Load types, Sterilisation Processess and Autoclaves *counterpressure*

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Agenda

Introduction

Load types, Sterilization processes & Autoclaves

Saturated Steam Autoclave

Generality & cycle description

Counterpressure Autoclaves

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Introduction: Autoclave, load types and Processess

Autoclave

Pressure Vessel intended to perform a Sterilization Process

Loads

- *Porous/Hard Goods Loads*
- *Liquid Load*

Processes

- *Saturated steam sterilization by direct contact*
- *Counterpressure sterilization: air mixture, Super-heated Water*

Agenda

Introduction

Load types, Sterilization processes & Autoclaves

Saturated Steam Autoclave

Generality & cycle description

Counterpressure Autoclaves

Generality & cycle description

Counter pressure autoclaves

Terminal treatment of solutions in **sealed containers**.

Aim is to "**neutralize**" the effects of the **overpressure**

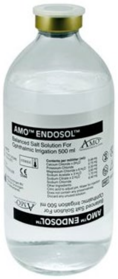
Liquid load in hermetically sealed containers

Two types of processes:

- **superheated water autoclave** (also, “water cascade”, or “water rain”)
- **air-over-steam** autoclave (also, “steam & air”)

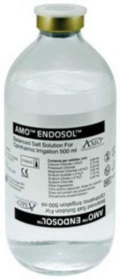
What happens when an aqueous solution in a sealed container is heated?

1. Water partially evaporates into the head space, but the *steam pressure* $\mathbf{P_v}$ in the head space depends only on the temperature, regardless to the head space volume, as *phase equilibria are not affected by mass transfer*



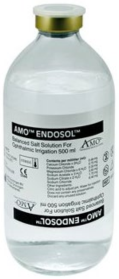
What happens when an aqueous solution in a sealed container is heated?

2. *Dissolved gases* partially leave the solution and generate a pressure **P_g** in the head space, that depends on temperature and chemical species



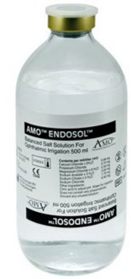
What happens when an aqueous solution in a sealed container is heated?

3. Gases (*air*) initially present in the head space expand, thus increasing their volume and/or their pressure $\mathbf{P_a}$, that depends on gas mass, temperature and head space volume



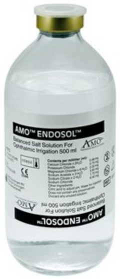
What happens when an aqueous solution in a sealed container is heated?

4. The liquid phase increases its volume (thermal expansion of the liquid is practically not containable) → *This tends to reduce the head space and increase the pressure*



What happens when an aqueous solution in a sealed container is heated?

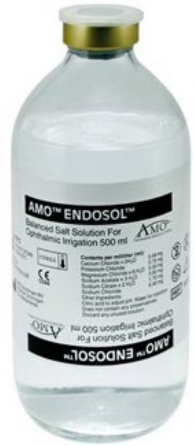
5. The overall capacity of the container increases thanks to the thermal expansion of its material (the thermal expansion is quite different for plastics, glass and metals). → *This tends to increase the head space and reduce the pressure*



What happens when an aqueous solution in a sealed container is heated?

$$P_v + P_g + P_a = \mathbf{P_h}$$

is the **total pressure in the head space**



Overpressure inside sealed container

The total pressure (P) generated inside the sealed container at the temperature T (ex. 121°C) is equal to:

$$P_{(T)} = Pv_{(T)} + Pa_{(T)}$$

Where:
Pv = Pressure of the water vapor
Pa = Pressure of the air

- Air initially present in the head space.
- Dissolved gases that come out of the solution.
- Reduction of the head space due to the thermal expansion of the liquid.

Example: Calculation of the counterpressure required at 121°C

P_v → It's a well-known value (121ºC → 2,05 bar abs)
P_a → It's calculated based on the temperature of the liquid

Counterpressure Autoclaves

> 100ml

Superheated water autoclave

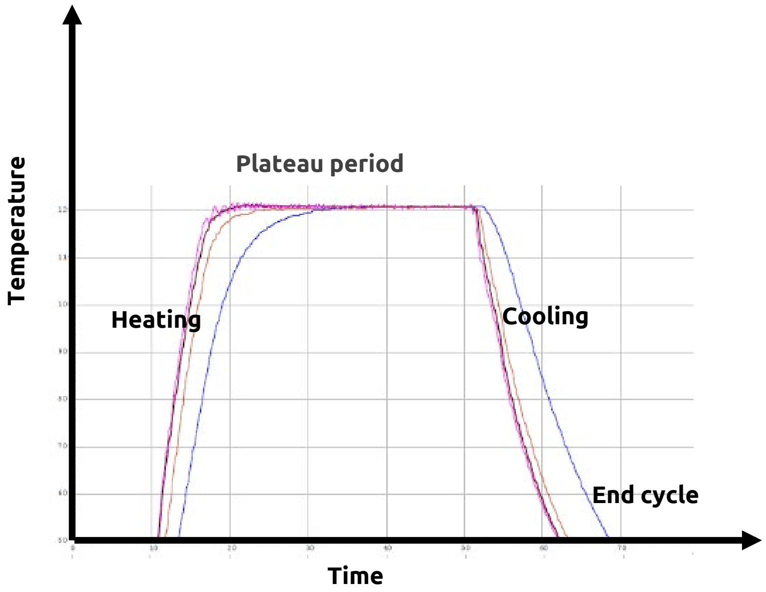
- **“Water cascade” sterilizers**
- **Counterpressure sterilization** through superheated water

