Reducing UPOPs and Mercury Releases from The Health Sector in Africa

Module 29:

Testing & evaluation of alternative technologies

UNDP

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- Technical requirements
- Qualification Tests:
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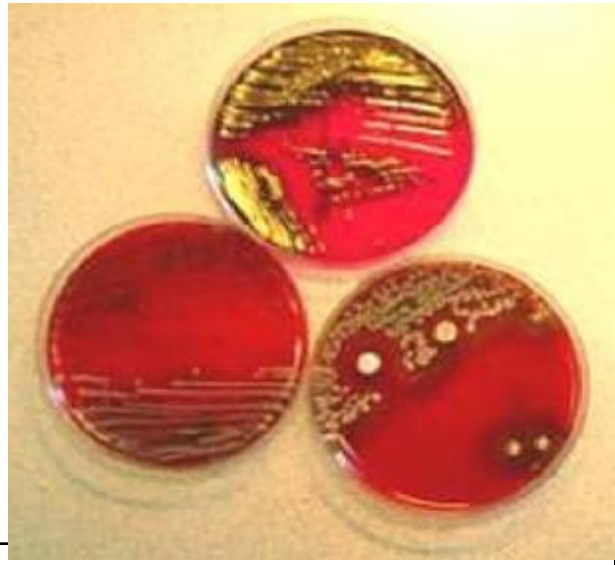
  - Validation Tests
  - Routine Tests
- Tests and loads



Recommendation – Risk groups:

- Classification of pathogen agents under consideration of the potential risks from waste contaminated with this pathogen.
- Existing Risk Groups:
  - Risk Group 1: (no or very low individual and community risk)
  - Risk Group 2: (moderate individual risk, low community risk)
  - Risk Group 3: (high individual risk, low community risk)
  - Risk Group 4: (high individual and community risk)

- Recommendation:
  - Concentrated agents of group 3 (e.g. cultures) and all waste contaminated with group 4 agents should be disinfected prior collection for central treatment.

Recommendation – Treatment Level

- Treatment level classification
  - Level 1 – Low Level Disinfection
  - Level 2 – Intermediate Level Disinfection
  - Level 3 – High Level Disinfection (≥ 99,99% pathogen reduction)
  - Level 4 – Sterilization (≥ 99,9999% pathogen reduction)

- Scientifically, treatment level 3 is sufficient for the waste treatment. Under consideration that today treatment technologies are available which easily will reach this level, out of security reasons a level 4 may be recommended.

Level 3 inactivation level

- Level 3 = Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of G. stearothermophilus spores and B. atrophaeus spores at a 4 Log_{10} reduction or greater
- Background 4 log_{10} - log_4 kill
  - It means 99.99% of the test spores must be killed
  - If 10,000 spores are put in a test, 9,999 must be killed
  - no more than 1 spore can survive

Tools for Quality Control

- **Biological**
  - A biological indicator contains live spores in a high concentration. If the sterilization process is sufficient to kill the spores in the indicator, it can be assumed that the bioburden on items is eliminated
- **Chemical**
  - Chemical indicators are made of paper that has been chemically treated to change color when it is subjected to a certain temperature.
- **Mechanical/Physical**
  - Mechanical monitoring tracks sterilization parameters. Sterilizers should automatically generate a printout or graph of the cycle length, temperature, and pressure that the operator must verify. Sterilization records should contain:
    - Contents of the load, Operator
    - Date and time, Cycle length
    - Temperature

Microbiological effectiveness

- The microbiological activity of moist heat is based on the temperature and the duration of contact between water molecules and microorganisms.
- Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of G. stearothermophilus spores and B. atrophaeus spores at a 4 Log_{10} reduction or greater

Temperatures (°C)	Minimum holding time (min)
121	20
134	10

Qualification Tests

- In general different testing levels for qualification of treatment device can be distinguished:
  1. Pre-validation requirements

Testing level	Qualification tests	Frequencies	Responsibility
Pre-validation tests	Type and safety tests	Before delivery	Manufacturer

  2. Validation including a) installation qualification, b) operation qualification and c) performance qualification.
  3. Routine testing, which includes frequent monitoring and testing of the equipment.

Validation: Installation & Operation

Installation qualification	**Water and Steam quality**	**Once a year**	**Purchaser**
	Correct delivery	Once after installation	Purchaser
	Correct Installation	Once after installation	Purchaser
	Complete Documentation	Once after installation	Purchaser
	Process description	Once after installation	Purchaser
	Process parameter and tolerances test	Once after installation	Purchaser
Operation qualification	Calibration of pressure and temperature systems	Once a year	Qualified technician / service company
	Air leakage test	Once after installation	Purchaser
	Air removal test (B&D Test)	Once after installation	Purchaser
	Microbiological Tests	Every 6 month	Purchaser / Qualified company
	Thermoelectric Tests	Once after installation: 3 time test processes in a row	Qualified service company

Validation: Performance qualification

Performance qualification	Thermoelectric tests	Requalification once a year: 1 test cycle	Qualified service company
	Microbiological Test	First time: 3 time test processes in a row and after that once a year: 1 test cycle	Qualified service company
	Interpretation of physical factors (pressure, time, temperature)	Once a year	Qualified service company

Routine Tests

Routine tests	Visual check	Daily	Operator
	Interpretation of physical factors (pressure, time, temperature)	Every cycle	Operator
	Hollow load test (PCD)	Every cycle	Operator
	Bowie and Dick test	Daily before operation	Operator

