permeate side of the system is designed to minimize dead space. High flow rate and the resulting shear forces help to avoid microbiological contamination where it originates.

3.2.3 Performance Criteria

For safe permeate production these performance criteria must be met:

- conductivity at sensor C3 < 90 µS/cm,
- temperature at sensor T1 < 38 °C,
- pressure at sensor P3 < 6 bar.

3.3 Front View ROI

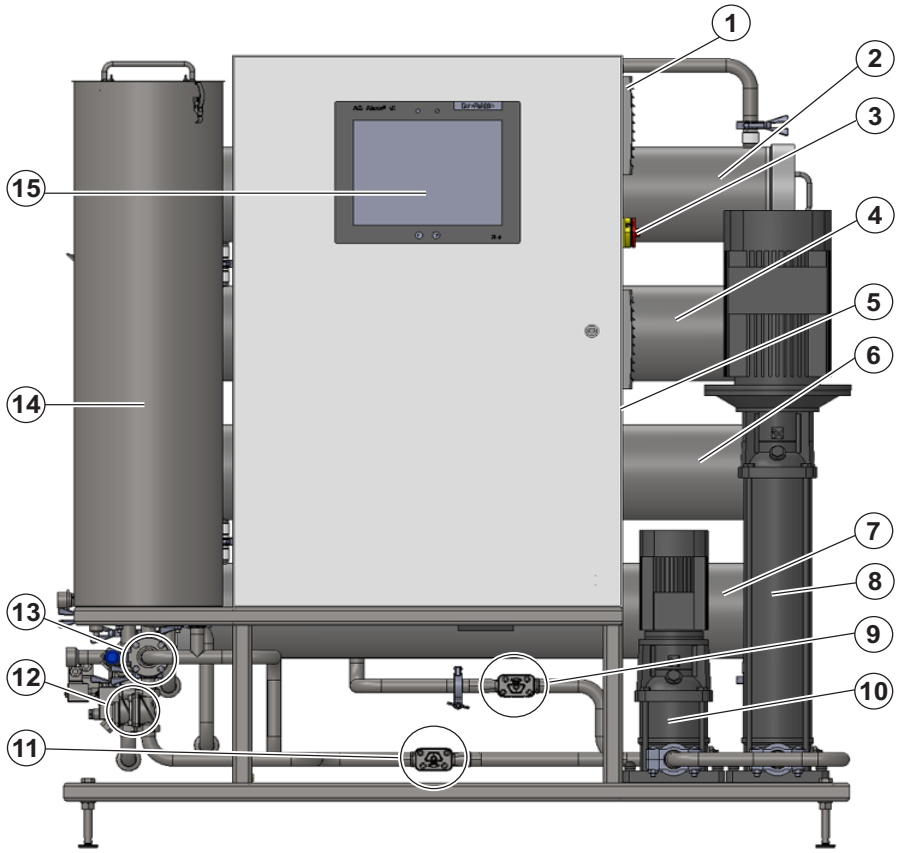


Fig. 3-1 Front view of the system

No.	Abbreviation	Description
1	-	Switch emergency operation button
2,4, 6-7	MM1.1-1.4	Membrane modules 1.1-1.4
3	-	Main switch RO I
5	-	Type plate RO I
8	M1.1	Pump 1.1
9	F2	Concentrate flow (1st stage)
10	M1.2	Pump 1.2
11	F3	Drain flow rate sensor
12	Y9	Solenoid valve concentrate discharge
13	K4	Butterfly valve tank discharge

No.	Abbreviation	Description
14	-	Supply tank
15	-	Display with 2 LEDs and 2 function keys

3.4 Side View ROI

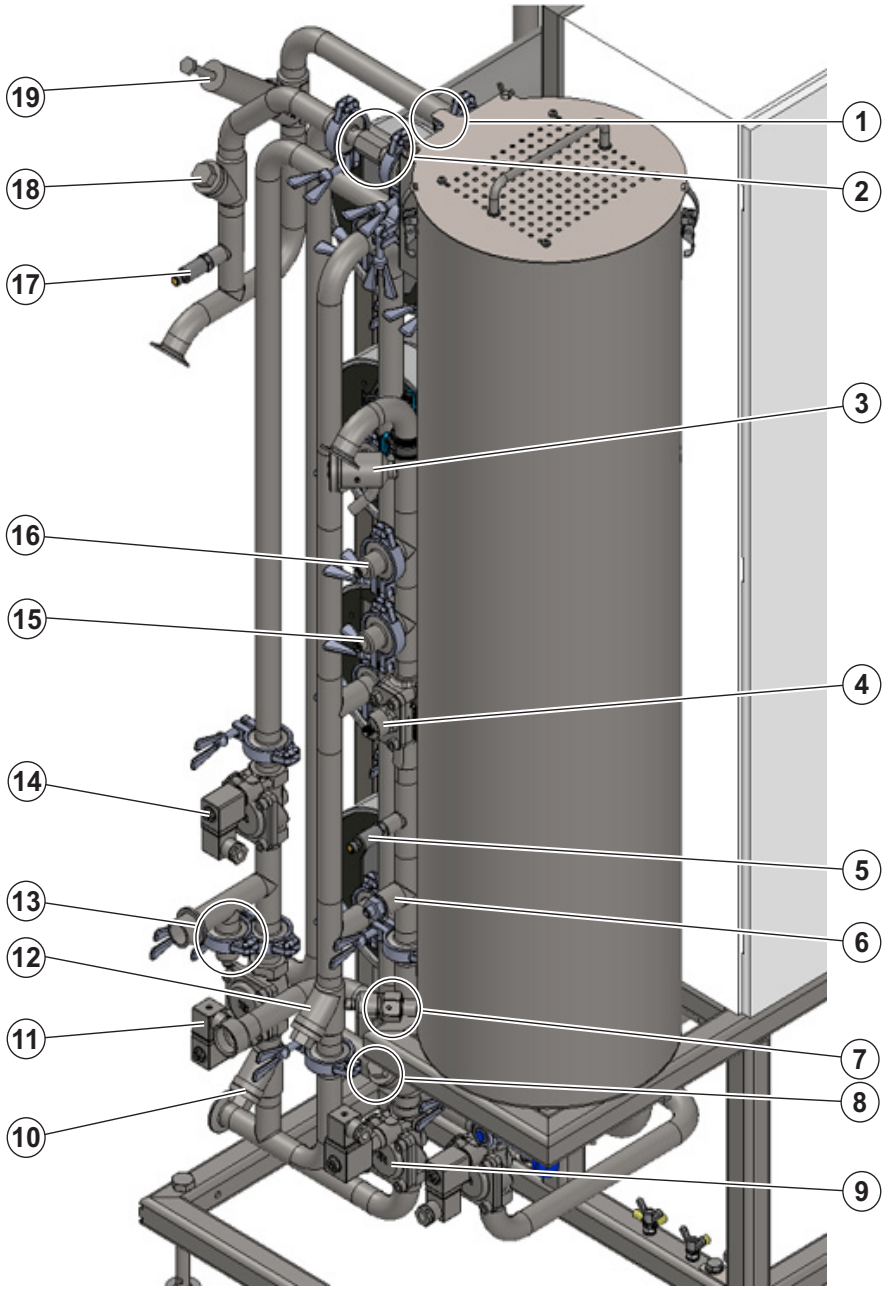


Fig. 3-2 Side view of the system

No.	Abbr.	Description
1	GS1	Tank cover proximity sensor
2	Vlim	Flow limiter

No.	Abbr.	Description
3	PH1	Ring piping feed sampling valve
4	F1	Permeate flow rate sensor
5	PS1	Ring piping pressure switch
6	T1	Permeate temperature sensor
7	P1	Supply tank level control pressure sensor
18, 10, 8	RSV3-5	Non-return valve
9	Y11	Solenoid valve emergency operation (only double stage)
11	Y12	Solenoid valve emergency operation (only double stage)
12	RSV1	Non-return valve
13	C1	Raw water conductivity sensor
14	Y10	Solenoid valve raw water feed
15	C3	Permeate conductivity sensor
16	C4	Redundant conductivity sensor
17	P3	Pressure sensor ring piping return
19	ÜV1	Ring piping overflow valve

3.5 Front View ROII

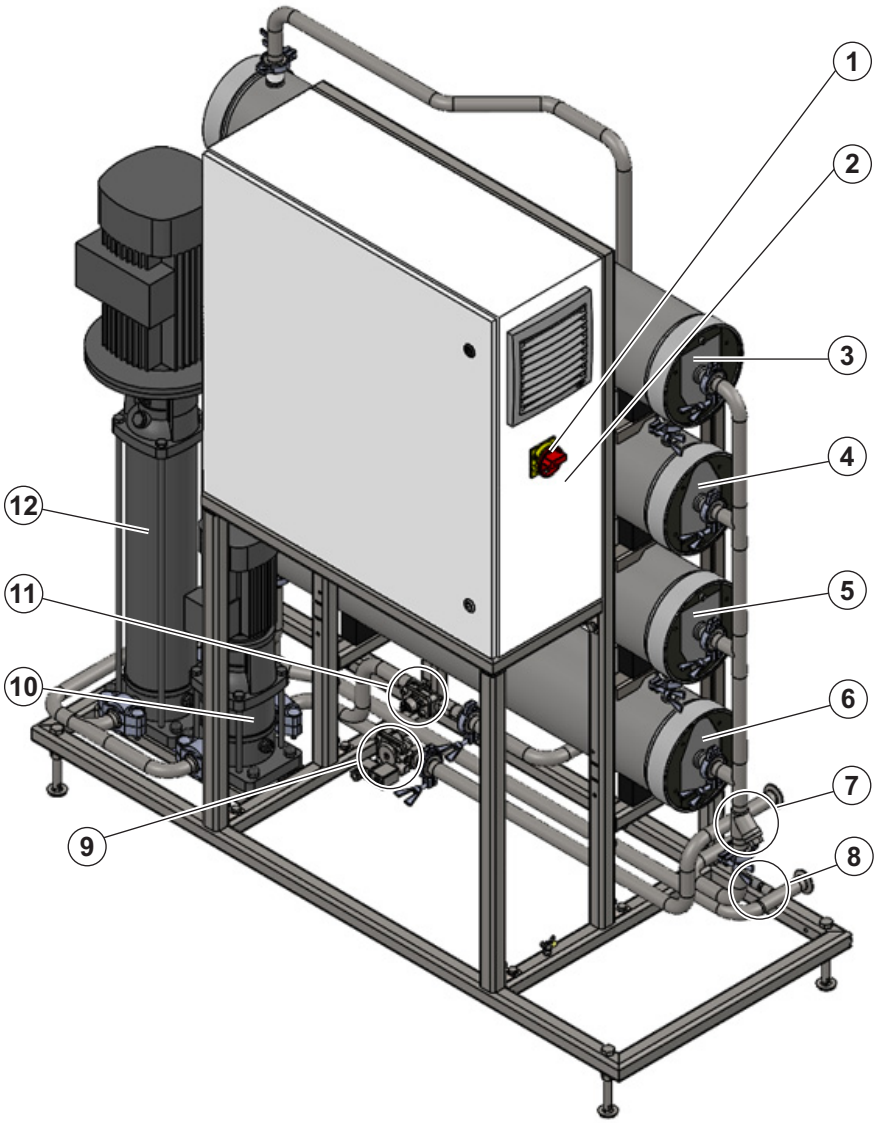


Fig. 3-3 Rear view of the system

No.	Abbreviation	Description
1	-	Main switch RO II
2	-	Type plate RO II
3-6	MM2.1-2.4	Membrane modules
7	RSV2	Non-return valve
8	P2	Pressure sensor before RO II
9	Y8	Solenoid valve concentrate RO II
10	M2.2	Pump 2.2

No.	Abbreviation	Description
11	F4	Concentrate flow rate sensor
12	M2.1	Pump 2.1

3.6 Operation

In a hospital or dialysis center, the AQUAboss nX system is installed in the osmosis room (see section 4.4 Installation Site (107)).

The user is located directly at the system to operate it. Alternatively, the user can use RemoteControl to operate it.

3.7 Type Plate

The following figure shows a sample type plate. See the type plate on the system for the actual figures and information.

1 Product name
2 Reference number
3 Serial number
4 Manufacturing date
5 Power consumption
6 Rated voltage
7 Rated frequency
8 Consult instructions for use
9 Medical device
10 CE mark and notified body identifier
11 Housing protection class
12 Temperature limit
13 Unique device identification and global trade item number
14 Manufacturer's address

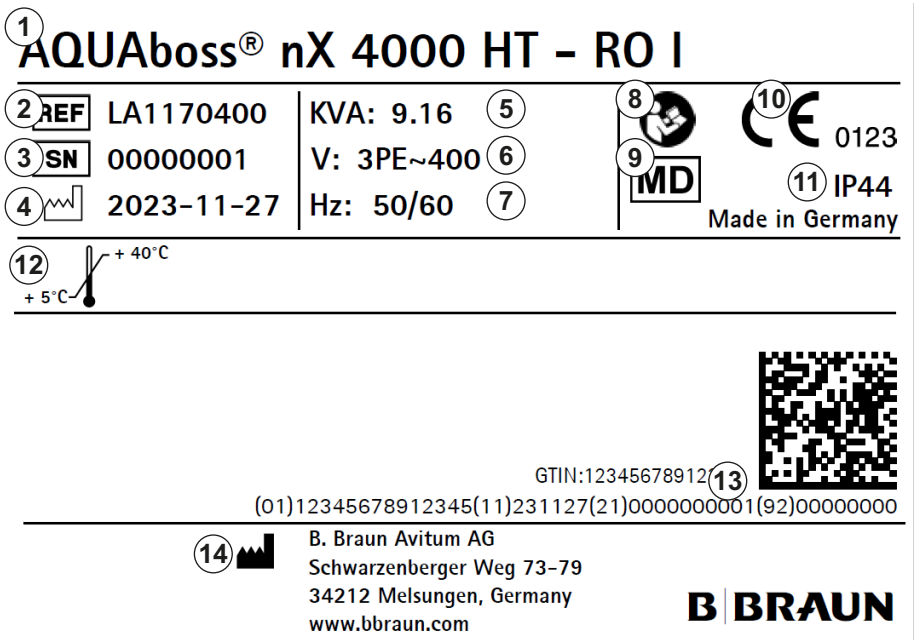
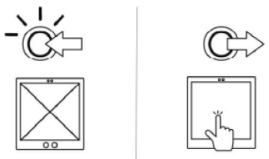


Fig. 3-4 Type plate

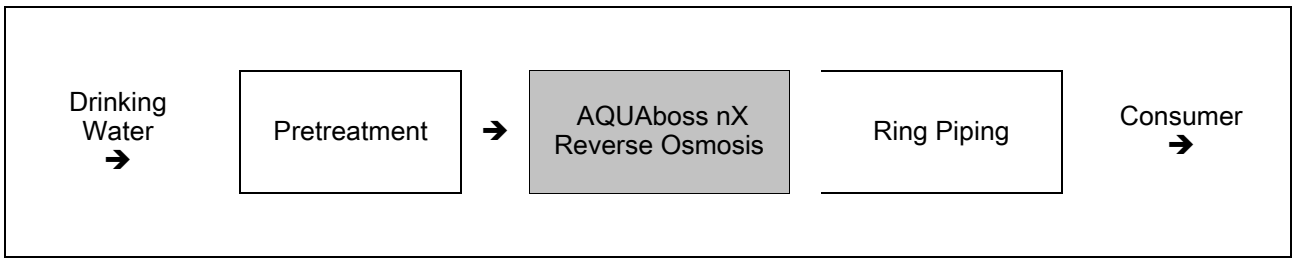
3.8 Symbols on the System

Symbols on the Reverse Osmosis System

Symbol	Description
	Follow instructions of use. Observe safety information.
IP 44	Housing protection class IP 44: • Protected against access to dangerous parts with a wire with a diameter of 1.0 mm or larger, • Protected against solid foreign bodies with a diameter of 1.0 mm or larger, • Protected against harmful effects caused by water splashed against the housing from any direction.
	Warning: hot surface (symbol is yellow on system)
	Protective earth terminal
3PE~	3-phase alternating current
	OFF (power, disconnect from grid connection)
	ON (power, connect to grid connection)
	Dangerous voltage (symbol is yellow on system)
	Warning: residual risks. Refers to the need to consult these instructions for use for important safety information.
	Symbol is located next to the Switch Emergency Operation button. See 3.12.5.6 Emergency Modes (102) for more information.

3.9 Diagrams

3.9.1 Basic Flow Diagram



Treatment to produce water for diluting concentrated dialysate typically involves a pretreatment system (e.g., filter, softener, activated carbon), an AQUAboss nX or AQUAboss nX HT reverse osmosis system, and a ring piping through which the product water is circulated and supplied to the consumer at various tapping points. Both the reverse osmosis system and the ring piping are medical devices that can be marketed independently of one another.

In Dialysis mode, all reverse osmosis systems produce water for diluting hemodialysis concentrate.

3.9.2 Process Flow Diagrams

3.9.2.1 Single Stage

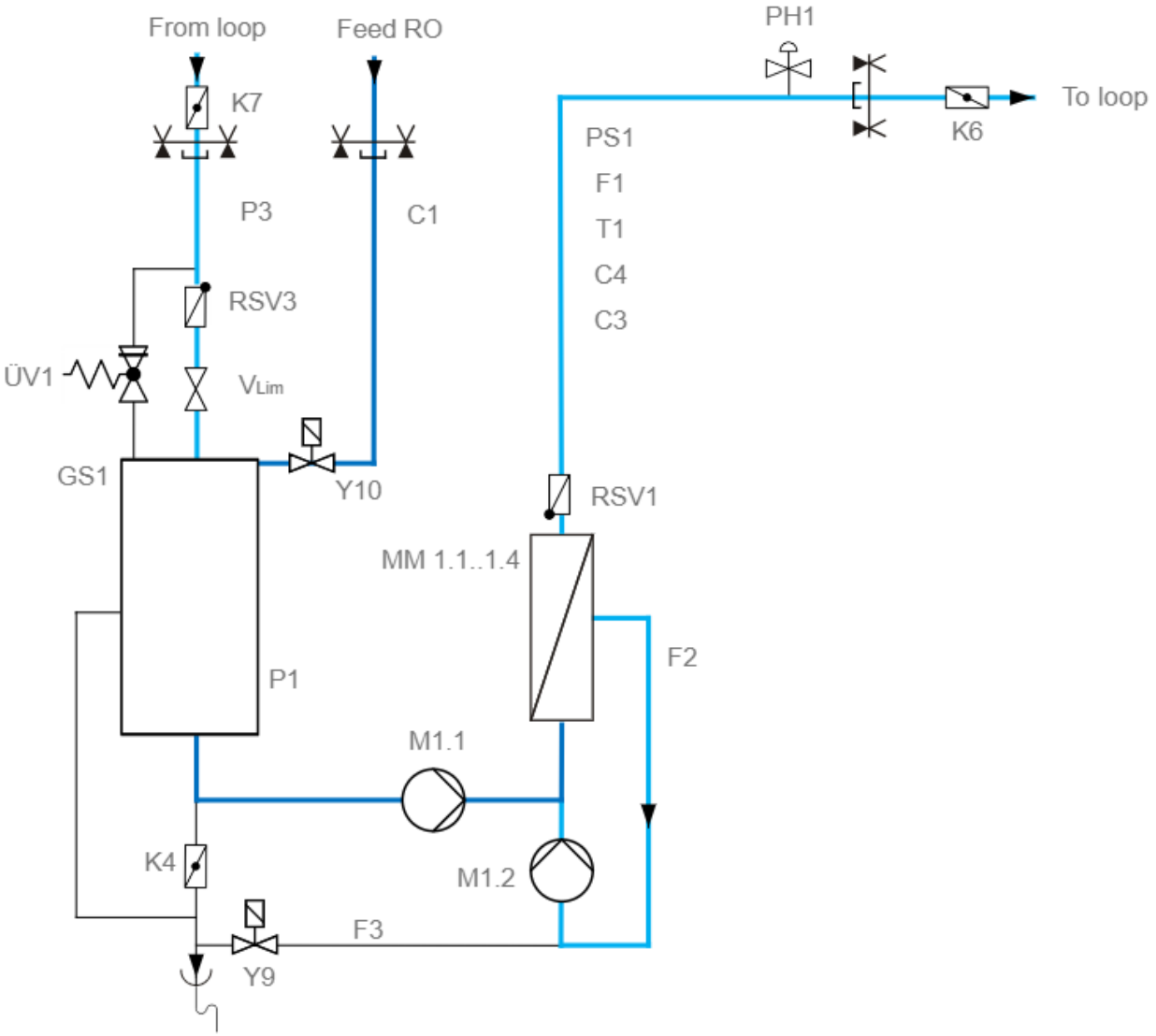


Fig. 3-5 Single stage flow diagram

3.9.2.2 Dual Stage

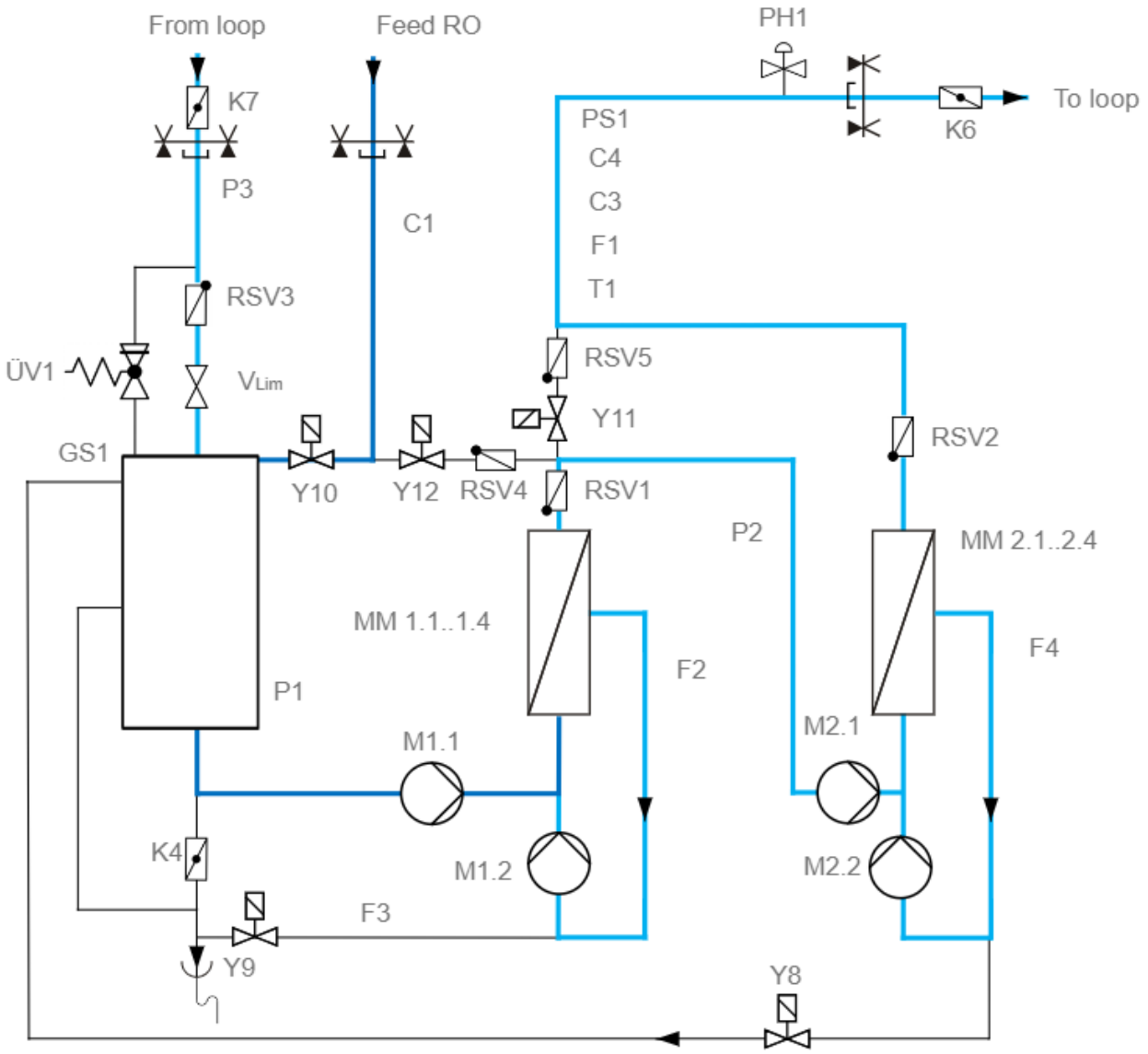


Fig. 3-6 Dual stage flow diagram

3.10 Functional Description

3.10.1 Water Supply

The system is fed with soft water supplied by an upstream softener. A 5 µm prefilter protects the reverse osmosis system from coarse impurities. Various prefilters are available; see the water connections in Section 11 Technical Data (159)).

Chlorinated drinking water needs to be treated with an activated carbon filter, since chlorine will irreversibly damage the membranes. No chlorine should be detectable in the feed water for the reverse osmosis system (see Section 11 Technical Data (159)).

These pretreatment units are not included in the delivery of an AQUAboss nX.

3.10.2 Supply Tank

The prefiltered, softened water is fed through Feed Valve Y10 into the supply tank. The water level in the supply tank is controlled by Pressure Sensor P1. Pressure Sensor P1 protects the integrated centrifugal pump from running dry. If the level falls below the P1 switching point (Tank level empty), the pump is switched off. Never operate the pump when the water level is below parameter “Tank level empty”. The electrical mechanical design of the supply tank lock prevents unintended opening of the supply tank.

The following is connected to the supply tank:

- Raw water feed via Y10
- Ring piping return
- Overflow
- Outlet to Pump M1.1 and tank drain
- Connection to SoftControl
- Discard from second stage

3.10.3 Flow Rate-based Control

As shown in the process diagram, the following is measured and analyzed:

- F1 permeate flow rate sensor
- F3 drain flow rate sensor

The discard is based on the volume of the permeate used and the water conversion factor (WCF) which is stored as a setting.

Optionally, a forced discard can be set which forces a discard after a certain time, if no discard occurred during the configured duration.

3.10.4 Ring Piping Pressure

The following factors affect the pressure in the ring piping:

- Max. consumption (number of dialysis stations and other consumers)
- Pipe geometry (cross-section, etc.)

At the end of the ring piping, Overflow Valve ÜV1 prevents overpressure and enables rinse functions. At max. consumption, the necessary volume of permeate must be fed into the ring piping at the required pressure. The opening pressure is around 3.5 bar.

3.10.5 Preventing Pressure Overload in the Ring Piping

It is possible for the pressure after the reverse osmosis system to increase when a shutoff valve is blocking the ring piping. The pressure switch PS1 prevents the pressure from exceeding a certain pressure level. After the system is switched off, the corresponding message appears on the display.

An excessive increase in pressure when the system is switched on will result in the pressure switch PS1 lowering the motor revolution speed and if this is not lowering the pressure ultimately switching off the system.

3.10.6 Temperature-based Discarding

When the permeate exceeds a temperature of 37°C (Temp.Discharge Start, adjustable from 20 to 37 °C), the system discards the concentrate via Y9. This occurs until the temperature has dropped below the lower set limit (Temp.Discharge Stop, adjustable 18 to 35 °C). The difference between the start and stop values is at least 2 °C, which is programmed in the software.

3.10.7 Leak Notifications

To prevent serious leaks in Standby mode, the system and ring piping are monitored for water loss. The fill level in the supply tank dropping below the P1 level while the system is in Standby mode indicates water loss in the ring piping or the system, and the system shuts off.

3.10.8 Redundant Conductivity Measurement

The permeate conductivity is measured by two redundant sensors C3 and C4 which are evaluated by two redundant processors. If one of these sensors returns no valid signal or the deviation between the two values is above a certain threshold, the hardware safety chain will open and the system enters the blocking state.

3.11 User Interface

3.11.1 Controls and Displays

1 LED indicator lights
2 Display
3 Function keys F1 and F2

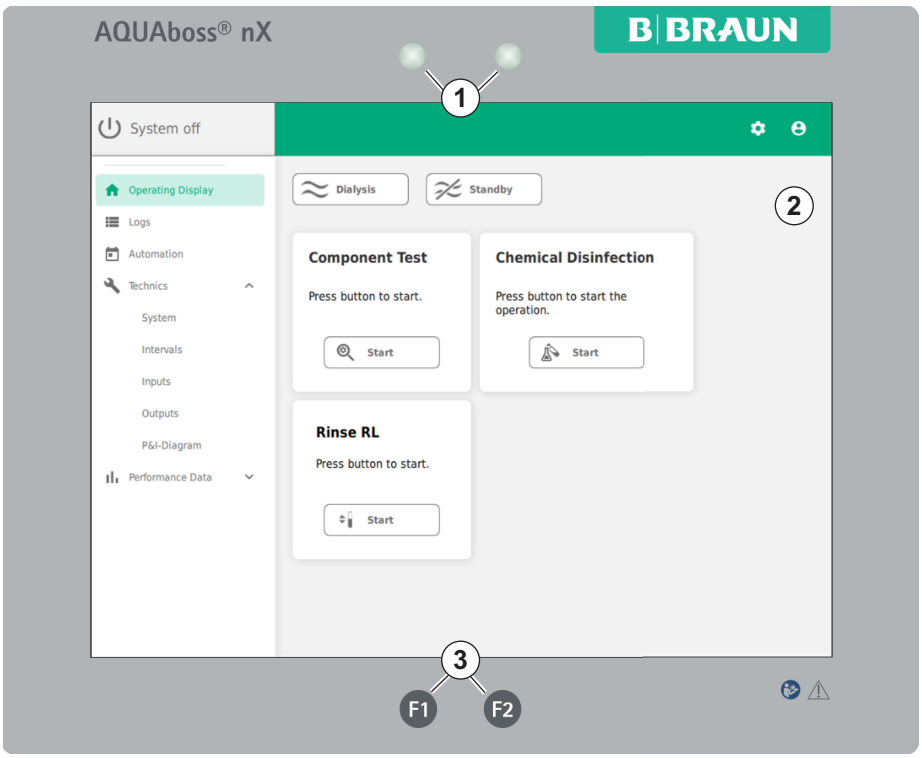


Fig. 3-7 Controls and displays of the AQUAboss nX

3.11.1.1 LED Indicator lights

Mode of Operation	Status LED1	Status LED2
System off (main switch)	Off	Off
System off	Green	Off
Dialysis mode	Green	Off
Standby mode	Green	Off
Chemical disinfection	Green	Orange
Thermal disinfection	Green	Orange
Alarm/service notice or hard water operation	Green	Yellow, flashing (2s period)
Error	Off	Red, flashing (2s period)

In Emergency mode, the LED assignment is different.

Emergency Mode Operation	Status LED1	Status LED2
Dialysis mode	Green, flashing (2s period)	Off
Standby mode	Green, flashing (2s period)	Yellow
Chemical disinfection	Off	Orange
Thermal disinfection	Off	Orange
Alarm/service notice or hard water operation	Not indicated during emergency mode operation	
Error	Off	Red, flashing (0.714s period)

3.11.1.2 Function keys F1 and F2

Pressing F1 and F2 confirms completion of chemical disinfection.

In display emergency mode, F1 starts dialysis and F2 starts standby mode (see 3.12.5.6 Emergency Modes (102)).

3.11.1.3 Display Emergency Mode Button

Beside the main switch there is a pushbutton. When this button is pressed, the display function is disabled and the function keys F1 and F2 are enabled. The button lights up when pressed. F1 starts dialysis and F2 starts standby mode.

3.11.1.4 Status Display

The status display is in the upper left corner of the display and shows the current operating mode of the RO system.

The following operation modes are possible:

- System off
- Dialysis
- Standby
- Dialysis Emergency Mode
- Standby Emergency Mode
- System Off Emergency Mode
- Thermal Disinfection
- Chemical Disinfection
- Service
- Initializing

3.11.1.5 Overview of All Icons

The operating system is controlled via the buttons displayed on the touchscreen. Different buttons are available depending on the selected menu and each button represents a specific action.

Icon	Description
	Mute sound alarm until next screensaver
	Edit mode (only with logged in user)
	Proceed to next step
	Go to previous step
	Reset changes
	Reset sampling note
	Reset prefilter change note
	Reset maintenance note

Icon	Description
	Add a new element
	Start procedure
	Skip current procedure
	Cancel procedure
	Discard unsaved changes
	Delete element
	Save changes
	Start data export
	Start software update
	Start component test
	Start RL rinsing
	Start chemical disinfection procedure
	Start component test to end emergency mode
	Confirm action
	Change to emergency mode
	Delete notes (only for service users)

Icon	Description
	Change to manual RL rinsing
	Change to automatic RL rinsing
	Login as user
	Start dialysis mode
	Start standby mode
	System off
	Expand card
	Discard changes
	Increase/decrease value
	Scroll pages up/down
	Scroll pages left/right

3.12 Menu Selection

3.12.1 Settings

1. Tap the gear icon ① in the header bar. A drop-down list of menu items will open.

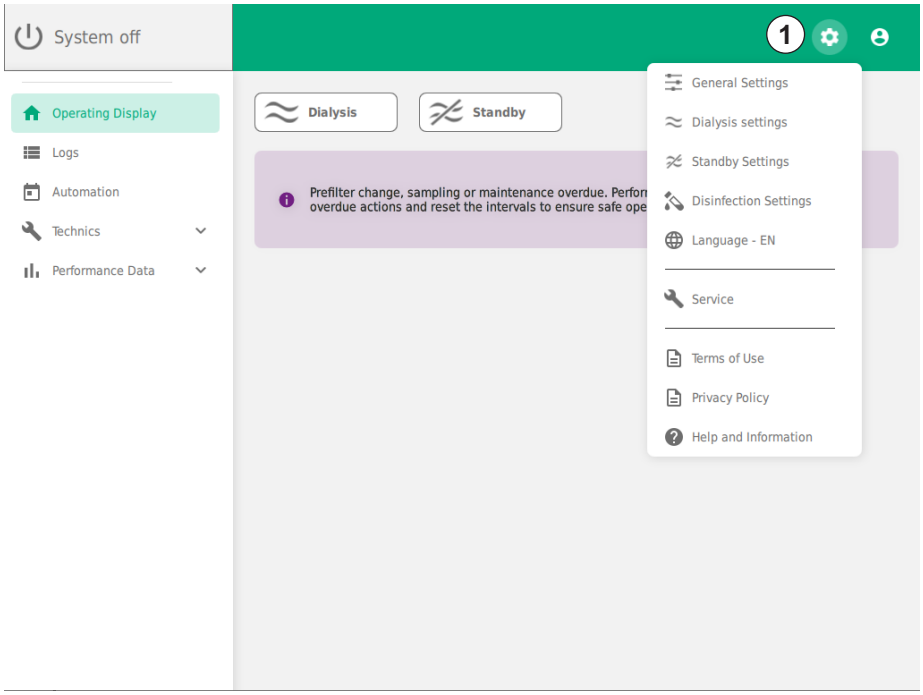


Fig. 3-8 Settings Drop-Down List

Within the settings menu items, the save button only gets enabled when changes to the current settings were made. The discard button discards all unsaved changes. Settings can only be changed when a user is logged in.

NOTICE!

Entry of incorrect values can impair the correct function of the control system or operational safety of the system.

3.12.1.1 General Settings

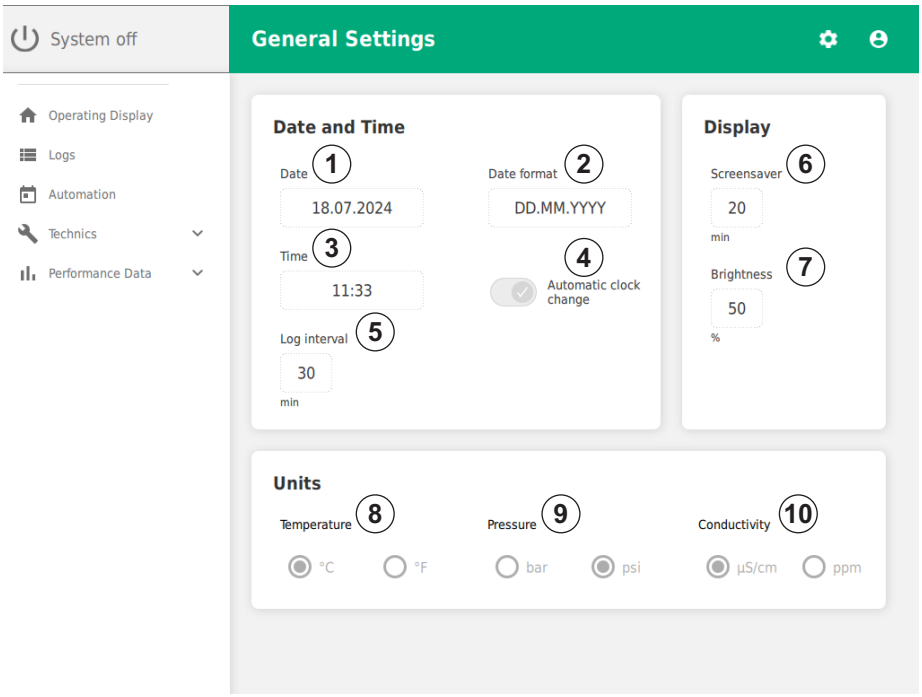


Fig. 3-9 General Settings

Parameter	Description
① Select Date	Defines the current date
② Select Date Format	Defines the date format
③ Time	Defines current time
④ Automatic Clock Change	Defines if daylight saving is performed automatically
⑤ Log Interval	Defines the interval in which logs are saved (only available for technicians)
⑥ Screensaver	Defines the time until screensaver is activated
⑦ Brightness	Defines display brightness
⑧ Temperature	Defines in which unit temperature values are shown
⑨ Pressure	Defines in which unit pressure values are shown
⑩ Conductivity	Defines in which unit conductivity values are shown

3.12.1.2 Dialysis Settings

The Dialysis Settings have three sub-sections: Operation, Rinse, and Discard.