Steam-air mixture autoclave

- **Steam air mixture** sterilizers able to perform counterpressure sterilization

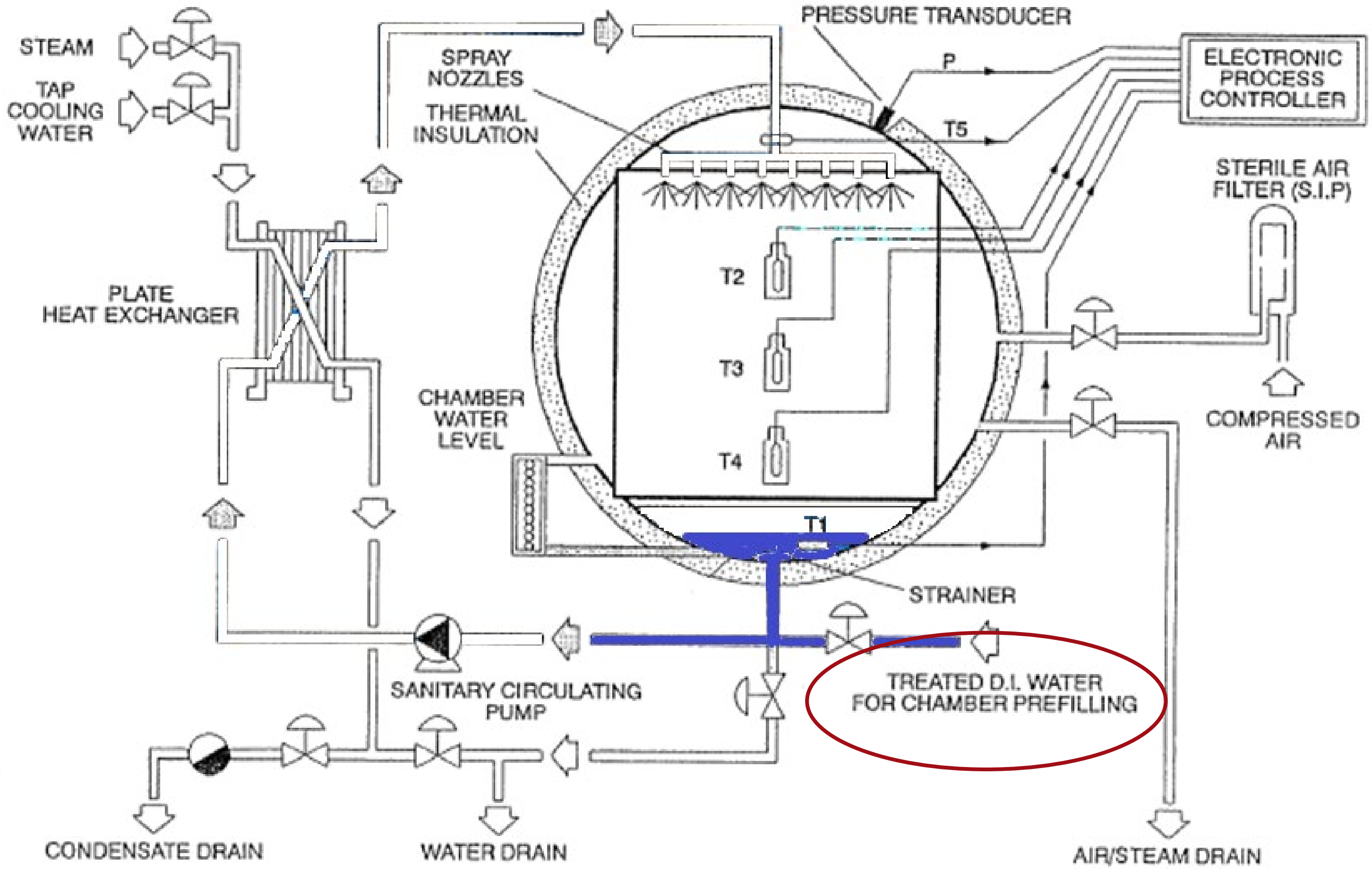
- At beginning the **air in the chamber is not removed**
- Suitable for treating loads in containers that may be **deformed** due to the difference in pressure between the chamber and the container itself.

