

Steam Sterilization Handbook

Hollow fiber cartridges for membrane separations



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Important safety considerations

- Always ensure that all lines and components of your system are steamable.
- Do not run steam through retentate side only. Steam must be introduced equally on retentate and permeate sides—see chapter 3 for complete steam sterilizing procedure.
- Ensure that no crimping, blockage, or unwanted valve shutoff occurs, to prevent rupture or component failure.
- Ensure that steam traps are positioned at low point drains to prevent condensate from cooling in the recirculation loop or permeate at any point.
- Know—and do not exceed—the maximum operating pressure of your system components.
- Monitor pressure with appropriate instrumentation during sterilization.
- Install cartridges with all requisite O-rings, connectors, and/or clamps.
- Develop and enforce standard operating procedures for effective sterilization.
- Work to maintain sterility by ensuring that no contaminant can enter the system prior to production.
- Check membrane filter cartridge and housing integrity after sterilization—see page 20 for details.
- Ensure that all system valves, lines, and configurations are set for processing before transitioning from sterilization to production.
- Steam that undergoes an abrupt expansion at high flow rates can carry latent heat, commonly called “superheated steam.” The high temperatures in superheated steam can cause damage to polymers and elastomers. Superheated steam can be avoided by properly reducing pressure through a sequence of regulators. The steam pressure on the upstream side of the regulator used to control the pressure on these membranes should not exceed 2 barg (30 psig).

Introduction

About this handbook

This handbook describes how to assemble, install, and steam sterilize GE Healthcare STM, SMO, and MSM membrane filter cartridges.

This handbook shows the general system features necessary to comply with the steps outlined in the protocol presented. For example, the bypass valves that are used to warm the system under low pressure conditions are critical to this sequence of operations. The membrane filter cartridge expands more than the stainless steel housing and the warming process is necessary to avoid thermal stress that could lead to a breach of integrity.

This handbook is designed for online viewing and navigation using Adobe® Acrobat®. Print the Acrobat file to obtain a hard copy. You can download this handbook from the GE Healthcare Web site.

Target audience

This handbook is intended for experienced users of microfiltration and ultrafiltration membrane filter cartridges. Specifically, the handbook addresses the needs of scientists, process engineers, and technicians who operate research, laboratory, pilot, and production filtration systems.

To use this handbook, you should know how to complete basic technical procedures. For example, you should be qualified to set up laboratory and pilot equipment; measure temperatures, pressures, and flows; and understand filtration applications. If you do not have these capabilities now, call GE Healthcare for assistance. See “Getting help” on this page for contact information.

Where to find more information

This handbook is a supplement to the *Operating Handbook, Hollow fiber cartridges for membrane separations*. In addition, GE Healthcare publishes easy-to-use handbooks related to its cross flow filtration equipment. You can view and download these handbooks from our Web site, www.gehealthcare.com

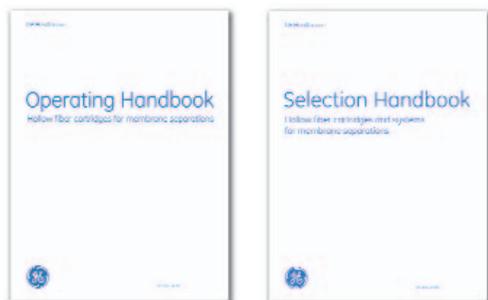


Figure 1. Other handbooks in the cartridge filter documentation set

Operating Handbook, Hollow fiber cartridges for membrane separations, a downloadable handbook posted on our Web site and available in hard copy from GE Healthcare and its distributors

Selection Handbook, Hollow fiber cartridges and systems for membrane separations, a downloadable handbook posted on our Web site and available in hard copy from GE Healthcare and its distributors

Getting help

Contact GE Healthcare customer and technical support teams by calling 1-800-526-3593 in the USA, or by contacting your local GE Healthcare office.

Safety

When using any laboratory, pilot scale, or production filtration equipment, the potential exists for personal injury unless you follow established safety procedures. When using GE Healthcare test procedures and products, you should follow OSHA, federal, state, and local safety mandates and regulations. You should follow your company’s safety procedures and the safety instruction provided in this handbook.

This handbook uses highlighted text with safety flags to provide safety information and expert advice:

► Safety

WARNING: A safety warning flag describes conditions or actions that can cause bodily harm and describes how to avoid the risk.

► Expert Advice

TIP: An expert advice tip flag provides information to use your hollow fiber membrane cartridge and system efficiently to achieve the best results.

Specific advice to help you work safely

Potentially, the heat or pressure of steam can rupture a weakened or improperly assembled connection, kinked hoses or lines, and other system components. Such a rupture can expose personnel to high pressure steam and cause severe injury.

