# STEAM IN PLACE (SIP)

A comprehensive overview of SIP, existing components, piping design, and the new technology used to reduce common problem occurrences

STERIFLOW

# WHAT IS **SIP?**

What are the rules and common piping practices employed to ensure that steam sterilization occurs on time without fail? What are SIP temperature validation alarms, or faults? Why do they occur? How does thermostatic steam trap operation affect the occurrence of temperature validation faults? What new technologies are available to mitigate common SIP problems?

Specific answers to these questions will be covered in this white paper. To begin, let's briefly review some fundamentals of process equipment steam sterilization (SIP), and the operating principles of sanitary balanced port thermostatic steam traps.

# FUNDAMENTALS OF
# PROCESS EQUIPMENT STEAM STERILIZATION

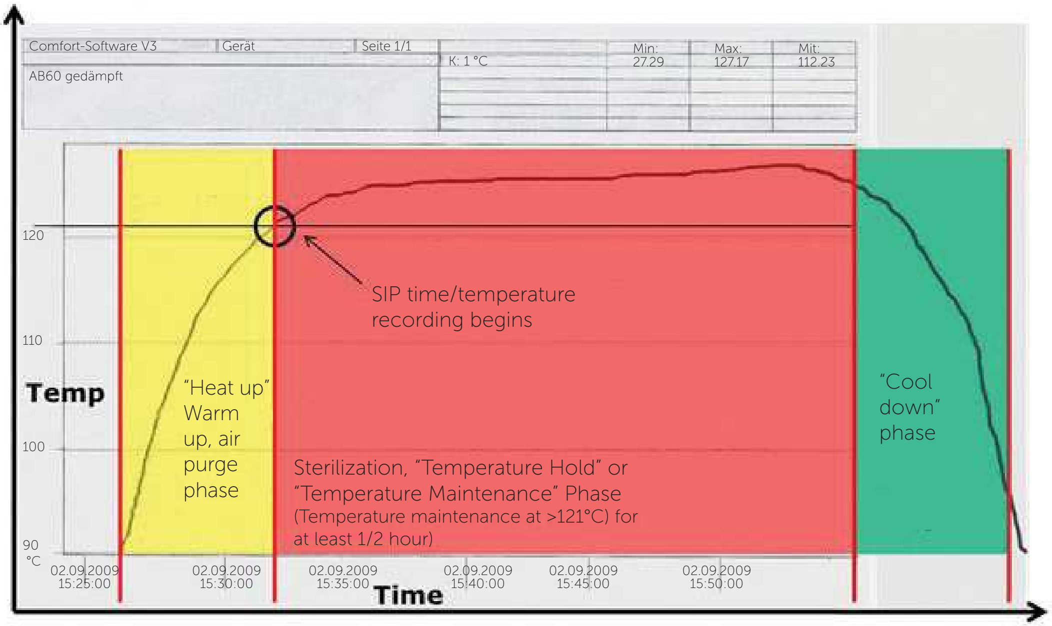


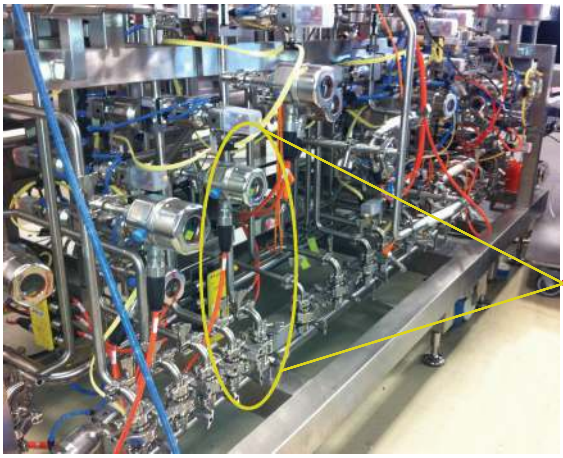

**Figure 1:** Time and temperature graph showing phases of Sterilization

SIP (Sterilize, or Steam In Place) is a timed sterilization of the upstream and downstream biopharmaceutical production train using clean steam. It is part of a 5 step sanitization routine that occurs after every production batch, and follows the final rinse after CIP (Clean In Place). SIP ensures that every square inch of the production train that comes in contact with drug substance inputs, drug substance, or the final drug product is "sterilized" to ensure that there is no microbiological activity in the system.

Clean Steam (made from USP Purified Water) is circulated through all of the process tubing during this stage, and enters large vessels through spray balls embedded in the vessel ceiling.

SIP is a temperature validated process, meaning that the sterilization event must be proven by measuring the temperature of the event and recording the data. The minimum sterilization regimen requires the injection of clean steam into all piping and vessels for at least 1/2 hour after they reach a minimum temperature of 250°F (121°C). If the temperature ever falls below 250°F (121°C) during the temperature hold period, a temperature validation fault is recorded, and SIP must be repeated.

Validation temperature sensors (usually RTD's) are placed at the condensate outlets of process equipment to make sure that the sterilization temperature meets the specific regimen designed for the process system. The sensing elements are usually designed with integral sheathes and Tri-Clamp™ connections and are clamped directly to tubing tees, or the element is inserted into a Tri-Clamp™ thermowell connected to the tee. The sensors are normally located twelve to eighteen (12 - 18) inches (300 - 450mm) upstream of the clean steam trap where the condensate exits the piping or vessel. See Figure 2.



