Steam-in-Place

Application Support Publication

aerospace
climate control
electromechanical
filtration
fluid & gas handling
hydraulics
pneumatics
process control
sealing & shielding

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Parker domnick hunter Process Filtration

Setting the standard

Parker domnick hunter brings extensive experience through our Scientists, Engineers and sales representatives to the process of offering specific filtration systems to meet the needs of your production process. Support services are available covering a wide range of activities including scale-up advice from laboratory through pilot scales to production systems, validation support, design and manufacturing of custom housings and filtration products and on-site technical support.

Committed to quality

Quality is of paramount importance to Parker domnick hunter. As such Parker domnick hunter has been certified to ISO9001 since 1987, providing a quality management system that covers the entire organization including R & D, production, warehousing, materials management and customer support. In addition, our manufacturing facilities operate to the principles of cGMP.

This commitment is underlined by our registration to ISO 14001 and certification to current ISO9001.

Validation and product certification

To certify that Parker domnick hunter products meet the required regulatory and quality standards of the industries that we supply, all filters are supplied with a certificate of conformance. These certificates are linked to validation documents for both prefilter and sterilizing grade membrane filter products that define methodologies and data appropriate to each filter type. This information typically includes:

- Technical specifications
- Biological safety testing including current USP <88> Class VI - 121 °C Plastics
- Extractable testing including 21CFR211.72 and 210.3(b), 6 for fibre releasing filters
- Purified water filtration quality including TOC, bacterial endotoxins, conductivity and particle release
- Chemical compatibility information
- Thermal stability
- Correlation of an appropriate non-destructive integrity test to a defined bacterial challenge
- Where appropriate this data is included in Parker domnick hunter's Drug Master File No. 7564 held at the US Food and Drug Administration repository.

Validation support services

Parker domnick hunter has extensive laboratory facilities and trained personnel capable of providing a range of validation services to support manufacturers in meeting their requirements for process validation relating to the use of filtration products.

Contents

Steam-in-place

The ability of a cartridge filter to be sterilized in-situ within its housing represents a significant operational advantage for many filter users. Steam-in-place (SIP):

- avoids the need to use chemical sanitizing agents or to compromise the integrity of the filtration installation
- minimizes operator hands-on time and plant downtime
- can be easily incorporated into automated production facilities.

To achieve reproducible sterilization conditions (typically a minimum of 121 °C ((249.8 °F) for 30 minutes) and to avoid damage to the installed filter cartridge(s), it is important to carefully design and monitor SIP procedures. Factors including steam temperature and quality, condensate removal, differential pressure and cooling cycles need to be considered.

The purpose of this document is to detail the recommended methods of SIP for Parker domnick hunter cartridge filters, to avoid accidental damage to cartridges and maximize the steam life of installed filters.

General principles

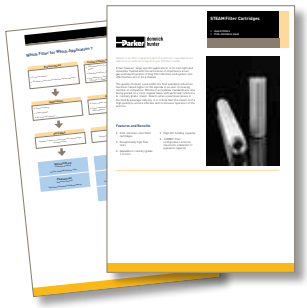
Steam quality

Condensate

Optimum steam sterilization of filter cartridges can be achieved using dry steam. Wet steam (steam containing a high level of condensed water) will not flow easily through the filter. This resistance to flow will generate increased differential pressure across the filter at elevated temperatures: conditions which cause maximum stress and possible damage to the filter cartridge. Condensate should therefore be removed by a manual valve or an automated steam trap, located as close to the filter as possible, to avoid condensate contact with the filter.

Particulate

Steam lines can suffer corrosion over a prolonged time period. Pipe corrosion can result in the presence of particulate consisting of metal fragments, which can be carried by the steam to the filter. These fragments will be retained by the filter resulting in accelerated blockage of the filter or worse, and could puncture the support materials and membrane resulting in a damaged filter.



Parker domnick hunter supplies a range of in-line steam filters to control particulate in steam lines so the filter cartridge to be steamed is protected.

Chemical additives

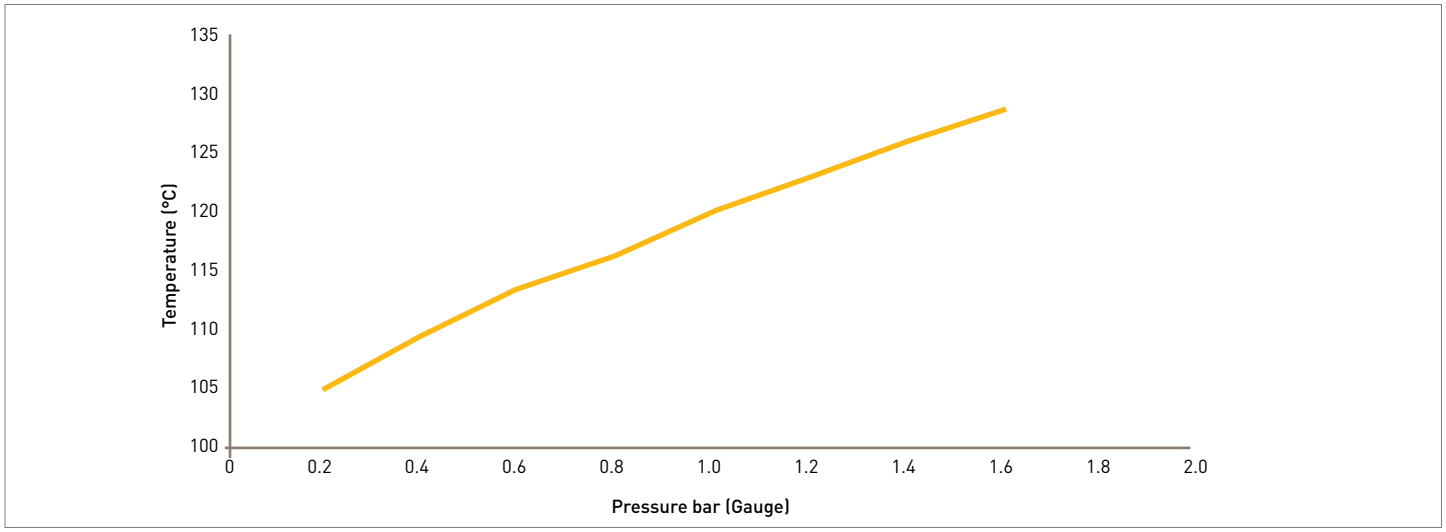
Chemicals are often added to the feed water in steam generators. These chemicals will form part of the steam and, therefore, will contact the filter cartridge being steam sterilized. Most standard steam generator additives do not pose any problem for the steam filter or filter cartridge being sterilized.

If you have any doubt regarding steam generator additives please contact Parker domnick hunter Technical Support Group.

Steam temperature

The temperature pressure relationship

There is a direct relationship between steam temperature and pressure. Increasing the steam pressure facilitates an increase in the temperature of the pressurized steam. The following graph illustrates this relationship.



