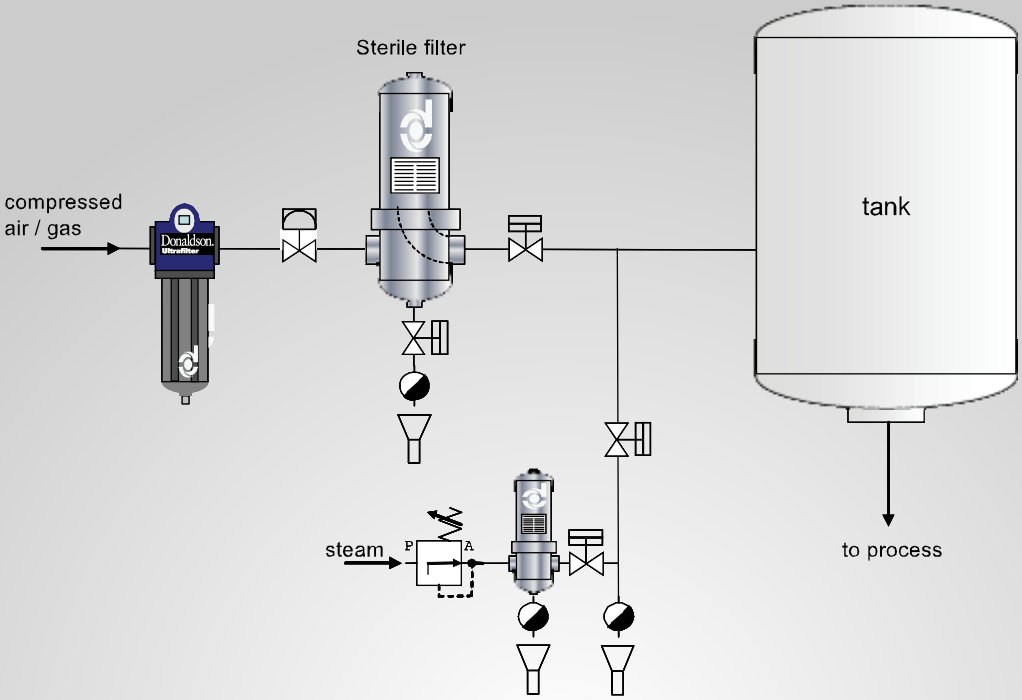
Donaldson
FILTRATION SOLUTIONS

FILTER STERILIZATION GUIDE

Steam Sterilization & Alternative Methods



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1. Introduction

Like compressed air, steam is often thought of as another utility – both are often generated at a central location and then distributed to various points-of-use throughout the facility, and both are often used to transfer energy. The similarities don't end there. Depending on the intended use, and whether or not they come into contact with the final product itself, both will have to be filtered to a greater or lesser extent. The intended use though is what drives the choice between these two utilities. When it comes to the transfer of energy, steam provides some unique characteristics which include, but are not limited to, the following:

Steam

… can be efficiently and economically generated at a central location from which controllable amounts of energy can be distributed to various points-of-use throughout the plant.

… has the ability to hold a great deal of energy, stored as heat, in a given volume

… gives up its heat energy at a constant temperature, eliminating heat gradients associated with other forms of energy transfer

… has a high rate of heat transfer, allowing for smaller heat transfer surface areas.

… has the ability to inactivate and kill micro-organisms by denaturising their intracellular proteins through energy input.

Due to these and many other desirable attributes, steam can be found in use within a multitude of industries and applications.

Industries	Applications
• Food and Beverage • Pharmaceutical • Chemicals • Metal Processing • Pulp & Paper • Power generation • Rubber & Plastics	• Sterilizing • Cooking • Cleaning • Drying • Curing • Temperature Control

1.1 Steam Terminology

Process Steam
Process Steam is the general term for steam used in process applications as a source of energy for process heating, pressure control and mechanical drives among others. Process steam does not generally come into contact with the final product.

Culinary Steam
Culinary Steam refers specifically to steam used in food processing, often required to meet 3-A Sanitary Standards and 3-A Accepted Practices for dairy and food processing. Culinary steam can, and often does, come into direct contact with the final product.

Clean Steam

The condensate of clean steam meets purity requirements of Water for Injection with the additional specifications to protect against corrosion of materials used in the construction of sterilizers and medical devices. The pyrogen content of this condensate is limited.

Dry Steam

Dry steam consists of 100% water vapor – no water droplets.

Saturated Steam

Saturated steam is said to be "saturated" with energy at a given and constant pressure when the addition of more heat to the generation system results in more steam, but no rise in steam temperature. In this state, the steam cannot hold more energy in a given volume unless pressure is allowed to rise.

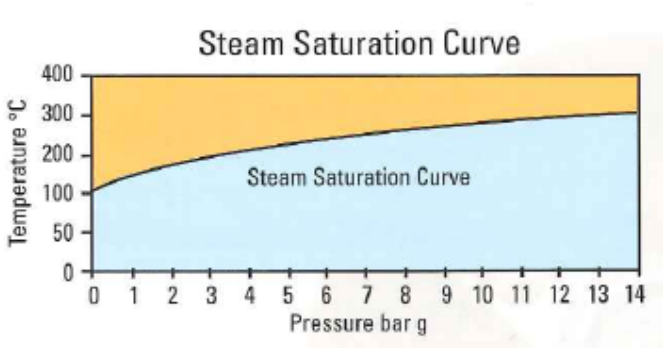


Figure 1

Dry Saturated Steam

Achieving the above states of dry and saturated steam simultaneously is possible in theory. It is nearly impossible in practice when systems are optimized for generating saturated steam. The actual level achieved is measured as the "dryness fraction".

Superheated Steam

When more heat energy is added to steam that has reached saturation, and no liquid water is present to consume that energy through evaporation, the temperature of the steam will rise. In this condition, steam is said to be "superheated".

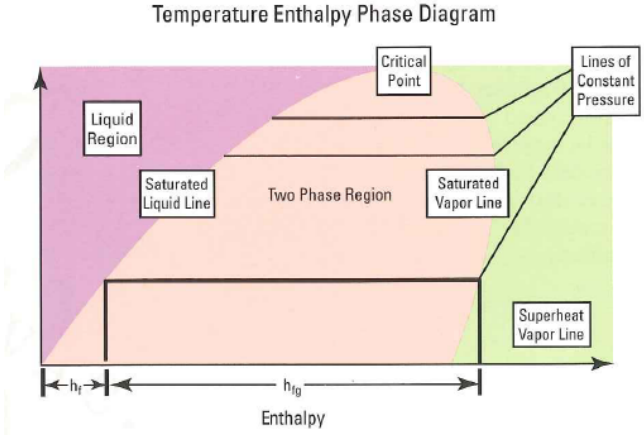


Figure 2

CIP (clean in Place)

CIP is the process of cleaning equipment where it is installed as opposed to taking it out of service and to a remote location.

SIP (Sterilize in Place)

SIP is similar to CIP, but with the goal of sterilizing the hardware where it is installed without disassembly.

1.2 Sterility

The term “sterile” means “free of micro-organisms capable of reproduction”. In recent years there has, however, been a general agreement that the term “sterile”, in the form that can only be understood as an absolute, is not always attainable in daily sterilization practice. In the case of the “safest” sterilization procedure, autoclaving, a contamination quota (probability of survival) of not greater than 10^{-6} is accepted as a “sterile” result.

Micro-organisms are inactivated when metabolically irreversible deleterious intracellular reactions occur. At high temperatures and in the presence of moisture, as in steam sterilization, the energy input from the steam inactivates micro-organisms by denaturising their intracellular proteins. Therefore, the procedures using confined saturated steam are the safest and most secure sterilization methods. Their results and the time they take are, however, significantly affected by:

- the type of micro-organisms involved
- their functional state (vegetative forms, spores), and
- the initial bacteria count and the desired final state (complete sterility or simply reduction of the number of bacteria)
- the ambient conditions, and
- the prevailing temperature

Table 1

Sterilization conditions for organisms using damp heat		
vegetative bacterial states, viruses	80 °C (176°F)	30 min.
Hepatitis viruses	100°C (212°F)	10 min.
Bacillus anthracis spores	105°C (221°F)	5 min.
Bacillus stearothermophilus spores and other bacilli and clostridia spores	121°C (250°F)	15 min.
Highly heat-resistant spores from thread-type agar (encountered occasionally)	134°C (273°F)	up to 6h

Generally, a filter is considered to be a sterilizing filter when, after being challenged with 1.0×10^{7} challenge organisms per square centimetre of effective filter area (EFA), the resulting filtrate is sterile. This is sufficient to challenge any oversized pores in the filter because preferential flow would be oversized pores.

The bacterial retention of a filter (i.e. its sterilizing ability) can be expressed quantitatively as the log reduction value (LRV), which is the logarithm (to the base of 10) of the ratio of total organisms in the challenge to the organisms in the filtrate when a filter is challenged to a specified microbial challenge.
A filter can be rated as a sterile filter if the LRV is greater than 7.

$$\mathrm{LRV} = \log\left[\frac{(\text{Number of organisms in the test suspension / aerosol})}{(\text{Number of organisms in the filtrate})}\right]$$

To obtain a sterile filtrate over a longer period of time, it is necessary to inhibit a growth of micro-organisms through the filter matrix. As steam is often already available in the installations to sterilize tanks, pipes or other devices, this steam is often used for the steam-sterilization of the filter element (and housing). Alternatives are gases or liquids with sterilising or disinfecting characteristics.

2. Filter Elements and housings for steam applications

2.1 P-GS Element

At the heart of the steam filtration system is the widely-used Donaldson Ultrex P-GS sintered stainless steel filter element. P-GS elements can be regenerated numerous times, allowing for long filter life and reduced operating costs. Utilizing P-GS elements to ensure high quality steam protects the equipment and processes that rely on that steam for efficient, clean and/or sterile operation.

The Ultrex P-GS features:

- 100% retention rate for gas and 98% retention rate for steam at 1, 5 and 25 micron
- Exceeds 3-A Accepted Practice in both efficiency and particle size removal for culinary steam
- Weldless sintered 316L SS media tube
- 304 SS end caps
- Double o-ring seal to eliminate cross-flow of unfiltered steam
- High porosity level for low pressure drop and high dirt-holding capacity
- Can be regenerated via ultrasonic bath or back flushing
- 13 models for optimized sizing to specific applications

2.2 P-SM Element for Prefiltration

In certain applications it can be beneficial to install a prefilter in front of the final P-GS steam filter. The Donaldson Ultramesh P-SM stainless steel mesh filter element is ideally suited for this application. P-SM elements are constructed entirely of stainless steel and can be regenerated numerous times, allowing long life and reduced operating costs. Utilizing P-SM elements as a prefilter will protect the final P-GS filter from excessive contamination and allow for longer filter life and reduced operating expenses over time.

The Ultramesh P-SM features:

- Absolute particle retention rates from 5 to 250 micron
- Multi-layered stainless steel mesh media
- Can be regenerated via back-flush or ultrasonic bath
- Heavy-duty construction ensures long life
- 13 models for optimized sizing to specific application

2.3 P-EG Steam Filter housing

Along with P-GS filter elements, Donaldson P-EG filter housings are widely used in steam filtration applications. Equipped with a variety of connections, P-EG housings are designed to yield low differential pressure at high flow rates.