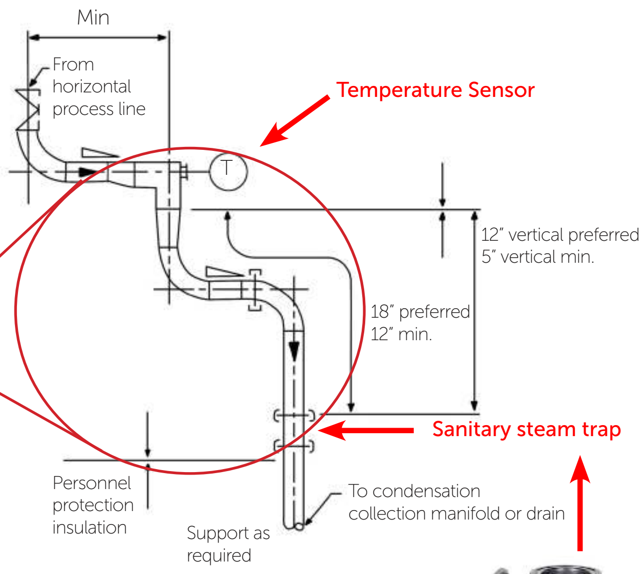
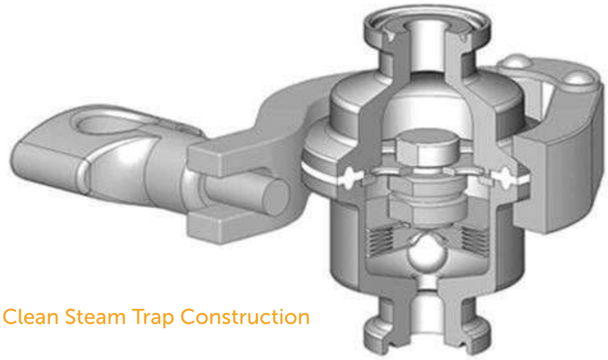



**Figure 2:** Typical validated condensate drain with steam trap

Recorded time/temperature data (like that in Figure 1) is stored in a PLC, Distributed Control System, or stand-alone database for later use by company quality engineers and auditors.

It is important to understand the information above before discussing how thermostatic steam trap operation can affect the occurrence of temperature validation faults.

# SANITARY BALANCED PORT THERMOSTATIC STEAM TRAP OPERATION



Clean Steam Trap Construction

Thermostatic traps operate like a thermostat (see cutaway illustration). As such, they are designed to close when the bellows senses saturated clean steam temperatures, preventing it from passing through the trap. Hence the name "steam trap". The closure occurs because the proprietary liquid/alcohol mixture inside the bellows vaporizes when it is exposed to clean steam temperatures. Pressure builds up inside the bellows expanding it and driving the attached plug (ball or conical tip) into the orifice at the trap outlet. The trap will stay in that closed position until the bellows temperature falls below steam saturation temperature. When that happens, the bellows contracts as the alcohol vapor condenses, lifting the plug off the seat and releasing any clean steam condensate that has collected upstream of the trap.

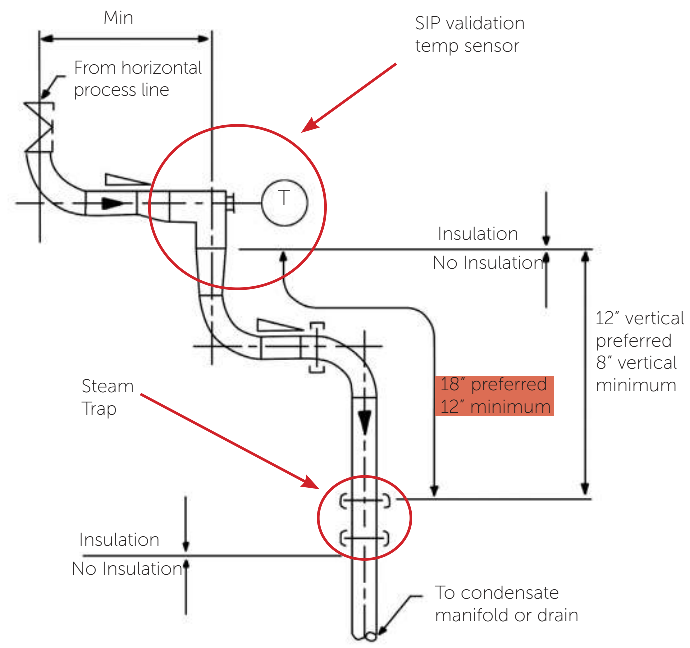



Figure 3

The condensate temperature when the bellows begins to contract, and the trap begins to open, is critical. That temperature, subtracted from the clean steam saturation temperature is called the traps subcool temperature. Subcooling in this context is defined as the number of degrees below saturation temperature that the trap begins to open. The lower the number the better because a lower number means less condensate will accumulate upstream of the trap. See Figure 3 for a typical clean steam drain piping illustration.

# VALIDATION TEMPERATURE ALARMS CAUSED BY HIGH SUBCOOLING TRAP OPERATION

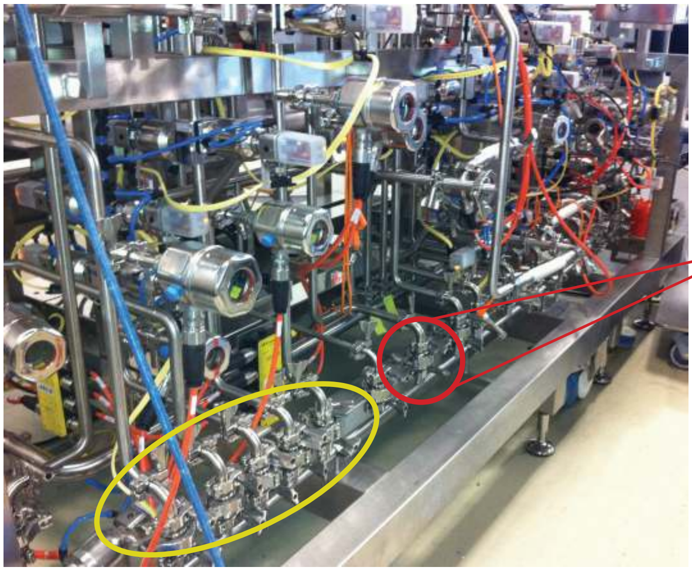
Most validation temperature alarms can be traced to two root causes. They are both related to condensate back-up upstream of the steam trap.

