Load types, Sterilisation Processess and Autoclaves *Saturated steam*

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PDA Parenteral Drug Association

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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

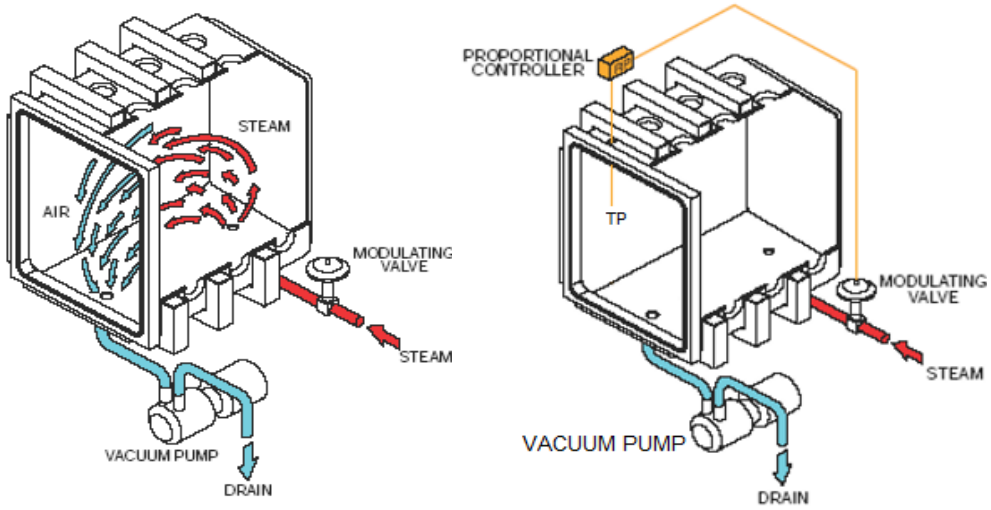
- Residual air acts as an **insulator**
- The presence of residual air in the chamber **negates the singular temperature–pressure relationship of saturated steam**

Saturated Steam Autoclave

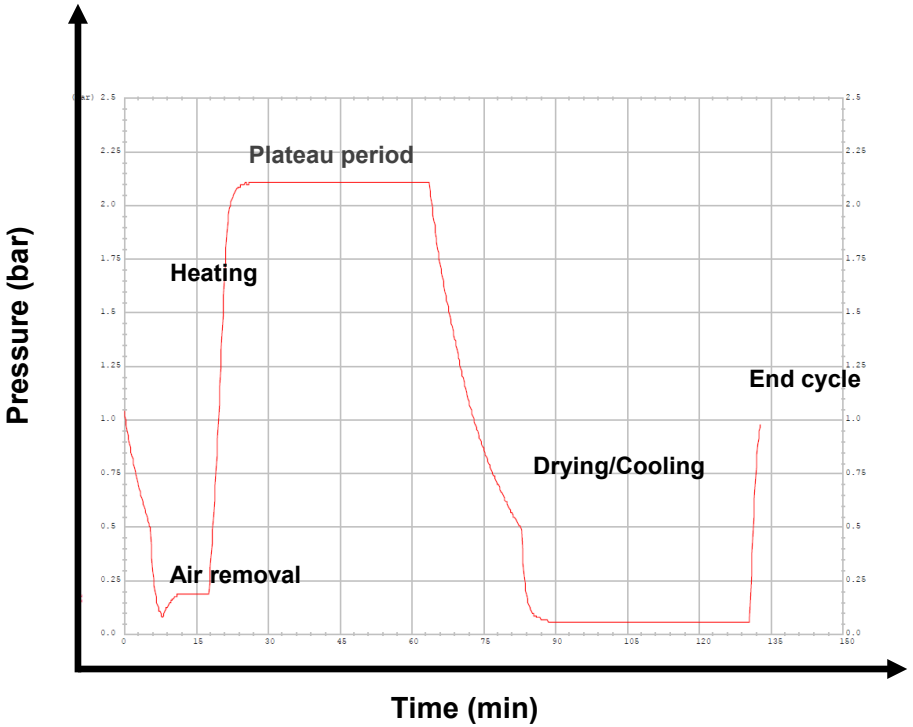
- **Fedegari Horizontal Pharmaceutical** is a highly flexible solution for **multi-purpose sterilization** in bio-pharma industries.
- From **solids** and **porous** to **liquids** in open or non-hermetically sealed containers.

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.

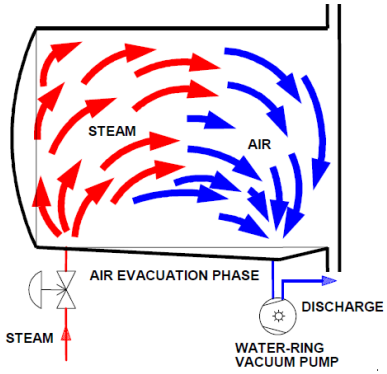


Process phases



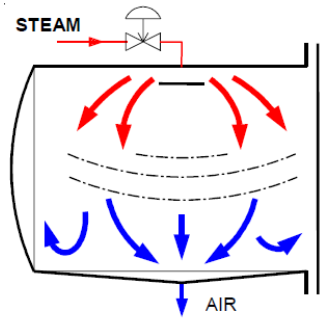
1. **Air removal** from the chamber and the product surfaces (e.g., by vacuum)
2. **Heating** & **Sterilization**
3. **Post-sterilization phases** (drying and/or cooling)

Initial air removal from the chamber



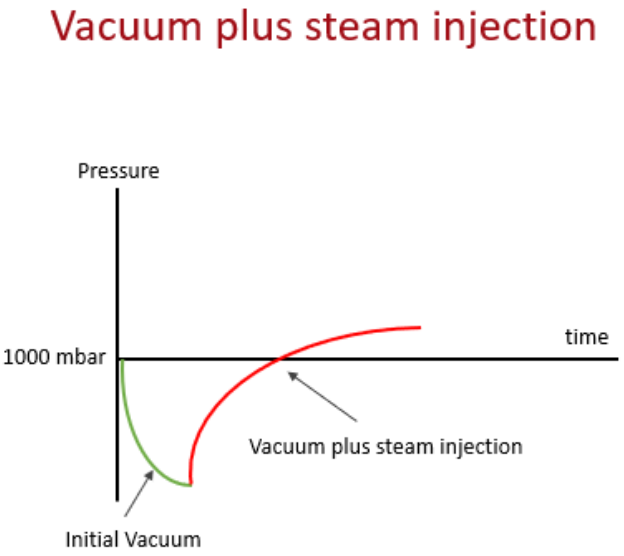
- ***Depressurization plus steam injection***
- ***Steam/ vacuum pulses***