To avoid the unexpected rupture of a filter system or connection due to improper assembly or overpressurization you should:

- Ensure you read the entire handbook before sterilizing a cartridge with steam
- Ensure all system components are steamable
- Ensure all system components are assembled correctly
- Know—and do not exceed—the maximum operating pressure of your system components

The *Operating Handbook, Hollow fiber cartridges for membrane separations*, describes the maximum operating pressure of the cartridge filters. To avoid exceeding the maximum operating pressure and to monitor the sterilization process effectively, it is critical that you install pressure gauges on the system as described in this handbook.

To avoid injury in the event of an unexpected steam leak, wear appropriate personal protection gear in accordance with your company’s safety policy (or national or regional regulations).

Return authorization

To return a cartridge purchased from GE Healthcare in the USA, call us at 1-800-526-3593 to obtain a return authorization number. Clean, sanitize, and securely package cartridges before returning them. Ship microfiltration cartridges dry. Include the details of its operational history—for example, pages from a laboratory notebook. Ship it prepaid to GE Healthcare Corporation, P.O. Box 1327, Piscataway, NJ 08855-1327, USA. We will repair or replace defective cartridges. Outside the USA, you can contact your local GE Healthcare representative using the telephone numbers listed on the back cover of this handbook.

Warranty

GE Healthcare Corporation warrants its hollow fiber cartridges to be free from defects in workmanship and materials for a period of 30 days after the date of shipment from GE Healthcare or its authorized dealers, provided that the cartridges have been operated in accordance with GE Healthcare published specifications and good engineering practices.

GE Healthcare shall have no liability under this warranty or otherwise for improper application or abuse of the subject cartridge or cartridges. This warranty is exclusive of all other implied warranties including merchantability or fitness for a particular purpose.

The information contained in this handbook is not intended to constitute any representation of warranty by GE Healthcare Corporation.

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Housing design and assembly

This chapter describes:

- Housing and cartridge design
- How to install a cartridge in a housing
- Where and how to install a housing in your filtration system

Housing and cartridge design

GE Healthcare manufactures three models of steamable housings and membrane filter cartridge elements identified by model designations STM, SMO, and MSM. The SMO and STM families are based on a 7.6-cm (3-in) diameter element. SMO cartridges have an open face and a single O-ring seal at each end. STM units have end caps at each face that neck down to a double O-ring seal for connection to stainless steel end fittings. Larger MSM steam-in-place (SIP) elements have a nominal 10.2-cm (4-in) diameter and an open face configuration.

Housing design

Housings are constructed of stainless steel and accept steamable, replaceable membrane filter cartridge elements. O-rings and end plates seal the membrane filter cartridge element in the housing. Sanitary connectors on the housing end plates enable connection to your filtration system (Fig 2).

Additional 0.5-in sanitary connections are used for low point condensate drain and steam trap installation.

Membrane filter cartridge element design

Hollow fiber membranes are cast of polysulfone, and are designed and tested for the temperatures and pressures required for auto-claving and steam-in-place sterilizing as described in this handbook. Membrane filter cartridges are machined of polysulfone also. The fiber bundles are held within the cartridge by coarse polypropylene screens. Fibers are potted at each end in CFR-listed food grade epoxy. All components conform to USP XXVII Class VI Biological Test for Plastics.

GE Healthcare supplies three families of steam-in-place designs: STM, SMO, and MSM. The SMO and STM designs have a diameter of 7.6 cm (3 in), while the MSM design is 10.2 cm (4 in). Each design is unique and requires a dedicated, matching membrane filter cartridge and housing. These devices are not interchangeable, although each of the designs incorporates similar features.

How to install a membrane filter cartridge element in a housing

Installing an STM cartridge element in an STM housing

Follow these steps to install an STM cartridge element into an STM housing (see Fig 2):

1. Install double O-rings at each end of the cartridge.



2. Place the stainless steel housing horizontally on a work bench and slide the cartridge element into the housing.



3. Holding the cartridge at one end, push a retentate end cap with 3-in gasket over the double O-rings at the other end of the element. Repeat this process to install the gasket and retentate end cap on the other end of the element.
4. Clamp the housing using the supplied 7.6-cm (3-in) Tri-Clamps®.

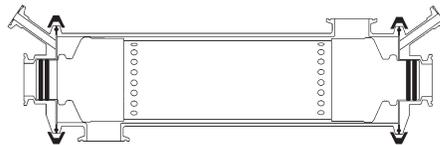


Figure 2. Cutaway view of an STM cartridge element in an STM housing

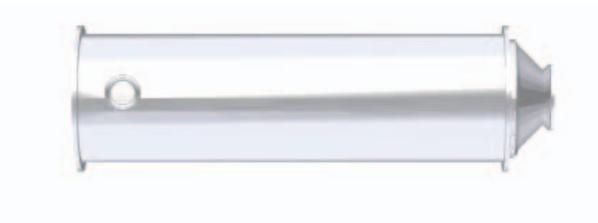
Installing an SMO cartridge element in an SMO housing

Follow these steps to install an SMO cartridge element into an SMO housing (see Fig 3):

1. Place the stainless steel housing horizontally on a workbench (see Fig 3 for positioning).
2. Position an O-ring around one end of the cartridge and push it into place using an end cap.



