NIPRO MEDICAL EUROPE

Instruction for use RO Systems | Variant: RO Medical

February 10, 2022 | Version: 3

Written by: NIPRO Pure Water

Document ID: MM 4037 RO-MED-IFU-1001

LNG: EN

Table of Contents

CE 0297

For the reverse osmosis type RO Medical, 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 RO Medical.
Please keep this instruction for use readily available and near the unit.

This instruction for use applies for the units with the serial number:

NIPRO Pure Water GmbH
Werner-von-Siemens-Str.2-6
76646 Bruchsal – Germany

Tel.: 0049 7251-32 19 7810
Fax: 0049 7251-61 89 943

Rev#	Date / Name	Description
1	04.10.22	First edition MDR
2	18.10.22	Update in various sections
3	10.02.23	Update of Warnings

1 General

This Instruction For Use is for the following variants:

- RO Medical

RO Medical:
Is a one-stage stainless steel RO system with chemical disinfection of the loop and device. Depending on the number of membranes, this system provides 350-1400 L/h pure water.

1.1 Water 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, and 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)

(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 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 RO Medical Basic may be combined with the following devices:

Permeate Tank
City Water Tank

1.4 Accessories and Consumable

1.4.1 Accessories

- Distribution loop/permeate loop

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

1.4.2 Consumables

- RO-Membrane item reference: SP-872

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

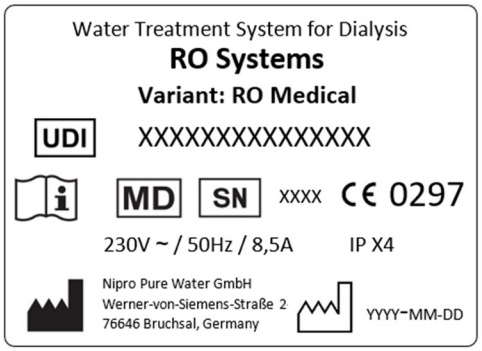
Protects system against frost and moisture.

Protects against strong shocks and impacts.

Only move unit upright and with an appropriate lift.

The system may be stored for a maximum of 1 year.

1.9 Product label



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
IPX 4	Protection against the ingress of liquids. Here, splash-water protection
	Manufacturer
	Manufacturing date

1.10 Warning on the Unit

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

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

The personnel should 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 RO Medical is a water purification system that uses reverse osmosis to remove microbiological, organic, and inorganic contaminants from the tap water.

The purified water is used to dilute dialysis concentrate to form dialysate 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 system may only be operated in perfect condition.
Before operating, check the following:

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

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

The system does not produce water for injections.

The system has pressurized parts.

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

The water treatment system RO Medical Basic may be used only for permeate supply of dialysis devices which have a temperature measurement (permeate temperature).

The system 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 center including:

- Dialysis center 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 centers with a restricted accessibility. These so-called utility or osmosis rooms are only accessible by trained staff.

2.2 Intended patient population

The device does not have direct contact with the patient. The permeate that the device produces 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 RO Medical Basic if the operating instructions are followed.

The device can automatically start 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 70 dB (A).

4 Technical Data

4.1 Permeate performance / Feed quantity

Temperature	1 Membrane	2 Membranes	3 Membranes	4 Membranes
15° C	350 l/h	700 l/h	1050 l/h	1400 l/h

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	<1500µS/cm
pH	6.5-8.5
Pressure	1-3 bar

4.3 Connections

Water feed	1” internal thread
Pure water connection	Hose nozzle d20
Drain	HT 40

4.4 Electrical data

Supply voltage	220-230 V, 1 Phase, 50/60 Hz
Fuse	Automat 16 A-K, Fi ΔI 30mA
Current consumption	9.9 A x 60 Hz
Degree of pollution	1

4.5 Display system

Conductivity	0-1000 µS/cm ±5%
Pressure switch	0-10 bar ±5%
Flow (sight glass)	300-3000 l/h ±5% 100-1000 l/h