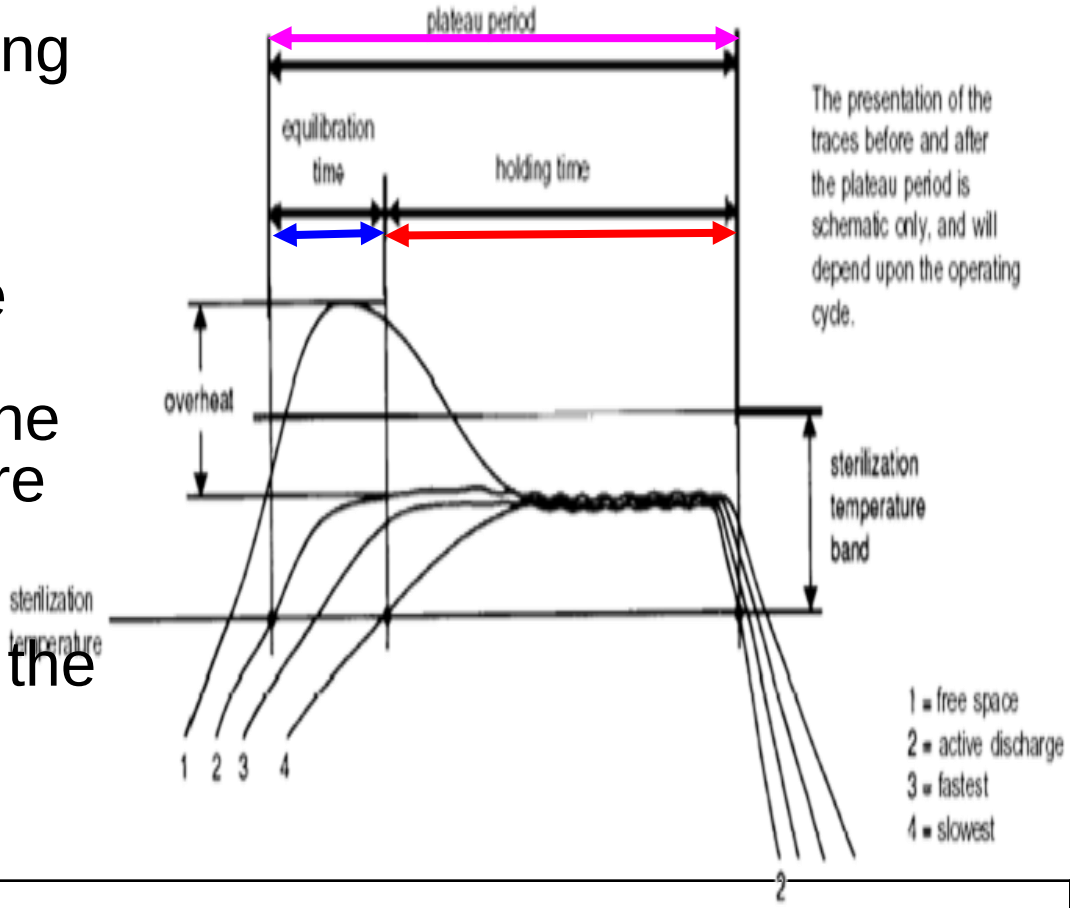
MONITORING & TESTING OF AUTOCLAVES

- Monitoring of treatment cycles (print-out)
- Microbiological tests (Small load, Full load, Porous load)*
- Thermometric tests (Small load, Full load)*
- Air removal and steam penetration
  - Bowie and Dick test*
  - Air leakage flow rate*
  - Air detector (small load, full load)
  - Air detector function
- Load dryness tests (Small load –textiles, Full load – textiles, Metal load)*

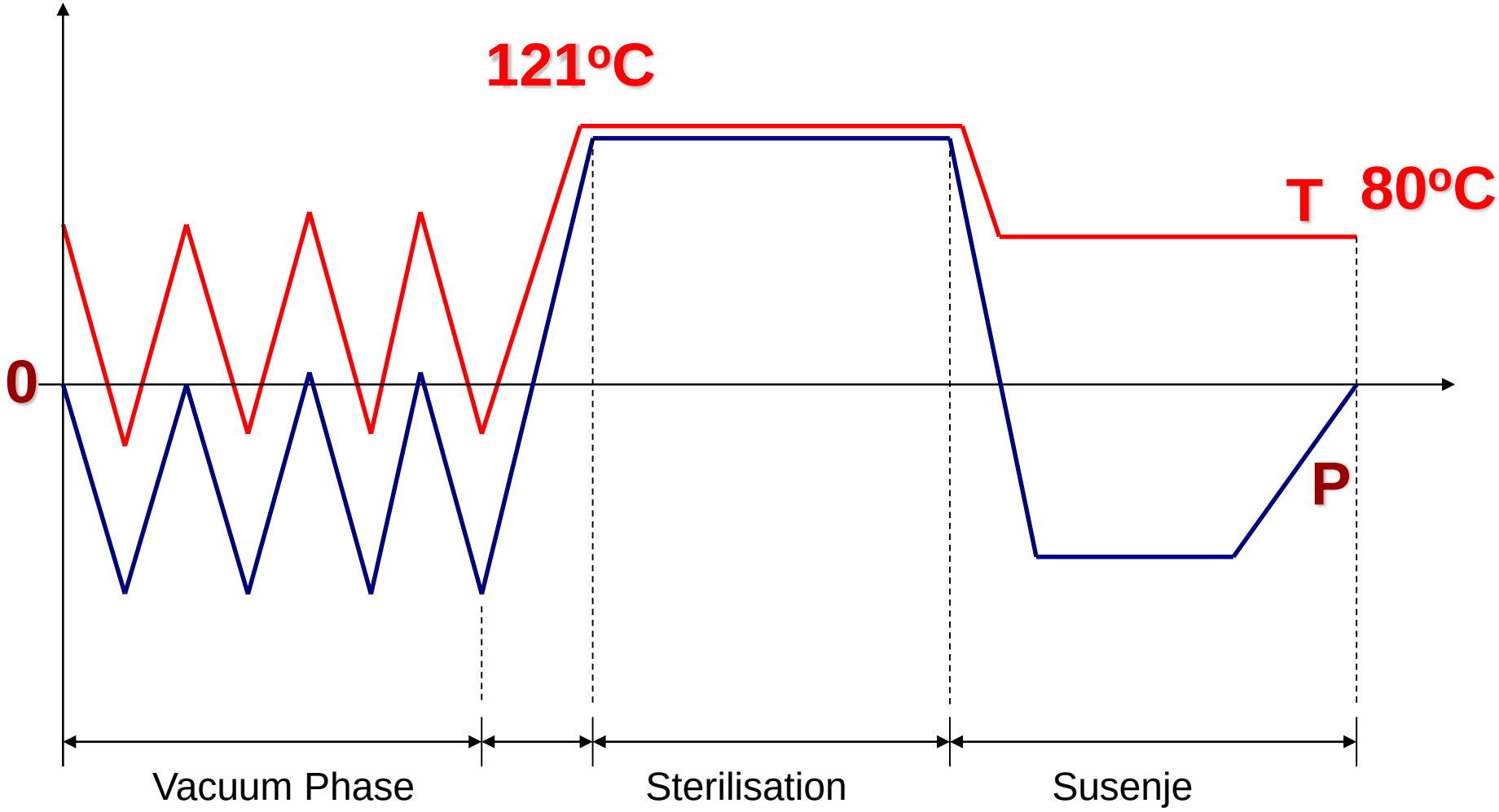
* Will be discussed during this training session

