



# Instructions for use



### Reverse osmosis system for the production of dialysis water

Rev. 2.6 KSA Date 2017-06-06 Software version 2.0





## **Dear Customers**,

In these operating instructions, 'RO' is used as the abbreviation for the reverse osmosis system. For general explanations, the reverse osmosis system is described as (Eco)RO Dia I/II C (HT) and also includes the HT option.

The water treatment system *Aquaboss*® (Eco)RO Dia I/II C is a medical product and fulfils the quality requirements specified in the standards ISO 23500 and ISO 26722.

If you have problems with this system which you are unable to solve by consulting these operating instructions, please contact either B. Braun directly, your service technician or your authorized B. Braun partner with as precise a description as possible of the problems you are having and your unit details.

These operating instructions must always be kept on the site where the water treatment system is installed.

These operating instructions include basic directives which are to be observed before commissioning and maintenance work. Therefore they must be read by the technical staff/user responsible before commissioning and/or maintenance work.

The system operator is obliged to adhere to the working, maintenance and technical safety check processes described in these operating instructions as well as to the respective intervals.

Where aspects of the operating instructions are not observed, B. Braun cannot guarantee safe operation of the system.

These operating instructions are an integral part of the supplied system and are to be handed over to the new owner if the system is resold.

B. Braun reserves the right to alter sections of these operating instructions or technical data without prior notice.

If you have any questions regarding these operating instructions or would like to make any comments or suggestions for improvement, please do not hesitate to contact us directly.

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### Suggestions for improvement

When working with these operating instructions, you may have an idea that could contribute to improving the contents. Please do not keep this idea to yourself – let us have your suggestions. This will make it possible for us to incorporate your suggestions in subsequent versions.

• Yes, I would like to make a suggestion!

	My address is:				
	Name:				
	Address:				
	Tel.:				
	Fax				
•	The item a	and revision numbers of the operating instructions to hand are as follows:			
	Item no.:				
•	My sugges	stion for improvement concerns the page(s):			
•	My sugges	stion:			

.....

Use further pages if necessary. You can also include pages you have copied from the operating instructions and improved by adding comments.

Please send your suggestion to:

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# Notes on the operating instructions

The operating instructions contain information on the safe use of the system.

According to the directive governing medical products, the user must convince himself of the correct function and proper state of the medical product before putting it to use, and heed the operating instructions and other information and maintenance instructions enclosed.

#### The operator must be instructed on the following points and committed to observe them:

- The medical product may only be set up, operated and used by persons who have participated in the required training or have knowledge of and experience with the product.
- The medical product may only be operated according to its **intended purpose** in accordance with the regulations of the current German medical product operator ordinance.
- The user must be committed to only operate the system when it is in its **intended condition**. The system must not be used or applied if there are any faults that could cause harm to patients, employees or third parties. The user must ensure that the devices function and are in **intended condition** prior to <u>any</u> use.
- The user must be instructed on safe handling of the products. This comprises theoretical basics, adequate handling and condition for the application.
- The operator is to be instructed on the permissible operating data (e.g. setting data for safety and monitoring facilities, functional tests).
- The user must be instructed on system maintenance and the elimination of operational faults.
- The user is obliged to inform his supervisor/operator immediately as to any changes on the system that affect safety and to observe all the safety instructions.
- The user must be instructed as to the risks, rules of behaviour and necessary protective measures to be taken when dealing with the substances used, and be trained to react correctly in the event of danger and provide first aid.
- Through instructions and checks, the operator must provide for cleanness and clarity where the system is used.
- The operator must fulfil his obligation to clearly regulate who is responsible for commissioning, operating and maintaining the system to ensure that such work is carried out by all the persons involved without any misunderstandings as to who is competent where safety aspects are concerned.

## Signs and symbols used in the operating instructions

<b>DANGER</b>	The signal word indicates a high-risk hazard which, if not avoided, will cause death or severe injury.
	The signal word indicates a medium-risk hazard which, if not avoided, may cause death or severe injury.
A Caution	The signal word indicates a low-risk hazard which, if not avoided, may cause minor or moderately severe injury.
	The signal word warns of material and environmental damage.
NOTE:	The signal word points to suggestions / details on the economical use or just to a simpler work step.

This symbol indicates a cross reference to a chapter within these operating instructions.