3. Slide membrane filter cartridge (which now has one O-ring in position) into one end of housing. Clamp end cap.



4. Add a second O-ring as shown below and clamp end cap.

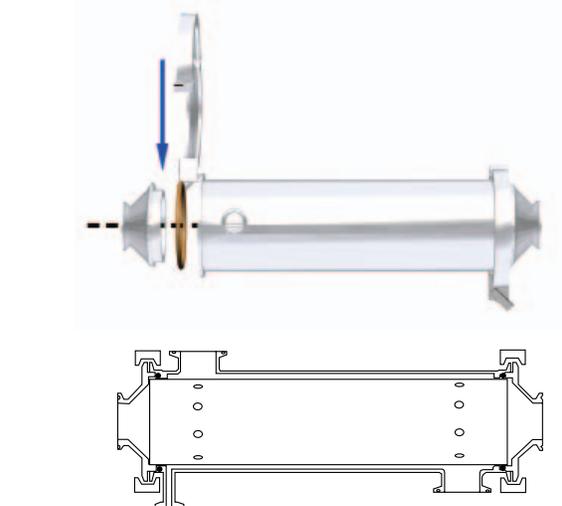


Figure 3. Position of components of SMO membrane filter cartridge and housing

Installing an MSM cartridge element in an MSM housing

Follow these steps to install an MSM cartridge element into an MSM housing (see Fig 4):

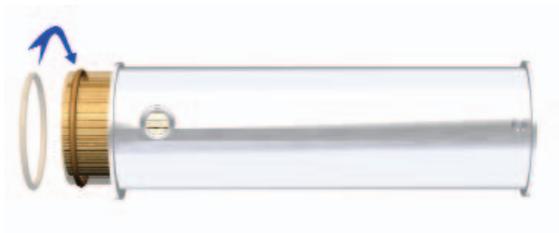
1. Install an O-ring on the groove at one end of the cartridge element. If the O-ring seems snug, moisten the O-ring with high purity water for lubrication.



- 2a. To properly center the membrane filter cartridge inside the housing, place the housing on a protective surface in a vertical orientation. Pushing down on the face of the cartridge, force the cartridge into the housing until the lower face makes contact with the surface of the table.



- 2b. Lay the cartridge in a horizontal position and continue to push the cartridge into the housing until the O-ring groove emerges from the other end.



3. Place the second O-ring in the groove and return the cartridge to a vertical orientation (housing down/cartridge up) and push the cartridge down until centered in the housing.



4. Secure the endplates with Tri-Clamp gaskets and clamps.

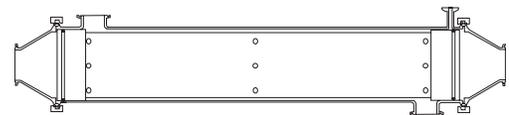


Figure 4. Maxcell MSM cartridge and housing

The design of the MSM housing and retentate end cap requires a Tri-Clamp gasket between the housing and end cap.

► Expert Advice

TIP: Do not strike the cartridge face. Use only hand pressure to apply a steady downward force.

Where and how to install the filter

Where to install the housing

To complete steam-in-place sterilization, you must integrate steam lines, steam traps, additional valves, and instrumentation into the filtration system. Specific installation requirements and design can vary according to process variables; however, a typical setup includes a steam line piped into the retentate port and a steam condensate line with a steam trap and isolation valve piped into the feed line (Fig 5).

► Expert Advice

TIP: We recommend that you connect the vent valve to an air line pressurized to about 1.03 barg (15 psig) to permit the use of an air “overpressure” condition at the end of the cycle, to ensure that no unsterilized air can infiltrate the system.

You should place a hydrophobic 0.2-micron microporous filter in the vent line to maintain sterility.

You may be able to use steam traps as small as 0.25 in, depending upon the size of your system.