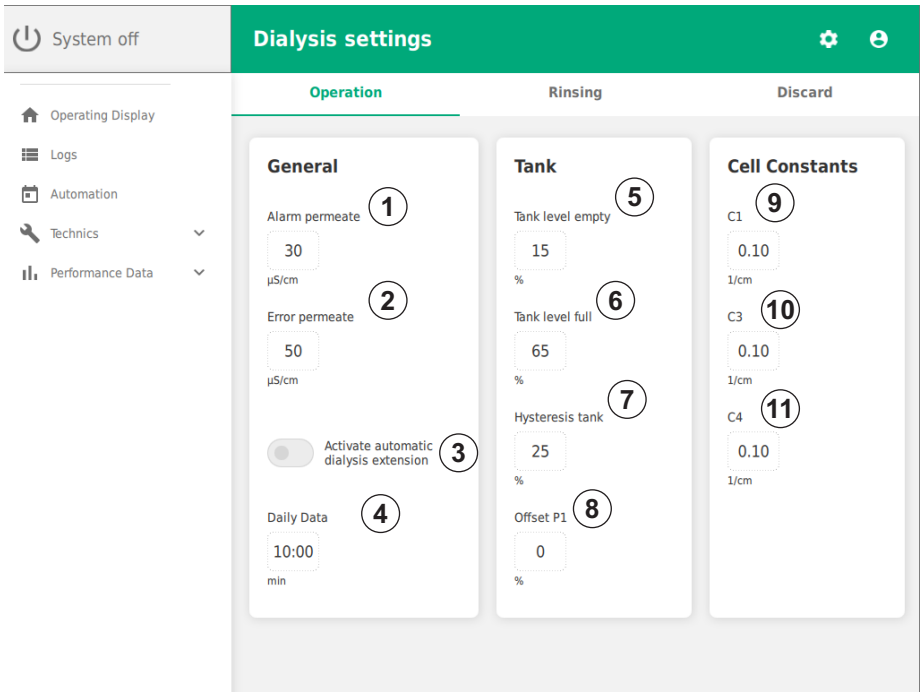


Fig. 3-10 Operation Tab

Parameter	Description
① Alarm Permeate	"Alarm permeate" determines the conductivity at which the user should be notified that the permeate at C3 is not of the desired quality. If the alarm limit is exceeded in Dialysis mode, Alarm 430 is output, the system stays in operation and the concentrate is discarded at the intervals defined in the "Disch.interval" parameter. The alarm acknowledges itself once the level drops back below the alarm limit. Setting range: 5–60 µS/cm (default: 30 µS/cm)
② Error Permeate	"Error permeate" determines the conductivity at C3 at which the reverse osmosis system shuts down for safety. If the limit is exceeded in Dialysis mode, Error 431 is output and the system shuts down. The error can be acknowledged after correcting the cause and starting a component test. Setting range: 5–200 µS/cm (default: 90 µS/cm)

Parameter	Description
③ Activate automatic dialysis extension	When activated dialysis mode is automatically extended for 15 minutes if there is still consumption near the end of an automation slot. After three automatic extensions (45 min in total) the automation stops, no matter if there is still consumption or not.
④ Daily data - Saving time	Defines time when daily data are saved and written to the logs.
⑤ Tank level empty	Defines value when the tank is empty Setting range: 5–15% (default: 15%)
⑥ Tank level full	Define the value when the tank is full Setting range: 50–100% (default: 65%)
⑦ Hysteresis tank	Defines value for the hysteresis of the tank Setting range:15–75% (default: 25%)
⑧ Offset P1	Defines the offset for P1 Setting range: -10–25% (default: 0%)
⑨ C1	Defines cell constant for C1 Setting range: 0.05–0.5 1/cm (default: 0.1 1/cm)
⑩ C3	Defines cell constant for C3 Setting range: 0.05–0.5 1/cm (default: 0.1 1/cm)
⑪ C4	Defines cell constant for C4 Setting range: 0.05–0.5 1/cm (default: 0.1 1/cm)

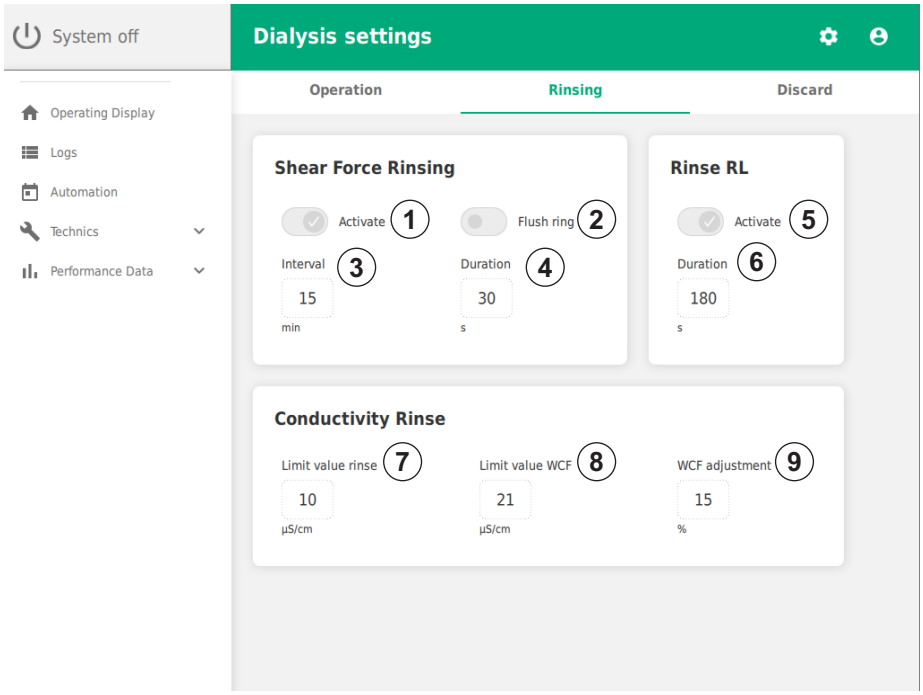


Fig. 3-11 Rinsing Tab

Parameter	Description
Shear Force Rinsing	
① Activate	Defines if shear force rinsing is enabled. Setting range: on (I)/off (0) (default: on (I))
② Flush ring	Defines if the ring is included in the shear force rinsing. Setting range: on (I)/off (0) (default: off (0))
③ Interval	Defines the interval in which shear force rinsing is performed. Setting range: 1–240 min (default: 15 min)
④ Duration	Defines the duration of shear force rinse. Setting range: 1–600 s (default: 30 s)
RL Rinse	
⑤ Activate	Defines if RL rinse is enabled. Setting range: on (I)/off (0) (default: on (I))
⑥ Duration	Defines the duration of RL rinse. Setting range: 20–600 s (default: 180 s)
Conductivity Rinse	

Parameter	Description
⑦ Limit value rinse	Defines the limit of conductivity which activates the conductivity rinse. Setting range: 5–80 µS/cm (default: 15 µS/cm)
⑧ Limit value WCF	Defines the limit of WCF which triggers the WCF adjustment. Setting range: 10–80 µS/cm (default: 35 µS/cm)
⑨ WCF adjustment	Defines the value for WCF decrement Setting range: 0–50% (default: 15%)

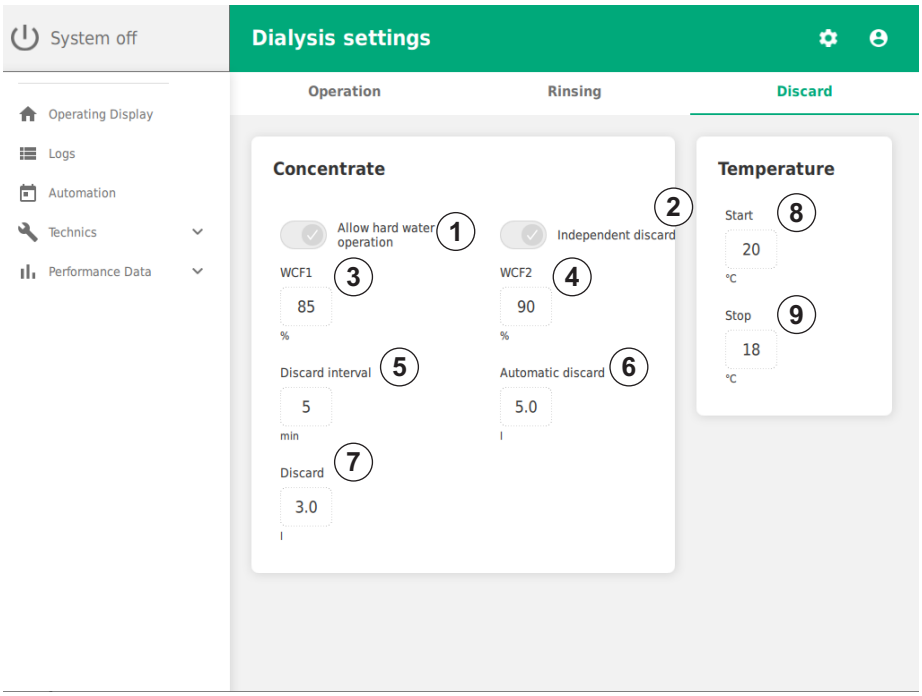


Fig. 3-12 Discard Tab

Parameter	Description
Concentrate	
① Allow hard water operation	Enabling "Hard water operation" overwrites the yield set in the "WCF" parameter with a fixed yield of 25%. Setting range: on (I)/off (0) (default: off (0))
② Independent discard	Defines if consumption independent discard (time watchdog) is enabled Setting range: on (I)/off (0) (default: off (0))
③ / ④ WCF1/WCF2	Water conversion factor for stage 1 (WCF1) or stage 2 (WCF2)Setting range: 25–95% (default: 85/90%)

Parameter	Description
⑤ Discard interval	Defines interval in which discharge has to happen (used by ② Independent discard) Setting range: 1–30 min (default: 5 min)
⑥ Automatic discard	Defines volume which is discarded by the ② Independent discard Setting range: 1–20 L (default: 5 L)
⑦ Discard	Defines volume threshold when solenoid valves open Setting range: 1–20 L (default: 3 L)
Temperature	
⑧ Start	Defines start temperature for temperature discard Setting range: 20–37 °C (default: 37 °C)
⑨ Stop	Defines stop temperature for temperature discard Setting range: 18–35 °C (default: 35 °C)

3.12.1.3 Standby Settings

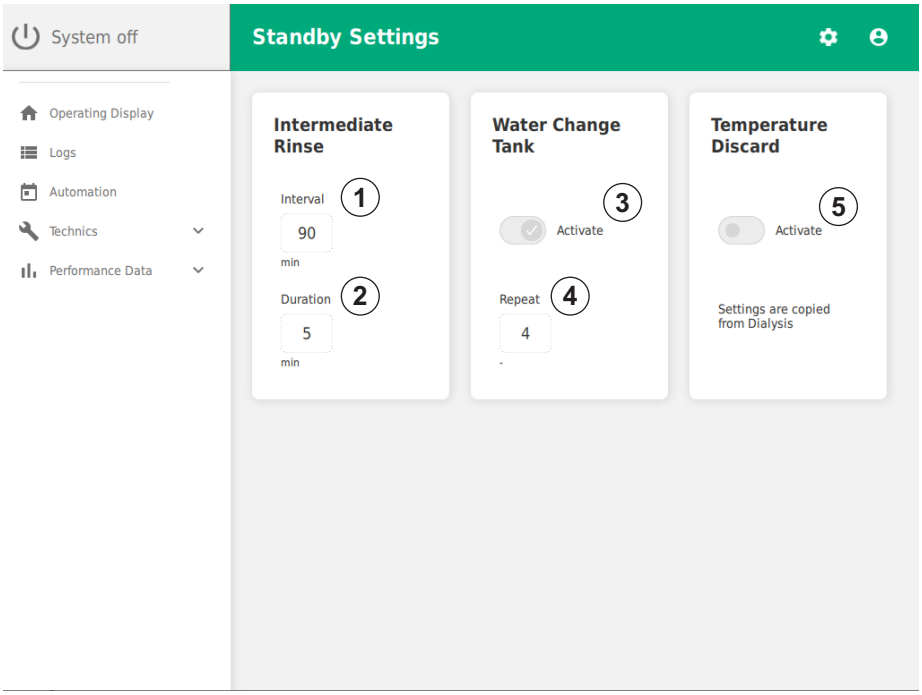


Fig. 3-13 Standby Settings

Parameter	Description
Intermediate Rinse	
① Interval	Defines interval for intermediate rinse Setting range: 1–180 min (default: 90 min)
② Duration	Defines duration for intermediate rinse Setting range: 1–120 min (default: 5 min)
Water Change Tank	
③ Activate	Defines if tank water change is enabled. Setting range: on (I)/off (0) (default: on (I))
④ Repetitions	Defines the number of repetitions after which tank water change is performed. Setting range: 1–20 (default: 4)
Temperature Discard	
⑤ Activate	Defines if temperature discard in standby mode is enabled. Settings are copied from dialysis mode settings. Setting range: on (I)/off (0) (default: off (0))

3.12.1.4 Disinfection Settings

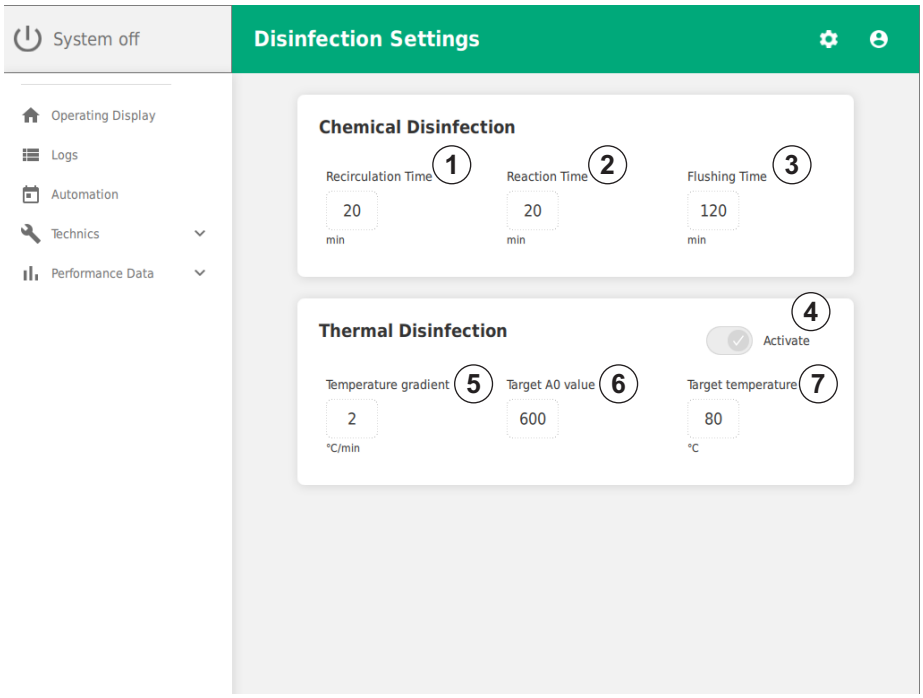


Fig. 3-14 Disinfection Settings

Parameter	Description
① Recirculation time	Defines the recirculation time for chemical disinfection Setting range: 5–60 min (default: 20 min)
② Reaction time	Defines the reaction time for chemical disinfection Setting range: 20–60 min (default: 20 min)
③ Flushing time	Defines the rinse time for chemical disinfection Setting range: 30–1440 min (default: 120 min)
④ Activate	Defines if thermal disinfection of the device is enabled. Setting range: on (I)/off (0) (default: off (0))
⑤ Temperature gradient	Defines the temperature gradient for thermal disinfection Setting range: 1–20 °C/min (default: 4 °C/min)

Parameter	Description
⑥ Target A0 value	Defines the target A0 value for thermal disinfection Setting range: 600–5000 (default: 600)
⑦ Target temperature	Defines the target temperature for thermal disinfection Setting range: 50–85 °C (default: 80°C)

3.12.1.5 Language Settings

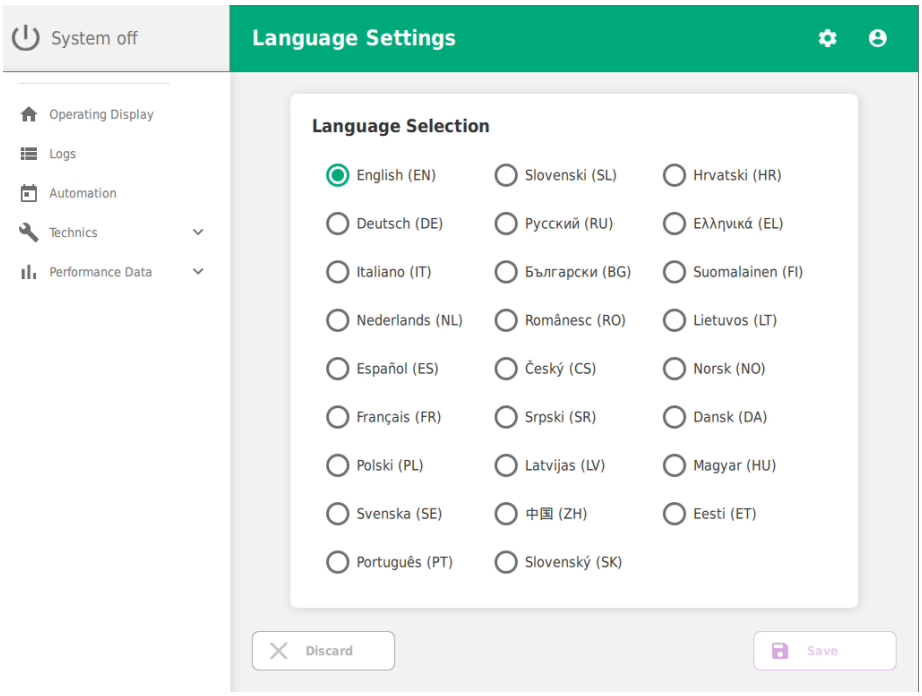


Fig. 3-15 Language Settings

Here the system language can be set.

3.12.1.6 Service Settings

Here the technical service can view and change basic settings for the RO system.

3.12.1.7 Terms of Use

For more information on Terms of Use such as intended use, water quality requirements, maintenance, liability and warranty, please read the corresponding chapters. By using our reverse osmosis system, you acknowledge that you have read and agree to these Terms of Use.

3.12.1.8 Privacy Policy

As part of the use of our AQUAboss nX product, personal data is processed for the purpose of logging on to the machine. In order to log in and assign the corresponding user rights, you must pick a user name and a password.

For the login of service technicians, the 4-2-2 name of the respective technician is also required. This data is stored exclusively on the machine. No other personal data is processed. Further information on data protection at B. Braun can be found at www.bbraun.de/dsgvo.

3.12.1.9 Help and Information

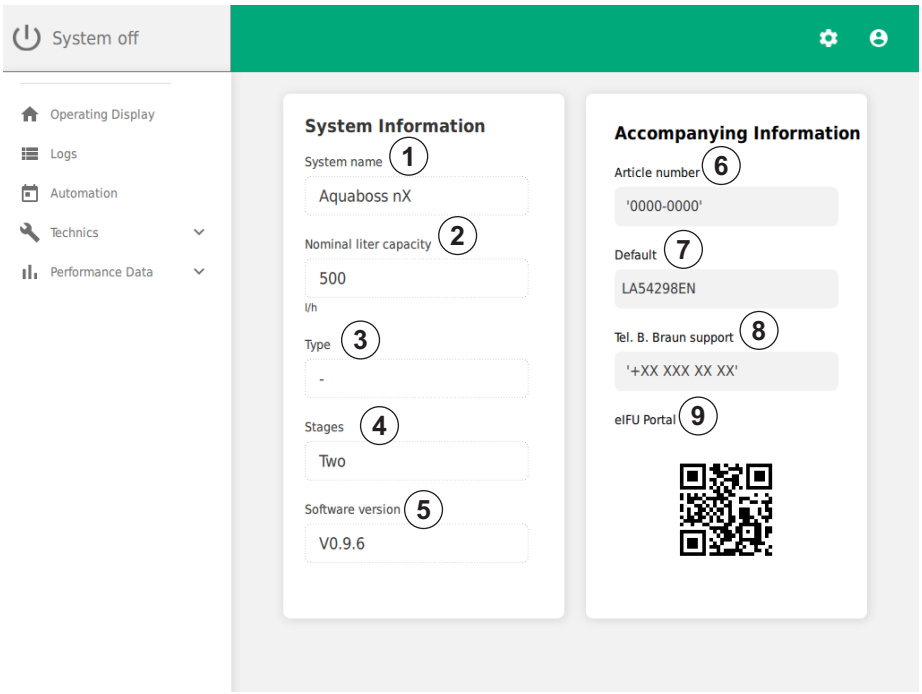


Fig. 3-16 Help and Information

Parameter	Description
① Device name	Shows the device name
② Nominal liter capacity	Shows the nominal maximum liter production
③ Type	Shows the device type (“hot” or “cold”)
④ Stages	Shows the number of stages (“one” or “two”)
⑤ Software version	Shows the currently installed software version
⑥ Article number System Language	Shows the article number of the IFU for the currently set system language
⑦ Article number English	Shows the article number of the English IFU
⑧ B. Braun support phone number	Phone number of the B. Braun support
⑨ QR Code eIFU	Link to the B. Braun eIFU website

Points 6,7, and 8 can only be entered by users with Technician user rights.

3.12.2 Drawer Side Panel

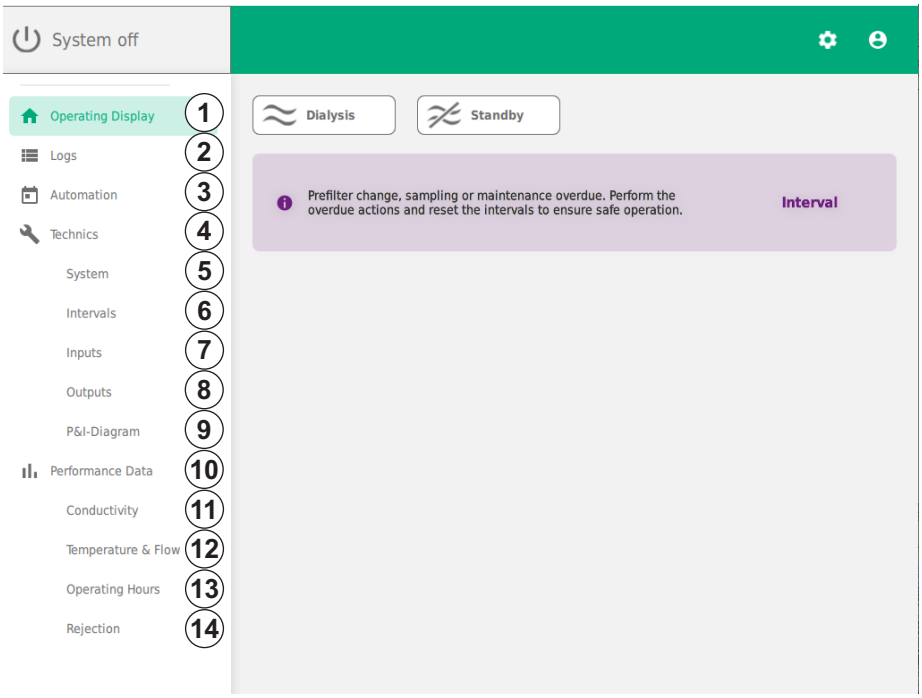


Fig. 3-17 Drawer Side Panel

Link	Description
① 3.12.2.1 Operating Display (74)	Shows overview of current operating mode
② 3.12.2.2 Logs (75)	Shows all different logs
③ 3.12.2.3 Automations (77)	Shows an overview of automations
④ 3.12.2.4 Technics (79)	Can be expanded and collapsed to show different menus
⑤ 3.12.2.4.1 System (79)	Different functions can be accessed here
⑥ 3.12.2.4.2 Intervals (84)	Shows interval overview
⑦ 3.12.2.4.3 Inputs (85)	Opens the inputs overview
⑧ 3.12.2.4.4 Outputs (86)	Opens the outputs overview
⑨ 3.12.2.4.4 Outputs (86)	Open the P&I diagram
⑩ 3.12.2.5 Performance Data (88)	Can be expanded and collapsed to show different menus
⑪ 3.12.2.5.1 Conductivity (89)	Opens an overview of conductivity

Link	Description
⑫ 3.12.2.5.2 Temperature & Flow (89)	Opens an overview of temperature and flow
⑬ 3.12.2.5.3 Operating Hours (90)	Opens an overview of the operating hours
⑭ 3.12.2.5.4 Rejection (92)	Opens an overview of the rejection

3.12.2.1 Operating Display

1 Start dialysis mode

2 Start standby mode

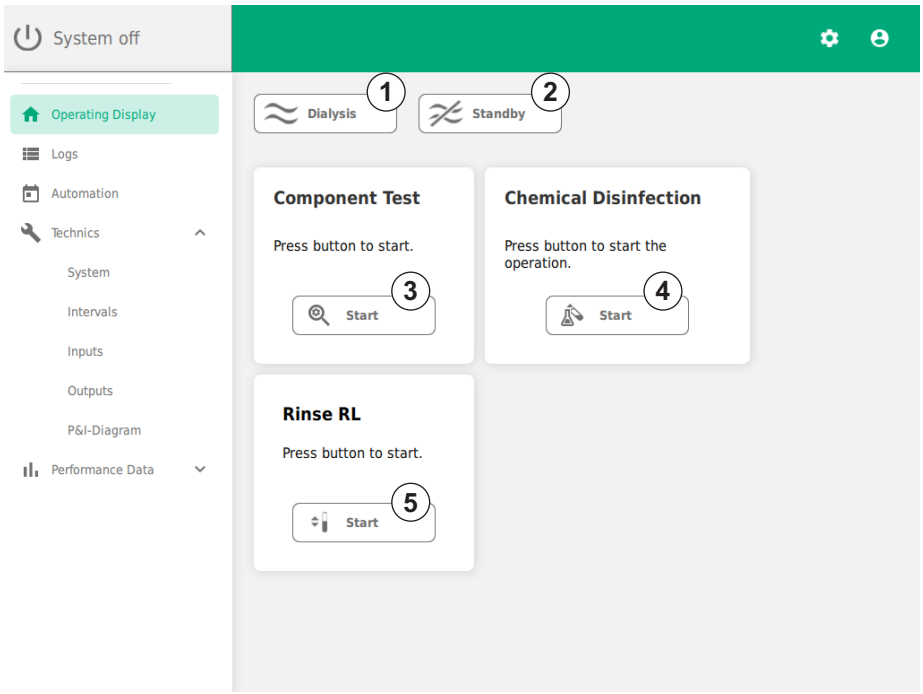


Fig. 3-18 Operating Display

Depending on which operating mode is currently active, the shown screen is different. For more information, see 3.12.5 Operating Modes (99).

3.12.2.2 Logs

Daily Data

1 Shows data set 1

2 Shows data set 2

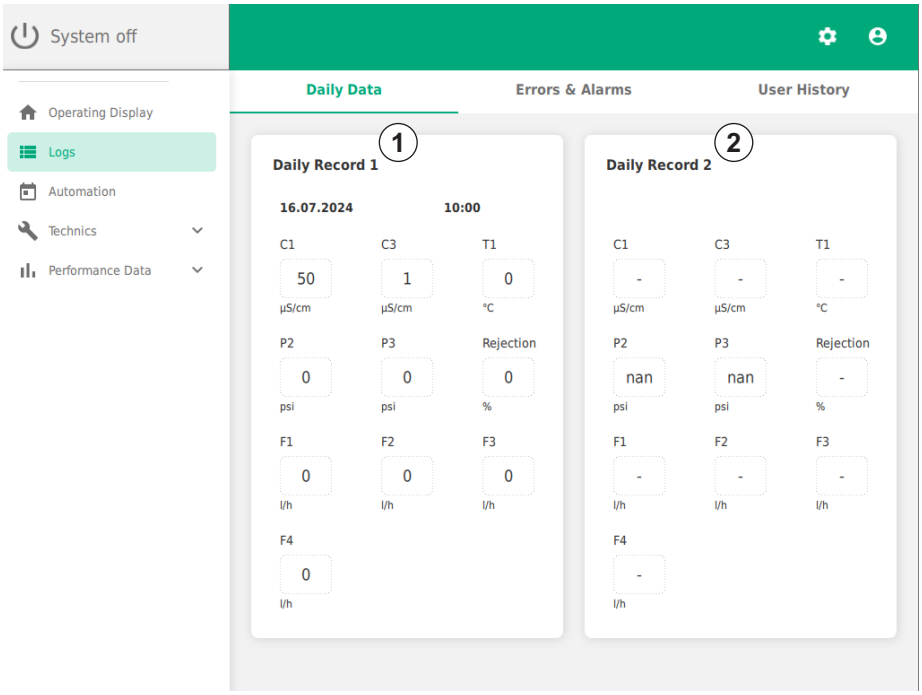


Fig. 3-19 Daily Data

- Daily Data sets are only saved when the reverse osmosis system is in Dialysis mode at the set saving time.
- Saving time can be edited in the dialysis settings.
- The Daily Data sets are a snapshot of the time point when they are taken.
- Data set 1 is always the newer data set.
- Only 2 data sets are saved.
- The older data set gets overwritten when a new data set is saved.

Errors and Alarms

1 Shows a list of all errors and alarms

2 Tap to scroll up/down

3 Tap on an entry to open error/alarm message

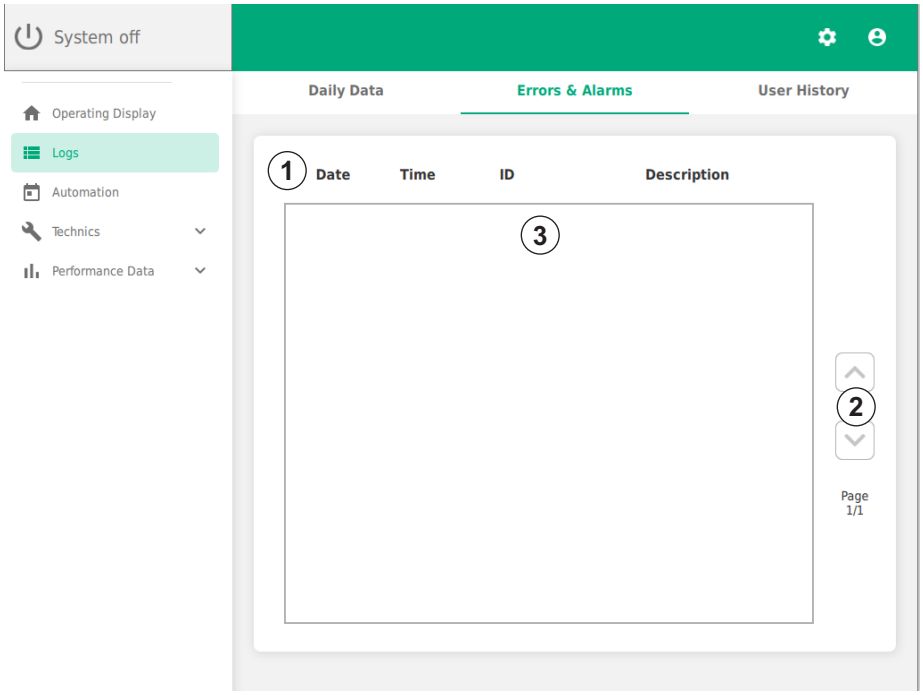


Fig. 3-20 Errors and Alarms

This menu contains information regarding current and past errors and alarms.

User History

1 Shows a list of all user actions

2 Tap to scroll up/down

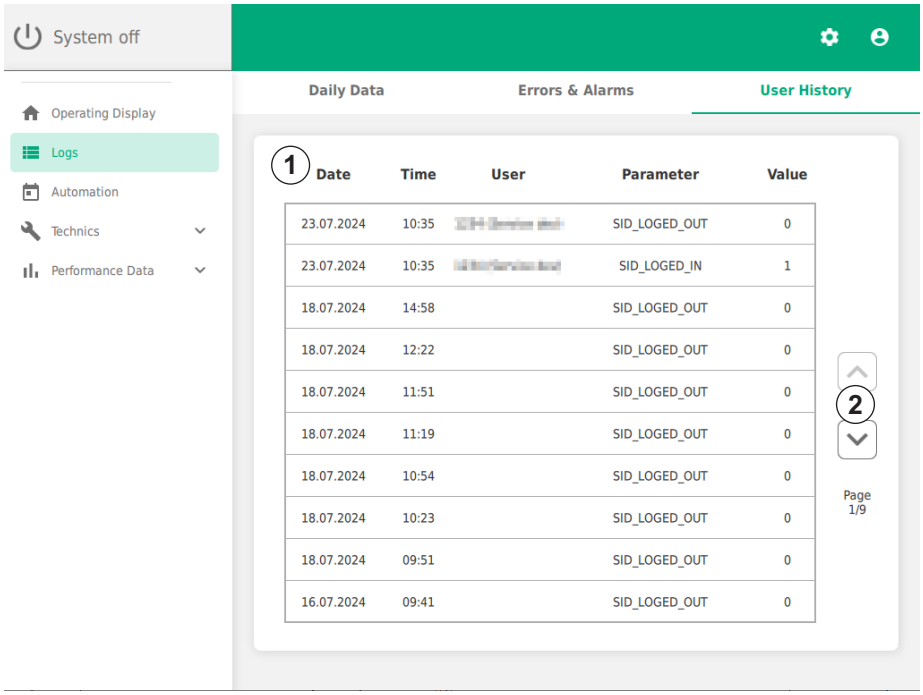


Fig. 3-21 User History

This menu contains a history of user actions.

3.12.2.3 Automations

1 Current day is highlighted
2 Current time is shown
3 Active saved automation
4 Inactive saved automation
5 Add new automation

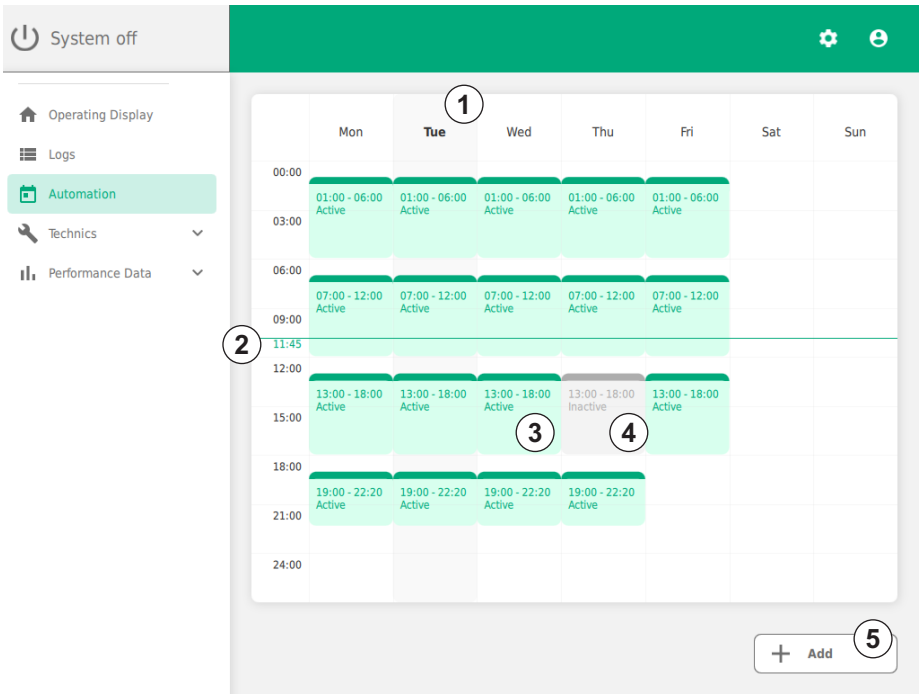


Fig. 3-22 Automations

- Works only in Dialysis and Standby mode; in other modes automations have no effect.
- At the start of an automation, the RO switches to Dialysis mode and at the end it swaps to Standby mode.
- Start times have to be set before stop times.
- Automations can start and end on different days.
- An automation can only be programmed in the time between Monday and Sunday. For example, if an automation from Saturday to Tuesday is required, it must be set up in two separate automations (one from Saturday to Sunday and one from Monday to Tuesday).
- Two automations cannot overlap.
- Inactive automations are shown as gray blocks on the calendar and are ignored as long as they are inactive. They are not deleted.
- The maximum number of automations is 20. When this amount is reached, an existing automation has to be deleted before a new automation can be created.
- If the system is already in Dialysis mode at the start of an automation, the Dialysis mode persists. At the end of the automation, the system switches to Standby mode.

Adding an Automation

1. To add an automation, you have to be logged in.
2. Click on the *Add* button in the lower right corner.
   ↳ A new window opens where the start and stop time can be set.

1 Start day
2 Start time
3 Stop day
4 Stop time
5 Activate/deactivate automation
6 Save changes

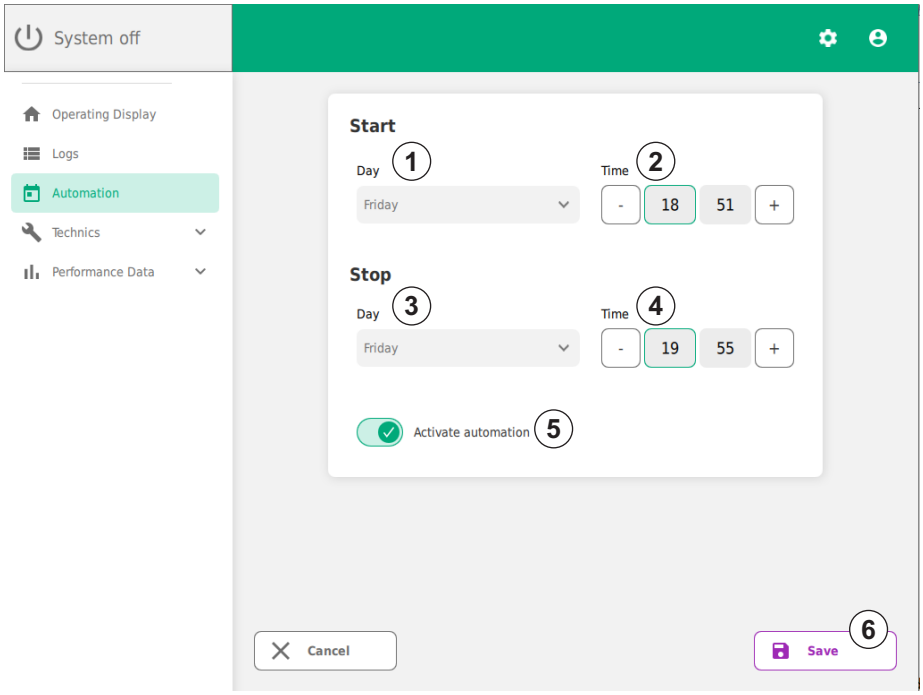


Fig. 3-23 Adding an Automation

3. Click on the *Save* ⑥ button.
   ↳ The new automation appears as a new block on the calendar.

Deleting an Automation

1. To delete an existing automation, you have to be logged in.
2. Click on an existing automation and then click on the *Delete* ① button.