READING PRINT OUTS

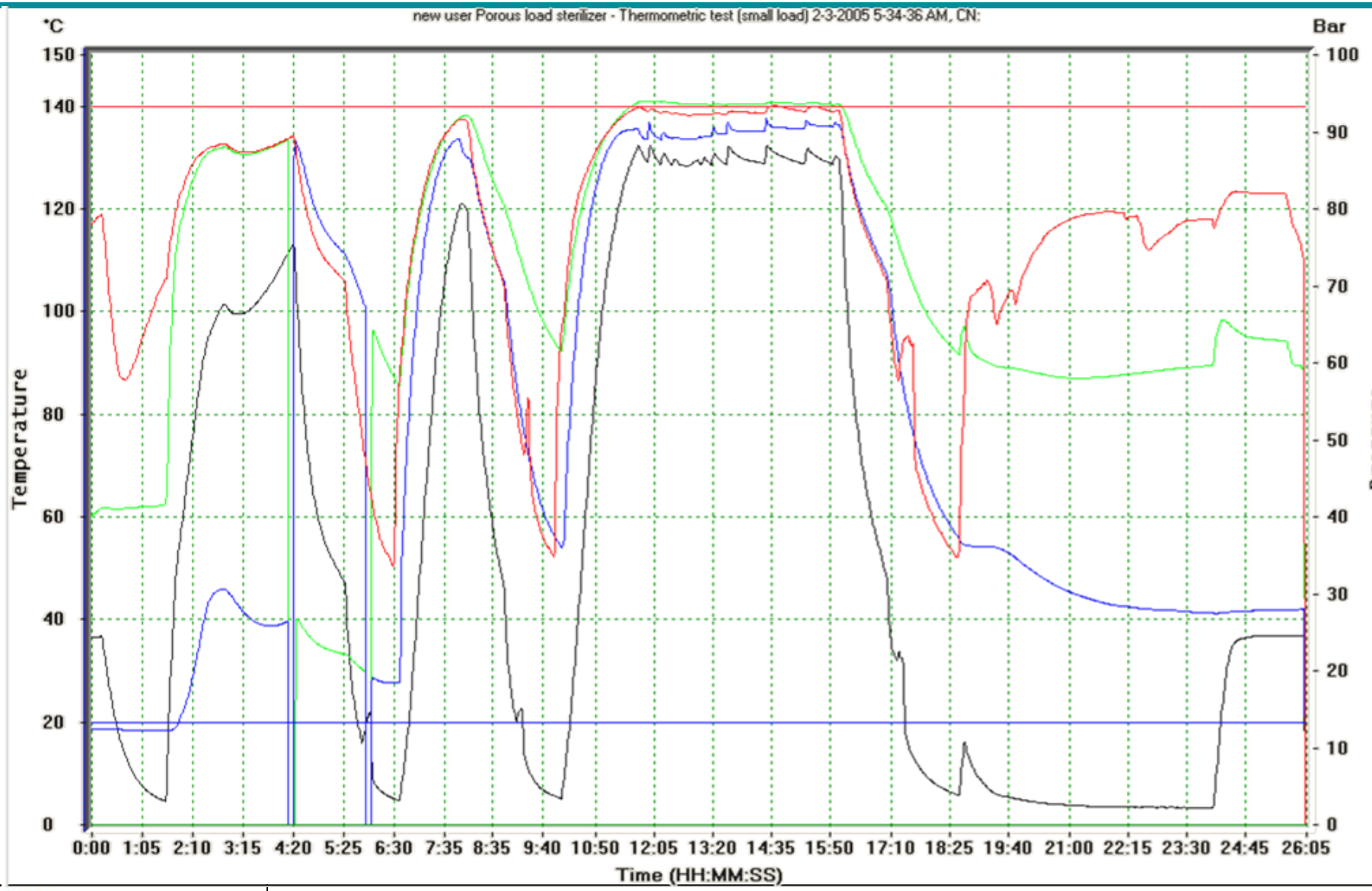
- Equilibration time
  - The equilibration time is the time difference between the chamber (drain) and load attaining the sterilisation temperature
- Holding time
  - The holding time is the time that the load temperature is within the sterilisation temperature band .
- Plateau period
  - Equilibration time plus the holding time



