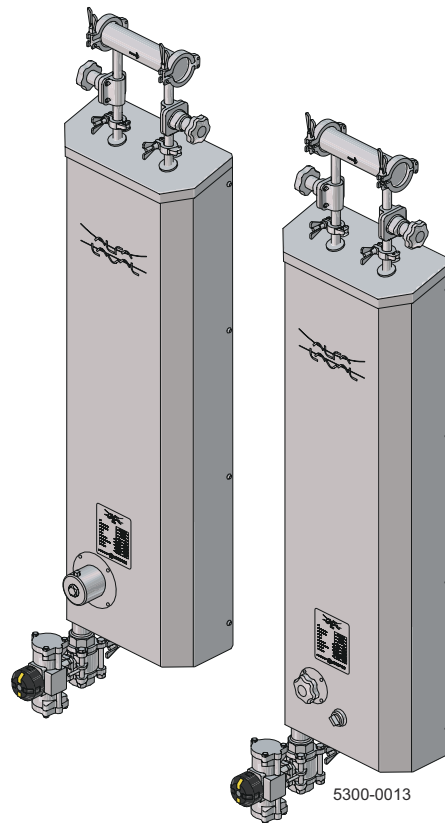


Pharma-line Point of Use



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Instruction Manual

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1 Description

1.1 Safety precautions

Unsafe practices and other important information are indicated in this manual.

Warnings are emphasized by means of special signs.

Important information

Always read this manual before using the module!

WARNING

Indicates that special procedures must be followed to avoid serious personal injury.

CAUTION

Indicates that special procedures must be followed to avoid damage to the module

Warning signs:



General warning



Caustic agents

Installation

- Always read the installation thoroughly. (See chapter 2 Installation and initial start-up)
- Always use a lifting crane or device when handling the module.
- Never touch the valves or the pipelines when processing hot liquids or when sterilising.
- Never dismantle the module with valves and pipelines under pressure.
- Never dismantle the module when it is hot.



Operation

- Always read the operation section thoroughly (See chapter 3 Operation)
- Never introduce hot fluid suddenly when module is empty or cold.
- Never shock the module with cold fluid when hot.
- Never dismantle the module with valves and pipelines under pressure.
- Never dismantle the valves when it is hot.
- Never touch the module or the pipelines when processing hot liquids or when sterilising.



- Never touch moving parts if the valve actuators are supplied with compressed air.
- Always rinse well with clean water after cleaning agent.

Always handle lye and acid with great care.



Maintenance

- Never service the module when it is hot.
- Never service the module with valves and pipelines under pressure.
- Never put your fingers through the valve ports if the actuator is supplied with compressed air.
- Never touch moving parts of the valves if the actuator is supplied with compressed air.



Transportations

- Always ensure that the module is securely fixed during transportation.
- Always transport module in a horizontal position.
- Never lift or elevate in any way other than as described in this manual.
- Always use a lifting crane or device when handling the module.



1.2 Recycling information

Unpacking

- Packing material consists of wood, plastics, metal.
- Wood can be reused, recycled or used for energy recovery.
- Plastics should be recycled or burnt at a licensed waste incineration plant.
- Metal should be sent for material recycling.

Maintenance

- All metal parts should be sent for material recycling.
- All non-metal parts must be taken care of in agreement with local regulations.

Scrapping

- At end of use, the equipment shall be recycled according to relevant, local regulations. Beside the equipment itself, any hazardous residues from the process liquid must be considered and dealt with in a proper manner. When in doubt, or in the absence of local regulations, please contact the local Alfa Laval sales company.

1.3 Application

The Pharma-line Point of Use is a compact point of use cooler for Water For Injection (WFI) or Purified Water (PW) systems. The Pharma-line Point of Use module is intended for points of use where water is drawn intermittently when needed.

The Pharma-line Point of Use module is mainly used in water systems in the pharmaceutical industry. A typical duty for the Pharma-line Point of Use is to cool WFI/water from 80-85°C to 20-40°C.