Graph temperature pressure relationship

1 Thermodynamic and Transport Properties of Fluids. SI units by G.F.C Rogers and Y.R Mayhew. Oxford Basil Blackwell 1981 (0631 128913).

To assure sterility, it is typically recommended that a temperature of 121 °C (249.8 °F) be maintained over at least 30 minutes. A pressure of 1.1 barg (15.95 psig) is required to achieve this temperature (actually equates to 121.8 °C (251.24 °F)).

It is important that appropriate devices are installed to directly record steam temperature and pressure upstream and downstream of the filter.

Differential pressure

Filters should generally be supplied with steam from the upstream side (normal flow direction). Steam flow from the downstream side should be avoided, but may be appropriate in some circumstances for air / gas filters. Reverse flow should not be used for liquid filters. Steam should not be applied to both sides of the filter at the same time as this can potentially trap a pocket of dry air between the steam supplies, reducing the heat transfer to the filter and therefore negatively impacting the steam sterilization conditions.

During normal steam sterilization cycles, as steam is applied to the filter housing, air is purged from the system such that saturated steam contacts and heats all the filter and housing surfaces. As the steam heats and subsequently flows through the cartridge filter, there will be an inherent resistance to that flow. The amount of resistance to the steam flow is measured as a drop in pressure across the filter and is called the differential pressure (dP).

The dP can be influenced by many factors including:

- the micron rating of the cartridge filter
- the degree of blockage due to retained contamination
- the influence of condensate
- the rate of steam flow through the cartridge filter

While filter cartridges can withstand high dP's (up to 5 barg (72.52 psig)) at ambient temperature, it is important to limit differential pressure at elevated temperature.

When a cartridge filter is heated to 121 °C (249.8 °F) or higher, significant stress is placed on the filter unit due to the change in physical properties of the cartridge componentry at elevated temperatures (e.g. increased plasticity of polymers).

It is therefore important that at temperatures of 121 °C (249.8 °F) or higher, the dP across the filter cartridge should not exceed 0.3 barg (4.35 psig) in the forward direction. dP above this level may lead to filter damage. When a hydrophobic gas filter is steam sterilized in the reverse direction, the dP across the filter cartridge should not exceed 0.1 barg (1.45 psig). It is paramount that the differential pressure is kept below this maximum.

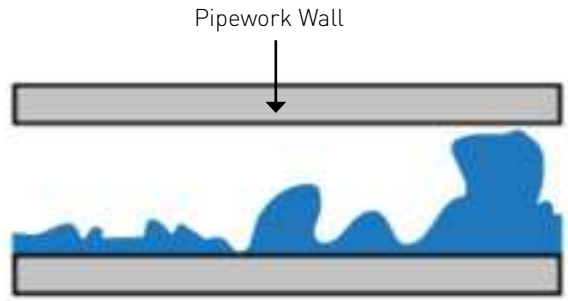
Consideration of process parameters to limit differential pressure during SIP is therefore critical and includes:

- Ensuring efficient condensate removal during the entire SIP cycle
- Minimizing steam flow rates through the cartridge filter
- Minimizing the downstream pipework steamed through the filter cartridge
- Controling and measuring the temperature and differential pressure during filter cartridge SIP
- Removal, post SIP, of as much of the steam as is practical to reduce condensate formation in the cartridge filter. This is particularly relevant for hydrophobic gas filter cartridges
- Controlled cooling of filter cartridges post SIP, to ensure hydrophobic filter cartridges are not blinded by condensate
- Controlled cooling of filter cartridges post SIP to prevent potential thermal shock by crash cooling or cold product introduction

Condensate removal

While saturated steam behaves as a gas and so flows easily through filters, contact with any cool surface (e.g. stainless steel housings or pipe-work) will lead to the generation of condensate as the steam cools. In some systems, very large volumes of condensate may be generated due to this process (e.g. multiple cartridge housings, extended pipework run, etc).

As soon as steam leaves the boiler it will begin to condense. This condensate first collects on the walls of the pipework in droplet form then accumulates to form a film that gravitates to the bottom of the pipe. When high velocities are involved this film can begin to build up into waves, the peaks of which break off, throwing water droplets into the steam flow. This results in very wet steam that has a tendency to condense even more. It can get to the stage where large slugs of condensate are propelled against filters, fittings and valves (water hammer) which can damage the installation.



Increasing condensate build up leading to water slugs

Fig.1.

The removal of condensate from any SIP system is important for a number of reasons:

- Condensate can 'blind' both hydrophilic and hydrophobic membranes to steam flow, potentially leading to filter damage due to the development of high differential pressures across the membrane at high temperature.
- Condensate will be at a temperature below the required steam sterilization temperature. It is therefore important to remove condensate to ensure effective steam sterilization.
- Hydraulic shock may occur due to 'slugs' of condensate being forced through the line.

In designing process systems, the effects of condensate generation can also be minimized by ensuring that housings are not located at the bottom of long pipe runs, or that these are steam sterilized separately from the filter.

Condensate drainage

The key to an efficient steam distribution system is that of condensate removal. Steam mains can produce a large amount of condensate especially on start-up from cold. Even a well lagged line can produce quantities of condensate which, if not properly managed, will cause problems.

To aid condensate removal, pipe lines should have a fall in the direction of flow of around 40 mm in every 10 meters of pipe run.

A condensate trap should be placed at each low point as shown in Fig.2.

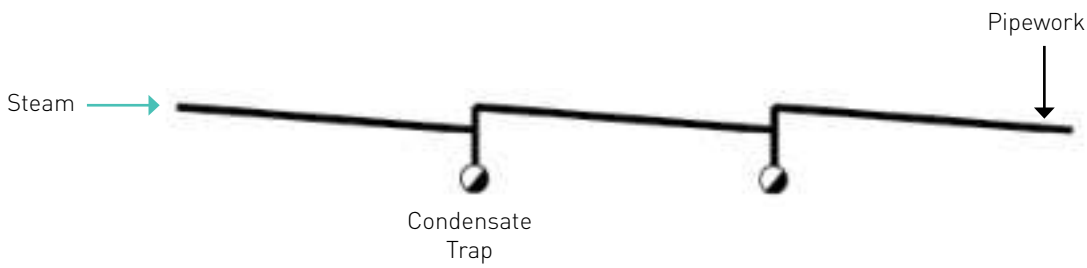


Fig.2.

Branch line connections taken from the top of the main carry the driest steam (Fig.3.). If connections are taken from the side, or even worse from the bottom (as in Figure right), they can accept the condensate and debris from the steam main. The result is very wet and dirty steam reaching the filter, which will affect performance in both the short and long term.