READING PRINT OUTS II

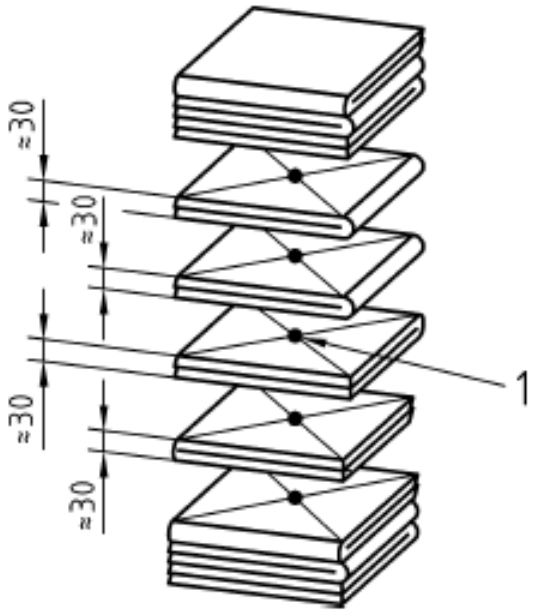


READING PRINT OUTS III

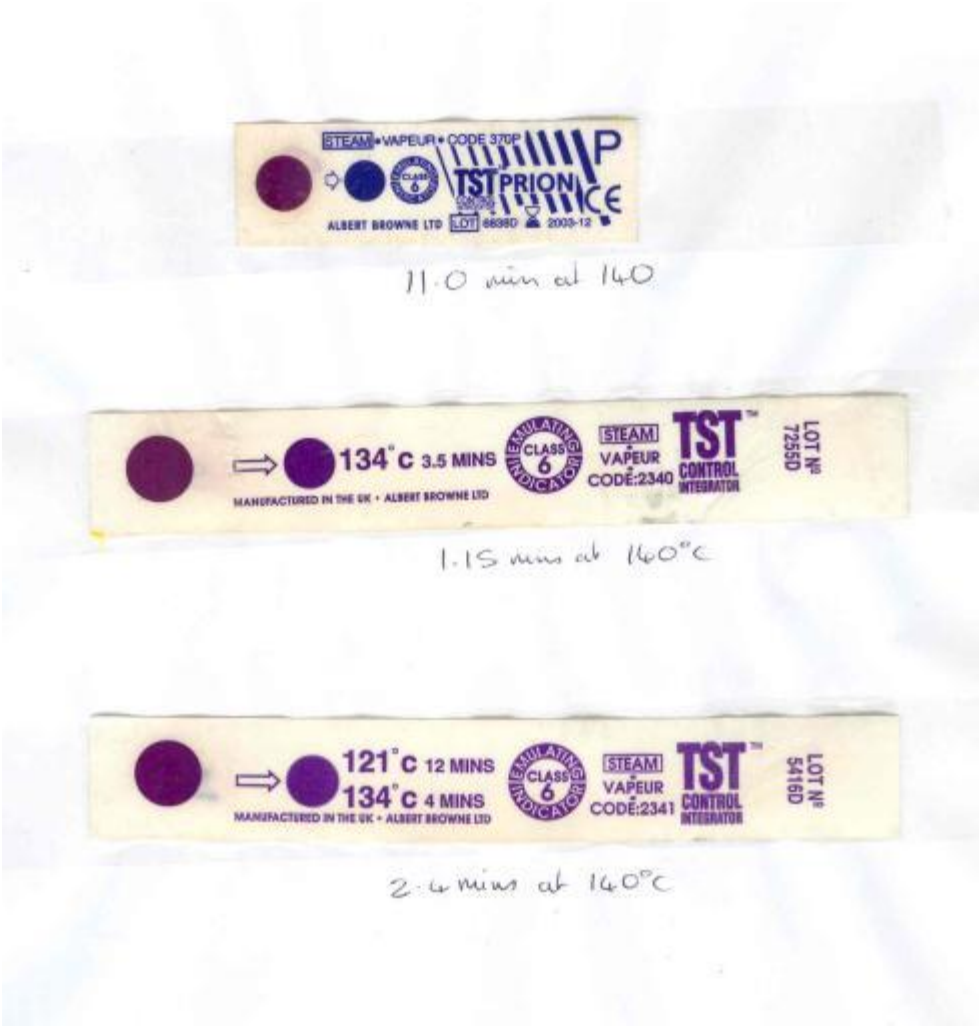


STANDARD TEST PACK

- The Standard Test pack is used to check that, at the levels at which the process variables are set, rapid and even penetration of steam into the pack is attained.
- Used for Bowie Dick test, the small load test, air detector tests, load dryness test
- The test pack shall be composed of plain cotton sheets, each sheet shall be bleached white and have an approximate size of 900 mm x 1200 mm.
- Sheets shall be folded to a size of 220 mm x 300 mm and then stacked to a nominal height of 250 mm.
- After compressing the pack shall be wrapped in fabric and then secured with tape not exceeding 25 mm in width. The total weight of the pack shall be 7 (± 0.7) kg.



