

Load types, Sterilisation Processes and Autoclaves *Saturated steam*

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Agenda

- **Introduction**
Load types, Sterilization processes & Autoclaves
- **Saturated Steam Autoclave**
Generality & cycle description
- **Counterpressure Autoclaves**
Generality & cycle description

Sterilisation by direct contact

A sterilization process, typically used for **porous/hard goods** where the sterilizing medium is **saturated steam**.

PDA TR N. 1, Glossary

Saturated steam is *“water vapour in a state of equilibrium between condensation and evaporation”*

UNI EN ISO 17665-1

The initial objective for saturated steam sterilization is that the **air** in the sterilizing chamber **must be replaced by saturated steam**.

USP 43 chapter 1229.1



- Residual air acts as an **insulator**
- The presence of residual air in the chamber **negates the singular temperature–pressure relationship of saturated steam**

Saturated Steam Autoclave

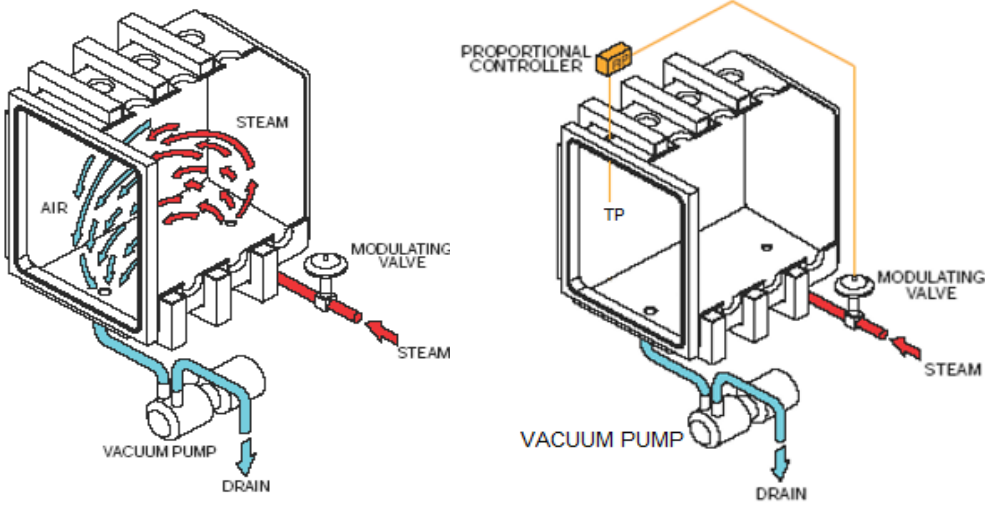


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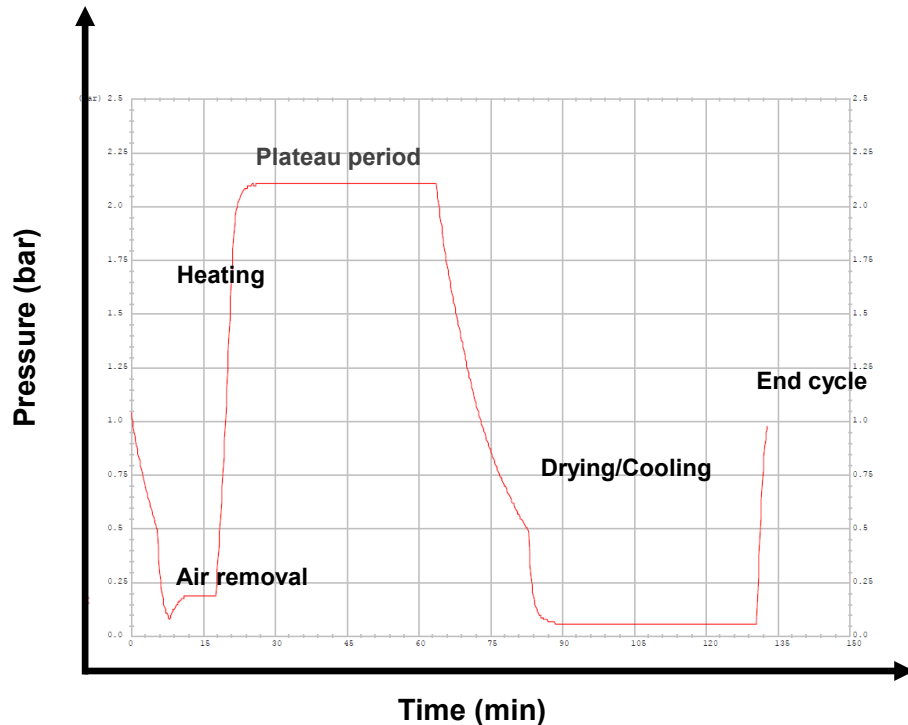
- **Fedegari Horizontal Pharmaceutical** is a highly flexible solution for **multi-purpose sterilization** in bio-pharma industries.
- From **solids** and **porous** to **liquids** in open or non-hermetically sealed containers.

Saturated Steam Autoclave

The **sterilization temperature is controlled according to a pressure signal**, thanks to the one - to - one correspondence of temperature and pressure for the pure saturated steam.

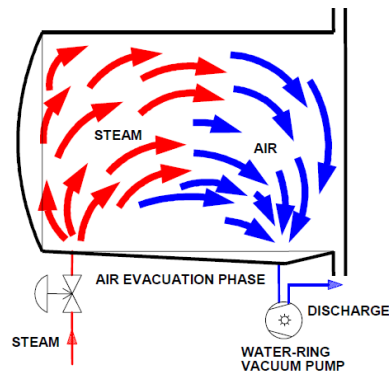


Process phases



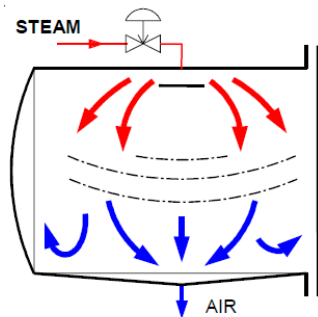
- 1 **Air removal** from the chamber and the product surfaces (e.g., by vacuum)
- 2 **Heating & Sterilization**
- 3 **Post-sterilization phases** (drying and/or cooling)

