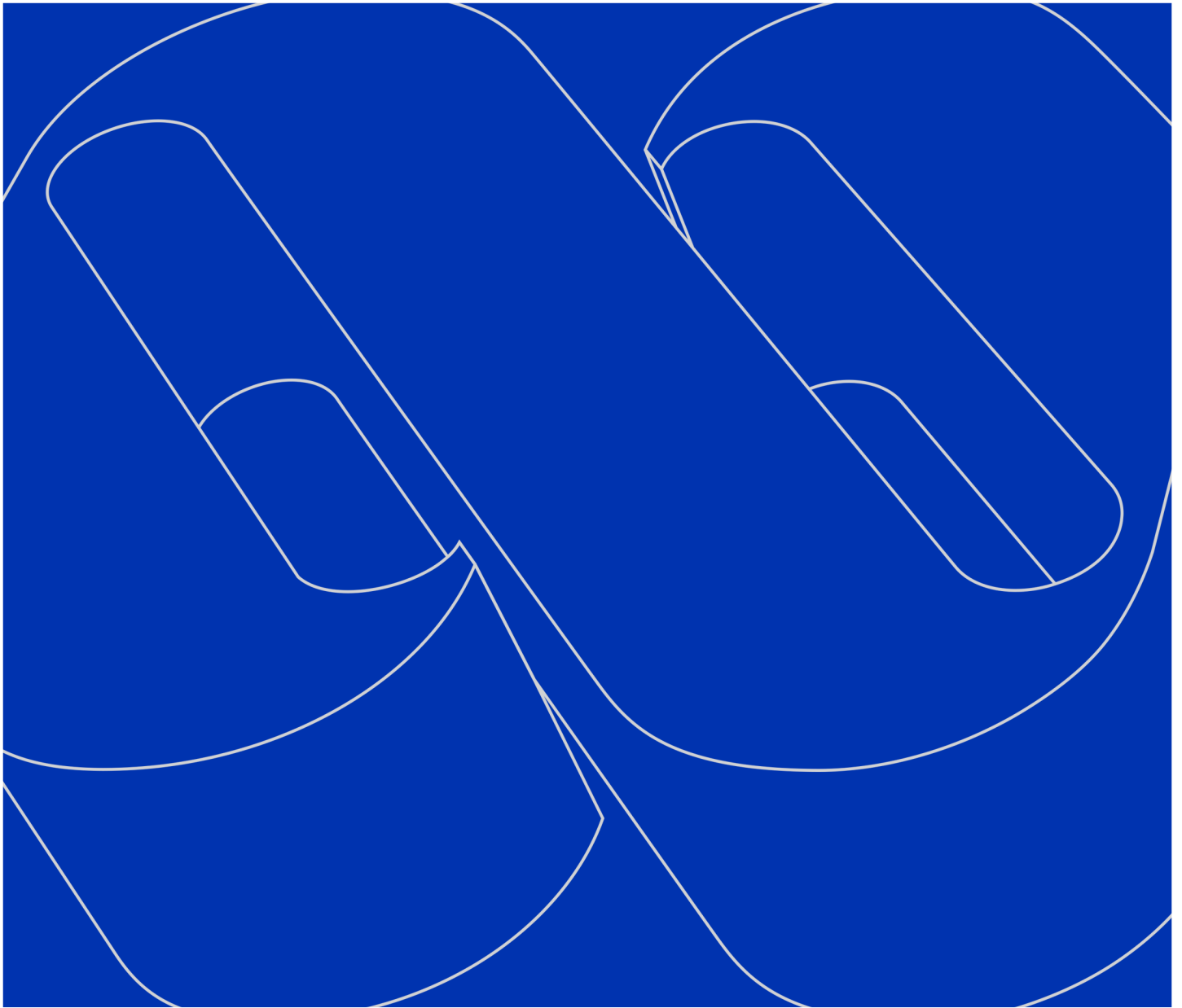




Instruction for use RO Systems | Variant: LiniXia

Variants: LiniXia, LiniXia L, LiniXia Pro, LiniXia DS, LiniXia DS L, LiniXia DS Pro

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Table of Contents

1. General	8
1.1. Permeate quality	9
1.2. Scope of supply	9
1.3. Unit configurations	9
1.4. Accessories and consumables	10
1.4.1. Accessories.....	10
1.4.2. Consumables	10
1.5. Notes for the operator	10
1.6. Laws and standards.....	10
1.7. Symbols used in this manual	10
1.8. Transport and storage	10
1.9. Product label	11
1.10. Warning on the unit.....	12
1.11. Preservation	12
1.12. Disposal	12
1.13. Instruction / Further documentation	12
1.14. Duration of usage.....	13
1.15. Report in case of a serious incident.....	13
2. Intended operation.....	14
2.1. Intended users / operators	15
2.2. Intended patient population.....	15
2.3. Contraindications / side effects	15
3. Safety	16
3.1. Risk assessment	16
3.1.1. Overall hazard assessment	16
3.1.2. General safety information	16
3.1.3. Hazards caused by electrical energy	16
3.2. EMC	17
3.3. Emissions.....	17
4. Technical data	18
4.1. Permeate performance / Feed quantity	18
4.2. Inlet water	18
4.3. Connections	18
4.4. Electrical data	19
4.5. Display system	20
4.6. Ambient conditions.....	20
4.7. Size.....	20



5. Description of the device	21
5.1. Flowchart	21
5.1.1. LiniXia: Single Stage.....	23
5.1.2. LiniXia L: Single Stage + Loop tank	24
5.1.3. LiniXia Pro: Single Stage + Loop tank + Inline heater	25
5.1.4. LiniXia DS: Double Stage.....	26
5.1.5. LiniXia DS L + Loop tank	27
5.1.6. LiniXia DS Pro: Double Stage + Loop tank + Inline heater	28
5.2. Components	29
5.2.1. 1 st Stage unit	29
5.2.2. 1 st Stage + 2 nd Stage units	30
5.2.3. Loop tank unit.....	31
5.2.4. Trolley unit.....	32
5.3. Operations	33
5.3.1. Permeate Production mode	33
5.3.2. Loop hot water disinfection process	33
5.3.2.1. Hot water preparation	34
5.3.2.2. Loop cold water flushing	34
5.3.2.3. Recirculation with leakage detection.....	34
5.3.2.4. Recirculation with dialysis disinfection	34
5.3.2.5. Emptying the tank	35
5.3.2.6. Loop cool down	35
5.3.3. RO Hot water disinfection process	35
5.3.3.1. Heating up.....	35
5.3.3.2. Disinfecting.....	35
5.3.3.3. Cooling down	35
5.3.3.4. Production test.....	35
5.3.4. Chemical disinfection process.....	36
5.3.5. Rinse mode	36
6. Installation	37
6.1. Environmental Conditions.....	37
6.2. Unpacking and moving instructions	37
6.2.1. Included items	38
6.2.1.1. 1 st Stage	38
6.2.1.2. 2 nd Stage / 1 st Stage + 2 nd Stage units	38
6.2.1.3. Loop tank	39
6.2.1.4. Trolley	39



6.3. Assembly (positioning the units)	40
6.3.1. 1 st Stage unit.....	40
6.3.2. 1 st Stage + 2 nd Stage units	42
6.3.3. 1 st Stage + 2 nd Stage units (Flex pipes).....	45
6.3.4. Loop tank.....	52
6.3.5. Trolleys.....	54
6.3.5.1. 9PV.....	55
6.3.5.2. 6PV.....	56
6.3.5.3. 4PV & 2PV	58
6.4. Electrical installation.....	61
6.5. Inter-cabinet communication	64
6.6. Pre-filtration	65
6.7. Assembling membranes	65
6.8. Input & output	68
6.8.1. Hydraulic connections:	68
6.8.2. External contacts:	69
6.8.3. Communication and service port:	70
7. Starting up.....	71
7.1. Electrical connection	71
7.2. Testing the supply cable and protective earth connection	71
7.3. Hydraulic connection	71
7.4. Rinsing the membranes	71
8. Operation.....	72
8.1. Control panel.....	72
8.1.1. Light indicators	73
8.1.2. Nurse Panel	73
8.2. Emergency operation.....	75
8.3. Main menu and sub-menus	76
8.3.1. Log in	76
8.3.2. Dashboard.....	76
8.3.3. Schedule	77
8.3.4. Event log.....	81
8.3.5. Diagram.....	83
8.3.6. Service	83
8.3.6.1. Calibration	84
8.3.6.2. Settings	85
8.3.6.3. User Management.....	89
8.3.6.4. Actions	90



8.3.6.5. Counters	91
8.4. Settings (Hardware)	92
8.4.1. Setting ring pressure (Permeate pressure)	92
8.5. Operation modes.....	93
8.5.1. Permeate production.....	93
8.5.2. Hot water disinfection	96
8.5.3. RO hot water disinfection	96
8.5.4. Hot water disinfection	97
8.5.5. RO and Loop hot water disinfection.....	98
8.5.6. Rinsing.....	101
9. Service mode	102
10. Maintenance and cleaning	103
10.1. External cleaning.....	103
10.2. Maintenance intervals	104
10.3. Replacing sterile filter of Loop tank	106
10.4. Chemical disinfection	107
10.5. Microbiological inspection	108
11. Malfunction	109
12. EMC manufacturer's declaration	117
13. Communication setup	119
13.1. Network interface distribution	119
13.2. Network settings	120
13.3. Ethernet port 0 - (Remote Configuration)	122
13.4. Ethernet port 1 - (Cloud communication)	123
14. Cloud setup.....	124
14.1. Connection steps.....	124
15. Nurse Panel setup instructions	126
15.1. Nurse Panel configuration.....	126
15.2. Tablet configuration	127





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

Foreword

This Instructions For Use (IFU) includes all information required for the installation and operation of the LiniXia reverse osmosis device.

Please keep this IFU readily available and near the unit.

This IFU applies to the units with the serial number:

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1	04.04.24	First edition
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3	10.07.24	Update in various sections
4	14.02.25	Nurse panel functionality added, settings' tables update and communication set-up updated.



1. General

This Technical Support Document is for the following variants:

- | | |
|------------------|--------------------------------------|
| ▪ LiniXia | Single Stage + Chemical disinfection |
| ▪ LiniXia L | Single Stage + Hot Loop |
| ▪ LiniXia Pro | Single Stage + Hot Loop + RO |
| ▪ LiniXia DS | Double Stage + Chemical disinfection |
| ▪ LiniXia DS L | Double Stage + Hot Loop |
| ▪ LiniXia DS Pro | Double Stage + Hot Loop + RO |

LiniXia: A Single Stage RO system with chemical disinfection of the Loop and device itself. Depending on the number of membranes, this system provides 350-2700 L/h pure water. This is the base of the LiniXia L (Single Stage, chemical and hot water disinfection of Loop), and LiniXia Pro (Single Stage, chemical and hot water disinfection of Loop and RO system).

LiniXia L: A Single Stage RO system with chemical disinfection and hot water disinfection of the Loop. Depending on the number of membranes, this system provides 350-2700 L/h pure water.

LiniXia Pro: A Single Stage RO system with chemical disinfection and hot water disinfection of the Loop and RO System. Depending on the number of membranes, this system provides 300-2700 L/h pure water.

LiniXia DS: A 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. It includes chemical disinfection of the loop and device itself. Depending on the number of membranes, this system provides 350-2700 L/h pure water. This is the base of the LiniXia DS L (Double Stage, chemical and hot water disinfection of Loop), and LiniXia DS Pro (double Stage, chemical and hot water disinfection of Loop and RO system).

LiniXia DS L: A Double Stage RO system with chemical disinfection and hot water disinfection of the Loop. Depending on the number of membranes, this system provides 350-2700 L/h pure water.

LiniXia DS Pro: A Double Stage RO system with chemical disinfection and hot water disinfection of the Loop and RO System. Depending on the number of membranes, this system provides 300-2700 L/h pure water.



1.1. Permeate quality

Microbiological Quality:

The microbiological quality of the dialysis water/permeate depends on several factors. Neglecting a factor could result in poor quality.

Examples of these factors:

- Quality of the inlet water (potable water, see chapter 4.2, WHO - Guidelines for drinking water quality)
- 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., interaction frequency of connecting or disconnecting dialysis machines to the dialysis water system shall be aligned with the cleaning interval)

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

Chemical quality:

In order to receive an indication of the water quality (permeate), 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 (various configuration see chapter 1.3)
- 1 connection set

1.3. Unit configurations

The unit can be expanded with one or two trolleys to increase permeate production capacity by adding additional membranes.



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

- RO-membrane (LiniXia L / L-Pro) -----item reference: SP-872 / SP-2167
- Filter cartridge (Loop tank) --- CON-456

1.5. Notes for the operator

The operator is responsible for:

- Competent and intended operation as described in the IFU
- Compliance with work safety and accident prevention provisions
- Technical instruction of operating personnel

1.6. Laws and standards

The LiniXia device complies with the MDR regulation, (EU) 2017/745.

- ISO 23500-1
- ISO 23500-2

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 the device against frost and moisture.



Protect against strong jolting and collisions.



Only move the device upright and with an appropriate lift.

- Environmental conditions: temperature between 3°C and 40°C.



1.9. Product label

The product label is located on the frame of the 1st Stage unit, on the side of the control box.



*Note: LiniXia variant product name will change for other configurations.

	Unique Device Identifier
	Consult IFU or consult electronic IFU.
	Indicates the item is a medical device.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
 Nipro Pure Water GmbH Werner-von-Siemens-Straße 2 76646 Bruchsal, Germany	Indicates the medical device manufacturer.
 YYYY-MM-DD	Indicates the date when the medical device was manufactured.
	WEEE symbol. Separate collection for electrical and electronic equipment.
	CE mark with the number of the Notified Body. Here, DQS MED.



1.10. Warning on the unit



Caution! Hot surface. Attached to the Loop tank, heater (1st Stage unit) and pressure vessels depending on the variants with hot water disinfection capability.



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



Warning "Caution pressurized device" on osmose unit / pressure vessels.

1.11. Preservation

If a unit is shut down for more than 24 hours, 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 environmentally 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 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 training is not necessary for this device.

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

- Circuit diagrams
- Spare parts list
- Technical manual



1.14. Duration of usage

The device is designed for a use of 10 years.

1.15. Report in case of a serious incident

Any serious incident that has occurred in relation to the device shall 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

LiniXia device is a water purification system that uses reverse osmosis to remove microbiological, organic, and inorganic contaminants from the inlet water.

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

LiniXia has no essential performance functions.

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 authorized by the manufacturer and may only be done with original replacement parts. Improperly performed repairs or modifications can lead to hazards to the user and/or may damage the device.



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 Loop.



The device does not produce water for injections.



The device has pressurized parts.



If the temperature sensor fails, the temperature in the permeate can increase. (Max 85°C)



The LiniXia water treatment device may only be used for the permeate supply of dialysis devices equipped with a temperature measurement (permeate temperature).



There is no direct contact between the patient and the device, and there is no patient application part.



2.1. Intended users / operators

The end-users of the LiniXia device are the 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 is given to the user(s).

The devices are installed in special rooms in dialysis centers with restricted accessibility. These so-called utility or osmosis rooms are accessible only by trained staff.

2.2. Intended patient population

There is no direct contact between LiniXia and the patient.

The permeate / RO water, that the LiniXia 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

There are no contraindications associated with the use of any device of the LiniXia device.

However, please consult the doctor responsible for the therapy.



3. Safety

3.1. Risk assessment

3.1.1. Overall hazard assessment

The LiniXia device complies with the requirements of the MDR, Regulation (EU) 2017/745, and the applicable standards for medical devices.

No dangers will be associated with the LiniXia device if the operating instructions are followed.

3.1.2. General safety information



Safety device regulations shall never be bypassed.



Do not place combustible material near the device.



Monitor the device and if you notice abnormal noises, leaks, or odors, turn off the equipment and contact technical service.



Contact technical service immediately if you detect damage to tubes or connections.



During the warning status, the LiniXia device is not capable of producing permeate.



Warning status is informed by a red light at the start of the 1st stage, a buzzer sound, and a red banner in display.



In case of emergency, the device can be separated completely from the mains with the main switch.

3.1.3. Hazards caused by electrical energy

The electrical safety of the unit must be checked at least once per year during a safety inspection.



3.2. EMC

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

WARNING: Use of this equipment adjacent to other equipment shall be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment shall be observed to verify that they are operating normally.

WARNING: Use of accessories, sensors, and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, leading to improper operation. Replacing these components with others with different specifications is not allowed.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) shall be used no closer than 30 cm (12 inches) to any part of the LiniXia RO device, including cables. Otherwise, it could result in degradation of the performance of this equipment.

Refer to chapter 15 for detailed information about EMC compliance with EN 60601-1-2.

3.3. Emissions

The device does not produce any dust or vibrations.

The noise level measured under laboratory conditions is 73,9 dB(A) during a full capacity operation.



4. Technical data

4.1. Permeate performance / Feed quantity

LiniXia / LiniXa L / LiniXia DS / LiniXia DS L:

Number of membranes	1	2	3	4	5	6	7	8
Permeate performance L/h [15°C]	350	700	1050	1400	1750	2100	2450	2800
Feed quantity min. at 3 Bar dynamic	1500	2000	2500	3000	3500	4000	4500	5500

LiniXia Pro / LiniXia DS Pro

Number of membranes	1	2	3	4	5	6	7	8
Permeate performance L/h [15°C]	300	600	900	1200	1500	1800	2100	2400
Feed quantity min. at 3 Bar dynamic	1500	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)
SiO ₂	<30 ppm
Fouling Index (S.D.I)	<3
Temperature	5-30°C
Conductivity	<1500 µS/cm
pH	6,5 - 8,5
Pressure	3-6 Bar

4.3. Connections

Water Supply	Potable water, connection, tri-clamp D50.5
Drain	HT 50



4.4. Electrical data

Variant	Supply	Consumption	Fuse
LiniXia	CEE 400 V AC 50/60 Hz	Max. 4,4 kW	1x Circuit breaker 4A 1x Circuit breaker 16A
LiniXia L		Max. 13,4 kW	2x Circuit breaker 4A 1x Circuit breaker 6A 2x Circuit breaker 16A
LiniXia Pro		Max. 20 kW	2x Circuit breaker 4A 1x Circuit breaker 6A 2x Circuit breaker 16A 1x Circuit breaker 32A
LiniXia DS		Max. 8 kW	2x Circuit breaker 4A 2x Circuit breaker 16A
LiniXia DS L		Max. 17,8 kW	3x Circuit breaker 4A 1x Circuit breaker 6A 3x Circuit breaker 16A
LiniXia DS Pro		Max. 22 kW	3x Circuit breaker 4A 1x Circuit breaker 6A 3x Circuit breaker 16A 1x Circuit breaker 32A



4.5. Display system

Conductivity C1, C2	0-2000 $\mu\text{S}/\text{cm} \pm 10\%$
Conductivity C3	0-200 $\mu\text{S}/\text{cm} \pm 10\%$
Pressure sensor P1, P4	0 to 25 Bar $\pm 5\%$
Pressure sensor P5, P6, P7, P8, P9	-1 to 9 Bar $\pm 5\%$
Flow sensor F1, F2	0 to 1800 L/h $\pm 10\%$
Flow sensor F3, F4	0 to 3600 L/h $\pm 10\%$
Level sensor L1	0 to 40 L $\pm 10\%$
Level sensor L2	0 to 400 L $\pm 10\%$
Temperature sensors	0 to 100°C $\pm 0.5^\circ\text{C}$

4.6. Ambient conditions

Storage / Transport	3 – 40°C
Operation	10 – 35°C
Relative humidity	<90% at 20°C not condensing
Air pressure	795 – 1062 hPa

4.7. Size

1 st Stage unit (mm)	2 nd Stage unit (mm)	Loop tank unit (mm)	Trolley (mm)
1110 x 750 x 1834	1110 x 750 x 1834	1110 x 750 x 1834	1100 x 750 x 1650

The LiniXia device is modular and, depending on the variant, it can be composed of one, two, or three units.

The basic configuration is made up of the 1st Stage unit.

Double Stage device (DS) involve the use of the 1st Stage and 2nd Stage units.

L and Pro variants add the Loop tank unit.

To increase permeate production capacity, the LiniXia RO system can be expanded with one or two trolleys to add additional membranes.



5. Description of the device

5.1. Flowchart

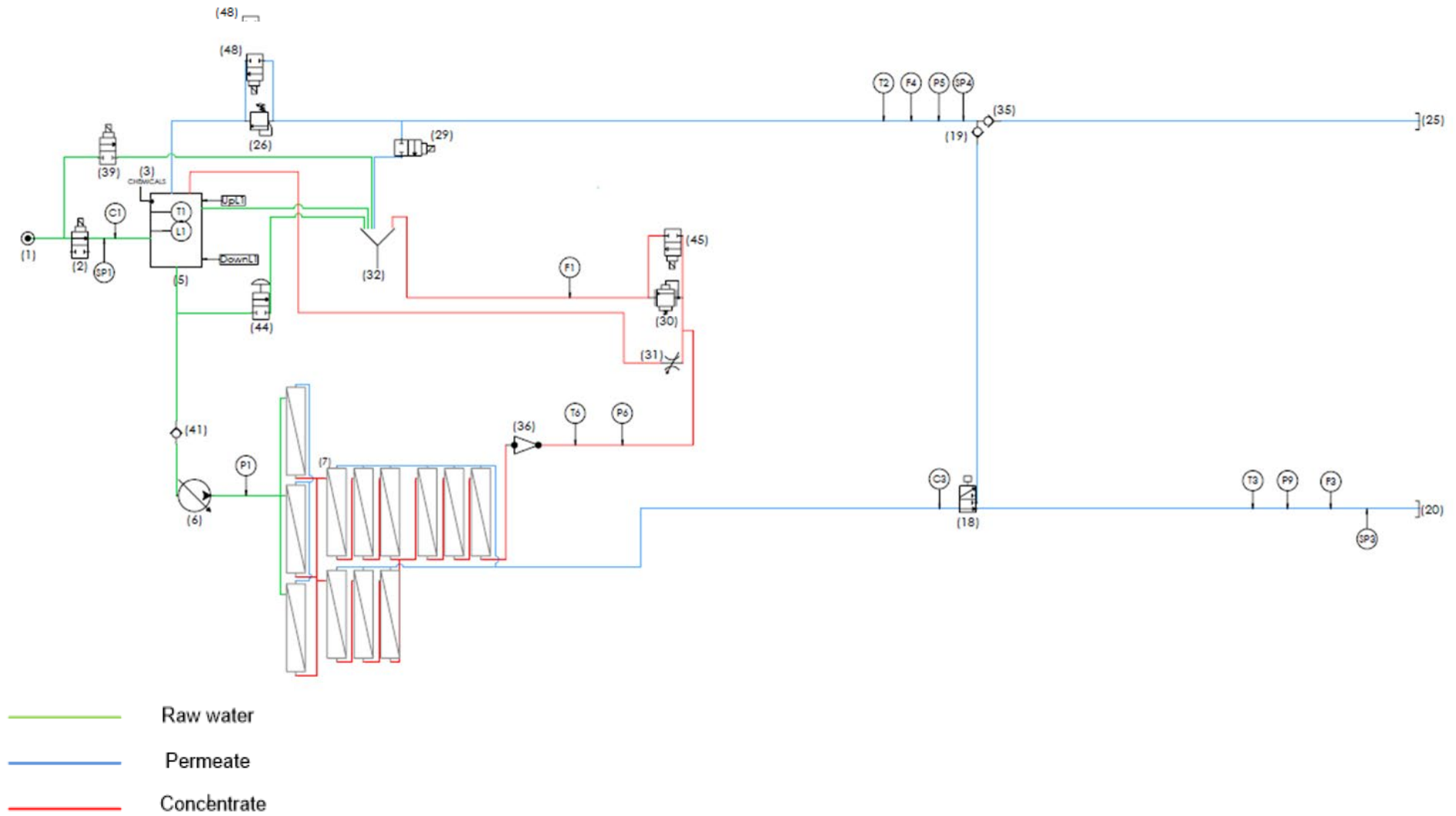
Legend	
Symbol	Description
	Inlet system
	Flow sensor
	Pressure sensor
	Temperature sensor
	Conductivity sensor
	Sample port
	Level sensor
	2 way valve with solenoid
	Tank
	Manual ball valve
	Variable unidirectional pump
	Check valve
	Membrane
	Restrictor
	Flow control valve
	Proportional valve
	Pressure retaining valve



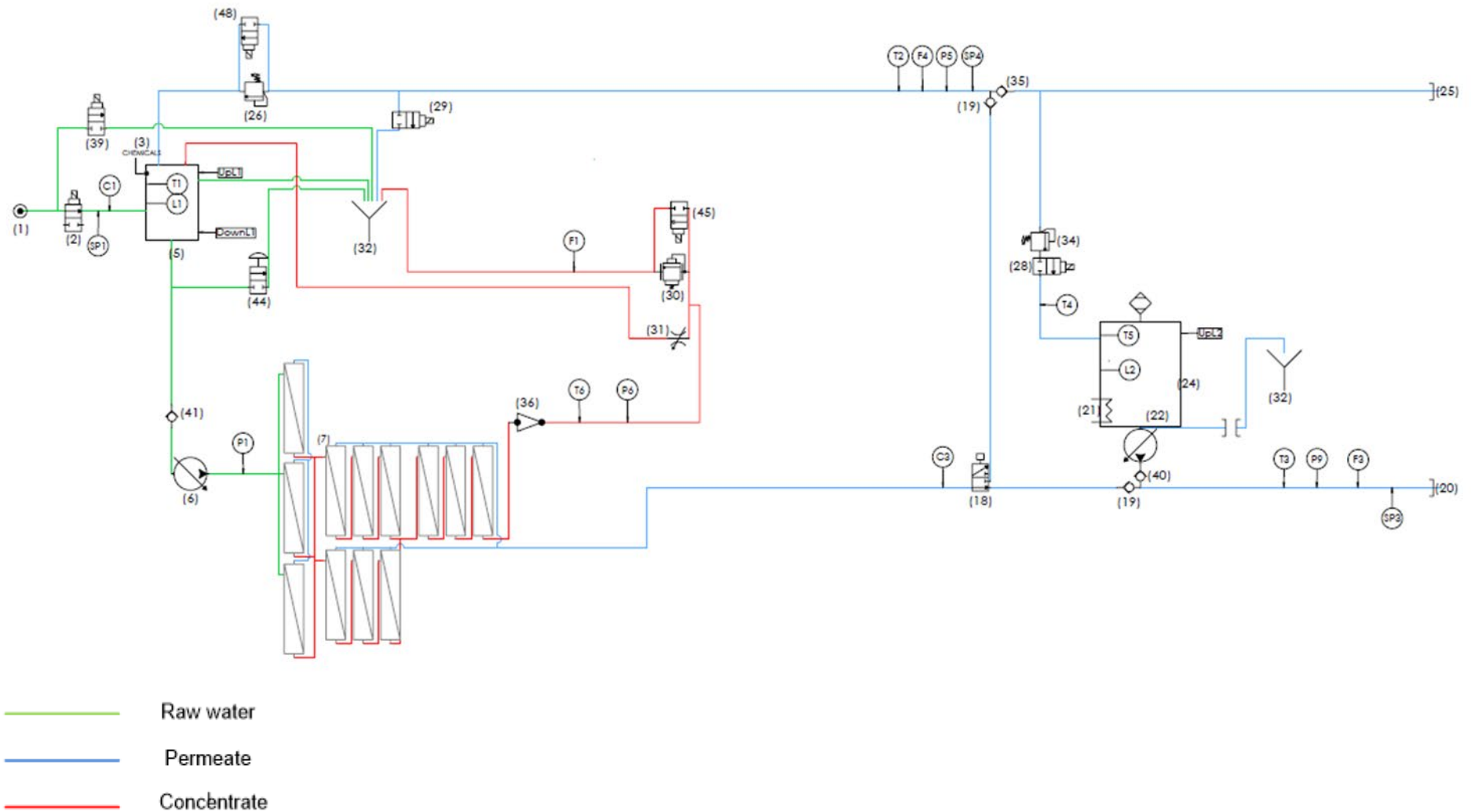
	3 way valve with motor
	Output system
	Heater
	Sterile filter



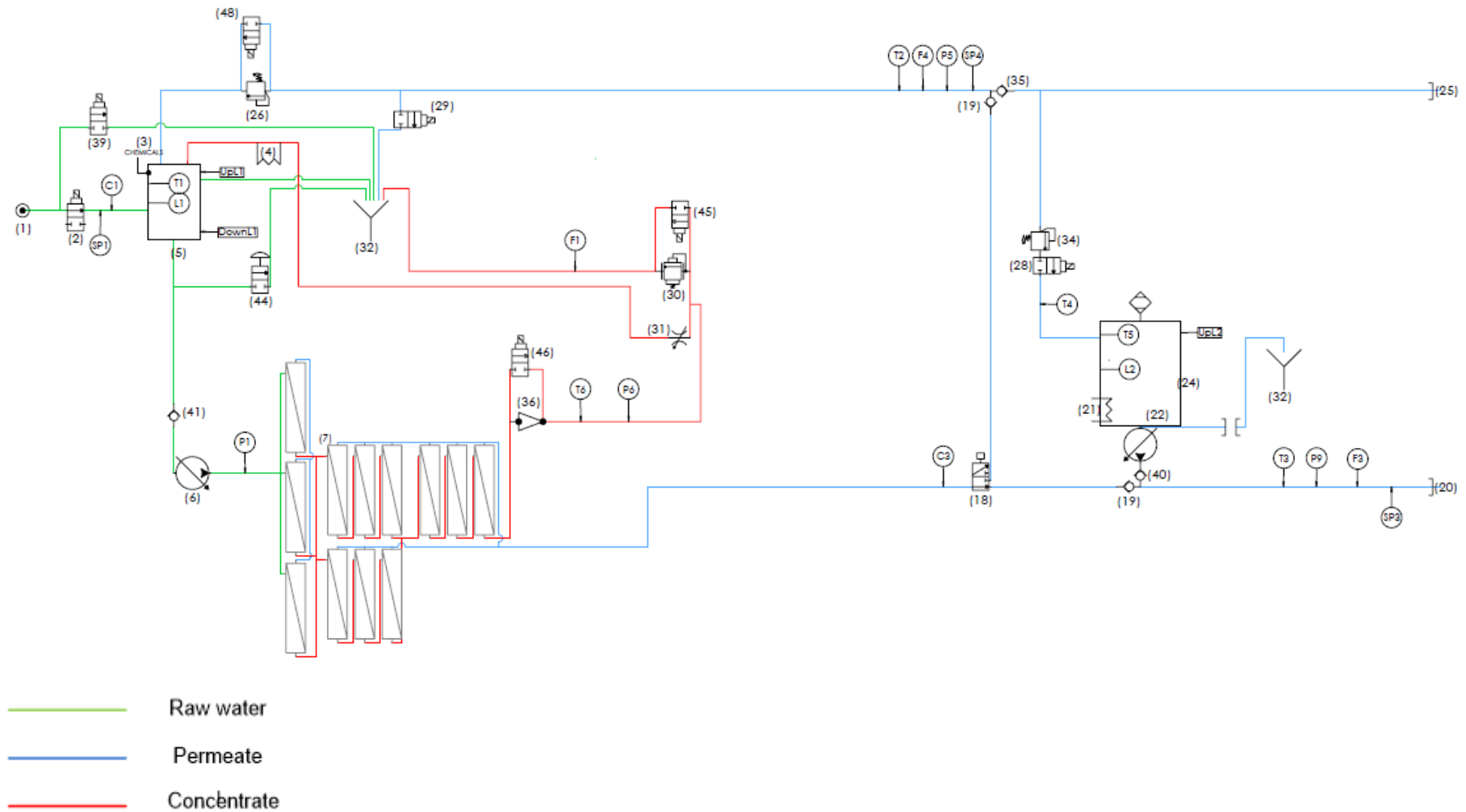
5.1.1. LiniXia: Single Stage



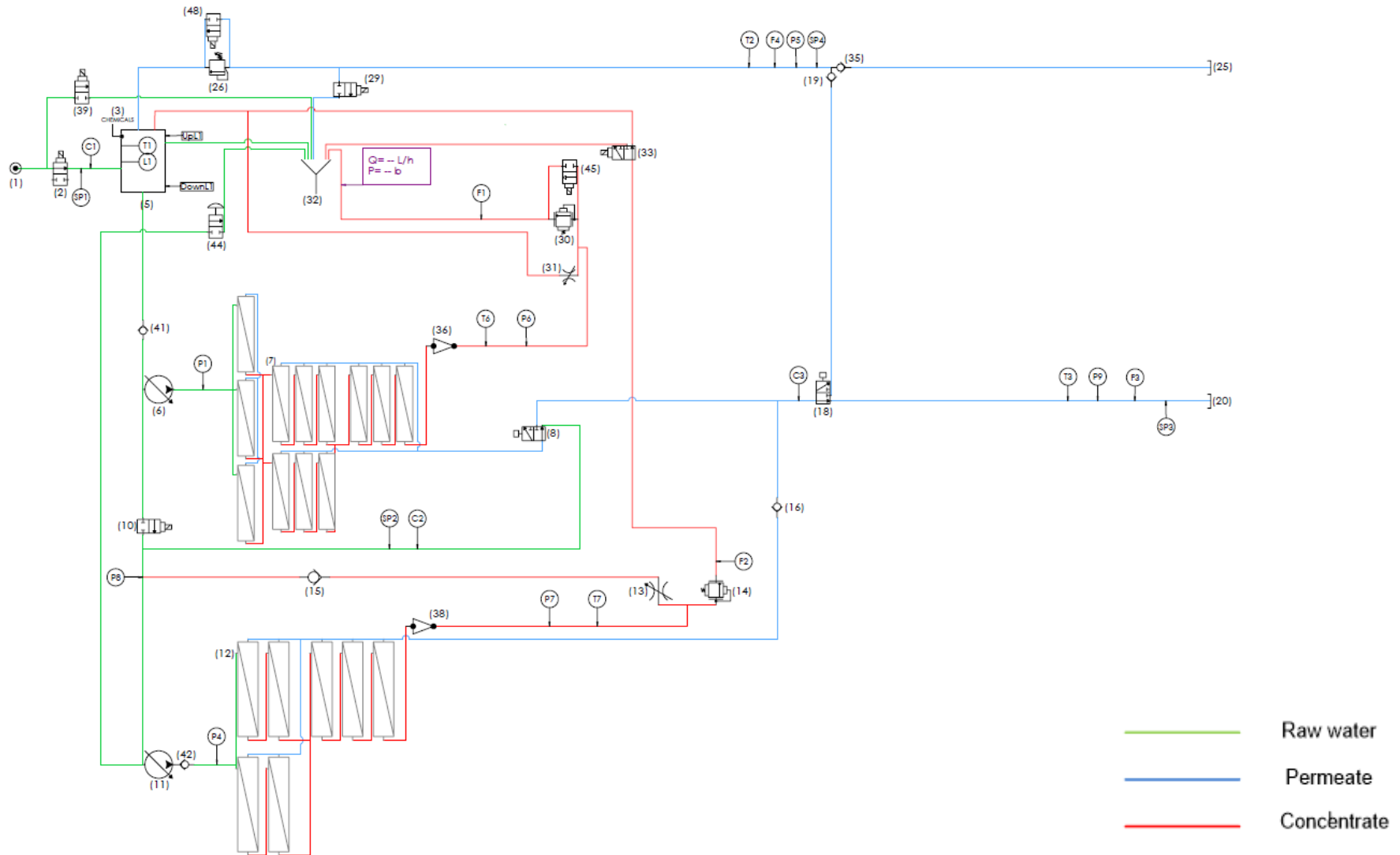
5.1.2. LiniXia L: Single Stage + Loop tank



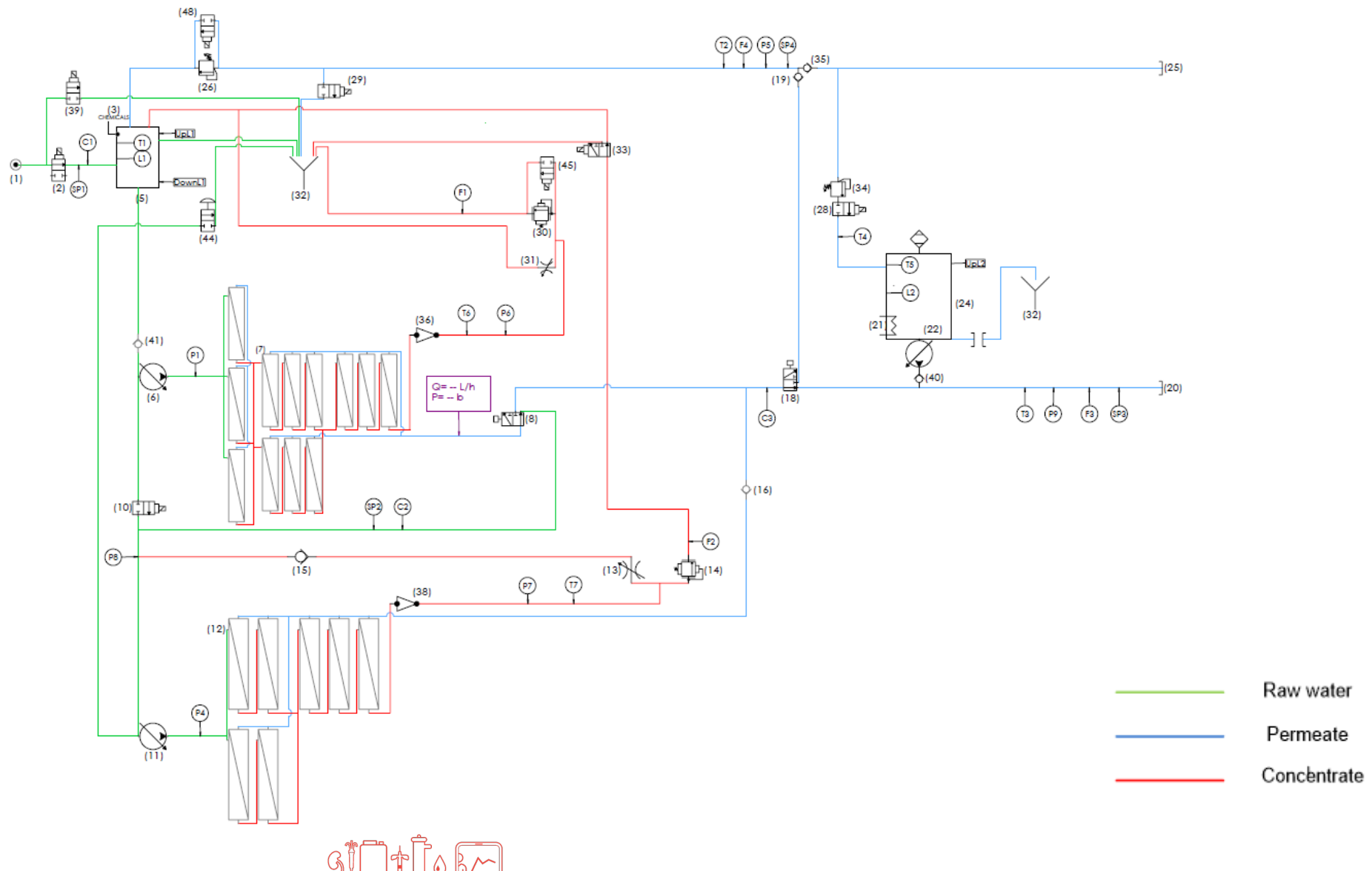
5.1.3. LiniXia Pro: Single Stage + Loop tank + Inline heater