As discussed previously, all sanitary thermostatic traps require that a minimum length of tubing be installed between the trap inlet and the validation temperature sensor to account for this buildup of condensate. See Figure 3. The standard distance that has been adopted (evolved) in the industry is 12″ - 18″ (~300 - 450mm). If a thermostatic trap requires significant subcooling before the bellows begins to contract and open the trap, clean steam condensate will back up and build in the tubing upstream of the trap[1] and may wet and cool the validation temperature sensor. If that occurs during temperature maintenance (after the system heats up to ≥ 250°F (121°C)), a temp validation alarm will occur if the sensor is cooled by 1/2°C or more.

[1] Note that condensate backup is a common occurrence during heat-up, as the amount of condensate produced can be significant. However, temperature validation does not officially begin until after the system being sterilized reaches its validation design temperature at some point above 250°F (121°C). At that point, the amount of steam required to keep the system at temperature and the associated condensate load is dramatically less. Therefore, it is important to choose a trap that has enough capacity to handle the larger heat up loads but with a low enough subcooling operation so that condensate is never allowed to build in the tubing during the significantly lower loads that occur once the system has reached validation temperature (temperature maintenance period when system temperature is ≥ 250°F (121°C).

**High subcooling trap operation is one of the two most frequent causes of validation temperature alarms.**

# VALIDATION TEMPERATURE ALARMS CAUSED BY HIGH SUBCOOLING TRAP OPERATION



Sanitary thermostatic traps fail in the open position.

If this trap fails open, saturated clean steam will enter the condensate header during Temperature Hold. Header pressure will rise, lowering the system differential pressure across, and flow through the other traps tied to that header.

Another common cause for condensate back up and validation temperature alarms can be the failure of an adjacent trap on a common condensate header.

Balanced port thermostatic traps fail when the SS bellows develops a leak and the alcohol fill escapes. Without its proprietary alcohol fill, the bellows can never expand (and close the trap) when exposed to steam temperature. The trap will remain open allowing clean steam to pass through the trap into the condensate header. This is especially problematic during Temperature Hold (low condensate creation), as the increase in condensate header pressure can cause on one or more traps connected to that header to back up condensate. Backup will occur because the differential pressure across all of the traps connected to that header will be reduced (DP = P1 - P2). Reduced differential pressure will result in reduced flow in one or more of the adjacent traps on the common header. In smaller volume (ID < 1") condensate headers, this low differential induced capacity reduction can cause condensate back up significant enough to wet the sensor and cause a low temperature alarm.*

Example: Assume the hot water Cv of one of the clean steam traps is 2. Using a sizing program and solving for flow with a differential pressure of 1.965 bar (assume P1 = 2 bar and P2 = 0.035 bar), that trap will allow flow of about 2423 Kg/hour.

If one of the traps on the common header fails during temperature Hold, and the pressure in the condensate header (P2) increases to 0.14 bar, it will decrease the differential pressure across all of the adjacent traps to 1.86 bar. Using a sizing program, we can see that a small decrease in differential pressure of 0.105 bar (1.965 - 1.86), will cause a decrease in flow of about 65 Kg/hour. With the same amount of condensate being generated by the system, and less flow out of each trap, more condensate will accumulate upstream of the traps. This will cause condensate to back up in the tubing and increase the probability that one or more of the temperature sensors will be wetted and cooled - Temperature Validation Alarm.

* This is the reason that safety factors should be used when sizing clean condensate headers - oversize them to accommodate this scenario.

# PROBLEM REMEDIATION

## IDEAS AND TOOLS TO MITIGATE COMMON SIP PROBLEMS

There are three common problems encountered during SIP:

- ☐ Temperature hold validation alarms
- ☐ Slow condensate drainage
- ☐ Not getting up to temperature or not getting up to temperature fast enough (slow heat-up)

These problems are significant because each delays completion of the sanitization regimen and therefore delays the productive utilization of the asset being sanitized. In other words, these problems cause lower annual production and revenue.*

* The potential loss is greatest in downstream purification and formulation assets as their batch cycle times are much shorter and usually more frequent. CMO's that exclusively formulate and fill should take note.

As previously discussed, the majority of Temperature Hold Validation Alarms can be corrected or prevented by doing one or more of the following:

1. Installing property sized, low subcooling traps in your temperature validated drain lines to minimize condensate back up
2. Make sure there is about 12" - 18" (300 - 450mm) of 3/4" tubing between the trap and temperature sensor to hold condensate back up
3. Properly size condensate headers so they can accommodate failed traps
4. Immediately replace failed traps on trap condensate headers*

However, there are some installations where the solutions above are impossible to implement. For example, there are compact installations, particularly under vessels and equipment where there is not enough space to install a vertical and horizontal downcomber (drip leg) of sufficient length to prevent condensate from backing up and wetting the sensor. Secondly, there are some installations where unforeseen condensate load variations occur that overwhelm the condensate leg and the trap. What do you do in these situations?