4.6 Ambient temperature

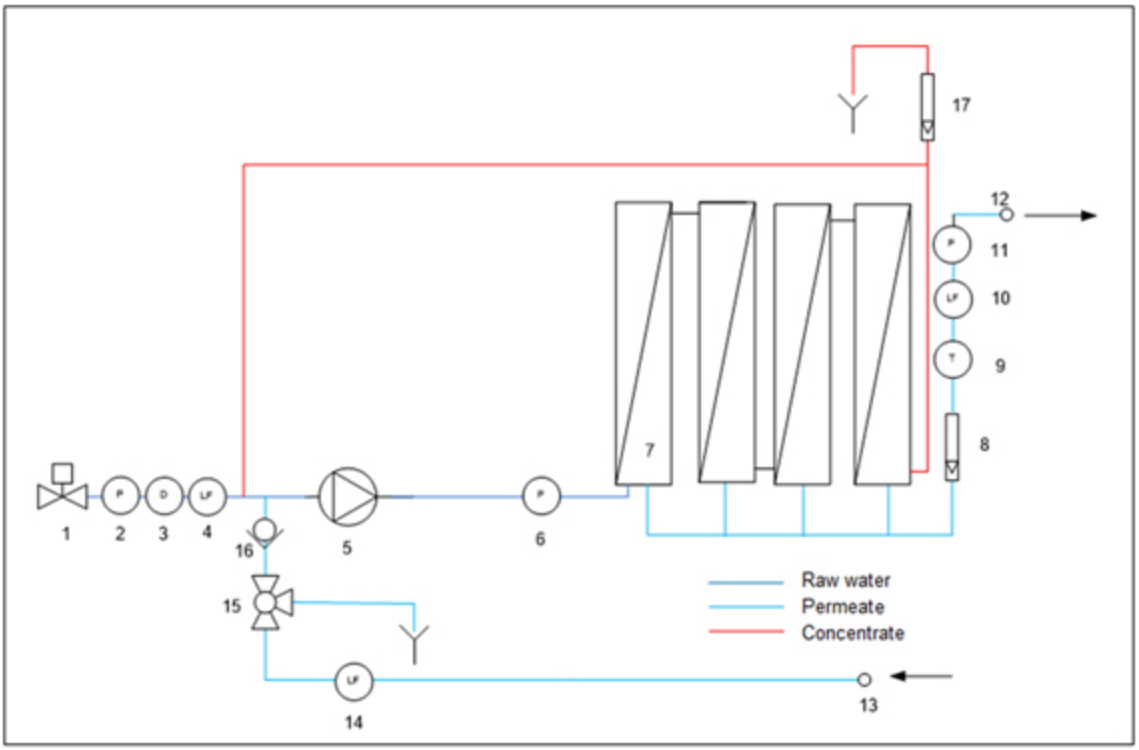
Storage / transport	1-40°C
Operation	10-35°C
Relative humidity	< 90% at 20°C not condensing
Air pressure	795-1062 hPa

4.7 Size

Size (LxWxH in mm)	100x500x1640

5 Description of the device

5.1 Flow Chart



1. Magnetic valve inlet
2. Pressure switch input
3. Disinfection point
4. Conductivity input
5. Pump (pressure 10-13bar)
6. Manometer (pressure 10-13 bar)
7. Reverse osmosis membrane (1-4 pieces)
8. Permeate flow rate indicator
9. Temperature sensor
10. Conductivity probe permeate flow
11. Permeate pressure switch
12. Connection back flow hose nozzle d20
13. Connection back flow hose nozzle d20
14. Conductivity ring back flow
15. Discard three-way ball valve permeate
16. Check valve
17. Flow indicator concentrate outflow

