NIPRO MEDICAL EUROPE

Instruction for use RO Systems | Variant: Phoenix One DS

PHOENIX ONE DS+; PHOENIX ONE DS+ FH

October 5, 2023 | Version: 5

Written by: NIPRO Pure Water

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CE 0297

For the reverse osmosis type Phoenix One DS, conformity is declared in accordance with REGULATION (EU) 2017/745 ANNEX IX CHAPTER I, III AND SECTION 4

Foreword

This Instruction For Use includes all information required for the installation and operation of the reverse osmosis model Phoenix One DS.
Please keep this Instruction For Use readily available and near the unit.

This Instruction For Use applies for the units with the serial number:

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1 General

This Instruction For Use is for the following variants:

- Phoenix One DS — Phoenix One with double stage
- Phoenix One DS+ — Phoenix One with double stage with hot water tank
- Phoenix One DS+ FH — Phoenix One with double stage with flow heater

Phoenix One DS:
The Phoenix One DS is a reverse osmosis double stage system, which means that the pure water passes a second stage after the first stage (two RO systems in series) and the wastewater from the second stage gets reused in the first stage. This enables higher dialysis water purity, full redundancy in case of breakdown of one RO stage, and reduced water wastage. The Phoenix One DS can be chemically disinfected, including the connected permeate loop.

Phoenix One DS+:
This system is the Phoenix One DS with a connected Heat Sanitisation System with tank. This add-on allows the distribution loop/Permeate loop and the connecting tubing to the dialysis machines to be disinfected using hot water provided by the Hot Water System with tank. The Phoenix One DS+ can be chemically disinfected, including the connected permeate loop.

Phoenix One DS+ FH:
This system is the Phoenix One DS extended with a Heat Sanitisation System Flow Heater. Phoenix One DS+FH can be chemically disinfected with the loop. This add-on allows the Distribution loop/Permeate loop and the connecting tubing to the dialysis machines to be disinfected using hot water provided by the Hot Water System with a flow heater.

1.1 Permeate quality

Microbiologic Quality:
The microbiological quality of the dialysis water depends on several factors. Neglecting a factor could result in poor quality.

Examples of these factors:
- Quality of the inlet water (potable water)
- Reverse osmosis rinse intervals as well as the type and frequency of disinfection of the dialysis water system
- Disinfection method of the water inlet side of the dialysis machines
- General center hygiene (e.g., frequency of connecting or disconnecting dialysis machines to the dialysis water system)

(These factors are in accordance with ISO 23500-1:2019.)

Chemical quality:
In order to receive an indication of the water quality, the conductivity of the water is measured. The conductivity is a measure of the amount of dissolved salts in the water and can be used as a performance parameter for osmosis.

Caution:
Conductivity alone does not give 100% certainty that the water is suitable for dialysis. Therefore, regular checks of the chemical and microbiological water quality must be carried out.

1.2 Scope of supply

The scope of delivery includes the following parts:

- 1 reverse osmosis
- 1 connection set

1.3 Unit combinations

The unit model Phoenix One DS may be combined with the following devices:

- Hot cleaning system Phoenix One DS+
- Hot cleaning system Phoenix One DS+ FH

1.4 Accessories and Consumables

1.4.1 Accessories

- Distribution loop/permeate loop

Must conform to ISO 23500-1:2019 and ISO 23500-2:2019.

1.4.2 Consumables

▪ Pre-filter 20” 5 µm	item reference: CON-447
▪ Pre-Filter 20” 10 µm	item reference: CON-448
▪ RO-Membrane 4”	item reference: SP-872
▪ RO-Membrane 8”	item reference: SP-1085
▪ Sterile Filter Tank*	item reference: CON-456

* for Tank version only

1.5 Notes for the Operator

The operator is responsible for:

- Competent and intended operation
- Compliance with work safety and accident prevention provisions
- Technical instruction of operating personnel

1.6 Laws and Standards

The following laws and standards are adhered to:

- REGULATION (EU) 2017/745
- EN 60601-1

1.7 Symbols used in this Manual

Indicates a dangerous situation. Disregard can result in personal injury or material damage.

Indicates information and valuable tips.

1.8 Transport and Storage

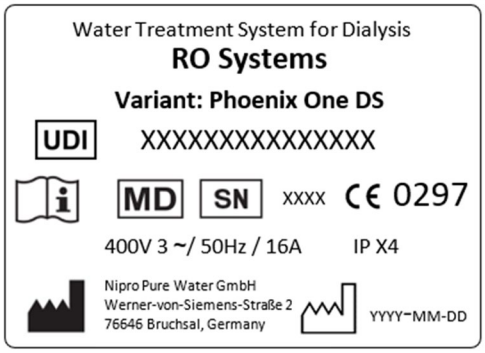
Protect unit against frost and moisture.

Protect against strong jolting and collisions.

Only move unit upright and with an appropriate lift.

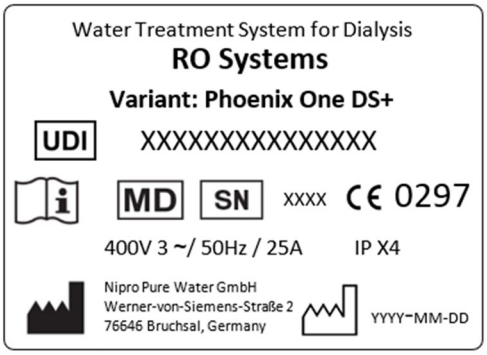
1.9 Product label

1.9.1 Phoenix One DS



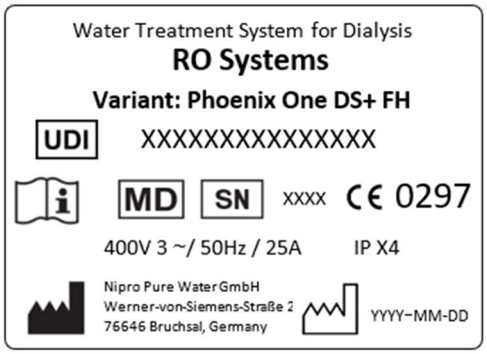
UDI	UDI Number
	Consult instruction for use
MD	Medical Device
SN	Serial number
CE 0297	CE mark with the number of the notified body. Here, DQS Medizinprodukte GmbH
IPX 4	Protection against the ingress of liquids. Here, splash-water protection
	Manufacturer
	Manufacturing date

1.9.2 Phoenix One DS+



UDI	UDI Number
	Consult instruction for use
MD	Medical Device
SN	Serial number
CE 0297	CE mark with the number of the notified body. Here, DQS Medizinprodukte GmbH
IPX 4	Protection against the ingress of liquids. Here, splash-water protection
	Manufacturer
	Manufacturing date

1.9.3 Phoenix One DS+ FH



UDI	UDI Number
	Consult instruction for use
MD	Medical Device
SN	Serial number
CE 0297	CE mark with the number of the notified body. Here, DQSMedizinprodukte GmbH
IPX 4	Protection against the ingress of liquids. Here, splash-water protection
	Manufacturer
	Manufacturing date

1.10 Warning on the Unit

Caution! Hot surface. Attached to the tank.

Caution! Voltage. Turn mains switch off before opening housing. Fixed on control cabinet.

1.11 Shutdown

If a unit is shut down for more than 5 days, preservation will be necessary.

Please contact NIPRO Pure Water before preservation.

1.12 Disposal

According to the WEEE guidelines of the European Union, the disposal of electronic devices and electronic sub-assemblies and parts into the general garbage is unlawful. These parts must be disposed of in an environmentally appropriate manner.

If not appointed otherwise and no private disposal management is available, these devices or possibly other environmental hazardous items can be sent back.

The filters and membrane can be disposed of via the general garbage.

1.13 Instruction / Further Documentation

Personnel using the machine must be warned against the hazards during operation as well as misuse of the product.

Personnel must understand the instructions of operation and the specialties of usage. Only instructed adults are allowed to operate this device.

The instruction by the manufacturer or authorized personnel takes place during the commissioning of the device.

Further trainings are not necessary for this device.

For qualified personnel, the following documents can be made available upon request:

- Circuit diagrams
- Spare parts list
- Technical manual

If the system is operated in combination with the hot cleaning system Phoenix One+ or hot cleaning system Phoenix One+ FH, an extension to these operating instructions is available.

1.14 Duration of usage

The device is designed for a use of 10 years.

1.15 Report in case of serious incident

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

2 Intended operation

The Phoenix One DS series are water purification systems that use reverse osmosis to remove microbiological, organic, and inorganic contaminants from the potable water.

The purified water is used to dilute dialysis concentrate to form dialysis fluid for dialysis machines used in hemodialysis therapies.

Other applications are only possible after consulting the manufacturer and receiving their approval.

The unit can only be maintained by the manufacturer or technicians trained by the manufacturer.

Only original replacement parts may be used for maintenance and repairs.

Installation operations, modifications, or repairs are only allowed to be performed by persons authorised by the manufacturer and may only be done with original replacement parts. Improperly performed reparations or modifications can lead to hazards to the user and/or may damage the system.

The device may only be operated in perfect condition.
Before operating, check the following:

- Loose or defective parts
- Defective cables and/or insulations
- Serious soiling

The device may only be operated with the appropriate ring line.

The system does not produce water for injections.

The device has pressurized parts.

If the temperature sensor fails, the temperature in the permeate can increase. (Max 60°C)

The water treatment system Phoenix One DS may only be used for permeate supply of dialysis devices which have a temperature measurement (permeate temperature).

The device has no direct patient contact and no patient application part.

2.1 Intended users

The end-users of the devices must be trained staff of the dialysis centre including:

- Dialysis centre technicians
- Nursing staff
- Physicians

The use is reserved for highly qualified professional users. An introduction/training must be given to the user.

The systems must be installed in special rooms in dialysis centres with a restricted accessibility. These so-called utility or osmosis rooms are only accessible by trained staff.

2.2 Intended patient population

The Reverse Osmosis Water Treatment Systems (RO Systems family) do not have direct contact with the patient.

The permeate / RO water, that the RO Systems of Reverse Osmosis Water Treatment Systems produce, is used by a dialysis machine for the preparation of dialysis fluid. For this reason, the patient group is dependent on the dialysis machine used.

2.3 Contraindications / side effects

None

3 Safety

3.1 Risk Assessment

There will be no dangers associated with the reverse osmosis model Phoenix One DS, Phoenix One DS+, and Phoenix One DS+ FH if the operating instructions are followed.

The device can be automatically started by way of an auto-start.

3.2 EMC

The device was developed and tested in accordance with current standards. Nevertheless, influence through electromagnetic fields cannot be completely excluded.

3.3 Emissions

The device does not produce dust or vibrations.
The noise level is under 71 dB (A).

4 Technical Data

4.1 Permeate performance / Feed quantity

Number of membranes	2	3	4	5	6	7	8
Permeate performance l/h [15°C]	700	1050	1400	1750	2100	2450	2800
Feed quantity min. at 3 bar dynamic	2000	2500	3000	3500	4000	4500	5500

4.2 Inlet water

Quality	Potable Water
Hardness	<1 °dH
Silicate	<25 mg/l
Chlorine	<0.1 ppm (mg/l)
Iron	<0.1 ppm (mg/l)
SiO2	<30 ppm
Fouling Index (S.D.I)	<3
Temperature	5-30°C
Conductivity	<2790 µS/cm
pH	6.5-8.5
Pressure	3-6 bar

4.3 Connections

Water feed	G 1” external
Permeate connection	TriClamp d50.5 DIN
Drain	HT 50

4.4 Electrical data

	Phoenix One DS	**Phoenix One DS+**	**Phoenix One DS+ FH**
Supply voltage	400 V, 3 Phases, 50 Hz 400 V, 3 Phases, 60 Hz	400 V, 3 Phases, 50 Hz 400 V, 3 Phases, 60 Hz	400 V, 3 Phase, 50 Hz 400 V, 3 Phases, 60 Hz
Fuse	Circuit Breaker 16 A	Circuit Breaker 25 A	Circuit Breaker 25 A
Degree of pollution	1	1	1

4.5 Display system

Conductivity	0-200 µS/cm ±5%
Pressure sensor	0-20 bar ±5%
Water meter	1 impl/l ±1%
Flow	0-5000 l/h ±1%

4.6 Ambient temperature

Storage / transport	1-40°C
Operation	10-35°C
Relative humidity	<90% at 20°C not condensing
Air pressure	795-1062 hPa

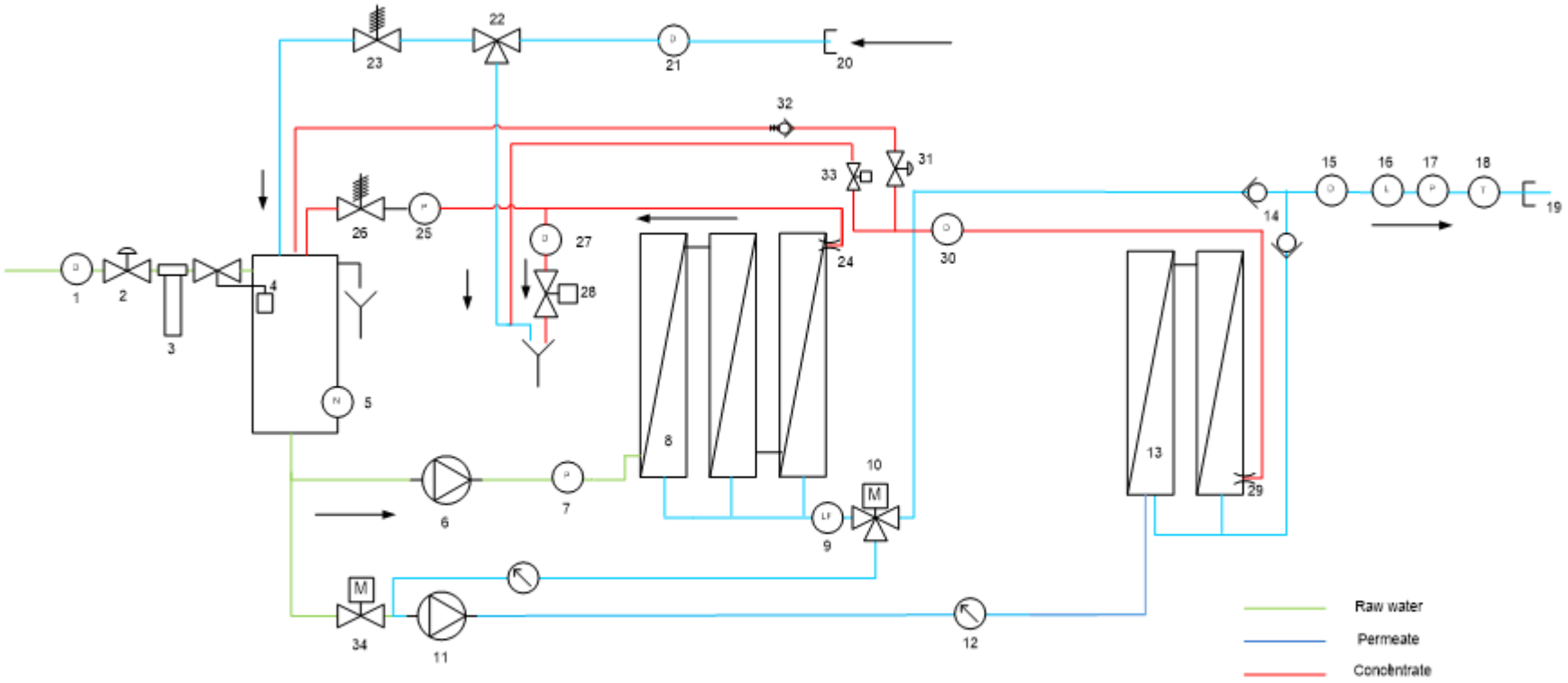
4.7 Size

	Phoenix One DS	Phoenix One DS+	Phoenix One DS+ FH
Size (LxWxH in mm)	1830x1000x1850	2910x950x1850	2400x950x1850