Initial air removal from the chamber



- **Depressurization plus steam injection**
- **Steam/ vacuum pulses**

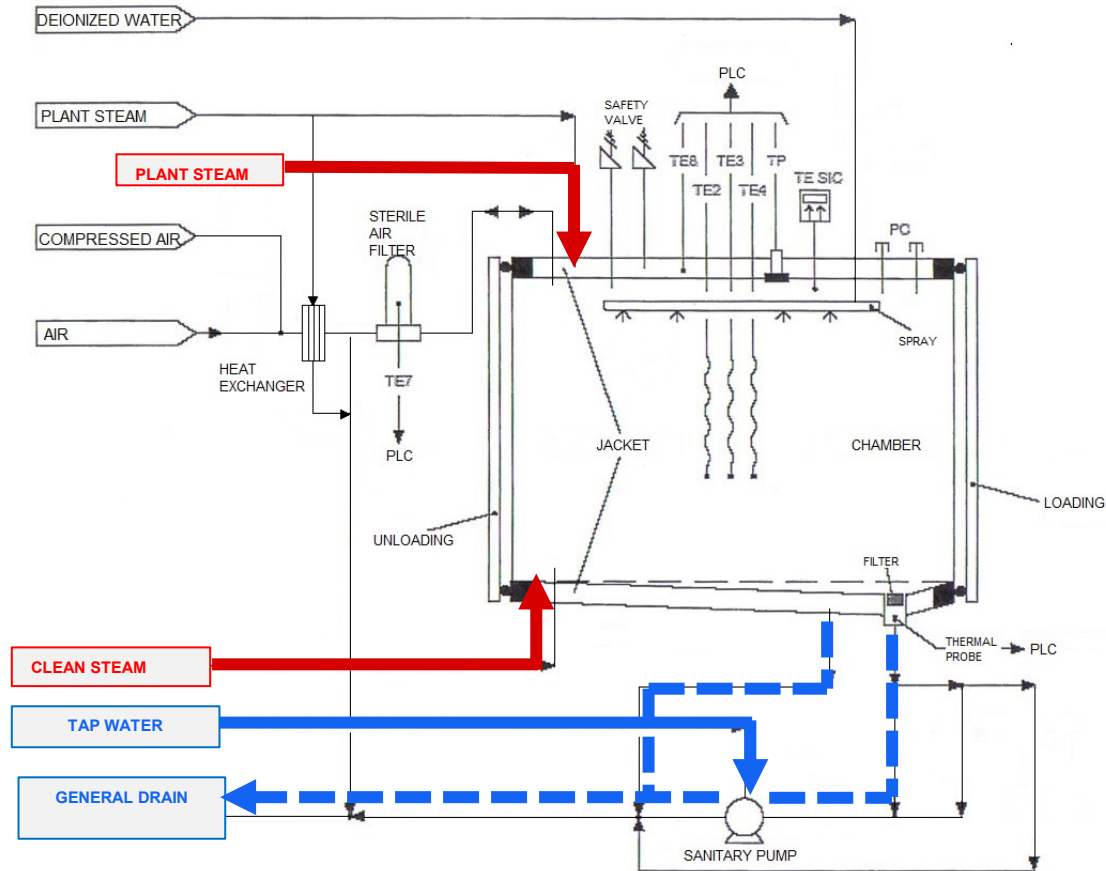
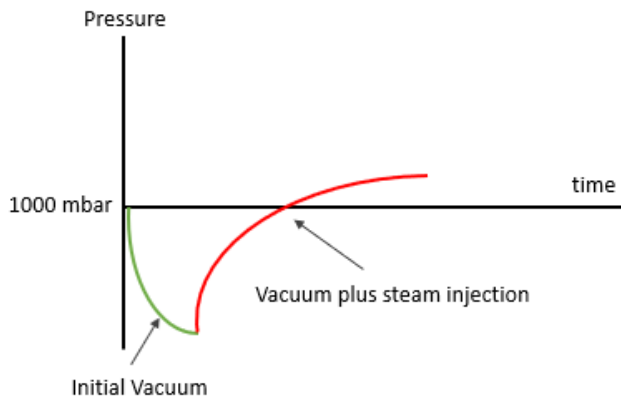
→ These methods removes air from the chamber using a mechanical **vacuum pump** or steam eductor.



- **Displacement by Gravity (open fluid containers)**

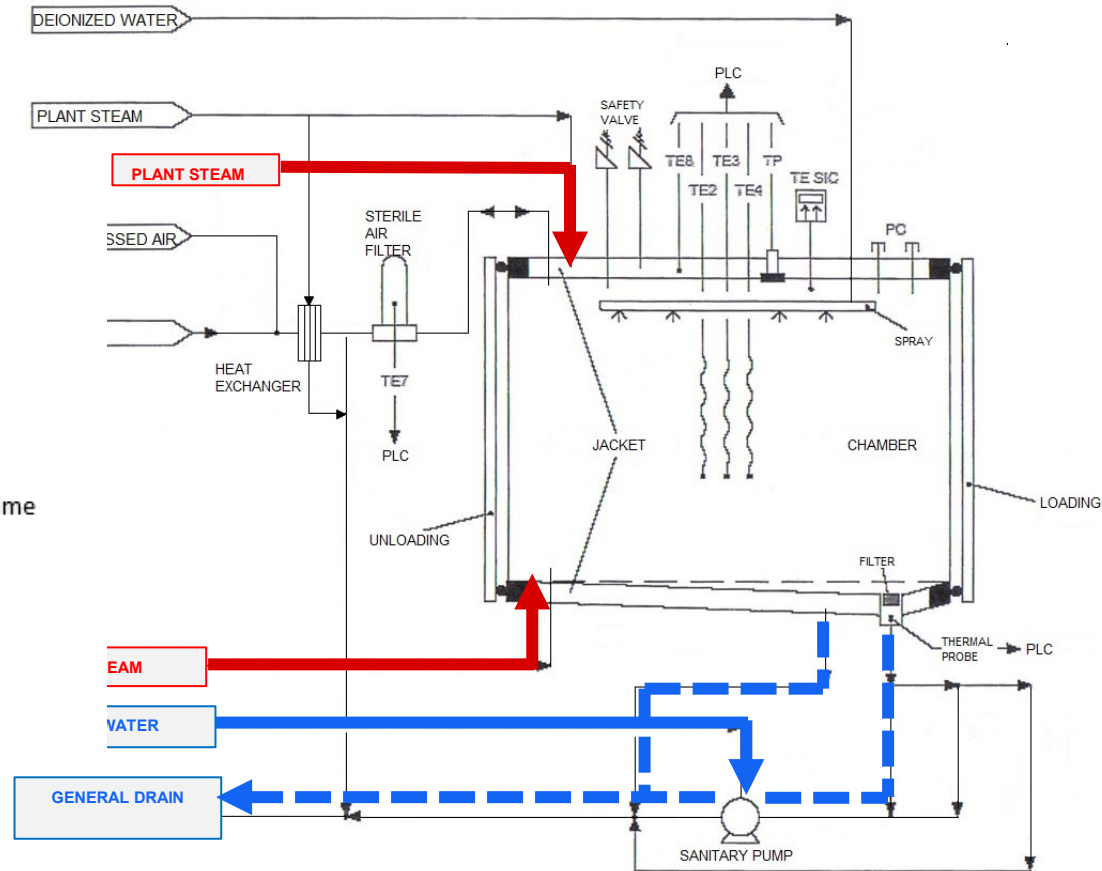
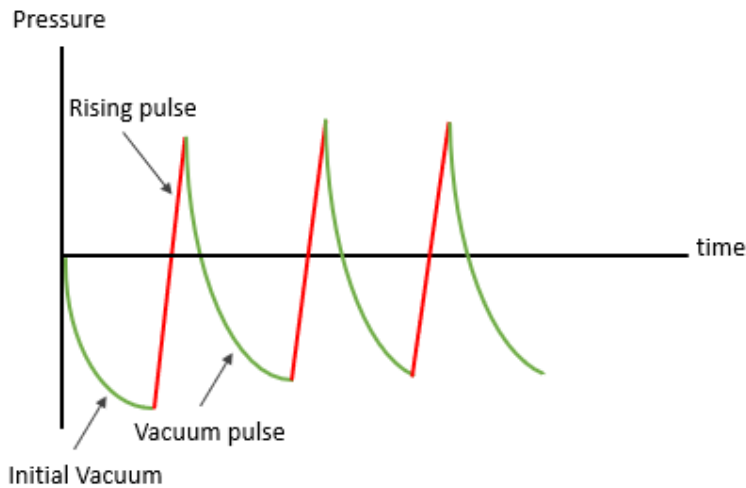
Depressurisation plus steam injection