1.4 Design

The Pharma-line Point of Use is a complete plug and play module designed in line with ASME BPE. It is delivered complete with heat exchanger, insulation, cabinet, valves, and pitot tube arrangement for connection to WFI/PW* main loop.

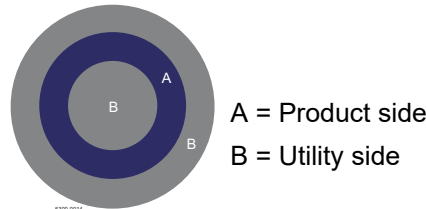
*WFI= Water For Injection

*PW= Purified Water

Triple tube design for optimum thermal efficiency

The Pharma-line Point of Use heat exchanger is made up of three tubes positioned concentrically within each other. Turbulators are inserted to promote turbulence. The tubes are bent as one, through 180 degrees.

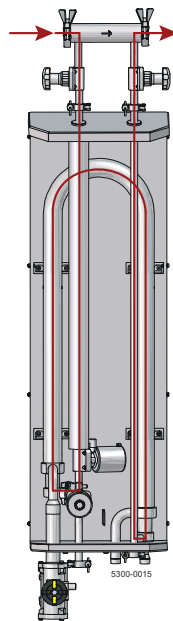
The WFI / PW passes through the center annular space, and the cooling medium is passing through the outer and inner channels in a counter current flow.



Stand-by mode

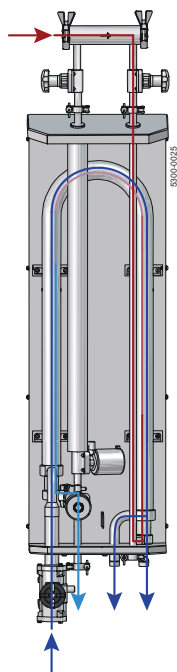
The Pharma-line Point of Use cooler can be regarded as a sub-loop of the main loop.

To maintain optimum hygienic conditions when the point of use cooler is in 'stand-by' mode, hot water from the main loop enters via a pitot tube and flows continuously through the point of use cooler and back to the main loop.



Cooling mode

Switching to 'cooling mode' enables cold WFI/PW to be withdrawn with no flushing or draining of the system required. Cold WFI is available within seconds, due to the Pharma-line Point of Use's low hold up volume, and high thermal efficiency.



It is also possible to withdraw hot WFI at the point of use.

Hygienic design

All product wetted parts in the Pharma-line Point-of-Use are electropolished and the tubes are seamless.

There are no internal welds in the Pharma-line Point of Use, eliminating the risk of cross contamination between the product and the utility side.

The Pharma-line Point of Use is fully drainable on the product side, with no dead legs.

2 Installation and initial start-up

2.1 Installation

A Pharma-line Point-of-Use module consists of the triple tube heat exchanger, insulation, cabinet, valves and a pitot tube arrangement. The user point valve is either manual or pneumatic and recirculation and cooling media valves are pneumatic.

Unpacking/delivery

1 CAUTION

Alfa Laval cannot be held responsible for incorrect unpacking.

Check the delivery for:

1. Complete module.
 2. Delivery note.
-

2

1. Remove any packing materials from the module/module parts.
 2. Inspect the module/module parts for visible transportation damage.
-

2.2 Installation recommendations

CAUTION: Alfa Laval cannot be held responsible for incorrect installation

Do not install the Pharma-line Point of Use under conditions that exceed those specified in chapter 5. Technical data.

- 1 The Pharma-line Point of Use should be installed on a wall or frame.
- 2 To access the mounting holes inside the cabinet, remove the cabinet cover by unscrewing 8 screws in both sides of cabinet.