5 Description of the device

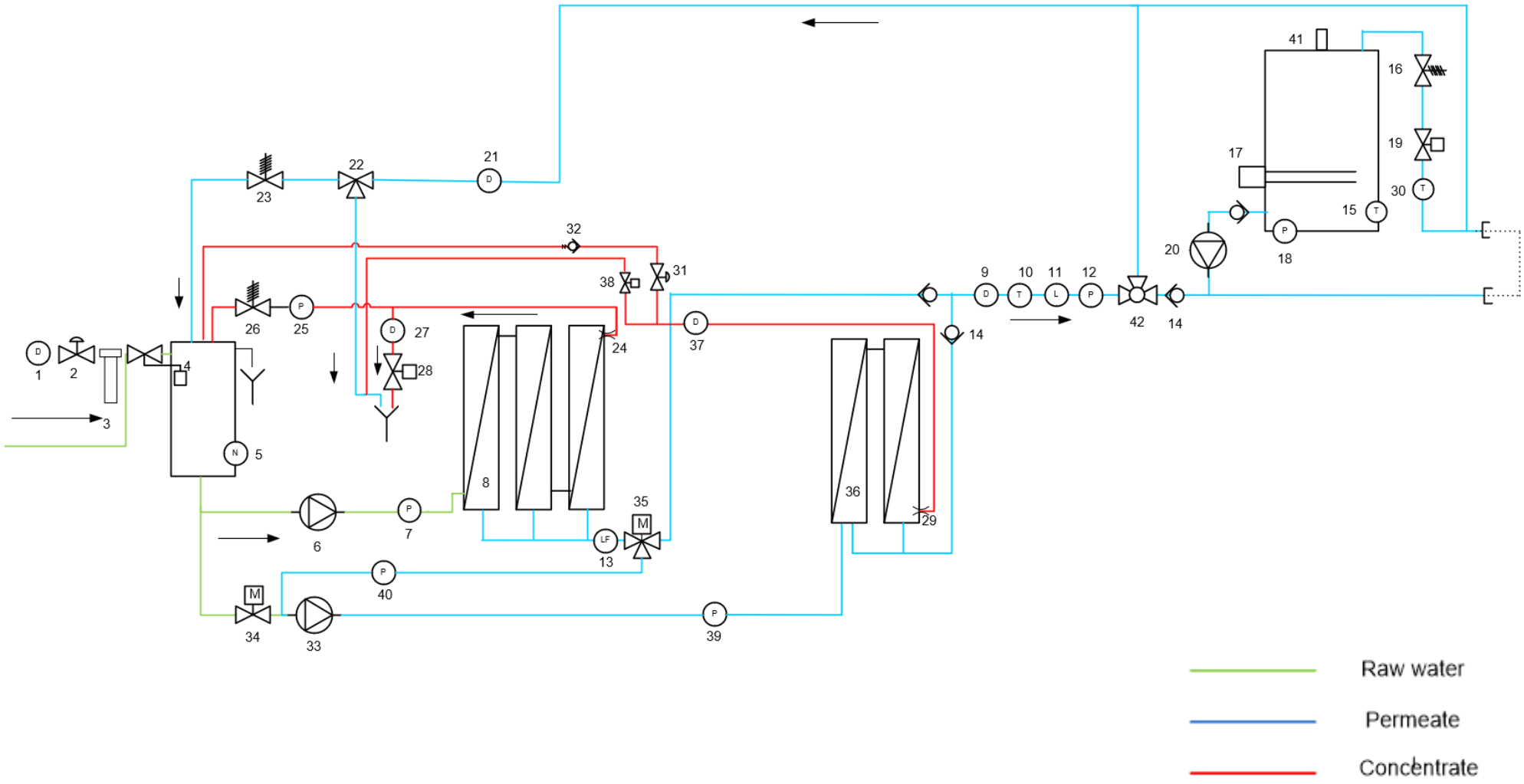
5.1 Flow Chart

5.1.1 Phoenix One DS



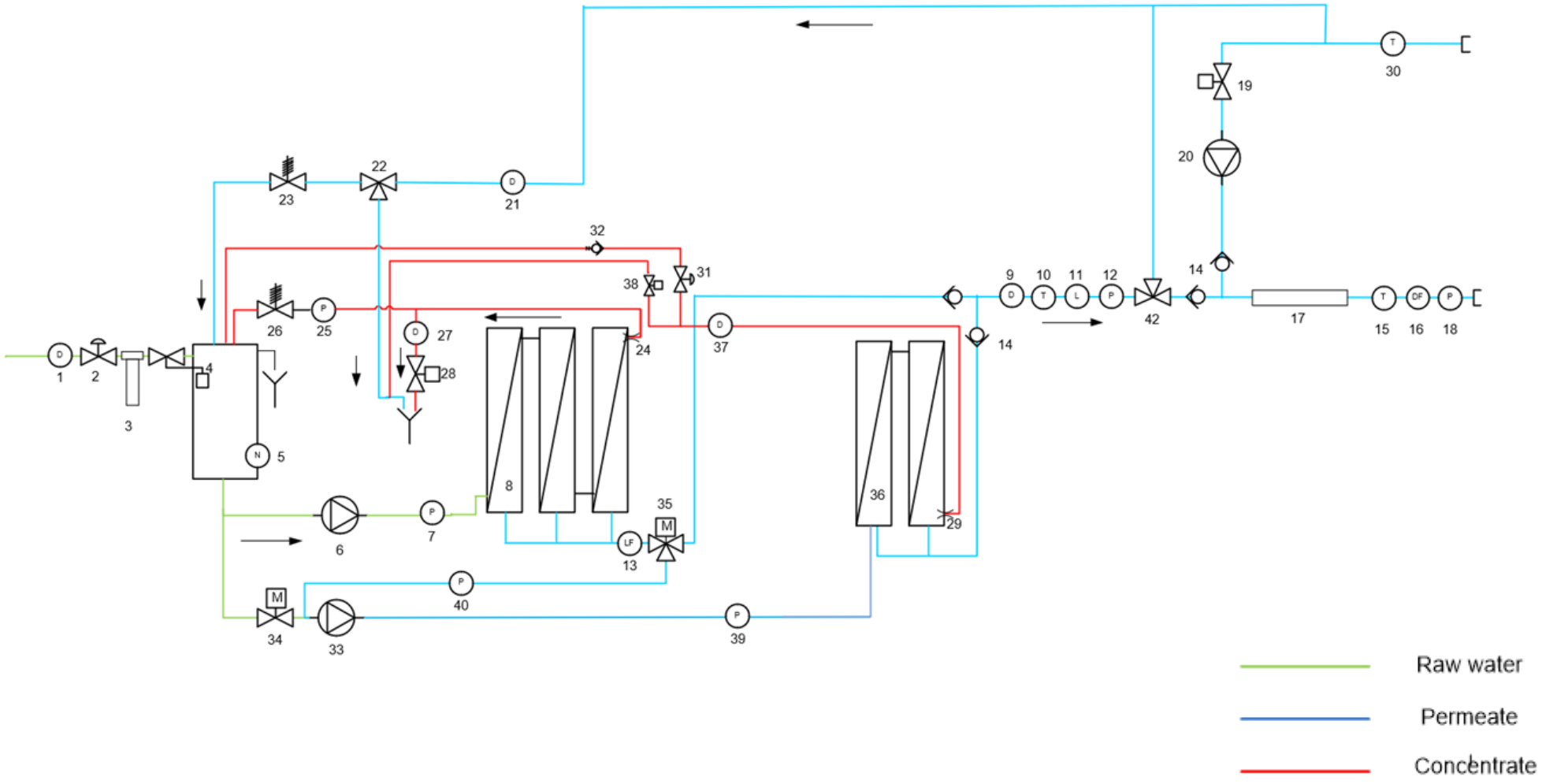
1 Water meter
2 Membrane valve input
3 Fine filter
4 Float valve
5 Dry running protection
6 Pressure increasing pump
7 Pressure sensor pump pressure
8 Reverse osmosis membrane 1st stage
9 Conductivity probe 1st stage
10 Three-way valve with motor
11 Pump 2nd stage
12 Manometer pump pressure 2nd stage
13 Reverse osmosis membrane 2nd stage
14 2 x Return valve permeate
15 Through flow display permeate
16 Conductivity probe 2nd stage
17 pressure sensor ring pressure
18 Temperature sensor permeate
19 Connection ring flow
20 Connection ring back flow
21 Through flow display permeate back flow
22 Three-way valve permeate to drain
23 Permeate pressure retaining valve
24 Concentrate restrictor 1st stage
25 Manometer concentrate pressure
26 Concentrate pressure retaining
27 Through flow display concentrate to drain
28 Concentrate valve to drain
29 Concentrate restrictor 2nd stage
30 Through flow concentrate 2nd stage
31 Adjustment concentrate flow 2nd stage
32 Return valve concentrate return 2nd stage
33 Magnetic valve emergency operation
34 Ball valve emergency operation with motor

5.1.2 Phoenix One DS+



1 Water meter
2 Diaphragm valve inlet
3 Filter
4 Floating valve
5 Dry running protection
6 Pressure increasing pump
7 Pressure sensor, pump
8 Reverse osmosis membrane, 1st stage
9 Flow display permeate, 2nd stage
10 Temperature probe, permeate 2nd stage
11 Conductivity probe, permeate 2nd stage
12 Pressure sensor, permeate 2nd stage
13 Conductivity probe, permeate 1st stage
14 Check valves, permeate
15 Temperature sensor, tank
16 Pressure retaining valve, tank
17 Heater, tank
18 Pressure sensor, tank
19 Solenoid valve, hot water sanitisation
20 Circulation pump
21 Flow display, permeate back flow
22 Three-way valve, permeate to drain
23 Pressure retaining valve, permeate
24 Concentrate nozzle, 1st stage
25 Pressure display, concentrate to train
26 Pressure retaining valve, concentrate
27 Flow display, concentrate to drain
28 Concentrate valve to drain
29 Concentrate nozzle, 2nd stage
30 Temperature sensor, back flow
31 Adjustment concentrate flow, 2nd stage
32 Check valve, concentrate 2nd stage
33 Pressure increasing pump, 2nd stage
34 Ball valve, emergency operation
35 Three-way valve with motor
36 Reverse osmosis membrane, 2nd stage
37 Flow display, concentrate 2nd stage
38 Solenoid valve, concentrate return 2nd stage
39 Pressure gauge, pump pressure 2nd stage
40 Pressure gauge, permeate 1st stage
41 Sterile filter, tank
42 Three-way valve, RO / RO and loop disinfection

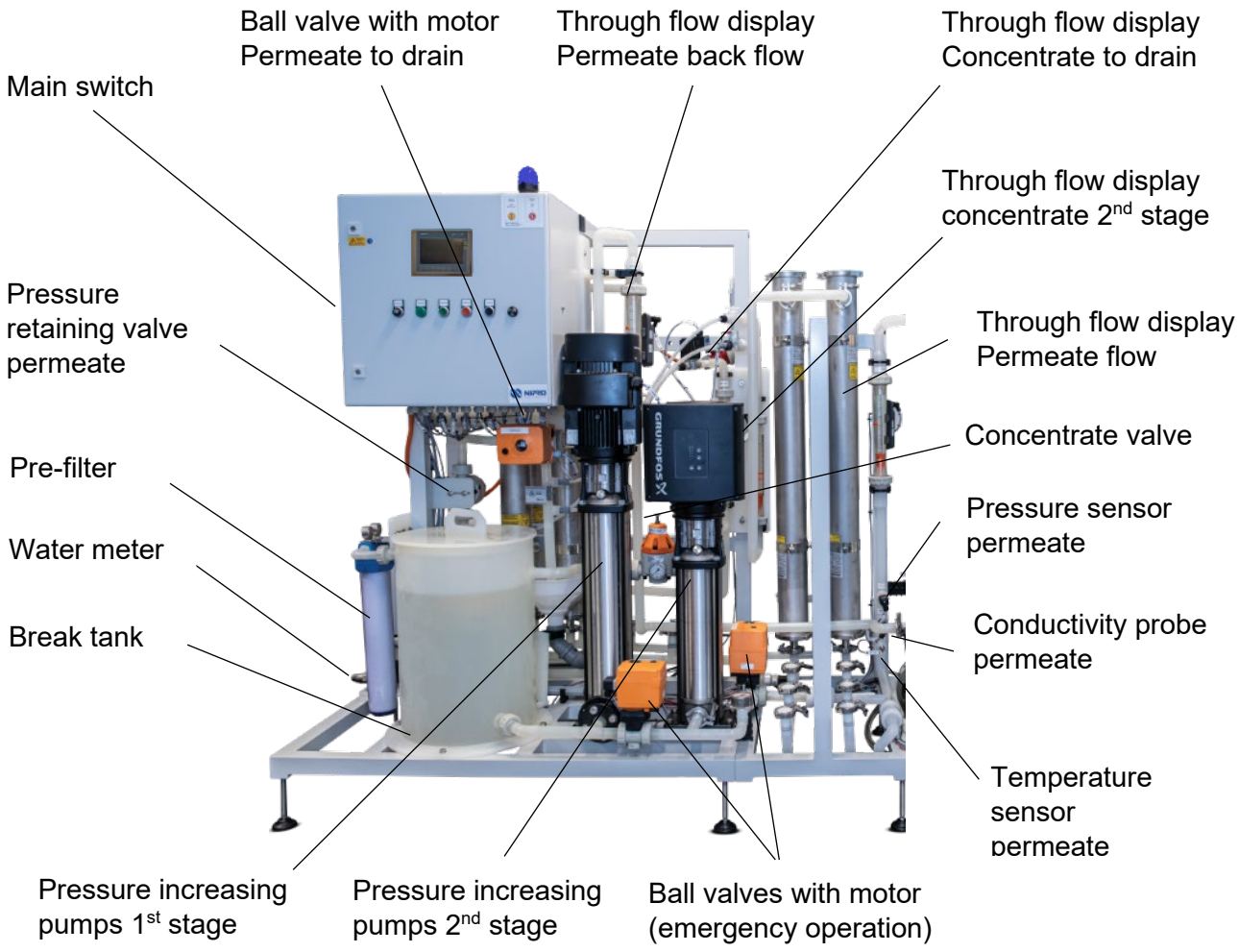
5.2.1 Phoenix One DS+ FH



1 Water meter
2 Diaphragm valve inlet
3 Filter
4 Floating valve
5 Dry running protection
6 Pressure increasing pump
7 Pressure sensor, pump
8 Reverse osmosis membrane
9 Flow display permeate, 2nd Stage
10 Temperature probe, permeate 2nd Stage
11 Conductivity probe, permeate 2nd Stage
12 Pressure sensor, permeate 2nd Stage
13 Conductivity probe, permeate 1st Stage
14 Check valves, permeate
15 Temperature sensor, loop inlet
16 Flow switch, loop inlet
17 Flow heater
18 Pressure gauge, loop inlet
19 Solenoid valve, hot water sanitisation
20 Circulation pump
21 Flow display, permeate back flow
22 Three-way valve, permeate to drain
23 Pressure retaining valve, permeate
24 Concentrate nozzle, 1st Stage
25 Pressure display, concentrate to train
26 Pressure retaining valve, concentrate
27 Flow display, concentrate to drain
28 Concentrate valve to drain
29 Concentrate nozzle, 2nd Stage
30 Temperature sensor, back flow
31 Adjustment concentrate flow, 2nd Stage
32 Check valve, concentrate 2nd Stage
33 Pressure increasing pump, 2nd Stage
34 Ball valve emergency operation
35 Three-way valve with motor
36 Reverse osmosis membrane, 2nd Stage
37 Flow display, concentrate 2nd Stage
38 Solenoid valve concentrate return, 2nd Stage
39 Pressure gauge pump pressure, 2nd Stage
40 Pressure gauge pump pressure, 1st Stage
41 Not used
42 Three-way valve, RO / RO and loop disinfection