Vacuum plus steam injection



The **vacuum pump** extracts both steam/condensate and air from the chamber

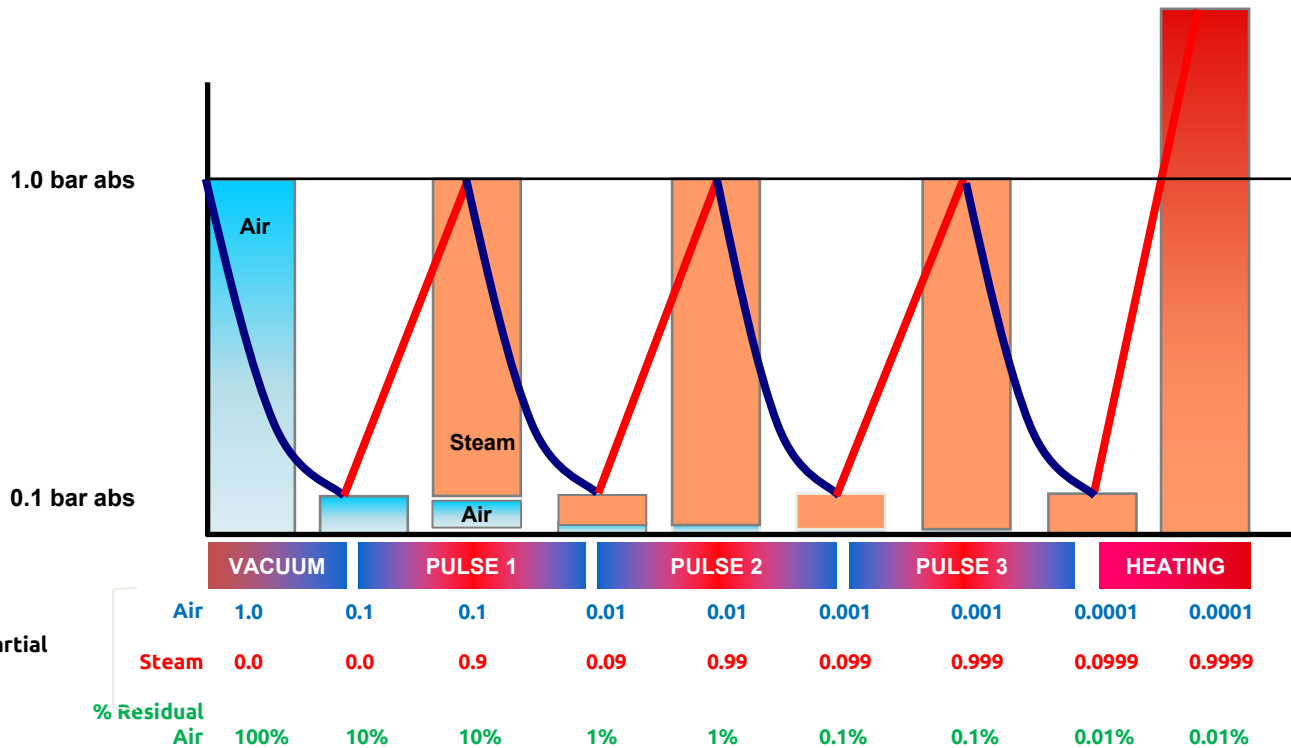
Pulsed Air Removal



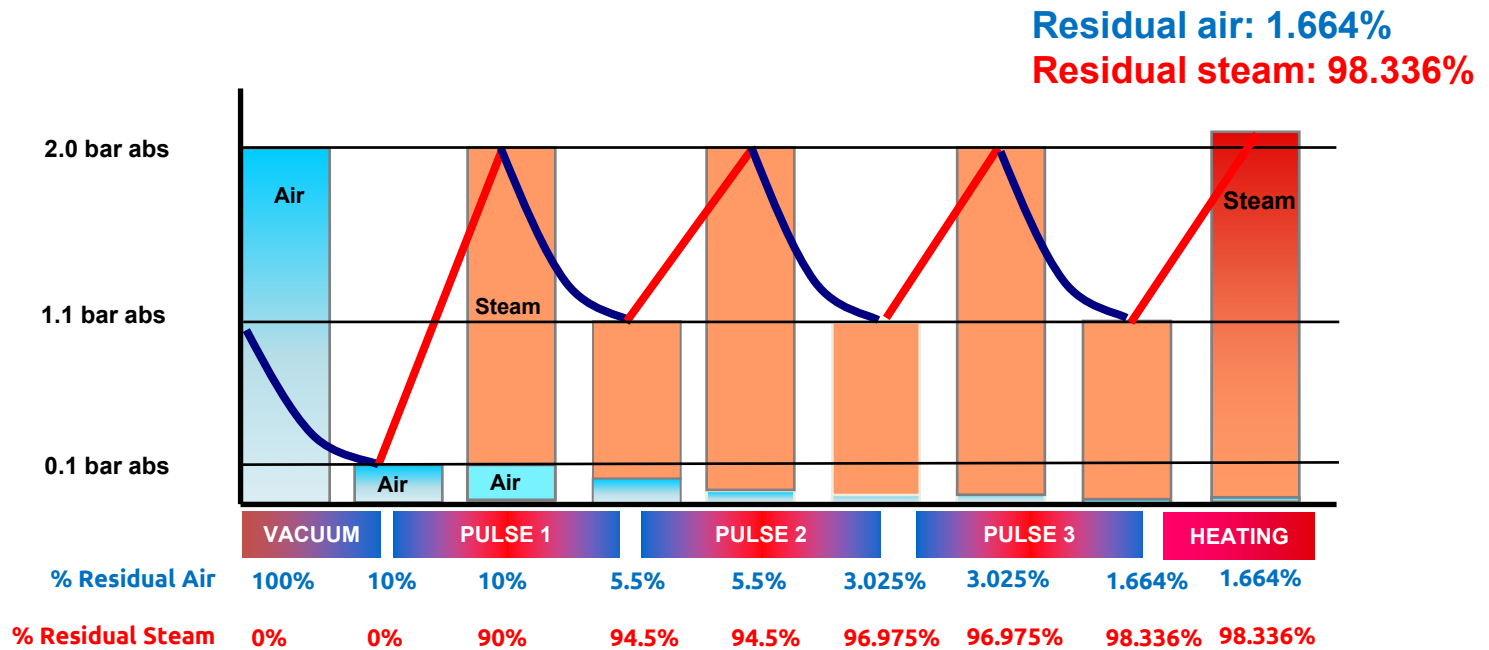
The **vacuum pump** extracts both steam/condensate and air from the chamber

