

Variables affecting validation



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A significant period of time is required to develop a robust sterilization process, this typically includes considerations such as: -

- **Load item positioning and layout**
- **Temperature uniformity during the ‘Sterilization’ phase**
- **Air removal performance**
- **Drying performance**
- **Cooling performance**

Once a process (program, load) has been developed and tested successfully through a ‘Performance Qualification’ (PQ), we typically consider the load ‘Validated’

Once a process (program/load) is validated...

Will it always perform the same..?

Could some external factors affect the 'Validated State'

YES

The 'Usual Suspects'

- Maintenance activities
- Calibration activities
- Operator activities
- Utilities
- What else?

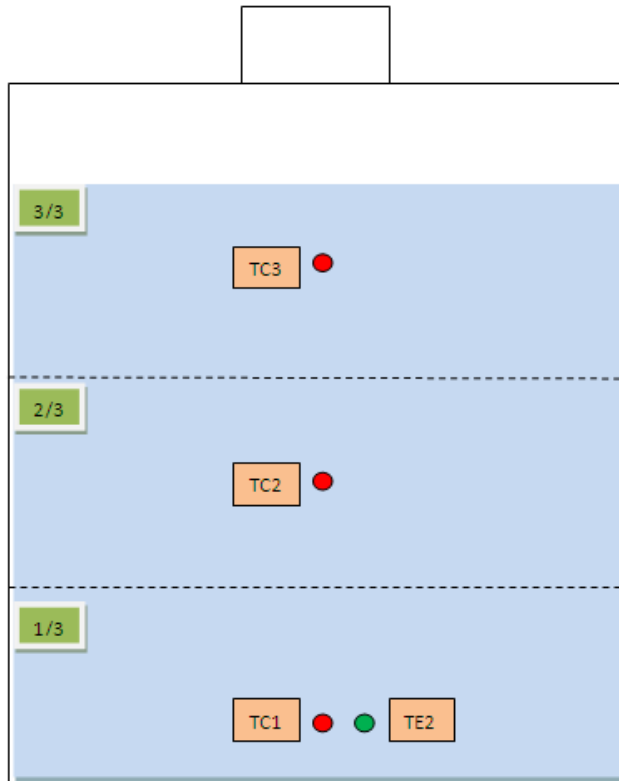
- Maintenance activities
 - Incorrect or lack of maintenance procedures?
 - Manufacturer trained?
 - OEM parts?
 - Master settings for adjustable devices?
 - Leaks (probe damage?)
- Calibration activities
- Operator activities
- Utilities
- What else?

- Maintenance activities
- Calibration activities
 - Correct range for instrument calibration?
 - Correct procedure for instrument calibration?
 - Type and accuracy of test equipment?
 - Adjustment or no-adjustment vs SOP acceptance criteria?
 - Environment?
- Operator activities
- Utilities
- What else?

- Maintenance activities
- Calibration activities
- **Operator activities**
 - Is there an SOP for the wrapping technique for wrapped items?
 - Are the options on which bag to select for the item, i.e. different brand, different colour?
 - How is the item tapped closed, is there a procedure of the closure technique?
 - Is the orientation and layout of the load as per the validation?
 - Is the chamber hot or cold?
 - What the load staged in a cool area or warm area?
- Utilities
- What else?