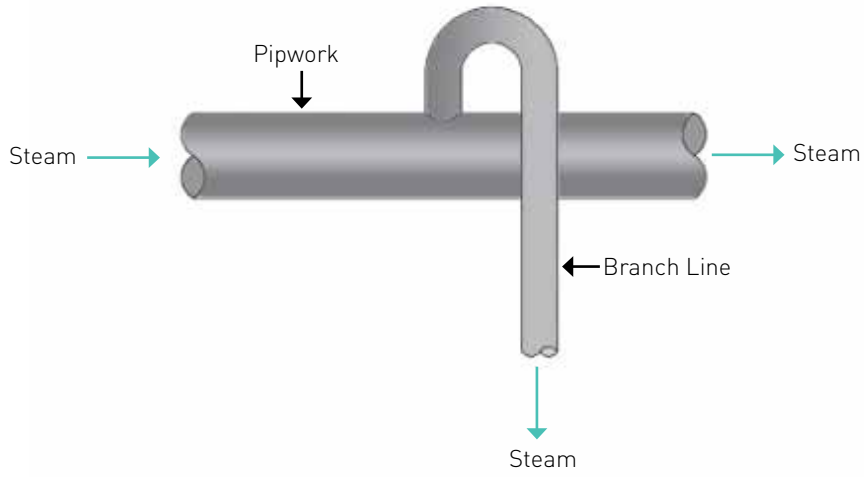


Fig.3.

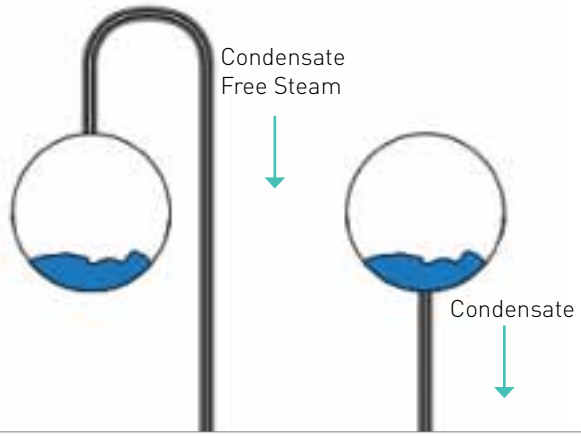


Fig.4.

A thermodynamic steam trap or condensate trap is a mechanical valve to remove condensate. They are located at points upstream and downstream of the filter where condensate would collect (i.e. low points in the system). These steam traps work on the principle that, as condensate collects, the temperature at the trap falls below that required for effective steam sterilization (121 °C (249.8 °F)). At this point the valve opens, drains the condensate and draws in live steam from the steam supply. Steam traps can be replaced by a manual valve that is left slightly open, but requires control by a skilled operator to ensure effective condensate removal without draining excessive steam.

Filter housing installation

Condensate removal is particularly important when steam sterilizing hydrophobic gas filter cartridges. Parker domnick hunter manufactures a range of gas filter housings which incorporate a plenum chamber. This upstream chamber collects steam condensate and inhibits contact with the hydrophobic filter cartridge.

The following considerations should be given to the installation of filter housings that will be steam sterilized:

- The installation should ensure that condensate cannot accumulate in the housing. Housings or upstream pipework should therefore be fitted with condensate drains.
- The cartridge and housing should be in a normal orientation (vertical, with the open end of the cartridge pointing downwards).
- The pipework downstream of the filter housing should be as short as possible. Parker domnick hunter recommends a maximum of 100 cm. Tanks downstream of the filter should always be steam sterilized separately.
- Pressure gauges capable of accurate reading in the range of 0-3 bar (0 - 43.51 psig) at the SIP temperature should be installed upstream and downstream of the filter housing, to allow differential pressure measurement.
- The pipework should be positioned at a slight incline allowing gravity to collect the steam condensate at a steam drain or steam trap.
- Length of pipeline, relative to steam flow rate, may result in pressure loss. The length of steam supply pipework should be kept to a minimum.

Cartridge filter steam life

Parker domnick hunter cartridge filters undergo extensive steam sterilization verification trials during their development. During these trials a number of filter cartridges from several production lots are steam sterilized at 121-142 °C (249.8 - 287.6 °F) depending on the filter type. After each 30-minute steam sterilization cycle the filter under test is integrity tested. Testing continues until the cartridge fails integrity test and the steam life for that cartridge type is then defined from this data, incorporating a safety margin.

Recommended maximum steam life for Parker domnick hunter filter cartridges at a range of temperatures is shown in the table below. It should be noted that these are only provided as guidelines as actual filter life will depend on individual steam sterilization conditions.

Filter Type	SIP Temperature	Maximum N° of Cycles (30 min cycles)
PROCLEAR PP	135 °C (275.0 °F)	30
PROCLEAR GF / GP	121 °C (249.8 °F)	10
PEPLYN PLUS / HA / HD	135 °C (275.0 °F)	30
PREPOR PP	135 °C (275.0 °F)	30
PREPOR GF / GP	121 °C (249.8 °F)	10
PROPOR SG / PES	130 °C (266.0 °F)	30
TETPOR LIQUID	142 °C (287.6 °F)	120
TETPOR PLUS	142 °C (287.6 °F)	30
BEVPOR P / BEVPOR M	130 °C (266.0 °F)	30
HIGH FLOW TETPOR II	142 °C (287.6 °F)	225
HIGH FLOW TETPOR H.T.	142 °C (287.6 °F)	120
TETPOR AIR	142 °C (287.6 °F)	120
HIGH FLOW BIO-X	142 °C (287.6 °F)	120
BIO-X II	142 °C (287.6 °F)	100

Integrity testing

Steam sterilization under carefully controlled conditions is an accepted process operation for filter cartridges. However, this does represent an aggressive process condition and can lead to filter damage should steam sterilization conditions deviate from controlled norms. It is therefore recommended that filter cartridges are integrity tested in-situ after steam sterilization and before use. For advice on in-situ integrity testing of filter cartridges please refer to Parker domnick hunter.

Practical SIP

The following sections in this guide provide step by step procedures for developing SIP protocols in the following operational conditions:

Liquid filters steamed in the forward direction
- Single stage system
- Double stage system

Gas filters steamed in the forward direction
- Single stage system
- Double stage system

Gas filters steamed in the reverse direction
- Single stage system
- Double stage system

Each procedure has a system diagram and valve sequence table to illustrate the step by step procedure. The procedures represent ideal systems for SIP, which may not be identical to existing systems. For recommendations, modifications or more information regarding these procedures please contact Parker domnick hunter Technical Support Group.

Prior to commencing the procedures, following assumptions have been made:

- The filter is dry / filters are dry
- All the valves are closed
- The system is leak tight (This can be tested with a pressure leak test)
- Wear protective equipment and be cautious with steam and hot surfaces

Forward SIP procedure single stage system

Liquid filter applications

1. Set the valves to positions indicated for pre steam-in-place.

2. Drain the product from the filter system and associated pipework. Opening valve V5 will aid this process.

3. Open valve V1 and allow the steam condensate to drain until the steam trap below valve V3 closes. Close valve V9.

4. Slowly open V3 allowing steam into the system: this will flow across the filters and through valve V4 & V5. This will allow the heating of the housing, the filters and associated pipework without generating a significant differential pressure across the filters. Note: the steam trap below valve V3 & V4 will receive the condensate and will repeatedly open and close.

