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## Reducing UPOPs and Mercury Releases from The Health Sector in Africa

# *Module 28: Autoclaves & Co – way of working*

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GLOBAL ENVIRONMENT FACILITY  
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# Content

- ▶ Steam treatment systems
  - Pressure cooker
  - Gravity flow autoclave
  - Pre-Vacuum autoclave
  - Pulsed autoclave
- ▶ Operation of steam treatment system
- ▶ Loading & Unloading of autoclaves
- ▶ Fractionated pre-vacuum autoclaves



# Main types of steam treatment plants

- ▶ Three different main types of steam treatment processes are used:
  - Gravity type Autoclaves (Pressure cookers), also called downward displacement sterilizers (Air is removed due to the density difference of air and steam)
  - Pre-vacuum autoclaves or “porous load autoclaves” (Air is mechanically removed and replaced by steam)
  - VSV-Autoclaves: “Vacuum-Steam-Vacuum Autoclaves” or “fractionated Autoclaves” (Air is several times removed and replaced by steam)





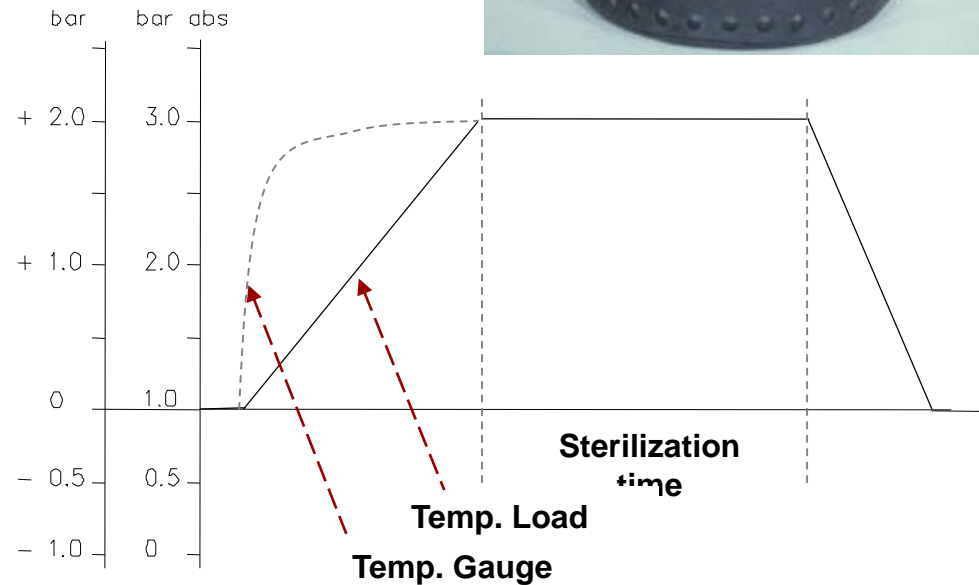
# The pressure cooker

## ► Basic components

- Pressure vessel
- Pressure valve
- Safety valve
- Pressure gauge

## ► But...

- No removal of air (Cold Island problem)
- Difficult drying of sterilized goods
- Only for unpacked goods



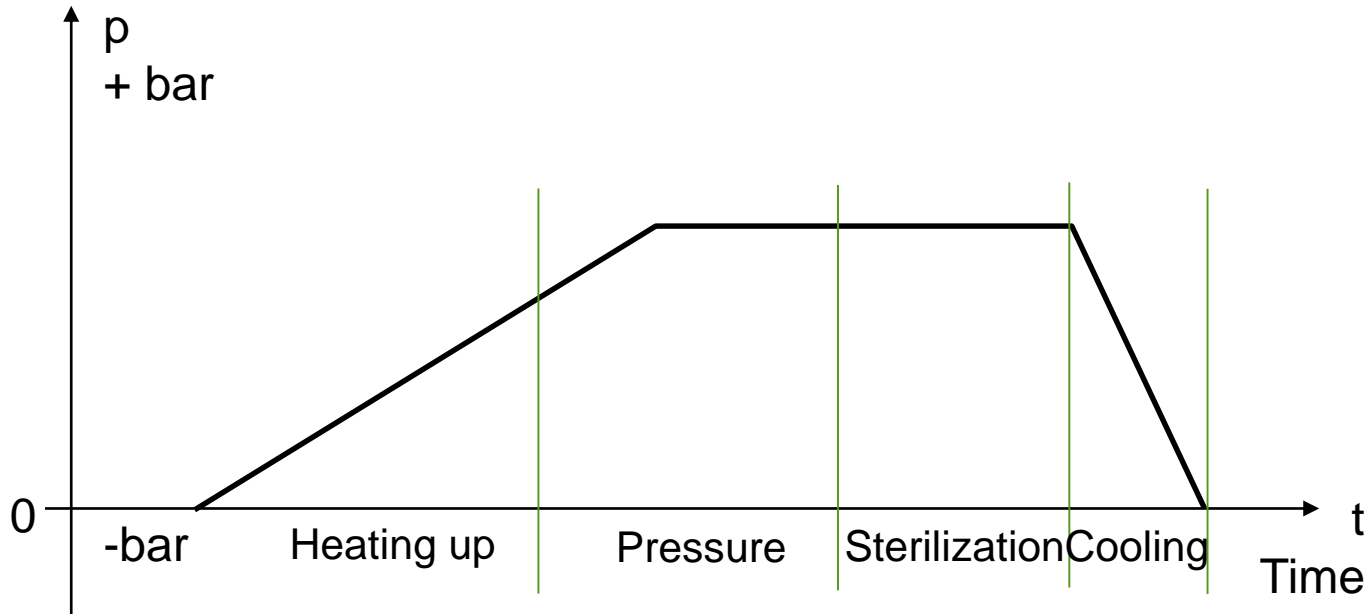


# Basic steam sterilization process

- ▶ Heating up and air removal (by gravity – air layering or stratification)
- ▶ Building up of pressure
- ▶ Sterilization time (Holding time)
- ▶ Reducing pressure and cooling down of the load

Note: Downward displacement of air has the risk that air is trapped in open containers, etc.

