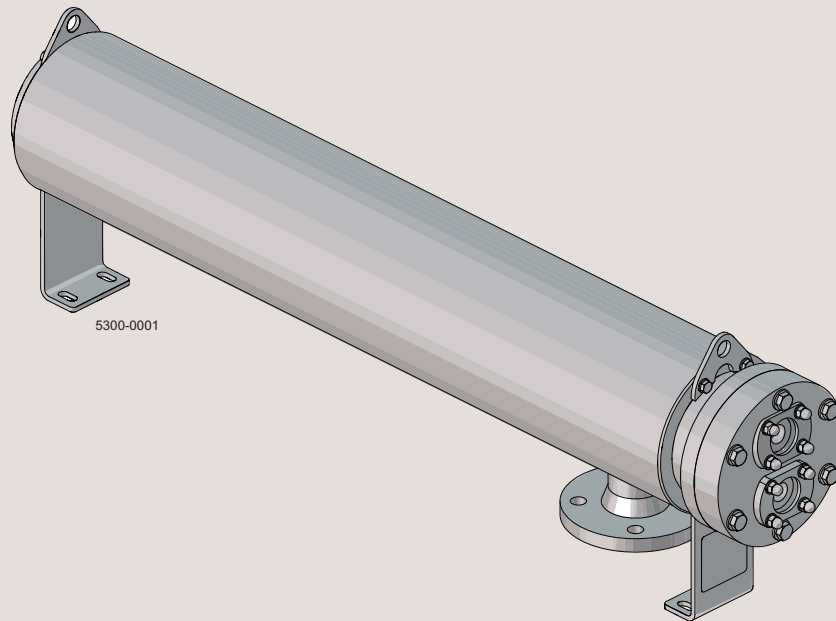


Instruction Manual

Alfa Laval Pharma-line S



ESE02599-EN2 2014-04

Original manual

The information herein is correct at the time of issue but may be subject to change without prior notice

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1 Description

1.1 Safety precautions

Installation:

Always read the installation thoroughly. (See chapter 2 Installation).
Always use a lifting crane or device when handling the heat exchanger.



Operation:

Always read the operation section thoroughly. (See chapter 3 Operation).
Never introduce hot fluid suddenly when heat exchanger is empty or cold.
Never shock the heat exchanger with cold fluid when hot.



Transportation:

Always transport the heat exchanger in a horizontal position.
Always ensure that the unit is securely fixed during transportation.
Never lift or elevate in any way other than as described in this manual.

1.2 Recycling information

Packing

- Packing materials consist of wood, plastics and 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 disposed of in accordance with local regulations.

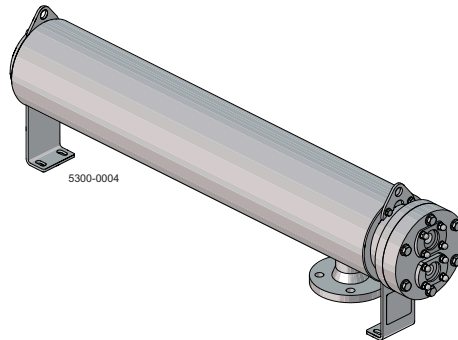
Scrapping

- At the end of use, the equipment should be recycled according to relevant, local regulations. Besides 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 your local Alfa Laval sales company.
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1.3 Application

The Alfa Laval Pharma-line S is a high quality, double tube sheet shell & tube heat exchanger designed for the pharmaceutical and biotechnology industries. The Pharma-line S is used in pharmaceutical water systems: Water For Injection (WFI), Purified Water (PW), and for heating or cooling of pharmaceutical products.

It is available in a number of standard sizes and meets the stringent hygiene standards imposed both by control authorities and the industry.



1 Description

1.4 Design

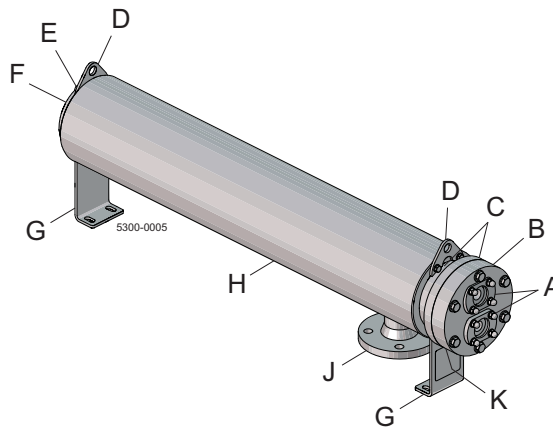
The Pharma-line S is in hygienic design in line with ASME BPE, USP and cGMP requirements.