5. When 'live' steam flows from valve V5 adjust valve V5 (leave it slightly open, so a 10 cm wisp of steam comes through valve V5). This will direct the steam through the heated filter. Close valve V10.

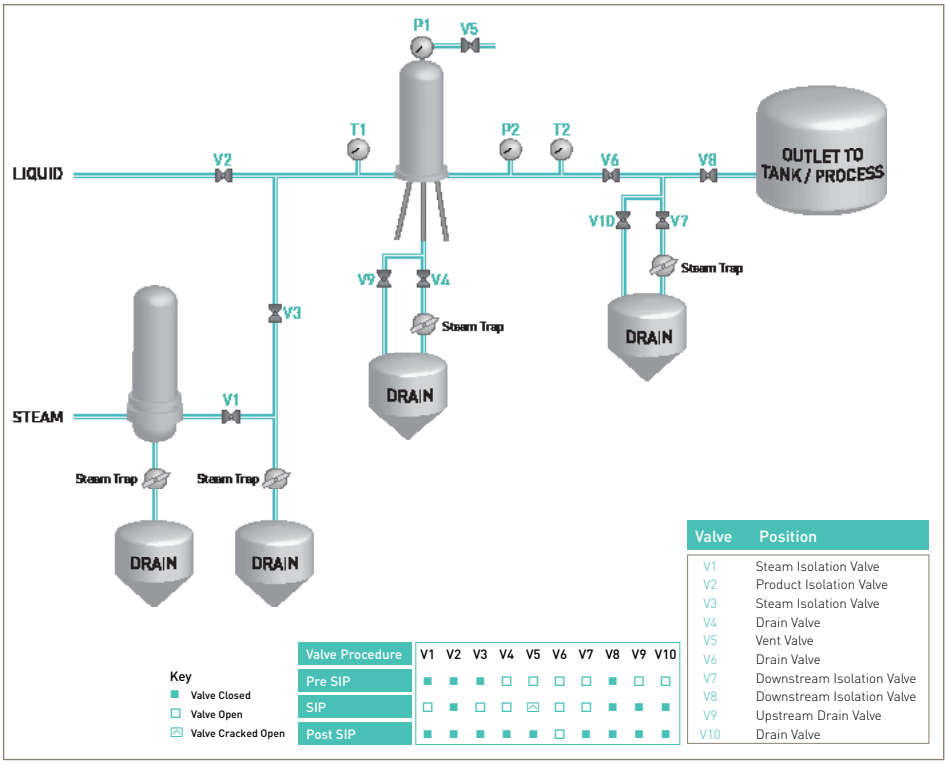
6. Observe the pressure gauges P1 and P2 and control the steam flow rate at valve V3 to ensure the differential pressure does not exceed 0.2 - 0.3 barg.

7. When the steam trap below valve V7 closes, the steam pressure will begin to rise.

8. Ensure the steam pressure / temperature does not exceed the maximum allowable pressure / temperature for the cartridge type being steamed. If reading from pressure gauges it is recommended the maximum steam pressure is 2.0 barg in the forward direction.

9. Steam sterilize the cartridges for 30 minutes ensuring the conditions stated in steps 6 to 8 are followed. The valves should now be in positions indicated for Steam-in-place.

10. On completion of the steam-in-place cycle, close V7, V4, V3 and V1 in that order.



11. Slowly open V10 to release the steam pressure from the filter system and associated pipework. When the pressure on P2 reads 0.1 barg pressure close valve V10. Fully open valve V9 to release the remaining steam pressure from the filter system. When the pressure on P1 reads 0.1 barg pressure, close valve V9 and V5.

12. Allow the system to cool for 30 minutes. The valves should now be in the positions indicated for post steam-in-place.

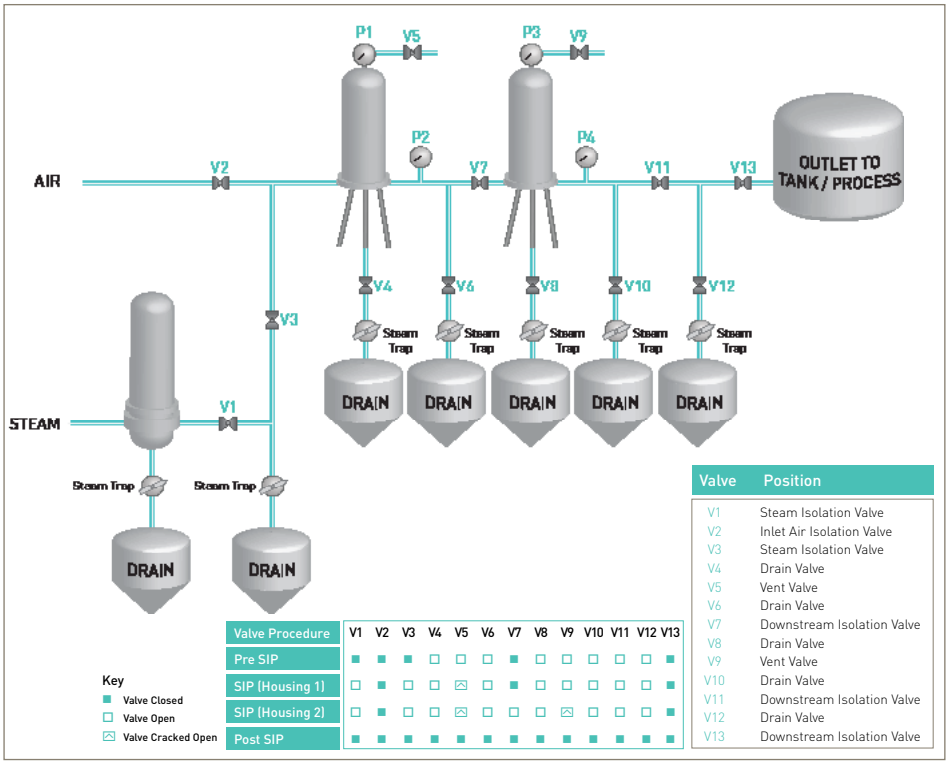
NOTES:

1. *A double downstream valve (V6, V8) is recommended so that under the cartridge steaming protocol the valves sealing faces of V6 can be effectively sterilized. The sealing valve faces of V8 can be similarly sterilized when the tank is steamed. When steam sterilizing the tank, V6 would be closed and V7 and V8 open. Normally the tank would be steamed separately before steaming the filter. If the filter is steamed before steaming the tank it is recommended that valve V6 is closed in the post steam-in-place settings to maintain sterility. The valve V6 must be closed after Step 11.*
2. *Valve V6 should be installed horizontally and valve V7 / steam trap installed immediately downstream of V6.*
3. *All drains should be fitted vertically to allow liquid removal .*
4. *Large volume downstream systems should not be steamed through the filter; e.g. when steaming process tanks a secondary steam supply should be used.*
5. *Open and close valves slowly.*