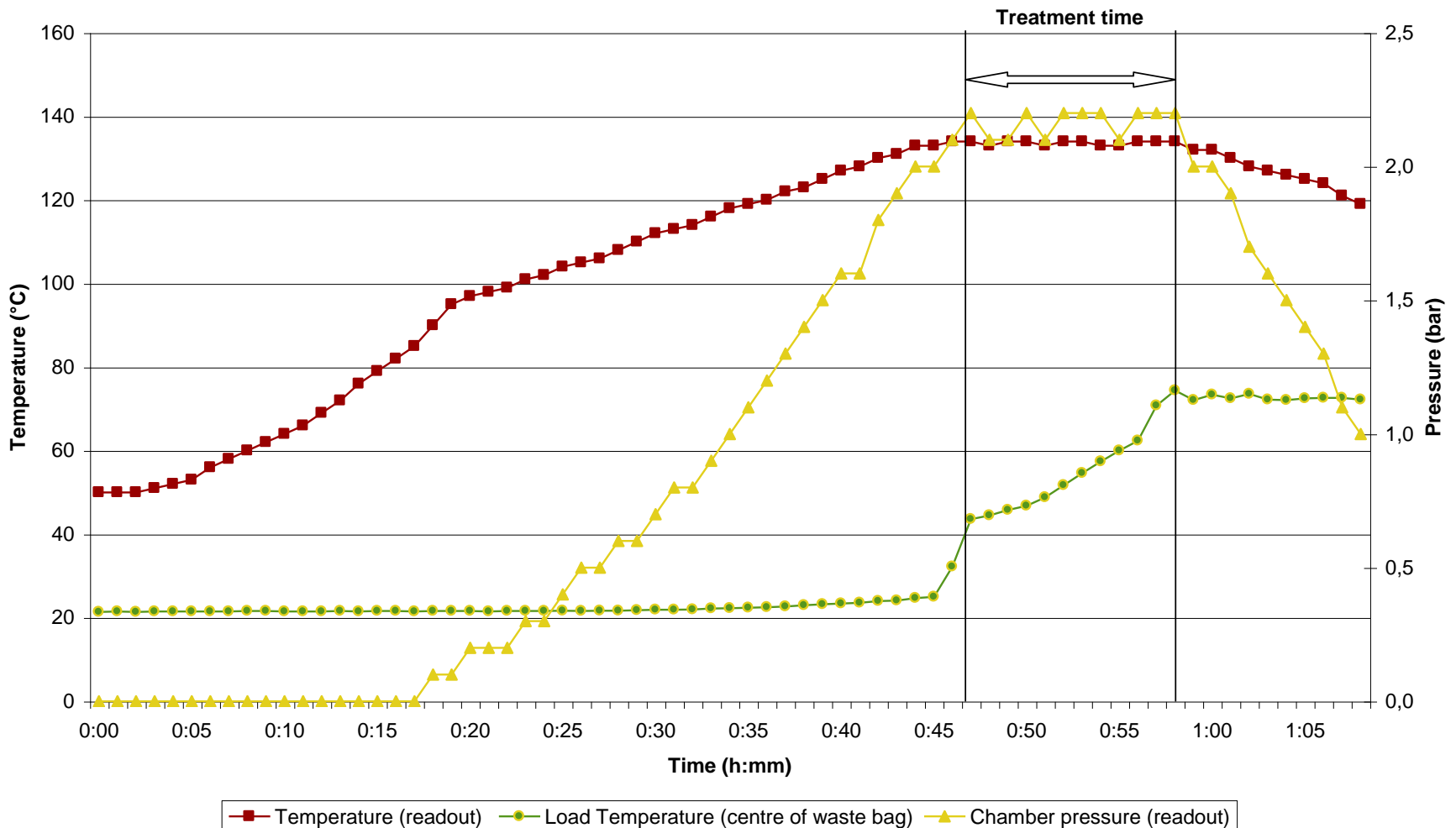
This cycle is only recommended for sterilization of non-hollow instruments and bottled fluids