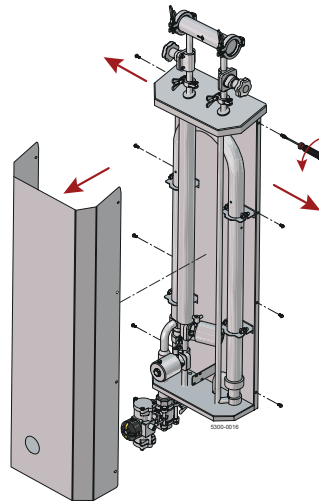


Figure 1: The location for 8 screws which connect cabinet cover to the back plate.

- 3 Mount the Pharma-line Point of Use with 6 pcs strong screws on the wall. Customers are responsible to make sure the strong screws and wall can bear the weight of unit.

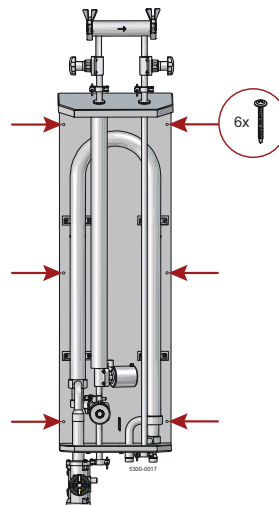


Figure 2: There are 6 holes in the back plate of cabinet for mounting the unit on a wall.

- 4 Mount again the cabinet cover.

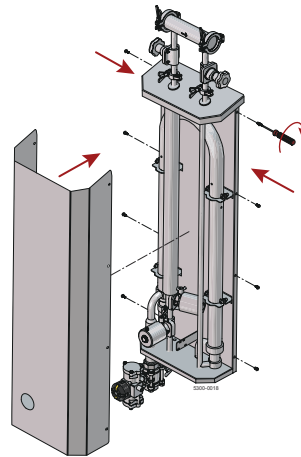


Figure 3: Connect the cabinet cover to the back plate with the 8 screws.

- 5 Depending on what type of module (automatic or manual), connect instrument air according to Fig 4 or Fig 5. Check valves specification for recommended air pressure. The instrument air should be free of oil and particles, otherwise the valve membrane can be affected, and dirt can end up to the cabinet.

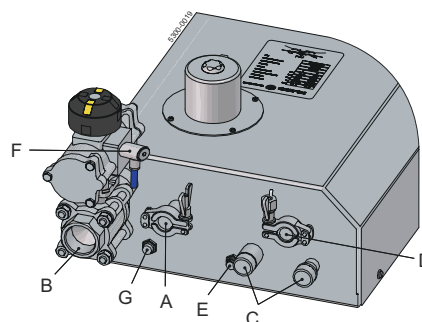


Figure 4: Automatic unit: Connect 6 mm instrument air tubing to E, F and G.

- A: User point outlet
- B: Cooling media inlet
- C: Cooling media outlet
- D: Drain (WFI)*
- E: Instrument air inlet: User point valve
- F: Instrument air inlet: Cooling media valve
- G: Instrument air inlet: Recirculation valve

* Only remove blind cap to drain during maintenance

In Pharma-line Point of Use Auto: all valves are controlled remotely by client.

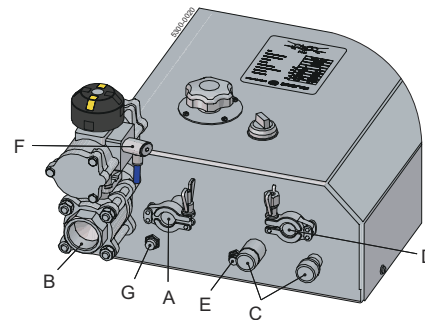


Figure 5: Manual unit: Connect 6 mm instrument air tubing to E.

A: User point outlet

B: Cooling media inlet

C: Cooling media outlet

D: Drain (WFI)*

E: Instrument air inlet: Air switch

F: Instrument air inlet: Cooling media valve.

G: Instrument air outlet: Air switch

NOTE: The Air switch controls both the Recirculation valve and the Cooling media valve. Therefore air tubing is connected between F and G at delivery.