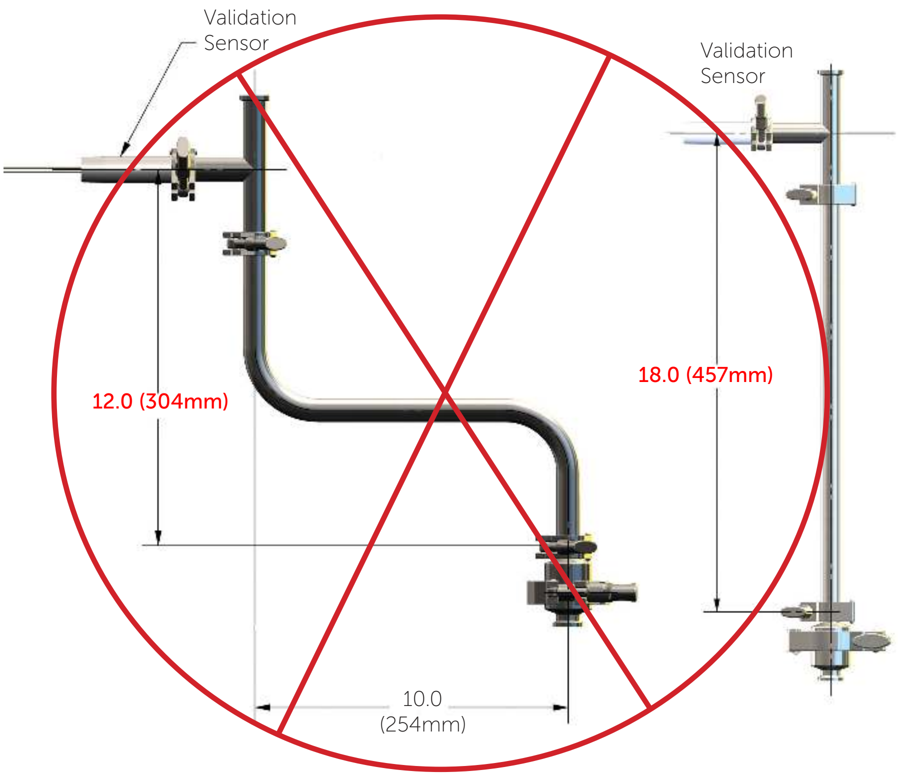
* Periodically use an ultrasonic leak detector to test for and find failed traps. Test during Temperature Hold.

## There are two potential solutions for space limited installations:

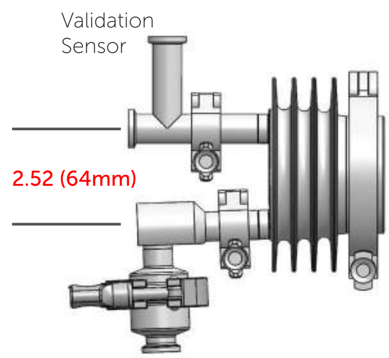
1. If you don't have the installation height for the required run of vertical tubing, increase the horizontal distance. Adding horizontal tubing distance can provide volumetric cushion to prevent condensate from reaching the sensor. As long as there is some[1] vertical tubing immediately below the sensor to provide drainage, an increase in the length of slightly sloped[2] horizontal tubing will provide the volume cushion you need to prevent sensor wetting and temperature validation alarms.

[1] This writer recommends a minimum of 4" (100mm) of vertical tubing directly below the steam trap coupled to at least 18" of sloped horizontal tubing before entering the drain.
[2] See ASME BPE 2016 section SD-2.4.3 for drainability and slope recommendations.

2. If you don't have the height or horizontal space to install any significant horizontal or vertical tubing (or you are not inclined to do so), you may want to install a product that was developed a few years ago by Steriflow Valve specifically for tight installations. The SSC product was designed to eliminate validation temperature alarms and for improving condensate drainage during all phases of SIP. See the concept illustrated below and data sheet at steriflowvalve.com.



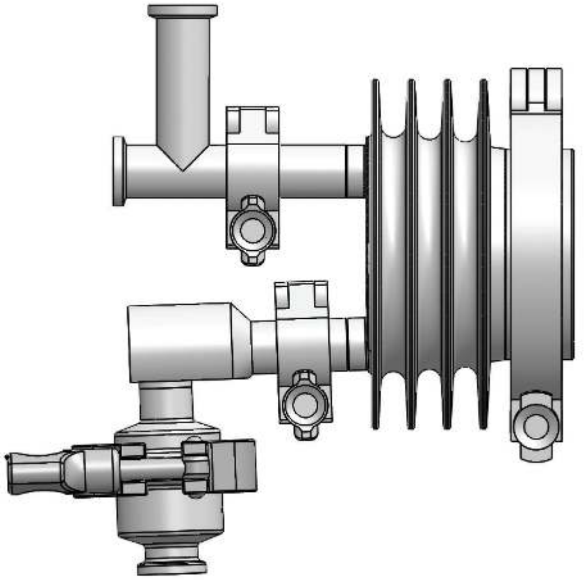

SSC Series (Sanitary Subcooled Condenser)



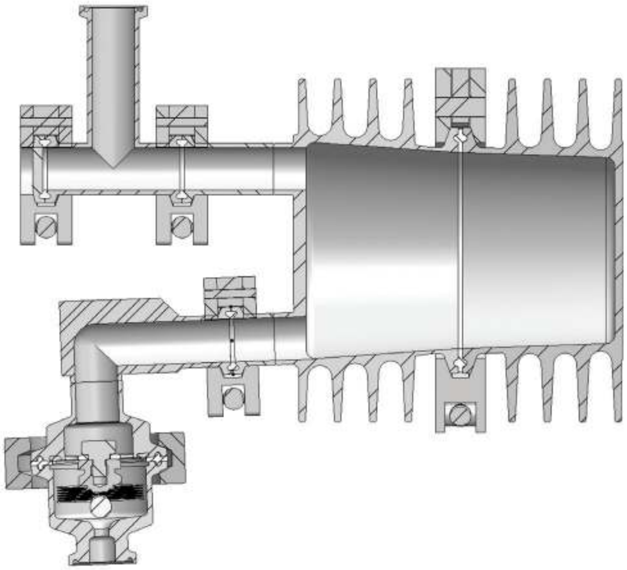
# WHAT IS A SANITARY SUBCOOLED CONDENSER?