Chemical Indicators: Examples



Air removal test: Bowie Dick

- Effective air removal from lumens, porous loads and other complex designs incorporating enclosed spaces is difficult.
- An autoclaving process that removes air from the treatment chamber to a low level may fail to remove sufficient air from a lumen to permit steam penetration

BOWIE DICK TEST

- The Bowie and Dick test was conceived as a test for the successful air removal from vacuum sterilisers.
- A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack.

Retention of air within the pack due to:

- an inefficient air removal stage,
- the presence of an air leak during the air removal stage,
- the presence of non-condensable gases in the steam supply,

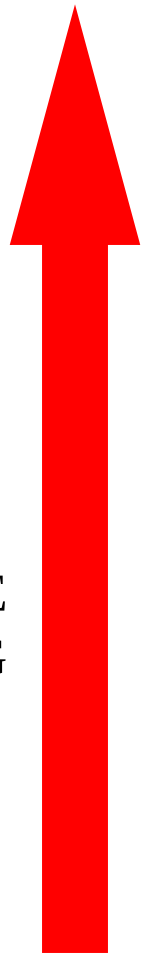
are circumstances which can lead to failure of the test.

Microbiological Test

- A microbiological indicator contains live spores (Geobacillus Stearothermophilus) in a defined concentration. If the treatment process is sufficient to kill the spores in the indicator, it can be assumed that the pathogens in the waste are eliminated.
- After treatment the spores have to be incubated and after the indicated time the color of the probe will change – the evaluation (incubation) can be done by an accredited lab.
- Microbiological and thermoelectric tests can be conducted at the same time. The use of a blind probe and a detailed documentation is necessary.

Why using Spores for the tests?

RESISTANCE TO KILLING



- **Bacterial spores (They are the most difficult to kill)**

- **Mycobacteria**
- **Viruses (Nonlipid - Polio)**
- **Fungi**
- **Bacteria**
- **Viruses (HIV, Hepatitis B, Herpes)**

MICROBIOLIGICAL INDICATORS

Types of indicators:

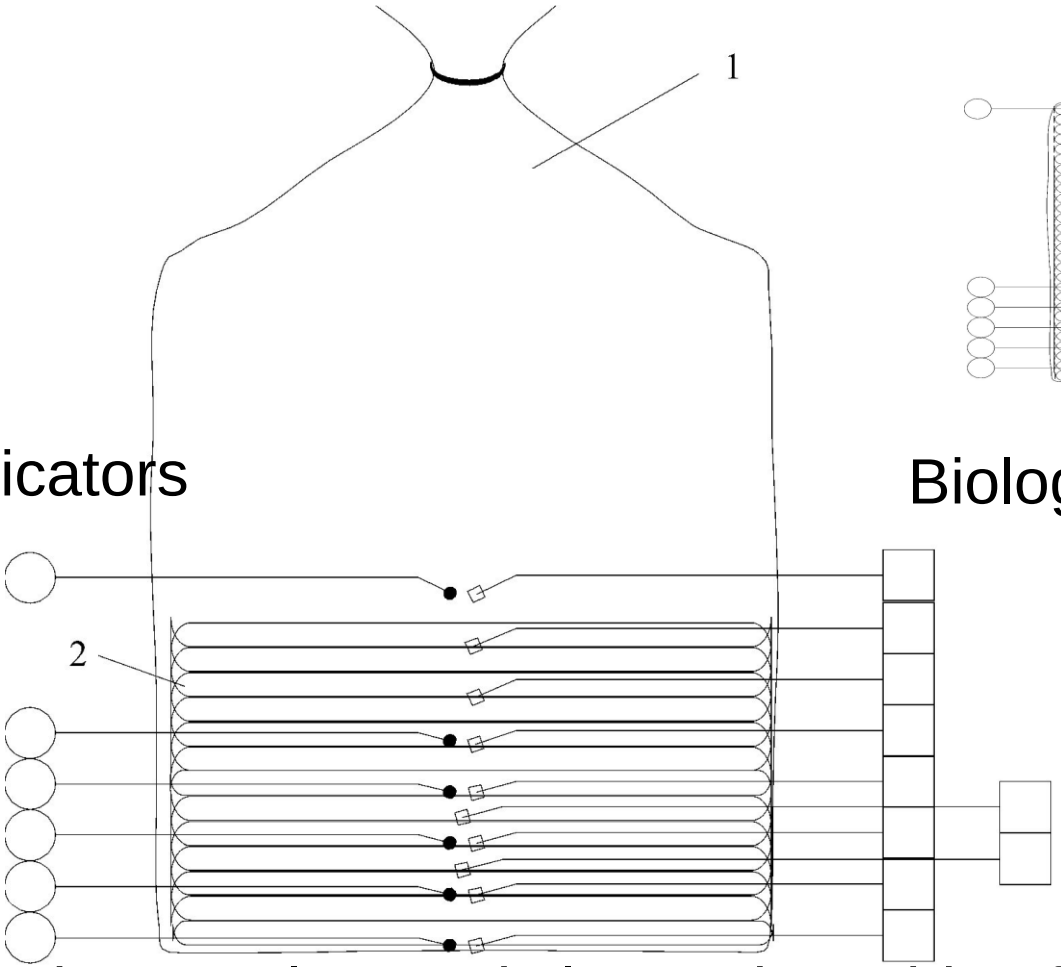
- **Spore stripes**
  - Bacteria-spores are inoculated on filter-strips
- **Spore suspensions**
  - Contain Geob. stearothermophilus and others in a defined concentration [CFU/ml] and absolute population [CFU/10ml]
- **Self-contained biological Indicators**
  - Outer plastic vial with a cap that is airsealed
  - Spore plate with a defined population of subtilis and/or stearothermophilus spores
  - glass ampoule with growth medium containing a pH- indicator
- **Ampoules**
  - for monitoring of sterilisation of liquids in glass bottles or solid materials