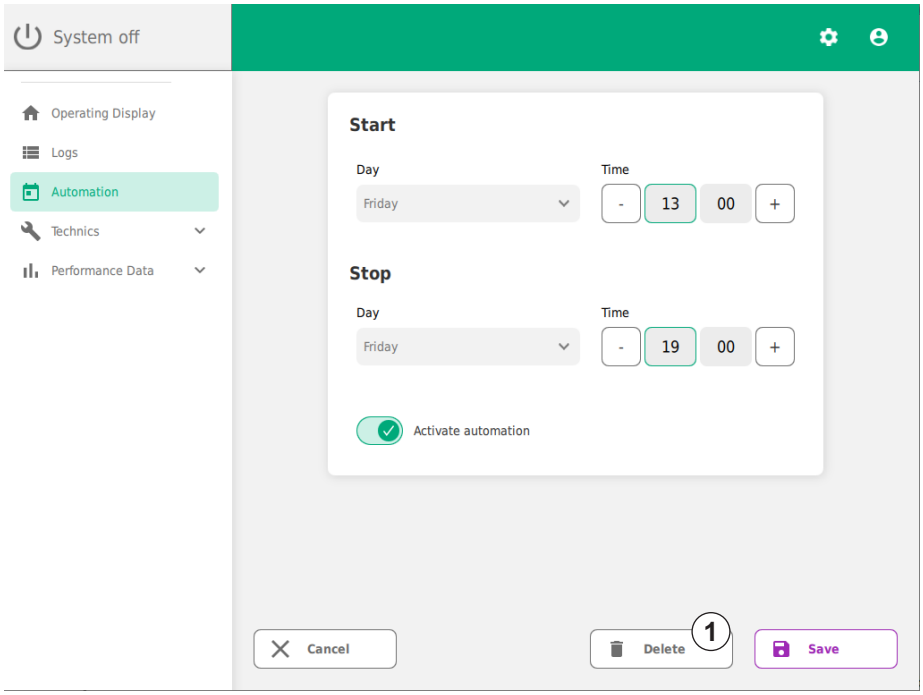


Fig. 3-24 Deleting an Automation

3. Click on the *Delete* ② button again to confirm that the automation should be deleted.

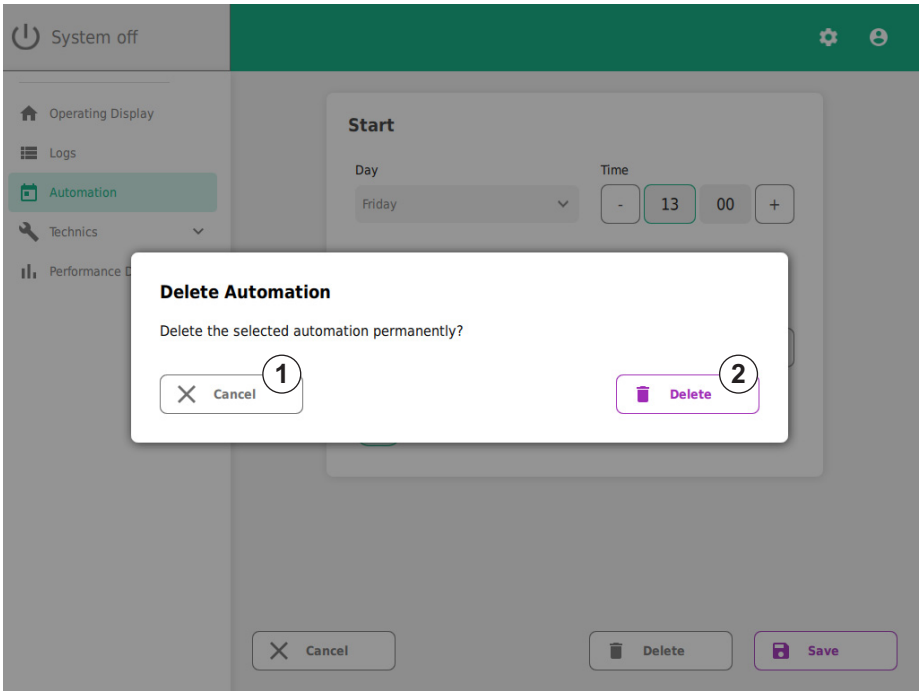


Fig. 3-25 Confirming Deletion

3.12.2.4 Technics

3.12.2.4.1 System

1 Start RL rinsing (system off)

2 Start component test (system off)

3 Start data export (only for technicians)

4 Start software update (only for technicians)

5 QR code for Service Portal (only for technicians)

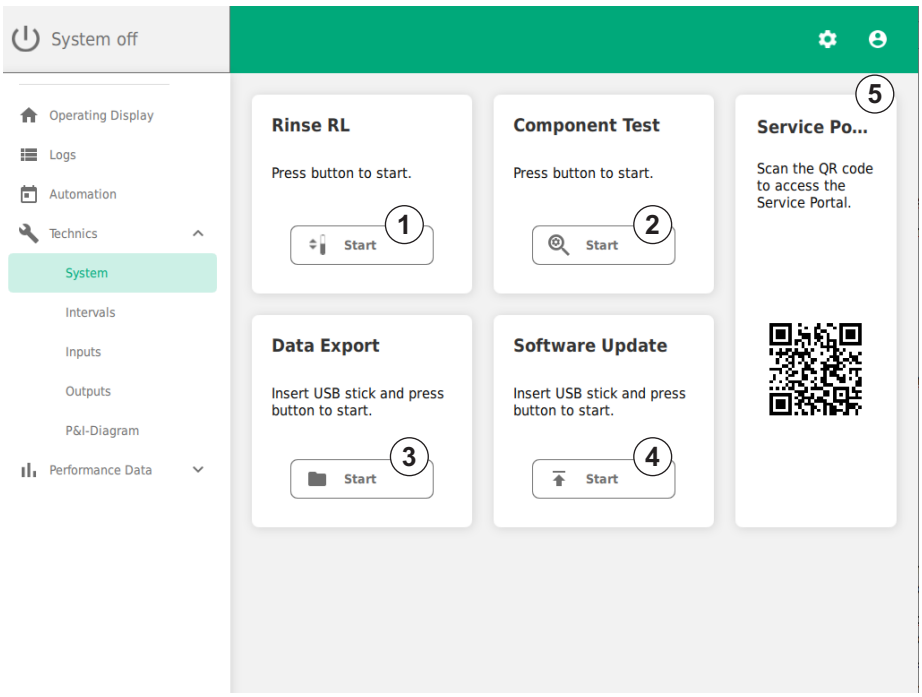


Fig. 3-26 System

Rinsing the Ring Piping (Rinse RL)

1 Shows remaining time

2 Cancel automatic RL rinsing

3 Switch to manual RL rinsing (only for technicians)

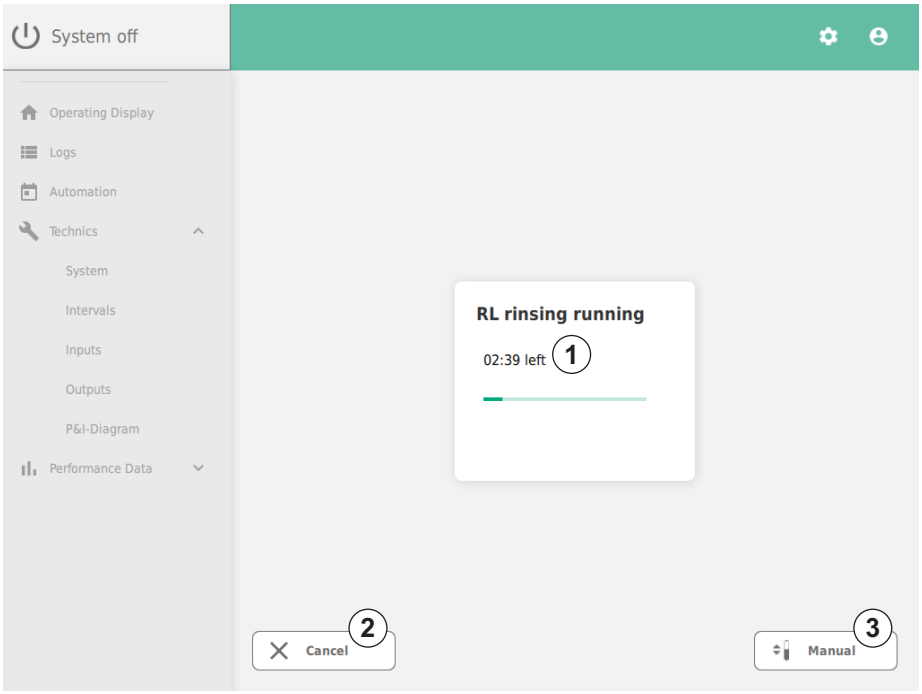


Fig. 3-27 Automatic RL Rinsing

1 Set value for M1.1/M2.1 Control

2 Cancel manual RL rinsing

3 Switch to automatic RL rinsing

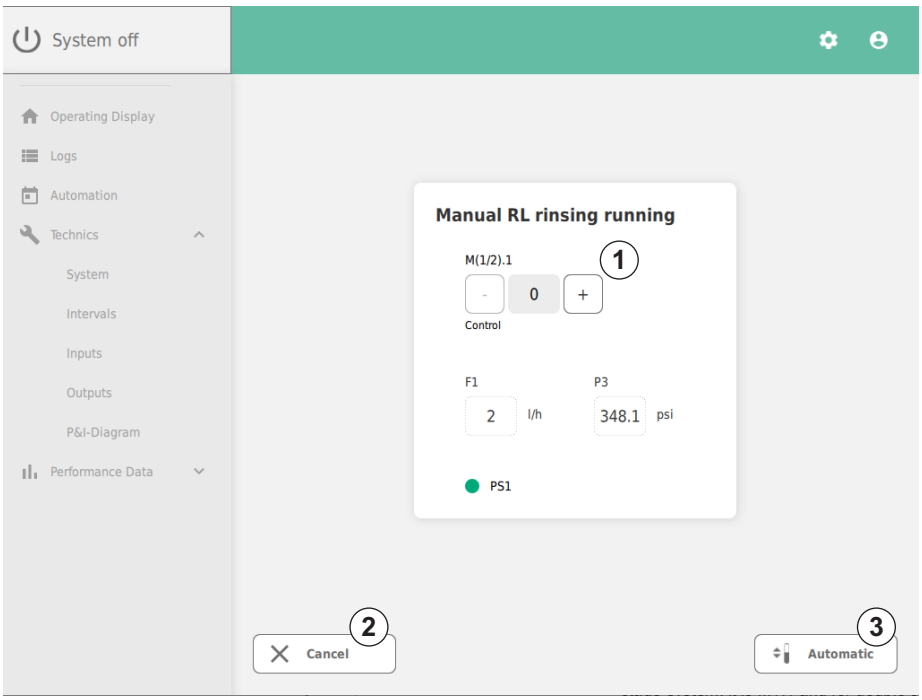


Fig. 3-28 Manual RL Rinsing

- During RL rinsing, the sidebar is locked.
- The system starts in automatic mode. The ring piping is rinsed for a specific time period at a specific pump speed.
- Users with the user rights Technician, Admin or Service can change the system to manual mode and adjust the pump speed.
- The adjusted pump is always the pump feeding into the ring. For single stage system, it is M1.1 and for double stage systems it is M2.1. The system automatically selects the correct pump.
- A ring piping rinse can be started manually in the System section, if the system is off.
- Rinse RL can be used to reduce high conductivity or temperature.

Component Test

1 Shows status of single components

2 Skip component test

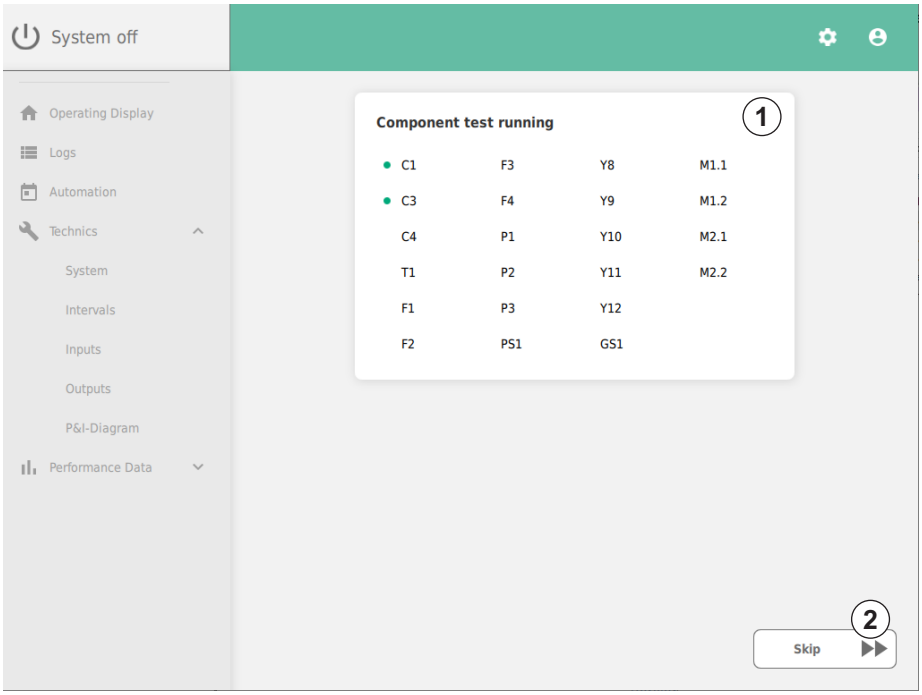


Fig. 3-29 Component Test

- A component test checks all components for their functionality.
- It is automatically executed before the first switch into Dialysis or Standby mode every day.
- It can be started manually in the System section, if the system is off.

Possible component statuses:

- Green (tested and okay)
- Red (tested and not okay)
- Yellow (not tested)

If the component test fails but single stage operation is possible, emergency mode can be selected (see 3.12.5.6 Emergency Modes (102)). Otherwise the system switches to error mode (see 3.12.6 Error State (103)). A component test can be started to leave emergency or error mode, if the defect has been remedied.

1 All components working

2 Confirm component test

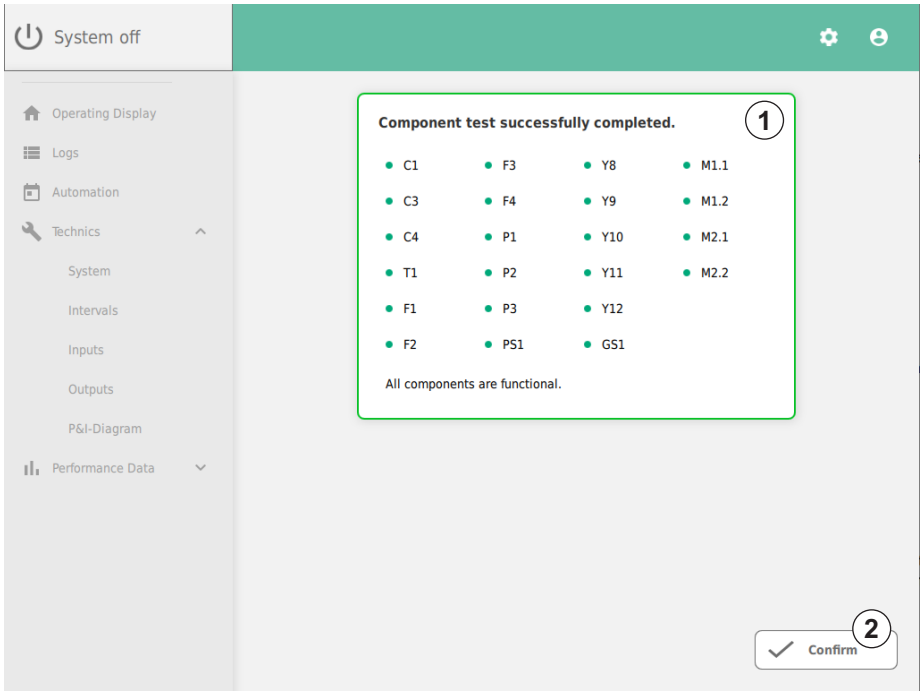


Fig. 3-30 Successful Component Test

After confirming a successful component test, the previous screen is shown. If the system started the component test automatically, it is also confirmed automatically.

1 One or more components failed

2 Start emergency mode (only for 2 stage devices and if missing component allows)

3 Confirm failed component test

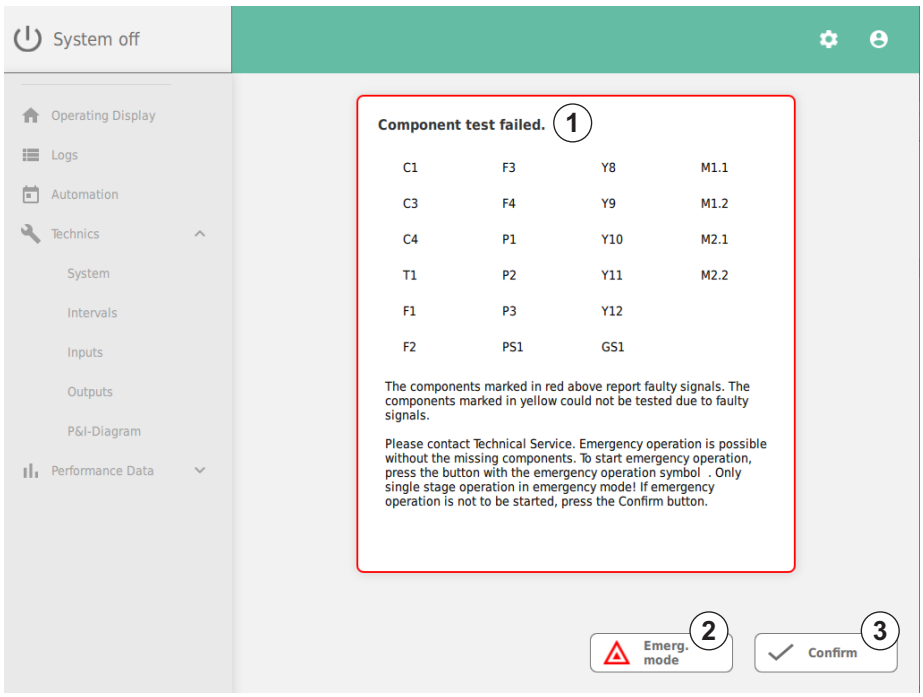


Fig. 3-31 Failed Component Test

After a failed component test, pressing the emergency operation button (available only in double stage systems and when the faulty component permits) activates single stage emergency operation. Error mode is initiated if the user manually confirms by tapping the *Confirm* ③ button.

Data Export

Only for technicians. A USB drive has to be inserted into the USB port inside the control enclosure. The USB ports are positioned on the back of the touch screen. Any of the USB ports can be used. Data is stored on the USB drive.

A failed data export can occur when the USB drive cannot be read or if it is removed during the process. Use a different USB drive and do not remove it while downloading data.

Software Update

The following information is only for service technicians.

- Insert a USB drive into the port inside the control cabinet. The USB ports are positioned on the back of the touch screen. Any of the USB ports may be used.
- The USB drive must contain a valid software file.
- Press button and confirm the start of the update.
- After an update, the system restarts automatically.
- In order to check if the new software version is installed, navigate to Help and Information via the gear icon.
- The old software version is held as a backup in case there is an issue with the new software version.

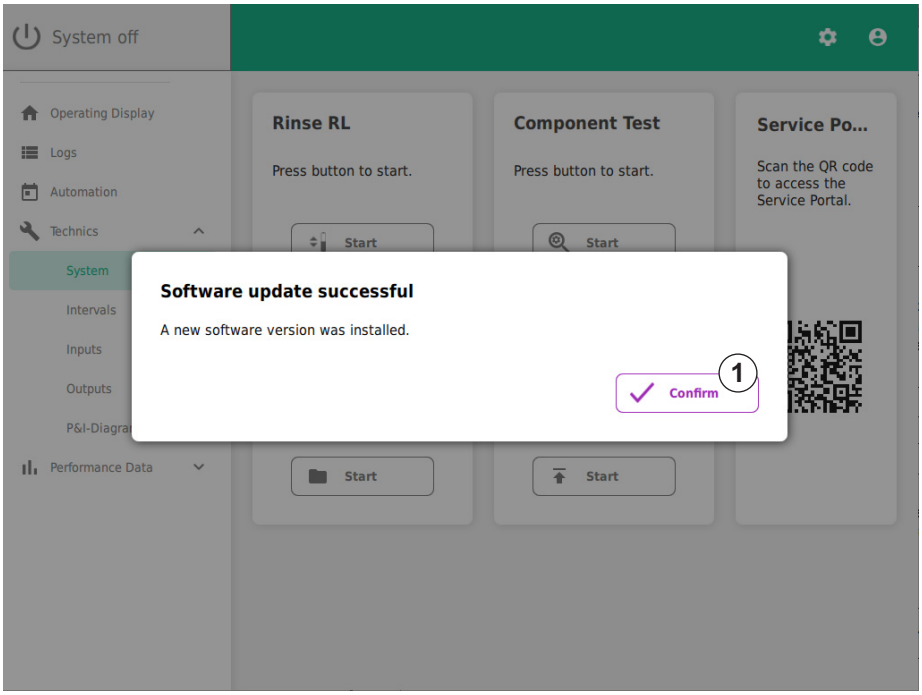


Fig. 3-32 Successful software update

3.12.2.4.2 Intervals

1 Set interval for next maintenance
2 Shows next due maintenance
3 Tap to reset note (only for technicians)
4 Set interval for prefilter change
5 Shows next due prefilter change
6 Tap to reset note
7 Set interval for sampling
8 Shows next due sampling (red when overdue)
9 Tap to reset sampling note
10 Discard unsaved changes
11 Save changes

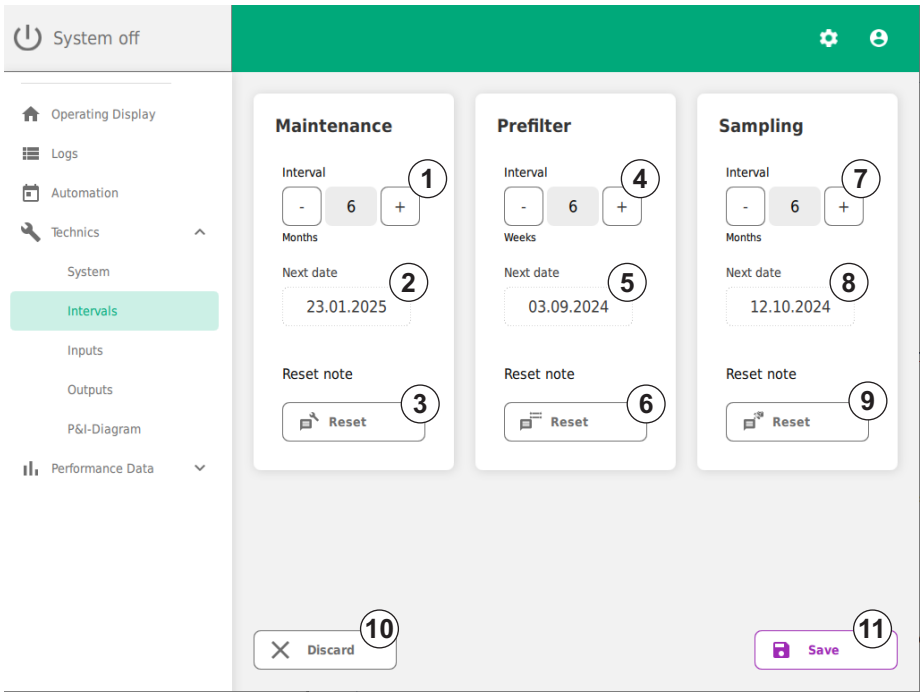


Fig. 3-33 Intervals

Changes are only possible with a logged in user account.

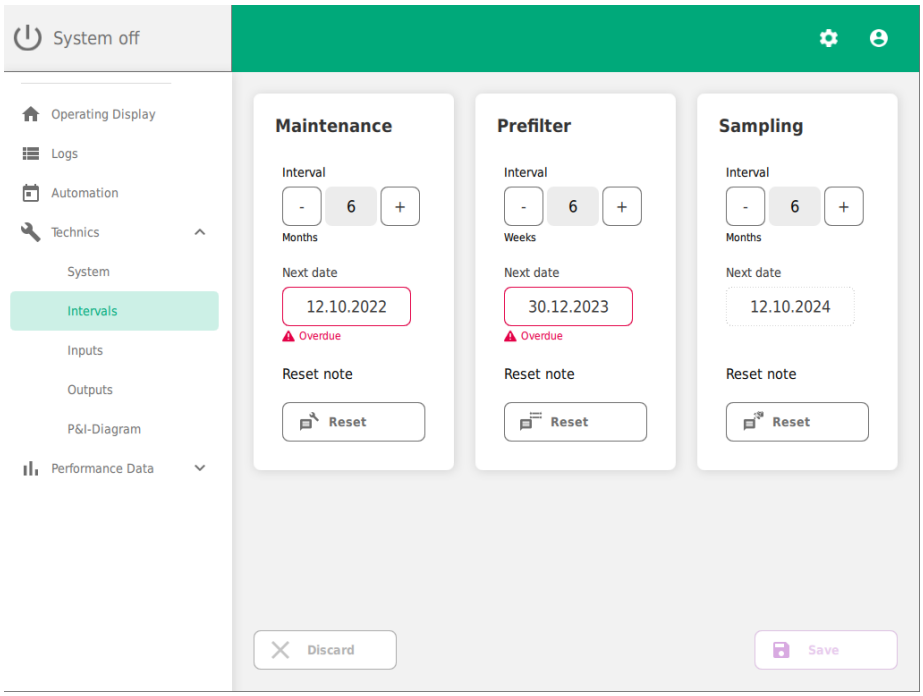


Fig. 3-34 Overdue intervals

When a service action is overdue, it is marked in red. If the reset is confirmed, the date of the next due action is refreshed to the next due date in the interval.

3.12.2.4.3 Inputs

Sensor Input

1 Shows real time sensor data

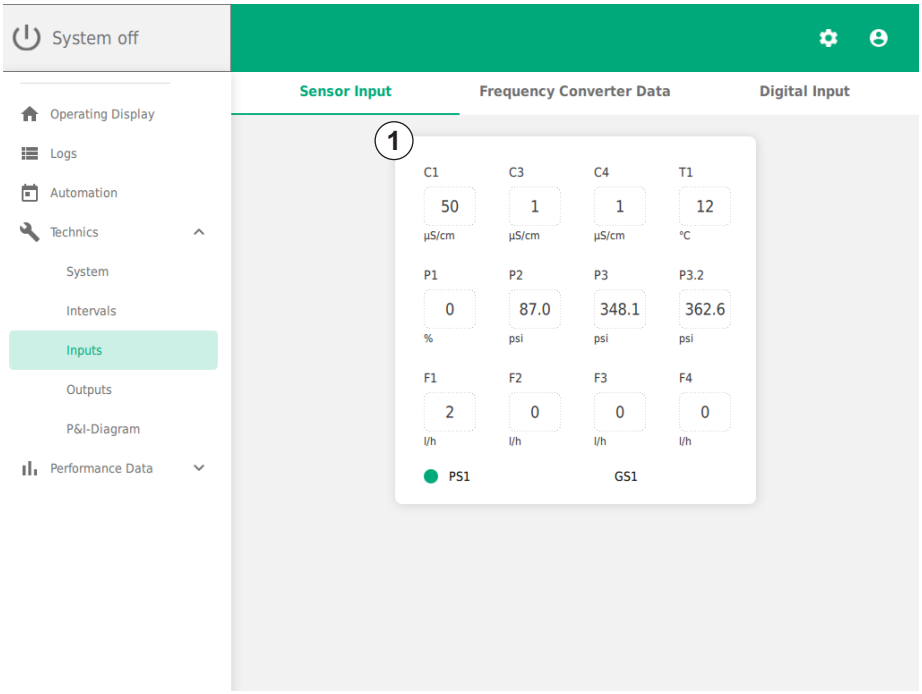


Fig. 3-35 Sensor Input

This screen shows the current values for all sensors in the system. The shown sensor data varies between single and double stage systems.

Frequency Converter Data

1 Shows total energy

2 Shows current energy consumption

3 Shows current engine speed

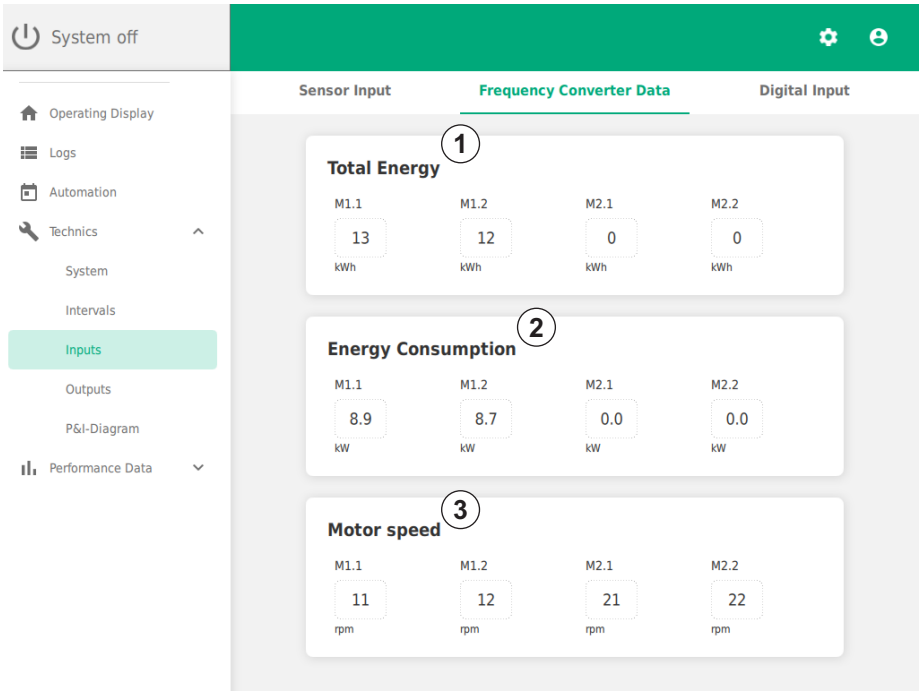


Fig. 3-36 Frequency Converter Data

This screen shows the current values for all frequency converters in the system. The shown frequency converter data varies between single stage and double stage systems.

Digital Input

1 Shows digital input signals

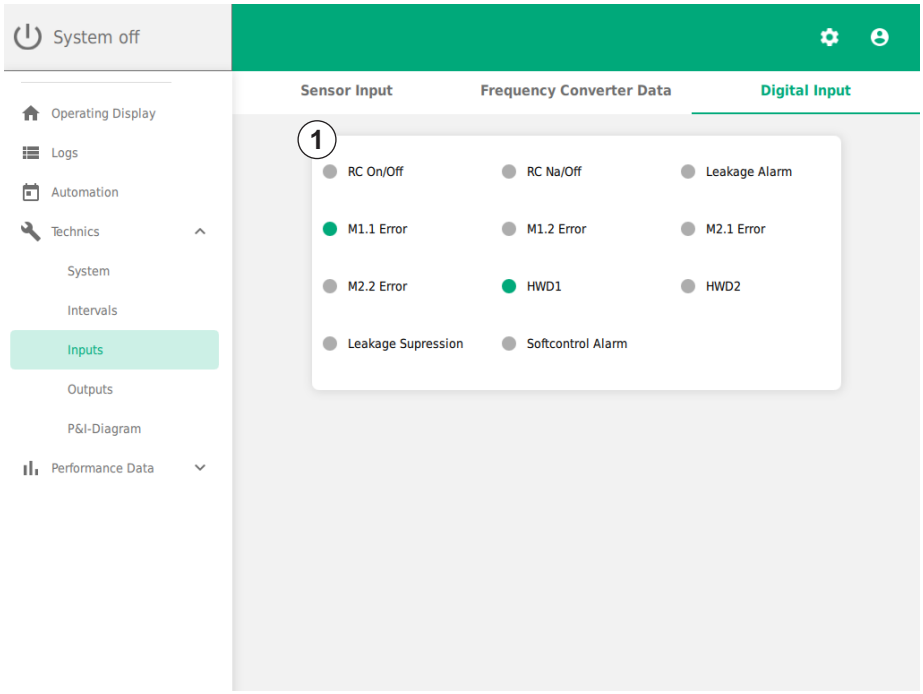


Fig. 3-37 Digital Input

This screen shows the current status of digital inputs in the system. The shown digital inputs vary between single stage and double stage systems.

3.12.2.4.4 Outputs

Actuators

1 Shows current state of valves

2 Shows current state of pumps

3 Tap to enter edit mode (must be logged in)

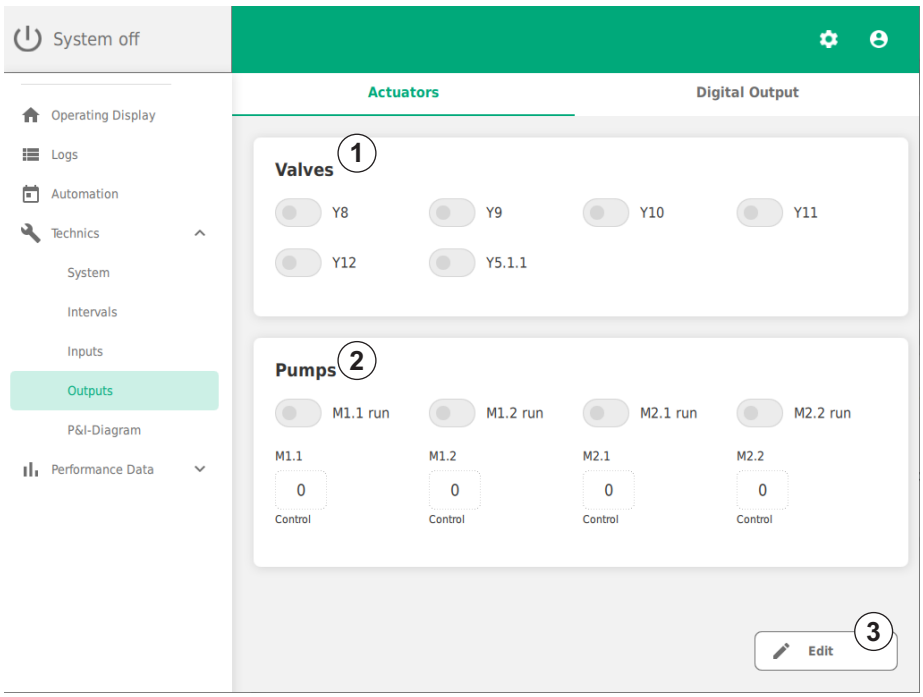


Fig. 3-38 Actuators

In this screen all components of the reverse osmosis system can be manipulated manually by logged in users after tapping the *Edit* button.

NOTICE!

Changes may only be performed by trained personnel.

Manual switching of digital outputs can cause damage to the system.

After tapping on *Edit*, the sidebar and header bar are disabled on this screen. The only exit from this screen is by tapping the *Reset* button.

The system then reinitializes and change back to the system off screen. Once this has happened, the system can be used again as normal.

Digital Output

1 Shows current state of digital output signals

2 Tap to enter edit mode (must be logged in)

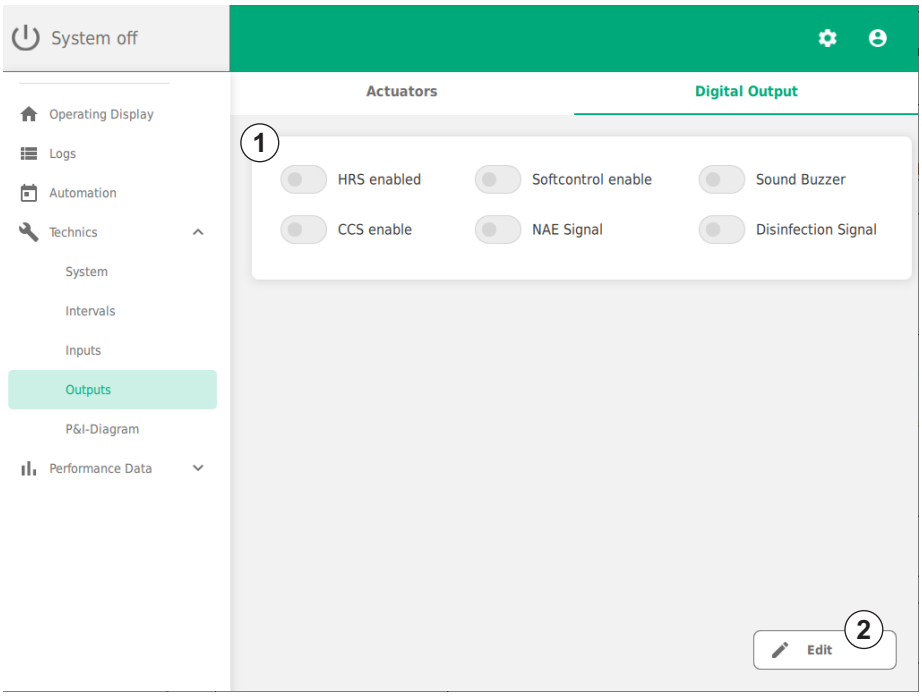


Fig. 3-39 Digital Output

In this screen all signals of the reverse osmosis system can be manipulated manually by logged in users after tapping the *Edit* button.

NOTICE!

Changes may only be performed by trained personnel.

Manual switching of digital outputs can cause damage to the system.

After tapping the *Edit* button, the sidebar and header bar are disabled on this screen. The only way to exit from this screen is to tap the *Reset* button. The system then reinitializes and change back to the system off screen. Once this has happened, the system can be used again as normal.