The Pharma-line S has no dead-legs and is fully drainable on the product side. All product wetted parts in the Pharma-line S are mechanically polished to Ra <0.5 µm.

The tubes are seamless and polished prior to bending. The Pharma-line S U-tubes are bent to a larger radius than required in ASME BPE. The Pharma-line S is easy to clean and can be steam sterilised. The gaskets are FDA approved and USP class VI.

Main components

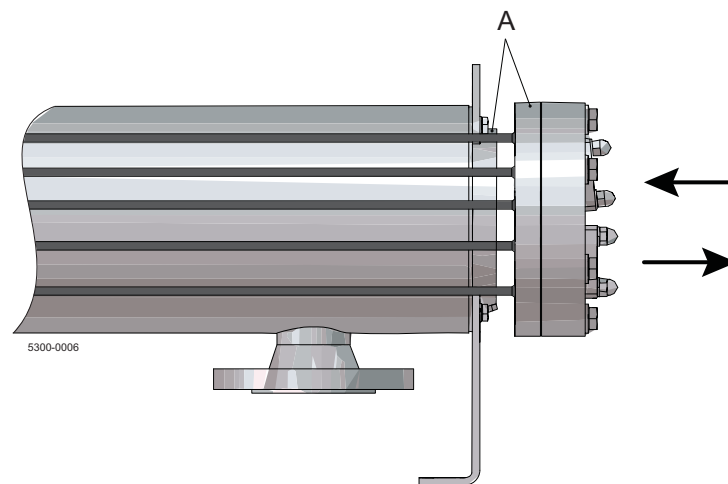
- A NAC plate connection
- B Fronthead
- C Tubesheet
- D Lifting lug
- E Vent
- F Flange connection
- G Leg
- H Shell
- J Flange connection



Tube sheet	Tubes are expanded into first sheet, welded and expanded into second sheet. Double tube sheet minimises the risk of contamination
Shell	Utility media flow on the shell side
Tube bundle	Product flows through a number of tubes which are bundled together
Vent	Vent connection on shell side for venting of air
Drain	Drain connection on shell side for draining
NAC plate connection on product side	Tri-clamp ferrule to be connected to the heat exchanger by an NAC plate. Tri-clamp ferrules and gaskets are not supplied
Flange connection on shell side	Inlet flange is at the back of the heat exchanger. Outlet flange is placed at the side of the shell
Lifting lug	
Legs	To be used when lifting the unit, fixed with bolts and movable, allowing for flexible positioning.

Working principles

In the Pharma-line S, the risk of mixing between the product and the heating or cooling (service) medium is eliminated as a result of the double tube sheet design. The product flows in the tubes while the service medium flows in a cross flow around the tubes, inside the shell. The service medium is sealed in the shell by the first tube sheet and the second tube sheet seals in the product. In the event of a leak, the leakage of either fluid is easily visually detected.



A = Tube sheets

Documentation

The Pharma-line S is delivered along with a complete documentation package, including:

- Approved drawings and pressure test certificate signed by the relevant body.
For Pharma-line S's in category I and II EC type examination and product verification from Zetterströms Rostfria AB.
Zetterströms Rostfria AB is certified to issue EC type examination and product verification under Lloyds register (NB No.0038)
- List of welders, welding procedures and welder's qualifications
- 3.1 Material certificates for pressure and product wetted steel parts
- FDA and USP class VI certificates for gaskets
- Liquid penetrant test report and procedure
- Surface roughness certificate
- Dimension control report or similar for applicable pressure vessel code
- Pressure test certificate
- Identification (technical sign)
- Quality system certificate
- CE documents when applicable.

Applicable for pressure vessel code TSG (China)

- Certificate of Conformity
- Radiographic test report
- Design calculations
- TSG Classified vessels are certified and registered at SELO

2 Installation

The Alfa Laval Pharma-line S can be installed either horizontally or vertically, on the floor, on the wall or in the ceiling. The flexible legs on Pharma-line S facilitate easy installation, either it is horizontally or vertically.

For easy installation, lifting lugs are fastened to the unit with screws. Before lifting, make sure the lifting lugs are properly secured. We recommend that the bolts are tightened before lifting the unit. If the Pharma-line S surface temperature is expected to be hot or cold, the heat exchanger should be insulated.