- Constructed of 304 SS (316L SS available)
- 18 sizes available for optimal performance in any given application
- Electro polished outer surface finish on models 0006 through 0288
- Bead blast surface finish on models 0432 through 1920
- Designed to accept the UF push-in filter element with double o-ring seal
- Optional inlet/outlet connection styles available

2.4 PG-EG sanitary grade filter housings

Donaldson PG-EG sanitary grade filter housings are 3-A certified to assure that their design meets the rigid sanitary requirements of the food, beverage and dairy industries. PG-EG housings can be equipped with a variety of connections and offer very low differential pressure at high flow rates.

- Available in either 304 or 316L SS
- 14 sizes available for optimal performance in any given application
- Electro polished inner and outer surface finishes on all models
- Sanitary pharma style vents/drains
- Designed to accept the UF push-in filter element with double o-ring seal
- Optional inlet/outlet connection styles available

3. Regeneration guidelines for steam filters

Both Donaldson P-GS and P-SM Filter elements can be regenerated using a number of different techniques. In general, the more frequently an element is cleaned, the better the regeneration. The following is some general background in methods of filter regeneration.

3.1 Counter-Flow

The filter media can be washed with either clean liquid or clean gas in a reverse, or counter-flow, cycle. Pulsing the flow to loosen attached particles can enhance cleaning. This method is excellent where retained particles are on the surface of the media as opposed to having penetrated deeper into the media pores. Use of a wire or nylon brush can also enhance this method of cleaning.

3.2 Solvent Cleaning

In some cases, oil and other contaminants in the steam cause particles to be retained on or within the filter media. Detergents and/or solvents might be required in these instances, not only to remove the oil or oil-like contaminants, but to allow particles to be released as well. After cleaning with solvents, rinse the element thoroughly and let all liquid evaporate.

3.3 Ultrasonic Cleaning

The most thorough regeneration can be achieved using ultrasonic cleaning. In this method, filter elements are immersed in a solvent (non-flammable!) or water bath in which ultrasonic waves lead to a loosening and removal of particles embedded in the media. Regeneration is nearly total, leaving elements close to their original state.

4. Design aids

4.1 Choice of steam filter pore size

The steam filter type and micron rating depend on the steam quality required by the specific application. But it is also important to consider the particle load in the pipes to avoid rapid blocking of the steam filters. It may be necessary to use a pre- and a fine filter.

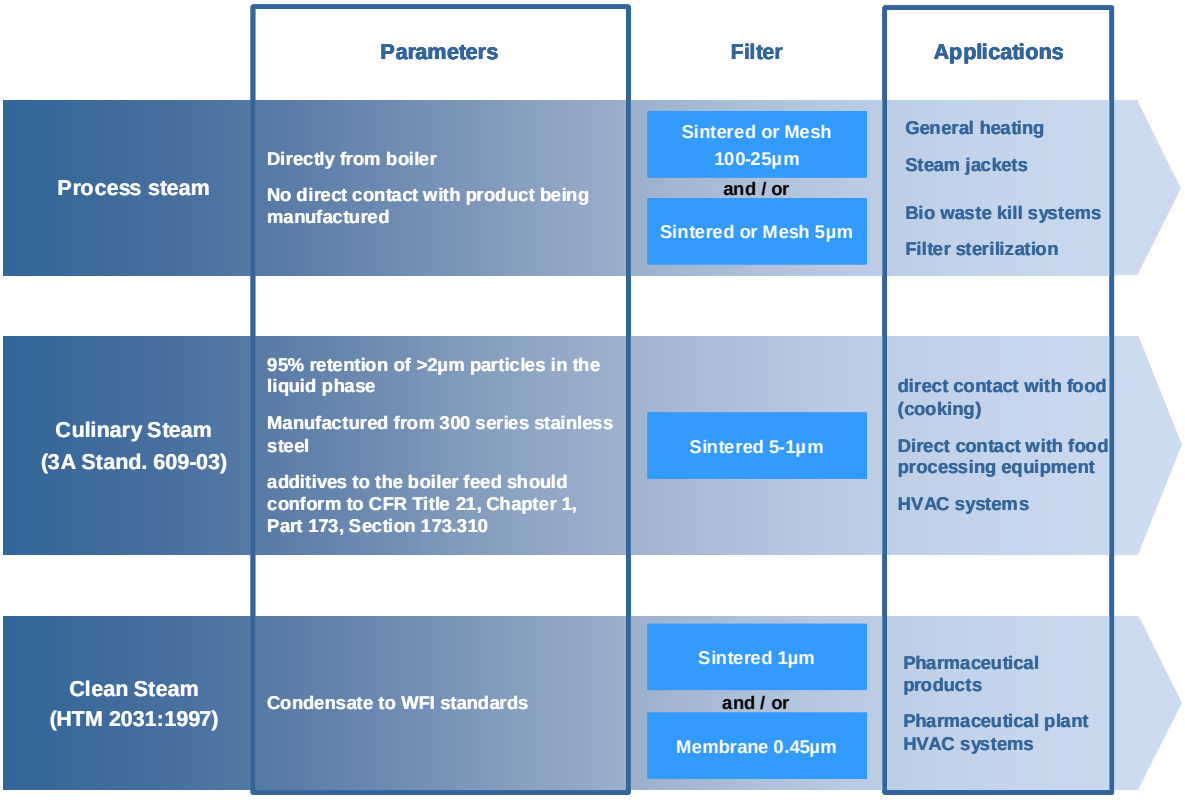


Figure 3

4.2 Calculation of required steam mass flow

To calculate the necessary steam mass flow for the sterilization of a housing or a tank, the following parameters will be needed.

Table 2

$t_{sterilization}$	sterilization temperature	[°C]	
$t_{operation}$	operation temperature	[°C]	
m_F	mass of filter housing or tank to be sterilized	[kg]	
Δh_v	evaporation enthalpy (Table 12)	[kJ/kg]	
c_p	specific heat capacity	$[\frac{kJ}{kg \cdot K}]$	stainless steel: $c_p = 0.477 \frac{kJ}{kg \cdot K}$
Q_{in}	heat quantity	[kJ]	
$\dot{m}_S$	steam mass flow	[kg/h]	
m_S	steam mass	[kg]	
$\Delta t = t_{sterilization} - t_{operation}$		[K]	

For a filter cartridge with housing or for a tank, there are general conditions and assumptions:

- Stainless steel heats up to the saturated steam temperature within approx. 20 minutes
- Approx. 70% of the heating-up energy is required in the first 3 minutes
- 60% of the steam condenses and gives up heat into the surface
- Only the filter housing or tank (without piping) is taken into consideration
- Steam flow velocity through the filter medium should be 0,02 – 0,04 m/s
- Steam flow velocity inside the piping should not exceed 25 m/s

The heat quantity that is required to heat a stainless steel body (e.g. filter housing) from operating temperature to sterilization temperature is calculated with

$$Q_{in} = m_F \cdot c_p \cdot \Delta t$$

According to the first law of thermodynamics, if pressure in a system is constant, the necessary heat quantity equals the enthalpy of evaporation.

$$Q_{in} = n \cdot \Delta h_v = m_S \cdot \Delta h_v$$

Here, n is equivalent to the mass m_S of steam that is necessary to heat up the system, in this case the housing or the tank. Therefore the mass of steam is calculated as:

$$m_S = \frac{Q_{in}}{\Delta h_v}$$

With the conditions and assumptions above and $\dot{m}_s = \frac{m_S}{t}$, the necessary maximum steam mass flow is calculated as

$$\dot{m}_S = \frac{m_F \cdot c_p \cdot \Delta t \cdot 0{,}7 \cdot 3600\text{sec}}{\Delta h_v \cdot 0{,}6 \cdot 180\text{sec} \cdot 1\text{h}} = m_F \cdot \frac{\Delta t}{\Delta h_v} \cdot 11{,}13$$

With this steam mass flow, the appropriate steam filter can be selected.

4.2.1 Choice of correct steam filter size according to calculated steam mass flow

For the Donaldson filter housings PG-EG & PF-EG the required steam flows $\dot{m}_S$ at 121°C & 141°C are given below.

Table 3

steam filter sizing for P-EG
(single housings with thread connection, multiple with flange connection)

Filter size	Housing	Mass	required steam flow at	
	P-EG	m_F [kg]	121°C $\dot{m}_S$ [kg/h]	141°C $\dot{m}_S$ [kg/h]
03/10	0006	1.7	0.87	10.6
04/10	0009	1.9	0.97	1.19
04/20	0012	1.9	0.97	1.19
05/20	0018	2.0	1.02	1.25
05/25	0027	2.6	1.33	1.62
07/25	0036	3.0	1.53	1.87
07/30	0048	4.3	2.12	2.68
10/30	0072	4.8	2.45	2.9
15/30	0108	5.3	2.7	3.31
20/30	0144	9.0	4.59	5.6
30/30	0192	10.8	5.5	25.5
30/50	0288	16.2	8.3	10.1
3x 20/30	0432	43.0	21.9	26.8
3x 30/30	0576	46.0	23.5	28.7
4x 30/30	0768	70.0	35.7	43.7
6x 30/30	1152	80.0	40.8	49.9

steam filter sizing for PG-EG
(single housings 3-A with clamp, multiple with flange)

Table 4

Filter size	Housing	Mass	required steam flow at	
	PG-EG	m_F [kg]	121°C $\dot{m}_S$ [kg/h]	141°C $\dot{m}_S$ [kg/h]
03/10	0006	1.5	0.76	0.94
05/20	0018	1.7	0.87	1.1
05/30	0032	2.1	1.1	1.3
10/30	0072	2.9	1.5	1.8
20/30	0144	4.5	2.3	2.8
30/30	0192	5.7	2.9	3.6
3x 20/30	0432	43	22	27
3x 30/30	0576	44	22.4	27.54
4x 30/30	0768	70	35.7	43,7
6x 30/30	1152	80	40.8	50
8x 30/30	1536	135	69	84.2
10x 30/30	1920	135	69	84.2

steam filter sizing for PF-EG
(standard and 3-A with Clamp)

Table 5

Filter size	Housing	Mass	required steam flow at	
	PF-EG	m_F [kg]	121°C $\dot{m}_S$ [kg/h]	141°C $\dot{m}_S$ [kg/h]
03/10	0003	1.2	0.61	0.75
05/20	0008	1.5	0.76	0.94
5/3 P7	0012	1.5	0.76	0.94
10/3 P7	0025	4.8	2.45	3.0
20/3 P7	0050	6.1	3.1	3.8
30/3 P7	0075	7.4	3.8	4.6
3x 10/3 P7	0080	13.8	7	8.6
3x 20/3 P7	0150	16.1	8.2	10
3x 30/3 P7	0225	18.6	9.5	11.6
5x 20/3 P7	0250	21.8	11.1	13.6
5x 30/3 P7	0375	24.9	12.7	15.5
8x 20/3 P7	0400	33.6	17.1	21
8x 30/3 P7	0600	37.9	19.3	23.6

4.3 Available steam filter sizes

With the calculated steam flows from Table 4 the necessary P-GS filter size can be chosen from the table below.

Table 6

P-GS filters available *)

Filter Element size	Housing	max. steam flow at 121°C saturated steam	max. steam flow at 141°C saturated steam
P-GS / P-SM	P-EG	$\dot{m}_S$ [kg/h]	$\dot{m}_S$ [kg/h]
03/10	0006	7.5	15
04/10	0009	11.25	22.5
04/20	0012	15	30
05/20	0018	22.5	45
05/25	0027	33.75	67.5
07/25	0036	45	90
07/30	0048	60	120
10/30	0072	90	180
15/30	0108	135	270
20/30	0144	180	360
30/30	0192	240	480
30/50	0288	360	720

*) with single elements; for multiple housings ask your Donaldson service engineer

To calculate the max. steam flow $\dot{m}$ at different temperatures, please use the following correction factors.