3

3.12.2.4.5 P&I Diagram

1 P&I Diagram 1 or 2 stages

2 Tap buttons to highlight component on diagram

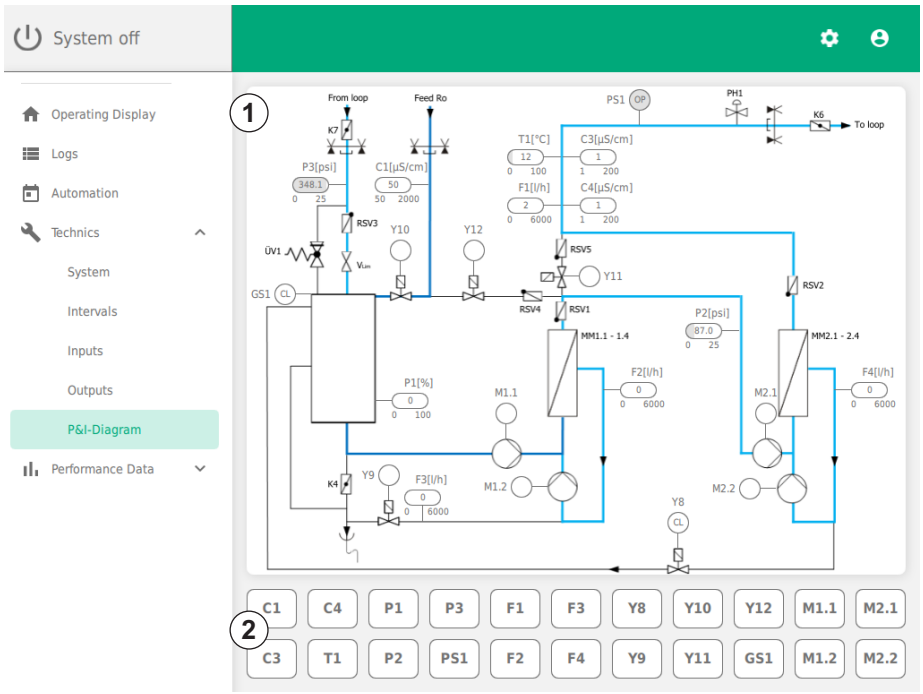


Fig. 3-40 P&I Diagram

On this screen, the position and current values of all components in the system are shown. Clicking on the button highlights the distinct component in the diagram. The depiction of the diagram varies between single and double stage systems but the functionality remains the same.

3.12.2.5 Performance Data

The graphs can be faded in or out by clicking on the corresponding element. By clicking on the Show All switch, all elements can be faded in or out at once. In the drop-down menu at the top, the time frame can be selected.

3.12.2.5.1 Conductivity

1 Selectable time period
2 Tap to show/hide all graphs
3 Tap to show/hide individual graphs

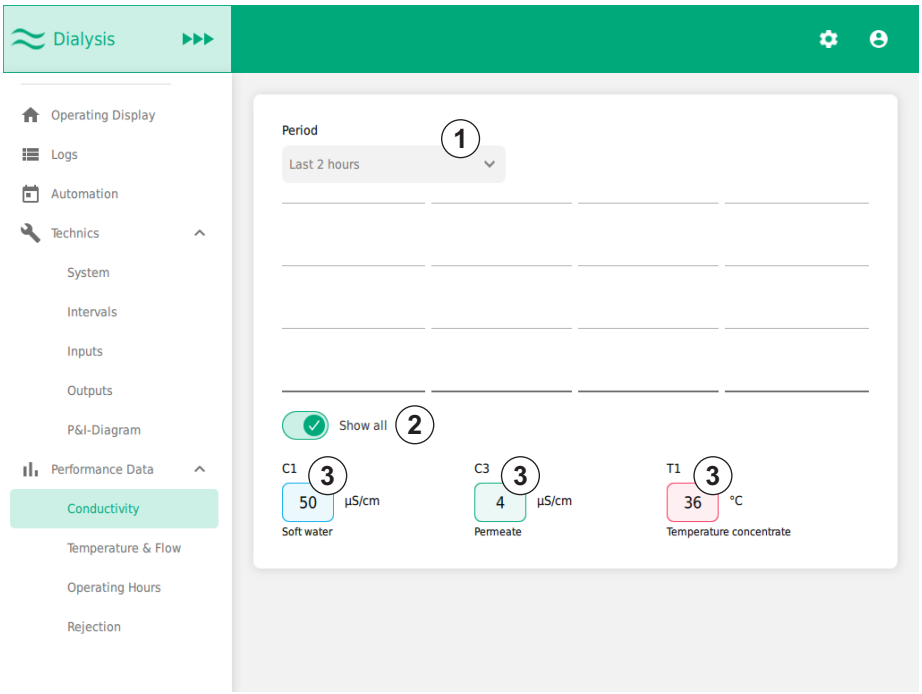


Fig. 3-41 Conductivity

The color of the elements soft water, permeate and temperature correspond to the color of the graph.

3.12.2.5.2 Temperature & Flow

1 Selectable time period
2 Tap to show/hide all graphs
3 Tap to show/hide individual graphs

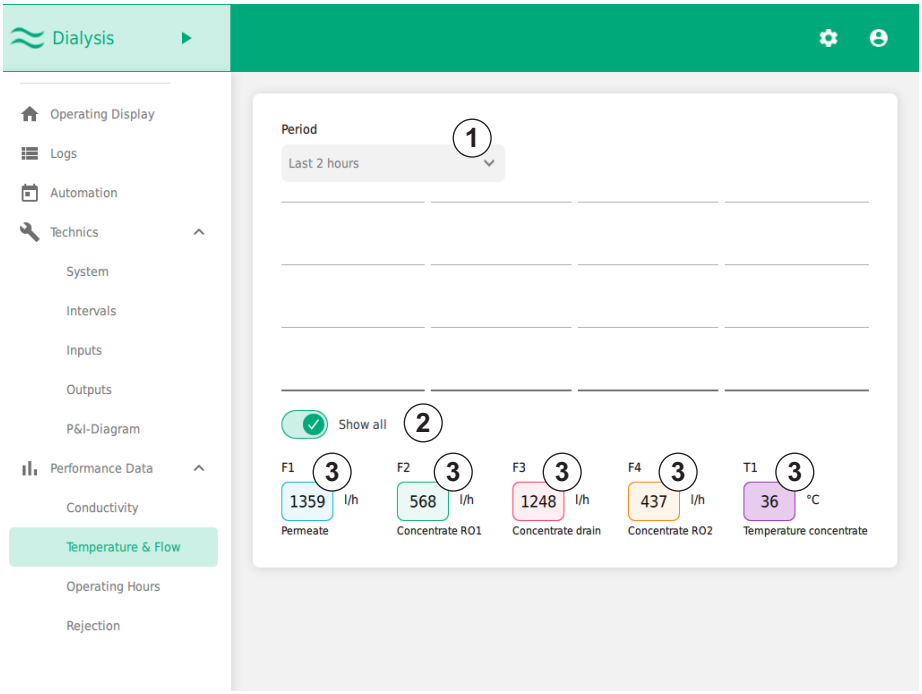


Fig. 3-42 Temperature & Flow

The color of the elements permeate, concentrate RO1, concentrate drain, concentrate RO2 and temperature correspond to the color of the graph.

3.12.2.5.3 Operating Hours

Pumps

1 Selectable time period
2 Tap to show/hide all graphs
3 Tap to show/hide individual graphs
4 Tap to open reset dialog (only for technicians)

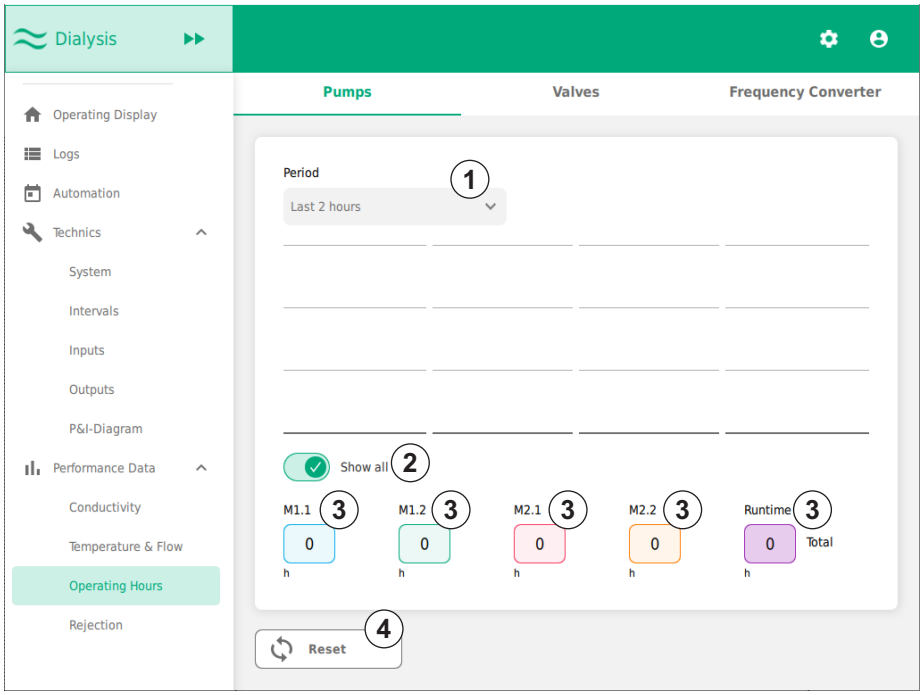


Fig. 3-43 Operating Hours Pumps

The color of the elements M1.1, M1.2, M2.1 and M2.2 correspond to the color of the graph. Users with the Technician user rights have the option to reset the operating hours by clicking on the *Reset* button, select or deselect the wanted components in the opened dialog and clicking on the *Confirm* button.

Valves

1 Selectable time period
2 Tap to show/hide all graphs
3 Tap to show/hide individual graphs
4 Tap to open reset dialog (only for technicians)

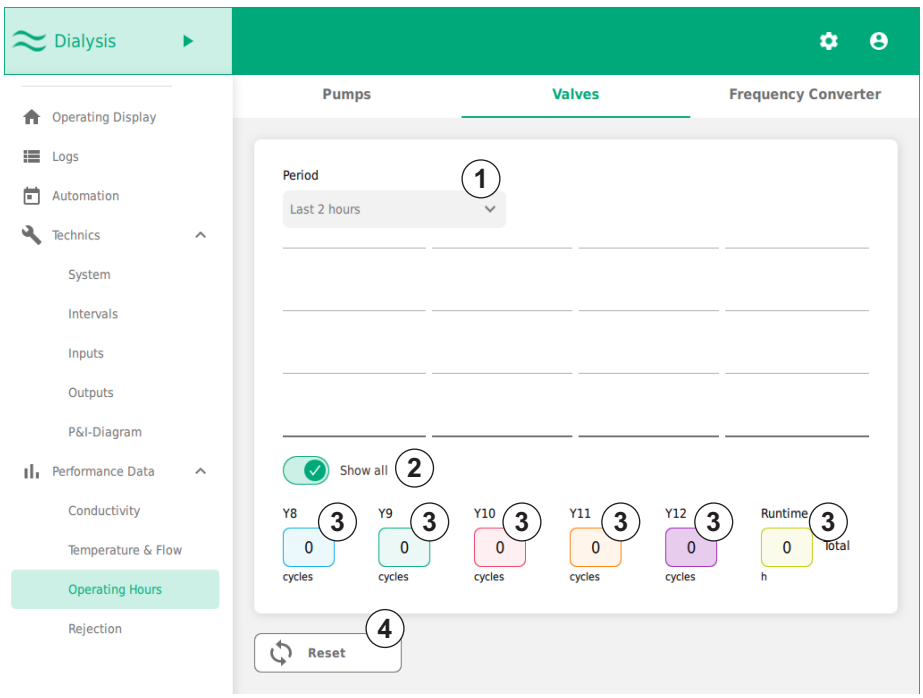


Fig. 3-44 Operating Hours Valves

The color of the elements Y8, Y9, Y10, Y11 and Y12 correspond to the color of the graph.

Users with the Technician user rights have the option to reset the operating hours by clicking on the *Reset* button, selecting the components in the opened dialog and clicking on the *Confirm* button.

1 Select components that should be reset

2 Cancel dialog

3 Confirm reset of selected components

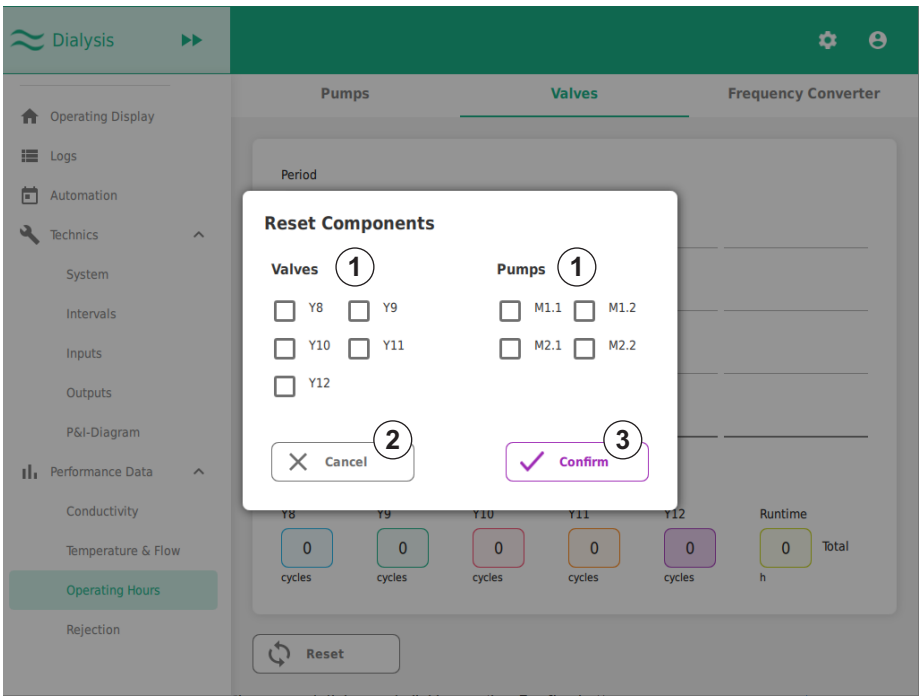


Fig. 3-45 Operating Hours Valves Reset

Frequency Converter

1 Selectable time period

2 Tap to show/hide all graphs

3 Tap to show/hide individual graphs

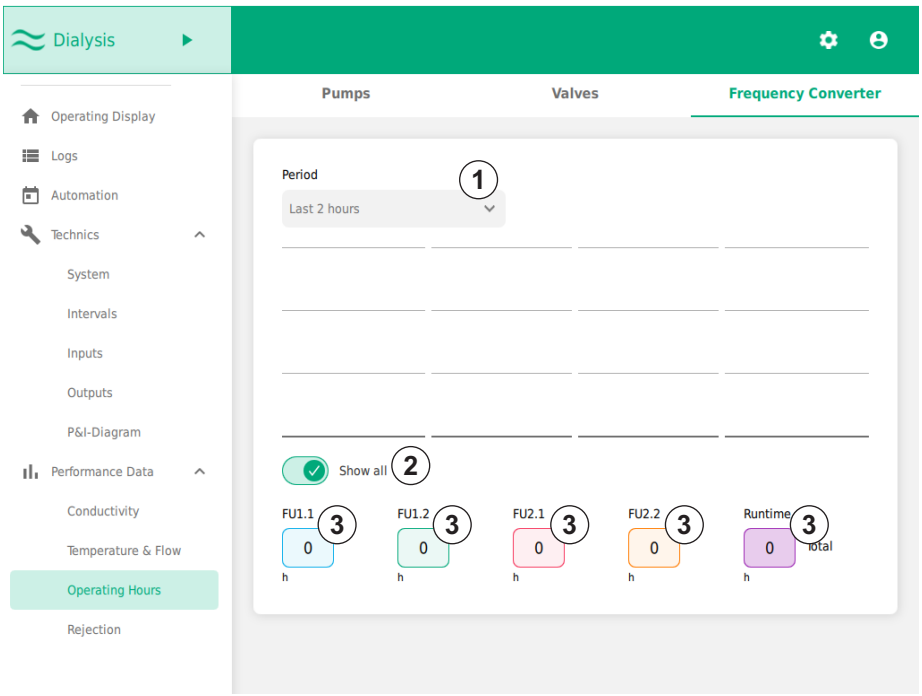


Fig. 3-46 Operating Hours Frequency Converter

The color of the elements FU1.1, FU1.2, FU2.1 and FU2.2 correspond to the color of the graph.

The operating hours of the frequency converter are reset automatically when the frequency converter is exchanged.

3.12.2.5.4 Rejection

1 Selectable time period
2 Tap to show/hide all graphs
3 Tap to show/hide individual graphs

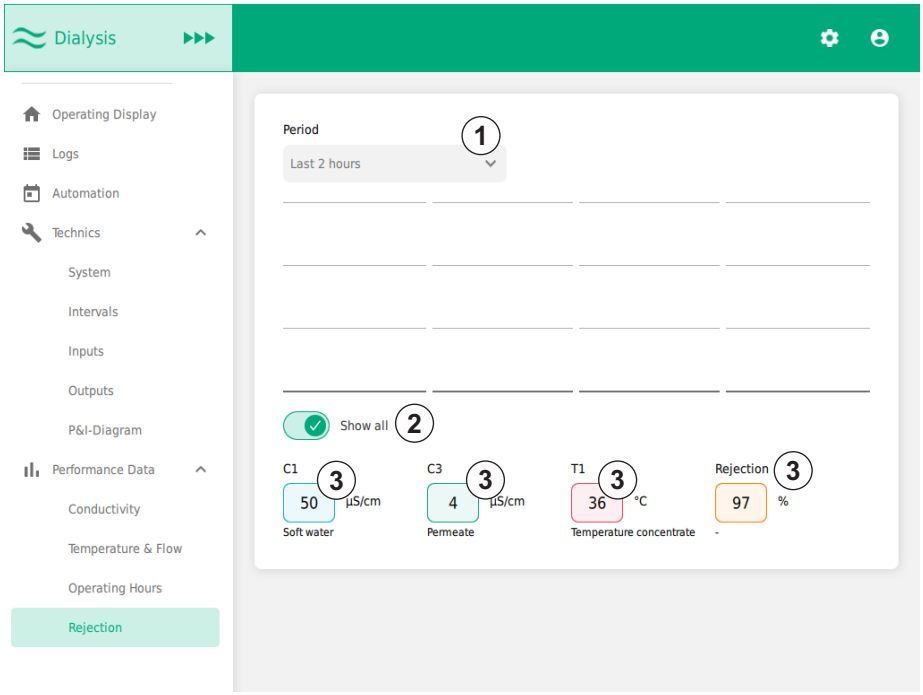


Fig. 3-47 Rejection

The color of the elements C1, C3, T1 and rejection correspond to the color of the graph.

3.12.3 Login

When no user exists yet, the user is redirected to user creation and must create an admin user.

1 Enter valid user name and password
2 Cancel login procedure
3 Tap to login

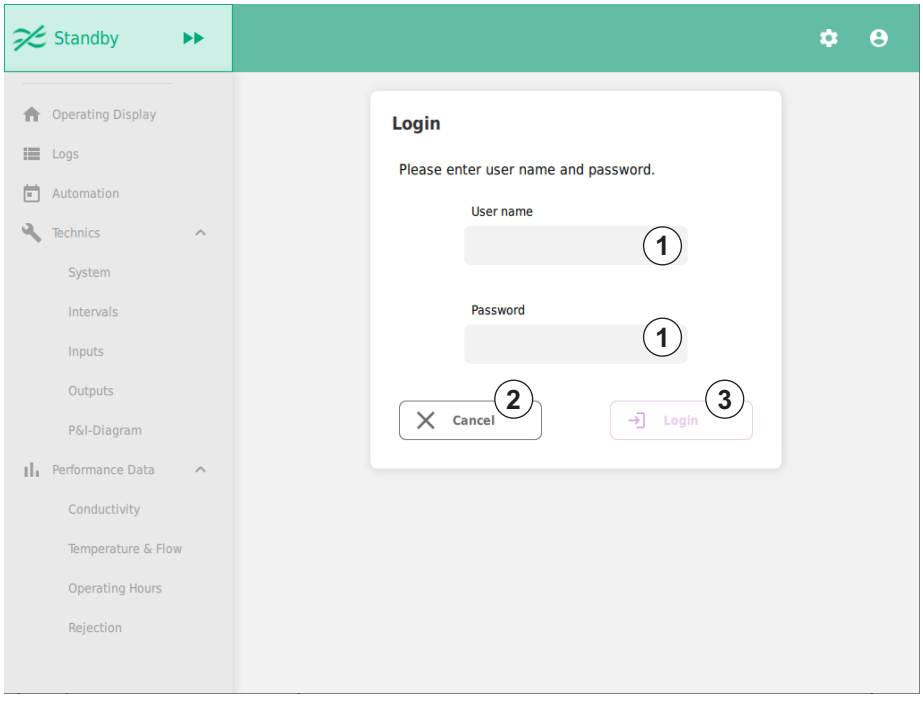


Fig. 3-48 Login

When the user name or password are invalid, both fields are marked and the wrong entry must be corrected.

3.12.4 User Management

User List

In order to access the user list, tap on user symbol in the top right corner and then on *User Management* ① .

1 User Management

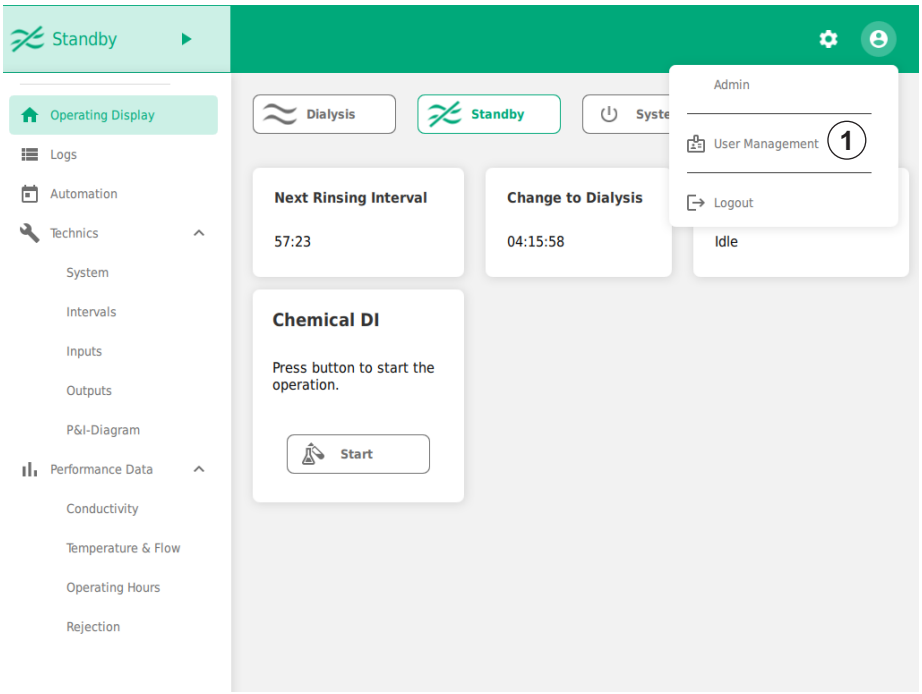


Fig. 3-49 User Management

All existing users are listed here.

1 Tap user item to edit (admins only)

2 Tap to scroll up/down

3 Tap to add new user (admins only)

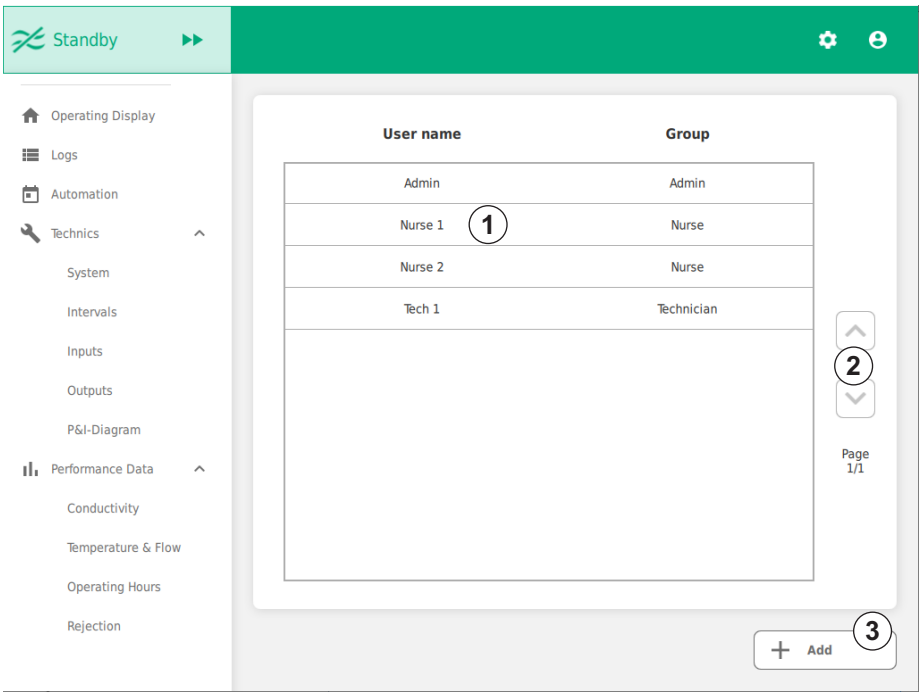


Fig. 3-50 User Management - User List

3

User Creation

To prevent privacy issues, do not use real names as user names.

Users with Admin user rights can create new users.

1. Tap on the *Add* ③ button.

1 Tap user item to edit (admins only)

2 Tap to scroll up/down

3 Tap to add new user (admins only)

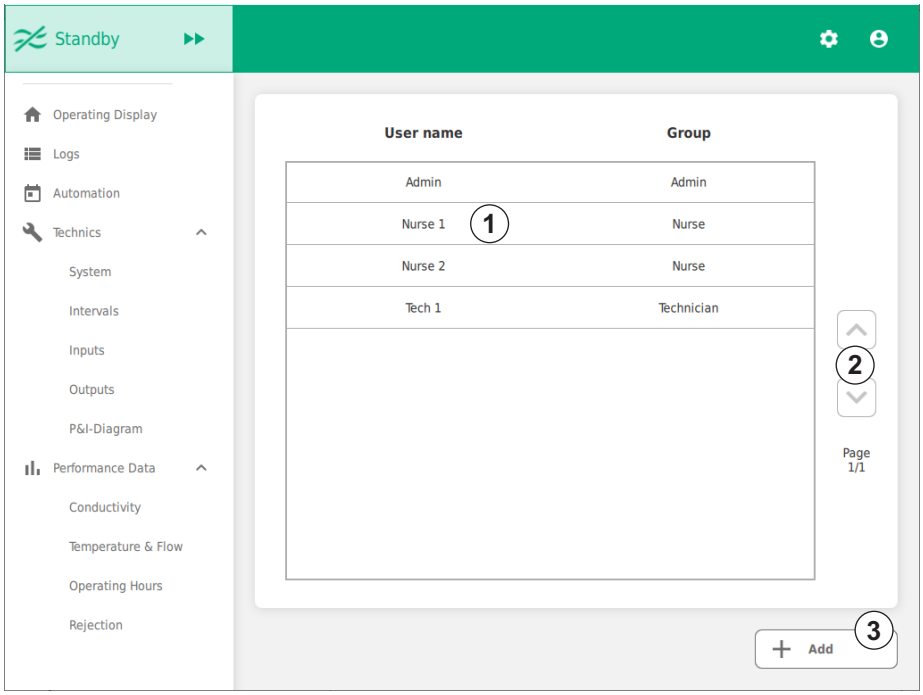


Fig. 3-51 User Management - User List

2. In the newly opened window, enter the user name, password and confirmation of the password and set the user rights. The password has a minimum of 4 digits.

1 Enter user name
2 Select appropriate user rights
3 Enter password
4 Confirm password
5 Cancel user creation
6 Save changes

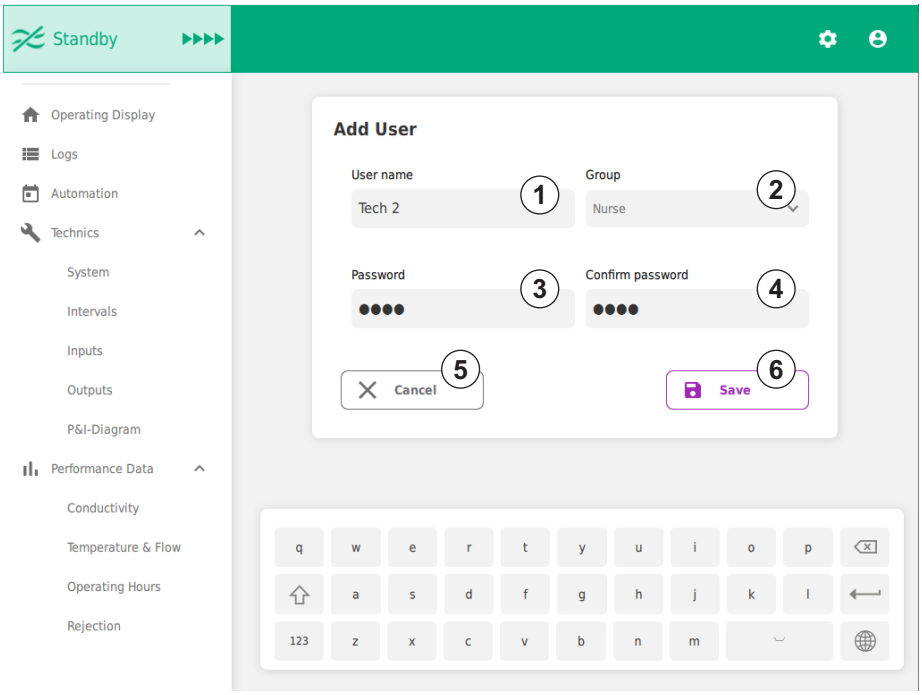


Fig. 3-52 User Management - User Creation

3. Click on the *Save* ⑥ button.

   ↳ The new user will appear on the list.

When the entered passwords do not match, the fields are marked in red and the input can be corrected.

User Editing

To prevent privacy issues, do not use real names as user names.

Users with Admin user rights can edit users.

1. In the user list, tap on the user you want to edit.

1 Tap user item to edit (admins only)

2 Tap to scroll up/down

3 Tap to add new user (admins only)

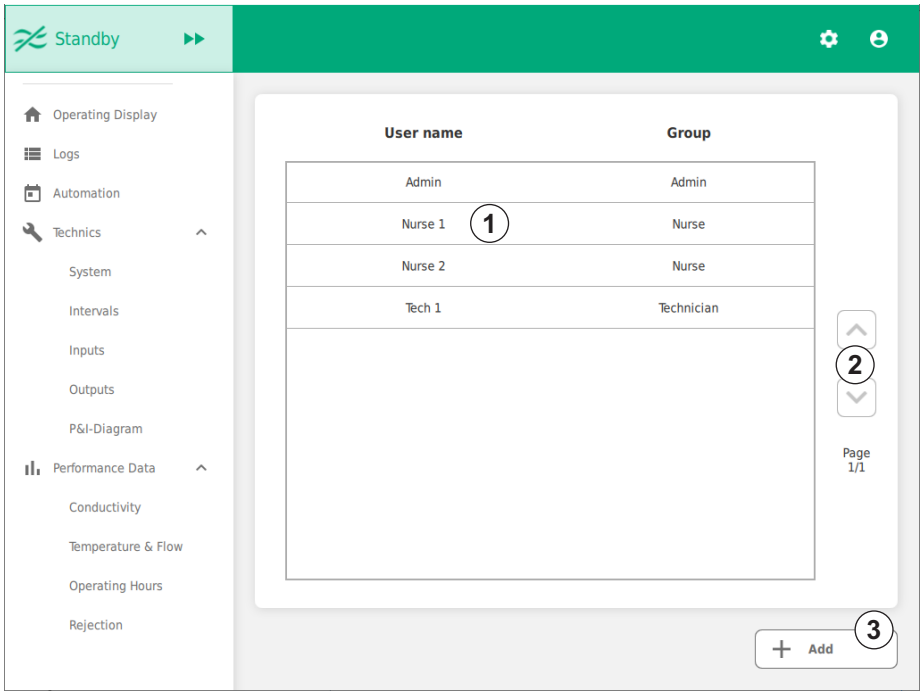


Fig. 3-53 User Management - User List

2. In the newly opened window, the following information can be changed:
   - User name
   - User rights
   - Password

1 Enter user name
2 Select appropriate user rights
3 Enter password
4 Confirm password
5 Cancel user editing
6 Delete existing user
7 Save changes

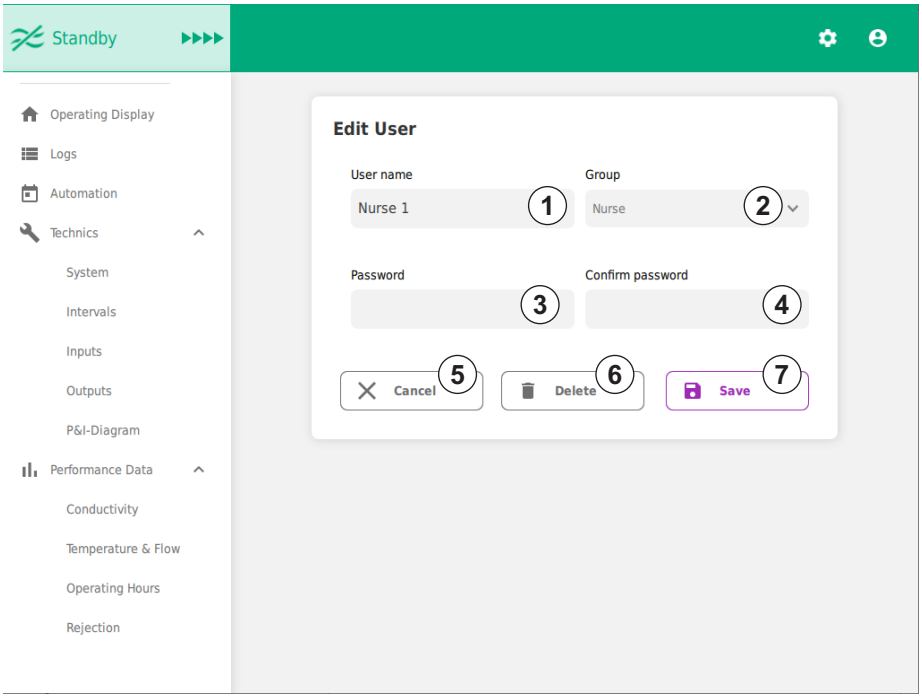


Fig. 3-54 User Management - User Editing

3. Click on the *Save* button.
   The changes made to the user will be saved.

User Deletion

The last remaining user with Admin rights cannot be deleted.

