Routine and Operational Tests

Reference Documents

EN285 → European Standard for Large Steam Sterilizers

CFPP 01-01
(Ex HTM2010) → Management and decontamination of surgical instruments:
Part C – Steam sterilization

UNI EN ISO 17665
(replaces UNI EN 554) → Sterilization of health care products / Moist heat

UNI EN ISO 11140-3
(replaces EN 867-3) → Sterilization of health care Products. Chemical indicators. Class 2 indicator system for use in the Bowie and Dick-type steam penetration test.

Air leakage test: Chamber vacuum leak test:

Air leakage test: Chamber vacuum leak test

The air leakage test is used to demonstrate that the quantity of air leakage into the sterilizer chamber during the periods of vacuum does not exceed a level that will inhibit the penetration of steam into the sterilizer load and will not be a potential cause of re-contamination of the sterilizer load during drying.

To verify this, we have to carry out the '**Chamber vacuum leak rate test**'

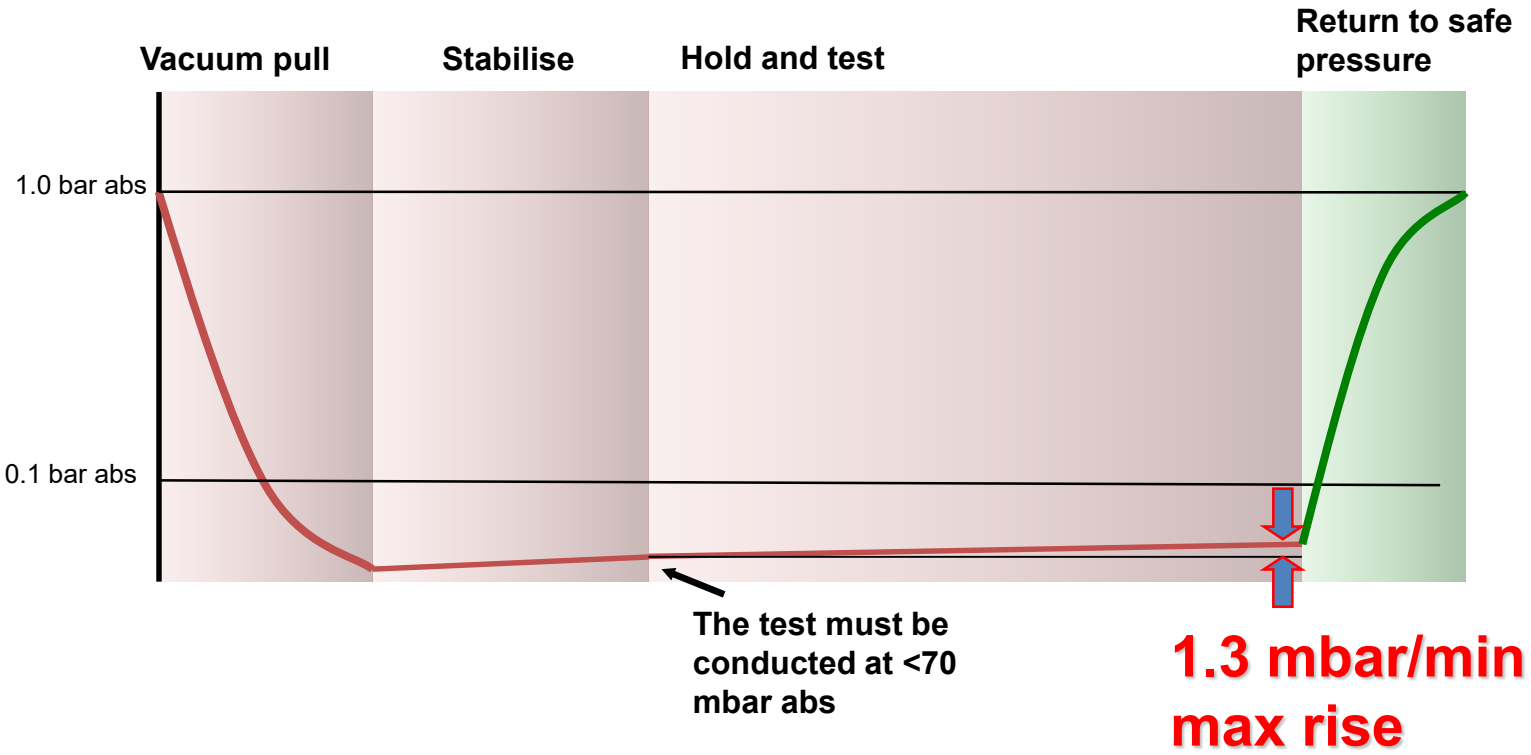
Air leakage test: Chamber vacuum leak test