## Signs and symbols used for reverse osmosis

	Caution, hot surface
i	Observe the operating instructions
	Protective earth connection
	Ground connection
$_{\rm 3N}\sim$	Three-phase alternating current with neutral conductor
$\bigcirc$	OFF (power supply, disconnect from mains supply)
	ON (power supply, connect with mains supply)
1	Dangerous voltage
$\overline{\mathbb{A}}$	Attention residual risks. Refers to the necessity of examining the operating instructions for important safety-related aspects.
	Shows the manufacturer of the medical product in compliance with the EU guidelines 90/385/EEC, 93/42/EEC and 98/79/EC an.
~~~	Shows the date on which the medical product was manufactured.
REF	Shows the manufacturer's article number so that a certain medical product can be identified.
SN	Shows the manufacturer's serial number so that a certain medical product can be identified.
	A symbol for the temperature limits. The temperature limits the medical product can safely be exposed to are shown.

## These operating instructions comprise two sections:

#### Part 1 – Operating Instructions

Here you will find subjects which are important for the normal operation of the system.

- 1. Security
- 2. Area of application and intended use
- 3. Accessories list (Eco)RO Dia I/II C (HT)
- 4. Use in combination with other equipment
- 5. Technical Description
- 6. Functions
- 7. Description of components
- 8. Commissioning / Decommissioning
- 9. Turning the equipment on
- 10. Dialysis mode (Dial)
- 11. Night operation (night)
- 12. Disinfection (DI)
- 13. Cleaning (C)
- 14. Entering system data and parameters
- 15. Special operating modes LC operation
- 16. Operating modes
- 17. Faults / Causes / Elimination
- 18. Emergency operating modes

#### Part 2 – Supplementary Operating Instructions

# Here you will find subjects which are important for commissioning and maintenance/technical safety checks.

- 1. Handover declaration for the operating instructions
- 2. Transport and setup
- 3. Work prior to initial commissioning
- 4. Commissioning
- 5. Commissioning log
- 6. System parameters
- 7. Technical data
- 8. Setup plan and terminal diagram
- 9. Maintenance and technical safety check (TSC)
- 10. Spare and wear parts list (Eco)RO Dia I/II C (HT)
- 11. Draft letter for municipal water suppliers

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## 1. Security

### **1.1** Risks due to non-observance of safety instructions

Non-observance of the safety instructions can lead to danger for the user and/or the patient. Non-observance may lead to the following risks:

- · Failure of important system functions.
- · Failure of prescribed methods of routine check and disinfection (DI)
- Danger to persons through electrical and mechanical reactions.

## 1.2 General safety

The *Aquaboss*® reverse osmosis system is built to state-of-the-art engineering standards and is safe in operation.

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

- Read and carefully observe these operating instructions, especially the safety instructions.
- Keep these operating instructions within easy reach of the reverse osmosis system (RO).
- Commissioning, operation and maintenance may only be carried out by authorized, trained and B. Braun-instructed specialists. Electrical work may only be carried out by authorized, trained and instructed electricians.
- All local safety and accident prevention regulations are always applicable for operating the system. These must be observed and maintained at all times.
- Observe instruction and warning signs.
- Consult a doctor immediately in the case of injuries, accidents or inflammation of the skin.
- The system must be disinfected after being at a standstill for a longer period (> 72 h), but at least once every year (from → Part 1, chapter 12).

## 1.3 Functional security

#### 1.3.1 Operational safety

#### 

The system pipelines are under pressure!

 $\rightarrow$  Before starting work on the system depressurize the pipelines. Opening screws or valves can lead to injury!

- An annual technical safety check (TSC) by B. Braun-authorized specialists is compulsory.
- The system is to be operated only with closed control cabinet.
- Insufficient water quality in the intake can cause an inferior and impermissible product quality (see requirement → Part 1, chapter 2.4).
- If the system comes to a sudden standstill, the operator should not immediately change to another operating mode. The system may have been stopped for manual adjustments to be made. Switching the system on again without warning can lead to severe injuries.
- The reverse osmosis system pipelines are under pressure. Opening screws or valves can lead to injury.
- Avoid contact with the product to be processed if it is a health hazard. First-aid treatment must be given in-house in the event of contact with the product.
- A daily report is to be drawn up on the conductivity values etc. in accordance with → Part 2, chapter 9.2.1 "Medical product log".
- If the permeate output is reduced by more than 20%, it is recommended that the number of connected consumers be reduced by the same amount so that the functioning of the individual connected devices is not affected.
- Never allow the pump to run dry.

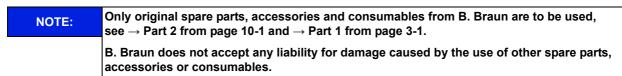
#### DANGER Electric shock!

Dangerous voltage when the control cabinet is open. Switch the reverse osmosis system off at the main switch and disconnect it from the mains.

#### 1.3.2 Safety during servicing

When the control cabinet is open:

- The RO must be switched off at the main switch (1) → Part 1, chapter 7.1 before routine checks and repair work are started.
- When work is being done on pumps and pressurized pipelines, these must be depressurized first to prevent injuries.
- Any damaged or removed instruction and warning signs or safety labels must be renewed without delay.
- All dismantled safety devices must be properly refitted after maintenance work has been completed.
- Unauthorized conversion work or modifications to the system can impair personal and system safety and are therefore prohibited.
- If the RO has a permanent connection, the system must be disconnected completely from the mains using the upstream separator. (Supply cable, connection terminals and network filter to prevent electromagnetic influence are located before the RO's main switch (1). IEC 61010-1)



### 1.4 Microbiological safety

When used for the intended purpose, the reverse osmosis system produces water to dilute haemodialysis concentrates.

The permeate quality is influenced by:

- The raw water quality => observance of the EU guideline 98/83/EC is required
- The pre-treatment (hardness, chlorine, heavy metals ...)
- The ring piping (size, material)
- Cleaning and disinfection cycles

After commissioning, the system is handed over in perfect working order (inc. microbiological test).

#### NOTE:

The operator is responsible for observing the limit values in accordance with the European Pharmacopoeia (Ph. Eur.) or ISO 13959 with respect to microbiological quality.

- → After the RO has been at a standstill ( >72 hours), carrying out disinfection is recommended.
- → There is a risk of the entire water treatment system becoming contaminated if the system is at a standstill for a longer period of time. This is also applicable for the connecting pipework if this is not automatically rinsed.
- → It is recommended that the permeate be tested for its microbiological quality at least every six months (see → Part 1, chapter 2.4 Bacteriology, pyrogenics).
- ➔ If the alarm limit of 50 KBE/ml for the total germ count and 0.125 I.U./ml for endotoxins has been exceeded, carry out disinfection (action limit).
- ➔ A continuously germ load can lead to the development of biofilm. Biofilm can usually only be eliminated by a combination of mechanical and chemical cleaning.
- → Exceeding the limit values according to the European Pharmacopoeia Ph.Eur. or ISO 13959 (see → Part 1, chapter 2.4) requires immediate cleaning and disinfection (alarm limit).

#### 1.5 **Residual risks**

NOTE:

Residual risks remain despite the measures taken to avoid such risks.

Residual risks are potential hazards which are not apparent, e.g.:

- Risks which can result from the product or flushing medium, such as allergies, inflammation of the skin or burns.
- Risks arising as a result of control system faults
- Hazard arising from misconduct of the operator

#### 1. Electrocution

The reverse osmosis system (Eco)RO Dia I/II C (HT) is operated with an electrical voltage of 400 V(AC). Improper opening of the switch cabinet or damage to the electrical cables can cause electrocution (risk of fatal injury!).

Any work on the system that requires the switch cabinet to be opened or contact with the connection cables may only be carried out when the system has been switched off (main switch to "0") and disconnected from the mains supply.

If the RO has a permanent connection, the system must be disconnected completely from the mains using the upstream separator. (Supply cable, connection terminals and network filter to prevent electromagnetic influence are located before the RO's main switch (1) (IEC 61010-1).

#### 2. Noise

A noise level of less than 80 dB(A) is measured up to a distance of 0.5 m from the system. The law does not require any measures regarding hearing protection for background noises of up to 75 dB(A). However, the noise level can increase in a location in which several sources of noise are positioned, thus requiring hearing protection. Therefore it is recommended that additional noise level measurement be carried out if there are several devices in one room, and all the groups of personnel (cleaning personnel, operators etc.) should be informed about individual measures for hearing protection.

#### 3. Head radiation

Reverse osmosis systems for hot cleaning (Eco)RO Dia I/II C HT can radiate heat during hot cleaning. Parts of the system, such as filled pipelines and membrane modules can reach temperatures of up to 90°C, which results in the risk of burns.

The symbol is marked with the symbol for "Caution, hot surface".

## **1.6** Contraindications and potential undesirable side effects

#### 1.6.1 Contraindications

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

Do not use the reverse osmosis system if the raw water does not satisfy the requirements of guideline 98/83/EC.

Do not use the reverse osmosis system if the freedom from disinfectant cannot be proved at all sampling points after chemical disinfection before dialysis.

#### 1.6.2 Side effects

Small amounts of aluminium and nitrate can pass through the reverse osmosis membrane even if the reverse osmosis system is used according to its intended use. Anaemia, neurological problems, cerebral diseases and changes in bone structure have been observed in association with increased aluminium values in the permeate. Nausea and vomiting as well as haemolysis have been observed in association with increased nitrate amounts.

Particularly in the case of increased nitrate or aluminium values in the raw water, make sure that the permeate satisfies the valid limit values for water to dilute concentrated haemodialysis solutions according to Ph.Eur. or ISO 13959.

## 2. Area of application and intended use

The operator is responsible for the intended use of the system.

The operational safety of the system supplied is only given when it is used as intended.

supplements to the guideline, see  $\rightarrow$  Part 2, chapter 7.3

The values specified in the technical data  $\rightarrow$  Part 2 from page 7-1 must be observed. Limit values must never be exceeded.

NOTE:	The intended use is the production of water for diluting haemodialysis concentrates, in accordance with the European Pharmacopoeia and ISO 13959.
	The <i>Aquaboss®</i> reverse osmosis system may only be used for the intended purpose and has been designed for a service life of 10 years.
	The quality of the feed water upstream of the water softener (ion exchanger) must comply
NOTE:	with the requirements of EC guideline 98/83/EC of the Council dated November 3, 1998, concerning the quality of water for human usage. For B. Braun-specific deviations from or

Intended use also includes observance of the commissioning, operating and maintenance instructions provided by the manufacturer, which are an integral part of these instructions, as well as taking any foreseeable misconduct into account.

During proper use, the minimum salt retention is 90%, based on the raw water conductivity in the feed flow of the reverse osmosis.

The hourly litre capacity of the system is, depending on the type, 500 l/h to 3000 l/h. A water temperature of  $< 6^{\circ}$ C in the feed reduces the hydraulic capacity. The device has been designed for continuous operation.

Permeate is not suitable for drinking.

<b>A</b> Caution	Wrong purpose.
	The water quality directly after reverse osmosis does not correspond with the requirements of ultra-pure water (UPW).
	ightarrow UPW requires an additional processing level and detailed validation of the overall system.

The devices of the (Eco)RO Dia I/II C (HT) series are electrical medical devices that are subject to special precautionary measures in terms of EMC; they must be installed and put into operation according to the instructions in  $\rightarrow$  Part 2, chapter 7.11.

Portable and mobile high-frequency communication equipment can influence electrical medical devices.

The devices of the (Eco)RO Dia I/II C (HT) series may not be used if they are located immediately next to or stacked on top of other devices. However, if this is required, the devices must be observed to check for proper use in this arrangement.

### 2.1 Functional features

- One-stage emergency mode for the first reverse osmosis stage or the second osmosis membrane possible.
- Emergency mode with soft water possible.
- Modular construction: the system performance can be changed merely by replacing/supplementing the pumps and membranes.
- Night operation: when it is not in permeate mode, the system regularly switches to a rinsing mode to prevent microbiological growth
- Impulse backflushing: the EcoRO Dia versions feature a regular rinsing mode for the membranes to remove deposits on the membranes.
- Unauthorized operating states that could endanger the connected medical products or even the patients are prevented due to measuring equipment and related control measures (alarm and error functions)
- · Economy mode: permeate production is reduced with low consumption.

Alternatively to hot cleaning there is also the possibility to disinfect chemically:

- Semi-automatic chemical disinfection and cleaning.
- Option "HT": in combination with a hot cleaning system (e.g. Aquaboss® HotRinse SMART) an EcoRO Dia II C HT system version can be disinfected thermally.
- Option ISS: An impulse shear force flushing of the ring piping (high flow speed) during night-time mode to prevent the formation of biofilms.

## 2.2 Essential feature

• Production of pure water (permeate with a low salt concentration) to dilute haemodialysis concentrates.

### 2.3 Application regulations

- No products or media are to be processed which, under the influence of pressure and temperature, tend to cause uncontrolled reactions such as higher viscosity, higher temperature, precipitation, frothing or the generation of gas which could cause the system limit values to be exceeded even for only a short time.
- The raw water must be treated in a correctly design pretreatment stage.
- A pretreatment stage can only be carried out subject to previous water analysis or the details provided by the municipal water suppliers. The values of the incoming raw water must be checked and recorded once a year.
- A water analysis must be requested by the system operator once a year.
- The municipal water suppliers (water board) must be consulted regarding the water quality/chlorination. You can find a corresponding sample letter in → Part 2, page 11-1.
- The local regulations for connecting the concentrate to the waste water drainage system must be observed (this also applies to draining disinfectant into the waste water system).
- Feed and waste water must be installed properly according to EN 1717 or other local regulations.
- Other operational purposes must be agreed in advance with the manufacturer.
- The system may only be transported, installed, used and repaired by specialists.
- Commissioning, operation and maintenance may only be carried out by authorized, trained and instructed specialists.
- Any use over and above this is deemed to be improper. The manufacturer shall not be liable for any damage resulting from this.
- The reverse osmosis system *Aquaboss*<sup>®</sup> has a short application period (< 30 days) in accordance with guideline 93/42/EEC Annex IX.

## 2.4 Water quality requirements

In order not to endanger patients' health, the water qualities of raw water and clean water must meet the respective guidelines that are assigned to the respective purpose, depending on their use.

#### Feed water/raw water requirements:

*Aquaboss*<sup>®</sup> reverse osmosis systems have been designed in such a way that they can usually be operated with feed water of "water for human consumption" quality in accordance with 98/83/EC with appropriate pretreatment.

The service lifetime of the reverse osmosis membranes used and the permeate quality of the product flow of the reverse osmosis system depend directly on the concentration of the individual water contents and can be/must be optimised through suitable pretreatment methods.

Daily logging of process parameters according to ISO 23500 is recommended ( $\rightarrow$  Part 2, chapter 9).

Definition/Water quality	Drinking water (water for human consumption)	Feed water for reverse osmosis Aquaboss <sup>®</sup> (Eco)RO Dia	Dialysis water/permeate (water for diluting concentrated haemodialysis solutions)		
Directive	98/83/EC	98/83/EC + procedural limit values	ISO 13959	European Pharmacopoeia	Recommendation applied hygiene <sup>1</sup>
Chemical/physical parame	ters [ppm]				
Sodium (Na)	200	200	70	50	50
Potassium (K)			8	2	8
Calcium (Ca)		Total hardness	2	2	2
Magnesium (Mg)		< 1°dH or < 1.79°f	4	2	4
Boron (B)	1.0	1			
Barium (Ba)		0.7	0.1		0.1
Beryllium (Be)		0.004	0.0004		0.0004
Ammonium (NH <sub>4</sub> )	0.5	0.1		0.2	0.2
Aluminium (Al)	0.1	< 0.01	0.01	0.01	0.01
Metals	0.1		0.01	0.01	0.01
- Copper (Cu)	2	1	0.1		0.1
- Arsenic (As)	0.01	0.01	0.005		0.005
- Lead (Pb)	0.01	0.01	0.005		0.005
( )		0.01	0.005		0.005
- Silver (Ag)	 0.05	0.1	0.005		0.005
- Chromium (Cr)		0.05	0.014		0.014
- Selenium (Se)	0.01				
- Stibium (Sb)	0.005	0.005	0.006		0.005
- Mercury (Hg)	0.001	0.001	0.0002	0.001	0.0002
- Nickel (Ni)	0.02	0.02			
- Tin (Sn)					
- Iron (Fe)	0.2	< 0.1			
- Cadmium (Cd)	0.005	0.005	0.001		0.001
- Zinc (Zn)		5.0	0.1	0.1	0.1
- Manganese (Mn)	0.05	< 0.01			
– Uranium (U)	0.010	0.01			
- Thallium (Ti)	-,-		0.002		
or sum of heavy metals			0.1	0.1	
Cyanide (CN)	0.05	0.05			0.02
Chlorine (Cl <sub>2</sub> )		Total chlorine: 0.0	0.1	0.1	0.1
1,2-dichlorethane	0.0030				
Chloramines					0.1
Chloride (CI)	250	250		50	50

Definition/Water quality	Drinking water (water for human consumption)	Feed water for reverse osmosis Aquaboss® (Eco)RO Dia	(wa	Dialysis water/pern ater for diluting conce haemodialysis solut	entrated
Directive	98/83/EC	98/83/EC + procedural limit values	ISO 13959	European Pharmacopoeia	Recommendation applied hygiene <sup>1</sup>
Fluoride (F)	1.5	1.5	0.2	0.2	0.2
Sulphate (SO <sub>4</sub> )	250	240	100	50	50
Nitrate (NO3)	50	10	2 (as N)	2	2
Nitrite (NO2)	0.5	0.5			
Polycyclic aromatic hydrocarbons	0.00010	0.0001			
Benzene	0.0010	0.001			
Bromate	0.010	0.01			
Tetrachlorethene and trichlorethene	0.010	0.005			
Trihalogenmethane	0.050	0.05			
Vinyl chloride	0.00050	0.0005			
Silicic acid (SIO <sub>2</sub> )		< 10			
pH Value	6.5 – 9.5	6.5 - 9.0			
Temperature		6–30°C			
Spec. conductivity	2500 µS/cm at 20 °C	< 1000 µS/cm at 20 °C			
Silting index SDI <sub>(15)</sub> Turbidity (NTU)	NTU < 1	SDI (15 min) < 5 (EcoRO Dia) < 3 (RO Dia) As per ASTM 4189			
Microbiological parameter	rs				
Total germ count [CFU/ml]	<pre>&lt; 100 (22 ±2 °C,</pre>	< 100 (22° C) < 100 (36° C)	< 100 (action at 50%) (17–23°C, 7d)	< 10 <sup>2</sup> (30–35°C, 5 d)	< 100 acc. to RKI (22 ± 2 °C, 3–7 d)
Enterococci	0 CFU/100ml	0 CFU/100ml			
EColi/ coliform	0 CFU/100ml	0 CFU/100ml			
Endotoxins [EU/ml]			<0.25 (action at 50%)	< 0.25	<0.25

#### Comment:

Directive 98/83/EC and ISO 13959 specify limit values for rare substances that are not listed here; these can be looked up in the original publications. Compared to earlier publications no information regarding phosphate is provided.

1. "Guideline for applied hygiene in dialysis units", ISBN 978-3-00-044348-0, 2013

Danger of poisoning and pyrogenic reactions. The operator is responsible for the selection of water treatment equipment and annual inspection of the permeate using the values of Ph. Eur and ISO 13959.
Danger caused by a chemical and/or microbial contamination.
 The permeate quality is connected to the quality of supply water. If the quality of supply water reduces significantly, changes to the permeate can lead to the acceptable levels being exceeded.
The operator is responsible for regular monitoring of limit values for supply water.

The water quality in the permeate is shown online via the conductivity (sum parameters of most substances in water). It depends on the pretreatment, the quality of the feed water and the temperature.

## 3. Accessories list (Eco)RO Dia I/II C (HT)

If cables, transformers or accessories other than those listed above are used, this may have a negative influence on jamming and noise immunity.

Item	Article number	Designation	Beschreibung (Description)
1	37754	Sterile filter 20", 0.2µm, absolute	Membrane filter Steril Hot Polysulfon, pre-rinsed with ultrapure water: Together with an <i>Aquaboss</i> <sup>®</sup> dialysis water treatment system, the <i>Aquaboss</i> <sup>®</sup> Hot Rinse hot-water disinfection system and the <i>Aquaboss</i> <sup>®</sup> sterile hot polysulphone membrane filter, a constant dialysis water quality of < 0.1 KBE/ml is guaranteed.
2	2000011	Aqua Control 1"	Autarchic device incl. sensor and safety solenoid valve. Thanks to the de-energized open design, a power supply is not required during operation. As a result, the valve tappet is not heated up, which in turn prevents calcification due to heat input and mal- functioning in the case of a leakage. Automatic periodic rinsing pre- vents jamming. The solenoid valve is integrated in the <i>Aquaboss</i> <sup>®</sup> pre-treatment stage if this option has been selected.
3	2000305	Aquaboss <sup>®</sup> -Control II	Remote control for reverse osmosis concentrate supply and hot- water disinfection system (display only) in one device. Alarm signals serve as an additional warning, but one-hundred percent discovery of faults can only take place via the system itself.
4	2001000	Aquaboss® Vision	<ul> <li>Visualisation system on the screen, including</li> <li>Graphic online representation of the flow diagram with the corresponding current mode of operation.</li> <li>Alarm signals serve as an additional warning, but one-hundred percent discovery of faults can only take place via the system itself.</li> <li>Overview of all system data and set parameters</li> <li>Input of all system data via a graphic user interface. Program settings can be saved and read in using HD or HDD</li> <li>System history in order to guarantee the latest possible preventative replacement of wear parts "just in time before expected failure"</li> <li>Continuous recording of operating data</li> <li>Archiving of all operation and fault messages in plain text</li> <li>Error history</li> <li>Graphic trend curves as historic documentation and for simplified fault analysis</li> <li>Online graphs for online fault analysis</li> <li>Operating instructions for the medical product, including search function for fast location</li> <li>Internet and network-capable (LAN) using TCP/IP</li> <li>For network connection: fault notification via e-mail function and transmittance of daily performance logs via SMTP server</li> </ul>
5	52089	Steady yellow light	12–240V, light elements as external alarm signals, optional connection, note: alarm signals serve as an additional warning, but one-hundred percent discovery of faults can only take place via the system itself.
6	51534	Flashing yellow element	24V DC, 1Hz, light elements as external alarm signals, optional connection, note: alarm signals serve as an additional warning, but one-hundred percent discovery of faults can only take place via the system itself.

Item	Article number	Designation	Beschreibung (Description)	
7	41460	Flashing yellow element	230V AC, 1Hz, light elements as external alarm signals, optional connection, note: alarm signals serve as an additional warning, but one-hundred percent discovery of faults can only take place via the system itself.	
8	41459	Steady green light	12–240V, light elements as external alarm signals, optional connection, note: alarm signals serve as an additional warning, but one-hundred percent discovery of faults can only take place via the system itself.	
9	2001015	Software licence	PV licence	
10	2100100	Kit for impulse shear force flushing	<ul> <li>Kit for equipping <i>Aquaboss</i><sup>®</sup>-EcoRO Dia systems, for the impulse-based increase in flow speeds in the primary and secondary loops to prevent the formation of biofilms, consisting of:</li> <li>V4A solenoid valve</li> <li>V4A pipe branch for integration of the system</li> <li>cable with plug to connect solenoid valve / control cabinet</li> <li>programme update</li> </ul>	
11	1350002	Hard water monitor <i>Aquaboss</i> ® Softcontrol II	<ul> <li>The <i>Aquaboss</i><sup>®</sup>-hard water monitor is a fully automatic, continuously working, independent measuring system for detecting hardness breakdowns. The <i>Aquaboss</i><sup>®</sup> Softcontrol does not use chemicals. Since its chemical composition is not altered, the water used can be added to the downstream reverse osmosis system without losses.</li> <li>Ion-specific hard water monitoring using the membrane detection principle of monovalent and bivalent ions</li> <li>Independent function without chemicals</li> </ul>	
12	3648101	Surge tank PWD 0-50	Surge tank for constant pressure conditions in the ring piping	
13	37962	Disinfectant 5 I	Disinfectant Dialox, 5 l jerry can	
14	52819	Minncare Cold Sterilant 6x 1 kg	Disinfectant Minncare, 6 x 1 kg	
15	52820	Minncare Cold Sterilant 2x 5 I	Disinfectant Minncare, 2x 5 I	
16	52821	Minncare Residual Test Strip	Test strips for detecting residues of the Minncare disinfectant	
17	52822	Minncare 1% Test Strip	Test strip for proving 1% residue of the disinfectant Minncare	
18	9126501	Overflow valve	Overflow valve ÜV2, ring piping feed	
19	8024900	Aquaboss ED	Switch for manual delay of the night-time mode in auto mode	
20	50663	Flowmeter 100 – 1000 l/h	Variable area flowmeter, polysulphone; hot water resistant	
21	50797	Flowmeter 200 – 2500 l/h	Variable area flowmeter, polysulphone; hot water resistant	

Item	Article number	Designation	Beschreibung (Description)
22	2000050	Filter unit 20"	Combined filter unit 20" single, 1"
23	2000051	Filter unit 20"	Combined filter unit 20" single, hose d25
24	2000052	Filter unit 20"	Combined filter unit 20" single, Mapress
25	2000060	Filter unit 20"	Combined filter unit 20" Duo, lockable, 1"
26	2000061	Filter unit 20"	Combined filter unit 20" Duo, lockable, hose d25
27	2000065	Filter unit 20"	Combined filter unit 20" Duo, 1"
28	2000066	Filter unit 20"	Combined filter unit 20" Duo, hose d25
29	2000070	Filter unit 20"	Combined filter unit 20" Duo, lockable, 1½"
30	2000075	Filter unit 20"	Combined filter unit 20" Duo, 1 <sup>1</sup> / <sub>2</sub> "
31	2000080	Filter unit 20"	Combined filter unit 20" quadruple, lockable, 1"
32	2000081	Filter unit 20"	Combined filter unit 20" Quadruple, lockable, d25 hose
33	2000085	Filter unit 20"	Combined filter unit 20" quadruple, lockable, 11/2"
34	9490400	Filter unit 20"	Combined filter unit 20" Duo with Mapress ø28, with ball cocks
35	9490500	Filter unit 20"	Combined filter unit 20" Duo with Mapress ø28, without ball cocks
36	9471800	Filter unit 20"	Combined filter unit 20" Duo with Mapress ø42, with ball cocks
37	9471700	Filter unit 20"	Combined filter unit 20" Duo with Mapress ø42, without ball cocks
38	9471900	Filter unit 20"	Combined filter unit 20" quadruple m Mapress ø28, with ball cocks
39	9490600	Filter unit 20"	Combined filter unit 20" quadruple m Mapress ø42, with ball cocks
40	899	Citric acid solution (company B.Braun) 6 I	Liquid concentrate for decalcification
	307	Citric acid solution (company B.Braun) 10 I	

NOTE:

Alarm signals provide an additional warning. Faults can only be discovered one hundred percent through the system itself.

## 4. Use in combination with other equipment

The operator combines the (Eco)RO Dia I/II C (HT) with further medical products such as ring piping, media supply units or dialysis machines.

The (Eco)RO Dia I/II C (HT) can be placed on the market completely independently from other medical products. No combination of medical products will be put into circulation by the manufacturer as a standard variation.

The manufacturer, B. Braun Avitum AG, stipulates the following reverse osmosis system requirements for combination with other equipment:

- Devices for the pretreatment of feed water (e.g. softeners, activated charcoal filters etc.) as well as systems for storing or distributing the pure water must meet the requirements of ISO 26722.
- When used in combination with permeate ring piping, these must be implemented in accordance with EN ISO 11197 (medical electrical equipment, specific requirements for the safety of medical supply units).
- When used in combination with media supply units (Medical Product Class I), the tapping points for permeate must be implemented in accordance with EN ISO 11197 (medical electrical equipment, specific requirements for the safety of medical supply units).
- Dialysis machines used in combination with the system (Medical Product Class IIb) must comply with standard DIN VDE 0753-4 [regulations for the use of haemodialysis machines].
- Furthermore, the dialysis machine must comply with standard IEC 60601-2-16 (special requirements for the safety of haemodialysis, haemodiafiltrations and haemofiltration units).
- A Class EA1 pipe disconnector is adequate for preliminary water treatment only if unhindered intake is ensured through the connected dialysis machines.
- The user must ensure that the devices function and are in a proper condition before using the combination of devices.
- It must be ensured that additional equipment that is connected to the analogue and digital interfaces of the device satisfies the appropriate EN specifications (e.g. IEC 60950 for data processing devices, IEC 61010-1 for measuring/control/laboratory devices and IEC 60601-1 for electro-medical devices). Furthermore, all configurations must satisfy the valid version of the system standard IEC 60601-1-1. The person who connects additional devices to the signal input or output section is a system configurator and is therefore responsible for ensuring that the valid version of system standard IEC 60601-1-1 is observed. If you have any questions please contact your local dealer or the Technical Services department.

The reverse osmosis system <i>Aquaboss</i> <sup>®</sup> has been designed for safe operation in combination with the <i>Aquaboss</i> <sup>®</sup> products (ring piping, hot cleaning).

Danger of poisoning 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 26722, the distribution of this water can impair the quality so much that it no longer meets the requirements of the DIN EN ISO 26722 standard, if the distribution system is not appropriately maintained.		
Maintenance/technical safety checks on the reverse osmosis system and connected distribution system must be undertaken according to the manufacturer's instructions.		

## 5. Technical Description

The *Aquaboss*® (Eco)RO Dia I/II C (HT) provides the operator with a consumption-controlled reverse osmosis system as single-level or multi-level model. A 4-line LCD plain text display allows all operating parameters to be called up and monitored at any time. The plain text display is available in 6 different languages.