Negative Steam/Vacuum Pulses

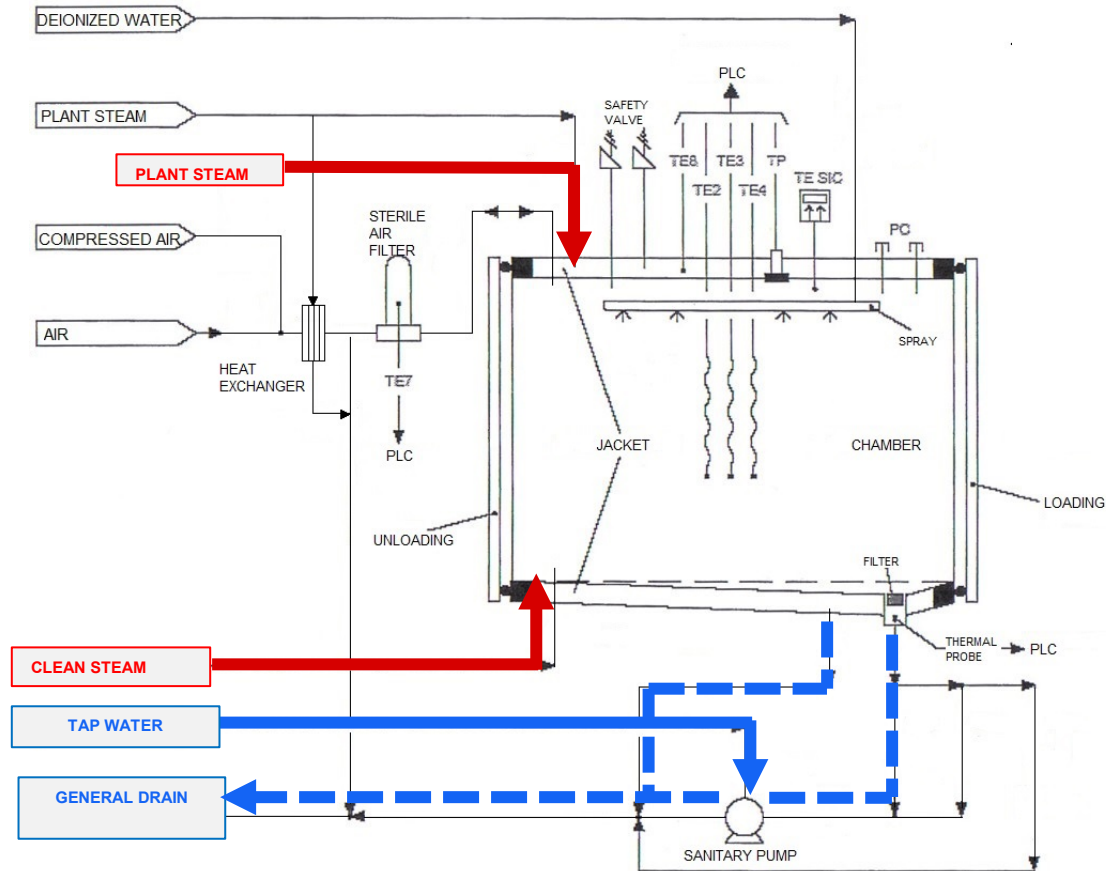
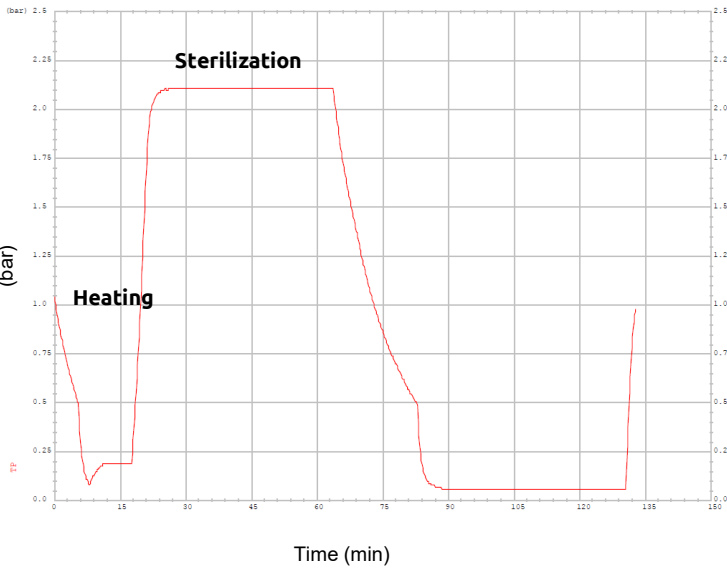
Residual air: 0.01%
Residual steam: 99.99%



Positive Steam/Vacuum Pulses



Heating & Sterilisation



Process phases

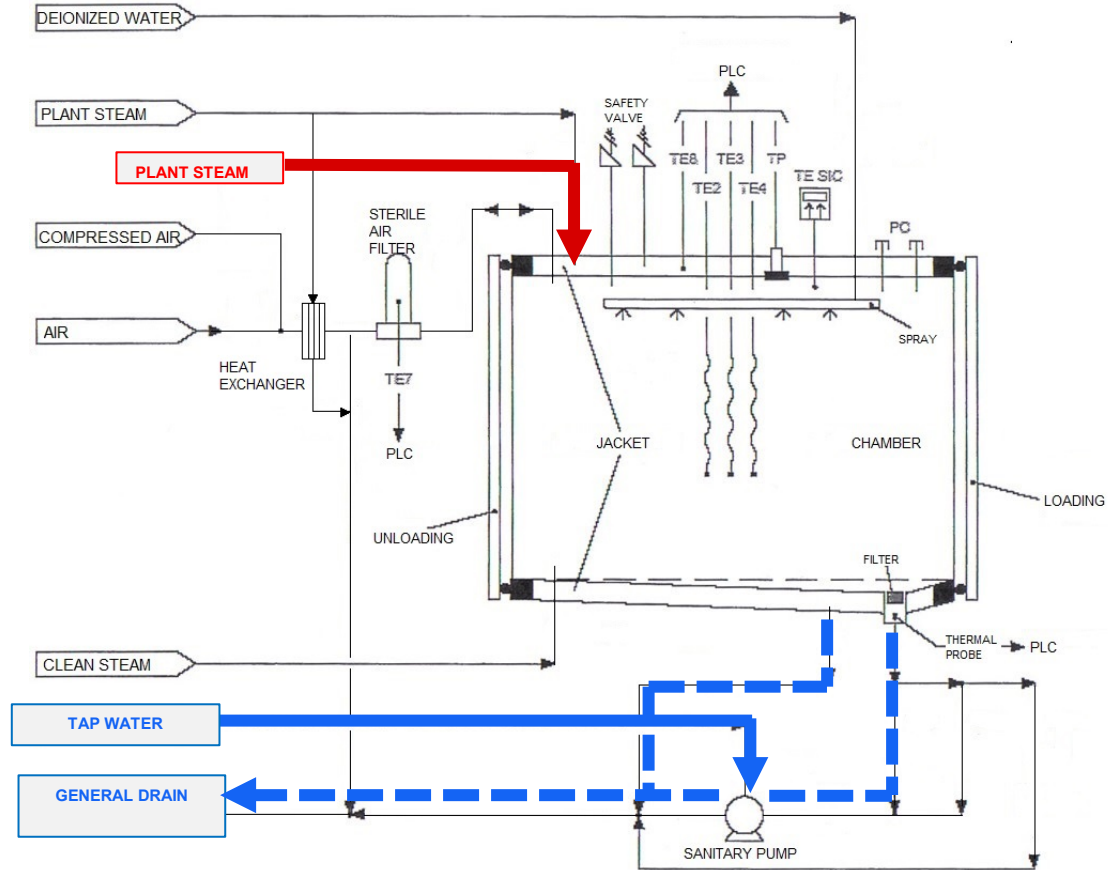
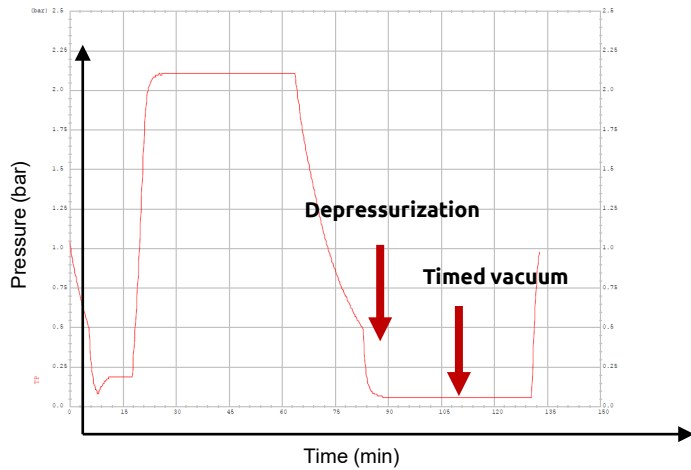
Drying