- *When the sterilizer is tested as described in Claus 18 the rate of pressure rise shall be within the specific limits [see 25.4 c] and in any case shall be not greater than 0.13kPa/min (1.3mbar/,min).* (Ref EN 285:2015 *8.2.3*)

- *If the sterilization process makes use of a vacuum, an air leakage test shall be carried out at specific intervals* (Ref EN ISO 17665: *12.1.5*)

- *The air leakage test is applicable to any Steriliser that employs vacuum to remove air from the load* (Ref CFPP 01-01 Part C *2.69*)

Air leakage test: Chamber vacuum leak test



Common causes of failure of the ‘Chamber vacuum leak rate test’?

- Condensate/water in the chamber before running the test?
- Leakage caused by tear in a temperature probe?
- Leakage caused by seals (o-rings) on the probe lead-through?
- Door seal leakage?
- Chamber connection?
- Chamber valve leakage?

Air leakage test: Chamber pressure leak test:

Air leakage test: Chamber pressure leak test

- With autoclaves that are not equipped with a vacuum pump (for example superheated water spray autoclaves)
- It is not a standardized test, therefore the definition of rational limits are the responsibility of the autoclave user
- For tightness testing purposes, the chamber is pressurized by compressed air to a pressure of 2 to 3 bar abs
- As compressed air injected into the chamber will increase in temperature, a rather long stabilization time (up to 30mins) is required to eliminate the effect of residual pressure loss due to further cooling during the test.
- The test is recommended in the case of high-pathogen/decontamination loads

Bowie & Dick test

Bowie & Dick Test

- The Bowie and Dick test is used to demonstrate the complete air removal (→ rapid penetration of steam in a critical porous load)

- We can use a standard test pack with an indicator sheet compliant with EN ISO 11140-3 in the approximate centre of the pack. Alternatively we can use a “disposable” test pack, single use only.

Bowie & Dick Test

- "If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam into the sterilizer load, a steam penetration test shall be carried out each day before the sterilizer is used."
  - (Ref. EN ISO 17665)

Bowie & Dick Test

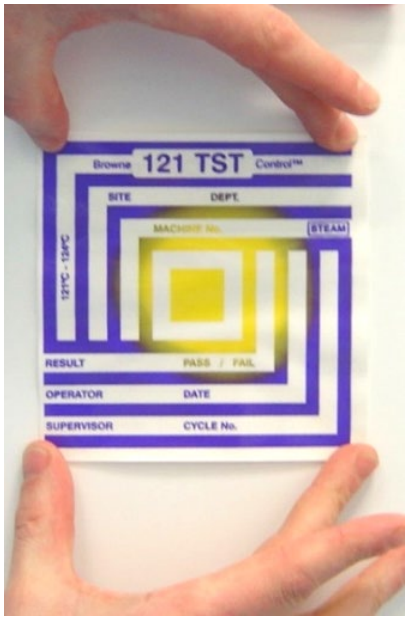
Indicator test sheet

The test pack is composed by an adequate number of plain cotton sheets, each bleached to a good white and having a size of ≈ 90 x 120 cm, folded four times and stacked, , with inserted halfway along the height of the stack a sheet of paper measuring 22 x 30 cm.

This sheet of paper bears concentric tracks of ink that changes color under humid heat (indicator compliant with EN 867-3)

Bowie & Dick Test

‘Chemical indicators are intended for use with individual packs of product to demonstrate that the pack has been exposed to the sterilisation process.
They have a defined color change, in which a visible change occurs after exposure to the specified variables at a level equal to or greater than that specified for the indicator.’
CFPP 01-01 –Part C: Steam sterilization