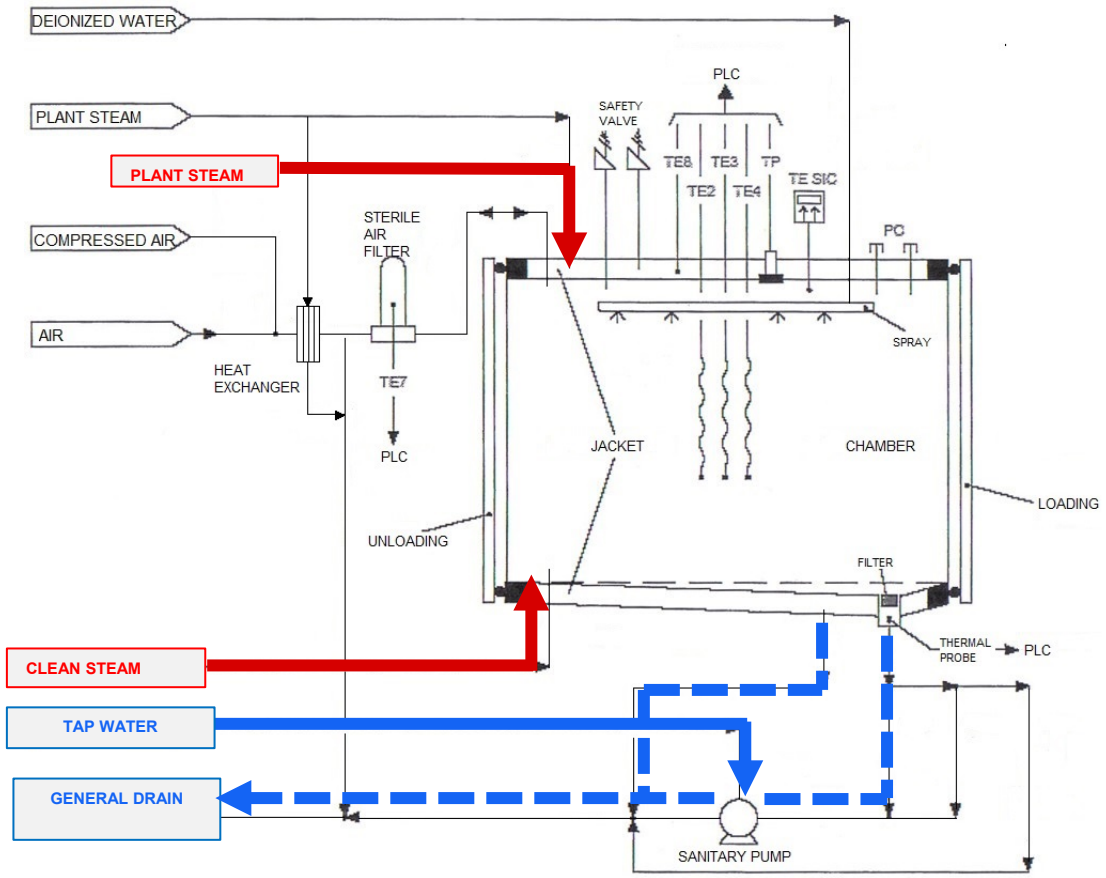
→ These methods removes air from the chamber using a mechanical **vacuum pump** or steam eductor.