Superheated water autoclave *process phases*

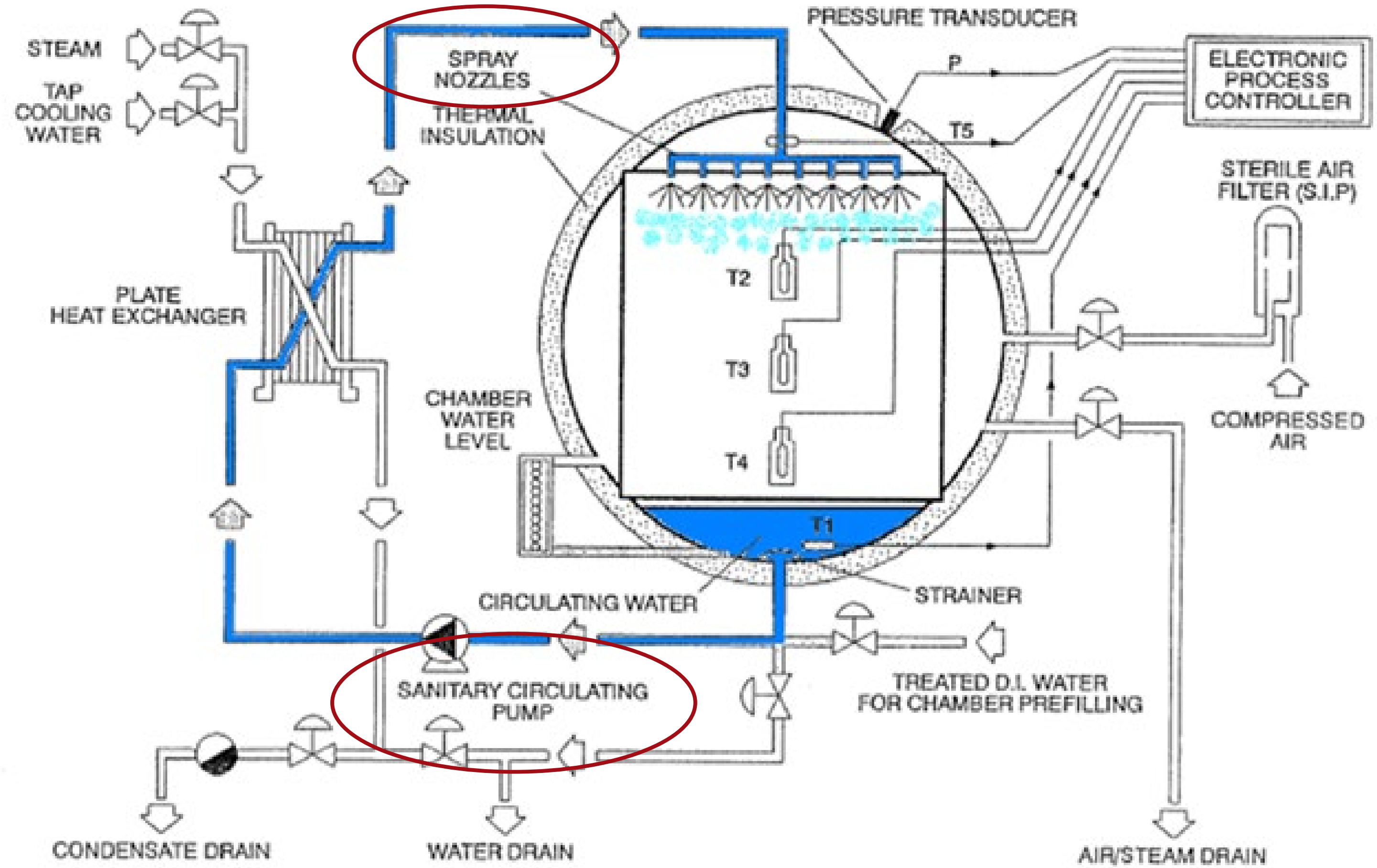


1. Chamber water filling
2. Water circulation
3. Heating & Sterilization
4. Cooling
5. Chamber drain
6. Atm pressure balance