CASE STUDY

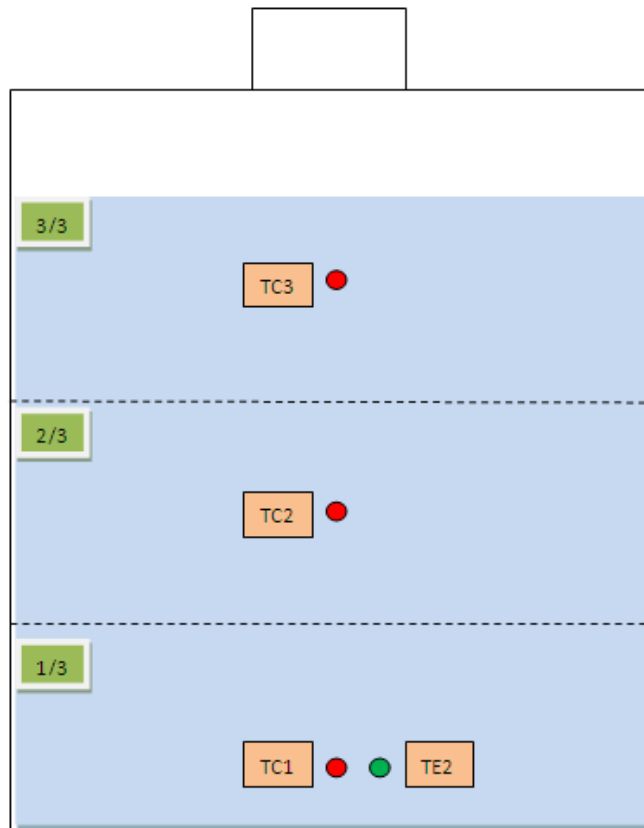
Heating to 120°C



10 lt. Duran bottle



Product probe placement: Case Study



Heating to 120°C

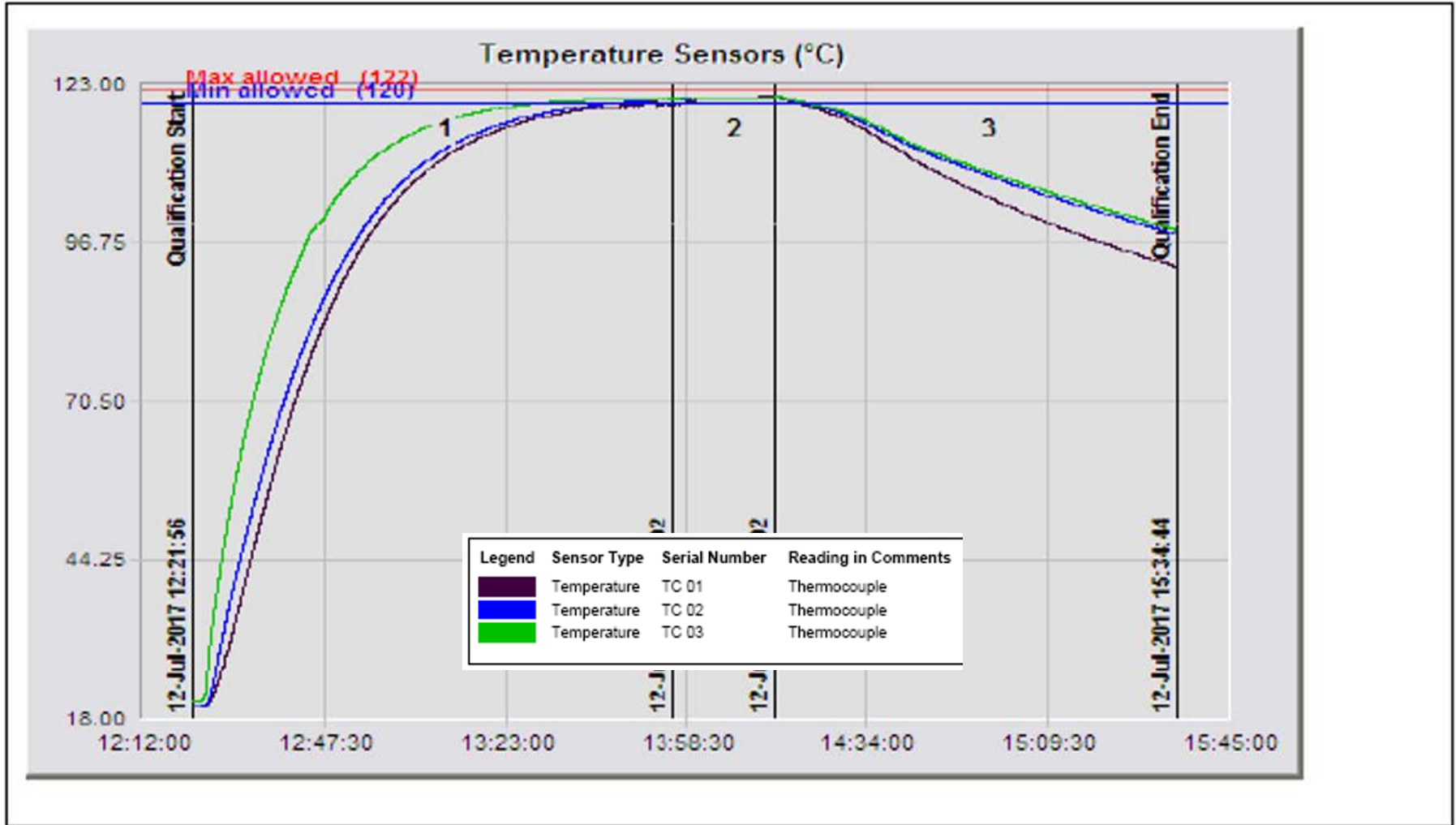
Fastest Thermocouple: **TC3**

Slower Thermocouple: **TC1**

Δt between faster and slower:

20:16 min

Product probe placement: Case Study



Heating to 120°C

- Maintenance activities
- Calibration activities
- Operator activities
- **Utilities**
 - What is the status of the steam quality, how frequently has this been tested?
 - Has the steam been tested with the load at maximum, i.e. all equipment connected to same header a max demand?