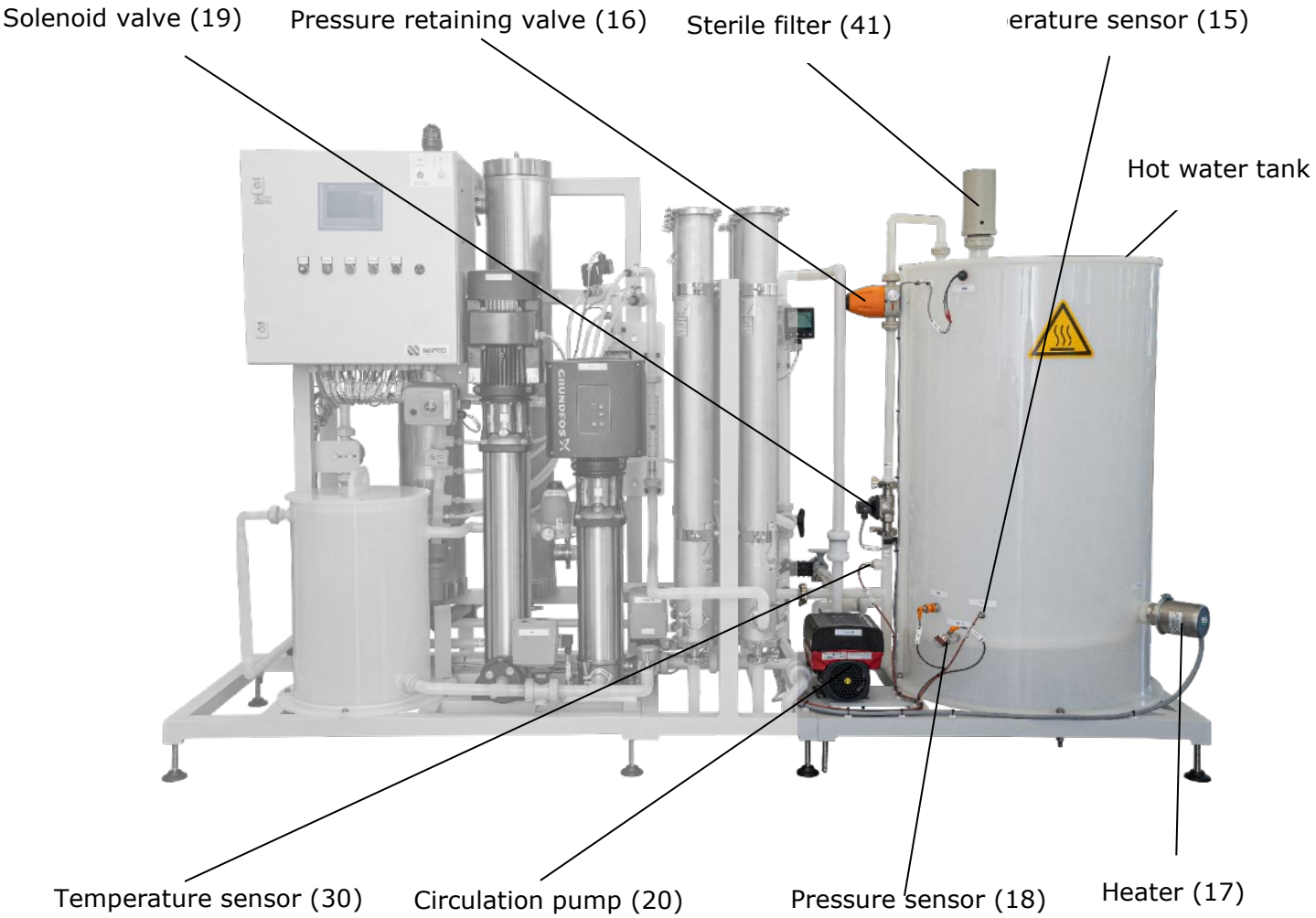
5.3 Components

5.3.1 Phoenix One DS



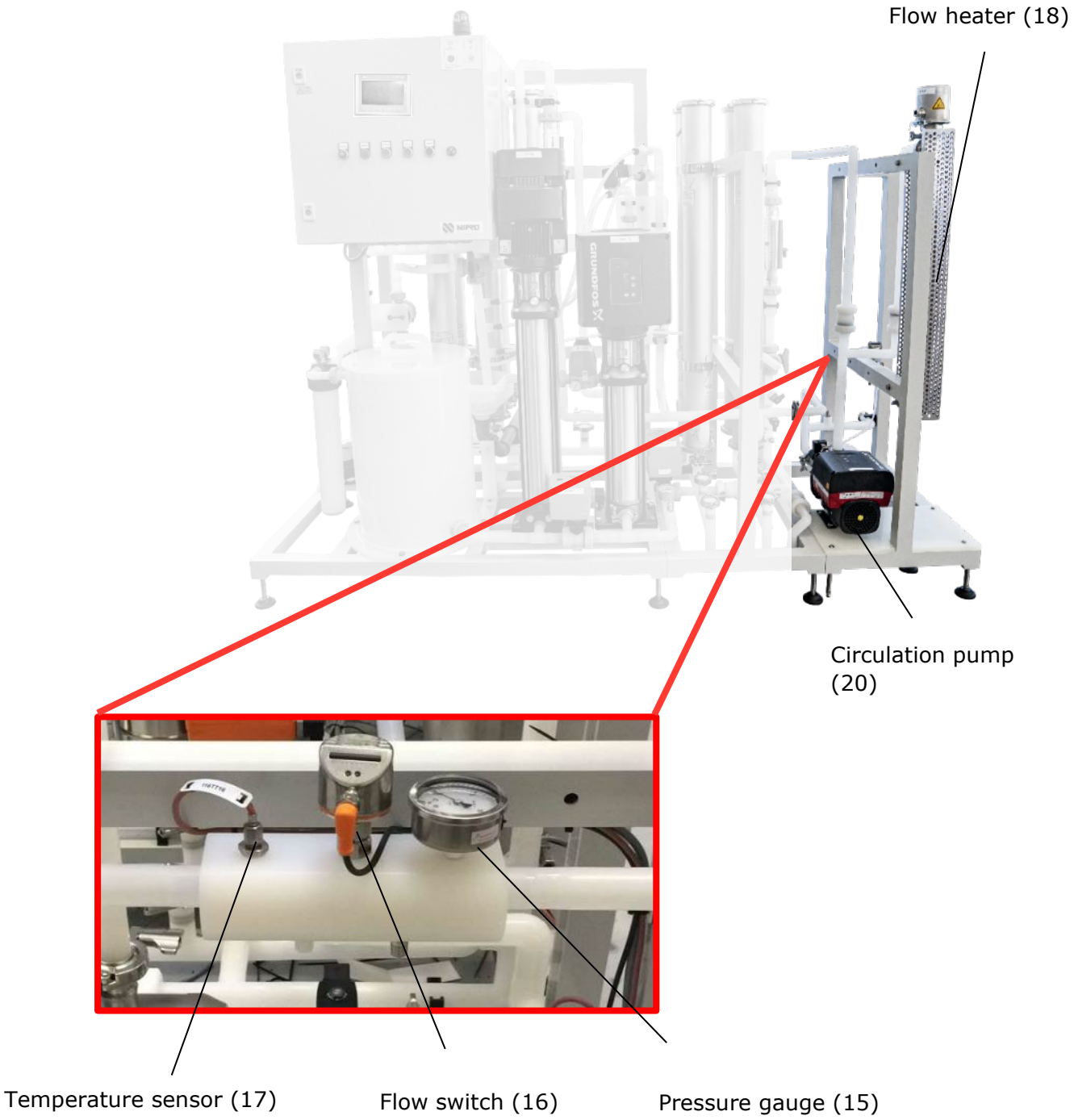
5.3.2 Phoenix One DS+

Additional components to Phoenix One DS+.



5.3.3 Phoenix One DS+ FH

Additional components to Phoenix One DS+FH.



5.4 Operations

5.4.1 Operation Sequence Permeate Production

Untreated water flows through the main water line and the fine filter into the break tank. The float valve mounted in the break tank regulates the water level in the tank.
The booster pump draws the water out of the tank and then presses it into the reverse osmosis membrane. At the reverse osmosis membrane, the water stream separates into the ***permeate stream*** (pure water) and the ***concentrate stream***. The conductivity of the permeate of stage 1 will be measured at the conductivity sensor.

In a double stage operation, the permeate of the first stage streams through the three-way valve and pump 2 to the second reverse osmosis membrane.

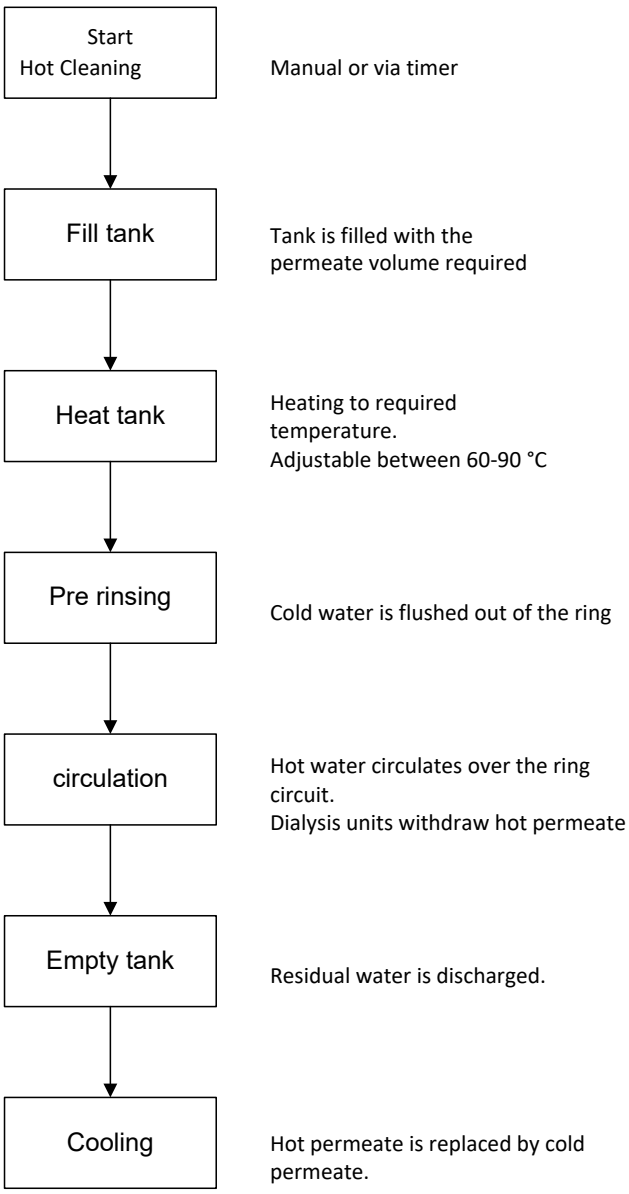
The quality of the produced permeate will be tested with the temperature probe and the conductivity probe. Afterwards, it will flow into the ring line to the consumption points.

Unused permeate will be returned to the break tank over the permeate pressure valve.

A portion of the concentration will flow through the concentrate valve back into the cycle. The rest will leave the device through the proportional valve to the drain. The ratio of concentrate returned to concentrate drainage is regulated by the proportional valve based on consumption.

5.4.2 Phoenix One DS+: Sequence Hot Cleaning

The tank is filled with permeate. The pressure sensor located on the bottom of the tank interrupts permeate production when the required filling level has been reached.
The tank is then heated.
When the respective temperature has been reached, the hot pure water circulates over the ring via a pump.
The temperature sensor at the end of the ring ensures that the complete ring is sufficiently heated.
When the required ring temperature has been reached, it is then possible to connect the dialysis units and to withdraw hot permeate from the ring circuit.
On completion of the circulation phase, the ring is cooled to normal operating temperature via cold permeate.



5.4.3 Phoenix One DS+ FH: Sequence Hot Cleaning

The three-way valve is closing the backflow of permeate to the drain and pre-tank. The solenoid valve opens and the circulation pump starts providing flow. The flow heater heats the water until the set temperature is reach at temperature sensor in the loop backflow.

After the circulation phase, the loop is cooled down with cold permeate to operating temperature.

6 Installation

The installation must be conducted by the manufacturer or by personnel trained and authorized by the manufacturer.

For first commissioning, disinfection is required.

Further details can be found in document in technical appendix.

6.1 Environmental Conditions

Conditions for the osmosis room:

- Relative air moisture <90% at 20°C non-condensing.
- Room temperature between 10°C and 35°C (frostproof).
- Equipped with floor drain, water supply, and electrical supply.

6.2 Assembly

- Bring the system into the appropriate position.
- Adjust machine feet until the device stands level and secure on the floor.

Do not store easily flammable or explosive materials in the vicinity of the device.

Do not store chemicals in the vicinity of the device.

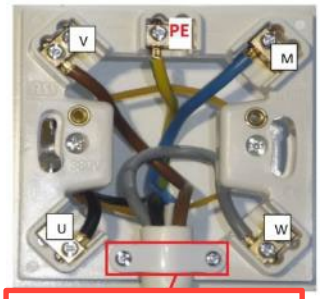
Only operate the device with the necessary water pre-treatment.

Room of osmosis may not be freely accessible. (Accessible to instructed personnel only).

6.3 Electrical installation

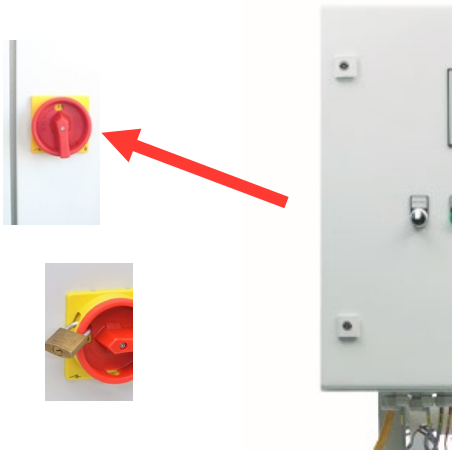
The installation may only be performed by a qualified electrician.

The system must be supplied by a permanent connection - connectors are not valid. Disconnect via the main switch at the control cabinet.



Strain relief

Connection box



Main switch.
For protection against a restart of the unit, the main switch can be locked with a padlock.