- Vacuum and time-controlled/vacuum hold

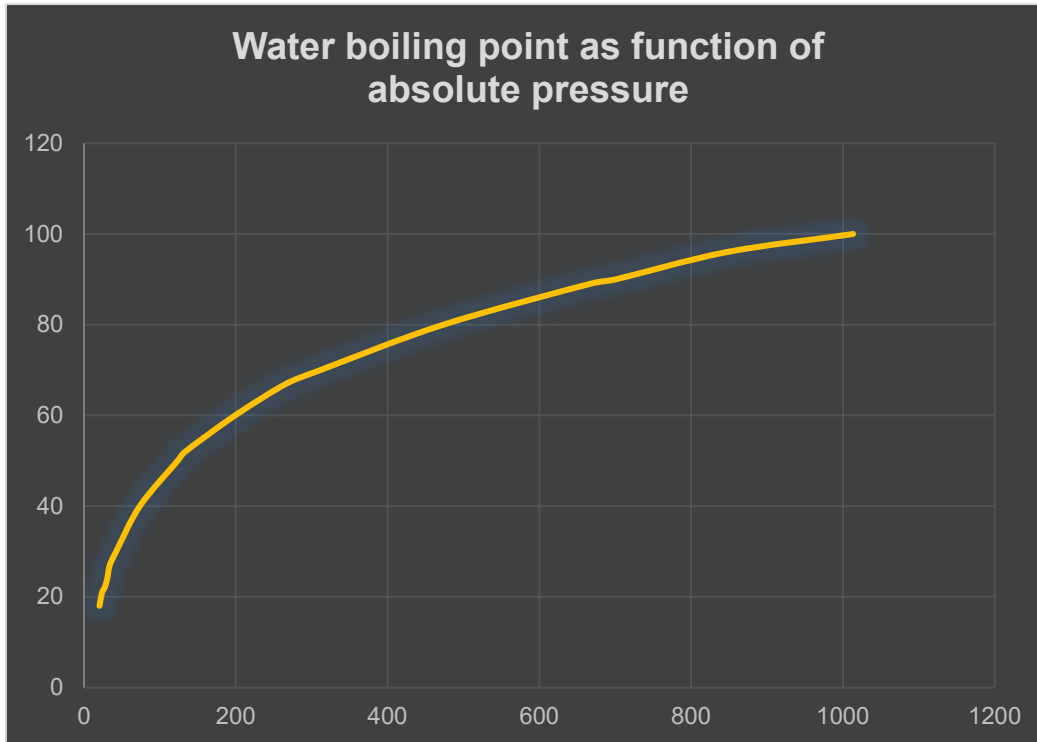
Cooling

- Indirect cooling
- Direct cooling

Vacuum Drying

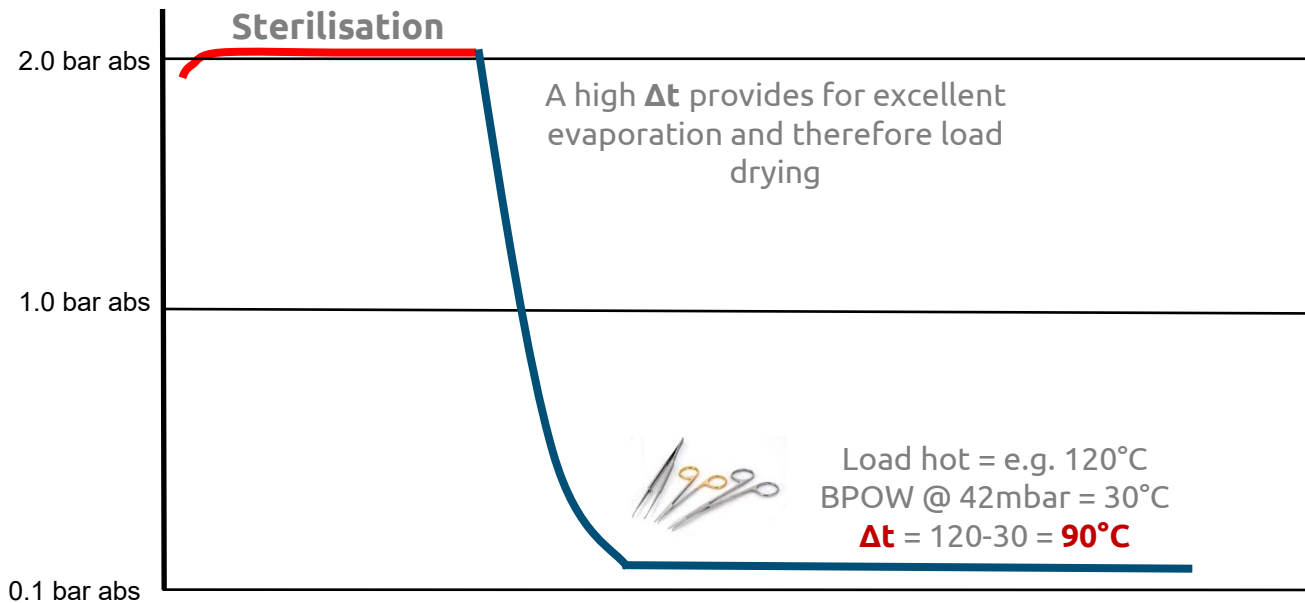


Vacuum Drying



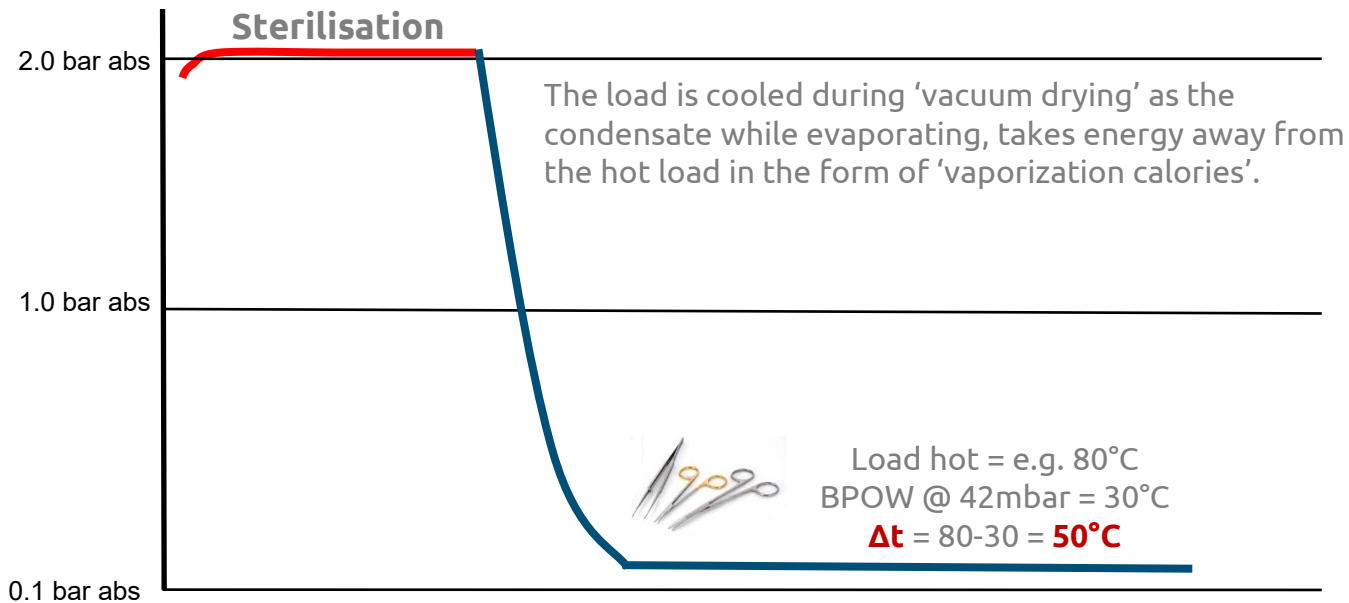
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846.6	96
700.6	90
666.6	89
473.4	80
311.5	70