1. To delete a user, tap on the user name ① that is to be deleted.

1 Tap user item to edit (admins only)
2 Tap to scroll up/down
3 Tap to add new user (admins only)

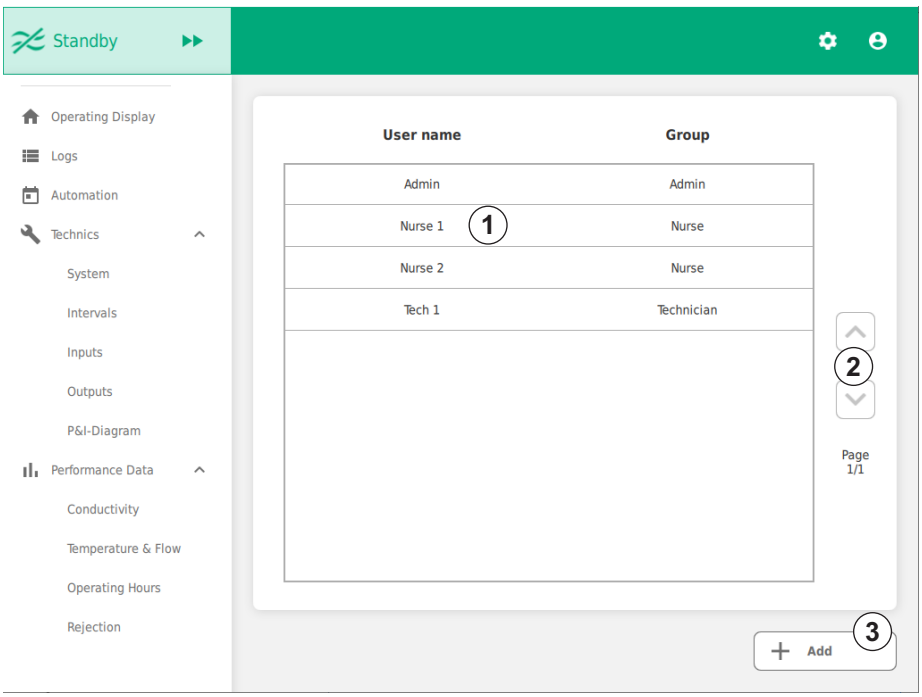


Fig. 3-55 User Management - User List

2. In the newly opened window, tap on the *Delete* ⑥ button.

1 Enter user name
2 Select appropriate user rights
3 Enter password
4 Confirm password
5 Cancel user editing
6 Delete existing user
7 Save changes

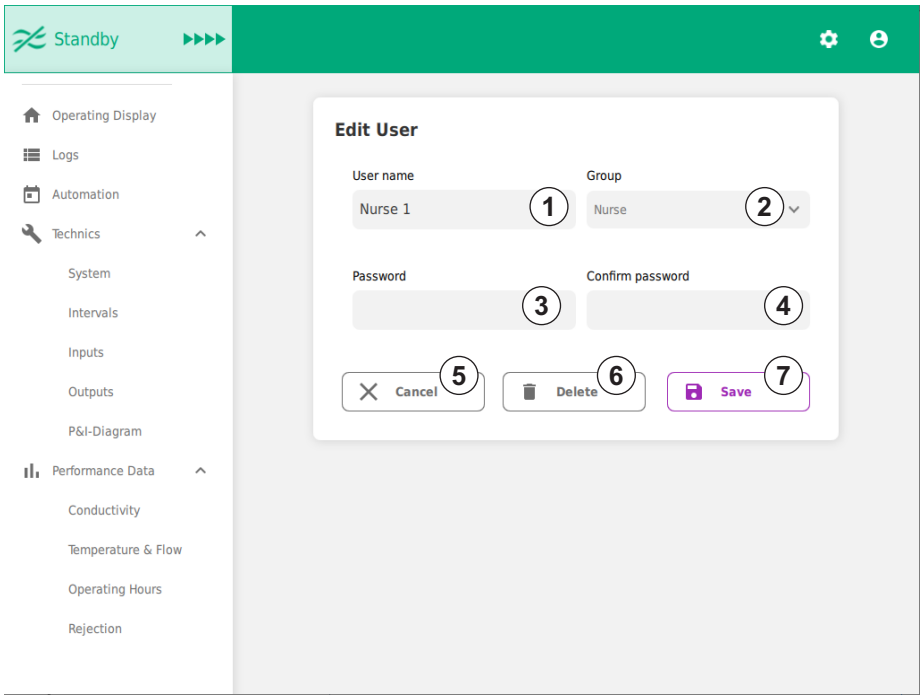


Fig. 3-56 User Management - User Editing

3. Tap the Delete ② button in order to permanently delete the user.

1 Cancel user deletion
2 Delete user permanently

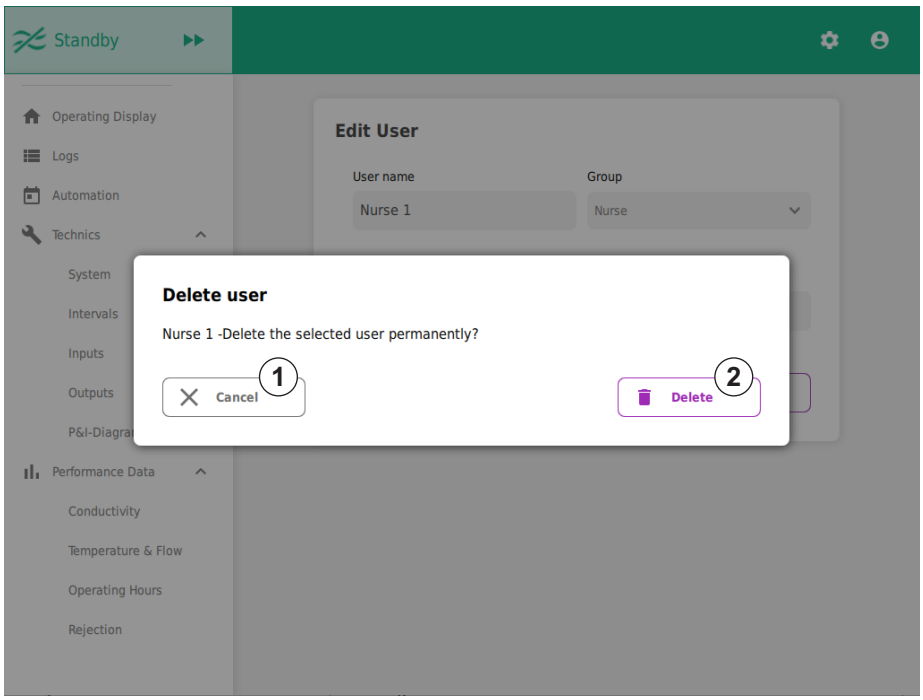


Fig. 3-57 User Management - User Deletion

3.12.5 Operating Modes

3.12.5.1 System Off

1 Start Dialysis button
2 Start Standby button
3 Start component test
4 Start chemical disinfection
5 Rinse RL

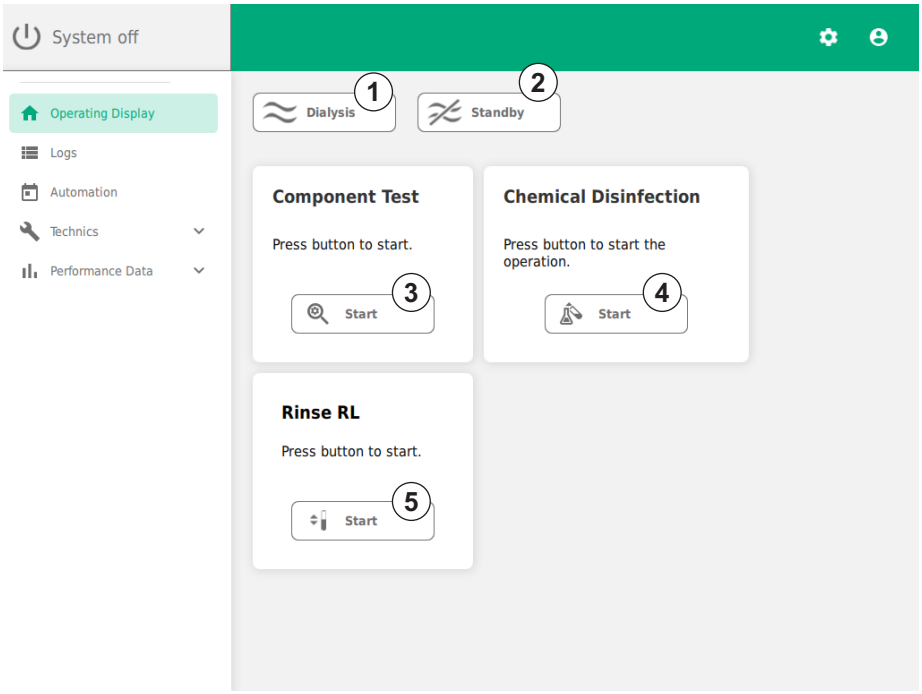


Fig. 3-58 System Off

To start System Off mode, hold the button for 1.5 seconds. When the system is in the operating mode System Off, no permeate is produced. When in System Off mode, functions such as component test, RL rinsing, chemical disinfection and manual operation of the components can be performed.

System Off mode should only be used during maintenance or error handling. Outside of dialysis times, the system should be set to Standby mode. During System Off Automatic mode is disabled.

3.12.5.2 Dialysis

1 Activated Dialysis button
2 Start Standby button
3 System Off button
4 Shows daily data
5 Shows current operating phase
6 Tap to expand

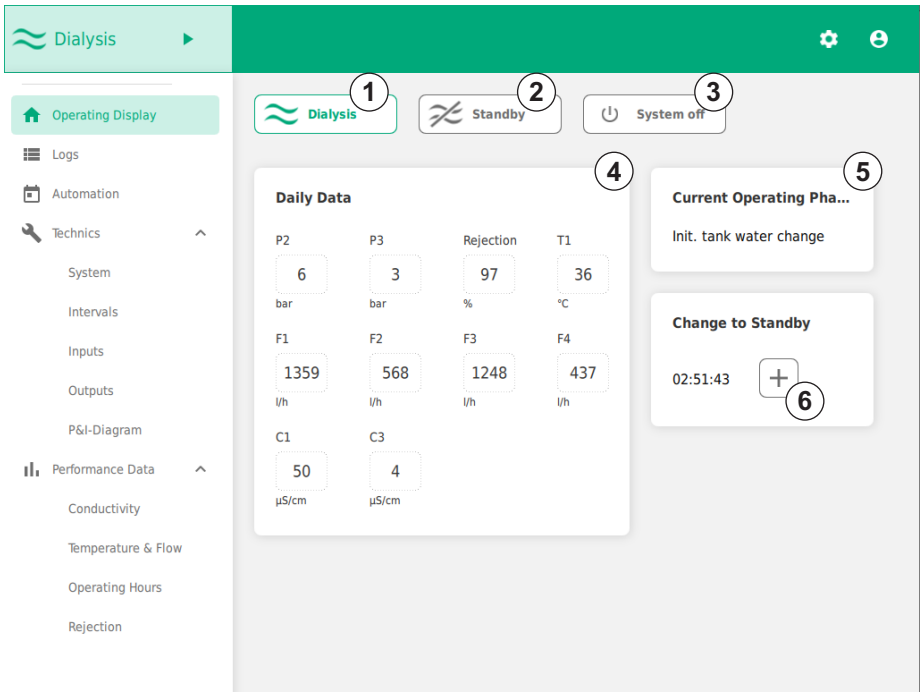


Fig. 3-59 Operating Mode Dialysis

Detailed information about this operating mode can be found in 5 Dialysis Mode (119).

1 Set additional dialysis time
2 Tap to cancel
3 Tap to save additional dialysis time

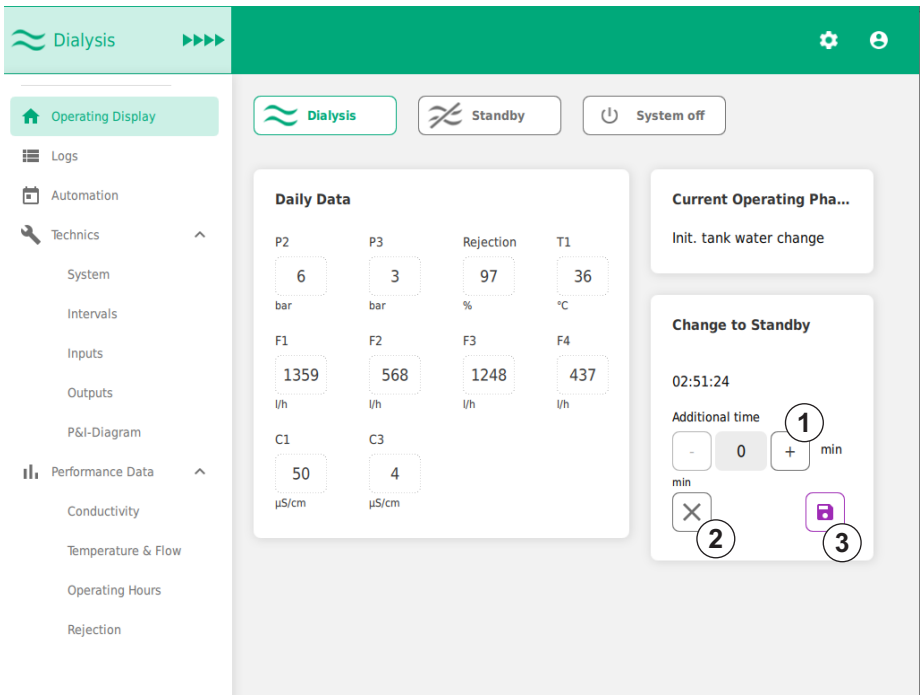


Fig. 3-60 Change to Standby mode

3.12.5.3 Standby

1 Start Dialysis button
2 Activated Standby button
3 System Off button
4 Shows countdown until next rinse interval
5 Shows countdown until next dialysis
6 Shows current operating pase
7 Start chemical disinfection procedure (only for technicians)

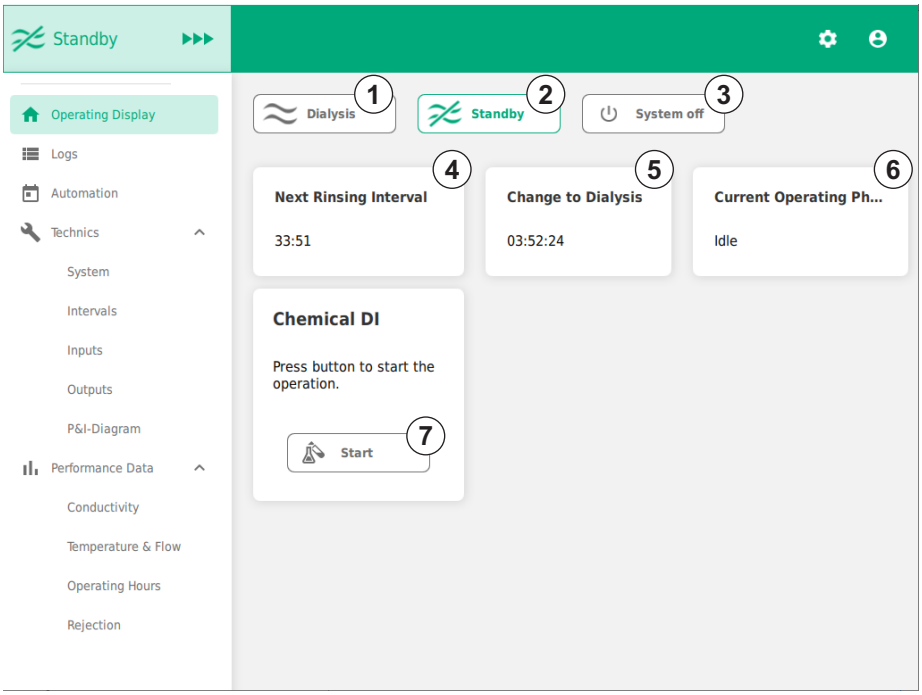


Fig. 3-61 Operating Mode Standby

Detailed information about this operating mode can be found in 6 Standby Mode (121).

3.12.5.4 Thermal Disinfection

1 Start Dialysis button (after cooldown)
2 Start Standby button (after cooldown)
3 Information on Thermal Disinfection
4 Time since start of Thermal Disinfection
5 Current operating phase
6 Current values for temperature and A0
7 Course of A0 during Thermal Disinfection

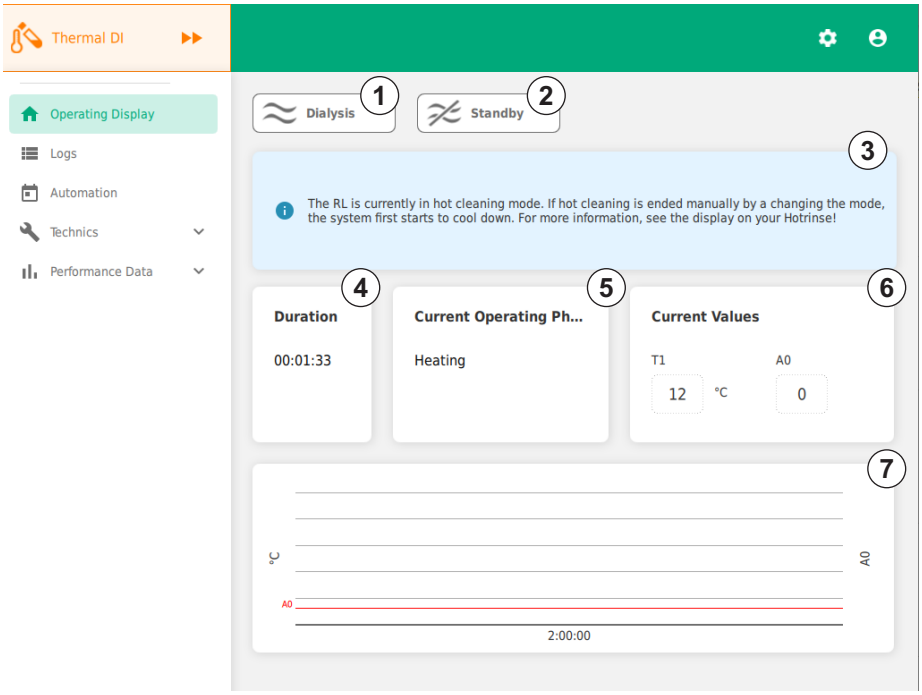


Fig. 3-62 Operating Mode Thermal Disinfection

Detailed information about this operating mode can be found in 7.2.2 Thermal Disinfection (135).

1 Programmed recirculation time
2 Programmed reaction time
3 Programmed rinse time
4 Return to previous screen
5 Edit programmed times
6 Continue to next screen

3.12.5.5 Chemical Disinfection

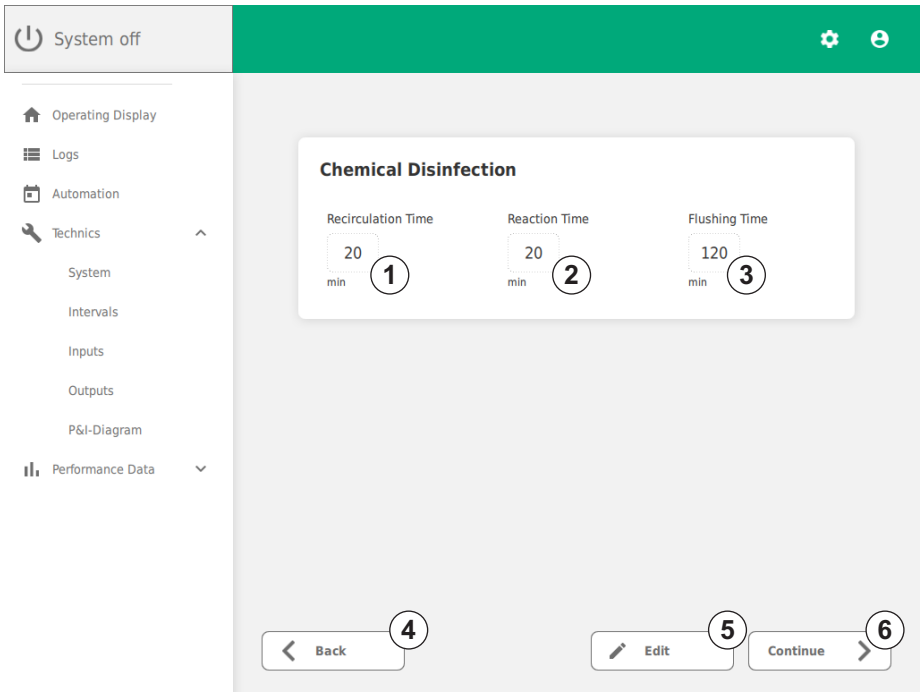


Fig. 3-63 Operating Mode Chemical Disinfection

Detailed information about this operating mode can be found in 7.2.1 Chemical Disinfection (126).

3.12.5.6 Emergency Modes

Detailed information about these operating modes and the blocking state can be found in 8.1 Emergency Modes and Blocking State (137).

3.12.6 Error State

In an error state, no operation is possible.

1 Tap button to mute sound until next screen saver
2 Start emergency mode
3 Confirm error message/ stay in error state

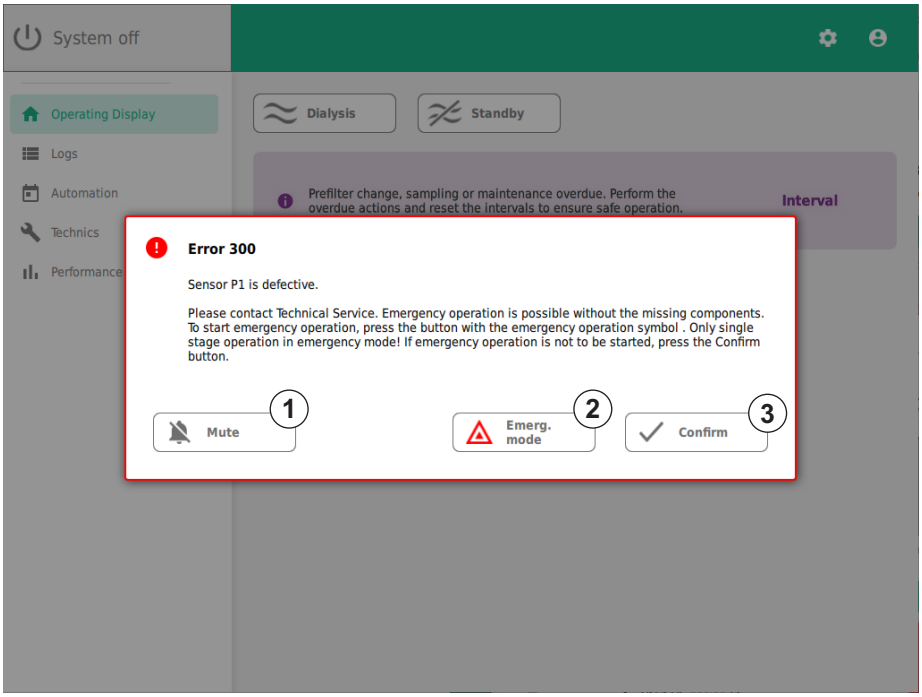


Fig. 3-64 Error State - Message

1 Tap button to mute sound until next screen saver
2 Tap to show more information on error
3 Start component test
4 Start RL rinsing (if possible)

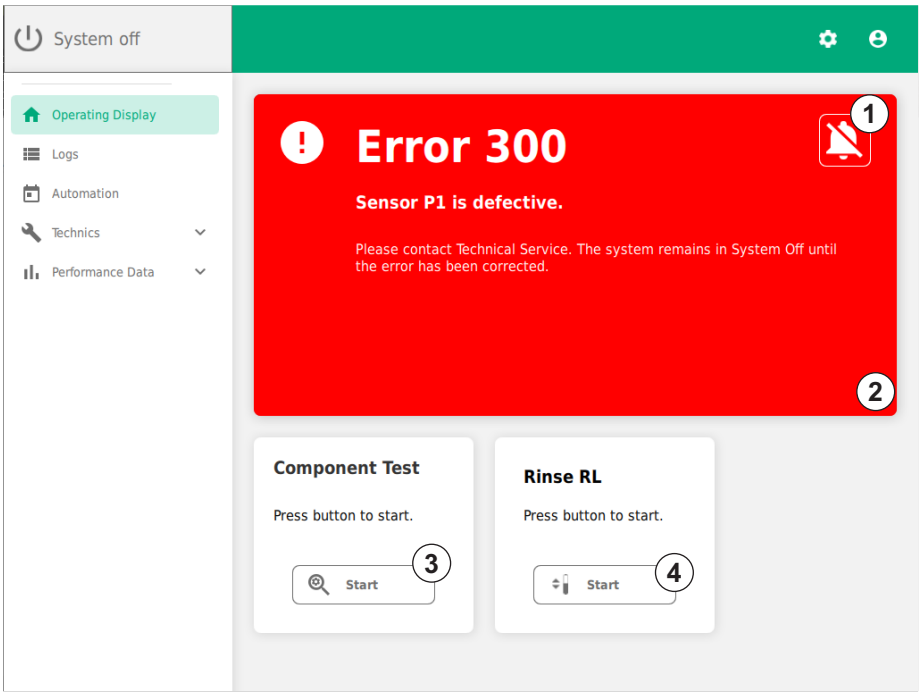


Fig. 3-65 Error State

4 Installation and Commissioning

NOTICE!

Only allow experienced transport experts to transport the device.

The system comes in a shipping crate. The shipping crate has handling information that must be observed:

Fragile goods, handle with care.

The arrows on the shipping crate must be pointing upward during transport and storage. Avoid rolling, swinging, heavy tipping or tilting and other forms of handling.

Keep the goods out of wet or very humid conditions.

The product has been properly preserved for a specific temperature range during transport.

Indicates the range of humidity to which the medical device can be safely exposed during transport.

Do not stack.

Unpacking the System

1. Check the shipping crate for signs of rough handling, water ingress or improper handling. Also check the shipping crate for transport damage and completeness.
   - If there is transport damage, keep the shipping crate and immediately notify the carrier and the manufacturer.
2. The shipping crate with the system inside can weigh up to 1,000 kg. This is why lifting equipment should be used that is rated for this load and is able to lift it.
3. Carefully remove the system from the shipping crate.
4. Place the device on a firm, even surface.

If storing for over 6 months, the system must be preserved again.

4.1 Transportation

The system is protected against frost down to -15 °C. The temperature during transport must not fall below -15 °C or exceed 40 °C. Relative humidity must stay between 30 and 75% (non-condensing).

Before initial startup, the system needs to be unpacked and left at the setup location at room temperature for 24h in order to acclimate to the temperature and humidity.

AQUAboss nX Shipping Crate	
Height	Up to 1,980 mm
Width	Up to 800 mm
Length	Up to 1,800 mm
Weight of shipping crate (with system)	Up to 1500 kg

A double stage system is delivered in two separate shipping crates.

4.2 Scope of Supply

The system is packaged and delivered with the following components:

- System (fully assembled)
- Instructions for use
- Circuit diagram
- QA acceptance certificate

4.3 Storage

To prevent microbial contamination, the AQUAboss nX must be protected with min. 400 mg/L sodium metabisulfite. The temperature during storage should not fall below 5 °C or exceed 40 °C. If storage is to exceed a month, 200–350 mg/L magnesium chloride must be added to the preservative solution. To protect the membranes, the preservative solution must be replaced no later than every 6 months. The relative humidity must stay between 30 and 75% (non-condensing).

For more information on storage and preservation, contact the technical service.

4.4 Installation Site

The setup location must meet the following structural requirements:

- Professional healthcare environment: application in hospital/dialysis centers only. Not for home use. Indoor use only. Wet cell possible (waterproof floor/walls with ELCP of all power supplies).
- Level industrial floor with a min. load rating of 500 kg/m^2.
- Shock-free and vibration-free
- 0.5 m clearance on all sides (with control cabinet door open) for maintenance purposes
- Acid-resistant flooring
- Control cabinet protected against direct water jets and heavy dust

The system is suitable for operation in covered and weather-protected locations (e.g., enclosed spaces). The system should be set up on a level surface near the necessary power and water connections, with attention paid to access to the connections and controls.

Only qualified and authorized personnel should be allowed to access the AQUAboss nX reverse osmosis system. The reverse osmosis system and, thus, the water supply room should be protected against unauthorized access.

4.5 On-Site Supply Connections

4.5.1 Pretreatment Stage: Hydraulic Connection

A pretreatment stage needs to be connected upstream of the system. This stage is available as an add-on option from B. Braun Avitum AG (see separate instructions for use for installation instructions) or must be supplied by the customer.

Before disinfecting the softener, disconnect it completely from power and from the reverse osmosis system.

Drinking water pressure should not exceed 6 bar. Observe the load ratings in the technical data and additional information on raw water requirements (11 Technical Data (159)).

- 1" drinking water connection (reverse osmosis system feed) with 1" ball valve (min. 3–6 bar flow pressure at max. system output)
- Type BA backflow preventer, 1" connection
- Backflushable prefilter with 105 µm filter unit and pressure gauge, 1" connection
- 1" water meter
- DN 20 leak or system shutoff valve if necessary
- Activated carbon multimedia filter if necessary
- Softener with adequate capacity (note 3 bar min. flow pressure)
- 5 µm prefilter
- Minimum DN20 hose connection for water supply between pretreatment stage and system

NOTICE!

The feed water upstream of the softener (ion exchanger) must meet the requirements of Directive (EU) 2020/2184 on the quality of water intended for human consumption. B. Braun Avitum AG-specific deviations from or addenda to the directives are listed in Section 2.13.3 Water Quality Requirements (32).

The following water connections are also required for the reverse osmosis system:

- Ring piping feed (DN25 Tri-Clamp)
- Ring piping return (DN25 Tri-Clamp)

4.5.2 Drain Connection

The following drain connections are required for the reverse osmosis system:

- Drain with DN50 siphon
- Unrestricted intake connection to drain per DIN 1988-100 and EN 1717.
- DN70 floor drain (5,000 L/h throughput) at the lowest point of the area or enclosed base pan with water sensor
- Drain connections for softener and reverse osmosis system should be run through floor drain (odor trap)
- Drain pipe temperature-stable up to 90 °C for hot water disinfection
- System connected to drain with solid or flexible minimum DN25 piping (observe unrestricted outlet)
- Concentrate hose must be fed and secured in drain through unrestricted fall section at least 2x its inner diameter
- Additional information on setup planning is found in the service manual.

4.5.3 Electrical Connection

Each AQUAboss nX stage requires a permanent electrical connection (depending on model, see Section 11 Technical Data (159)) that is secured by a 30 mA GFCI which is compatible with the used frequency converters. The building must have the electrical safety equipment required by national regulations.

- Stainless steel ring piping ground (6 mm^2)
- Additional protective conductor from system frame to grounding bar of the building (min. 10 mm^2)
- See Tbl. 4-1

For power data, see 11.1 Performance Data (159).

⚠ CAUTION!

Electrical stroke or risk of burn if water enters system or plugs.

⚠ WARNING!

Risk of electric shock if the system is not properly grounded.

- To avoid the risk of electric shock, this system must only be connected to a power supply with a protective earth conductor.

⚠ DANGER!

Risk of electrocution

- Only authorized, trained and instructed electricians should perform electrical work.

Make sure the local supply voltage, frequency and fusing match the data on the type plate and the technical data (11 Technical Data (159)). If not, do not connect the system to power.

The system's control units are housed in a control cabinet on the front of the system.

The control units and relays come wired to a terminal strip inside the control cabinet as shown in the circuit diagram.

The following control/display elements are in the building installation:

- Main switch/circuit interrupter
- Circuit breaker
- Ground-fault circuit interrupter

These components must be compatible with frequency converters.

Depending on the customer's setup, B. Braun Avitum AG or authorized personnel can also connect an alarm device to the system per the circuit diagram, although it must be ensured that all signals going to the system from external devices are sent through dry contacts in the corresponding add-on devices.

Cable	Specified Length
Remote Control	> 30 m
Hot Rinse SMART	< 30 m
Soft Control	< 30 m
Aqua Control	< 30 m
CMS	< 30 m
Double Ring Piping system	< 30 m
CAN BUS	< 30 m

Cable	Specified Length
Nexadia	< 5m

Tbl. 4-1 Cable list and length

NOTICE!

Do not change the once installed final application due to EM DISTURBANCE. If the environment does not correspond to the conditions listed by the manufacturer, some actions are required to match those conditions. Please contact the manufacturer.

The climatic environmental conditions could affect the life of critical components of the AQUAboss nX. The presence of transmitters near the AQUAboss nX could affect its performance. The distances mentioned in the tables prepared by the manufacturer can help to prevent any disturbances of the equipment in normal operation.

4.5.4 Permanent Electrical Connection

For a permanent electrical connection, the setup location must have the following safeguards:

- Overcurrent protection device, see Section 11 Technical Data (159)
- 30 mA/4-pole ground-fault circuit interrupter
- Appliance switch or circuit breaker, see Section 11 Technical Data (159)
- Power cable, see Section 11 Technical Data (159).

⚠ WARNING!

Risk of electric shock if the system is not properly grounded.

- To avoid the risk of electric shock, this system must only be connected to a power supply with a protective earth conductor

NOTICE!

Permanent electrical connections should always be set up by authorized personnel in accordance with national rules and regulations.

The appliance switch or circuit breaker should be labeled as disconnecting the reverse osmosis system from power. The switch or breaker should be near the system and easily accessible for the user. Surges and undervoltage in the power supply can damage the reverse osmosis system. B. Braun Avitum AG recommends only connecting the reverse osmosis system to emergency power per EN 6280-13.

The disconnect device should meet the requirements of IEC 60947-1 and IEC 60947-3. The switch or breaker should not interrupt the protective earth conductor.

Installing a permanent power supply cable should meet the requirements of IEC 60601-1/8.11.

Permanent electrical connection cables should meet the requirements of IEC 60601-1/8.11.

Central AQUAboss nX reverse osmosis systems come configured with a clockwise phase rotation. Check the phase rotation before starting up the system.

4.6 Flushing the Preservative

The reverse osmosis system is typically delivered with the membranes preserved. After connecting the water line and drain, the preservative must first be flushed before connecting the system to the ring piping. Make sure the open permeate line can reach the drain connection or an appropriate floor drain.

1. Open the water supply and turn on the system at the main switch. As soon as the system states “System Off” in the upper left corner, it is ready for use. The desired operating mode can be selected on the display.
2. To flush the preservative, select Dialysis mode. The supply tank fills up. When the lower P1 switching point is exceeded, the control system turns on the pumps and the system begins (preliminary) permeate production to flush the system and permeate tube.
3. To properly flush the preservative, create a permeate consumption (for example into the drain).
4. Create a constant flow.
5. Open the bleed screw, see Fig. 4-1. Do not remove the screw. Removing the screw can damage the inside of the pump.
6. Wait until the water flow is constant, see Fig. 4-2.
7. Close the bleed screw, see Fig. 4-3.

NOTICE!

Irreversible damage to the pump, air in the pump body

Always bleed all pumps and the modules in the pressure pipes.

- Carefully open the bleed screw until the water flow is constant. Then close the bleed screw (see Fig. 4-1 Opening the bleed screw (112), Fig. 4-2 Water flow becomes constant (112) and Fig. 4-3 Closing the bleed screw (113)).

Bleeding the Pump

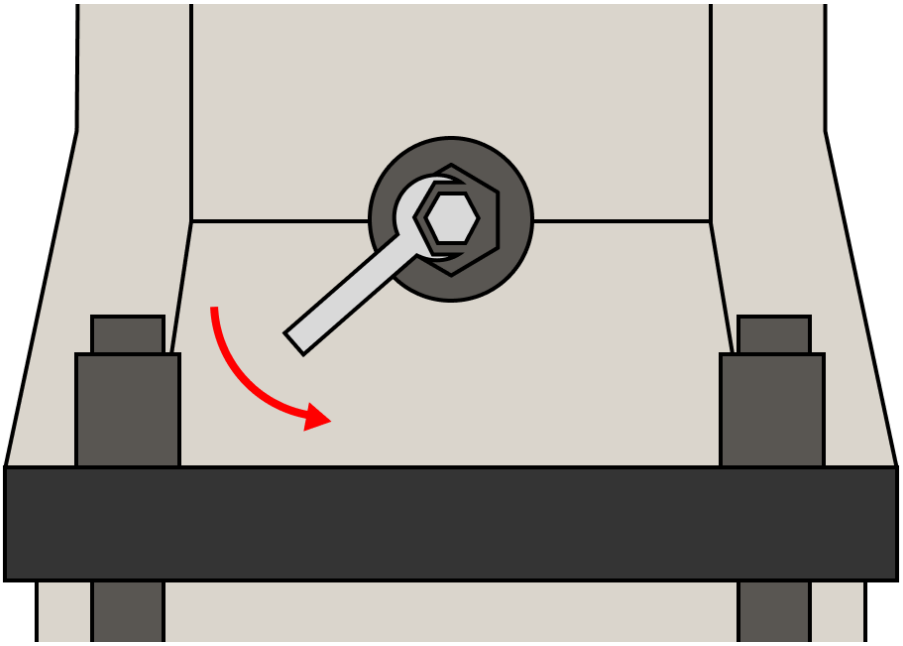


Fig. 4-1 Opening the bleed screw

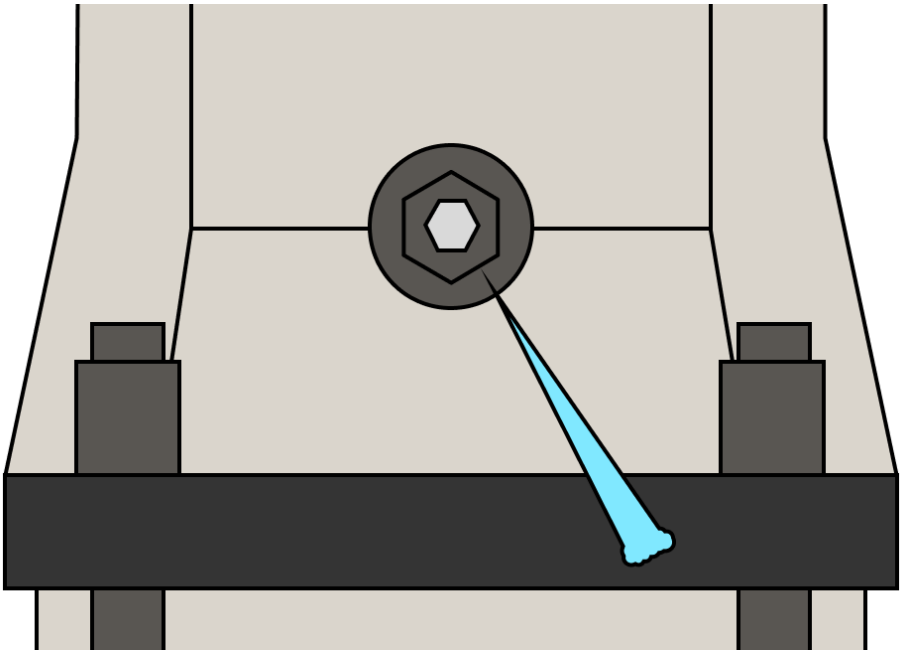


Fig. 4-2 Water flow becomes constant

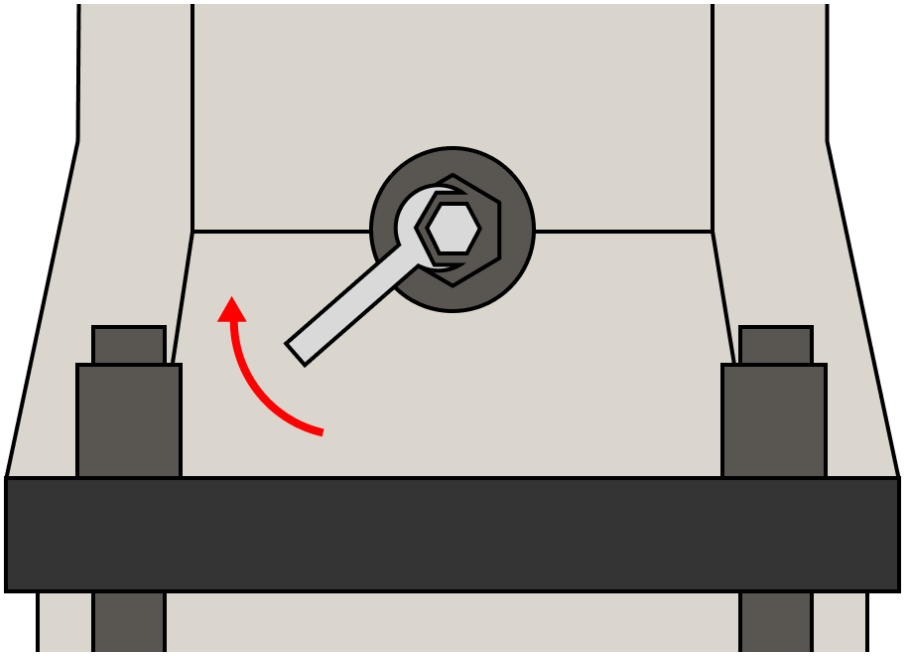


Fig. 4-3 Closing the bleed screw

Once turned back on, the pumps build the necessary operating pressure.

If the system is in Dialysis mode, the conductivity display shows a downward trend in permeate conductivity. Once conductivity drops to a normal level (2–10 µS/cm depending on raw water quality and configured yield), the device can be shut off and the ring piping can be fully connected.

After the system is flushed, the ring piping is flushed and bled for a period of time. Then the entire system needs to be disinfected; see Section 7.2 Disinfection (124). After disinfecting, make sure there is no disinfectant in the device or ring piping; see Section 9.5 Disinfection Report (155).

4.7 Initial Startup Preparations

The customer/service technician needs to complete the following tasks before startup:

- Set up and level the system
- Connect the system to the pretreatment stage
- Install the water connection
- Install the drain connection
- Install the electrical connection
- Perform initial startup, incl. menu language selection
- Fill out the startup report

4.8 Initial Commissioning

Only trained specialists or a trained representative authorized by B. Braun Avitum AG should perform the initial startup. Improper initial startup can result in injury and property damage. During initial startup, the customer/operating personnel is/are extensively instructed on using the system.

Documentation and water quality monitoring conform to ISO 23500-1.

Before initial startup, make sure the pretreatment system has been sufficiently flushed and all prefilters have been installed.