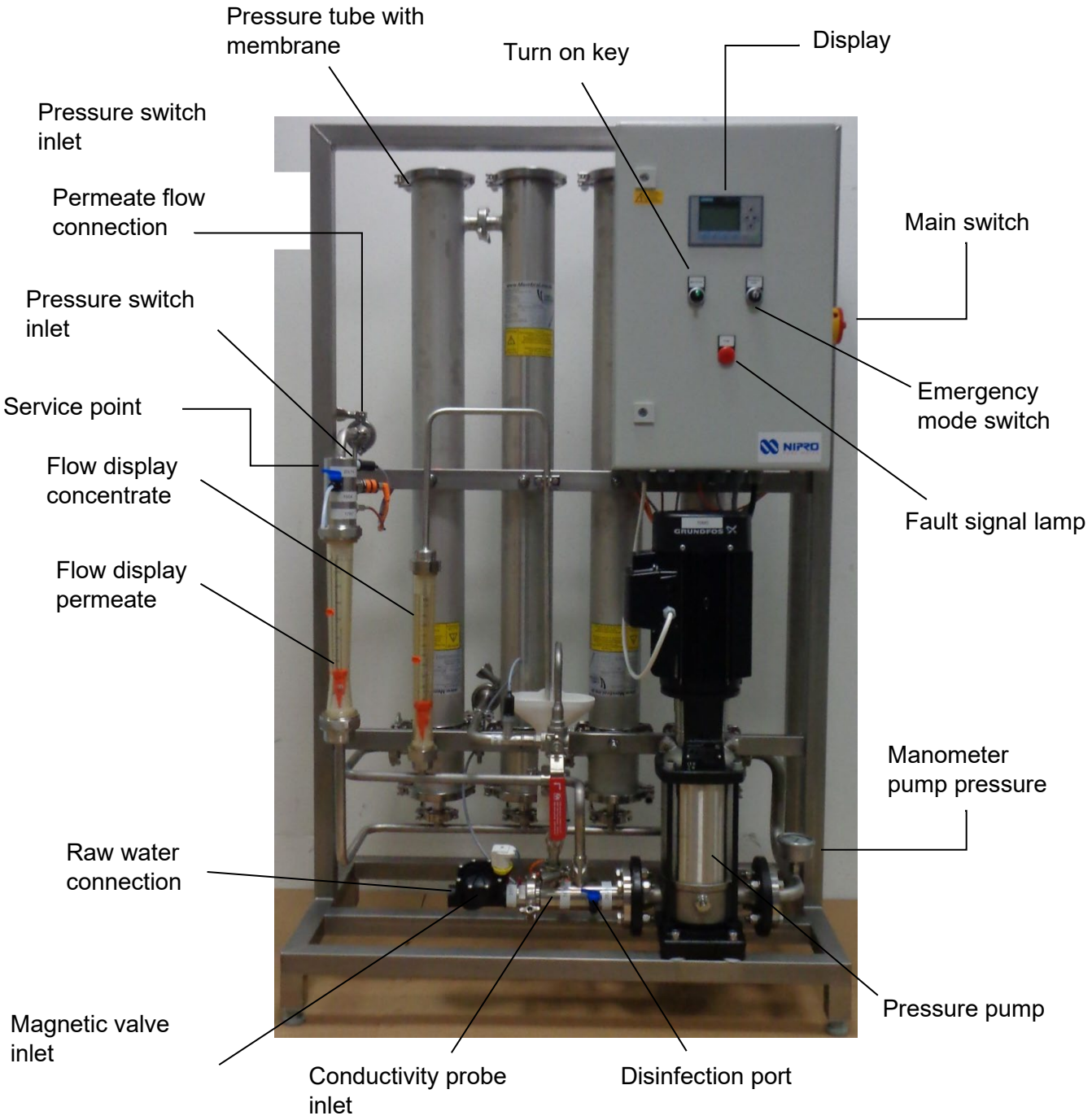
5.2 Operations sequence

If the toggle switch is turned to the ‘On’ position, the magnetic valve (1) opens and water flows into the system. After a short delay, the pump (4) will start.

Now the water is pressed into the reverse osmosis membrane at a pressure of 10-15 bar. The flow is divided into a permeate and a concentrate part. The permeate content flows through the flow indicator (7), the temperature sensor (8), the conductivity probe (9), and the pressure switch (10) into the ring line. The unused permeate flows back into the RO Medical via the connection (12).

To save water, the concentrate portion is divided up again - one portion is given into the drain via the flow indicator (17), the other is fed back in front of the pump.

5.3 Components



6 Installation

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

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 (frost-proof)
- 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.

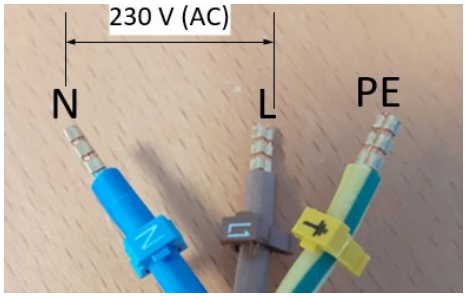
Only operate the device with the necessary water pre-treatment.

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

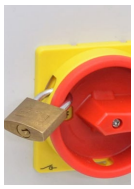
6.3 Electrical installation

The installation may be performed only by a qualified electrician.

The device must be supplied by a permanent connection, connectors are not valid. The disconnection must be via the main switch at the control cabinet. The power cord must be provided with a strain relief.