2.1 Clearance for dismantling

Provide sufficient clearance at the stationary head side to permit dismantling of the front head cover and possible future inspection of the tubes.

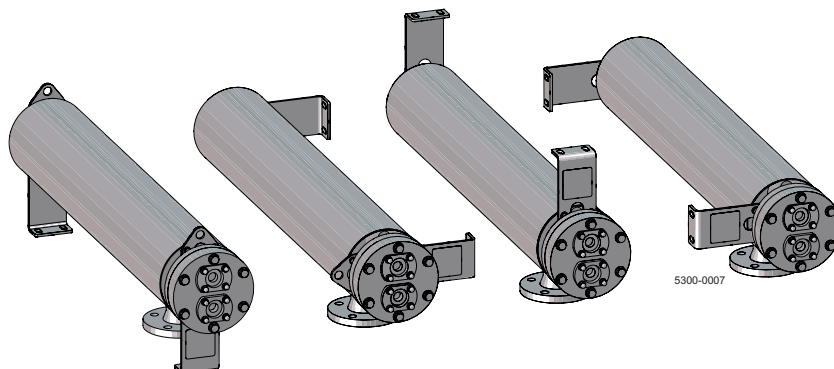
2.2 Foundations

Foundations and/or supports must be adequate so that the exchanger will not settle and impose excessive strain on the exchanger. Foundation bolts should be set to allow for setting inaccuracies.

2.3 Positioning and slope

The legs can be fixed in 4 different positions, 0°, 90°, 180° and 270° which allows for a flexible installation, depending on where the unit is to be installed.

Once the positioning of the unit has been decided, move the legs the desired position, tightening the bolts carefully before installation.



2.3.1 Horizontal positioning

This is a typical installation. At the time of delivery, the legs are positioned horizontally.

Note that the exchanger must have a minimum slope of 1% and a maximum of 5%. The slope is required to ensure that the tube side is fully drainable. The unit is not designed with a slope. Consequently, we recommend that the unit is tilted using a suitable bracket or spacer.

2.3.2 Vertical positioning

If vertical positioning and full drainability is required on the product side, the unit should be installed with the product connections downwards.

If the fluid on the utility side is steam, the flow should always be downwards, meaning that the inlet is on the top of the unit and the outlet at the bottom, in order to be able to drain any condensate.

2.4 Levelling

The heat exchanger must be set so that pipe connections can be made without forcing them. However, small forces may be unavoidable. Acceptable forces are as follows:

- acceptable forces in all directions on the tube side are max 50 N
- acceptable forces in all directions on the shell side are max 100 N

2.5 Cleanliness provisions

Connector protectors

All exchanger openings should be inspected for foreign material. Protective plugs should not be removed until just prior to installation.

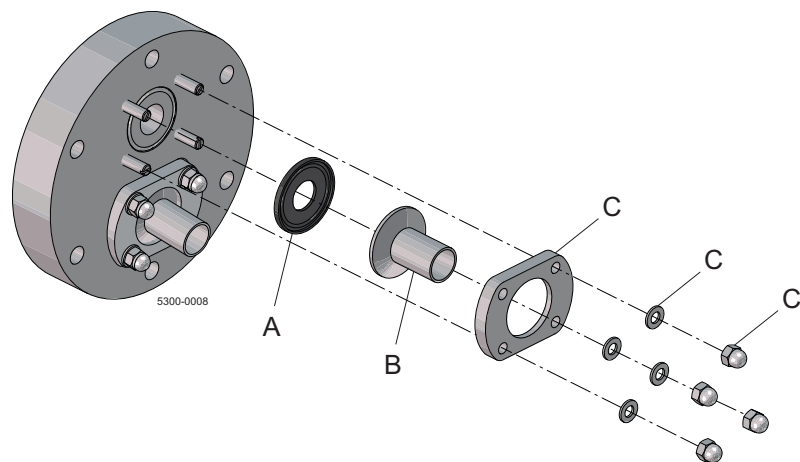
Dirt removal

The entire system should be clean before starting operation.

2.6 Connecting the heat exchanger to the piping system

Connection product side; the NAC plate must be disassembled from the heat exchanger.

Mount the NAC plate on the piping before welding the Tri-clamp (TC) ferrule.



A: Not supplied with the heat exchanger

B: Not supplied with the heat exchanger

C: NAC plate supplied with the heat exchanger

NOTE: It is important that the NAC plate is assembled on the pipe before the TC is welded to the pipe.

