AUTOCLAVE PROBLEM – WHAT WOULD YOU DO?

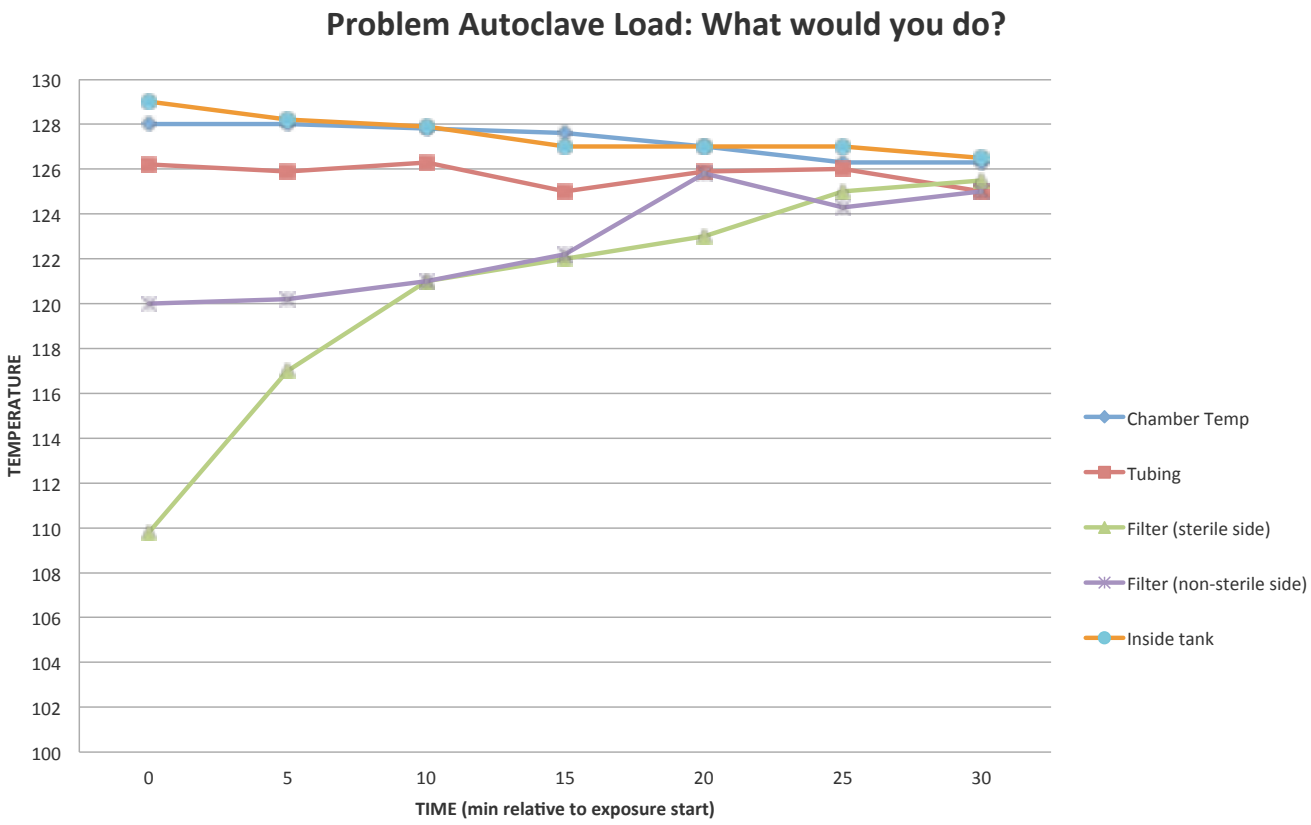
Moist heat sterilization (autoclaving) is vital to your process. It's complex and very high risk when things go wrong. It is absolutely vital you have expert knowledge of the principles and practice and what to do when things go wrong.