Connection cable RO Medical



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

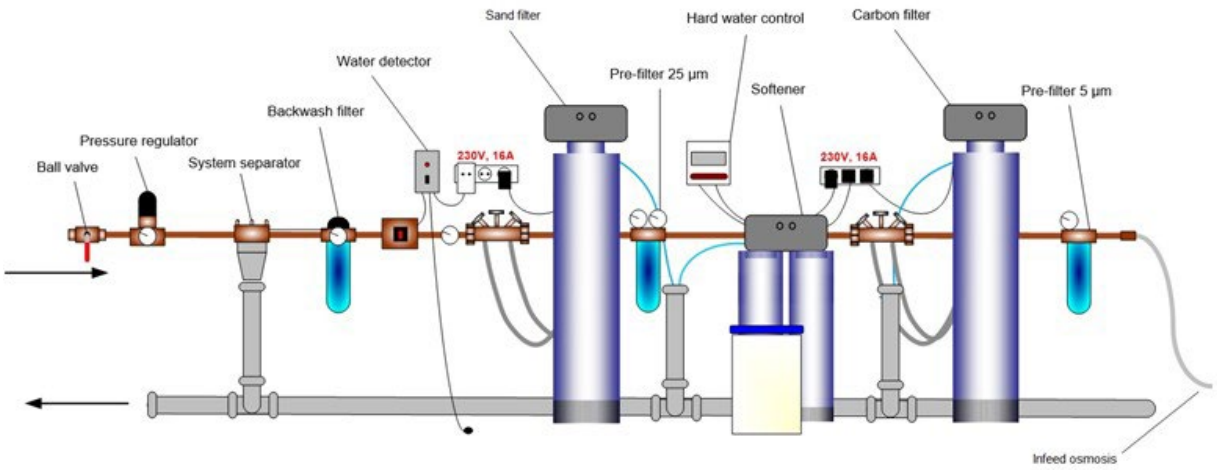
Safety class I

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 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!
Connect the RO Medical after that, 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.

6.5 Commissioning

Caution, device damage!

The device must be preconnected by a suitable pre-filter and a softening system as well as a pressure reducer.

For first commissioning, disinfection is required.

6.6 Initial installation

1. Connect and check the raw water connection (1), permeate flow (2), permeate back flow (3), and waste water (4).


2. Open the inlet valve manually. To do this, turn the white magnet coil 45° counter-clockwise.

   Now, water is running into the device.

3. Carefully open the screw for the pump venting until a water outlet can be seen. Then close the screw again and reset the solenoid.

4. Make sure that the wall-mounted taps at the start and end of the ring are open.

5. Start the device using the toggle switch.

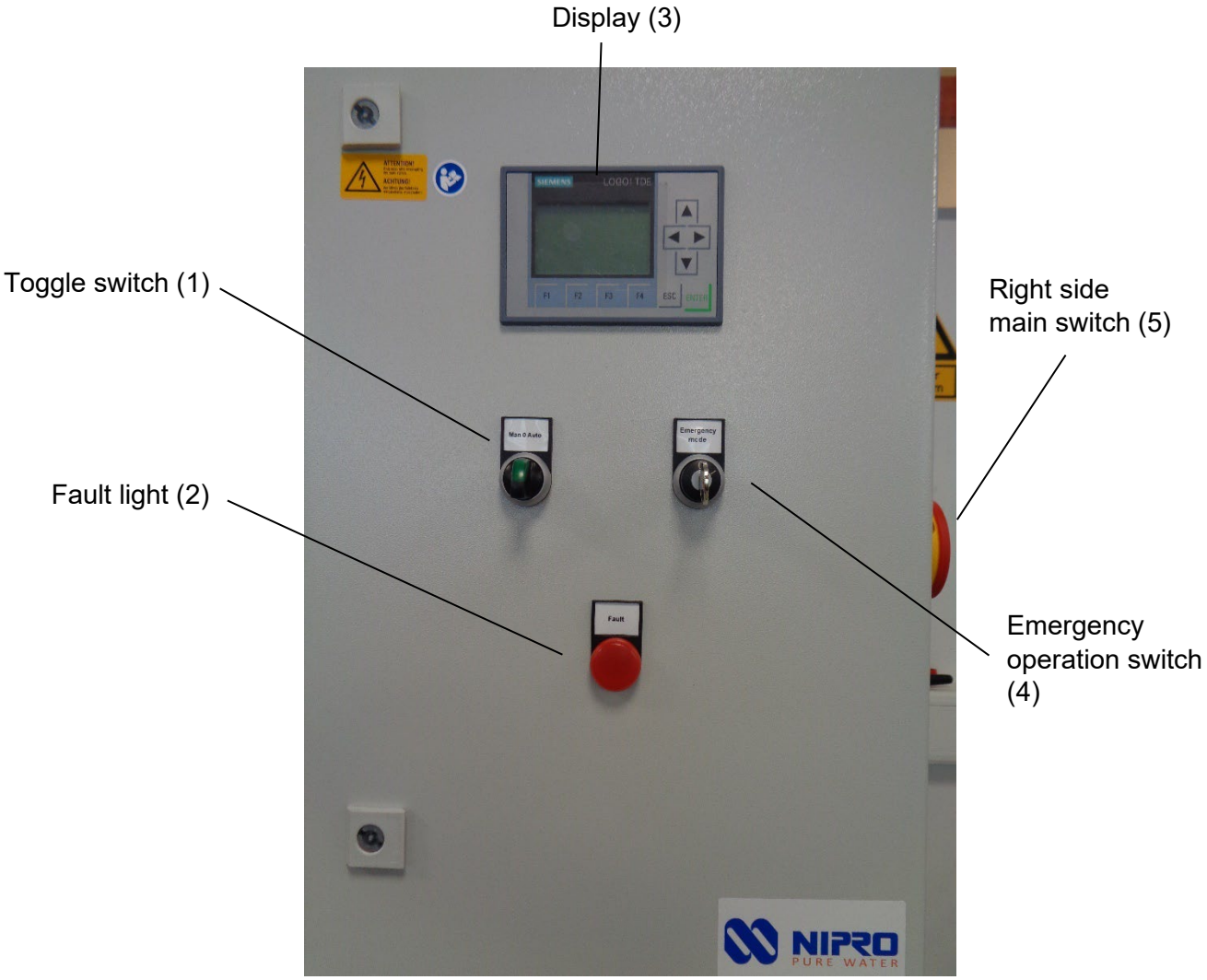
6. Check all connections for leaks.