# Temperature: Cycle A

Standard process cycle: 134 °C, 10 min

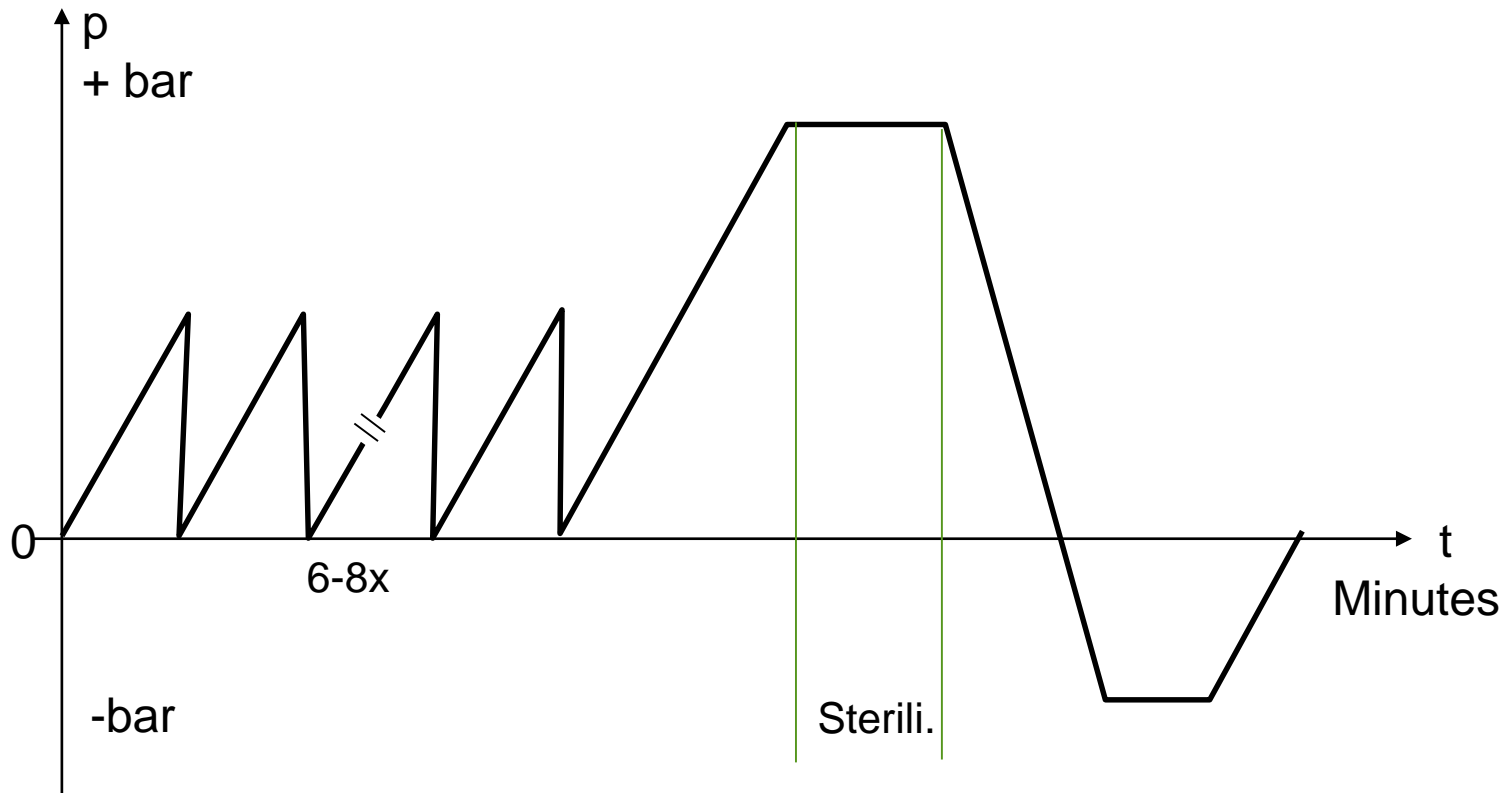




# Advanced gravity flow cycle

- ▶ Fractionate downward displacement (support by pulsing)
- ▶ Building up of pressure, Sterilization (Holding time)
- ▶ Drying of the load by post-vacuum (pressure release and closing of the autoclave)

Note: Requires very long process cycle times (> 1 hours)

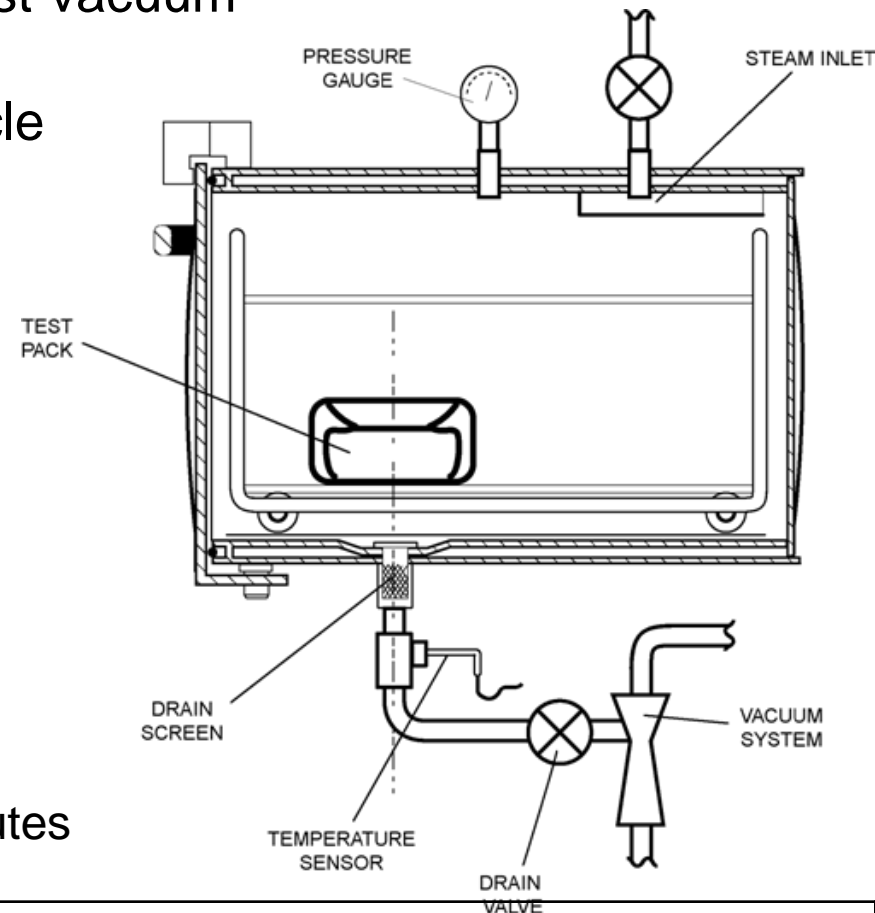
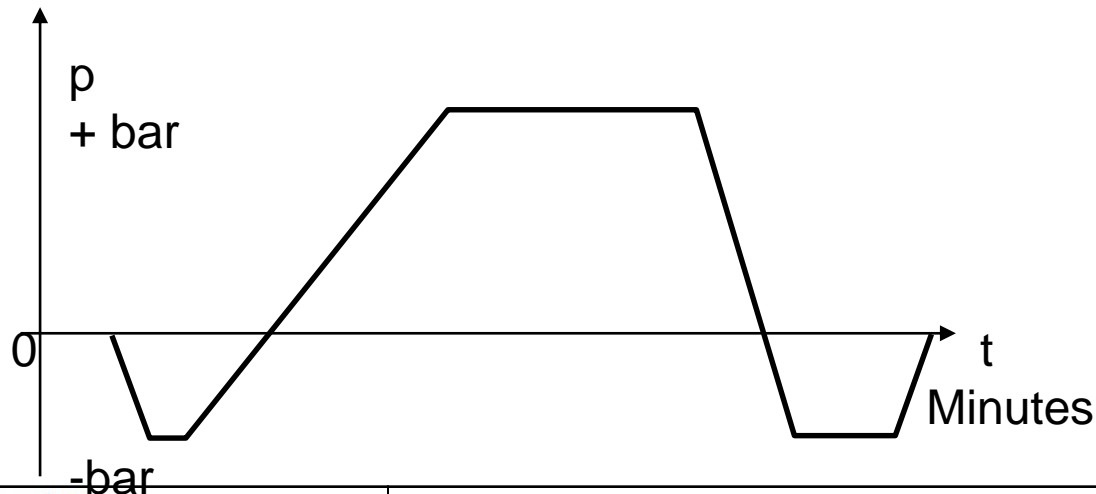