2 Installation

2.7 Fitting and piping

Bypass valves

It may be desirable for the user to provide valves and bypasses in the piping system to enable inspection and repairs.

Test connections

It may be desirable for the user to install a thermometer well and pressure gauge connections close to the exchanger.

Vents and drains

It may be desirable for the user to install vent and/or drain valves close to the heat exchanger. The shell side is equipped with the option to vent and drain.

Vent and drain valves should be provided so the unit can be purged to prevent air, vapour or gas binding.

Before use of the vent and/or drain connection, it is necessary to install/connect piping to threaded hole 1/8" BSP.

Drains may discharge into an open manifold.

Pulsation and vibration

Care should be taken to eliminate or minimise the transmission of fluid pulsations and mechanical vibrations into the heat exchanger.

Safety relief devices

The user is responsible for installing the required safety devices.

3.1 Design and operating conditions

The heat exchanger must not be operated under conditions, which exceed those specified on the name plate.

Warning! Failure to operate the heat exchanger within the design pressure and temperature specified on the name plate may result in damage to the heat exchanger and potential injury to adjacent personnel.

Fluid and/or steam velocities in excess of design operating conditions on either the shell or tube side of the heat exchanger can cause damaging erosion and/or vibrations in the tubes and tube plates.

If the heat exchanger surface temperature is expected to be hot or there are local regulations related to surface temperature, it is the user's responsibility to either insulate the unit or take precautions by labelling the unit with a warning about the hot surface temperature in order to avoid risk of injury to personnel.

3.2 Operating procedures

Before operating the heat exchanger, please refer to the name plate for any special instructions.

Local safety and health regulations must be observed.

Incorrect start-up or shut-down sequences may cause leaking of tube-to-tube sheet and/or bolted flanged joints.

It is the customer's responsibility to ensure proper start-up and operation when running media with a higher risk of damage to the heat exchanger. This applies especially when running media of temperatures below freezing-point (0°C).

3.2.1 Start-up operation

During start-up, all vent valves should be opened and left open until all passages have been purged of air and are completely filled with fluid. Fluid must be introduced so as to minimise differential expansion between the shell and the tubes. We recommend that the colder medium is established first, followed by the gradual introduction of the hotter medium.

Caution! Flow rate adjustment should be made slowly in order to avoid the risk of a pressure surge (water hammer). A water hammer is a short-lasting pressure peak that can appear during start-up or shut-down of a system, causing liquids to travel along a pipe as a wave at the speed of sound. This can cause considerable damage to the equipment.

Dual Application If the heat exchanger is intended for dual application duties, it should be allowed to come to ambient temperature between heating and cooling cycles.

3.2.2 Operation

In all installations, there should be no pulsation of fluids since this causes vibration and strain.

3 Operation

3.2.3 Shut-down operation

The heat exchanger must be shut down in a manner that minimises different expansions between shell and tubes. When shutting down the system, the heat exchanger should be drained completely. To reduce water retention after drainage, the tube side of the heat exchanger should be blown out with air.

Temperature shocks

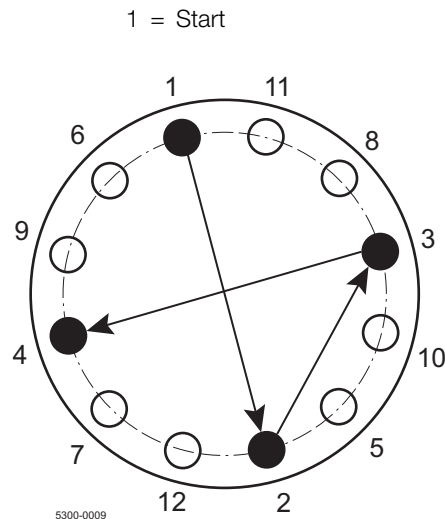
The heat exchanger should not be subjected to sudden temperature fluctuations. Hot fluid must not be suddenly introduced when the unit is cold, nor cold fluid suddenly introduced when the unit is hot.

Bolted joints

The heat exchanger is pressure tested before leaving the manufacturer in accordance with EN 13445 standard requirements for PED, or in accordance with ASME VIII standard requirements for ASME. However, normal relaxing of the gasketed joints may occur in the interval between testing at the manufacturer and installation on site. Therefore, all external bolted joints may require retightening after installation and, if necessary, after the heat exchanger has reached operating temperature.