Once validated, the water can be used for its intended purpose.

NOTICE!

During commissioning, the intervals for the microbial sampling are determined. According to ISO 23500-1, monthly sampling is advised.

4.9 Handover Certificate for Instructions for Use

Handover Certificate for Instructions for Use	
1. AQUAboss nX Reverse Osmosis System	
AQUAboss nX	
Serial no.	
Year of manufacture	
2. Customer Address	
Company	
Street	
Postal code, city	
3. Confirmation of Handover of Instructions for Use	
We have purchased the system specified in 1. Upon handover of the system, we were given the instructions for use for:	
System no.:	
In the languages	Qty.:
	Qty.:
	Qty.:
Company stamp	

Handover Certificate for Instructions for Use	
Customer name in print	
_____ Date	_____ Customer Signature
4. Date of System Handover	
Date:	
5. Maintenance and Servicing Personnel	
The following persons have been named by the customer and been instructed, trained and briefed by B. Braun Avitum AG regarding the following system features: Safety equipment, hazard areas, improper use, setting up and using all operating modes	
_____ Name (customer personnel)	_____ Signature
_____ Name (customer personnel)	_____ Signature
_____ Name (customer personnel)	_____ Signature
□ B. Braun Avitum AG commissioning log	
□ Customer commissioning log	
Company Stamp/Customer Signature	
The system was handed over to the customer by	
Name (print)	
_____ Date	_____ Service Technician Signature

4.10 Electromagnetic Compatibility (EMC)

The AQUAboss nX series devices listed in the EMC tables comprise all variants of the series:

- AQUAboss nX
- AQUAboss nX HT

NOTICE!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment should be observed to verify that it is operating normally.

Guidance and Manufacturer's Declaration on Electromagnetic Emissions		
The AQUAboss nX series devices are intended for operation in an environment like the one specified below. The customer or user of an AQUAboss nX should ensure it is operated in such an environment.		
Emission Measurements	**Conformity**	**Electromagnetic Environment Guidance**
HF emissions per CISPR11	Group 1	The AQUAboss nX uses high-frequency energy solely for its internal functions. Therefore its HF transmission is very low and it is unlikely that there will be any interference with neighboring devices.
HF emissions per CISPR11	Class A[a]	
Transmission of harmonic according to I<16 A EN 61000-3-2 I>16 A EN 61000-3-12	N/A	
Transmission of voltage fluctuations/flickering according to I<16 A EN 61000-3-3 I<75 A EN 61000-3-11[b]	N/A	

a. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

b. Has not been tested because EUT does not produce flicker nor voltage fluctuations.

Guidance and Manufacturer's Declaration on Electromagnetic Susceptibility			
The AQUAboss nX series devices are intended for operation in an environment like the one specified below. The customer or user of an AQUAboss nX should ensure it is operated in such an environment.			
Susceptibility Test	**IEC 60601 Test level**	**Conformity Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	Floors should be made of wood or concrete or have ceramic tiles. If the floor covering is made of synthetic material, the relative humidity must be at least 30%.
Fast transient electrical emissions/bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz burst	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz burst	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration on Electromagnetic Susceptibility			
Voltage dips, short interruptions and fluctuations in the voltage supply according to IEC 61000-4-11	0% U_T; ½ periods and 1 periods at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 70% U_T; for 25/30 periods (50/60 Hz) 0% U_T; for 250/300 periods (50/60 Hz)	0% U_T; for ½ periods and 1 periods at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 70% U_T; for 25/30 periods (50/60 Hz) 0% U_T; for 250/300 periods (50/60 Hz)	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment. If the user requires use of advanced functions for the AQUAboss nX even if interruptions in the power supply occur, it is recommended that the AQUAboss nX be fed from an uninterruptible power supply or a battery.
Magnetic field for the power supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the mains frequency should have values typical of an industrial environment.
NOTE: V_T is the AC line voltage prior to application of the test level.			

4

Guidance and Manufacturer's Declaration on Electromagnetic Susceptibility			
Portable and mobile RF communication equipment should be used no closer to any part of the AQUAboss nX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. 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.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 V_{RMS} 150kHz to 80 MHz outside ISM bands and radio amateur band* 6 V_{RMS} 150 kHz to 80 MHz in ISM bands and radio amateur band*	10 V_{RMS} 150kHz to 80 MHz outside ISM bands and radio amateur band* 10 V_{RMS} 150 kHz to 80 MHz in ISM bands and radio amateur band*	If the measured field strength in the location in which the AQUAboss nX is used exceeds the applicable RF compliance level, the AQUAboss nX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AQUAboss nX.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz–6 GHz 80% AM at 1 kHz	10 V/m 80 MHz–6 GHz 80% AM at 1 kHz	Minimum separation distance shall be calculated by the following equation: $E = \frac{6}{d}\sqrt{P}$ E is the immunity test level in [V/m]d is the minimum separation in [m]P is the maximum power in [W]
Near fields of wireless HF communications equipment IEC 61000-4-3	27 V/m 380–390 MHz 50% PM 18 Hz 28 V/m 430–470 MHz FM ±5 kHz deviation,1kHz sine 9 V/m 704–787 MHz 50% PM 217 Hz 28 V/m 800–960 MHz 50% PM 18 Hz 28 V/m 1700–1990 MHz 50% PM 217 Hz 28 V/m 2400–2570 MHz 50% PM 217 Hz 9 V/m 5100–5800 MHz 50% PM 217 Hz	27 V/m 380–390 MHz 50% PM 18 Hz 28 V/m 430–470 MHz FM ±5 kHz deviation,1kHz sine 9 V/m 704–787 MHz 50% PM 217 Hz 28 V/m 800–960 MHz 50% PM 18 Hz 28 V/m 1700–1990 MHz 50% PM 217 Hz 28 V/m 2400–2570 MHz 50% PM 217 Hz 9 V/m 5100–5800 MHz 50% PM 217 Hz	RF wireless equipment maximum output power and separation distance tested (at 30 cm):TETRA 400: max 1.8 WGMRS 460, FRS 460: max 2 WLTE Band 13 and 17; max 0.2 WGSM 800/900: max 2 W TETRA 800: max 2 W iDEN 820: max 2 W CDMA 850: max 2 W LTE Band 5: max 2 WGSM 1800/1900: max 2 W CDMA 1900: max 2 W DECT: max 2 W LTE Band 1, 3, 4 and 25: max 2 W UMTS: max 2 WBluetooth: max 2 W WLAN 802.11b/g/n: max 2 W RFID 2450: max 2 W LTE Band 7: max 2 WWLAN 802.11 a/n: max 0.2 W
			Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration on Electromagnetic Susceptibility			
Proximity magnetic fields IEC 61000-4-39	30 kHz/CW/8 A/m[a]	Not tested[b]	
* The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 to 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.			

a. Test applicable only to ME equipment and ME systems intended for use in the Home Healthcare environment.
b. The test against IEC 61000-4-39 is not applicable, since no device is magnetically sensitive and no RFID devices are expected to be closer than 0.15 m during intended use.

Recommended Separation Distances Between Portable and Mobile HF Telecommunications Equipment and an AQUAboss nX

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

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz–80 MHz outside ISM and amateur radio frequency bands* d = 0.35 √ P**	150 kHz–80 MHz outside ISM and amateur radio frequency bands* d = 1.2 √ P**	80 MHz–2.7 GHz (for defined RF wireless transmitters, see above table) d = 0.6 √ P
0.01	0.04	0.12	0.06
0.1	0.13	0.38	0.19
1	0.4	1.2	0.60
10	1.3	3.8	1.9
100	40	12	6

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

$$E = \frac{6}{d}\sqrt{P}$$

* The ISM bands (stands for industrial, scientific and medical, i.e. the frequency bands used for industrial, scientific and medical purposes) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 to 40.7 MHz. The amateur frequency bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

** Formulas coming from Ed. 3 of the IEC 60601-1-2.

NOTICE!

The AQUAboss nX is an electrical medical device. Special EMC safety measures are required and the system should always be installed in compliance with the EMC information provided here.

NOTICE!

EMC testing covers only the frequencies described in EN 60601-1-2.

Requirements for the AQUAboss nX reverse osmosis system: Production of water for diluting concentrated dialysate per Ph. Eur. and ISO 23500-3, no alarm/error messages and no change in operating mode.

5 Dialysis Mode

Chlorine in potable water can cause harm to the patients and the reverse osmosis system. Daily check of water quality is mandatory.

According to ISO 23500-1 testing for total chlorine should be performed at the beginning of each treatment day prior to the patient's initiating treatment. Where chloramine is used to disinfect the potable water supply at a level of 1 mg/L or more, testing should be repeated prior to beginning of each patient shift; if there are no set patient shifts, testing should be perfromed approximately every 4 h during operation.

Dialysis mode (permeate production) is used to supply the connected dialysis machines. The dialysis machine dilutes hemodialysis concentrate into ready-to-use dialysate.

For more information on the automatically programmed dialysis times, see section 3.12.2.3 Automations (77).

NOTICE!

Disinfection cannot be performed during dialysis.

1. Tap the *Dialysis* ① button in the main menu to start this operating mode.

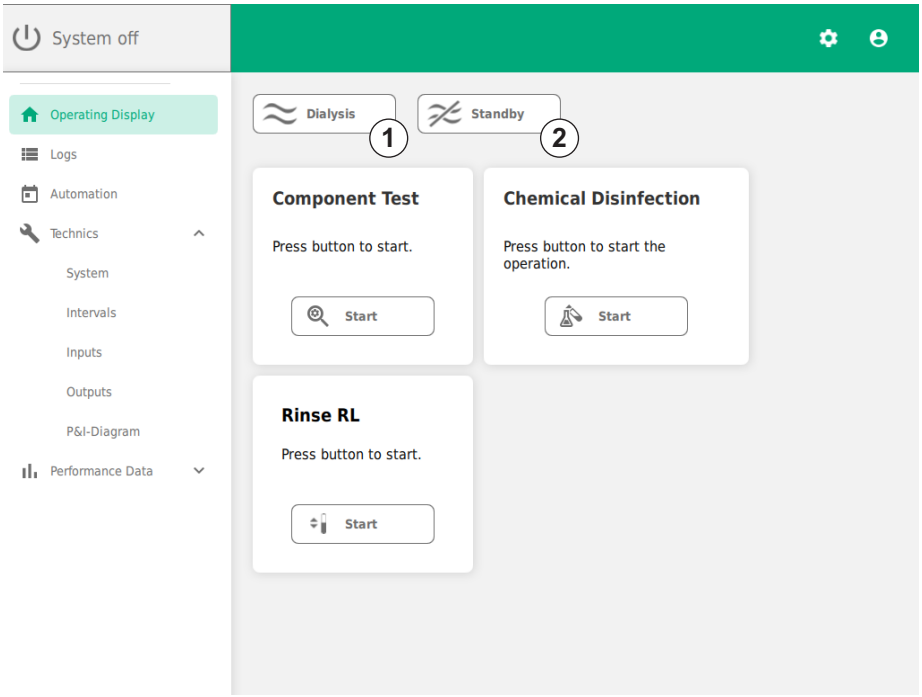


Fig. 5-1 Main menu

- The system fills the supply tank with raw water/soft water, then automatically switches to Dialysis mode.
- The selected operating mode is shown in the top status bar.

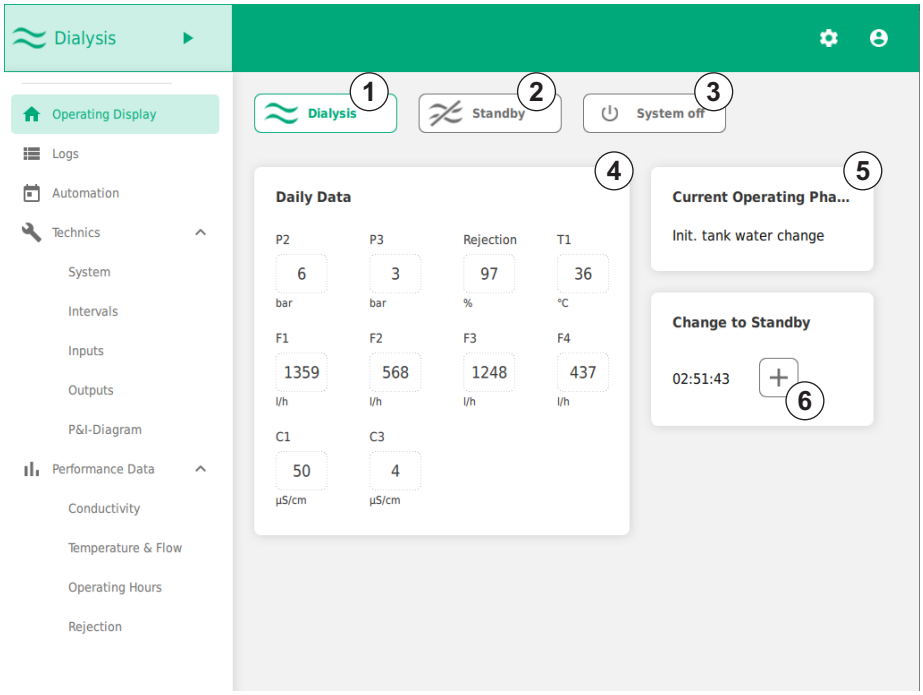


Fig. 5-2 Dialysis menu

If there is any water in the supply tank on system start (e.g., when starting after Standby mode), the supply tank is first emptied. It is then filled with raw water/soft water.

Once the tank is full, the system automatically switches to Dialysis mode. While in this mode all sensor data regarding conductivities, flow rates and temperature and rejection in % are shown. Also the time until next standby is shown if an automation is saved.

The temperature units (°C/°F), pressure units (bar/psi) and conductivity units (µS/cm/ppm) can be changed in display settings, see section 3.12.1.1 General Settings (63).

In Automatic mode, the end of dialysis can be extended manually if necessary.

1. To extend the automation, click on the + button ⑥ in the “Change to standby” group box.

   ↳ The box will extend and show an element in which the desired time can be selected.

2. Click on the Save button to change the end time.

   ↳ This is a one-time change and will not be saved for the next automation.

6 Standby Mode

If permeate is not needed for a prolonged period (e.g., overnight or over the weekend), the system can be switched to Standby mode. In this mode, the system flushes itself and the connected ring piping at preset intervals. This prevents standing water and counteracts the formation of biofilm that can grow between dialysis sessions due to a lack of circulation.

The system will automatically flush the ring piping and the modules at set times. To switch to this mode, turn the system on at the main switch. Tap the *Standby* button or program the Standby mode flushing data during Automatic mode to start Standby mode. To program the Standby mode flushing data, see 3.12.2.3 Automations (77).

NOTICE!

During Standby mode, permeate cannot be extracted from the ring piping and dialysis is therefore not possible.

Tap the *Dialysis* button at any time to switch the machine back to Dialysis mode.

Enabling of the permeate temperature monitor prevents an uncontrolled increase in temperature above a set value.

NOTICE!

Risk of leakage

Activating the temperature rinsing feature will cause the RO system to discard and take in raw water. The system will not monitor for leaks during this time.

Temperature discard OFF:	The temperature monitor responds (see 3.12.5.3 Standby (101)) and any interim flush in progress is interrupted. Once the temperature drops below a programmed lower limit and the configured standby interval has elapsed, the next standby flush begins.
Temperature discard ON:	The water is discarded via Y9 according to the set start and stop values. When temperature flush is on, the system does not monitor for leaks.

The AQUAboss nX can be thermally disinfected in combination with a HRS. The reverse osmosis system must be in Standby mode for this and thermal disinfection must be requested by the HRS. The thermal disinfection can not be started through the AQUAboss nX. The hot water cleaning settings are configured in the Disinfection menu. Thermal disinfection (hot water cleaning) is described in Section 7.2 Disinfection (124) .

Starting Standby Mode:

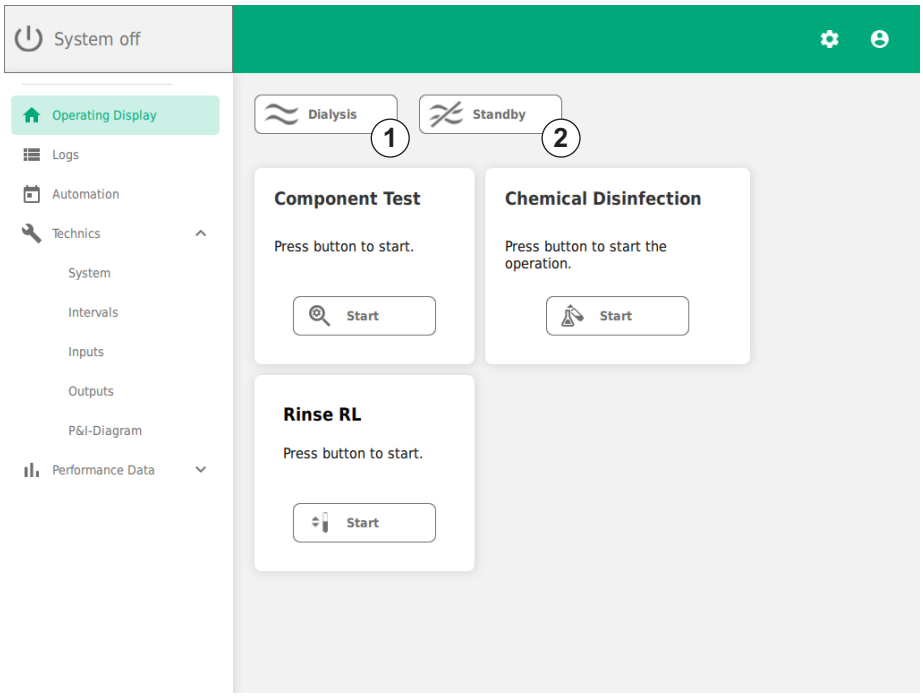


Fig. 6-1 Operating Display

1. Tap the *Standby* ② button to start Standby mode.

   Tapping the Standby button while in Dialysis mode or another operating mode will start Standby mode.

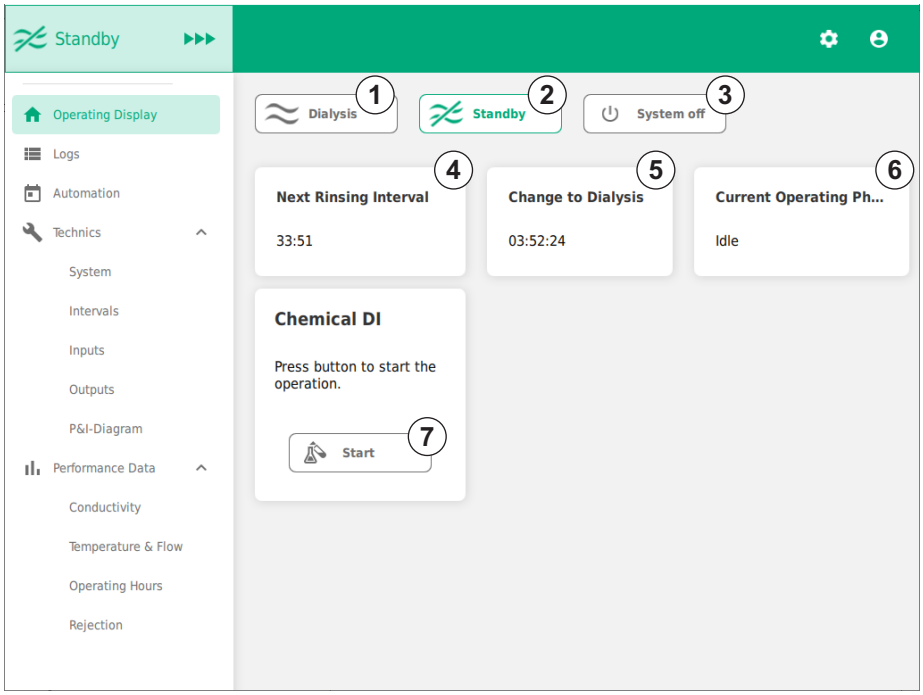


Fig. 6-2 Standby mode

In Standby mode the system will flush the ring piping in defined intervals and duration. The parameters can be changed in the 3.12.1.3 Standby Settings (69) using the gear icon.

7 Disinfection and Cleaning

7.1 Surface Disinfection and Cleaning

7.1.1 Surface Disinfection

⚠ CAUTION!

Risk of skin burns or blindness

- The surface of the system should be regularly cleaned with a suitable cleaning agent.
- When working with liquid disinfectants, it is mandatory to take personal protective measures (gloves, apron, protective goggles).

⚠ CAUTION!

Risk of damage to system from liquid ingress

- Make sure liquid does not get inside the system.
- Do not use too much liquid to wipe down the surface.
- Only use suitable cleaning agents. Instructions and warnings of those cleaning agents must be adhered to.
- Liquids may not get into plugs, sockets or inside the cabinet as liquids may lead to electric shock.

The products in the table below for cleaning and disinfecting surfaces are available from B. Braun. Other products and technical data are available upon request.

Product	Concentration	Manufacturer
Meliseptol rapid	100%	B. Braun
Hexaquart XL	2%	B. Braun
Isopropanol/Ethanol[a] Not for use on the touchscreen!	70%	Various

Tbl. 7-1 Solutions for external disinfection

a. Clean with ethanol (max. 70%), isopropanol (60–70%) based cleaning agents

Cleaning the Display and Housing

⚠ CAUTION!

Electrical stroke or risk of burn if water enters system or plugs.

NOTICE!

Do not use too much liquid to wipe down the display. If necessary, dry it off with a soft cloth.

1. Thoroughly clean the parts of the housing and the display with an approved cleaning agent (see above table).
2. Only use cleaning agents as instructed.
3. Inspect for soil after cleaning and repeat the process until no soil remains visible.

7.1.2 Cleaning the Reverse Osmosis System

Before any disinfection, B. Braun Avitum AG recommends cleaning the membranes with citric acid (e.g., B. Braun 50% citric acid solution). Cleaning is performed using the same procedure as for chemical disinfection and can be started by clicking on the *Start* button in the chemical disinfection tile when the system is OFF (see 7.2.1 Chemical Disinfection (126)). This option is only available when the logged in user has technician rights or higher.

Instead of a disinfectant, a cleaning agent (e.g., B. Braun 50% citric acid solution) is fed.

7.2 Disinfection

NOTICE!

Record all disinfections in the designated log and in the medical devices log, see section 9.3.1 Medical Device Log (150).

NOTICE!

If total viable microbial counts in AQUAboss nX are monitored on a monthly basis, disinfection must be carried out whenever the action limit for the total viable microbial counts is exceeded but at least once a year (after citric acid cleaning). If the reverse osmosis system is monitored less frequently, preventive disinfection on a monthly basis is recommended.

Only trained personnel authorized by the manufacturer should disinfect a B. Braun Avitum AG reverse osmosis system and it is recommended to do so at least once a year. If an elevated germ count is discovered in the permeate, disinfect the reverse osmosis system (action limit: 50 CFU/mL for total viable count and/or 0.125 IU/mL for endotoxins).

The AQUAboss nX is disinfected at the owner's instruction:

- After initial startup and preservative flush.
- As a preventive measure if specified during system validation.
- When the microbial action, warning or alarm limits are reached or exceeded.
- After opening the system for maintenance or repairs, or other structural interventions.

If possible, thermal disinfection of the AQUAboss nX HT reverse osmosis system is preferable to chemical disinfection.

Before Disinfection

To improve the effectiveness of disinfection, make sure the membrane modules are free of organic and chemical contamination. Clean the membrane modules with citric acid first to remove hardness components and iron deposits on the membrane.

For systems that cannot be thermally disinfected by design, disinfect water-bearing parts with disinfectants containing peracetic acid. Chemical disinfectants should conform to EN 1040 (Chemical disinfectants and antiseptics: test procedure for basic bactericidal activity). The following disinfectants (combination treatments) have been approved for disinfecting AQUAboss nX reverse osmosis systems:

- Puristeril® 340 (Fresenius)
- Dialox® (Seppic/Gambro Medizintechnik)
- Peresal® (Henkel Hygiene GmbH)
- Minncare Cold Sterilant (Minntech)

⚠ DANGER!

Chemical disinfection

Risk of acute toxicity during chemical disinfection

- Only perform disinfection at times when dialysis is not taking place. Dialysis should not be possible at these times.
- Prior to starting disinfection, the permeate connection to the dialysis machines must be removed.
- If a softener is used: Softeners should only be operated with a Type BA backflow preventer.
- Take appropriate measures in the treatment rooms to indicate that the reverse osmosis system is being disinfected (see 12.2 Hazard Label (188)).
- There is a risk of acute toxicity if disinfectants or cleaning agents are taken or administered.
- Only clean and disinfect the system with the attending physician's approval.

⚠ CAUTION!

Do not store the disinfectant on top of the reverse osmosis system. Follow the manufacturer's instructions for storing the disinfectant.

The AQUAboss nX has been tested and approved in combination with the approved disinfectants. Record all disinfections in the designated log and in the medical devices log; see 9.3.1 Medical Device Log (150).

When handling disinfectants, observe the disinfectant manufacturer's warnings and wear PPE.

⚠ WARNING!

This system provides a software comfort function for disinfection. Operator is obliged to monitor and record disinfection schedule, disinfection time and concentration and/or temperatures according to the parameters he has determined during validation according to ISO 23500-1 (Preparation and quality management of fluids for hemodialysis and related therapies - Part 1: General Requirements). Filling in the disinfection report for each disinfection is mandatory.

7.2.1 Chemical Disinfection

General Procedure

1. Flush the reverse osmosis system.
2. Fill the supply tank.
3. A concentration of approx. 2.0% commercial disinfectant is required to safely eliminate water-borne bacteria (see Tbl. 7-2 Disinfectant application concentrations (127)). The supply tank is used as the stock solution and the concentration of disinfectant shall not exceed 8% (otherwise the membrane will be damaged). Consult the manufacturer if contamination by fungi/yeast, virus/viral or spore-forming bacteria is verified.
4. The contents of the supply tank will circulate until the entire system has reached a uniform concentration of disinfectant. This can be determined, e.g., by comparing the conductivity levels in the ring piping supply and return.
5. The dwell time (at the final concentration of the disinfectant) is at least 20 min. The exact dwell time needs to be taken from the disinfectant manufacturer data sheet.
6. Following disinfection, flush the reverse osmosis system and ring piping. The following tests are available to specifically check for disinfectant:

   - For H_2O_2 (peroxide test—Merck REF 1011)
   - For peracetic acid (peracetic acid test—Merck REF 110084)
   - For Minncare (Minncare residual test strips—REF LA52821)

To check for disinfectant, test all permeate tapping points individually. B. Braun Avitum AG recommends checking for disinfectant again if the disinfected and flushed reverse osmosis system has not been in use for 30 min.

NOTICE!

Contamination in the water treatment system can cause an unspecified disinfectant reaction that can greatly reduce the concentration of effective disinfectant. In certain cases, the amount of disinfectant needed can differ greatly from the calculated requirement.

NOTICE!

Discoloration of the test strips only indicates that the disinfectant concentration is above the test strip's limit of detection. It cannot be used to determine the concentration of active ingredient.

NOTICE!

The contents of the supply tank need to be mixed thoroughly, since different specific densities of disinfectant and permeate can lead to striations at the bottom of the tank.

WARNING!

Risk of toxicity

- Ensure the permeate at each dialysis station is free of disinfectant after disinfecting and before starting dialysis.

Product	Concentration	pH Level
Puristeril®	3%	2.7
Dialox®	2%	2.8
Peresal®	2%	2.7
Minncare®	1%	3.5

Tbl. 7-2 Disinfectant application concentrations

L/h	Stages	Total RO Liquid Amount [L]	Disinfectants [L]		
			Puristeril® 3%	Dialox® 2% Peresal® 2%	Minncare® 1%
500	2	189	5.7	3.8	1.9
1000	1	125	3.8	2.5	1.3
1000	2	189	5.7	3.8	1.9
1500	1	154	4.6	3.1	1.5
1500	2	247	7.4	4.9	2.5
2000	1	154	4.6	3.1	1.5
2000	2	247	7.4	4.9	2.5
2500	1	183	5.5	3.7	1.8
2500	2	305	9.2	6.1	3.1
3000	1	183	5.5	3.7	1.8
3000	2	305	9.2	6.1	3.1
3500	1	212	6.4	4.2	2.1
3500	2	363	10.9	7.3	3.6
4000	1	212	6.4	4.2	2.1
4000	2	363	10.9	7.3	3.6

Tbl. 7-3 RO disinfectant application concentrations

The following table applies only when the reverse osmosis system is used with a B. Braun Permeate Ring Piping.

RL Linear Meters at 25 mm Inner Diameter	RL Volume [L]	Disinfectants [L]		
		Puristeril® 3%	Dialox® 2% Peresal® 2%	Minncare® 1%
50	24.5	0.7	0.5	0.25
100	49.1	1.5	1.0	0.5
150	73.6	2.2	1.5	0.74
200	98.2	2.9	2.0	1.0
250	122.7	3.7	2.5	1.23
300	147.3	4.4	2.9	1.5
350	171.8	5.2	3.4	1.72
400	196.3	5.9	3.9	2.0

Tbl. 7-4 RL disinfectant application concentrations

NOTICE!

Drinking water contamination

- Before starting disinfection, make sure the softener and reverse osmosis system are only being operated with a Type BA backflow preventer.

NOTICE!

Only use the disinfectants approved by B. Braun Avitum AG.

Instructions

To follow these instructions, you need to be logged in as a user in the Admin or Technician user group in order to perform a chemical disinfection.

1. Tap the Operating Display Option in the side panel.
2. Tap the *Start* button in the chemical disinfection tile (the tile is visible only if the logged in user has the required rights).
3. Check the disinfection settings. If any settings need to be edited, click on the *Edit* ⑤ button. If the settings are correct, click on *Continue* ⑥ .

1 Recirculation Time
2 Reaction Time
3 Flushing Time
4 Return to previous screen
5 Edit values
6 Continue with chemical disinfection

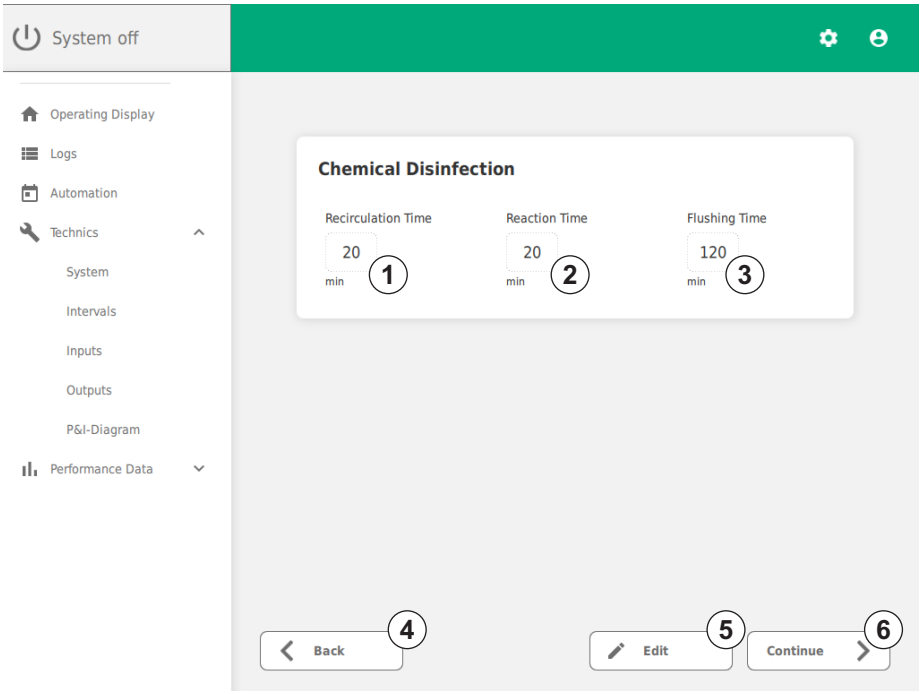


Fig. 7-1 Disinfection main menu

4. Before the chemical disinfection can be started safety precautions must be completed. The responsible persons must be informed about the disinfection, the dialysis machines must be disconnected and the system must be clearly marked for disinfection. After completing the items in the checklist and checking off the boxes, tap the *Start* ③ button.

1 Required safety precautions
2 Return to previous screen
3 Start chemical disinfection

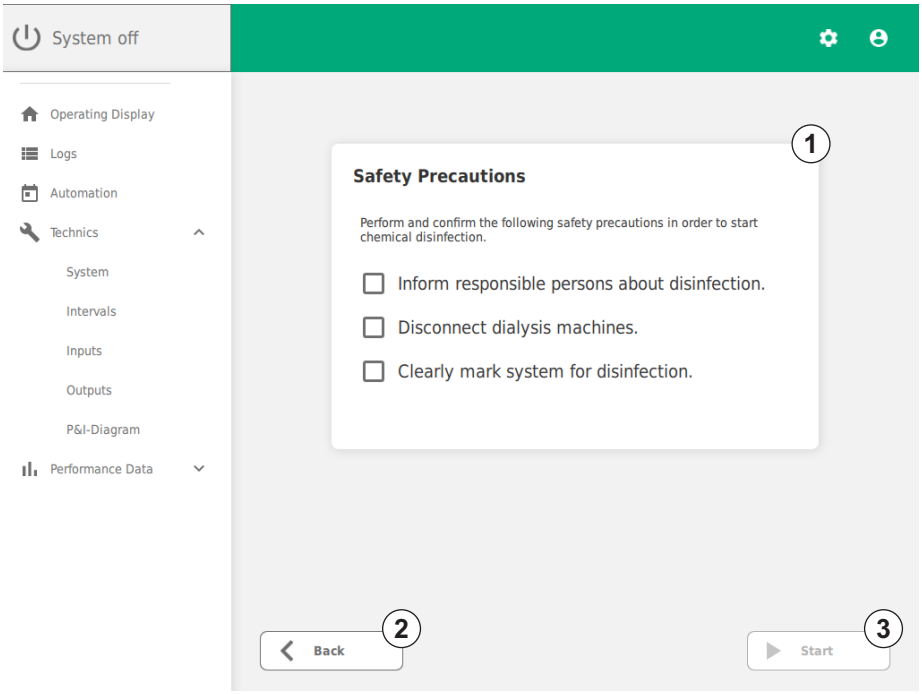


Fig. 7-2 Disinfection safety precautions

5. Click on *Confirm* ② in the pop up window.
   ↳ Chemical disinfection starts.

1 Return to previous screen

2 Confirm start of chemical disinfection

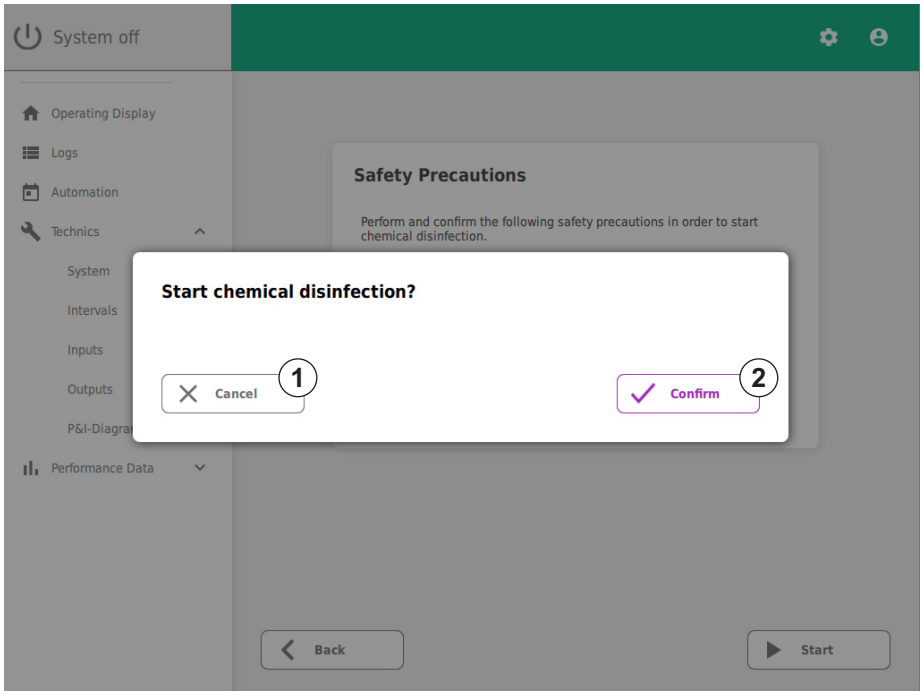


Fig. 7-3 Chemical disinfection prompt

While the program runs, users in the Admin or Technician user group can skip phases.

6. Once disinfection starts, the first step is a check of the supply tank level. If the supply tank is full, it is first emptied until value for parameter Tank level empty is reached. The value for Tank level empty can be edited in the Dialysis Settings using the gear icon before starting the disinfection.

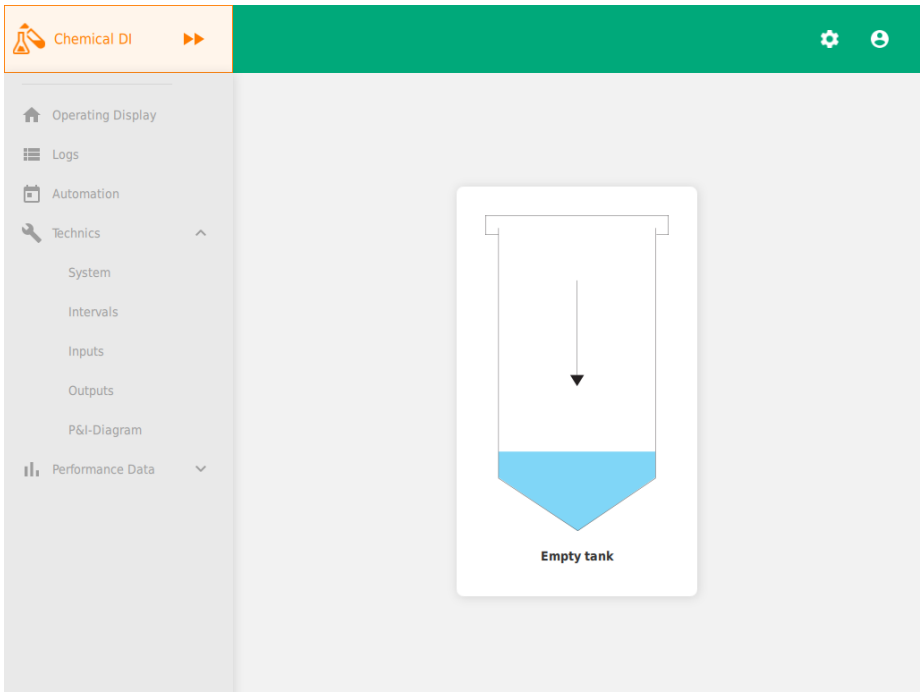


Fig. 7-4 Emptying supply tank

7. A dialog window appears prompting you to add the disinfectant. Add the disinfectant to the supply tank and tap the *Confirm* ① button.
   - The tank is now filled until tank level full is reached.
   - The system then switches to recirculation mode.