# Pre-vacuum autoclave

- ▶ Heating up of the jacket to avoid condensation on the pack
- ▶ Mechanical removal of air (Vacuum pump or venturi system)
- ▶ Building up of pressure, Sterilization (Holding time)
- ▶ Drying of the load by mechanical post-vacuum

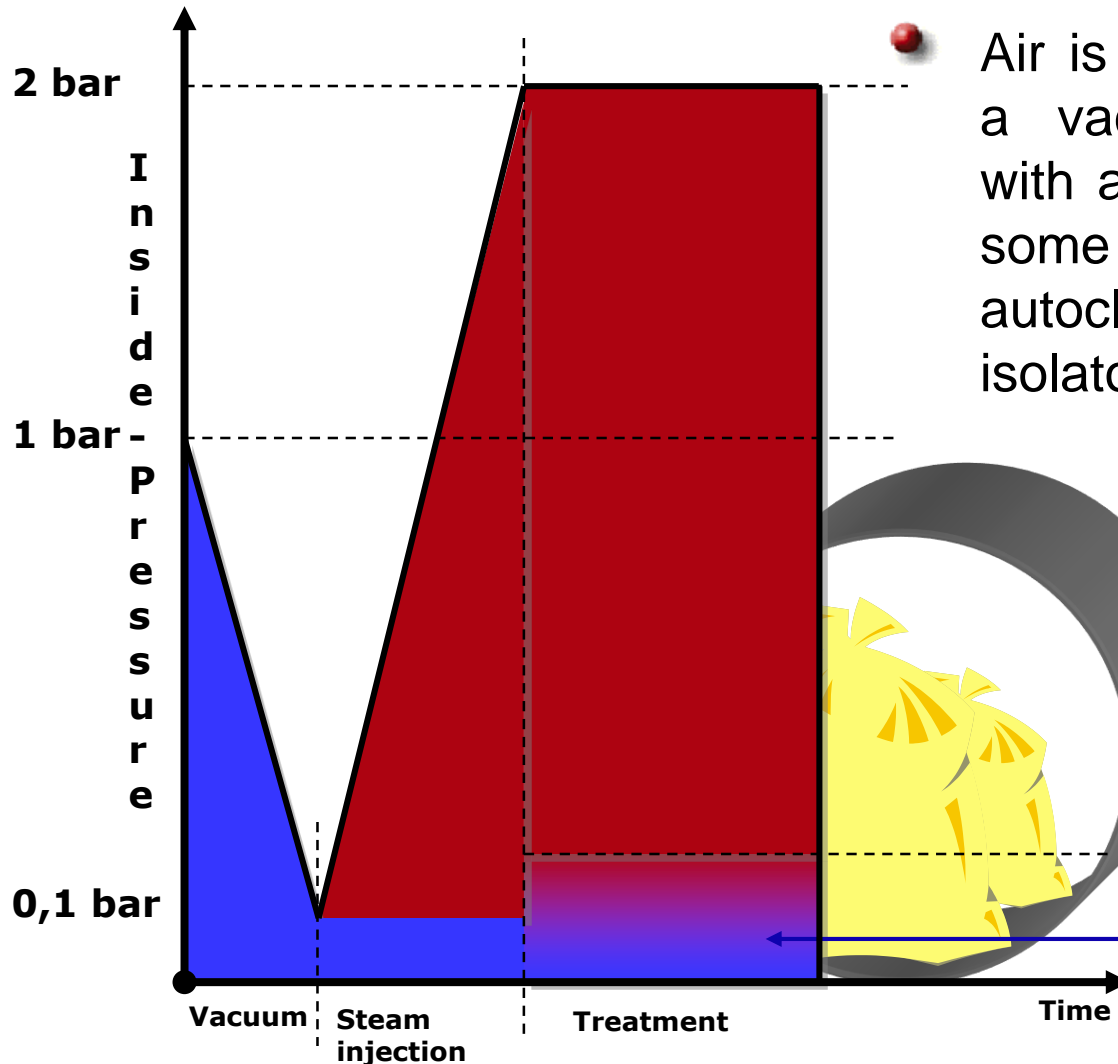
Note: Requires very long process cycle times







# PRE-VACUUM AUTOCLAVES: TREATMENT CYCLE



Air is mechanically removed by a vacuum-pump. By working with a single pre-vacuum cycle, some air will remain in the autoclave and may act as an isolator.

To minimise this problem longer treatment times are required. In some countries this cycle is not accepted.