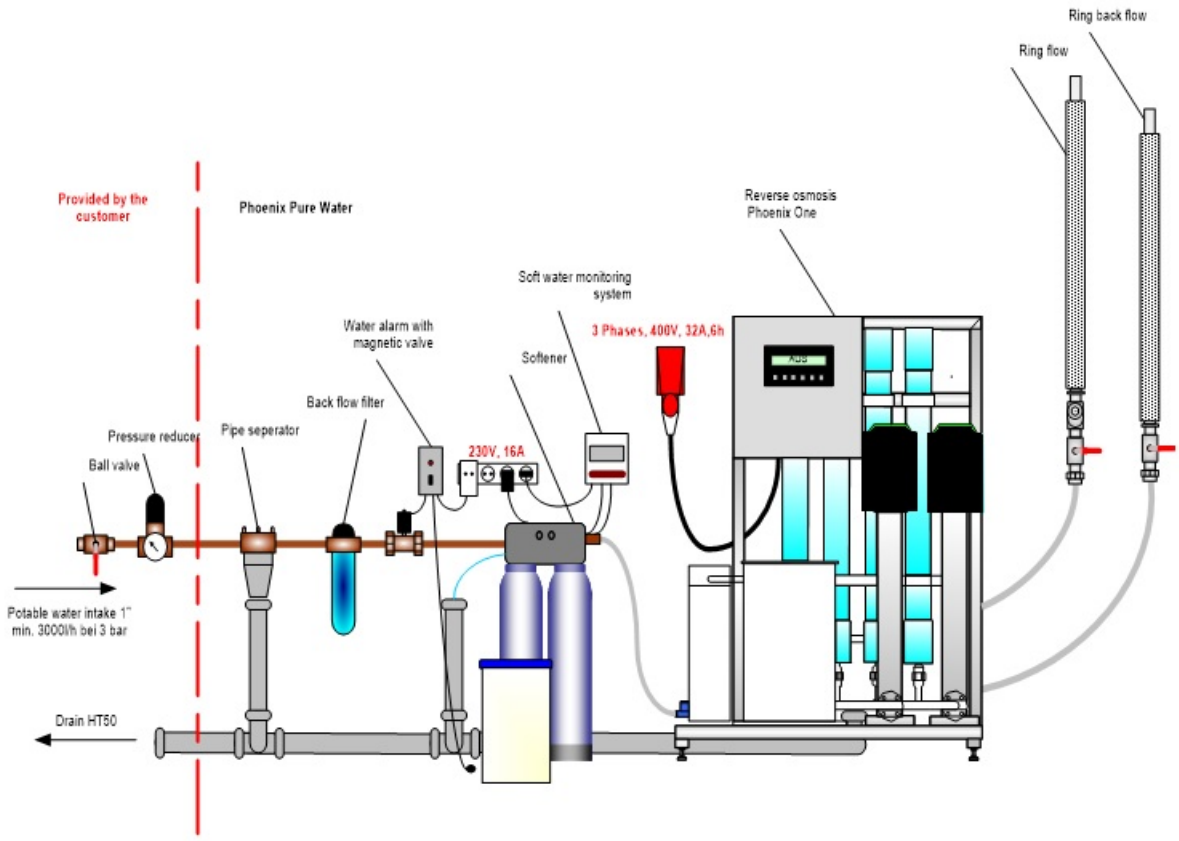
Safety class I

The device is equipped with a protective earth terminal for prevention against a high touch current.
For prevention of the hazard of an electric shock, this device may only be connected to a power supply with a protective earth.

The power cord is fixed to the system and cannot be replaced.

6.4 Pre-filtration (Example)

Install the necessary water pre-treatment equipment first!
Only then connect to the RO and start up.

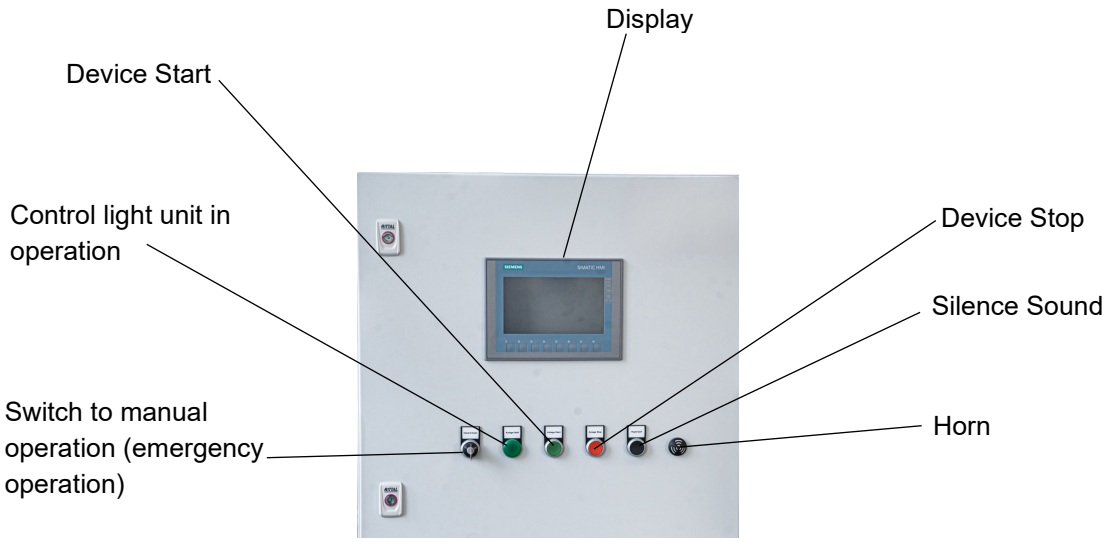


Local water works regulations and DIN EN 1717 must be followed.

The water pre-treatment must be adapted to the local potable water quality.

7 Operation

7.1 Control Panel

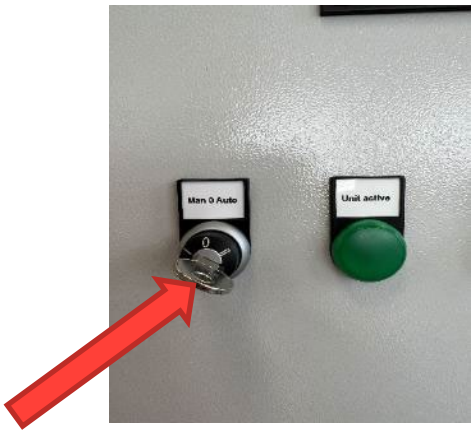


Name	Type	Function
Device Start	Button	Starts the permeate production.
Control light unit in operation	Light	If the unit is in operation, this will be signalled with a green light.
Switch manual operation	Switch Man, 0, Auto	Switch with three positions: 1 Man: If the controls fail, the unit can be switched to emergency operation. 2 0: Unit off (no clean, no time start) Auto: The unit will be operated by the controls.
Horn	Signal	Horn will activate if an alarm is present, or if device is running in emergency mode.
Silence Sound	Button	Turns off the horn if pressed (tone off). A long press of the button removes any alarms present.
Device Stop	Button	Stops the device.
Keyboard		Calls up operation value and settings for service.
Display	Touch	Displays operation values and notifications.

7.2 Emergency operation

Only use emergency operation if the automatic function fails. Have device repaired as soon as possible.

Attention!
There is no monitoring of the water inflow during the emergency operation. Therefore, a continuous water inflow must be guaranteed.
Absent water causes the **destruction of the pump**.



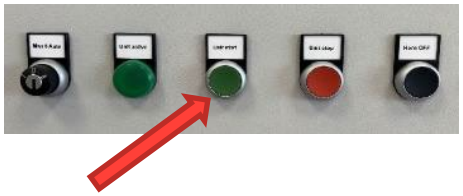
Turn the key of the operating switch to “Manual”.

To turn off the device, turn switch to position 0.

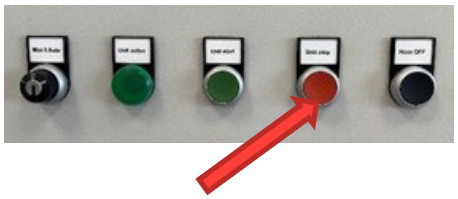
In an emergency operation, all automatic functions are turned off. No cleaning cycle, no automatic start, and/or stop will be conducted.

The permeate quality will not be monitored.

7.3 Manual On / Off

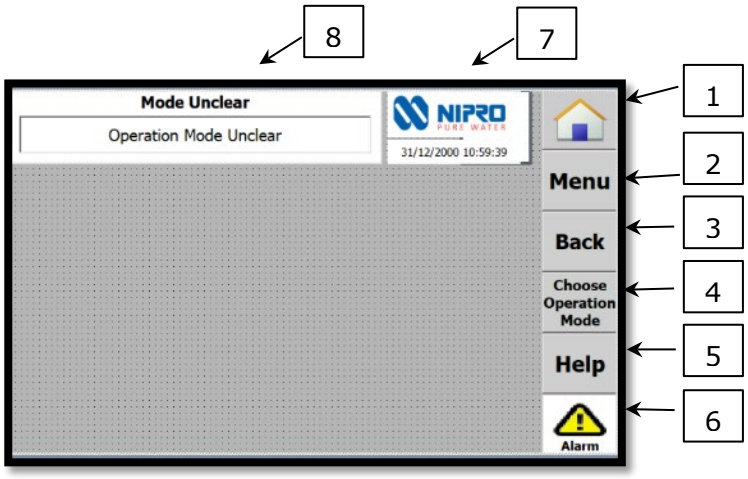


Press the green button to start the device. The green light will turn on.



Press the red button to stop the device. The green light will turn off.

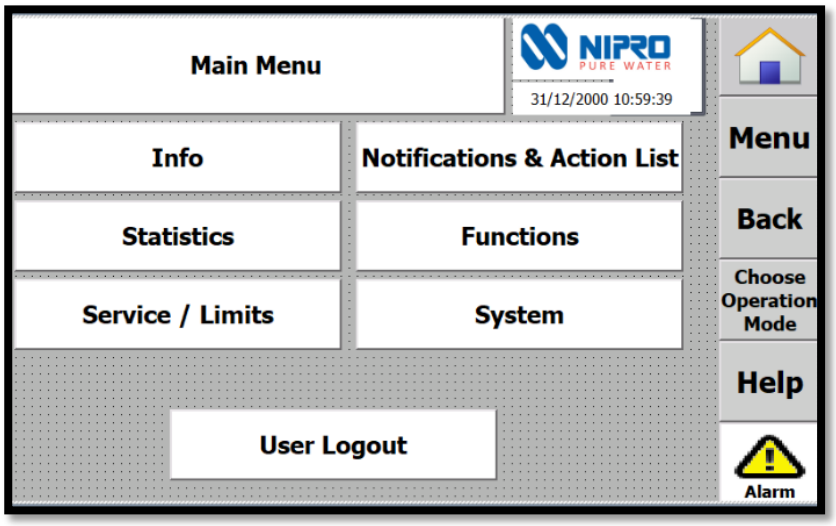
7.4 Quick access keys



1. **Home button**
2. **Access to Main Menu**
3. **Back to last page**
4. **Choose operation mode**
5. **Help**
6. **Access Alarms and Notifications**
7. **Display of date and time**
8. **Navigation information**

To start the selected program, the green start button must be pressed. The device will start shortly after. Press the red button to stop the device.

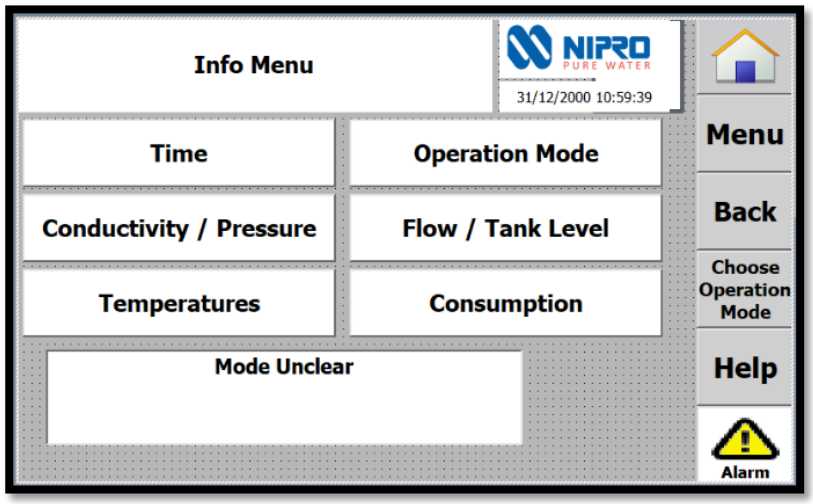
7.5 Main Menu and sub menus



Sub Menus Service / Limits and System are protected via password access.

7.6 Menu Info

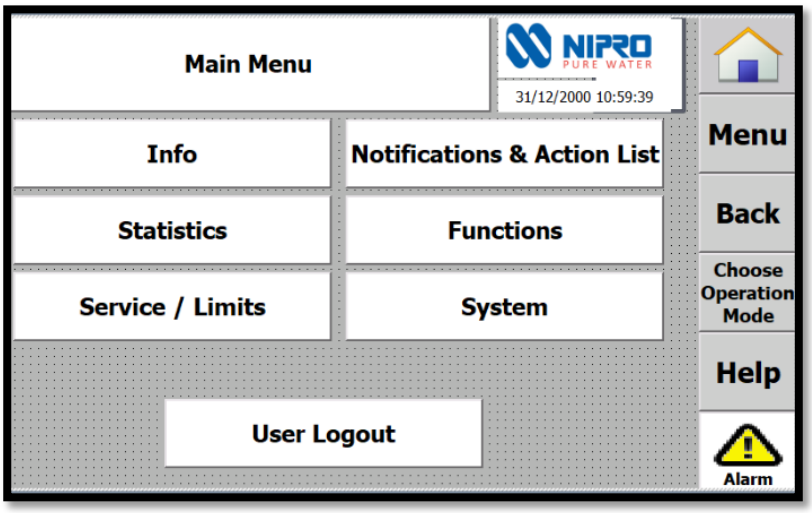
Select **Main Menu** and select **Info**:



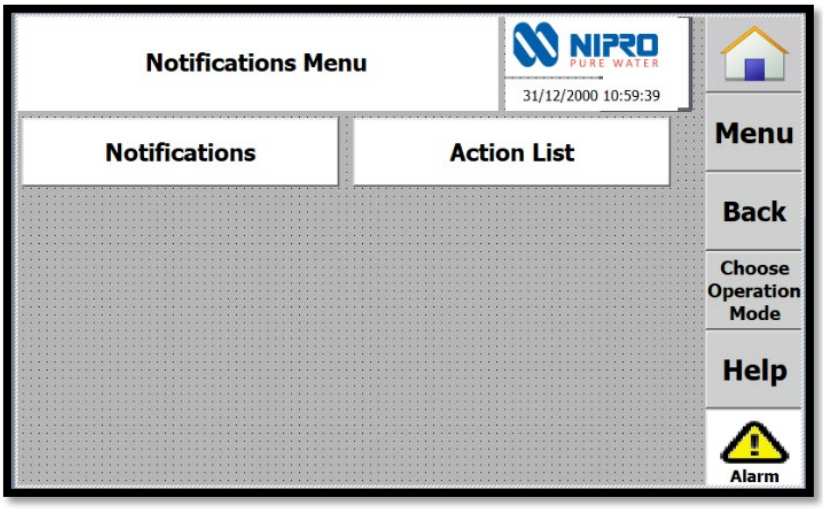
1. **Time:** See Date and Time
2. **Operation Mode:** See selected operation mode
3. **Conductivity / Pressure:** See current values of conductivity and pressure
    a. *Conductivity 1st and 2nd stage*
    b. *Pressure pump*
    c. *Pressure loop*
4. **Flow / Tank Level:** See current values of flow and levels
    a. *Raw water inlet*
    b. *Concentrate flow*
    c. *Backflow loop*
    d. *Inlet loop*
    e. *Level tank* ***(only Phoenix One DS+)***
5. **Temperatures:** See current values of temperature
    a. *Permeate temperature*
    b. *Temperature loop end* ***(Pheonix One DS+ and Phoenix One DS+ FH)***
    c. *Hot tank temperature* ***(only Phoenix One DS+)***
6. **Consumption:** See current values consumptions
    a. *Permeate consumption*
    b. *Yield*