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

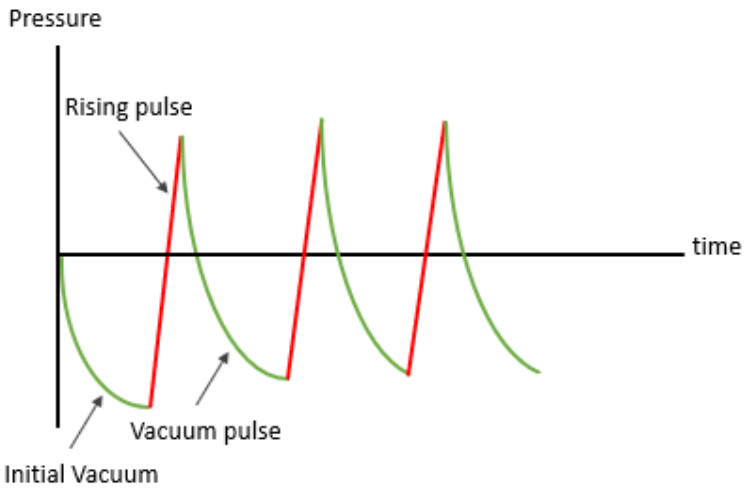
Depressurisation plus steam injection

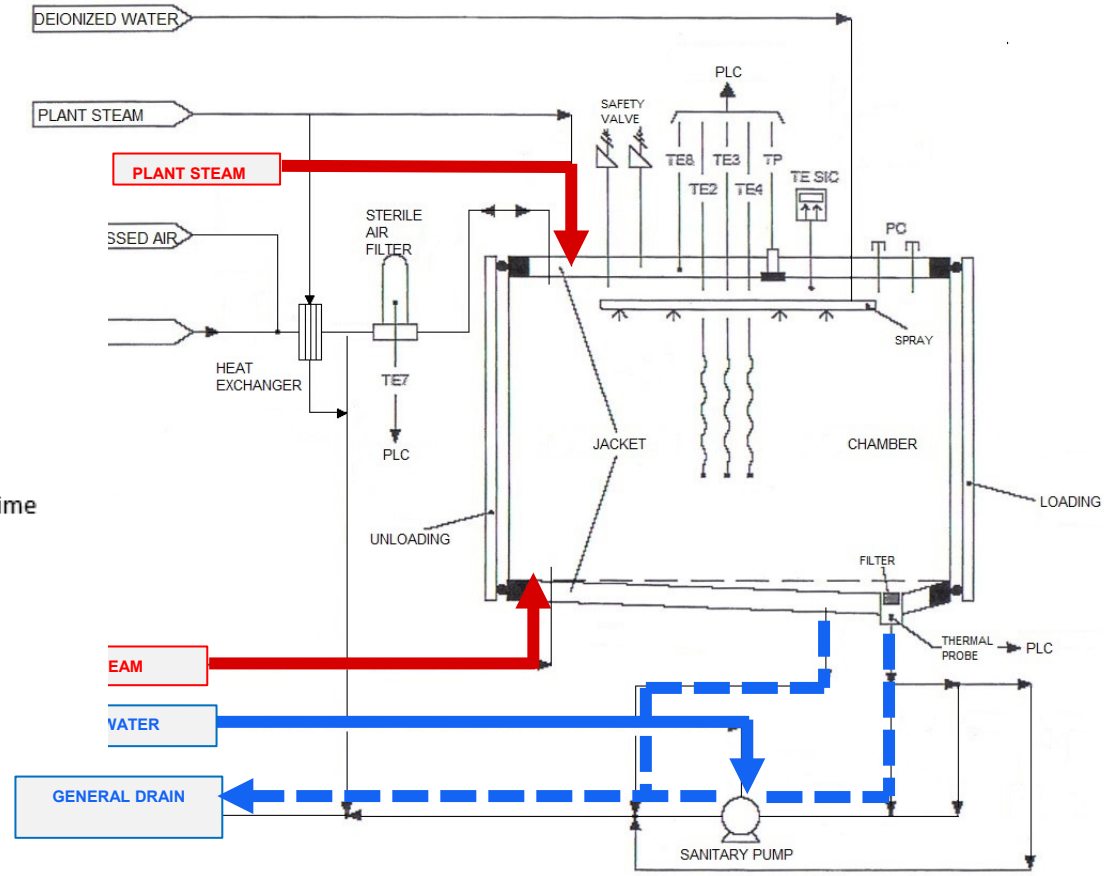




The **vacuum pump** extracts both steam/condensate and air from the chamber

Pulsed Air Removal





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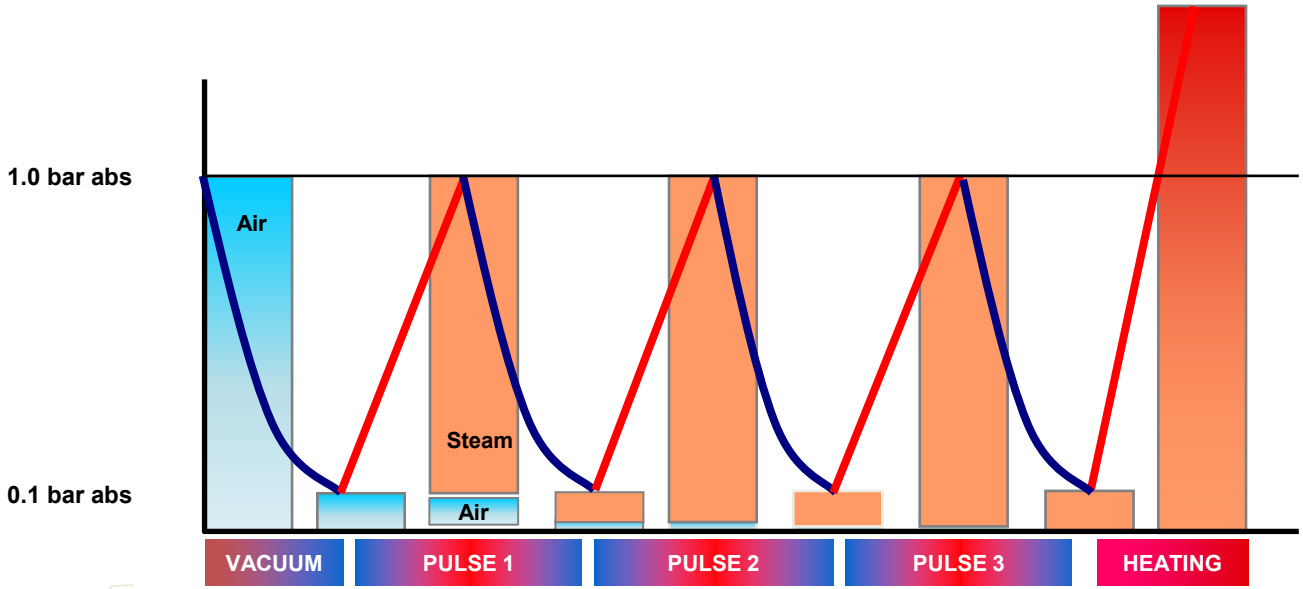
Negative Steam/Vacuum Pulses

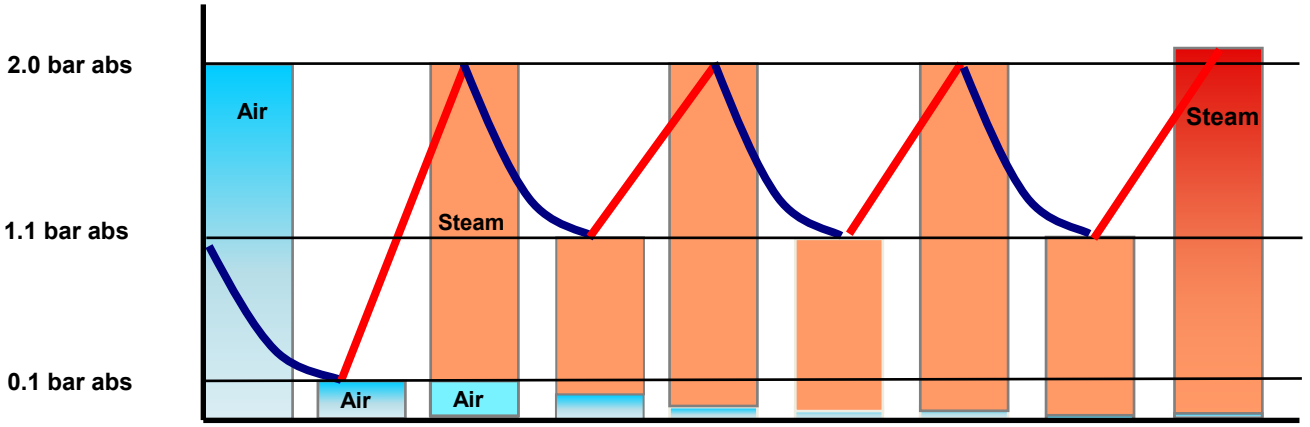
Residual air: 0.01%
Residual steam: 99.99%



Theoretical partial pressure									
Air	1.0	0.1	0.1	0.01	0.01	0.001	0.001	0.0001	0.0001
Steam	0.0	0.0	0.9	0.09	0.99	0.099	0.999	0.0999	0.9999
% Residual Air	100%	10%	10%	1%	1%	0.1%	0.1%	0.01%	0.01%