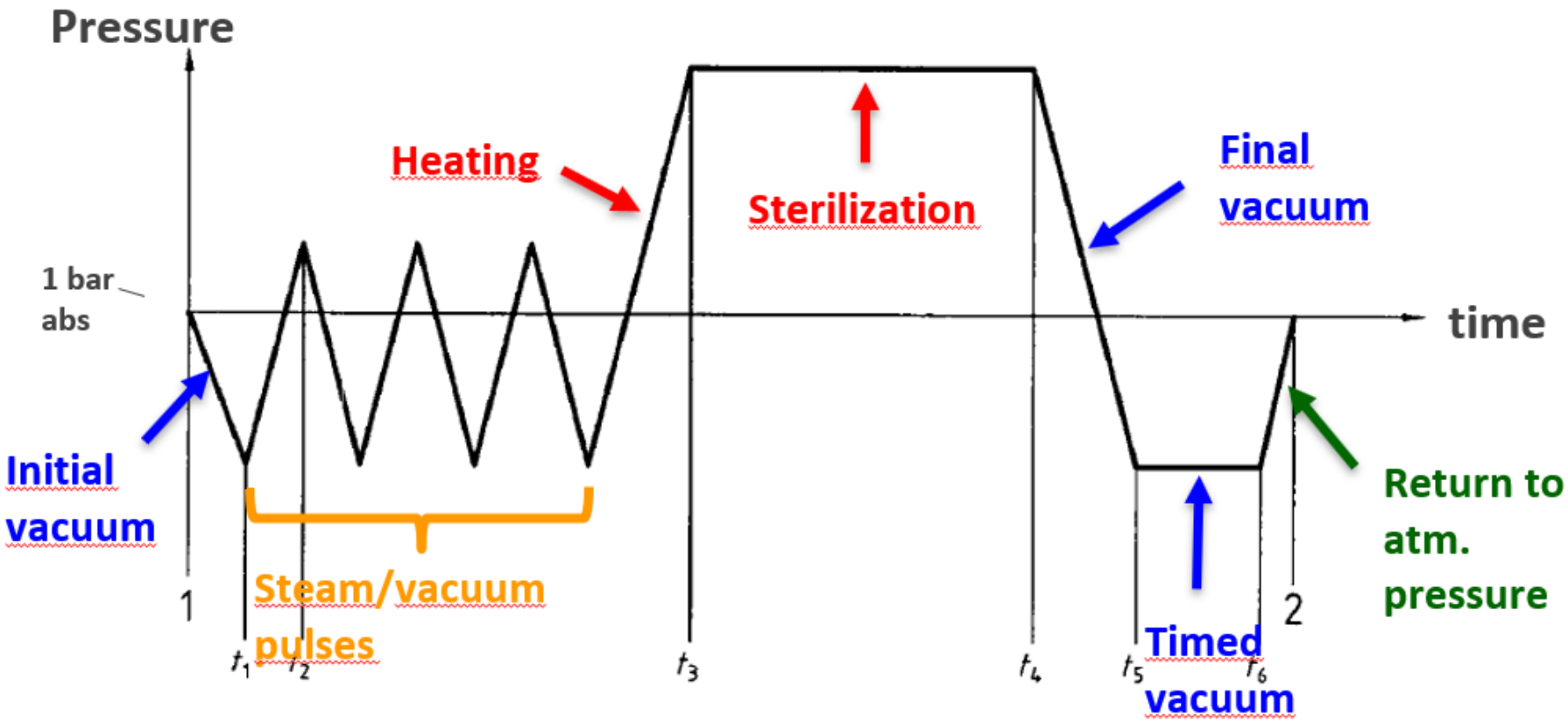
Bowie & Dick Test

‘Bowie - Dick indicators are intended to demonstrate the rapid and even penetration of steam and, by implication, **the adequacy of air removal’**

UNI EN ISO 15882 Chemical indicators- guidance for the selection, use and interpretation of the results

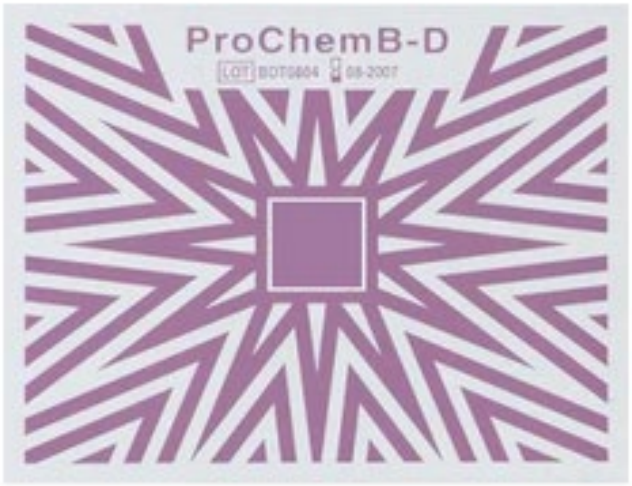
- In Pharma/Biotech, typically - 121°C for 8.3mins
- In healthcare/hospital, typically - 134°C for 3.5mins
- Both types are widely available and should match your typical production cycle temperature range.
- Not a test of the sterilisation phase actually in use
- Not a test of drying or cooling