266.6	67
199.1	60
133.3	52
123.3	50
73.48	40
42.33	30
33.86	27
30.48	24
27.09	22
23.71	21
20.32	18

Vacuum Drying



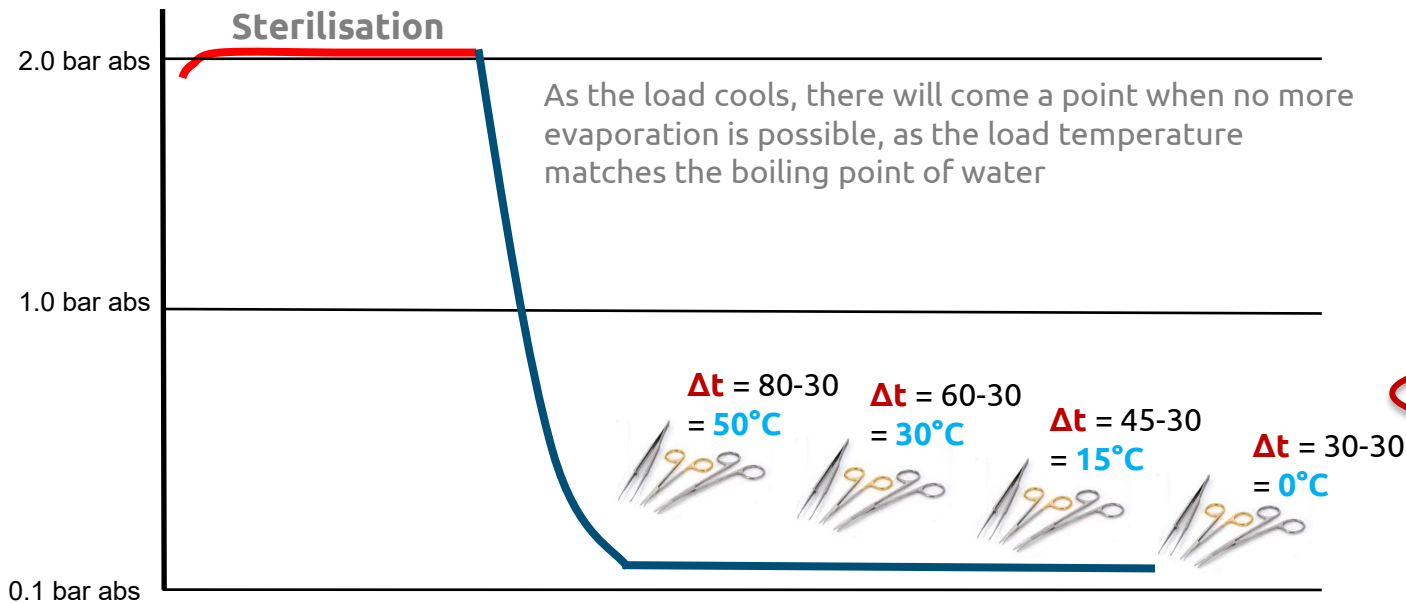
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Vacuum Drying



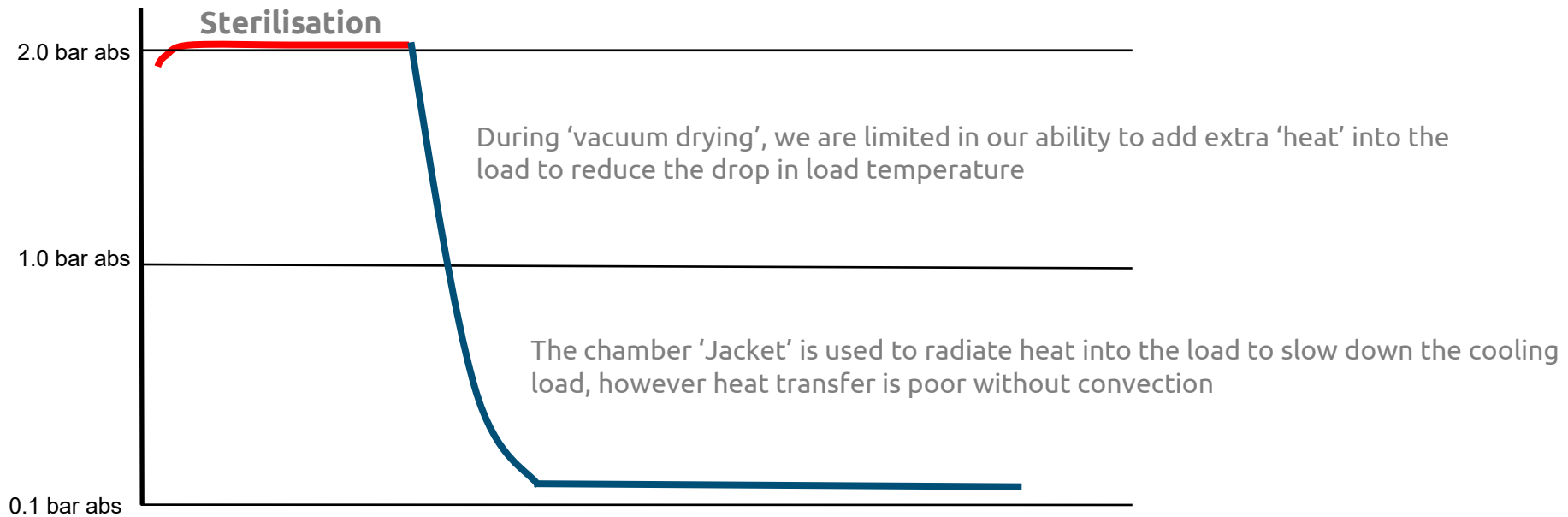
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Vacuum Drying