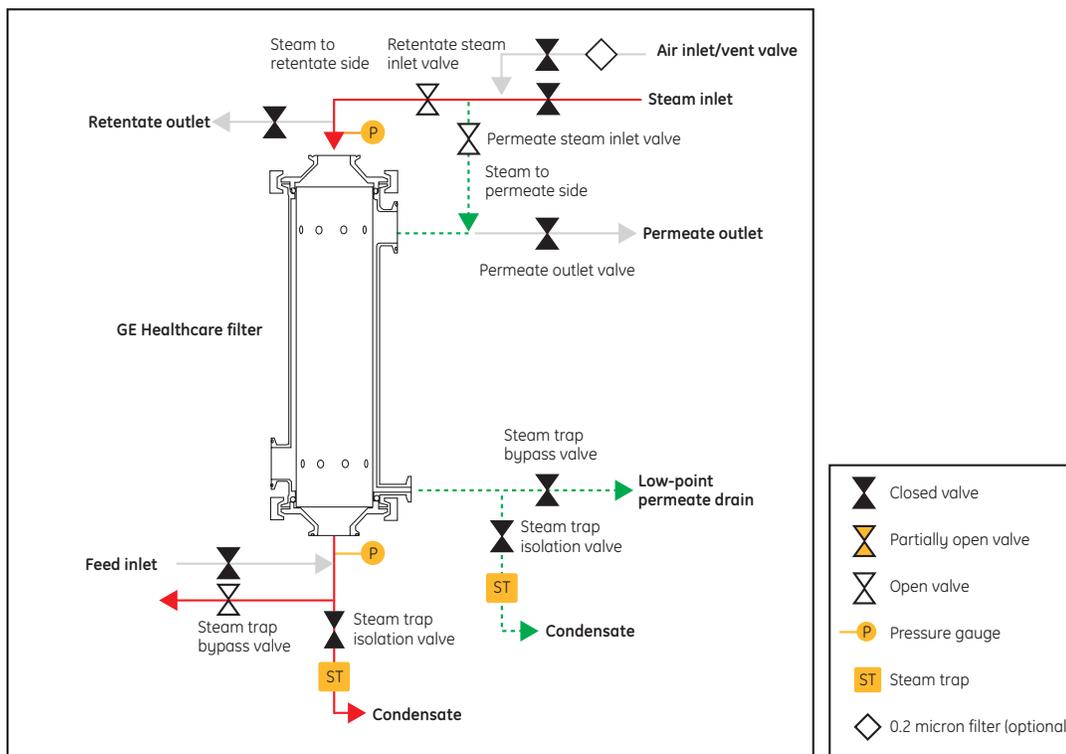
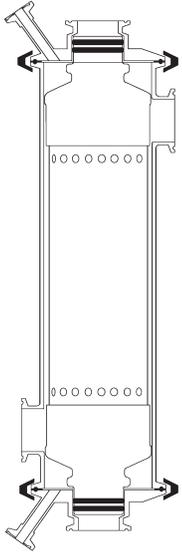


Figure 5. Typical installation of steam-in-place equipment

How to install the housing

Pipe the housing into your system using established standards for piping and pipe support. Consult national, regional, local, and your company's piping regulations and guidelines.

Steamable housing models STM, SMO, and MSM use sanitary connectors to connect feed, retentate, permeate, drain, and vent ports. Connect the ports to your system using sanitary connectors, O-rings, and Tri-Clamps (Fig 6).

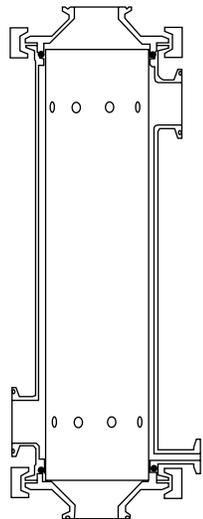


Housing 35STM

Length = 43.4 cm (17.1 in)
Diameter = 9.1 cm (3.6 in)
Permeate ports = 1.5-in Tri-Clamp
Feed/retentate ports = 1.5-in Tri-Clamp
Drain/vent ports = 0.5-in Tri-Clamp

Housing 55STM

Length = 75.2 cm (29.6 in)
Diameter = 9.1 cm (3.6 in)
Permeate ports = 1.5-in Tri-Clamp
Feed/retentate ports = 1.5-in Tri-Clamp
Drain/vent ports = 0.5-in Tri-Clamp

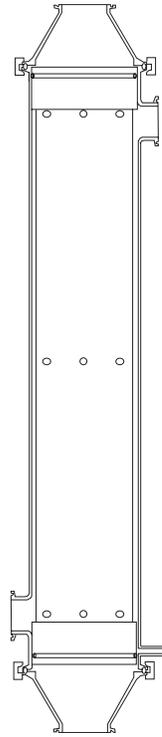


Housing 35SMO-DP

Length = 37.3 cm (14.7 in)
Diameter = 9.1 cm (3.6 in)
Permeate ports = 1.5-in Tri-Clamp
Feed/retentate ports = 1.5-in Tri-Clamp
Drain port = 0.5-in Tri-Clamp

Housing 55SMO-DP

Length = 69.3 cm (27.3 in)
Diameter = 9.1 cm (3.6 in)
Permeate ports = 1.5-in Tri-Clamp
Feed/retentate ports = 1.5-in Tri-Clamp
Drain port = 0.5-in Tri-Clamp



Housing 45MSM-DP

Length = 52.8 cm (20.8 in)
Diameter = 11.4 cm (4.5 in)
Permeate ports = 1.5-in Tri-Clamp
Feed/retentate ports = 2-in Tri-Clamp
Drain port = 0.5-in Tri-Clamp

Housing 65MSM-DP

Length = 75.7 cm (29.8 in)
Diameter = 11.4 cm (4.5 in)
Permeate ports = 1.5-in Tri-Clamp
Feed/retentate ports = 2-in Tri-Clamp
Drain port = 0.5-in Tri-Clamp