7. Open the shut-off valve permeate to the drain.

8. Allow the device to discard permeate for at least 30 minutes.

7 Operation

7.1 Control Panel



1. **Toggle switch system on**
   This is used to switch the device on and off.

2. **Fault light**
   Lights up when there is a fault.

3. **Display**
   Displays conductivity and faults.

4. **Key switch emergency operation**
   The device can be switched to emergency operation here.

5. **Main switch**
   With this, the device can be switched off completely.

7.2 System on / off without permeate tank

System on
To start the device, turn the toggle switch to the right (on position).
The green lamp lights up.
The pump starts after a short delay.

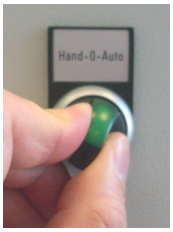
System off
Reset toggle switch (position 0).
The green lamp goes out.
Pump stops.

If the device is switched off using the toggle switch, the rinse intervals are carried out as programmed. If no rinsing is to take place, the device must be switched off completely at the main switch. However, this is only recommended for decommissioning.

7.3 Device on / off with permeate tank

If the RO Medical is connected to a permeate tank, the toggle switch must be set to "Auto". Since the device switches off automatically when the tank is full, it is not necessary to reset it to position 0.

Caution, danger of overflow!
If the RO Medical-Basic is operated with a permeate tank, the system may only be started via "Auto". **In the "On" position, there is a risk of overflow**.



Device on
To start the system, turn the knob switch to the right.
If the permeate tank is empty, the system starts automatically.
If the tank is already full, the osmosis waits to start until the level in the tank drops.

7.4 Emergency operation

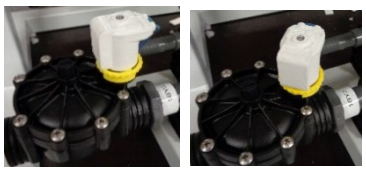
Caution!
If the HC Medical hot cleaning system is connected, the following steps must be carried out before emergency operation:

1. Check HC Medical for pending alarms.
2. Carefully touch the lines of the HC Medical and check whether they are warm.

Do not carry out emergency operation when the lines are warm!!

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

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



1. Open the inlet valve manually. To do this, turn the white magnet coil 45° counter-clockwise.

   Now, water runs into the device.