Recommended bolt tightening procedure

If the bolts are tightened, it is important that they are tightened uniformly and in a diametrically staggered pattern.



4.1 Inspection

At regular intervals and as frequently as experience indicates, an examination should be made of the interior and exterior condition of the unit. Failure to keep all tubes clean may result in decreased performance of the heat exchanger.

4.2 Indication of fouling

Heat exchangers subject to fouling or scaling should be cleaned periodically. A light sludge or scale coating on the tube greatly reduces its thermal efficiency. An increase in pressure drop and/or reduction in performance usually indicates that cleaning is necessary. The unit should first be checked for air or vapour binding to confirm that this is not the cause for the reduction in performance. Since the difficulty of cleaning increases rapidly as the scale thickness or deposit increases, the intervals between cleaning should not be excessive.

4.3 Disassembly for inspection or cleaning

Before disassembly, the user must ensure that the unit has been depressurised, vented and drained. To inspect the inside of the tubes and also make them accessible for cleaning, remove the front head cover. Always replace the gasket when the front cover is loosened to make sure that the gasket seals correctly.

4.4 Locating leaks

The heat exchanger has double tube sheets and a leakage in the joint in the inner tube sheet will show as a leakage between the double tube sheets. A leakage in the joint in the outer tube plate will also show as a leakage between the double tube sheets.

The following procedure may be used to locate perforated or split tubes inside the shell.

- Remove the front head cover and apply pressure in the shell. Any leakage coming out of any tube shows a leakage in a tube inside the shell.

4.5 Cleaning the heat exchanger

The heat transfer surfaces of the heat exchanger must be clean to ensure satisfactory performance.

The method selected is the choice of the operator and will depend on the type of deposit and the facilities available in the plant.

Cleaning compounds must be compatible with the metallurgy of the heat exchanger.

Caution! If necessary, use proper protective equipment, such as safety boots, safety gloves and eye protection, when using the cleaning agents.

4.6 Gasket replacement

Remove the front head cover to replace the gasket.

Tighten the bolts after replacement of the gasket.

It is important that bolts are tightened uniformly and in a diametrically staggered pattern, see section 3 Operation.

The bolts should first be tightened to 15 Nm (for all bolts) then tightened to 30 Nm. Then tighten the bolts to 50 Nm and finally torque the bolts with full torque (70 Nm).

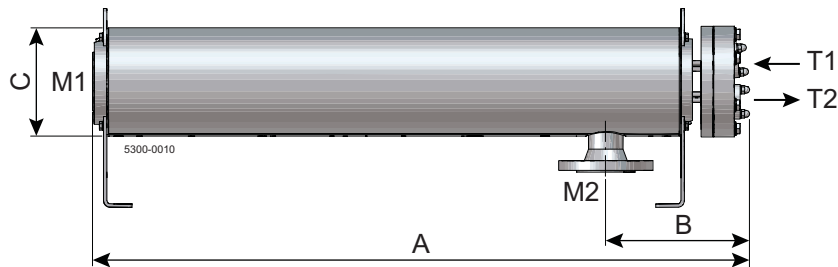
5 Technical data

5.1 Technical data

Technical data	
Heat transfer area	0.1 - 4.0 m ²
Design temperature	-10°C - 150°C
Design pressure	FV/10 barg
Product wetted steel parts	316 L stainless steel, seamless tubes
Gaskets	PTFE (FDA compliance & USP class VI certified)
Connections	Plate to connect to Tri-clamp on tube side and flanges on service side
Pressure vessel codes	PED and TSG (China) when necessary
Welding	according to SS-EN ISO 15614-1, SS-EN287-1, SS-EN 1418, ASME IX
Surface finish product wetted parts	Mechanically polished with Ra <0.5 µm

Options

- Insulation mineral wool (ASTM C795) with stainless steel 304 cladding



- A: Total length of heat exchanger
 B: Length from product inlet connection to utility flange
 C: Largest diameter of the unit

Standard units, measurements (approximate) [mm]