7.7 Menu Notification

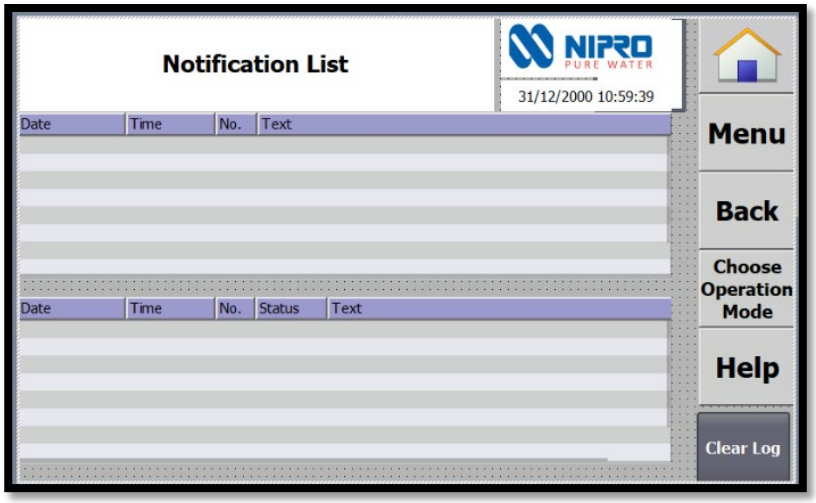
Select **Main Menu** and proceed to **Notifications**:



Select **Notification** or **Action List**:



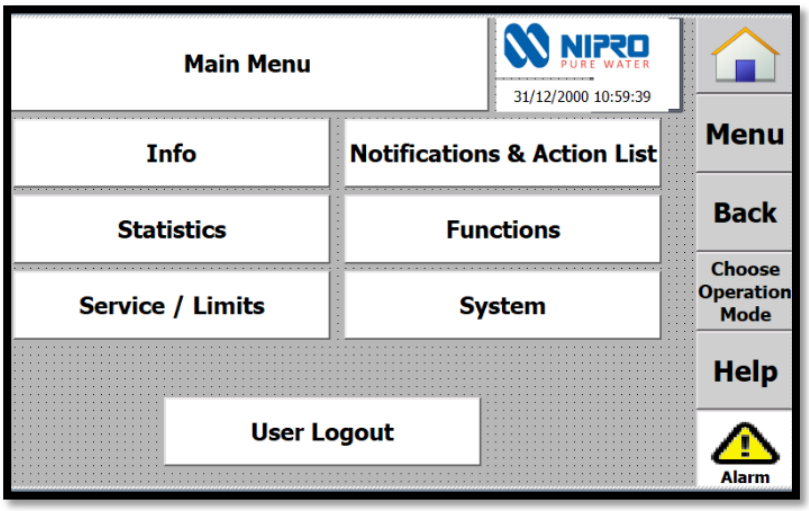
New and old notifications can be reviewed in the following list:



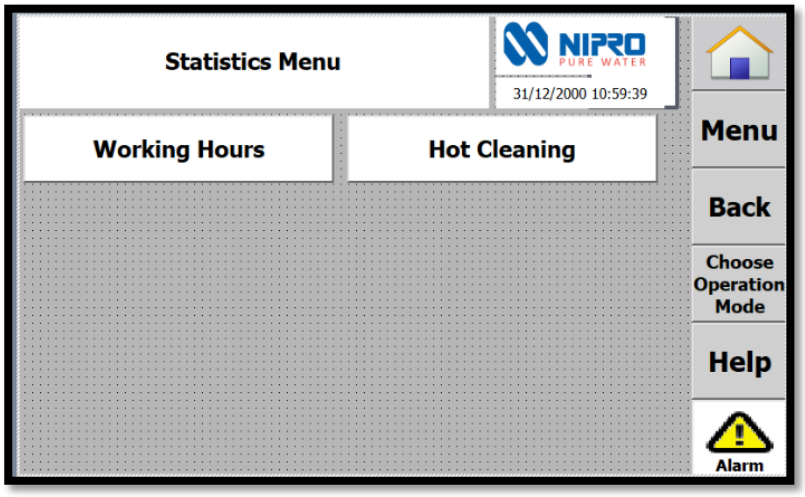
Actions carried out can be reviewed here as well:

7.8 Menu Statistics

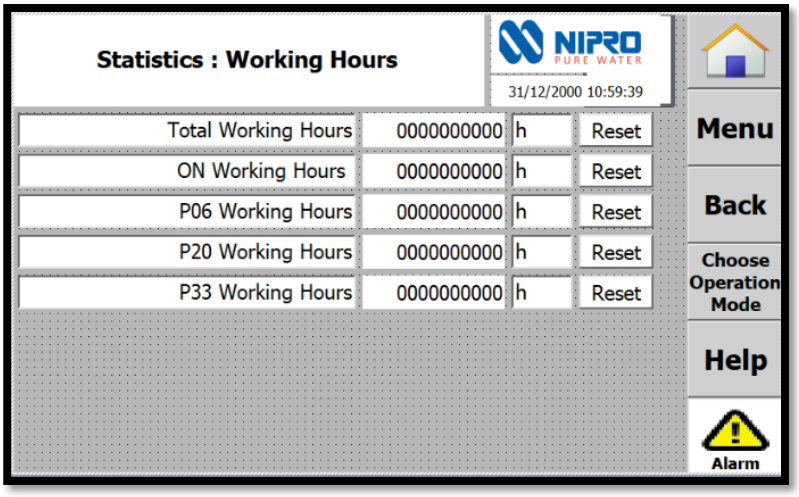
Select **Statistics** from the **Main Menu**:



Select either **Working Hours** or **Hot Cleaning** to review data:

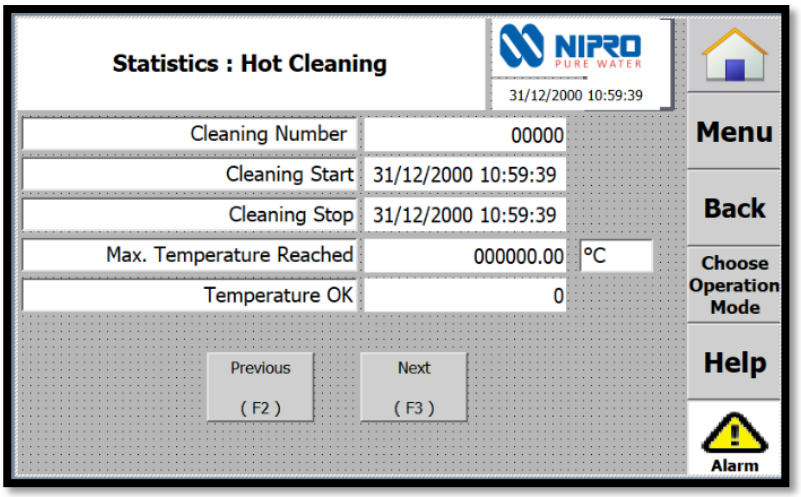


To view **Working Hours**:



Statistics: Operating Hours	
Total Operating Hours	Displays the total working of the device.
ON Operating Hours	Displays the working hours of the device in RO mode.
P06 Operating Hours	Displays the working hours of Pump P06.
P20 Operating Hours	Displays the working hours of Pump P20 **(+ and FH Variants)**.
P33 Operating Hours	Displays the working hours of Pump P33.

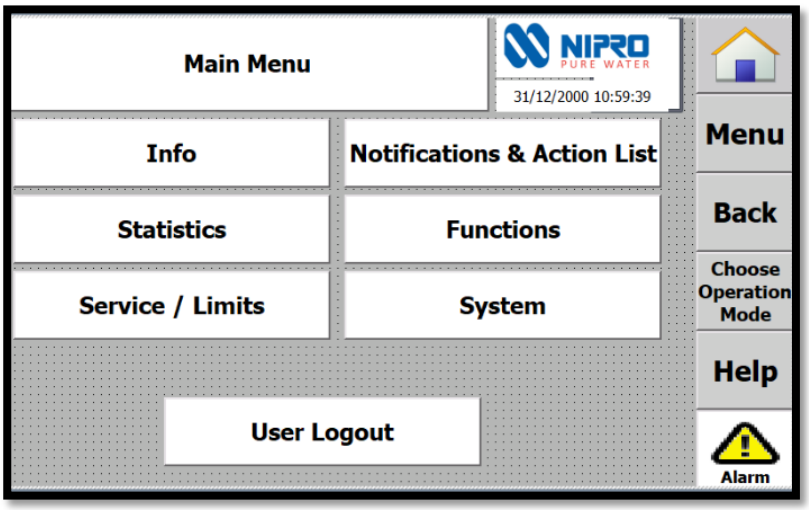
To view **Hot Cleaning** *(available for Phoenix One DS+ and Phoenix One DS+ FH only)*:



Statistics: Hot Cleaning	
Cleaning Number	Represents the identifying number of each Hot Cleaning performed thus far.
Cleaning Start	Indicates the starting time and date of the current Hot Cleaning.
Cleaning Stop	Indicates the stopping time and date of the current Hot Cleaning.
Max. Reached Temperature	Displays the highest temperature reached by the device during Hot Cleaning.
Temperature OK	Signifies whether the Hot Cleaning successfully reached the required temperature or not (1 = Yes, 0 = No).

7.9 Menu Functions

Select **Functions** from the **Main Menu**:

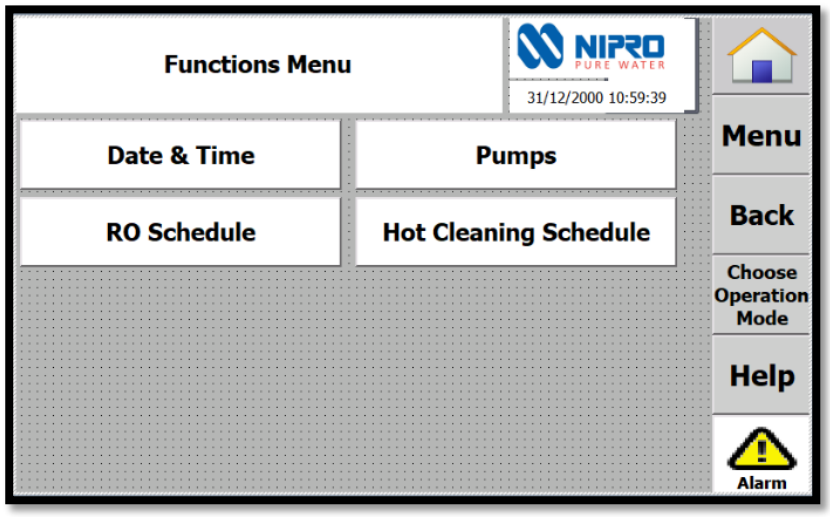


In this menu, the following actions are possible:

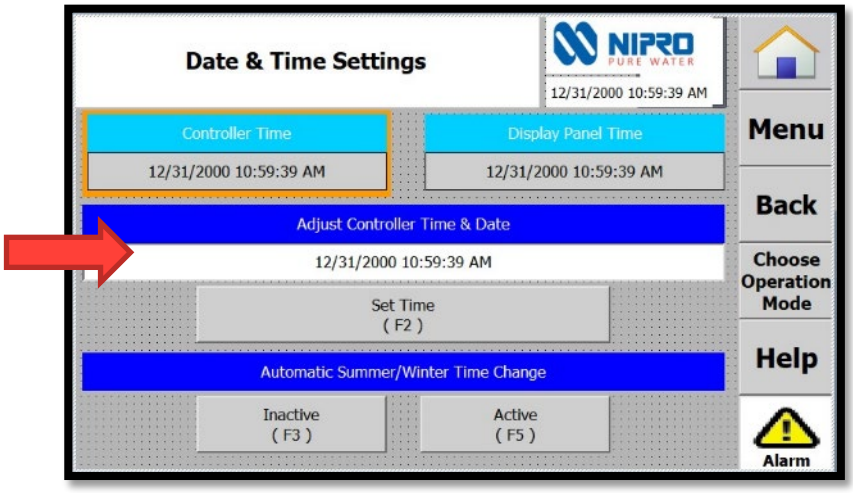
- Change the Date and Time
- Select the pump desired to operate
- Configure and set a timer for permeate production
- Configure and set a Hot Cleaning ***(Hot Cleaning is available with Phoenix One DS+ and Phoenix One DS+ FH only)***

7.10 Set Clock

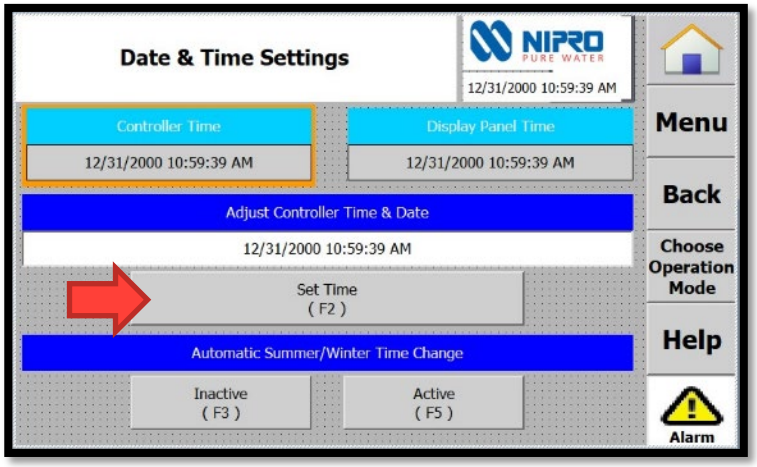
Select the **Date & Time** menu:



Change date and time at controller:

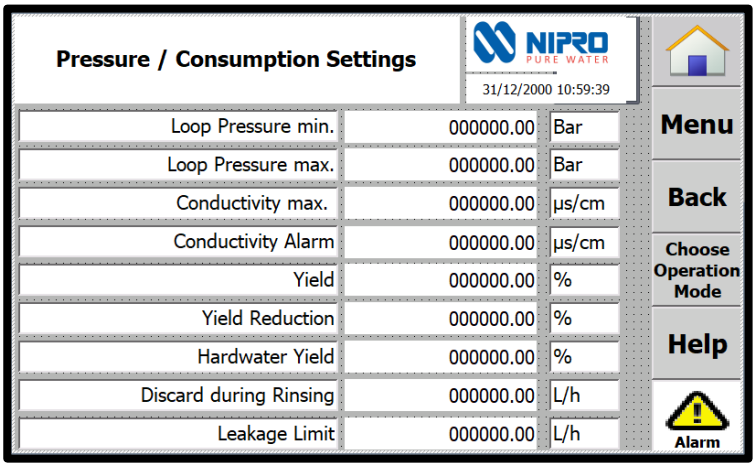


Tap on **Set Time** or press the **F2** button on the display panel to confirm the new settings:



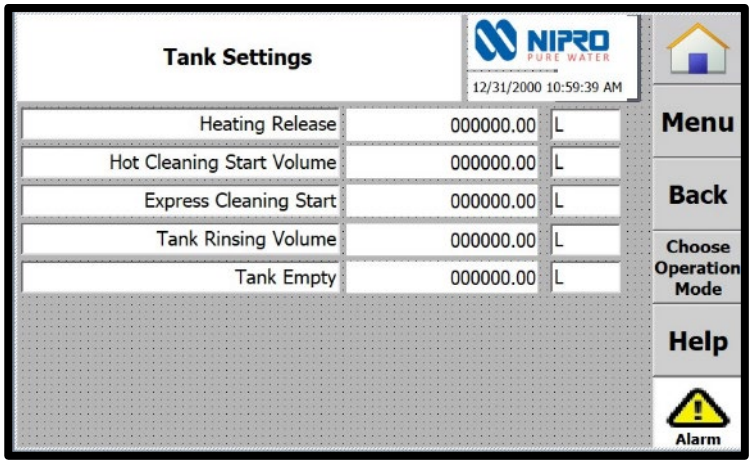
7.11 Service/Limits Parameters

7.11.1 Pressure/Consumption Settings



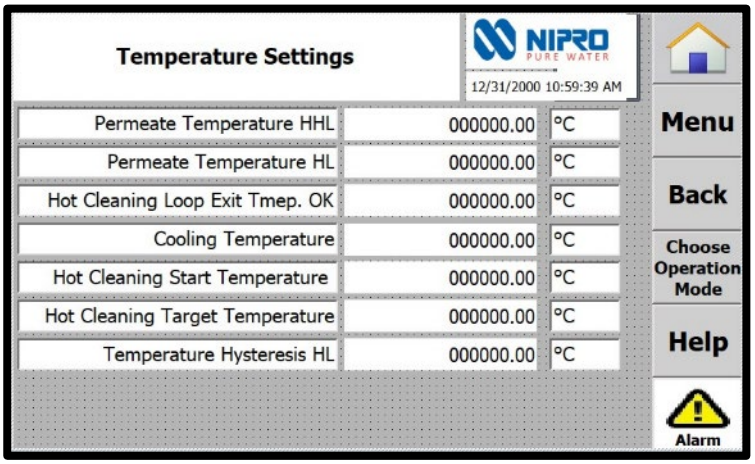
Service/Limits: Pressure / Consumption Settings	
Loop Pressure Min	Minimum allowed loop pressure which the device can operate under (in Bar).
Loop Pressure Max	Maximum allowed loop pressure which the device can operate under (in Bar).
Conductivity Max	Critical conductivity value at which the device shuts down upon reaching/exceeding.
Conductivity Alarm	Value which triggers an alarm stating that the conductivity is rising in value. Does not shut off the device.
Yield	The efficiency of the device under normal operating conditions.
Yield Reduction	Drop of efficiency by specified percentage when Conductivity Alarm value is reached.
Hardwater Yield	Drop of efficiency to specified percentage if a Hardwater Alarm is triggered.
Discard during rinsing	Sets the concentrate reject while rinsing.
Leakage Limit	Limit of leakage allowed during operation which the device can ignore and continue running.

7.10.2 Tank Settings *(ONLY IN One DS+ VARIANT)*



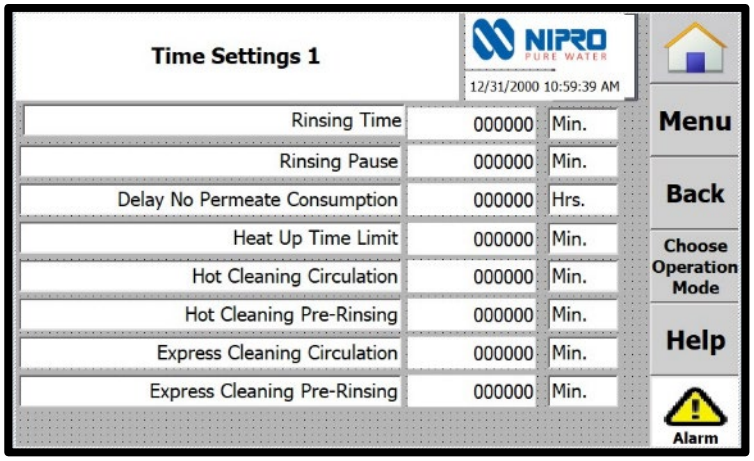
Service/Limits: Tank Settings	
Heating Release	Minimum volume required to start the tank heater.
Hot Cleaning Start Volume	Fill level of the tank needed to allow for Hot Cleaning to commence.
Express Cleaning Start Volume	Volume which the tank needs to start an Express Cleaning.
Tank Rinsing Volume	Volume which the tank needs to contain to perform a Tank Rinsing.
Tank Empty	Volume at/under which the tank is considered empty.

7.11.3 Temperature Settings



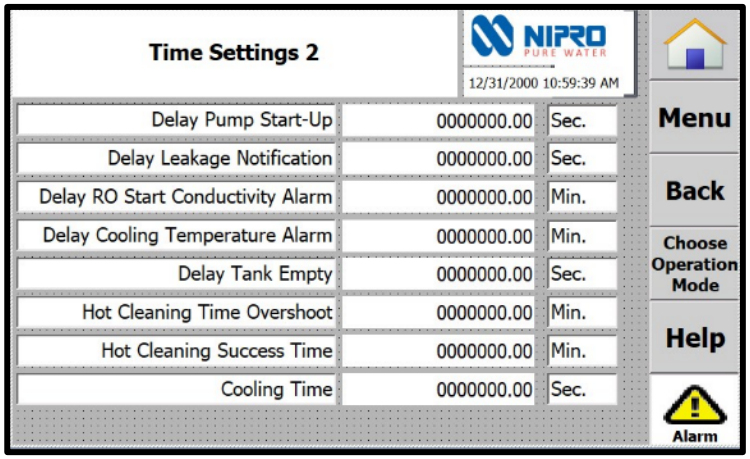
Service/Limits: Temperature Settings	
Permeate Temperature HHL	Temperature of the permeate that triggers a system shutdown.
Permeate Temperature HL	Temperature of the permeate that triggers an alarm indicating the temperature is rising. System doesn't shut down.
Hot Cleaning Loop Exit Temp. OK	Temperature required to be reached during Hot Cleaning to prompt a pass.
Cooling Temperature	Target Temperature which the device needs to reach when cooling is running.
Hot Cleaning Start Temperature	Minimum Temperature which the device needs to reach in order to start a Hot Cleaning
Hot Cleaning Target Temperature	Target Temperature which the heater needs to reach when heating up during hot cleaning or **(Only in OneDS+ Variant)** pre-heating.
Temperature Hysteresis HL	Degrees to drop temperature by when HL notification is triggered.

7.11.4 Time Settings 1

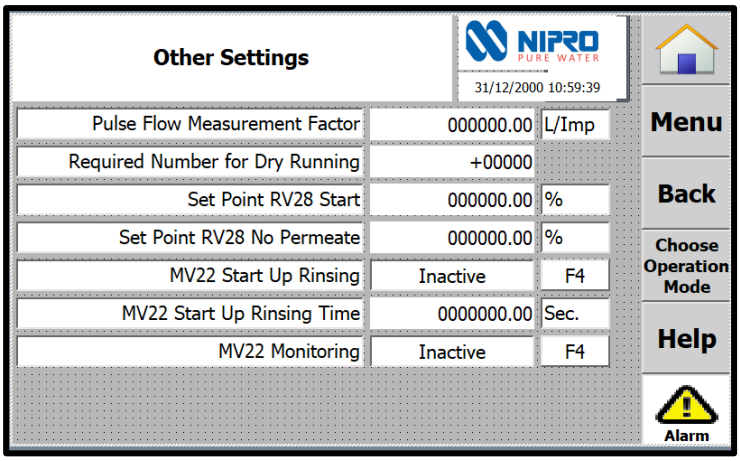


Service/Limits: Time Settings 1	
Rinsing Time	Specifies duration of rinsing.
Rinsing Pause	Specifies duration of pause between rinsing cycles.
Delay No Permeate Consumption	Time after which alarm for no permeate consumption is triggered and device is shut down.
Heat Up Time Limit	Time limit for the heater to reach the specified target temperature.
Hot Cleaning Circulation	Specifies duration of circulation once a Hot Cleaning is initiated.
Hot Cleaning Pre-Rinsing	Specifies duration of rinsing during Hot Cleaning which takes place before the circulation **(Only in One DS+ Variant)**.
Express Cleaning Circulation	Specifies duration of circulation once an Express Cleaning is initiated.
Express Cleaning Pre Rinsing	Specifies duration of rinsing during Express Cleaning which takes place before the circulation **(Only in One DS+ Variant)**.

7.11.5 Time Settings 2



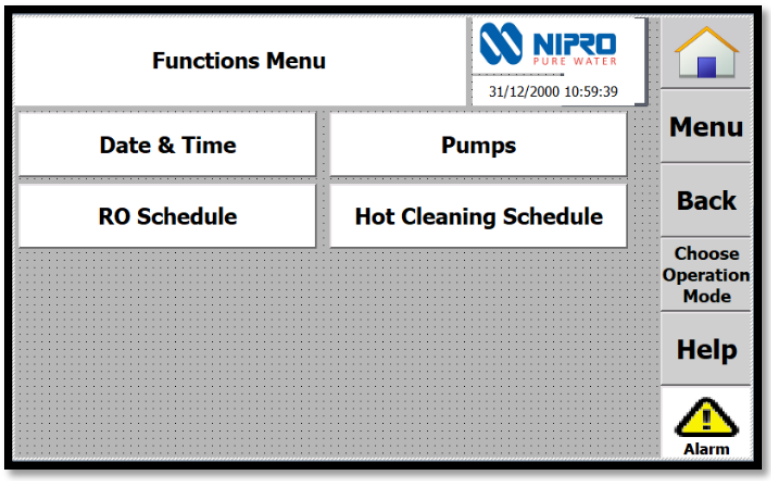
Service/Limits: Time Settings 2	
Delay Pumps Start Up	Delays the activation of the pumps upon start up by specified duration.
Delay Leakage Notification	Delays the triggering of the leakage alarm by specified duration.
Delay RO Start Conductivity Alarm	Delays the triggering of the conductivity alarm upon start-up by specified duration.
Delay Cooling Temperature Alarm	Delays the triggering of the cooling alarm by specified duration.
Delay Tank Empty	Delays when the tank is considered empty by specified duration. **(Only in One DS+ Variant)**.
Hot Cleaning Time Overshoot	Time limit to trigger alarm if no change of temperature and/or level is recorded during Hot Cleaning.
Hot Cleaning Success Time	Time which temperature must be held for during Hot Cleaning to prompt a pass.
Cooling Time	Time allotted for device to perform cooling.



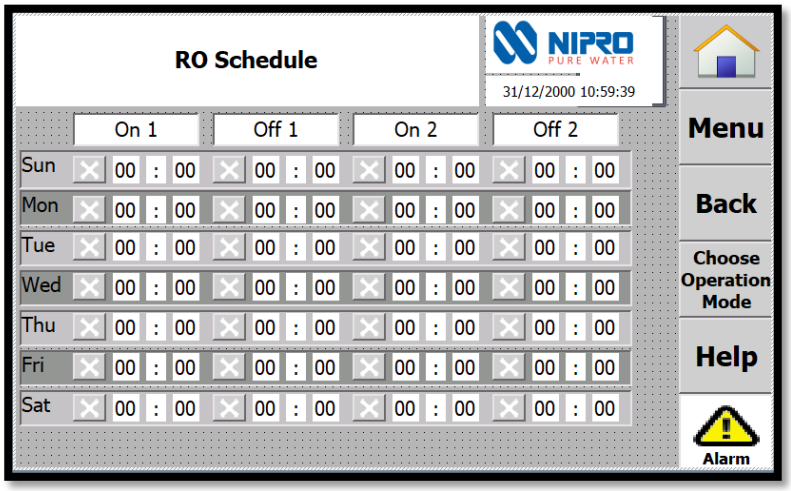
Service/Limits: Other Settings	
Pulse Flow Measurement Factor	Determines the factor which the flow meter pulse uses to measure the flow.
Required Number for Dry Running	Sets the number of times the device can run without water before triggering the dry running alarm and shutting down. The device would need to be restarted after alarm.
Set Point RV28 Start	Percentage of concentrate to be drained by the device upon start for a set duration of time.
Set Point RV28 No Permeate	Percentage of concentrate to be drained if the device doesn't detect any permeate consumption after set time.
MV22 Start Up Rinsing	Toggles the activation of MV22 to send permeate to drain upon RO Start. **(One DS + and FH Variants only)**.
MV22 Start Up Rinsing Time	Specifies how long MV22 is to drain water for. **(One DS + and FH Variants only)**.
MV22 Monitoring	Toggles if MV22 is to be monitored upon activation or not. **(One DS + and FH Variants only)**.

7.11 Timer

Select **RO-Schedule**:



In this menu, two start and stop timers can be set per day. Select the day the RO system should start and enter the start time and stop time.



7.12 Hot Cleaning for Phoenix One DS+ and Phoenix One DS+ FH & Related Settings

These options are available for Phoenix One DS+ and Phoenix One DS+ FH only.

For safety reasons it is only allowed to conduct max. one hot water sanitisation per day.

Danger of scalding!
During the whole sequence of hot water sanitisation.

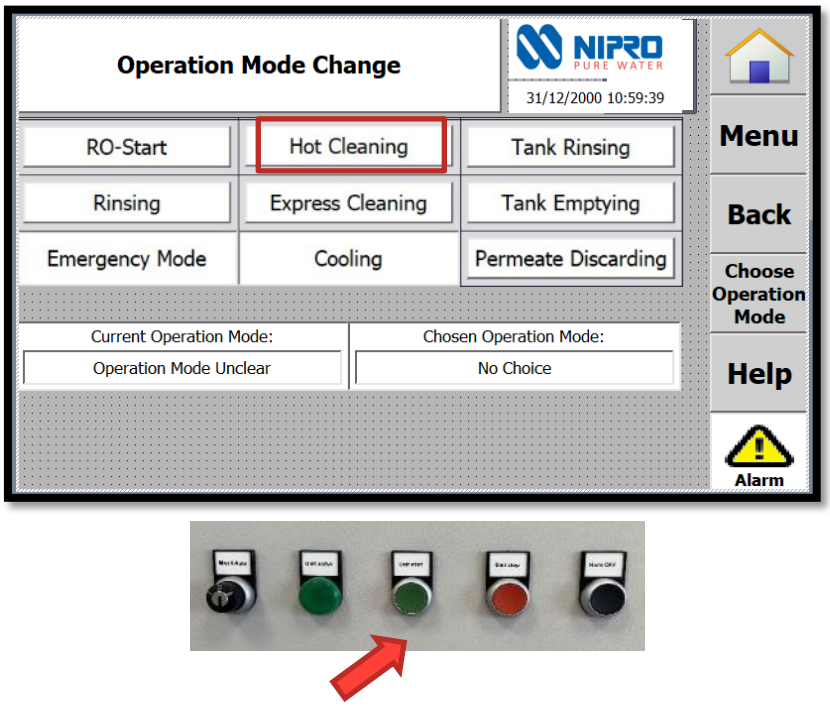
Interval and parameter of hot water sanitisation must be confirmed during commissioning.

7.12.1 Manual start

These options are available for Phoenix One DS+ and Phoenix One DS+ FH only.