## IDEAS AND TOOLS TO MITIGATE COMMON SIP PROBLEMS

SSC is an acronym for Sanitary Subcooled Condenser. It's an appropriate name as it is a compact, finned, gravity drainable, condensate-holding chamber that gets installed immediately downstream of the temperature validation sensor and upstream of the trap. In addition to optimizing installation space, the SSC eliminates the possibility for validation temperature alarms and improves condensate drainage. See the figures below.



SC-075-HS1 Single Section



SSC-075-VS2 Double Section, Cutaway

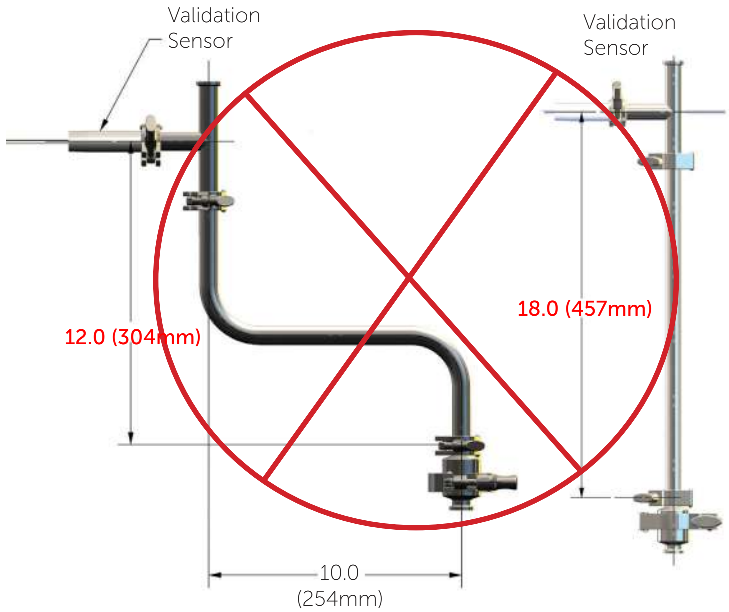
# THE SSC SERIES
# EXPLAINED

## The SSC delivers 3 significant user benefits:

1. Allows the installation of temperature validated sensor/drip leg/trap assemblies in tight places, where there isn't enough room to install the traditional 12" - 18" (300 - 460mm) drip leg between the validation sensor and trap.
2. The SSC is a finned, volume collection chamber for the accumulation of condensate downstream of the validation temperature sensor, upstream of the trap. The SSC's large chamber eliminates the possibility that condensate will back up and wet and cool the temperature sensor.
3. The SSC subcools condensate before it enters the thermostatic steam trap, contracting the bellows and further opening the trap orifice. This results in a significant increase in the traps ability to drain condensate quickly, lessening heat up time.

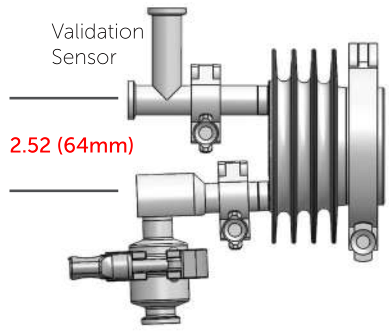
**A single section SSC is the volumetric equivalent of a 46.9" (1,2m), 3/4" drip leg installed between the validation sensor and steam trap**

## Traditional Design



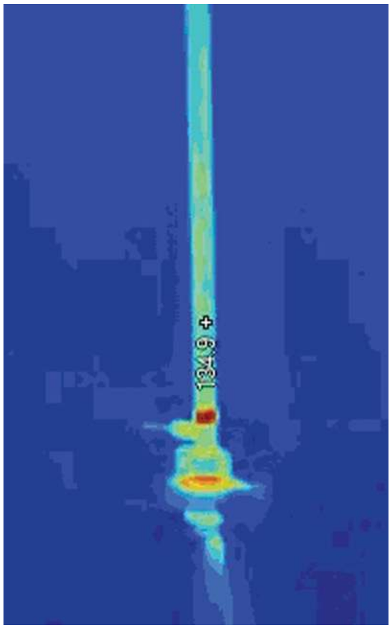

Sanitary tubing volume = 89 mL

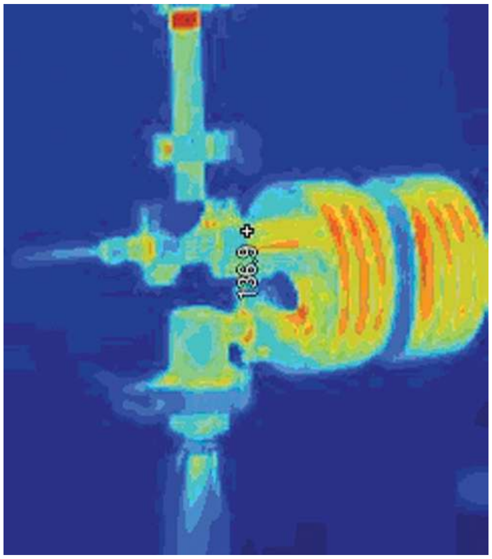
## SSC Design




SSC, Single Section Volume = 232 mL

The SSC has 5 times more radiant surface area than an 18" downcomber. The fins allow ambient air to completely enfold the SSC. The air is heated, rises and is displaced by cooler air from below. The radiant and convective heat loss combine to subcool entering condensate approximately 30°F (-1°C). The temperature difference causes the trap bellows to contract further, allowing a substantial increase in flow.