A special rinsing and disinfection program developed for compact systems with the integrated *Aquaboss*<sup>®</sup> impulse backflushing system ensures maximum dialysis water hygiene. Thanks to the compact design size, the system is suitable for the location-independent production of dialysis water.

An consumer-focused logical control system makes high water yield possible even under unfavourable raw water conditions. In this respect, the raw water consumption depends solely on the ultrapure water requirements of the end user.

A menu-guided plain text display enables the operator to monitor all production parameters and system functions including the disinfection mode in an individual and reproducible way.

#### Special advantages

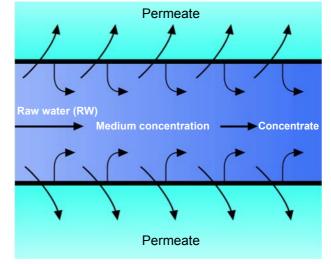
- Disconnection from the mains / free water intake as per EN 1717
- User-friendly operation thanks to menu-guided control system with plain text display
- Low water consumption including rinsing water for Aquaboss® softener and standstill rinsing
- Shut-down and standstill flushing with leakage monitoring during night time mode
- Compact model
- Membrane blockage protection using *Aquaboss*<sup>®</sup> impulse backflushing and conductivity check of the WCF (for EcoRO version only)
- Optional impulse shear force rinsing
- Durable stainless steel design
- Low energy consumption
- Hot disinfection operation of the connected loop possible
- · Hot sanitation of the 1st and 2nd stage for EcoRO Dia II C HT version
- Password protection for adjustable unit data

## 5.1 Functional principle

The (Eco)RO Dia I/II C (HT) works on the reverse osmosis principle. Reverse osmosis describes a process involving a pressure-operated cross-filtration system. Water flows at high pressure (up to max. 20 bar) tangentially over a semi-permeable membrane. As is the case with normal filtration, the system is cleaned by allowing one component (water) of the mixture to be separated to pass through the membrane with almost no hindrance, while other components (dissolved and undissolved water contents) are held back to a greater or lesser extent and leave the filtration unit in the concentrate flow. This is a purely physical separation process in the molecular range which does not change the components being separated either chemically, biologically or thermally.

## 5.2 Design features

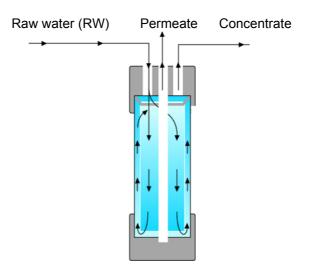
# 5.2.1 *Aquaboss*<sup>®</sup> impulse backflushing (EcoRO-version only)



#### Figure 5-1: Impulse backflushing

The patented impulse return rinsing feature is designed to increase membrane service life, since the particles that lead to membrane blockage are returned to the concentrate flow.

### 5.2.2 *Aquaboss*<sup>®</sup> membrane module with no dead space



#### Figure 5-2: Membrane module with no dead space

Thanks to the new design of the membrane module (patented), it is guaranteed that the dead space between the outside of the membrane and the inside of the pressure pipe is continually flushed. All the connections for raw water, concentrate and permeate are located on the top of the module. The concentrate is extracted at the upper pressure pipe side.

#### 5.2.3 Single pipe construction

The single pipe construction ensures the membrane has a long service life. The membrane pipe is made of stainless steel (1.4571/1.4404).

#### 5.2.4 Minimum dead space piping in stainless steel

A minimum of dead space throughout the entire system has been provided. Moreover, the risk of biofilm growth on the pipe walls is restricted to a considerable extent by the high flow rate and the resulting shear forces.

## 6. Functions

## 6.1 Basic flow diagram



Water treatment for generation of water to dilute concentrates for haemodialysis generally consists of a pretreatment (e.g. filter, softener, activated charcoal...), a single or dual stage reverse osmosis

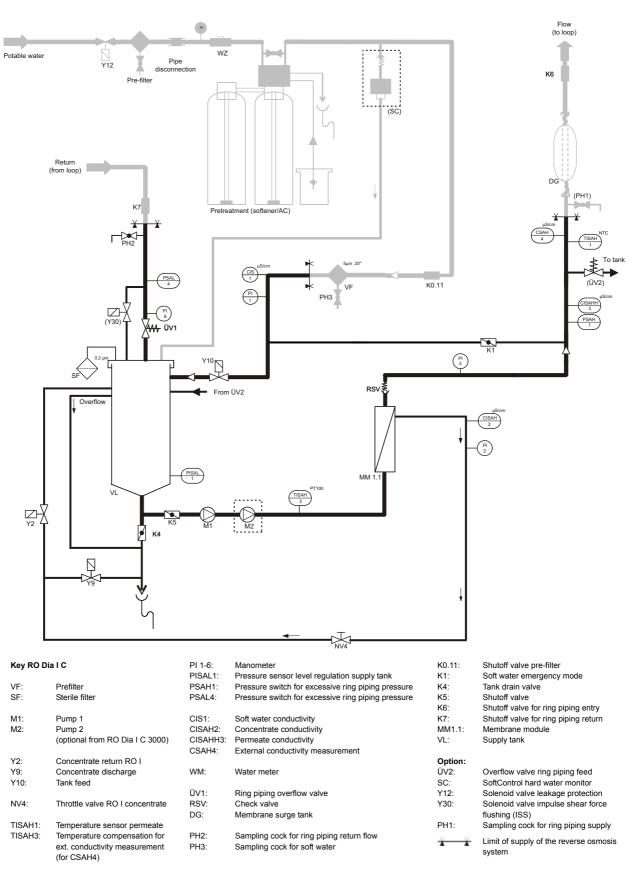
(Eco)RO Dia I C (Eco)RO Dia II C or EcoRO Dia II C HT

and a ring piping through which the dialysis water circulates and is made available to the user at different tapping points.

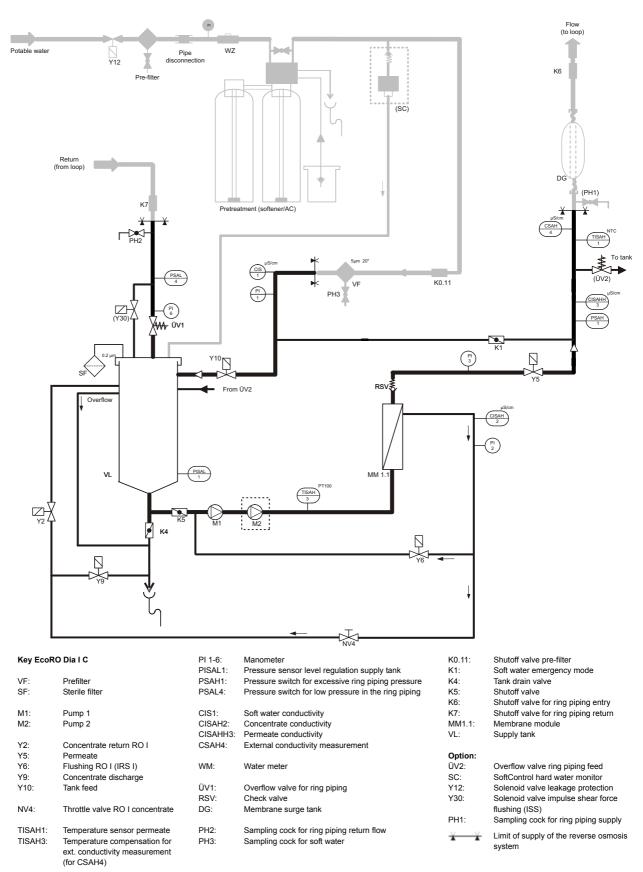
All reverse osmosis produce water in dialysis mode for the dilution of haemodialysis concentrate.

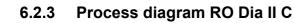
## 6.2 Process diagrams

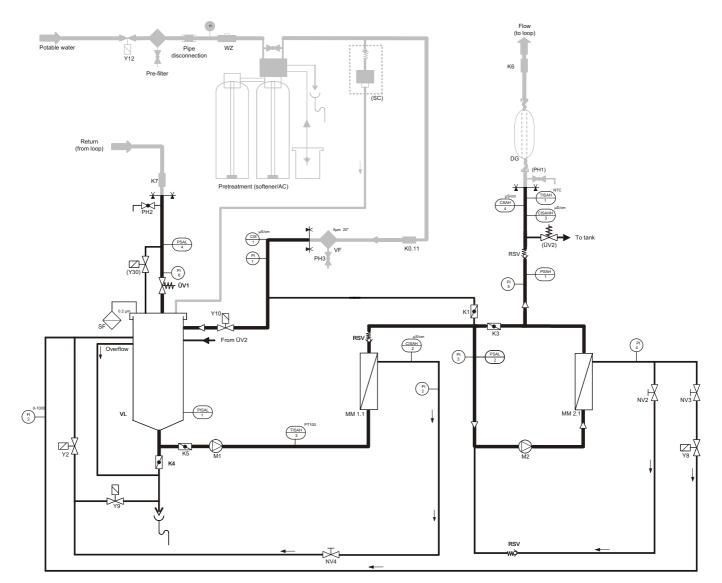
## 6.2.1 Process diagram RO Dia I C









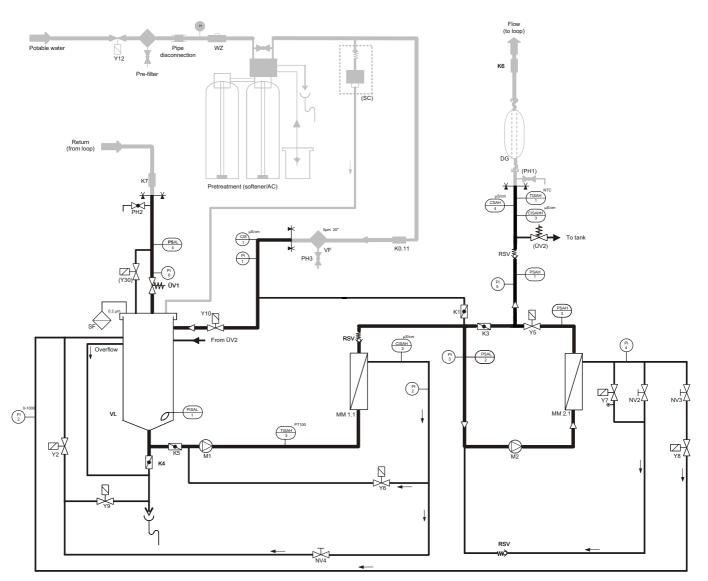


#### Key RO Dia II C

Key RO Dia II C		PI 1-6: PISAL1:	Manometer Pressure sensor level regulation supply tank
VF:	Prefilter	PSAH1:	Pressure switch for excessive ring piping pressure
SF:	Sterile filter	PSAL2:	Pre-pressure RO II
		PSAL4:	Pressure switch for low pressure in the ring piping
M1:	Pump 1		
M2:	Pump 2	CIS1:	Soft water conductivity
Y2:	Concentrate return RO I	CISAH2:	Concentrate conductivity
Y8:	Concentrate return RO II	CISAHH3:	Permeate conductivity
Y9:	Concentrate discharge	CSAH4:	External conductivity measurement
Y10:	Tank feed		
		WM:	Water meter
NV2:	Throttle valve RO II concentrate	FI2:	Flow meter concentrate RO II
NV3:	Throttle valve RO II concentrate		
NV4:	Throttle valve RO I concentrate	ÜV1:	Overflow valve for ring piping
		RSV:	Check valve
		DG:	Membrane surge tank
TISAH1:	Temperature sensor permeate		
TISAH3:	Temperature compensation for ext.	PH2:	Sampling cock for ring piping return flow
	conductivity measurement (for CSAH4)	PH3:	Sampling cock for soft water

K0.11:	Shutoff valve pre-filter
K1:	Shutoff valve for emergency operating mode RO II
K3:	Shutoff valve for emergency operating mode RO I
K4:	Tank drain valve
K5:	Shutoff valve
K6:	Shutoff valve for ring piping entry
K7:	Shutoff valve for ring piping return
MM1.1-2.1:	Membrane modules
VL:	Supply tank
Option:	
ÜV2:	Overflow valve ring piping feed
SC:	SoftControl hard water monitor
Y12:	Solenoid valve leakage protection
Y30:	Solenoid valve impulse shear force flushing (ISS)
PH1:	Sampling cock for ring piping supply
<del>X X</del>	Limit of supply of the reverse osmosis system





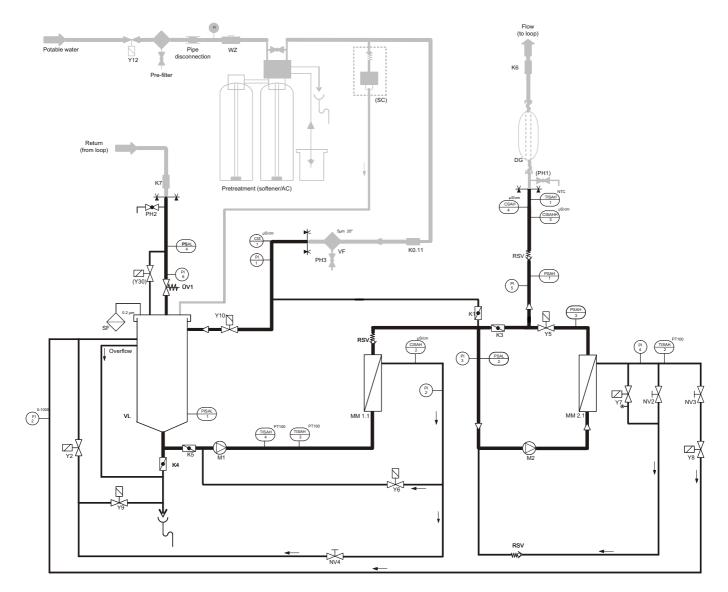
#### Key EcoRO Dia II C

		PISAL
VF:	Prefilter	PSAH
SF:	Sterile filter	PSAL
		PSAH
M1:	Pump 1	PSAL
M2:	Pump 2	
		CIS1:
Y2:	Concentrate return RO I	CISA
Y5:	Permeate	CISA
Y6:	Flushing RO I (IRS I)	CSAH
Y7:	Flushing RO II (IRS II)	
Y8:	Concentrate return RO II	WM:
Y9:	Concentrate discharge	FI2:
Y10:	Tank feed	
		ÜV1:
NV2:	Throttle valve RO I concentrate	RSV:
NV3:	Throttle valve RO II concentrate	DG:
NV4:	Throttle valve RO I concentrate	
		PH2:
TISAH1:	Temperature sensor permeate	PH3:
TISAH3:	Temperature compensation for ext.	
	conductivity measurement (for CSAH4)	
	,	

PI 1-6:	Manometer
PISAL1:	Pressure sensor level regulation supply tank
PSAH1:	Pressure switch for excessive ring piping pressure
PSAL2:	Pre-pressure RO II
PSAH3:	Overpressure RO II.
PSAL4:	Pressure switch for low pressure in the ring piping
CIS1:	Soft water conductivity
CISAH2:	Concentrate conductivity
CISAHH3:	Permeate conductivity
CSAH4:	External conductivity measurement
WM:	Water meter
FI2:	Flow meter concentrate RO II
ÜV1:	Overflow valve for ring piping
RSV:	Check valve
DG:	Membrane surge tank
PH2:	Sampling valve ring piping return
PH3:	Sampling cock for soft water

K0.11:	Shutoff valve pre-filter
K1:	Shutoff valve for emergency operating mode RO II
K3:	Shutoff valve for emergency operating mode RO I
K4:	Tank drain valve
K5:	Shutoff valve
K6:	Shutoff valve for ring piping entry
K7:	Shutoff valve for ring piping return
MM1.1-2.1:	Membrane modules
VL:	Supply tank
Option:	
ÜV2:	Overflow valve ring piping feed
SC:	SoftControl hard water monitor
Y12:	Solenoid valve leakage protection
Y30:	Solenoid valve impulse shear force flushing (ISS)
PH1:	Sampling cock for ring piping supply flow
<del>X X</del>	Limit of supply of the reverse osmosis system





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Throttle valve RO II concentrate

Throttle valve RO II concentrate

Throttle valve RO I concentrate

Temperature sensor permeate Temperature sensor concentrate RO II

Key for EcoRO Dia II C HT

NV2:

NV3:

NV4:

TISAH1:

TISAH2:

TISAH4:	Temperature sensor feed RO I
PI 1-6:	Manometer
PISAL1:	Pressure sensor level regulation supply tank
PSAH1:	Pressure switch for excessive ring piping pressure
PSAL2:	Pre-pressure RO II
PSAH3:	Overpressure RO II.
PSAL4:	Pressure switch for low pressure in the ring piping
CIS1:	Soft water conductivity
CISAH2:	Concentrate conductivity
CISAHH3:	Permeate conductivity
CSAH4:	External conductivity measurement
WM:	Water meter
FI2:	Flow meter concentrate RO II
CD 14	
ÜV1:	Overflow valve for ring piping
RSV:	Check valve

Temperature compensation for ext. conductivity measurement (for CSAH4)

TISAH3:

DG:

Check valv	e
Membrane	surge tank

PH2:	Sampling cock for ring piping return flow
PH3:	Sampling cock for soft water
K1:	Shutoff valve for emergency operating mode RO I
K3:	Shutoff valve for emergency operating mode RO I
K4:	Tank drain valve
K5:	Shutoff valve
K6:	Shutoff valve for ring piping entry
K7:	Shutoff valve for ring piping return
MM1.1-2.1:	Membrane modules
VL:	Supply tank
Option:	SoftControl hard water monitor
SC:	Solenoid valve leakage protection
Y12:	Solenoid valve impulse shear force flushing (ISS)
Y30:	Sampling cock for ring piping supply
PH1:	Limit of supply of the reverse osmosis system

# 6.3 Functional description

## 6.3.1 Water supply

In general the system is fed by soft water which is made available through an upstream softening plant. A 5  $\mu$ m-pre-filter protects the RO membranes from coarse contamination. There are various pre-filter variations to select (see  $\rightarrow$  Chapter 3 Accessories).

Chlorinated drinking water must be treated with an activated carbon filter since chlorine will cause irreversible damage to the membranes ( $\rightarrow$  Part 2, chapter 7 "Technical data").

These pretreatment units are not included in the scope of supply of an (Eco)RO Dia I/II C (HT).

## 6.3.2 Supply tank

The prefiltered softened water enters the supply tank through feed valve **Y10**. The level in the supply tank is controlled with pressure sensor **PISAL1**. Pressure sensor **PISAL1** protects the built-in circulation pump against low water levels. If the level drops below the switch point **PISAL1** (**LSAL1**), the pump switches off. The pump must not be operated if the water level in the container has undercut the level **LSAL1** / **PISAL1**.

## The following are connected to the supply tank:

- Internal circulation via Y2
- Soft water intake via Y10
- Ring piping return flow via ÜV1
- Soft control (optional)
- Overflow
- Bypass valve Y30 to the overflow valve for the ring piping return (optional, impulse shear force flushing)
- Aeration and ventilation filter (tank respiration)
- Outlet to pump M1
- Tank emptying

## 6.3.3 Dual-stage reverse osmosis

The raw water flows over a 5  $\mu$ m pre-filter as well as past the closed flap K1 (for the dual-stage RO) and enters the free intake to the storage tank VL via the solenoid Y10.

From there, it is delivered by means of pump **M1** to the membrane module by passing through a reverse osmosis membrane. The "feed" flow is divided into the concentrate flow and, following passage of the membrane barrier, the permeate flow.

The concentrate flow leaves the membrane module through the needle valve **NV4** which restricts the volume of water discharged and ensures a constant production pressure.

The pressure set by the needle valve NV4 can be read off on manometer PI2.

The regulated concentrate flow is either routed back to the supply tank internally via a solenoid valve **Y2** or discharged to the drain via solenoid valve **Y9**. The cycle rate **Y2/Y9** and thus the regulation of the concentrate amount to be discharged, depends on the quantity of permeate removed and the set yield factor WCF.

The generated permeate passes the spring-loaded check valve **RSV** after leaving the membrane module and flows via pump **M2** with increased pressure to the membrane module by passing through a reverse osmosis spiral-wound membrane. The "feed" flow is divided into the concentrate flow and, following passage of the membrane barrier, the permeate flow. The permeate flows through the opened solenoid valve **Y5** and past **PSAH1** and **CISAHH3**, whereby the correct permeate pressure and quality are monitored before entering the loop. In larger systems, part of the permeate amount produced flows back into the supply tank through the overflow valve **OV2** if the amount removed is too low in order to keep the ring piping pressure constant. The concentrate flow leaves the membrane module and passes through the needle valves **NV2** and **NV4** which restrict the volume of water discharged and ensures a constant production pressure. The pressure set by the needle valves can be read off on manometer **PI4**. The regulated concentrate flow is guided back by a solenoid **Y8** in part internally to the supply tank and partly upstream of pump **M2**.

The permeate enters the ring piping, which can be blocked by ball cock **K6**, via a hose bridge. The water flows through the surge tank **DG** and is guided to the individual tapping points. The end of the ring piping can be blocked off using ball cock **K7**. An additional hose bridge is used to reconnect the ring piping to the reverse osmosis system.

The permeate flowing back from the ring piping passes sampling cock **PH2**, pressure sensor **PSAL4** (minimum pressure ring piping) overflow valve **OV1** during its return to the reverse osmosis system. The ring piping pressure set at the **OV1** can be read off on manometer **PI6**.

## 6.3.4 Impulse return rinsing

## Impulse backflushing (IRS), 1st stage

In the(Eco)RO Dia I/II C impulse backflushing (IRS) of the first membrane stage of the (Eco)RO Dia I C and EcoRO Dia II C 1 can be used to clean the membrane and provide preventative protection from biofilm formation (see  $\rightarrow$  Chapter 5.2.1).

By closing solenoid valves **Y5** (permeate exit), **Y2** (internal circulation), **Y9** (concentrate drain) and **Y6** (flushing valve) with the M2 pump running, pressure can be built up, and is subsequently relieved by opening the solenoid **Y6**. This procedure will be termed "impulse backflushing" in this document. This procedure will be termed "impulse return rinsing" in this document.

The flushing duration and frequency are programmed in sub-menu 6 (device data). When switching von Dia I into night-time mode an impulse return rinsing of the 1st stage is always performed

## Impulse backflushing (IRS), 2st stage

In the (Eco)RO Dia II C system, impulse return rinsing (IRS) can also be used for mechanical cleaning of the 2nd membrane stage.

Here, the pump transports feed water to the closed solenoid valves Y7, Y5 and Y8 to build up pressure.

By opening **Y7** and **Y8** and transporting additional water via **M1** and **M2**, water flows at an increased speed over the second stage membrane for a short time.

The increased concentrate flow speed removes the deposits on the membrane to a large extent and thus maintains permeate capacity long term. During this flushing procedure, permeate valve **Y5** remains closed.

The flushing duriation and frequency is programmed in the submenu 6. (device data).

## 6.3.5 Control according to conductivity

#### Measured and assessed according to the process diagram:

Raw water conductance	CIS 1
Concentrate conductance	CISAH2
Permeate conductance	CISAHH3

For additional safety the conductivity is recorded independently from the control (CSAH4).

The output of the reverse osmosis system is regulated by the yield in % Water Conversion Factor (WCF). The concentrate of the reverse osmosis stage(s) is returned to the supply tank for economic reasons. However, in order not to impair the permeate quality or to damage the membrane during operation with this operating mode, the concentrate flow has to be drained regularly.

In order to control the concentrate drainage via valve **Y9**, the following control values are calculated from the measured values of raw water and concentrate conductivity:

## Start factor

The quotient of the conductivity of the concentrate  $CISAH2-LF_{K}$  as well as the conductivity of the soft water  $CIS1-LF_{WW}$  is defined as start factor (control value 1).

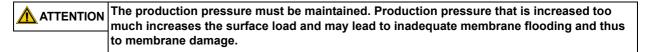
On reaching the preset start factor (setting from value: 4.0) the concentrate drainage is started. A start factor of 4.0 means that the concentrate conductivity has reached 4.0 times the raw water conductivity. This corresponds to a water conversion of about 75%.

## Stop factor

The quotient of the concentrate conductivity  $CISAH2-LF_{K}$  as well as the conductivity of the raw water  $CIS1-LF_{WW}$  is defined as stop factor (control value 2) which causes the concentrate drainage to stop. The stop factor has to be at least 0.2 units below the start factor.

The concentrate drainage is effected via the solenoid valve **Y9** until the stop factor is reached or until the lower level switch **LSAL1** is reached.

## 6.3.6 System production pressure



The amount of permeate increases proportionally with production pressure **PI2.** The production pressure is adjusted by **NV4.** Only personnel authorized by the manufacturer are permitted to make such adjustments. Analogue to this the air pressure in the pressure accumulator container is adjusted.

## 6.3.7 Ring piping pressure

Factors which influence pressure in the ring piping:

- the maximum consumption (number of dialysis stations and other consumers)
- the minimum flow speed required (to avoid the formation of biofilm)
- · the minimum supply pressure at the last tapping point
- The pipe geometry (pipe cross-section etc.)

The overflow valve  $\ddot{U}V1$  at the end of the ring piping must be set to pressure **PI6** in accordance with these requirements. At full demand rate, the required amount of permeate must be fed into the ring piping with the required pressure. The factory setting of  $\ddot{U}V1$  is 2.5–3.5 bar. The flow speed in the primary ring piping must reach 0.5 m/s (with full discharge).

## 6.3.8 Membrane pressure vessel in the ring piping

The required constant pressure and an adequate supply of permeate is ensured by installing a membrane pressure vessel (not part of the delivery scope of a Ro Dia I/II C). In turn, the size of the vessel and the necessary membrane air pressure depend on the factors listed under "System production pressure"  $\rightarrow$  Part 1, page 6-9.

NOTE:	B. Braun recommends a weekly check of the Hydrowatch on the installed membrane pres- sure vessel (DG). The results of the check are to be documented in the medical product log
	$\rightarrow$ Part 2, page 9-4. If the red indicator is visible in the viewing glass, please contact your B. Braun Avitum AG service technician <u>immediately.</u>
	The Hydrowatch must be checked before and after each disinfection. If the red indicator is

## 6.3.9 Prevention of excess pressure in the ring piping

visible, the ring piping must not be disinfected.

An increase in pressure after reverse osmosis may well be possible if a shutoff cock is blocking the ring piping. The pressure switch **PSAH1** prevents the pressure increasing above the set value "Pressure **PSAH1**". After the system is switched off, the corresponding message appears on the display. A faulty expansion membrane on the surge tank (**DG**) also leads to an increase in pressure when the system is switched on, and thus to the system being switched off via pressure switch **PSAH1** (fault message **Alarm 03** or **Error 03**).

## 6.3.10 Temperature-dependent discharge

On reaching a permeate temperature over 35  $^{\circ}$ C (upper temp. limit value; parameterizable from 20–35  $^{\circ}$ C) the system drails the concentrate via **Y9** for 1 min. This happens until the temperature has fallen under the lower set temp. limit value.

The system switches off if the permeate temperature rises to above 40 °C (fault message Error 28).

## 6.3.11 Night-time mode

If no permeate is required for a longer period of time (e.g. weekend or night), the system can be switched to "night-time mode". In this operating mode the system flushes itself in preset cycles, incl. the connected ring piping. This prevents the formation of biofilm, whereas in normal standby phases the generation of microorganisms is promoted.

The system is switched on automatically at the set times to flush out the ring piping and the modules.

The system is switched on at the main switch (1). The night-time mode is selected via the function keys or programmed to auto mode by entering the night-time flushing data.

NOTE: During "night-time mode" no permeate withdrawal is permitted from the ring piping and thus no dialysis is possible.

Operators can change to dialysis mode at any time by pressing the dial key.

Monitoring the permeate temperature prevents uncontrolled increase of the temperature exceeding a set value.

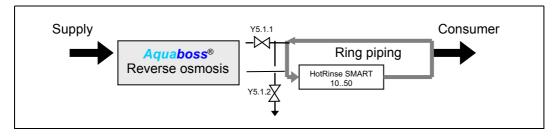
If the temperature monitoring is tripped, the started night-time flushing is interrupted. After falling under a programmed temperature value and after expiry of the set night-time pause, the next night-time flushing is started.

During night-time mode it is possible to produce permeate for an externally connected CMS.

Additionally, the RO offers the possibility to provide permeate during night-time mode in combination with a hot cleaning system (e.g. *Aquaboss*<sup>®</sup> HotRinse SMART series) in order to flush a connected ring piping. This combination is secured via signal exchange of both systems.

## Hot water cleaning of the ring piping ...

... with HotRinse SMART 10..50 (inline)



## 6.3.12 Shut-off flushing

Shut off rinsing is carried out when changing over from dialysis to night-time mode.

With the system running, water intake via Y10 is shut down until the liquid level has dropped to level **LSAL1**. During this time, the concentrate is discharged via Y9 and recirculated through Y6 during impulse return rinsing (only with EcoRO version).

Impulse return rinsing takes place when the system is switched from "dialysis mode" to "night-time mode" and when "dialysis mode" is switched on (only EcoRO version). During this, the pump conveys a greater volume flow through the membrane according to the smaller drop in pressure. The increased concentrate flow speed caused by this and the brief excess pressure on the permeate side remove the deposits on the membrane to a large extent and thus maintain permeate capacity long term.

## 6.3.13 Leak messages

To prevent major leaks during "night-time mode", the system inc. the ring piping is checked for water loss.

If the filling level in the supply tank drops to below **LSAL1** during night-time mode, this means that water is being lost in the ring piping or in the system, and the system shuts down (fault message **Error 16**).

## 6.3.14 Impulse shear force flushing (optional)

The impulse shear force flushing operation (ISS) flushes out the primary and secondary ring pipings at maximum flow speed and impulse-type flow.

The ring piping pressure set at overflow valve and the permeate withdrawal in dialysis mode reduce permeate production and, as a result, the theoretical possible maximum flow speed in the ring piping. By installing bypass valve **Y30** parallel to the overflow valve, it is possible to produce the maximum amount of permeate as a result of the low counter-pressure with solenoid valve **Y30** open. The resulting high flow speed acts as shear force on the pipeline wall.

In addition, the flow speeds are varied by the cyclic closing and opening of the valve **Y30**, which prevents biofilm growth. Furthermore, faster ventilation of the ring piping is made possible as well as filling or flushing out with disinfectant at each tapping point in the ring piping.

This mode of operation runs within disinfection, cleaning and during night-time flushing cycles.

As a result, there is no noise nuisance caused by media flow.

## 6.3.15 Hot RO (only EcoRO Dia II C HT)

Combined with an external hot-water cleaning system (e.g. *Aquaboss*<sup>®</sup> HotRinse Smart 10...50) the (Eco)RO Dia II HT can be disinfected in night-time mode with hot water up to 85 °C, and thus optimise the microbiological quality of the permeate as an alternative or supplement to chemical disinfection.

With hot disinfection there is no need to check for disinfectant residue.

With HotRO II activated (menu item 10.2), hot water is guided to the 1. and 2. membrane stage (Hot RO I + II) via the temperature-resistant storage tank during night-time operation and after release of the hot-cleaning system connected.

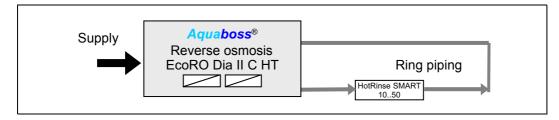
Temperature monitoring is performed at sensors **TISAH4**, **TISAH2** and **TISAH1**. Level regulation in the supply tank is by means of the pressure sensor **PISAL1**.

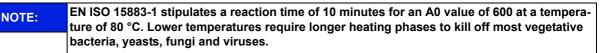
Hot cleaning can be interrupted at any time. Dialysis mode, however, is only possible after the cooling phase has been completed.

## Hot cleaning of the ring piping AND the EcoRO Dia II C HT

(1st and 2nd osmosis stage)

... with HotRinse SMART 10..50





(Reference: EN ISO 15883-1 "Cleaning disinfection devices [...]")

# 7. Description of components

# 7.1 Description of the system



Figure 7-1: Aquaboss® (Eco)RO Dia I/II C (HT) Front view

- 1 Main switch  $\rightarrow$  "1" on and "0" off
- 2 Display 4 lines with 20 characters each
- 3 Display-guided key control (function keys F1, F2, F3, F4)
- 4 Type plate
- 5 Function lamp "Dialysis mode" (green)
- 6 Function lamp "Night-time mode" (green)
- 7 Function lamp "Rinse / IRS" (yellow)
- 8 Function lamp "Disinfection" (yellow)
- 9 Function lamp "Alarm" (red)

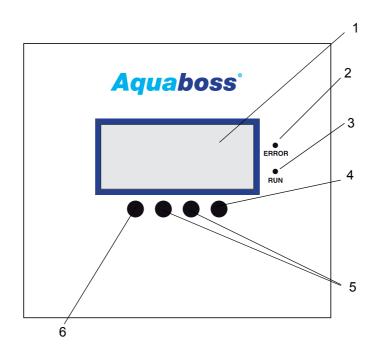
# 7.2 Display and keypad

The parameters and operating states are displayed on a 4-line LCD display.

There are 2 LEDs to the right of the display which indicate either correct operation (green) or an error / alarm (red.

Operator guidance via the display and the four keys is a fast and simple possibility of viewing and changing the operating parameters (only personnel authorised by the manufacturer is permitted to make operation-relevant changes).

B. Braun advises proceeding with the help of the operating instructions when using the system for the first time and when operators are not familiar with the system.



## Figure 7-2: Display with function keys

- 1 LCD display, 4 lines
- 2 LED red, error/alarm
- 3 LED green, operation
- 4 Enter key (F4)
- 5 Setting keys (F2, F3)
- 6 Menu key, ESC (F1)

# 8. Commissioning / Decommissioning

 Commissioning, operation and maintenance may only be carried out by authorized, trained and B. Braun-instructed specialists. Electrical work is to be carried out only after completely disconnecting the system from the power supply and only by authorized, trained and instructed electricians.

## Electric shock!

Dangerous voltage when the control cabinet is open. Switch the reverse osmosis system off at the main switch and disconnect it from the mains.

- Read and carefully observe these operating instructions, especially the safety instructions
   → Part 1 from page 1-1 before starting up, operating and servicing the system!
- When putting into operation, check to make sure all water connections have been made properly
   → Part 2 from page 3-1 and that all connections are leakproof.
- Commissioning is documented in the commissioning log ( $\rightarrow$  Part 2 from page 5-1).

## 8.1 System start-up

Open the water feed (upstream of the system) and switch the system to ON at the main switch (1).

- 1. Init. test
- 2. The supply tank is emptied.
- 3. After the level falls short of LSAL1/PISAL1 the tank fills up again.
- 4. The control unit switches on the pump and the system starts to produce permeate.
- 5. The pump must be bled during initial commissioning or commissioning after parts which are in contact with water have been opened (see → Part 2, chapter 4 "Commissioning")

## 8.2 Production stoppage

The system can be left filled with water for a short time e.g. overnight, if it is not to be operated in the nighttime mode. However, there is an increased risk of contamination in the system and ring piping in this case.

The system should be switched on some time before the first dialysis to flush out the system and ring piping.

There is a night-time mode for periods without dialysis.  $\rightarrow$  Part 1 from page 12-1.

## 8.3 Machine start-up after shutdown due to a fault

If the system is at a standstill due to a fault, the cause will be shown on the display. The reason for the fault should be eliminated if possible.

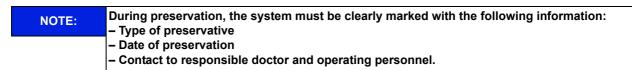
→ Part 1 from page 17-1

The control system may need to be reset, depending on the problem. This is done by switching the main switch off and on again or by pressing the reset key on the display.

# 8.4 Putting the machine out of operation

If the system is to be shut down for a longer period, it is recommended that the system be treated with preservative. Please consult our "Technical information sheet PRESERVATION"  $\rightarrow$  Part 1 from page 8-3 for information about preserving the system. When the system has been shut down for longer periods, it must be checked for softener contamination.

After a longer period of standstill, the system is put into operation again as described under "Work prior to initial commissioning"  $\rightarrow$  Part 2, page 3-1.



After preservation, disinfection must be carried out according to  $\rightarrow$  Part 1, chapter 12 "Disinfection (DI)" before normal start-up to exclude any hazard to the patients! Preservation is recorded in a separate log provided for this purpose, as well as in the medical product log ( $\rightarrow$  Part 2, chapter 9.2.1).

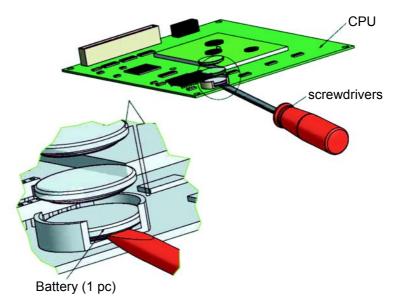
## 8.5 Return and disposal



The medical product contains a battery. Used batteries should be taken for recycling. The battery is located on the CPU in the control cabinet and can be lifted off the PCB using a screwdriver:

## The following steps are to be followed:

- 1. Switch the main switch to "0"
- 2. Screw off the EMC cover
- 3. Replace the battery



## Figure 8-1: Battery removal



NOTE:

In accordance with legislative regulations, B. Braun Avitum AG offers to take back systems it supplies and dispose of these as stipulated by legislation.

The materials used meet the requirements of directive 2011/65/EU OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

# 8.6 Technical information sheet for PRESERVATION with sodium metabisulphite



Observe the manufacturers' safety data sheets.

Protection against contamination and stabilization of reverse osmosis membranes

• Before preservation, flush the membranes with good-quality water free of chlorine (dissolved solid matter: SDI < 5). Use 120 litres of water for each 8-inch membrane.

Number of modules	Sodium metabi- sulphite [gr]	MgCl <sub>2</sub> [gr]	Glycerin 86% for -5°C [litres]	Glycerin 86% for -9°C [litres]	Glycerin 86% for -17°C [litres]	Total volume of liquid for RO [litres]
1	45	30	9.0	12.8	18.0	90
2	55	35	11.0	15.7	22.0	110
3	65	40	13.0	18.5	26.0	130
4	75	45	15.0	21.5	30.0	150
5	85	50	17.0	24.5	34.0	170
6	95	55	19.0	27.5	38.0	190

 Table 8-1:
 Filling volumes of preservative / antifreeze

## Preservation using sodium metabisulphite

- If biofouling of the membrane is not to be expected and if the membrane is to be protected for storage, a solution with 0.5 wt./vol.% sodium metabisulphite can be used.
- 9.5% wt./vol.% glycerin must be added to guarantee frost protection down to -5 °C.
- It is helpful to produce a basic solution with sodium metabisulphite in a 20-fold concentration and to fill the supply tank with this basic solution.

## Stabilisation

- 200 350 mg/l magnesium chloride (MgCl2) must be added to maintain membrane stability if this solution is to be stored for longer than one month.
- Let the preservative solution circulate through the membrane. Recirculate the solution through the mixing tank for at least 20 minutes. The temperature must not exceed 35 °C.
- It is helpful here, too, to produce a basic solution with MgCl<sub>2</sub> in a 20-fold concentration and to fill the supply tank with this basic solution.

## Emptying the supply tank

• Empty the mixing tank down the waste drain when the protective treatment has been completed.

If the system is exposed to a temperature of 0 °C (during transport etc.), it must be emptied completely (especially the membrane), as otherwise freezing water could cause the pipe-
lines and membrane to be destroyed.

