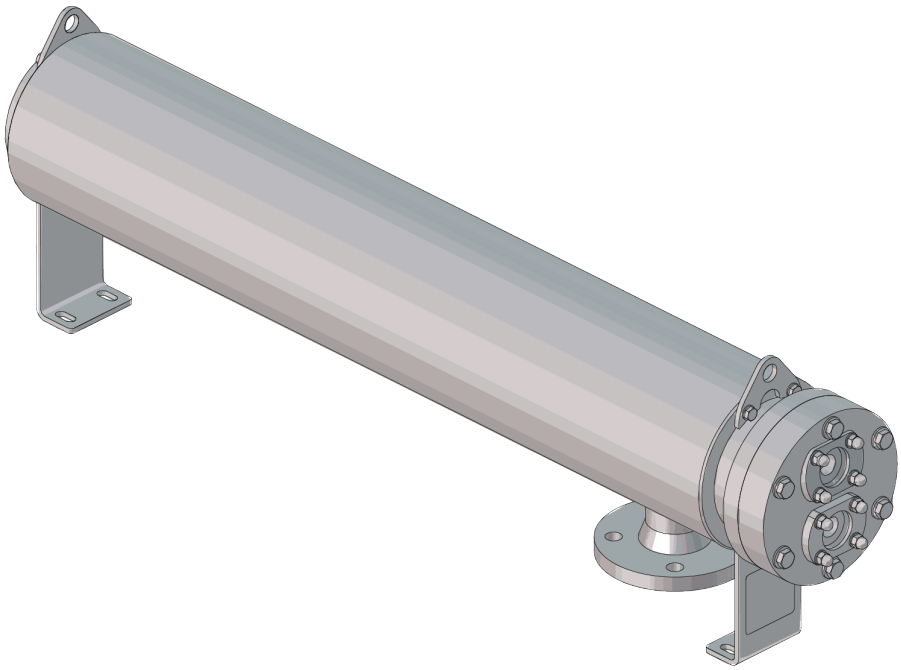
Alfa Laval

Pharma-line Shell and Tube



Lit. Code 200010355-1-EN-GB
Manual No. ESE02599-EN3

Instruction Manual

BRITISH ENGLISH

Published by
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The original instructions are in English

Contents

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1 Safety Information

1.1 Warning signs

Pay attention to the safety instructions in this manual. Below are definitions of the three grades of warning signs used in the text where there is a risk for injury to personnel.

DANGER

DANGER indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTE

NOTE indicates a potentially hazardous situation which, if not avoided, may result in property damage.

1.2 Safety Precautions

	Operators must read and understand the **"Safety, Installation and Operating Instructions"** given in this manual and respective component's manual from technical documentation before carrying out any work on the system or before you put the system into service! Not following the instructions can result in serious accidents.

Safety Sign	
	Use protective foot wear - Safety Shoes
	Use eye protection - Safety Glasses
	Use protective hand wear - Safety Gloves
	Wear protective equipment - Helmet

Safety Sign	
	Use ear protection in noisy environments.- Noise Protector
	Use protective clothing
	Immediate STOP

Safety

Installation

- **Always** read the installation thoroughly. (See chapter *Installation* on page 11).
- **Always** use a lifting crane or device when handling the heat exchanger.

Operation

- **Always** read the operation section thoroughly. (See chapter *Operation* on page 15).
- **Never** introduce hot fluid suddenly when heat exchanger is empty or cold.
- **Never** shock the heat exchanger with cold fluid when hot.

Maintenance

- Always read the maintenance section thoroughly. (See chapter *Maintenance* on page 19).

Transportation and Lifting

- **Always** transport the heat exchanger in a horizontal position.
- **Always** ensure that the unit is securely fixed during transportation.
- The parts must be lifted using the lifting points indicated or as specified in the documents.
- Lifting operations must be carried out by personnel certified for operating forklifts and/or cranes.
- **Never** lift or elevate in any way other than as described in this manual.

2 Description

2.1 Recycling Information

Packing

Packing material consists of wood, plastics, cardboard boxes and in some cases metal straps.

- Wood can be reused, recycled or used for energy recovery.
- Plastics should be recycled or burnt at a licensed waste incineration plant.
- Metal straps should be sent for material recycling.

Maintenance

During maintenance wear parts in the machine are replaced.

- All metal parts should be sent for material recycling.
- All non-metal parts must be disposed of in accordance with local regulations.