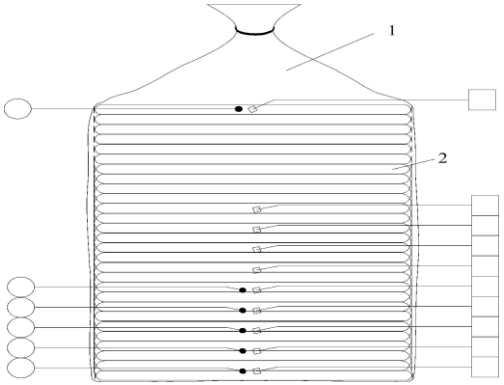
MICROBIOLOGICAL TESTS – TO DO

Carrying out Microbiological test:

- The test is used to demonstrate, that at the levels at which controls are set, test organisms placed in a standard test pack can be killed.
- Five of six biological indicators are placed in a standard pack.
- The treatment cycle to be tested is carried out.
- The indicators are collected.
- The six biological indicators are cultured.
- The test organisms in the untreated biological indicator shall be demonstrated as being viable or the test shall be regarded as not valid and must be repeated.

Position of Chemical / Biological Indicators





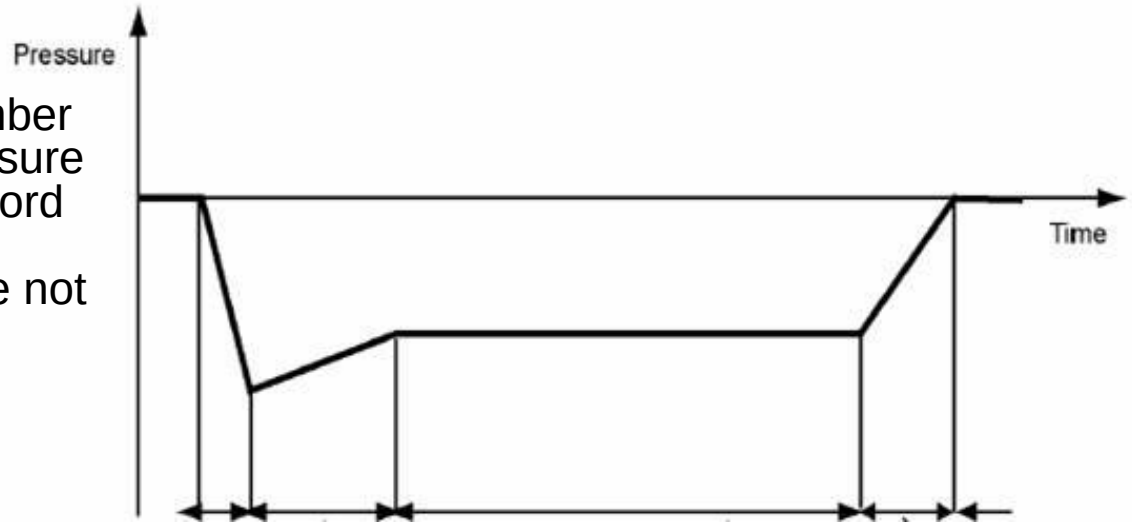
Chemical Indicators

Biological Indicators

NOTE: One Thermo element is located outside of the bag in the chamber

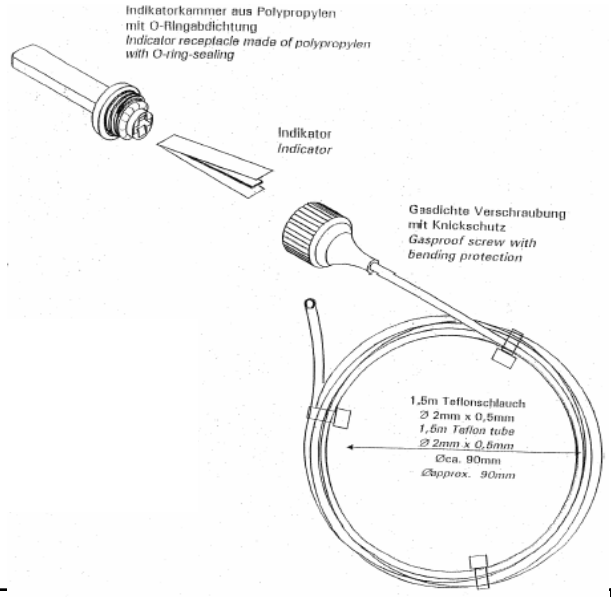
AIR LEAKAGE TEST

- The air leakage test is used to demonstrate that the quantity of air leakage into the steriliser chamber during the periods of vacuum does not exceed:
  - a level which will inhibit the penetration of steam into the steriliser load
  - will not be a potential risk to the re-contamination of the steriliser load during drying
- Procedure:
  - Create the lowest operating vacuum of the sterilisation cycle air removal stages
  - Close all the valves connected to the steriliser chamber and stop the vacuum pump
  - Allow evaporation of condensation in the chamber
  - Record the absolute pressure (p1), wait 10 minutes, record absolute pressure (p2)
  - The pressure rise shall be not greater than 0,13 kPa/min (1,3 mbar/min).