2. Set the key switch to position 1. Pump starts up.

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

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

7.5 Operating display

System Off **Set: 90:00** **Actual: 25:22** **Until rinsing**	**Device is off**. Rinsing interval (target) is set to 90 minutes. 25:22 min have already passed. If the actual value reaches the set point, the system goes into rinsing.
System On **LF Flow 008** **LF Backflow 008** **Microsiemens**	**Device is on**. The current conductivities are displayed.
Rinsing **LF Flow 008** **LF Backflow 008** **Microsiemens**	**Device is being rinsed.** The current conductivity is displayed.

8 Malfunction

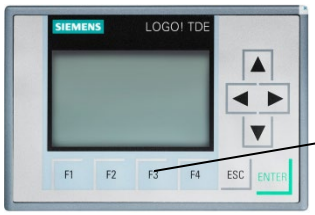
The device discerns between notifications and alarms. Notifications are simply for information; the appropriate measures will be started automatically. Alarms on the other hand will always result in the device shutting down.

8.1 Error messages

Display	*Error Description*	*Troubleshooting*
Error Motor protection triggered Check 1Q5	The motor protection switch of the pump has been triggered. Check motor protection switch. If this alarm occurs frequently, the pump must be checked.	Turn the motor protection switch back to position 1.
Error Over temperature Check 17R7	The temperature of the permeate has reached 38°C. The system switches off to protect the membranes.	The system must be cooled (see next page).
Error Over pressure Check 16S4	The permeate pressure has exceeded 6 bars.	Check the start and end of the ring taps. Check the setting of the permeate pressure retention valve.
Error Inlet water missing Check 16S5	The pressure switch 1 has responded.	Check water inlet.
Error Conductivity	The conductivity has exceeded the limit of 100µS/cm.	There is probably a defect in the membranes. **Call service.**

8.2 Clear alarms

Reset the error message
Follow the notes in Display.



Reset the alarm by pressing the F3 key.

9 Maintenance and cleaning

9.1 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.

9.2 Maintenance Intervals

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

Measure	Period	Notes	Responsible
Fill salt at softener	Daily		User
Chemical disinfection	If needed and once per year (preventive) or action level reaches (TVC 50 CFU/ml) or endotoxin 0.125 EU/ml)		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)		User
Chemical analysis	Every 12 months (in accordance with ISO 23500-3)		User

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.

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

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

9.3 Chemical Disinfection

A chemical disinfection should only be performed upon a new installation or when high pathogen values are encountered.

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

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

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

9.4 Microbiological Inspection

Necessary Values

(According to 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:

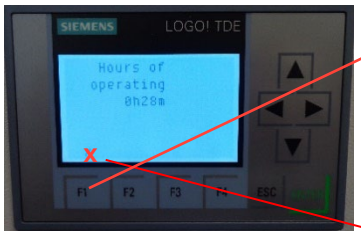
Nutrient medium:	TGEA (OXID Nr.CM 127), R2A
Incubation temperature:	22°C ± 2°C

Endotoxin(s) determination:

Method: GEL-Clot; Cromogen; Turbid metric

10 Display / Parameter

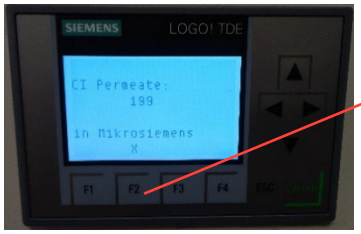
10.1 Retrieval of the operating hours / conductivity records



Press the F1 key. The operating hours are displayed.

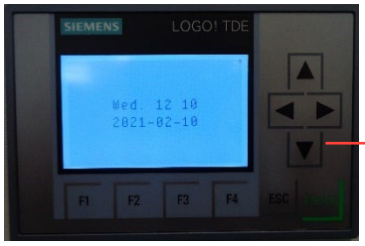
If the key is pressed again, the display changes back to the standard display.

The X indicates which key can be used to switch back to the standard display.



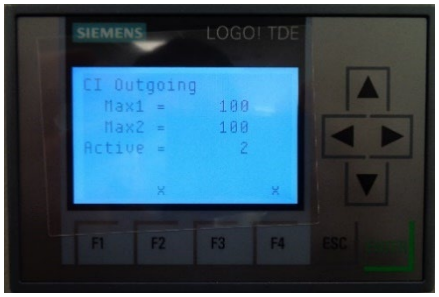
Press the F2 key. The conductivities are displayed.

If the key is pressed again, the display changes back to the standard display.



To view the time and date, press the down arrow.

10.2 Change the conductivity parameter



Press the F4 key and F2 key simultaneously.