 Only leave the preservative solution in the membrane after completing the steps above if the membrane will <u>not</u> be subject to frost.

## Flushing

- To flush out the preservative solution (element 8040), a maximum permeate production and a concentrate flow of at least 60 l/min (35 min 45 min) is required.
- Flushing can be terminated when the conductivity in the permeate (display) is 2–10 µS/cm (depending on yield and raw water constitution).

NOTE:	During preservation, the system must be clearly marked with the following information:	
	Type of preservative	
	Date of preservation	
	Contact to responsible doctor and operating personnel.	

After preservation, disinfection must be carried out according to  $\rightarrow$  Part 1, chapter 13 before normal start-up to exclude any hazard to the patients!

Preservation is recorded in a separate log provided for this purpose, as well as in the medical product log ( $\rightarrow$  Part 2, chapter 9.2.1).

# 9. Turning the equipment on



## System test conductance comparison

After switch-on at the main switch (1), a three-stage init. test is carried out:

- 1. CPU
- 2. Pump switch-off path:
  - Temperature of permeate and concentrate
  - Verification of the conductance value

Once the initial test has been processed correctly, the red LED illuminates briefly once and the green LED is permanently illuminated. The tank is emptied and refilled during the initial test. Dialysis is not possible during the initial test. If the initial test is not processed correctly within 15 minutes, a fault message is issued with specification of a fault code.

#### wd. dd.mm.yy hh:mm Operating mode Operating phase F1 F2 F3 F4

## Operating status and phase display

Following the successful initial test, operating status and phase are shown on the display. The system always starts up in the mode it was in when switched off.

Activities can be activated using the function keys F1, F2, F3 and F4 depending on the status.

wd. dd.mm.yy hh:mm Operating mode Routine check Menu DI Dial Night

wd. dd.mm.yy hh:mm Error xx Video copy Menu (Reset)

## Maintenance request

Alternating with the operating modes of the system, the respective due service service requests are displayed. If routine checks are due, this is indicated additionally by flashing in the 3rd line.

## Indication of a fault / error message

If a fault is determined during operation, a fault message appears. The system may be switched off, depending on the type of fault. ( $\rightarrow$  Part 1, page 17-1 et seq.).



After the power supply has been interrupted, the system always switches to the mode of operation that was last active.

# 9.1 System type (Eco)RO Dia I C with 1 pump

#### wd. dd.mm.yy hh:mm Alarm 05 Pump M1 ESC Menu

#### Indication of a fault / error message

If a fault is detected for pump M1, a fault message appears (see chapter "Fault messages" on page 17-1). The system immediately switches off.

# 9.2 System type (Eco)RO Dia I C with 2 pumps

## wd. dd.mm.yy hh:mm Alarm 05 Pump M1 Menu wd. dd.mm.yy hh:mm Alarm 26 Pump M2

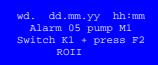
#### Indication of a fault / error message

If a fault is detected for pump M1, the fault message Alarm 05 appears, see chapter "Fault messages"). The system remains in operation with M2.

If a fault is detected for pump M2, the fault message Alarm 26 appears, system does not switch off, IRS off (see chapter "Fault messages"). The system remains in operation with M1.

# 9.3 System type (Eco)RO Dia II C

Menu



wd. dd.mm.yy hh:mm Alarm 26 pump M2 Switch K3 + press F1 ROI

wd. dd.mm.yy hh:mm Alarm 26 pump M2 Press F2, then F1 ROI Y5.1

## Indication of a fault / error message

If a fault is detected for pump M1, the system switches off and the fault message Alarm 05 appears. Instructions for activating emergency mode (see chapter "Fault messages") are displayed.

The emergency mode ROII is activated by switching the disc valve K1 and pressing the function key F2 (ROII).

If a fault is detected for pump M2, a fault message appears instructing to activate emergency mode (see chapter "Fault messages"), without the system switching off.

The emergency mode ROI is activated by switching the disc valve K3 and pressing the function key F1 (ROI).

## Display if Hot RO II is activated

The emergency mode is activate by switching on solenoid valve Y5.1 and by pressing function key F1 (RO I).

# 10. Dialysis mode (Dial)

Dialysis mode (permeate production) supplies the connected dialysis machines. (Among other things, the dialysis machine dilutes haemodialysis concentrate to provide ready-to-use dialysate.)

NOTE:	Disinfection is not permitted during dialysis.
Syste	<b>Initial menu for initiating dialysis mode</b> After the functional key Dial has been pressed, the selected system operating status appears in the menu. The respective operating phase simultaneously displayed. Filling/emptying the supply tank is shown as a separate operating phase.
Dialys: Empty	Dialysis mode, operating phase "empty tank" If there is still some water in the supply tank when the system is started up (e.g. following start after night-time mode) the supply tank is emption in a first step. Then the supply tank is filled with raw water/softened water.
Dialys: Fillin	Dialysis mode, operating phase "fill tank" Dialysis mode, operating phase "fill tank" The system automatically switches to dialysis mode. Night Off
Dialys: RH:+++% L	Dialysis mode, display of permeate conductivity During operation the permeate conductivity (in µS/cm) and the reserve During operation the permeate conductivity (in µS/cm) and the reserve (in %) is shown as an operating phase. This is calculated using the following equation: % Retention rate (RH) = $\frac{\text{Raw water TDS} - \text{Permeate TDS}}{\text{Raw water TDS}} *100$
	or % Retention rate (RH) = Raw water conductivity – Permeate conductivity *100

% Retention rate (RH) = <u>Kaw water conductivity – Permeate conductivity</u> \*100 Raw water conductivity

# 11. Night operation (night)

If no permeate is required for a longer period of time (e.g. weekend or night), the system can be switched to "night-time mode". In this operating mode the system flushes itself in preset cycles, incl. the connected ring piping. This counteracts the formation of biofilm which is promoted in periods without dialysis due to lack of circulation.

The system is switched on automatically at the set times to flush out the ring piping and the modules.

The system is switched on at the main switch (1). The night-time mode is selected via the function keys or programmed to auto mode by entering the night-time flushing data.

NOTE:	During "night-time mode" no permeate withdrawal is permitted from the ring piping and thus no dialysis is possible.
	Operators can change to dialysis mode at any time by pressing the dial key.
	Withdrawal of permeate during night-time mode leads to a leakage signal.

Activating monitoring the permeate temperature in menu 4.2 prevents uncontrolled increase of the temperature exceeding a set value.

If the temperature monitoring is tripped, the started night-time flushing is interrupted. After falling under a programmed lower temperature value and after expiry of the set night-time pause, the next night-time flushing is started.

## Hot cleaning

Additionally, the RO offers the possibility to provide permeate during night-time mode in combination with a hot water cleaning system (e.g. *Aquaboss*<sup>®</sup> HotRinse SMART series) in order to flush a connected loop. This combination is secured via signal exchange of both systems.

## Hot RO

EcoRO Dia II C HT systems can effect hot dinsinfection of the complete reverse osmosis (stage 1 and 2) in night-time mode if the Hot RO I + II mode is activated.

operating phase.

wd. dd.mm.yy hh:mm System off Menu DI Dial **Night** 

## Initial menu for initiating night-time mode

To activate this operating mode, press the function key Night during dialysis mode or another operating mode.

Night operation, display of the "shut off rinsing" operating phase

After night-time mode has been initiated, shut off rinsing is shown as the

wd. dd.mm.yy hh:mm Night operation Shut-off flushing Menu D/C Dial

wd. dd.mm.yy hh:mm Night operation Interm. flushing/Break Menu DI Dial Off

## Night operation, display of operating phases "Break" and "Intermediate flushing"

After the shut off rinsing an intermediate flushing is immediately initiated and after completion the system switches to pause.

After shutdown flushing has been completed, the operating phase "Break" is shown between intermediate flushing.

## wd. dd.mm.yy hh:mm Night operation Break Menu DI Dial Off

wd. d	ld.mr	n.yy	hh:mm		
Night operation					
	Ext	. CMS			
Menu	DI	Dial	Off		

## Deactivate night-time mode

If no night flushing data is entered  $\rightarrow$  Part 1, page 14-3, "night-time mode deactivated" appears as operating message.

## External CMS

If an external CMS is connected it is possible to produce permeate in night-time mode for this system.

A CMS signal is processed slope-triggered or pulse-triggered (see  $\rightarrow$  Chapter 14.6.2).

On activation of the CMS signal in night-time mode the leakage message is suppressed.

## **CMS** active

It the external CMS requires permeate a message will be shown in the display.

wd.		n.yy I Rinse	hh:mm		
active					
Menu	DI	Dial	Off		

## Hot Rinse

Hot rinse is connected and ready (hardware handshake).

## Impulse shear force flushing (option)

The impulse shear force flushing (controlled by Y30) for the minimisation of biofilm in the ring piping is performed regularly after the intermediate flushing in night-time mode. This operating mode is not shown on the display.

NOTE:

30 min prior to the night-time mode (automatic program) the reverse osmosis system emits a signal that can be processed by Aquaboss<sup>®</sup> ED.

It is possible to extend the dialysis operation contrary to the programming.

# 12. Disinfection (DI)

Thermal disinfection of the reverse osmosis system EcoRO Dia II C HT is generally preferable to chemical disinfection. A B. Braun reverse osmosis system may only be disinfected (DI) by B. Braun-authorized and trained personnel. Disinfection is recommended at least once per year. The reverse osmosis system must be disinfected (DI) if the germ count in the permeate is found to be higher than normal (action limit 50 CFU/ml and/or 0.125 I.U/ml).

Disinfection of the (Eco)RO Dia I/II C (HT) is carried out following instructions of the operator.

- Following initial commissioning and flushing out of the preservative
- · As a preventative measure according to the system validation specification
- · When the microbiological action, warning or alarm limits are attained or exceeded
- After opening the system for maintenance or repair work or other constructional intervention

Before disinfection (DI):

- The Hydrowatch on the membrane surge tank (DG) must be checked before each chemical disinfection process. If the red indicator is visible, the ring piping must not be disinfected.
- To increase the effectiveness of disinfection (D), it must be ensured that the membrane modules are free of organic and chemical contamination. The membrane modules must be cleaned (C) beforehand with a commercial membrane cleaner to remove hardness salts or iron deposits on the membrane.
- Chemical disinfectants must comply with EN 1040:2005 (Chemical disinfectants and antiseptics: test
  procedure for bactericide basic action).

	Chemical disinfection.
DANGER	Acute risk of poisoning during chemical disinfection.
	Disinfection (DI) may only be carried out during the dialysis-free period.     It must not be possible to carry out dialysis!
	<ul> <li>The permeate must be disconnected from the dialysis machines before the disinfection pro- cess is started.</li> </ul>
	• If a softener is used: softeners may only be used with a pipe disconnector of the type EA1 or with a free intake.
	• Disinfection of the reverse osmosis system must be signaled using appropriate measures in the treatment rooms (see → Part 2, page 11-2).
	<ul> <li>The disinfectant must not be stored on the reverse osmosis system. The manufacturer's specifications must be heeded for storage of the disinfectant.</li> <li>Acute risk of poisoning if disinfectants or cleaning agents are taken or administered.</li> <li>Cleaning and disinfection may only be carried out by order of the attending physician.</li> </ul>

In case of systems that cannot be disinfected thermally due to their construction, the disinfection of the water carrying parts is carried out with chemical disinfectants. Chemical disinfectants must comply with EN 1040 (Chemical disinfectants and antiseptics: test procedure for bactericide basic action).

The following disinfectants (combination treatments) have been approved for the disinfection (DI) of *Aquaboss*<sup>®</sup> reverse osmosis systems:

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

The (Eco)RO Dia I/II C (HT) was tested for its material resistance in combination with the approved disinfectants and released.

Disinfection is recorded in a separate log provided for this purpose, as well as in the medical product log ( $\rightarrow$  Part 2, chapter 9.2.1).

The warning instructions of the disinfectant manufacturers must be observed when these products are being used, and personal protective equipment must be worn.

# 12.1 Chemical disinfection (DI)

NOTE: Make sure the contents are well mixed in the supply tank, because layers can form on the bottom of the tank due to the different specific densities of the disinfectant and permeate.

- 1. Rinse the reverse osmosis system by starting the night-time mode.
- 2. Fill the supply tank with permeate
- 3. The commercial preparation is to be provided as an approx. 2.0% solution for reliable water bacteria disinfection (DI) (see → Table 12-1). In this respect, a basic solution is used in the supply tank, where the concentration of the disinfectant must not exceed 8% (otherwise the membrane would be damaged!). Consult B. Braun in the case of proven contamination by fungi/yeast or spores.
- 4. The contents of the supply tank are circulated as long as necessary until the presence of disinfectant can be proved in the ring piping return.

NOTE: Contamination in the water treatm reaction to occur which can great

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

The colouring of the test strips merely indicates that the disinfectant concentration is above the limit to be determined by the test strip. It cannot be used to determine the concentration of the active ingredient. The reaction time (with the final concentration of the disinfectant) is at least 15 minutes. The reaction time of the disinfectant in its diluted form on membranes must not exceed 30 minutes and must be completed directly by a rinsing process.

- 5. Following disinfection (DI), the reverse osmosis system and ring piping are flushed with permeate. The following tests are available for specifically testing for disinfectant residue:
  - for H<sub>2</sub>O<sub>2</sub> (peroxide test Merck art. nr. 10011) or
  - for peracetic acid (peracetic acid test Merck art. no. 110084)
  - for Minncare (Minncare residual test stripes art. no. 52821)

A separate check must be made at all permeate tapping points to make sure there is no disinfectant left in the system. This check must be repeated to ensure there is no disinfectant left in the system after the disinfected and rinsed RO has stood still for 30 minutes.

NOTE:	Only use disinfectants approved by B. Braun.
	Soiling of the drinking water
	Before starting disinfection, make sure that softener and reverse osmosis system are only being operated with a pipe disconnector of the type EA1 or with a free intake.

#### Table 12-1: Disinfectant application concentration

Preparation	Conc	рН
A) Puristeril®	3 %	2.0
B) Dialox®	2 %	2.5
C) Peresal®	2 %	2.3
D) Minncare®	1 %	3.5
E) Minncare®	3 %	2.5

Number of 8" modules (8040)	Disinfectant in litres		
	A–C	D	E
1	1.5	0.75	2.25
2	3.0	1.5	4.5
3	4.5	2.25	6.75
4	6.0	3	9
5	7.5	3.75	11.25
6	8.5	4.25	12.75

## Table 12-2:Disinfectant application concentration

Ring piping, running metres with	Disinfectant in litres		
internal diameter of 20 mm	A–C	D	E
50	0.3	0.15	0.45
100	0.6	0.3	0.9
150	0.9	0.45	1.35
200	1.2	0.6	1.8
250	1.6	0.8	2.4
300	1.9	0.9	2.7
350	2.2	1.1	3.3
400	2.5	1.25	3.5

Surge tank volume in litres	Disinfectant in litres		
	A–C	D	E
25	0.2	0.1	0.3
50	0.3	0.15	0.45

## 

#### Risk of poisoning!

Ensure that the permeate at each individual treatment place is free from disinfectants after the disinfection process and prior to starting the dialysis.

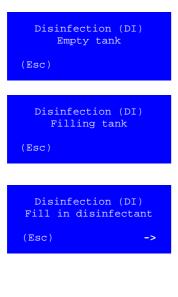
NOTE:	The system must be disconnected completely from the mains supply line before disinfection (DI) of the softener. It is absolutely essential to disconnect the reverse osmosis system
	during disinfection (DI).

wd.	dd.mm.yy System of		
Menu	DI	Dial	Night

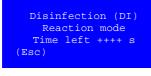
The (Eco)RO Dia I/II C (HT) has a menu-guided disinfection program. The disinfection times are set as described in the section "Entering disinfection data" ( $\rightarrow$  Part 1, page 14-4).

Disinfection of the device is triggered by pressing the function key **DI** in the initial menu or in night-time mode.

# Disinfection (DI) Starting Disinfection mode Esc **5s->**



#### Disinfection (DI) Recirculation mode Time left ++++ s (Esc)



Open valve PH2

Disinfection (DI)

- >

## Initial screen at start of disinfection mode

The user moves to the following disinfection phase by pressing the -> **5s** key for more than 5 seconds. Pressing the Esc key returns the user to the old operating mode. The disinfection process (D) can only be cancelled at a later stage if this was permitted in the initial settings (The Esc function is only faded in after activation of the cancel possibility under menu item 6.27 ( $\rightarrow$  Part 1, page 14-13).

## Filling the disinfectant

In a first step the fill level of the supply tank is checked. If the supply tank is full, the adjoining screen is shown and the supply tank is emptied.

Afterwards the supply tank (VL) is filled to the minimum (LSAL1).

## Initial screen at start of disinfection mode

Next the system will request the addition of disinfectant to the supply tank. The disinfectant solution is added via the disinfectant filling opening in the lid of the supply tank (remove protective stopper). Only the disinfectants listed by B. Braun may be used for disinfection (DI).

## **Recirculation mode**

Move to the next disinfection phase by pressing the -> key "Recirculation mode".

Disinfection (DI) can be cancelled prematurely by pressing ESC.

## Recirculation mode with display of remaining testing time

After the recirculation time has expired the screen changes to the reaction mode. **Esc** can be pressed to end recirculation prematurely.

## Reaction mode with display of remaining testing time

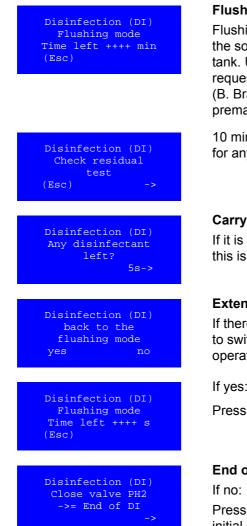
After the reaction time has expired the screen changes to the flushing mode display. **ESC** can be pressed to end reaction time prematurely.

## Open valve

Move to the next disinfection phase by pressing the -> key. Disinfection (D) is cancelled prematurely by pressing **Esc**. After the reaction time has expired, you will be asked to quickly discharge the disinfectant (DI) at the valve of the ring piping return (**PH2**) (discharge using the connected hose). The opening of the valve is confirmed by acknowledging this display message (-> Press key). This is followed by the disinfection phase "Flushing mode": After flushing mode has been initiated, the time left is shown on the display.

NOTE:

Kindly observe the local discharge limit values into the sewage system.



## Flushing mode with display of remaining testing time

Flushing is effected alternating between filling the tank, activation of the solenoid valves involved and complete emptying of the supply tank. Using the ESC key, the flushing mode can be cancelled and the request to prove the presence of disinfectant appears prematurely (B. Braun however, does not advise cancelling any flushing mode prematurely).

10 minutes before expiry of the flushing time you are asked to check for any residual disinfectant.

## Carrying out proof of disinfectant

If it is verified that the system no longer contains any disinfectant, this is confirmed by pressing the **5s** -> key (5 seconds).

## Extending the flushing phase

If there is residual disinfectant in the system the user is requested to switch back to flushing mode by pressing yes. No activates the operating mode End of disinfection (D).

If yes:

Pressing the "yes" key returns the user to the flushing mode.

## End of disinfection (DI)

Pressing -> moves the system out of disinfection mode and into the initial state.

#### 12.2 Thermal disinfection (option)

Option HT is only available for EcoRO Dia II C reverse osmosis systems.

The option "HT" (hot total) permits the hot cleaning of the complete reverse osmosis (first and second RO). During this process the hot water is fed into the supply tank from the end of the ring piping.

The possibility of hot cleaning the reverse osmosis of the 1st and 2nd membrane stage is preset by the control cabinet and design reasons.

Danger of poisoning due to detached construction materials and destruction of components!
ightarrow In combination with a hot cleaning system only temperature-resistant original materials up to a minimum of 90°C must be used.

# 12.3 EcoRO Dia II C HT (HT – Hot Total for hot cleaning of 1st and 2nd osmosis stage)

The function Hot RO can only be activated for EcoRO Dia II C HT versions!

N	

Hot cleaning is not possible in the "off" operating state.

Hot-water sanitation of the complete reverse osmosis (1st and 2nd membrane stage) is a chemical-free supplement to tried-and-trusted methods of disinfection which optimises the microbiological quality of the permeate. It is carried out in night-time mode.

For the system version EcoRO Dia II C HT this can be carried out in combination with an external hot water system (z. B. *Aquaboss*<sup>®</sup> HotRinse SMART). This system also has to be ready to disinfect the reverse osmosis with hot water using the parameters for hot cleaning (see  $\rightarrow$  Chapter 15.3).

wd. dd.r	nm.yy	hh:mm
HotRO	heati	ng
TISAH1	: XX	°C
TISAH2	: XX	°C
TISAH4	: xx	°C
Menü	Dial	Cool

As soon as the reverse osmosis changes to night-time mode and the connected hot water system returns corresponding release signals to the RO, the hot disinfection is started.

In order to protect the membranes the heating speed has to be controlled. The temperatures at the 3 measuring points intake (TISAH4), concentrate 2nd stage (TISAH2) and permeate (TISAH1) are displayed alternately.

wd. dd.r	nm.yy	hh:mm
HotRO II	Hold	temp.
TISAH1	: XX	°C
TISAH2	: XX	°C
TISAH4	: XX	°C
Menü	Dial	Cool

After reaching the set temperature (heating temperature) it is maintained for a preset duration (see  $\rightarrow$  menu 10.3 and 10.4).

# NOTE:

A cancellation of the hot cleaning cycle during the HotRO phase is possible at any time by pressing the "Cool" key (F4). After the active cooling temperature has been reached, the system changes into night-time mode.

wd. dd.m	m.yy hh:mm
HotRO II	Cool-down
TISAH1:	XX °C
TISAH2:	XX °C
TISAH4:	XX °C
Menü	Dial

The temperature-controlled cooling is activated with fresh, cold feed water.

The system only switches to night-time mode after the setpoint temperature (cooling temperature) has been reached.

The hot cleaning cycle can be cancelled at any time during the HotRO phase by pressing the "Dial" key (F3). The dialysis mode, however, is enabled only after the cooling temperature has been reached.

If the hot cleaning cycle is terminated, the counter of fully performed hot cleaning cycles (see menu 10.5) is not increased by 1. A terminated/interrupted hot cleaning cycle is counted as not performed and is hygienically inefficient.

# 13. Cleaning (C)

## Technical information sheet DECALCIFICATION of Aquaboss®-reverse osmosis systems

The (Eco)RO Dia II system is cleaned with the aid of the disinfection program. Cleaning (C) is recorded in a separate log provided for this purpose, as well as in the medical product log ( $\rightarrow$  Part 2, chapter 9).

NOTE:	A B. Braun reverse osmosis system may only be cleaned (C) by B. Braun-authorised and trained personnel.
	The reverse osmosis system may be cleaned only with detergents recommended by B. Braun.
	After every cleaning process it has to be ensured that there are no traces of cleaning agents. This also applies if a second cleaning or disinfection cycle follows!
	Chemical disinfection.
DANGER	Risk of poisoning!
	Cleaning (C) may only be carried out during the dialysis-free period.
	It must not be possible to carry out dialysis!
	• The warning instructions of the cleaning agent manufacturers must be observed when these products are being used, and personal protective equipment must be worn.
	• The permeate must be disconnected from the dialysis devices before the cleaning process is started.
	<ul> <li>If a softener is used: softeners may only be used with a pipe disconnector of the type EA1 or with a free intake.</li> </ul>
	• The system must be disconnected completely from the mains supply line before cleaning (C) of the softener.
	Acute risk of poisoning if disinfectants or cleaning agents are taken or administered.
	Cleaning and disinfection may only be carried out by order of the attending physician.
	<ul> <li>Cleaning of the reverse osmosis system must be signaled using appropriate measures in the treatment rooms (see → Part 2, page 11-2)</li> </ul>

## Citric acid cleaning of 8" modules to remove metal hydroxides and calcium carbonate

- Prior to the cleaning process: Flush the system with permeate. 120 litres of permeate are required for the complete flushing of an 8" module.
- Put a 2% citric acid solution in the supply tank (citric acid solution from B. Braun art. no. 899/307). The quantities of citric acid required can be found in the following table. To prevent the pH value on the membrane from dropping below pH 2.0, we recommend adding sodium hydroxide to the solution in the supply tank. The addition of sodium hydroxide does not influence the effectiveness of the citric acid since the calcium of the CaCO<sub>3</sub> forces the sodium out of the Ca citrate so that it enters the solution.) The recommended pH value for citric acid cleaning is pH 4.0 – 4.2.

## Table 13-1: Amounts of descaling agents required

Number of 8" modules (8040)	Citric acid in I
1	4.8

Increasing the citric acid concentration by more than 2% does not increase the effectiveness of the rinsing process.

- Cleaning is carried out with the permeate valve closed and internal recirculation completely open.
- System pressure must not exceed 6 bar during cleaning.
- Iron which has been deposited on the membrane is also released during citric acid rinsing. When the citric acid solution becomes saturated with iron, it turns a reddish brown colour in the supply tank and has to be replaced. Complete removal of the iron hydroxide from the membrane has been effected if three rapid tests for iron, at an interval of 5 min, are within 10%.
- After the acid flushing has been completed, the system must be rinsed with water. For this, at least 150 litres of water per 8" element (or at least 1 hour of rinsing time) are required. Flushing may only take place at low pressure (6 bar).

# 14. Entering system data and parameters



The program branches into the parameter setting level by requesting the program item **Menu** from the basic control unit state and during dialysis mode. System characteristics can be retrieved in the sub-programme items in this level. In addition, the system control parameters can be modified.

Parameters that are related to the system's functional safety and parameters used by technical service personnel for checking system functions are password-protected and may only be changed by authorized personnel.

If there is the option of hot cleaning (Hot RO), this will be shown in the menu under section 10. If this mode is not available the menu list will stop at section 9 "LC operation".

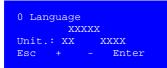
#### Selecting the menu item

Esc switches to the previous menu.

- ↑ previous menu item / selection.
- $\checkmark$  subsequent menu item / selection.

Enter activates selection.

## 14.0 Language, menu item 0

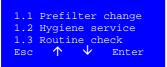


The **menu item 0** indicates the current user language, the units and the display of the conductivity.

German, French, English, Dutch, Norwegian and Swedish can be selected as languages.

Units: EU/US and mS/cm / TDS

## 14.1 Timer reset, menu item 1



## **Resetting the timer functions**

The menu items 1.1–1.3 are used to reset the timer messages.

Reset is used to reset the selected function.

Timer settings are made under menu item 6.15 – 6.17.

# 14.2 Input of date / time, menu item 2

	e / Tim	e	
Weekda	ay: xx.		
Date:	xx.xx.	xx.	
Time:	xx:xx		
Esc		Enter	

Input screen date / time

# 14.3 Input of automatic on / off, menu item 3

**Menu items 3.1 – 3.7** are used for programming the automatic start of reverse osmosis. A maximum of 2 automatic start and stop times can be entered for each weekday. If the system is to remain in use through 24:00 / 00:00 h (change of day), no stop time is given for the first day of operation, the stop time is programmed as first time value for the 2nd day. In case of missing time entries the timer searches for up to 3 days in advance for logic entries.

NOTE:	After automatic mode has finished the control unit automatically switches to the initial
NOTE:	operating mode (system "off" or "night oper.").

3.1	Monday
3.2	Tuesday
3.3	Wednesday
3.4	Thursday
3.5	Friday
3.6	Saturday
3.7	Sunday
3.8	Clear auto prog.
Esc	$\wedge \psi$ Enter

## Automatic mode, selection of the weekday

3.1	Monda	iy	
0n	: (	- )ff -	
0n	: (	)ff -	
Esc			Enter

Automatic mode, selection of start / stop times. Value input (00:01 to 23:59, 00:00 = --.-- = Off)

3.8 Clear auto prog. Reset = clear all			
Esc			Enter

Automatic mode, delete program Pressing the reset key deletes all entries 3.1 – 3.7

Chapter 14

# 14.4 Input of night-time flushing data, menu item 4

The control system offers the possibility of starting the system during
standstill periods (night) at repeat intervals for a programmable flush
duration. This flushes the reverse osmosis and the ring piping and
reduces the risk of contamination during standstill times (e.g. system
switched off at main switch).

If the system reaches a limit temperature it is possible to cool the system down to a lower, adjustable temperature value by feeding raw water.

## Night-time flushing times, temperature flushing

In **menu item 4** parameters can be set for the night-time flushing data and the deactivation and activation of a temperature flushing can be carried out.

4.1	Night	flush	time
Thte	erval:	xxxMir	h
Time	9:	xxMir	1
Esc	+	- H	Inter

4.1 Night flush time

lush. Hot

Temp. discharge

Rinse Enter

4.2



4.3	Inter for H On	
Esc		Enter

## Night-time rinsing data

Input of values for flushing interval and flushing duration

Night-time flushing data are set in menu item 4.1.

0 ... 180 minutes have been planned as values for the flushing interval, 0 = off.

1...10 minutes have been planned for the flushing duration.

## **Temperature flushing**

In **menu item 4.2.** the release or blockage of the raw water feed in night-time mode as well as the setting of the temperature limit values is carried out.

In **menu item 4.3** an intermediate rinse with active Hot Rinse can be permitted. The permeate then circulates via ÜV2.

## 14.5 Input disinfection data, menu item 5

**Menu item 5** is used for setting the system data for cleaning or disinfection. The data should be chosen in such a way that each point in the system can come into contact with a sufficient concentration of disinfectant (recirculation time) and that a sufficient contact time is guaranteed with the cleaning solution or disinfectant (reaction time).

5 DI data	
Recirculat.:	xx Min
React. time:	xx Min
Flush. time:	xx.x h
Esc + -	Enter

#### DI data

(limit values: recirculation time: 5 ... 60 minutes; reaction time: 20 ... 60 minutes; flushing time in hours 0.5 – 24h)

NOTE:

Cleaning or disinfection data can only be entered when the service code is active or input has been cleared through menu item 6.20.