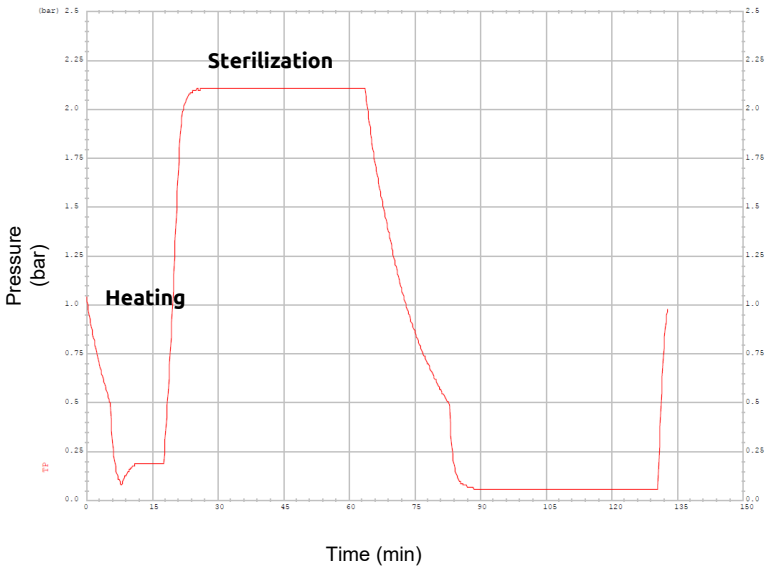
Positive Steam/Vacuum Pulses

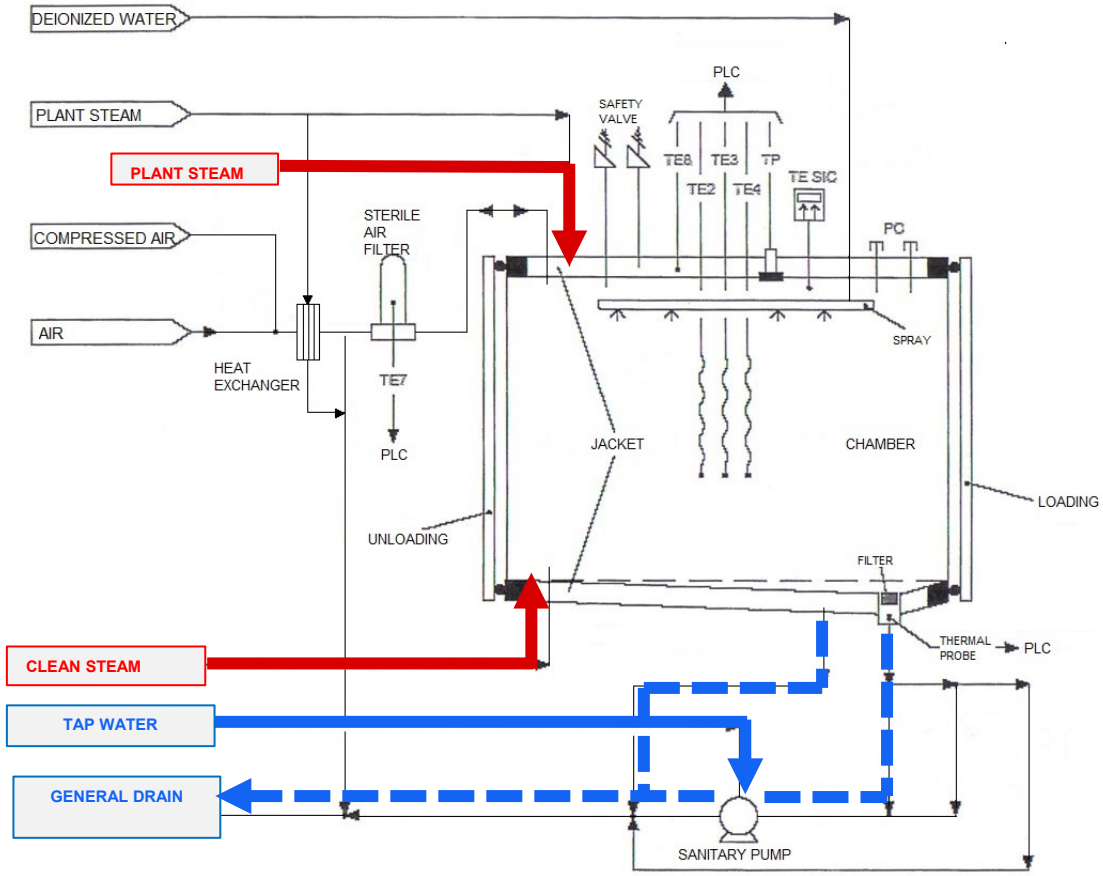
Residual air: 1.664%
Residual steam: 98.336%



% Residual Air	100%	10%	10%	5.5%	5.5%	3.025%	3.025%	1.664%	1.664%
% Residual Steam	0%	0%	90%	94.5%	94.5%	96.975%	96.975%	98.336%	98.336%

Heating & Sterilisation





Process phases

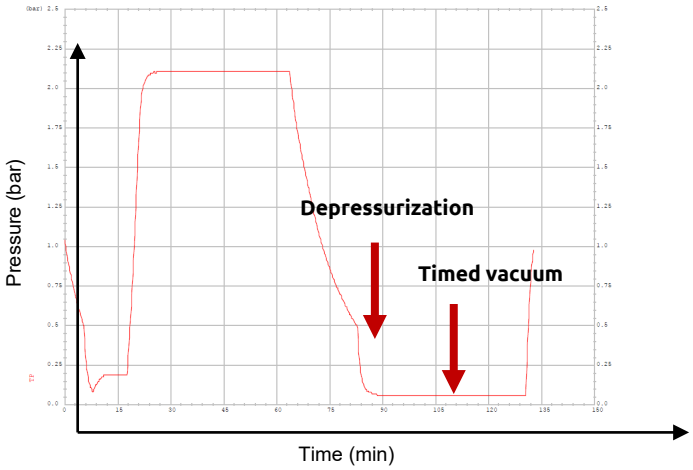
Drying

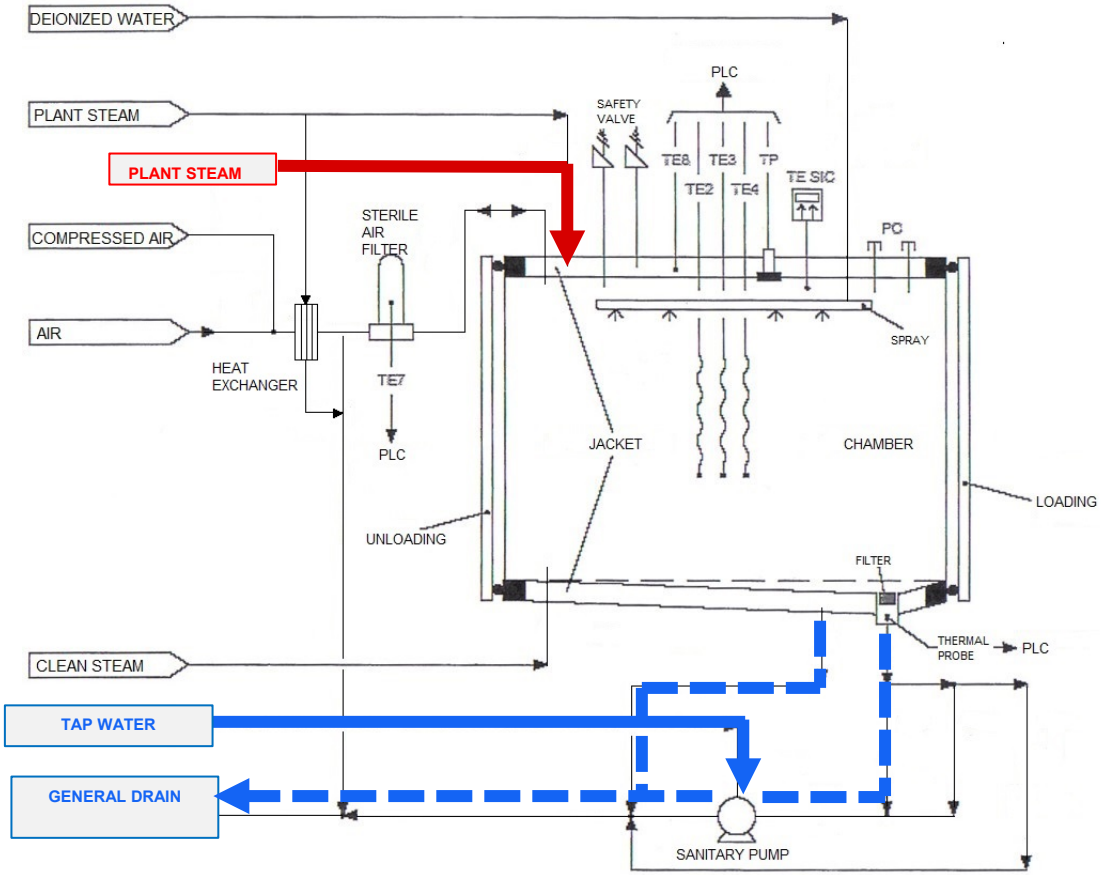
- Vacuum and time-controlled/vacuum hold

