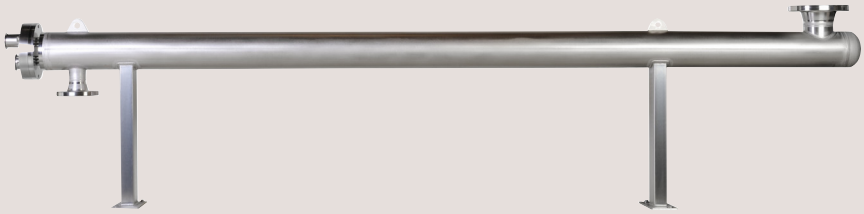
Instruction Manual

Pharma-line



ESE02198-EN 2012-05

Original manual

Table of contents

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

1 Description

1.1 Safety precautions

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

Operation
- Always read the operation section throughly (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 its upright position.
- Always ensure that the unit is securely fixed during transportation.
- Never lift or elevate in any way other than described in this manual.

1.2 Recycling information

Packing
- Packing material consist 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 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 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 industry.

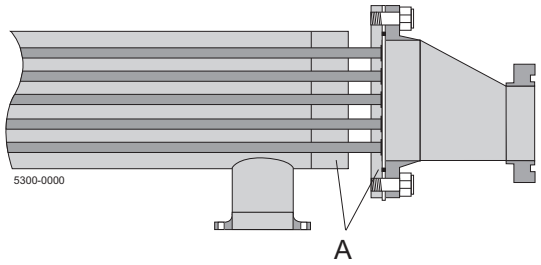
1.4 Design

The Pharma-line is in hygienic design in accordance with FDA guidelines. The Pharma-line has no dead legs and is fully drainable on the product side. All product wetted parts in the Pharma-line are either electropolished to Ra <0.4 µm, or mechanically polished to Ra <0.5 µm or Ra <0.8 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. The Pharma-line is easy to clean and can be steam sterilized. The gaskets are FDA approved and USP class VI.

Working principles

In the Pharma-line 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 the product. In the event of a leak the leakage of either fluid is easily visually detected.



A = Tube sheets

Documentation

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

- Approved drawings and pressure test certificate signed by Notified body according to ASME VIII division 1 classified Pharma-lines and Pharma-lines classified in category > III according to PED (97/23/EC). For Pharma-lines in category • III Zetterströms Rostfria AB is certified to approve drawings and issue pressure test certificate for PED (97/23/EC) under Lloyds register (NB.No 0038)
- List of welders, welding procedure and welder qualification
- 3.1 Material certificates pressure and product wetted steel parts
- FDA and USP class VI certificates gaskets
- Liquid penetrant test report and procedure
- Surface roughness certificate
- Dimension control report
- Pressure test certificate
- Identification (technical sign)
- Quality system certificate
- CE documents

Other documentation/procedures on request.

2 Installation

The Pharma-line can be installed either horizontally or vertically. For an easy installation, lifting lugs and mounting plates are welded on the unit.

2.1 Clearance for dismantling

Provide sufficient clearance at the stationary head side to permit dismantling of the Front head / Rear end cover and possible future inspection of the tubes.

2.2 Foundations

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

2.3 Levelling

The heat exchanger must be set so that pipe connections can be made without forcing. However, small forces might be unavoidable, small forces are then acceptable, i.e.
- acceptable forces in all directions on tube side are max 50 N
- acceptable forces in all directions on shell side are max 100 N

2.4 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.

2.5 Fittings and piping

By-pass valves
It may be desirable for the user to provide valves and by-passes in the piping system to permit inspection and repairs.

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

Vents
It may be desirable for the user to install vent valves close to the exchanger.

Drains
Drains may discharge into an open manifold.

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

Safety relief devices
It is the users responsibility to install the required safety devices.

3.1 Design and operating conditions

The heat exchanger must not be operated at conditions, which exceed those specified on the nameplate.

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

3.2 Operating procedures

Before placing the heat exchanger in operation, reference should be made to the name plate for any special instruction.

Local safety and health regulations must be considered.

Improper start-up or shutdown sequences may cause leaking of tube-to-tube sheet and/or bolted flanged joints.

It is the customers responsibility to carefully pay attention and doing a proper start-up and operation when running media with a higher risk for damages on the heat exchanger. Applies especially when running media below freezing-point (0°C).

Start-up operation

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.
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 in a manner to minimize differential expansion between the shell and the tubes.
Note! Adjustments of flow rates should be made slowly in order to avoid the risk of pressure surge (water hammer). 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.

Shutdown operation

The heat exchanger must be shut down in a manner that minimizes different expansions between shell and tubes. When shutting down the system, the heat exchanger should be drained completely.

Temperature shocks

The heat exchanger should not be subjected to abrupt 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 manufacturers shop 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 in the manufacturer´s shop and installation at the job 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 diametrically staggered pattern.