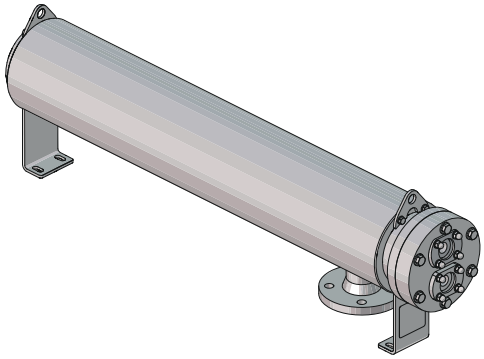
Scrapping

At the end of use, the equipment must 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.

2.2 Application

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

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



2.3 Design

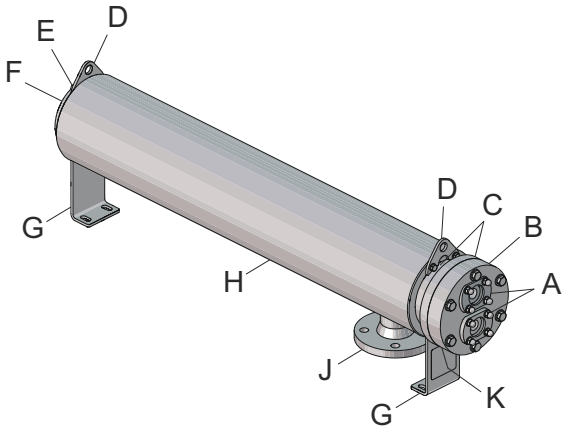
The Pharma-line is designed in line with ASME BPE, USP and cGMP requirements.

The Pharma-line has no dead-legs and is fully drainable on the product side. All product wetted parts in the Pharma-line are mechanically polished to Ra<0.5 µm or electropolished to Ra<0.4 µm.

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

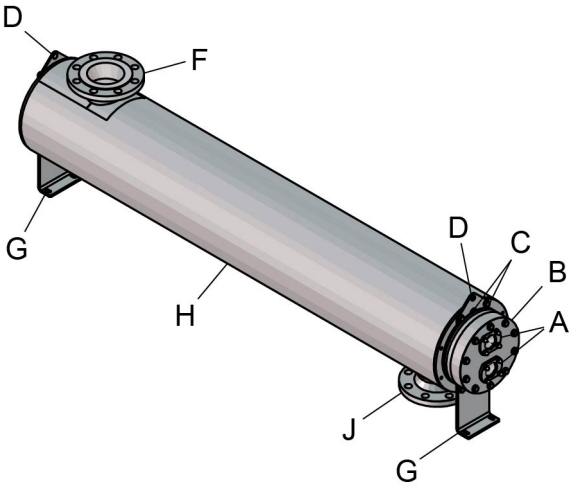
Main components Pharma-line S:

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



Main components Pharma-line P:

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

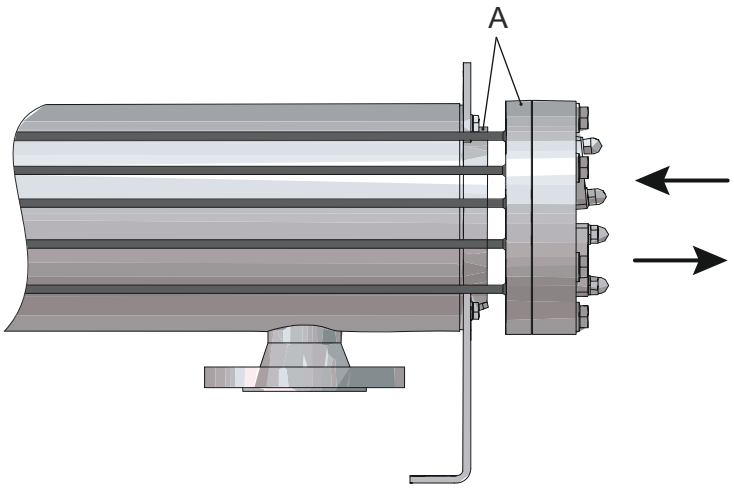


Tube sheet	Tubes are expanded into first sheet, welded and expanded into second sheet. Double tube sheet minimises the risk of contamination
Shell	Utility media flow on the shell side
Tube bundle	Product flows through a number of tubes which are bundled together
Vent	Vent connection on shell side for venting of air (included on Pharma-line S)

Drain	Drain connection on shell side for draining (included on Pharma-line S)
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	To be used when lifting the unit, fixed with bolts and movable, allowing for flexible positioning
Legs	To be used when lifting the unit, brackets fixed with bolts and movable, allowing for flexible positioning.

Working principles

In the Pharma-line, the risk of mixing between the product and the heating or cooling (service) medium is eliminated because 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

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3 Installation

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

> **NOTE**
>
> Some units can only be installed horizontally.

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 surface temperature is expected to be hot or cold, the heat exchanger should be insulated.

3.1 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.