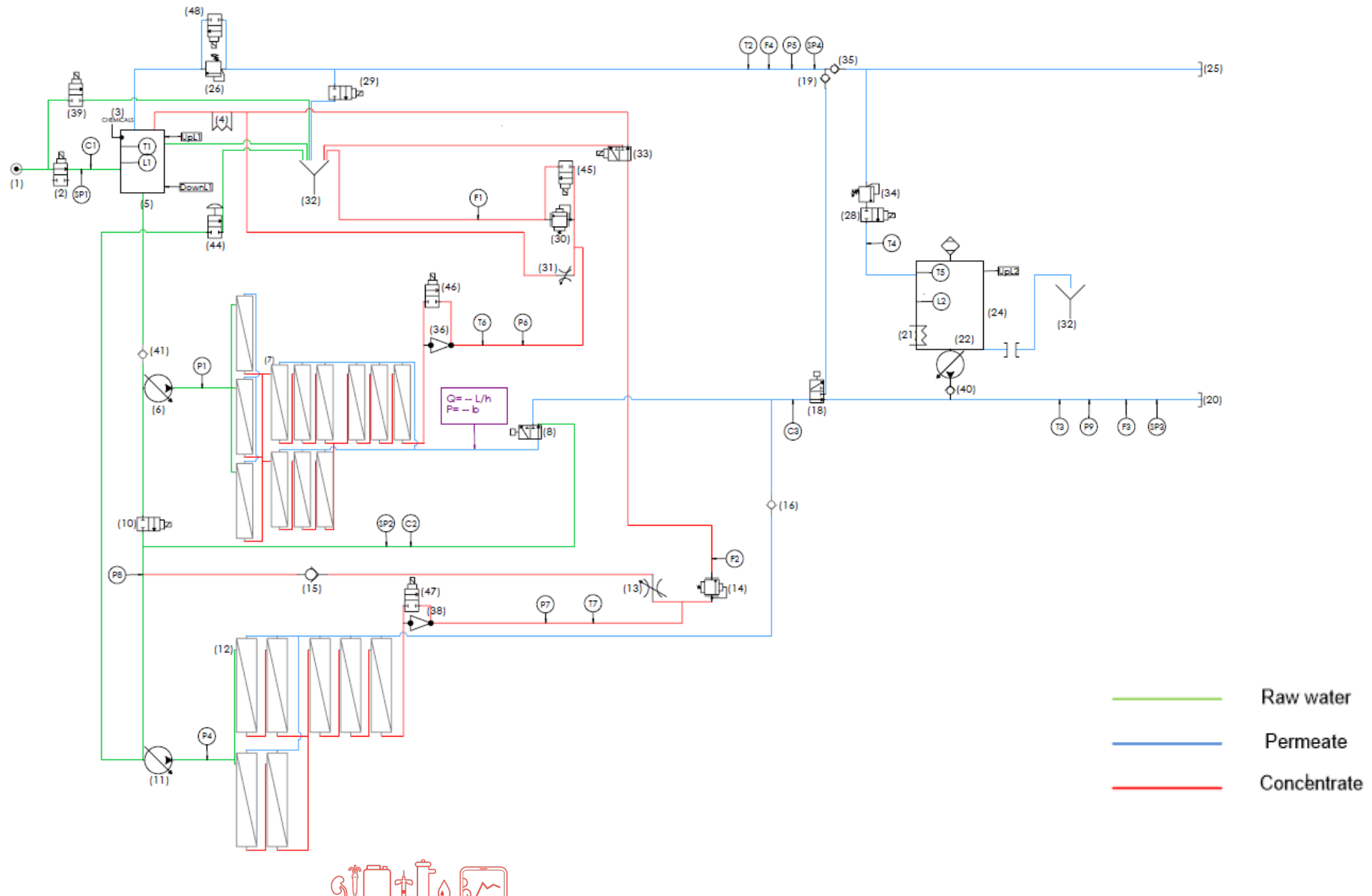
5.1.4. LiniXia DS: Double Stage



5.1.5. LiniXia DS L + Loop tank

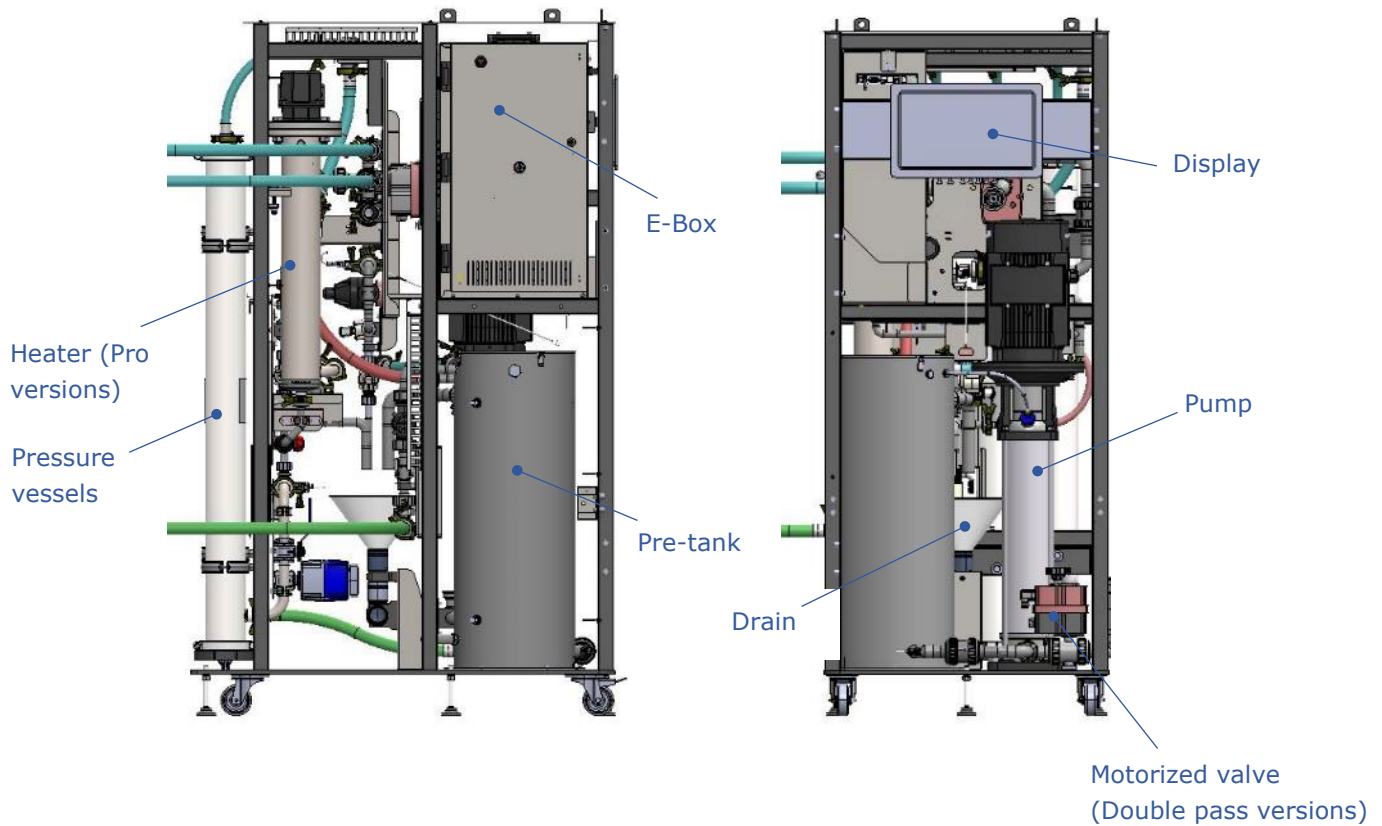


5.1.6. LiniXia DS Pro: Double Stage + Loop tank + Inline heater



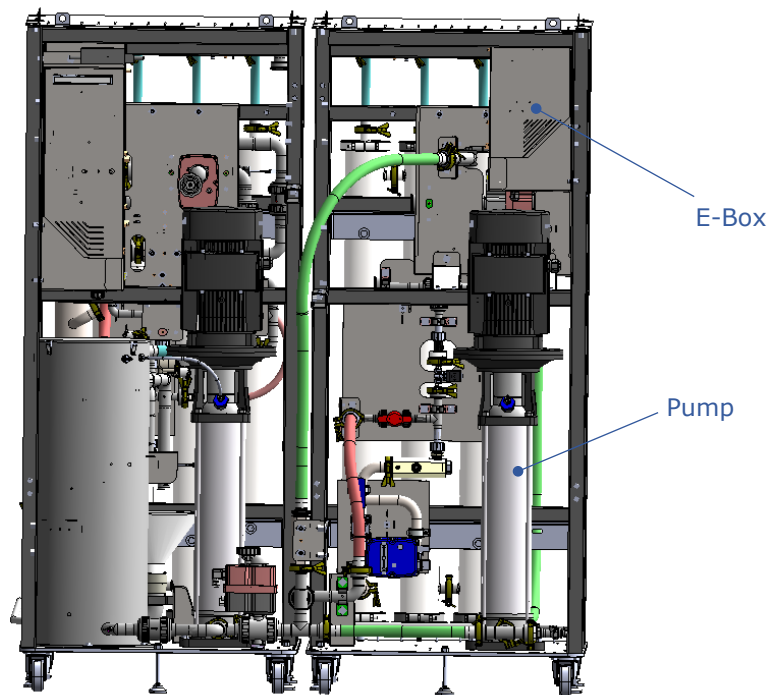
5.2. Components

5.2.1. 1st Stage unit

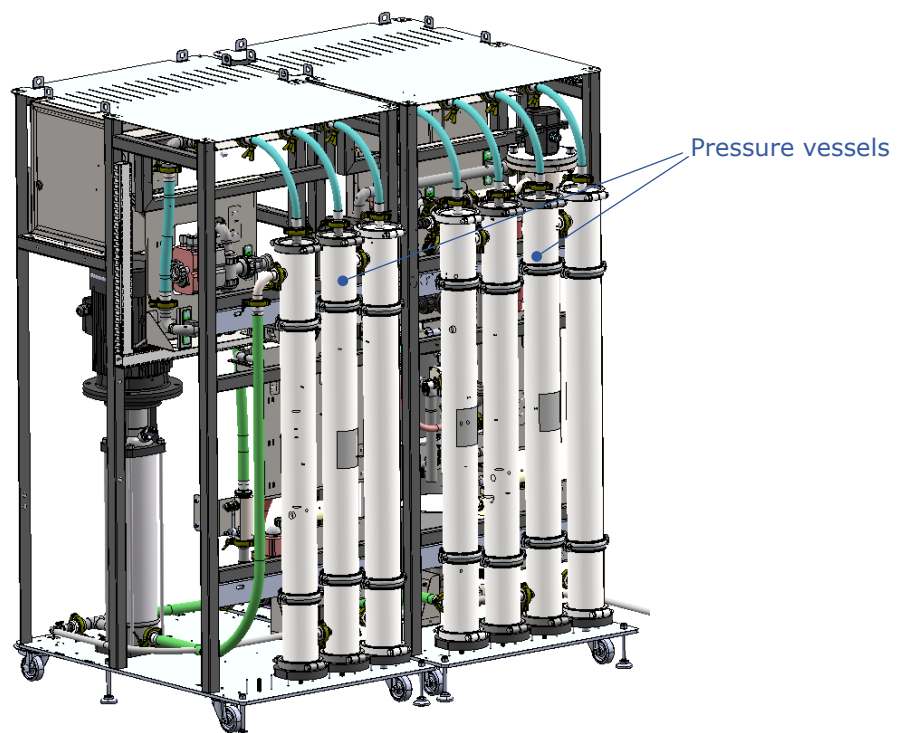


5.2.2. 1st Stage + 2nd Stage units

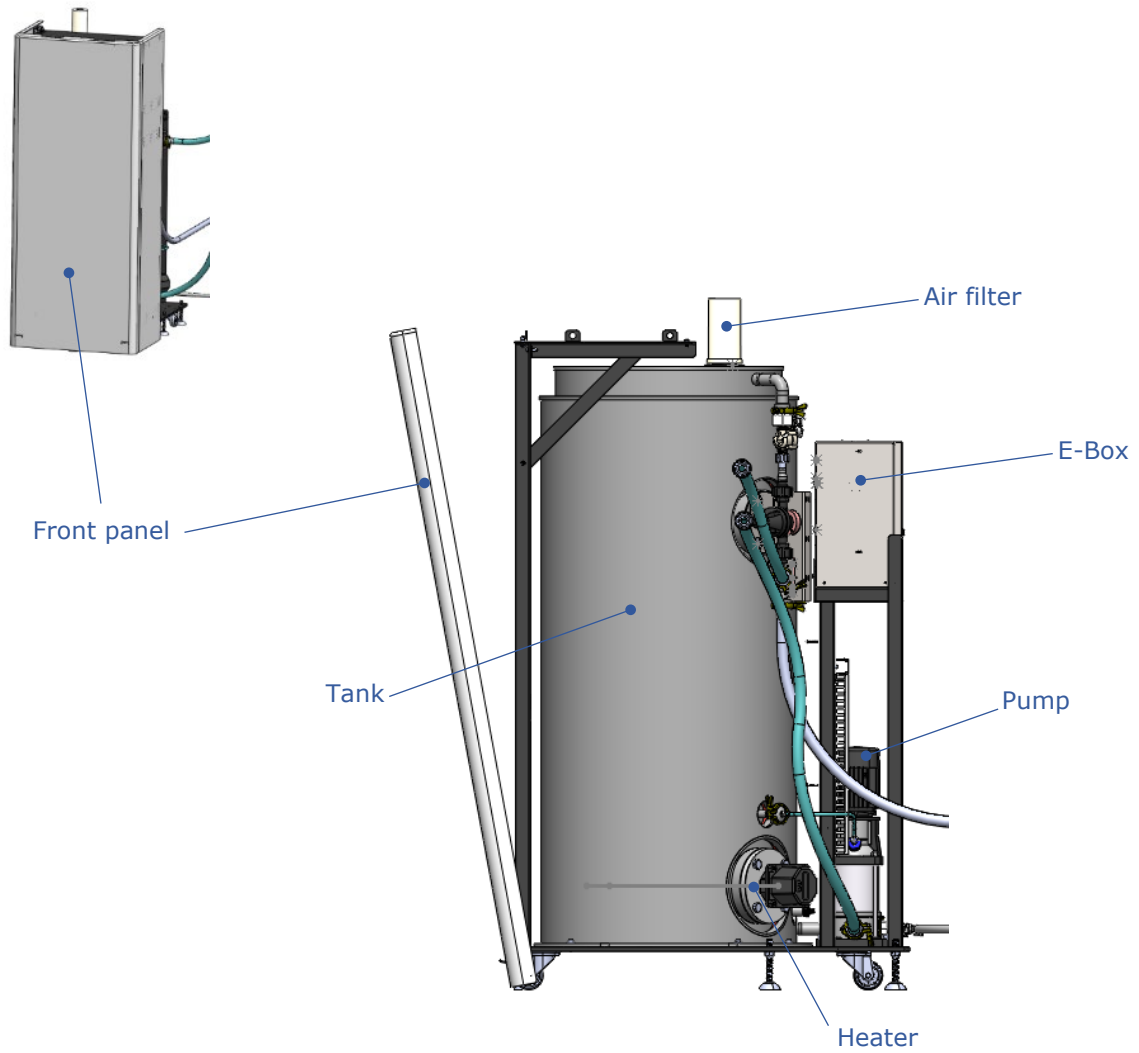
Front view (without covers):



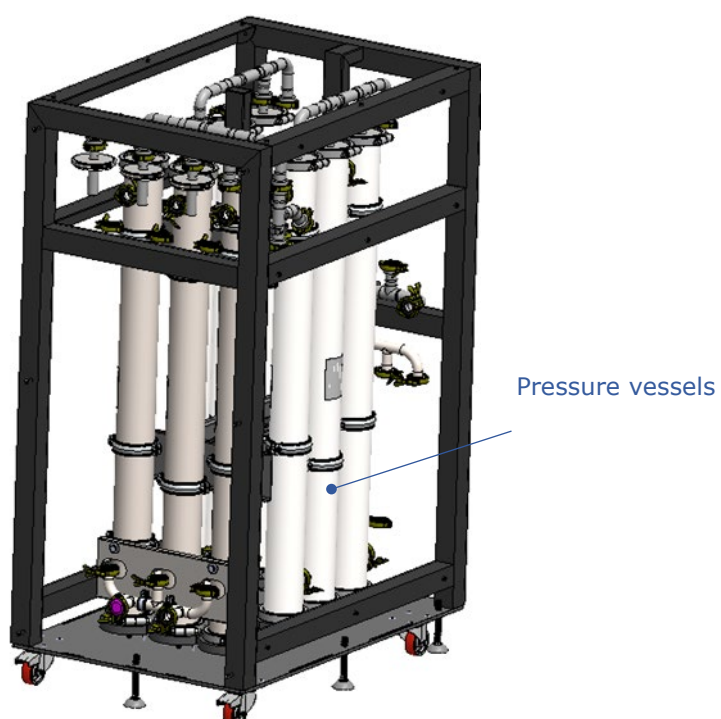
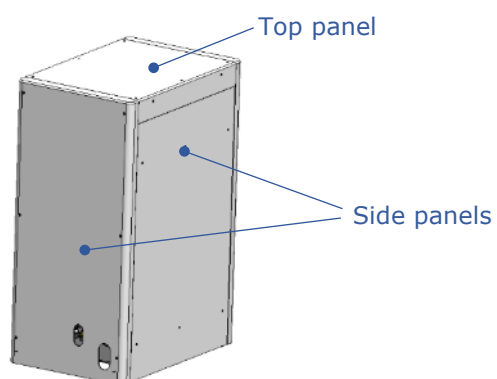
Rear view:



5.2.3. Loop tank unit



5.2.4. Trolley unit



5.3. Operations

The LiniXia device, depending on the different variants, has the following operating modes:

- Permeate Production mode – Production of permeate and hemodialysis can take place.
- Hot Water Disinfection process (Loop, RO, or RO+Loop) – Hot sanitation of the device. During this mode, hemodialysis treatment is not allowed.
- Chemical Disinfection process (RO or RO+Loop) – Each chemical disinfection includes a rinse of the device before ending the process. No hemodialysis is allowed.
- Rinse mode – Rinse of the system when not in use. Frequency and duration are set by an authorized user.
- Standby mode – device is in standby, waiting for the next step to be processed.

All mentioned components in this chapter, with their respective numbers, can be found in the follow chart chapter 5.1.

5.3.1. Permeate Production mode

During Permeate Production, the device is delivering permeate to the permeate Loop for use in dialysis machines.

Inlet water is allowed to flow to the pre-tank (5) through the solenoid valve (2). As soon as a minimum level in the tank is reached, the boost pump (6) is activated sending feed water to the membranes (7). At the reverse osmosis membranes, the water stream separates into the permeate stream (purified water) and the concentrate stream.

The permeate quality is measured by means of the conductivity sensor C3. At the start of permeate production, the conductivity of the permeate may temporarily exceed an adjustable maximum level for a brief period. The motorized valve (18) bypasses the Loop until the permeate conductivity falls below this limit. This ensures that permeate with a sufficiently pure quality is sent to the dialysis machines.

The return path of the Loop flows through a pressure keeping valve (26) which sets the pressure level of the Loop circuit. Finally, the unused permeate is returned to the pre-tank for reuse.

The concentrate stream flows through a restrictor valve (36) limiting its flow rate. This flow is then divided; part of it is sent to the drain, and the remaining part is sent back to the pre-tank through the secondary restrictor valve (31). The amount of concentrate sent to the drain is regulated by the proportional valve (30) and the solenoid valve (45).

The amount of concentrate sent to the drain, and the pressure delivered by the boost pump are continuously readjusted by the device based on permeate conductivity, use, return flow, and temperature. This optimization ensures the quality of the permeate while minimizing water and energy usage as well as maintaining the device in a safe operating condition.

For a Double Stage device, two hydraulic circuits like the one described above are put in series. This allows the permeate of the first Stage to be used as feed for the second Stage. The behavior of the second Stage is analogous to the first Stage except that the concentrate flow of the second is partially sent back to the pre-tank, and partially recirculated to the second Stage feed.

Single Stage operation in a Double Stage device is possible. If chosen, the device adjusts the motorized valves (8) and (10) accordingly (see chapter 13).

5.3.2. Loop hot water disinfection process

The devices with a Loop tank will be able to disinfect the Loop using hot permeate. The process will follow the next steps.



5.3.2.1. Hot water preparation

With this process, the Loop tank is filled in with permeate up to the adjusted level and heated up to the disinfection temperature.

To fill the tank, a regular permeate production is performed while the solenoid valve (28) is opened, until the set level of the tank is reached in level sensor L2. During this process, the pressure keeping valve (34) will set the pressure in the Loop. This valve must be adjusted to a pressure lower than that of the pressure keeping valve (26).

For a scheduled disinfection, this filling process can be concurrent with the permeate production mode. In this case, the tank is filled with the produced permeate not used by dialysis machine.

Also, in the case of scheduled disinfection, it can be chosen to trigger the preparation well in advance, and keep the permeate at an intermediate temperature, lower than the disinfection temperature, but high enough to prevent bacterial growth, for a certain period of time. This feature will allow for a long permeate production concurrently, while reducing energy loss by heat dissipation.

Temperature sensor T5 and the tank heater (21) are used throughout the entire Loop disinfection process to control the temperature in the tank.

If the Loop disinfection has been triggered manually, the next step of the process is performed immediately after the disinfection temperature is reached.

If the Loop disinfection is scheduled, the next step will begin according to the scheduled time.

5.3.2.2. Loop cold water flushing

This process is performed at the start of the proper Loop disinfection.

The Loop pump (22) starts sending hot permeate to the Loop, while the solenoid valve (29) is sending the cold Loop return flow to the drain, preventing this water from cooling down the water inside the tank. The volume of water sent to the drain during this process may be adjusted using the settings.

5.3.2.3. Recirculation with leakage detection

As soon as the cold-water flushing is over, valve (29) is closed, and the flow from the Loop return is recirculated to the tank.

The heater control is active throughout the whole recirculation process, with the target being the disinfection temperature.

During this first period of recirculation, the device is sensitive to leakages in the Loop. If there is a reduction in the volume of the water in the tank during this period, a warning for Loop leakage will be issued, and the device will stop.

None of the dialysis machine shall consume hot water for disinfection during this period.

5.3.2.4. Recirculation with dialysis disinfection

During this second period of recirculation, the leakage detection is disabled. Dialysis machines may consume water for the disinfection of the machines.

While in both recirculation processes, the temperature of the return flow of the permeate Loop will be monitored by means of the sensor T4. This sensor will provide information of the lowest temperature point of the Loop. This temperature is used to calculate in real time the achieved A_0 value of the disinfection.



5.3.2.5. Emptying the tank

If the programmed disinfection includes an RO disinfection, the current and following processes will be performed after the RO disinfection. Otherwise (if no RO disinfection has been requested), this process is executed immediately after the recirculation periods are completed.

Heating of the Loop tank is now disabled. The valve (29) opens, and the return flow of the Loop is sent to the drain. This continues until the Loop tank is empty.

5.3.2.6. Loop cool down

The device is activated to produce permeate. This permeate is cold and is sent to the Loop.

This process is kept until the temperature at the Loop return (T2) falls below the permitted maximum temperature of the permeate.

5.3.3. RO Hot water disinfection process

During this process, the device is exposed to hot water for disinfection at a configured temperature for a configured period of time. This process is done through 4 different steps:

- Heating up
- Disinfecting
- Cooling down
- Production test

5.3.3.1. Heating up

At this step, the pumps are running at low pressure and the valves 46, 47 (if it's a Double Stage device), and 48 are kept open. The permeate is recirculated and the temperature of the device is gradually increased up to the disinfecting temperature.

If was a previous disinfection of the Loop, and there is hot water left on the Loop tank, the device will use this hot water to increase the temperature. When the eventual water in the tank is no longer available, the device will increase the temperature by means of an in-line heater.

5.3.3.2. Disinfecting

The device maintains the disinfecting temperature for the feed water during the configured period. The valves 46, 47, and 48 are cyclically opened and closed, so that the hot water is present in all the sections of the piping. A_0 value is calculated after measuring the temperature of the concentrate.

5.3.3.3. Cooling down

After the disinfecting period has elapsed, the device gradually reduces the temperature. Cool inlet water is introduced while hot concentrate water is sent to the drain in a controlled manner. Cooling down is complete when the temperature of the concentrate falls below the maximum limit.

5.3.3.4. Production test

To finalize, the device briefly tests the integrity of the membranes by performing the initial step of permeate production.



5.3.4. Chemical disinfection process

The device can be disinfected by means of the introduction of disinfectant chemicals. This process shall be performed by a trained technician only.

It consists of the following steps:

- The device fills the pre-tank and performs a short rinsing.
- The operator is asked to introduce the disinfectant chemicals into the pre-tank.
- The device recirculates the water in the device for a configured period of time. Actuators are set in the same configuration as regular permeate production. If the operator has selected to disinfect the Loop simultaneously, valve (18) is set to send the water to the Loop. Otherwise, valve (18) is set to recirculate.
- The operator is asked to verify the concentration of disinfectant in the system.
- The device stops and allows the chemicals contact to the system for a configured period of time.
- The device flushes the chemicals in 2 main stages:
 - Bulk flushing: A Double Stage system is set in parallel. Concentrate and permeate are sent to the drain.
 - Alternate Path flushing: Valves are actuated so that all sections of the piping are flushed effectively.
- The operator is asked to verify that the disinfectant chemicals have been completely removed from the system.

5.3.5. Rinse mode

When the device is in standby, in order to prevent permeate from remaining stagnant for a prolonged period of time, a periodic rinsing of the device and the loop will be performed.

The rinsing operation is analogous to regular permeate production. The duration and frequency of the rinsing can be adjusted.



6. Installation



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



For the initial commissioning, chemical disinfection is required.

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



The room may not be freely accessible. (Accessible to instructed personnel only).



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



Do not store chemicals in the vicinity of the device.

6.2. Unpacking and moving instructions

LiniXia units are delivered in a carton box on a pallet. Use a lifter to move them.

Please open the transport box carefully.

Once the unit is out of the carton box, it can be moved using its own wheels. To do this, it is necessary to have released the brakes and the adjustment feet.



The unit shall be moved carefully in order to avoid injuries.



6.2.1. Included items

6.2.1.1. 1st Stage

Description	QTY
Front panel assembly	1
Side panel assembly left	1
Side panel assembly right	1

6.2.1.2. 2nd Stage / 1st Stage + 2nd Stage units

Description	QTY
Front panel assembly*	1
Jig cabinets	2
Sheet metal fixation cabinets	6
Spacer for cabinets	3
Nut M8 DIN934	3
Screw M6x25 DIN912	6
Screw M8x80 DIN933	3
Washer M6 DIN9021	6
Washer M8 DIN9021	6
Washer M6 R 88120	6
Washer M8 R 88120	6

*Note: "Side panel assembly right" is provided with 1st Stage unit and mounted in 2nd Stage unit.

Flex pipes 1st Stage 2nd Stage

Flex pipes 1st Stage-2nd Stage

Description	QTY
Piping inlet 1 st pump (Double pass)	1
Sheet metal valve concentrate 2 nd pass	1
Spacer clipped suport DN25	1
Clipped support pipe D32 mm	1
Assy sensors permeate 2 nd pass	1
Flex pipe 1' – 2x clamps - L420 mm	1
Flex pipe 1' – 2x clamps - L600 mm	2
Flex pipe 3/4" – 2x clamps - L600 mm	1
Flex pipe 3/4" – 2x clamps - L960 mm	1
Flex pipe 1' -2x clamps - L1340 mm	1
Flex pipe 1' - 2x clamps - L725 mm	1
Flex pipe 3/16" – male G1/4 – loose nut G1/4 – 1290 mm	1



Description	QTY
Clamp S 50	15
Gasket DN25 29,7 x 50,5 ISO1127	15
Nut M5 DIN985	1
Screw M5 x 16 DIN7984	1
Screw M6 x 12 DIN912	4
Screw M6 x 25 DIN912	2
Screw M5 x 16 DIN7984	4
Washer M6 DIN9021	6
Washer M6 R 88120	6

6.2.1.3. Loop tank

Description	QTY
Side panel assembly left	1
Front 2 nd stage assembly	1
Side panel assembly right	1

6.2.1.4. Trolley

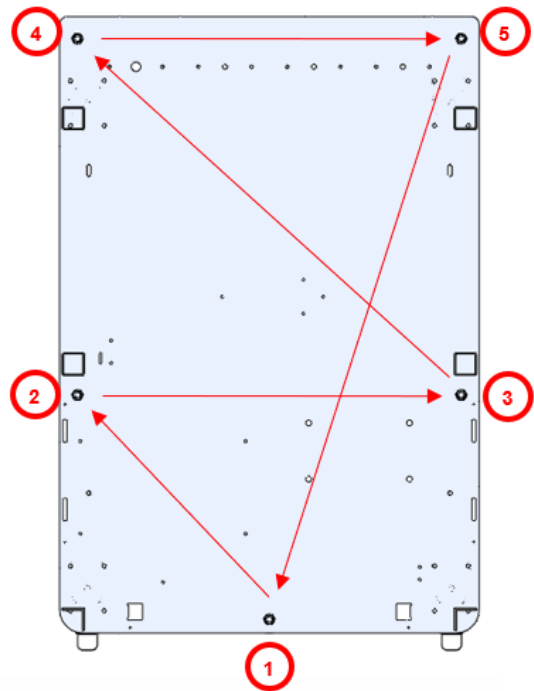
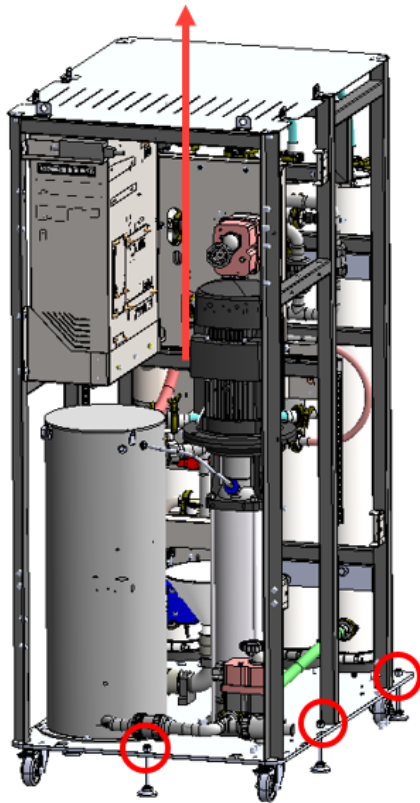
Description	QTY			
	9PV	6PV	4PV	2PV
Side panel trolley	2	2	2	2
Front panel trolley	1	1	1	1
Rear panel trolley	1	1	1	1
Top panel trolley	1	1	1	1
Screw M6 x 45 DIN7991	34	34	34	34
Piping elbow 90° TRI-clamp	1	2	1	1
Flex pipe 1" – 2x Clamps - L3000 mm	3	3	3	3
Clamp S 50	8	10	8	8
Gasket DN25 29,7 x 50,5 ISO1127	8	10	8	8



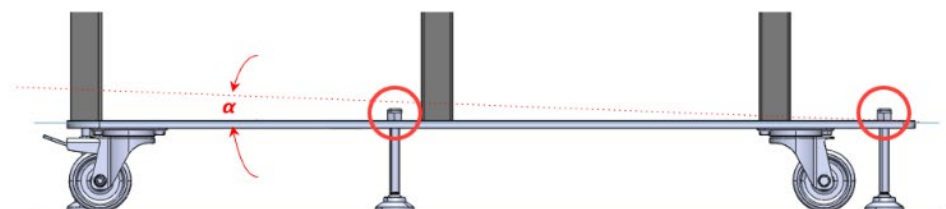
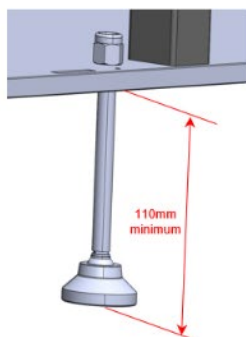
6.3. Assembly (positioning the units)

6.3.1. 1st Stage unit

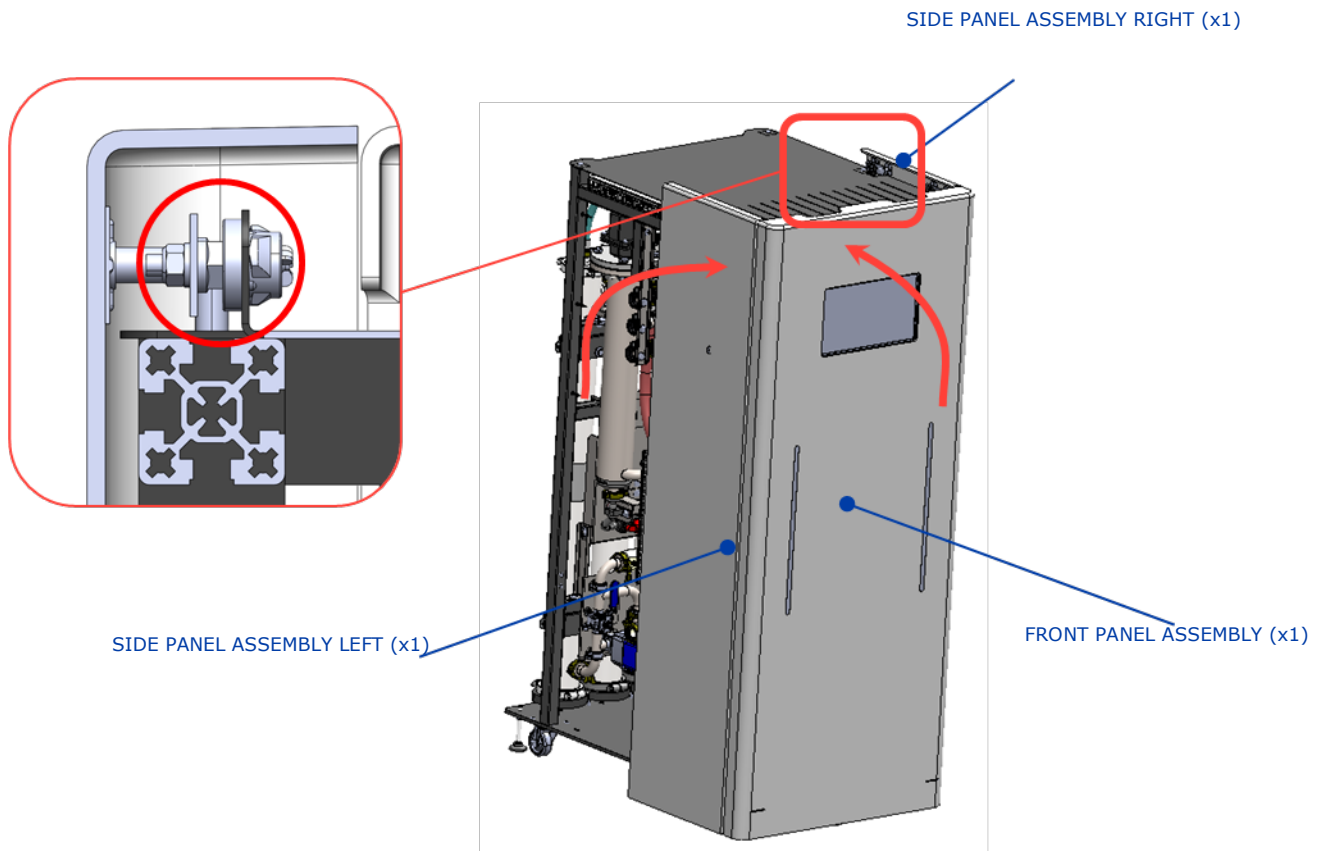
- 1- Once at the final location, use the feet (x5) to elevate the cabinet. For correct elevation, follow the sequence of the different steps to ensure good stability.



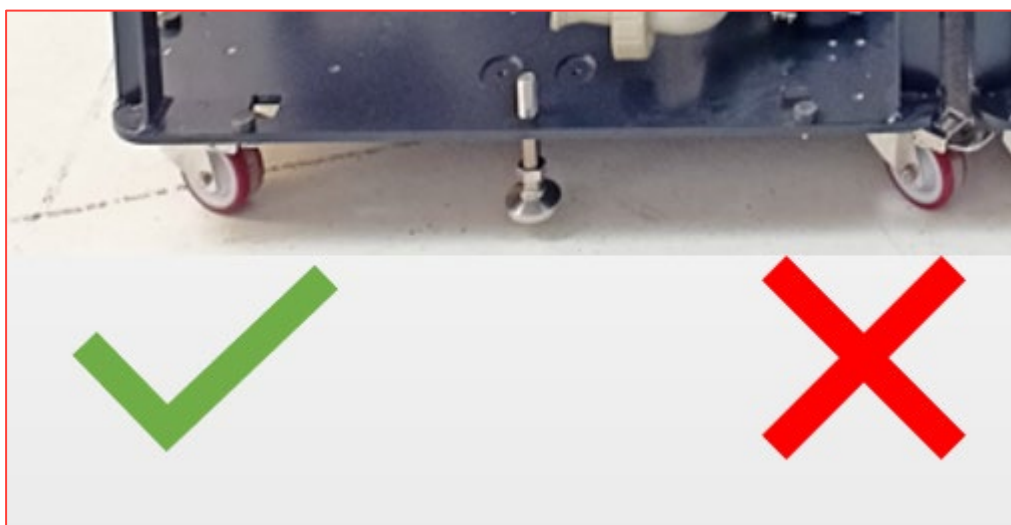
- 2- Elevate the 1st Stage unit around 110 mm from the ground (to the bottom base). To avoid an angle of inclination, use an angle meter. Following this, tighten the nuts on the feet (x5) completely.



3- Assemble all panels.

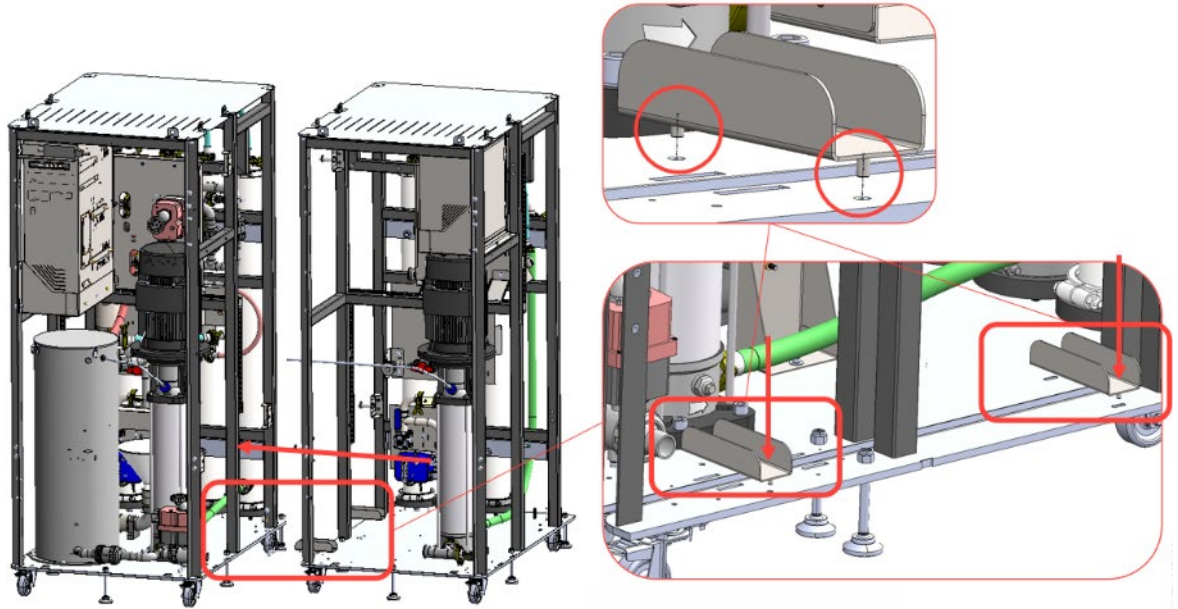


Note: To correctly mount the panels, and to prevent any interference, the front wheels must be turned, keeping the brake lever either hidden or not protruding beyond the perimeter of the base.

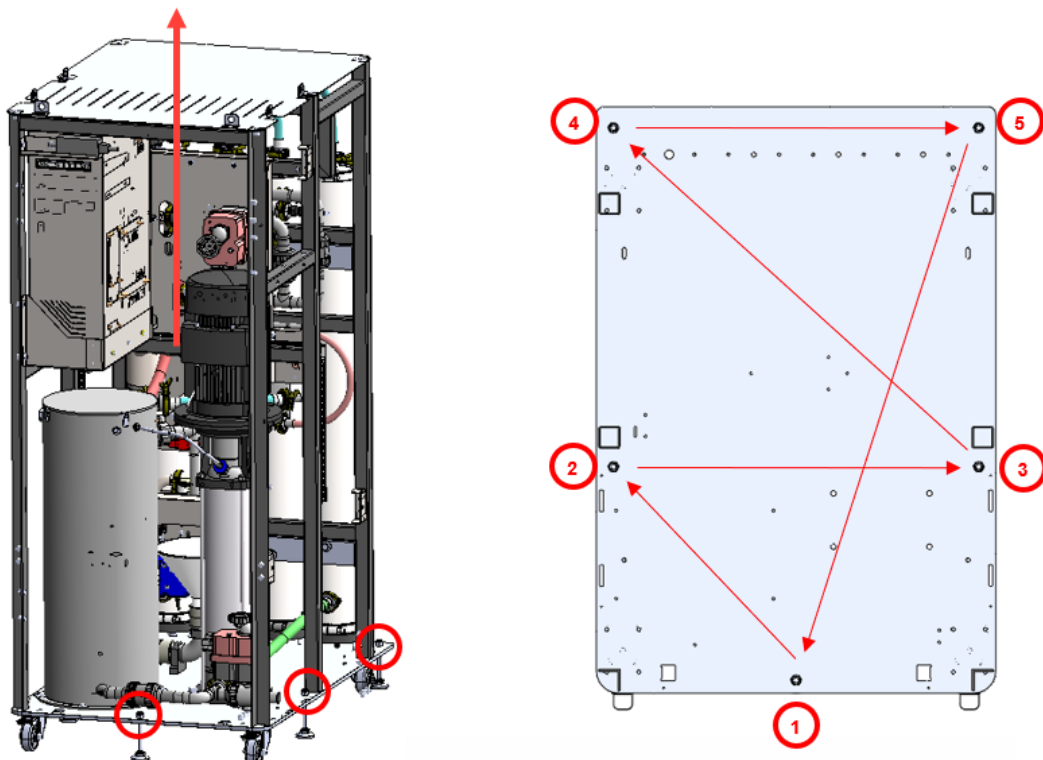


6.3.2. 1st Stage + 2nd Stage units

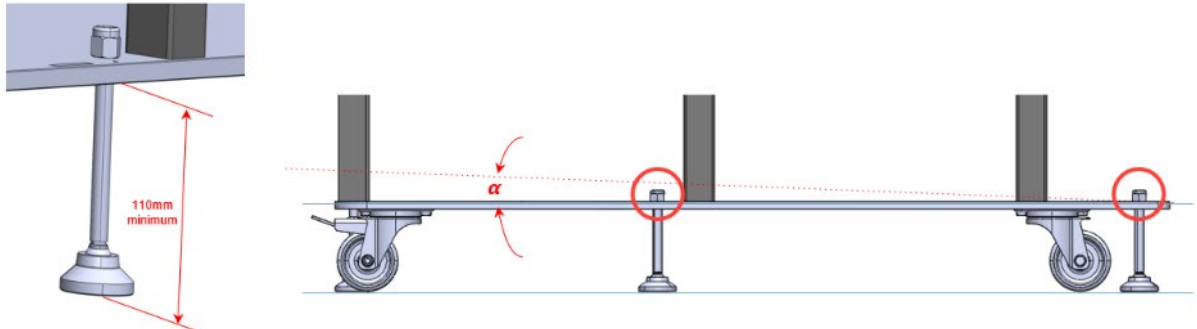
- 1- Position the 1st Stage unit in the room. Prior to this, verify the lengths of the flexible pipes (inlet and outlet) with your room's inlets, outputs, and drain. Close and align the cabinets between them. Use the jigs to ensure the correct position.