1 Confirm that disinfectant was added

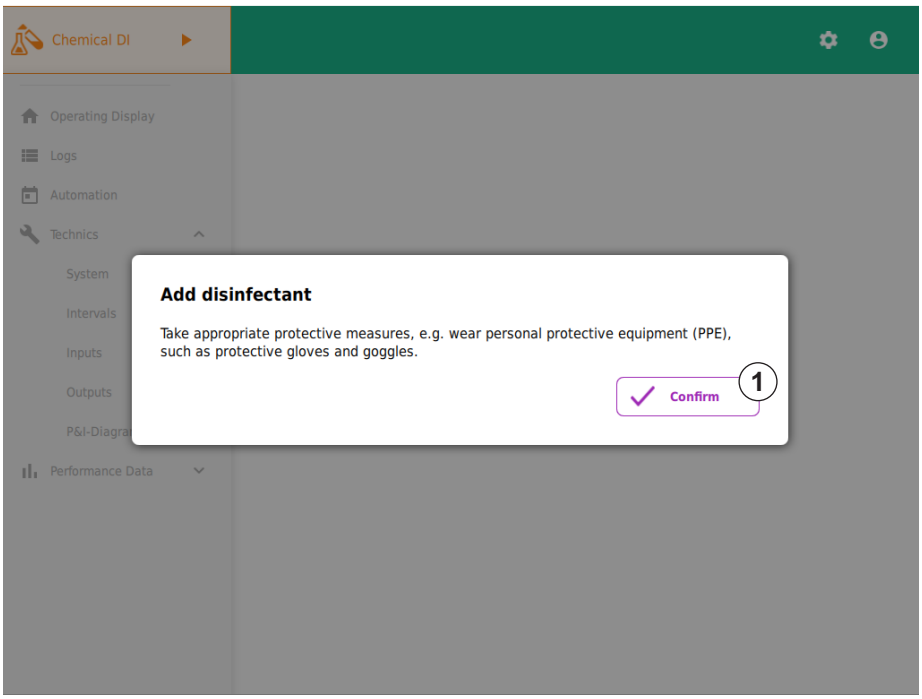


Fig. 7-5 Adding disinfectant

Only disinfectants and quantities listed by B. Braun Avitum AG must be used for disinfection.

8. During Recirculation mode, the disinfectant is distributed in the device and ring piping.
   - The *Skip* ① button allows disinfection steps to be skipped.

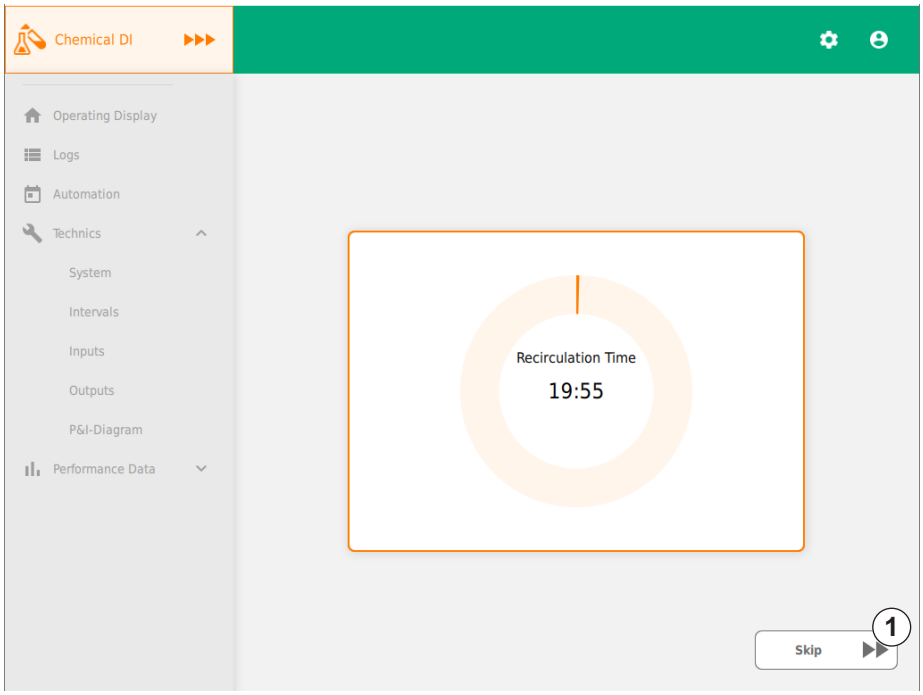


Fig. 7-6 Recirculation

9. After recirculation time has elapsed, the system switches to Reaction mode.

1 Skip Reaction time (only Technicians)

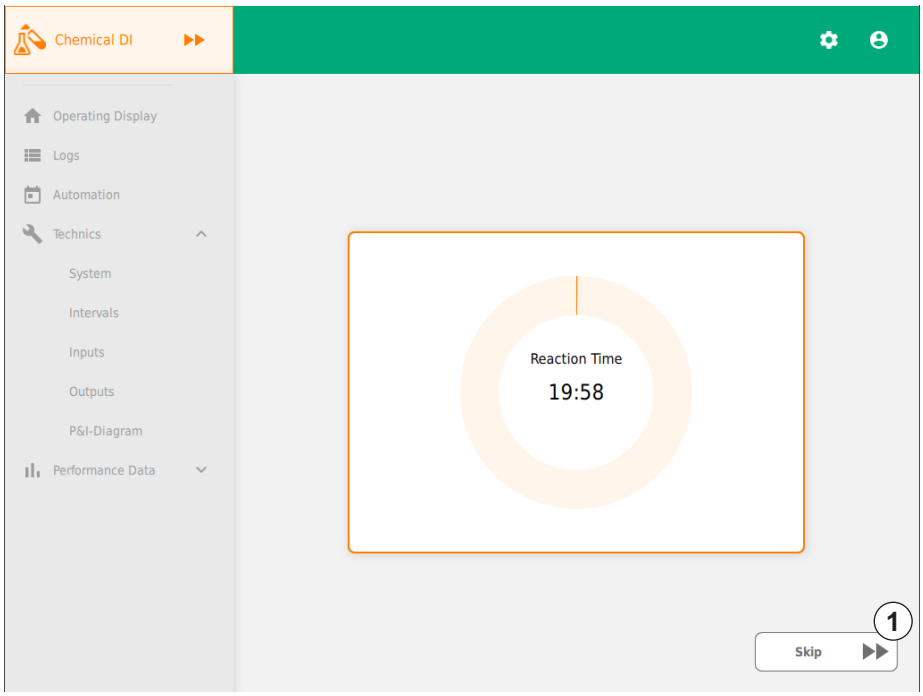


Fig. 7-7 Reaction

10. After the reaction time has elapsed, the screen will display the request to open the sampling tap. After opening the sampling tap, tap on *Confirm* ①.

    ↳ While this is being displayed, the Flushing mode runs in the background.

1 Confirm sampling tap was opened

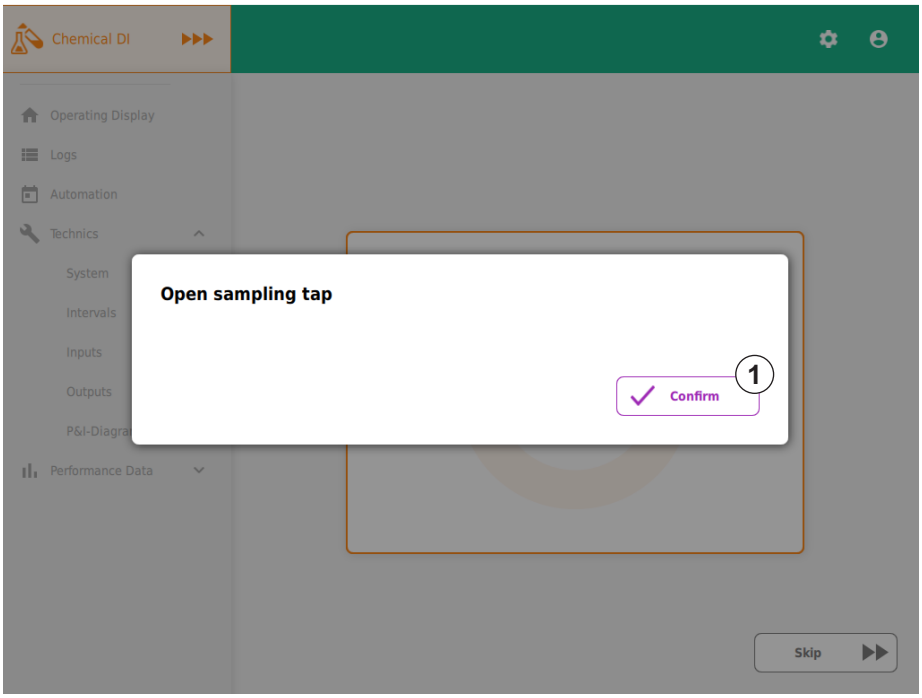


Fig. 7-8 Open Sampling Tap

11. After reaction time has elapsed, the system switches to Flushing mode. The time remaining is shown on the display.

    ↳ Flushing occurs in alternating stags of filling the tank, pulsing the solenoid valves involved, then completely emptying the tank.

1 Skip Flushing time (only Technicians)

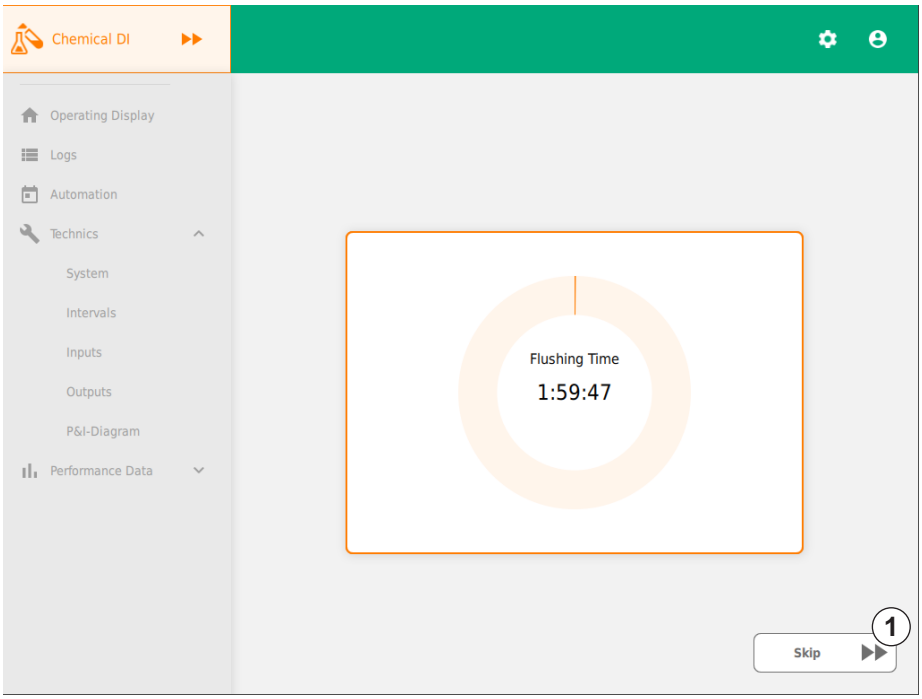


Fig. 7-9 Flushing

NOTICE!

Make sure local discharge regulations for wastewater containing disinfectant are observed.

12. The query below is displayed 15 minutes before the end of Flushing mode. Check for disinfectant in the system.
    - If there is no disinfectant remaining the system, tap the *Confirm* ② button.
    - Tap the *Cancel* ① button if there is still disinfectant in the system which returns the system to Flushing mode.

1 Cancel if there is disinfectant

2 Confirm if there is no disinfectant

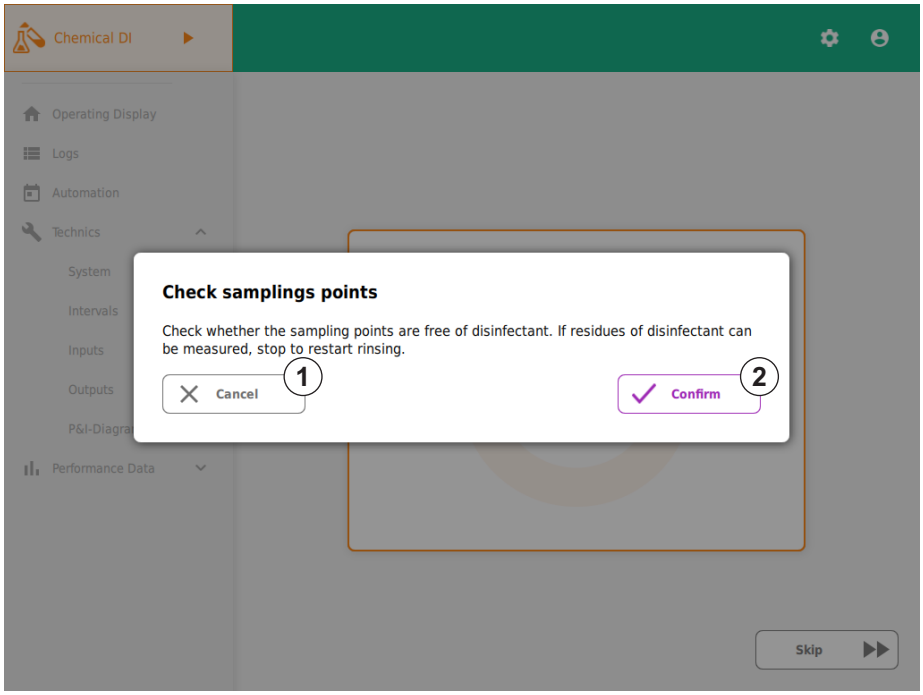


Fig. 7-10 Verification prompt

13. Close the sampling valve.
14. Press the F1 and F2 keys at the same time to end chemical disinfection. If the buttons are not pressed within 60 seconds the system automatically returns to the previous dialog.

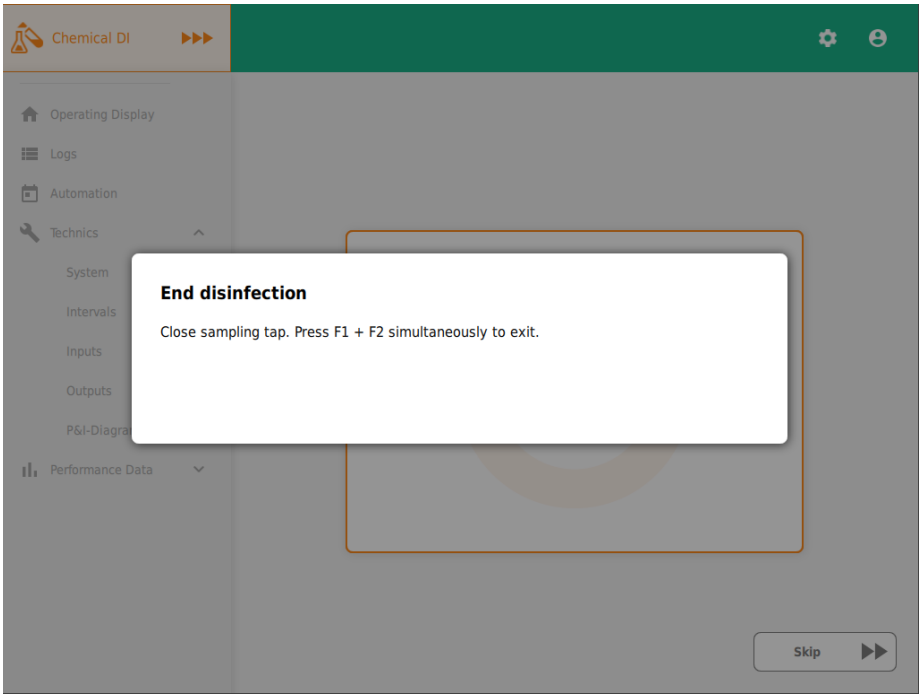


Fig. 7-11 Ending chemical disinfection

7.2.2 Thermal Disinfection

RO system with the HT addition can be thermally disinfected. For this, an HRS is required and it can only be performed in Standby mode.

Thermal disinfection has to be configured in the HRS, as the AQUAboss nX only provides the water. Thermal disinfection is started automatically when the signal is sent from the HRS and the next Dialysis mode on the RO is still at least 2 hours away.

In the disinfection settings (gear icon), the parameters for a successful thermal disinfection can be changed. It is also possible to disinfect the RO as well, or only the ring piping.

The thermal disinfection parameters have to be set on the HRS.

The RO is only disinfected with a maximum of 85 °C. The HRS automatically bypasses the RO above 85 °C. The Ring Piping is still disinfected with 90°C.

If a thermal disinfection is running, this is indicated on the display. The current operating temperature, duration and A0 value are displayed. The desired A0 value can be set on the AQUAboss nX.

The A0 value is calculated by the following formula from ISO 15833-1 as soon as T1>= 70°C: A0 = $\sum 10^{[(T1-80)/10]} \Delta t$

⚠ WARNING!

Risk of toxicity from dissolved structural materials and destruction of components

- Only original materials resistant to up to 90 °C should be used.

⚠ WARNING!

During thermal disinfection the system can reach up to 85 °C. Some parts of the system can become hot. Do not touch any metal parts or any parts that are marked with the “Hot Surface” label.

NOTICE!

ISO 15883-1 prescribes for an A0 value of 600 a dwell time of 10 min at a temperature of 80 °C. Lower temperatures require longer heating stages in order to kill off most vegetative bacteria, yeast, fungi and viruses (see ISO 15883-1 "Washer-disinfectors – Part 1: General requirements, terms and definitions, and tests").

i For effective thermal disinfection ring piping must be insulated against waste heat.

Stopping Thermal Disinfection

Thermal disinfection can be stopped at any time by tapping the Dialysis or Standby buttons. If the temperature is lower than what is set for cooldown when the Dialysis button is tapped, the system switches to Dialysis mode. If the temperature is higher, the cooldown stage begins and the system only switches to Dialysis mode once it has dropped below the cooldown temperature.

Tapping the Standby button begins cooldown by feeding fresh supply water into the system. Once the cooldown temperature is reached, the system switches to Standby mode.

A stopped/canceled hot water disinfection is not considered completed and is hygienically inefficient.

8 Alarms and Troubleshooting

8.1 Emergency Modes and Blocking State

Dialysis, Standby and System Off Emergency Mode

During emergency mode with only 2nd stage running, it is advised to open valve K4 at the tank to prevent overflowing of the tank.

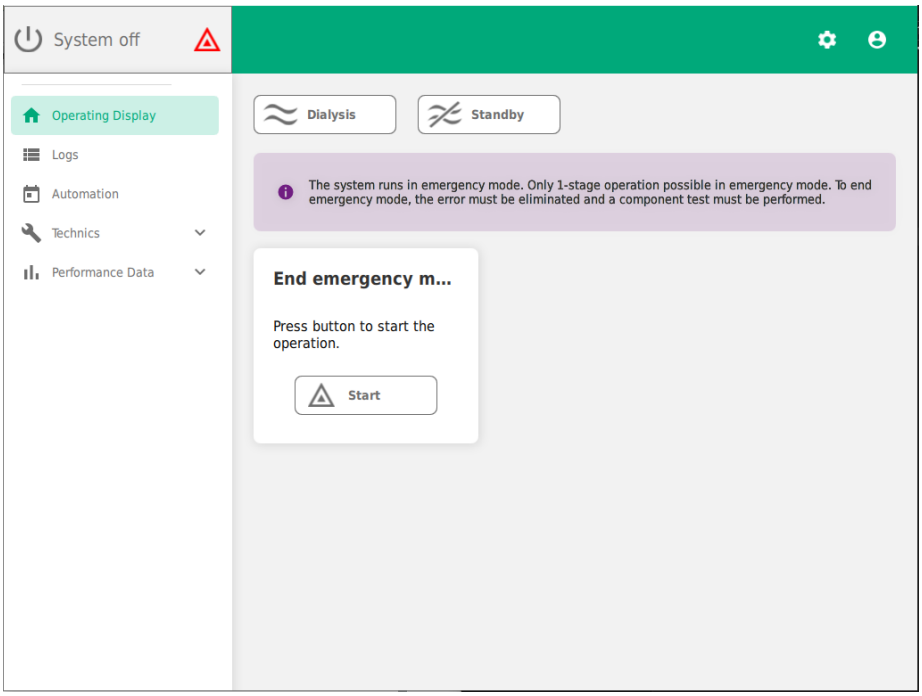


Fig. 8-1 Emergency Mode Operation

When an error occurs in a double stage system that only affected one of the two stages, the working stage can continue running in emergency mode. When emergency mode is possible, it can be started by clicking on the emergency mode button in the error dialog or component test.

An active emergency mode is indicated by an emergency icon in the operating indicator in the upper left corner of the touchscreen.

The emergency mode can be ended by solving the issue and successfully completing a component test.

Blocking state

The RO enters a blocking state when the failing components do not allow for emergency mode operation or emergency mode is not desired. The RO then stays in System Off until the issue is solved or emergency mode is started through a component test.

The Blocking state is indicated by a red error message in the operation display screen and a red flashing LED2.

The Blocking state can be ended by solving the issue and successfully completing a component test.

Display Emergency Mode:

When the display or touchscreen stops working, the emergency switch on the right side of the control cabinet in the upper right corner can be pressed. The switch lights up when it is activated.

When activated, the RO can be switched between Dialysis mode and Standby mode by pressing F1 for Dialysis and F2 for Standby, if the last operating mode allows it.

8.2 Fault Messages

If a fault is detected in the system, the alarm/error with fault number and a brief description of the fault will appear in a pop up dialog. The yellow control cabinet LED will light up in if it is an alarm and the red LED will light up if it is an error.

In case of an error, an audio signal is activated in addition to the LED signal. At a distance of 30 cm from the system, the volume of the audio signal is 85 dB. As soon as an alarm/error is detected, it is simultaneously transmitted via the alarm relay to the distributed alarm system, if connected.

If an error or alarm is confirmed but the cause is not solved, the dialog will pop up again at the start of the following day.

8.2.1 ALARM

When there is a deviation from normal operation that impairs the system's performance, the system attempts to remedy the alarm through the control system.

Alarm Indication

- The display shows the fault message as a dialog with yellow border.
- The yellow LED on the control cabinet turns on and flashes.
- With the alarm relay, a message can be sent to the higher-level system, e.g., a host system.

The first alarm message is retained, even if subsequent alarms occur. An error always has priority and overwrites an alarm.

The alarm is automatically reset once the cause has been remedied.

8.2.2 ERROR

The system automatically shuts off.

Error Indication

- The display shows the fault message dialog with a red border.
- The red LED on the control cabinet turns on and flashes.
- With the alarm relay, a message can be sent to the higher-level system, e.g., a host system.
- An audio signal is active.

The first error message persists even if subsequent faults occur. An error always has priority and overwrites an alarm.

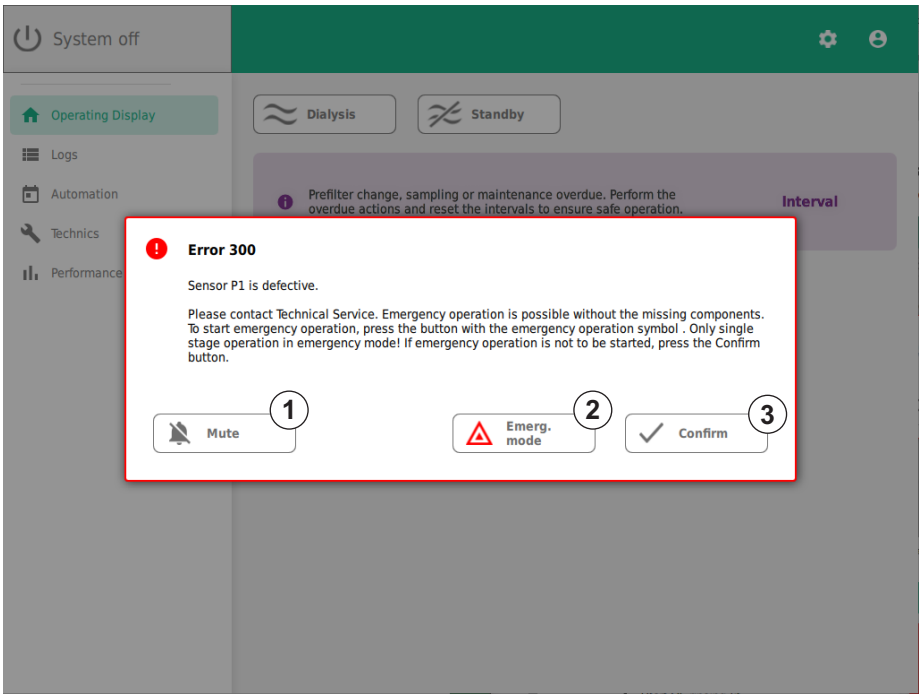


Fig. 8-2 Error 300 Pop Up

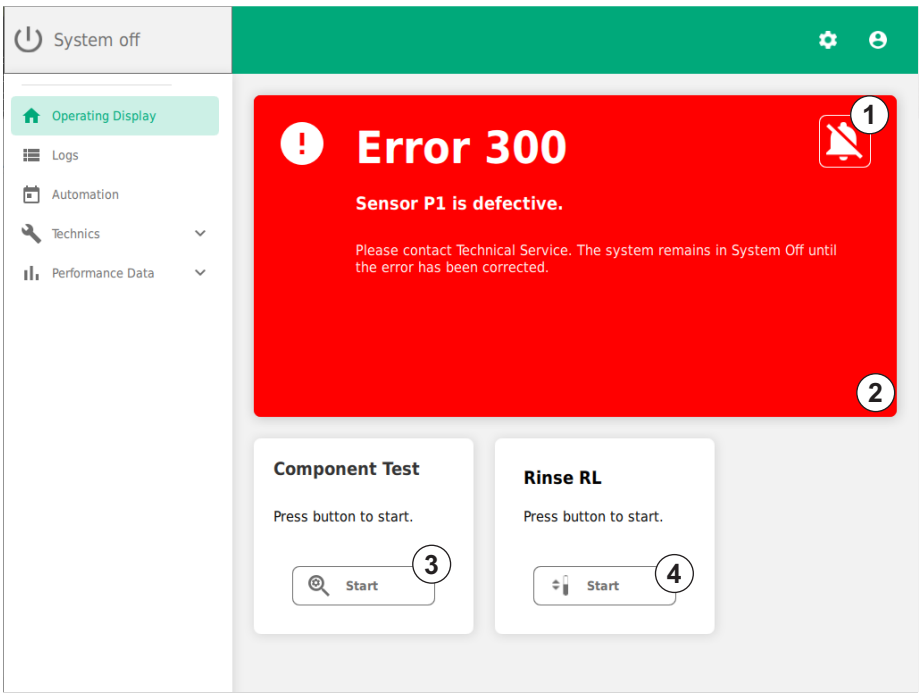


Fig. 8-3 Information about error after confirmation

When an error occurs in a double stage system and the failed component test allows it, an emergency single stage mode can be activated. For more information see 8.1 Emergency Modes and Blocking State (137). If this is not wanted or the system is a single stage system, it will switch to a Blocking state, see Blocking state (137).

After the error is remedied, a component test has to be completed successfully to leave the Blocking state.

8.3 Troubleshooting

8.3.1 Fault Code

Fault No.	Fault Text	Cause/Remedy
100	Time recording is defective or data transmission to time recording is interrupted. The automatic operation is deactivated.	Please contact Technical Service.
101	The configuration file could not be read.	Please restart the system. If the problem persists, contact Technical Service.
102	The monitoring processor is defective.	Please contact Technical Service.
103	The operating status could not be detected.	Please restart the system. If the problem persists, contact Technical Service.
104	F1 or F2 key pressed for longer than 30 s.	Ensure that the keys are not pressed for longer than 30 seconds. If the error persists, contact Technical Service.
105	Safety circuit is defective.	Please contact Technical Service.
106	Invalid mode change from chemical disinfection.	Please contact Technical Service.
107	Safety circuit is open.	Please contact Technical Service.
108	Safety circuit is open.	Please contact Technical Service.
109	MMI has been reset.	Please restart the system. If the problem persists, contact Technical Service.
120	Invalid configuration of monitoring processor	Ensure that the DIP switch is set correctly. If the error persists, contact Technical Service.
200	Prefilter change, sampling or maintenance overdue. Perform the overdue actions and reset the intervals to ensure safe operation.	Perform the overdue action and confirm on the Intervals screen.
201	Prefilter change, sampling or maintenance overdue. Perform the overdue actions and reset the intervals to ensure safe operation.	Perform the overdue action and confirm on the Intervals screen.
202	Prefilter change, sampling or maintenance overdue. Perform the overdue actions and reset the intervals to ensure safe operation.	Perform the overdue action and confirm on the Intervals screen.
300	Sensor P1 is defective.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.

Fault No.	Fault Text	Cause/Remedy
301	Sensor P2 is defective.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
302	Sensor P3 is defective.	Please contact Technical Service.
303	Switch PS1 is defective.	Please contact Technical Service.
304	Sensor P3.2 is defective.	Please contact Technical Service.
310	Sensor F1 is defective.	Please contact Technical Service.
311	Sensor F2 is defective.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
312	Sensor F3 is defective.	Please contact Technical Service.
313	Sensor F4 is defective.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
320	Sensor T1 is defective.	Please contact Technical Service.
330	Sensor C1 is defective.	Please contact Technical Service.
331	Sensor C3 is defective.	Please contact Technical Service.
332	Sensor C4 is defective.	Please contact Technical Service.
340	Valve Y5.1.1 is defective.	Please contact Technical Service.
341	Valve Y11 is defective.	Please contact Technical Service.
342	Valve Y12 is defective.	Please contact Technical Service.
343	Valve Y8 is defective.	Please contact Technical Service.
344	Valve Y9 is defective.	Please contact Technical Service.
345	Valve Y10 is defective.	Please contact Technical Service.
350	Frequency inverter FU1 is defective or has an error.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
351	Frequency inverter FU2 is defective or has an error.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
352	Frequency inverter FU3 is defective or has an error.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.

Fault No.	Fault Text	Cause/Remedy
353	Frequency inverter FU4 is defective or has an error.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
371	The circuit breaker of the 2nd stage has been tripped.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
380	Switch GS1 is open or defective.	Check whether the tank cover is closed. If the problem persists, please contact Technical Service.
390	Emergency operation was not acknowledged within the specified time.	Please contact Technical Service and, if necessary, acknowledge emergency operation.
401	Lower tank level reached.	Please wait, tank is being filled.
402	Tank could not be filled sufficiently.	Please restart the system. If the problem persists, contact Technical Service.
403	Pressure in 2nd stage too low.	Please wait. Pressure is being built up.
404	Sufficient pressure in 2nd stage could not be built up.	Please contact Technical Service. Double stage systems can continue to be operated in emergency mode.
405	Pressure at the ring piping end is very low.	The reason for this may be very high permeate consumption.
407	Pressure at the ring piping end is very high.	The reason for this may be very large fluctuations in permeate consumption.
408	Overpressure in ring piping.	Please restart the system. If the problem persists, contact Technical Service.
414	Insufficient discard.	Please restart the system. If the problem persists, contact Technical Service.
416	Unforeseen water loss.	Check system and ring piping for leakage and connected devices.
417	Unforeseen water loss detected by water detector.	Check system and ring piping for leakage and connected devices.
420	System water is warm. Temperature discard is started if necessary.	Wait until the set water temperature is reached.
421	System water is too hot.	Rinse ring piping ("Rinse RL") or allow system to cool down.
430	Permeate conductivity above alarm value.	Permeate line is rinsed.
431	Permeate conductivity above the error value.	Rinse ring piping ("Rinse RL") or contact Technical Service.

Fault No.	Fault Text	Cause/Remedy
433	Deviation of conductivity control too large.	Rinse ring piping ("Rinse RL") or contact Technical Service.
434	Hardwater breakthrough detected.	Contact the technical service and activate hard water operation if applicable.
440	Pressure in the water inlet is low.	Check prestage.
500	There was an interruption during disinfection. Effectiveness of disinfection not ensured.	Please repeat disinfection.
520	Temperature too high.	Allow the system to cool down.
521	A0 value was not reached. Effectiveness of disinfection not ensured.	Please check thermal disinfection settings.
522	Temperature too high after thermal disinfection.	Allow the system to cool down.
540	No discard via 2nd stage.	Check whether valve Y8 opens.
541	Permanently no discard via 2nd stage.	Please contact Technical Service.

8.3.2 Other Faults

Fault	Cause	Effect/Remedy
Supply tank empty	• Water supply • Y10	• Check water supply and pretreatment
Pump making noise	• Not enough water in supply tank • Fill level below "Tank level empty" parameter, air can be suctioned and cause knocking and vibrating sounds	• Shut off pump • Let supply tank fill to "Tank level empty" parameter • Switch on pump
Pump not pumping	• Motor protector defective • Pump defective	• Check motor contactor • Check pump • If fault not found, contact technical service
Ring piping pressure too high	• Shutoff valve closed • ÜV1 defective or closed • Ring piping pressure greater than set pressure for Pressure Switch PS1	• Open closed shutoff valve • Check ÜV1

Fault	Cause	Effect/Remedy
Ring piping pressure too low	• Permeate consumption too high • Permeate production too low	• Check produced permeate quantity • Check ring piping for leaks
Display not working	• MMI defective • Display unit defective	• Device keeps working in automatic mode • Manual mode switches can be done when emergency switch on the side is pressed (see Display Emergency Mode: (138)) • Device can be turned on and off at the main switch • Contact technical service

9 Preventive Maintenance and Technical Safety Inspection

The functional safety of the reverse osmosis system can only be maintained when the medical devices log is properly kept and made accessible to the technician during the TSC/maintenance.

The AQUAboss nX is a low-maintenance system:

- If the system is operated with an upstream softener, make sure soft water is always provided. The soft water should be tested regularly.
- Compare the conductivity levels with a portable measuring instrument on a monthly basis.
- Replace the prefilter every 4–8 weeks. A reminder can be programmed under Section 3.12.2.4.2 Intervals (84).
- The alarms 200, 201 and 202 can be reset via the menu Technics > System > Intervals, see section 3.12.1.6 Service Settings (71).
- Replace the ventilation filter (tank ventilation) once per year.
- All log data (fault history, user and operating logs) can be transferred to the flash drive. For more information, see section 3.12.2.4.1 System (79).
- The installed software does not need maintenance.
- The device is not intended to be serviced while in use with a patient.

⚠ WARNING!

Non-compliance with safety testing procedures can lead to serious injuries and functional failure of the system.

Follow the instructions on specific checks of your system in Section 9.2 Specific Checks for Your System (148).

Keep the medical devices log (see Section 9.3.1 Medical Device Log (150)) up to date.

Follow the instructions on maintenance and TSCs in the TSC supplement to the Service Manual.

⚠ WARNING!

Risk of component failure from lack of maintenance and TSCs

The reverse osmosis system may become inoperable and result in permeate unavailability.

- An expert authorized by B. Braun Avitum AG will perform a TSC every second year.

⚠ WARNING!

Risk to patient due to system failure or failure to meet permeate requirements

- Following maintenance, repairs, replacement of components or other changes, the owner should provide documentation that the system conforms to the original specifications (permeate quality, material compatibility).

The manufacturer will make available circuit diagrams, component part lists, descriptions, calibration instructions or other information that will assist service personnel to repair those parts of the device that are designated by the manufacturer as repairable by service personnel, on request.

⚠ WARNING!

Risk of toxicity and pyrogenic reactions

Even if the reverse osmosis system produces water of a quality that meets the requirements of the international standard DIN EN ISO 23500-2, the distribution of this water can degrade its quality to such a degree that it no longer meets the requirements of DIN EN ISO 23500-2 if the distribution system is not properly maintained.

- The reverse osmosis system and connected distribution system should be maintained/checked according to the manufacturer's instructions.

⚠ WARNING!

Risk of toxicity and pyrogenic reactions

Failure to comply with the manufacturer's maintenance and disinfection specifications can result in degraded permeate quality or reduced system function.

NOTICE!

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

9.1 Functional Safety

⚠ WARNING!

The pipes in the system are pressurized.

Opening fittings or valves can result in injury.

- Depressurize the pipes before working on the system.
- Use personal protective equipment.

Operational Safety

- Experts authorized by B. Braun Avitum AG will perform a technical safety check (TSC) every second year.
- Inadequate feed water quality can result in inadequate and unacceptable product quality (see 2.13.3 Water Quality Requirements (32)).
- If the system is unexpectedly at a standstill, do not immediately switch to a different operating mode; it may have been stopped for manual intervention. Starting the system back up suddenly can result in serious injury.
- The pipes in the reverse osmosis system are pressurized. Opening fittings or valves can result in injury.
- If the product being processed is harmful to health, avoid coming into contact with it. If this happens regardless, begin first aid procedures.
- Conductivity levels, etc. should be logged daily per 9.3.1 Medical Device Log (150).
- Do not allow the pump to run while dry.
- Do not modify, remove, bypass or bridge safeguards.
- Portable and mobile HF communication equipment can affect electrical medical devices.

⚠ WARNING!

Only operate the system with the control cabinet closed.

⚠ WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AQUAboss nX, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

9.2 Specific Checks for Your System

This form contains specifications from the manufacturer regarding specific checks that have been specially determined for your system. These specific checks should be performed at the specified intervals.

In addition to this, the medical devices log should be kept up to date and the maintenance and TSC measures performed and logged. For more information, see Section 9.3.1 Medical Device Log (150).

Specific Checks to Perform	Description	Interval	Comments

9.3 Medical Device Log and TSC Log Book

The owner of the AQUAboss nX reverse osmosis system should keep a medical devices log.

A medical devices log provides important information on the functionality of the reverse osmosis system, which is why it should be kept near the machine.

The functional safety of the reverse osmosis system can only be maintained when the medical devices log is properly kept and made accessible to the technician during the TSC/maintenance.