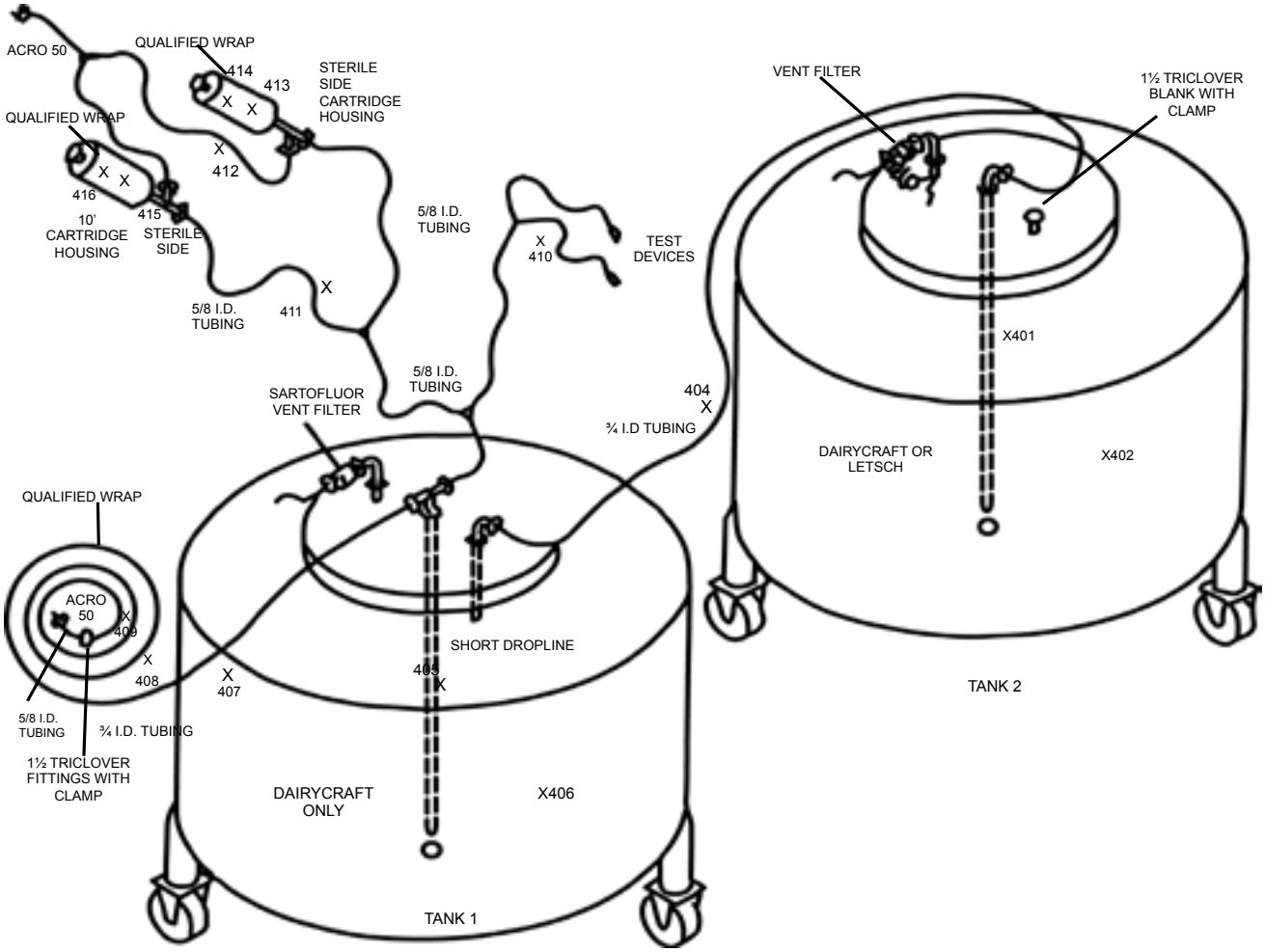
For those of you involved in moist heat sterilization, consider the following case study. Are there any concerns with this data? If so what could be done to overcome them?

The autoclave chart shows the temperature recorded at various points in the assembly, both shown below:

- Chamber temperature – free space
- Tubing – location 404
- Filter (sterile side) – location 413
- Filter (non-sterile side) – location 414
- Inside tank – location 402

Exposure started when all probes reached 100°C and therefore there was accumulation of F0. All probes show a minimum F0 of 30 and all are above 121°C for at least 15 minutes.





> Discuss this case study with your colleagues. The more you practice problem solving, the easier it becomes

> List the contributing factors causing the poor performance

> What corrective and preventive actions would you take to minimize risk?

See document 'Autoclave Problem 2' on the next page, for the model answer.

AUTOCLAVE PROBLEM – INTERPRETATION OF AUTOCLAVE CHARTS

The slow rise to temperature of some probes is clear evidence of the presence of air.

- The heat-up stage of the cycle is not shown, so we cannot tell how long it took for other probes to reach temperature, nor can we tell what air removal processes (vacuum purges, etc) were used (if any!).
- Even at the end of the cycle, there is still a 2° difference between the temperature in parts of the load and the chamber. These should be coincident.
- The use of F0 calculations is not appropriate for porous loads. This shows only that temperature has been achieved, not whether there has been effective steam penetration. In this case, the temperature has clearly been reached only by conductive heating. To reach 121°C for 15 minutes, the steam set point has been raised to ~128°C and the cycle time has been increased.

The fundamental problem is the complexity of the assembly to be sterilized. Your options might be to:

- Redesign it
- Split it into several parts (but this would require aseptic assembly!)
- Increase vacuum pulsing and/or dwell times
- Use larger vent filters

For more information, contact **pharmamail@nsf.org** or visit **www.nsfpharmabiotech.org**

Cite as: NSF International. July 2017. Autoclave Problem – What Would You Do? NSF: York, UK.

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