Looking at the clean steam trap capacity table, we can see trap capacity difference between 20°F (-7°C) subcooled condensate and 5°F (-15°C) at a trap differential pressure of 20 psi (1,4 bar). When condensate is cooled just an additional 15°F (-9.4°C) trap capacity increases 1324 lbs/hr (601 kg/hr).

This significant increase in draining capacity lessens heat-up time.

| Condensate Temp Below Saturation (Subcooled Temp) | Capacity - lbs/hr (kg/hr) @ Differential Pressure - psi (bar) | | | | | |
|---|---|---|---|---|---|---|
| | 10 (0,69) | 20 (1,38) | 30 (2,07) | 50 (3,45) | 75 (5,17) | 90 (6,21) |
| 5°F lbs/hr | 195 (88,5) | 373 (169) | 3549 (249) | 870 (395) | 1012 (459) | 1165 (528) |
| 10°F lbs/hr | 490 (222) | 813 (369) | 1142 (518) | 1715 (778) | 2207 (1001) | 2437 (1105) |
| 20°F lbs/hr | 1127 (511) | 1697 (770) | 2202 (999) | 3074 (1394) | 3932 (1784) | 4139 (1877) |
| Cold Water lbs/hr | 2580 (1170) | 3648 (1655) | 4468 (2027) | 5768 (2616) | 6944 (3150) | 7504 (3404) |

**The Proof:** A mulitnational pharmaceutical company tested the SSC on fixed and mobile formulation vessels at their fill finish facility and decreased heat up times by an average of 10.5 minutes. Using the SSC at this particular facility would allow them to save enough time to increase production by 8 additional batches per year. The facility engineer bought 6 additional SSC assemblies after the successful trial.

# SPECIAL SIP APPLICATIONS FOR LARGE VESSELS

Next, we will discuss special SIP applications. In particular, how Process Design Engineers have traditionally designed the outlet tubing of large vessels to accommodate clean steam sterilization.

Biopharm International addressed the subject of vessel steam sterilization and vessel SIP tubing design in an article published in 2003.[1] The article discusses the amount of clean steam required to heat up and hold sterilization temperature in various sizes of process vessels.

- A 40,000L biopharmaceutical vessel* will produce about 2500 lbs/hr (1134 kg/hr) of peak condensate during heat-up and approximately 27 lbs/hr (12 kgs/hr) during Temperature Hold.
- By contrast, a 600L vessel will only product about 100 lbs/hr (45.36 kg/hr) of peak condensate during heat-up and approximately 2 lbs/hr (0,91 kg/hr) during Temperature Hold.

While 2500 lbs/hr (1134 kgs/hr) is within the load capacity of most standard steam traps (at normal SIP differential pressures), those traps can only handle that load at very high levels of subcooling. (See MK93 capacity chart). If the condensate is subcooled to the point where its temperature is 20°F (-7°C) or cooler than the steam saturation temperature - it is significantly backing up in the drain line upstream of the trap.

Most high capacity traps can handle large vessel heat-up loads at lower levels of subcooling (See MK94 capacity chart) but they still drain slowly because the condensate will be subcooled 10°F (-12°C) at that load.

Since these high condensate loads only occur during heat-up there is no worry about validation alarms. However, it may manifest as slower heat-up time.

**Mark 93 Flow Capacity**

| Condensate Temp Below Saturation (Subcooled Temp) | Capacity - lbs/hr (kg/hr) @ Differential Pressure - psi (bar) | | | | | |
|---|---|---|---|---|---|---|
| | 10 (0,69) | 20 (1,38) | 30 (2,07) | 50 (3,45) | 75 (5,17) | 90 (6,21) |
| 5°F lbs/hr | 195 (88,5) | 373 (169) | 3549 (249) | 870 (395) | 1012 (459) | 1165 (528) |
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| 20°F lbs/hr | 1127 (511) | 1697 (770) | 2202 (999) | 3074 (1394) | 3932 (1784) | 4139 (1877) |
| Cold Water lbs/hr | 2580 (1170) | 3648 (1655) | 4468 (2027) | 5768 (2616) | 6944 (3150) | 7504 (3404) |

**Mark 94 Flow Capacity**

| Condensate Temp Below Saturation (Subcooled Temp) | Capacity - lbs/hr (kg/hr) @ Differential Pressure - psi (bar) | | | | |
|---|---|---|---|---|---|
| | 10 (0,69) | 20 (1,38) | 30 (2,07) | 40 (2,76) | 50 (3,45) |
| 5°F lbs/hr | 1490 (677) | 1980 (900) | 2705 (1230) | 3355 (1525) | 3750 (1705) |
| 10°F lbs/hr | 2410 (1096) | 3370 (1532) | 4310 (1959) | 5080 (2309) | 5675 (2580) |
| 20°F lbs/hr | 4090 (1859) | 5510 (2505) | 6585 (2993) | 7910 (3596) | 8630 (3923) |
| Cold Water lbs/hr | 6460 (2936) | 9110 (4141) | 11550 (52502) | 12800 (5818) | 14410 (6550) |

[1] Designing a Shorter Vertical Leg for Sanitary Steam Traps, Sept 01, 2006, by Richard Kral, George W. Page, Jr. Bio-Pharm Inter-National Volume 19, Issue 9

* The article did not define the vessel mass or geometry, which can affect the load.