**Air is heavier than steam and will settle at the ground**

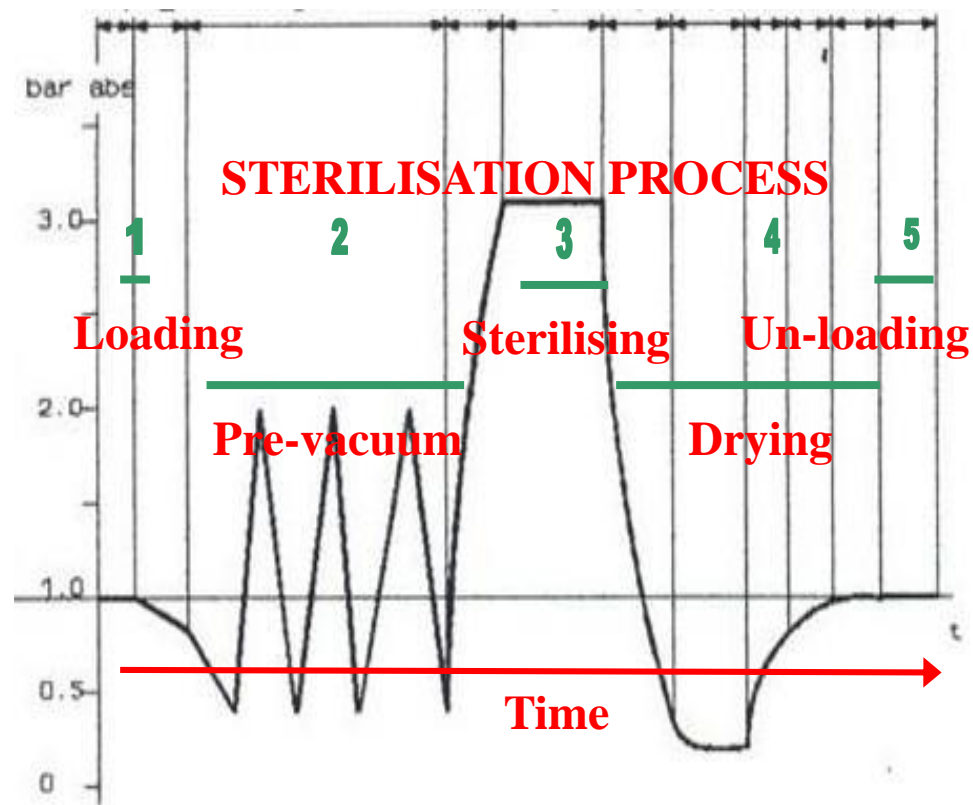


# VSV AUTOCLAVE: TREATMENT CYCLE

Typical infectious waste treatment process – VSV autoclave:

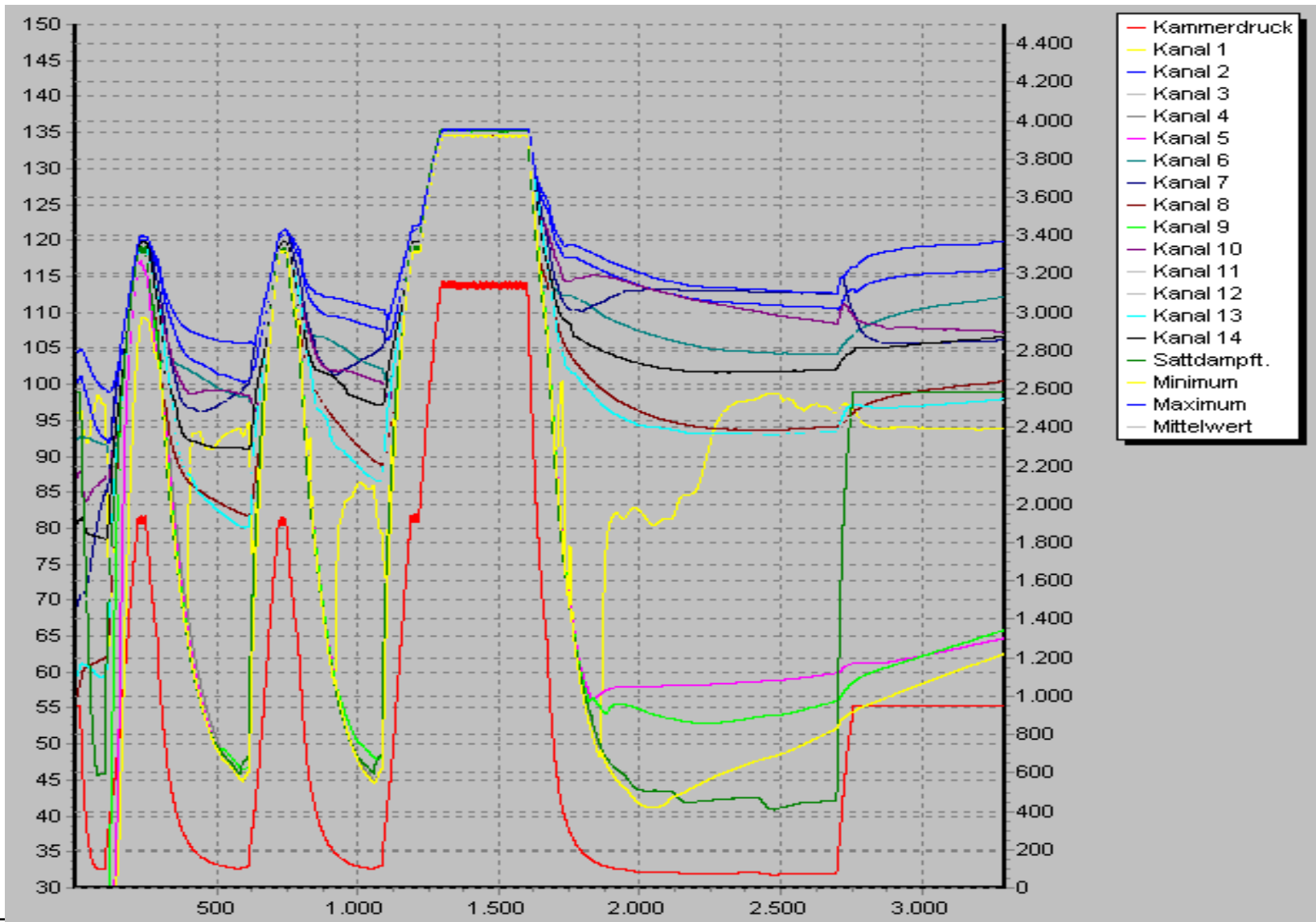
1. Loading of the autoclave
2. VSV-Phase (high vacuum)
3. Waste sterilisation phase
4. Drying / Cooling phase
5. Unloading of the autoclave

After treatment, the waste can be disposed of as non-risk healthcare waste. If highly infectious waste was treated (for reasons of bio-security) this waste should still be treated as normal infectious waste.