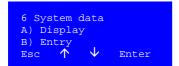
## 14.6 System data, menu item 6

**Menu item 6** can be viewed both during dialysis mode and in night-time mode. The menu includes the option of viewing (menu item 6A) or changing (menu item 6B) the system parameters set by the service staff from B. Braun Avitum AG during commissioning.

Changes may only be carried out by staff who have been authorized to do so.

Entering incorrect values can endanger the intended functioning of the control system. ATTENTION

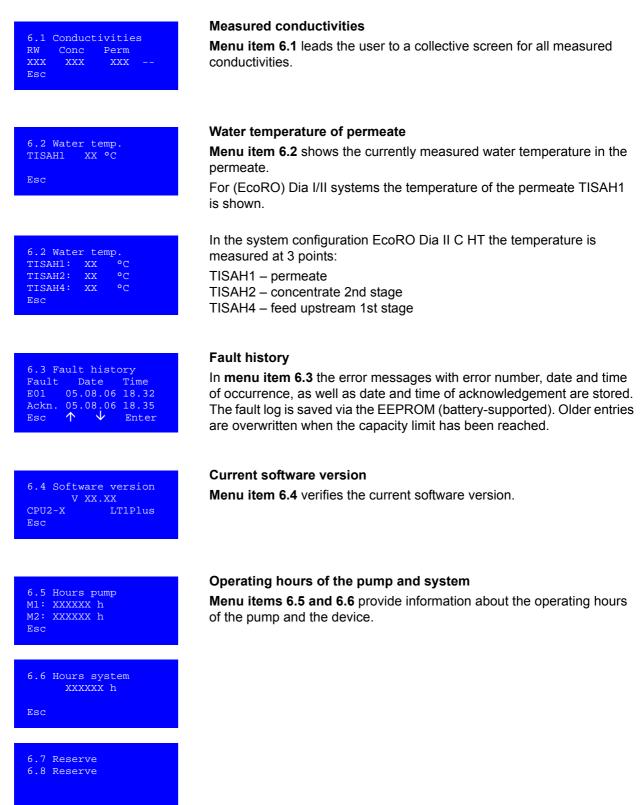
The initial menu offers the user the selection of having the set system data displayed "A Display" or entering these by pressing "B Program".



#### Equipment data

## 14.6.1 Display of system data, menu A display

## Menu items 6.1 - 6.32



6.9 Economy mode M2 off LSHL2: xx sec M2 On LSHL2: xx sec Esc

## Economy mode (only (Eco)RO Dia II)

In case of low water consumption the pump of the 2nd osmosis stage can be switched off and thus the performance reduced.

Energy consumption is reduced. The control is effected automatically and depends on the change in level in the supply tank.

Economy mode controls pump 2 independently from the upper float switch LSHL2.

- If LSHL2 is not undercut for the time (M2 off), M2 switches off. The operation is maintained with pump M1 only. Operation is maintained with pump M1 only. LSHL2 exceeded => timer M2 off active. If the time LSHL2 = 0 to LSHL2 = 1 is greater than the setting M2 Off => M2 switches off.
- If LSHL2 is not exceeded again for the time (M2 On) or minimum pressure PSAL4 = 1, M2 switches on again (if activated). LSHL2 undercut => timer M2 On active.
   If the time LSHL2 = 1 to LSHL2 = 0 is larger than the setting M2 On => M2 will switch on again.
   If the pressure at PSAL4 is undercut, M2 will switch on again and all timers are reset.
   LSHL2 undercut and timer M2 Off > 80% of the set time => M2 switches on again.

Factory setting: Economy mode off = --

	Start Conc.Dis. Stop conc.dis.
6.12	Disch.interval

## Start and stop factors for concentrate discharge

In the **menu items 6.10 – 6.12** the start and stop factors of the concentrate discharge are displayed. Menu point **6.12** informs about the period of time during which the concentrate discharge is performed if the conductivity detection is disturbed (e.g. safety discharge in case of cable break of the electrode).

In order to prevent unnecessary heating of the supply tank it has proved of value to program the start and stop factors with a difference of 0.3 units.

	Conductivity limits of the permeate
6.13 Limit 1 Perm. 6.14 Limit 2 Perm. 	The conductivity limit values of the permeate are shown in <b>menu items 6.13 and 6.14</b> . If the alarm value is reached, a pre-alarm (alarm 27) is issued without system function being impaired. If the limit value is reached the system switches off automatically (error 8).
6.15 Change prefilt.	Reminder intervals for maintenance and service work
6.16 Hygiene service 6.17 Routine check	<b>Menu items 6.15 – 6.17</b> provide information about the reminder intervals for maintenance and service work selected $\rightarrow$ Part 1, page 10-1, page 14-14 and $\rightarrow$ Part 2, page 9-1.
	Cell constants of the conductivity electrodes and conductivity
6.18 Cell/cond. rw 6.19 Cell/cond conc 6.20 Cell/cond perm	<b>Menu items 6.18 – 6.20</b> provide an overview of the cell constants of the conductivity electrodes set as well as about the conductivities currently measured in the volume flow.
	System type and menu language
6.21 Choose system	Menu item 6.21 verifies the system type.
6.22 Y2/Y9 interval 6.23 Imp.sh.f.rins.	Cycle rate of the solenoid valves and activation state of the impulse shearing force flushing

The **menu items 6.22 – 6.24** show information about the set cycle rate of the solenoid valves in the concentrate range (**Y2/Y9** interval); in the permeate range during impulse backflushing (**Y5/Y6** interval, only for EcoRO) as well as about the activation state of the impulse shear force flushing.

6.24	Eco I	RS I
Per.	time	= xx min
Press	s=##s	Flush=##s
Esc		- Enter
	+	

**IRS 1nd stage** (impulse return rinsing 1nd membrane stage) The selection of the period duration per-duration (15 ... 90 min) indicates

The time for pressure buildup and the flush duration of the IRS can be selected in sec. units.

Press. (3 ... 10); flush (5 ... 15)

the time distance between the flushing cycles.

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6.25 Temp.discharge	Start and stop values for the temperature of the concentrate
Start= XX °C	Menu item 6.25 shows the currently selected start and stop values
Stop= XX °C	the temperature of the concentrate when the compulsory discharge
Esc	activated.
6.26 IRS operation	Impulse return rinsing permitted (IRS)
On / Off	Menu item 6.26 informs if impulse backflushing (IRS) is permitted e
Esc	during dialysis operation.
6.27 Change DI-time	<b>Interruption of disinfection cycle</b>
permitted / disabled	The state of the possibility of interrupting the disinfection cycle can I
Esc	shown under <b>menu item 6.27</b> .
<pre>6.28 M2 night oper. 6.29 M2 disinfection 6.30 M2 hot cleaning</pre>	Activating pump M2 Menu items 6.28 – 6.30 control the operation of pump M2 outside of dialysis operation. 6.30 is visible as an option for EcoRO Dia II C wi Hot II RO only.
6.31 Eco IRS II	<b>IRS 2nd stage</b>
Per. time = xx min	(impulse return rinsing 2nd membrane stage; only EcoRO Dia II C)
Press=##s Flush=##s	Analogue to the menu item 6.24, in this submenu the parameters of
Esc	impulse backflushing of the 2nd membrane stage are shown/set.
	Range: Per. time 60 180 min Press. 3 10 sec Flush 5 15 sec
	If the interval timers of the IRS 1st stage and the IRS 2nd stage exp simultaneously, an impulse return rinsing cycle of the 2nd stage is performed.

6.32 Ext. CMS xxxxxxxxxxxxxxxx

Esc

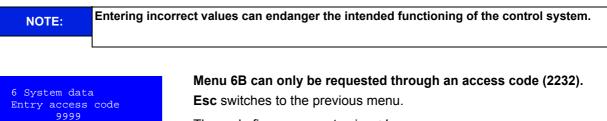
The input signal can be processed either slope-triggered or pulse-triggered.

# 14.6.2 Entering system data menu B program

Enter

#### Menu items 6.9 – 6.32

Esc



The code figures are set using +/-.

Enter activates selection.

The access code deactivates itself automatically after 30 minutes, if no parameterisation is effected in menu 6B or menu 7. By switching off the device at the main switch and after a waiting time of 10 sec the access code can also be deleted. The access code can also be deleted by switching the system off at the main switch and then waiting 10 sec. Modified parameters are activated only after a system restart.

$\begin{array}{c} 6.11\\ 6.12\\ 6.13\\ 6.14\\ 6.15\\ 6.16\\ 6.18\\ 6.19\\ 6.20\\ 6.21\\ 6.22\\ 6.23\\ 6.24\\ 6.25\\ 6.26\\ 6.27\\ 6.28\\ 6.29\\ 6.30\\ \end{array}$	Start Conc.Dis. Stop conc.dis. Disch.interval Limit 1 Perm Limit 2 Perm Change prefilt. Hygiene service Routine check Cell/cond conc Conc.meas. perm. Choose system Y2/Y9-interval Imp.sh.f.rins. Eco IRS I Temp.discharge IRS operation Change DI-time M2 night oper. M2 disinfection
6.31	Eco IRS II
6.32	Ext. CMS
Esc	↑ ↓ Enter

#### Collective screen sub-menu 6B

6.9 Economy mode M2 off LSHL2: xx sec M2 On LSHL2: xx sec Esc + - Enter
6.10 Start Conc.Dis. X.X Esc + -
6.11 Stop conc.disch.
X.X
Esc + -
6.12 Disch.interval
XX min
Esc + -
6.13 Limit 1 Perm. + xx uS/cm
Esc + -
6.14 Limit 2 Perm. + xx uS/cm

#### Economy mode

In case of low water consumption it is possible to switch off the pump. Value range: M2 Off => 1-300 sec. M2 On => 1- 30 sec.

Off = 0 is shown as "--" and economy mode is deactivated.

#### Start concentrate discharge

The start value is the ratio conductivity concentrate/conductivity raw water and is a measure for the system yield. The start value must be between 1 (0 % yield) and 6 (88 % yield).

Value range: stop value of menu 6.10 to 6.12

#### Stop concentrate discharge

The stop value is the ratio conductivity concentrate/conductivity raw water where the concentrate discharge is terminated. In order to avoid unnecessary heating of the supply tank, there should not be more than 0.3 – 2 units between the start and stop factor.

Value range: 1.2 to start value of menu 6.10

#### Concentrate discharge interval

If the measurement of the conductivity is impaired, a time is programmed here to activate the compulsory discharge of the concentrate.

Max. interval duration: 1 ... 15 min.

#### Conductivity alarm value permeate feed

If the alarm value (limit value 1) is reached, a pre-alarm is issued without system function being impaired.

Input range =  $5 \dots 60 \mu$ S/cm.

# Esc

#### Conductivity limit value permeate feed

If the limit value is reached the system switches off. Input range = 5 ... 200  $\mu$ S/cm.



#### Change prefilter

This menu item sets the interval (in weeks) in which a reminder is issued that the prefilter needs to be changed. 4 to 8 weeks.

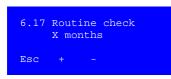
The new value is only taken over following the next timer reset!



#### Hygiene check

This menu item sets the interval (in months) in which a reminder is issued that the hygiene service is due. 0 to 12 months.

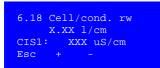
The new value is only taken over following the next timer reset!



#### Maintenance interval

This menu item sets the interval (in months) in which a reminder is issued that system maintenance is due. 0,3,6,9,12 months.

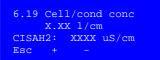
The new value is only taken over following the next timer reset!



#### Cell constant (conductivity) raw water

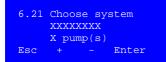
This menu item sets the cell constant (CC) of the conductivity electrode for raw water. Changes in CC can be read off on the changed **conductivity**.

This should be effected only usind a calibrated measuring device.



#### Cell constant (conductivity) concentrate

This menu item sets analogue to **6.19** the cell constant **(CC)** of the conductivity electrode for concentrate.



#### Cell constant (conductivity) permeate feed

This menu item sets analogue to **6.20** the cell constant **(CC)** of the conductivity electrode for the permeate feed.

#### Definition of the system type

The menu defines the system type and the number of controlled pumps.

System type:

RO Dia I C EcoRO Dia I C RO Dia II C EcoRO Dia II C

Pumps: 1 or 2 pumps

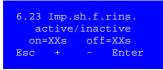
The system variant for EcoRO Dia II C HT is specified.

			erval = XXs
Esc	+	-	Enter

#### Cycle rate of MV Y2/Y9

In order to prevent faster emptying of the supply tank during concentrate discharge, the operating phase "concentrate discharge" can be terminated via **Y9** by means of internal concentrate circulation (via **Y2**).

Value range Y2 = 5 to 20 sec., Y9 = 5 to 60 sec.



#### Impulse shear force flushing (optional)

The menu is used to paramaterise the impulse shear force flushing (**ISS**).

On = opening time: 3 to 10 sec. Off = closing time 3 to 30 sec.

NOTE:

The function of the ISS can be superimposed by the safety pressure monitoring of the ring piping (PSAL4) so that the set values cannot take effect.

6.24	Eco I	IRS 1	
Per.	time	= X2	K min
Press	s=XXs	Flu	ısh=XXs
Esc			Enter





**IRS 1nd stage** (impulse return rinsing 1nd membrane stage) In this menu the parameters are set for impulse return rinsing.

Period duration: 15 to 90 min. Pressure buildup: 3 to 10 sec. Flush mode: 5 to 15 sec.

#### Temperature discharge

This menu point is used for setting the parameters for temperature discharge.

Value range: 20 to 35 °C (recommended temp. difference 5K).

# Impulse return rinsing operation (IRS) on or off (optional, only for EcoRO version)

The menu permits switching on and switching off of the **IRS** during dialysis mode. **IRS** cycles during the shut off rinsing and the night-time mode are not affected.

BC		
6 20	M2 night oper.	
	M2 disinfectior	1
	M2 hot rinsing	-
Esc	2	
6.31	Eco IRS II	

6.27 Change DI-time

permitted/disabled

#### Input disinfection times and possibility to abort

In **menu item 6.27** there is the possibility to modify the disinfection data of **menu item 5** and to permit or deny an abortion of a disinfection cycle.

Disinfection can be interrupted by pressing the **Esc** key in order to access the respective following **DI** phase.

#### Activating pump M2

**Menu items 6.28 – 6.30** control the operation of pump M2 outside of dialysis operation.

6.31	Eco I	RS :	ΙI	
Per.	time	= 3	xx	min
Pres	s=##s	Fl	usł	1=##s
Esc			I	Inter

#### **IRS 2nd stage** (impulse return rinsing 2nd membrane stage)

Analogue to the menu item 6.24, in this submenu the parameters of the impulse backflushing of the 2nd membrane stage are shown/set.

Range:	Per. time	60	180 min
	Press.	3	10 sec
	Flush	5	15 sec

If the interval timers of the IRS 1st stage and the IRS 2nd stage expire simultaneously, an impulse return rinsing cycle of the 2nd stage is performed.



#### **External CMS connection**

The signal of an external CMS (concentrate mixing system) is forwarded to the reverse osmosis either slope-triggered or pulse-triggered.

This makes it possible for the reverse osmosis to receive the command to produce permeate even during night-time mode.

#### Slope-triggered:

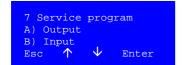
The (Eco)RO Dia I/II C produces permeate as long as the signal is active. If the signal ceases, the RO returns to the night-time mode.

#### Pulse-triggered:

The incoming signal is an impulse. For each impulse the RO in night-time mode changes between standby-mode and permeate production.

If hot cleaning is activated (HWD1 signal or HWD2 signal = 1) the CMS signal processing is suppressed until the hot cleaning is finished (HWD1 / HWD 2 = 0).

# 14.7 Service program, menu item 7



In the service program the digital inputs can be viewed and all outputs can be individually set and deleted for test purposes.

#### 14.7.1 Setting/deleting outputs, menu 7A outputs

7 Ser	vice	pro	ogram	
Entry	acc	ess	code	
	99	99		
Esc			Enter	

#### Menu 7A can only be requested through an access code.

**Esc** switches to the previous menu.

+/- value input

Enter activates selection.

When accessing service programme A the current mode of operation is interrupted and all outputs are switched off. When service program A is left, the control is reset and an init. test is performed. After the init. test has been passed, the system returns to the state it was in before the service program was activated.

#### Overview menu setting outputs

0/1 = Output not set/set

Esc switches to the previous menu.

- $\uparrow \qquad \text{Move selection upwards.}$
- $\checkmark$  Move selection downwards.

	Risk of system damage!	
	No monitoring of limit values takes place when the outputs are switched manually in the ser- vice menu. All safety shutdowns are disabled.	
	Manual switching must be carried out by authorised technical staff.	I

### 14.7.2 Considering inputs, menu 7B inputs

HWD1	Х
HWD2	Х
PKZ Pump M2	Х
Softcontrol	Х
PKZ Pump M1	Х
Remote control	Х
Emergency mode	Х
Level LSAL1	Х
Level LSHL2	Х
Loop syst. PSAH1	Х
Pressure PSAL2	Х
Loop syst. PSAL4	Х
Night op. delay	
Pressure PSAH3	Х
Ext. CMS	Х
Aqua Control	Х
HotROII DI8	Х
HotRO DI7	Х
Esc 🔨 🗸	

#### Considering digital inputs

**Menu 7B** makes it possible for the operator to consider the switch states of the digital inputs even during normal system operation.

0/1 = Input not set / set

**Esc** switches to the previous menu.

- $\uparrow$  Move selection upwards.
- $\checkmark$  Move selection downwards.

# 15. Special operating modes

# 15.1 Hard water operation, menu item 8



If in emergency situations there is no softened water available over a limited period of time (hard water alarm, otherwise defect), the permeate production can be maintained using drinking water, by activating the hard water mode with "ON" in menu item 8.

In this operating phase the interval for the discharge of the concentrate is increased.

As soon as the conductivity of the concentrate reaches 1.4 times the conductivity of fresh water, the concentrate is discharged into the sewage system.

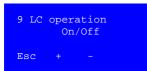
This prevents any blockage of the membrane and possible damage.

The concentrate discharge is stopped when the ratio factor 1.2 is reached.

Activated hard water mode is shown by a flashing signal in the display.

NOTE: Cleaning the reverse osmosis becomes necessary after hard water operation. During hard water operation an extensive test of the water qualities (drinking water, permeate) regarding chemical and microbiological parameters is recommended.

# 15.2 Low conductivity operation (LC), menu item 9



Concentrate discharge time-controlled (M6.12 interval), conductivity-controlled discharge deactivated.

LC operation if cond. raw water less than 100 µS/cm.

#### Low conductivity in raw water

- ➔ Discharge data suppressed
- ➔ Time-controlled

Low conductivity (LC) operation can be selected, (activate using the "on" key), if the conductivity in the drinking/or soft water is less than 100  $\mu$ S/cm.

In this operating mode the concentrate discharge is not controlled via the ratio of conductivities between concentrate and fresh water.

The discharge is effected in adjustable time intervals ( $\rightarrow$ menu item 6.12). This reduces water consumption to a minimum without any damage to the membrane system.

The activated LC operation is indicated visually by an alternating message in the main display.

# 15.3 Hot RO, menu item 10

The possibility of hot cleaning the reverse osmosis is only possible with system EcoRO Dia II C HT. The release is preset electrically and mechanically.



Esc

Esc

Hot cleaning is not possible in the "off" operating state.

#### 15.3.1 HotRO, only for EcoRO Dia II C HT

10 HotRO 10.1 HotRO I/II 10.3 Manual mode 10.4 Auto. Operation 10.5 Heating cycles Esc   Enter	
10.1 HotRO I/II Heating: xx°C Cooling: xx°C Esc + - Enter	
10.2 Manual mode (1=Yes/0=No): x	

Enter

Monday Tuesday Wednesday Thursday Friday Saturdays Sunday Clearing all Esc	Enter
Monday	

Clearing all	
please wait Menu	Reset

This menu item contains the parameterisation of the hot cleaning of stage 1 and 2 of the reverse osmosis.

Esc = return to the menu

- ↑ = upper submenu
- ↓ = lower submenu

Enter = selection submenu

The target temperature for heating as well as the cooling temperature after hot cleaning is selected in menu 10.1 with keys F2 ("+") and F3 ("-").

Esc = return to the menu

Enter = change between "Heating" and "Cooling"

The duration of hot cleaning (= hold time after reaching the set temperature) can be selected in menu 10.2 "Manual mode" using keys F2 ("+") and F3 ("-").

Esc = return to the menu

Enter = change between "Heating" and "Cooling"

In menu 10.4 "Auto mode" the hot cleaning process can be individually programmed for each weekday in coordination with the external hot cleaning.

Esc = return to the menu

- ↑ = upper submenu
- ↓ = lower submenu

Enter = selection submenu

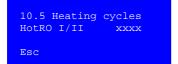
The duration of the hot cleaning (= hold time after reaching the set temperature) can be set for each weekday using keys F2 ("+") and F3 ("-")

Esc = return to the menu

**Value range**: -- = Off; 20...90 min

Default: -- = Off

Using the submenu "Clearing all" the auto parameters from Monday to Sunday will be deleted.



In the **menu 10.5** "Heating cycles" the number of the fully performed hot cleaning cycles will be displayed.

Hot cleaning cycles that were terminated prematurely using the keys "Dial", "Cool" or by malfunctions are considered as not performed.

These details are used for control and documentation purposes of the hot disinfection processes.

Esc = return to the menu

### 15.3.2 HotRO, for optionally extended EcoRO Dia II C HT



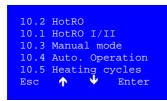
The system EcoRO Dia II C HT can be converted to a reverse osmosis that can be hot cleaned using optional add-on package. HotRO: hot cleaning of **1st and 2nd osmosis stage** 

Esc = return to the menu

- ↑ = upper submenu
- ↓ = lower submenu

**Enter** = selection submenu

#### Submenu 10.2 HotRO



The parameters for the full hot cleaning are programmed by selecting 10.2 HotRO.

The set temperatures of the heating and cooling phases for hot cleaning are programmed by selecting 10.1 HotRO I/II.

Under 10.3 "Manual mode" and 10.4 "Auto mode" just as in  $\rightarrow$  Chapter 15.3.1: *"HotRO, only for EcoRO Dia II C HT"* the duration of the hold phase is defined.

In menu 10.5 "Heating cycles" the number of the fully performed, fault-free hot cleaning cyles is displayed.

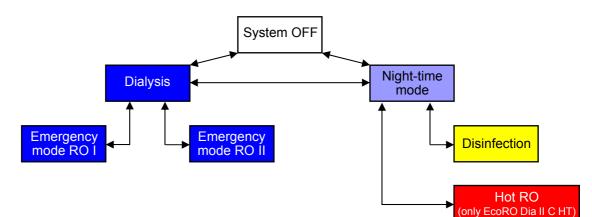
**Esc** = return to the menu

- ↑ = upper submenu
- **↓** = lower submenu

Enter = selection submenu

# 16. Operating modes

# 16.1 Overview of operating modes



# 16.2 ABBREVIATIONS

	Valve designation									
Cool	Placeholders for valves (SV)									
Y2	Concentrate return									
Y5	Permeate valve, system type EcoRO Dia I C / II C									
Y5.1.1/Y6.1.1	Ring piping return flow (only with/to HotRinse)									
Y6	Swell valve 1st stage, system type EcoRO Dia I C / II C									
Y7	Swell valve 2nd stage, system type EcoRO Dia II C									
Y8	Concentrate return RO II									
Y9	Concentrate discharge									
Y10	Tank feed									
Y 30	Impulse shear force flushing									
	·									
NOTE: Only one solenoid valve is switched on simultaneously. (delay 1 sec. each)										

#### Table 16-1: Valve designation

Cool	Placeholder for
#)	Start condition:         LSAL1 (lower lev. switch) exceeded         and delay 10s expired         Start if         ratio cond.(conc/raw) > control value 1         or cond. permeate > limit value 1         or cond. concentrate > control value 3         or measurement range cond. concentrate reached         or time-controlled         or temperature > limit value
0	Off
1	on
Y2/Y9	Y2 and Y9 mutually indexing with 1 sec. overlapping in function menu item 6.22
Y5/Y6	Y5 and Y6 indexing (normal: Y5=1,Y6=0 pressure: Y5=0,Y6=0 swell: Y5=0,Y6=1 in function menu item 6.24
LSHL2	On, if LSHL2 (upper level switch) undercut Off, if LSHL2 (upper level switch) reached
AUTO	On, if LSAL1 (lower level switch) exceeded plus delay 10s expired Off, if LSAL1 (lower level switch) undercut
(-xxs)	Time delay of xx seconds
(Mx.xx)	Can be set in the menu x.xx

#### Table 16-2:Further abbreviations

# 16.3 Functions

#### 16.3.1 Function of solenoid valve Y5.1.1/Y6.1.1 (to HotRinse)

The solenoid valve ring piping return 5.1.1/ 6.1.1 has the following function:

Operating mode	Operating phase	Key functions. In order to							
Power up test	all	off if hot cleaning active, otherwise on							
Control unit off	all	Off							
Dialysis mode	all	off, if hot cleaning / Hot RO or emergency mode ROII enabled, otherwise on							
Night-time mode	Shut-off flushing	off, if hot cleaning / Hot RO active, otherwise on							
	Break-out	Off							
	Interm. flushing	off, if hot cleaning / Hot RO active, otherwise on							
	Deactivated	Off							
Disinfection mode	all	on							

# 16.4 Operating phases

		all	Eco version	all	Eco version	EcoRO Dia II C version	only 2-stage	all	all	all	only Hot version	only Hot version	all	all	all
Operating mode	Operating phase	MV Y2	MV Y5	MV Y5.1.1	MV Y6	MV Y7			MV Y10	MV Y30	SV Y5.1	MV Y90	Pump M1	Pump M2	TISAH NTC
		DO 09	DO 10	DO 18	DO 11	DO 12	DO 13	DO 14	DO 15	DO 16	DO 17	DO 20	K1101	K1102	
System OFF	System OFF	0 Y2/9	0 Eco=1	0	0	0	0	0 Y2/9	0	0	0	0	0 Auto	0	0
Dialysis	Empty tank	M6.22	RO=0 Eco=1	1	0	0	1	M6.22	0	0	0	0	(-2s)	0	0
	Filling tank	1	R0=1	1	0	0	1	(-2s)	LSHL2	0	0	0	0	0	0
	Operation	1	Eco=1 RO=2	1	0	0	1	0	LSHL2	0	0	0	Auto (-2s)	Auto (-7s)	1
	IRS RO I pressure build-up	1	0	1	0	0	0	0	LSHL2	0	0	0		⊦2 pumps ⁄/2=Auto	1
	IRS RO I Flush	1	0	1	1	0	0	0	LSHL2	0	0	0		=Auto,M2=0	1
	IRS RO II Pressure build-up II	1	0	1	0	0	0	0	LSHL2	0	0	0	Auto (-2s)	0	1
	IRS RO II Flush	1	0	1	0	1	1	0	LSHL2	0	0	0	Auto	Auto	1
	Concentrate discharge	Y2/9 M6.22	1	1	0	0	1	Y2/9 M6.22	LSHL2	0	0	0	Auto	Auto	1
	Temperature discharge	Y2/9 M6.22	1	1	0	0	1	Y2/9 M6.22	LSHL2	0	0	0	Auto	Auto	1
	Emergency mode RO I	1	0	1	0	0	0	0	LSHL2	0	1	0	Auto (-2s)	0	1
	Emergency mode RO II	0	1	1	0	0	1	0	0	0	0	0	0	Auto (-7s)	1
Night-time mode	Shut-off rinsing emptying tank	0 (-2s)	Y5/6 (30/5)	1	Y5/6 (30/5)	0	1	1	0	0	0	0	Auto (-2s)	0	0
	Shut-off rinsing filling tank 1	0	0	1	0	0	0	0	to LSAL1=1	0	0	0	0	0	0
	Shut-off rinsing filling tank 2	0	0	1	0	0	0	0	LSHL2	0	0	0	0	0	0
	Interm. flushing	1	1	1	0	0	1	0	0	M6.23 (-60s) 0/1 cycl.	0	0	Auto (-2s)	M6.28 Auto (-7s)	1
	IRS RO I pressure build-up	1	0	1	0	0	0	0	0	0	0	0		-2 pumps	1
	IRS RO I Flush	1	0	1	1	0	0	0	0	0	0	0		M2=Auto =Auto,M2=0	1
	IRS RO II Pressure build-up II	1	0	1	0	0	0	0	0	0	0	0	Auto (-2s)	0	1
	IRS RO II Flush	1	0	1	0	1	1	0	0	0	0	0	Auto	Auto	1
	Temperature rinsing	Y2/9 M6.22	1	1	0	0	1	Y2/9 M6.22	LSHL2	0	0	0	Auto	0	1
	Empty tank	0 (-2s)	Y5/6 (30/5)	1	Y5/6 (30/5)	0	1	1	0	0	0	0	Auto	0	1
	Filling tank 1	0	0	1	0	0	0	0	LSAL1	0	0	0	0	0	0
	Filling tank 2	0	0	1	0	0	0	0	LSHL2	0	0	0	0	0	0
	Break	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Intermediate flushing if from Hot Rinse HWD1=1	Y2/9 M6.22	1	0	0	0	1	Y2/9 M6.22	LSHL2	0	0	0	Auto (-2s)	M6.28 Auto (-7s)	1
	Signal from Ext. CMS DI20=1	Y2/9 M6.22	1	1	0	0	1	Y2/9 M6.22	LSHL2	0	0	0	Auto (-2s)	M6.28 Auto (-7s)	1

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<b>~</b>	
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only HT & Hot	only HT	all	all	all	all	all	all	all	all	all	
TISAH2	TISAH4	Relay	Relay	Relay	Relay	Lamp	Lamp	Lamp	Lamp	Lamp	Conditions
420mA	420mA	DI K1106	Dialysis K1103	Release K1104	Alarm	Dialysis DO 01	Night operation DO 02	Rinsing DO 03	DI DO 04	Alarm DO 05	
0	0	0	0	0	1	0	0	0	0	0	
0	0	0	1	0	1	1	0	0	0	0	Until level drops below LSAL1 (DI09=0)
0	0	0	1	0	1	1	0	0	0	0	Filling until LSHL2 (DI10=0) is exceeded
											LF evaluation (only after 120s)
0	0	0	1	0	1	1	0	0	0	0	Acc. to setting M6.24/6.26/6.31 After press. build-up
0	0	0	1	0	1	1	0	0	0	0	Acc. to setting M6.24 After press. build-up IRS RO I to flush IRS RO I
0	0	0	1	0	1	1	0	1	0	0	Acc. to setting M6.24 After flush IRS RO I back to operation
0	0	0	1	0	1	1	0	0	0	0	Acc. to setting M6.31 After press. build-up IRS RO II to flush IRS RO II
0	0	0	1	0	1	1	0	0	0	0	Acc. to setting M6.31 After flush IRS RO II back to operation
0	0	0	1	0	1	1	0	0	0	0	Until control value 2 is reached or time-controlled M6.12 (in LC mode)
											No concentr. discharge in emergency op. RO II
0	0	0	1	0	1	1	0	0	0	0	Acc. to setting M6.25 start+stop value
0	0	0	1	0	0	1	0	0	0	1	IRS RO I+RO II deactivated LF evaluation (after 120s)
0	0	0	1	0	0	1	0	0	0	1	IRS RO I+RO II deactivated LF evaluation (after 120s)
0	0	0	0	0	1	0	1	Y6=1 then1	0	0	Until below LSAL1 (DI09=0) or timer reaches max. idle time (300s)
0	0	0	0	0	1	0	1	0	0	0	Filling to LSAL1 (DI09=1), after 1 min. filling to tank 2
0	0	0	0	0	1	0	1	0	0	0	Filling until LSHL2 DI10=0)
0	0	0	0	1	1	0	1	0	0	0	Time-controlled M4.1, leak monitoring active if night temp flushing locked + water temp.≥ start value (M6.25): no interm. flushing For Eco version interm. flushing starts with IRS RO I. Then acc. to. M6.24After pressurisation time RO I or RO II
0	0	0	0	1	1	0	1	0	0	0	Acc. to setting M6.24 After press. build-up IRS RO I to flush IRS RO I
0	0	0	0	1	1	0	1	1	0	0	Acc. to setting M6.24 After lapse of flush IRS RO I back to interm. flushing
0	0	0	0	1	1	0	1	0	0	0	Acc. to setting M6.31 After pressurisation IRS RO II to flush IRS RO II
0	0	0	0	1	1	0	1	0	0	0	Acc. to setting M6.31 After lapse of flush IRS RO II back to interm. flushing
0	0	0	0	1	1	0	1	0	0	0	Start: Night temp. flushing = ON (M4.2) and temp. ≥ start value (M4.2) Stop: Temp. ≤ stop value (M4.2) or max. flush. time = 5 min
0	0	0	0	1	1	0	1	Y6=1 then1	0	0	Until level drops below LSAL1 (DI09=0)
0	0	0	0	1	1	0	1	0	0	0	Filling to LSAL1 (DI09=1), after 1 min. filling to tank 2
0	0	0	0	1	1	0	1	0	0	0	Filling until LSHL2 (DI10=0), then back to interm. flushing
0	0	0	0	1	1	0	1	0	0	0	Time-controlled M4.1, leak monitoring active
0	0	0	0	1	1	0	1	0	0	0	Operation only if ON in menu 4.3 Otherwise see conditions/remarks for interm. flushing
0	0	0	0	1	1	0	1	0	0	0	Active only if HWD1 and/or HWD2 = 0 and no hot cleaning RO Ilor HT Rejection until control value 2 is reached or time-controlled M6.12 (in LC mode)

		all	Eco version	all	Eco version	EcoRO Dia II C version		all	all	all	only Hot version		all	all	all
Operating mode	Operating phase	MV Y2	MV Y5	MV Y5.1.1	MV Y6	MV Y7	MV Y8	MV Y9	MV Y10	MV Y30	SV Y5.1	MV Y90	Pump M1	Pump M2	TISAH1
		DO 09	DO 10	DO 18	DO 11	DO 12	DO 13	DO 14	DO 15	DO 16	DO 17	DO 20	K1101	K1102	NTC
Disinfection	Empty tank	0	Y5/6	1	Y5/6	0	0	1	0	M6.23	0	0	Auto	0	0
	Filling tank	0	(30/5)	1	(30/5)	0	0	0	LSAL1	0/1 cycl. 0	0	0	(-2s) 0	0	0
	Prompt:	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Fill in disinfectant	0	0	0	0	0	0	0	0	0	0	0	0		0
	Recirculation	1	1	1	0	0	1	0	LSHL2	M6.23 0/1 cycl.	0	0	Auto (-2s)	M6.29 Auto (-7s)	1
	IRS RO I pressure build-up	1	0	1	0	0	0	0	LSHL2	M6.23 0/1 cycl.	0	0		⊦2 pumps	1
	IRS RO I Flush	1	0	1	1	0	0	0	LSHL2	M6.23 0/1 cycl.	0	0		M2=Auto =Auto,M2=0	1
	IRS RO II Pressure build-up II	1	0	1	0	0	0	0	LSHL2	0	0	0	Auto (-2s)	0	1
	IRS RO II Flush	1	0	1	0	1	1	0	LSHL2	0	0	0	Auto	Auto	1
	Reaction time	0	0	1	0	0	0	0	LSHL2	0	0	0	0	0	1
	Flushing mode	Y2/9 M6.22	1	1	0	0	1	Y2/9 M6.22	LSHL2	M6.23 0/1 cycl.	0	0	Auto (-2s)	M6.29 Auto (-7s)	1
	IRS RO I pressure build-up	1	0	1	0	0	0	0	LSHL2	M6.23 0/1 cycl.	0	0	Eco I C -	⊦2 pumps	1
	IRS RO I Flush	1	0	1	1	0	0	0	LSHL2	M6.23 0/1 cycl.	0	0		M2=Auto =Auto,M2=0	1
	IRS RO II Pressure build-up II	1	0	1	0	0	0	0	LSHL2	0	0	0	Auto (-2s)	0	1
	IRS RO II Flush	1	0	1	0	1	1	0	LSHL2	0	0	0	Auto	Auto	1
	End flushing mode Prompt Check disinfectant request	0	0	0	0	0	0	0	LSHL2	0	0	0	0	0	0
HotRO II	Heat up	0	#1	0	0	1	0	0	0	0	0	#1	0	Auto (-7s)	1
	please wait	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	M10.3 cool down passive	0	1	0	0	1	0	0	0	0	0	0	0	#2	1
	M10.3 cool down active	Y2/9 M6.22	0	#3	0	0	#4	Y2/9 M6.22	LSHL2	0	1	0	Auto	0	1
	Hot RO II active, Hot Rinse cooling + HWD2	1	0	0	0	0	0	0	LSHL2	0	1	0	Auto	0	1
	Hot RO II active, Hot rinse cooling + ROI dialysis mode	Y2/9 M6.22	0	#3	0	0	0	Y2/9 M6.22	LSHL2	0	1	0	Auto	0	1
	Intermediate flushing RO, Hot RO II active, + HWD1 = 1	Y2/9 M6.22	0	0	0	0	0	Y2/9 M6.22	LSHL2	0	1	0	Auto (-2s)	M6.28 Auto (-7s)	1
HotRO I/II	Heat up	1	1	#5	#6	#6	#6	0	0	#6	0	0	Auto (-2s)	#6	1
	Hold temperature	1	1	#5	#6	#6	#6	0	0	#6	0	0	Auto	#6	1
	Cool down	1	1	0	#6	0	#7	#8	LSHL2	0	0	0	Auto	0	1

40
(D)
4.15

only HT & Hot	only HT	all	all	all	all	all	all	all	all	all	
TISAH2	TISAH4	Relay	Relay	Relay	Relay	Lamp	Lamp	Lamp	Lamp	Lamp	
		DI	Dialysis	Release	Alarm	Dialysis	Night operation	Rinsing	DI	Alarm	Conditions
		K1106	K1103	K1104	K1105	DO 01	DO 02	DO 03	DO 04	DO 05	
0	0	1	0	0	0	0	0	Y6=1 then1	1	1	Until level drops below LSAL1 (DI09=0)
0	0	1	0	0	0	0	0	0	1	1	Filling until LSAL1 (DI09=1)
0	0	1	0	0	0	0	0	0	1	1	Continue using display + keyboard
	-		-	-	_			-			Time-controlled menu 5
0	0	1	0	0	0	0	0	0	1	1	After 60s recirculation to IRS RO I pressure
0	0	1	0	0	0	0	0	0	1	1	Acc. to setting M6.24 After press. build-up IRS RO I to flush IRS RO I
0	0	1	0	0	0	0	0	Y6=1 then1	1	1	Acc. to setting M6.24 After lapse of flush IRS RO I back to recirc. 30s after termination IRS RO I flush continue to IRS RO II pressurisation
0	0	1	0	0	0	0	0	0	1	1	Acc. to setting M6.31 After pressurisation RO II to flush RO II
0	0	1	0	0	0	0	0	0	1	1	Acc. to setting M6.31 After lapse of flush RO II back to recirculation + until time menu 5 recirc. time lapsed, repeat
											lines 31,32,33,34 + 35.
0	0	1	0	0	0	0	0	0	1	1	Time-controlled menu 5 Time-controlled acc. to menu 5: Check after expiry for disinfectant. Display "Check disinfectant
0	0	1	0	0	0	0	0	0	1	1	freedom" 10 min before end of flushing mode, alternating 15s with display "flushing mode time left".
											After 120s flushing mode to IRS RO I pressurisation
0	0	1	0	0	0	0	0	0	1	1	Acc. to setting M6.24 After press. build-up IRS RO I to flush IRS RO I
								Y6=1			Acc. to setting M6.24
0	0	1	0	0	0	0	0	then1	1	1	After flush expiry IRS RO I back to flushing mode 30s after termination IRS RO I flush cont. to IRS RO II pressurisation
0	0	1	0	0	0	0	0	0	1	1	Acc. to setting M6.31 After pressurisation RO II to flush RO II
											Acc. to setting M6.31
0	0	1	0	0	0	0	0	0	1	1	After lapse of flush RO II back to flushing mode + until time menu 5 recirculation time exp., repeat lines 37,38,39,40 +41.
											Keyboard back to flushing mode or end disinfection,
0	0	1	0	0	0	0	0	0	1	1	End = return to basic state, night mode of off
											Until heat-up temp reached (Menu10) or HWD1 = 0 or
1	0	1	0	1	1	0	1	0	1	0	HWD2 = 1