* Only remove blind cap to drain during maintenance

In Pharma-line Point of Use Manual:
When Air switch is turned ON, it will open the cooling valve and close the recirculation valve.

-
- 6 Both outlet connections on the cooling media side shall be used.
-
- 7 Do not install shut off valve on the cooling media outlet.
-
- 8 If Pharma-line Point of Use is installed in a closed cooling system, non-return valves and appropriate safety valves should be fitted on the utility side.
-
- 9 It is recommended that the hygienic side always have a higher pressure than the utility side.

- 10 To ensure the Pharma-line Point of Use is drainable, it is recommended to install it in a vertical position. If installed in a horizontal position the Pharma-line Point of Use is no longer drainable.
- 11 It is recommended to have approximately 200 mm of straight section of the main-line before the pitot tube arrangement, in order to avoid vortices that might disrupt the flow in stand-by mode.

2.3 The pitot tube arrangement

In stand-by mode, hot water from the main loop enters via the pitot tube, Fig. 1, and flows continuously through the point-of-use cooler and back to the main loop.

The pitot tube can be turned 180 degrees if needed.

The pitot tube has an etched arrow on it that should point in the direction of the flow in the main line/WFI line. Fig. 2.

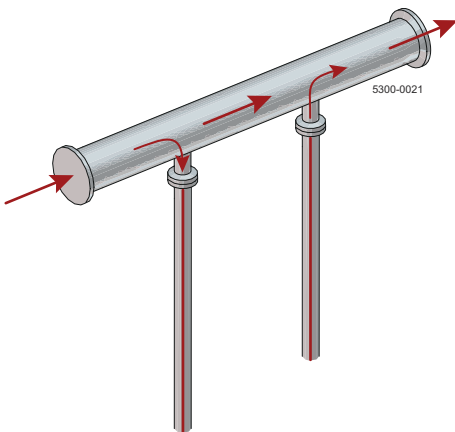


Fig. 1. Pitot tube connected to the WFI/PW main line.

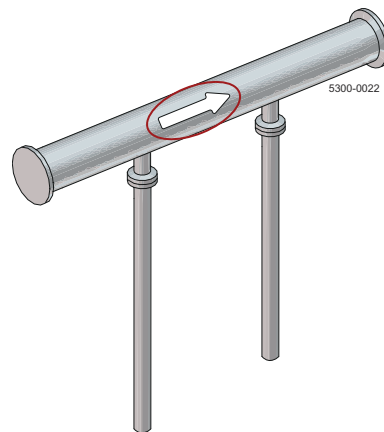


Fig. 2. An arrow on the pitot tube shows the direction of the flow in the WFI/PW main line.

2.4 Initial start-up procedure

When taking a module into operation, slowly start to circulate the cold medium only. Make sure that the entire cold side is free of air. The air will be pushed out at a higher flow rate.

The hot medium should then be gradually introduced until all passages are filled with hot fluid.

Check that hygienic side has a higher pressure than the utility side.

3 Operation

3.1 Initial Start-up

See the directions given in chapter 2.4 Initial start-up procedure.

Operator should be aware about the risk of hot water before any extraction of WFI/PW.



3.2 Normal Operation

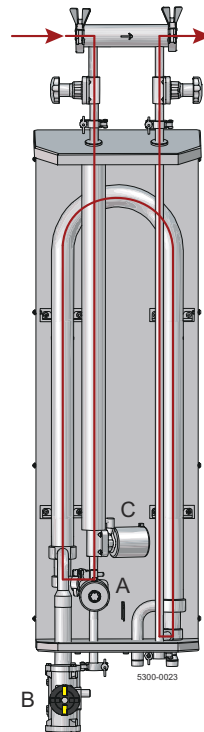
The operation directions below imply that the heat exchanger has been equipped with a pitot tube, see description in chapter 2.3 The pitot tube arrangement.

3.3 Stand-by mode

When the module is in stand-by mode the N/O recirculation valve is open. To maintain optimum hygienic conditions when the module is in 'stand-by' mode, hot water from the main WFI/PW loop enters via a pitot tube and flows continuously through the point of use cooler and back to the main loop.