# Sample print out – autoclave test





# Modern VSV-Autoclaves (EN 285 conform)





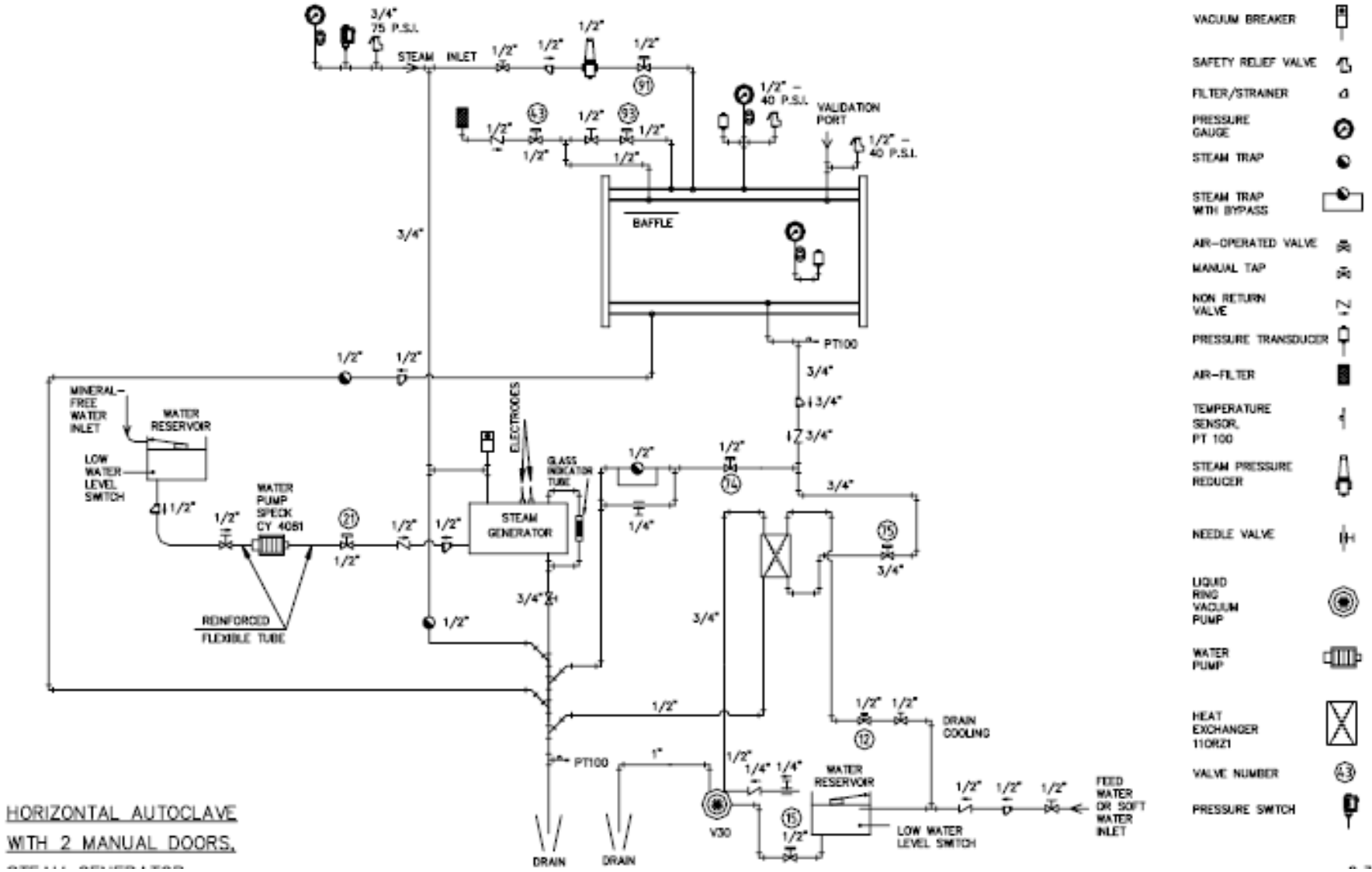
# VSV-Autoclaves (EN 285 conform)

- ▶ The fractionated pre-vacuum process is currently the most safe sterilization process for all materials in which air can be entrapped and which are heat resistant!
- ▶ A complete sterilization cycle is possible within 45 Minutes!





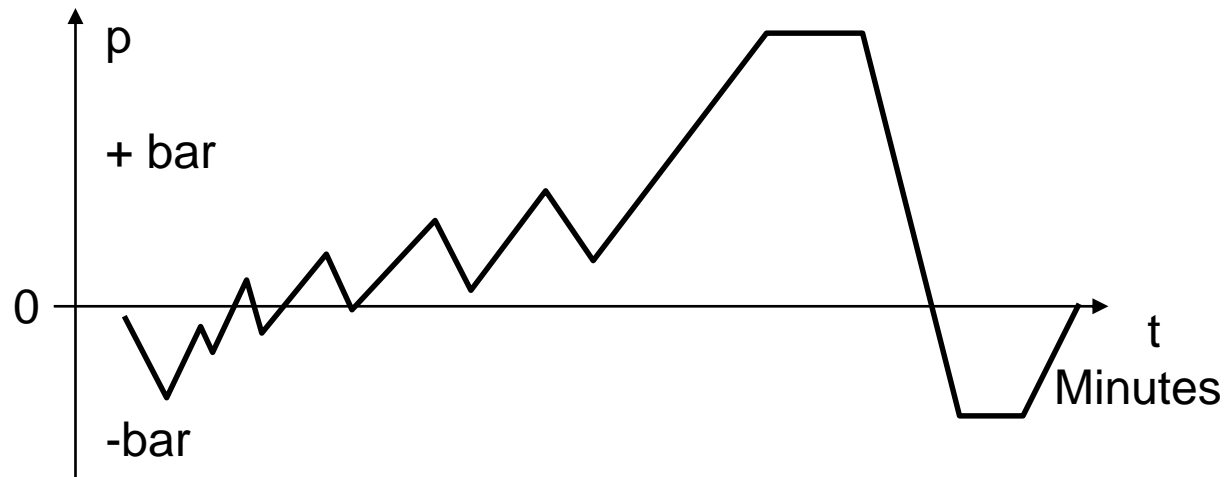
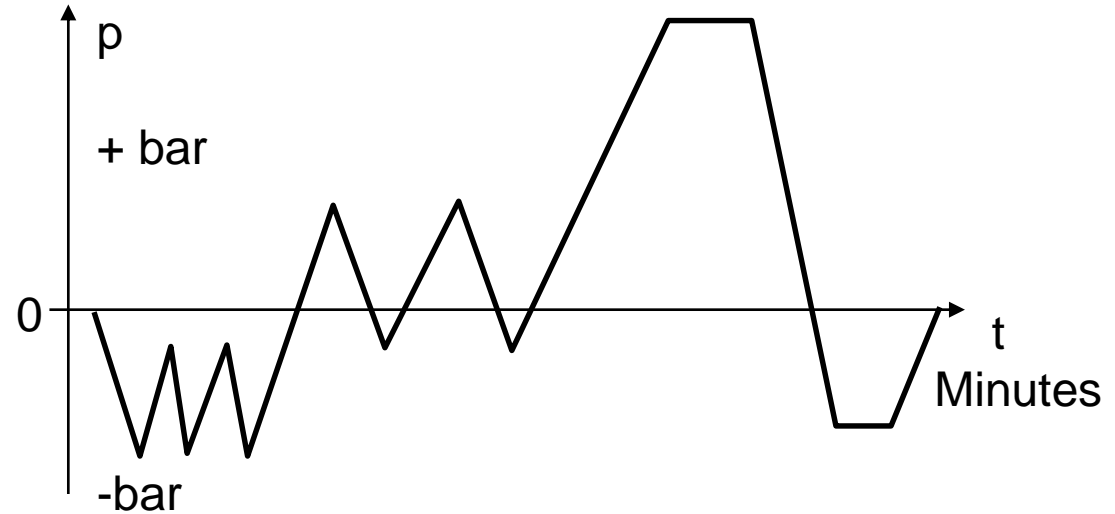
# P&I Diagram - VSV-Autoclave