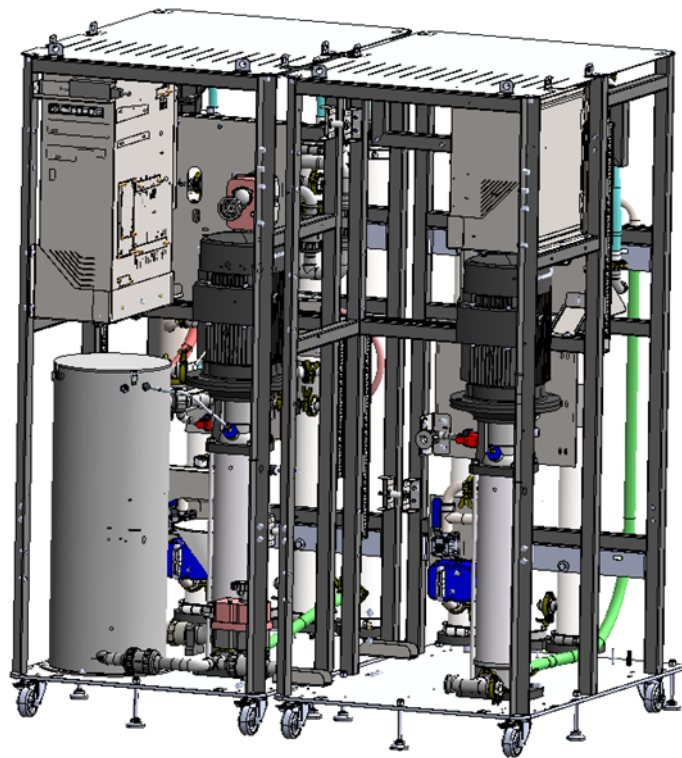
- 2- Remove the jigs. Then, use the feet (x5) to elevate the cabinet. For proper elevation, follow the sequence of the different steps to ensure good stability.



- 3- Elevate the 1st Stage unit around 110 mm from the ground (to the bottom base). To avoid an angle of inclination, use an angle meter. Following this, tighten the nuts on the feet (x5) completely.

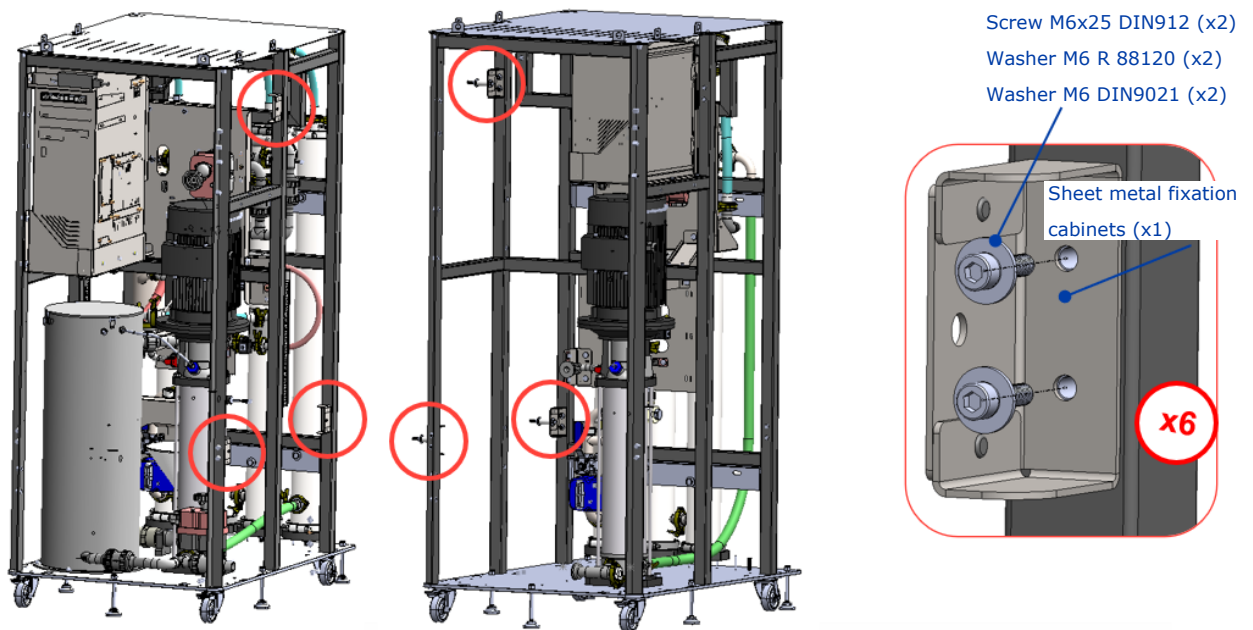


- 4- Repeat steps 2 and 3 for the 2nd Stage unit.



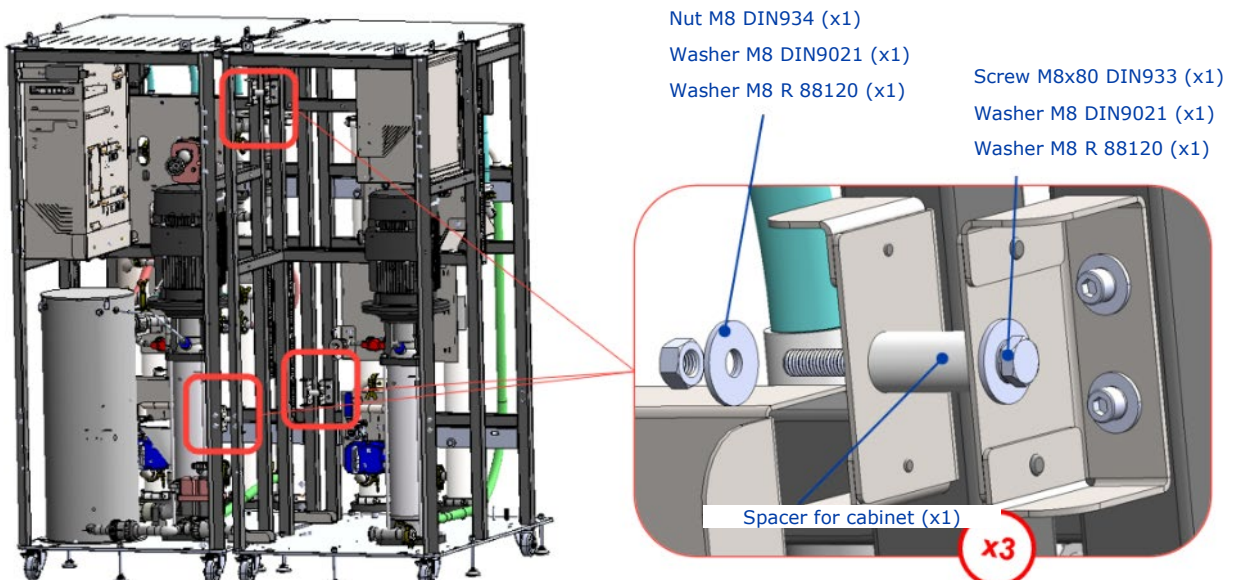
5- Add the brackets in the marked positions, screwing the bolts in completely.

TORQUE: 3 Nm



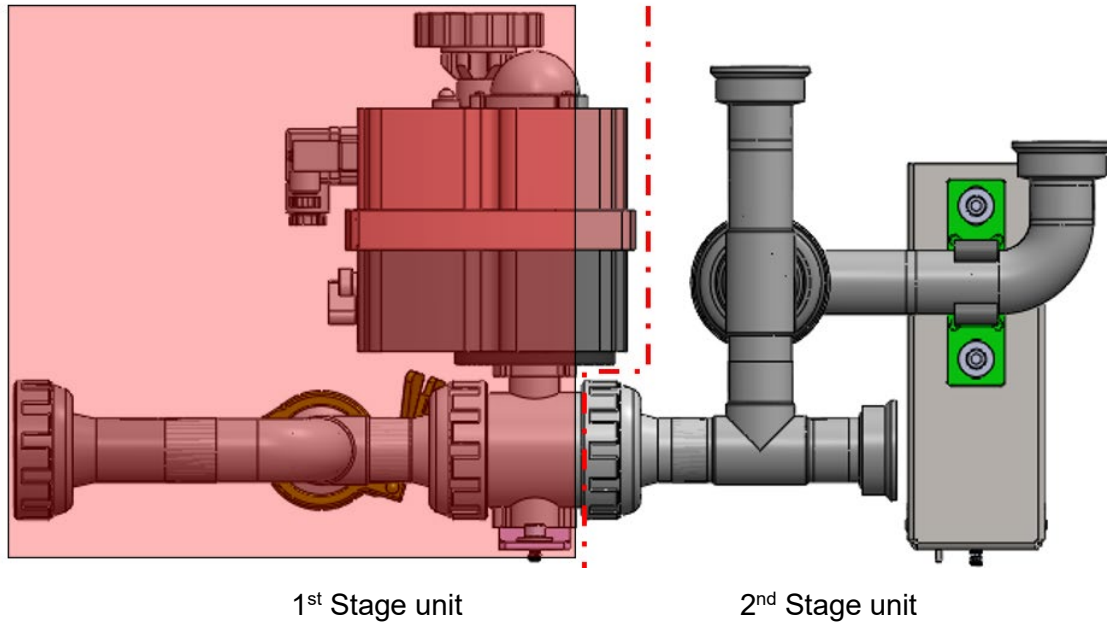
6- Add the spacers between the brackets, then tighten the bolts and nuts completely.

TORQUE: 3 Nm

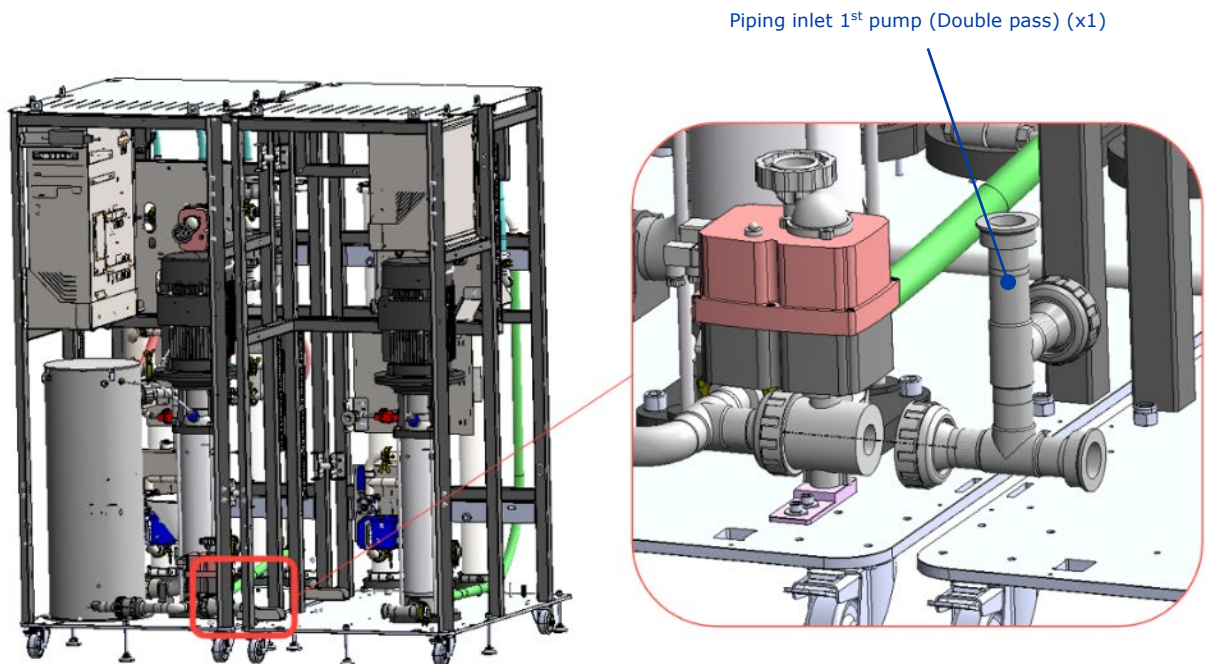


6.3.3. 1st Stage + 2nd Stage units (Flex pipes)

- 1- This device is divided into different units. This chapter explains the parts assembled in the 2nd Stage unit.

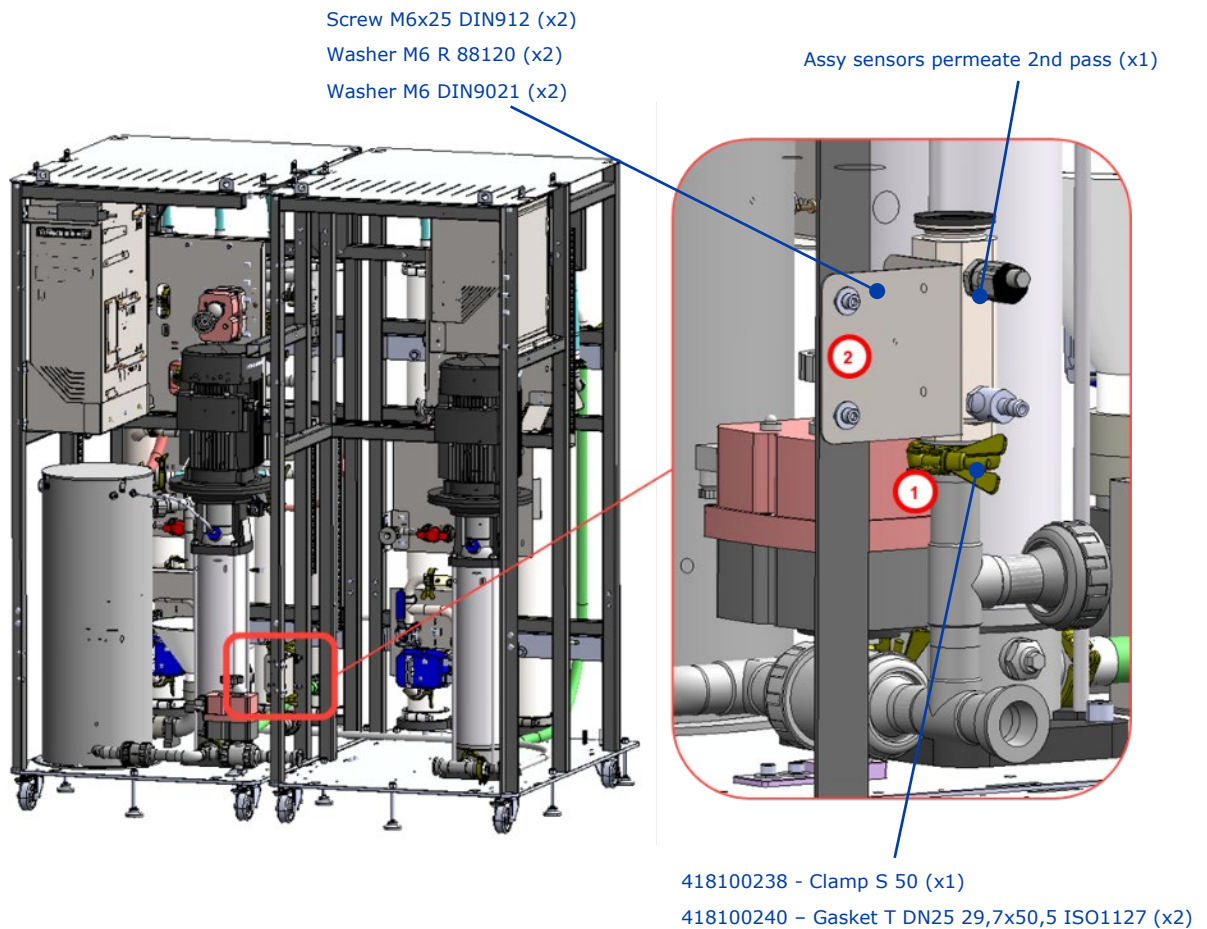


- 2- Connect the T-section of the plastic piping to the motorized valve, ensuring correct orientation. Tighten the loose nut manually.

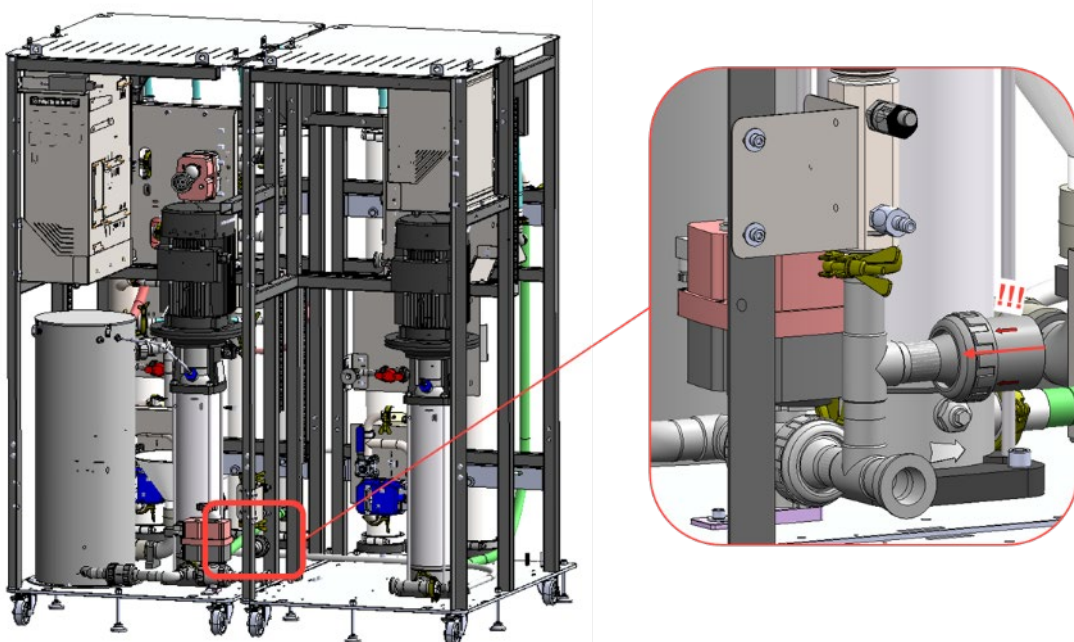


- 3- Connect the sensor block to the plastic piping with the gasket and manually close the tri-clamp (1). Then, tighten the bolts to the beam (2).

TORQUE: 3 Nm

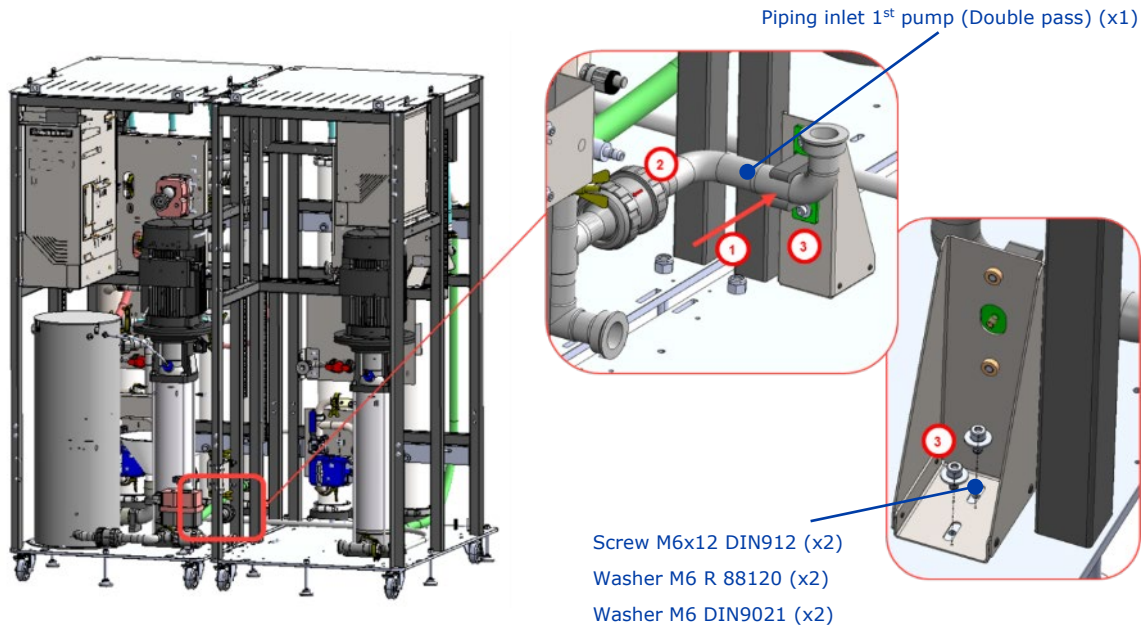


- 4- Manually screw the T-section to the check valve, ensuring correct orientation as shown in the picture.

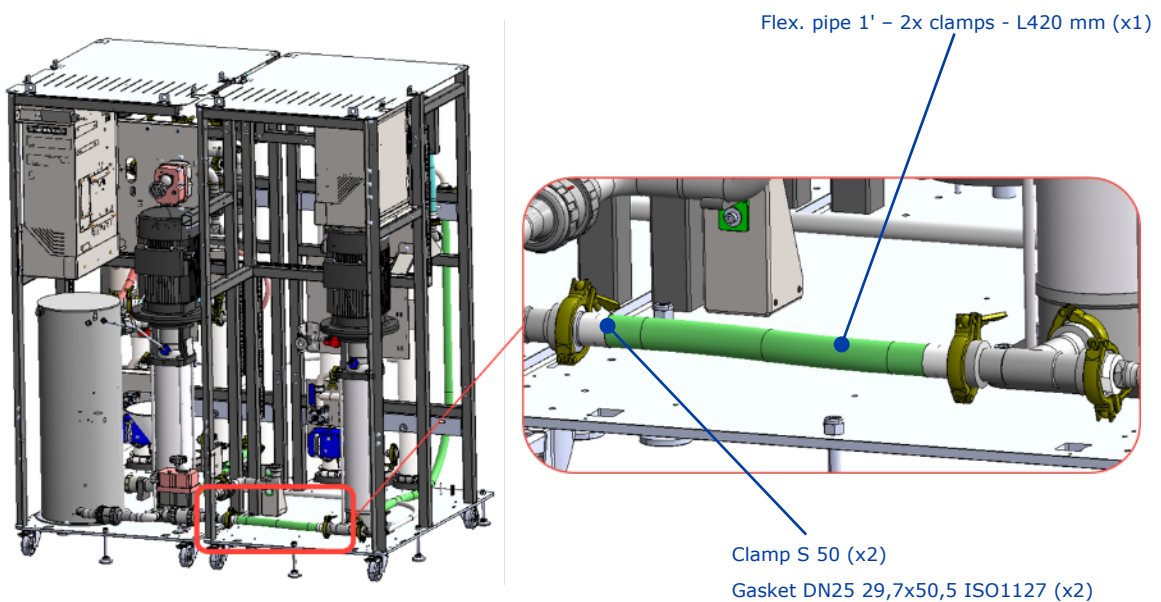


- 5- Add the support into the 2nd Stage base and clip the plastic piping (1). After that, manually screw the loose nut onto the check valve (2). Finally, tighten the bolts of the bracket and support completely.

TORQUE: 2 Nm

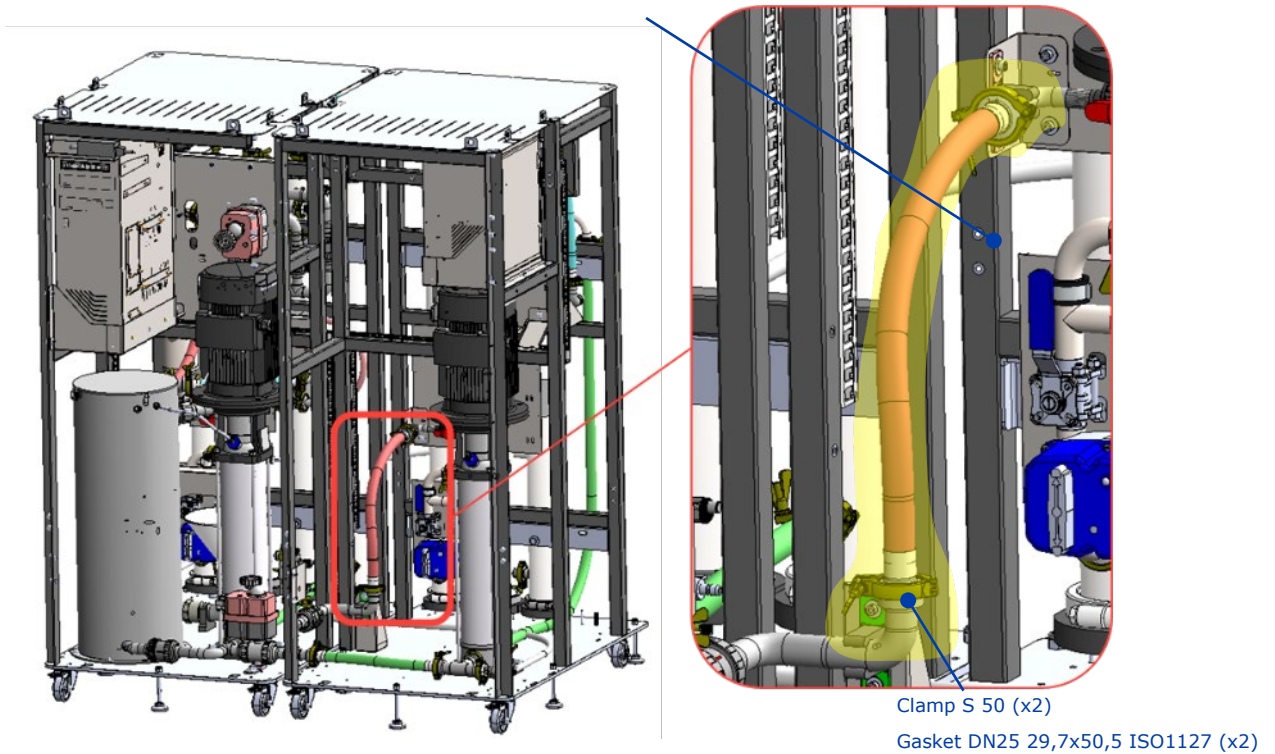


- 6- Connect the T-section of the 1st Stage unit to the T-inlet pump piping with the flexible pipe and gaskets. Manually close the tri-clamps.



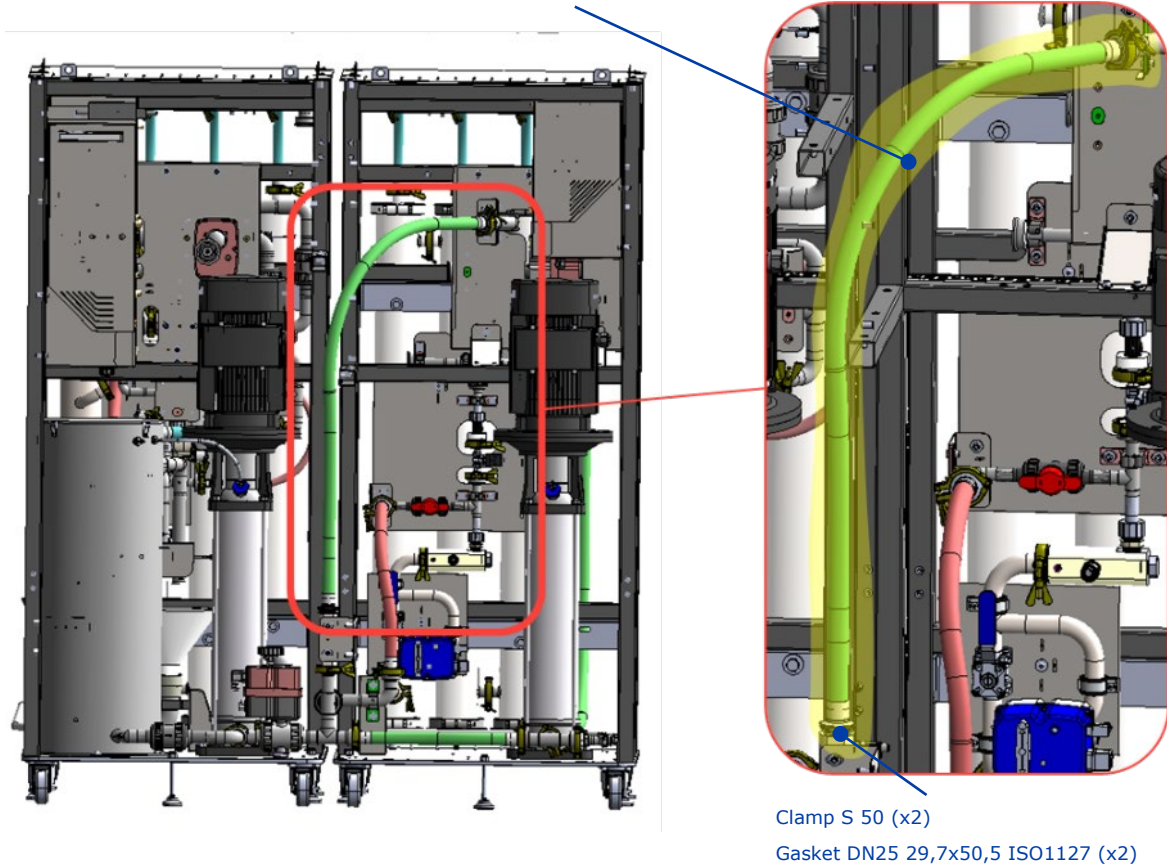
- 7- Connect the elbow section of the 1st Stage unit to the concentrate clamp with the flexible pipe and gaskets. Manually close the tri-clamps.

Flex. Pipe 1' – 2x clamps - L600 mm (x1)

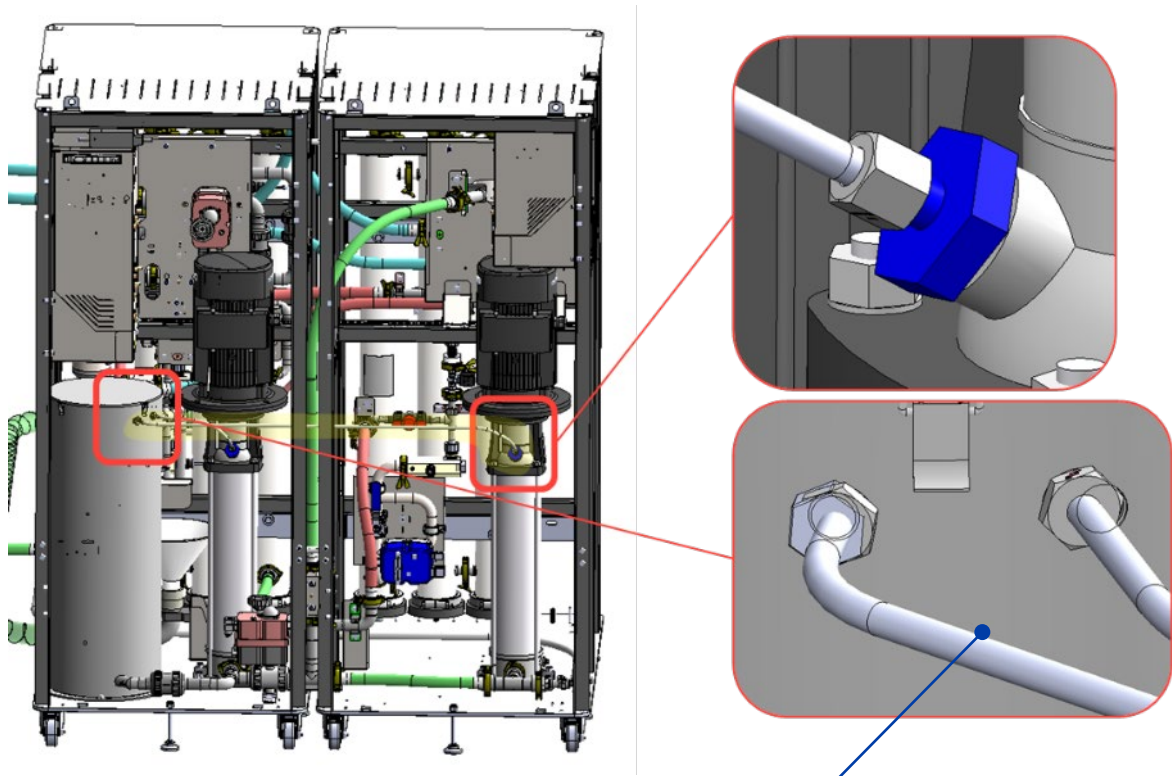


- 8- Connect the sensor block to the 45° elbow section with the flexible pipe and gaskets. Manually close the tri-clamps

Flex.pipe 1' – 2x clamps - L1340 mm (x1)

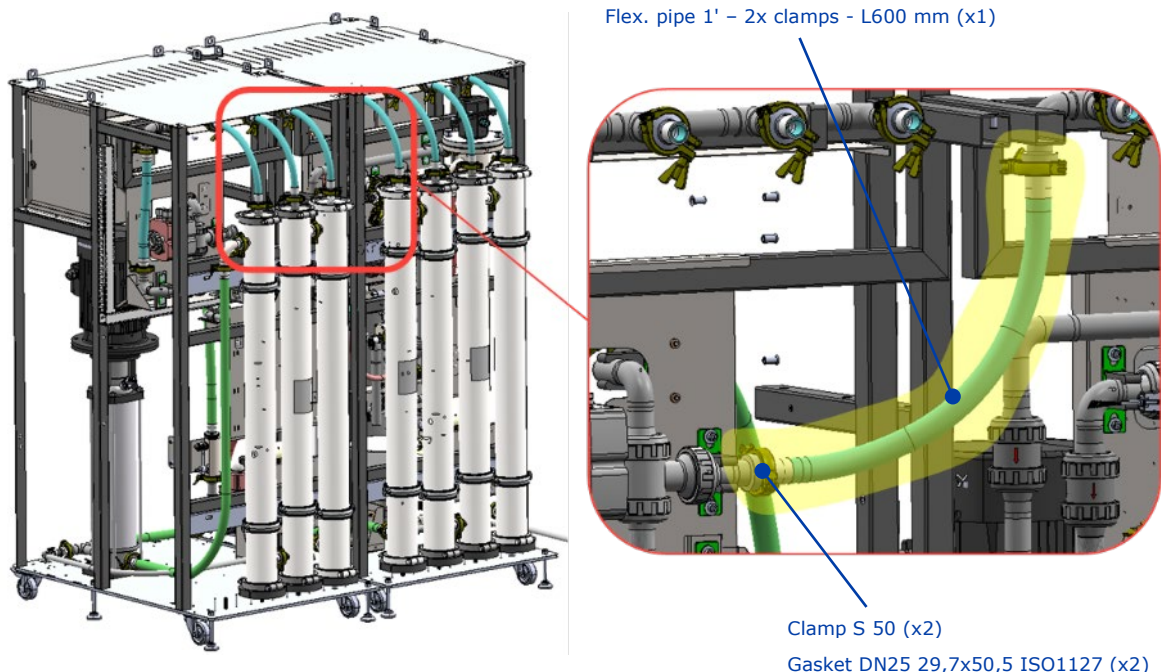


- 9- Connect the 2nd Stage unit fitting pump to the pre-tank. Manually screw the fitting completely into the pre-tank.



Flex. pipe 3/16" - male G1/4 - Loosen nut G1/4 - 1290 mm (x1)

- 10- Connect the 1st Stage unit collector to the inlet motorized valve with the flexible pipe and gaskets. Manually close the tri-clamps.



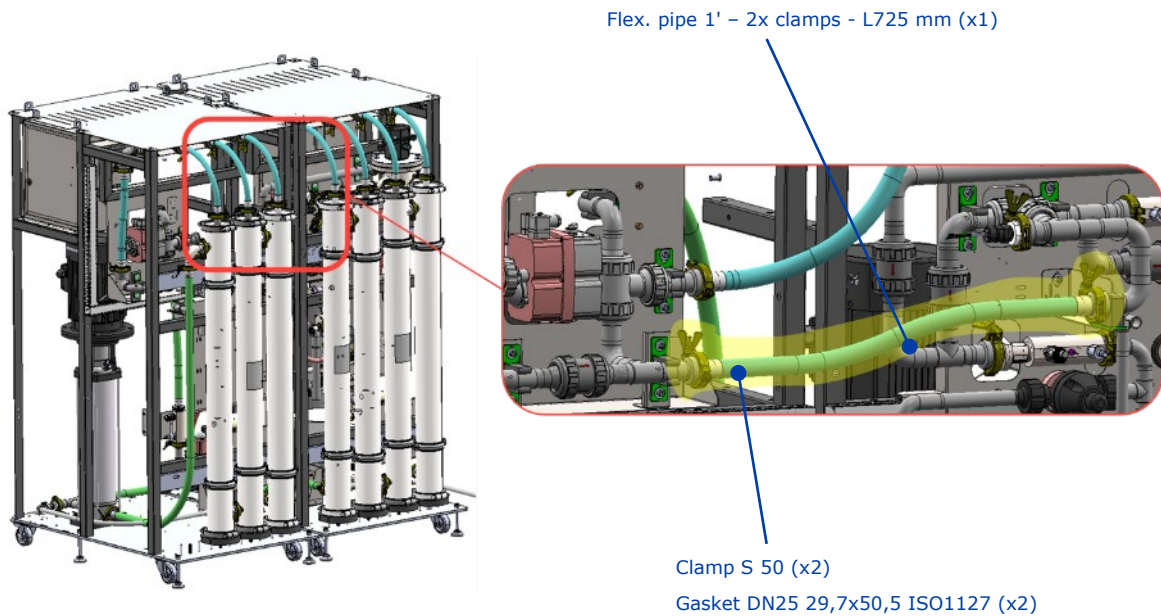
Flex. pipe 1' - 2x clamps - L600 mm (x1)

Clamp S 50 (x2)

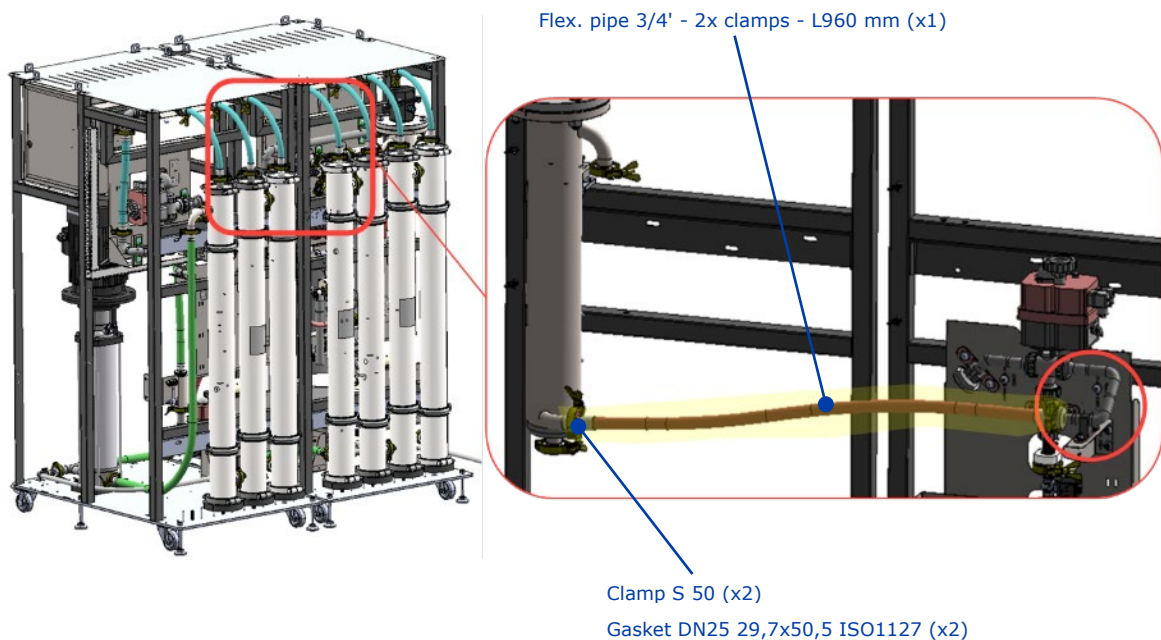
Gasket DN25 29,7x50,5 ISO1127 (x2)



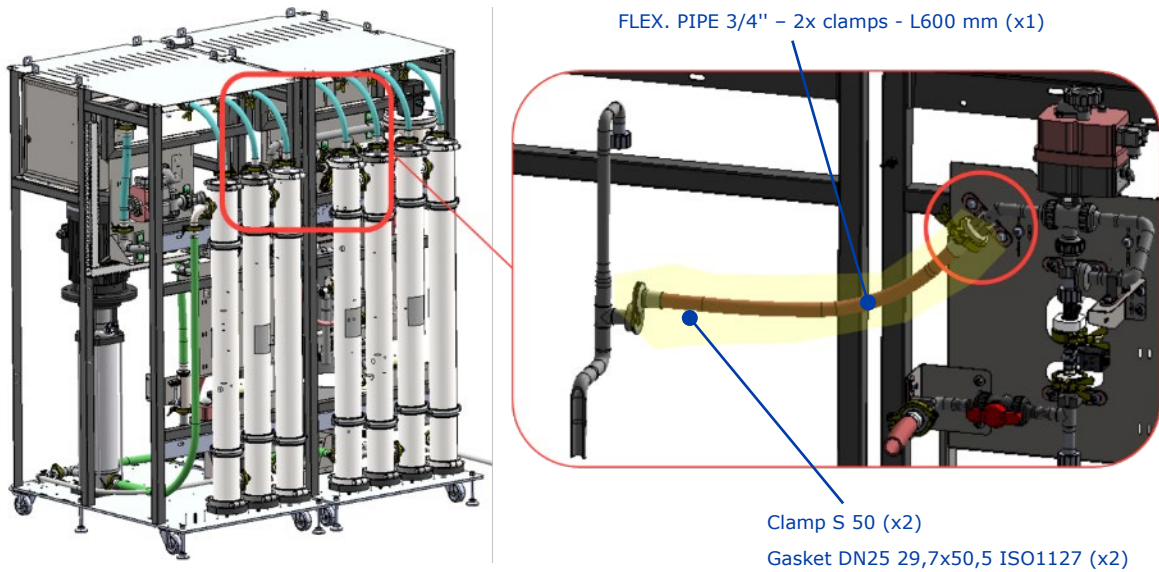
11- Connect the 1st Stage unit permeate to the 2nd Stage unit permeate with the flexible pipe and gaskets. Manually close the tri-clamps.



12- Connect the 3-way valve of the concentrate (2nd Stage unit) to the heater/concentrate recirculation (1st Stage unit) with the flexible pipes and gaskets. Manually close the tri-clamps.

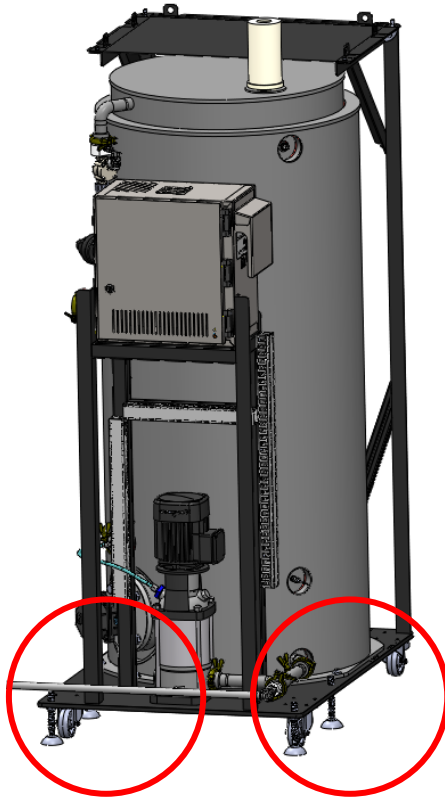


- 13- Connect the 3-way valve of the concentrate (2nd Stage unit) to the drain (1st Stage unit) with the flexible pipe and gaskets. Manually close the tri-clamps.