Forward SIP procedure 2 stage system

Liquid filter applications

1. Drain the product from the filter system and associated pipework. Opening Valves V5 and V9 will aid in this process.
2. Set the valves to positions indicated for pre steam-in-place.
3. Open valve V1 and allow the steam condensate to drain until the steam trap below valve V3 closes.
4. Slowly open V3 allowing steam into the system: this will flow across the filter(s) and through valve V4 and V5. This will allow the heating of the housing, the filter(s) and associated pipework without generating a significant differential pressure across the filters. *Note: the steam traps below valve V3 & V4 will receive the condensate and will repeatedly open and close.*
5. When 'live' steam flows from valve V5, partially close the valve until only a trickle of steam is vented to atmosphere. This will direct the steam through the heated filter.
6. Observe the pressure gauges P1 and P2 and control the steam flow rate at V3 to ensure the differential pressure does not exceed 0.2 - 0.3 barg.
7. When the steam trap below valve V6 closes, the steam pressure will begin to rise.
8. Slowly open V7 allowing steam into the system: this will flow across the filter(s) and through valve V8 and V9. This will allow the heating of the second housing, the filter(s) and associated pipework without generating a significant differential pressure across the filters. Note: the steam traps below valve V3, V4, V6 and V8 will receive the condensate and will repeatedly open and close.
9. When 'live' steam flows from valve V9, partially close the valve until only a trickle of steam is vented to atmosphere. This will direct the steam through the heated filter in the second housing.
10. Observe the pressure gauges P3 and P4 and control the steam flow rate at V7 to ensure the differential pressure does not exceed 0.2 - 0.3 barg.



11. When the steam trap below valve V10 closes, the steam pressure will begin to rise.
12. Ensure the steam pressure / temperature does not exceed the maximum allowable pressure / temperature for the cartridge type(s) being steamed. If reading from pressure gauges it is recommended the maximum steam pressure is 3.0 barg in the forward direction.
13. Steam sterilize the cartridges for 30 minutes ensuring the conditions stated in steps 5, 9 and 11 are observed. The valves should now be in position indicated for steam-in-place (housing 2).
14. On completion of the steam-in-place cycle, close valves V12, V8, V10, V4, V6, V3 and V1 in that order.
15. Slowly open valves V5, V9 and V10 to release steam pressure from the filter system and associated pipework.
16. When the pressure on P2 reads 0.1 barg, close valve V9. When the pressure on P4 reads 0.1 barg, close valve V10. Fully open valve V5 to release the remaining steam pressure from the filter system. When the pressure on P1 reads 0.1 barg pressure, close valve V5.
17. Allow the system to cool for 30 minutes. The valves should now be in the positions indicated for post steam-in-place.
18. Close valves V11 and V7.

NOTES:

1. *Valve V13 should be steam sterilized in conjunction with the downstream process, with V11 closed.*
2. *Valve V11 should be installed horizontally and valve V12 / steam trap installed immediately downstream of V11.*
3. *All drains should be fitted vertically to allow liquid removal .*
4. *Large volume downstream systems should not be steamed through the filter; e.g. when steaming process tanks a secondary steam supply should be used.*
5. *Open and close valves slowly.*

Parker domnick hunter

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Forward SIP procedure single stage system

Air filter applications

1. Set the valves to positions indicated for pre steam-in-place.

2. Open valve V1 and allow the steam condensate to drain until the steam trap below valve V3 closes.

3. Slowly open V3 allowing steam into the system: this will flow across the filters and through valve V4 & V5. This will allow heating of the housing, the filters and associated pipework without generating a significant differential pressure (dP) across the filters. Note: the steam trap below valve V3 & V4 will receive the condensate and will repeatedly open and close.

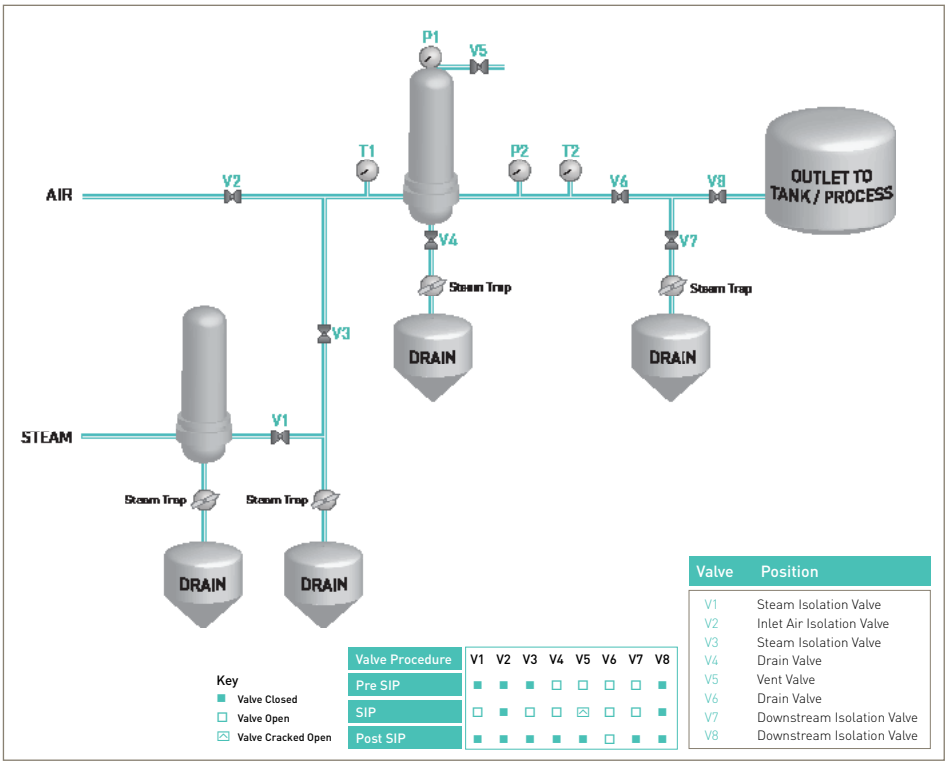
4. When 'live' steam flows from valve V5, adjust valve V5 (leave it slightly open, so a 10 cm wisp of steam comes through valve V5). This will direct the steam through the heated filter.

5. Observe the pressure gauges P1 and P2 and control the steam flow rate at valve V3 to ensure the differential pressure (dP) does not exceed 0.2 - 0.3 barg.

6. When the steam trap below valve V7 closes, the steam pressure will begin to rise.

7. Ensure the steam pressure / temperature does not exceed the maximum allowable pressure / temperature for the cartridge type being steamed. If reading from pressure gauges it is recommended the maximum steam pressure is 3.0 barg in the forward direction.

8. When the temperature at T2 is above 121.1 °C (249.98 °F) or when the steam pressure at P2 gauge is 1.1 barg, the total steam time is started. Sterilization should be 30 minutes or as established during validation. During the sterilization phase both temperature and pressure should be recorded regularly. Ensure the conditions stated in steps 5 to 7 are followed. The valves should now be in positions indicated for steam-in-place.