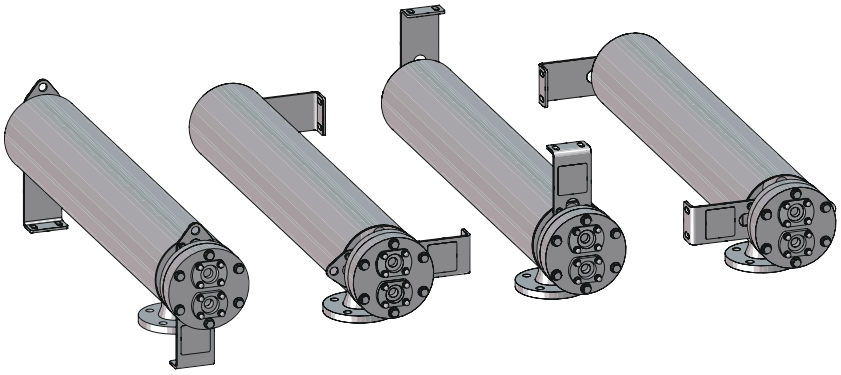
3.2 Foundations

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.

3.3 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.



3.3.1 Horizontal Positioning

At the time of delivery, the legs are positioned horizontally. The legs are same length.

T2 is sloped 5° (8.75%) so for full drainability the slope of the complete heat exchanger should be installed with a minimum slope of 1% and a maximum of 5%. The slope is required to ensure that the tube side is fully drainable. We recommend that the unit is tilted using a suitable bracket or spacer under the leg.

3.3.2 Vertical Positioning

If the Pharma-line is positioned vertically and full drainability is required on the tube side, the unit should be installed with the tube side 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, to be able to drain the condensate.

> **NOTE**
>
> Some models are 4-pass units and cannot be fully drained on the tube side if installed vertical. Please check the drawing for details.

3.4 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

3.5 Cleanliness Provisions

Connector protectors

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

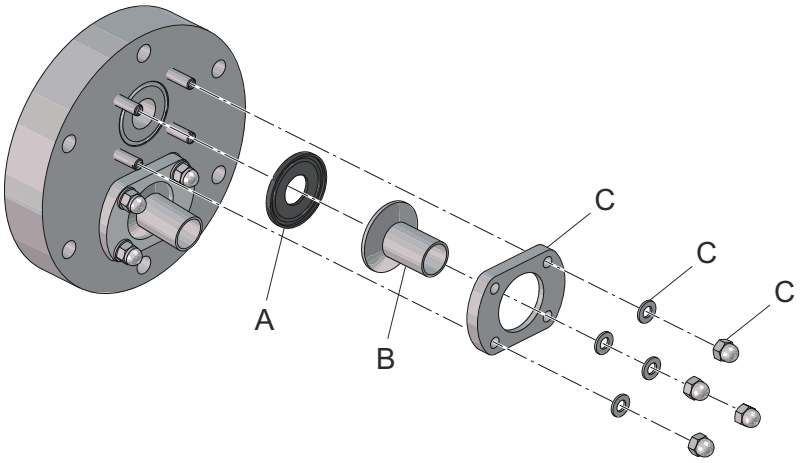
Dirt removal

The entire system should be clean before starting operation.

3.6 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.

3.7 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.

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.

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4 Operation

4.1 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.

4.2 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).

4.2.1 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. At start-up or after the unit not been in operation for couple of days it is important that fluid is introduced stepwise into the heat exchanger. 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.

Both product and utility media should be introduced slowly, starting with a low flow rate and then step by step continue to increase the low until the flow rate the unit is designed for has been reached.

Important to make sure there are no air present in the system.

It is recommended to install vent valves in close connection to both the utility side and the product side to ensure easy removal of possible air in the system.

⚠ 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.

4.2.2 Operation

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

4.2.3 Shut-down Operation

The heat exchanger must be shut down in a manner that minimises different expansions between shell and tubes. If the system will be shut down for a shorter period, make sure the unit is filled up with water completely and no air is available in the system. If the system should be shut down for a longer period and/or the unit should be disconnected from the system, it is recommended to completely drain the heat exchanger.

If emptying the heat exchanger it is important to dry it completely. Recommended to empty it and then dry it by blow air into it, to make sure no product nor utility media is left in the unit.

If a small amount of moisture remains in the tubes or shell and when combined with air it might cause corrosion of the stainless tubes and other parts, hence it is important to secure no moisture is present. 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.