The conductivity in the return is displayed.

Press the ESC key for 3 seconds, the first value is marked.

Press ENTER.

Set the value with the arrow keys (up / down). Complete the entry with ENTER.

Press the ESC key.

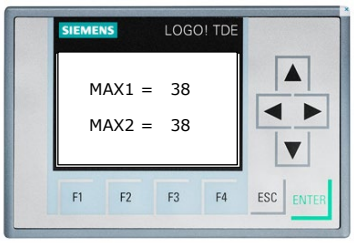
Press the F4 and F2 keys simultaneously to return to the standard display.

Both parameters (MAX1 and MAX2) must be set to the same value.

Standard value = 100 µS / cm

If the conductivity in the back flow reaches the value set here, the conductivity alarm is activated.

10.3 Change parameter temperature



Press the F4 key and F3 key simultaneously.

The temperature is displayed.

Press the ESC key for 3 seconds, the first value is marked.

Select corresponding value with the arrow keys.

Press ENTER.

Set the value with the arrow keys (up / down). Complete the entry with ENTER.

Press the ESC key.

Press the F4 and F3 keys simultaneously to return to the standard display.

Both parameters (MAX1 and MAX2) must be set to the same value.

Default value = 38°C

If the temperature reaches the value set here, the over temperature alarm is activated.
CAUTION!
Max. 40°C is allowed, higher temperatures damage the membranes.

Technical Appendix

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

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

11 Replacement of the reverse osmosis membrane

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

Visual check of damage new membrane before installation is required. Preservation solution must be clear.

The settings and functions described below may be carried out only by technically trained personnel.

1. Switch off the system at the main switch.

2. Open wing screw and take off the clip.

3. Lift module cover by using a screwdriver.

4. Take off the cover.

5. Take the end plug out of the module.

6. Pull out the membrane by using a tong.

7. Reinstall the new membrane in reverse order.
Take care of the flow direction and
position of the gasket.

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

12 Service Parameters

The settings and functions described below may be carried out only by technically trained personnel.

ATTENTION, SYSTEM DAMAGE!
Incorrect settings can lead to damage.

Arrow key down and then press the ESC key. (Service mode)

Then Logo settings> ENTER> Program> ENTER> Set parameters> ENTER> select the appropriate parameter (B001-B040)

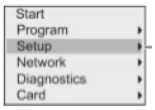
Parameter	Function	default value
T Pump	Pump start time delay	3sec
Time to Rinse	Rinse waiting time	60m
T Rinse	Rinse time	10m
T Conductivity	Conductivity alarm delay at start	2m
W Qty NOK	Dry running protection	5sec
T2 Conductivity	Conductivity alarm delay at operation	30sec
B025	Hours count	
T Temperatur	Temperature alarm delay	10sec
Conductivity	Conductivity adjustment (permeate)	
B040	Timer (auto start)	

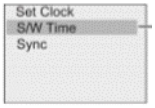
12.1 Adjustment of the conductivity

- Select parameter Conductivity
- "Ax" value = displays conductivity
- Select value "B" and confirm with Enter
- Change the value with the arrow keys (+00001 = current value +1)
- To change in minus, first enter the value and after the change the sign (-00001 = current value -1)
- press Enter
- Press ESC several times (until time is displayed), then arrow key up

12.2 Setting date and time

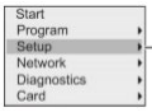
- ▼ key arrow down
- Press ESC
- Select service mode (▼ key arrow down, ESC)
- LOGO Settings <ENTER> Setup <ENTER> Clock <ENTER> Set Clock <ENTER>
- Set the time and date with the arrow keys <ENTER>
- To exit press ESC 5x and ▲ arrow key up

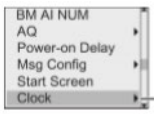


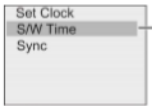


12.3 Summer / Winter time

- Select service mode (▼ arrow key down, ESC)
- LOGO Settings <ENTER> Setup <ENTER> Clock<ENTER>S/W Time – Select the S/W Time







– "④": disables automatic S/W time conversion
– "⑤" represents the start and end of European summertime
– "⑥" represents the start and end of summertime in the United Kingdom
– "⑦" represents the start and end of daylight-saving time (summertime) in the United States prior to 2007
– "⑧" represents the start and end of daylight-saving time (summertime) in the United States in 2007 and later years
– "⑨" represents the start and end of Australian summertime
– "⑩" represents the start and end of Australian/Tasmanian summertime
– "⑪" represents the start and end of New Zealand summertime
– "⑫": Here you can enter any month, day, and time zone difference