Type	Shell OD (mm)	Nozzles size Tube	Nozzle size Flange	A	B	C
Pharma-line S 1 [mm]						
Pharma-line S 1 - 0.1	76	1"	DN50	1150	225	195
Pharma-line S 1 - 0.3	89	1"	DN50	1150	225	195
Pharma-line S 1 - 0.4	101	1"	DN50	1150	225	195
Pharma-line S 1 - 0.6	104	1 1/2"	DN50	1150	230	195
Pharma-line S 1 - 0.7	141	2"	DN80	1150	260	245
Pharma-line S 1 - 1.1	141	2"	DN80	1150	260	245
Pharma-line S 1 - 1.2	168	2"	DN80	1150	260	245
Pharma-line S 2 [mm]						
Pharma-line S 2 - 0.3	76	1"	DN50	2150	225	195
Pharma-line S 2 - 0.6	89	1"	DN50	2150	225	195
Pharma-line S 2 - 1.0	101	1"	DN50	2150	225	195
Pharma-line S 2 - 1.3	114	1 1/2"	DN50	2150	230	195
Pharma-line S 2 - 1.4	141	2"	DN80	2150	260	245
Pharma-line S 2 - 2.4	141	2"	DN80	2150	260	245
Pharma-line S 2 - 2.6	168	2"	DN80	2150	260	245
Pharma-line S 3 [mm]						
Pharma-line S 3 - 0.4	76	1"	DN50	3150	225	195
Pharma-line S 3 - 1.0	89	1"	DN50	3150	225	195
Pharma-line S 3 - 1.6	101	1"	DN50	3150	225	195
Pharma-line S 3 - 2.0	114	1 1/2"	DN50	3150	230	195
Pharma-line S 3 - 2.2	141	2"	DN80	3150	260	245
Pharma-line S 3 - 3.7	141	2"	DN80	3150	260	245
Pharma-line S 3 - 4.0	168	2"	DN80	3150	260	245

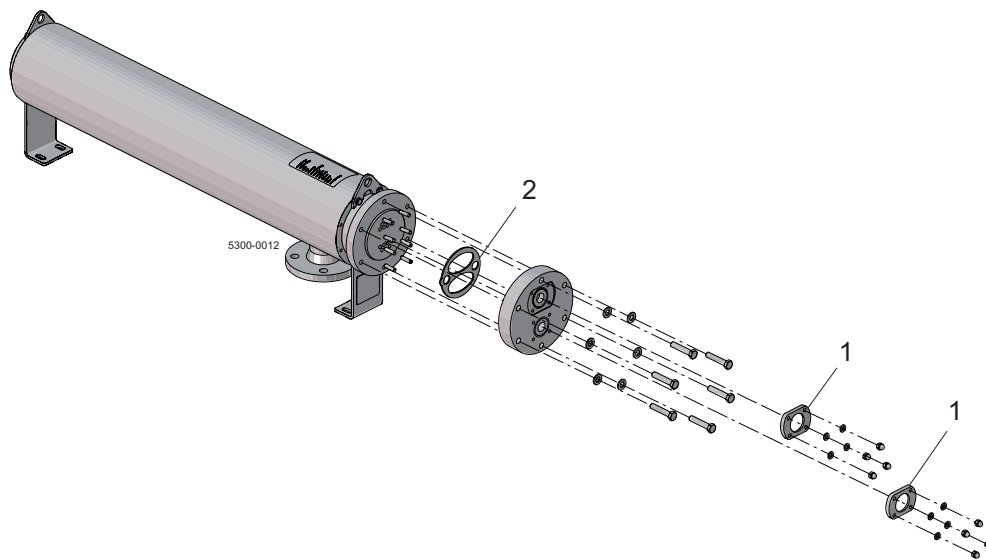
Nozzle schedule

Item	Service	Facing	Standard and dimension
T1	Tube inlet	NAC plate for Tri-clamp	Suitable for ASME BPE
T2	Tube outlet	NAC plate for Tri-clamp	Suitable for ASME BPE
M1	Shell inlet	Weld neck flange	DIN2635/EN1092-1
M2	Shell outlet	Weld neck flange	DIN2635/EN1092-1

6 Spare Parts

Gaskets and plate flanges are available as a spare part for Pharma-line S. Replacement gaskets should be purchased in the material originally provided with your heat exchanger. When ordering replacement gaskets or plate flange, please refer to the item No. in the spare part list for Pharma-line S.

6.1 Alfa Laval Pharma-line S



6 Spare Parts

Gaskets and plate flanges are available as a spare part for Pharma-line S. Replacement gaskets should be purchased in the material originally provided with your heat exchanger. When ordering replacement gaskets or plate flange, please refer to the item No. in the spare part list for Pharma-line S.

Parts list

Pos.	Qty	Denomination
1	1	Plate flange
2	1	Gasket PTFE

How to contact Alfa Laval

Contact details for all countries are continually updated on our website.

Please visit www.alfalaval.com to access the information directly.

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