The pitot tube ensures that the product is kept circulating in the point-of-use cooler, keeping it self-sanitized.

The velocity in the main line must be >1.0 m/s in order to achieve a turbulent flow during stand-by mode.



Stand-by mode

A (User point valve) = Close

B (Cooling media valve) = Close

C (Recirculation valve) = Open

3.4 Hot WFI/PW or hot flushing

When hot WFI / PW or hot flushing is needed: Open the user point valve in 'stand-by' mode.



3.5 Cooling mode

- 1 In manual module turn the air switch to ON mode, the N/O recirculation valve will be closed, and the N/C cooling media valve will be opened.

In automatic module client should close the N/O recirculation valve and open the N/C cooling media valve with their control system.

- 2 To extract cold WFI/PW, open the user point valve and be aware that for the first few seconds the water will be hot.



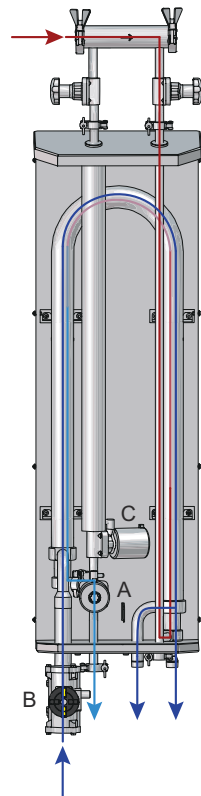
Cooling mode

A (User point valve) = Open

B (Cooling media valve) = Open

C (Recirculation valve) = Close

The cooling media valve opens. The recirculation valve is closed. Cold WFI/PW is available with seconds.



3.6 Shut down

Shut down procedure

If the system is to be completely shut down for a long period of time:

Drain all fluids from the module. Remaining fluids on the inside may cause corrosion. Water must be drained from tubes when there is a possibility of freezing.

4 Maintenance

4.1 Inspection

Since the heat exchanger is not openable it is recommended that it be used for clean duties only.

4.2 Cleaning the utility side



Chemical cleaning of the utility side will ensure the performance of the Pharma-line Point of Use is kept. In general, inorganic deposits are cleaned with acidic cleaning solutions and organic deposits with alkaline cleaning solutions.

Proprietary cleaning agents should be used in accordance with the manufacturer's instructions. In this way, the compatibility with the materials of construction (metal and elastomers) is secured and warranties apply. The whole cleaning protocol (choice of cleaning agent, its concentration, temperature, and time) must be related to the composition of the fouling species. Some guidelines are given in the table below to clean various common fouling species.

The flow rate during the cleaning of the utility side should always be at least the same as the production's flow rate. An increased flow rate may be required in some cases.

Cleaning agents – Fouling

Type of deposit	Cleaning agent	Typical conditions
Organic (microbiological growth, algae, slime, proteins, grease...)	AlfaCaus	10 vol.%, 60°C
Calcium carbonate, Calcium phosphate	Alpacon Descalant	10 vol.%, 60°C
Iron oxides	AlfaPhos	10-20 vol.%, 60°C

CAUTION Never use hydrochloric acid or other cleaning substances containing chlorides as their presence will inevitably lead to corrosion of stainless steel alloy components.

After every chemical cleaning, rinse thoroughly with water.

4.3 Steam-In-Place (SIP) for the product side

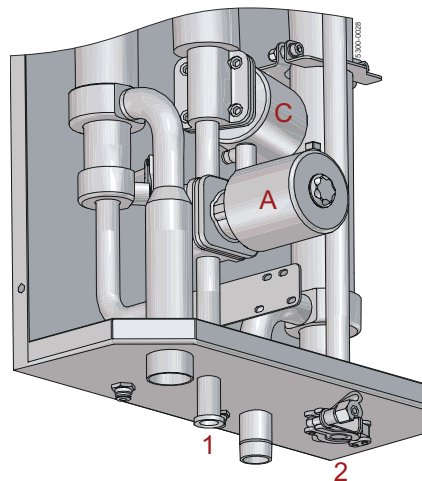


Steam-In-Place process is normally not needed due to self-sanitized sub-loop set up. However, if needed, follow the procedure below.