9. On completion of the steam-in-place cycle, close V7, V3 and V1 in that order.

10. a) Fully open V5 to flash-dry the filter (or 10b).
    b) Open V2 to allow compressed air into the system. The pressure of the air should be no more than 0.5 barg above the steam pressure.

11. Allow the system to cool for 15 minutes, then close V4 and V5. The valves should now be in the positions indicated for post steam-in-place.

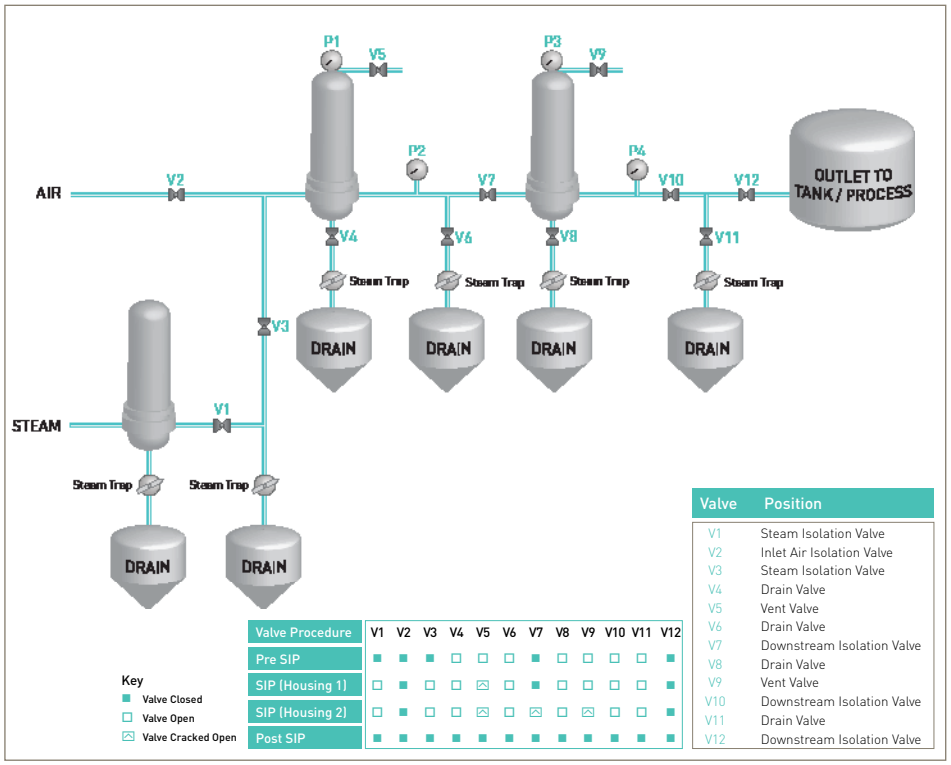
NOTES:

1. *A double downstream valve (V6, V8) is recommended so that under the cartridge steaming protocol the valves sealing faces of V6 can be effectively sterilized. The sealing valve faces of V8 can be similarly sterilized when the tank is steamed. When steam sterilizing the tank, V6 would be closed and V7 and V8 open. If the same steam supply is used to sterilize the tank as well as the filter, a steam filter of a suitable flow rate capacity must be selected.*
2. *Valve V6 should be installed horizontally and valve V7 / steam trap installed immediately downstream of V6.*
3. *All drains should be fitted vertically to allow liquid removal.*
4. *Valve V6 and V8 should be placed as close as possible to the filter housing.*
5. *Large volume downstream systems should not be steamed through the filter; e.g. when steaming process tanks a secondary steam supply should be used.*
6. *Installation / use of Parker domnick hunter air filter housings which utilize a plenum chamber are recommended, as this facilitates the collection and drainage of condensate.*
7. *Open and close valves (including valves V1 and V3) slowly.*
8. *Pipework that carries live steam to the air sterilizing filters should be well insulated to minimize the amount of condensate occuring at the filters.*

Forward SIP procedure 2 stage system

Air filter applications

1. Set the valves to positions indicated for pre steam-in-place.
2. Open valve V1 and allow the steam condensate to drain until the steam trap below valve V3 closes.
3. Slowly open V3 allowing steam into the system: this will flow across the filter(s) and through valve V4 and V5. This will allow the heating of the housing, the filter(s) and associated pipework without generating a significant differential pressure across the filters. *Note: the steam traps below valve V3 & V4 will receive the condensate and will repeatedly open and close.*
4. When 'live' steam flows from valve V5, nearly completely close valve V5 (leave it slightly open, so a 10 cm wisp of steam comes through the valve V5). This will direct the steam through the heated filter.
5. Observe the pressure gauges P1 and P2 and control the steam flow rate at V3 to ensure the differential pressure (dP) does not exceed 0.3 barg (4.35 psi).
6. When the steam trap below valve V6 closes, the steam pressure will begin to rise.
7. Slowly open V7 allowing steam into the system: this will flow across the filter(s) and through valve V8 and V9. This will allow the heating of the second housing, the filter(s) and associated pipework without generating a significant dP across the filters. *Note: the steam traps below valve V3, V4, V6 and V8 will receive the condensate and will repeatedly open and close.*
8. When 'live' steam flows from valve V9, nearly completely close valve V9 (leave it slightly open, so a 10 cm wisp of steam comes through the valve V9). This will direct the steam through the heated filter in the second housing.
9. Observe the pressure gauges P3 and P4 and control the steam flow rate at V7 to ensure the dP does not exceed 0.3 barg (4.35 psi). Also make sure the that the dP over the first filter housing (P1 and P2) does not exceed 0.3 barg (4.35 psi).
10. When the steam trap below valve V11 closes, the steam pressure will begin to rise.
11. Ensure the steam pressure / temperature does not exceed the maximum allowable pressure / temperature for the cartridge type(s) being steamed. If reading from pressure gauges it is recommended the maximum steam pressure is 3.0 barg (43.51 psi) in the forward direction.
12. Steam sterilize the cartridges for 30 minutes ensuring the conditions stated in steps 5, 9 and 11 are observed. The valves should now be in position indicated for steam-in-place (housing 2).
13. On completion of the steam-in-place cycle, close valves V11, V10, V9, V8, V6, V5, V4, V3 and V1 in that order.
14. Open valve V2 to allow compressed air into the system. The pressure of the air should be no more than 0.3 barg (4.35 psi) above the steam pressure. Open V5 and V9 slightly to allow some air flow through the valves. Adjust Valve V7 in such a way so there is also flow of air through Valve V9. The dP over each filter should not exceed 0.3 bar (4.35 psi) in the forward direction during the cooling period.
15. Allow the system to cool for 15 minutes,close valves V5 and V9. Close valve V7. Close valve V2.