Bowie & Dick Test

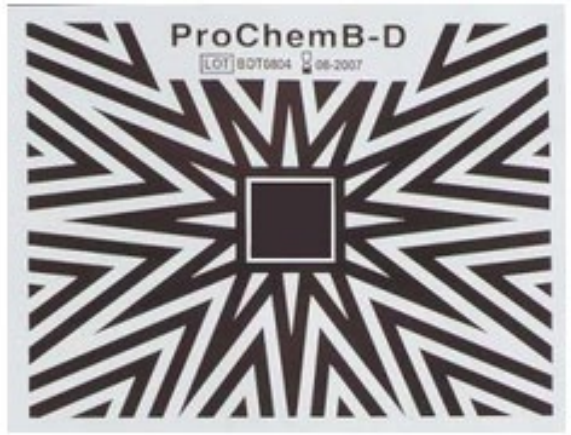


Bowie & Dick Test

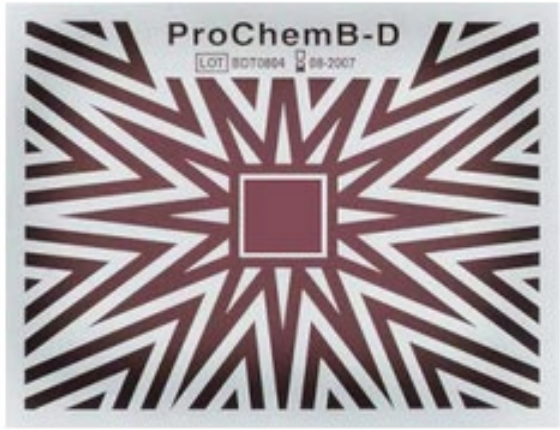
Bowie&Dick test: result



Unexposed



Pass



Fail

Common causes of failure of the 'Bowie & Dick test'

- The air has not been sufficient extracted from the chamber and therefore from the porous load
- The steam contained unacceptable quantities of non-condensable gases (NCGs) such as air or CO_2
- There is a leak in the chamber

Bowie & Dick Test

- An unsatisfactory result indicates that the sterilizer should not be used until the fault has been identified and rectified.
- It's common to conduct a series of test in order to identify the cause of the failed process.
- Conducting an air leak test will identify chamber leaks
- Calibration checks on the pressure transducer and temperature sensors will identify miscalibration or faulty probes

Hollow load test

Hollow load test

- The hollow load test is used to demonstrate that the air has been extracted completely even from critical hollow bodies (→ the steam penetrates them adequately)

- Critical Hollow Bodies: reference bodies that are not porous and are structurally provided with recesses that are critical for air elimination and/or steam penetration (ex. pipes that are open at both ends (or at just one end) with a considerable length with respect to the internal opening)

Hollow load test

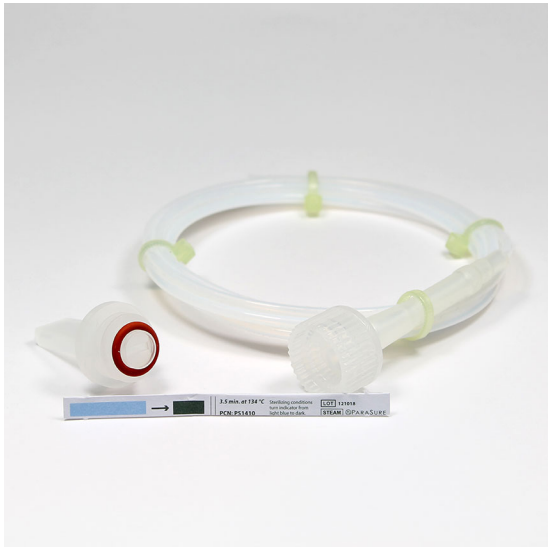
Test device: a tube with a length of 1500 mm, an internal diameter of 2 mm, walls with a thickness of 0.5 mm, connected hermetically to a small cylindrical capsule with an equally hermetic closure; the other end of the tube is open; the material is usually entirely Teflon.

A strip of paper impregnated with a color changing substance is place in the capsule.

All the material for the Helix Test is commercially available.