# VSV – Treatment cycle

- ▶ Different Cycle possible, depending of specific need and goods to be autoclaved
- ▶ Cycle must be validated and tested by the manufacturer
- ▶ Only use recommended process cycle
- ▶ Programming of process cycle should only be carried out by experts and needs testing.

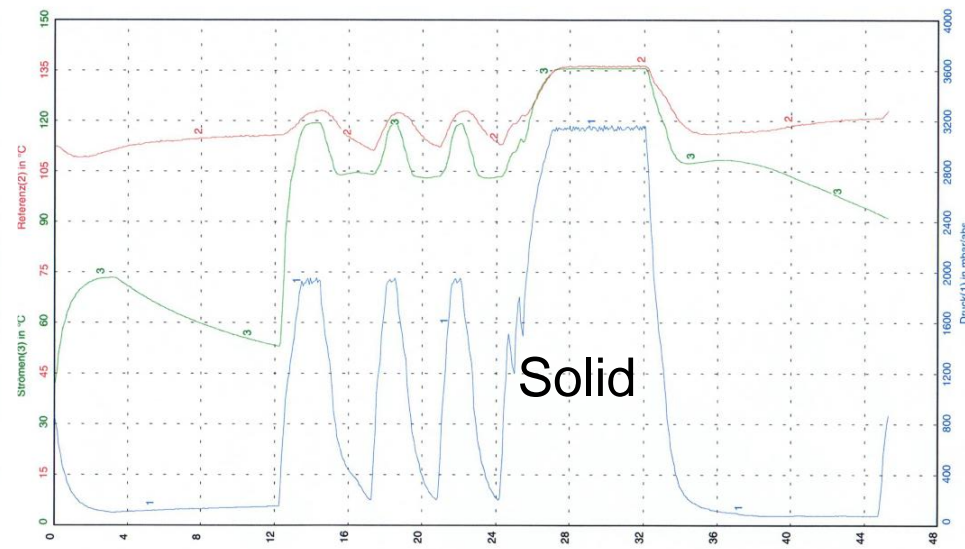
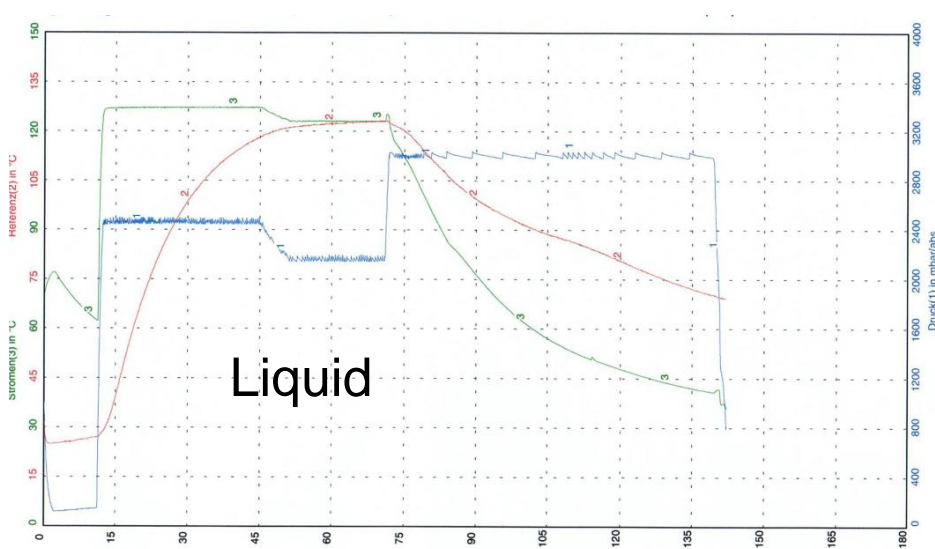






# Autoclaving: Fluids - Solids

- ▶ Autoclaves for the treatment of solid waste shall not be used for the treatment of fluids and vice versa
  - Fluids heat up much slower
  - Fluids have to be cooled down longer – risk while opening the chamber – overcooking!
- ▶ But...Autoclaves with two different treatment processes for liquid and solid waste are available!