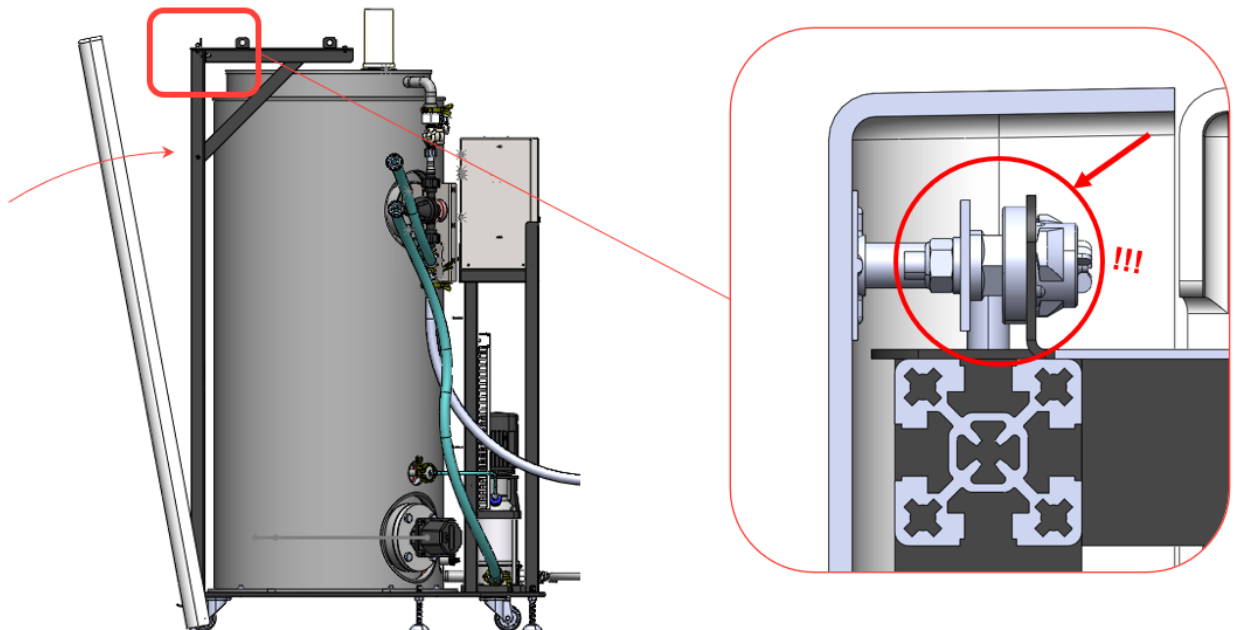


6.3.4. Loop tank

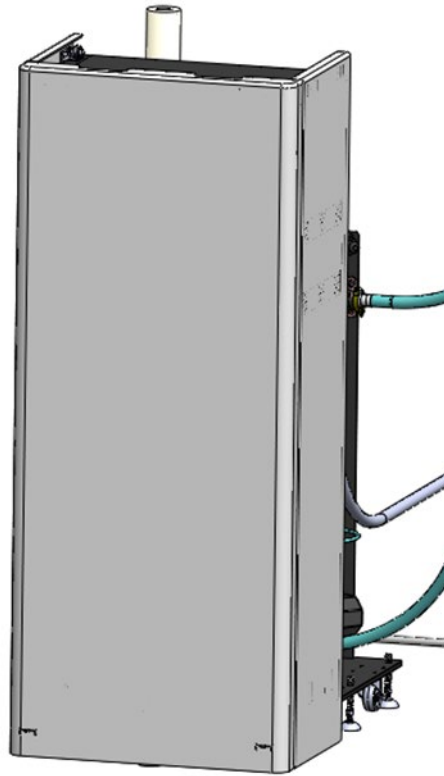
- 1- In the final part of the installation, screw in the feet to raise the unit.



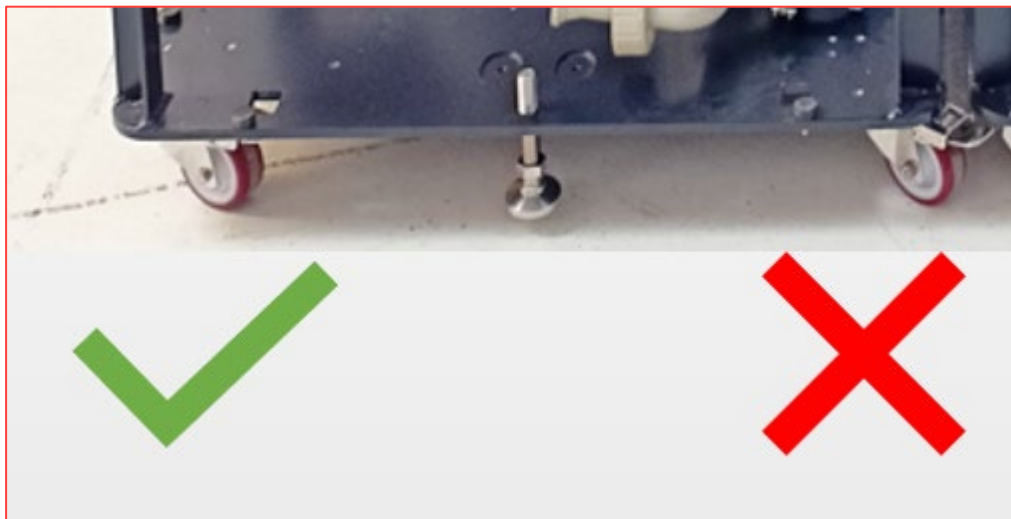
- 2- Add the front panels by rotating and positioning the hooks into the base holes. Following that, clip the parts to the top area.



3- Repeat the previous step with the lateral panels.

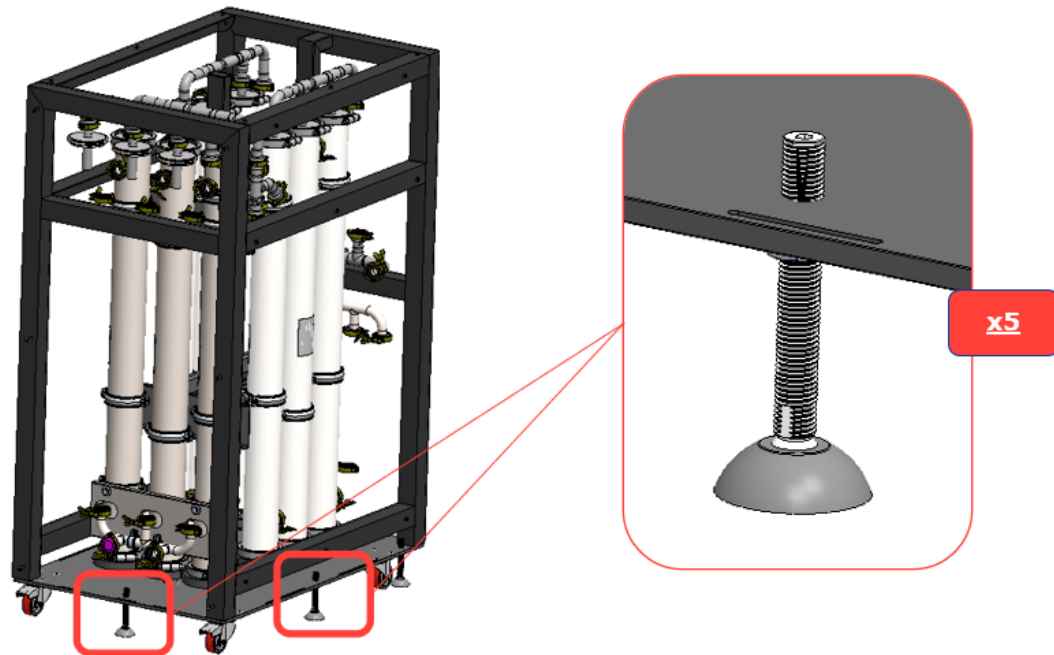


Note: To correctly mount the panels, and to prevent any interference, the front wheels must be turned, keeping the brake lever either hidden or not protruding beyond the perimeter of the base.

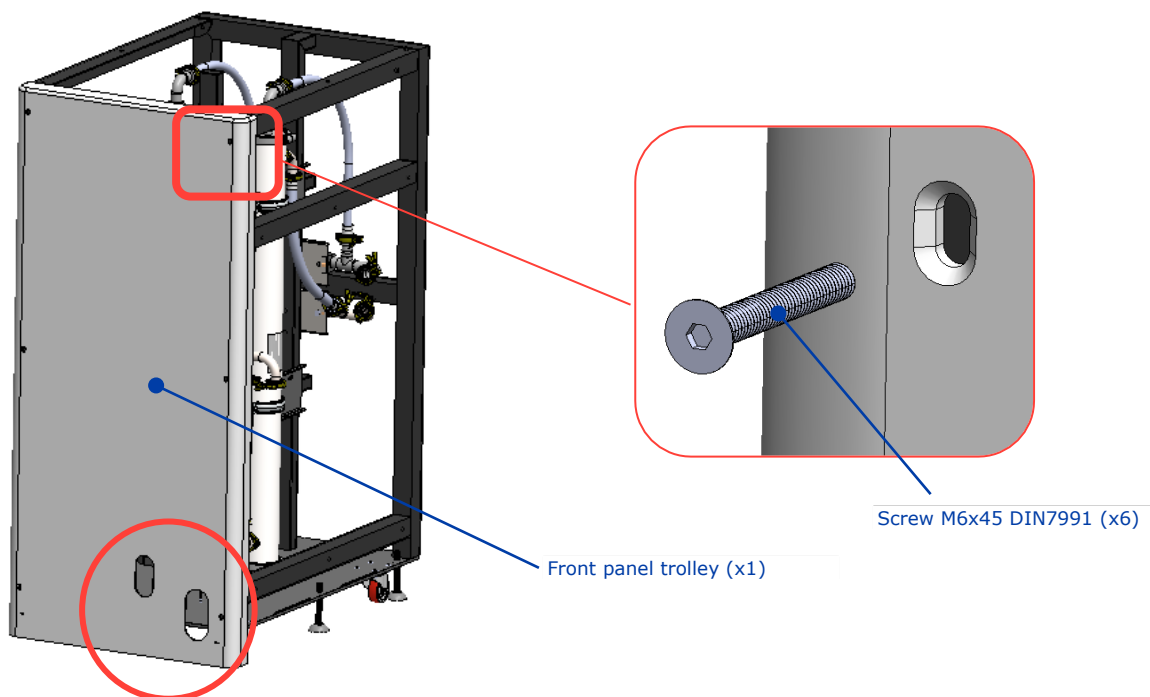


6.3.5. Trolleys

- 1- When assembling the unit in the final stage of installation, use the feet to secure its position.



- 2- Add the front panel with holes, positioning these holes for the inlet and output of flexible pipes.

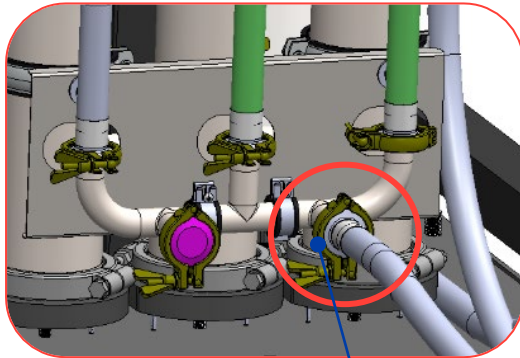


- 3- Then, connect the flexible pipes in each position.

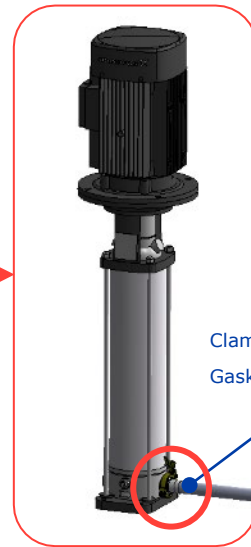


6.3.5.1. 9PV

Inlet

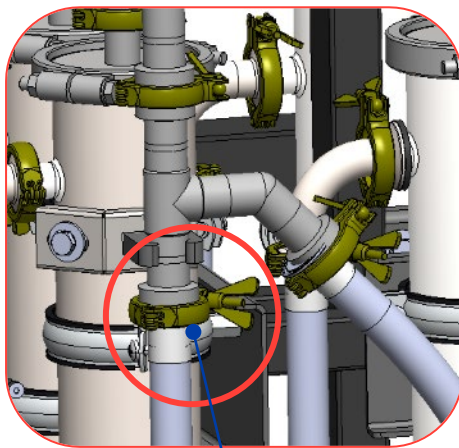


Flex. PIPE 1" - 2CLAMPS - L3000MM (x1)
Clamp S 50 (x1)
GASKET DN25 29,7x50,5 ISO1127 (x1)

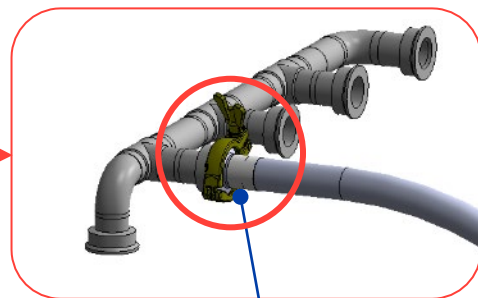


Clamp S 50 (x1)
Gasket DN25 29,7x50,5 ISO1127 (x1)

Permeate



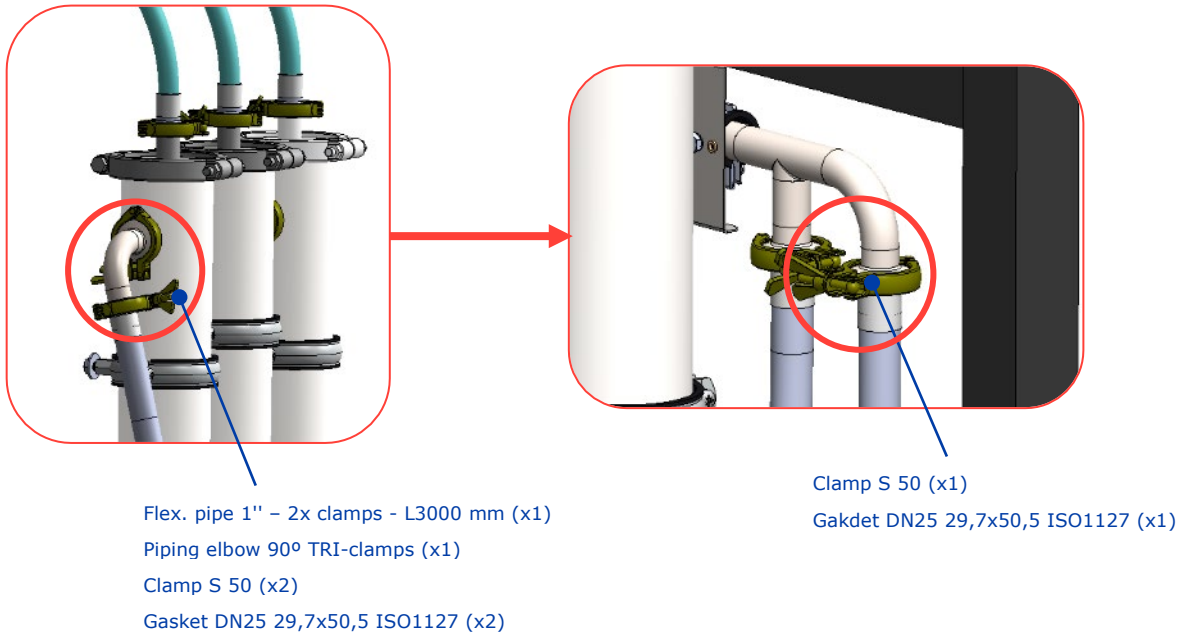
Flex. pipe 1" – 2x clamps - L3000 mm (x1)
Clamp S 50 (x1)
Gasket DN25 29,7x50,5 ISO1127 (x1)



Clamp S 50 (x1)
Gasket DN25 29,7x50,5 ISO1127 (x1)

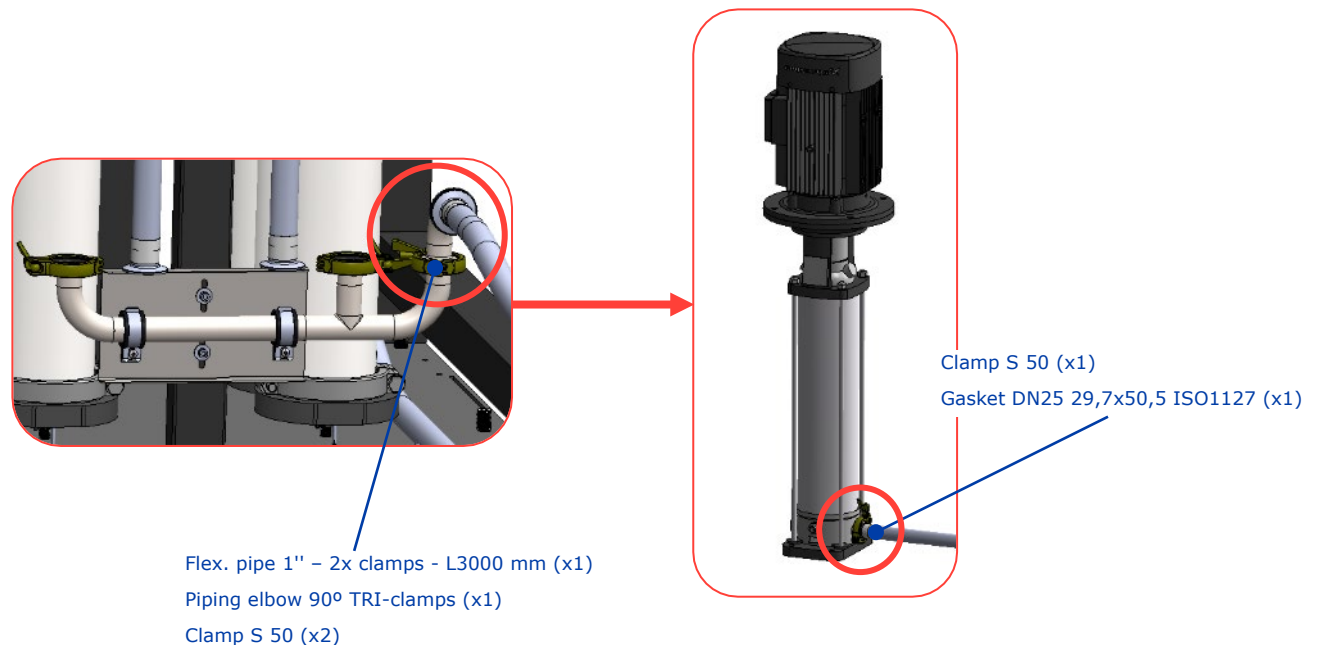


Concentrate

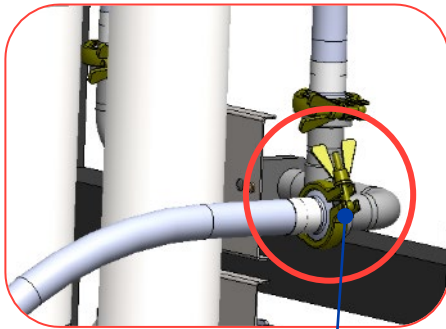


6.3.5.2. 6PV

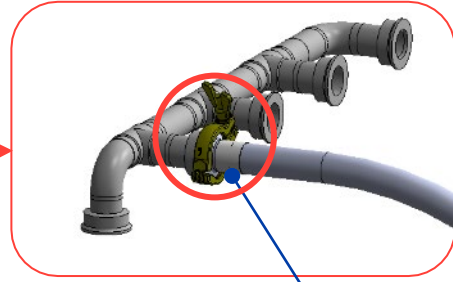
Feed



Permeate

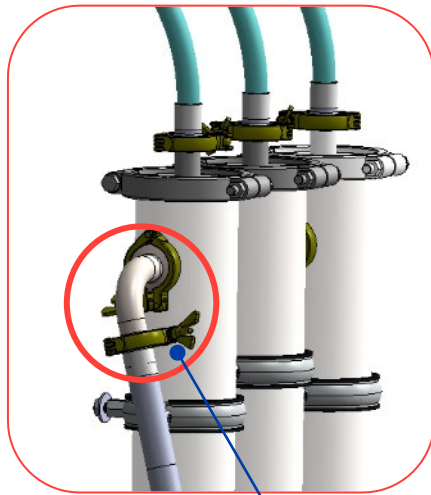


Flex. pipe 1" – 2x clamps - L3000 mm (x1)
Clamp S 50 (x1)
Gasket DN25 29,7x50,5 ISO1127 (x1)

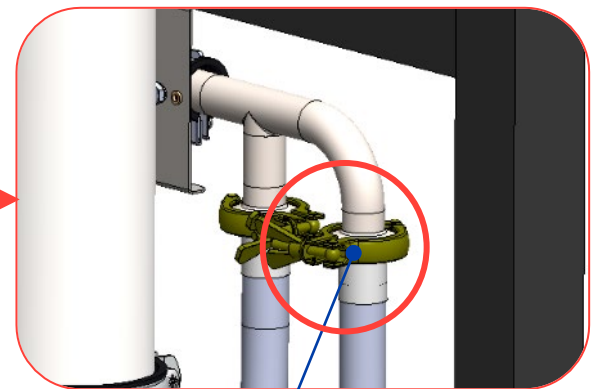


Clamp S 50 (x1)
Gasket DN25 29,7x50,5 ISO1127 (x1)

Concentrate



Flex. pipe 1" – 2x clamps - L3000 mm (x1)
Piping elbow 90° TRI-clamps (x1)
Clamp S 50 (x2)

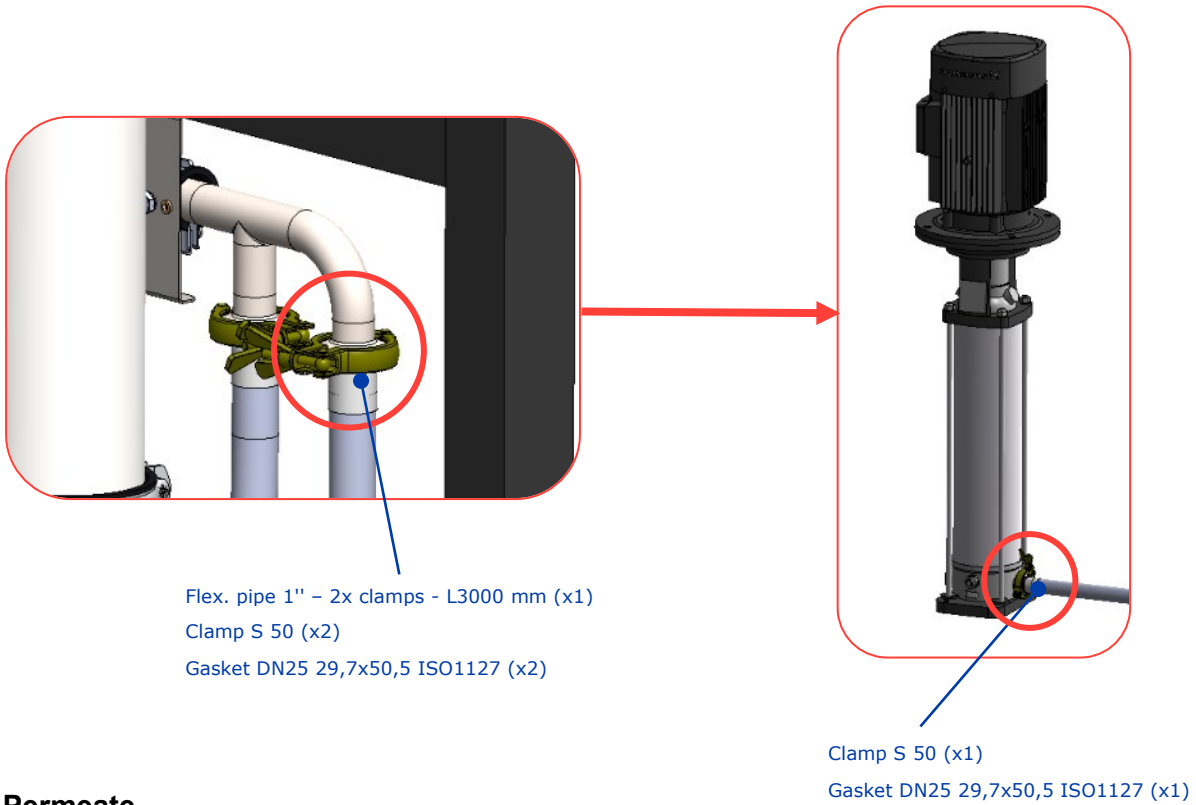


Clamp S 50 (x1)
Gasket DN25 29,7x50,5 ISO1127 (x1)

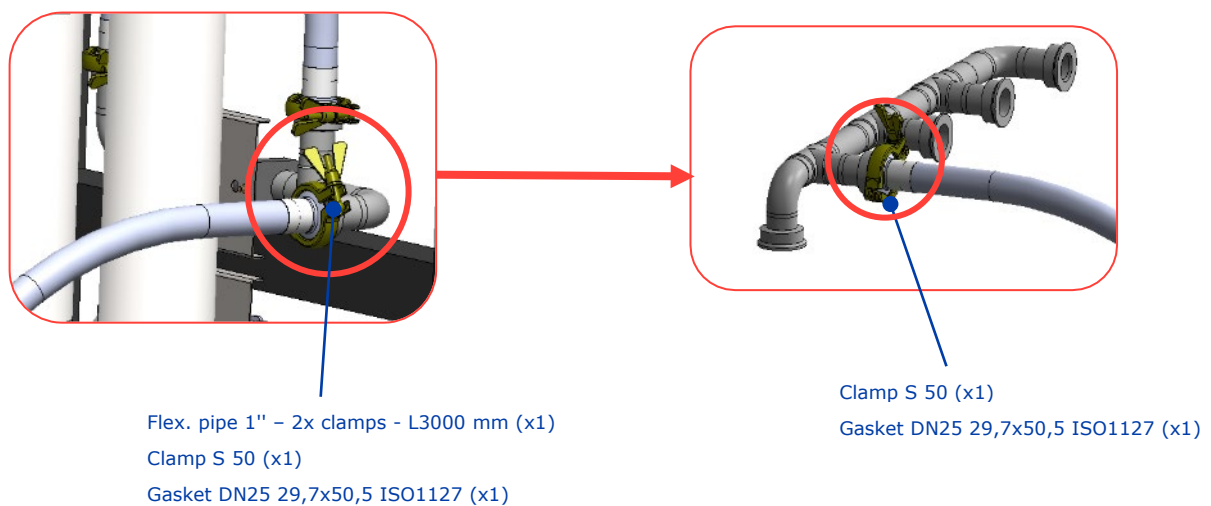


6.3.5.3. 4PV & 2PV

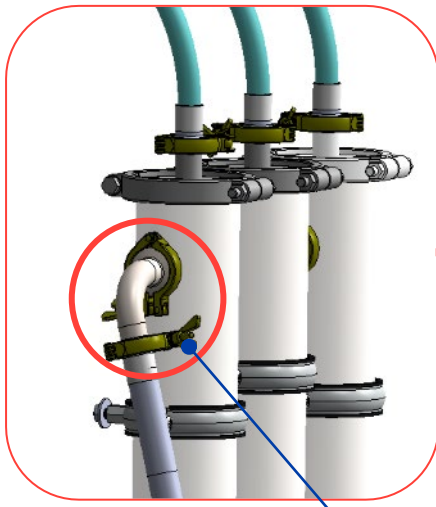
Feed



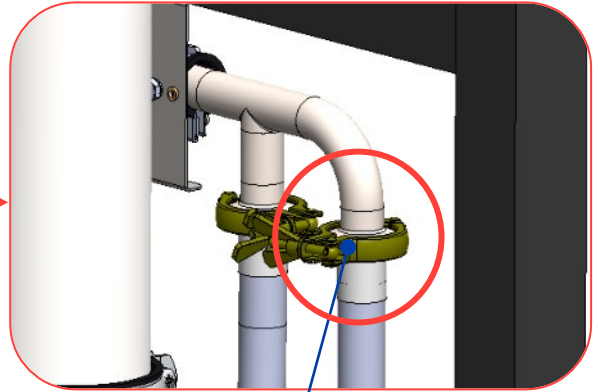
Permeate



Concentrate



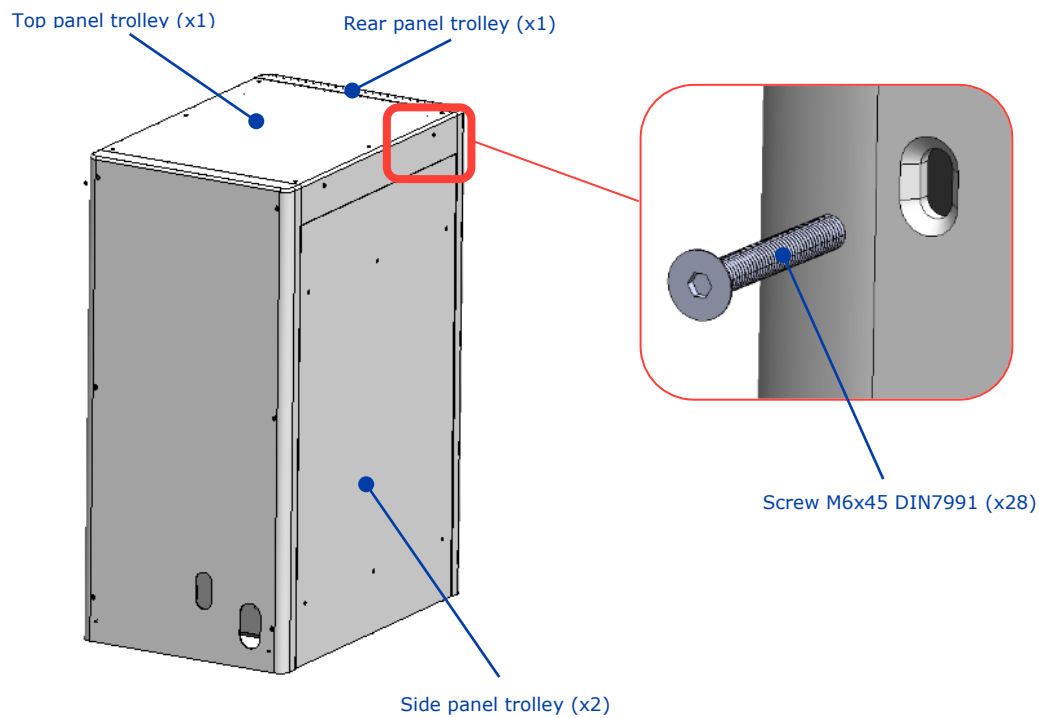
Flex. pipe 1" – 2x clamps - L3000 mm (x1)
Piping elbow 90° TRI-clamps
Clamp S 50 (x2)
Gasket DN25 29,7x50,5 ISO1127 (x2)



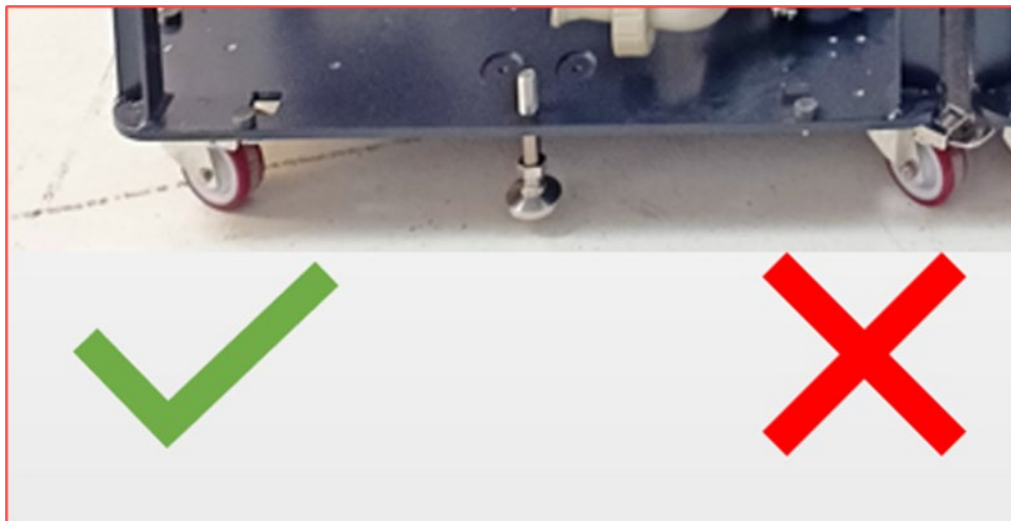
Clamp S 50 (x1)
Gasket DN25 29,7x50,5 ISO1127 (x1)



4- Finally, assemble the rest of the panels to completely close the unit.



Note: To correctly mount the panels, and to prevent any interference, the front wheels must be turned, keeping the brake lever either hidden or not protruding beyond the perimeter of the base.



6.4. Electrical installation



The installation must be performed exclusively by a qualified electrician.



The device requires a permanent connection, the use of connectors are not permitted.



Safety class I

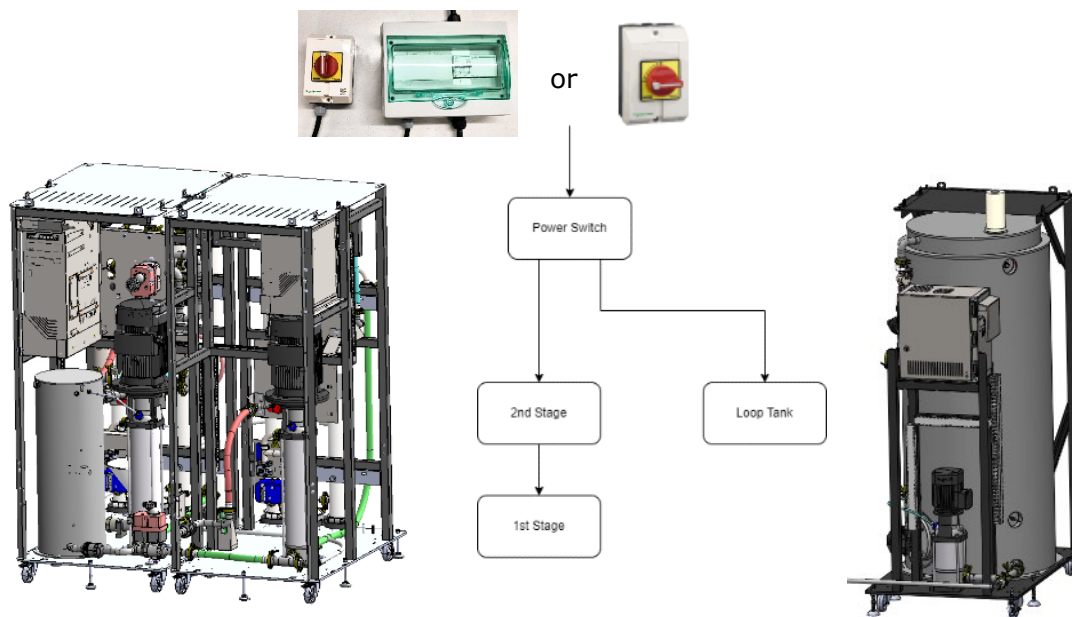
The device is equipped with a protective earth terminal for prevention against a high touch current.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a mains supply with a protective earth connection.



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

The power supply to the device shall be set up in accordance with the following scheme:

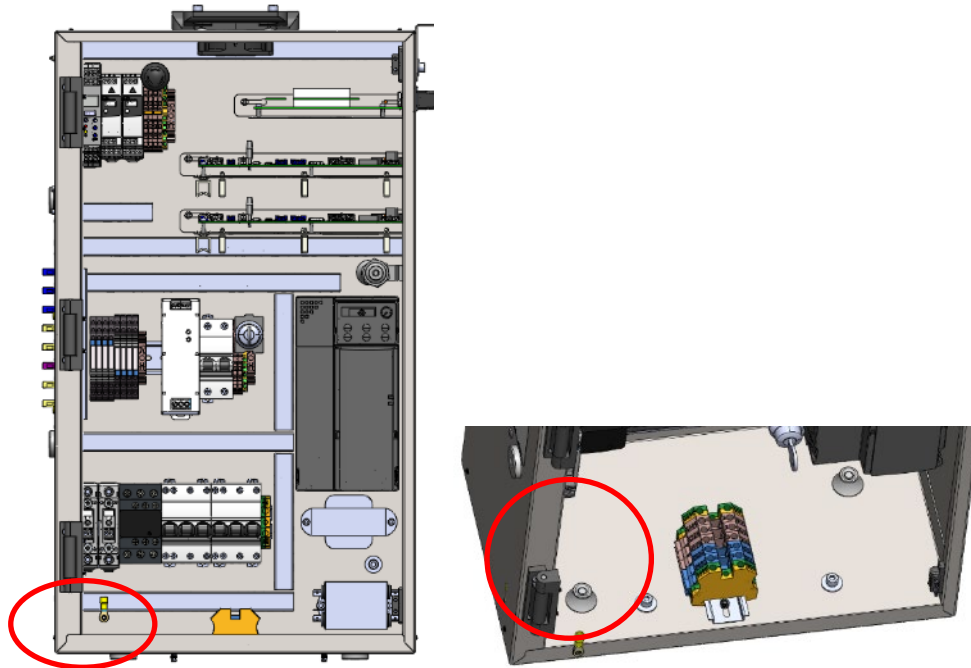


The power switch delivered with the device shall be placed in a convenient location for proper operation.

For variants of the device including Loop tank, the output of the power switch shall be connected both to the Loop tank and to the 1st Stage. For other variants, the output of the power switch shall be connected directly to the 1st Stage.

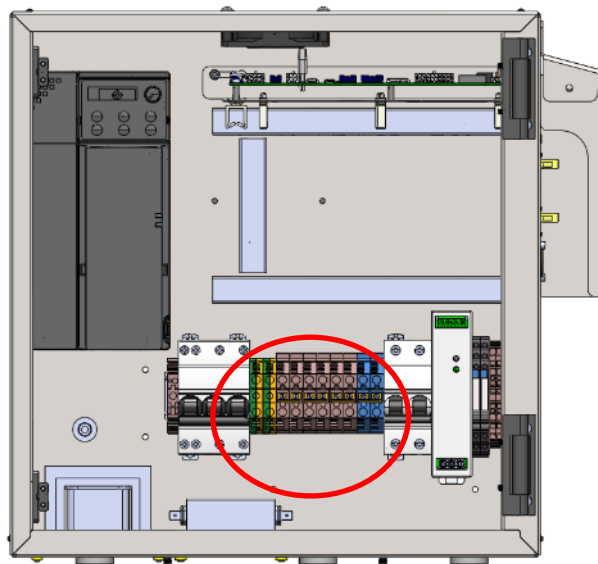


Details of power ports of 1st Stage control box:

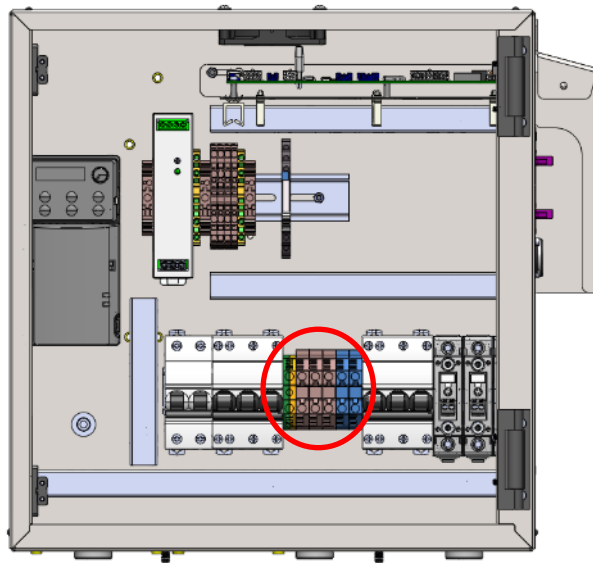


For variants with Double Stage, the output of the power switch shall be connected to the 2nd Stage control box. The 2nd Stage control box shall then provide power to the 1st Stage control box.