REMOVING CONDENSATE EFFICIENTLY FROM VESSELS DURING SIP IS IMPORTANT, BUT IT'S NOT THE ONLY JOB THAT A TRAP HAS TO DO

Clean Steam Traps also have to handle the large volume of air that will be displaced at the beginning of SIP.

A 15,000L biopharmaceutical vessel holds 15,000L of air. As a general design rule, air should be removed in the first 5 minutes of SIP in order to minimize heat-up time (air acts as an insulator in steam tubing and vessels). Moving 15,000L of air in 5 minutes represents a flow rate of 3000 N L/min. Plugging that into a Cv calculator with a 25 psi differential, we find we need a trap with a Cv of 4.9 in order to move that much air through the trap.

MARK 93 SANITARY STEAM TRAP

MARK 94 SANITARY STEAM TRAP

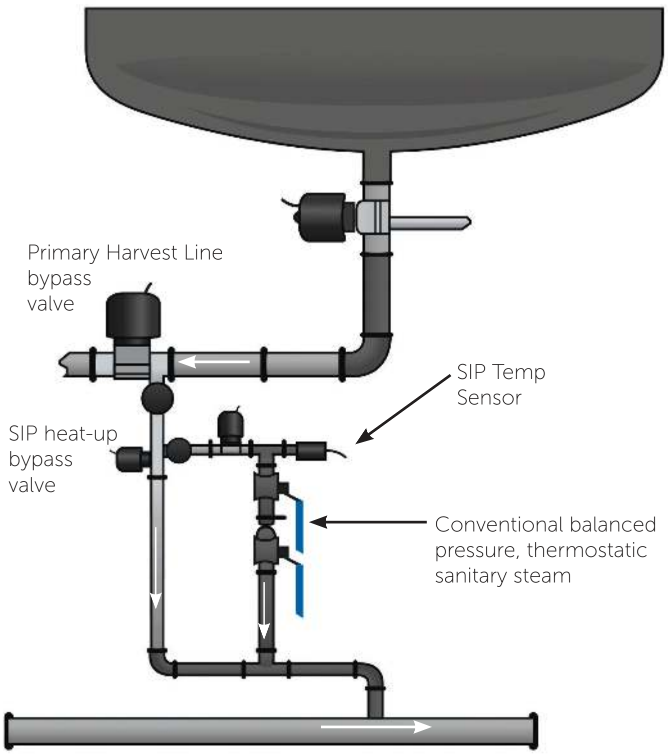
The Mark 93, a mid-capacity trap has a Cv of 3.8. Calculating for flow, we find that the MK93 can only remove about 2300 N L/minute or about 11,500 liters of air in 5 minutes. In fact, prior to the recent technological development discussed below, no commercially available traps could remove that amount of air in a timely manner.

Lastly, during heat-up, air and condensate do not drain independent of each other. Both combine in a mixed phase flow which further complicates draining.

# SPECIAL SIP APPLICATIONS: CONVENTIONAL SIP PROCESS DESIGN FOR LARGER VESSELS

In this section, we will discuss how process engineers traditionally design validated SIP vessel drains to accommodate sanitization liquids, air and condensate flow.

In order to drain liquids and expedite air and condensate flow out of larger vessels (usually > 600L), most process designers include a 1" primary bypass from the tank outlet - harvest line to drain. When heat-up is complete (a few minutes before temperature hold starts), a second 3 way bypass valve diverts the flow from the bypass drain line through a conventional steam trap and back to drain.




### Heat-up

- During SIP heat-up, air and condensate are diverted through the Primary Harvest Line 3-way bypass valve directly to drain

### Temperature Maintenance

- When the SIP temperature sensor reaches ~ 203°F (95°C)*, the SIP heat-up bypass valve opens to direct the lighter condensate load through the steam trap.

* Actual temperature depends upon DCS/ PLC configuration

Note: during sanitization (pre SIP), most users divert Rinse and CIP liquids through the Primary Harvest Line 3-way bypass valve directly to drain. Note that some end users elect to divert those fluids through a secondary Harvest Line 3-way bypass valve further downstream for that purpose.

# SPECIAL SIP APPLICATIONS: PROBLEMS WITH CONVENTIONALLY DESIGNED SIP DRAINS FOR LARGE VESSELS

The piping bypass arrangement discussed in the previous section effectively handles fluids, air and condensate. However, there are two problems associated with bypass use.

1. **Inefficient use of clean steam and slow pressure build-up** because of live steam loss, resulting in longer SIP heat-up times and higher operating expense.

During the typical 10-15 minutes of heat-up, the 1″ bypass is wide open to drain, resulting in slow pressure/temperature build-up. After the initial expulsion of air, a significant amount of clean steam is lost to drain resulting in longer than required heat-up and higher operating expense.

2. **High initial Capital cost** - a conventional bypass loop consists of the following components and labor. The total installation expense conservatively costs about $5800 USD.