Housing 85MSM-DP

Length = 134 cm (52.7 in)
Diameter = 11.4 cm (4.5 in)
Permeate ports = 1.5-in Tri-Clamp
Feed/retentate ports = 2-in Tri-Clamp
Drain port = 0.5-in Tri-Clamp

Optional elbow adapters are available for 85MSM stainless steel housing (SS-85MSM-EL-DP)

Figure 6. Connection specifications for representative sizes of STM, SMO, and MSM housings

Expert tips

Introduction

In many cross flow filtration applications—particularly in the pharmaceutical and biotechnology fields—the sterility of the filter must be ensured before using it. Steaming-in-place is one method to sterilize cartridge filters. Steaming-in-place requires the proper equipment, operated properly and consistently, to ensure complete sterilization and validation. Therefore, the goal of this chapter is to provide recommendations and techniques to help ensure efficient and effective steam sterilization.

General recommendations

Streamlining the steam-in-place process

From an operational standpoint, here are some steps that can be taken to streamline the steam-in-place process:

- Permanently install the steam-in-place components on the filtration system to save setup time and not disturb the process system.
- Ensure all components in the system, such as valves and pressure gauges, are steamable by reviewing equipment specifications. Using steamable process equipment ensures safety and minimizes component replacement and maintenance.

Process design for effective sterilization

Cartridge integrity and proper sterilizing steps are required to help ensure sterilization.

Establish, through trials, a sterilization procedure that provides the desired results. Validate this procedure, and write and use standard operating procedures (SOPs) for consistency.

Superheated steam can overheat the cartridge, causing damage to the cartridge or influencing membrane performance. Ensure the temperature and quality of the steam is consistent.

As part of your SOP, check all valve positions before operating or steam cleaning your system.

Do not induce a backpressure on the membrane cartridge.

Steam sterilizing procedure

The five SIP stages

To steam sterilize a GE Healthcare STM, SMO, or MSM cartridge assembly in a steam-in-place application, inject steam into both the feed and permeate ports using the steps and process conditions described below. Steam penetrates both sides of the filter membrane and condensate exits from two low-point steam traps.

There are five stages:

1. Configure system for steaming
2. Introduce steam, flush, and hold
3. Cool and pressurize
4. Check filter integrity
5. Configure system for processing

► Safety

WARNING: GE Healthcare filter cartridges and stainless steel housings are steamable. If other components in your filtration system are not designed to withstand steaming, they can rupture, causing injury from projectiles and live steam. To prevent injury due to rupturing, ensure all components in the system—such as valves and pressure gauges—are steamable. Confirm steamability by reviewing equipment specifications. If a steam leak occurs and personnel are not wearing proper personal protection, severe injury can result. Wear appropriate personal protection gear in accordance with company safety policy, or national or regional regulations.

► Safety

The following procedure is specific to steam-in-place of the cartridge and housing only. When steaming-in-place large process vessels or process systems with a large void volume, it is recommended that the steam line be introduced separately from the filter. It is possible to introduce steam into small process systems via one steam line, however this must be done very carefully and slowly to prevent reverse steam pressure on the filter cartridge.

Stage 1—Configure system for steaming

Configure the system for steaming (see Fig 7) as follows:

1. Ensure all glycerine is removed from ultrafiltration cartridges.
2. Isolate the steam traps.
3. Close the feed inlet, permeate outlet, low-point permeate drain, retentate outlet, and air inlet/vent valves.
4. Open the retentate and permeate inlet steam valves.
5. Open the feed steam trap bypass valve.
6. Close the permeate steam trap bypass valve.