Complete and correctly kept log books are essential for determining the type of maintenance and checks that need to be periodically performed.

For every check performed, the type of check, the date it was performed and the person who performed it need to be entered in the proper log book.

These instructions for use contain templates for a medical devices log and an operating log. Copy these pages as often as you need.

9.3.1 Medical Device Log

The medical devices log for the AQUAboss nX contains information about the system as well as an operating log.

	System Information	
1.	Description/System Type	
2.	Serial No.	
3.	GMDN Code	14-437
4.	Owner Handover Date	
5.	Names of Trained Persons (in Print)	
6.	Function Tests	Per operating log
	i Interval	Daily
	ii Authorized	Trained personnel from 5 Trained personnel from B. Braun Avitum AG
7.	Technical Safety Checks	Per TSC list
	i Interval	Annually
	ii Authorized	Trained personnel from B. Braun Avitum AG
8.	Malfunctions	See entries in operating log
9.	Incident Reports to Authorities and Manufacturer	See entries in operating log

Operating Log

The system's performance should be recorded daily in the medical devices log, including all operating conditions.

Serial No.: _____

Month/Year: _____

Date	Pretreatment: Free Chlorine	Pretreatment: Hardness (°dH °fH)	C3 Permeate Conductivity (µS/cm)	C1 Raw Water Conductivity (µS/cm)	F1 Flow in L/h	F2 Flow in L/h[c]	F4 Flow in L/h[b]	Temperature in °C T1	Rejection in %	Comments[a]	Initials
01											
02											
03											
04											
05											
06											
07											
08											
09											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
22											
23											
24											
25											
26											
27											
28											
29											
30											
31											

a. Including malfunctions, consequences of malfunctions, operator errors, incidents.
b. Only available in double stage systems
c. Only available in double stage systems

9.3.2 Maintenance and TSC Log Book

All maintenance and TSCs performed on the system should be recorded in the maintenance/TSC log book.

TSCs should be performed every year.

Serial No.: .....

Maintenance Performed	Date	Runtime in h	Description of Maintenance, Comments	Initials

9.4 Cleaning Report

Customer Details

Order number:	
Customer:	
Address:	
Zip code/city:	

Customer's Competent Person

Name			
Company			
Phone		**E-mail:**	

Cleaning Carried Out By

Name			
Company			
Phone		**E-mail:**	

Reason for Cleaning

☐ Handover by installation ☐ Modification/extension ☐ Modification/extension ring piping

☐ Maintenance ☐ Other

Other: _____

Cleaning

1. Inform the customer's competent person of the cleaning. ☐
2. Disconnect all dialysis machines. ☐
3. Clearly mark that the system is operating in cleaning mode. ☐
4. Check Hydrowatch on the surge tank. The red indicator shall not be visible. ☐

Cleaning is carried out on system type:

☐ Reverse Osmosis Type:		Serial No.:
☐ Heating System Type:		Serial No.:
☐ Ring Piping Type:	☐ Stainless steel ☐ PEX ☐ PVC ☐ T-Pieces ☐ Bulbs	
	Length of loop:	Manufacturer:

	Before cleaning	After cleaning	Unit
Permeate conductivity			µS/cm / TDS
pH value of concentrate			-
Permeate per hour			l/h / gpm
Temperature of permeate			°C / °F

Detergent used					
Expiry date:		Concentration:		Quantity:	
Circulation time:		Reaction time:		Flushing time:	

The conductivity of the permeate is the same or less than before the cleaning) max. ± 3 µS/cm / TDS). ☐

The pH value of the concentrate is about the same (± 0.1 pH) as before. ☐

NOTICE!

It is required to carry out a disinfection on the whole system after a cleaning. This includes the reverse osmosis system, the Hot Rinse SMART 10-50 and the whole ring piping, including secondary loops, etc.

Cleaning Details

Start time of cleaning: _____

End time of cleaning: _____

Place, date: _____

Signature technician: _____

Signature customer: _____

9.5 Disinfection Report

Order by Customer

Disinfection ordered by/Name	
Customer/Order number	
Street	
Zip Code	

⚠ WARNING!

Before the next dialysis treatment is carried out, ensure again that the test for residual disinfectant is negative.

NOTICE!

To prove effectiveness of the disinfection a bacterial test in the permeate is recommended within 5 – 7 days.

Analysis: An analysis of microbiological tests and endotoxins has to be carried out according to ISO 23500-3.

NOTICE!

Samples must be kept cool and be couriered to the lab within 6 hours.

The customer acknowledges that they have to ensure all tapping points are tested again for residual disinfectant before connecting patients to dialysis machines.

_____

Signature Customer

Carry Out by Technician

Disinfection carried out by:		Date:	

Execution:

1. Inform the customer's competent person of the disinfection (signature above). ☐
2. Disconnect all dialysis machines. ☐
3. Clearly mark that the system is being disinfected. See the Danger Card in the IFU. (Art. No.: LA53264) ☐
4. Check Hydrowatch on the surge tank. The red indicator shall not be visible. ☐
5. Cleaning is carried out using program mode "C". ☐ n/a ☐
6. Disinfection is carried out using program mode "D" or "DI". ☐

Disinfection is carried out on system type:

Reverse Osmosis Type:	Serial No.:
Ring Piping: m	SS ☐ PEX ☐ T-Pieces ☐ Bulbs ☐
Number of Tapping Points:	

9

Disinfectant used:

Type of disinfectant:	
Quantity added:	Reaction time:
Expiry date:	Circulating time:
Concentration (see IFU):	Flushing time:
Residual disinfectant test: 1. H_2O_2 (Peroxide test – Merck Art. No. 10011) Art. No.: 34200398 ☐ 2. Peracetic acid (Peroxyacecid test – Merck Art. No. 110084) Art. No.: 34200399 ☐	

7. The reverse osmosis system and the main ring piping must be flushed out with permeate after being disinfected. ☐
8. All permeate tapping points have to be checked individually to ensure the absence of disinfectant. ☐
   If there is still residual disinfectant, go back to step 7.
9. Repeat the test for residual disinfectant after the system has been flushed out and stood still for 30 min. ☐
   If there is still disinfectant, go back to step 7.

I have ensured that the check for residual disinfectant is negative at all tapping points. ☐

End time of disinfection: _____

Place, date: _____

Signature technician: _____

10 Items used in combination with AQUAboss nX

Only products sold by B. Braun should be used to guarantee the proper function of the device.

Current spare parts lists can be found in the B. Braun Service Portal.

Article Number	Item
LA2000050	Combined filter unit 20” single, 1”
LA2000051	Combined filter unit 20” single, hose d25
LA2000052	Combined filter unit 20” single, Mapress
LA2000060	Combined filter unit 20” Duo, lockable, 1”
LA2000061	Combined filter unit 20” Duo, lockable, hose d25
LA2000065	Combined filter unit 20” Duo, 1”
LA2000066	Combined filter unit 20” Duo, hose d25
LA2000070	Combined filter unit 20” Duo, lockable, 1½”
LA2000075	Combined filter unit 20” Duo, 1½”
LA2000011	Water monitor 1”
LA1350002	Hardness monitoring AQUAboss SoftControl

List of Ring Pipings by B. Braun Avitum AG

Article Number	Item
LA2500125	PERMEATE RING PIPING PVC #25
LA2500132	PERMEATE RING PIPING PVC #32
LA2510122	PERMEATE RING PIPING VA #22
LA2510128	PERMEATE RING PIPING VA #28
LA2510134	PERMEATE RING PIPING VA #34
LA2521125	PERMEATE RING PIPING PEX-A #25
LA2521132	PERMEATE RING PIPING PEX-A #32

The pressure loss at the end of the ring piping must not exceed 3 bar.

When using ring pipings by manufacturers other than B. Braun Avitum AG the requirements listed in 11.3 Ring Piping Requirements (182) must be respected.

11 Technical Data

11.1 Performance Data

11.1.1 400 V/50 and 60 Hz Version

Single Stage

		AQUAboss® nX I						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1140100	LA1140150	LA1140200	LA1140250	LA1140300	LA1140350	LA1140400
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Standard membrane						
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 400 V 50/60 Hz permanent connection						
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	3.1	3.1	4.6	4.6	4.6	6.0	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.62	0.62	0.65	0.65	0.65	0.68	0.75
	A	0.89	0.89	0.93	0.93	0.93	0.97	1.08
Max. power pump	kW	2.6	2.6	3.3	3.3	3.3	4.1	6.6
Max. current pump	A	5.48	5.48	6.98	6.98	6.98	8.38	12.78
Power full-load "Dialysis"	kVA	4.23	4.23	5.24	5.24	5.24	6.20	9.16
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						

		AQUAboss® nX I						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

		AQUAboss® nX I HT						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1160100	LA1160150	LA1160200	LA1160250	LA1160300	LA1160350	LA1160400
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Heat-disinfectable membrane						
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 400 V 50/60 Hz permanent connection						
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN3-23	CRN3-23	CRN3-23	CRN5-22	CRN5-22
	kW	2.2	2.2	3.0	3.0	3.0	5.5	5.5
	A	4.6	4.6	6.0	6.0	6.0	10.4	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.65	0.65	0.68	0.68	0.75	0.75	0.75
	A	0.93	0.93	0.97	0.97	1.08	1.08	1.08
Max. power pump	kW	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	6.98	6.98	8.38	8.38	12.78	12.78	12.78
Power full-load "Dialysis"	kVA	5.24	5.24	6.20	6.20	9.16	9.16	9.16
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						

		AQUAboss® nX I HT						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

Double Stage

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1150050	LA1150100	LA1150150	LA1150200	LA1150250	LA1150300	LA1150250	LA1150400
Number of stations[a]		14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Standard membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/Hz	3~PE 400 V 50/60 Hz permanent connection							
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	3.1	3.1	3.1	4.6	4.6	4.6	6.0	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.62	0.62	0.62	0.65	0.65	0.65	0.68	0.75
	A	0.89	0.89	0.89	0.93	0.93	0.93	0.97	1.08
Max. power pump	kW	2.6	2.6	2.6	3.3	3.3	3.3	4.1	6.6

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Max. current pump	A	5.48	5.48	5.48	6.98	6.98	6.98	8.38	12.78
Power full-load "Dialysis"	kV A	4.23	4.23	4.23	5.24	5.24	5.24	6.20	9.16
RO II									
Electrical connection	V/ Hz	3~PE 400 V 50/60 Hz permanent connection							
Pump M2.1	M2. 1	CRN1-15	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-23	CRN3-23
	kW	1.5	1.5	1.5	1.5	2.2	2.2	3.0	3.0
	A	3.1	3.1	3.1	3.1	4.6	4.6	6.0	6.0
Pump M2.2	M2. 2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kV A	0.12	0.12	0.12	0.12	0.15	0.15	0.17	0.17
	A	0.17	0.17	0.17	0.17	0.22	0.22	0.25	0.25
Max. power pump	kW	2.6	2.6	2.6	2.6	3.3	3.3	4.1	4.1
Max. current pump	A	5.48	5.48	5.48	5.48	6.98	6.98	8.38	8.38
Power full-load "Dialysis"	kV A	3.73	3.73	3.73	3.73	4.74	4.74	5.69	5.69
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1170050	LA1170100	LA1170150	LA1170200	LA1170250	LA1170300	LA1170350	LA1170400
Number of stations[a]		14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Heat-disinfectable membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/Hz	3~PE 400 V 50/60 Hz permanent connection							
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN1-21	CRN3-23	CRN3-23	CRN5-22	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	3.0	3.0	5.5	5.5	5.5
	A	4.6	4.6	4.6	6.0	6.0	10.4	10.4	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.65	0.65	0.65	0.68	0.68	0.75	0.75	0.75
	A	0.93	0.93	0.93	0.97	0.97	1.08	1.08	1.08
Max. power pump	kW	3.3	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	6.98	6.98	6.98	8.38	8.38	12.78	12.78	12.78
Power full-load "Dialysis"	kVA	5.24	5.24	5.24	6.20	6.20	9.16	9.16	9.16
RO II									
Electrical connection	V/Hz	3~PE 400 V 50/60 Hz permanent connection							
Pump M2.1	M2.1	CRN1-21	CRN1-21	CRN3-17	CRN3-17	CRN3-23	CRN3-23	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	2.2	3.0	3.0	5.5	5.5
	A	4.6	4.6	4.6	4.6	6.0	6.0	10.4	10.4
Pump M2.2	M2.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Cabinet	kV A	0.15	0.15	0.15	0.15	0.17	0.17	0.25	0.25
	A	0.22	0.22	0.22	0.22	0.25	0.25	0.36	0.36
Max. power pump	kW	3.3	3.3	3.3	3.3	4.1	4.1	6.6	6.6
Max. current pump	A	6.98	6.98	6.98	6.98	8.38	8.38	12.78	12.78
Power full-load "Dialysis"	kV A	4.74	4.74	4.74	4.74	5.69	5.69	8.66	8.66
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

11.1.2 380 V/60 Hz Version

Single Stage

		AQUAboss® nX I						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1140102	LA1140152	LA1140202	LA1140252	LA1140302	LA1140352	LA1140402
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Standard membrane						
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 380 V 60 Hz permanent connection						

		AQUAboss® nX I						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	3.1	3.1	4.6	4.6	4.6	6.0	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.62	0.62	0.65	0.65	0.65	0.68	0.75
	A	0.94	0.94	0.98	0.98	0.98	1.03	1.13
Max. power pump	kW	2.6	2.6	3.3	3.3	3.3	4.1	6.6
Max. current pump	A	5.48	5.48	6.98	6.98	6.98	8.38	12.78
Power full-load "Dialysis"	kVA	4.23	4.23	5.24	5.24	5.24	6.20	9.16
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

		AQUAboss® nX I HT						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1160102	LA1160152	LA1160202	LA1160252	LA1160302	LA1160352	LA1160402
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Heat-disinfectable membrane						

		AQUAboss® nX I HT						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 380 V 60 Hz permanent connection						
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN3-23	CRN3-23	CRN5-22	CRN5-22	CRN5-22
	kW	2.2	2.2	3.0	3.0	5.5	5.5	5.5
	A	4.6	4.6	6.0	6.0	10.4	10.4	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.65	0.65	0.68	0.68	0.75	0.75	0.75
	A	0.93	0.93	0.97	0.97	1.08	1.08	1.08
Max. power pump	kW	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	6.98	6.98	8.38	8.38	12.78	12.78	12.78
Power full-load "Dialysis"	kVA	5.49	5.49	6.49	6.49	9.6	9.6	9.6
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

Double Stage

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1150052	LA1150102	LA1150152	LA1150202	LA1150252	LA1150302	LA1150352	LA1150402
Number of stations[a]		14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Standard membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/Hz	3~PE 380 V 60 Hz permanent connection							
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	3.1	3.1	3.1	4.6	4.6	4.6	6.0	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.62	0.62	0.62	0.65	0.65	0.65	0.68	0.75
	A	0.94	0.94	0.94	0.98	0.98	0.98	1.03	1.13
Max. power pump	kW	2.6	2.6	2.6	3.3	3.3	3.3	4.1	6.6
Max. current pump	A	5.48	5.48	5.48	6.98	6.98	6.98	8.38	12.78
Power full-load "Dialysis"	kVA	4.23	4.23	4.23	5.24	5.24	5.24	6.20	9.16
RO II									
Electrical connection	V/Hz	3~PE 380 V 60 Hz permanent connection							
Pump M2.1	M2.1	CRN1-15	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-23	CRN3-23
	kW	1.5	1.5	1.5	1.5	2.2	2.2	3.0	3.0
	A	3.1	3.1	3.1	3.1	4.6	4.6	6.0	6.0
Pump M2.2	M2.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Cabinet	kVA	0.12	0.12	0.12	0.12	0.15	0.15	0.17	0.17
	A	0.18	0.18	0.18	0.18	0.23	0.23	0.26	0.26
Max. power pump	kW	2.6	2.6	2.6	2.6	3.3	3.3	4.1	4.1
Max. current pump	A	5.48	5.48	5.48	5.48	6.98	6.98	8.38	8.38
Power full-load "Dialysis"	kVA	3.92	3.92	3.92	3.92	4.99	4.99	5.98	5.98
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

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a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1170052	LA1170102	LA1170152	LA1170202	LA1170252	LA1170302	LA1170352	LA1170402
Number of stations[a]		14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Heat-disinfectable membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/Hz	3~PE 380 V 60 Hz permanent connection							

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN1-21	CRN3-23	CRN3-23	CRN5-22	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	3.0	3.0	5.5	5.5	5.5
	A	4.6	4.6	4.6	6.0	6.0	10.4	10.4	10.4
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.65	0.65	0.65	0.68	0.68	0.75	0.75	0.75
	A	0.98	0.98	0.98	1.03	1.03	1.13	1.13	1.13
Max. power pump	kW	3.3	3.3	3.3	3.3	4.1	4.1	6.6	6.6
Max. current pump	A	6.98	6.98	6.98	6.98	8.38	8.38	12.78	12.78
Power full-load "Dialysis"	kVA	5.49	5.49	5.49	6.49	6.49	9.60	9.60	9.60
RO II									
Electrical connection	V/Hz	3~PE 380 V 60 Hz permanent connection							
Pump M2.1	M2.1	CRN1-21	CRN1-21	CRN3-17	CRN3-17	CRN3-23	CRN3-23	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	2.2	3.0	3.0	5.5	5.5
	A	4.6	4.6	4.6	4.6	6.0	6.0	10.4	10.4
Pump M2.2	M2.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	2.38	2.38	2.38	2.38	2.38	2.38	2.38	2.38
Cabinet	kVA	0.15	0.15	0.15	0.15	0.17	0.17	0.25	0.25
	A	0.23	0.23	0.23	0.23	0.26	0.26	0.38	0.38
Max. power pump	kW	3.3	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	6.98	6.98	6.98	8.38	8.38	12.78	12.78	12.78
Power full-load "Dialysis"	kVA	4.99	4.99	4.99	4.99	5.98	5.98	9.10	9.10
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

11.1.3 220 V/60 Hz Version

Single Stage

		AQUAboss® nX I						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1140101	LA1140151	LA1140251	LA1140251	LA1140301	LA1140351	LA1140401
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Standard membrane						
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 220 V 60 Hz permanent connection						
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	5.4	5.4	8	8	8	10.4	18
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.15	4.15	4.15	4.15	4.15	4.15	4.15
Cabinet	kVA	0.62	0.62	0.67	0.67	0.67	0.71	0.79
	A	1.62	1.62	1.76	1.76	1.76	2.08	2.08
Max. power pump	kW	2.6	2.6	3.3	3.3	3.3	4.1	6.6
Max. current pump	A	9.55	9.55	12.15	12.15	12.15	14.55	22.15

		AQUAboss® nX I						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Power full-load "Dialysis"	kVA	4.26	4.26	5.3	5.3	5.3	6.25	9.23
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

		AQUAboss® nX I HT						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1160101	LA1160151	LA1160201	LA1160251	LA1160301	LA1160351	LA1160401
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Heat-disinfectable membrane						
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 220 V 60 Hz permanent connection						
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN3-23	CRN3-23	CRN3-23	CRN5-22	CRN5-22
	kW	2.2	2.2	3.0	3.0	5.5	5.5	5.5
	A	8	8	10.4	10.4	18	18	18
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.15	4.15	4.15	4.15	4.15	4.15	4.15

		AQUAboss® nX I HT						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Cabinet	kVA	0.67	0.67	0.71	0.71	0.79	0.79	0.79
	A	1.76	1.76	1.86	1.86	2.08	2.08	2.08
Max. power pump	kW	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	12.15	12.15	14.55	14.55	22.15	22.15	22.15
Power full-load "Dialysis"	kVA	5.3	5.3	6.25	6.25	9.23	9.23	9.23
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

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a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

Double Stage

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1150051	LA1150101	LA1150151	LA1150201	LA1150251	LA1150301	LA1150351	LA1150401
Number of stations[a]		14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Standard membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/ Hz	3~PE 220 V 60 Hz permanent connection							

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	5.4	5.4	5.4	8	8	8	10.4	18
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.15	4.15	4.15	4.15	4.15	4.15	4.15	4.15
Cabinet	kVA	0.62	0.62	0.62	0.67	0.67	0.67	0.71	0.79
	A	1.62	1.62	1.62	1.76	1.76	1.76	1.86	2.08
Max. power pump	kW	2.6	2.6	2.6	3.3	3.3	3.3	4.1	6.6
Max. current pump	A	9.55	9.55	9.55	12.15	12.15	12.15	14.55	22.15
Power full-load "Dialysis"	kVA	4.26	4.26	4.26	5.3	5.3	5.3	6.25	9.23
RO II									
Electrical connection	V/Hz	3~PE 220 V 60 Hz permanent connection							
Pump M2.1	M2.1	CRN1-15	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-23	CRN3-23
	kW	1.5	1.5	1.5	1.5	2.2	2.2	3.0	3.0
	A	5.4	5.4	5.4	5.4	8	8	10.4	10.4
Pump M2.2	M2.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.15	4.15	4.15	4.15	4.15	4.15	4.15	4.15
Cabinet	kVA	0.12	0.12	0.12	0.12	0.17	0.17	0.21	0.21
	A	0.31	0.31	0.31	0.31	0.45	0.45	0.55	0.55
Max. power pump	kW	2.6	2.6	2.6	2.6	3.3	3.3	4.1	4.1
Max. current pump	A	9.55	9.55	9.55	9.55	12.15	12.15	14.55	14.55
Power full-load "Dialysis"	kVA	3.76	3.76	3.76	3.76	4.8	4.8	5.75	5.75
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1170051	LA1170101	LA1170151	LA1170201	LA1170251	LA1170301	LA1170351	LA1170401
Number of stations[a]		14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Heat-disinfectable membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/Hz	3~PE 220 V 60 Hz permanent connection							
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN1-21	CRN3-17	CRN3-17	CRN5-22	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	3.0	3.0	5.5	5.5	5.5
	A	8	8	8	10.4	10.4	18	18	18
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.15	4.15	4.15	4.15	4.15	4.15	4.15	4.15
Cabinet	kVA	0.67	0.67	0.67	0.71	0.71	0.79	0.79	0.79
	A	1.76	1.76	1.76	1.86	1.86	2.08	2.08	2.08
Max. power pump	kW	3.3	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	12.15	12.15	12.15	14.55	14.55	22.15	22.15	22.15

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Power full-load "Dialysis"	kVA	5.3	5.3	5.3	6.25	6.25	9.23	9.23	9.23
RO II									
Electrical connection	V/Hz	3~PE 220 V 60 Hz permanent connection							
Pump M2.1	M2.1	CRN1-21	CRN1-21	CRN3-17	CRN3-17	CRN3-23	CRN3-23	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	2.2	3.0	3.0	5.5	5.5
	A	8	8	8	8	10.4	10.4	18	18
Pump M2.2	M2.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.15	4.15	4.15	4.15	4.15	4.15	4.15	4.15
Cabinet	kVA	0.17	0.17	0.17	0.17	0.21	0.21	0.29	0.29
	A	0.45	0.45	0.45	0.45	0.55	0.55	0.77	0.77
Max. power pump	kW	3.3	3.3	3.3	3.3	4.1	4.1	6.6	6.6
Max. current pump	A	12.15	12.15	12.15	12.15	14.55	14.55	22.15	22.15
Power full-load "Dialysis"	kVA	4.8	4.8	4.8	4.8	5.75	5.75	8.73	8.73
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

11.1.4 208 V/60 Hz Version

Single Stage

		AQUAboss® nX I						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1140101	LA1140151	LA1140251	LA1140251	LA1140301	LA1140351	LA1140401
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Standard membrane						
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 208 V 60 Hz permanent connection						
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	5.8	5.8	8.6	8.6	8.6	11.2	20.2
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Cabinet	kVA	0.62	0.62	0.67	0.67	0.67	0.71	0.79
	A	1.72	1.72	1.86	1.86	1.86	1.97	2.2
Max. power pump	kW	2.6	2.6	3.3	3.3	3.3	4.1	6.6
Max. current pump	A	10.3	10.3	13.1	13.1	13.1	15.7	24.7
Power full-load "Dialysis"	kVA	4.33	4.33	5.39	5.39	5.39	6.37	9.69
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%

c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

		AQUAboss® nX I HT						
Type		**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1160101	LA1160151	LA1160201	LA1160251	LA1160301	LA1160351	LA1160401
Number of stations[a]		28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	1	2	2	3	3	4	4
	Type	Heat-disinfectable membrane						
Permeate flow[b /c]	L/h	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%						
Electrical connection	V/Hz	3~PE 208 V 60 Hz permanent connection						
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN3-23	CRN3-23	CRN3-23	CRN5-22	CRN5-22
	kW	2.2	2.2	3.0	3.0	5.5	5.5	5.5
	A	8.6	8.6	11.2	11.2	20.2	20.2	20.2
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Cabinet	kVA	0.67	0.67	0.71	0.71	0.79	0.79	0.79
	A	1.86	1.86	1.97	1.97	2.2	2.2	2.2
Max. power pump	kW	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	13.1	13.1	15.7	15.7	24.7	24.7	24.7
Power full-load "Dialysis"	kVA	5.39	5.39	6.37	6.37	9.69	9.69	9.69
Protection class	IP	44 (pump 55)						
Connection soft water from RO		G1” internal thread						
Connection to RL from RO		Tri Clamp DN25						
Connection from RL from RO		Tri Clamp DN25						
Connection to drain from RO		R1” internal thread						
Width	mm	1612.5						
Depth	mm	640						
Height	mm	1723						
Weight	kg	335	380	383	428	428	483	506

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

Double Stage

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number		LA1150051	LA1150101	LA1150151	LA1150201	LA1150251	LA1150301	LA1150351	LA1150401
Number of stations[a]		14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Standard membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/Hz	3~PE 208 V 60 Hz permanent connection							
Pump M1.1	M1.1	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-17	CRN3-23	CRN5-22
	kW	1.5	1.5	1.5	2.2	2.2	2.2	3.0	5.5
	A	5.8	5.8	5.8	8.6	8.6	8.6	11.2	20.2
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Cabinet	kVA	0.62	0.62	0.62	0.67	0.67	0.67	0.71	0.79
	A	1.72	1.72	1.72	1.86	1.86	1.86	1.97	2.2
Max. power pump	kW	2.6	2.6	2.6	3.3	3.3	3.3	4.1	6.6
Max. current pump	A	10.3	10.3	10.3	13.1	13.1	13.1	15.7	24.7
Power full-load "Dialysis"	kVA	4.33	4.33	4.33	5.39	5.39	5.39	6.37	9.69
RO II									
Electrical connection	V/Hz	3~PE 208 V 60 Hz permanent connection							

		AQUAboss® nX II							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Pump M2.1	M2.1	CRN1-15	CRN1-15	CRN1-15	CRN1-15	CRN3-17	CRN3-17	CRN3-23	CRN3-23
	kW	1.5	1.5	1.5	1.5	2.2	2.2	3.0	3.0
	A	5.8	5.8	5.8	5.8	8.6	8.6	11.2	11.2
Pump M2.2	M2.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Cabinet	kVA	0.12	0.12	0.12	0.12	0.17	0.17	0.21	0.21
	A	0.33	0.33	0.33	0.33	0.47	0.47	0.58	0.58
Max. power pump	kW	2.6	2.6	2.6	2.6	3.3	3.3	4.1	4.1
Max. current pump	A	10.3	10.3	10.3	10.3	13.1	13.1	15.7	15.7
Power full-load "Dialysis"	kVA	3.83	3.83	3.83	3.83	4.89	4.89	5.87	5.87
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

	AQUAboss® nX II HT							
Type	**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Article Number	LA1170051	LA1170101	LA1170151	LA1170201	LA1170251	LA1170301	LA1170351	LA1170401
Number of stations[a]	14/10	28/20	42/30	56/40	70/50	84/60	98/70	112/80

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Membrane(s)	Qty.	2	2	4	4	6	6	8	8
	Type	Heat-disinfectable membrane							
Permeate flow[b /c]	L/h	500	1000	1500	2000	2500	3000	3500	4000
Salt rejection rate		Ions > 90%							
RO I									
Electrical connection	V/Hz	3~PE 208 V 60 Hz permanent connection							
Pump M1.1	M1.1	CRN1-21	CRN1-21	CRN1-21	CRN3-17	CRN3-17	CRN5-22	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	3.0	3.0	5.5	5.5	5.5
	A	8.6	8.6	8.6	11.2	11.2	20.2	20.2	20.2
Pump M1.2	M1.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Cabinet	kVA	0.67	0.67	0.67	0.71	0.71	0.79	0.79	0.79
	A	1.86	1.86	1.86	1.97	1.97	2.2	2.2	2.2
Max. power pump	kW	3.3	3.3	3.3	4.1	4.1	6.6	6.6	6.6
Max. current pump	A	13.1	13.1	13.1	15.7	15.7	24.7	24.7	24.7
Power full-load "Dialysis"	kVA	5.39	5.39	5.39	6.37	6.37	9.69	9.69	9.69
RO II									
Electrical connection	V/Hz	3~PE208 V 60 Hz permanent connection							
Pump M2.1	M2.1	CRN1-21	CRN1-21	CRN3-17	CRN3-17	CRN3-23	CRN3-23	CRN5-22	CRN5-22
	kW	2.2	2.2	2.2	2.2	3.0	3.0	5.5	5.5
	A	8.6	8.6	8.6	8.6	11.2	11.2	20.2	20.2
Pump M2.2	M2.2	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4	CRN5-4
	kW	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
	A	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Cabinet	kVA	0.17	0.17	0.17	0.17	0.21	0.21	0.29	0.29
	A	0.47	0.47	0.47	0.47	0.58	0.58	0.81	0.81
Max. power pump	kW	3.3	3.3	3.3	3.3	4.1	4.1	6.6	6.6

		AQUAboss® nX II HT							
Type		**500**	**1000**	**1500**	**2000**	**2500**	**3000**	**3500**	**4000**
Max. current pump	A	13.1	13.1	13.1	13.1	15.7	15.7	24.7	24.7
Power full-load "Dialysis"	kVA	4.89	4.89	4.89	4.89	5.87	5.87	9.19	9.19
Protection class	IP	44 (pump 55)							
Connection soft water from RO		G1” internal thread							
Connection to RL from RO		Tri Clamp DN25							
Connection from RL from RO		Tri Clamp DN25							
Connection to drain from RO		R1” internal thread							
Width	mm	1612.5							
Depth	mm	1280							
Height	mm	1723							
Weight	kg	579	579	669	672	765	765	874	898

a. At a continuous HD flow of 500/800 mL/min. Some dialysis machines require flow rates during flushing.
b. Raw water temperature: 10°C; membrane throughput deviation +- 15%
c. Raw water: 10°C; 500 ppm NaCl; Backpressure 3.0 bar; calculated membrane age: 3 years; 3-year flux decline: 10%; total WCF 75%

Subject to change.

11.2 Design Data

Design Data	
Permeate output	See Section 11.1 Performance Data (159)
Electrical connection	See Section 11 Technical Data (159) See type plate of system, clockwise phase rotation or permanent connection
Permeate–concentrate ratio	25% when operating with hard water 75% when operating with soft water
Ambient temperature	5–40 °C
Internal housing temperature (control system)	5–50 °C
Internal housing temperature (hydraulics)	5–90 °C
Relative humidity	30–75%, non-condensing

Design Data	
Air pressure	90–106 kPa (100% permeate output) 80–106 kPa (min. 90% permeate output)
Materials in contact with product	1.4404, 1.4571, 1.4435 stainless steel, ethylene propylene diene monomer (EPDM), polypropylene, polysulfone, polyvinylidene fluoride (PVDF), polyamide, polyether ether ketone (PEEK)

11.3 Ring Piping Requirements

Ring Piping Requirements	
Pressure loss at ring piping end	Δ p < 3 bar
Material	PVDF, PEX, PVC Recommended: etched 316L stainless steel with R_a < 0.8 µm
Pressure resistance (min.)	10 bar
Consumption point design	Minimal dead-space per 6-d rule (GMP)

⚠ WARNING!

Risk of toxicity from dissolved structural materials and destruction of components

- Only original materials resistant to up to 90 °C should be used.

11.4 RO Modules

RO Modules	
Spiral-wound module membrane	D = 8”; H = 40”
Material	PA composite
Max. chlorine concentration in intake	0 ppm
SDI_{15}	< 3
pH range in Dialysis/Standby mode	5–9
pH range for chemical cleaning (temporary only)	2–11

11.5 Pumps

Pumps	
Material	Pump housing: stainless steel 1.4408 Impeller: AISI 316 stainless steel
Mechanical seal	EPDM or FKM
IE class	IE3
IP rating	IP55
Insulation class	F
Max. ambient temperature	60 °C
Weight (net)	39–50 kg

11.6 Membrane pressure vessel

Membrane pressure vessel	
Pressure	Max. 25 bar
Material	1.4404 AISI 316 L
Connections	
Process water intake	R 1/2" (after machining DN25 Tri-Clamp)
Permeate outlet	R 1/2" (after machining DN25 Tri-Clamp)
Concentrate outlet	R 1/2" (after machining DN25 Tri-Clamp)

11.7 Specifications

Conductivity Raw Water C1

		Evaluation ROI	Evaluation ROII
Measuring range	1–1000 µS/cm	yes	yes
Accuracy	± 50 µS/cm		
Setting range	CC/CD C1 0.05–0.50 cm^{-1}		

The displayed conductivity is compensated to 25 °C.

Conductivity Permeate C3

		Evaluation ROI	Evaluation ROII
Measuring range	1–1000 µS/cm	yes	yes
Accuracy	± 50 µS/cm		
Setting range	CC/CD C3 0.05–0.50 cm^{-1} Alarm Permeate see chapter 3.12.1.2 Dialysis Settings (64) Error Permeate see chapter 3.12.1.2 Dialysis Settings (64)		

The displayed conductivity is compensated to 25 °C.

Redundant Conductivity Permeate C4

		Evaluation ROI	Evaluation ROII
Measuring range	1–1000 µS/cm	yes	yes
Accuracy	± 50 µS/cm		
Setting range	CC/CD C2 0.05–0.50 cm^{-1}		

The displayed conductivity is compensated to 25 °C.

Flow Rate Permeate F1

		Evaluation ROI	Evaluation ROII
Measuring range	300–6000 L/h	yes	yes
Accuracy	± 1.5%		
Setting range	N/A		

Flow Rate Ring Piping Return F2

		Evaluation ROI	Evaluation ROII
Measuring range	300–6000 L/h	yes	yes
Accuracy	± 1.5%		
Setting range	N/A		

Flow Rate Drain F3

		Evaluation ROI	Evaluation ROII
Measuring range	300–6000 L/h	yes	yes
Accuracy	± 1.5%		
Setting range	N/A		

Flow Rate Concentrate F4

		Evaluation ROI	Evaluation ROII
Measuring range	300–6000 L/h	no	yes
Accuracy	± 1.5%		
Setting range	N/A		

Permeate Temperature T1

		Evaluation ROI	Evaluation ROII
Measuring range	0–100 °C	yes	yes
Accuracy	± 0.75 °C		
Setting range	N/A		

Permeate Pressure P3

		Evaluation ROI	Evaluation ROII
Measuring range	0–25 bar	yes	yes
Accuracy	± 1.25%		
Setting range	N/A		

Concentrate Pressure P2

		Evaluation ROI	Evaluation ROII
Measuring range	0–25 bar	no	yes
Accuracy	± 1.25%		
Setting range	N/A		

Concentrate Pressure P1

		Evaluation ROI	Evaluation ROII
Measuring range	0–100 mbar	yes	yes
Accuracy	± 1.7%		
Setting range	N/A		

Concentrate Pressure GS1

		Evaluation ROI	Evaluation ROII
Measuring range	0 (open)/1 (closed)	yes	yes
Accuracy	N/A		
Setting range	N/A		

Concentrate Pressure PS1

		Evaluation ROI	Evaluation ROII
Measuring range	-1-10 bar	yes	yes
Accuracy	± 1.65%		
Setting range	N/A		

11.8 Circuit Diagram

Circuit Diagram	
Electrical Diagram No. • AQUAboss nX	• LA8724600

11.9 Fuses

Amount	4
F1	Fuse 0.5 A 5x20 mm 250 VAC FST
F2	Fuse 1A 5x20 mm 250 VAC FST
F3, F4	Fuse 4 A 5x20 mm 250 VAC Flink

Fuse F1	
Body material	Glass
Tripping characteristic	Time-Lag T
Size	5 x 20 mm
Nominal current	500 mA
Nominal voltage (AC)	250 V
Breaking capacity	35 A @250 VAC

Fuse F2	
Body material	Glass
Tripping characteristic	Time-Lag T
Size	5 x 20 mm
Nominal current	1 A
Nominal voltage (AC)	250 V
Breaking capacity	35 A @250 VAC

Fuses F3 and F4	
Body material	Ceramic
Tripping characteristic	Super-Quick-Acting (FF)
Size	5 x 20 mm
Nominal current	4 A
Nominal voltage (AC)	250 V
Breaking capacity	1500 A @250 VAC

12 Appendix

12.1 Sample letter to municipal water utility

To [Municipal Water Utility]

[Place], [Date]

To Whom It May Concern:

The artificial kidney places strict quality requirements on the water used. For your information, I have enclosed a copy of the current quality standard for water for diluting concentrated dialysate. Not meeting this standard can put patients' lives at risk.

Particularly chemicals such as aluminum, fluoride, free chlorine and chloramine, which are generally used in municipal water treatment, can greatly harm the health of dialysis patients.

At our dialysis center, we have installed a water treatment system that allows us, under normal conditions, to achieve the quality standard for water for diluting concentrated dialysate. This water treatment system was specially designed and constructed for the average composition of the water supplied by you.

The system consists of a combination of the following components depending on configuration: pre-treatment, reverse osmosis system and/or a post-treatment. These components are able to remove all constituents from the drinking water that are harmful to patients.

We request that you immediately inform us of any change in water composition, particularly the use of disinfectants such as chlorine or the addition of other chemicals, so we can have appropriate measures taken to protect our patients.

Thank you in advance for your understanding and cooperation.

Kind regards,

12.2 Hazard Label

Risk of Acute Toxicity During Chemical Disinfection/Cleaning

Only clean and disinfect the system with the attending physician's approval.

Prior to starting disinfection and cleaning, the permeate connection to the dialysis machines must be removed.

After disinfection/cleaning and before connecting the tube to the dialysis machine, check every tapping point to make sure the permeate contains no traces of the chemicals used for cleaning and disinfecting.