Details of the power ports of the 2nd Stage control box - ports are duplicated so that they can be used to deliver power to the 1st Stage control box:



Details of power ports of Loop Tank control box:

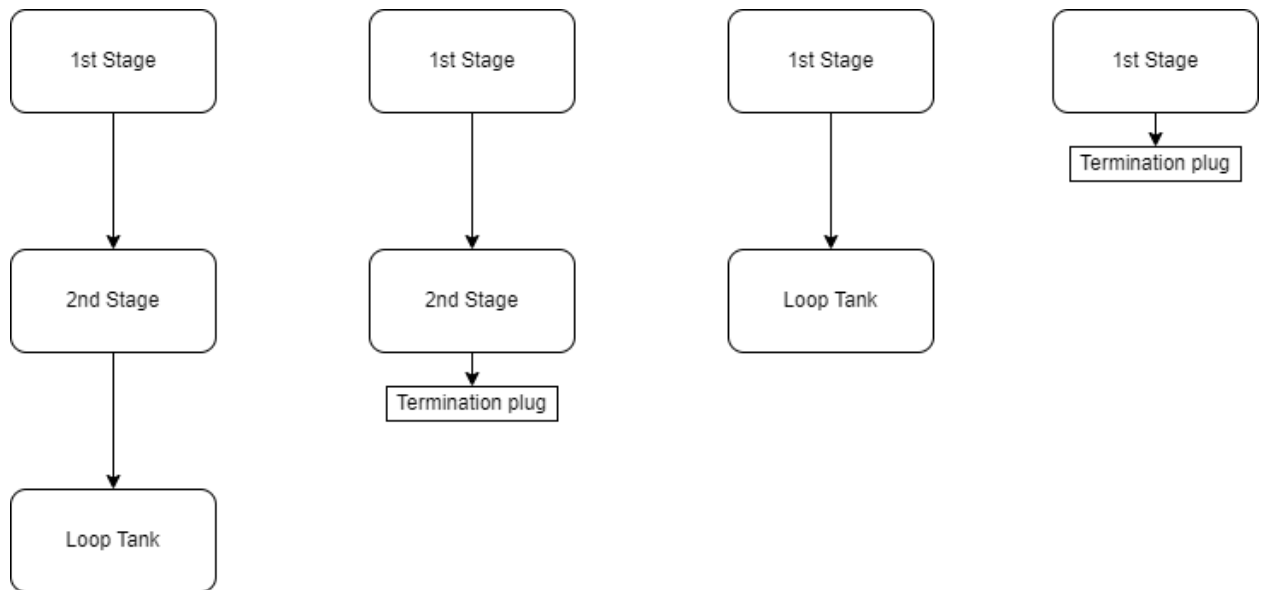


The conventional color code shall be used for the connections:

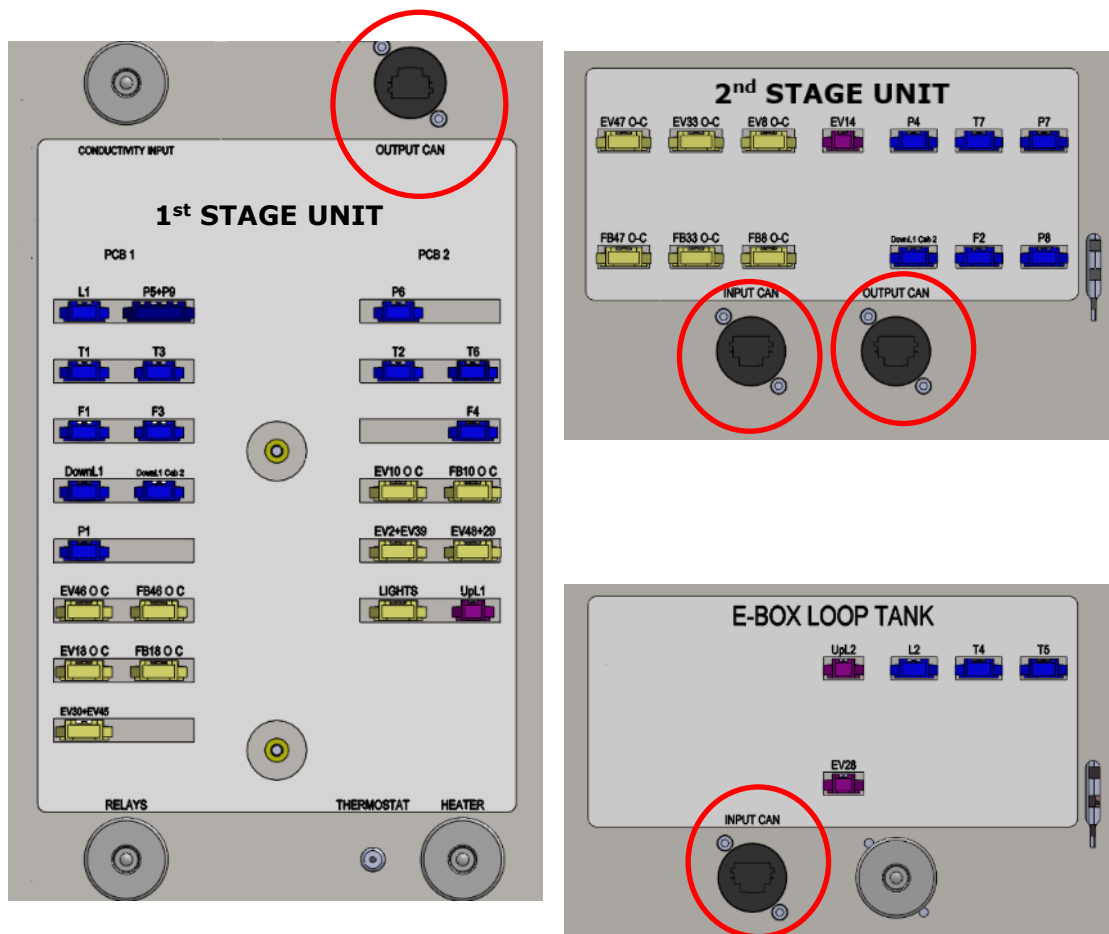
- Green / Yellow: Earth
- Blue: Neutral
- Grey: L1, L2, L3

6.5. Inter-cabinet communication

The control box of each unit must communicate with every other unit, so that all processes are synchronized. The topology of the communication, depending on variant, must follow this scheme:



The location of the inter-unit communication is indicated in the following images:



6.6. Pre-filtration

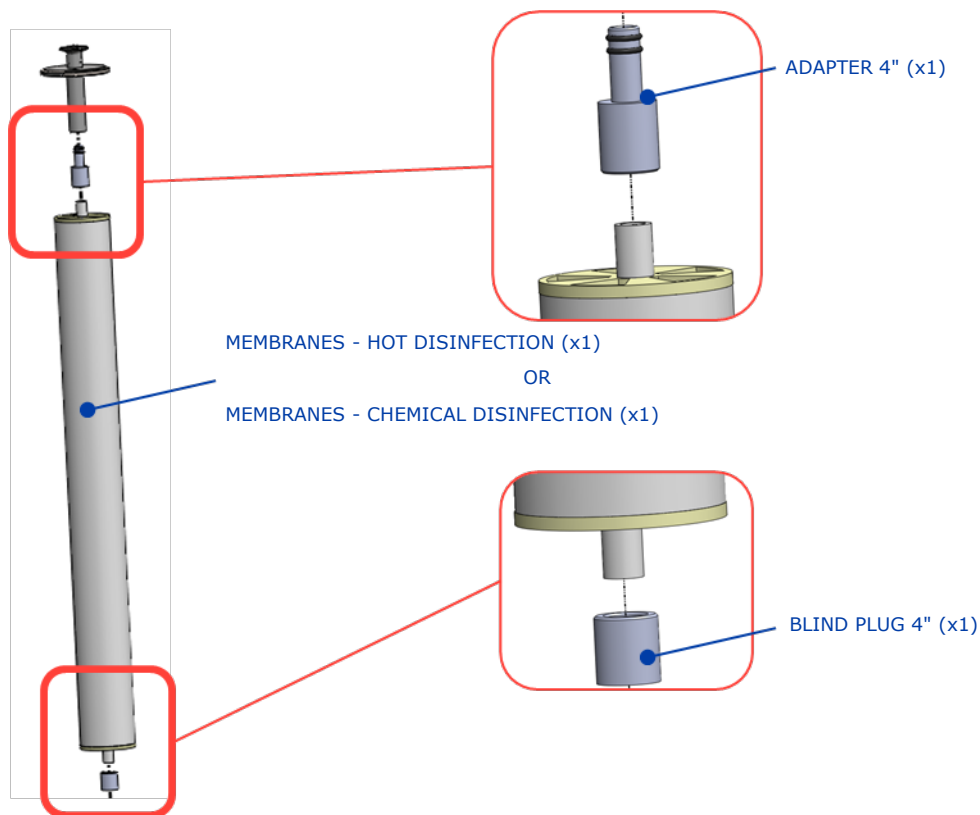


Before connecting the LiniXia and starting up, ensure that the inlet water complies with the quality requirements indicated in chapter 4.2.

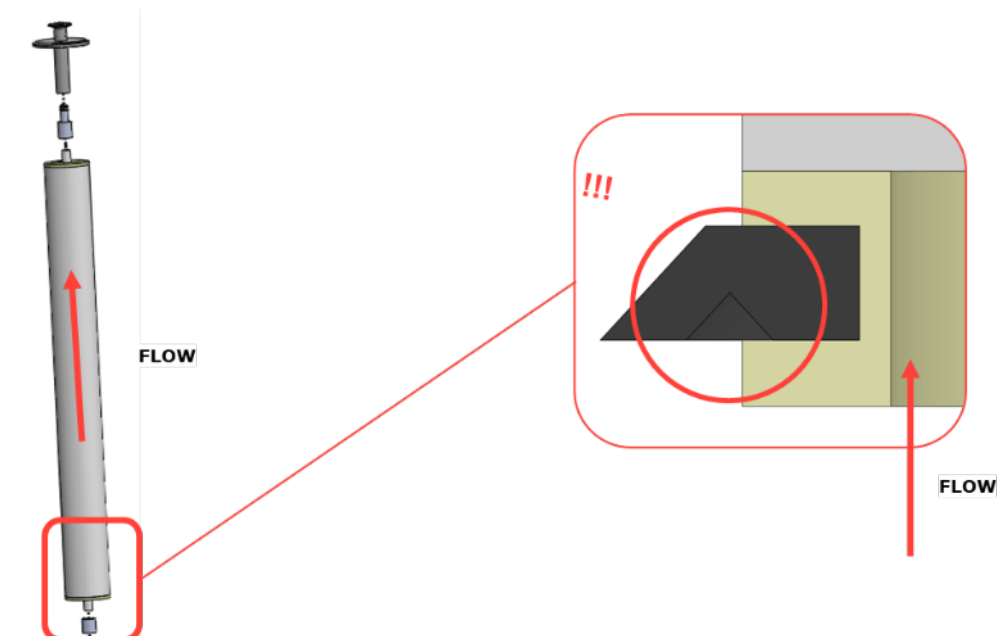
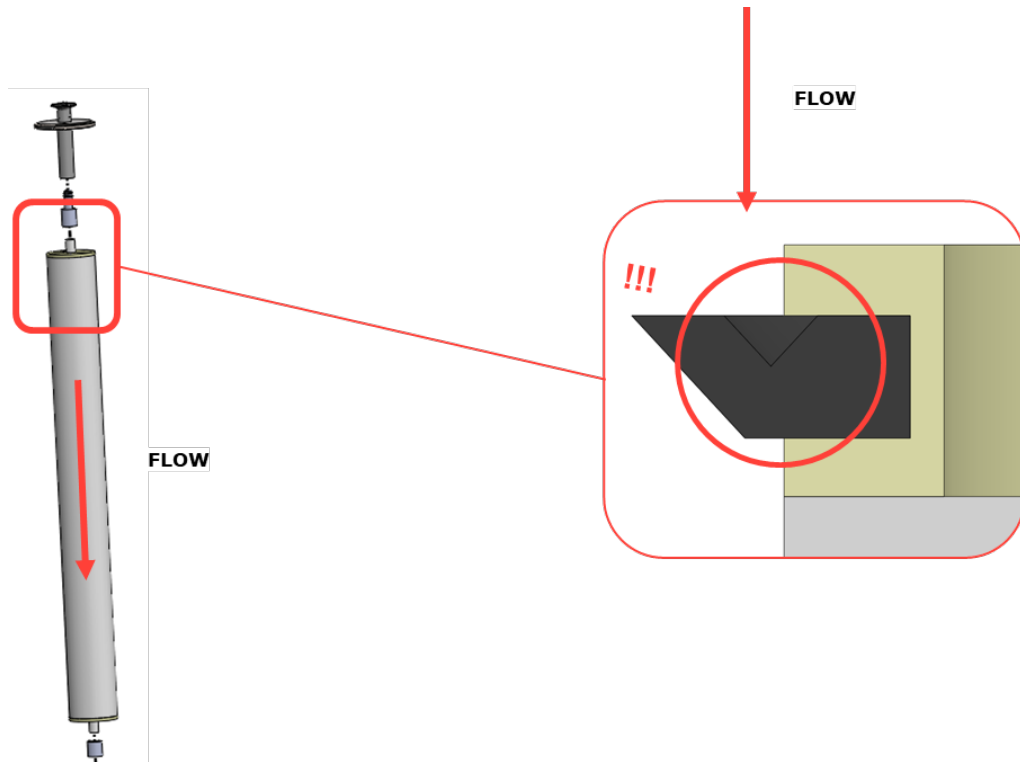
6.7. Assembling membranes

The device is delivered without installed membranes. The membranes are packed separately beside the device.

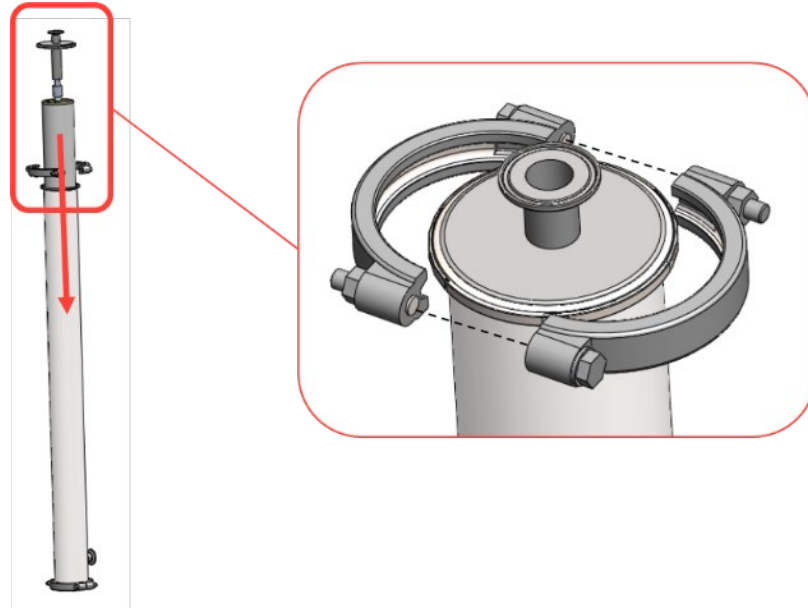
- 1- Select the appropriate membrane (hot/chemical) and add the adapters to the top and bottom connections.



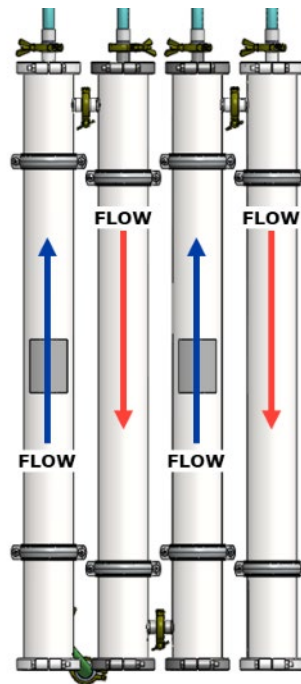
- 2- HOT MEMBRANES: Depending on the flow direction, assemble and orient the membrane O-ring to the top/lower housing.



- 3- Inset the membrane into the pressure vessel with the top inlet. Following that, close the vessel with the flange.



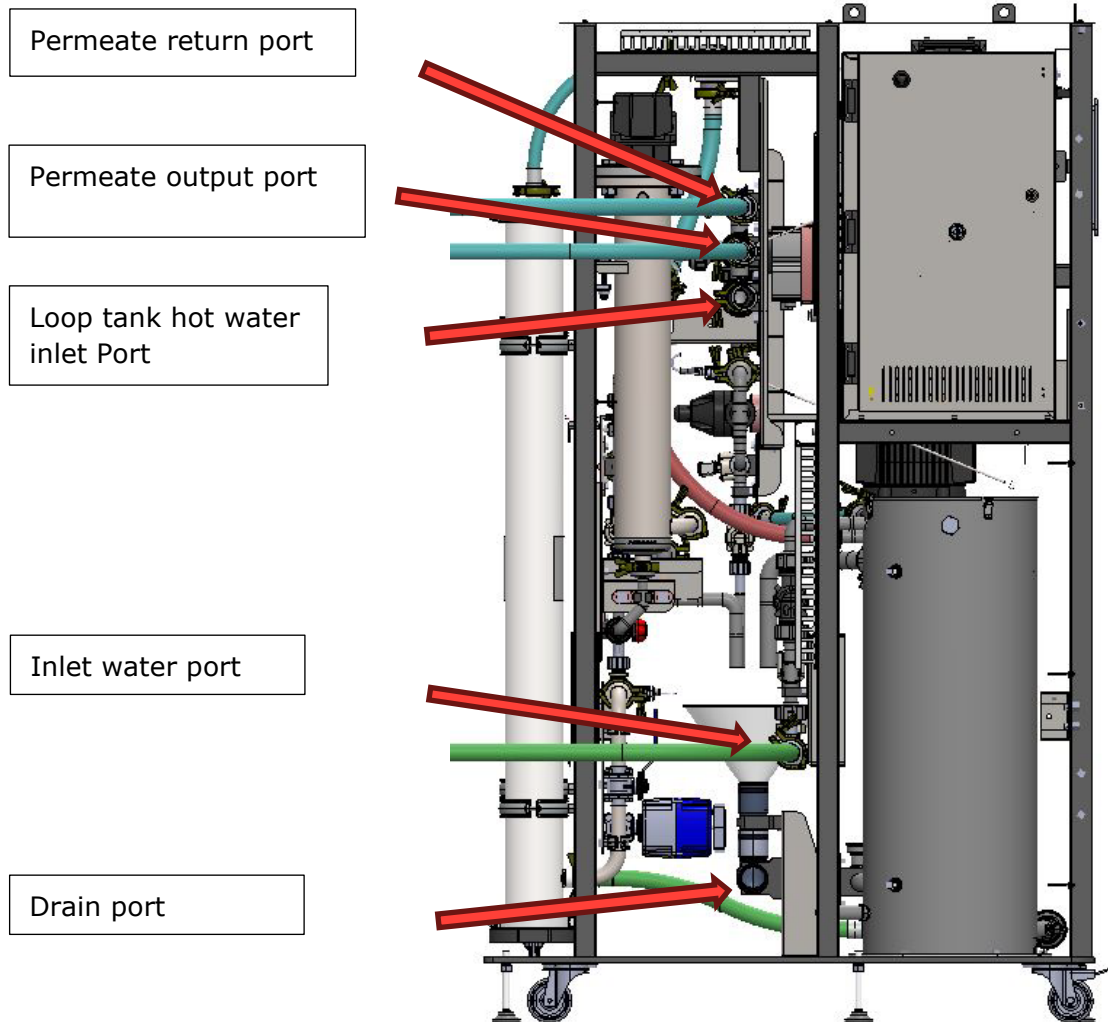
- 4- Follow the flow diagram and correctly assemble the PVs, depending on the quantity, in each position.



6.8. Input & output

6.8.1. Hydraulic connections:

Location of hydraulic connections in 1st Stage unit:



6.8.2. External contacts:

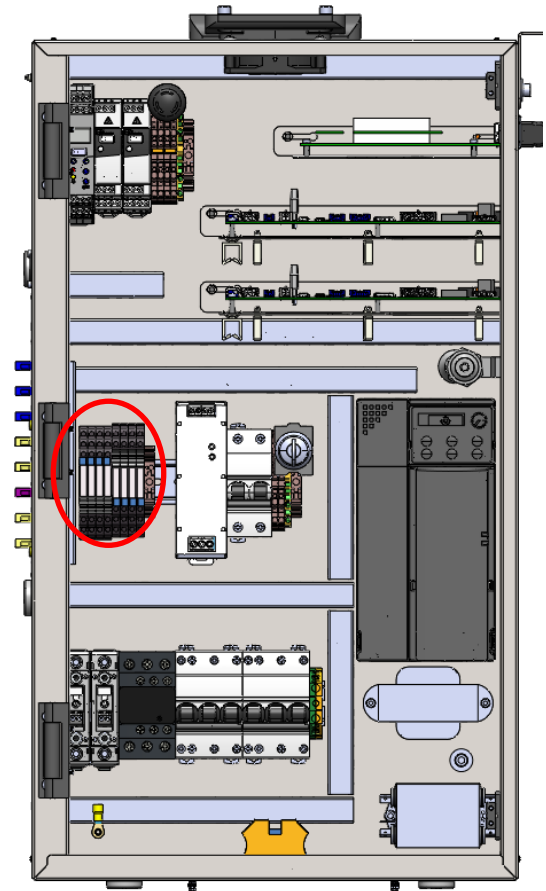
Identification and location of the external contacts in the 1st Stage control box:

Inputs:

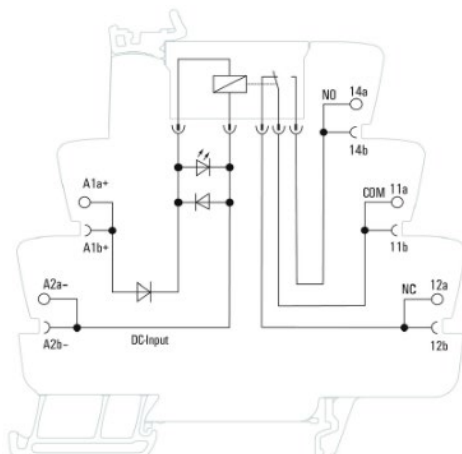
- 1: external start
- 2: external stop
- 3: chlorine alarm
- 4: floor water

Outputs:

- 5: chemical pump
- 6: warning
- 7: lights R
- 8: lights G
- 9: lights B

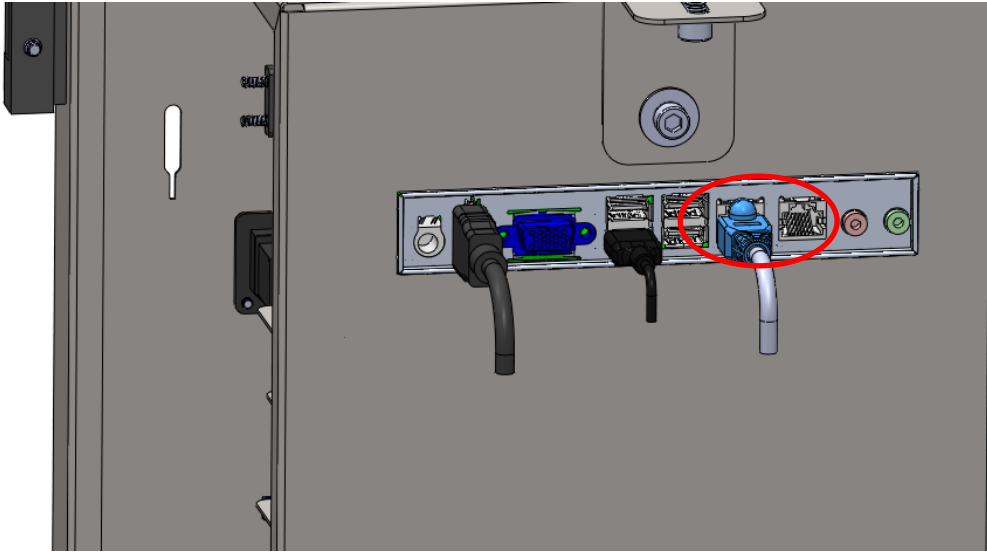


- External contact inputs shall use 24Vdc to activate the relays.
- Schematic of relay ports for inputs and outputs:



6.8.3. Communication and service port:

Ports for communication and service are found in the front part of the control box of the main unit (1st Stage). The position is indicated in the following image:



7. Starting up

7.1. Electrical connection

For electrical connection, follow chapter 6.4 Electrical Installation, respecting the input ratings indicated in the product label of the LiniXia variant to be installed.

7.2. Testing the supply cable and protective earth connection

Inspect the connection cable and test the protective ground connection according to maintenance protocol FB62.

7.3. Hydraulic connection

Feed water supply shall fulfil the requirements described in chapter 4.2.

Physical connection to inlet water and drain is defined in chapter 4.3.



Ensure that inlet water complies with quality requirements indicated in chapter 4.2.

After this, connect the device and start up.

7.4. Rinsing the membranes

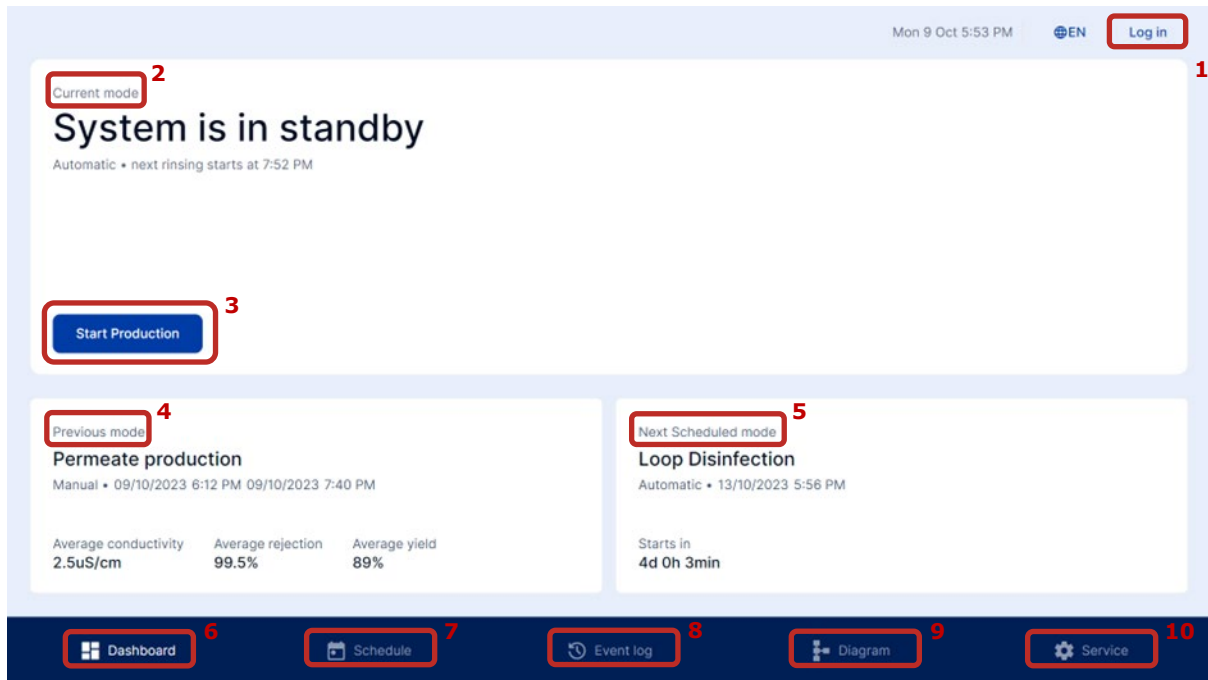
To rinse the membranes, the Chemical Rinsing mode shall be activated through the service menu.

See chapter 8.3.6.4 Actions, for Chemical Rinsing procedure.



8. Operation

8.1. Control panel



1. Log in button
2. Current Mode
This area displays information regarding the current operation mode.
3. Start Production button
This button allows the launch of permeate production.
This is the only operation that can be launched without the need to be logged in.
Therefore, anyone with access to the device can launch a permeate production.
4. Previous Mode
Information about the completed previous operation mode.
5. Next Scheduled mode
Information regarding the next scheduled operation.
6. Dashboard
Button to access the dashboard section.
7. Schedule
Button to access the schedule section.
8. Event log
Button to access the Event log section.
9. Diagram
Button to access the Diagram section.
10. Service
Button to enter the Service menu.



8.1.1. Light indicators

LiniXia has a status light on the front of the 1st Stage unit. This light provides information about the status of the device, notifications, and warnings.

The color code is described in the following table:

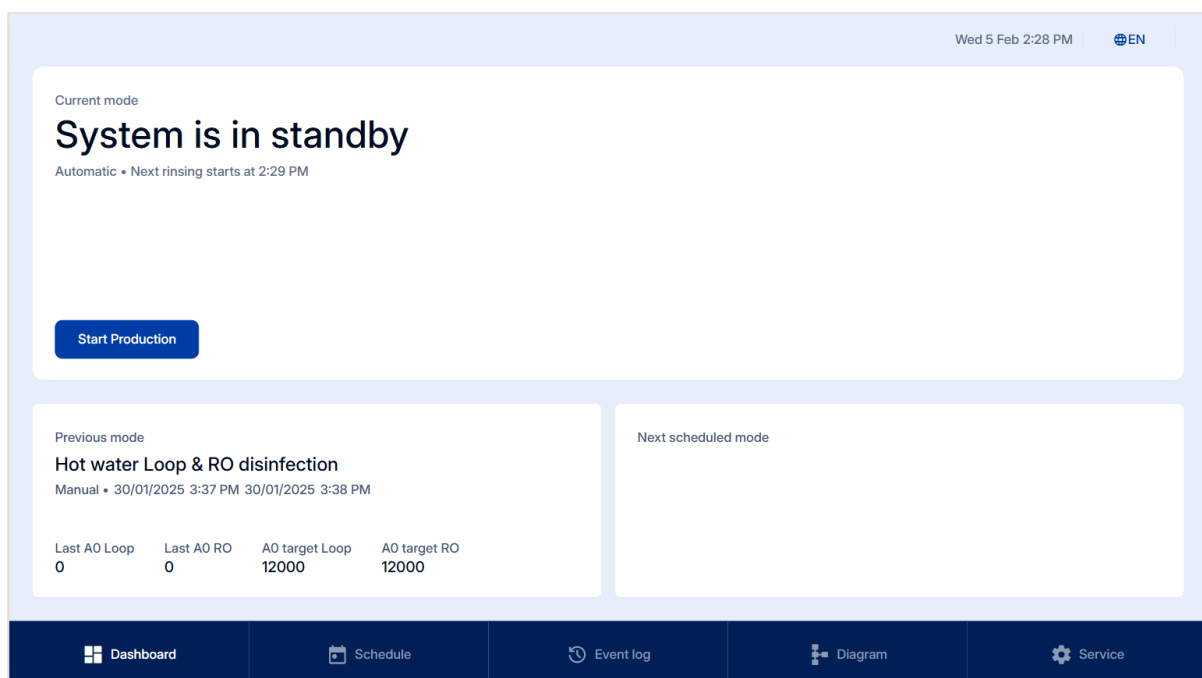
		No notification	Notification Active
Status	Stand-by	White flashing	Yellow permanent
	Rinse	Green flashing	Yellow permanent
	Production	Green permanent	Yellow permanent
	First pass or second pass only mode for Double Stage systems	Yellow permanent	Yellow permanent
	Loop hot water disinfection	Blue flashing	Blue flashing
	RO hot water disinfection	Blue flashing	Blue flashing
	RO chemical disinfection	Blue / Yellow alternating	Blue / Yellow alternating
	Warning	Red permanent	Red permanent

Additionally, if there is an active warning, the device has a buzzer that emits a specific 80 dB sound.

8.1.2. Nurse Panel

The Nurse Panel is an option, that allows users to perform operations that do not require logging in.

The login option is not available.





The Nurse Panel must be kept in a restricted area to be accessible for authorized staff only.



8.2. Emergency operation

LiniXia has an emergency operation mode, so that in the event of a software failure preventing the continuation of an ongoing dialysis treatment, it can be safely terminated without harming the patient.

To proceed with the emergency mode, the left side panel of the 1st Stage unit must be removed to access the key located on the e-cabinet door.

To enter the emergency mode, turn the key of the operating switch to position I.



To turn off emergency operation mode, turn the switch to position 0.



Switch position II is to activate the chemical disinfection mode.



In emergency operation, all actuators are controlled by hardware. Permeate production runs at a fixed rate. The display shows that emergency mode is activated.

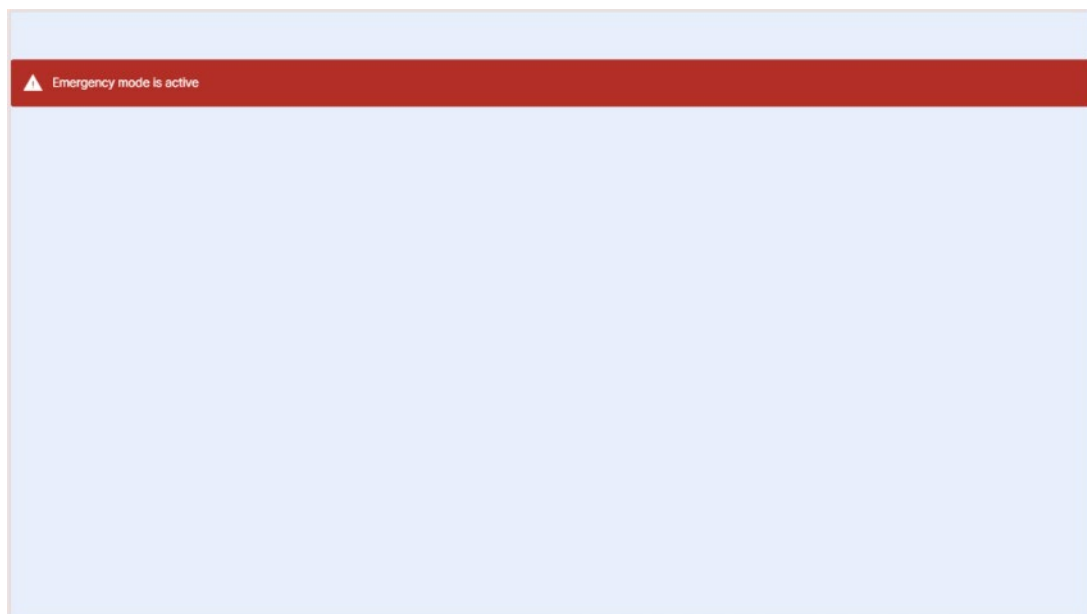


The permeate quality will not be monitored.



The use of the emergency mode shall be limited to a minimum and shall be used if the conductivity is within range.

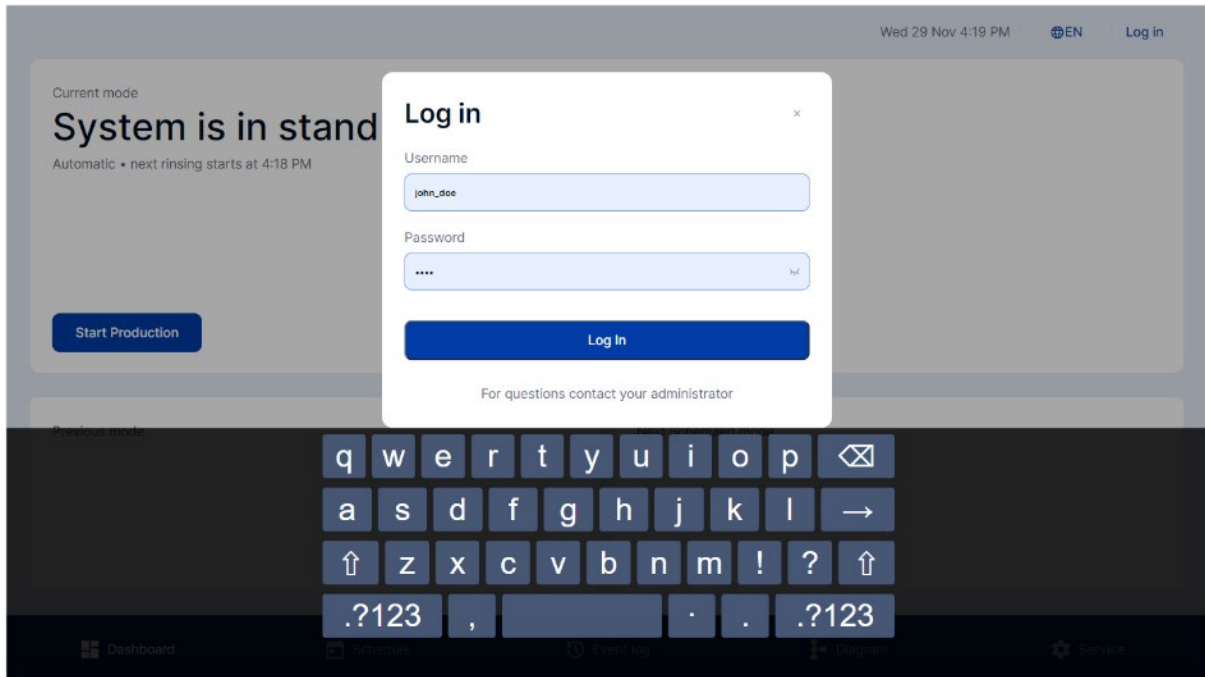
Emergency mode display information:



8.3. Main menu and sub-menus

8.3.1. Log in

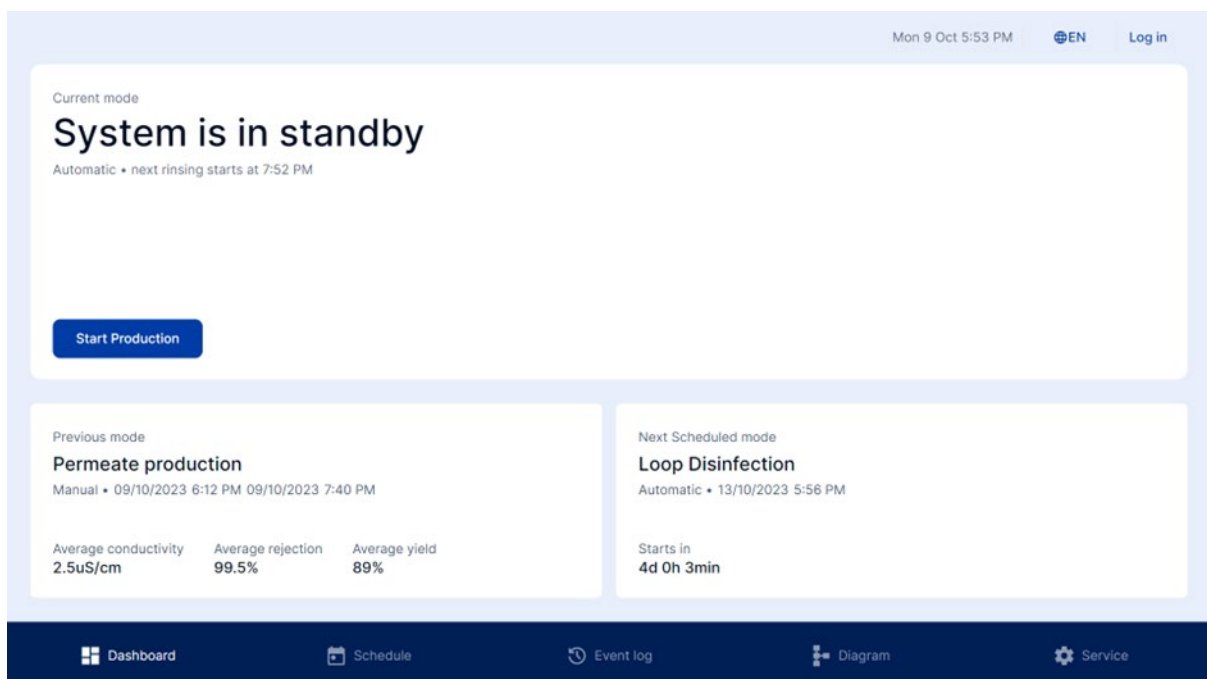
Log in to access the functionalities available for registered users.



8.3.2. Dashboard

Dashboard views display information about Current Mode, as well as Previous Mode and Scheduled Mode.

The main functionalities available are accessible through this view.

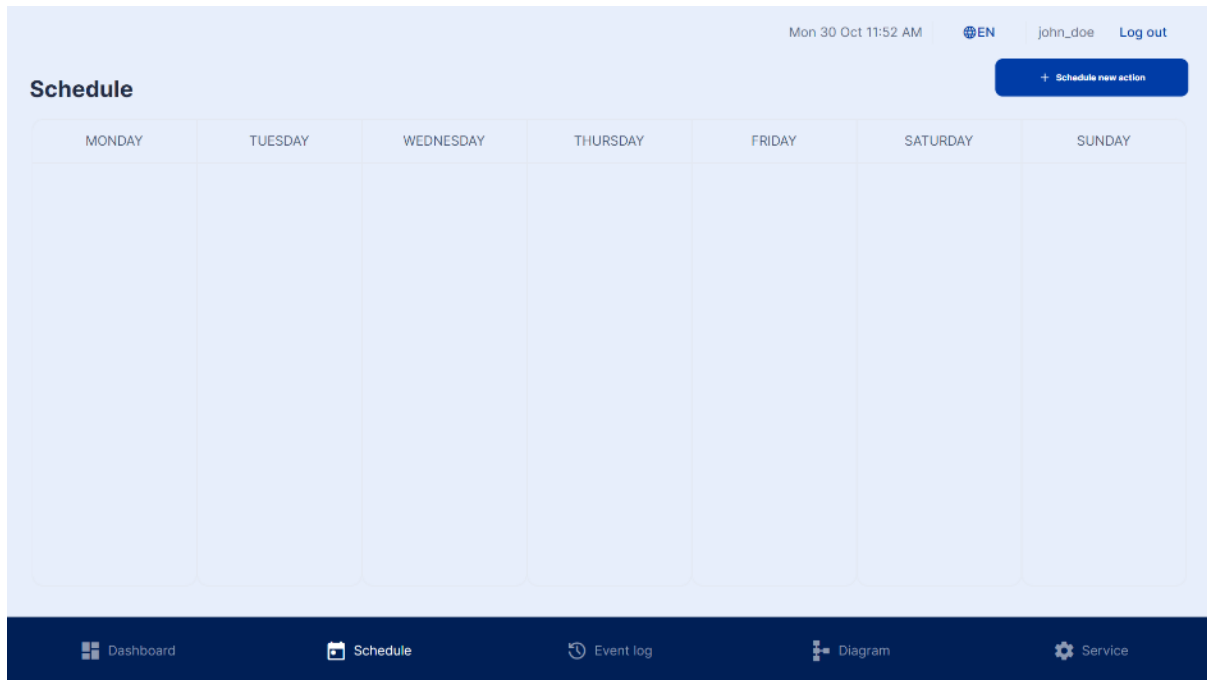


8.3.3. Schedule

The scheduler allows the programming of the start and stop times for permeate production throughout a week. It also allows the programming of the start of hot water disinfection automatically.