Table 7

Pressure [bar abs.]	1	2	3	4	6	10
Saturated Steam temperature [°C]	100	121	134	140	160	180
Correction Factor	0.5	1	1.5	2	3	5

4.3.1 Example calculation

A fruit tank of 1000 l volume and a mass of 300 kg should be sterilized at 141°C. Maximum allowable differential pressure for the tank is 100 mbar. The operating temperature is 5°C. The steam is led into the tank and further into the vent filter housing, which is a PG-EG 0018 with a P-SRF N 05/20. The mass to be heated is 300kg + 1.7kg = 301.7 kg. The steam should be filtered with a P-GS 5 µm.

With the above formulas, there is

$$\dot{m}_S = \frac{m_F \cdot c_p \cdot \Delta t \cdot 0.7 \cdot 3600\text{sec}}{\Delta h_v \cdot 0.6 \cdot 180\text{sec} \cdot 1\text{h}} = m_F \cdot \frac{\Delta t}{\Delta h_v \cdot 1\text{h}} \cdot 11.13 = 301.7\text{kg} \cdot \frac{136\text{K}}{2140\text{kJ/K} \cdot 1\text{h}} \cdot 11.13 = 213.4 \frac{\text{kg}}{\text{h}}$$

With a look into the P-GS sizing table (Table 6), the appropriate steam filter size is a P-EG 0108 with an element P-GS 15/30.

For this filter combination the resulting pressure drop is in the range of 0.05 bar, the amount of condensate built up 3 kg/hour and the steam velocity 13 m/s (the maximum steam velocity inside a piping system should not exceed 25 m/s).

5. Steam sterilization of filter cartridges

For many filter users and applications it is mandatory that filter cartridges be sterilized with steam, either in situ (Steam in Place, SIP) or ex situ. Especially for SIP, the design of the sterilization procedures, including factors such as steam temperature and quality, condensate removal, differential pressure and cooling cycles, need to be considered carefully. If they are well adapted to the production facilities the following can be minimized: operator hands on time, plant downtime, contamination by filter cartridges through the opening of housings and element failure due to excessive stress. The procedures can be easily incorporated into automated production facilities.

The detailed recommendations given in this document give advice on how to achieve reproducible and definite sterilization conditions. They should help to avoid accidental damage to cartridges and installations and maximise the service lifetime of all installed filters.

It should be noted, however, that the procedures described here may require modification for the on-site conditions.

5.1 General steam sterilization procedures

The entire sterilization time is calculated on the basis of the heating-up and cooling-down phases. This is made clearer by an example time and temperature diagram:

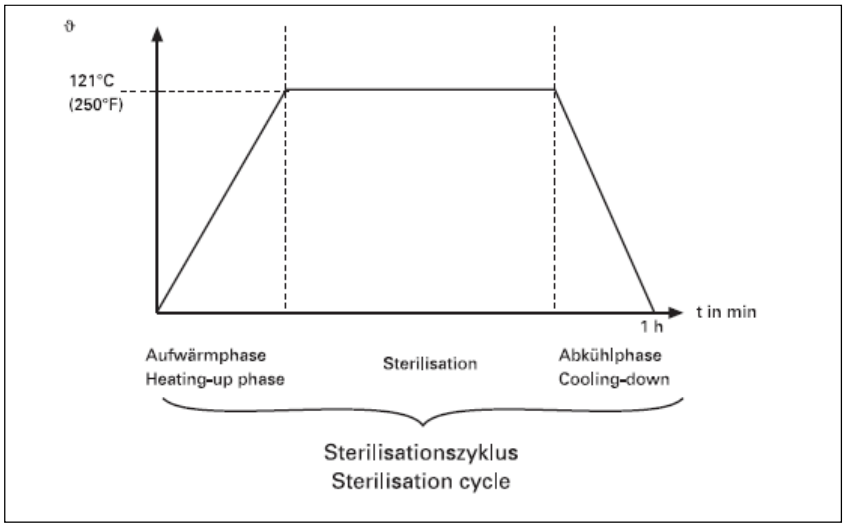


Figure 4: standard sterilization cycle

The entire sterilization cycle here is covered within 1 hour. The distribution of the sterilization time and the heating-up and cooling-down phases depends on the temperature ϑ. The following are recommended values that have to be adjusted to the specific installation:

Table 8

ϑ	Sterilization time	Heating-up and cooling-down phase	Time for sterilization cycle
121°C	30 min.	30 min.	60 min.
131 – 134	20 min.	40 min.	60 min.
141	10 min.	50 min.	60 min.

5.2 Cartridge filter steam life

During filter cartridge development, all Donaldson filters undergo extensive steam sterilization verification. They are sterilized at different temperatures and with different standardised procedures and are integrity tested at regular intervals in between the sterilizations.

The resulting maximum steaming time plus a safety margin give the steam life for the cartridge type. Donaldson gives no warranty on this steam life, as the final steam life at the installation depends on several parameters that should be known for the process used or determined and optimised on the basis of experience or process validation steps:

Sterilization:

- sterilization temperature
- time of a sterilization cycle
- steam treatment
- pH value of the steam
- automatic or manual valve guide
- method and duration of cooling after sterilization
- method and duration of drying after sterilization
- amount of steam flowing through the element during sterilization

Filtration:

- design of the filter (flow rate)
- absolute pressure, pressure variations
- pre-filtration
- length of use of the filter cartridge or the pre-filtration process respectively
- contamination of the filter surface
- drying behaviour of the filter

The filter steam life, determined at Donaldson under standardised lab conditions, is stated in the technical data sheet for each single filter type.

5.3 Integrity testing

It is recommended that filter cartridges are integrity-tested in situ or ex situ in regular intervals. Even the most carefully controlled sterilization as well as the normal use will lead to gradual deterioration of the filter which must be monitored to avoid contamination of the process.

5.3.1 DOP Test

The DOP Test (formerly Dioctyl-Phtalate, now Dispersed Oil Particles) is a test during which paraffin oil droplets are dispersed in a nozzle to a size of about 0.2 µm and transported to the filter in a clean air flow. The concentration of oil particles is measured before and after the filter, giving a retention efficiency for the filter element in percent. If that efficiency is ≥ 99.99998%, the filter is intact and can be used as a sterile filter. This test is used for depth filters only.

To get a correct measurement, it is important that the filter is dry during testing. The test device can not differentiate between water droplets coming from the filter cartridge and oil droplets and will give a faulty measurement result for wet filters. This should be noted especially when steam sterilized filter cartridges are DOP tested immediately after the steam sterilization process.

Donaldson offers a Filter Test Center (FTC) for fast and reliable integrity tests based on DOP measurements for depth filters.

5.3.2 Bubble Point Test

The bubble point test is used for membranes only. Prior to the test the elements need to be wetted with a suitable wetting agent. Then the filter cartridges will be exposed to air or nitrogen. By increasing the so called transmembrane pressure a proportional increase of a diffusive Gas flow through the wetted filter pores can be monitored. By a further increase of the pressure applied, the thin liquid layer in the membrane pores will be dislodged and the gas flows through, building bubbles. This range of the applied pressure correlates with the Bubble Point Range of this specific filter element. Since the Bubble Point is depending on the pore size it can be used to verify the integrity of the element tested.

Donaldson offers the integrity tester “Membra – Check” for fast and reliable Bubble Point, Forward Flow, Pressure Hold and Water Intrusion Tests for membrane filters.

For additional advice on integrity testing of filter cartridges or further information on the Donaldson integrity test devices please refer to your Donaldson sales engineer or service technician.

5.4 Steam quality

Several contaminations as well as installation design features can lead to reduced filter life. Abrasive particles coming from corroded piping and large amounts of condensate that are forced through the filter cartridge are prevalent failure causes. Particles tend to punctuate or block the filter, while condensate in combination with elevated temperatures causes maximum stress on the filter media, increased pressure drop and eventually even complete collapse or burst of the filter element.

- use dry steam, which can flow easily through the filter
- use a manual condensate valve or a steam trap to remove all condensate from the filter housing an the pipes
- avoid all condensate contact with the filter
- use Donaldson steam filters to clean the sterilization steam from particles that can collect in the lines

- avoid wet steam, which will not flow easily through the filter (contains lots of condensate); this increase of pressure drop together with elevated temperatures causes excessive stress on the filter element
- don't eliminate costs by ignoring particulate filters; the particles in the steam can block or puncture the filter that is steam sterilized
- don't use aggressive chemical additives in the steam; these can damage the filter to be sterilized

6. Insertion of filter cartridges

To avoid contamination of the filter cartridges and housings, the following handling rules should be followed:

- Before opening the sterile goods packaging, thoroughly disinfect hands.
- Open the packaging only immediately before use.
- Do not talk while opening sterile packaging, do not cough over sterile goods, etc.
- If necessary, use gloves and mouth protection.
- Do not push the sterile goods through the foil packaging, open the packaging using scissors.
- If moisture has built up inside the packaging after autoclave sterilization and storage, this is not considered "sterile contamination" but the filter must be considered non-sterile and be returned to sterilization.

Please note that all Donaldson (sterile) filters are delivered unsterile in unsterile packaging! Please sterilize the filter elements before first use if needed for the application.

7. Steam in Place

The following sections in this guide provide step by step procedures for developing SIP protocols in three operational conditions, i.e. forward flow for liquid filters and forward or reverse flow for gas filters.

Table 9

	forward flow	reverse flow
asymmetric liquid membrane	procedure 7.1	*not recommended*
symmetric liquid membrane	procedure 7.1	*not recommended*
asymmetric gas membrane	procedure 7.2	procedure 7.3
symmetric gas membrane	procedure 7.2	procedure 7.3
gas depth filter	procedure 7.2	procedure 7.3
liquid depth filter	procedure 7.2	procedure 7.3

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 your Donaldson sales engineer.

- the differential pressure across the filter should not exceed 0.2 – 0.3 barg in forward SIP and 0.1 barg in reverse SIP
- the steam pressure should be about 300 mbar above the required saturated steam pressure
- the steam pressure/temperature must not exceed the maximum allowable pressure/temperature for the cartridge type being steamed
- conditions of temperature and pressure should stay at a constant level

7.1 Forward Steam-in-Place Procedure Liquid Filter Applications

For liquid filters, the forward SIP is always the recommended procedure. Most liquid filters have an asymmetric membrane or depth filter media that is rather open to flow in the forward direction but restricts flow in reverse direction. That can lead to high pressure drops in steam sterilization and a possible damage to the filter element. Further, the steam could transport particles on the clean side of the filter if inserted in the reverse direction.

If membrane filters are sterilized, they must be wetted with water first. The vent valve V5 of the filter housing is opened and the housing filled with fluid (water or other medium). The vent valve is closed and the membrane is rinsed with the liquid (in the direction of filtration!) under a pressure of 0.3 bar for 5 min. Afterwards, the liquid is released from the housing by

the drain valve V4. This can be done by using pressurised air or nitrogen with a maximum pressure of 0.5 bar or by opening the vent valve V5. The filter is now wetted and can be steam sterilized.