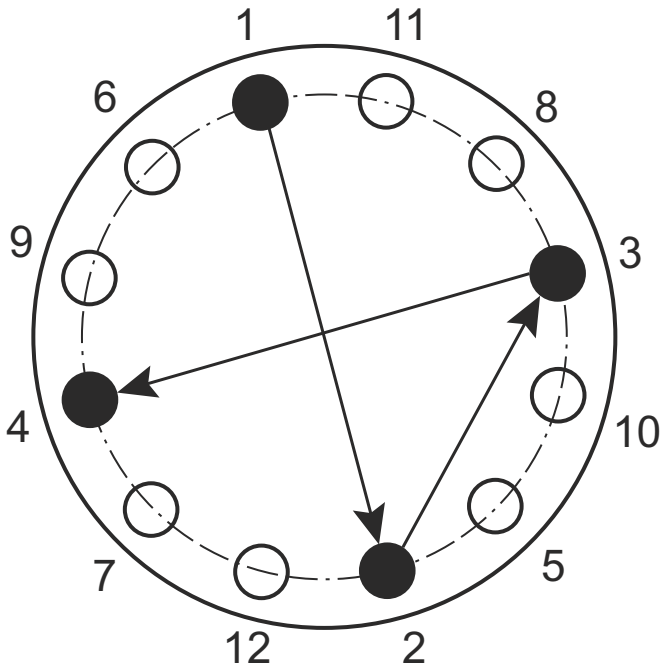
Bolted joints

The heat exchanger is pressure tested before leaving the manufacturer. 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.

1 = Start



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5 Maintenance

5.1 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.

5.2 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.

5.3 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.

When loosening the bolts make sure they do not get jammed. Rotate the bolts with a fixed ring spanner using small movements in clock and counterclockwise direction to loosen the bolts.

NOTE

Do not use power tools.

5.4 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.

5.5 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.

5.6 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 *Operation* on page 15.

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).

6 Technical Data

6.1 Technical Data

Technical data of standard models	
Design temperature	-10ºC - 200ºC
Design pressure	FV / 10 or 15 barg
Product wetted steel parts	316 L stainless steel, seamless tubes
Gaskets	PTFE (FDA compliance & USP class VI certified)
Connections	NAC Plate to connect to Tri-clamp on tube side and flanges on service side
Pressure vessel codes	PED, ASME and TSG (China)
Welding	according to SS-EN ISO 15614-1, SS-EN287-1, SS-EN 1418, ASME IX
Surface finish product wetted parts	Ra < 0.5µm MP or Ra < 0.4µm EP acc to ASTM B912

Options

- Standard insulation: 30mm mineral wool (ASTM C795) with 0.6mm AISI 304 sheathing
- Removable tube bundle

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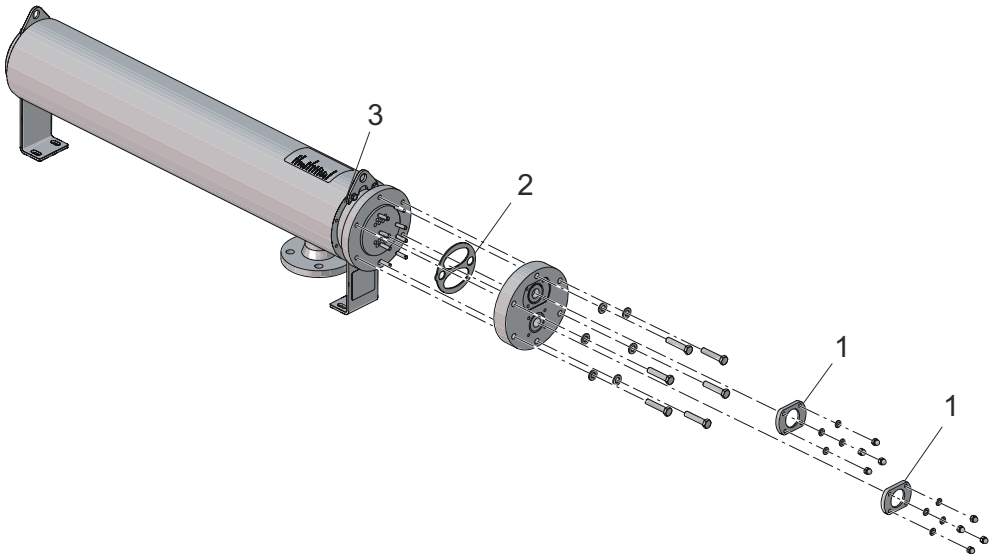
7 Spare Parts

Gaskets and plate flanges are available as a spare part for Pharma-line. 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.



Part list:

Pos.	Qty	Denomination
1	2	Plate flange
2	1	Gasket PTFE
3	1	O-ring for Removable Tube Bundle (option)

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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8 Appendix 1: Project-Specific Documentation

NOTE

The Pharma-line is delivered along with a complete documentation package, Refer Q-doc from *https://findmycert.alfalaval.com*.