			Ŭ	•		Ů		Ū		Ŭ	#1: if ∆Temp > 2K/min: Y5 and Y90 = 0 for 20sec. If temp > 90°C (Alarm31) -> after cool-down
											15min. Wait, then continue acc. to Menu10.3 Cooling active/passive
1	0	1	0	1	1	0	1	0	1	0	HWD2=1 cont. to cooling with HWD2
1	0	1	0	1	1	0	1	0	1	0	#2: Activate M2 every 15min for 30s, then check temp. Continue if temp. (Menu10.3) is reached,
1	0	1	0	1	1	0	1	0	1		#3: HWD1 = 1 → Y5.1.1 = 0, otherw.: Y5.1.1 = 1
1	0	1	0	1	1	0	1	0	1		#4: Y8 = 1, if∆Temp > 2K/min: Y8 = 0 for 20s. If HWD2 = 0 then back to cooling
			U	1	<b>'</b>	0		U		0	
1	0	1	0	1	1	0	1	0	1	0	LF evaluation #3: HWD1 = 1 → Y5.1.1 = 0, otherw.: Y5.1.1 = 1
1	0	0	0	1	1	0	0	0	0	0	Operation only if ON in menu 4.3 Operating phases + conditions line 16-24 intermediate flushing.
								Y6=1			<ul> <li>#5 = close Y5.1.1 if Δ T ≥ 2°K/min., open if Δ T ≤ +2°K/min.</li> <li>#6 = open Y30 every 120s for 1s if Y30 is closed again and open Y6 for 2s if Y6 is closed</li> </ul>
1	1	1	0	1	1	0	1	then1	1	0	again, open Y7 for 2s and in parallel M2 on, if Y7 open then close Y8
											Heating until temperature Menu 10 Heating up is reached, then go to line 51 Hold
								Y6=1			<ul> <li>#5 = Close Y5.1.1 if Δ T ≥ 2°K/min., open if Δ T ≤ +2°K/min.</li> <li>#6 = open Y30 every 120 s for 1s,if Y30 is closed again, open Y6 for 2s if Y6 is closed again,</li> </ul>
1	1	1	0	1	1	0	1	then1	1	0	• #6 = open Y30 every 120 s for 1s,if Y30 is closed again, open Y6 for 2s if Y6 is closed again, open Y7 for 2s and in parallel M2 on, if Y7 open then close Y8
											• Keep temperature acc. to setting Menu 10 Heating up, then go to line 52 HotRO cool-down.
								•			<ul> <li>#7 = Close Y8 if Δ T ≥ 2°K/min., open if Δ T ≤ +2°K/min.</li> <li>#8 = Close Y9 if Δ T ≥ 2°K/min., open if Δ T ≤ +2°K/min.</li> </ul>
1	1	1	0	1	1	0	1	0	1	0	<ul> <li>#8 = Close Y9 If Δ 1 ≥ 2"K/min., open if Δ 1 ≤ +2"K/min.</li> <li>If temperature Menu 10 Cooling down is reached, back to line 25 "Night mode break"</li> </ul>
	1						1				· · · · · · · · · · · · · · · · · · ·

# 17. Faults / Causes / Correction

# 17.1 Fault messages



When a fault is determined in the system, the following appears in the display:

Error or alarm with fault number short fault description

### 17.1.1 Fault types

A distinction is made between the fault types ALARM and ERROR.

#### ALARM

A deviation from standard mode has been established. The effects can impair system operation. The control system is not switched off automatically, reduced operation will be continued.

These are low-priority alarm conditions which require attention by the operator (as per IEC 60601-1-8).

#### An alarm is indicated as follows:

- Relay collective alarm and function lamp alarm on
- LED red/green flash (1 Hz) alternately
- LCD indicates fault

The alarm can reset itself automatically when operating states change.

#### ERROR

A fault has been established. The effects can lead to system damage. The system is switched off automatically.

An error message is a medium-priority alarm condition which requires a reaction/action by the operator (as per IEC 60601-1-8).

#### Signaling an error:

- · Relay collective alarm on and function lamp alarm
- Error-LED on (red)
- LCD indicates fault

After correction of the fault the reset key has to be pressed to reset the error message or the system has to be shut down for a short time using the main switch.

An error message overwrites an alarm message. The first error message is retained even if further errors are established.

If operating and fault lamp flash alternately, the safety chain has been interrupted.

B. Braun recommends that the alarm output (fault message) and warning information output (disinfection mode) be connected to a central alarm. This can be the B. Braun remote control system, for example.

If the system is in emergency mode an alarm signal is emitted (lamp relay collective alarm).

# 17.2 Causes of faults and their correction

### 17.2.1 Fault codes on the displays

Alarm/Error	Cause / Condition	Characteristics
wd. dd.mm.yy hh:mm Error 01 CPU Menu	CPU defective RAM, Watchdog, EPROM error	DI: with fault: Delay: No Self-acknowledging: Reset key:
Initiate operating phase	System OFF	

wd. dd.mm.yy hh:mm Error 02 Watchdog LT/ext.sup.	Watchdog LT/ ext.spg. and ext. EC measurement is displayed alternately. => Watchdog has triggered	DI: with fault: Delay: Self-acknowledging: Reset key:	
alternating	=> External feed missing	Resel key.	
Ext. CD-Measuring Menu	=> External CD measuring (JUMO)		
Initiate operating phase	System OFF		

wd. dd.mm.yy hh:mm Alarm 03 Exc. press. rp PSAH1 Menu	Ring piping pressure too high, pressure switch (PSAH1) has triggered. Pump M2 off	DI: with fault: Delay: Self-acknowledging: Reset key:	DI 13 = 0 No Yes 
Initiate operating phase			
Dialysis mode:	Pump M1 + M2 off		
Emergency mode RO I:	Pump M1 off		
Emergency mode RO II:	Pump M2 off		
Night-time mode:	Pump M1 + M2 off		
Disinfection:	Pump M1 + M2 off		
Hot RO:	Pump M1 off		

wd. dd.mm.yy hh:mm	Ring piping pressure too high, pressure switch	DI: with fault:	DI 13 = 0
Error 03	(PSAH1) has triggered.	Delay:	No
Exc.press. rp. PSAH1	If > 3x per minute, system off	Self-acknowledging:	
Menu Reset	Reset through keypad	Reset key:	Yes
Initiate operating phase	System OFF		

wd. dd.mm.yy hh: Alarm 04 Hard water alarm Menu Re		Message from external hard water monitor	DI: with fault: Delay: Self-acknowledgi Reset key:	DI 16 = 1 No ng: Yes
Initiate operating phase				
Dialysis mode:		System remains in operation as per menu 8 hard water operation, reset through keypad		et through keypad
Emergency mode RO I:		System remains in operation as per menu 8 hard water operation, reset through keypad		
Emergency mode RO II:	Emergency mode RO II: System remains in operation as per menu 8 hard water operation, reset through keypa		et through keypad	
Night-time mode: System remains in operation				
Disinfection: System remains in operation				
Hot RO:		System remains in operation		

Alarm/Error	Cause / Condition	Characteristics	
Display: (Eco)RO Dia I C			
wd. dd.mm.yy hh:mm Alarm 05 Pump M1 Menu Display: (Eco)RO Dia I C	Overcurrent pump M1 Motor protection switch triggered	DI: with fault: DI 1 = 0 Delay: No Self-acknowledging: No Reset key: No	
wd. dd.mm.yy hh:mm Alarm 05 pump M1 Switch Kl + press F2 ROII			
Initiate operating phase			
Dialysis mode:	See chapter 18 description emergency mode		
Emergency mode RO I:	Not active		
Emergency mode RO II:	Not active		
Night-time mode:	See chapter 18 description emergency mode		
Disinfection:	See chapter 18 description emergency mode		
Hot RO:	System OFF		

wd. dd.mm.yy hh:mm Error 06 Temp. permeate Menu	Temperature 0° C or > 40° C (active only in init. test)	DI: with fault: Delay: Self-acknowledging: Reset key:	TISAH1 No  Yes
Initiate operating phase	System OFF	·	
Hot RO II:	No function		
Hot RO:	No function		

wd. dd.mm.yy hh:mm Alarm 07 Recipient tank empty Menu	Level below float switch LSAL1	DI: with fault: Delay: Self-acknowledging: Reset key:	DI 9 = 0 5 sec. Yes No
Initiate operating phase			
Dialysis mode:	Pumps off		
Emergency mode RO I:	Pumps off		
Emergency mode RO II:	No function		
Night-time mode:	Leakage alarm		
Disinfection:	Pumps off		
Hot RO:	Pumps off		

wd. dd.mm.yy hh:mm Error 08 Cond.perm.1 > limit Menu Reset	Permeate flow above limit 2 Menu 7.9.5 <u>Conditions:</u> – only active after 120 sec. Start dialysis mode – 1st concentrate discharge terminated	DI: with fault: Delay: Self-acknowledging: Reset key:	CISAHH3 No No Yes
Initiate operating phase	System OFF		

Alarm/Error	Cause / Condition	Characteristics	
wd. dd.mm.yy hh:mm Alarm 10 Cond. raw water Menu	Analogue value conductance raw water not in the permitted tolerance range. (Cond.raw < 25µS/cm or ADC value > 252) Analysis only in dialysis mode after 1st concentrate discharge	DI: with fault: CIS1 Delay: No Self-acknowledging: Yes Reset key: No	
Initiate operating phase		•	
Dialysis mode:	System remains in operation concentrate discharge time-controlled see menu 6.12		

wd. dd.mm.yy hh:mm Alarm 11 Cond. concentrate Menu	Analogue value conductance concentrate despite return flushing not in the permitted tolerance range. (Cond-conc. < 30 $\mu$ S/cm or ADC value >252) Analysis only in dialysis mode after 1st concentrate discharge. Fault is not suppressed during return rinsing.	DI: with fault: Delay: Self-acknowledging: Reset key:	CISAH2 No Yes No
Initiate operating phase			
Dialysis mode:	System remains in operation concentrate discharge time-controlled see menu 6.12		

	wd. dd.mm.yy Error 12 Cond. perm. Menu	1	Analogue value conductance permeate not in the permitted tolerance range. (Cond. perm = 0 or ADC value > 240) Evaluation only in dialysis mode.	DI: with fault: Delay: Self-acknowledging: Reset key:	CISAHH3 No No Yes
Initiate operating phase		ISE	System OFF		

Eri	nm.yy hh:mm cor 14 etection VL Reset	Level switch defective	DI: with fault: Delay: Self-acknowledging: Reset key:	DI 09 / DI 10 4 sec. No Yes
Initiate operating phase		System OFF		

- 11-	Overpressure RO II. Pressure switch PSAH3 triggered.	 DI 19 = 0 5 sec No No
Initiate operating phase	System OFF	

	LSAL1 was undercut during night-time mode pause or intermediate rinse.	DI: with fault: Delay: Self-acknowledging: Reset key:	DI 09 = 0 No No No
Initiate operating phase	System OFF		

	EEPROM interrupted	DI: with fault: Delay: No Self-acknowledging: No Reset key: No	
Initiate operating phase	System OFF		

Alarm/Error	Cause / Condition	Characteristics
wd. dd.mm.yy hh:mm Alarm 18 RTC Menu	Real time clock defective or data transmission to real time clock interrupted	DI: with fault: Delay: No Self-acknowledging: No Reset key: No
Initiate operating phase	System continues to run, no automatic operation per	ossible

wd. dd.mm.yy hh:mm	Tank inlet Y10 more than 300 sec continuously open without the tank being filled (LS 2 exceeded).	DI: with fault:	
Alarm 19		Delay:	300 sec
Raw water inflow		Self-acknowledging:	
Menu		Reset key:	No
Initiate operating phase	Dialysis mode: System continues to run. Init. test: sy	vstem OFF	

wd. dd.mm.yy hh:mm Alarm 20 Cond.conc./rw >limit Menu Alternating display	<ul> <li>Ratio cond. (conc./raw water) larger 7</li> <li>active only after termination of</li> <li>1st temperature discharge</li> </ul>	DI: with fault: Delay: Self-acknowledging: Reset key:	 30 min Yes No
wd. dd.mm.yy hh:mm Flow conc. too low Y9 faulty/NV4 closed			
Initiate operating phase	System continues to run	·	

wd. dd.mm.yy hh:mm Error 20 Cond.conc./rw >limit Menu	<ul> <li>Ratio cond. (conc./raw water) larger 9</li> <li>Message is suppressed during alarm 10 or 11</li> <li>active only after termination of</li> <li>1st temperature discharge</li> </ul>	DI: with fault: Delay: 10 sec Self-acknowledging: No Reset key: No
Initiate operating phase	System OFF	

wd. dd.mm.yy hh:mm	Emergency switch still activated	DI: with fault:	DI 03 = 1
Alarm 21		Delay:	No
Start emerg. oper.		Self-acknowledging:	Yes
Menu		Reset key:	No
Initiate operating phase	System continues to run		

wd. dd.mm.yy hh:mm Error 22 No change of level Menu Reset	No change in level can be enforced during the init. test	DI: with fault: Delay: Self-acknowledging: Reset key:	 No No Yes
Initiate operating phase	Initiating operating phase/action		
Dialysis mode:	Only active in init. test		
Emergency mode RO I:	Not active		
Emergency mode RO II:	Not active		
Night-time mode	Not active		
Disinfection:	Not active		
HotRO:	Not active		

Alarm/Error	Cause / Condition	Characteristics	
wd. dd.mm.yy hh:mm Alarm 23 Low press.ring.PSAL4 Menu	Pressure switch PSAL4 triggered. Only active in dialysis mode when pump is running and Y30 closed.	DI: with fault: Delay: Self-acknowledging: Reset key:	DI 14 = 1 No Yes No
Initiate operating phase	System continues to run		

	wd. dd.mm.yy hh:mm Error 25 TISAH1 Temp. too low Menu	Wire break temperature sensor or temperature <= 0° C (always active)	DI: with fault: Delay: Self-acknowledging: Reset key:	TISAH1 No No No
Initiate operating phase		System OFF		

Display: (Eco)RO Dia I C 2 pumps	Overcurrent pump M2. Motor protection switch has triggered.	DI: with fault: Delay:	DI 02 = 0 No
wd. dd.mm.yy hh:mm Alarm 26 Pump M2 Menu		Self-acknowledging: Reset key:	Yes No
Display: (Eco)RO Dia II C			
wd. dd.mm.yy hh:mm Alarm 26 pump M2 Switch K3 + press F1 ROI			
Display: (Eco)RO Dia II C + Hot RO II			
wd. dd.mm.yy hh:mm Alarm 26 pump M2 Press F2, then F1 ROI Y5.1			
Initiate operating phase	See chapter 18 description emergency mode		

wd. dd.mm.yy hh:m Alarm 27 Cond.perm.1>al. val Menu	Permeate flow above limit 1	DI: with fault: Delay: Self-acknowledging: Reset key:	CISAHH3 No Yes No
Initiate operating phase	System continues to run. A time-controlled concentrate discharge is displayed, see menu 6.17		

wd. dd.mm.yy hh:mm Error 28 TISAH1 temp.>limit Menu Reset	Permeate temperature ≥ 38° C (only when cond. evaluation or night-time rinse is active) or temper- ature measuring with reference resistor is beyond tolerance (in init. test only) or temperature outside measurement range (always active)	DI: with fault: Delay: Self-acknowledging: Reset key:	TISAH1 60 sec No Yes
Initiate operating phase			
Dialysis mode:	System OFF. Reset via keyboard with new start of init. test.		
Emergency mode RO I:	System OFF. Reset via keyboard with new start of init. test.		
Emergency mode RO II:	System OFF. Reset via keyboard with new start of init. test.		
Night-time mode:	System OFF. Reset via keyboard with new start of init. test.		
Disinfection:	Recirculation mode is terminated and changed to reaction mode		
Hot RO:	Not active		

Alarm/Error	Cause / Condition	Characteristics
wd. dd.mm.yy hh:mm Error 29 Pumps failed Menu	Overcurrent pump M1+ M2. Both motor protection switches failed	DI: with fault: DI 01/DI 02 = 0 Delay: No Self-acknowledging: Yes Reset key: No
Initiate operating phase	System OFF	

wd. dd.mm.yy hh:mm Alarm 30 Prim.pres M2 PSAL2 Menu	Pressure switch PSAL2 triggered. New for EcoRO Dia II C	DI: with fault: Delay: Self-acknowledging: Reset key:	DI 12 = 0 10 sec. Yes No
Initiate operating phase			
Dialysis mode:	Pump M2 off		
Emergency mode RO I:	Not active		
Emergency mode RO II:	Not active		
Night-time mode:	Pump M2 off		
Disinfection:	Pump M2 off		
Hot RO:	Not active		

wd. dd.mm.yy hh:mm Error 30 Prim.pres M2 PSAL2 Menu Reset	Pressure switch PSAL2 > triggered 3x within 1 minute. New for EcoRO Dia II C	DI: with fault: Delay: Self-acknowledging: Reset key:	DI 12 = 0 No No Yes
Initiate operating phase			
Dialysis mode:	Pump M2 off		
Emergency mode RO I:	Not active		
Emergency mode RO II:	Not active		
Night-time mode:	Pump M2 off		
Disinfection:	Pump M2 off		
Hot RO:	Not active		

wd. dd.mm.yy hh:mm Alarm 31 TISAH2 temp too high Menu	Temperature RO II too high or cable break. Temperature > 90 ° C.	DI: with fault: Delay: Self-acknowledging: Reset key:	TISAH2 5 sec after undercutting 90°C alarm is self-acknowledging No
Initiate operating phase			
Dialysis mode:	Not active		
Emergency mode RO I:	Not active		
Emergency mode RO II:	Not active		
Night-time mode:	Not active		
Disinfection:	Not active		
Hot RO:	Hot RO cooling phase, alarm is self-acknowledging after undercutting 90°C, cooling phase is continued		

Alarm/Error	Cause / Condition	Characteristics	
wd. dd.mm.yy hh:mm Alarm 32 TISAH1 temp too high Menu	Temperature TISAH1 > 90° C	DI: with fault: Delay: Self-acknowledging: Reset key:	TISAH1 5 sec after undercutting 90°C alarm is self-acknowledging No
Initiate operating phase			
Dialysis mode:	Not active		
Emergency mode RO I:	Not active		
Emergency mode RO II:	Not active		
Night-time mode:	Not active		
Disinfection:	Not active		
Hot RO:	– With cable break always error 25		
	<ul> <li>– Temperature TISAH1 ≥90°C to Hot RO cooling phase, alarm is self-acknowledging after undercutting 90°C, cooling phase is continued</li> </ul>		

wd. dd.mm.yy hh:mm Alarm 33 TISAH4 temp too high Menu	Temperature RO I too high or cable break. Temperature TISAH4 > 90° C	DI: with fault: Delay: Self-acknowledging: Reset key:	TISAH4 5 sec after undercutting 90°C alarm is self-acknowledging No	
Initiate operating phase				
Dialysis mode:	Not active	Not active		
Emergency mode RO I:	Not active			
Emergency mode RO II:	Not active			
Night-time mode:	Not active			
Disinfection:	Not active			
Hot RO:	Hot RO cooling phase, alarm is self-acknowledging after undercutting 90°C, cooling phase is continued			

wd. dd.mm.yy hh:mm Alarm 34 Max heating time Menu	RO did not manage to reach the heating tempera- ture in the maximum heating time of 240 minutes	DI: with fault: Delay: Self-acknowledging: Reset key:	TISAH1 TISAH2 TISAH4 No No No
Initiate operating phase			
Dialysis mode:	Not active		
Emergency mode RO I:	Not active		
Emergency mode RO II:	Not active		
Night-time mode:	Not active		
Disinfection:	Not active		
Hot RO:	Hot RO cooling phase		

wd. dd.mm.yy hh:mm	Alarm from external water monitor	DI: with fault:	DI 21 = 0
Alarm 35		Delay:	10 sec.
Aqua Control		Self-acknowledging:	Yes
Menu		Reset key:	No
Initiate operating phase	System OFF		

# 17.2.2 Other possible faults

Fault	Cause	Effect / Correction
Recipient tank empty		<ul> <li>→ Check whether the system is in a flushing/rinsing, disinfection or discharging mode.</li> <li>→ If yes, have the operating mode ended by the program or end it by switching the system off and on again, and switch to dialysis mode.</li> </ul>
Pump is making noises	<ul> <li>Too little water in the supply tank.</li> <li>As soon as the pump runs at a filling level below LSAL1, air can be suctioned in. This air causes banging and vibration noises.</li> </ul>	<ul> <li>→ Switch off pump.</li> <li>→ Fill supply tank to level LSHL2.</li> <li>→ Switch pump on again</li> <li>→ Replace prefilter.</li> </ul>
Pump is not pumping	<ul> <li>Motor protection switch defective.</li> <li>Pump defective.</li> </ul>	<ul> <li>→ Check motor protection.</li> <li>→ Check pump.</li> <li>→ Inform Service if the fault cannot be found.</li> </ul>
Pressure too high in the ring piping	<ul> <li>Shut-off valves closed.</li> <li>Overflow valve defective or closed.</li> <li>Ring piping pressure higher than the pressure set at the overflow valve.</li> </ul>	<ul> <li>→ Open any closed shut-off valves.</li> <li>→ Check overflow valve.</li> <li>Check the ring piping pressure at manometers PI5 and PI6.</li> <li>As a rule, pressure PI5 (start of ring piping) is higher than PI6.</li> </ul>
Pressure too low in the ring piping	<ul><li>Volumes of discharged permeate too high.</li><li>Permeate production too low.</li></ul>	
battery empty		<ul> <li>No direct effect on dialysis mode.</li> <li>→ Ensure that the system is not disconnected from the permanent power supply.</li> <li>→ When the system is disconnected from the power supply it is reset to the standard parameters. Date/time are reset.</li> </ul>

• = Effect,  $\rightarrow$  = Correction

# 18. Emergency operating modes

In the event of system malfunctions, such as partial failures e.g. of a pump of the RO stages or control system, there are different emergency operation possibilities available. In replacement operation mode "Emergency mode I/II" water transport continues using one RO stage.

Heed the warning notes.

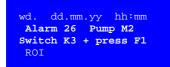
In case that a replacement operation mode has to be activated, the B. Braun service has to be contacted.

# 18.1 Production of permeate in emergency mode

In the event of failure of a pump or a complete RO stage a switchover to the respective next other stage of the RO is effected in order to permit continuous operation.

The "Alarm" lamp lights up; the display message informs about the respective work step.

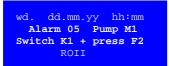
## 18.1.1 Emergency operation via RO I



During **emergency mode RO I**, permeate production takes place in the connected ring piping using the 1st RO stage.

- Open the valve flap K3 (K1 closed)
- Start using **F1** key ("ROI")

## 18.1.2 Emergency mode via RO II



During **emergency mode RO II**, water transport takes place in the connected ring piping using the 2nd RO stage.

- Open the valve flap **K1** (**K3** closed)
- Start using **F2** key ("ROII")
- Concentrate discharge at NV3 using the B. Braun service, increase to largest display value, however ensure that a sufficient quantity of permeate is produced.

Constant concentrate discharge takes place through NV3.

# 18.2 Emergency mode with soft water

Soft water can be fed into the ring piping if all the pumps and the control system fail.

NOTE:	B. Braun advises carrying out a comprehensive analysis of the soft water quality with regard to chemical and microbiological limit values if soft water is used for emergency operation.
	The emergency operation of a dialysis machine with soft water is only permitted in agree- ment with and written approval by the physician carrying out the treatment.
	Disinfection of the dialysis machine in soft water emergency operation is only permitted after complete separation (pipeline separation) between the dialysis machine and the soft water supply.

- 1. Switch the system off at the main switch
- 2. Place the sterile filter insert in the pre-filter (note intake water pressure).
- 3. Open valves **K1/K3 (K1** lever position: horizontal = closed, vertical = open) by pulling the flap lever outwards and rotating it 90° to the top.
- 4. Switch on the hard water monitor by hand (if available).

In the event of SW emergency mode, B. Braun recommends closing the flap at the ring piping return **K7** in order to avoid a premature depletion of the softener.

If the water intake pressure is greater than the ring piping pressure set at ÜV1, the water passes through to the supply tank through this overflow valve:
<ul> <li>Danger of supply tank overflowing, even without dialysis machines and consumers connected!</li> </ul>
<ul> <li>The softener will become depleted prematurely.</li> <li>In this case B. Braun recommends to install a stop valve at the end of the loop and to close it during soft water emergency operation. The consumption then corresponds to the water consumption for dialysis.</li> </ul>

# 18.3 Emergency operation when the control system fails

When the control system fails, the system can be operated manually. Open solenoids Y2, Y9, Y8, Y5 and Y10 manually.

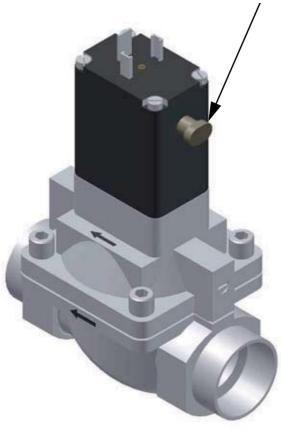
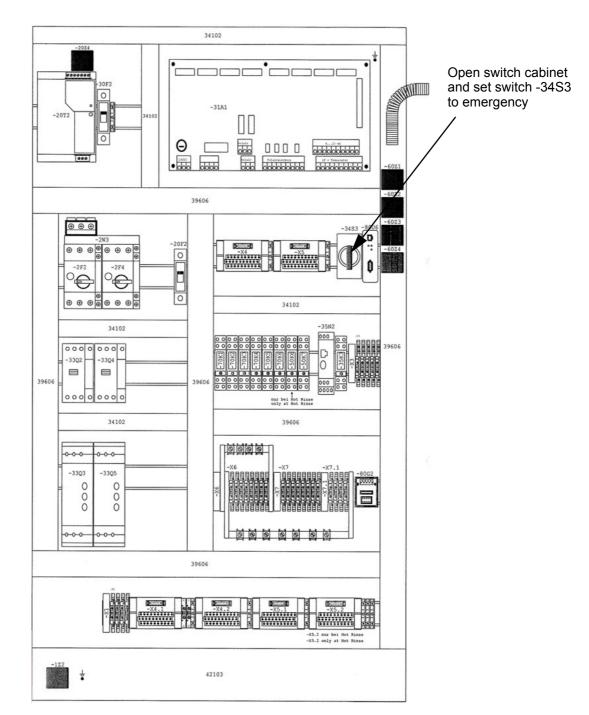


Figure 18-1: Solenoid valve



#### Figure 18-2: Switch cabinet

Open switch cabinet and set switch -34S3 to emergency. Pumps start.

NOTE: The conductivity is assessed only by means of an external conductivity measuring device and no longer via the control!

When the set limit value is exceeded (factory setting 180 mS/cm) the pumps are switched off. In case of manual operation of the system without conductivity monitoring by the control (CPU), the permeate quality has to be monitored with an external conductivity measuring device by the operator.

# 18.4 Detailed view of the emergency valves (using the example of a 2-step system)

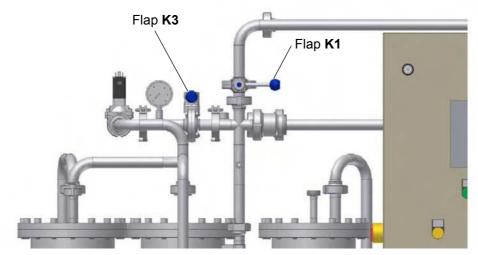


Figure 18-3: Emergency operation valve flaps K1/K3 (in this case in normal position: K1 and K3 closed)

If there is a Hot RO II function available, flap K3 is replaced by solenoid valve Y5.1. The valve is opened during:

- Emergency mode through RO I, according to regulation ( $\rightarrow$  Chapter 18.1.1)
- Manual soft water operation by turning the small grey lever on the valve directly (→ Fig. 18-1)

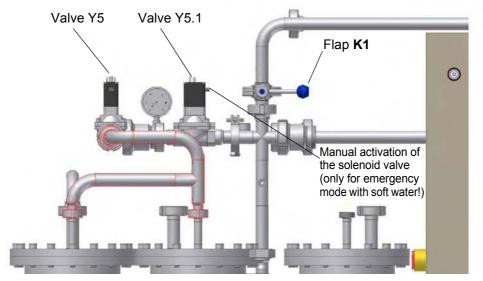


Figure 18-4: Emergency operation fittings K1/Y5.1

During emergency mode via RO 1, valve Y5.1 is opened via the control ( $\rightarrow$  Chapter 18.1).

During emergency operation with soft water, the fittings K3 and Y5.1 are opened manually (by manual turning) ( $\rightarrow$  Chapter 18.2).

During soft water operation, no active control of conductivity takes place through the RO. For this reason, water hardness must be checked regularly according to legal regulations.

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# 1. Handover declaration for the operating instructions

# 1.1 *Aquaboss*<sup>®</sup> reverse osmosis system

System (Eco)RO Dia
Serial number
Year of construction

## 1.2 Customer's address

Company	 	 	 

Postcode, city

Street .....

# 1.3 Confirmation of handover of operating instructions

We have purchased the system specified under section 1.1. Together with the system, we were also given the operating instructions for:

System number .......................Quantity ............Quantity ...........Quantity ...........Quantity ............Quantity ...........Quantity ...........Quantity ...........Quantity ...........Quantity .......Quantity .......Quantity .......Quantity ......Quantity ......Quantity ......Quantity ......Quantity ......Quantity ......Quantity ......Quantity ......Quantity .....Quantity ....Quantity ...

Customer's signature

Date

# 1.4 System handover date

## 1.5 Maintenance and servicing personnel

The following persons have been named by the customer and have been instructed and trained on the system by B. Braun and made aware of:

Protective equipment, hazardous areas, impermissible types of operation, set-up, operation, maintenance and servicing.

Name (customer staff)	Signature
Name (customer staff)	Signature
Name (customer staff)	Signature
<ul> <li>B. Braun commissioning log</li> <li>Customer-specific commissioning log</li> </ul>	g
Company stamp / Customer's signatu	ire



# The system was handed over to the customer by

#### Name, block letters

Date Signature

# Chapter 2

# 2. Transport and setup

# 2.1 Transportation



Only have transport carried out by experienced transport experts.

There are handling instructions printed on the packaging; these must be heeded.



Fragile goods – handle with care.



Transport and storage must be carried out in such a manner that the arrows on the packaging point upwards.

Rolling, swinging, severe tilting or tumbling and other such ways of handling must be avoided.



The goods must be protected from the wet and high humidity.



The product has been preserved accordingly for the temperature range prevalent during transport.

- If the system is to be kept in storage for more than 6 months, preservation must be repeated.
- The weight of the system including packaging can be up to 1000 kg. For this reason, lifting gear should be used which is dimensioned for this load and can bear it.

The system is delivered in a wooden crate.

- Check the shipment for transport damage and completeness.
- In case of any transport damage, keep the packaging and inform the shipping agent and manufacturer immediately!
- Remove the system carefully from the wooden crate.
- Place the device on solid, even ground.

# 2.2 Scope of Supply

The system is packed and delivered with the following components:

- Completely assembled system
- These operating instructions
- Circuit diagram
- QA acceptance log

# 3. Work prior to initial commissioning

Before commissioning, the following work must be carried out by the customer / a service technician:

- Setup and alignment of the system
- Connection to the pre-treatment stage
- Installation water connection
- Installation waste water connection
- Installation of the electrical connection
- Initial commissioning incl. language selection in the menu navigation
- Complete commissioning log

# 3.1 Requirements at the place of installation

- Horizontal industrial floor with a permissible load of at least 1000 kg/m<sup>2</sup>.
- Impact- and vibration-free.
- 0.5 m free space on all sides of the system for maintenance work (with opened switch cabinet doors).
- Acid-resistant floor covering.
- Protect the control cabinet from direct water jets and high levels of dust.
- The system is suitable for operation in roofed and weather-protected locations (e.g. closed rooms).

# 3.2 On-site connections to media supply

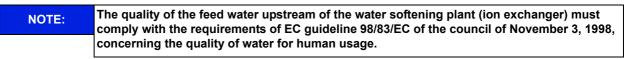
Connections to the media supply and pretreatment stage are not supplied with the reverse osmosis system.

# 3.2.1 Pretreatment stage, hydraulic connection

The system must be connected to an upstream pretreatment stage.

This is supplied either as an optional extra by B. Braun (see the separate operating instructions for installation instructions) or must be installed by the customer.

- Drinking water connection (feed reverse osmosis system) 1" with ball valve 1" (min. 3 – 6 bar flow pressure at full system performance).
- Pipe disconnector, connection 1", type EA1
- Before the softening plant is disinfected, it must be disconnected completely from the mains and the reverse osmosis system.
- Return flushing pre-filter with 130 µm filter unit with manometer, 1" connection.
- Water meter, 1"
- Leakage or system shutoff valve DN 20
- Activated charcoal if necessary
- Softening plant with sufficient capacity (note min. flow pressure 3 bar)
- Pre-filter 5µm
- The drinking water pressure must not exceed 6 bar. Note the connection values in the technical data and additional information about raw water requirements → Part 2, page 7-1.



#### The following water connections must also be made available for the reverse osmosis system:

- Loop feed (milk pipe thread NW 20)
- Loop return (threaded connection for milk pipe, NW 20)
- The connections are to be made by means of a 19 x 27 fabric hose or hot-water-resistant reinforced hose and a threaded hose connector for flexible connection.

The quality of the raw water upstream of the softening plant (ion exchanger) must comply with the requirements for the quality of drinking water ( $\rightarrow$  Part 1, chapter 2.4, ff.).

#### 3.2.2 Sewage connection

The following waste water connections must also be made available for the reverse osmosis system:

- Drain with siphon DN50.
- When installing the drain, take care that the waste water connection to the drain is implemented as a free intake in accordance with EN 1717.
- Floor drain DN70 (5000 I/h water throughput) at the lowest point in the room or in a closed floor trough in connection with Aqua Control.
- For additional information about setup layout see  $\rightarrow$  Chapter 8 "setup plan".
- The waste water connections for the softening plant and the osmosis system should be able to be routed through the floor drain (odour trap).
- When operating in combination with hot water disinfection, the drain pipes must be stable up to temperatures of 95°C.

#### 3.2.3 Electrical connections

\Lambda DANGER

- The (Eco)RO Dia I/II C requires a 16A-CEE socket (60Hz) and the EcoRO Dia II C HT 900 1600
  requires a 32A-CEE socket (60Hz), protected by a residual current-operated circuit breaker 30 mA.
- Observe backup fuse requirements on-site in accordance with national regulations.
- 4x shockproof socket (230 V) protected by residual current-operated circuit breaker (FI).
- Alarm cable 7 × 0.75 mm<sup>2</sup> (option).
- Remote control cable (option).
- RJ45 connection (LAN for operation with Aquaboss<sup>®</sup> vision) (option).

For specifications see  $\rightarrow$  Part 2, chapter 7.

#### Electric shock!

Danger of fatality due to dangerous voltage.

ightarrow Electrical work may only be carried out by authorized, trained and instructed electricians!

#### 3.2.4 For permanent system connection (see $\rightarrow$ Part 2, chapter 8.3)

NOTE: A permanent system connection must always be carried out in accordance with national requirements and regulations by authorized personnel.

The following safety equipment must be installed on-site for permanent connection to be possible:

- Excess current protection device max C 16A or C 32A
- Residual current-operated circuit breaker 30mA / 4-pole
- Device or power switch 16A or 32A
- Supply cable at least 5 x 2.5 mm<sup>2</sup> or 5 x 6,0 mm<sup>2</sup> (L1, L2, L3, N, PE)

The function of the device or power switch as a separator of the reverse osmosis from the mains must be marked by a label. The switch must be near the device and easily accessible for the operator. Over- and undervoltages in the power supply can damage the reverse osmosis system. B. Braun Avitum AG recommends always connecting the reverse osmosis system to emergency power supplies in accordance with DIN EN 6280-13.

Chapter 3

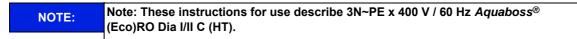
The separator must meet the requirements in accordance with IEC 60947-1 and IEC 60947-3. The switch must not interrupt the earthing conductor.

When a permanent mains cable is attached, it has to meet the requirements according to IEC 61010-1/6.10.2.

The device or power switch must meet the requirements of IEC 60947-1 and IEC 60947-3. The device or power switch must not interrupt the earthing conductor.