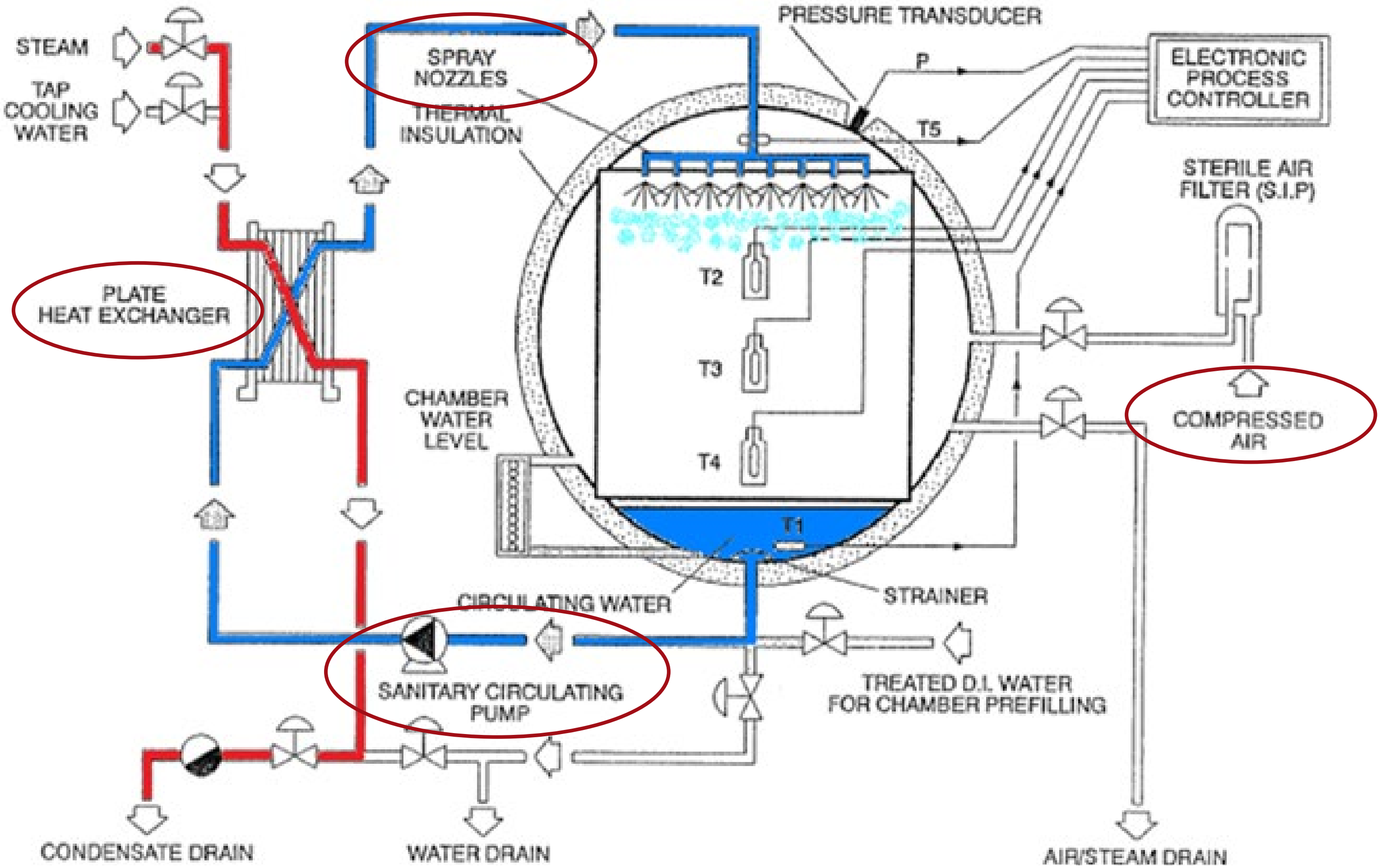
Phase 1: Chamber water filling



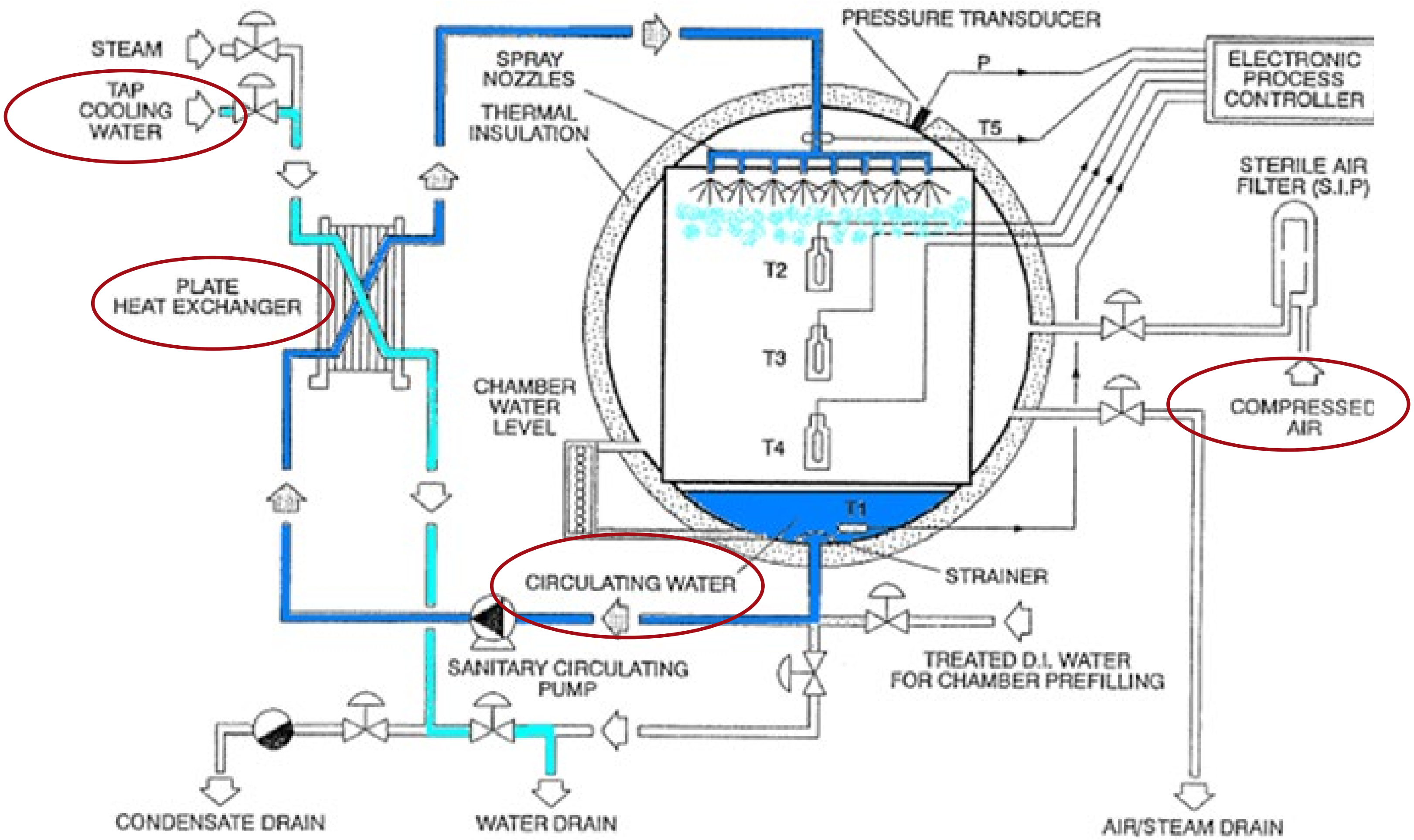
Phase 2: Water circulation



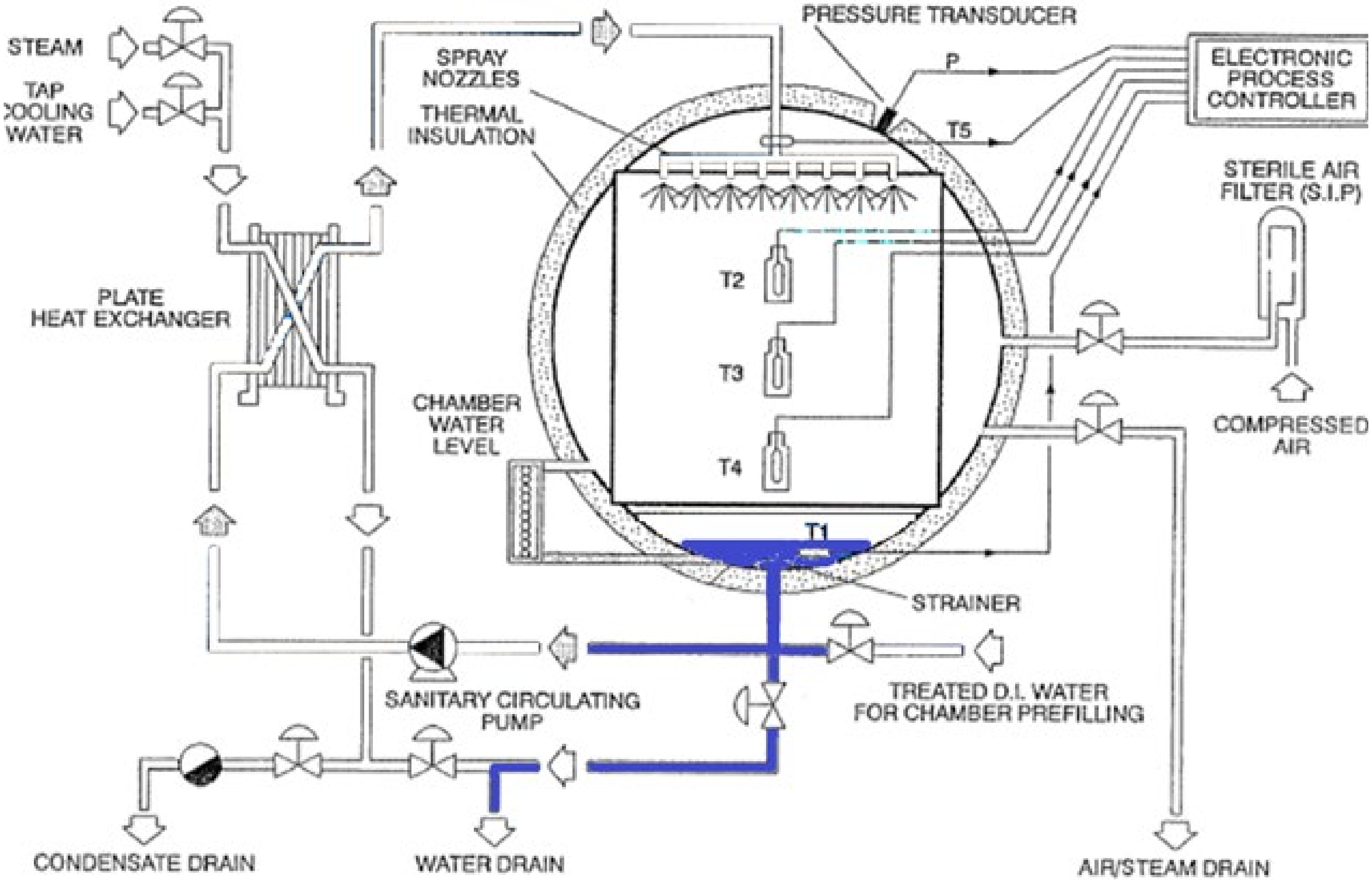
Phase 3: Heating & Sterilisation



Phase 4: Cooling