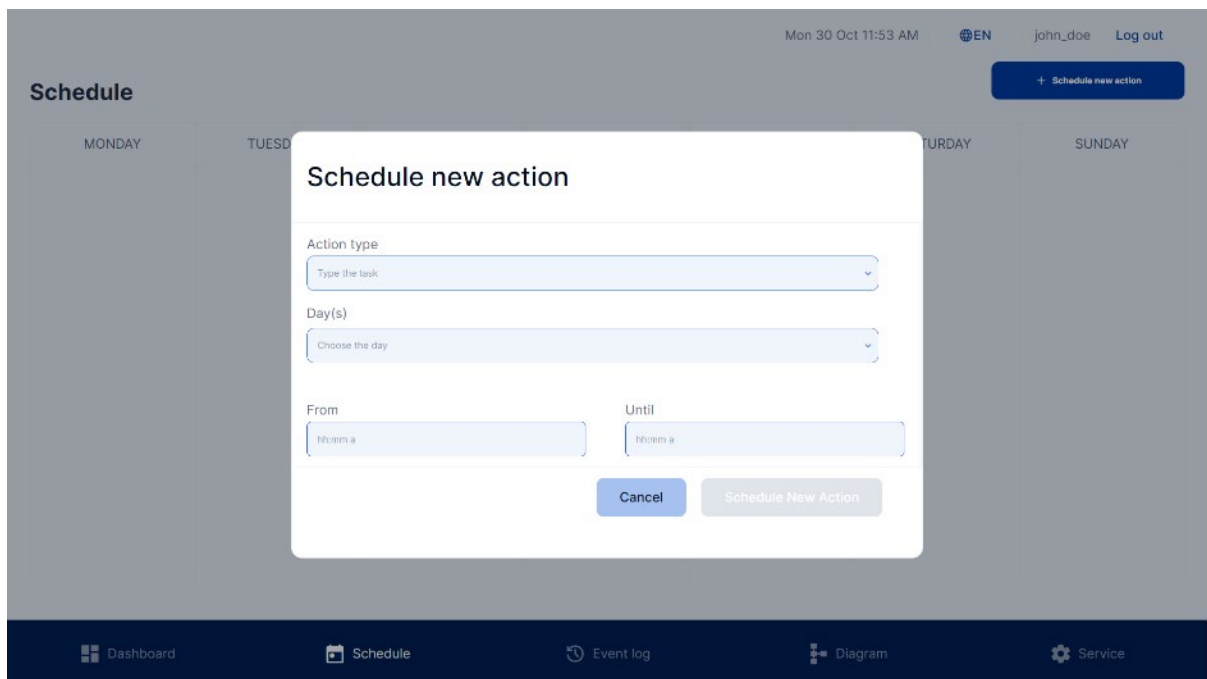
It is possible to program up to 5 separated permeate production periods per day.

Hot water disinfection scheduling is limited to 1 disinfection of each kind per day.



The screenshot shows the 'Schedule' interface. At the top right, it displays 'Mon 30 Oct 11:52 AM', 'EN', 'john_doe', and 'Log out'. Below this is a blue button labeled '+ Schedule new action'. The main area is a calendar grid with columns for MONDAY, TUESDAY, WEDNESDAY, THURSDAY, FRIDAY, SATURDAY, and SUNDAY. The grid is currently empty. At the bottom, there is a dark blue navigation bar with icons and labels for 'Dashboard', 'Schedule', 'Event log', 'Diagram', and 'Service'.

Click "Schedule new action" to introduce an item to the scheduler.



The screenshot shows the 'Schedule new action' modal form. The form has a title 'Schedule new action'. It contains four input fields: 'Action type' with a dropdown menu showing 'Type the task', 'Day(s)' with a dropdown menu showing 'Choose the day', 'From' with a text input field showing '11:00:00', and 'Until' with a text input field showing '11:00:00'. At the bottom of the form are two buttons: 'Cancel' and 'Schedule New Action'. The background shows the same 'Schedule' interface as the previous screenshot, but it is dimmed.



Select action type.

The screenshot shows the 'Schedule new action' dialog box. The 'Action type' dropdown is set to 'Permeate'. Below the dropdown, there are four radio button options: 'Permeate' (selected), 'Hot Disinfection', 'RO Disinfection', and 'Loop Disinfection'. At the bottom of the dialog, there are two buttons: 'Cancel' and 'Schedule New Action'. The background shows a calendar view for the week of Monday to Sunday, and a top navigation bar with 'Dashboard', 'Schedule', 'Event log', 'Diagram', and 'Service'.

Select weekday(s). Multiple selection is possible.

The screenshot shows the 'Schedule new action' dialog box with the 'Action type' set to 'Permeate'. The 'Day(s)' section shows a list of weekdays: Monday, Tuesday, Wednesday, Thursday, Friday, and Saturday. The first five days (Monday through Friday) are selected with checkboxes. The 'Day(s)' dropdown is open, showing the selected days. At the bottom of the dialog, there are two buttons: 'Cancel' and 'Schedule New Action'. The background shows a calendar view for the week of Monday to Sunday, and a top navigation bar with 'Dashboard', 'Schedule', 'Event log', 'Diagram', and 'Service'.



Select start time and, if applicable, stop time.

The screenshot shows the 'Schedule' modal form in a web application. The form is titled 'Schedule' and has a '+ Schedule new action' button in the top right. The background shows a calendar grid with days from Monday to Sunday. The modal form contains the following fields:

- Action type:** A dropdown menu with 'Permeate' selected.
- Day(s):** A dropdown menu with 'Monday' selected.
- From:** A text input field with 'Now' selected.
- Until:** A text input field with 'Now' selected.
- Time selection table:** A table with columns 'Hr', 'Min', and 'Am/Pm'. The table shows a grid of time slots from 01 to 06 hours. The 'AM' column is selected, and the '12:00 AM' slot is highlighted.

At the bottom of the modal, there are two buttons: 'Cancel' and 'Schedule New Action'.

The screenshot shows the 'Schedule new action' modal form in a web application. The form is titled 'Schedule new action' and has a '+ Schedule new action' button in the top right. The background shows a calendar grid with days from Monday to Sunday. The modal form contains the following fields:

- Action type:** A dropdown menu with 'Permeate' selected.
- Day(s):** A dropdown menu with 'Monday', 'Tuesday', 'Wednesday', and 'Thursday' selected.
- From:** A text input field with '04:00 AM' selected.
- Until:** A text input field with '06:15 PM' selected.
- Time selection table:** A table with columns 'Hr', 'Min', and 'Am/Pm'. The table shows a grid of time slots from 03 to 09 hours. The 'PM' column is selected, and the '06:15 PM' slot is highlighted.

At the bottom of the modal, there are two buttons: 'Cancel' and 'Schedule New Action'.



Mon 30 Oct 11:57 AM

EN

john_doe

Log out

Schedule

+ Schedule new action

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
4:00 AM - 6:15 PM Permeate production	4:00 AM - 6:15 PM Permeate production	4:00 AM - 6:15 PM Permeate production	4:00 AM - 6:15 PM Permeate production	4:00 AM - 6:15 PM Permeate production		

Dashboard

Schedule

Event log

Diagram

Service



8.3.4. Event log

Event log view displays information on previous user actions, device information, notifications, and warnings.

Mon 30 Oct 4:47 PM

EN

john_doe

Log out

Event log

⌵

Pick date range

Event group

Trigger

Clear all

Trigger

Event group

Date

Date	Event group	Event type	Operation	Trigger	Parameters
30/10/2023 6:19 PM	Information	Hot Loop disinfection	Loop is disinfecting		
30/10/2023 6:17 PM	Audit	Setting (NF enable)	Updated	john_doe	
30/10/2023 6:17 PM	Audit	Setting (NF scope id)	Updated	john_doe	
30/10/2023 6:17 PM	Audit	Setting (NF model id)	Updated	john_doe	

Dashboard

Schedule

Event log

Diagram

Service

The Group of events can be filtered.

Mon 30 Oct 4:48 PM

EN

john_doe

Log out

Event log

⌵

Pick date range

Event group

Trigger

Clear all

Trigger

Event group

⌵

Notification

Warning

Audit

Information

Date

Event

type

Operation

Trigger

Parameters

30/10/2023 6:19 PM	Inform	oop disinfection	Loop is disinfecting		
30/10/2023 6:17 PM	Audit	Setting (NF enable)	Updated	john_doe	
30/10/2023 6:17 PM	Audit	Setting (NF scope id)	Updated	john_doe	
30/10/2023 6:17 PM	Audit	Setting (NF model id)	Updated	john_doe	

Dashboard

Schedule

Event log

Diagram

Service



Mon 30 Oct 4:48 PM

EN

john_doe

Log out

Event log

⌵

Pick date range

Information

Trigger

Clear all

Trigger

Event group

Information x

Date

Date	Event group	Event type	Operation	Trigger	Parameters
30/10/2023 6:19 PM	Information	Hot Loop disinfection	Loop is disinfecting		
30/10/2023 6:10 PM	Information	Snapshot	Start	Automatic	
30/10/2023 6:09 PM	Information	Hot Loop disinfection	Tank is filling and water is heating		
30/10/2023 6:09 PM	Information	Hot Loop disinfection	Start	Manual	

Dashboard

Schedule

Event log

Diagram

Service

The Trigger of events can be filtered.

Mon 30 Oct 4:50 PM

EN

john_doe

Log out

Event log

⌵

Pick date range

Information, Audit

john_doe

Clear all

Trigger

John_doe x

Event group

Date

Automatic

Manual

john_doe

tech2_default

nephro

nephro_default

Date	Event group	Event type	Operation	Trigger	Parameters
30/10/2023 6:17 PM	Audit	Setting (	Updated	john_doe	
30/10/2023 6:17 PM	Audit	Setting (	Updated	john_doe	
30/10/2023 6:17 PM	Audit	Setting (NF model id)	Updated	john_doe	
30/10/2023 6:17 PM	Audit	Setting (NF device id)	Updated	john_doe	

Dashboard

Schedule

Event log

Diagram

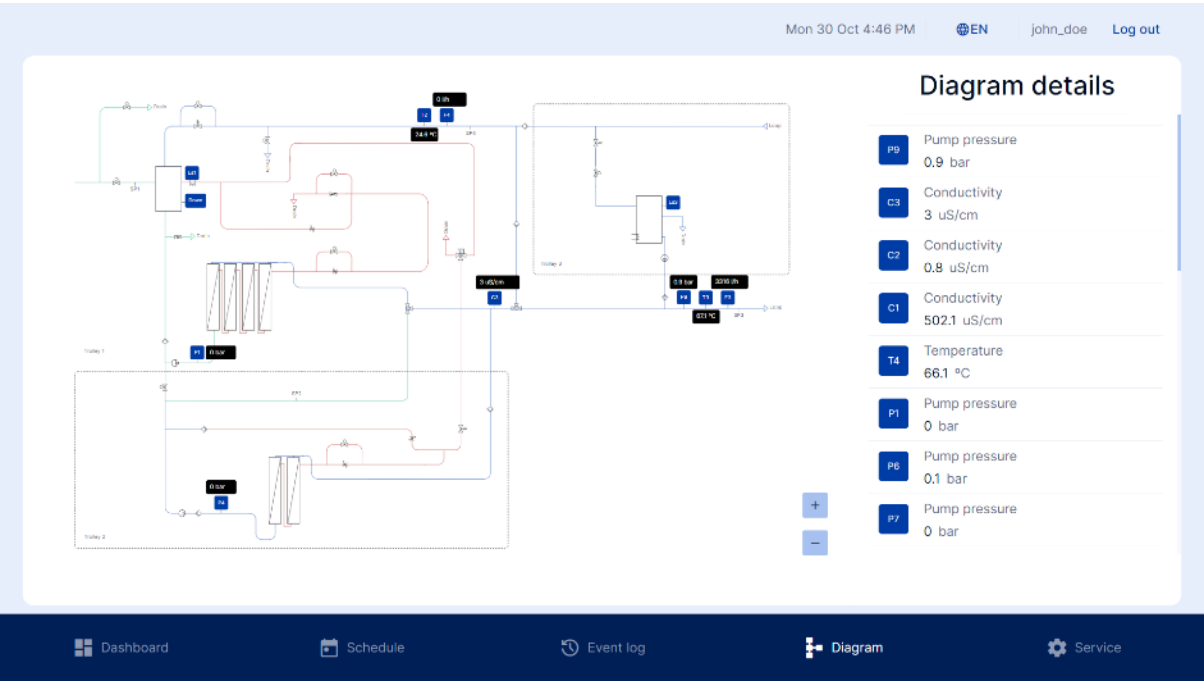
Service



8.3.5. Diagram

Diagram View shows information of Sensor Values and Actuator Status. Zooming in is available. Additional details are shown after zooming in.

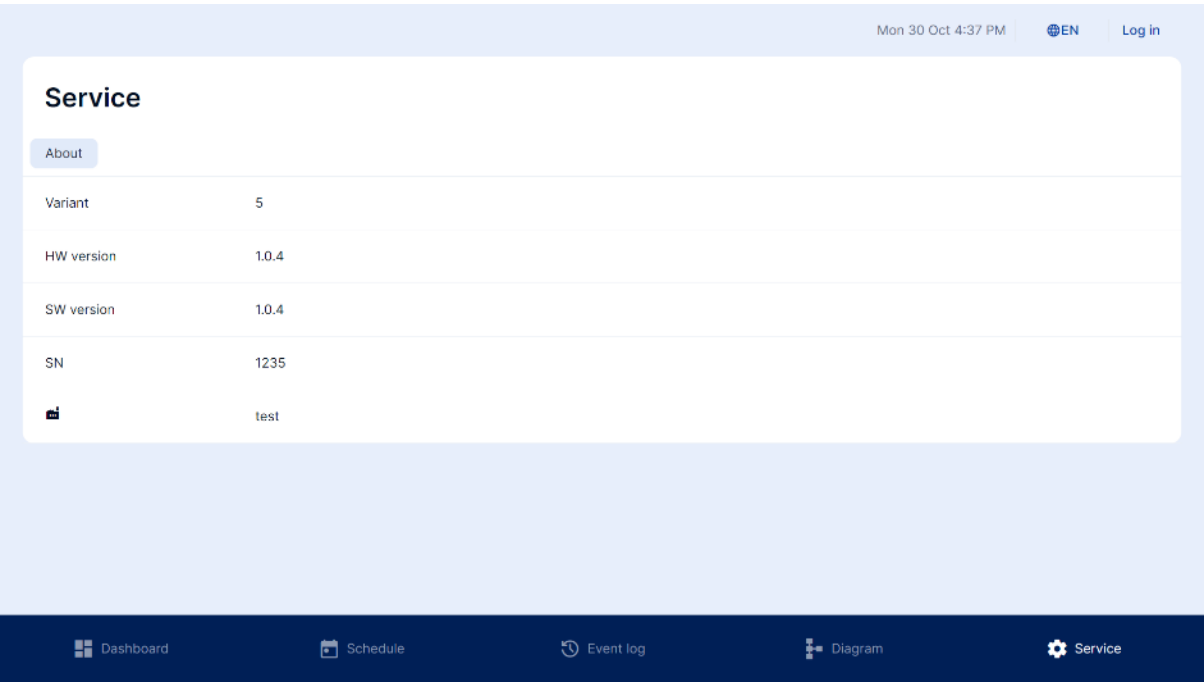
Under Maintenance Mode, actuators can be operated individually. After exiting Maintenance Mode, the actuators will return to the default condition.



8.3.6. Service

- About

If not logged in, only the “About” section is accessible:



If logged in, additional menus are visible:

Mon 30 Oct 4:37 PM

EN

john_doe

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Variant	5
HW version	1.0.4
SW version	1.0.4
SN	1235
	test

 Dashboard

 Schedule

 Event log

 Diagram

 Service

8.3.6.1. Calibration

Mon 30 Oct 4:38 PM

EN

john_doe

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Calibration item	Calibration value	Sensor value	
T1 Offset	0 °C	22.79 °C	 
T2 Offset	0 °C	24.15 °C	 
T3 Offset	0 °C	24.76 °C	 
T4 Offset	0 °C	25.23 °C	 
T5 Offset	0 °C	62.26 °C	 
T6 Offset	0 °C	22.22 °C	 

 Dashboard

 Schedule

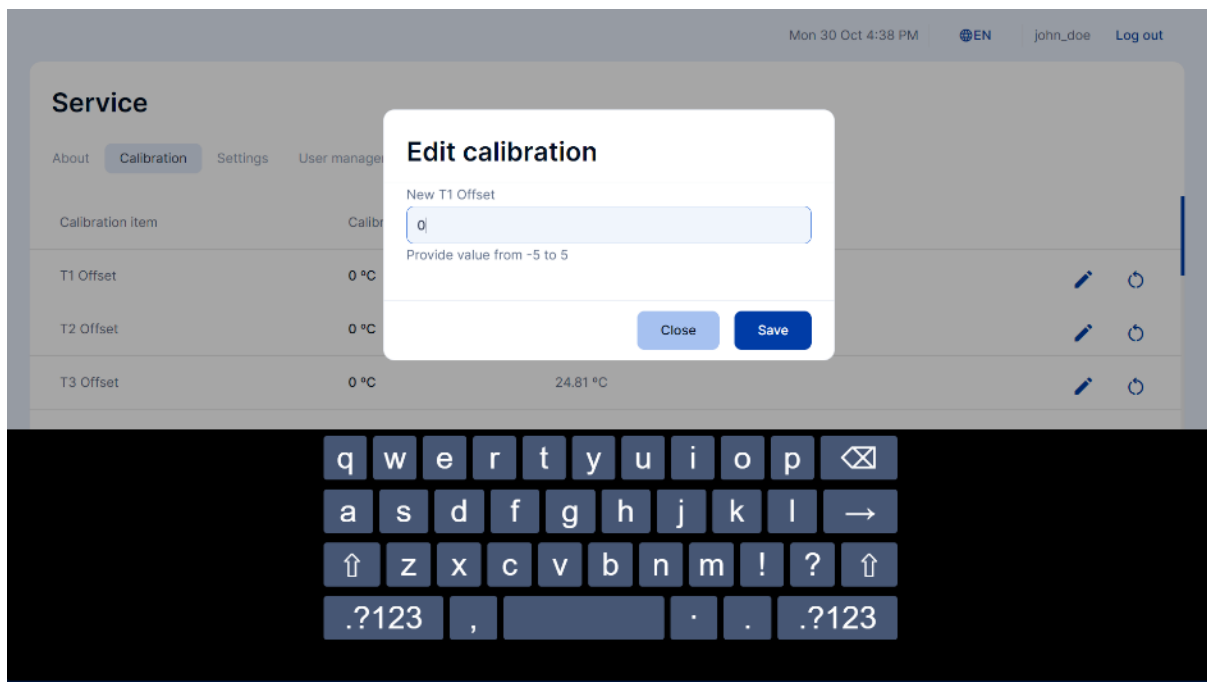
 Event log

 Diagram

 Service



To edit calibration parameters, click on the pencil icon of each parameter:



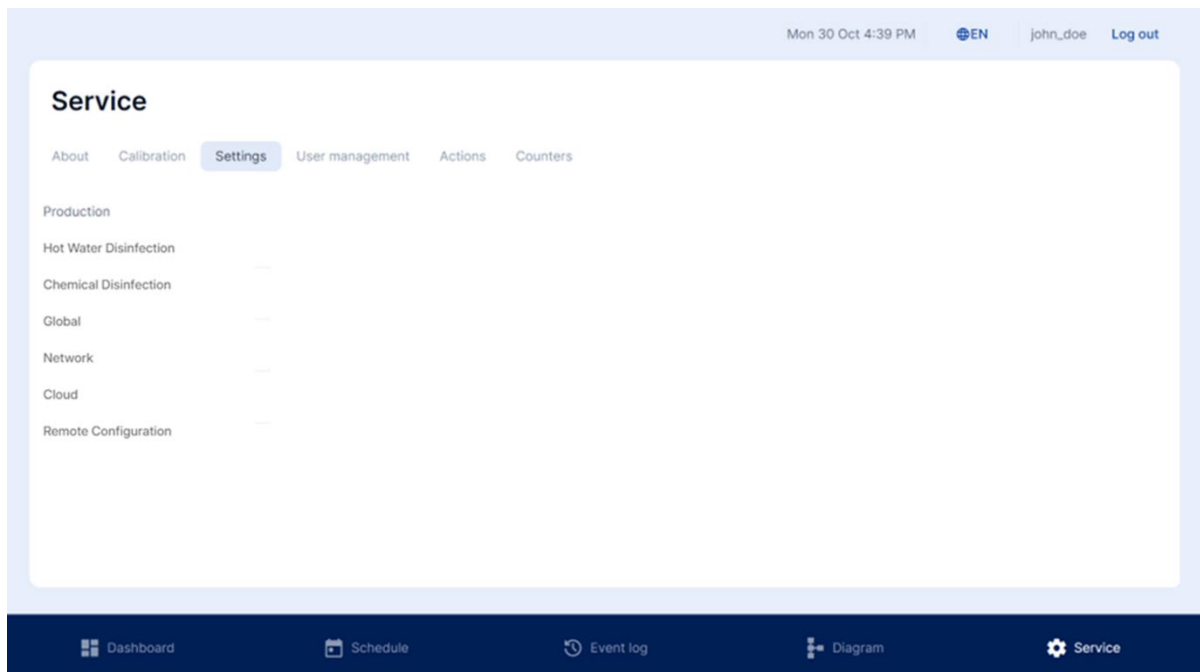
8.3.6.2. Settings

Click Settings tab to access settings information.

See chapter 11 for detailed information for each setting.

Settings can be edited in this view.

Ensure that you understand the implications of each change.



Settings are organized in functional groups, with tabs accordingly placed on the left.

Thu 30 Jan 11:07 AM

EN

nipro_default

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Production

Hot Water Disinfection

Chemical Disinfection

Global

Network

Cloud

Remote Configuration

Transmembrane pressure (max.)	9 bar		
Transmembrane pressure (min.)	2 bar		
Minimum loop return flowrate	300 l/h		
Production maximum conductivity	100 uS/cm		
Temperature regulation threshold	30 °C		
Permeate flowrate regulation threshold	1100 l/h		
Conductivity target	6 uS/cm		

Dashboard

Schedule

Event log

Diagram

Service

Thu 30 Jan 11:08 AM

EN

nipro_default

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Production

Hot Water Disinfection

Chemical Disinfection

Global

Network

Cloud

Remote Configuration

Loop tank filling level	380 l		
Loop tank storage temperature	60 °C		
Loop disinfection temperature	85 °C		
Loop disinfection recirculation time	60 min		
Monitors disinfection duration	60 min		
Cooling drain	OFF		
RO disinfection temperature	80 °C		

Dashboard

Schedule

Event log

Diagram

Service



Thu 30 Jan 11:08 AM

EN

nipro_default

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Production	Recirculation period RO	15 min		
Hot Water Disinfection				
Chemical Disinfection	Recirculation period RO + Loop	30 min		
Global	Chemicals contact time	30 min		
Network	Loop chemical draining time	15 min		
Cloud				
Remote Configuration	Bulk flushing time	30 min		
	Alternate path flushing time	20 min		
	Chemical pump used	OFF		

Dashboard

Schedule

Event log

Diagram

Service

Thu 30 Jan 11:09 AM

EN

nipro_default

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Production	Duration of standby	180 min		
Hot Water Disinfection				
Chemical Disinfection	Duration of rinsing	10 min		
Global	Chlorine detection	OFF		
Network	Floor water detector	OFF		
Cloud				
Remote Configuration	Hardwired input	OFF		
	Login session timeout	15 min		
	Volume units	Liters		

Dashboard

Schedule

Event log

Diagram

Service



Tue 28 Jan 3:15 PM

EN

nipro_default

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Production

Local IP Eth0

10.205.40.28/16

Hot Water Disinfection

Local IP Eth1

10.205.40.27/24

Chemical Disinfection

Local gateway Eth0

10.205.40.151

Global

Local DNS 1

8.8.8.8

Network

Local DNS 2

8.8.8.8

Cloud

Automatic IP Eth0

ON

Remote Configuration

Automatic IP Eth1

ON

Dashboard

Schedule

Event log

Diagram

Service

Tue 28 Jan 3:13 PM

EN

nipro_default

Log out

Service

AboutCalibrationSettingsUser managementActionsCounters

Production

Telemetry refresh period

5 min

Hot Water Disinfection

Cloud device ID

nipro-linixia-001-dev

Chemical Disinfection

Cloud model ID

dtmi:com:example:linixia;1

Global

Cloud scope ID

0ne00A4DA09

Network

Cloud enable

ON

Cloud

Cloud connection status

Disconnected

Remote Configuration

Cloud actions

OFF

Dashboard

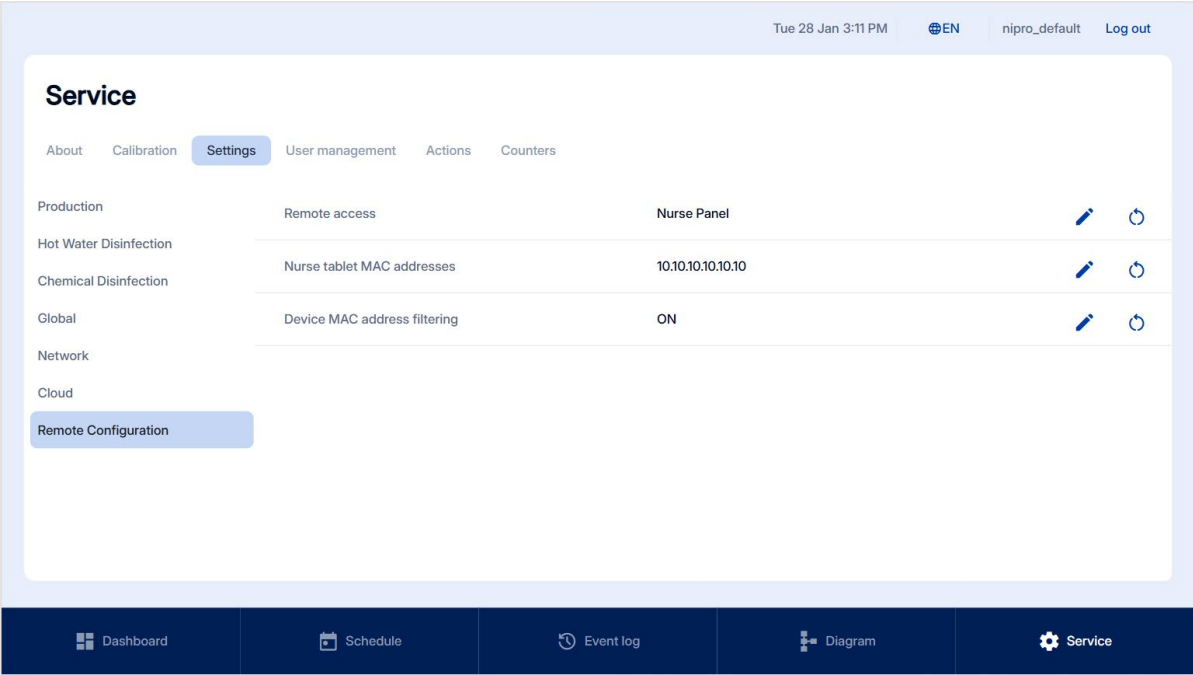
Schedule

Event log

Diagram

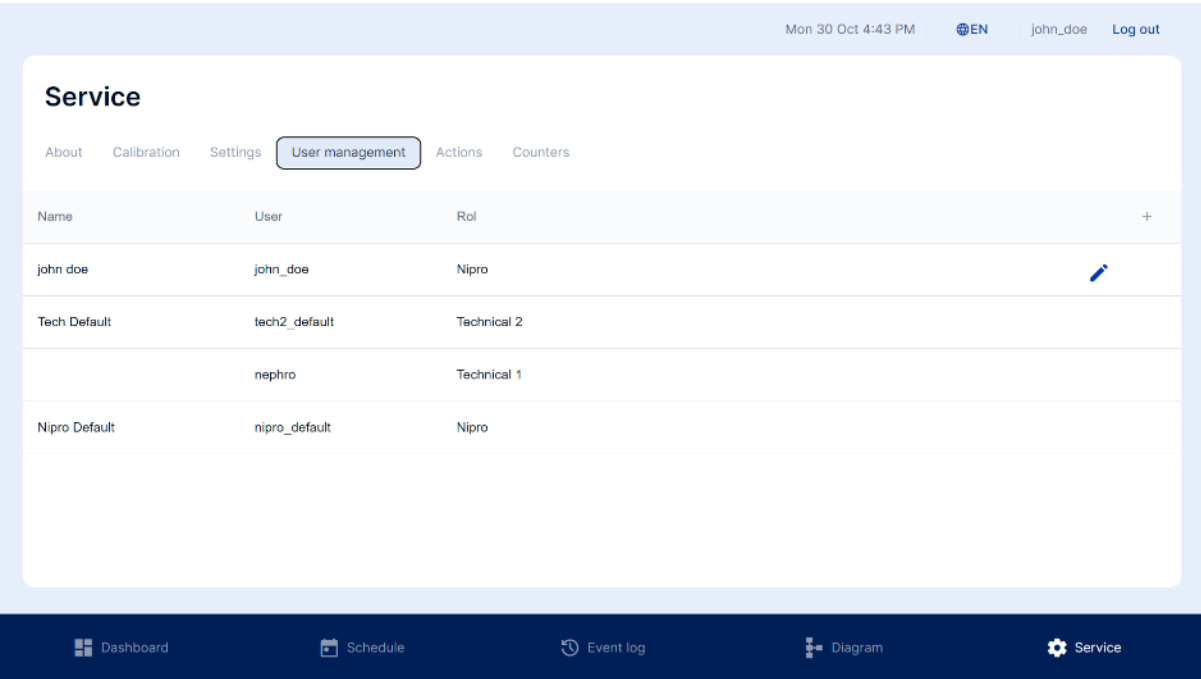
Service





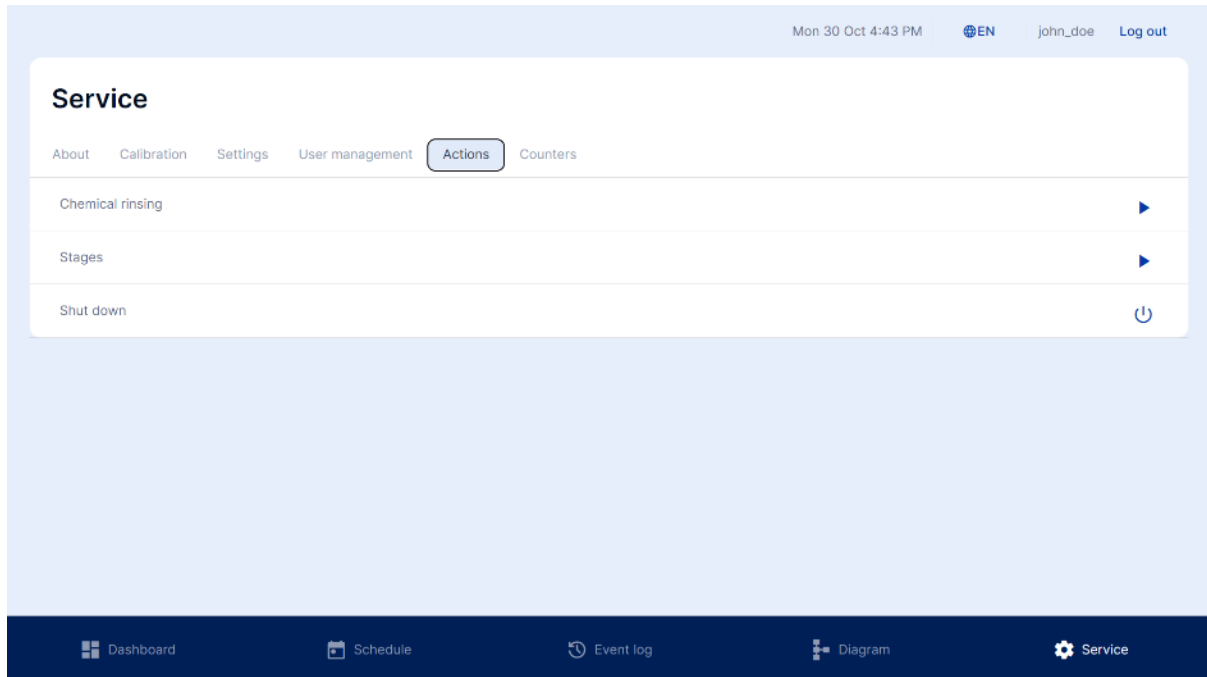
8.3.6.3. User Management

Users can be created, deleted, or edited through the User Management tab.



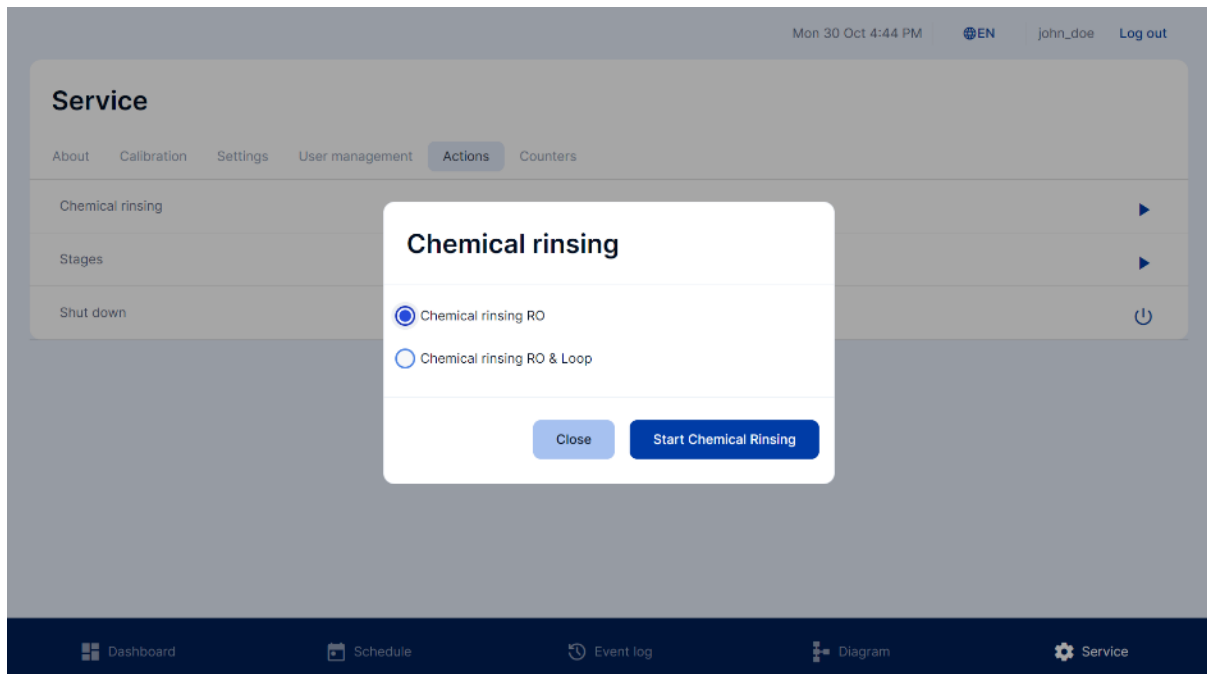
8.3.6.4. Actions

Special actions can be accessed through the Actions tab.

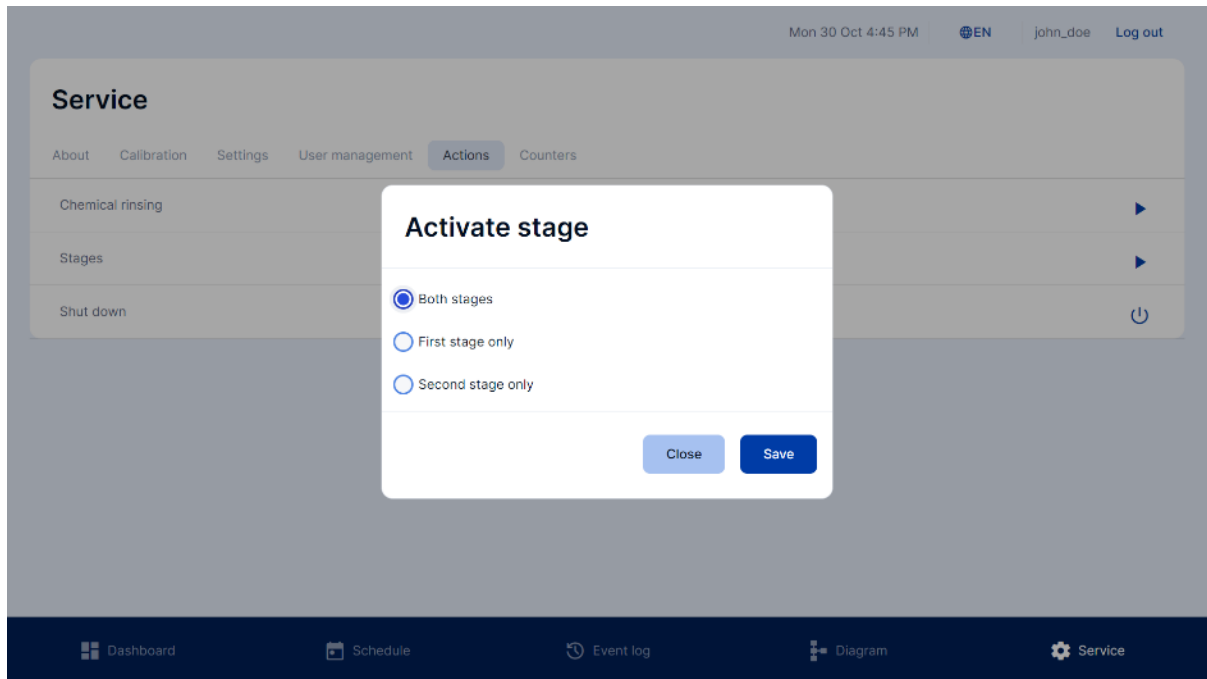


Select Chemical Rinsing to perform a rinsing of the device in order to remove any possible chemicals remaining in the device.

Refer to the Rinsing part of the chemical disinfection for the procedure of this action (chapter 5.3.5).

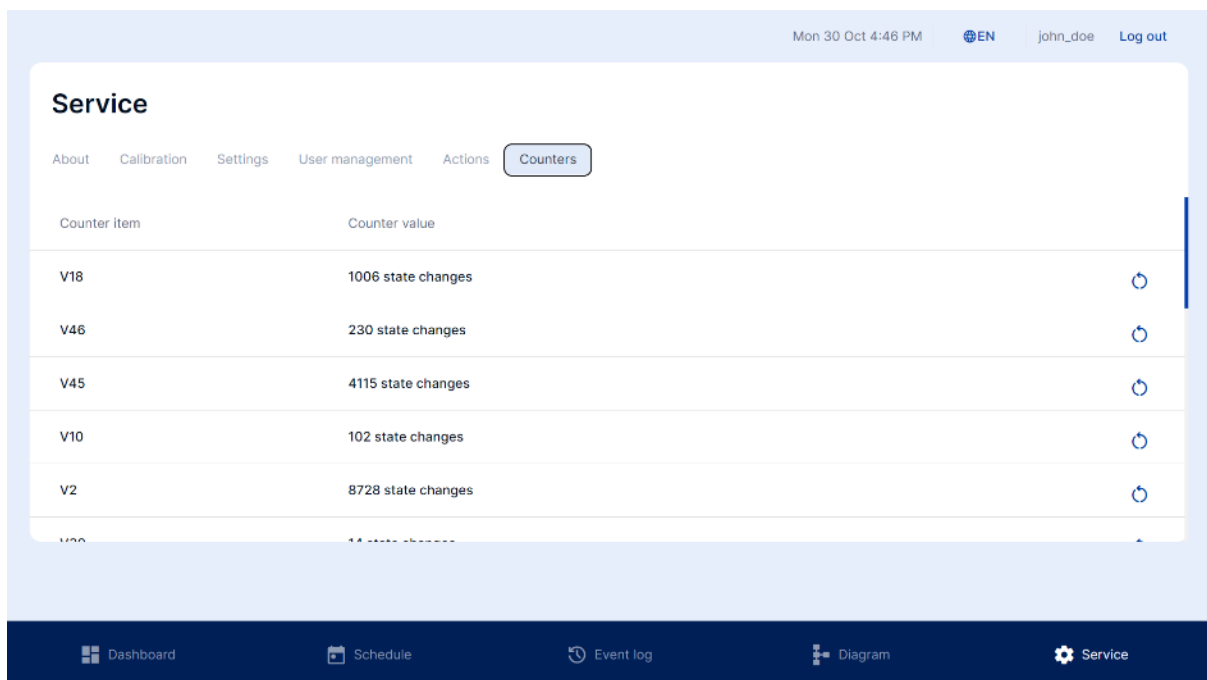


A Double Stage device can be operated with a Single Stage mode if required. Select “Stages” in the Actions tab for this purpose.



8.3.6.5. Counters

Information of the use of actuators is available through the Counters tab.

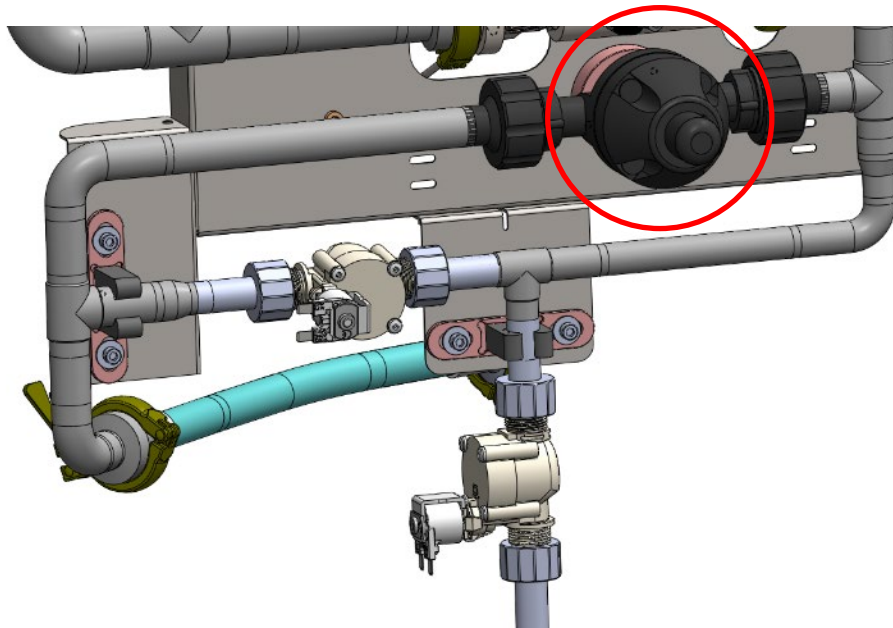


8.4. Settings (Hardware)

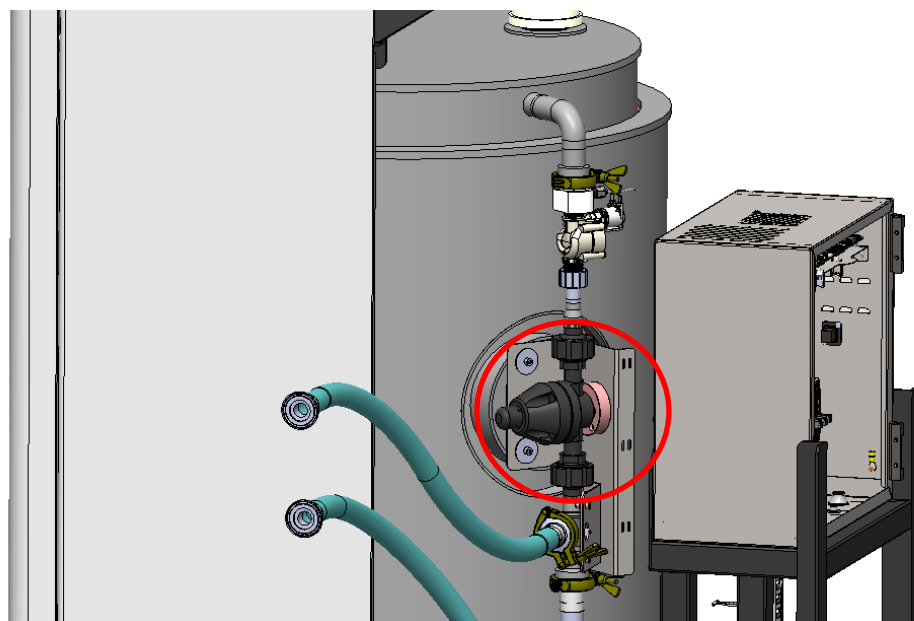
8.4.1. Setting ring pressure (Permeate pressure)

All mentioned components in this chapter, with their respective numbers, can be found in the follow chart chapter 5.1.