Cooling

- Indirect cooling
- Direct cooling

Vacuum Drying





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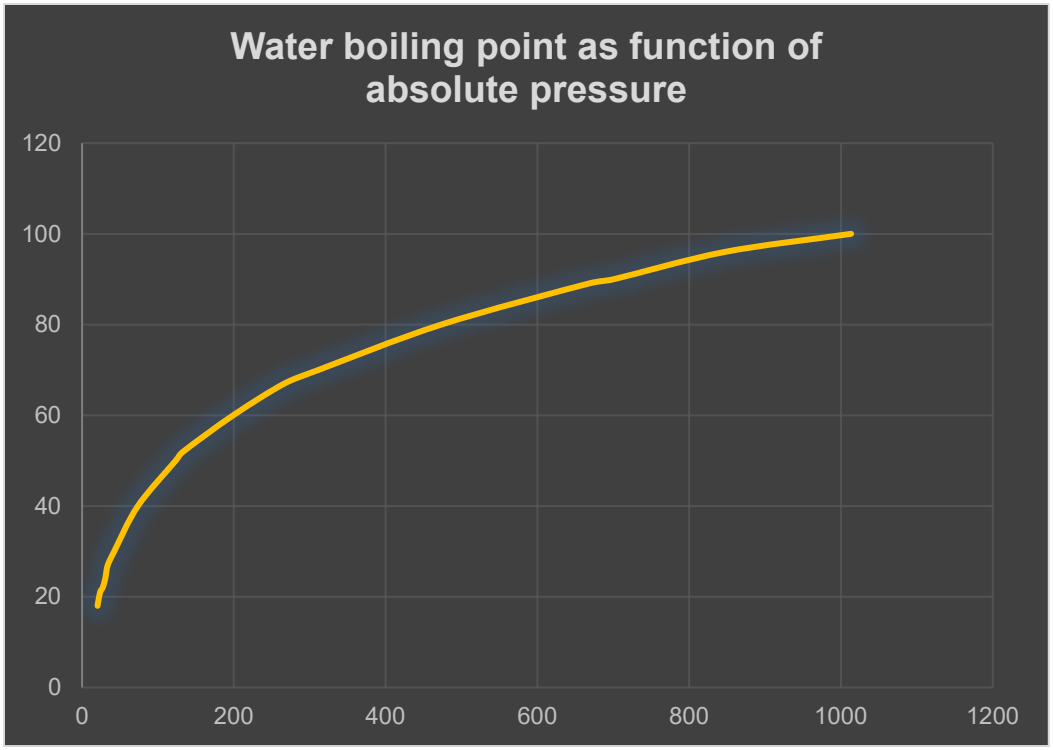
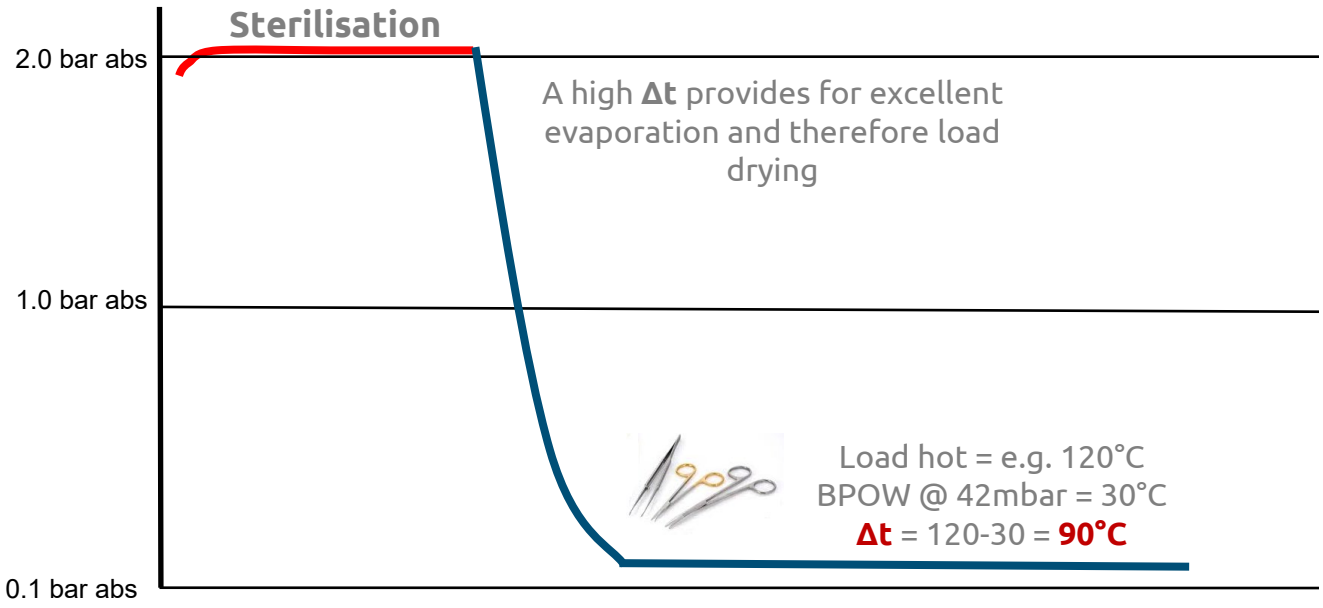


mbara	degC
1013.3	100
846.6	96
700.6	90
666.6	89
473.4	80
311.5	70
266.6	67
199.1	60
133.3	52
123.3	50
73.48	40
42.33	30
33.86	27
30.48	24
27.09	22
23.71	21
20.32	18

Vacuum Drying



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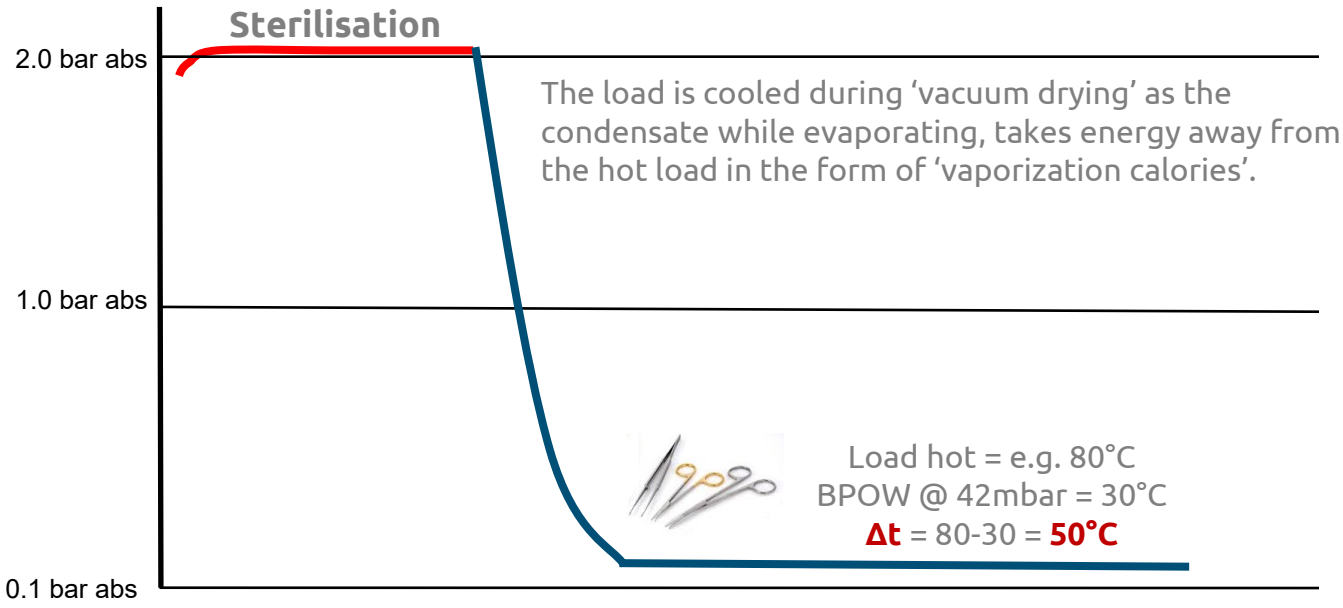