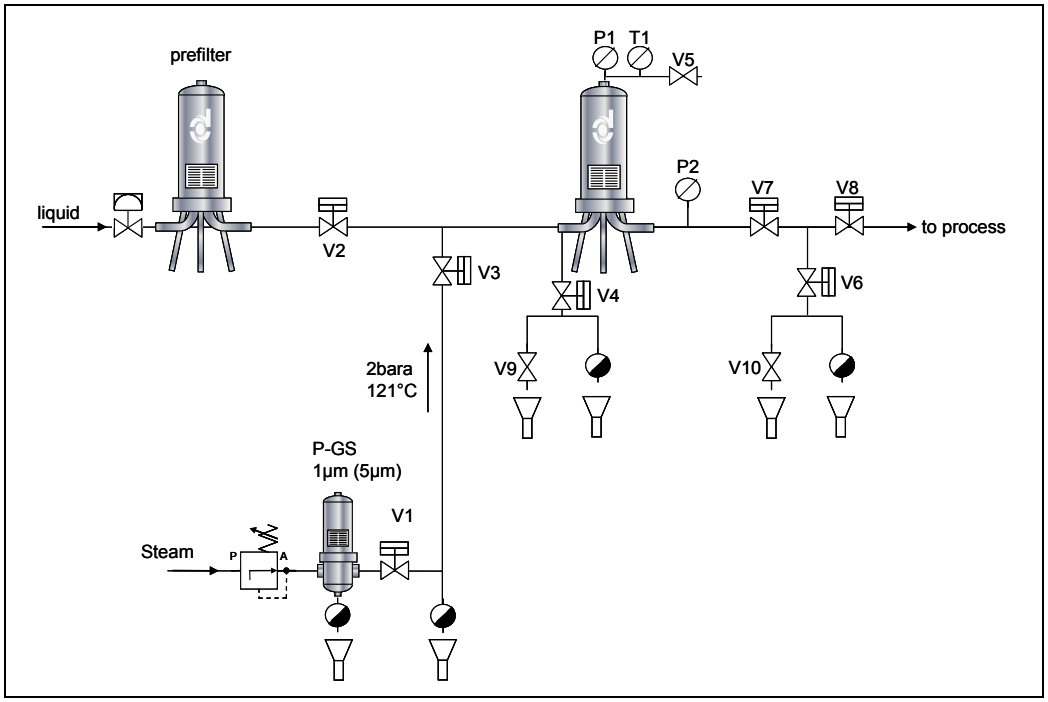


Figure 5: Forward steam in place procedure for liquid filters

1) Open valves V4, V6, V7, V9 and V10.
2) Drain the product from the filter system and associated piping. 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 piping without generating a significant differential pressure across the filters.
5) When 'live' steam flows from valve V5 and T1 shows sterilization temperature, close valve V5. This will direct the steam through the heated filter. Close valve V10.
6) Observe the pressure gauges P1 and P2, control the steam flow rate at valve V3 and set the sterilization steam pressure to ca. 300 mbar above the required saturated steam pressure (P1).
7) Ensure that the differential pressure between P1 and P2 does not exceed 0.2 - 0.3 barg.
8) When the steam trap below valve V6 closes, the steam pressure will begin to rise.
9) Steam sterilize the cartridges for the time specified ensuring the conditions of temperature and pressure stay at a constant level.
10) On completion of the Steam-In-Place cycle, close V4, V6, V3 and V1 in that order.
11) Slowly open V10 to release the steam pressure from the filter system and associated piping. 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.

Remarks:

- A double downstream valve is recommended so that under the cartridge steaming protocol the valves sealing faces of V7 can be effectively sterilized. The sealing valve faces of V8 can be similarly sterilized when the tank is steamed. When steam sterilising the tank, V7 would be closed and V6 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 V7 is closed in the post Steam-In-Place settings to maintain sterility. The valve V7 must be closed during Step 10.
- Valve V7 should be installed horizontally and valve V6 / steam trap installed immediately downstream of V7.
- All drains should be fitted vertically to allow liquid removal.
- Large volume downstream systems should not be steamed through the filter; e.g. when steaming process tanks a secondary steam supply should be used.

7.2 Forward Steam-in-Place Procedure Air Filter Applications

The forward SIP procedure is suitable and the best choice for all gas filters. The steam is always inserted on the unclean side of the filter keeping possible particle contaminations out of the process.

For the steam sterilization of sterile air depth filters or membrane filters it is not necessary to wet the filter element.

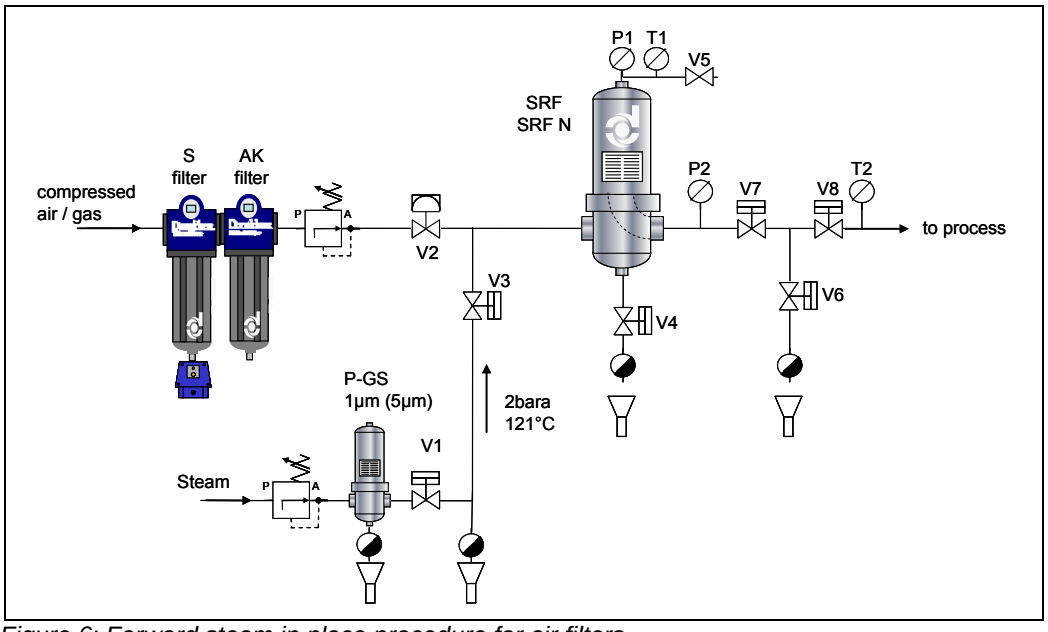


Figure 6: Forward steam in place procedure for air filters

1) Open valves V4, V5, V6, and V7
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 the heating of the housing, the filters and associated piping without generating a significant differential pressure across the filters.
4) When 'live' steam flows from valve V5, close valve V5. This will direct the steam through the heated filter.
5) Observe the pressure gauges P1 and P2, control the steam flow rate at valve V3 and set the sterilization steam pressure to ca. 300 mbar above the required saturated steam pressure (P1).
6) Ensure the differential pressure across the filter 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) 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.
9) Steam sterilize the cartridges for the time specified ensuring the conditions stated in steps 5 to 7 are followed.
10) On completion of the Steam-In-Place cycle, close V4, V6, V3 and V1 in that order.
11) Fully open V5 to flash-dry the filter (or 11).
12) 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.
13) Allow the system to cool for 15 minutes, then close V5 (flash-dry only).

Remarks:

- A double downstream valve is recommended so that under the cartridge steaming protocol the valves sealing faces of V7 can be effectively sterilized. The sealing valve faces of V8 can be similarly sterilized when the tank is steamed. When steam sterilising the tank, V7 would be closed and V6 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 V7 is closed in the post Steam-In-Place settings to maintain sterility. The valve V7 must be closed during Step 10.
- Valve V7 should be installed horizontally and valve V6 / steam trap installed immediately downstream of V7.
- All drains should be fitted vertically to allow liquid removal.
- Large volume downstream systems should not be steamed through the filter; e.g. when steaming process tanks a secondary steam supply should be used.

7.3 Reverse Steam-in-Place Procedure Air Filter Applications

As an alternative to a forward flow steam sterilization in some cases a reversed flow steaming seems even more appropriate. While depth filters usually stand a reversed flow steaming without any problems a certain attention is to be paid to membrane filters which are more sensitive towards this SIP procedure. Additionally the steam quality must be closely monitored in this procedure to avoid contamination with particles on the clean side of the filter.

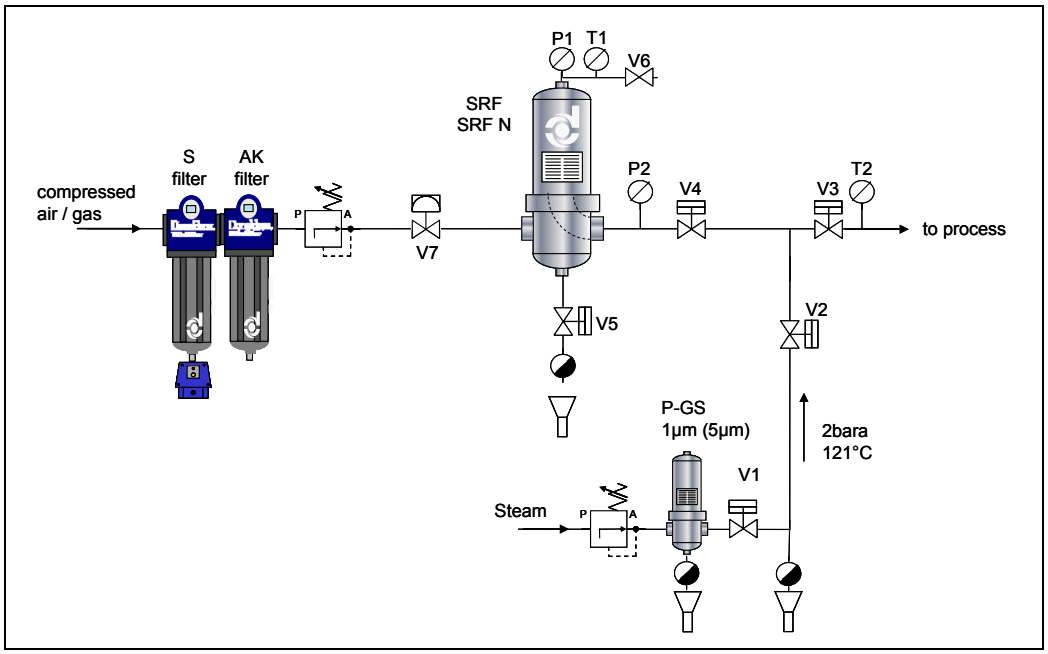


Figure 7: Reverse steam in place procedure for air filters

1) Open valves V4, V5 and V6
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 differential pressure across the filter does not exceed 0.1 barg. If it exceeds 100 mbar stop the sterilization procedure and rectify the cause of the pressure drop before proceeding with the sterilization routine.
5) When live steam flows from valve V6, close valve V6. 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 differential pressure using gauges P1 and P2. If it exceeds 100 mbar stop the sterilization procedure and rectify the cause of the pressure drop before proceeding with the sterilization routine.
7) Steam sterilize the cartridges for the time specified.
8) On completion of the steam cycle time, close V4, V2, V1 in that order.
9) Rapidly open V6 to flash dry the filter (or step 10).
10) Open V7 slowly to allow 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 V6 (flash-dry only).

Remarks:

- A double downstream valve is recommended so that under the cartridge steaming protocol the valves sealing faces of V7 can be effectively sterilized. The sealing valve faces of V8 can be similarly sterilized when the tank is steamed. When steam sterilising the tank, V7 would be closed and V6 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 V7 is closed in the post Steam-In-Place settings to maintain sterility. The valve V7 must be closed during Step 10.

- Valve V7 should be installed horizontally and valve V6 / steam trap installed immediately downstream of V7.
- All drains should be fitted vertically to allow liquid removal.
- Large volume downstream systems should not be steamed through the filter; e.g. when steaming process tanks a secondary steam supply should be used.