Permanent connecting cables must correspond with the requirements from IEC 61010-1/6 10.2.

Central *Aquaboss*<sup>®</sup> reverse osmosis systems are configured with a clockwise rotating field in the factory. Check the rotating field before commissioning the system.



## 3.3 Setup and alignment of the system

The system is set up on a flat surface near the power and water connections provided. Make sure that the connections and control elements are easily accessible.

#### 3.4 Connection to the pre-treatment stage, water connection

The water supply of the system is connected by a hose connection DN 20 to the pretreatment stage.

For additional information about setup layout see  $\rightarrow$  Part 2, chapter 8 "setup plan".

#### 3.5 Installation waste water connection

Connection of the system via rigid or flexible piping to the waste water DIN 50-note free draining.

The concentrate hose must be routed into the drain and secured over a free-drop path of at least twice its inner diameter.

# 3.6 Installation of the electrical connection

Electric shock!

#### DANGER

Danger of fatality due to dangerous voltage.

ightarrow Electrical work may only be carried out by authorized, trained and instructed electricians!

- Earth stainless steel loop (6 mm<sup>2</sup>).
- Equipotential bonding from osmosis switch cabinet to earthing bar of the house (6 mm<sup>2</sup>).
- Check whether the local operating voltage, frequency and fuse protection corresponds to the data on the type plate and the technical data see → Chapter 3.2.3. The system must not be connected if deviations are found.
- The command devices to control the system are mounted in a control box on the front of the system.
- The command devices and relays have already been wired to a terminal strip inside the control box in accordance with the circuit diagram.
- The (Eco)RO Dia I/II C (HT) is connected with a 16 A-CEE plug (60Hz), item no. 37700 incl. 5 m cable, with a 32 A CEE plug (60Hz) item no. 34181 incl. 5 m cable or permanent connection.

#### The following command/display elements are mounted in the building installation:

- Main switch / circuit interrupter
- Power protection switch
- Residual current-operated circuit breaker

Depending on the customer's equipment, B. Braun or authorized personnel can connect:

- a hard water monitor
- a remote control
- a concentrate mixing system and/or
- an alarm signal facility

to the system in accordance with the circuit diagram. It must be ensured that all signals which are connected to the system from external facilities are provided as potential-free contacts in the appropriate supplementary equipment.

# 4. Commissioning

Initial commissioning may only be performed by trained specialists or a trained representative authorized by B. Braun. Incorrect commissioning of the system can lead to damage to the system and personal injury. The customer/operating personnel are instructed fully on the use of the system when it is commissioned.

Documentation and monitoring of the water quality are carried out as per ISO 23500.

Before initial commissioning, care must be taken that the pretreatment system has been sufficiently flushed and all pre-filters are installed.

The water can be used in accordance with the designated purpose following successful validation.

## 4.1 Language selection

First of all, the display language set must be checked and changed if necessary. The menu navigation and display messages can be provided in English and other languages.

The system is switched on at the main switch. Via the main menu 0 the required language is selected using the -/+ keys. **Enter** takes you to the sub-menu where the required units can be selected. **Esc** confirms the selection and the main menu 0 appears on the display again.

# 4.2 Flushing out the preservative

As a rule, the system is supplied with preserved membranes. This is why the preservative must be flushed out before the system is connected to the ring piping. Care must be taken that the **open** permeate line is long enough to reach the waste water connection or an appropriate floor drain.

- The water supply is opened and the system switched on at the main switch. A self-testing sequence is performed (initial test). The device is now ready for operation. The device can be put in the desired operating mode by using the display and buttons.
- Select the dialysis operating mode to flush out the preservative. The supply tank starts to fill up. Once the level is above the lower level switch LSAL1 (or the lower switch point of pressure sensor PISAL1) the control unit switches the pump on and the system starts (temporary) permeate production (in this case to flush out the system and the permeate hose). On the display it can be checked if the set production pressure of approx. 15 bar is reached.

If too little pressure (< 5 bar) should build up over a longer period of time (30 seconds), the pump may not be rotating in the correct direction (right rotary field). In this case, the system must be switched off at the main switch, disconnected from the power supply before two phases of the power supply are exchanged.

Note the rotation arrows on the pump head ( $\rightarrow$  Fig. 4-1 to 4-3). Electrical work may only be carried out by authorized, trained and instructed electricians.

Irreversible pump damage, air in the pump body.
Bleed all the pumps and the modules in the pressure pipes.
$\rightarrow$ Open the bleeding screw carefully until a constant water flow occurs. Then close the bleeding screw (see $\rightarrow$ Fig. 4-1 to 4-3)



Figure 4-1: Open the bleeding screw



Figure 4-2: Constant flow of water occurs



Figure 4-3: Close the bleeding screw

After being switched on again, the pump will build up the required operating pressure.

If the system is running in dialysis mode, the conductivity indicator (on the display) indicates whether the permeate conductivity is decreasing. If the conductivity has reached a normal value (2–10  $\mu$ S/cm depending on raw water condition and set yield), the device can be switched off using the keyboard and the ring piping can be fully connected.

After the system has been flushed, the ring piping is also rinsed and aerated for some time. Then disinfection must be carried out  $\rightarrow$  Part 1 from page 12-5. After disinfection it must be ensured that there is no disinfectant left in the device and ring piping  $\rightarrow$  Part 1 from page 12-5.

# 5. Commissioning log

After the system has been commissioned, the following commissioning log is to be completed and signed by the persons involved.

At the time when the system is handed over, the pretreatment unit and the reverse osmosis system are to be connected to the municipal drinking water network in accordance with legislation and local regulations.

If the plant and equipment are moved to another location, the operator is obliged to install the entire system in compliance with the legal and local regulations applicable at the new site.

# 5.1 System parameters

Then the set system parameters must be adapted to local conditions.

→ Part 2 from page 7-4

Chapter 5

Со	mmissioning log	Order Number		
	Customer	Address		
	SYSTEM DESIGNATION	SERIAL NUMBER (S(/N)		
	Software	S/N Римр М1		
		S/N PUMP M2		
	S/N LT	S/N CPU		
S	/N MEMBRANE MM1.1	MM1.2		
	MM2.1	MM2.2		
Othe	er Applicable Documents			
Qua	lity acceptance log (date, no, tester)			
Ope	rating instructions rev./language			
Circ	uit diagram rev./no.			
List	of spare parts			
	dover declaration for the operating instructions Part 2 – Page 1-1)			
Testi	ing equipment/testing equipment number:			
Elec	trical safety (Secutest SIII):			
Con	ductivity/temp. measurement:			
Visu	al inspection:			
Surfa	ace/ ID/ Overall impression / Damage			
All a	ccessories present:			_
		LI-/ I//A)		
	ck for correct power supply (reference: type plate $\rightarrow$ V/	· · · · · · · · · · · · · · · · · · ·		
	nbination with other medical devices (hot cleaning system water cleaning system type / serial number		ension / length / material	
			0	
Fun	ctional inspection:		OK n.0	SК
1.	Connection of (Eco)RO Dia I/II C (HT) to ring p	iping (water supply, DN 20/ DN25)		
	Check for leaks (30 min at bar)			
	Water hardness in RO feed (setpoint: < 1°dH)		°dH □	
	Free chlorine in the RO feed (reference: <0.1 mg/		mg/l	
2.	Connection/installation of accessory parts (Aqua C	Jontrol, Tiasn lamps,)	0	
3.	Electrical connection of control cabinet			
υ.				

4.	Repeat test for medical electrical devices as per DIN EN 62353 (IEC 62353:2007)					
	ATTENTION: Implementation of the	ne test i	n compliance w	ith IEC 62353		
	Test before commissioning:					
	Protective class:		1			
	Mains connection:	PIE		= permanently conn		
				manently installed e	,	
		NPS		= non-detachable p	ower supply cable	e
4.1	Visual inspection Mains supply cable, overall system:				□ ок	□ n.OK
4.2	Protective conductor resistance		Measured valu	e Limit value	□ ОК	□ n.OK
	Measurement between mains supply cat and housing	le	R <sub>SL</sub>	<0.300Ω	□ ОК	□ n.OK
4.2.1	····· · · · · · · · · · · · · · · · ·	le	D	<0.3000		
4.2.2	and mounting plate Measurement between mains supply cat		R <sub>SL</sub>	<0.300Ω	□ OK	□ n.OK
4.2.2	and door/front plate	ne.	R <sub>SL</sub>	<0.300Ω		
4.3	Leakage resistance Touch all accessible conductive parts wit a test probe	h	R <sub>ISO</sub>	>2.0MΩ	□ ок	□ n.OK
4.4	Leakage current Mains connection PIE: With permanently of DEVICE LEAKAGE CURRENT is not Mains connection NPS: measurement of Device leakage current	necessa	ry.	RENT is required.		
	(substitute measurement):			<1.0mA		□ n.OK
4.5	Function test			⊂ □ n.OK		<u> </u>
4.6	Measurement log available			⊂ □ n.OK		
4.7	Safety or functional faults were not estab	lished.				
4.8	No direct risk, the faults discovered were to be eliminated quickly.	able				
4.9	Device must be taken out of circulation u the faults have been eliminated.	ntil				
4.10	Device does not comply with the requirer Modifications/replacement of component putting out of operation is recommended	s/				
4.11	The next repeat test is necessary in:		□ 12	2 months		

Test carried out by

.....

Date, signature

.....

					_				
Functional test (manual measurements with approved testing equipment only!) Motor protection switch							ок	n.OK	
Engine circuit-breaker	Rated currer	nt pu	mp	Type motor protection switch	n	Set swito Simple ra	hpoint ated current		
M1									
M1									
LSAL1 Dry run/pump pro	tection		•			•			
LSHL2 Tank full									
PISAL1 Dry run/pump pro	otection (for HT ver	sion)	)						
Fuses Fault messages									
Temperature shutdown									
Service program outputs	(manual setting o	f out	puts po	ssible)					
Potential-free outputs		OK	n.OK		OK	n.OK			
D	isinfection mode			Dialysis mode			Night-time mode		
	Collective alarm			Hard water monitor					
	Auto Off 30 min					□			
Testing mechanical con	nponents								
Check valves functional									
K1 replacement operation	n mode functional								
K3 replacement operation	n mode functional								
K4 tank drain functional									
K5 feed functional									
Flap setting for automatic	dialysis mode (n	ot er	nergeno	cy mode!) correct					

5.

Dialysis mode	Reference		Measured value	OK n.OK
Raw water conductivity (Message in display, CIS 1 Cell constants CC:	µS/cm	Deviation to man. reference measurement Reference < 10 μS/cm	µS/cm	
Concentrate water conductivity (Message in display, CISAH 2 Cell constants CC:	µS/cm	Deviation to man. reference measurement Reference < 10 μS/cm	µS/cm	
Conductivity of permeate (display, CISAHH 3 Cell constant ZK:1/cm)	µS/cm	Deviation to man. reference measurement Reference < 2 µS/cm	µS/cm	
Temperature raw water TISAH4 (if available)	°C	Deviation to man. reference measurement Target < 3°C	°C	
Temperature of concentrate TISAH2 (if available)	°C	Deviation to man. reference measurement Target < 3°C	°C	
Temperature permeate TISAH1	°C	Deviation to man. reference measurement Target < 3°C	°C	
Concentrate pressure PI2 $\pm$ 5% (see specifications $\rightarrow$ Part 2, chapter 7.1	) bar	Concentrate pressure PI4 $\pm$ 5% (if available) (see specifications $\rightarrow$ Part 2, chapter 7.1)	bar	
Permeate output $\pm 2\%$ ) (see specifications $\rightarrow$ Part 2, chapter 7.1	) l/h	Calculated salt retention LF <sub>Permeate</sub> / LF <sub>Raw water</sub> (setpoint: > 95%	%)	

	act.	n.act.			
LC operation			Reference		Measured value
Conductivity permeate (message in display, CISAHH 3)			µS/cm	Permeate output (setpoint: see enclosures chart "system output" ± 2%)	l/h
Permeate temperature (manual measurement)			°C	Concentrate flow volume (manual measurement)	l/h

Hard water operation (function test with softened water!)		Reference		Measured value
Conductivity permeate (message in display, CISAHH 3)		µS/cm	Permeate output (setpoint: see enclosures chart "system output" ± 2%)	l/h
Permeate temperature (manual measurement)		°C	Concentrate flow volume (manual measurement)	l/h

HotRO (hot rinsing RO 1 <sup>st</sup> and 2 <sup>nd</sup> stage) $\Box$	Reference	Measured value
Heat-up time (<2400 min)	min Heat-u	up temperature (>60°C) °C
meter heating cycle (setpoint +1)	Coolin	g temperature (<40°C) °C

- Introduction of concentrate discharge via menu 2.6

- Introduction of hard water operation via menu 2.7

#### Power failure test

- Switch the system on and operate in dialysis mode.

- Interruption of power supply (via the main switch).

- If power fails again, the previous operating state (dialysis mode) is re-established.

□ OK □ n.OK

#### Set switching points

Menu	Designation	Unit	Scope	Factory setting	Customer setting	
0	Language	Language I				
	Unit	EU: °C, bar US: °F, psi Permeate quality: μS/ cm or TDS (= ppm <sub>(NaCl)</sub> )	EU/ US – μS/cm/ TDS	EU / µS/cm		
1	Timer reset					
1.1	Change prefilter	DD.MM.YY		Current		
1.2	Hygiene check	DD.MM.YY		Current		
1.3	Maintenance	DD.MM.YY		Current		
2	Date/time	DD.MM.YY hh:mm		Current		
3	Automatic on/off		On/ off	Off		
3.1	Monday	On: ss:mm Off: ss:mm	00:00 = Off 00:01 – 23:59(h)			
3.2	Tuesday	On: ss:mm Off: ss:mm	00:00 = Off 00:01 – 23:59(h)			
3.3	Wednesday	On: ss:mm Off: ss:mm	00:00 = Off 00:01 – 23:59(h)			
3.4	Thursday	On: ss:mm Off: ss:mm	00:00 = Off 00:01 – 23:59(h)			
3.5	Friday	On: ss:mm Off: ss:mm	00:00 = Off 00:01 – 23:59(h)			
3.6	Saturdays	On: ss:mm Off: ss:mm	00:00 = Off 00:01 – 23:59(h)			
3.7	Sunday	On: ss:mm Off: ss:mm	00:00 = Off 00:01 – 23:59(h)			
3.8	Delete auto prog.					
4	Night-time rinsing data					
4.1	Night-time rinsing times	min	Rinsing interval: 1180 Rinsing duration: 110 0 = off			
4.2	Temperature flushing	°C/ °F	permitted/disabled 2038°C			
4.3	Rinsing with Hot Rinse		On/ off	Off		
5	Disinfection data					
	Recirculation time	min	560			
	Reaction time	min	2060			
	Flushing time	Н	0.524			

Menu	Designation	Unit	Scope	Factory setting	Customer setting
6	Equipment data				
6.9	Economy mode	sec sec	M2 off: 1300 M2 on: 130	300 5	
6.10	Start conc. discharge		1.06.0		
6.11	Stop conc. discharge		1.2Start value		
6.12	Conc. discharge interval	min	115		
6.13	Limit value 1 perm.	µS/cm	560		
6.14	Limit value 2 perm.	µS/cm	5200		
6.15	Change prefilter	Weeks	48		
6.16	Hygiene check	Months	012		
6.17	Maintenance intervals	Months	0, 3, 6, 9, 12		
6.18	CC/Cond. raw water	1/cm	0.100.20	Check	
6.19	CC/Cond. concentrate	1/cm	0.100.20	against testing	
6.20	CC/Cond. permeate	1/cm	0.100.20	equipment	
6.21	System type			as per order	
6.22	Y2/Y9 interval	sec sec	Y2: 520 Y9: 560		
6.23	ISS	sec sec	enabled/disabled On: 310 off: 330		
6.24	Eco IRS	min sec sec	Duration: 1590 Pressr: 310 Flush: 515		
6.25	Temperature discharge	°C	Start/Stop: 2037		
6.26	IRS operation		On/off		
6.27	Input disinfection		permitted/disabled		
6.28	M2 night operation		On/off		
6.29	M2 disinfection		On/off		
6.30	M2 hot rinsing		On/off		
6.31	Eco IRS II	min sec sec	Duration: 60180 Prss: 310 Flsh: 515		
6.32	Ext. CMS		Slope-triggered/ pulse-triggered		
7	Service program				
8	Hard water operation		On/off		
9	LC operation		On/off		

Menu	Designation	Unit	Scope	Factory setting	Customer setting
10	HotRO II				
10.1	Week days	Today Monday Sunday	0/1 0/1	0 0	
10.2	Heat up	°C	On/off 5085	Off 50	
10.3	Cooling	°C	Enabled/disabled 3540	Disabled 35	
	HotRO				
10.1	HotRO I/II	°C °C	Heat up: 5085 Cool down: 3540	50 40	
10.3	Manual mode	min	1=Yes/0=No 2090	0 20	
10.4	Automatic mode	min	MondaySunday:/ 2090	(Off)	
	ÜV1	bar	Setpoint: $3.5 \pm 0.5$ Setpoint with HotRinse: $2.0 \pm 0.5$		
	ÜV2 (option)	bar	Setpoint: 5.0 ± 0.5		
	PSAH 1	bar	Setpoint system off: 6 ± 0.5		
	PSAL 4	bar	Setpoint: 1 ± 0.5		
Switc	ching points programmed	l			
Carry	y out disinfection	□ or	Carry or	ut hot rinse	
Reco	ord disinfection using sep	. disinfection log	-		

and then take samples for chemical analysis as per ISO 13959 Sample number: ..... Training of responsible personnel/customer (see handover declaration) Programming phases Use of operating instructions Programming carried out according to customer's wishes: ..... Repairs carried out: ..... Remarks/faults established: ..... Date ..... Date ..... Signature B. Braun technician Signature customer

# 6. System key data

# Manufacturer's address

#### B. Braun Avitum AG

Schwarzenberger Weg 73-79 34212 Melsungen Germany Tel.: +49 (56 61) 71-5 Fax: +49 (56 61) 75-0

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# Type plate

The type plate is on the side of the switch cabinet.

Artikel-Nr. Article no.	REF	Herstellungsdatum Date of production	~
Serien Nr. Serial No.	SN	Erwartete Lebensdauer Expected life time	Jahre years
Aufnahmeleistung Power consumption	KVA	Umgebungstemp. Ambient temp.	Min-Ma:
Frequenz Frequency nominal	Hz	Betriebsdruck Operating pressure	Max bar
Nennspannung Voltage nominal	v	(li)	Made in Germany
BB	RAUN	B. Braun Avitum AG Schwarzenberger Weg 73-	79 📫

Figure 6-1: Example of a type plate

When ordering spare parts, please quote the following:

- Equipment type
- Serial number (SN)
- Description and article number
- Required quantity

NOTE:	Only original spare parts, accessories and consumables from B. Braun are to be used. $ ightarrow$ Part 2 from page 10-1 and $ ightarrow$ Part 1, page 3-1.
	B. Braun does not accept any liability for damage caused by the use of other spare parts, accessories and consumables.

#### **Technical data** 7.

# 7.1

Specifications (REFERENCE: DOCUMENT ID 087)

#### (Eco)RO Dia I C

Туре	l/h	500	700	900	1200	1600	2000	3000
Article number	EcoRO	1109053	1109073	1109093	1109123	1109163	1109203	1109303
	RO	1108053	1108073	1108093	1108123	1108163	1108203	1108303
Number of dialysis stations***		14/10	20/14	25/18	34/24	45/32	57/40	86/60
Membran configuration		1	1	1	1	2	2	3
Membran type	RO I	E2	E1	E2	E4	E1	E1	E1
	Art.no.	48752	48751	48752	52134	48751	48751	48751
Membran type	RO II	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	Art.no.							
Pressure PI2	bar	12.6	12.5	17	12.6	13	15.1	15
Pressure PI4	bar	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Permeat flow */**	l/h	500	700	900	1200	1600	2000	3000
Salt rejection rate			Single ch	arged ions >	95%, doubl	e charged ic	ons > 99%	
ÜV2		No	No	No	Option	Option	Yes	Yes
Electrical connection	V/Hz			31	~400V / 60	Hz		
	Plug	CEE16A	CEE16A	CEE16A	CEE16A	CEE16A	CEE16A	CEE16A
Pumps	M1	CRN3-17	CRN3-23	CRN5-22	CRN5-15	CRN5-15	CRN5-22	CRN5-15
	Art.no.	53192	52181	53190	53189	53189	53190	53189
	kW	2.2	3	5.5	4	4	5.5	4
	А	4.45	6.2	10.6	7.8	7.8	10.6	7.8
	M2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	CRN5-8
	Art.no.							53191
	kW							2.2
	A							4.45
	М3	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	Art.no.							
	kW							
	А							
Cabinet	kVA	0.377	0.377	0.377	0.377	0.377	0.377	0.377
	A	1.61	1.61	1.61	1.61	1.61	1.61	1.61
Max. power pumps	kW	2.2	3	5.5	4	4	5.5	6.2
Max. current pumps	А	4.45	6.2	10.6	7.8	7.8	10.6	12.25
Power full-load operation M1+M2	kVA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	8.85
Power part-load operation M1	kVA	3.46	4.67	7.71	5.77	5.77	7.71	5.77
Protection class	IP			4	4 (Pumps 5	5)		
Output alarm				Potential fr	ree changeo	ver contact		
External IN				Make co	ontact, poter	ntial free		
Drain	DN				25			
Width	mm	1000	1000	1000	1000	1295	1295	1310
Depth	mm	910	910	910	910	910	910	906
Height	mm	1745	1745	1745	1745	1745	1745	1745
Weight	kg	330	345	370	370	430	430	575

#### (Eco)RO Dia II C

Туре	l/h	500	700	900	1200	1600
Article number	EcoRO	1120053	1120073	1120093	1120123	1120163
	RO	1110053	1110073	1110093	1110123	1110163
Number of dialysis stations***		14/10	20/14	25/18	34/24	45/32
Membran configuration	1/11	1/1	1/1	1/1	2/2	2/2
Membran type	RO I	E2	E1	E1	E1	E1
	Art.no.	48752	48751	48751	48751	48751
Membran type	RO II	E2	E2	E1	E2	E1
	Art.no.	48752	48752	48751	48752	48751
Pressure PI2	bar	13.6	13.5	14	10.5	13.6
Pressure PI4	bar	12.6	14.3	13	12.1	12.5
Permeat flow */**	l/h	500	700	900	1200	1600
Salt rejection rate		Single cl	harged ions >	95%, double	e charged ior	ıs > 99%
ÜV2		No	No	No	Option	Option
Electrical connection	V/Hz		31	N~400V / 60ŀ	Ηz	
	Plug	CEE16A	CEE16A	CEE16A	CEE16A	CEE16A
Pumps	M1	CRN3-17	CRN5-15	CRN5-15	CRN5-15	CRN5-15
	Art.no.	53192	53189	53189	53189	53189
	kW	2.2	4	4	4	4
	А	4.45	7.8	7.8	7.8	7.8
	M2	CRN3-17	CRN3-17	CRN3-17	CRN3-17	CRN3-17
	Art.no.	53192	53192	53192	53192	53192
	kW	2.2	2.2	2.2	2.2	2.2
	А	4.45	4.45	4.45	4.45	4.45
	М3	n.a.	n.a.	n.a.	n.a.	n.a.
	Art.no.					
	kW					
	А					
Cabinet	kVA	0.377	0.377	0.377	0.377	0.377
	А	1.61	1.61	1.61	1.61	1.61
Max. power pumps	kW	4.4	6.2	6.2	6.2	6.2
Max. current pumps	A	8.9	12.25	12.25	12.25	12.25
Power full-load operation M1+M2	kVA	6.54	8.85	8.85	8.85	8.85
Power part-load operation M1	kVA	3.46	5.77	5.77	5.77	5.77
Protection class	IP		4	4 (Pumps 55	j)	
Output alarm			Potential f	ree changeov	ver contact	
External IN		Make contact, potential free				
Drain	DN			25		
Width	mm	1580	1580	1580	1900	1900
Depth	mm	930	930	930	930	930
Height	mm	1805	1805	1805	1805	1805
Weight	kg	450	490	515	635	650

#### EcoRO Dia II C HT

Туре	l/h	500	700	900	1200	1600
Article number	EcoRO	1130053	1130073	1130093	1130123	1130163
	RO	n.a.	n.a.	n.a.	n.a.	n.a.
Number of dialysis stations***		14/10	20/14	25/18	34/24	45/32
Membran configuration	1/11	1/1	1/1	1/1	2/2	2/2
Membran type	RO I	G20TS	G20FTS	G20FTS	G20TS	G20FTS
	Art.no.	49772	49773	49773	49772	49773
Membran type	RO II	G20TS	G20TS	G20FTS	G20TS	G20FTS
	Art.no.	49772	49772	49773	49772	49773
Pressure PI2	bar	12.4	16.6	17	12.7	18.5
Pressure PI4	bar	12.3	14.6	16.4	12.5	13.7
Permeat flow */**	l/h	500	700	900	1200	1600
Salt rejection rate		Single cl	harged ions >	• 95%, double	e charged ior	ns > 99%
ÜV2		HRS	HRS	HRS	HRS	HRS
Electrical connection	V/Hz		31	N~400V / 60ŀ	Ηz	
	Plug	CEE16A	CEE16A	CEE32A	CEE16A	CEE32A
Pumps	M1	CRN3-23	CRN3-23	CRN5-22	CRN3-23	CRN5-22
	Art.no.	52181	52181	53190	52181	53190
	kW	2.2	2.2	5.5	2.2	5.5
	А	6.2	6.2	10.6	6.2	10.6
	M2	CRN3-17	CRN3-17	CRN3-23	CRN3-17	CRN3-17
	Art.no.	53192	53192	52181	53192	53192
	kW	2.2	2.2	2.2	2.2	2.2
	А	4.45	4.45	6.2	4.45	4.45
	M3	n.a.	n.a.	n.a.	n.a.	n.a.
	Art.no.					
	kW					
	А					
Cabinet	kVA	0.377	0.377	0.377	0.377	0.377
	А	1.61	1.61	1.61	1.61	1.61
Max. power pumps	kW	4.4	4.4	7.7	4.4	7.7
Max. current pumps	А	10.65	10.65	16.8	10.65	15.05
Power full-load operation M1+M2	kVA	7.75	7.75	12.00	7.75	10.79
Power part-load operation M1	kVA	4.67	4.67	7.71	4.67	7.71
Protection class	IP		4	4 (Pumps 55	5)	<u> </u>
Output alarm			Potential f	ree changeov	ver contact	
External IN				ontact, poten		
Drain	DN			25		
Width	mm	1580	1580	1580	1900	1900
Depth	mm	955	955	955	955	955
Height	mm	1805	1805	1805	1805	1805
Weight	kg	450	490	515	635	650

#### NOTE

\* Feed water temperature 6°C; Tolerance of membrane +/- 15%

\*\* Feed water: 6°C, 500ppm NaCl; backpressure 3.5bar; age of membrane: 3 years, flux decline at 3 years: 10%

\*\*\* At a continuous HD flow of 500/800 ml/min. Some dialysis machine might require a higher flux during flushing or rinsing

#### Subject to alterations

# 7.2 Design data

Design data	
Permeate output	see $\rightarrow$ Chapter 7.1 "Specifications"
Electrical connections	400 V / 60 Hz / CEE 32 30 mA triggering current via GFCI $\rightarrow$ Nameplate $\rightarrow$ Part 2, page 6-1, clockwise rotation field
	(Eco)RO Dia I C: 16 A CEE (Eco)RO Dia II C: 16 A CEE EcoRO Dia II C HT 500;700;1200: 16 A CEE EcoRO Dia II C HT 900;1600: 32 A CEE or permanent connection
Permeate concentrate ratio	25 % for hard water operation
	50 % for soft water operation
Increase ambient temperature	5 – 40 °C
Internal temperature of housing (control)	5 – 70 °C
Internal temperature of housing (hydraulics)	5 – 90 °C
Relative air humidity (control)	max 75 % rel. hum., non-condensing
Materials in contact with the product	Stainless steel 1.4404; 1.4408; 1.4571; 1.4581; 1.4435; Ethylene- propylene-dien-monomer (EPDM); Polypropylene; Polysulphone; Polyvinylidene fluoride (PVDF); Polyamide

# 7.3 Feed water / raw water requirements

**Aquaboss**<sup>®</sup> reverse osmosis system have been designed in such a way that they can usually be operated with feed water quality of "drinking water" quality (according to98/83/EC) (see  $\rightarrow$  Part 1, chapter 2). For individual water contents B. Braun prescribes values which deviate from 98/83/EC (see table  $\rightarrow$  Part 1 from page 2-3).

The service lifetime of the reverse osmosis membranes used and the permeate quality of the product flow of the reverse osmosis system depend directly on the concentration of the individual water contents and can be optimised through suitable pretreatment methods.

Raw water requirements	
Water intake (raw water)	At least four times the pure water capacity (when using a pretreatment system, the minimum water consumption for this system must be added)
Static pressure, minimum (removal only)	3 bar
Static pressure, maximum	6.0 bar
pH range	$9.5 \ge pH \ge 5.00$
Free chlorine (permanent load)	max. 0.0 ppm
Fine filter 5 μm Silt Density Index (SDI)	$\leq$ 5 (for EcoRO versions), $\leq$ 3 (for RO versions)
Raw water setting value TDS (as NaCl)	500 ppm
Temperature range	6 – 30 °C

# 7.4 Ring piping requirements

Ring piping requirements	
Flow speed (min.)	0.5 m/s (at maximum consumption)
Pressure at the ring piping end (min.)	2.5 bar (at maximum consumption) Pressure loss Dp < 3.6 bar
Werkstoff	PVDF, PEX, PVC recommended: stainless steel 316 L electro-polished with $R_a < 0.8 \mu m$
Pressure resistance (min.)	10 bar
Construction of tapping points	Minimum dead space acc. to 6-d rule (GMP)

Danger of poisoning due to detached construction materials and destruction of components!

 $\rightarrow$  In combination with a hot cleaning system only temperature-resistant original materials up to a minimum of 90°C must be used.

# 7.5 RO modules

RO modules	
Spiral wound membrane module	D= 8"; H= 40"
Material	PA Composite
Max. chlorine concentration in the feed	<1ppm
SDI15	<5
pH range during dialysis/night mode	3–9
pH range for chemical cleaning	2–11

# 7.6 Pumps

Pumps		
Werkstoff	Pump housing: stainless steel 1.4408 impeller: stainless steel AISI 316	
Mechanical seal	EPDM	
IE class	IE3	
Type of protection:	IP55	
Insulation class	F	
Ambient temperature max.	60 °C	
Net weight	40–90 kg	

# 7.7 Membrane pressure pipe

Membrane pressure pipe MM 4040 / 8040		
Pressure	max. 25 bar	
Material	1.4571	
Ports		
Intake pump	R 1/2" (after treatment milk pipe thread NW20)	
Permeate drain	R 1/2" (after treatment milk pipe thread NW20)	
Concentrate drain	R 1/2" (after treatment milk pipe thread NW20)	

# 7.8 Wiring diagram

Wiring diagram	
Electrical circuit diagram no.	
– (Eco)RO Dia I/II C	87 252 XX

# 7.9 Command equipment

The control system consists of an operating unit (with CPU) and a power pack. The power pack can be supplemented by an external data and address bus. The operating unit and the power pack are connected by means of a flat ribbon cable. With the exception of RS232, external connections are made with plug block terminals via the power pack.

#### 7.9.1 LC display

LC display	
Character height	4.75 mm
Number of characters per line	20
Number of lines	4
Background illumination:	blau

#### 7.9.2 LED display

LED display	
System under voltage	LED "operation" lights up (green)
Alert	LED "operation" alarm (red)

#### 7.9.3 Operation

Operation is by means of 4 short-stroke keys (display-guided).

#### 7.9.4 Data retention

Data retention	
Setting and program data	Stored by EEPROM
Guaranteed data retention	10 years
Min. guaranteed storage cycles	100'000
Real time clock	buffered by lithium battery

#### 7.9.5 Watchdog

#### Watchdog CPU:

The correct program sequence is monitored by an integrated watchdog (micro-controller). When the CPU watchdog is triggered, the system is reset and an internal system test is carried out. (Max. reset time = 2 sec.)

#### Watchdog power pack:

Data transfer is monitored by a watchdog in the power pack. If the power pack watchdog is not addressed in good time, operation is interrupted immediately and a system fault is signaled (max. reset time = 1 sec.)

# 7.10 Input and output signals

# 7.10.1 Digital inputs

Digital inputs	
Quantity	max. 32
Excitement	24 V DC, low safety voltage
Line current	1.0 to 2.0 mA DC

#### 7.10.1.1 Assignement of digital inputs

	Assignment	Key functions. In order to		Assignment	Key functions. In order to
1	PKZ Pump M1	Function OK = 1	17	HWD1	Hot water system in operation
2	PKZ Pump M2	Function OK = 1	18	HWD2	Functioning hot water system monitored for leakages
3	Switch emer- gency mode	Switching on pumps when the control system fails	19	Pressure PSAH3	System pressure
4			20	Ext. CMS	Connection CMS
			21	Aqua Control alarm	
6			22		
7	Activation Hot RO I/II		23		
8			24		
9	Level switch Tank LSAL1	Lower level switch Level exceeded = 0 Level undercut = 1	25		
10	Level switches Tank LSHL2	Upper level switches Level exceeded = 1 Level undercut = 0	26		
11	Delay Night-time mode		27		
12	Min. pre-pressure PSAL2	Pre-pressure via set minimum value = 1; If 0, pump M2 off	28		
13	Max. RL pressure PSAH1	Ring piping pressure below set max. value = 1 if 0 = system off	29		
14	Min. RL pressure PSAL4	Ring piping pressure via set min. value = 0; if 1 = switch off shearing force valve	30		
15	Remote control	Pulse-triggered Switch night-time to dialysis and dialysis to night-time mode	31		
16	Hard water alarm	Hardness measurement OK = 0, if 1 = collective fault signal	32		

# 7.10.2 Analogue inputs conductivity recording

Analogue inputs conductivity recording	
Quantity	4, with additional board extendable to 6
Activation	9V AC, 5kHz rectangle
Current potential	Low safety voltage
Resolution	8bit
Internal fuse	Short-circuit and limited external voltage protection
Cell constant	0.15
Adjustment	0.10 … 0.20 can be adjusted individually
Comment	Temperature compensation as function of analog temperature input as per EN27888 (NF) Temp. range 0 – 40 °C

#### 7.10.2.1 Raw water CIS 1

Raw water	
Measuring range	50 … 2000 μS/cm
Accuracy	Range 50 μS/cm, ± 5 μS/cm … 500 μS/cm range 500 … 2000 μS/cm, ± 25 μS/cm
Load impedance	3000 150 Ohm (cell constant 0.15 taken into account)
ext. wiring	Parallel resistance of 30 kOhm (wire break monitor)

#### 7.10.2.2 Concentrate CISAH2

Concentrate	
Measuring range	50 7700 μS/cm
Accuracy	Range 50 μS/cm, ± 5 μS/cm … 1000 μS/cm range 1000 … 7700 μS/cm, ± 25 μS/cm
Load impedance	3000 50 Ohm (cell constant 0.15 taken into account)
ext. wiring	Parallel resistance of 30 kOhm (wire break monitor)

#### 7.10.2.3 Permeate 1 (feed) CISAHH3

Permeate	
Measuring range	1 200 μS/cm
Accuracy	Range 1 30 μS/cm, ± 1 μS/cm range 30 200 μS/cm, ± 3 μS/cm
Load impedance	150,000 750 Ohm (cell constant 0.15 taken into account)
ext. wiring	Parallel resistance of 30 kOhm (wire break monitor)

## 7.10.3 Analogue inputs 4...20mA

Analogue inputs 420mA	
Quantity 5	
Current potential	Low safety voltage
Resolution	8bit
Тур	420 mA interface

#### 7.10.3.1 Analog input 1 TISAH2

Analogue input 1 TISAH2		
Port Temperature sensor, temperature concentrate RO II		
Тур	PT 100 class B	
Measuring range	-20 +120 °C	
Material	Stainless steel 1.4571	
Type of protection:	IP65	

#### 7.10.3.2 Analog input 2 TISAH4

Analogue input 2 TISAH4		
Port Temperature sensor, temperature concentrate RO I		
Тур	PT 100	
Measuring range	-20 +120 °C	
Material	Stainless steel 1.4571	
Type of protection: IP65		

# 7.10.4 CSAH4 (external conductivity measurement; Jumo)

Permeate 2		
Measuring range	1 1000 μS/cm	
Accuracy	≤ 2 %	
Switch point	180 μS/cm (except in "disinfection mode")	
Hysteresis	5 μS/cm	
Temperature compensation	25 °C	
Type of protection:	IP20	

## 7.10.5 Temperature measurement / Permeate TISAH1

Analog input for temperature measurement of permeate	
Sensor	NTC
Activation	0.5 mA