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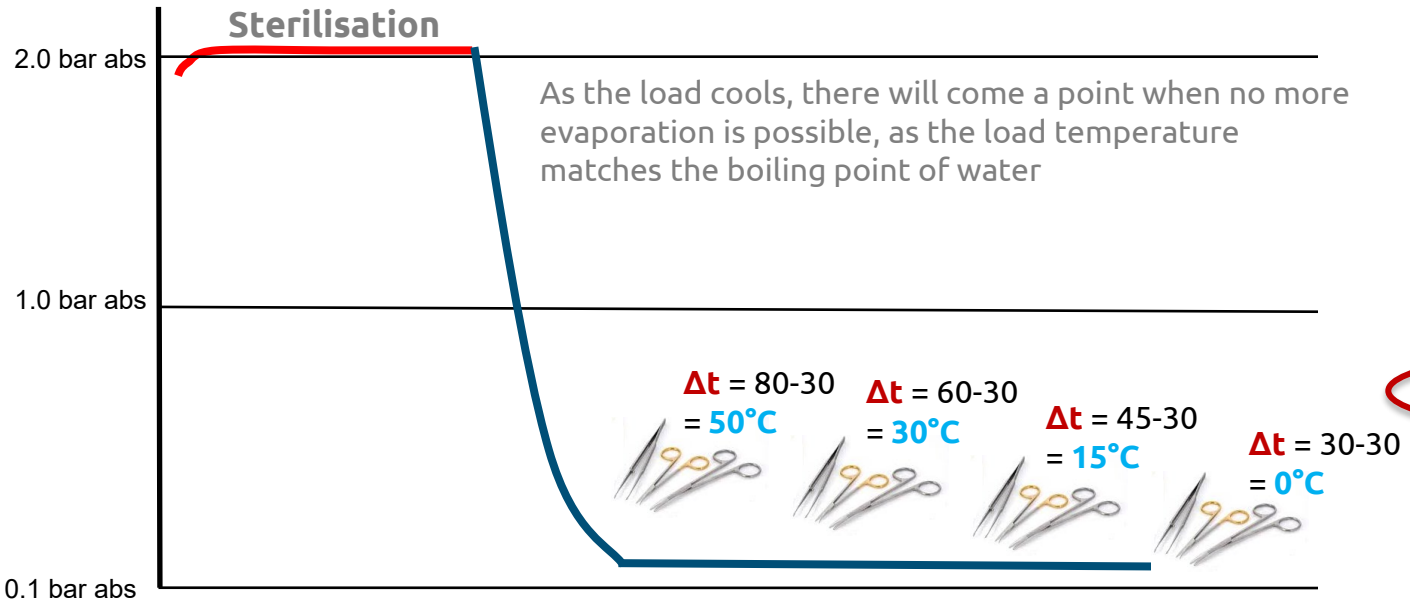

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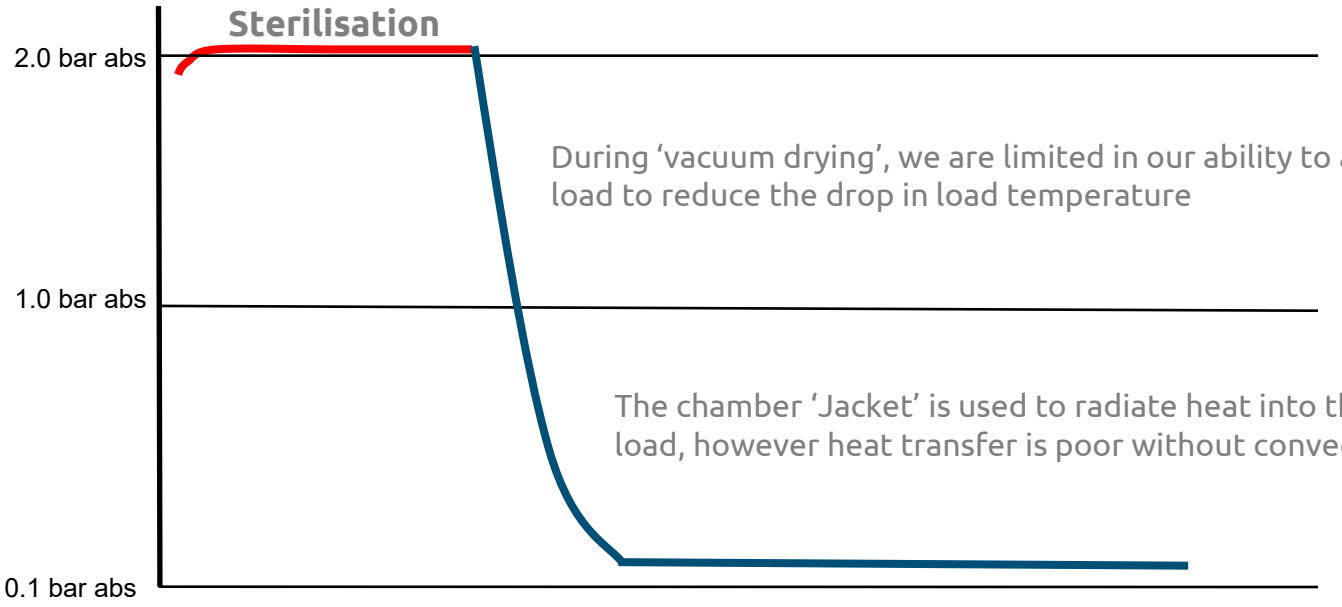
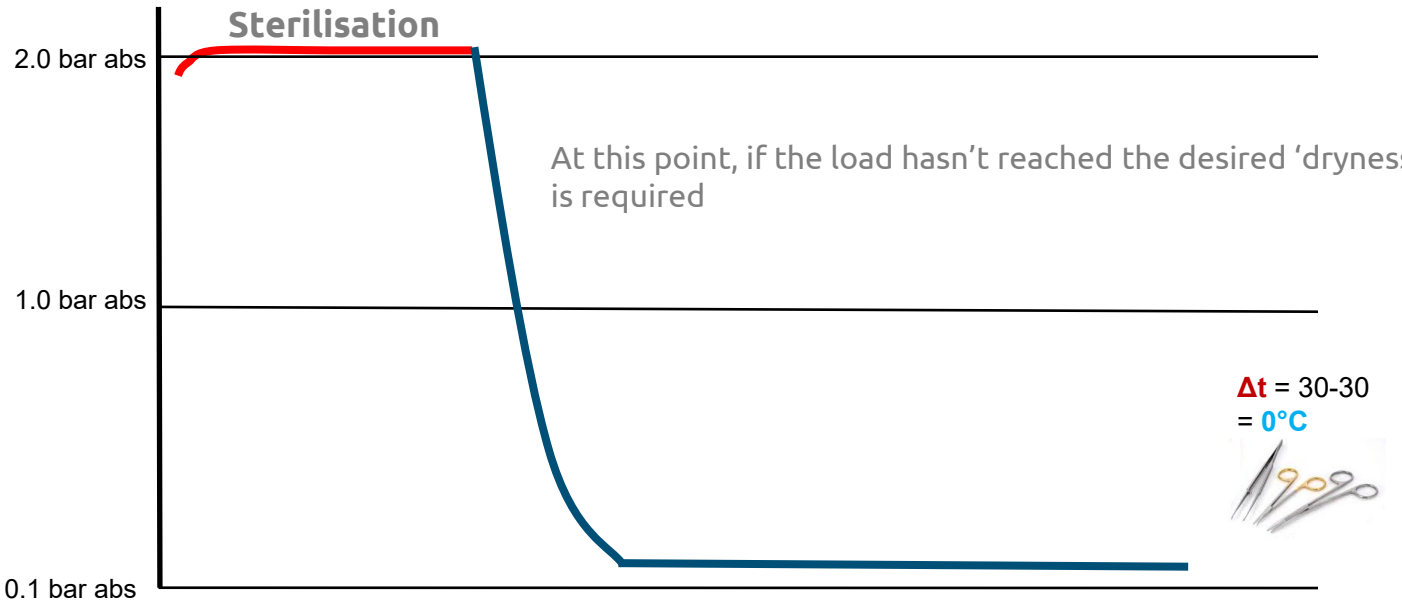