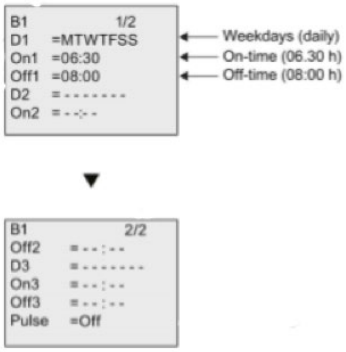
To exit press ESC 5x and ▲ arrow key up

12.4 Auto Start (Timer)

Select service mode

Logo settings < ENTER > Program < ENTER > Set parameters
< ENTER > Select parameter B040<ENTER>

To exit, press ESC 5x and ▲ arrow key up



To set the on-/off- times:
- Move the cursor to one of the parameters of the timer.
- Press ENTER. The cursor is positioned on the day of the week.
- Press up and down key to select one or several days of the week.
- Press right arrow key to move the cursor to the first position of the on-time.
-Set the on-time.
Modify the value at the respective position, using the up and down keys and move to the cursor to the various positions, using the right and left arrow keys.
At the first position, you can only select the value - -:- - (- -:- - means: No on-/off-times set).
- Press right arrow key to move the cursor to the first position of the off-time.
- Set the off-time
- Confirm your entries with ENTER.

The prefix "D=" (Day) has the following meaning: ● M: Monday ● T: Tuesday ● W: Wednesday ● T: Thursday ● F: Friday ● S: Saturday ● S: Sunday

Uppercase letters indicate a specific day of the week. A "-" indicates no selection for the day of the week.

12.5 Service point

The service point can be used for water withdrawal to check water temperature and conductivity.

Service point may only be opened, if operating pressure in the system is reached.
Service point must be closed prior to each system start. Service point may be operated only by **technically-trained personnel**.

13 Disinfection

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. Only approve a thoroughly rinsed system for treatment use.


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


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

Disinfectant: MINNCARE® Cold Sterilant (Article Nr.:489)


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

1. Connect the disinfection pump to the disinfection point.

2. Open the three-way valve permeate to the drain.

3. Start the device.

4. Start the disinfectant pump.

5. Check for correct disinfectant concentration at the permeate outlet with test strips. Use Minncare Test Strips Indication 1% for this.

6. Let the disinfectant pump run until sufficient disinfectant is detected.

7. Close the three-way valve permeate to the drain.

8. Switch off the system.

9. Restart the system after 20 minutes.

10. Open the three-way valve permeate to the drain.

11. Let the system run until no more disinfectant can be detected at the permeate drain. Use Minncare residual test strips for this.

12. Close the three-way valve permeate to the drain.

13. Check that all dialysis stations are free from disinfectants.

Switch the system off during disinfection with a conductivity alarm, clear the alarm, and restart the system.

RISK OF DEATH!

Before the next dialysis, each sampling point must be tested again to ensure that it is free from disinfectants.

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

13.1 Disinfection Protocol

Dialysis center	
Section	
Contact person	
Function	
Street / Bldg. No.	
Postcode / City	
Unit model :	RO Medical
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 re-test **all** dialysis stations for **disinfectant**. This test must be conducted before the dialyses are performed.

_____

Date

_____

Signature

14 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 only used 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.
The cable length between the power supply unit and the cable entry through the housing wall is 150 cm.

Warning
The use of other accessories, 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 for all parts of the device, including cables, calculated on the basis of one of the following equations depending on the transmission frequency. Recommended safety distance:
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	$d = 1.2\sqrt{P}$ 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. 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 land mobile radios, amateur radio stations, AM and FM radio, and TV transmitters), cannot be theoretically calculated in advance. To identify the electromagnetic environment with regard to 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.

Max. output of the transmitter (W)	Minimum distance in accordance with the frequency of the transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with a maximum output not specified above, the recommended distance d in meters (m) can be calculated in accordance with the equation appropriate for the frequency of the transmitter, whereby P is the maximum output of the transmitter in Watts (W) in accordance with the specifications of the manufacturer. NOTE 1: For 80 MHz and 800 MHz, the safety distance applies for the higher frequency range. NOTE 2: These guide values may not apply to all situations. Spreading of electromagnetic waves is also influenced by absorption and reflection via buildings, items, and persons.			