# Norms and regulations

- ▶ ISO 17665:2006, Sterilization of health care products — Moist heat
  - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
  - Part 2: Guidance on the application of ISO 17665-1 provides guidance for validation and routine control of moist heat sterilization processes for medical devices.
- ▶ EN 285:2006, *Sterilization — Steam sterilizers — Large sterilizers*
- ▶ Tests and performance requirements for small sterilizers are given in EN 13060.
- ▶ ANSI/AAM ST79:2006: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- ▶ DIN 58949-3 [60] deals with the use of steam disinfection apparatus for treatment of waste from public and private medical facilities. The standard deals with types of test, test loads, test apparatus and biological indicators, extent of testing as well as procedure and expression of results (only German language).



# Technical Recommendation I:

- ▶ Treatment Chamber:
  - Full steam jacket required to minimize condensate and ensure good drying results
  - Chamber made from high Quality stainless steel (like AISI 3161)
  - Good insulation required for jacket, door and piping
  - Must withstand a vacuum test (lower than 1 mbar/min rise at 80 mbar)
- ▶ Vacuum System:
  - Pressure range of 900 mbar to 55 mbar
  - Average suction power  $V$  (in  $m^3/h$ ) of:  $0,033 * \text{Volume of the pressure vessel (in } 0,1m^3)$
  - Temperature of cooling water after usage must be below  $65^\circ C$



# Technical Recommendation II:

- ▶ Process temperature
  - The process temperature should allow sterilization, recommended are 121°C ( $T_{Des}^0_{+4}$ ), better 134°C ( $T_{Des}^0_{+4}$ ).
- ▶ Exhaust air treatment
  - Membrane filters should be used, placed between pressure vessel and next component.
  - disinfection of the filter shall be possible in a built-in condition
  - Filters must be heat pressure and steam resistant, of hydrophobic type
  - Only validated membrane filter with validation of 0,01µm in gaseous substances and 0,2 µm for liquids
- ▶ Condensate treatment
  - Condensate from the process must thermal sterilized before disposal.
  - Recommended is a separate treatment in extra vessel
- ▶ Process steering shall be fully automatic
  - Special requirements for the steering system are existing



# Technical Recommendation III:

- ▶ Recommendations for steam quality
  - The treatment plant shall be designed to operate with a steam supply which is provided with a condensate trap within 2 m of the connection to the sterilizer.
  - Saturated steam, containing up to 3,5 % V/V of non-condensable gases when tested
- ▶ For the process steps, attention must be paid in particular to the total hardness, total salt content and chloride content. The following values are recommended as minimum requirements:
  - Total hardness: < 3°dH (< 0,5 mmol CaO/l)
  - Total salt: < 500 mg / l
  - Chloride content: < 100 mg / l
  - pH value: 5 – 8



# Maintenance of autoclave systems

► Typical parts for yearly, monthly or weekly preventive maintenance

- Door system
- Door Mechanism Operation
- Pressure Vessel Safety
- Vessel Inspection
- Fan and Drive System
- Steam generator
- Vacuum System
- Pneumatic System
- Autoclave Interior
- Cooling System
- Motor Control
- Monitoring Sensors

ASME No.	Month	January				February			
Year:	Week	1	2	3	4	1	2	3	4
<b>Door System</b>									
Clean lower 1/3 of locking ring	1 week								
Inspect door seal for flin groove of the door	1 week								
Inspect door seal for nicks, gouges or embedded debris	1 week								
Inspect sliding surfaces & wedges for excessive wear & alignment	1 week								
Inspect for operation, clean and lube lock ring & shaft flange (SS30)	1 month								
Check hydraulic pump reservoir fluid level	2 month								
Lubricate door wedges surfaces with SS30	3 month								
Inspect heat seal & repair if required	6 month								
Clean and apply protectant to door seal	6 month								
Strip wedges & flanges of lubricant and re-lube with SS30	1 year								
Inspect hydraulic lines, fittings and cylinder packing for leaks	1 year								
Check wear plates for gouging, indicates door out of alignment	1 year								
<b>Door Mechanism Operation</b>									
Inspect control assembly	1 year								
Inspect door interlock cylinder & micro-switch for proper operation	1 month								
Obtain a magnetic partial exam of lugs, wedges & closure	1 year								
<b>Pressure Vessel Safety</b>									
Check and verify all pressure safety interlocks	6 month								
Block flush pressure sense line	6 month								
Activate Man-In-Vessel Alarm & confirm operation	6 month								
Calibrate or replace relief valves	1 year								
Replace rupture disks	1 year								
Check and calibrate pressure in autoclave switch & interlocks	1 year								
<b>Vessel Inspection</b>									
Inspect vessel and nozzles for cracking, surface pitting	6 month								
Inspect vessel for high surface operating temperature	6 month								
Obtain a magnetic partial examination of vessel and nozzles	3 year								
Inspect vessel for minimum thickness	5 year								
<b>Fan and Drive System</b>									
Remove housing, check all bolts, piping & electrical connections	1 year								
Inspect and grease fan shaft, seal & drive bearing	1 year								
Inspect and drain bell housing	1 week								
Inspect connection of fan wheel & motor shaft, tighten as required	1 year								
Inspect sheave guards, belt guards and motor seal linkage	1 year								
<b>Electrically Heated Vessels</b>									
Check functionality and operation of contactors and SCR	1 year								
Check functionality and operation over-temperature controller	1 year								
<b>Vacuum System</b>									
Inspect pump packing	6 month								
Vent receiver tank and drain condensation	1 month								
<b>Pneumatic Systems</b>									
Test clean and range adjust all IP transducers	6 month								
Inspect and range adjust all pneumatic control valves	6 month								
Drain & adjust all instruments and valve air regulators	2 month								
<b>Autoclave Interior</b>									
Clean debris from inside of vessel	1 week								
Check the sheet metal screws for tightness and clean sheet metal	3 month								
Check bolts for tightness	1 year								
<b>Cooling System</b>									
Inspect and replace worn fan belts	6 month								
Inspect cooling valve for leakage	6 month								
Drain tank and refill	1 year								
<b>Motor Control Center</b>									
Check contactors, starters, & circuit breakers	1 year								
Verify that all contactors are tight, including the incoming power	1 year								
<b>Part Monitoring Sensors</b>									
Calibrate all vacuum transducers	2 month								
Check vacuum system fittings for tightness and leaks	6 month								
Check system PID tuning and adjust if required	6 month								