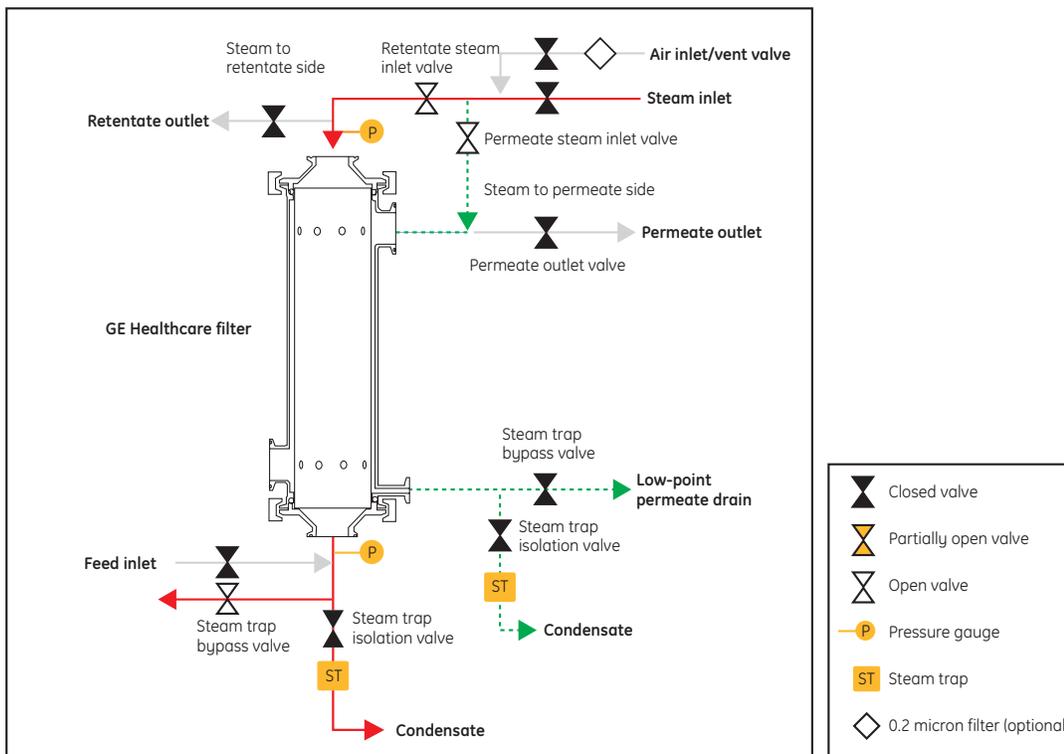


Figure 7. Starting setup for Stage 1—configure system for steaming

Stage 2—Introduce steam, flush, and hold

Steam the cartridge following these steps:

Introduce steam

1. Crack open the steam inlet valve or adjust regulator to 0.07 barg (1 psig). Steam and water should trickle from the steam trap bypass valve (feed). Adjust the steam inlet valve so that the system outlet temperature reaches about 100°C (212°F) in five to ten minutes (Fig 8).
2. Once the system outlet temperature reaches 100°C, wait five minutes and open the permeate steam trap bypass valve. Wait five more minutes. Close both steam trap bypass valves.
3. Open the steam trap isolation valves, maintaining steam flow into both sides (retentate and permeate) of the filter. Condensate will drain from the steam traps.

Steam flush—slowly increase the pressure

4. Open the process retentate valve slightly.
5. Slowly open the main steam inlet valve.
6. Let the pressure increase, but do not exceed 1.03 barg (15 psig).

Hold steam at pressure

7. Open the process feed, retentate outlet, and permeate outlet valves slightly.
8. If introducing steam to the remainder of a small process system, slowly open the retentate outlet and feed inlet valves, ensuring the steam pressure does not drop. When the remainder of the process system comes up to pressure, fully open the retentate outlet and feed inlet valves.
9. Steam for 30 minutes at the specified pressure.

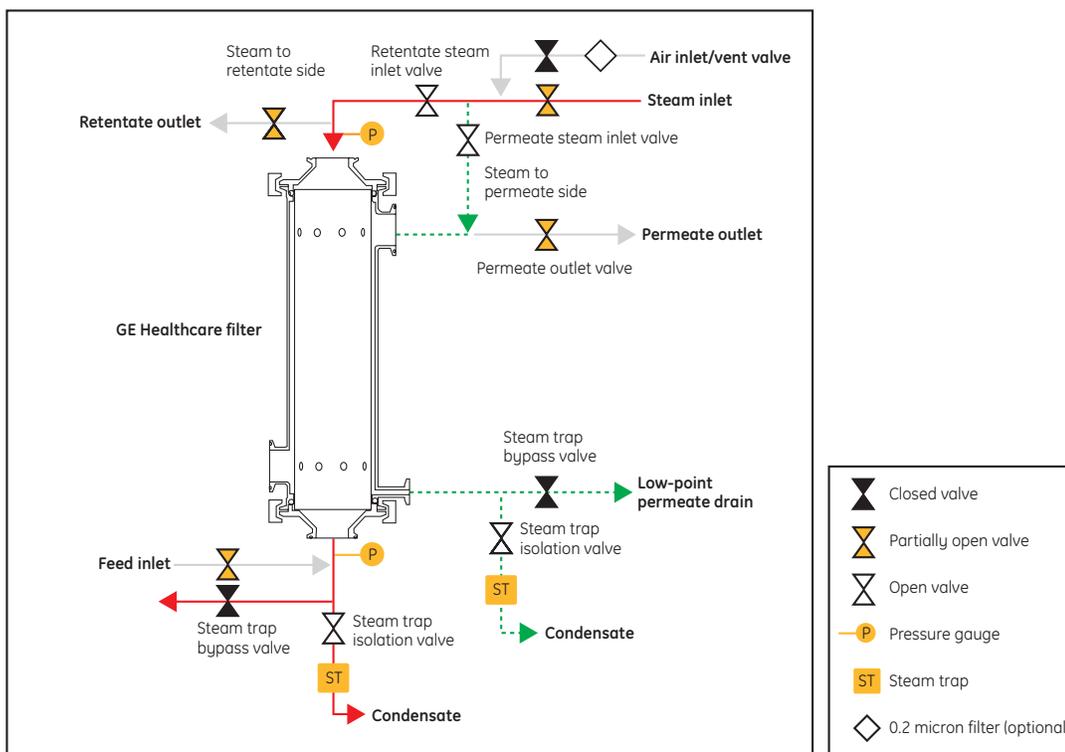


Figure 8. Starting setup for Stage 2—introduce steam, flush, and hold

Stage 3—Cool and pressurize

Cool the cartridge element and housing following these steps:

1. Close the steam inlet valve (Fig 9).
2. Release the pressure by opening one of the steam trap bypass valves and slowly opening the air inlet/vent valve.
3. Allow the cartridge and system to cool to ambient temperature. Typically cooling requires about four hours at ambient temperature.