NOTES:

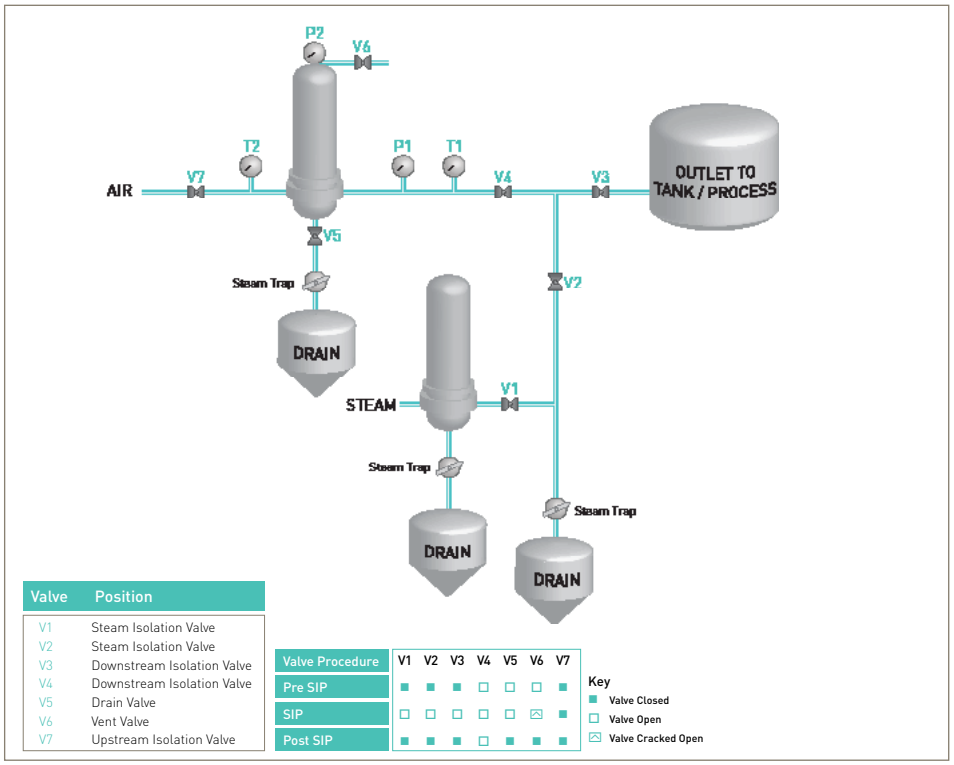
1. *Open and close valves slowly. Also steam should be turned on slowly.*
2. *Valve V12 should be steam sterilised in conjunction with the downstream process, with V10 closed.*
3. *Pipe lines that carry live steam to the air sterilizing filters should be well insulated to minimize the amount of condensate arriving at the filters*
4. *All drains should be fitted vertically to allow liquid removal.*
5. *Large volume downstream systems should not be steamed through the filters in housing 1 and 2; e.g. when steaming process tanks a secondary steam supply should be used.*
6. *Valve V10 and V12 should be placed as close as possible to the filter housing. If long lengths of pipe are present, the initial steam flows will be high as the downstream volume is pressurized. This high steam flow can damage the cartridge due to rising differential pressure.*
7. *Also the distance between housing 1 and 2 should be kept to a minimum, not more than 100 cm.*

Reverse SIP procedure single stage system

Air filter applications

Note: This method is typically suited to single cartridge systems.

1. Set the valves to positions indicated for pre steam-in-place.
2. Open valve V1 and allow the steam condensate to drain until the steam trap below valve V2 closes.
3. Slowly open V2 allowing steam into the system.
4. Observe the pressure gauges P1 and P2 and control the steam flow rate at valve V2 to ensure the dP across the filter does not exceed 0.1 barg. If the dP exceeds 100 mbar stop the sterilization procedure and rectify the cause of the pressure drop before proceeding with the sterilization routine.
5. When line steam flows from valve V6, adjust valve V6 (cracked open). When the steam trap below valve V5 closes, the steam pressure will begin to rise.
6. Ensure steam pressure / temperature does not exceed the maximum allowable pressure / temperature for the cartridge type being steamed. Continue to monitor the dP using gauges P1 and P2. If the differential pressure exceeds 100 mbar stop the sterilization procedure and rectify the cause of the pressure drop before proceeding with the sterilization routine. When the temperature at T2 is above 121.1 °C (249.98 °F) or when the steam pressure at P2 gauge is 1.1 barg the total steam time is started. Sterilization should be 30 minutes or as established during validation. During the sterilization phase both temperature and pressure should be recorded regularly.
7. The valves should now be in the positions indicated for steam-in-place. On completion of the steam cycle time, close V2 and V1 in that order and then rapidly open V6 to flash dry the filter (or 8b).



8. Isolate steam supply (close V2 and V1) and open V7 to allow air into the system. The pressure of the air should be no more than 0.5 barg above the steam pressure.
9. Allow the system to cool for 15 minutes then close V5 and V6, the valves should now be in positions indicated for post Steam-in-place.

NOTES:

1. *A double downstream valve (V4, V3) is recommended so that under the cartridge steaming protocol the valve sealing faces of V4 can be effectively sterilized - the sealing valve faces of V3 can be similarly sterilized when the tank is steamed. When steam sterilizing the tank V4 should be closed and valve V3 open. If the same steam supply is used to sterilize the tank as well as the filter, a steam filter of a suitable flow rate capacity must be selected.*
2. *All drains should be fitted vertically to allow liquid removal.*
3. *There should be a 'fall' in the pipework from V3 so that liquid can drain into the tank.*
4. *Large volume downstream systems should not be steamed through the filter; e.g. when steaming process tanks a secondary steam supply should be used.*
5. *Installation / use of Parker domnick hunter air filter housings which utilise a plenum chamber are recommended, as this facilitates the collection and drainage of condensate.*
6. *Valve V7 should be placed as close as possible to the filter housing. If long lengths of pipe are present, the initial steam flows will be high as the downstream volume is pressurized. This high steam flow can damage the cartridge.*
7. *Open and close valves slowly. Also steam should be let in slowly.*
8. *Pipework that carries live steam to the air sterilizing filters should be well insulated to minimize the amount of condensate occurring at the filters.*

Reverse SIP procedure 2 stage system

Air filter applications

Note: This method is typically suited to single cartridge systems.

1. Set the valves to positions indicated for pre steam-in-place.
2. Open valve V1 and allow the steam condensate to drain until the steam trap below valve V2 closes.