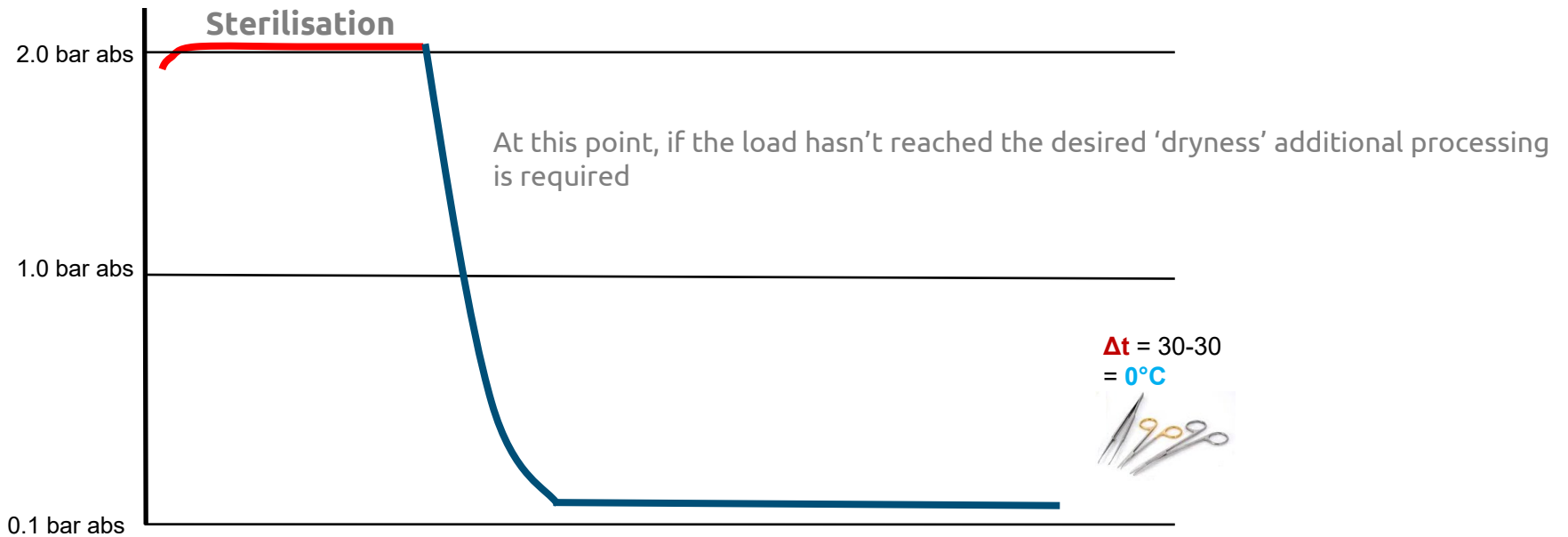


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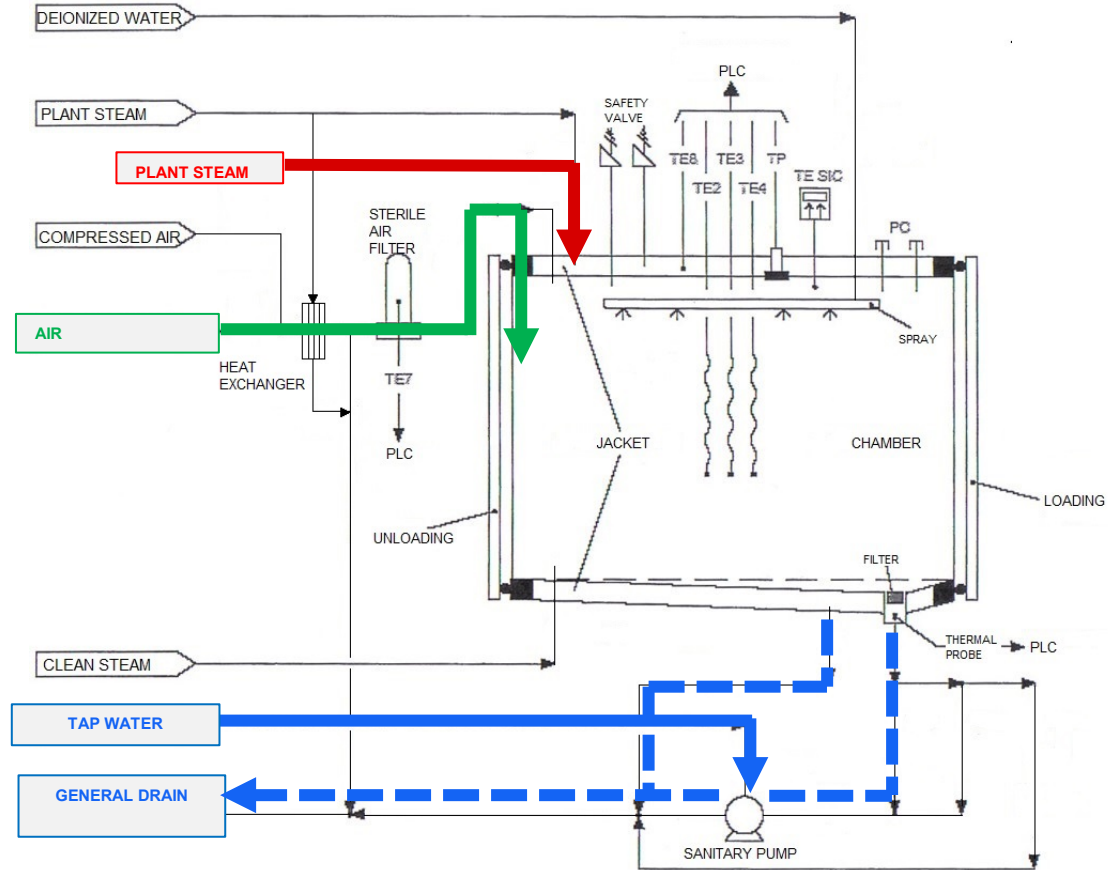
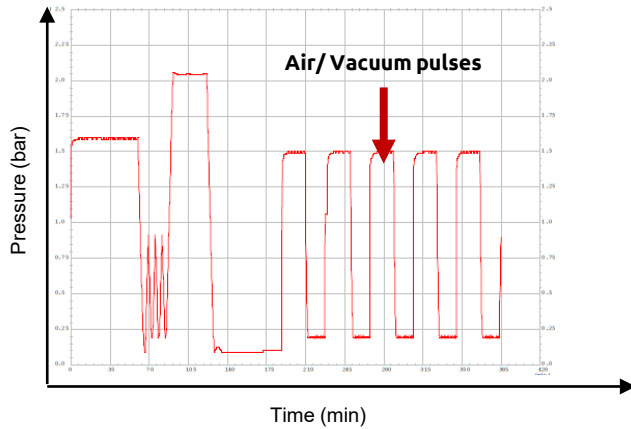
Vacuum Drying