4 Maintenance

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. Neglect in keeping 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 indicate 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 cleanings should not be excessive.

4.3 Disassembly for inspection or cleaning

Before disassembly the user must assure 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/read end cover.

Always replace the Seal when the front cover is loosened to make sure that the Seal 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 of the heat exchanger

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

4.6 Gasket replacement

Remove the front head/rear end cover to replace the Seal.

Tight the bolts after replacement of the Seal.

It is important that bolts are tightened uniformly and in diametrically staggered pattern.

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

5.1 Technical data

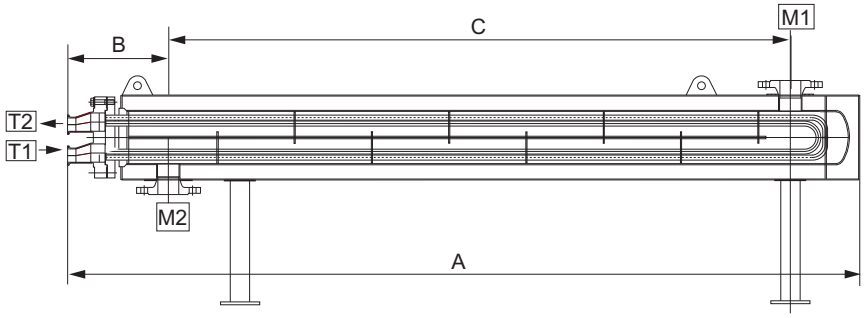
Technical data	
Heat transfer area	0.1 - 8.5 m^2 (standard range)
Design temperature	150°C (available up to 200°C)
Design pressure	FV/10 barg, higher pressures available
Product wetted steel parts	316 L stainless steel, seamless tubes
Gaskets	PTFE (FDA compliance & USP class VI certified)
Connections	Tri-clamp on tube side and flanges on service side (other options available)
Pressure vessel codes	PED and ASME VIII (U-stamp as option)
Welding	according to ASME IX and EN-288-3, EN 287-1
Surface finish product wetted parts	Electropolished with Ra<0.4 µm or mechanically polished with Ra <0.5 µm or Ra<0.8 µm

Options
- Passivation
- Insulation Mineral wool (ASTM C795) with stainless steel 304 cladding
- Removable tube bundle

Custom made
Other designs and documentation are available on request.

5 Technical data

Standard units, measurements (approximate)



Type	Shell OD (mm)	A (mm)	B (mm)	C (mm)
Pharma-line 1				
Pharma-line 1 - 0.1	73	1200	180	860
Pharma-line 1 - 0.3	89	1200	190	860
Pharma-line 1 - 0.4	102	1200	190	860
Pharma-line 1 - 0.6	114	1200	200	860
Pharma-line 1 - 0.7	140	1200	210	860
Pharma-line 1 - 0.8	114	1200	200	860
Pharma-line 1 - 1.1	140	1200	210	860
Pharma-line 1 - 1.2	168	1200	220	860
Pharma-line 1 - 2.5	219	1200	253	860
Pharma-line 2				
Pharma-line 2 - 0.3	73	2200	180	1860
Pharma-line 2 - 0.6	89	2200	190	1860
Pharma-line 2 - 1.0	102	2200	190	1860
Pharma-line 2 - 1.3	114	2200	200	1860
Pharma-line 2 - 1.4	140	2200	210	1860
Pharma-line 2 - 1.7	114	2200	200	1860
Pharma-line 2 - 2.4	140	2200	210	1860
Pharma-line 2 - 2.6	168	2200	220	1860
Pharma-line 2 - 5.5	219	2200	253	1860
Pharma-line 3				
Pharma-line 3 - 0.4	73	3200	180	2860
Pharma-line 3 - 1.0	89	3200	190	2860
Pharma-line 3 - 1.6	12	3200	190	2860
Pharma-line 3 - 2.0	114	3200	200	2860
Pharma-line 3 - 2.2	140	3200	210	2860
Pharma-line 3 - 2.7	114	3200	200	2860
Pharma-line 3 - 3.7	140	3200	210	2860
Pharma-line 3 - 4.0	168	3200	220	2860
Pharma-line 3 - 8.5	219	3200	253	2860

Nozzle schedule

Item	Service	Facing	Standard and dimension
T1	Tube inlet	Tri-Clamp	Free
T2	Tube outlet	Tri-Clamp	Free
M1	Shell inlet	Weld neck flange	Free
M2	Shell outlet	Weld neck flange	Free

5.2 Spare Parts

Gasket is available as spare part for Pharma-line.
Replacement gaskets should be purchased in the material originally provided with your heat exchanger.

Please refer to the heat exchanger serial no. or drawing no. when ordering replacement gasket.

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.