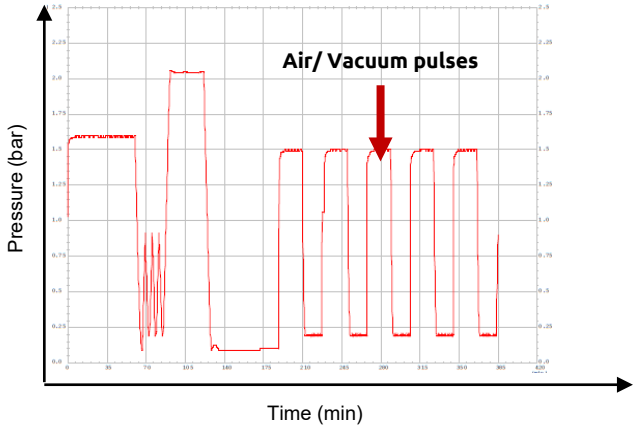
During 'vacuum drying', we are limited in our ability to add extra 'heat' into the load to reduce the drop in load temperature

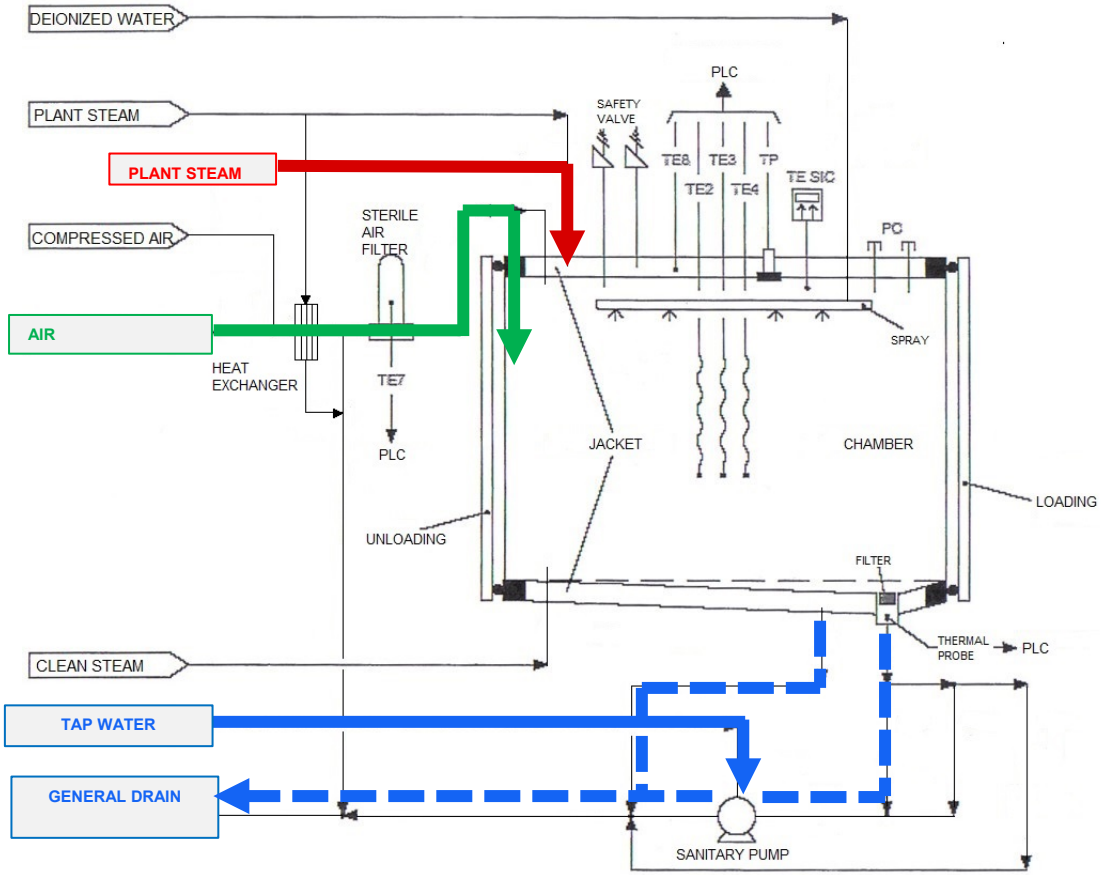
The chamber 'Jacket' is used to radiate heat into the load to slow down the cooling load, however heat transfer is poor without convection