Note: It is recommended that the vent valve be connected to air pressure adjusted to approximately 1.03 barg (15 psig). Maintaining positive pressure will assure that no unsterilized air infiltration will occur anywhere in the system. A sterile, 0.2-micron hydrophobic filter must be positioned in the vent line to maintain sterility.

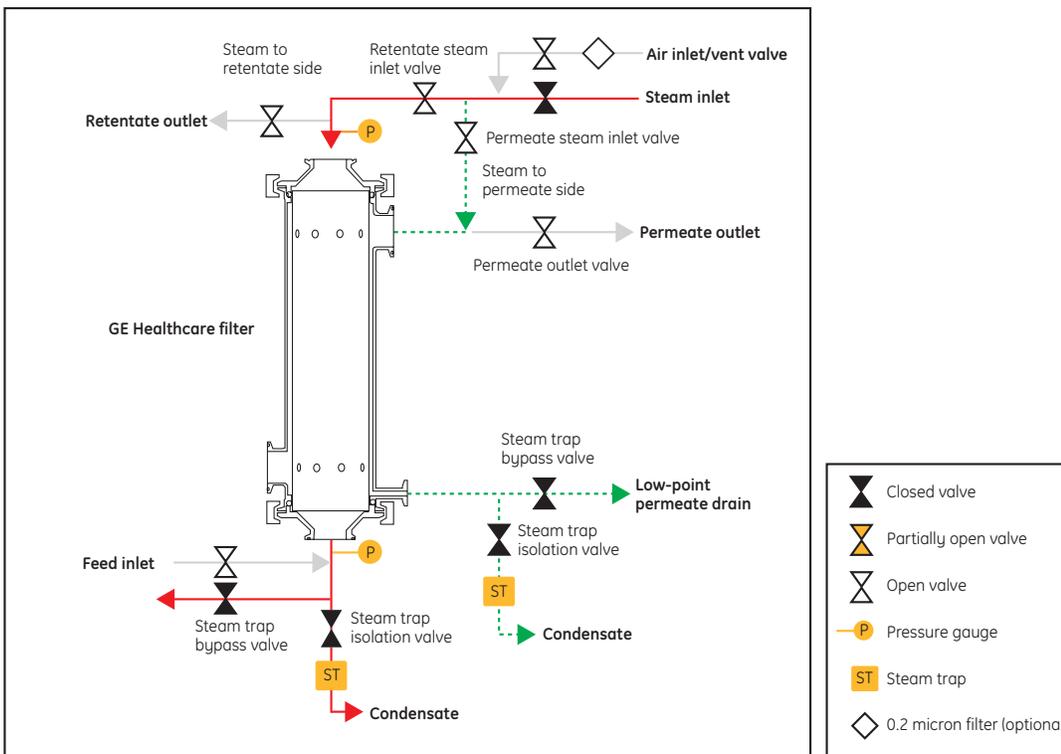


Figure 9. Starting setup for Stage 3—cool and pressurize

Stage 4—Check filter integrity

Checking the integrity of the filter is optional, but recommended and sometimes required in many applications. See the GE Healthcare *Integrity testing handbook* for additional details. The basic steps to complete integrity testing include:

1. Close all valves except the air inlet/vent valve, retentate steam inlet valve, and permeate steam trap bypass valve (Fig 10).

2. Attach flexible tubing to permeate steam trap bypass valve and immerse in a beaker of water.

3. Perform pressure hold integrity test by introducing air at approximately 0.34 barg (5 psig) through the air vent. Watch for bubbles emanating from the permeate drain.