Select **Choose Operation Mode** and select **Hot Cleaning** mode:

New selected mode is displayed in pre-selected window. Start Hot Cleaning by pressing the green button.



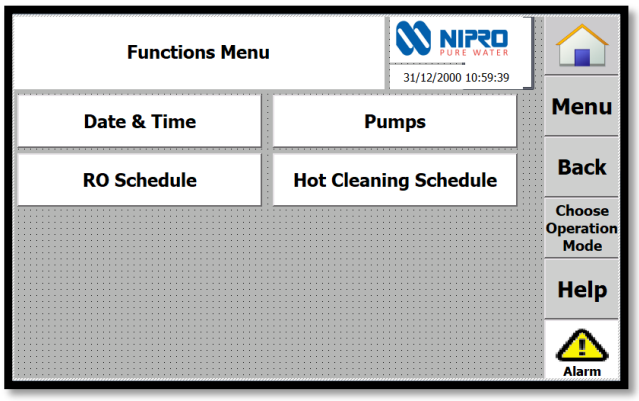
7.12.2 Suspend Hot Cleaning

At any time, Hot Cleaning can be stopped by pressing the red button. The unit cools down independently.

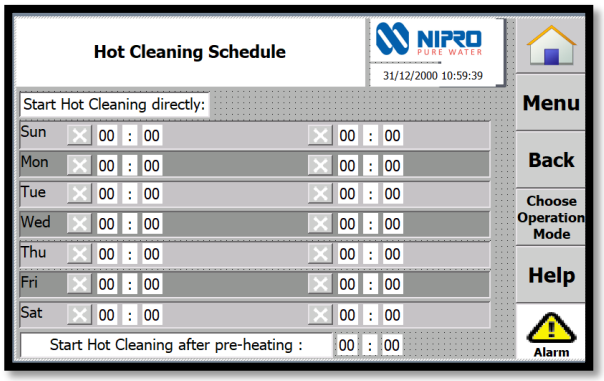
7.12.3 Hot Cleaning timer

These options are available for **Phoenix One DS+** and **Phoenix One DS+ FH** only.

Select **Hot Cleaning Schedule**:



Select the weekday when Hot Cleaning is needed. For Phoenix One DS+, a preheating option is available. This option allows the hot water tank to be filled and pre-heated during normal operation and the Hot Cleaning starts at the set time.

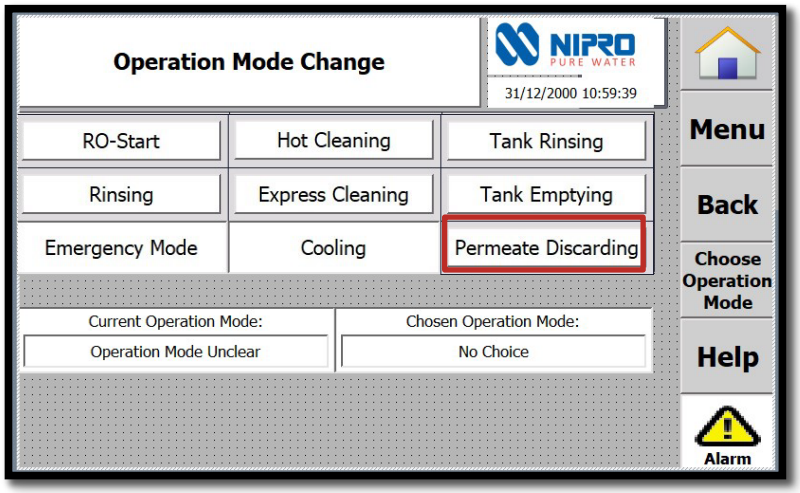


8 Maintenance and cleaning

8.1 Drain permeate

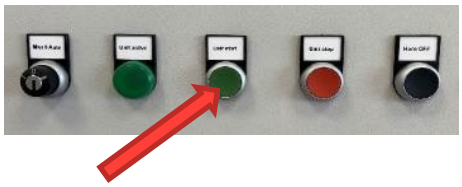
In the Mode “permeate to drain”, the complete permeate will be discarded to the drain at the ring end. The concentrate discharge is 100%.

Select **Choose Operation Mode** and select **Permeate Discarding** mode:



Newly selected mode is displayed in pre-selected window.

- Open ball valve permeate to drain **(Phoenix One DS only)**
- Start **Permeate Discarding** by pressing the green button.



Manual ball valve permeate to drain for Phoenix One DS only.

8.2 External Cleaning

A slightly damp, lint-free cloth can be used to remove dirt stains and dust from pipes and other surfaces.

Do not clean the device with solvents.

Stains from softening salts or disinfectants must be removed immediately.

8.3 Maintenance Intervals

No service or maintenance work may be carried out during treatment.

Measure	Period	Notes	Responsible
Change pre-filter	2 months or after pressure drops >1 bar	If the filter shows discoloration, a change must be performed as well.	User
Fill salt at softener	Daily		User
Hot water sanitisation	1 per week	Circulation time shall be at least 1 hour at 85°C. Relevant for variants: Phoenix One DS+ Phoenix One DS+ FH	Manufacturer or persons authorized by manufacturer
Chemical disinfection	If needed and once per year (preventive). or Action level is reached (TVC* 50 CFU/ml or endotoxin 0.125 EU/ml) *Total viable microbial count	Concerned products: Phoenix One DS	Manufacturer or persons authorized by manufacturer
Chemical disinfection	As needed and once per year (preventive), or Action level is reached (TVC 50 CFU/ml or endotoxin 0.125 EU/ml)	If units of combination for hot water sanitization are available: Phoenix One DS+ Phoenix One DS+ FH	Manufacturer or persons authorized by manufacturer
Maintenance	Yearly		Manufacturer or persons authorized by manufacturer
Safety related check	Every 2 years		Manufacturer or persons authorized by manufacturer
Microbiological analysis	Every 3 months (in accordance with ISO 23500-3:2019)		User
Chemical analysis	Every 12 months		User

	(in accordance with ISO 23500-3:2019)		

Not replacing the filter or replacing it too late can lead to damage of the reverse osmosis.

Interval and parameter of chemical disinfection must be confirmed during commissioning.

Interval and parameter of hot water sanitisation must be confirmed during commissioning (Phoenix One DS+ and Phoenix One DS+ FH only)

After maintenance and/or changes at the system, a chemical disinfection needs to be carried out.

After maintenance and/or changes at the system, a hot water sanitisation needs to be carried out. (Phoenix One DS+ and Phoenix One DS+ FH only)

After opening the system, a chemical disinfection needs to be carried out.

After opening the system, a hot water sanitisation needs to be carried out. (Phoenix One DS+ and Phoenix One DS+ FH only)

8.4 Pre-filter Replacement

1. Stop the device by pressing the red button.

2. Close the membrane valve (2) by turning it clockwise.

3. Open the filter casing with the filter key by turning it clockwise.

4. Unscrew the blue union nut. Pull it away (downwards) together with the filter casing.
5. Remove the old filter.
6. Empty the filter casing.
7. Unpack the new filter and set it in the casing.

8. Screw the filter casing back in (counterclockwise). Ensure that the filter is centred.
9. Reattach the filter casing using the filter key.

10. Reopen the membrane valve. Ensure that the filter is not leaking.

When the system is switched on again, there may be strong hissing noises.

8.5 Replacing sterile filter of hot tank

These options are available for Phoenix One DS+ only.

Risk of Scalding!
Do not replace the sterile filter during hot cleaning.

1. Turn the upper part of the filter casing anticlockwise.

2. Remove the filter casing.

3. Pull out the old filter upwards.
4. Spray surface disinfectant onto the filter seating in the lower part of the filter casing.

5. Remove the filter from the packaging and insert.
6. Replace the upper part of the filter casing and turn clockwise.

8.6 Chemical Disinfection

A chemical disinfection should be kept to a minimum and if required according to IFU.

Disinfection may be performed only by **NIPRO Pure Water** or by **instructed** persons.

Caution when handling disinfectants!
Peracetic acids can cause damage to your health. Always **read** safety **instructions** before handling.

Before the next **dialysis, each** consumption point must be tested for **disinfectant traces.**

8.7 Microbiological Inspection

Necessary Values
(These values are in accordance with ISO 23500.)

- Pathogens <100 CFU/ml no traces of *Pseud. aeruginosa* and *E. coli*
- Endotoxins <0.25 EU/ml

Inspection Interval

Inspection of permeate every 3 months.

Inspection Method

Pathogen count determination:

Nutrient medium: TGEA (OXID Nr.CM 127), R2A
Incubation temperature: 22°C ± 2°C

Endotoxin(s) determination:

Method: GEL-Clot; Cromogen; Turbid metric

9 Malfunction

The device discerns between notifications and alarms. Notifications are simply for information; the appropriate measures will be started automatically. Alarms, on the other hand, will always result in the device shutting down.

Notification / Malfunction	Meaning	Measure	Notes	Error Code
Display remains dark, the device does not start	Power supply is missing.	Is the power supply connected? Check the main switch, power cable, and building circuit breaker.		N.A.
Green light is lit but the device does not produce permeate	Pump will not start.	Check the pump's motor protection fuse. Check water level in break tank. Contact NIPRO Pure Water Service.	The pump is blocked for one minute after a low water alarm.	N.A.
Unit will no longer start upon pressing the green button	Undefined device state.	Turn off the main switch and turn it back on after 3 seconds.		N.A.
Unit automatically shuts down on its own when not being used for dialysis	Automatic shutdown has been programmed.	Change programming.	The service password is required to make changes.	N.A.
Error: Insufficient water	Too little or no water is flowing into the device.	Check the water supply and pre-filter.	The device is blocked for one minute after this error occurs. After this minute, the device can be restarted.	911

Error: Conductivity too high	The conductivity is higher than the set range of allowed values. Possible causes: • There is a defect in the membrane. • There is a defect in the sensor.	Contact NIPRO Pure Water.	After a restart, the device will run for 15 minutes. (Conductivity alarm suppressed)	909

Notification / Malfunction	Meaning	Measure	Notes	
Error: Intake temperature too high	The temperature is higher than the set range of allowed values. Possible causes: • Intake water is too warm • No permeate is being extracted	If no permeate is being extracted for an extended period, shut down the device or use the automatic shutdown function	With intake temperature of >25°C, it may be necessary to increase the size of the concentrate drain.	908
Error: Ring pressure max.	The ring pressure is higher than the set range of allowed values.	Open valves on ring end and ring start and reset pressure.	See section 11	913
Error: Ring pressure min.	The ring pressure is lower than the set range of allowed values.	Check the ring line for leaks. Reset ring pressure.	See section 11	912
Error: Leak	During cleaning, the device detected permeate extraction.	Check the ring for leaks.		916
Error: Leak sensor	The external leak sensor has shut down the device.	Check the ring for leaks. Reset the water sensor.		917
Error: Pump P06	The motor protection fuse has been tripped.			901

Too little permeate is being produced	The performance of the membranes is decreasing. This may be caused by one of the following factors: • Blockage • Intake water is getting colder	Check pump pressure; should be 14 bars. To resolve the problem quickly, pump pressure may be slightly increased.	**Only change pump pressure after coordinating with NIPRO Pure Water.**	N.A.
Notification: Conductivity rising	Conductivity has exceeded the 1st limit value (HL).	**No immediate measure necessary.** The device will automatically start a cooling program.	Should this notification be generated often, the device should be inspected by NIPRO Pure Water.	918
Notification Temperature rising	Temperature has exceeded the 1st limit value (HL).	**No measure necessary.** The device will automatically start a cooling program.	During the summer months, this notification may occur more often.	919

Technical Appendix

The settings and functions described in the following pages may be performed only by technically trained personnel.

No service or maintenance work may be carried out during treatment.

10 Fuses

10.1 Over Temperature Safety Fuse

These options are available for Phoenix One DS+ and Phoenix One DS+ FH only.

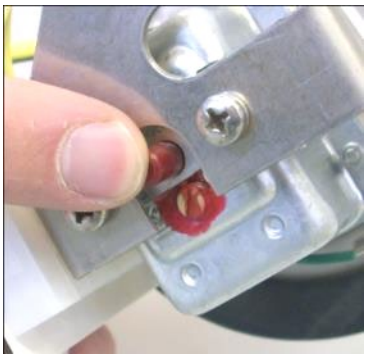
An over-temperature safety fuse is triggered in the heating if temperatures exceed 100 °C. Heating can be restarted by resetting the safety fuse.
If the safety fuse triggers several times, please contact Phoenix Pure Water Service.

Danger to Life!
Switch off the main switch before opening the heating.

Caution! Do not execute this work during hot cleaning.

1. Remove the safety pin and open the clip.

2. Remove the cover carefully



3. Re-activate the safety fuse by pressing on the red safety button

4. Put the cover back carefully. Close the clip and put the safety pin back.

11 Settings

11.1 Setting Ring Pressure (Permeate Pressure)

Increasing the permeate pressure will lead to lower permeate performance.

1. Press the green button to start the device.
2. Select Ring Pressure from the Info menu.

3. Remove the black protection cap from the valve.

4. Loosen the counter nut.

5. Use an Allen wrench to set the pressure. The pressure level will be shown on the display.
6. Retighten the counter nut.
7. Reattach the protection cap.

Pressure may be set only between 3 and 6 bars. If a higher pressure is required, the limit values will need to be adjusted.

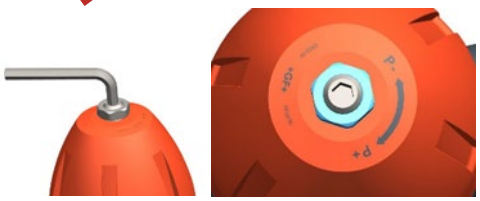
11.2 Setting Concentrate Pressure

Carry out work conscientiously!
The concentrate pressure directly affects the concentrate drain amount. Setting the pressure too high will consume more water. Setting the pressure too low can lead to damage of the membrane.

1. Remove the black protection cap.

2. Loosen the counter nut.

3. Start the device.

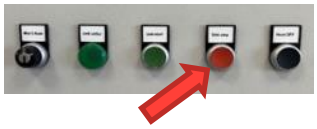


4. Set the concentrate pressure to 1 bar ± 0.2 by turning the concentrate valve (emergency operation valve) (26). The pressure can - read 0-4 bar on the manometer.

12 Replacement of the reverse osmosis membrane

Beware of pressure!
Membrane tubes are under pressure. Open carefully!

Visual check of damage to the new membrane before installation is required. The preservation solution must be clear.



1. Stop the device by pressing the red button.

2. Open the wing screw and take off the clip**.**

3. Lift the module cover by using a screwdriver.

4. Take off the cover.

5. Take the end plug out of the module.

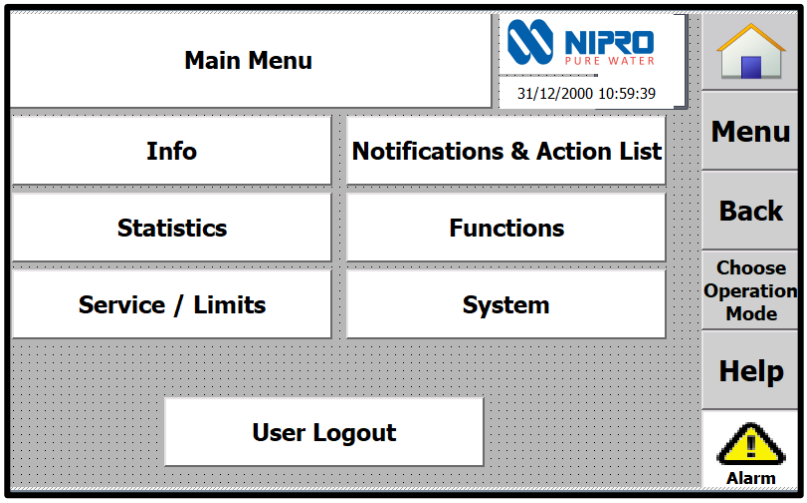
6. Pull the membrane out by using a tong.