7.4 Alternative Steam-in-Place Procedures Air Filter Applications

The following figures show alternative reverse steam in place procedures. If controlled closely, these are alternatives to the above explained and recommended procedure.

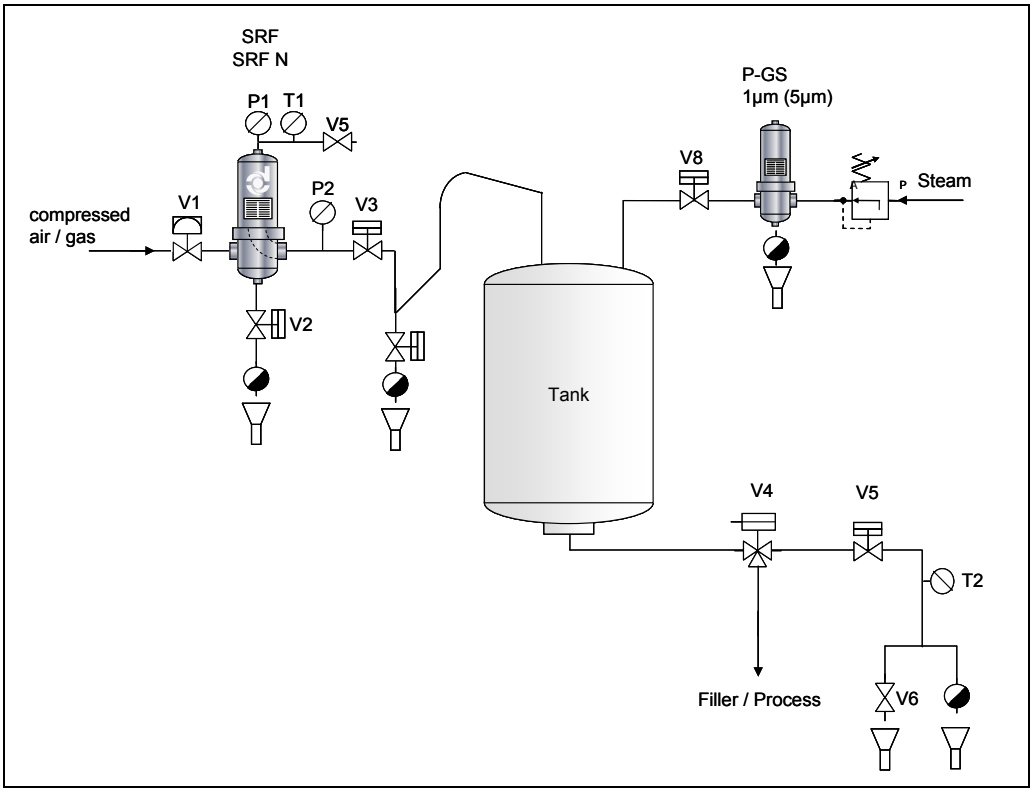


Figure 8: Reverse steam sterilization of compressed air / gas filter via tank

In this procedure, the filter is sterilized together with the tank and the piping leading to the process (e.g. a filler). It is important to carefully control the process so that not all of the steam volume is forced through the filter. Further, there should be an aseptic valve (V3) and a siphon between filter and tank to prevent the intrusion of chemicals during the CIP procedure.

7.5 Drying procedure

The filter elements will contain a certain amount of humidity after steam sterilization and must be dried to get their optimum performance values. Depending on the type of filter, this drying process can take some minutes and will lead to a temporary increase of differential pressure. The more humidity a filter contains, the lower should be the volume flow of (compressed) air at the beginning of the drying process. It can be increased to operating conditions as soon as the filter is dry. The high differential pressure during the first seconds can easily lead to a damage of the filter, e.g. cracks in the filter media due to increased mechanical stress.

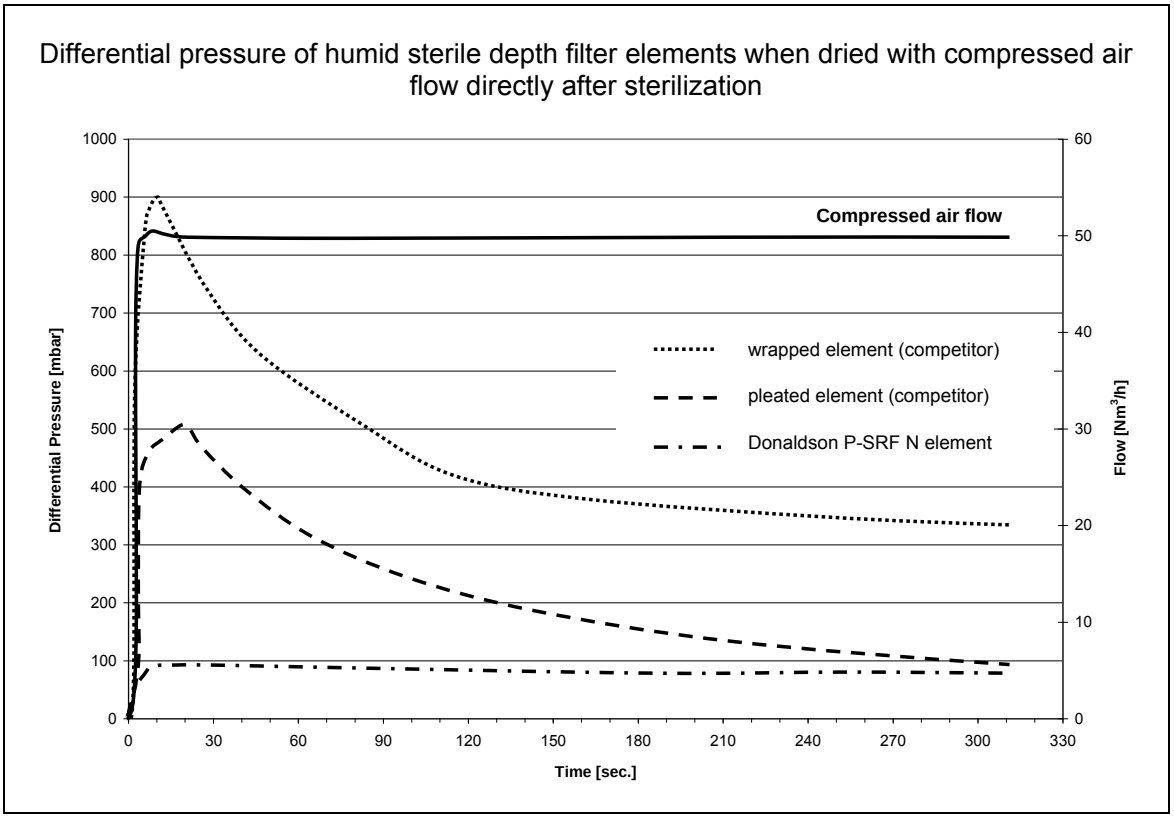


Figure 9

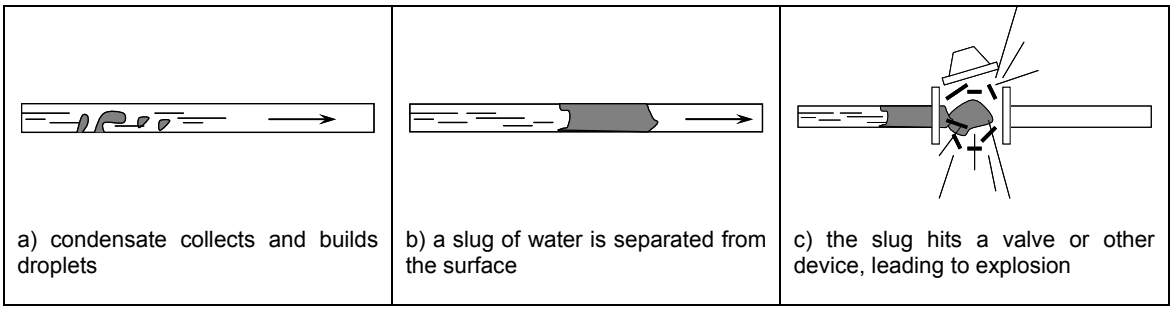
8. Installation of Filters / System design

Even though the steam sterilization of whole production systems is not a new technology, potential errors may happen during design or handling of the systems. These can have severe effects on the filters installed but also on other parts of the installation. In addition to reduced service life time of the filter elements to be sterilized, potentially higher costs due to repair and maintenance design and handling errors might also have a severe impact on health and safety of the personnel.

This section gives some advice on how to install filters correctly and which mistakes in the design of a system could lead to filter failure.

8.1 Condensate removal

Whilst saturated steam behaves as a gas and so flows easily through filters, contact with any cool surface (e.g. stainless steel housings or piping) will lead to the generation of condensate as the steam cools. Especially at the beginning of a steam sterilization, all surfaces have to heat up to the desired sterilization temperature. During this period, large amounts of the steam are transformed into condensate. Depending on the steam temperature, the size and isolation of pipes, tanks or other devices, very large volumes of condensate may be generated due to this process.



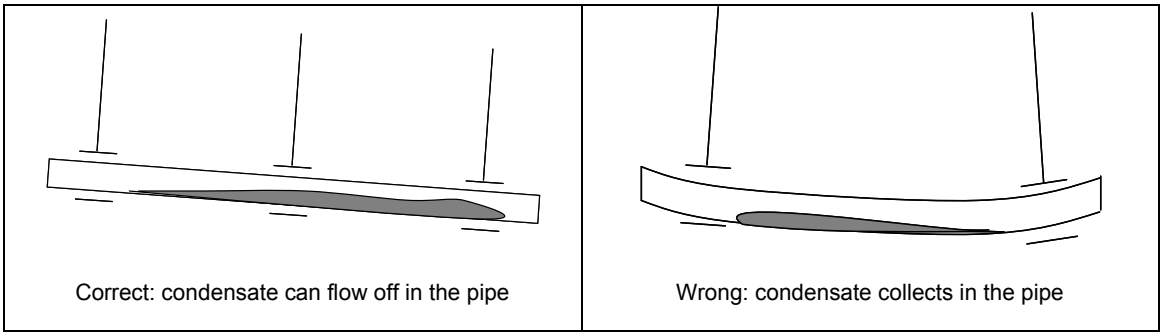
a) condensate collects and builds droplets

b) a slug of water is separated from the surface

c) the slug hits a valve or other device, leading to explosion

Figure 10

If this condensate collects at the bottom of pipes, e.g. due to a sagging pipe, it will be transported in the flowing steam later on. The condensate forms into big drops that travel with high speed in the steam. Velocities can easily reach 20 m/s (that is 72 km/h). If the drops collide with this speed on a valve, elbow or other device, they can induce a local pressure of several thousand bar, crushing steel easily and resulting in severe damage to people and devices.



Correct: condensate can flow off in the pipe

Wrong: condensate collects in the pipe

Figure 11

In addition to this, condensate can have several effects on filters. Even the smallest droplets of condensate, travelling in the steam, can cause damages to filters that are steam sterilized. They can disrupt membranes as well as depth filters if the velocities are too high. Combined with poor steam pre-treatment (e.g. particles in the steam), the filter is subject to a real barrage. The best filter will not stand such a treatment for a long time.