4. If only small bubbles emanate, the cartridge has integrity.

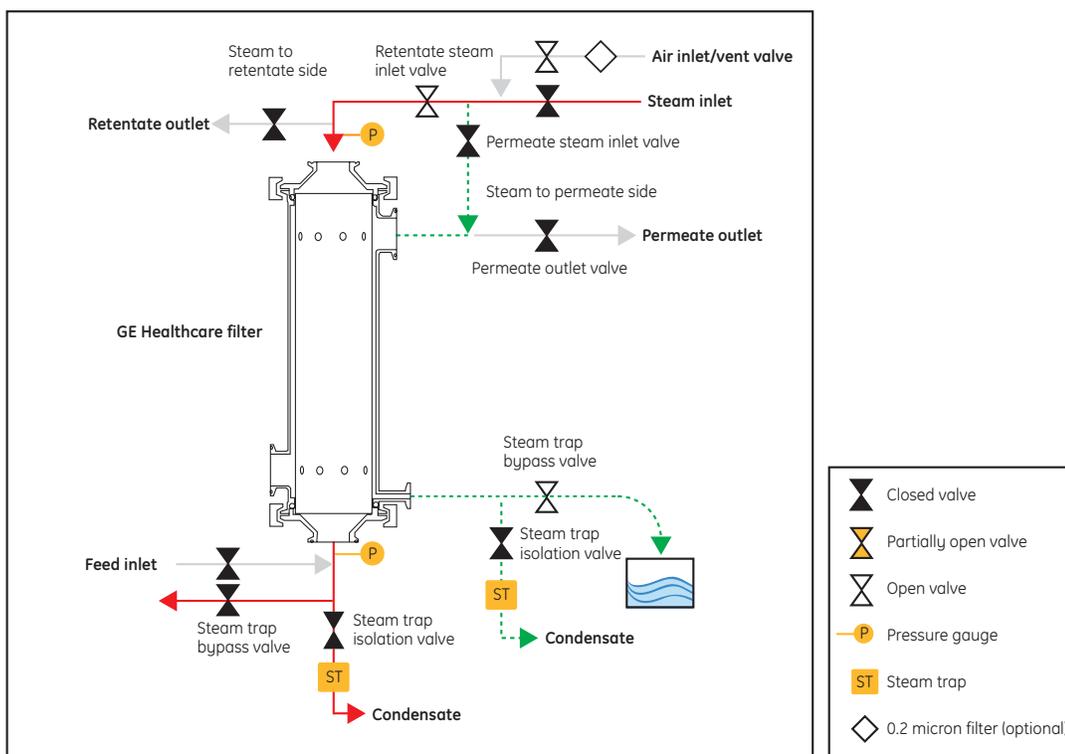


Figure 10. Starting setup for Stage 4—check filter integrity

Stage 5—Configure system for processing

Follow these steps to configure the system for processing:

1. Close the air inlet/vent valve, retentate, and permeate steam inlet valves, and steam trap bypass valves.
2. Open feed inlet valve, permeate outlet valve, and retentate outlet valve.
3. The system is now ready for processing.

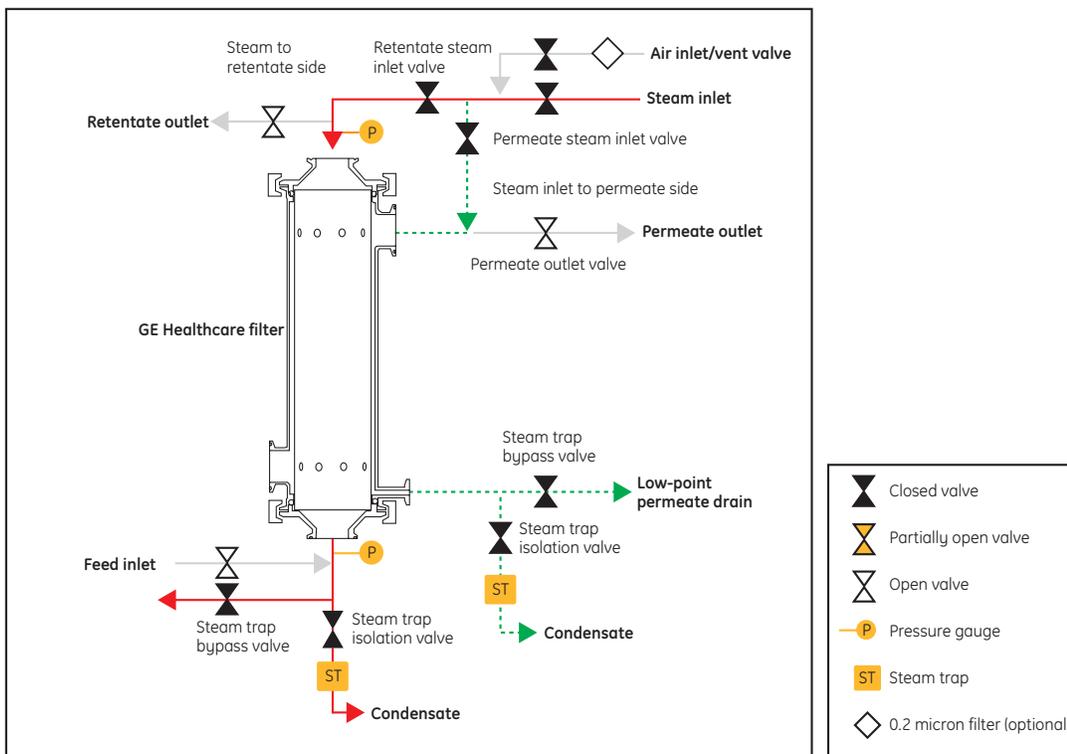


Figure 11. Starting setup for Stage 5—configure system for processing

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