Hollow Load Test: PCD

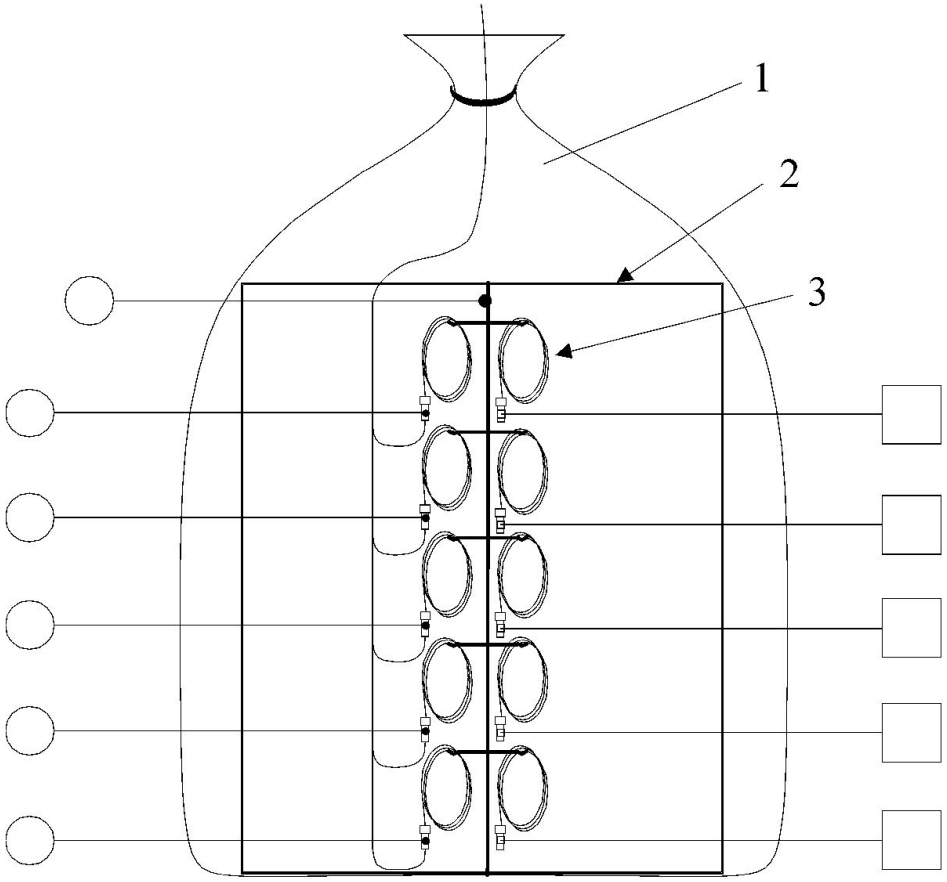
- A process challenge device (PCD) simulates the worst-case conditions for the attainment of the specified disinfection conditions within items to be disinfected.
- The device is so constructed that a biological or chemical indicator can be placed within the device in the position, which is the most difficult for the disinfection agent to reach.
- Chemical indicators are used as indicators for each charge.



PCD Locations: Hollow load test

Empty Bag

Chemical Indicators



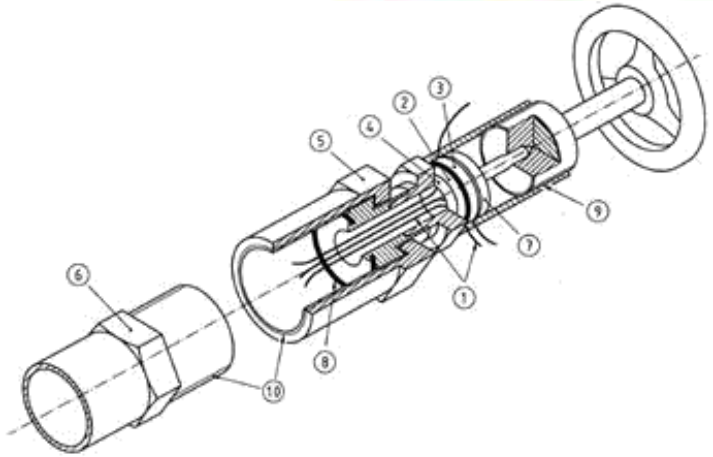
Biological Indicators

NOTE: One Thermo element is located outside of the bag in the chamber (not shown)

THERMOMETRIC TESTS

Thermometric tests:

- To demonstrate that after the air removal stage of the sterilisation cycle, sterilising conditions are obtained within the steriliser chamber and standard test pack.
- The standard test pack is chosen to represent the maximum density of porous load material which a steriliser conforming to this standard is designed to process.
- The more air there is to remove, the more exacting will be the test; that is why this pack is used by itself in an otherwise empty steriliser chamber.
- Conduct treatment cycle and record cycle parameters
- Check Thermo-logger if requirements are reached

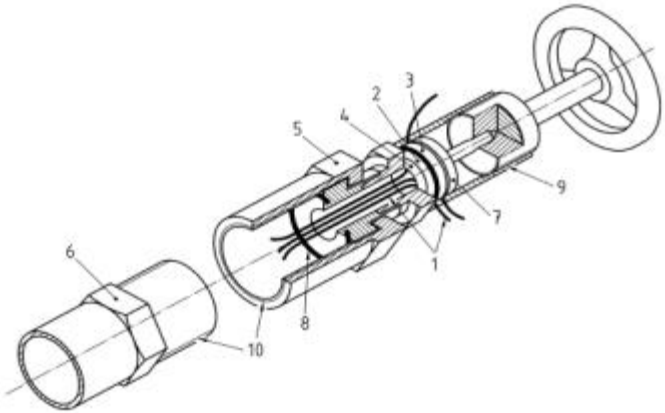


Thermoelectric Tests I

- Reference Load tests
  - Reproducibility within acceptable limits should be checked using a minimum of three replicate cycles for the first validation of an autoclave.
  - For the following re-qualifications one test cycle is sufficient.
  - The test loads shall comprise a variety of materials, the composition of which should reflect that of the waste material to be treated.
  - Measuring implements (biological indicators and thermo-elements) shall be distributed at critical points throughout the test load in a representative manner