 - Is the steam supply adequately trapped at point of use?
 - Could condensate backup in the plant steam line to the jacket?
 - Vacuum pump water temperature fluctuations?
- What else?

CASE STUDY

Could system demand affect the quality, flowrate and pressure of the steam at the point of use?

350kg/h

250kg/h

250kg/h



150kg/h

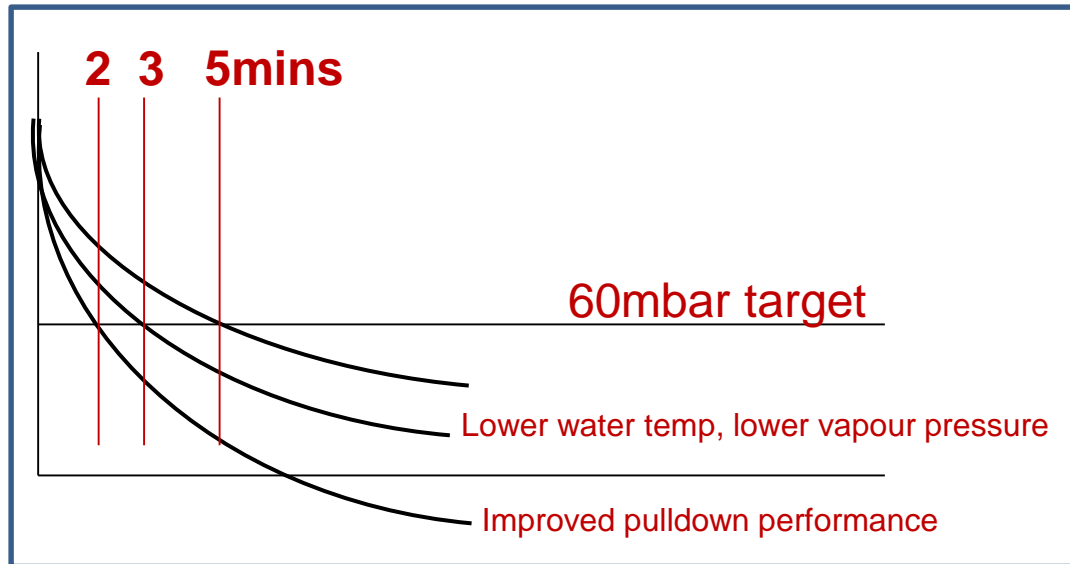


1000kg/h

CASE STUDY

Vacuum Pump Performance vs water temperature

A change in water temperature to the vacuum pump will have an affect on vacuum performance and ultimate vacuum achieved



- Maintenance activities
- Calibration activities
- Operator activities
- Utilities
- **What else?**

Thank you.