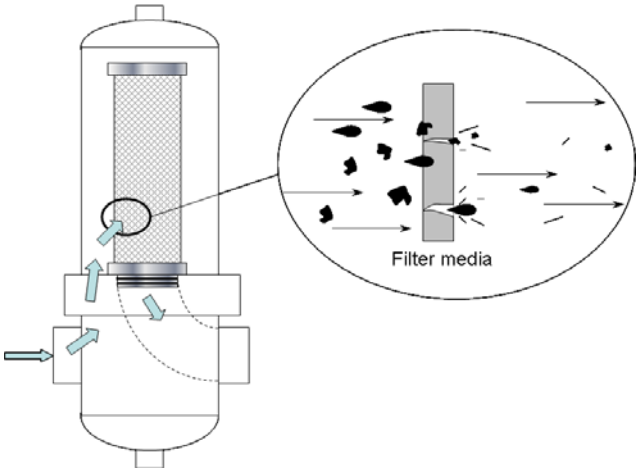


Figure 12: Condensate droplets or particles can cause damages to the filter, possibly followed by contamination of the process.

- 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.

- use steam traps or condensate drains in the housing and in the piping; locate them at the points up- and downstream where condensate would collect (low points)
- install all piping at a slight incline (1:100 – 1:200), allowing gravity to collect the steam condensate at a steam drain or steam trap
- install the filter housing in normal vertical direction, filter opening pointing downwards so that condensate can not accumulate inside the filter element
- install filters at the top side of tanks where they will be sterilized together with the tank
- minimize steam flow rates through the filter
- remove as much steam as possible from the system post SIP to avoid building of excessive amounts of condensate
- control the cooling of the filter elements after sterilization to avoid blinding of the filters through condensate (most important with hydrophobic gas filters)

- avoid sterilising downstream tanks, long piping or filters through the filter as steam flow is too high
- don't use a simple valve for condensate removal if there is no skilled operator to control flow through the valve (effective condensate removal without draining excessive steam)
- don't install filters at the lower end of piping leading to the top side of a tank or other device; the piping will fill with condensate during tank or filter sterilization and drown the filter, possibly causing damage to the filter cartridge
- avoid installing long piping; it will result in pressure drop in the pipes and in increased amounts of condensate build up

8.2 Steam pre-treatment

As mentioned above, particles in the steam can cause damages in the structure of filter cartridges, punching holes into the filter matrix. Further, particles collecting in the filter will lead to flow restriction and finally to a blocking of the filter. This pressure drop on the filter, combined with high temperature during sterilization, will lead to a weakening of the filter structure and in the worst case to a destruction of the filter.

In addition, it is best to avoid all kind of particle sources in the installation.

- install steam pre-filters
- use filtered supply water
- run maintenance on steam generators in regular intervals
- use equipment (piping etc.) made of stainless steel

- avoid installing piping made from carbon steel
- don't use filters that are blocked with particles; during sterilization, filters are stressed significantly through elevated temperatures; high differential pressure can damage the filter

8.3 Miscellaneous design rules

In addition to the points mentioned above, there are several rules that should be followed to get an optimised filter installation, resulting in optimised service life.

- apply steam from the upstream side of the filter (normal flow direction) if sterilizing membrane filters
- limit differential pressure on the filter during sterilization to max. 0,3 barg
- minimize downstream piping steamed through the filter cartridge
- measure and control temperature during sterilization
- measure and control pressure drop during sterilization
- install a vent valve at the top of the housing to let out air at the beginning of the sterilization; remaining air will lead to a decrease of the temperature inside the housing and can lead to incomplete inactivation of micro-organisms

- don't apply steam from both sides of the filter at the same time; it can potentially trap air pockets that reduce heat transfer and negatively impact sterilization conditions

8.4 Pipe design

In an installation with steam sterilization procedures, the pipes, tanks and all other devices are subject to frequent temperature changes. Steel pipes change their length with about 0.011mm per meter length and °C temperature change. In a pipe of 10 m length, the heating from 40°C to 140°C will lead to a lengthening of 11mm.

$$(L_2 - L_1) = 0.011 \cdot L_1 \cdot (t_2 - t_1) mm$$

To avoid damage, it is necessary that all pipes have expansion joints as well as loose and fixed bearings.

Further, all pipes must be installed with a decline of 1:100 – 1:200 to allow free flow of condensate to the condensate drains.

8.5 Potential design and handling errors

In the following some design and handling errors are listed which may dramatically shorten the service life time of the filter(s) to be sterilized.

8.5.1 Miscellaneous mistakes

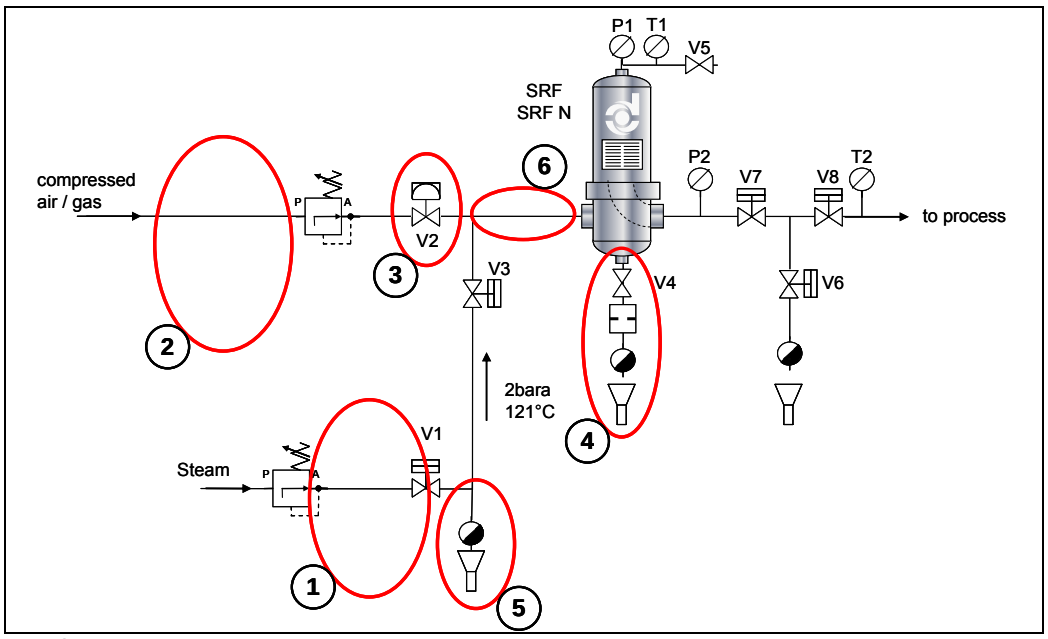


Figure 13

(1) no steam filter installed; this can lead to high particle load of the sterile filter and increase of differential pressure

(2) bad compressed air quality; this can lead to high particle load of the sterile filter and increase of differential pressure

(3) too high flow rates at drying after sterilization; this can lead to damages by pressure shock

(4) uncontrolled flow through the condensate drain of the filter housing; loss of steam and energy as well as excessive steam flow through the filter; danger of pressure shock

(5) insufficient condensate removal; this can lead to damages in the filter media when condensate is pressed through

(6) no isolation on the piping; that will lead to increased build-up of condensate and energy losses

8.5.2 Sterilization of tanks through the filter

If a device or a process is sterilized through the sterile air filter in front, steam flow might be too high. This may lead to increased differential pressure. To avoid that, insert steam between sterile air filter and tank. The filter will be sterilized in reverse flow during tank sterilization.

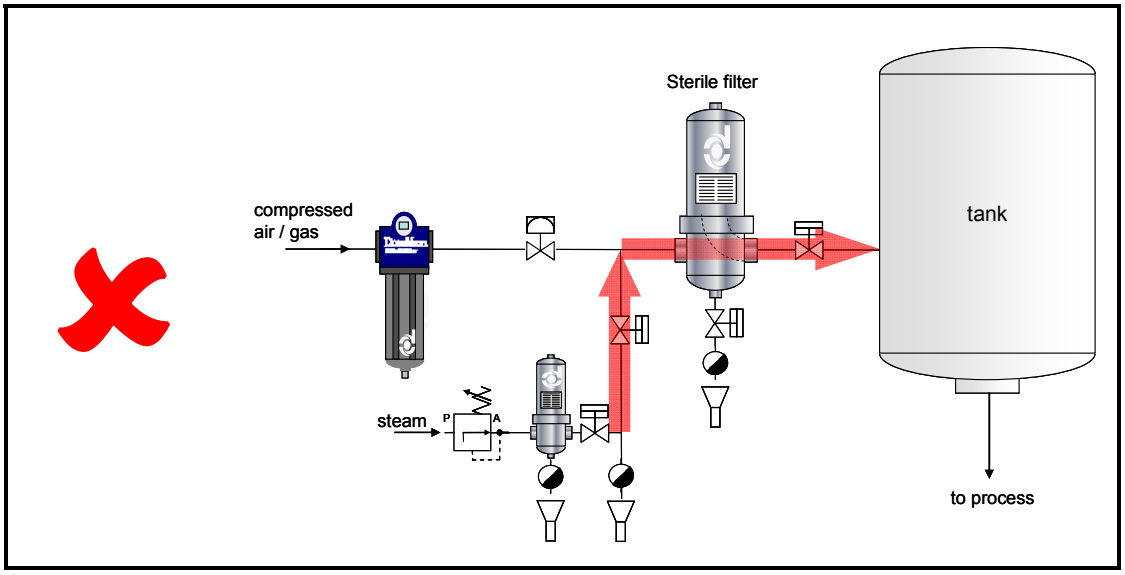


Figure 14

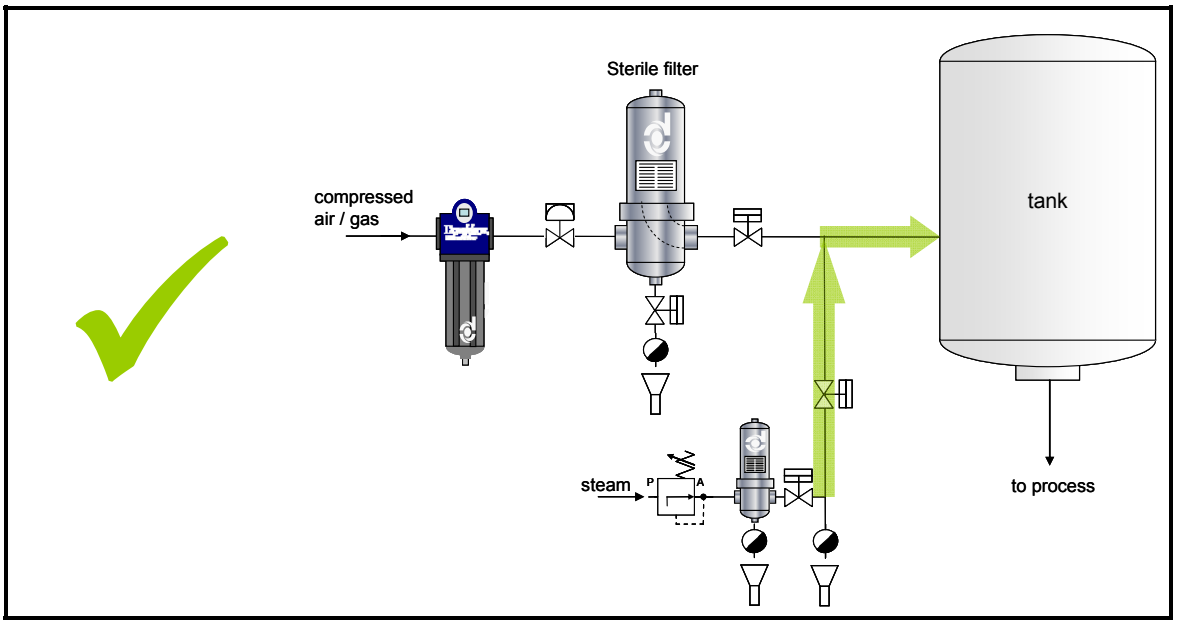


Figure 15

8.5.3 Condensate floods the filter housing

If filter housings are installed at the bottom of a pipe leading to the top of a tank without condensate removal, the filter will be flooded with condensate filling inside the pipe. That will rapidly decrease filter life, especially with a hydrophobic membrane filter.