1. Switch the Pharma-line Point of Use to stand-by mode (C open)
2. Drain the product side
 - a. Open User Point (A)
 - b. Open drain point (2)

3. Drain the utility side and keep drained during SIP procedure.
 - a. **CAUTION:** To avoid pressure build up above design conditions, it is very important that the utility side is equipped with suitable safety valves or burst discs.
4. Switch the Pharma-line Point of Use to cooling mode (C closed)
5. Close drain point (2) on product side
6. Install steam trap on ferrule at user point (1)
7. Turn on steam (from main line)
8. Measure the temperature on the outlet condensate (1)
 - a. **Note:** Holding time according to applicable Standard Operating Procedure
9. Turn the Pharma-line Point of Use to stand-by mode (C open)
10. Open user point valve (A)
11. Measure the temperature on the outlet condensate (1)
 - a. **Note:** Holding time according to the applicable Standard Operating Procedure
12. Turn off steam
13. Drain out the condensate
14. Close user point valve (A)
15. Remove steam trap
16. Allow the system to cool

CAUTION: Check valve diaphragm specifications in order not to exceed maximum recommended steam pressure/temperature and time.



4.4 Gaskets

Inspect the gaskets between ferrules and change them if needed.

5 Technical data

Technical data	
Heat transfer area	0.33-0.66 m ²
Connections product side	Tri-clamps ASME BPE
Connections utility side	One inlet: 1¼" Female. Two outlets: ¾" Male BSP threaded
Wetted part material	316 L stainless steel, seamless tubes
Surface finish (wetted part)	Ra<0.5µm Electropolished
Non-wetted part material in module	Insulation: Armaflex (thickness: 20mm) Cabinet: 304 Brushed plate (thickness: Back plate 1,5mm. Front plate 1,25mm)
Welding procedure	ASME IX
Weight of module	22-46 kg
Design Pressure	Pneumatic user point valve (PTFE diaphragm) 6 barg Pneumatic user point valve (EPDM diaphragm) 10 barg Manual user point valve (PTFE diaphragm) 10 barg
Design temperature	140°C
Pressure vessel code	Normally not applicable due to small internal volume. See drawing for details

5.1 Technical Specification

The Pharma-line Point of Use module is available in three standard sizes: PoU200, PoU300 and PoU400. Each size will be offered with either manual or pneumatic point of use valve. Considering three sizes and two types of point of use valves, total there are 6 standard models for offering.

Model	User point valve type	Approx. effective length (m)	Heat transfer area (m²)	Dimension (H x W x D) mm
Pharma-line PoU200 Man	Manual	2	0.33	1383 x 380 x 297
Pharma-line PoU200 Auto	Pneumatic	2	0.33	1383 x 380 x 297
Pharma-line PoU300 Man	Manual	3	0.5	1883 x 380 x 297
Pharma-line PoU300 Auto	Pneumatic	3	0.5	1883 x 380 x 297
Pharma-line PoU400 Man	Manual	4	0.66	2383 x 380 x 297
Pharma-line PoU400 Auto	Pneumatic	4	0.66	2383 x 380 x 297

5.2 Spare parts list

For details see documentation for specific serial number. In general, see below.

- Gasket for $\frac{3}{4}$ " clamp connection
- Clamp ring $\frac{3}{4}$ "
- Diaphragm for all diaphragm valves
- User point manual valve (only in manual module)
- User point NC pneumatic valve (only in automatic module)
- Recirculation NO pneumatic valve
- Cooling media NC pneumatic valve
- Air tubing 6x1mm
- Air switch (only in manual module)
- Silicone bushing