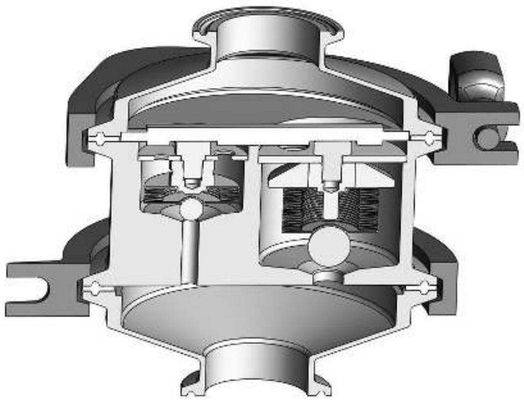
| Bill of Material: Bypass Loop | | | |
|---|---|---|---|
| QTY | MATERIAL DESCRIPTION | UNIT COST ($) | TOTAL COST ($) |
| 1 | 1″ automated diaphragm valve fab assy with inlet bypass | 1,800 | 1,800 |
| 2 | panel mounted solenoid for air control to 3-way valve | 174 | 348 |
| 1 | 20′ control air tubing | 20 | 20 |
| 1 | 1″ BPE 90° T-clamp elbow | 73 | 73 |
| 2 | 1″ x 26″ BPE tubing | 30 | 60 |
| 2 | BPE Tee, 2″ tube end run x 1″ T-clamp branch | 212 | 424 |
| 1 | 1: sanitary steam trap, std. capacity (eg MK93) | 535 | 535 |
| 2 | 1″ sanitary ball valves | 155 | 310 |
| 4 | Qty 1, 1″ T-clamp ferrule, short | 23 | 94 |
| 1 | Qty 1, I/O port | 250 | 250 |
| | TOTAL MATERIAL COST | | **$ 3,914** |
| Labor | | | |
| HRS | LABOR DESCRIPTION (Field OH rates) | UNIT COST ($) | TOTAL COST ($) |
| 3.5 | cut and fit | 80 | 280 |
| 4 | orbital welds 8 | 80 | 320 |
| 4 | polishing | 80 | 320 |
| 1 | control air tubing | 60 | 60 |
| 1 | stringing landing wire | 60 | 60 |
| 1 | configuring DCS/PLC I/O | 100 | 100 |
| 3 | commissioning | 120 | 360 |
| 3 | validation | 160 | 450 |
| | TOTAL LABOR COST | | **$ 1,950** |
| | TOTAL CAPITAL COST | | **$ 5,864** |

# SPECIAL SIP APPLICATIONS: NEW SOLUTION FOR SIP DESIGN FOR LARGER VESSELS

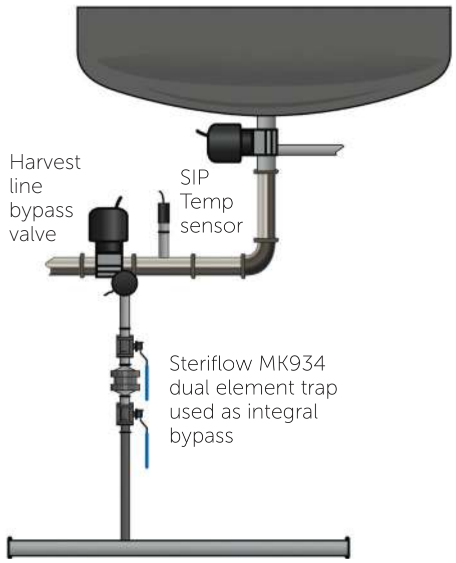
In 2008, Steriflow looked at the problems associated with the conventional bypass piping design, and started work on an alternate design to alleviate those problems. They developed a trap with enough capacity to handle most rinse/CIP/rinse sanitization flows and the air and condensate flows associated with SIP.

The result was the world's first dual element clean steam trap, the MK934. It works in the following manner:

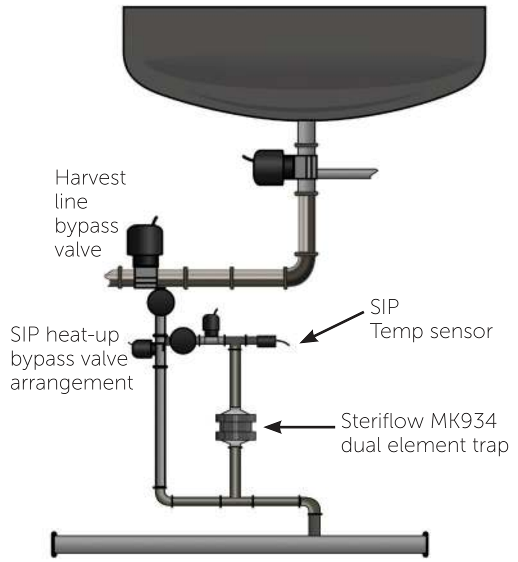
- Two bellows assemblies work together to handle sanitization liquids (rinse/CIP/rinse) and the heat-up and maintenance loads of larger vessels
- During heat-up, both bellows are open, providing excel-lent capacity for eliminating air and condensate
- The higher capacity bellows is designed to close when the vessel temperature is between 194°F and 212°F (90°C and 100°C). This allows the lower subcooling MK93 bellows to handle the smaller loads generated during temperature maintenance.
- No clean steam is lost during operation of the trap. Both bellows will close when the bellows sense saturated steam temperatures.



Benefits:
Heat-up time improvement: No lost clean steam - all enthalpy from entering steam heats the vessel, none lost to drain
CAPex: Approx. $2800 USD less to construct than the traditional piping arrangement
OPex: Less clean steam used than with traditional piping arrangement




MK934 without bypass used for all sanitization flows (CIP, Rinse and SIP)




MK934 for SIP flows only (SIP and Rinse handled by bypass to drain)

## ABOUT THE AUTHOR

**Karl J. Lutkewitte has spent his career working for two companies. For the last 10 years, Karl has been with Richards Industries' Steriflow Division as the Product Manager, and more recently as Product and Sales Manager. He has been with Richards Industries for almost 20 years. For 12 prior years he was with two Emerson Electric Companies: Emerson Process Management – Rosemount, and the Alco Controls Division.**

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