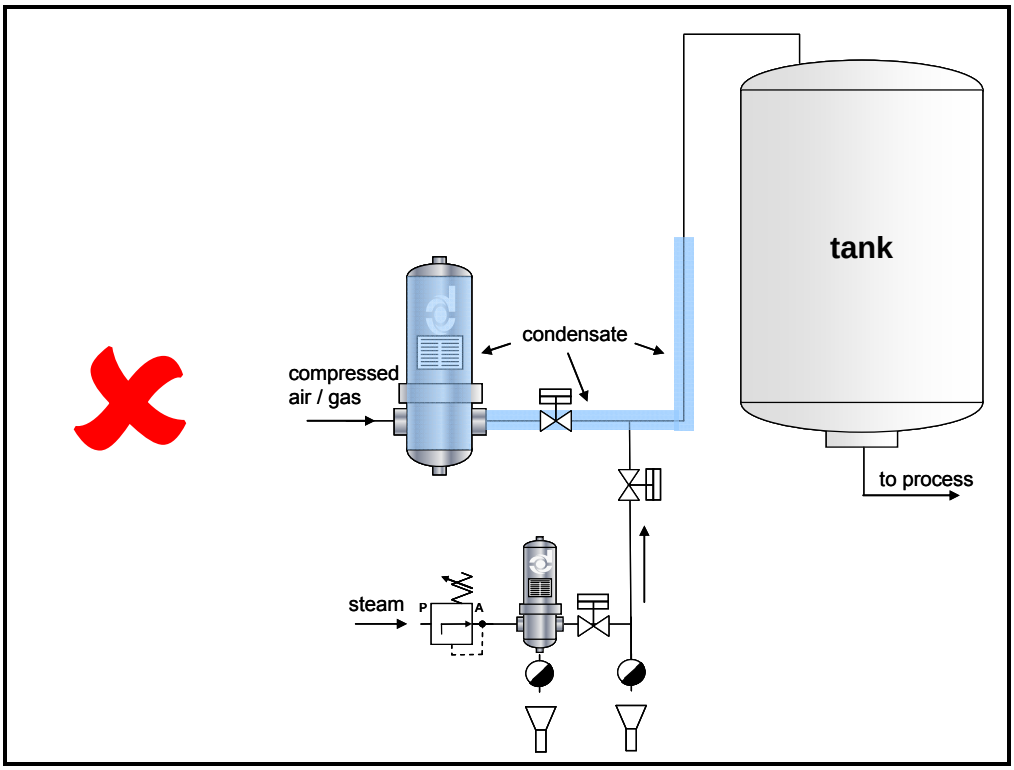


Figure 16

Installation of an aseptic valve with condensate drain or installation of the filter on top of the tank (protected by a siphon) will avoid this problem.

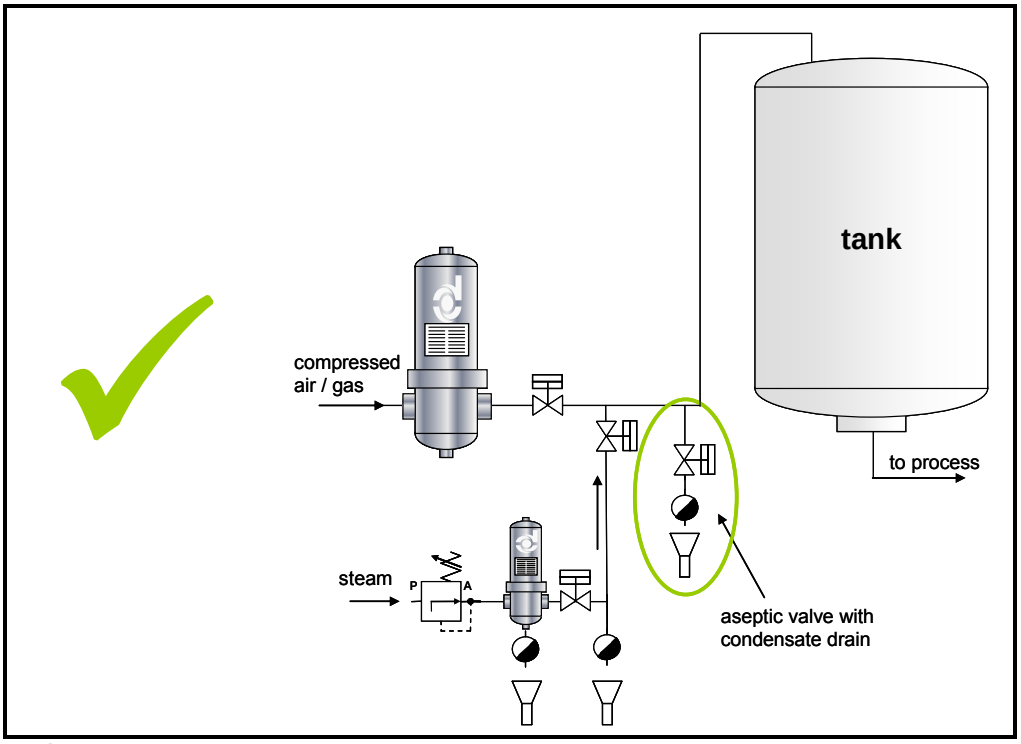


Figure 17

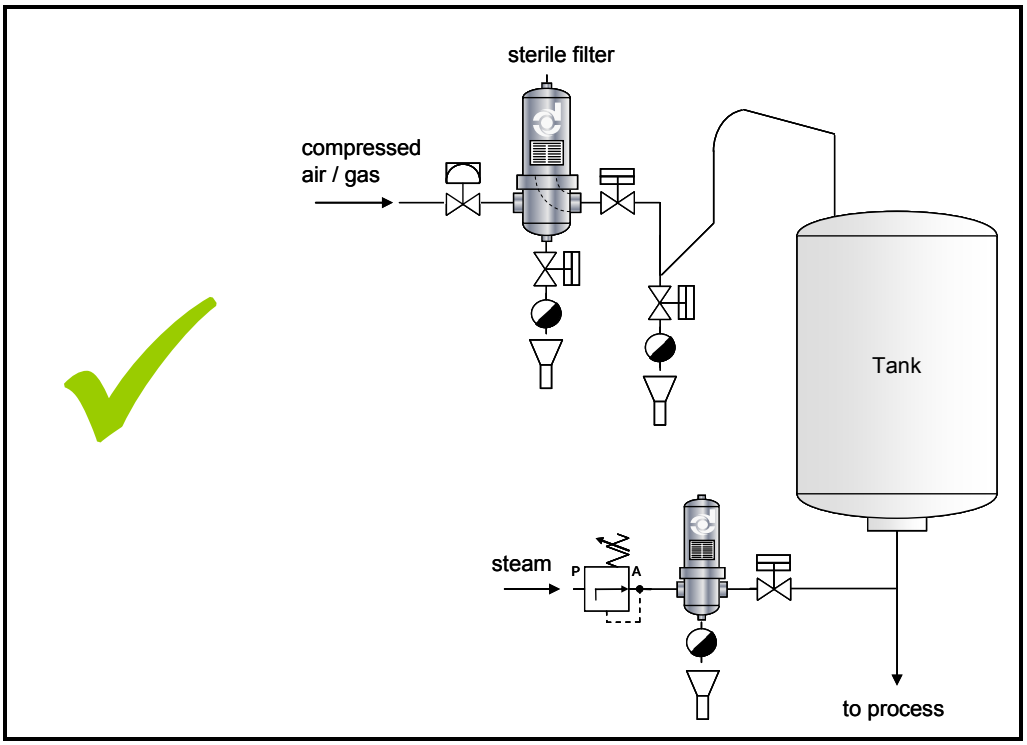


Figure 18

9. Autoclaving

Sterilization in an autoclave is a very gentle method of sterilization. Therefore, it is used for all filter cartridges with a low pressure resistance as well as for capsules.

Capsule filters must be completely wetted before the autoclaving process. This is implemented by closing the outlet, opening the ventilation valve and allowing clean water to run into the filter. Once the water starts pouring out of the ventilation valve, open the outlet and allow the water to run through the capsule filter for at least one minute (ca. 100 ml/min). The capsule is then emptied and packed in a bag or wrapped.

Single filter cartridges or capsule filters are wrapped in aluminium foil or autoclave bags/autoclave paper prior to sterilization, best with an indicator that shows a change in color when coming in contact with steam. Filter and housing can also be sterilized together, then the in- and outlet of the housing will be covered with aluminium foil.

Figure 19: Capsule filter in special sterilization bag; the indicator on the bag changes color when in contact with steam

Filters sterilized with aluminium foil cover or paper wrap should be installed immediately after sterilization. Only filters in autoclave bags can be stored for a longer period prior to use. Then the packaging must be rechecked for damages before installation. If there is moisture visible inside the packaging or if the packaging is damaged, the filter must be considered non-sterile and must be autoclaved again.

The sterilization temperature and sterilization time can be determined as described in chapter 5.1.

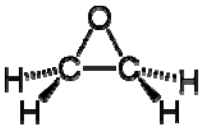
10. Alternative Sterilization Methods

In addition to steam sterilization, there are several other sterilization methods in use which are shortly noted in the following section.

10.1 Sterilization with Ethylene-Oxide (EO) / Oxiran

10.1.1 Physical-chemical properties

- Colorless gas with slight smell of ether
- Soluble in water, alcohol, blood and acetone
- Highly explosive (in air: 3 Vol% to 80 Vol% EO)



10.1.2 Principle of Function

- Strong protoplasm toxin
- Irreversible reaction with functional groups in protein side chains
- Deactivation of DNA & RNA through alkylation reaction

10.1.3 Methods

a) Vacuum method (DIN 58948 Part 1)

b) Cartridge gas sterilization

c) Evacuation (vacuum of p(abs) < 55mbar)

- Wetting (conditioning) to ca. 55-85% relative air humidity
- Open cartridge, introduction of sterilization gas (ca. 1400 mg)
- Sterilization with slight gauge pressure (<1 barg) and 50 – 60°C (90 min.)
- Repeated post-evacuation and purging while avoiding microbial contamination

d) Constant pressure method

e) Excess pressure method (DIN 58948 Part 2)

f) Conventional pressure method

- Gas: Cartox (10% EO, 90% CO2)
- Pressure: 3-7 bar
- Rel. air humidity: 55 – 85%

g) Sterivit method

- Gas: Cartox (10% EO, 90% CO2)
- Pressure: 6-7 bar
- Rel. air humidity: 70-80%
- Sterilization time: 20 – 40 minutes

For exact handling guidelines, please refer to the appropriate literature / suppliers

10.1.4 Relevant Handling Parameters

- Doubling the EO concentration halves the sterilization time
- Optimum sterilization effect at ca. 55°C (reduction in sterilization time with increasing temperature.)
- Sterilization goods must be wetted before applying the EO gas with a relative humidity at 55 – 85%
- Increase of 1 bar to 7 bar reduces sterilization time by up to 88%
- Packaging must be permeable to EO and water vapor

10.1.5 Toxicity

- MAK (Germany): 10ppm (~ 0.018mg/l breathing air)
- Inhalation: Dog LD100 = 710ppm
- Odour threshold: 700ppm

10.1.6 Miscellaneous Info

Handling

- Special exhaust equipment required for storage of EO-inert gas cartridges (DIN 58948 Part 6).
- Carcinogenic & mutagenic
- Systems must be explosion protected
- Specific disposal of waste gases
- Relatively long charging time for all methods

Effect

- No difference to heat methods for vegetative germs and spores
- Result dependent on many factors (conc., temp., pressure, moisture, etc.)