Vacuum Drying



Hot Air Drying





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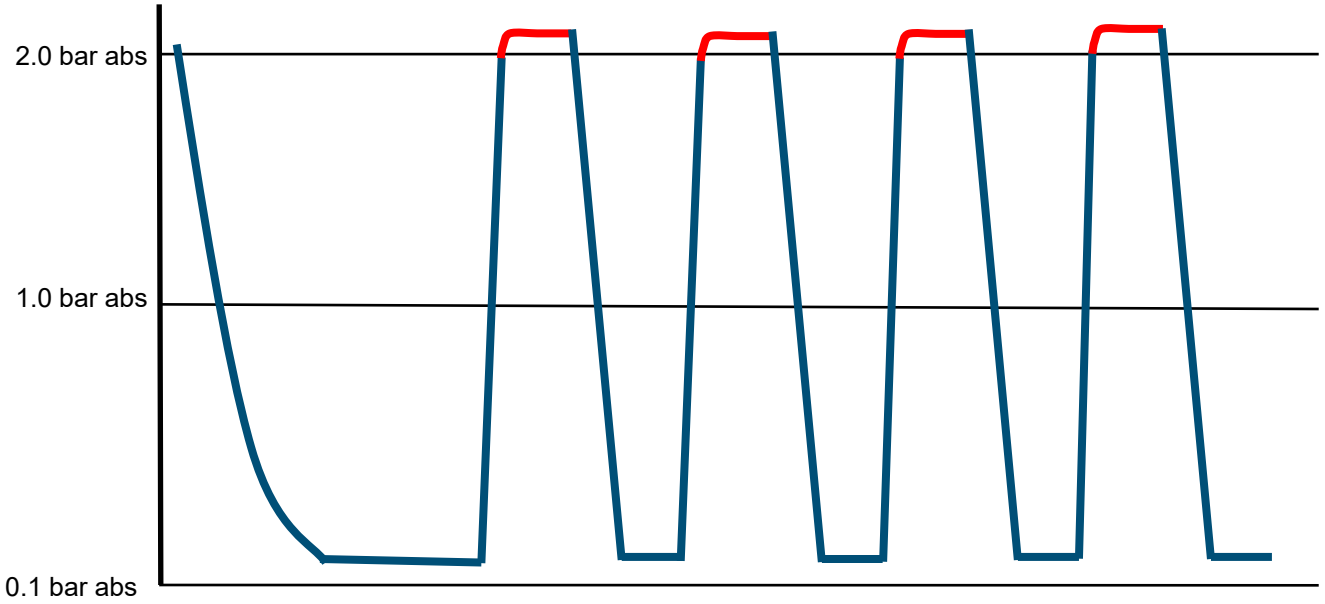

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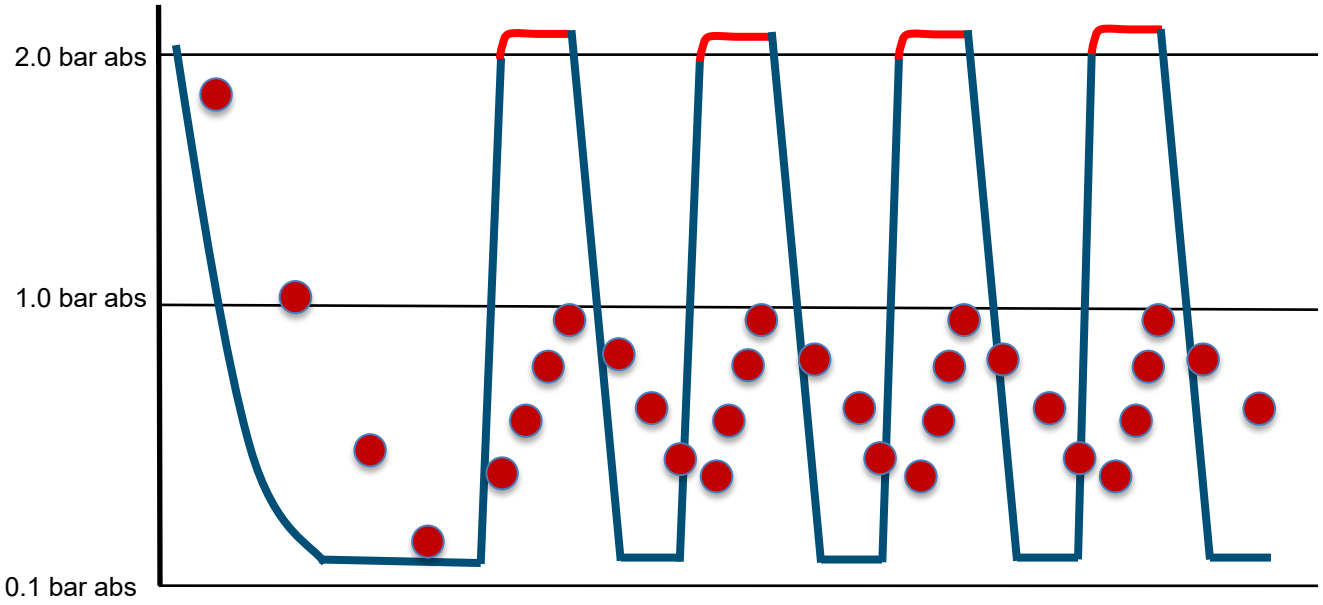


Cooling

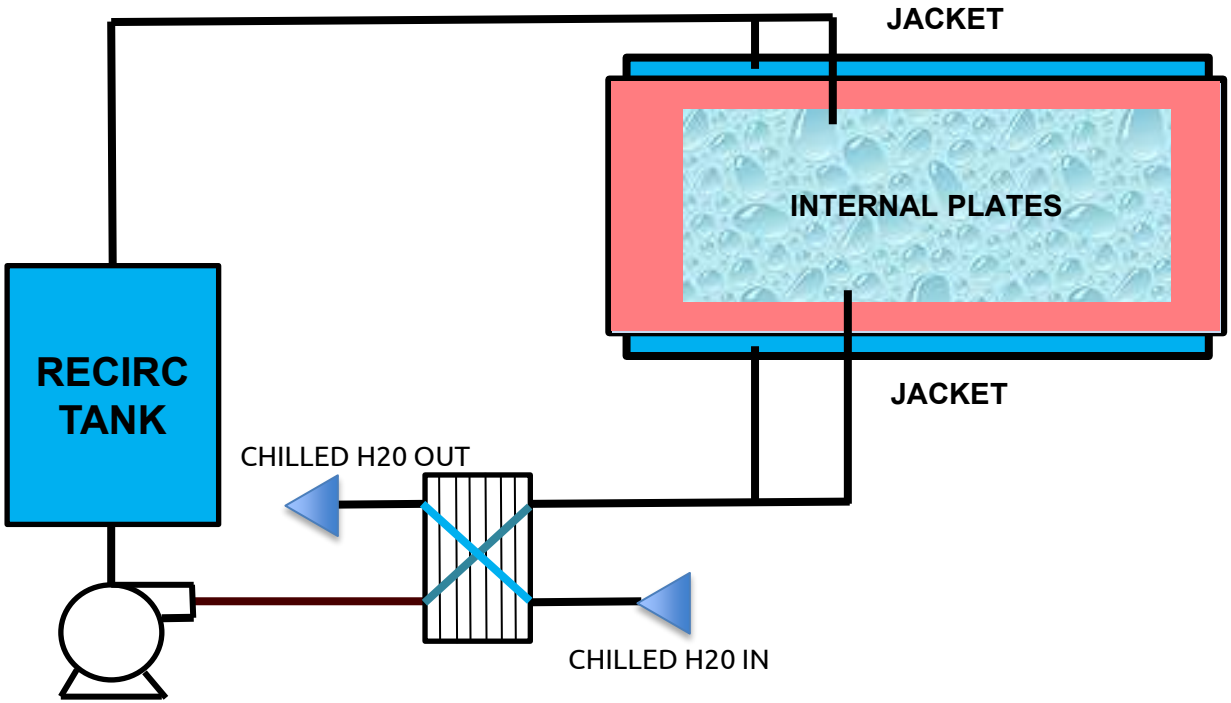
Indirect cooling

- Water circulation in the jacket
- Air counterpressure

Direct cooling

- Spray of sterile water onto the load

Cooling


JACKET
INTERNAL PLATES
RECIRC TANK
JACKET
CHILLED H20 OUT
CHILLED H20 IN

Thank you!