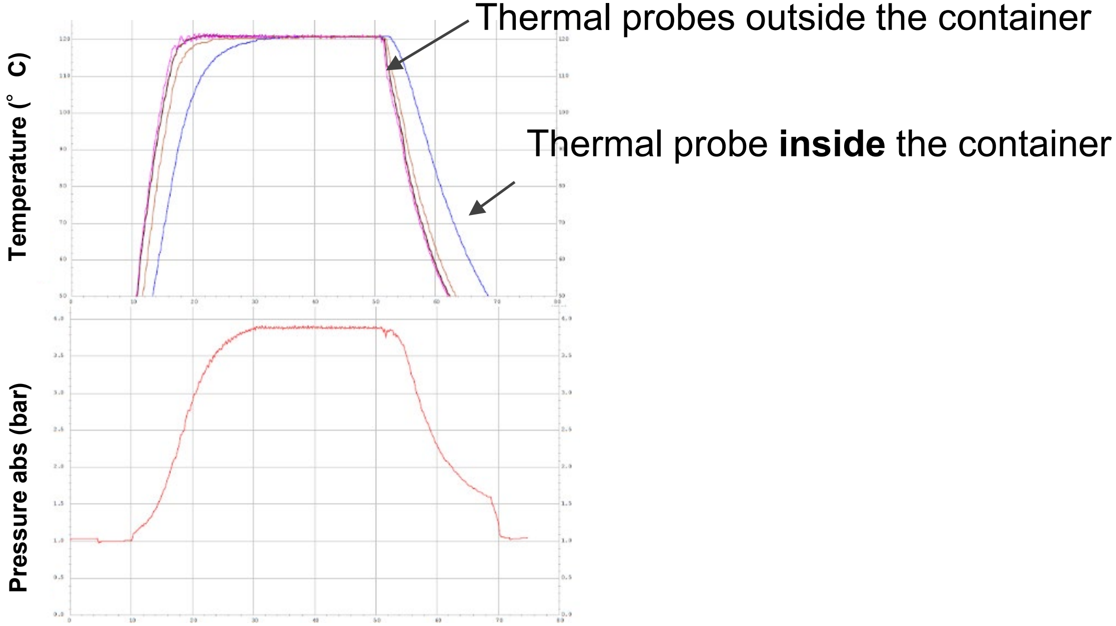


Phase 5: Chamber drain



Thermal and pressure profiles

- The **control of the process** is based on the temperature
- **Chamber pressure** is independent from the temperature
- During all stages, the **counterpressure** is controlled