Analog input for temperature measurement of permeate	
Current potential Low safety voltage	
Measuring range	0 100 degrees Celsius
Accuracy	Class B
Type of protection:	IP20

#### 7.10.6 Digital outputs, control valves

Digital outputs, control valves	
Quantity	32
Excitement	24 V DC, low safety voltage
Load	390mA at 24 V DC, 150 mA at 9 V DC (economy mode) or 4A activation current (max. 1 sec.1 valve simultaneously) max. 3A/output port (8 outputs)
Internal fuse	Short-circuit-proof, temperature protection
Simultaneity	max. 4 solenoid valves

# 7.10.7 Assignment of digital outputs

	Assignment		Assignment
1	Signal lamp dialysis mode	17	
2	Signal lamp night-time mode	18	MV Y5.1.1
3	Signal lamp flushing	19	LED MV Y5.1.1
4	Signal lamp disinfection	20	
5	Signal lamp alarm	21	
6		22	
7	Signal output 30 min before night-time mode	23	
8		24	
9	MV Y2	25	
10	MV Y5	26	
11	MV Y6	27	
12	MV Y7	28	
13	MV Y8	29	
14	MV Y9	30	
15	MV Y10	31	
16	MV Y30	32	

## 7.10.8 Relay output pump M1 / (M2)

Relay output pump M1 / contactor		
Number of relays	2	
Relay coil	24 V DC / 15 mA	
Contacts	Change-over contact	
Load	40 V / 8A	
Internal fuse	None	

Relay	Name	Contacts	Key functions. In order to
C1101	Pump M1	Change-over contact	Switching on and off of pump M1
C1102	Pump M2	Change-over contact	Switching on and off of pump M2

## 7.10.9 General relay output

Relay output pump M1 / contactor	
Number of relays	4
Relay coil	24 V DC / 15 mA
Contacts	floating
Load	24 V DC / 2 A
Internal fuse	None
Relay K1106	Disinfection On = make contact closed, active in dialysis mode and during hot cleaning
Relay K1103	Dialysis mode On = make contact closed HWD1/HWD2 On = Off open while hot disinfection active
Relay K1104	Release = make contact closed in night-time mode, active after shutdown flushing and during hot cleaning
Relay K1105	Collective alarm = changeover contact

#### 7.10.10 Interface RS232

Serial interface for data traffic with host computer (PC, mainframe etc.). Connection via standard interface 5V-V24 or 5V current ring piping.

## 7.11 EMC guidelines

The devices of series (Eco)RO Dia I/II C (HT) listed in the EMC table comprises all variants of the series

- RO Dia I C
- EcoRO Dia I C
- RO Dia II C
- EcoRO Dia II C
- EcoRO Dia II C HT

Guidelines and manufacturer's declaration - electromagnetic transmission

The devices of the (Eco)RO Dia I/II C (HT) series are designed for operation in an environment as described below. The customer or user of an (Eco)RO Dia I/II C (HT) should ensure that it is operated in such an environment.

Transmission measurements	Conformity	Electromagnetic environment – guidelines
HF transmission according to CISPR 11	Group 1	The (Eco)RO Dia I/II C (HT) 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 neigh- bouring devices.
HF transmission according to CISPR 11	Class B	The (Eco)RO Dia I/II C (HT) is suitable for use in facilities other than those in the home, as well as
Transmission of harmonics according to	Conforms, but the start-up current level of the pumps	in facilities that are directly connected to a public power supply network that also supplies buildings that are used for residential occupancy.
I<16 A EN 61000-3-2	must be observed.	
I>16 A EN 61000-3-12		
Transmission of voltage fluctua- tions/flickering according to	Conforms, but the start-up current level of the pumps	
I<16 A EN 61000-3-3	must be observed.	
I>16 A EN 61000-3-11		

## Guidelines and manufacturer's declaration - electromagnetic interference

The devices of the (Eco)RO Dia I/II C (HT) series are designed for operation in the electromagnetic environment described below. The customer or user of an (Eco)RO Dia I/II C (HT) should ensure that it is operated in such an environment.

Test of interference immunity	IEC 60601 test level	Conformity level	Electromagnetic environment – guidelines	
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 con- crete 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 610004-4	± 2 kV for mains cables ± 1 kV for input and output cables Burst 100 kHz	± 2 kV for mains cables ± 1 kV for input and output cables Burst 100 kHz	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 differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.	
Voltage dips, short-term interruptions and fluc- tuations in the voltage supply according to IEC 61000-4-11	0 % U <sub>T</sub> (for ½ periods and 1 periods (at 0, 45, 90, 135, 180, 225, 270, 315 degrees)	0 % U <sub>T</sub> (for ½ periods and 1 periods (at 0, 45, 90, 135, 180, 225, 270, 315 degrees)	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 (Eco)RO Dia I/II C (HT) even if interruptions in the power supply	
	70 % U <sub>T</sub> (for 25/30 periods (50/60 Hz) 0 % U <sub>T</sub> (for 250/300 periods	70 % U <sub>T</sub> (for 25/30 periods (50/60 Hz) 0 % U <sub>T</sub> (for 250/300 periods	occur, it is recommended that the (Eco)RO Dia I/II C (HT) be fed from an uninterruptible power supply or a battery.	
Magnetic field for the power supply frequency (50 Hz and 60 Hz) according to IEC 61000-4-8	(50/60 Hz) 30 A/m	(50/60 Hz) 30 A/m	Magnetic fields for the mains frequency should have values typical of an indus-trial environment.	

NOTE:  $U_T$  is the AC supply voltage before applying the test level

### Guidelines and manufacturer's declaration - electromagnetic interference

The devices of the (Eco)RO Dia I/II C (HT) series are designed for operation in the electromagnetic environment described below. The customer or user of an (Eco)RO Dia I/II C (HT) should ensure that it is operated in such an environment.

Test of interference immunity	IEC 60601 test level	Conformity level	Electromagnetic environment – guidelines
			Portable and mobile radio devices should not be used more closely to the (Eco)RO Dia I/II C (HT), including the cables, than the recommended electrical clearance that is calculated for the appropriate equation for the transmitting frequency.
			Recommended electrical clearance:
Guided HF emission according to IEC 61000-4-6	3 V <sub>eff</sub> 150 kHz to 80 MHz 6 V <sub>eff</sub> in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	3 V <sub>eff</sub> 150 kHz to 80 MHz 6 V <sub>eff</sub> in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	The minimum distance should be calculated by using the following equation: $E = \frac{6}{d}\sqrt{P}$
Radiated HF emis- sion according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	E is the interference immunity test level in [V/m] d is the minimum distance in [m] P is the maximum power in Watt [W]
			Wireless HF communication devices maximum power and distance (of 30 cm):

#### Guidelines and manufacturer's declaration - electromagnetic interference

The devices of the (Eco)RO Dia I/II C (HT) series are designed for operation in the electromagnetic environment described below. The customer or user of an (Eco)RO Dia I/II C (HT) should ensure that it is operated in such an environment.

Test of interference immunity	IEC 60601 test level	Conformity level	Electromagnetic environment – guidelines
Close range of wire- less HF communi- cation devices	27 V/m 380–390 MHz 50 % PM 18 Hz	27 V/m 380–390 MHz 50 % PM 18 Hz	TETRA 400: max 1.8 W
IEC 61000-4-3	28 V/m 430–470 MHz FM ±5 kHz Hub, 1kHz Sinus	28 V/m 430–470 MHz FM ±5 kHz Hub, 1kHz Sinus	GMRS 460, FRS 460: max 2 W
	9 V/m 704–787 MHz 50 % PM 217 Hz	9 V/m 704–787 MHz 50 % PM 217 Hz	LTE Band 13 and 17; max 0.2 W
	28 V/m 800–960 MHz 50 % PM 18 Hz	28 V/m 800–960 MHz 50 % PM 18 Hz	GSM 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 W
	28 V/m 1700–1990 MHz 50% PM 217 Hz	28 V/m 1700–1990 MHz 50% PM 217 Hz	GSM 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 W
	28 V/m 2400–2570 MHz 50% PM 217 Hz	28 V/m 2400–2570 MHz 50% PM 217 Hz	Bluethooth: max 2 W WLAN 802.11b/g/n: max 2 W RFID 2450: max 2 W LTE Band 7: max 2 W
	9 V/m 5100–5800 MHz 50% PM 217 Hz	9 V/m 5100–5800 MHz 50% PM 217 Hz	WLAN 802.11 a/n: max 0.2 W
			For all frequencies, the field strength of stationary radio transmitters according to local inspection <sup>1)</sup> should be less than the conformity level.
			Interference is possible in the neighbourhood of all devices that are marked with the following symbol.

NOTE 1: The higher frequency range applies for 80 MHz and 800 MHz.

NOTE 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

COMMENT 3: 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.

<sup>1)</sup> The field strength of stationary transmitters such as base stations of mobile phones and mobile land radio communications service devices, amateur radio stations and AM and FM radio and television transmitters can theoretically not be predetermined precisely; to determine the electromagnetic environment in terms of stationary transmitters, the location should be studied in detail. If the measured field strength at the spot where an (Eco)RO Dia I/II C is used exceeds the above conformity level, the (Eco)RO Dia I/II C should be observed to ensure that it functions properly. If unusual performance characteristics are observed, additional measures may be necessary, such as changing the orientation or moving the (Eco)RO Dia I/II C to another location.

Recommended electrical clearances between portable and mobile HF telecommunication devices and an (Eco)RO Dia I/II C (HT)

The devices of the (Eco)RO Dia I/II C (HT) series are designed for operation in an electromagnetic environment in which HF emissions are monitored. The customer or user of an (Eco)RO Dia I/II C (HT) can help avoid electromagnetic interference by maintaining the minimum clearance between portable and mobile HF telecommunication devices (transmitters) and an (Eco)RO Dia I/II C (HT) – depending on the output and on the communication device, as described below.

Nominal power of the transmitter	Electrical clearance depending on the transmitting frequency			
	150 kHz to 80 MHz outside of ISM and amateur radio frequency bands	150 MHz to 80 MHz outside of ISM and amateur radio frequency bands	80 MHz to 2.7 GHz (for defined wireless communication devices, see previous table)	
	d = 2 √ P	d = 1.0 √ P	d = 2.0 √ P	
0.01 W	0.20	0.10	0.20	
0.1 W	0.63	0.32	0.63	
1 W	2.0	1.0	2.0	
10 W	6.3	3.2	6.3	
100 W	20	10	20	

In the case of transmitters whose maximum nominal power is not listed in the table above, the recommended electrical clearance of d in metres (m) can be determined using the equation that belongs in the respective column, whereby P is the maximum electrical clearance in Watts (W) according to the information provided by the transmitter manufacturer.

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

NOTE 1: The higher frequency range applies for 80 MHz and 800 MHz.

NOTE 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

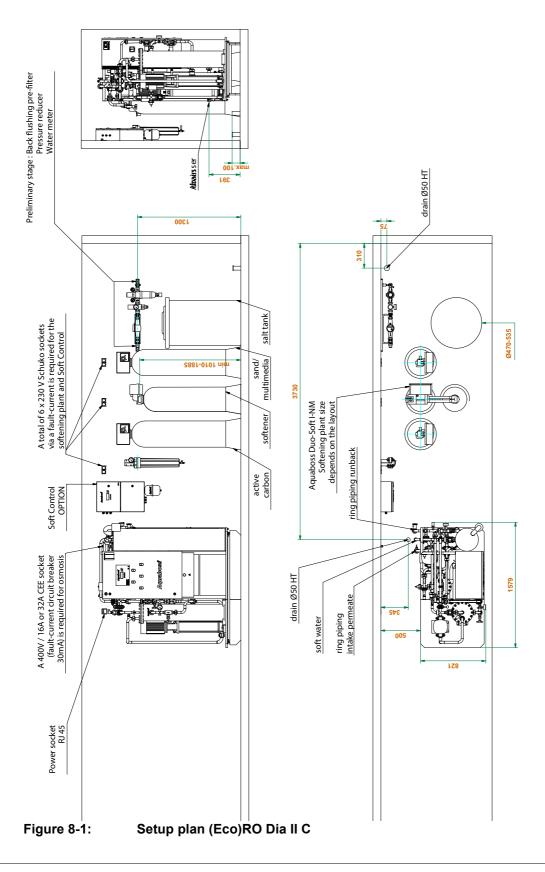
COMMENT 3: The ISM bands (stands for industrial, scientific and medical, i.e. the frequency bands used for industrial, scientific and medical purposes) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 to 40.7 MHz. The amateur frequency 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.

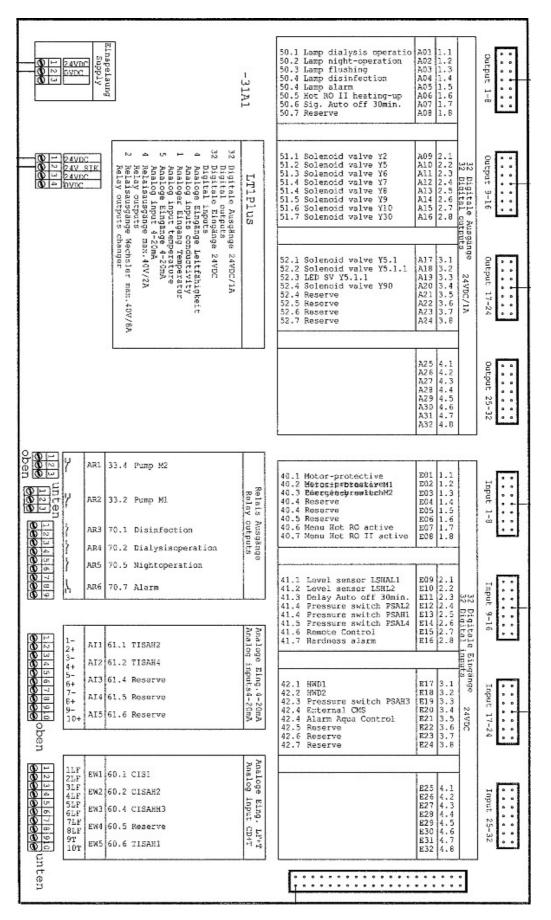
NOTE:

The devices of the (Eco)RO Dia I/II series may not be used if they are located immediately next to or stacked on top of other devices.

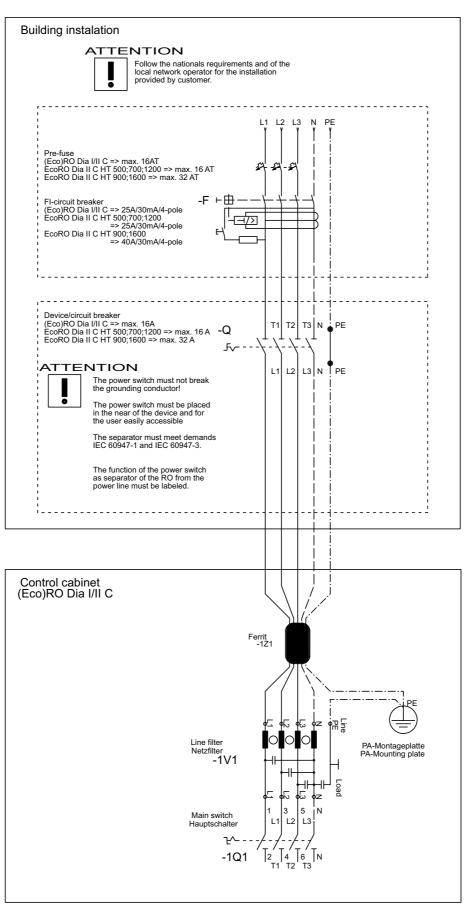
# 8. Setup plan and terminal diagram

# 8.1 Setup plan (Eco)RO Dia II C





## 8.3 Installation summary – building installation / permanent connection



#### 9. Maintenance and technical safety checks (TSC)

The functional safety of the reverse osmosis system can only be maintained if the medical product log is maintained properly and made accessible to technicians during the TSC / routine check work.

The (Eco)RO Dia I/II C (HT) is a low-maintenance system:

- If the system is operated with an upstream softening plant, care must be taken that soft water is always available. Check the soft water regularly.
- Comparison / adjustment of the conductivity values must be carried out once a month by means of a hand-held measuring instrument.
- The prefilter has to be replaced every 4-8 weeks. A reminder message can be programmed under menu item 6.10.
- The ventilation and venting filter for tank respiration has to be replaced once yearly.
- B. Braun recommends a weekly check of the Hydrowatch on the installed membrane pressure vessel (DG). The results of the check are to be documented in the medical product log  $\rightarrow$  Part 2, page 9-4. If the red indicator is visible in the viewing glass, please contact your B. Braun Avitum AG service technician immediately.

Part 2, page 9-2	
ep the medical product log.	
ightarrow Part 2, page 9-3	
oserve instructions for maintenance and the TSC.	
Part 2, page 9-6	

	Component failure due to non-compliance with the maintenance and technical safety checks!
	Reverse osmosis system immobilization and therefore permeate production is not possible.
$\rightarrow$ An annual technical safety check (TSC) by B. Braun-authorized specialists sory.	

Risk to the patient due to system failure or non-compliance with the demands on the permeate.
$\rightarrow$ After maintenance, repair, exchange or components or other changes, the operator must provide documented proof that the system corresponds with the original specifications (permeate quality, material compatibility).
Danger of poisoning 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 26722, the distribution of this water can impair the quality so much that it no longer meets the requirements of the DIN EN ISO 26722 standard, if the distribution system is not appropriately maintained.

Maintenance/technical safety checks on the reverse osmosis system and connected distribution system must be undertaken according to the manufacturer's instructions.

#### Danger of poisoning and pyrogenic reactions. Non-compliance with the manufacturer's maintenance instructions and disinfection instructions can lead to a decline in the permeate quality or functional impairment to the system.

WARNING

## 9.1 Specific checks for your system

On this form, you will find the stipulations entered by B. Braun for specific checks which have been laid down especially for your system. The specific checks must be carried out at the intervals given here.

Independently of this, the medical product log ( $\rightarrow$  Part 2, page 9-4) must be kept and the maintenance and technical safety check measures ( $\rightarrow$  Part 2, page 9-5) must be carried out and logged.

Specific checks to be carried out	Description	Interval	Notes

## 9.2 Medical product log and maintenance / technical safety check log

The operator has to keep a medical product log for the systems (Eco)RO Dia I/II C and EcoRO Dia II C HT.	
All data carriers are permitted for the medical product log.	
Please always keep the completed pages near the system.	
Operating protocol $\rightarrow$ Part 2, page 9-5	
Maintenance and technical safety check log $ ightarrow$ Part 2, page 9-6	
Maintenance plan and technical safety check $ ightarrow$ Part 2, page 9-7	

The functional safety of the reverse osmosis system can only be maintained if the medical product log is maintained as intended and made accessible to technicians during the technical safety check / routine check work.

Completely and correctly kept logbooks are absolutely essential to determine the type of maintenance and checks to be carried out periodically.

The type of activity, the date carried out and the person doing the work must be entered in the respective log book every time a check is made.

Sample pages for the medical product log and the maintenance and technical service check log are provided in these operating instructions. You can copy these pages as often as required.

## 9.2.1 Medical product log

The medical product log for (Eco)RO Dia I/II C or EcoRO Dia II C HT contains information on the system and an operating protocol.

Sy	System details:		
1.	Description/system type:		
2.	Serial number		
3.	GMDN Code	14 – 437	
4.	Date of handover to the operator		
5.	Names of trained persons (block letters)		
6.	Functional tests i Interval ii Authorised	As per operational log Daily Trained personnel from point 5 Trained personnel from B. Braun Avitum AG	
7.	Safety inspections i Interval ii Authorised	As per bill of material Annually Trained personnel from B. Braun Avitum AG	
8. 9.	Functional faults Report of incidents to authorities and manufacturer	See entries in operational log See entries in operational log	

## 9.2.2 Operating protocol (Eco)RO Dia I/II C (HT)

The plant performance must be recorded daily in the medical product log in accordance with the medical products operator's directive dated June 29, 1998, including details of all operation conditions.

Serial no.: ..... Month / Year: ....

	Visa																															
Remarks and also functional problems,																																
Hydro-	watch OK																															
Temperature	in °C TISAH1																															
Pressure	Pl4 in bar																															
Pressure																																
Concentrate	conductivity CISAH2 (µS/cm)																															
Raw water	conductivity CIS1 (µS/cm)																															
	conductivity CISAHH3 (µS/cm)																															
	Hardness (°dH °fH)																															
	Free chlorine (ppm)																															
	Date	01	02	03	40	05	90	07	08	60	10	÷	12	13	4	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

# Maintenance and technical safety check log for (Eco)RO Dia I/II C, EcoRO Dia II C HT

All the maintenance, technical safety checks, disinfection and cleaning carried out on the system must be recorded in the maintenance and technical safety check log.

The technical safety checks (TSC) are to be carried out annually.

Serial no.:....

Maintenance work carried out	Date	Running time in h	Description of maintenance work, remarks	Visa

# Maintenance plan and technical safety check (TSC) (Eco)RO Dia I/II C (HT)

Dialysis centre:	 Serial number (SN):		
	 Type of line:	EcoRO Dia I C RO Dia I C EcoRO Dia II C RO Dia II C	
Postal code, city:		EcoRO Dia II C HT	
Inventary number:	 Number of modules 1st stage:		
Order number:	 Number of modules 2nd stage:		
Testing equipment number:	 Pump type M1:		
Conductivity:	 M2:		
Electrical safety (Secutest SIII):	 Manufacture date:		
Temperature:	 Date:		

1.	Pretreatment (option)	Changed	Carried out / OK	Last changed month year	Values / data / remarks
1.1	Overall visual assessment, inc. air-tightness; complete pretreatment				
1.2	Water filter, flushing type				Тур
1.2.1	Check degree of soiling (visual inspection)				
1.2.2	Carry out flushing operation				
1.3	Aqua Control				Тур
1.3.1	Function test				
1.4	Pipe disconnector				Тур
1.4.1	Function test for disconnection and flow setting				
1.5	Read water meter				m³

2.	Sand/iron filter (option) Type:, SN:	Changed	Carried out / OK	Last changed month year	Values / data / remarks
2.1	Overall visual assessment inc. seals				
2.2	Check control head for functioning				

3.	Softening plant / Ion exchanger Type:, SN:	Changed	Carried out / OK	Last changed month year	Values / data / remarks
3.1	Overall visual assessment inc. seals				
3.2	Start manual regeneration				
3.3	Replace resin every 10 years				
3.4	Clean injector if required				
3.5	Replace brine valve if required				

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3.	Softening plant / Ion exchanger Type:, SN:	Changed	Carried out / OK	Last changed month year	Values / data / remarks
3.6	Clean salt tank (annually)				
3.7	Salt filling level				cm
3.8	Set brine filling level				cm
3.9	Raw water hardness				°dH
3.10	Soft water hardness 1°dH				°dH
3.11	Set capacity				m³
3.12	Bypass valve setting (check)				
3.13	Check control head for functioning				

4.	Active carbon filter Type:, SN:	Changed	Carried out / OK	Last changed month year	Values / data / remarks
4.1	Overall visual assessment				
4.2	Check control head for functioning				

5.	Reverse osmosis system	Changed	Carried out / OK	Last changed month year	Values / data / remarks
5.1	Total running time of system				
5.2	Running time pumps M1 / M2				
5.3	Overall visual assessment inc. air-tightness				
5.4	Pre-filter Check filter change interval, check min. every 6 weeks in the log, chap. 9				
5.5	Dairy couplings checked and re-tightened, replace seals every 5 years				
5.6	Module cover screws OK				
	Flapsetting of SW bypass, jency mode ROI/ROII 2) normal setting closed				
5.8	Flap setting K4=closed; K5/K6/K7=open				
5.9	Replace ventilation and aeration of tank (annually)				
5.10	Solenoid valves				
5.10.1	Check function Y2, Y5, Y6, Y8, Y9, Y10, Y30 (+ option: Y5.1, Y7, Y90)				
5.10.2	Flush all MV + replace seal sets (every 5 years)				
5.11	Pressure switch	Switch point	PSAH1 🗆		6.0 bar + 2.0 bar □ OK □ n.OK
	check function of switching point	Switch point	PSAL2		0.5 bar ± 0.3 bar □ OK □ n.OK
		Switch point	PSAL4 🗆		6.0 bar + 2.0 bar □ OK □ n.OK
		Switch point	PSAH3 🗆		0.5 bar ± 0.3 bar □ OK □ n.OK

5.	Reverse osmosis system	Changed	Carried out / Of			Values	s / data / rei	mark	S
5.12	Pumps and motors								
5.12.1	Check sliding ring seal in pump head, replace if necessary	M1 🗆 M1 🗆	Check M1 Check M2			Airtight, no	running noi	ises	
5.12.2	2 Check motor protection switch, adjust if necessary	M1 □ (A)		set:	_ (A)	(1.0 x rated	current)		
		M1 □ (A)			_ (A)	(1.0 x the n	ominal curr	ent)	
5.13	Check float switch								
5.13.1	Replace float switch for a pressure sensor (on HT systems)								
5.13.2	Replace LSAL1 (every 3 years)								
5.13.3	Replace LSHL2 (every 3 years)					30	I 🗆 50 I		
5.13.4	Check pressure sensor PISAL1 (for HT systems)								
5.14	Check membrane pressure vessel / Hydrowatch								
5.14.1	Air pressure check / setting at least 1.0 bar (ring piping depressurized)								bar
	Green indicator visible		Yes ⊑ No ⊑ (if No, replace → 5.14.3	] ;					
5.14.2	Leak test (visual inspection)								
5.14.3	B Replace membrane pressure vessel (no later than every 5 years or as necessary)								
5.15	System data								
5.15.1	If necessary update software (when replacing software pay attention to valid operating manual!)								on old n new
5 15 2	2 Control measurements								
	2.1 Conductivity			•	1		1		
0.10.2	testing equipment number:		ned water	Reference	-	sured value	Deviation		n.OK
			entrate	μS/cm μS/cm		μS/cm μS/cm			
				μS/cm		μS/cm			
				nanual device neate ± 2 μS/c		deviation for S	W and conc.	± 10	μS/cm,
5.15.2	2.2 Temperature			Reference	Меа	sured value	Deviation	OK	n.OK
		□ TISA	H1	°C		°C	°C		
		□ TISA	H2	°C		°C	°C		
		Check with	calibrated r	nanual device:	max.	deviation. ± 3 °	° C		
5.15.3	3 Check/read out alarm/limit values		□ OK □ n.Oł	ĸ					
	Set value	Measu	red value	upon trigger	ing	ng Value within range of $\pm 2 \ \mu S$			
	5.12.3.1 Alarm value			-				.OK	
	5.12.3.2 Limit value µS/cm			. µS/cm			K ⊡n	.OK	

5.	Reverse osmosis system	Changed	Carrie out / C		Last changed month year	Values / o	data / remarks
5.15.4	Check temperature discharge	Start v	alue	Ме	asured value	Switch	point ± 3 °C
			°C		°C	D OK	□ n.OK
			°C		°C	D OK	□ n.OK
5.15.8	5 Check fault history						
5.15.6	Fill out "Service report" log						
5.15.7	/ Initiate all operating states						
5.15.8	3 Log system performance						
5.15.9	<ul> <li>O Check Economy mode</li> <li>(only (Eco)RO Dia I/II C with 2 pumps)</li> <li>2nd pump switches off</li> <li>2nd pump switches on</li> </ul>					Function OK Function OK	Time M2 off/sec
5.16	Electrical installation						
5.16.1	Check terminals – ensure all cables are tight						
5.16.2	2 Check insulation of all cables, replace if necessary						
5.16.3	3 Replace CPU battery (every 5 years)						
5.16.4	Check setting of ÜV1 each year (2.5 bar ± 0.5 bar, with HRS 2.0 bar ± 0.5 bar)						

6.	Cleaning & disinfection (only if required or when stipulated by the operator:)	Carried out / OK		Values / data / re	emarks
6.1	Citric acid flushing **	Yes □ No □			
6.2	Disinfection carried out **	Yes □ No □	Disinfection fi Yes □ N	lling opening sealed a o □	gain?
6.3	Hot disinfection carried out (option HT)	Yes □ No □	Min °C	(min. at 80 °C 20 min)	□ OK □ n.OK

7.	Special work	Changed	Carried out / OK	Last changed month year	Values / data /	remarks
7.1	Module replacement					
					Serial no. old	Serial no. new
7.2	Pump replacement					
					Serial no. old	Serial no. new
7.3	Motor replacement					
					Serial no. old	Serial no. new
7.4	Replace coils Y2, Y5, Y6, Y8, Y9, Y10, Y30, Y5.1, Y7, Y90					
7.5	Replace relay on all relay modules					
7.6	Replace seals on flaps K1, K3, K4, K5 if required					
7.7	Other			•		
						Comments:

8.	Repeat test for medical electrical devices as per DIN EN 62353	Measured value	Limit value	Values / da	ta / remarks
	ATTENTION: Implementation of the test i	n compliance with	IEC 62353		
	□ Repeat test □ Test after repair Protective class: 1 Mains connection: PIE □ NPS □	(permanently insta	y connected ME-de alled equipment) nable power supply		
8.1	Visual inspection Mains supply cable, overall system:				□ n.OK
8.2	Protective conductor resistance Measurement between mains supply cable and housing	R <sub>SL</sub>	<0.300Ω	□ ОК	□ n.OK
8.2.1 8.2.2	Measurement between mains supply cable and mounting plate Measurement between mains supply cable and door/front plate	R <sub>SL</sub>	<0.300Ω <0.300Ω	□ ОК	□ n.OK
8.3	Leakage resistance Touch all accessible conductive parts with a test probe		>2.0MΩ	□ ОК	□ n.OK
8.4	Leakage current Mains connection PIE: With permanently installer of DEVICE LEAKAGE CURRENT is not necessa Mains connection NPS: measurement of DEVICE	ary.			
	Device leakage current (substitute measurement):	I <sub>EGA</sub>	<1.0mA	□ОК	□ n.OK
8.5	Function test	□ ОК	□ n.OK		·
8.6	Measurement log available	□ ОК	□ n.OK		
8.7	Safety or functional faults were not established.	C	]		
8.8	No direct risk, the faults discovered were able to be eliminated quickly.	C	2		
8.9	Device must be taken out of circulation until the faults have been eliminated.	C	ב		
8.10	Device does not comply with the requirements – Modifications/replacement of components/ putting out of operation is recommended.				
8.11	The next repeat test is necessary in:	□ 12 r	months		

.....

Date, signature

Chapter 9

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9.	Handover	Carried out / OK	Values / data / remarks
9.1	Start dialysis / standby operating mode		
9.2	Have fault-free handover confirmed		

NO	T	Ξ:

It is recommended to have the successful disinfection verified by determining the germ count / endotoxin content.

Service technician, block letters Place / date, signature
The system was taken over in perfect condition
System operator, block letters Place / date, signature

## 9.2.3 DISINFECTION LOG (reference to document E07FB02)

Customer	
Street	
Postal code and city	
Disinfection ordered by	on
Disinfection initiated by	on

## Execution:

1.	Inform responsible persons about cleaning	
2.	Disconnect dialysis devices	
3.	Clearly mark system for cleaning.	
	See $\rightarrow$ Part 2, page 11-2 "DANGER – Disinfection/cleaning is being carried out".	
4.	Check Hydrowatch: red indicator is not visible	
5.	Perform cleaning using the program default "R" and cleaning log	
6.	Perform disinfection using the program default "DI" or "D"	
_	<b>.</b> . <b>.</b>	

NOTE: The warning and safety instructions of the operating manual must always be followed!

Disinfection carried out on the following:

Reverse osmosis system	SN:
Ring piping	
Tapping points permeate/sampling	

## **Disinfectant used:**

Expiry date	Qty	
Concentration	Circulating time	
Reaction time	Flushing time	

<ol> <li>After disinfection (DI), flush the reverse osmosis (RO) and ring piping with permeate</li> <li>specific check for disinfectant residue for:</li> </ol>	
<ul> <li>H<sub>2</sub>O<sub>2</sub> (peroxide test – Merck item no. 10011) or</li> </ul>	
<ul> <li>peracetic acid (peracetic acid test – Merck item no. 110084) or</li> <li>chlorine (chlorine test – Merck item no. 117925)</li> </ul>	
3. Check for disinfectant residue at all permeate tapping points(individually)	
4. Repeated check for disinfectant residue after 30 min. standstill of the disinfected and flushed RO	
I have made sure that the check for residual disinfectant is negative at all tapping points	
NOTE:It is guaranteed that a test to prove there is no residual disinfectant in the system will be carried out at all tapping points before the next dialysis begins. To prove effective disinfection, a determination of bacterial count in the permeate	

is recommended within 5–7 days of disinfection

Sampling: – wear sterile single-use gloves – Clean sampling tap (at least ring p – Open sampling tap and flush with – Fill permeate sample in sterile sam a sampling filter (item no 50346) w		terile single-use gloves sampling tap (at least ring p sampling tap and flush with meate sample in sterile sam bling filter (item no 50346) w	
End of disin	fection:		Signature of customer:
City/date			Signature of technician:

#### 9.2.4 CLEANING LOG (reference to document E07FB18)

Customer	
Street	
Postal code and city	
Cleaning ordered by	on
Cleaning initiated by:	on

## **Carried out:**

- 1. Inform responsible persons about cleaning
- 2. Disconnect dialysis devices
- 3. Clearly mark system for cleaning
- 4. Check Hydrowatch: red indicator is not visible
- 5. Perform cleaning using the program default "R" and cleaning log Stop
- 6. Write down times: : Start

The warning and safety instructions of the operating manual must always NOTE: be followed!

System and serial no.	ОК	N/A		
Reverse Osmosis			SN.:	
Ring piping + secondary rings				Ring piping length:
HotRinse SMART 10-50			SN.:	
	Before of	cleaning	After cleaning	Unit
Permeate conductivity				μS/cm
pH value in the concentrate				
Permeate hourly throughput				l/h
Permeate temperature				°C

## **Cleaning agent used:**

Expiry date	Qty	
Concentration	Circulating time	
Reaction time	Flushing time	

#### I have made sure that

- the permeate conductivity determined after cleaning is less or equal to the permeate conductivity before cleaning (max. +3µS/cm)

ΟΚ

- the pH value in the concentrate has the same value (±0.1 pH) before and after cleaning

NOTE	It has been ensured that disinfection will be carried out after cleaning of the reverse osmosis system, the ring piping, secondary rings and HotRinseSMart 10-50.	
End of cleaning:	Signature of customer:	_
Place/date:	Signature of technician:	

# 10. Spare and wear parts list (Eco)RO Dia I/II C (HT)

A detailed spare parts list is included in the scope of delivery for the system.

See TM187.

# 11. Draft letter for municipal water suppliers

[municipal water supplier]

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•••••

[City], [Date]

Dear Sir or Madam,

Artificial kidneys make high demands on the quality of water used. For your information, I have enclosed a copy showing the present quality standard for water used to dilute concentrated haemodialysis solution. If this quality standard is not met, it can lead to situations which threaten the lives of patients.

Especially chemicals such as aluminium, fluorides, free chlorine and chloramines, which are generally used for municipal water treatment, can have a detrimental effect on the health of haemodialysis patients.

In our dialysis centre, we have installed a water treatment system which, under normal conditions, enables us to achieve the standard of water quality required for diluting concentrated haemodialysis solutions. This water treatment system has been designed and configured to process the average composition of water that you supply.

The system consists of a softening plant and a reverse osmosis system. These components are capable of removing all the water components harmful to patients found in drinking water.

We would like to ask you to inform us immediately if there are any changes in the composition of the water, particularly about the use of any disinfectants such as chlorine, or dosing of any other chemicals, so that we can take the necessary steps to protect our patients.

We would like to thank you in advance for your considerate cooperation.

Yours sincerely



# DANGER

# Acute risk of poisoning during chemical disinfection/cleaning

Cleaning and disinfection may only be carried out by order of the attending physician.

The permeate must be disconnected from the dialysis devices before the disinfection and cleaning process is started.

After disinfection/cleaning, make sure that the permeate is free of residues from chemicals used for cleaning and disinfection before connecting the hose with the dialysis machine at each delivery point.

Art. No.: 53264