7. Reinstall the new membrane in reverse order. **Pay attention to the flow direction and position of the gasket.**

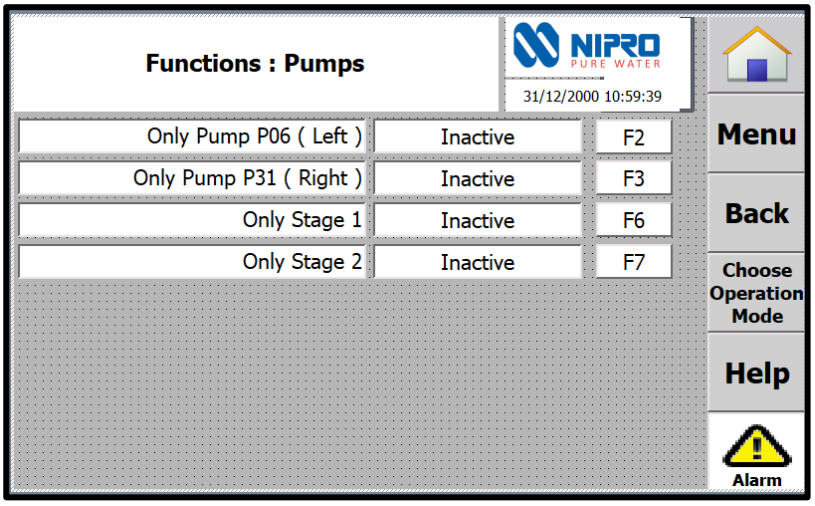
Rinse the membrane!
After the new membrane has been installed, the mode “**Permeate Discarding**” must be turned on for 20 minutes.

13 Decommissioning of a pump

Select **Functions** from the **Main Menu**:



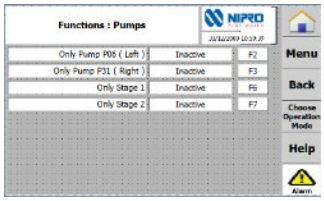
Select the needed stage of operation.



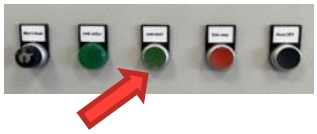
Please Note! : Stage 1 & 2 options are only available for DS variants. Pump options are only available for single stage variants. Pump P31 = Single stage variants. P33 = Double stage variants.

If only stage 2 is selected, the speed of the second pump must be changed (see 13.1).

13.1 Emergency operation only “2nd Stage”



1. As already described in section 14, select emergency operation “only 2nd stage".



2. Press the green button.

3. Set the value by pressing the arrow button at the pump.

   (Pump pressure 10-15 bars)

14 Disinfection

14.1 Disinfection Instructions

Disinfection may be performed only by **NIPRO Pure Water** or by **instructed** persons.

Caution when handling disinfectants!
Peracetic acids can cause damage to your health. Always **read safety instructions** before handling.

Carry out work conscientiously! **Danger!**
Ensure that no dialysis can be performed while disinfecting. Approve only a thoroughly rinsed system for treatment use.


CAUTION!
While using chemicals.
Wear safety gloves and safety goggles during the tasks described here.


CAUTION!
Do not eat, drink, or smoke while working.

Disinfectant: MINNCARE® Cold Sterilant (Article Nr.:489) **Note:** Use of Dialox™ is also possible.


Detection method: MINNCARE® Test Strips Residual (Article Nr.:490)
MINNCARE® Test Strips 1 Indication (Article Nr.:491)

1. Fill cold sterilant into the break tank (1 litre).
2. Start rinsing.
3. After 5-10 minutes, test the back flow into the break tank for disinfectant.
4. If the test is positive (blue test strips), turn off the device for 40 minutes and make sure it does not restart or operate during this time.
5. Start the permeate drain program. (Open the three-way permeate drain valve for variants without motor rotary valve if necessary.)
6. After 30 minutes:

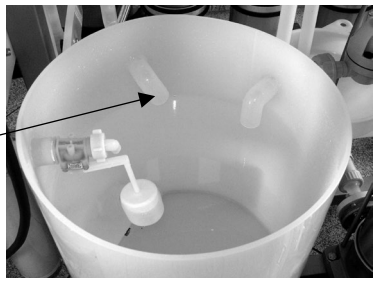
    - Start emergency operation 1st stage for 5 minutes to flush the line between 1st and 2nd stage.
    - Start emergency operation 2nd stage for 5 minutes to flush the pipeline between the pumps.
    - Start “Permeate to Drain” again for 30 mins.
    - Perform these procedures at least 2 times.

7. Test the permeate back flow at the nozzle in the break tank (see image) for disinfectant:

    - If disinfectant is still present (test strips), return to **step 6.**
    - Otherwise, proceed to **step 8.**

8. Test all consumption points for disinfectant. If disinfectant is still detectable, return to **step 6.**
9. Document disinfection (see section 14.2).

Permeate back flow



Break Tank

Three-way valve to drain position.

Before the next dialysis, each collection point must be tested again with Test Strips Residual for the absence of disinfectants.

*** Free of disinfection means 0ppm -** no discoloration of the test strip.
See the color scale on the packaging of the test strip residual.

14.2 Disinfection Protocol

Dialysis center	
Section	
Contact person	
Function	
Street / Bldg. No.	
Postcode / City	
Unit model	☐ Phoenix One ☐ Phoenix One DS
Heating Unit	☐ Hot Tank (+) ☐ Flow Heater (+ FH) ☐ None
Serial number	
Ring line length	

Disinfectant type	Inoculated amount in litres	
Wash time in minutes	Wait time in minutes	
Rinse time in minutes	Tested for disinfectant at all dialysis stations and results were negative?	☐ Yes

If disinfection was performed, the operator is obligated by his/her signature to retest all dialysis stations for **disinfectant**. This test must be conducted before each dialysis is performed.

_____

Date

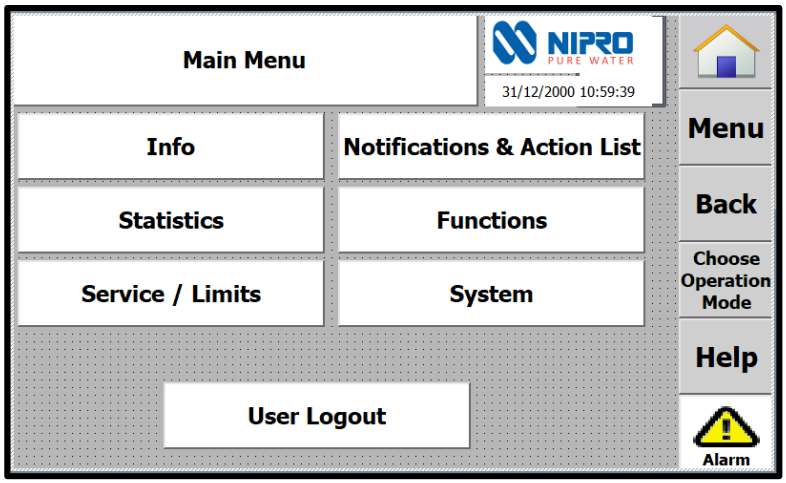
_____

Signature

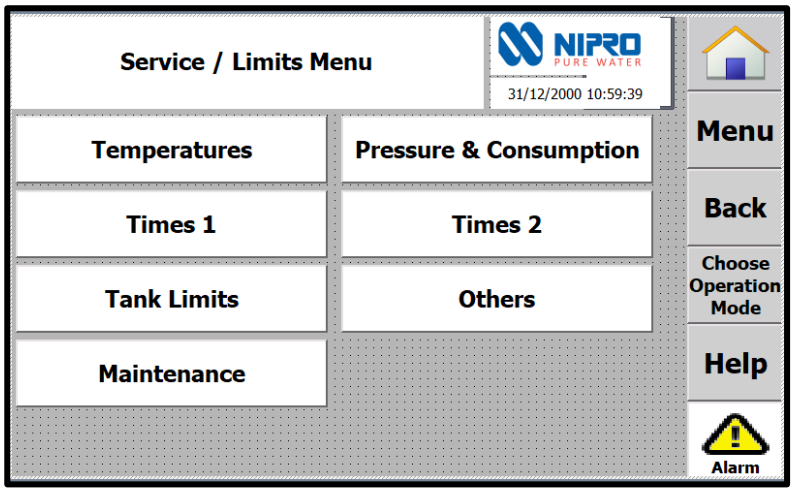
15 Service/Limits

Limit values can be changed here. This section can only be accessed with a password.

Go to main **Main Menu** and select **Service / Limits** and enter the password:



Select the required menu to set parameters:



HL (High Level) = Notification will be generated (1st limit value)
HHL (High High Level) = Alarm point (device will be shut down)

Limit	Meaning	Default	Notes
Temp. Permeate HHL	Max. permeate temperature. Reaching this temperature will lead to a shutdown.	38°C	
Temp. Permeate HL	At this temperature, a cooling program will start. (Concentrate drain will be increased)	32°C	
Temp. Ring end	The temperature to be reached at the ring end during hot water sanitization.	80°C	*One DS+* *One DS+ FH*
Temp. Cool	The temperature to be cooled to after hot water sanitization.	35°C	*One DS+* *One DS+ FH*
Temp. Tank	The temperature the tank will be heated to.	85°C	*One DS+*
Ring pressure min.	If the ring line pressure drops below this pressure, the device will shut down.	0.5 bar	
Ring pressure max.	At this value, the device will shut down due to pressure that is too high.	5 bars	
Conductivity max.	At this value, the device will shut down due to conductivity that is too high.	100 µS/cm	
Conductivity Alarm	At this value, the yield will be reduced.	50 µS/cm	
Yield	Desired yield.	80%	
Reduce yield	If the limit value “Conductivity alarm“ is reached, the yield will be reduced by the value entered here.	10%	
Yield hard water	If an error in the softening device is registered by the external hardness gauge, the yield will be reduced to this value.	60%	
Rinse time	Duration of the idle rinsing.	5 min	
Rinse interval	Interval until the next rinsing.	180 min	
Permeate min. delayed	If no permeate is required for longer than the value entered here, the device will automatically shut down.	5 h	
Heat max.	If the set temperature is not reached within this amount of time, the hot water sanitization will abort.	300 min	*One DS+* *One DS+ FH*
Circulation	Circulation time during hot water sanitization.	20 min	*One DS+* *One DS+ FH*

Limit	Meaning	Default	Notes
Pre-rinse hot water sanitisation	Rinse time for hot water sanitization.	5 min	*One DS+*
Circulation quick cleaning	Circulation time during quick cleaning.	10 min	*One DS+* *One DS+ FH*
Pre-rinse quick cleaning.	Rinse time for quick cleaning.	3 min	*One DS+*
Clearance Heating	Minimum fill level to start heating.	100 l	*One DS+*
Contents hot water sanitization	Tank fill level for hot water sanitization.	300 l	*One DS+*
Contents quick cleaning	Tank fill level for quick cleaning.	150 l	*One DS+*
Contents rinse tank	Required rinse amount for cleaning the tank.	100 l	*One DS+*
Contents empty	The tank will be displayed as empty at or below the value entered here.	5 l	*One DS+*

16 EMC manufacturer’s Declaration

Electromagnetic emissions and electromagnetic immunity

The RO device is intended for use in electromagnetic environments as described below.
The customer or the operator of the RO should ensure that the device is used only in such an environment.

This EMC manufacturer's declaration is based on the use of the power supply unit from Phoenix Contact.
The power supply is installed in the control cabinet.

Warning
The use of other accessories, as well as other power supply units and cables than specified can lead to increased emissions and/or reduced interference immunity of the RO.

Requirements
During the interference immunity tests, the temperature accuracy and conductivity accuracy were checked.

Emission measurement	**Compliance**	**Electromagnetic environment - Guidelines**
RF emission in accordance with CISPR 11 / EN 5511	Group 1	The device only uses RF energy for its internal function. Its RF emissions are therefore very low and interference to nearby electronic devices is unlikely.
RF emission in accordance with CISPR 11 / EN 55011	Class B	The device is suitable for use at any location, including residential areas and facilities directly connected to the public low voltage grid for residential buildings.
Harmonics in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations/flickers in accordance with IEC 61000-3-3	Fulfilled	

Immunity test	**Test level – IEC 60601**	**Compliance level**	**Electromagnetic environment - Guidelines**
Discharge of static electricity (ESD) in accordance with EIC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor should be made of wood, concrete, or of tiles. In case of synthetic flooring, relative air humidity should be at least 30%.
Electrical fast transient burst/immunity test in accordance with IEC 61000-4-4	±2 kV for power cables ±1 kV for input and output cables	±2 kV for power cables ±1 kV for input and output cables	The quality of supply voltage should comply with that of a typical commercial or hospital environment.

Surge voltage in accordance with IEC 61000-4-5	±1 kV outer conductor-outer conductor ±2 kV outer conductor-ground	±1 kV outer conductor-outer conductor ±2 kV outer conductor-ground	The quality of supply voltage should comply with that of a typical commercial or hospital environment.
Voltage drops, short interruptions, and fluctuations in supply voltage in accordance with IEC 61000-4-11	95% voltage drop for ½ period 60% voltage drop for 5 periods 30% voltage drop for 25 periods 95% voltage drop for 5 s	95% voltage drop for ½ period 60% voltage drop for 5 periods 30% voltage drop for 25 periods 95% voltage drop for 5 s	The quality of supply voltage should comply with that of a typical commercial or hospital environment. If the device is to continue functioning uninterruptedly in case of power interruptions, it is recommended that the device be operated via uninterrupted power supply or a battery.
Magnetic field at supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	In supply frequency, the magnetic fields should comply with the values characteristic of locations in a typical commercial or hospital environment.
Conducted RF disturbances in accordance with IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms 150 kHz to 80 MHz	When operating portable or mobile RF communication devices (transmitters), a safety distance should be observed to all parts of the device, including cables, calculated based on one of the following equations depending on the transmission frequency. Recommended safety distance: $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Whereby P is the maximum nominal output of the respective transmitter specified by the manufacturer in Watts (W), and d is the recommended safety distance in meters (m). The field strength of stationary RF transmitters, which is definable via electromagnetic site survey **a.**, should be below the compliance level of the individual frequency ranges **b.**
Radiated RF disturbances in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

			Disturbances are possible near devices which bear the symbol below. 
Note: These guide values may not apply to all situations. Spreading of electromagnetic waves is also influenced by absorption and reflection via buildings, items, persons, and animals.			
a. The field strength of stationary transmitters (e.g., base stations of mobile phones (mobile/cordless) and mobile radios, amateur radio stations, AM and FM radio, and TV transmitters), cannot be theoretically calculated in advance. To identify the electromagnetic environment regarding stationary RF transmitters, an electromagnetic site survey should be considered. If the field strength identified at the location at which the device is used exceeds the RF compliance level specified above, the device should be closely observed. It may be necessary to take additional measures (e.g., changing the alignment or transposition of the device). **b.** Across the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.			

Recommended minimum distances between portable and mobile RF communication devices and the RO

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