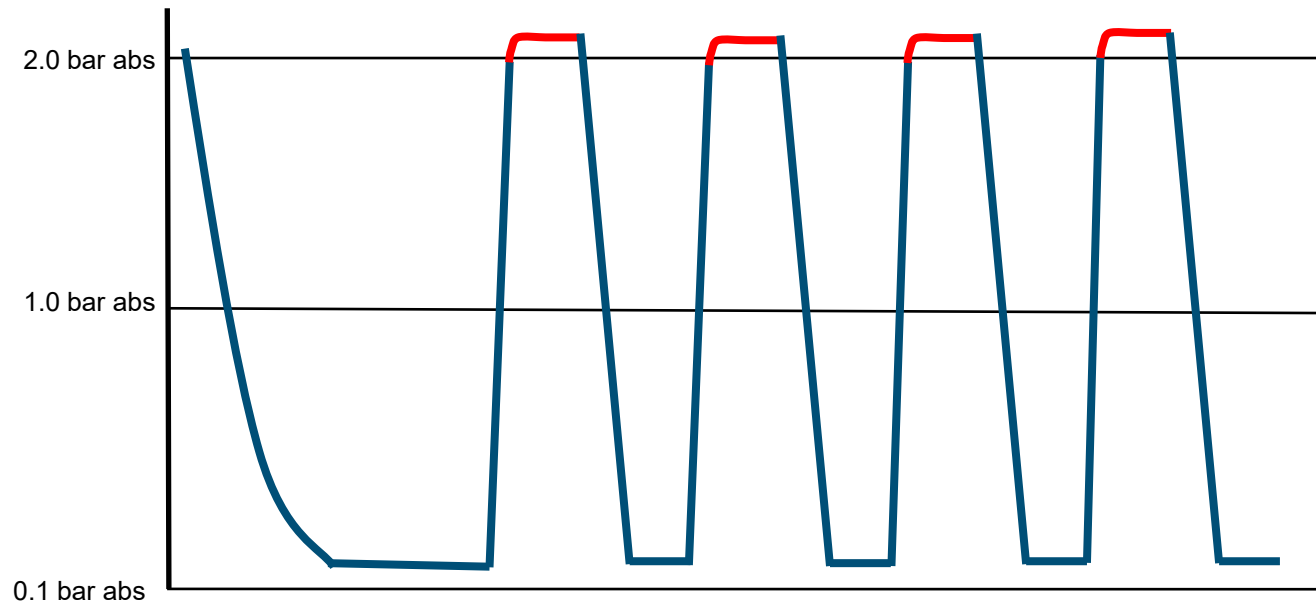
Vacuum Drying



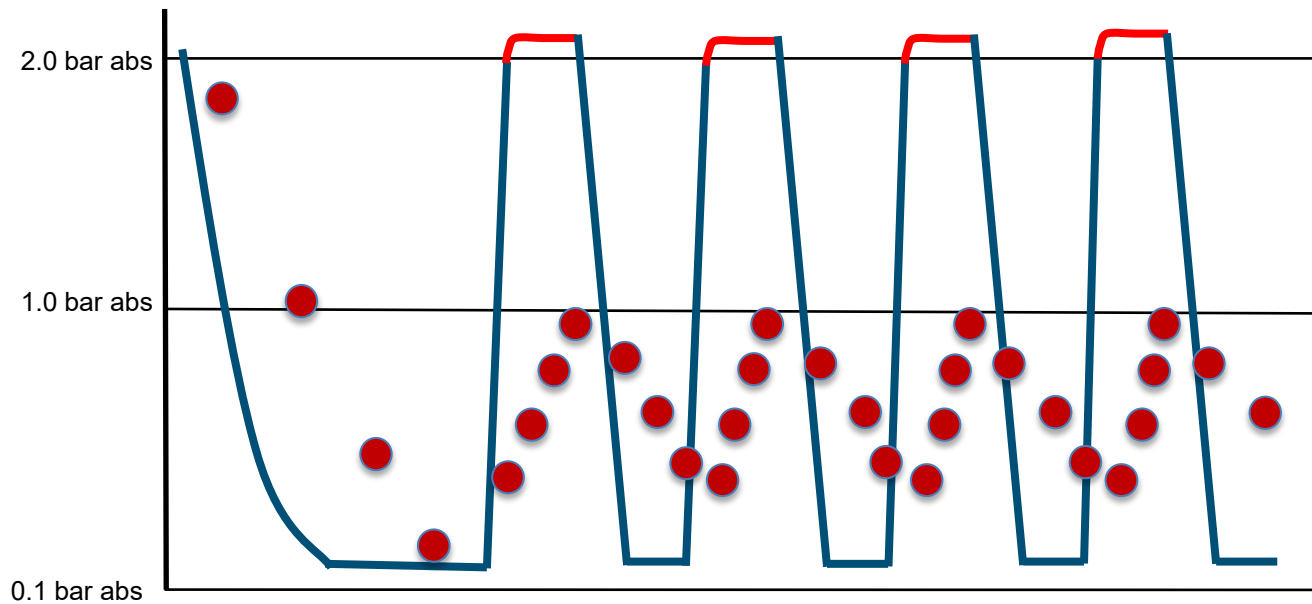
Hot Air Drying



Hot Air Drying



Hot Air Drying



Cooling

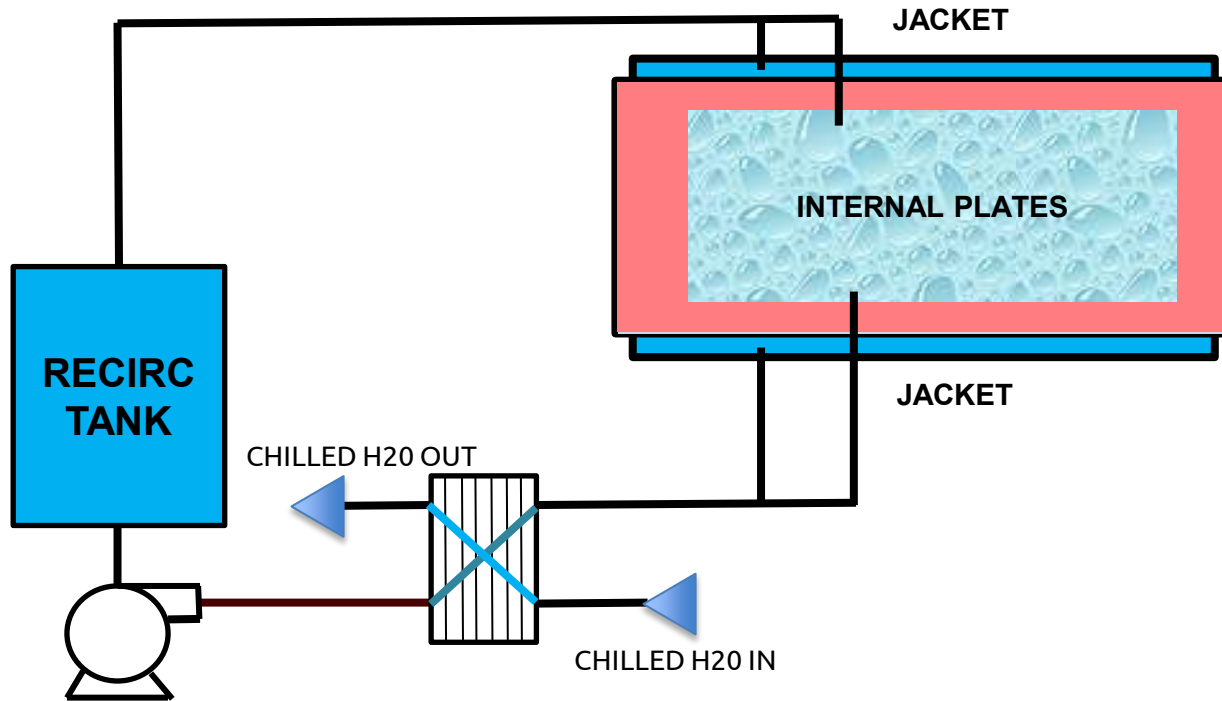
Indirect cooling

- Water circulation in the jacket
- Air counterpressure

Direct cooling

- Spray of sterile water onto the load

Cooling



Thank you!