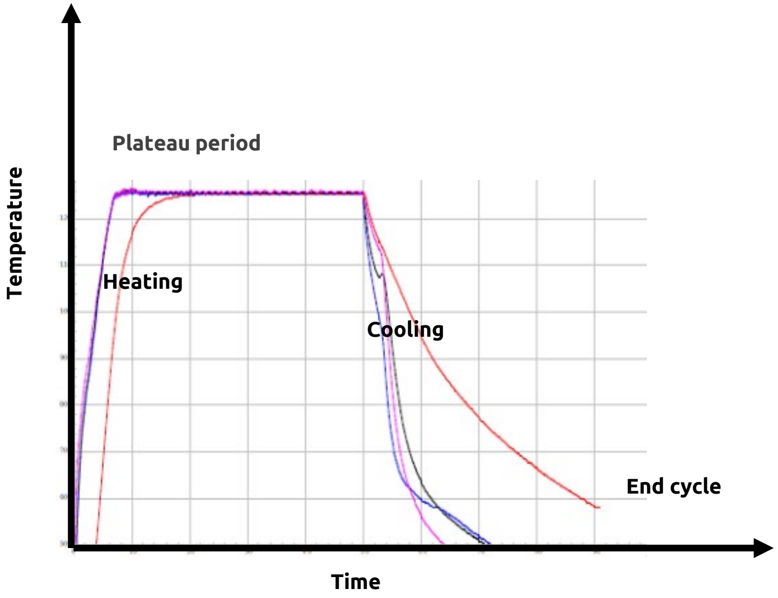


Steam requirements

In **superheated water** autoclaves:

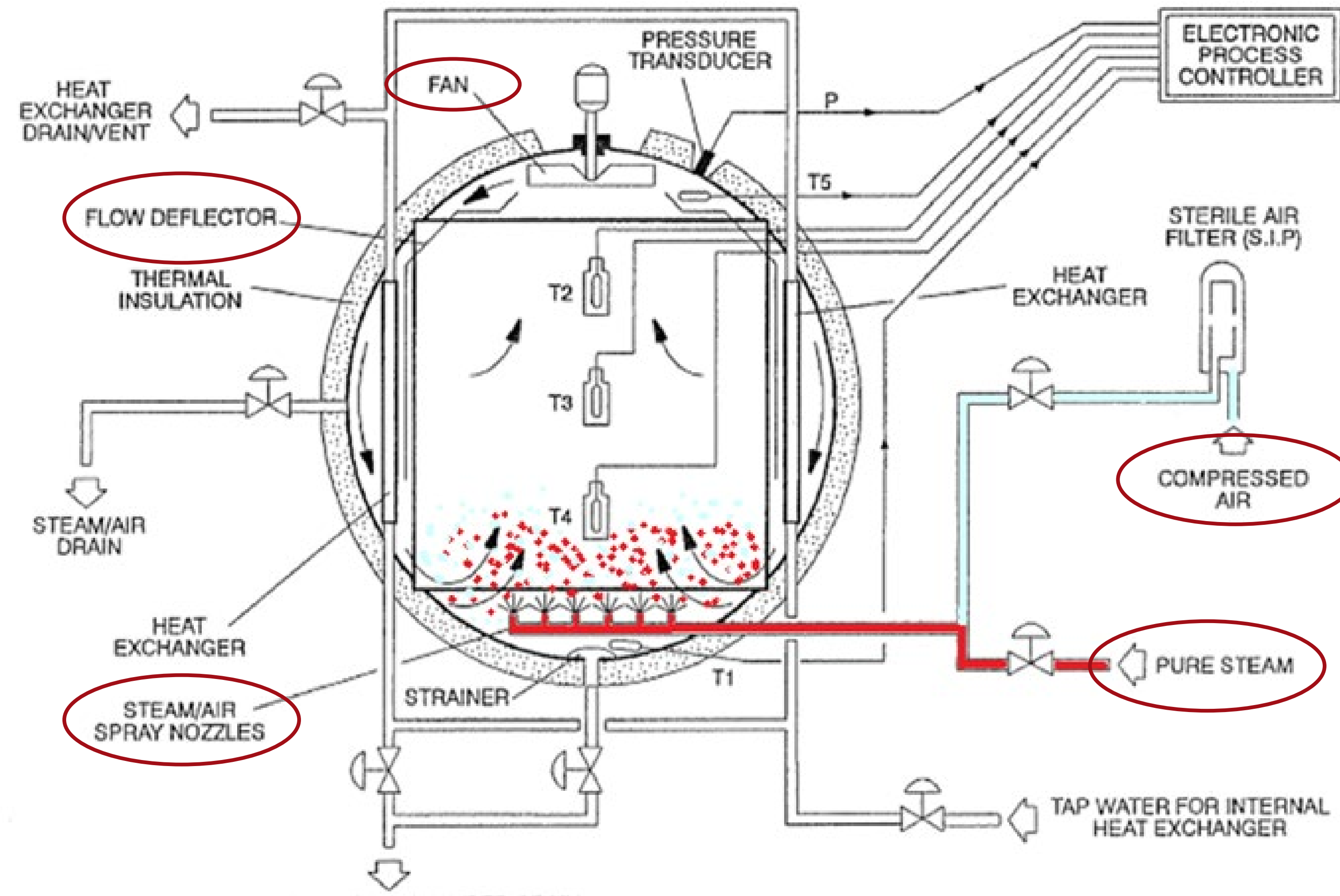
- there is no contact between steam and product
- there is no problem of incompatible steam additives
- steam quality is relevant only from the energetic point of view
- energy must be spent to heat not only the load and the autoclave framework, but also the circulating water
- energy recovery is partially possible with higher investment costs