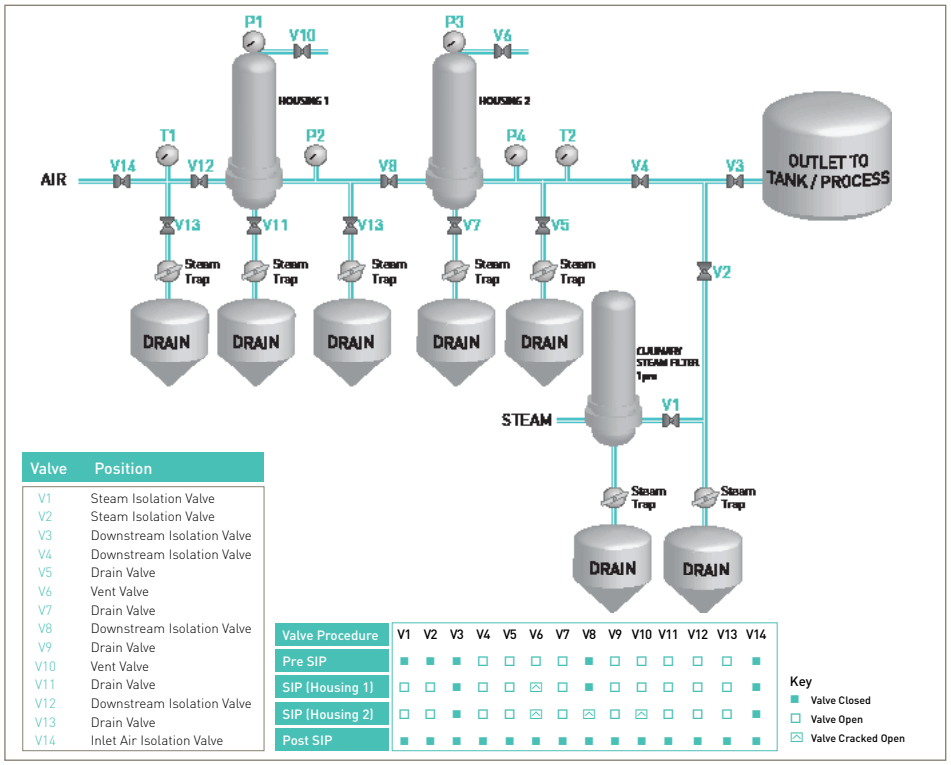
Slowly open V2 allowing steam into the system: this will flow through valve V4 and V5. Observe the pressure gauges P3 and P4 and control the flow rate at valve V2 to ensure the dP (differential pressure) across the filter does not exceed 100 mbarg (1.45 psi). If the dP exceeds 100 mbar (1.45 psi) stop the sterilization procedure and rectify the cause of the pressure drop before proceeding with the sterilization routine. Note: the steam traps below valve V2 & V5 will receive the condensate and will repeatedly open and close.

3. When 'live' steam flows from valve V6, nearly completely close valve V6 (leave it slightly open, so a 10 cm wisp of steam comes through the valve V6). When the steam trap below valve V7 closes, the steam pressure will begin to rise.

Open valve V8 slightly allowing steam into the second housing: this will flow through valve V9. When the steam trap below valve V9 closes it will flow through the filter. Make sure the dP over the second filter (P4 and P3) does not exceed 0.1 bar (1.45 psi).

Observe the pressure gauges P3 and P4 and the pressure gauges P1 and P2 and control the flow rate at valve V2 to ensure the Dp (differential pressure) across each filter does not exceed 0.1 barg (1.45 psi). If the dP exceeds 100 mbar (1.45 psi) stop the sterilization procedure and rectify the cause of the pressure drop before proceeding with the sterilization routine. *Note: The steam traps below valve V2, V5, V7 and V9 will receive the condensate and will repeatedly open and close.*

4. When 'live' steam flows from valve V10, close valve V10 nearly completely. Allow a 10 cm wisp of steam through valve V10. When the steam traps below valve V11 and V13 close, the steam pressure will begin to rise.
5. Ensure the steam pressure / temperature does not exceed the maximum allowable pressure / temperature for the cartridge type(s) being steamed. If the dP (check for each of the 2 filters separately) exceeds 100 mbar (1.45 psi) stop the sterilization procedure and rectify the cause of the pressure drop before proceeding with the sterilization routine.
6. When the temperature at T1 is above 121.1 °C (250 °F) or when the steam pressure at P1 gauge is 1.1 barg (16 psi), the total steam time is started. Sterilization should be 30 minutes or longer, as established during validation. During the sterilization phase both temperature and pressure should be recorded regularly.
7. Steam sterilize the cartridges for 30 minutes ensuring the conditions stated in steps 3, 6 and 8 are observed. The valves should now be in position indicated for steam-in-place (housing 1).
8. On completion of the Steam-in-place cycle, close valves V13, V11, V10, V9, V7, V6, V5, V2 and V1 in that order.
9. Open valve V14 to allow compressed air into the system. The pressure of the air should be no more than 0.3 barg (4.35 psi) above the steam pressure. Open V6 and V10 slightly to allow some air flow through the valves. Adjust Valve V8 in such a way so there is also flow of air through Valve V6. The dP over each filter should not exceed 0.3 bar (4.35 psi) in the forward direction during the cooling period.
10. Allow the system to cool for 15 minutes, then close valves V6 and V10. Close Valve V8. Close valve V14.
11. The valves should now be in position indicated for post SIP.



Valve	Position
V1	Steam Isolation Valve
V2	Steam Isolation Valve
V3	Downstream Isolation Valve
V4	Downstream Isolation Valve
V5	Drain Valve
V6	Vent Valve
V7	Drain Valve
V8	Downstream Isolation Valve
V9	Drain Valve
V10	Vent Valve
V11	Drain Valve
V12	Downstream Isolation Valve
V13	Drain Valve
V14	Inlet Air Isolation Valve

Valve Procedure	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14
Pre SIP	■	■	■	□	□	□	□	■	□	□	□	□	□	■
SIP (Housing 1)	□	□	■	□	□	▨	□	■	□	□	□	□	□	■
SIP (Housing 2)	□	□	■	□	□	▨	□	▨	□	▨	□	□	□	■
Post SIP	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Key
■ Valve Closed
□ Valve Open
▨ Valve Cracked Open

NOTES:

1. *Open and close valves slowly. Also steam should be turned on slowly.*
2. *Valve V3 should be steam sterilized in conjunction with the downstream process, with V4 closed.*
3. *Pipe lines that carry live steam to the air sterilizing filters should be well insulated to minimize the amount of condensate arriving at the filters.*
4. *All drains should be fitted vertically to allow liquid removal.*
5. *Large volume downstream systems should not be steamed through the filters in housing 1 and 2; e.g. when steaming process tanks a secondary steam supply should be used.*
6. *Valve V14 should be placed as close as possible to the filter housing. If long lengths of pipe are present, the initial steam flows will be high as the downstream volume is pressurized. This high steam flow can damage the cartridge due to rising differential pressure.*
7. *Also the distance between housing 1 and 2 should be kept to a minimum, not more than 100 cm.*

Technical Support Group activities

Parker domnick hunter have a trained team of Scientists and Engineers available to answer questions regarding the technical capabilities of our products, to assist in the selection and design of appropriate filtration systems and to provide user training programs. The following services can be delivered both on-site and in-house:

- Filterability testing to optimize filter system design
- Advice on the development of integrity testing, steam sterilization and clean-in-place procedures
- Development of validation protocols
- Troubleshooting
- Facility audits to ensure continued optimization of filter use
- Operator training including filtration theory, filter system design and management, validation, etc.

For more information on any of the above support services please contact your local Parker domnick hunter representative.

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