To adjust the pressure of the Loop, the pressure keeping valve (26) needs to be adjusted. It is located in the 1st Stage cabinet, as shown in the next figure. Adjust the pressure while Permeate Production or Rinsing is being performed.



During the Loop tank filling-in operation, the pressure keeping valve (28) is opened, allowing the remaining permeate to flow into the Loop tank. To allow for this operation to be performed properly, the pressure keeping valve (34) needs to be adjusted to a lower pressure than the pressure keeping valve (26), but sufficient for regular permeate production. Location of the pressure keeping valve (34) can be found in the picture below.





Pressure may be set only between 1 and 6 Bars.

8.5. Operation modes

8.5.1. Permeate production

To issue a Manual Start of Permeate Production, select the available button on the Dashboard, and confirm the dialog box.

Mon 9 Oct 5:53 PM | EN | Log in

Current mode

System is in standby

Automatic • next rinsing starts at 7:52 PM

Start Production

Previous mode

Permeate production

Manual • 09/10/2023 6:12 PM 09/10/2023 7:40 PM

Average conductivity	Average rejection	Average yield
2.5uS/cm	99.5%	89%

Next Scheduled mode

Loop Disinfection

Automatic • 13/10/2023 5:56 PM

Starts in
4d 0h 3min

Dashboard | Schedule | Event log | Diagram | Service

Mon 9 Oct 5:55 PM | EN | Log in

Current mode

System is in standby

Automatic • next rinsing starts at 7:52 PM

Start Production

Manual start of Permeate Production

This action will be overridden next time a scheduled permeate production begins. For more environmentally conscious use, please stop the manual permeate production once permeate is no longer needed.

Close **Start Production**

Previous mode

Permeate production

Manual • 09/10/2023 6:12 PM 09/10/2023 7:40 PM

Average conductivity	Average rejection	Average yield
2.5uS/cm	99.5%	89%

Next Scheduled mode

Loop Disinfection

Automatic • 13/10/2023 5:56 PM

Starts in
4d 0h 0min

Dashboard | Schedule | Event log | Diagram | Service

After a brief period of permeate quality conditioning, the permeate will be sent to the Loop.



Conductivity of permeate is available in the Dashboard view. Additional details on permeate condition are available - select More details”.

Mon 9 Oct 5:49 PM | EN | john_doe | Log out

Current mode

Producing permeate

Manual

Conductivity [More details >](#)

2.5 uS/cm

Stop Production

Previous mode

Permeate production

Manual • 09/10/2023 4:24 PM 09/10/2023 5:54 PM

Average conductivity

2.4uS/cm

Average rejection

99.5%

Average yield

74%

Next Scheduled mode

Loop Disinfection

Automatic • 13/10/2023 5:56 PM

Starts in

4d 0h 7min

Dashboard

Schedule

Event log

Diagram

Service

Mon 9 Oct 5:49 PM | EN | john_doe | Log out

Current mode

Producing permeate

Manual

Conductivity

2.5 uS/cm

Estimated TDS

128 ppm

Temperature

33.7 °C

Permeate use

355 l/h

Yield

82 %

Rejection ratio

99.5 %

<Less details

Stop Production

Previous mode

Permeate production

Manual • 09/10/2023 4:24 PM 09/10/2023 5:54 PM

Average conductivity

2.4uS/cm

Average rejection

99.5%

Average yield

74%

Next Scheduled mode

Loop Disinfection

Automatic • 13/10/2023 5:56 PM

Starts in

4d 0h 6min

Dashboard

Schedule

Event log

Diagram

Service



Production can be stopped with “Stop Production” button.

The screenshot shows the RO System interface with a modal dialog titled "Stop permeate production". The dialog contains the text: "You are about to stop permeate production. Please ensure all treatments are finished and permeate is no longer necessary." and two buttons: "Close" and "Stop Production".

Current mode
Producing permeate
Manual

Conductivity	Estimated TDS	Temperature	Permeate use	Yield	Rejection ratio	<Less details
2.6 us/cm	128 ppm	33.7	000	01	005	

Stop Production

Previous mode
Permeate production
Manual • 09/10/2023 4:24 PM 09/10/2023 5:54 PM

Average conductivity	Average rejection	Average yield
2.4uS/cm	99.5%	74%

Loop Disinfection
Automatic • 13/10/2023 5:56 PM

Starts in
4d 0h 5min

Dashboard Schedule Event log Diagram Service

The screenshot shows the RO System interface with the "Stopping production" screen. The screen displays the current mode as "Manual" and the conductivity as 2.6 us/cm. It also shows the previous mode as "Permeate production" and the next scheduled mode as "Loop Disinfection".

Current mode
Stopping production
Manual

Conductivity [More details >](#)
2.6 us/cm

Previous mode
Permeate production
Manual • 09/10/2023 4:24 PM 09/10/2023 5:54 PM

Average conductivity	Average rejection	Average yield
2.4uS/cm	99.5%	74%

Next Scheduled mode
Loop Disinfection
Automatic • 13/10/2023 5:56 PM

Starts in
4d 0h 4min

Dashboard Schedule Event log Diagram Service

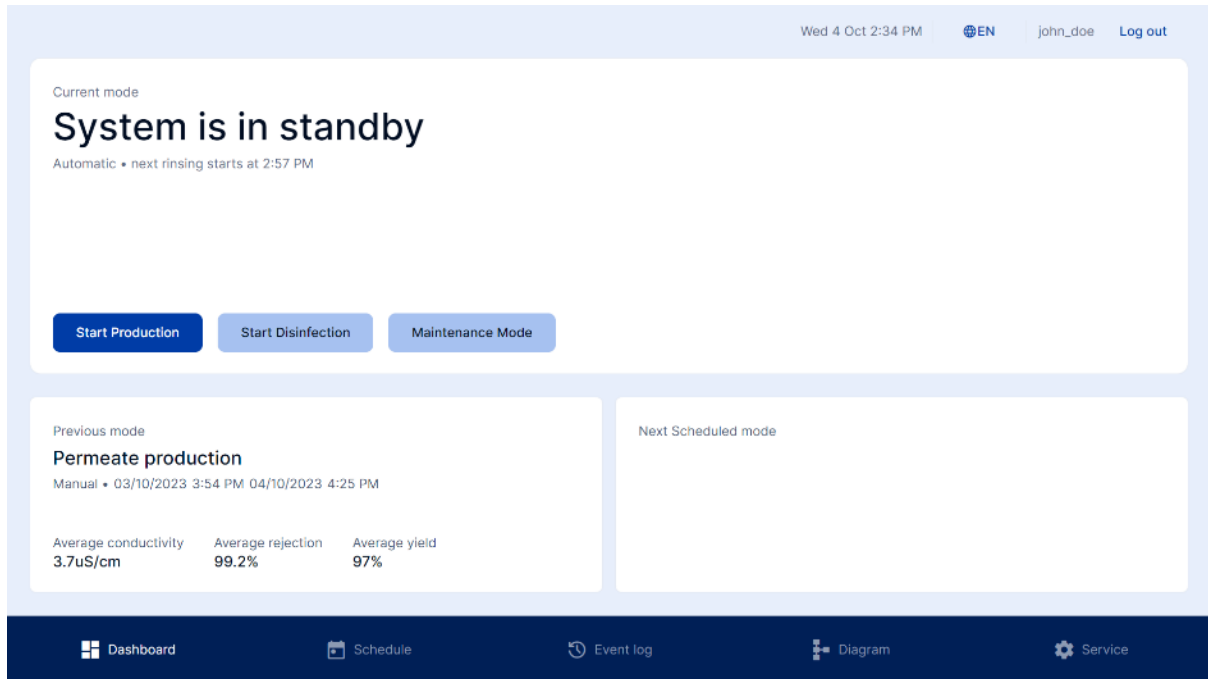
This operation can also be performed from the Nurse Panel, as it is not necessary to log in to start or end a permeate production.



8.5.2. Hot water disinfection

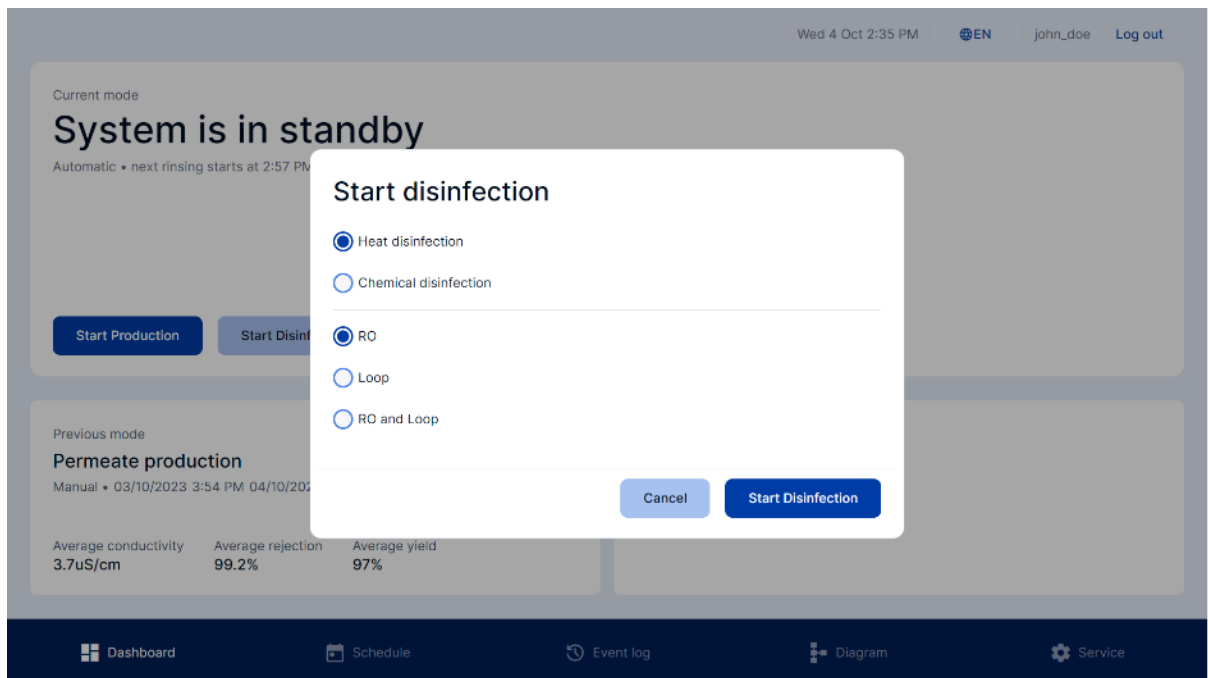
To perform a hot water disinfection of the RO, the Loop, or both, select “Start Disinfection” in the Dashboard view.

Only users who are logged in can access this function.



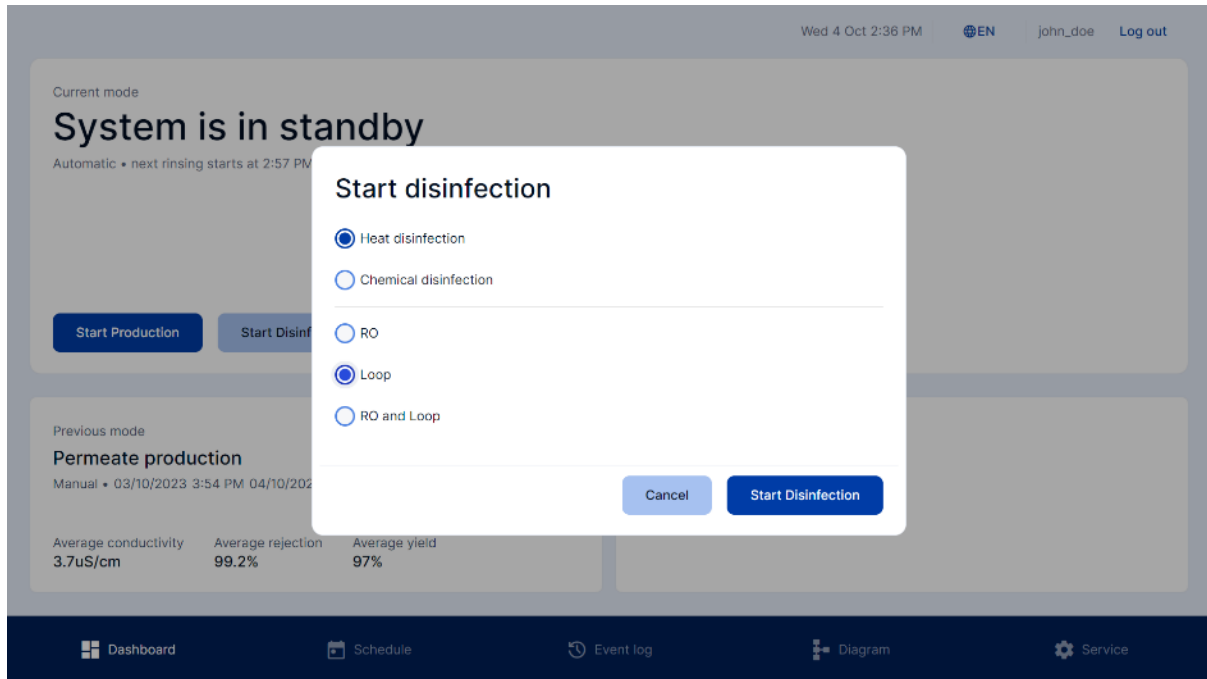
8.5.3. RO hot water disinfection

For a manual hot water disinfection of the RO, select the options.

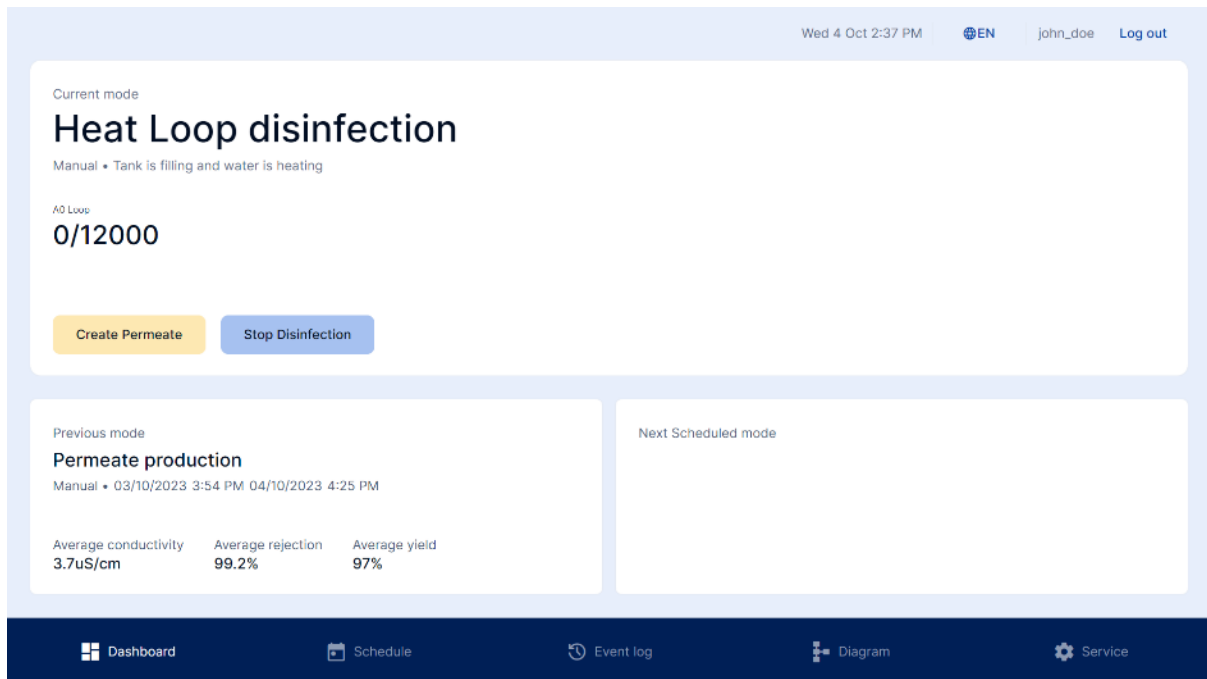


8.5.4. Hot water disinfection

For a manual hot water disinfection of the Loop, select the options.



Prior to the Loop disinfection, the Loop tank will be filled and heated up.

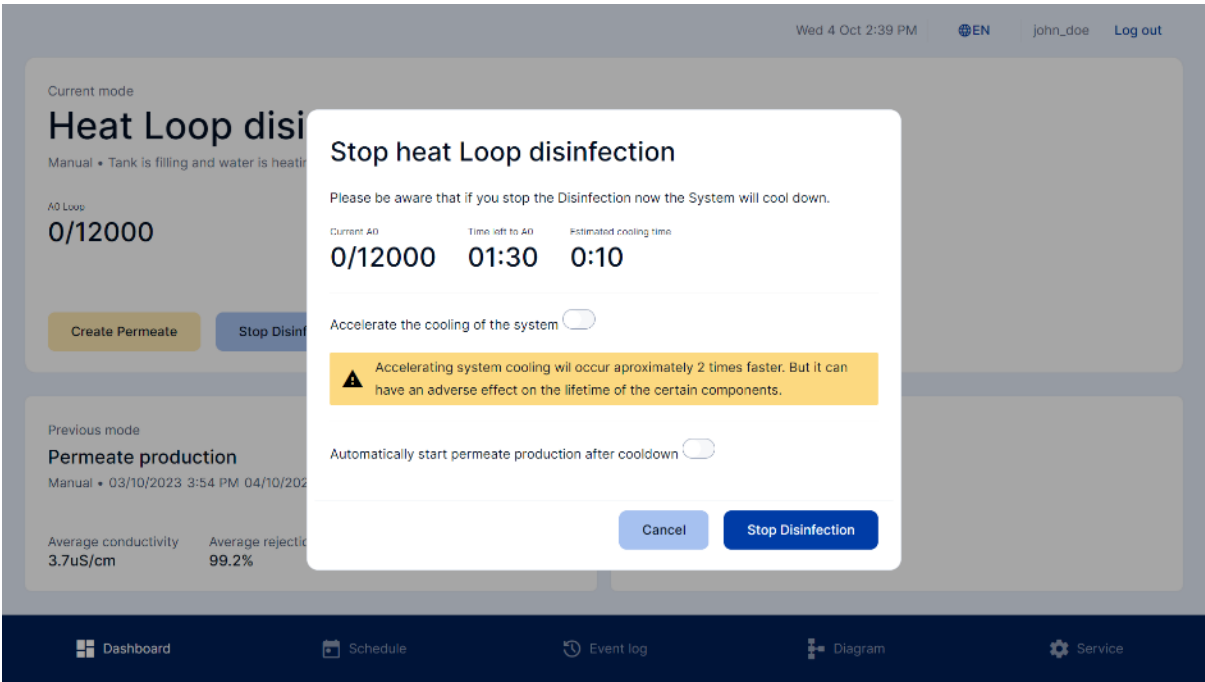


The process can be stopped by pressing the Stop Disinfection button. A cool down will be necessary before the device is available for permeate production.

Permeate Production can be triggered automatically after cooling down if the relevant option in the dialog box is selected.

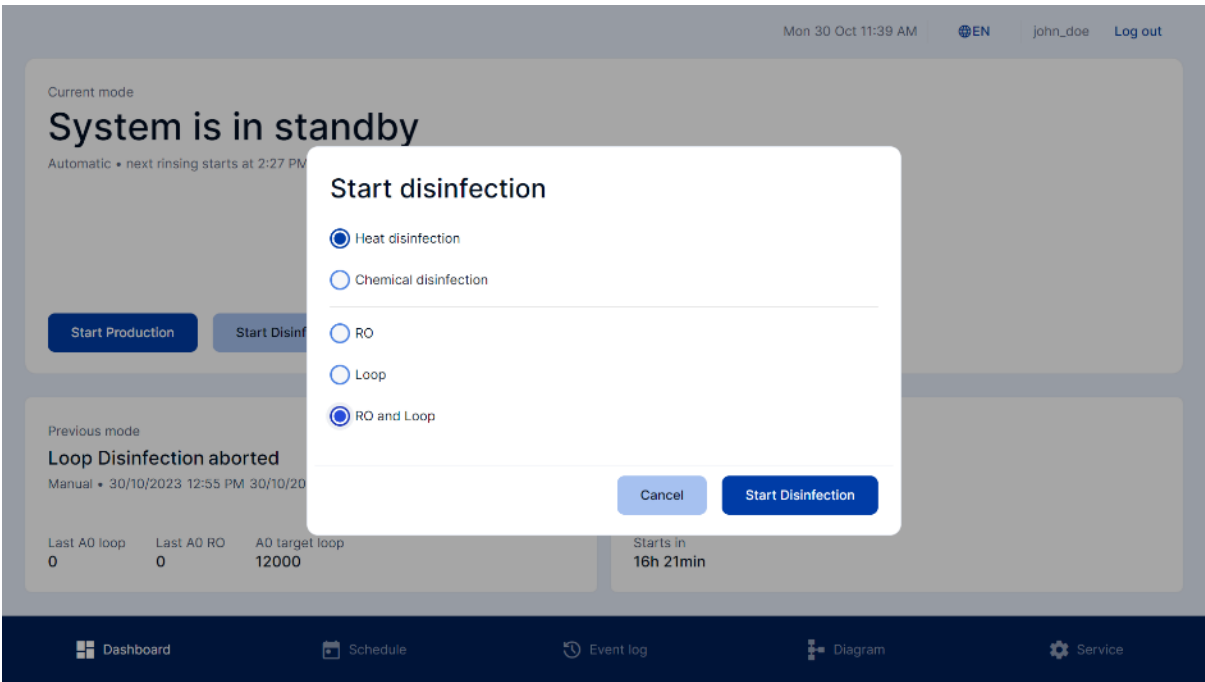
If Permeate Production is needed urgently, the cooling process can be accelerated at the expense of the lifetime of the membranes.





8.5.5. RO and Loop hot water disinfection

Consecutive Loop and RO hot water disinfection can be selected.



The dashboard view will give information on the different stages of the process.

Mon 30 Oct 12:34 PM

EN

john_doe

Log out

Current mode

Heat RO & Loop disinfection

Manual • Loop is disinfecting

A0 Loop

7/12000

A0 RO

0/12000

Create Permeate

Stop Disinfection

Previous mode

Heat Loop & RO disinfection aborted

Manual • 30/10/2023 1:14 PM 30/10/2023 1:48 PM

Last A0 loop

0

Last A0 RO

0

A0 target loop

12000

A0 target RO

12000

Next Scheduled mode

Heat Loop & RO disinfection

Automatic • 30/10/2023 10:00 PM

Starts in

9h 25min

Dashboard

Schedule

Event log

Diagram

Service

Mon 30 Oct 12:43 PM

EN

john_doe

Log out

Current mode

Heat RO & Loop disinfection

Manual • Disinfecting dialysis machines

A0 Loop

109/12000

A0 RO

0/12000

Create Permeate

Stop Disinfection

Previous mode

Heat Loop & RO disinfection aborted

Manual • 30/10/2023 1:14 PM 30/10/2023 1:48 PM

Last A0 loop

0

Last A0 RO

0

A0 target loop

12000

A0 target RO

12000

Next Scheduled mode

Heat Loop & RO disinfection

Automatic • 30/10/2023 10:00 PM

Starts in

9h 16min

Dashboard

Schedule

Event log

Diagram

Service



Mon 30 Oct 12:52 PM
EN
john_doe
Log out

Current mode

Heat RO & Loop disinfection

Manual • RO is heating

A0 Loop

244/12000

A0 RO

0/12000

Create Permeate

Stop Disinfection

Previous mode

Heat Loop & RO disinfection aborted

Manual • 30/10/2023 1:14 PM 30/10/2023 1:48 PM

Last A0 loop	Last A0 RO	A0 target loop	A0 target RO
0	0	12000	12000

Next Scheduled mode

Heat Loop & RO disinfection

Automatic • 30/10/2023 10:00 PM

Starts in
9h 7min

Dashboard
Schedule
Event log
Diagram
Service

Mon 30 Oct 2:00 PM
EN
Log in

Current mode

Heat RO & Loop disinfection

Manual • RO is disinfecting

A0 Loop

244/12000

A0 RO

18/12000

Create Permeate

Previous mode

Heat Loop & RO disinfection aborted

Manual • 30/10/2023 1:14 PM 30/10/2023 1:48 PM

Last A0 loop	Last A0 RO	A0 target loop	A0 target RO
0	0	12000	12000

Next Scheduled mode

Heat Loop & RO disinfection

Automatic • 30/10/2023 10:00 PM

Starts in
8h 0min

Dashboard
Schedule
Event log
Diagram
Service

8.5.6. Rinsing

When the device is in standby mode, the device performs a Rinsing procedure periodically. The purpose is to maintain the quality of the permeate that remains in the device and the Loop.

The Rinsing procedure is quite similar to a regular Permeate production, with the difference that no permeate consumption is expected. The period and duration of the Rinsing can be adjusted in Settings.

Mon 30 Oct 3:05 PM | EN | john_doe | Log out

Current mode

System is in standby

Automatic • next rinsing starts at 3:17 PM

Start Production

Start Disinfection

Maintenance Mode

Previous mode

Heat Loop & RO disinfection aborted

Manual • 30/10/2023 1:55 PM 30/10/2023 4:22 PM

Last A0 loop
244

Last A0 RO
114

A0 target loop
12000

A0 target RO
12000

Next Scheduled mode

Heat Loop & RO disinfection

Automatic • 30/10/2023 10:00 PM

Starts in
6h 54min

Dashboard

Schedule

Event log

Diagram

Service

Mon 30 Oct 3:17 PM | EN | john_doe | Log out

Current mode

System is rinsing

Automatic

Rinsing time left:
04:45

Start Production

Stop Rinsing

Previous mode

Heat Loop & RO disinfection aborted

Manual • 30/10/2023 1:55 PM 30/10/2023 4:22 PM

Last A0 loop
244

Last A0 RO
114

A0 target loop
12000

A0 target RO
12000

Next Scheduled mode

Heat Loop & RO disinfection

Automatic • 30/10/2023 10:00 PM

Starts in
6h 47min

Dashboard

Schedule

Event log

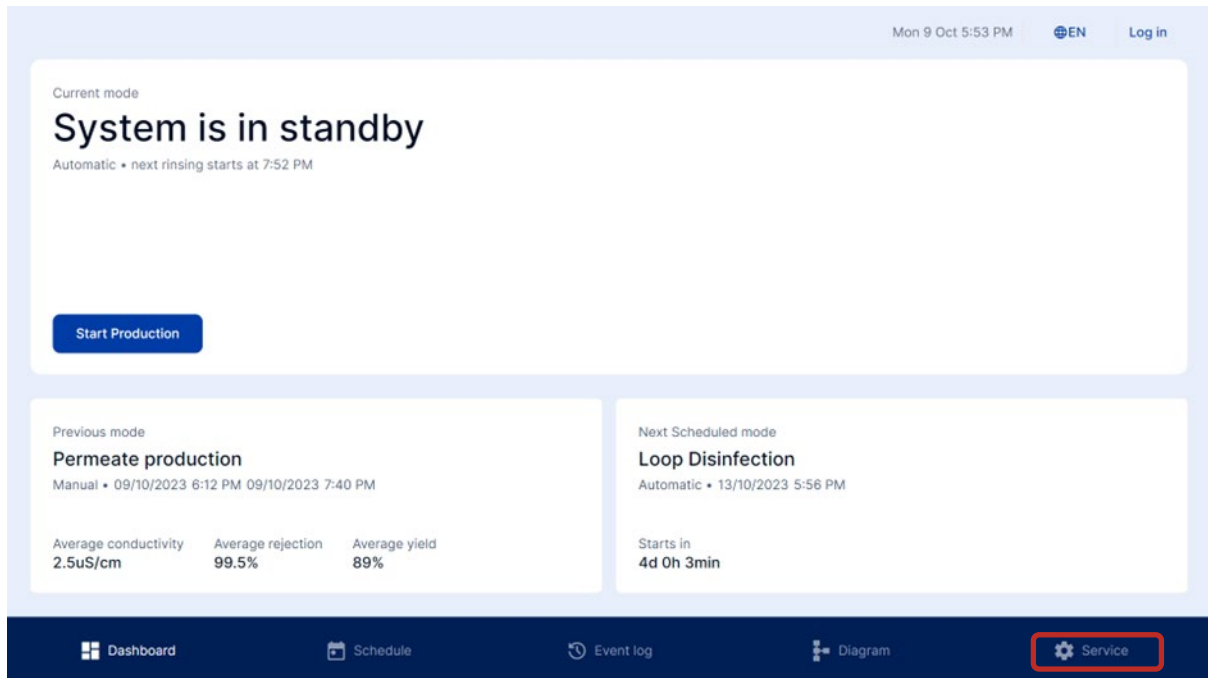
Diagram

Service

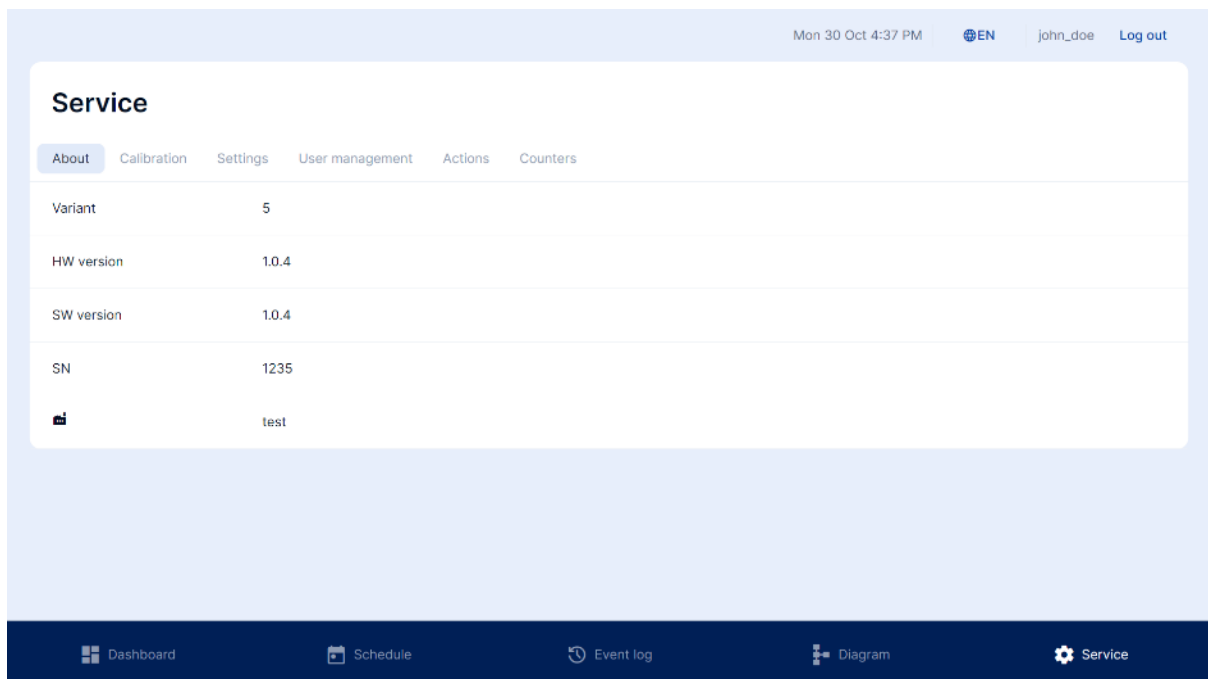


9. Service mode

To access service mode, click on the "Service" icon in the lower right-hand corner of the dashboard screen:



If logged in, "Service" screen will appear with all the options available:



From this point, it is possible to enter the following sections and consult/edit them.

- About
- Calibration
- Settings (also refer to chapter 12).
- User management
- Actions
- Counters

*Detailed information of each section can be viewed in chapter 8.3.6



10. Maintenance and cleaning

10.1. 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.



10.2. Maintenance intervals



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



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 disinfection must be confirmed during commissioning (LiniXia L, LiniXia Pro, LiniXia DS L, and LiniXia DS Pro)



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



After maintenance and/or changes to the device, a hot water sanitization needs to be carried. (LiniXia L, LiniXia Pro, LiniXia DS L, and LiniXia DS Pro)

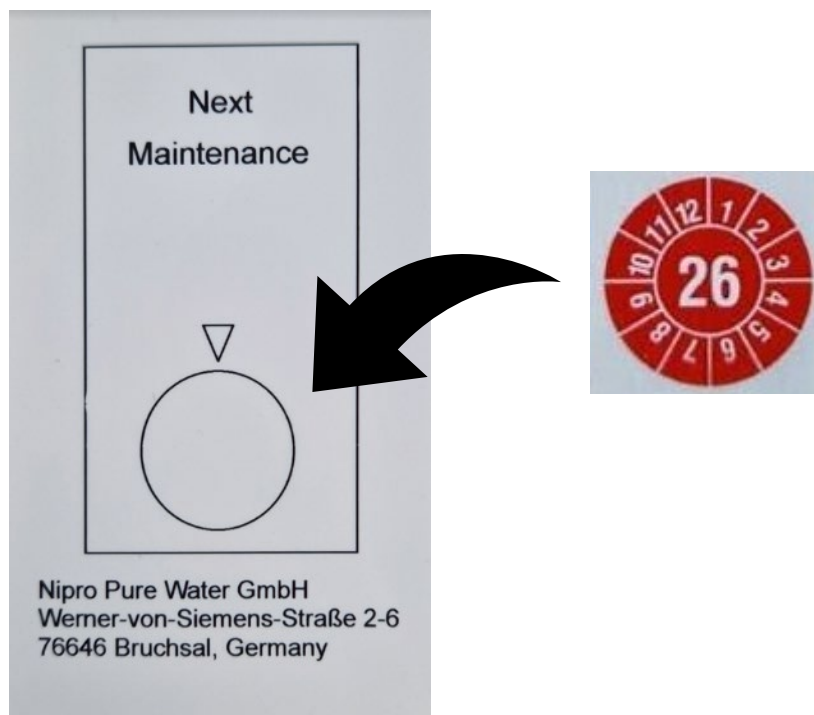


After opening the system, a chemical disinfection needs to be carried out.



After opening the system, a hot water disinfection needs to be carried out. (LiniXia L, LiniXia Pro, LiniXia DS L, and LiniXia DS Pro)

After carrying out a maintenance operation, the date of the next intervention will be indicated using the following sticker:



Measure	Period	Notes	Responsible
Hot water disinfection of RO	1x per week	Circulation time shall be at least 1 hour at 85°C. <u>Applicable to:</u> LiniXia L LiniXia Pro LiniXia DS L LiniXia DS Pro	Manufacturer or persons authorized by manufacturer
Chemical disinfection	As needed and 1x per year (preventive); or, when Action level is reached (TVC 50 CFU/ml or endotoxin 0,125 EU/ml)	<u>Applicable to:</u> LiniXia LiniXia DS	Manufacturer or persons authorized by manufacturer
Chemical disinfection	As needed and 1x per year (preventive); or, when Action level is reached (TVC 50 CFU/ml or endotoxin 0,125 EU/ml)	Applicable to the following combination for hot water disinfection are available: LiniXia L LiniXia Pro LiniXia DS L LiniXia DS Pro	Manufacturer or persons authorized by manufacturer
Sterile filter	1x per 6 months	Applicable to the following combination for hot water disinfection are available: LiniXia L LiniXia Pro LiniXia DS L LiniXia DS Pro	Manufacturer or persons authorized by manufacturer
Maintenance	1x per year	The flow meter must be changed 1x every 2 years	Manufacturer or persons authorized by manufacturer
Safety related check	1x per year		Manufacturer or persons authorized by manufacturer
Microbiological analysis	1x every 3 months (in accordance with ISO 23500-3)		User
Chemical analysis	1x per year (in accordance with ISO 23500-3)		User



10.3. Replacing sterile filter of Loop tank



Sterile filter is only available with LiniXia L, Pro, DS L, and DS Pro versions.



Risk of Scalding!

Do not replace the sterile filter during hot cleaning.



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



2. Remove filter casing.



3. Pull out the old filter upwards.
4. Spray surface disinfectant onto the filter sitting 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.



10.4. Chemical disinfection



Disinfection may only be performed by **NIPRO Pure Water** or by **authorized and 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**.

Refer to chapter 14 for chemical disinfection procedure and precautions.



10.5. 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 once 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



The action levels are established in chapter 10.3, following the recommendations of ISO 23500-3:2019.

The user is responsible for knowing the latest published version of the standard.



Please consider local restriction(s) and regulation(s).