Steam-Air mixture autoclave *process phases*

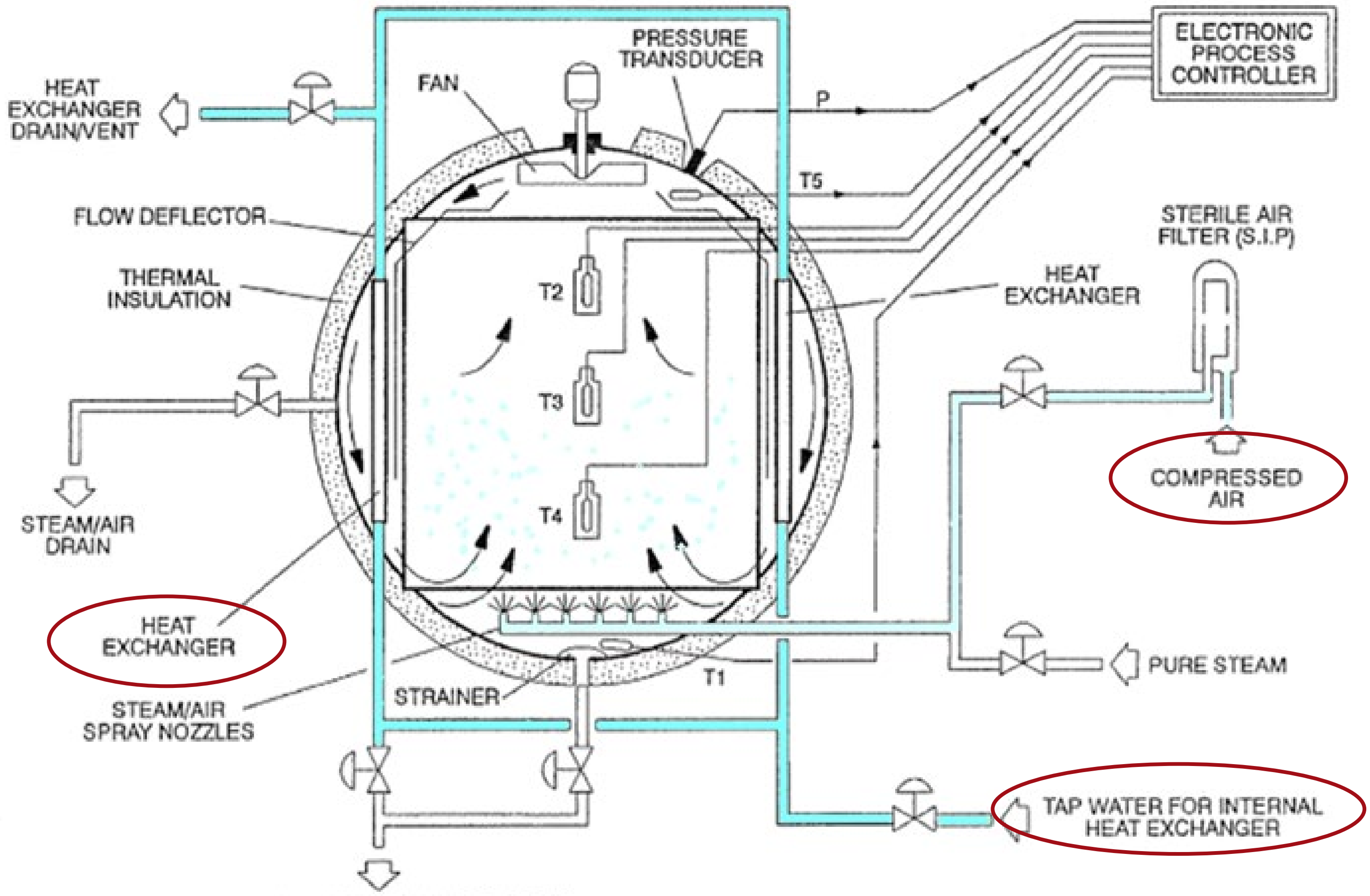


1. Heating & Sterilization
2. Cooling
3. Atm pressure balance

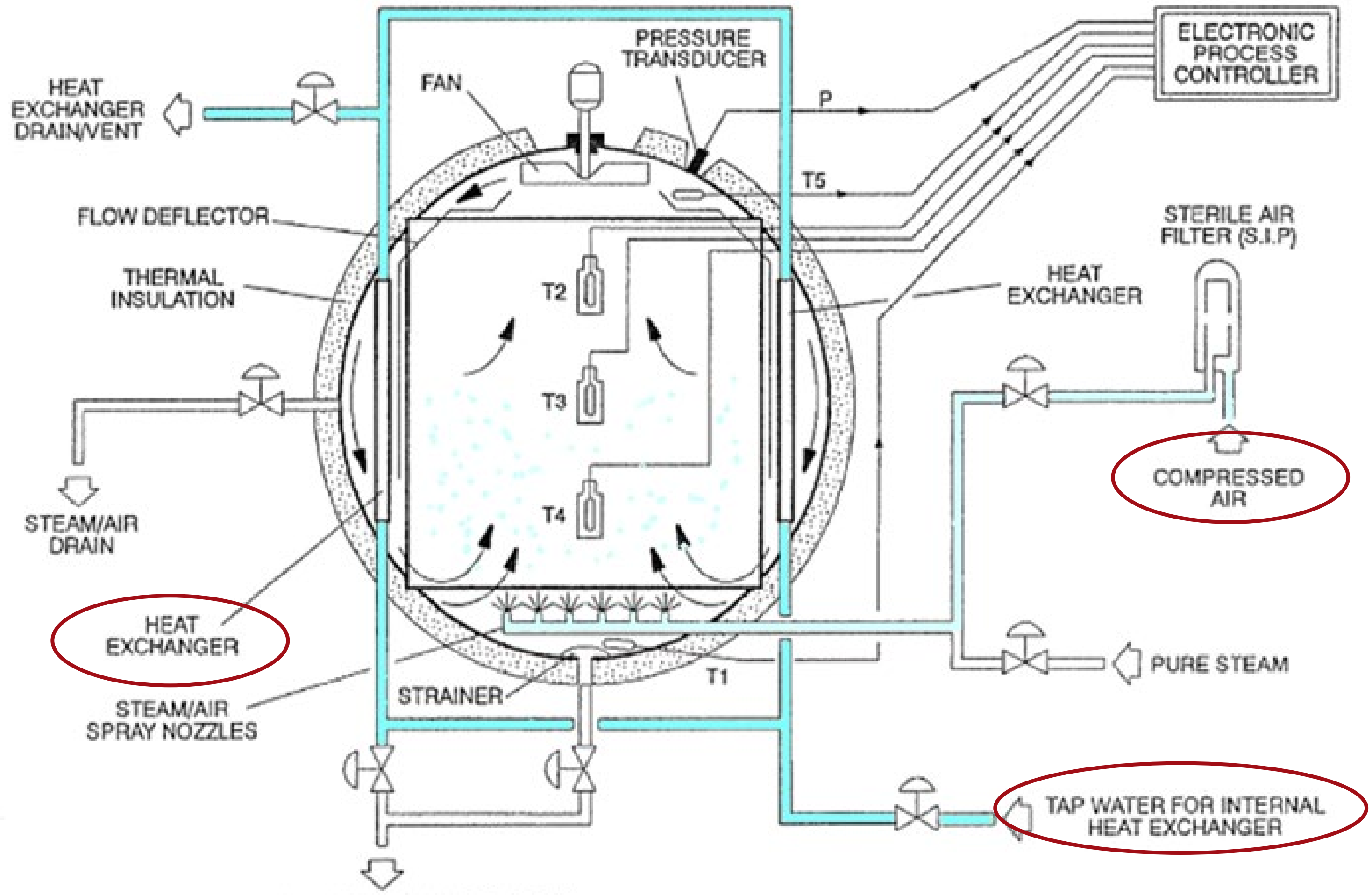
Phase 1: Heating & Sterilisation



Phase 2: Cooling



Phase 2: Cooling



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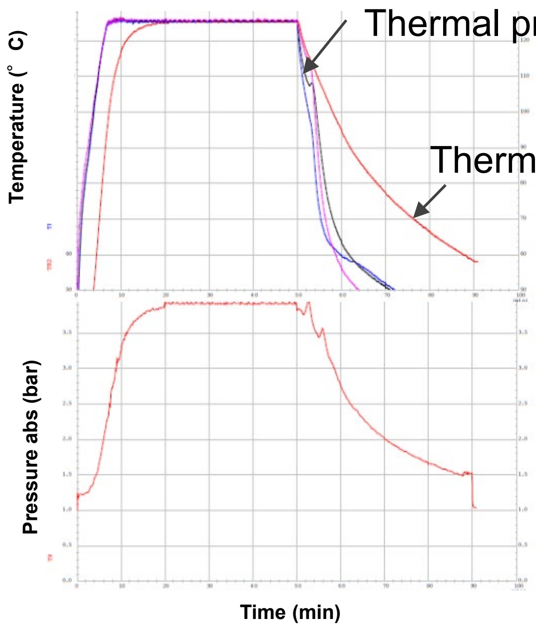

Note: the FOA and FOW charts are similar because they are both counterpressure machines.

Steam requirements

In **air-over-steam** autoclaves:

- there is contact between steam and product, just as in saturated steam autoclaves
- steam heats only or heats and sterilizes depending on the type of load (containers or “difficult” products: blood-bag systems, dialysis filters, containers in blister)
- if the steam heats and sterilizes, the same steam quality requirements do apply, as in the case of saturated steam sterilization, but..
- a further difficulty derives from the independence of pressure and temperature due to the presence of air; the ratio of partial pressures of steam and air is usually between 3 and 1.1 (most commonly about 1.5)

Comparison

Superheated Water

- \+ Easy controlled modulated heating and modulated cooling
- \+ Shorter process duration
- \+ No appreciable consumption of clean steam (used only for filter sterilization)
- – Product is unloaded wet
- – Higher water consumption (for initial filling)
- – Higher energy consumption (to heat the circulation water)
- – Blushing phenomenon (i.e., whitening of the PVC due to water absorption)

Air-over-steam

- – Controlled modulated heating but not possible modulated cooling
- – Longer process duration (mainly because of indirect cooling)
- – Low unloading temperatures require much time
- – Modulated cooling impossible; (but modulated heating possible)
- – Consumption of clean steam
- \+ Lower energy consumption
- \+ Product could be easily unloaded dry
- \+ No PW/UPW/WFI water consumption
- \+ Blushing phenomenon very rare

Thank you!