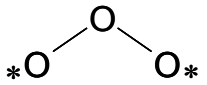
Residue problems

- Residues of EO in sterilization goods
- Formation of ethylene chlorohydrin in presence of products containing chlorine.

10.2 Sterilization with Ozone

10.2.1 Physical-chemical properties

- Colorless gas with characteristic odour
- Soluble in water
- Concentrated ozone-air mixtures are explosive



10.2.2 Principle of Function

- Irreparable oxidation of cell walls
- Oxidation and decomposition of fatty acids (arachidonic acids)
- Formation of peroxides with proteins and lipids

10.2.3 Relevant Handling Parameters

Ozone concentration

- From concentrations of 5µg/ml water, the extermination time is under 1 minute.
- Ozone distortion: Free ozone reacts with many substances
- Light effect: Ozone decomposes in light very rapidly
- Ozone works better at 0°C than 20°C (fungi: 5-10ppm at 0°C, 900ppm at 20°C)
- Antimicrobial effect optimal at pH=2, effect is just 1% at pH=7.8

10.2.4 Toxicity

- MAK (Germany): 0.1ppm
- Odour threshold: 1:100000
- Effective against both bacteria/spores (1-5 ppm) and fungi and viruses

10.3 Sterilization with Gamma Rays

10.3.1 Physical parameters

- X-ray irradiation
- Wavelengths: 10^{-6} to 10^{-5} µm
- Dose designation: 1 rad to 100 rad ~ 1 J/kg ~ 1 Gy (Gray)

10.3.2 Principle of Function

- Generation of radicals
- Irreparable damage to DNA/RNA

10.3.3 Toxicity

- Viruses > spore formers > gram-positive bacteria > fungi > gram-negative bacteria
- 99.999% of all vegetative bacteria with doses of 100,000 rad
- 100% only with 500,000 rad
- Micrococcus radiodurans (minced meat): 600,000 rad

10.3.4 Material Sensitivity towards Gamma Rays

Table 10

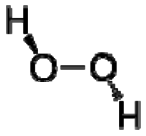
Product	Radiation sensitivity	Single sterilization	Multiple sterilization
HP polyethylene	Good	G	G
LP polyethylene	Good	G	G
Polypropylene	Limited	F	P
Polyvinyl chloride	Satisfactory	G	P
Polyamide	Weak to good	G	F
Polyethylenterephtalate	Good	G	G
Cellulose acetate	Satisfactory to good	G	P
Epoxy resins	Excellent	G	G
Polystyrene	Excellent	G	G
Polyvinylidene chloride	Weak	G	P
Polyvinyl acetate	Average	G	P
Acetal copolymers	Weak	P	P
Polycarbonate	Satisfactory	G	P
Polyether sulfone	Good	G	G
Polytetrafluoroethylene	Very limited	F	P
Polyvinylidene fluoride	Satisfactory	F	P
Polyurethane rubber	Excellent	G	G
Butadiene styrene	Good	F	F
Silicon rubber	Weak	P	P

(G=Good, F=Fair, P=Poor)

10.4 Sterilization with Vapor Phase Hydrogen Peroxide (VPHP)

10.4.1 Physical-chemical properties

- H_2O_2 is a colorless liquid
- weak acid with strong oxidizing properties, powerful bleaching agent



10.4.2 Principle of Function

- Denaturation of Proteins
- Oxidation and decomposition of fatty acids

10.4.3 Method

- use e.g. for sterilization of bottles, cups etc. in filling machines
- H_2O_2 solution is vaporized on a hot plate (180°C) and inserted into a (hot) air flow via venturi nozzle; concentration and gas flow temperature depend on the application
- alternative method used for autoclave chambers: VPHP is generated by heating 30% H_2O_2 solution and adding it to the chamber at 1ml/30sec.;after 50 min. at 55°C the concentration in the chamber reaches about 3mg/l and sterilization is complete and followed by aeration and cooling of the chamber

Donaldson P-SRF N filters are fully resistant against H_2O_2 in a concentration up to 33% for more than 50 hours and have been successfully validated for VPHP sterilization.

10.5 Chemical Disinfection

For Physical/chemical Properties and Principle of Function: see Table 11

10.5.1 Relevant Handling Parameters

a) The disinfection medium must have the highest possible specificity for the organism to be inactivated and the effectiveness must be proven!

b) The following effects on micro-organisms can be differentiated according to the effectiveness

- denaturation
- oxidation
- surface active

c) The effectiveness of disinfection is greatly influenced by the following points

- Efficiency range
- Action duration
- Concentration
- pH optimum
- Temperature
- Stability and durability
- Additional components present (tensides, proteins, catalysers, etc.)

For environmental reasons, chlorine and phenol-based disinfection media as well as aldehydes should be avoided.

A chemical disinfection is not an appropriate replacement for saturated steam Sterilization!

10.5.2 Method

a) Chemical disinfection of hydrophilic filter cartridges

- Rinsing with water after product filtration
- Rinsing with disinfection solution. Note concentration, temperature and contact time according to manufacturer instructions.
- Empty filter; dispose of disinfection medium.
- Depending on disinfection medium used: neutralise filter or rinse with water.

b) Chemical disinfection of hydrophobic filter cartridges

- Hydrophilisation of filter by rinsing with alcohol (ethanol / IPA 60:40)
- Rinsing with disinfection solution. Note concentration, temperature and contact time according to manufacturer instructions.
- Rinsing out of disinfection medium (neutralisation). Rinse out residues of neutralisation medium with water.
- Wet membrane with IPA/water (60:40); implement integrity test if needed.
- If IPA residues are unacceptable, the membrane must be rinsed again with water.
- Dry membrane by applying sterile compressed air (best warm up to app. 50°C).

Caution: When selecting the disinfection medium, note the chemical resistance of the membrane/medium.

Table 11: different chemical agents for disinfection and their properties

Active ingredient	Conc.	Action time	Effectiveness range	Application area	Advantages	Disadvantages
Aldhydes Formaldehyde Glutaraldeyhyde Glyoxal	0.5-5% aqueous solution	Hours	Practically complete effectiveness range	Formaldehyde: Room, equipment and surface disinfection Glutaraldehyde: Viruses	Stable, persistent, biologically degradable, material compatible	Resistance development, suspicion of carcinogenic effect for formaldehyde, harmful to health, mucous membrane irritant, inactivated by proteins, penetrates poorly into solid surfaces
Alcohols Ethanol Propanol Isopropanol	70-90% aqueous solution	up to 30 min. for viruses	Not effective against bacterial spores, relatively ineffective against non-lipiod viruses	Disinfection of small areas, hand and skin disinfection	Stable, material-safe, biologically degradable, partly skin compatible, only slightly inactivated by proteins	No sporicide effect, danger of fire and explosion, skin-degreasing, no depot effect due to rapid evaporation
Per-compounds Hydrogen peroxide Per-acetic acid Potassium peroxo monosulfate	0.02% aqueous solution	0.5-2 hours for viruses	Practically complete effectiveness range	Surface disinfection, liquid disinfection	Biologically degradable	Unstable, partly caustic, explosion hazard at >15%, transport and storage unpressurised
Halogens Sodium hypochlorite Chlorine dioxide Sodium chlorite	1-5% aqueous solution	10-30 minutes	Virucide, sporicide, not effective against various gram-positive bacteria and yeast types	Laundry disinfection, sewage disinfection, swimming pool disinfection		Unstable, poor biodegradability, waste water limit value 1 mg/l, mucous membrane irritant, corrosive on metals
Halogenated phenols m-cresol, p-chlorine-m-cresol p-chlorine-m-cylenol	0.1-5% aqueous solution	10-30 minutes	Relatively ineffective against spores, effectiveness gaps against viruses and	Disinfection immersion baths, abrasion and surface disinfection	Stable, persistent, material-friendly	Poor bio-degradability, harmful to health, corrosive

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(10) Donaldson Steam Filter Sizing Program

12. Appendix

12.1 Saturated Steam Table

Table 12

Pressure p_{abs} bar	Temperature t °C	Volume steam v" m^3/kg	Density steam ρ" kg/m^3	Heat content steam h" kJ/kg	Evaporatioon enthalpy Δh_v kJ/kg
1	99,63	1,694	0,590	2675,4	2257,9
1,1	102,32	1,549	0,646	2679,6	2250,8
1,2	104,81	1,428	0,700	2683,4	2244,1
1,3	107,13	1,325	0,755	2687,0	2237,8
1,4	109,32	1,236	0,809	2690,3	2231,9
1,5	111,37	1,159	0,863	2693,4	2226,2
1,6	113,32	1,091	0,917	2696,2	2220,9
1,7	115,17	1,031	0,970	2699,0	2215,7
1,8	116,93	0,977	1,023	2701,5	2210,8
1,9	118,62	0,929	1,076	2704,0	2206,1
2,00	120,23	0,89	1,13	2706,30	2201,60
2,50	127,43	0,72	1,39	2716,40	2181,00
3,00	133,54	0,61	1,65	2724,70	2163,20
4,00	143,62	0,46	2,16	2737,60	2133,00
5,00	151,84	0,37	2,67	2747,50	2107,40
5,50	155,46	0,34	2,92	2751,60	2096,00
6,00	158,84	0,32	3,17	2755,50	2085,00
7,00	164,96	0,27	3,67	2762,00	2064,90
8,00	170,41	0,24	4,16	2767,50	2046,50
9,00	175,36	0,21	4,66	2772,10	2029,50
10,00	179,88	0,19	5,15	2776,20	2013,60
11,00	184,07	0,18	5,64	2779,70	1998,50
12,00	187,96	0,16	6,13	2782,70	1984,30
13,00	191,61	0,15	6,62	2785,40	1970,70
14,00	195,04	0,14	7,11	2787,80	1957,70
15,00	198,29	0,13	8,09	2789,90	1945,20
16,00	201,37	0,12	8,58	2791,70	1933,20
17,00	204,31	0,12	9,07	2793,40	1921,50
18,00	207,11	0,11	9,56	2794,80	1910,30
19,00	209,80	0,10	10,05	2796,10	1899,30

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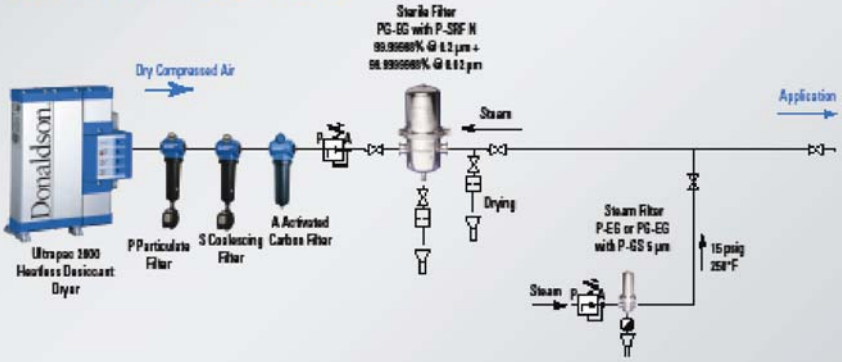

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