11. Malfunction



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

KEY	Fault	Fault detection	Cause or possible causes	Effects on operation of system
NOTIFICATION_PRETANK_OVERFLOW	Pre-tank overflow	Up level sensor detected	Inlet valve leakage, reflow from vessels	None
NOTIFICATION_LOOP_UNDERPRESSURE	Loop under pressure	Return pressure lower than minimum (1 Bar) for 30 seconds	Insufficient permeate production, Loop leakage, Loop pressure incorrectly adjusted	None
NOTIFICATION_T3_UNAVAILABLE	Permeate temperature unavailable	T3 no reading	Defective sensor or sensor connection	Higher concentrate to drain flow
NOTIFICATION_F1_UNAVAILABLE	Concentrate flow sensor fault	F1 no reading	Defective sensor or sensor connection, problem in concentrate to drain valves	To target Higher concentrate to drain flow
NOTIFICATION_C3_UNAVAILABLE	Permeate Conductivity sensor fault	C3 no reading	Defective sensor or sensor connection	Higher concentrate to drain flow
NOTIFICATION_L1_UNAVAILABLE	Pre-tank level sensor unavailable	L1 no reading	Defective sensor or sensor connection	Use Up Level Sensor instead
NOTIFICATION_F3_UNAVAILABLE	Flow sensor F3 unavailable	F3 no reading	Defective sensor or sensor connection	Higher concentrate to drain flow
NOTIFICATION_F4_UNAVAILABLE	Flow Sensor F4 unavailable	F4 no reading	Defective sensor or sensor connection, insufficient permeate production	None
NOTIFICATION_CHEMICAL_SWITCH_OFF	Chemical Switch off	Chemical switch off during disinfection	Chemical switch turned off during chemical disinfection	Disinfectant may not reach Loop
NOTIFICATION_PRETANK_FILLING_TIMEOUT_OUT	Pre-tank filling timeout	Pre-tank filling timeout during heat RO disinfection and chemical removal	Defective inlet valve, low inlet pressure	Disinfection stop



KEY	Fault	Fault detection	Cause or possible causes	Effects on operation of system
NOTIFICATION_RO_HEATING_TIMED_OUT	RO heating timeout	Cannot achieve end target temperature	Defective heater, defective contactors, tripped circuit breaker	Disinfection stop
NOTIFICATION_HOT_WATER_PREPARATION_FAILED_LEVEL	Loop tank preparation failure	Tank level not achieved on start request	Defective tank inlet valve	Disinfection stop
NOTIFICATION_PERMEATE_CONDUCTIVITY_HIGH	Permeate conductivity higher than target	Conductivity over stabilization target, but below maximum limit	Defective concentrate to drain valves, membrane issue, Inlet water quality	None
NOTIFICATION_HOT_WATER_PREPARATION_FAILED_TEMP	Loop tank preparation failure	Tank temperature not achieved on start request	Defective heater, defective contactors, tripped circuit breaker	Disinfection stop
NOTIFICATION_P6_UNAVAILABLE	1 st pass concentrate pressure unavailable	P6 in error	Defective sensor or sensor connection	None
NOTIFICATION_P7_UNAVAILABLE	2 nd pass concentrate pressure unavailable	P7 in error	Defective sensor or sensor connection	None
NOTIFICATION_P5_UNAVAILABLE	Loop return pressure unavailable	P5 in error	Defective sensor or sensor connection	None
NOTIFICATION_P9_UNAVAILABLE	Loop supply pressure unavailable	P9 in error	Defective sensor or sensor connection	None
NOTIFICATION_T4_UNAVAILABLE	Loop tank inlet temperature unavailable	T4 in error	Defective sensor or sensor connection	None
NOTIFICATION_C1_UNAVAILABLE	Inlet conductivity unavailable	C1 in error	Defective sensor or sensor connection	None
NOTIFICATION_C2_UNAVAILABLE	Concentrate conductivity unavailable	C2 in error	Defective sensor or sensor connection	None
NOTIFICATION_F2_UNAVAILABLE	Concentrate flow sensor fault	F2 no reading	Defective sensor or sensor connection, problem in concentrate to drain valves	Higher concentrate flow
NOTIFICATION_PERMEATE_TEMPERATURE_HIGH	Permeate temperature high	Permeate temperature over regulation margins but below maximum limit	High inlet water temperature, defective concentrate to drain valves	None



KEY	Fault	Fault detection	Cause or possible causes	Effects on operation of system
NOTIFICATION_HOT_WATER_PREPARATION_WARM_TEMP	Loop tank temperature below hot target	Tank hot temperature not achieved on start request but temperature over level of bacterial growth prevention	Insufficient time in settings adjustment, defective Heater	None
NOTIFICATION_L2_UNAVAILABLE	Loop tank level unavailable	L2 in error while not in Hot water disinfection	Defective sensor or sensor connection	None
NOTIFICATION_T1_UNAVAILABLE	Pre-tank temperature unavailable	T1 in error while not in Hot water disinfection	Defective sensor or sensor connection	None
NOTIFICATION_T2_UNAVAILABLE	Permeate return temperature unavailable	T2 in error while not in Hot water disinfection	Defective sensor or sensor connection	None
NOTIFICATION_T5_UNAVAILABLE	Loop tank temperature unavailable	T5 in error while not in Hot water disinfection	Defective sensor or sensor connection	None
NOTIFICATION_T6_UNAVAILABLE	1 st pass concentrate temperature unavailable	T6 in error while not in Hot water disinfection	Defective sensor or sensor connection	None
NOTIFICATION_T7_UNAVAILABLE	2 nd pass concentrate temperature unavailable	T7 in error while not in Hot water disinfection	Defective sensor or sensor connection	None
NOTIFICATION_PUMP_6_VFD_ERROR	Pump (6) VFD error	VFD error reported while not in use	Defective VFD or communication, tripped circuit breaker	None
NOTIFICATION_PUMP_11_VFD_ERROR	Pump (11) VFD error	VFD error reported while not in use	Defective VFD or communication, tripped circuit breaker	None
NOTIFICATION_PUMP_24_VFD_ERROR	Pump (24) VFD error	VFD error reported while not in use	Defective VFD or communication, tripped circuit breaker	None
NOTIFICATION_HOT_WATER_IN_LOOP_TANK	Loop tank is keeping water hot after disinfection abort	Loop tank is keeping water hot after disinfection abort	Aborted hot water disinfection	None
WARNING_LOOP_LEAKAGE	Loop leakage	Loop tank level decrease during Loop disinfection	Leakage in the loop	Stop & Block
WARNING_OUTPUT_PUMP_PRESSURE_LOW	Output Pump problem	Deliver pump pressure (P1 Single & Double Stage, P4 Double Stage) below minimum for 30 seconds	Defective pump, defective pressure sensor, defective membrane	Stop & Block



KEY	Fault	Fault detection	Cause or possible causes	Effects on operation of system
WARNING_FOLLOWER_PUMP_PRESSURE_LOW	Pump (6) problem Double Stage	P8 pressure below - 0,8 Bar for 30 seconds	Defective 1 st Stage pump, blocked 1 st Stage membranes	Stop & Block
WARNING_PUMP_6_VFD_ERROR	Pump (6) VFD error	VFD Error reported while in use	Defective VFD or communication, tripped circuit breaker	Stop & Block
WARNING_PRETANK_EMPTY	Pre-tank empty	Low level sensor inactive or L1 below minimum during Production or Rinsing	Defective inlet valve, low inlet pressure	Stop pump until tank fill enough
WARNING_LOOP_OVERPRESSURE	Loop overpressure	Pressure in permeate output higher than maximum	Obstruction in Loop	Stop & Block
WARNING_CONDITIONING_PERMEATE_TIMEOUT	Conditioning permeate timeout	Timeout for conditioning permeate	Defective inlet valve, low inlet pressure, inlet water quality, defective membranes, problem in concentrate to drain valves, defective conductivity sensor	Stop & Block
WARNING_PERMEATE_CONDUCTIVITY_HIGH	Permeate conductivity warning	Conductivity over allowed maximum or hardware conductivity alarm active	Inlet water quality, defective membranes, problem in concentrate to drain valves, defective conductivity sensor	Bypass the permeate and repeat conditioning permeate
WARNING_PERMEATE_TEMPERATURE_HIGH	Overtemperature	T1 or T3 over the absolute maximum	High inlet water temperature, defective concentrate to drain valves	Stop & Block
WARNING_PERMEATE_FLOW_HIGH	Permeate flowrate too high	Reading of F3 (permeate to Loop) or F4 (recirculation) over limits	Setting of minimum pump pressure too high, defective membranes, defective pump pressure sensor	Stop & Block
WARNING_CHLORINE_PRESENT	Chlorine presence warning input	Chlorine sensor input is active	Chlorine sensor input is active	Stop & Block
WARNING_RO_COOLING_TIMED_OUT	RO cooling down timeout	Cannot achieve cooling down	High inlet water temperature, defective concentrate to drain valves	Stop & Block
WARNING_BOARD_MISSING	Board unreachable	Cannot communicate with control boards	CAN communication problems, unplugged CAN connector, 24V power supply issue, tripped circuit	Critical Fault



KEY	Fault	Fault detection	Cause or possible causes	Effects on operation of system
			breaker, defective control board	
WARNING_LOOP_TANK_OVERFILLED	Loop tank up-L2 active	Loop Tank Up-L2 active	Defective Loop tank inlet valve	Stop & Block
WARNING_PRETANK_EMPTY_MAX_RETRIES	Repetitive self-recovery warnings	WARNING_PRETANK_EMPTY raised 3 times	Defective inlet valve, low inlet pressure	Stop & Block
WARNING_PERMEATE_CONDUCTIVITY_HIGH_MAX_RETRIES	Repetitive self-recovery warnings	WARNING_PERMEATE_CONDUCTIVITY_HIGH raised 3 times	Inlet water quality, defective membranes, problem in concentrate to drain valves, defective conductivity sensor	Stop & Block
WARNING_CHEMICAL_SWITCH_ON_MAX_RETRIES	Repetitive self-recovery warnings	WARNING_CHEMICAL_SWITCH_ON raised 3 times	Chemical switch turned on when not in chemical disinfection	Stop & Block
WARNING_PRETANK_EMPTY_DISINFECTION_RECYCLING	Pre-tank empty during Chemical or RO hot recycle	Low level sensor unactive or L1 below minimum	Defective inlet valve, low inlet pressure	Stop & Block
WARNING_P8_UNAVAILABLE	Second stage input pressure sensor failure	P8 in error while not in Standby	Defective sensor or sensor connection	Stop & Block
WARNING_P1_UNAVAILABLE	First stage output pressure sensor failure	P1 in error while not in Standby	Defective sensor or sensor connection	Stop & Block
WARNING_P4_UNAVAILABLE	Second stage output pressure sensor failure	P4 in error while not in Standby	Defective sensor or sensor connection	Stop & Block
WARNING_L1_UNAVAILABLE	Pre-tank level unavailable	L1 in error while in Disinfection	Defective sensor or sensor connection	Stop & Block
WARNING_L2_UNAVAILABLE	Loop tank level unavailable	L2 in error while in Hot water disinfection	Defective sensor or sensor connection	Stop & Block
WARNING_T1_UNAVAILABLE	Pre-tank temperature unavailable	T1 in error while in Hot water disinfection	Defective sensor or sensor connection	Stop & Block
WARNING_T2_UNAVAILABLE	Permeate return temperature unavailable	T2 in error while in Hot water disinfection	Defective sensor or sensor connection	Stop & Block
WARNING_T3_UNAVAILABLE	Permeate supply temperature unavailable	T3 in error while in Hot water disinfection	Defective sensor or sensor connection	Stop & Block
WARNING_T5_UNAVAILABLE	Loop tank temperature unavailable	T5 in error while in Hot water disinfection	Defective sensor or sensor connection	Stop & Block



KEY	Fault	Fault detection	Cause or possible causes	Effects on operation of system
WARNING_T6_UNAVAILABLE	1 st pass concentrate temperature unavailable	T6 in error while in Hot water disinfection	Defective sensor or sensor connection	Stop & Block
WARNING_T7_UNAVAILABLE	2 nd pass concentrate temperature unavailable	T7 in error while in Hot water disinfection	Defective sensor or sensor connection	Stop & Block
WARNING_PUMP_11_VFD_ERROR	Pump (11) VFD error	VFD Error reported while in use	Defective VFD or communication, tripped circuit breaker	Stop & Block
WARNING_PUMP_24_VFD_ERROR	Pump (24) VFD error	VFD Error reported while in use	Defective VFD or communication, tripped circuit breaker	Stop & Block
WARNING_MOTORIZED_VALVE_V18_STALL	Valve V18 end sensor not detected	Motorized valve end sensor	Defective valve or valve connection	Stop & Block
WARNING_MOTORIZED_VALVE_V46_STALL	Valve V46 end sensor not detected	Motorized valve end sensor	Defective valve or valve connection	Stop & Block
WARNING_MOTORIZED_VALVE_V46_STALL	Valve V47 end sensor not detected	Motorized valve end sensor	Defective valve or valve connection	Stop & Block
WARNING_MOTORIZED_VALVE_V33_STALL	Valve V33 end sensor not detected	Motorized valve end sensor	Defective valve or valve connection	Stop & Block
WARNING_MOTORIZED_VALVE_V10_STALL	Valve V10 end sensor not detected	Motorized valve end sensor	Defective valve or valve connection	Stop & Block
WARNING_MOTORIZED_VALVE_V8_STALL	Valve V8 end sensor not detected	Motorized valve end sensor	Defective valve or valve connection	Stop & Block
WARNING_REQUIRE_S_RO_FLUSHING	System requires a RO chemical flushing	RO Chemical Disinfection halted due to another warning or power loss	Power loss or warning during chemical disinfection	Block all processes but a RO Chemical Rinsing
WARNING_REQUIRE_S_RO_AND_LOOP_FLUSHING	System requires a RO+Loop chemical flushing	RO+Loop Chemical Disinfection halted due to another warning or power loss	Power loss or warning during chemical disinfection	Block all processes but a RO+Loop Chemical Flushing
WARNING_REQUIRE_S_COOL_DOWN	System requires a cool-down	Halted Hot water disinfection	Power loss or warning during hot water disinfection	Automatic cool-down of the RO and Loop
WARNING_VERSION_MISALIGNED	Version of the SW/FW components mismatched	Version self-test	Mismatch in SW versions	Critical Fault
WARNING_PARAMETERS_WRONG	PCB parameters wrong	Parameters self-test	Mismatch in internal parameters	Critical Fault



KEY	Fault	Fault detection	Cause or possible causes	Effects on operation of system
WARNING_SETTINGS_WRONG	System settings wrong	Wrong settings	Settings not loaded properly	Critical Fault
WARNING_FLASH_WRONG	PCB flash wrong	Flash self-test	SW not loaded properly	Critical Fault
WARNING_FLOOR_WATER_DETECTED	Hardwired input	Floor water input is active	Floor water sensor input is active	Stop & Block
WARNING_LOOP_TANK_EMPTY	Loop tank emptied during hot Loop disinfection	L2 level lower than minimum during Loop disinfection	Insufficient water in Loop tank for monitor's consumption	Stop & Block
WARNING_CHEMICAL_SWITCH_ON	Chemical switch on	Chemical switch on when not intended	Chemical switch turned on when not in chemical disinfection	Stop until deactivated





12. EMC manufacturer's declaration

This EMC manufacturer's declaration is based on the correct installation and operation according to the instructions of this manual.

Emission measurement	EMC Standard	Compliance
RF Radiated Emissions	EN 55011 and 55032	Class A Group 1
Continuous Conducted Emissions	EN 55011	Class A Group 1
Voltage Fluctuations and Flicker Emissions	EN 61000-3-3 and EN 61000-3-11	Fulfilled
Harmonic Current Emissions	EN 61000-3-2 and EN 61000-3-12	Class A

Immunity Test	EMC standard	Immunity test levels & Compliance
Electrostatic discharges Immunity	EN 61000-4-2	±8 kV contact ±2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
RF Electromagnetic Field Immunity	EN 61000-4-3	Freq. range: 80 MHz – 2.7 GHz Electric Field: 3 V/m 80% AM 1 kHz
Fast Transients in Burst Immunity	EN 61000-4-4	AC Mains input, ± 2 kV 100 kHz repetition frequency
Surge Transients Immunity	EN 61000-4-5	Line-to-line ± 0,5 kV, ± 1 kV Line-to-ground ± 0,5 kV, ± 1 kV, ± 2 kV
RF Current Injections Immunity	EN 61000-4-6	3 V _{RMS} 0,15 MHz – 80 MHz 6 V _{RMS} in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Low Frequency Magnetic Field Immunity	EN 61000-4-8	30 A/m 50 Hz and 60 Hz
Voltage Dips and short Interruptions Immunity	EN 61000-4-11 and EN 61000-4-34	voltage dip: 0% residual voltage for 0.5 cycle At: 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°



Immunity Test	EMC standard	Immunity test levels & Compliance
		----- voltage dip: 0 % residual voltage for 1 cycle ----- voltage dip: 70 % residual voltage for 25 cycles (at 50 Hz) At: 0° ----- voltage interruption: 0 % residual voltage for 250 cycles (at 50 Hz)

The device was developed and tested in accordance with EN 60601-1-2. Nevertheless, influence through electromagnetic fields cannot be completely excluded.

WARNING: Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, sensors, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, leading to improper operation. Replacing these components with others with different specifications is not allowed.

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



13. Communication setup

The system has an option that grants remote control to the device. This remote control is divided into two functions:

- Technician mode
- Nurse Panel

Both functions are limited to trained technical staff.

In addition, remote access enables monitoring of operational parameters for our Technical Service and authorized personnel.

Connection of the PEMs to IT-Networks with other equipment could result in previously unidentified risks.



The responsible organization should identify, analyse and control these risks.

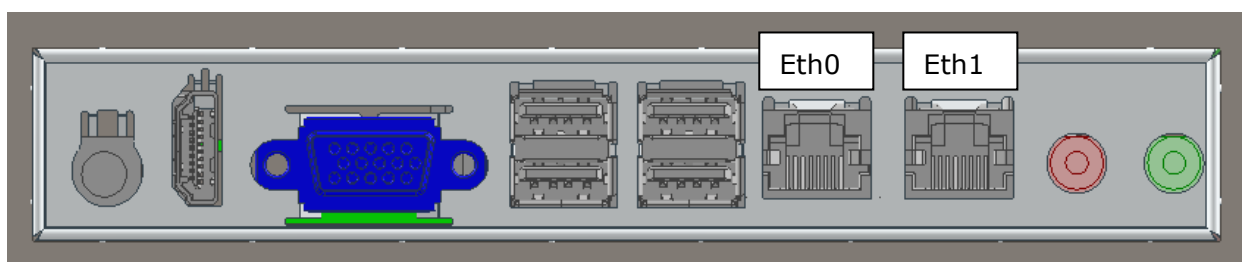
Changes to the IT-Network could introduce new risks, where changes include configuration, the connection of additional items, disconnection of items, update/upgrade of the equipment connected.

13.1. Network interface distribution

Linixia's left port (Eth0) must be used for Nurse panel and Technician mode.

- Nurse panel: Connected to hospital VLAN
- Technician mode: Connected directly to technician PC.

Linixia's right port (Eth1) must be used for Cloud communication through a secure Network.



The secure Network must fulfill state-of-the-art standards to ensure Linixia's device security. Current constraints (mandatory):

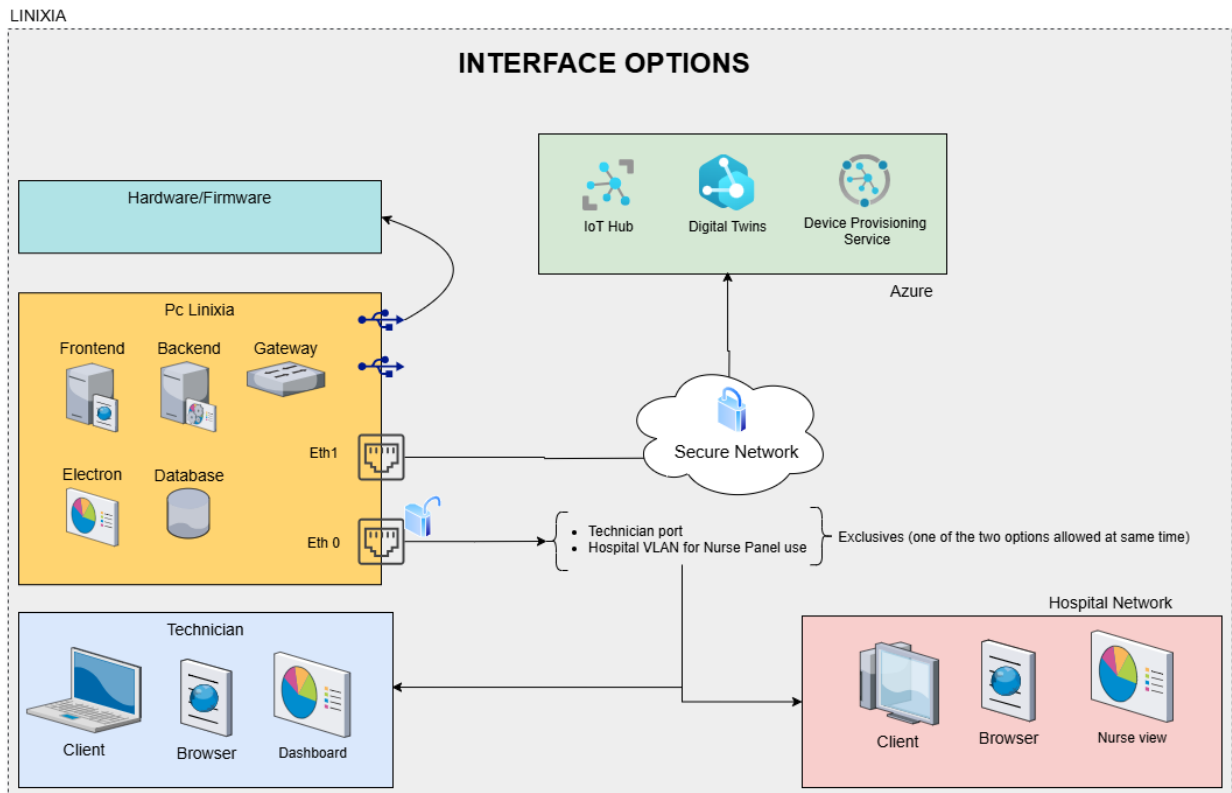
- VPN implementation to secure remote access:
 - VPN tunneling protocol: i.e., SSTP or WireGuard
 - Data encryption using AES-256-GCM
 - Access control: i.e., Authentication via MSCHAPv2 over PPP
 - Server authentication: Using certificate with 2048-bit RSA key



- Network monitoring SW

Strongly recommended:

- Using IDS/IPS to detect and prevent attacks.
- Network segmentation: Implementing VLANs.



13.2. Network settings

Once the interfaces are connected to the desired networks, basic ethernet port connectivity can be configured through Linixia's UI (Service → Settings → Network):



Mon 10 Feb 12:47 PM | EN | nipro_default | Log out

Service

About Calibration **Settings** User management Actions Counters

Production	Local IP Eth0	10.205.40.26/24	↻
Hot Water Disinfection	Local IP Eth1	10.205.40.27/24	↻
Chemical Disinfection			
Global	Local gateway Eth0	10.205.40.151	↻
Network	Local DNS 1	8.8.8.8	↻
Cloud	Local DNS 2	8.8.8.8	↻
Remote Configuration			
	Automatic IP Eth0	ON	✎ ↻
	Automatic IP Eth1	ON	✎ ↻

Dashboard Schedule Event log Diagram Service

Eth0:

- Automatic IP
- Local IP
- Local gateway
- DNS1
- DNS2

Eth1:

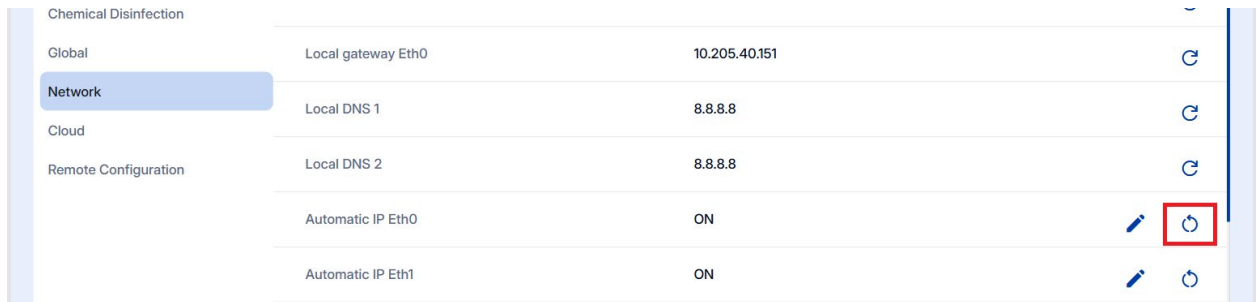
- Automatic IP
- Local IP
- Local gateway

When booting the device, the SW will set the configuration stored through the settings. Note that it will not get the device's network configuration, it will overwrite the one stored in the data base.

When modifying any of the network settings, the SW will try to set the value in the device interface configuration and refresh the setting screen with the latest interface information. If everything from this process went well, a "Successfully updated" message will appear on the screen. If there is an issue throughout the process (regardless if it's from the SW not being able to set the value or the network not accepting the format) an "Error updating the setting" message will appear.

Each of the ethernet ports can be configured to work with static or dynamic (DHCP) configuration by switching "Automatic IP" setting. When automatic IP is enabled, the other network settings modification will be disabled as the device will pull the settings assigned by the Network. When switching to automatic IP, the network can take some time to assign those parameters, so manual refresh may be necessary by clicking the following button:





13.3. Ethernet port 0 - (Remote Configuration)

When this interface is used for Nurse panel connections only incoming packets within the same IP segment must be routed through this port.

i.e. if Local IP Eth0 is set to “10.205.20.1/24” only the incoming connections from “10.205.20.x” will be routed through this port.

For more extended IP range, modify ip submask. i.e. “10.205.20.1/16” will route “10.205.x.x”.

This routing must be done through the desired gateway, which can be configured through “Local gateway Eth0”.

Note: After typing the Local IP address for the first time, the setting may appear as empty, because “Local gateway” is a required value. After entering the gateway, if the values are accepted, both of them will appear updated on the screen.

Another consideration for the Nurse panel is that if “MAC filtering setting” is enabled, only packets coming from a registered MAC address will be accepted through this port.

For further Nurse panel configuration instructions check “File 1” in “Related documents” section.

For Technician mode, the ethernet port 0 settings must be configured for P2P connection. This can be done by plugging an ethernet cable from Linixia’s Eth0 port and Technician’s PC ethernet port. And then set Linixia’s Local IP Eth0 as Technician’s PC default gateway and Linixia’s Local gateway Eth0 as Technician’s PC IP address.

An example of a working configuration:

Linixia’s settings:

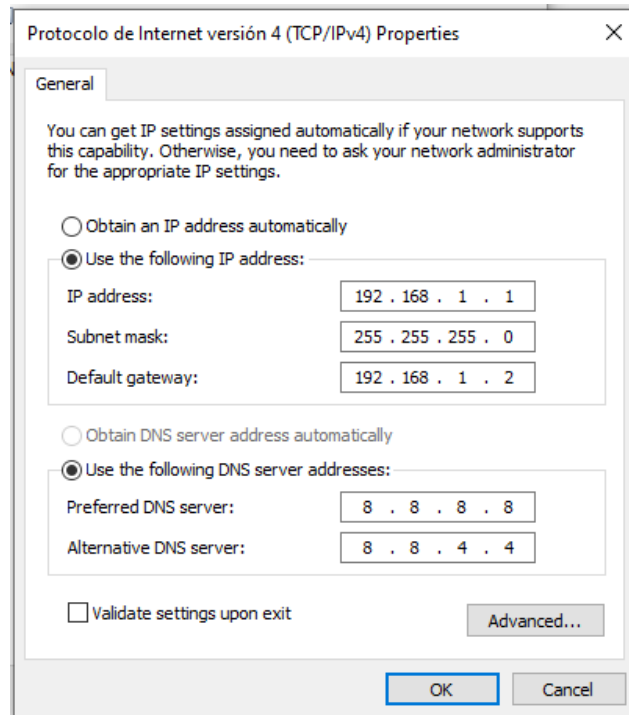
- Local IP Eth0: 192.168.1.2/24
- Local gateway Eth0: 192.168.1.2

Technician’s PC:

- Ethernet port IP address: 192.168.1.1
- Ethernet port submask: 255.255.255.0
- Ethernet port default gateway: 192.168.1.2



An example of the Technician's PC Ethernet port configuration:



Note: Make sure that LiniXia's MAC filtering setting is OFF and other network connections are disabled on the technician's PC.

13.4. Ethernet port 1 - (Cloud communication)

This interface will be used for internet connection to communicate with Cloud services.

Local gateway Eth1 will be used as the device's default gateway, so any outgoing response packet not coming from Eth0 IP address segment, will be routed through this interface gateway.

Internet connection can be checked by accessing the terminal and executing "ping google.com". Remember that terminal access can be done by entering ctrl+alt+F2. For network troubleshooting it is necessary to manage the configuration through Linux networking commands or by checking the error log file ("/var/log/manager_network.err.log").

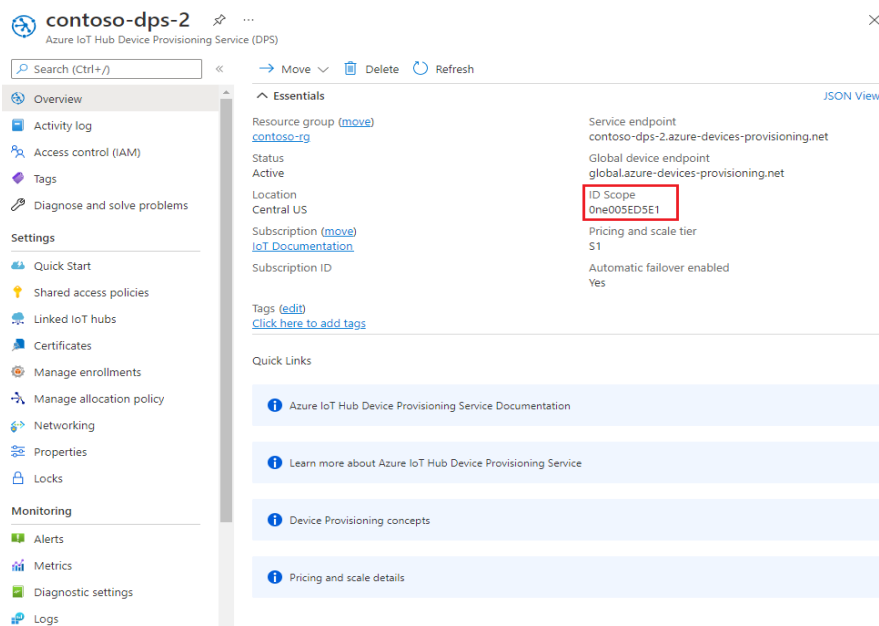
For further Cloud configuration instructions, check chapter 20.



14. Cloud setup

14.1. Connection steps

1. The machine must have internet connection. In order to do so, the device can be connected to the *eth1* port for the internet. Make sure that these ports are correctly configured through the UI, see next chapter for more Network considerations.
2. Once the machine is connected to the network, the device should be configured to reach cloud resources. The certificate and key downloadable from the cloud system must be included in the following path in the device installation: `/home/protean/data/backend`. During development and testing phase this key has been provided by the customer
3. The file names for the connection must be: **nipro-linixia-001-dev.crt** and **nipro-linixia-001-dev.key**.
4. After booting the device, the settings found in the cloud tab must be synchronised with what is found in the Cloud. (Cloud device id, Cloud model id and Cloud scope id). See images below.



The screenshot displays the 'Service' settings interface. At the top, there's a header with the date 'Tue 28 Jan 3:13 PM', language 'EN', user 'nipro_default', and a 'Log out' link. Below the header, the 'Service' title is followed by tabs: 'About', 'Calibration', 'Settings' (active), 'User management', 'Actions', and 'Counters'. A sidebar on the left lists modules: 'Production', 'Hot Water Disinfection', 'Chemical Disinfection', 'Global', 'Network', 'Cloud' (selected), and 'Remote Configuration'. The main content area shows settings for the 'Cloud' module:

Setting	Value	Actions
Telemetry refresh period	5 min	[Edit] [Refresh]
Cloud device ID	nipro-linia-001-dev	[Edit] [Refresh]
Cloud model ID	dtmi:com:example:linxia;1	[Edit] [Refresh]
Cloud scope ID	One00A4DA09	[Edit] [Refresh]
Cloud enable	ON	[Edit] [Refresh]
Cloud connection status	Disconnected → Connected	[Refresh]
Cloud actions	OFF	[Edit] [Refresh]

The bottom navigation bar contains icons and labels for 'Dashboard', 'Schedule', 'Event log', 'Diagram', and 'Service'.

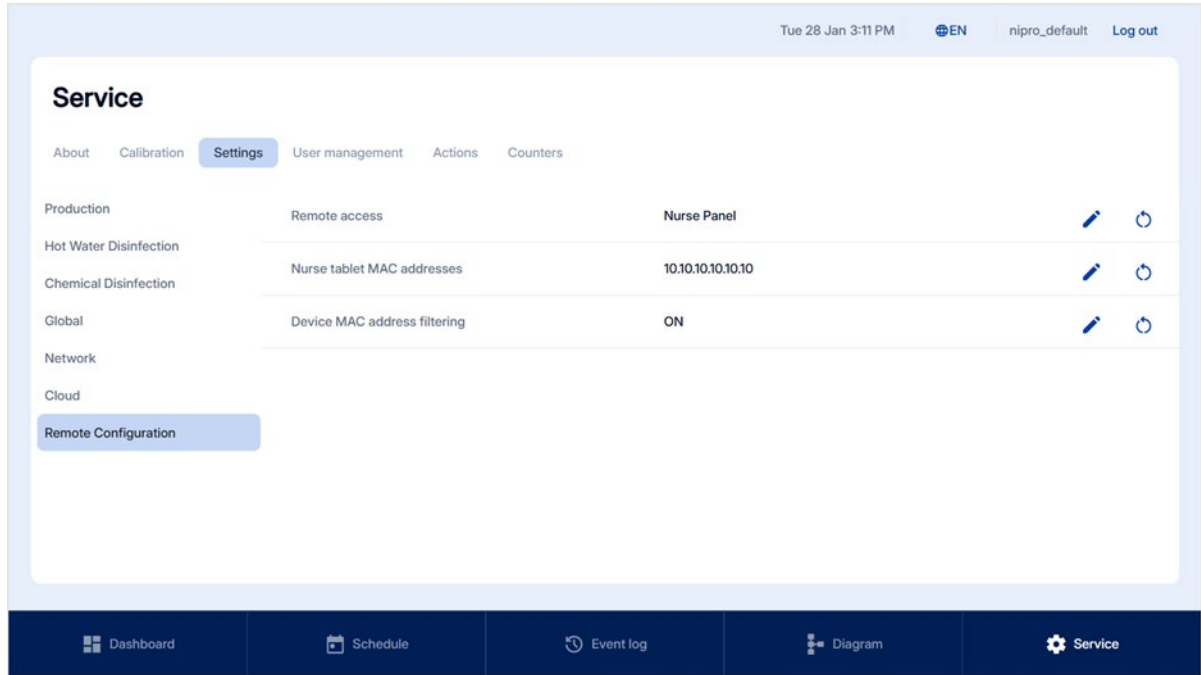
5. Deactivate and activate the “Cloud enable” setting in order to restart the connection to the Cloud.
6. To troubleshoot the Cloud connection backend logs can be used. Please find them in **/home/protean/data/backend/logs**.



15. Nurse Panel setup instructions

15.1. Nurse Panel configuration

The settings for Nurse Panel use and configurations are located in *Service -> Settings -> Remote Configuration*.

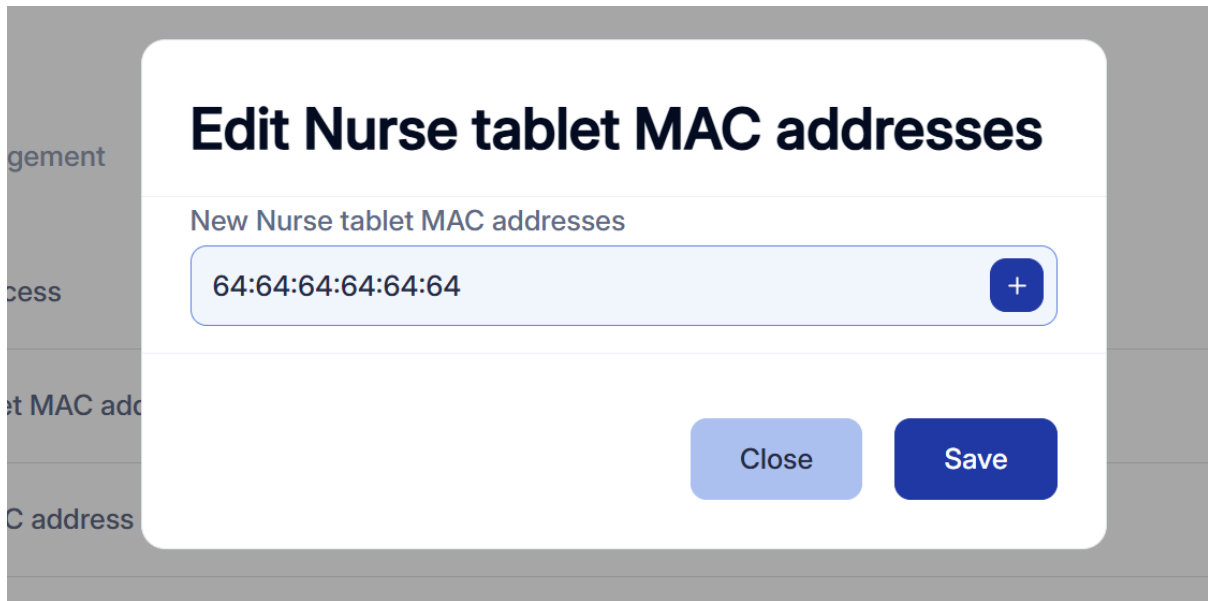


Summary of the functionalities of the settings and possible values:

- **Remote Access:** It has two possible values that change the connection operation with the machine.
 - Nurse Panel: In this mode the devices that connect will have restricted access to the device and will only be able to perform operations of a non-logged in user.
 - Technician Mode: This mode is intended for direct connection of the technician, allowing full access to the connected device with a logged-in user.
- **Nurse tablet MAC addresses:** This setting allows the MAC addresses of the devices to which access is to be granted. This setting will **only work if the system is in Nurse Panel mode and the Device MAC address filtering setting is enabled**.
- **Device MAC address filtering:** This setting allows the devices to be filtered by the software by MACs specified in the previous setting.

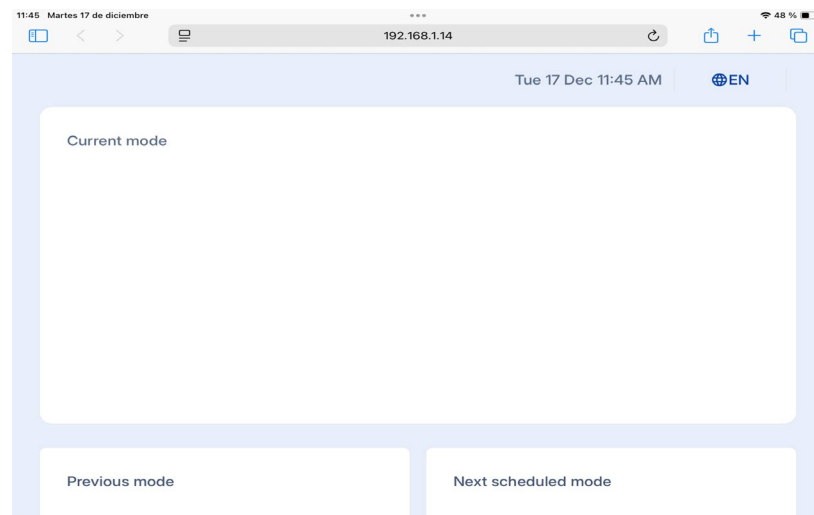
By default, the system shall be in Nurse Panel mode with MAC filtering devices enabled. This will not allow the connection of any device, it will be necessary to obtain the MAC address of the desired device, after that add it into the indicated field as you can see in the image. It is necessary to disable "Private Wi-Fi address" in the tablet system settings to use a static MAC address. The desired MAC values can be added, and upon clicking the "Save" button, the configuration will be applied to the system's firewall.





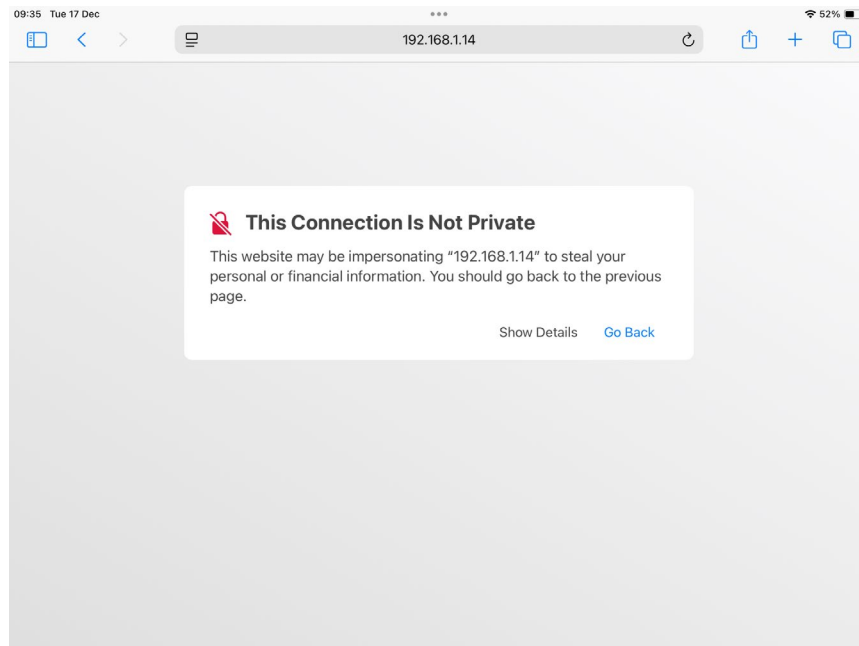
15.2. Tablet configuration

As shown in the first image, the dashboard will not display any information. During the tablet's initial connection to the device, **it will be necessary to enable insecure communication between the UI and the server**. This configuration is required due to the use of self-signed certificates.

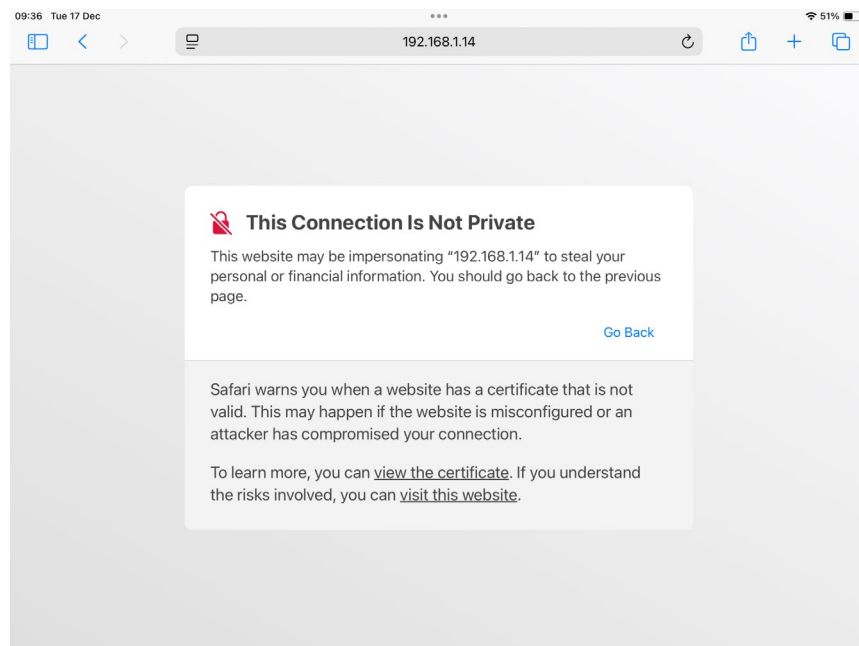


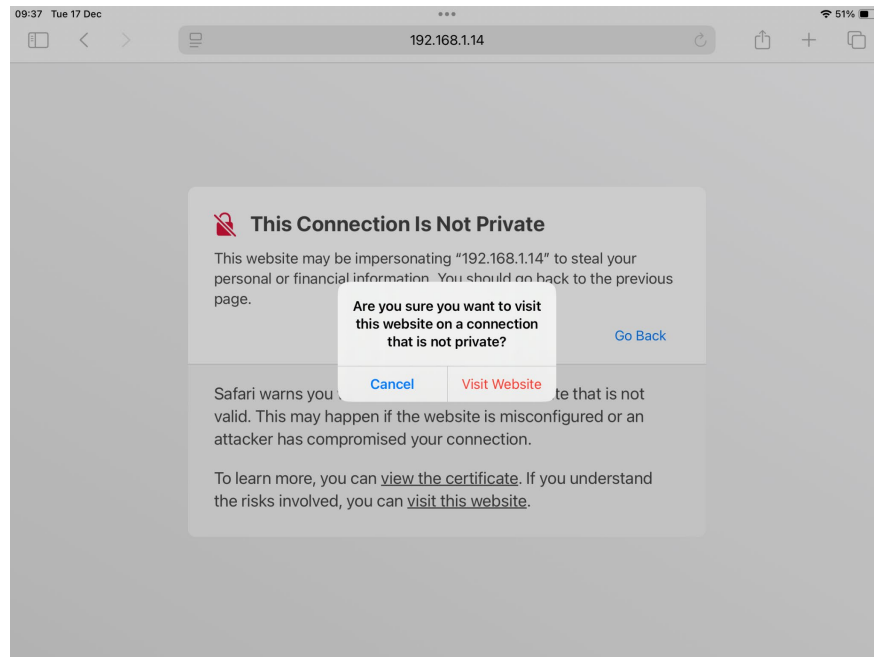
To accept insecure communication, it will be necessary to access the server using the browser through the URL <https://<device-ip>:3000>. Upon access, an informational message about trusting the connection will be displayed. Follow the steps shown in the following images to accept the connection.





Click on **visit this website.**





Refreshing the page will show this message.



After these steps, it will be necessary to return to the dashboard view at URL <http://<device-ip>:4200>, at this point information shall be displayed.