Thermoelectric tests II

- Thermometric tests use accurate measuring equipment to monitor temperatures and pressures independently of the instruments fitted to the autoclave.
- Thermoelectric tests shall be conducted with thermo elements or thermocouples. The thermocouples are connected to computerized multichannel recording systems that can record and print temperature data



Key

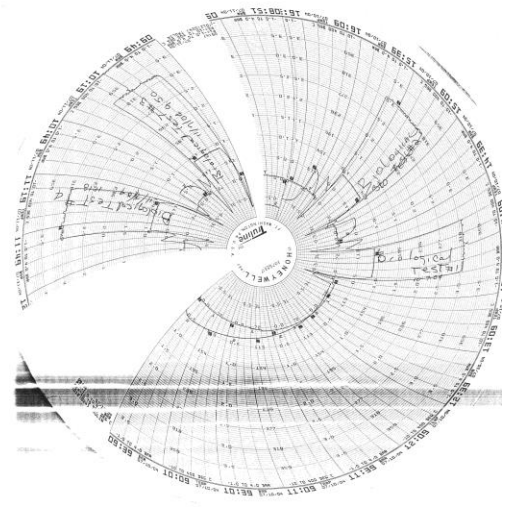
1	temperature sensor wire	6	adaptor
2	silicon rubber washer	7	metal thrust spigot
3, 4	metal thrust washer	8	O-ring
5	metal body	9	castellated to permit entry of leads
		10	pipe thread EN ISO 228-G1 A

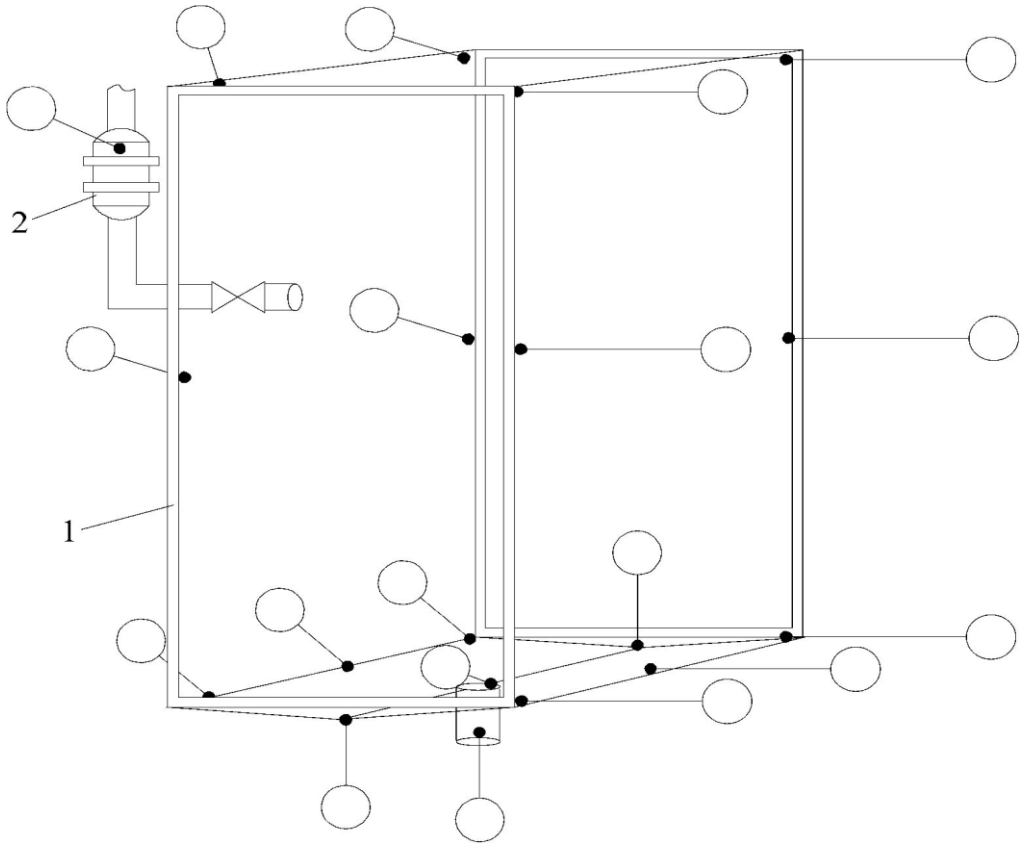
Thermoelectric tests III

- Temperature / Pressure Data Logger
  - according ISO EN 17665, EN 285, pr DIN 58929 / DIN EN 13060 und ISO 15883
  - Needle length 1200 mm, ø 1,2 mm
- For the validation of steam sterilizers according to ISO 17665 as well as for the validation of washer-disinfectors and washer-disinfectors for endoscopes according to ISO 15883.

Position of Temperature Sensors

- Thermo elements (the numbers can be put and described)





Validation Report

- The final stage of the validation program requires the documentation of all acquired data.
  - It includes the calibration certificates for calibrating instrumentation, calibration records, and methods for calibrating the measuring instruments, gauges, and recorders as well as the accuracy verification data of thermocouples.
- Further content:
  - Logbook, the standard operating procedures (SOPs) used with the autoclave, procedures for preventive and unscheduled maintenance, and recalibration programs.
- The validation report also should include the user's training records.