The test is passed if the strip of paper changes its color as specified

Hollow load test

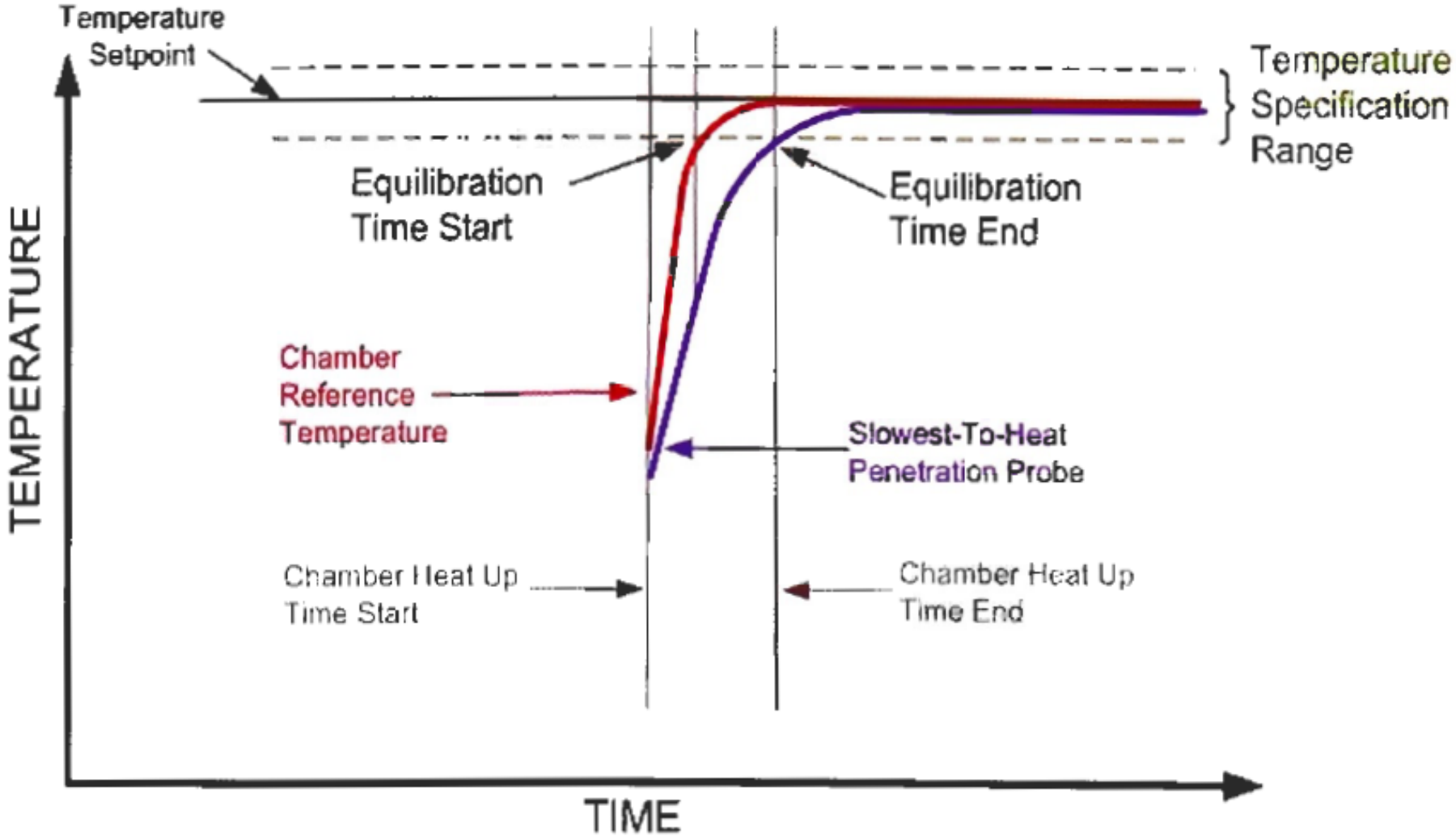


Hollow load test

Equilibration Time

Equilibration Time period which elapses between the attainment of the sterilization temperature at the reference measurement point (normally the coldest point of the chamber) and the attainment of the sterilization temperature at all points within the sterilization load.

In saturated steam processes, an Equilibration Time too long signifies that the program or the autoclave is unable to remove rapidly the air from the chamber and from the load and therefore unable to make the steam penetrate rapidly therein (ex. verify the number, depth, breadth of the vacuum-steam pulses)



Steam Quality Testing

Steam Quality References - Standards

EN285: 2015 Steam Sterilizers – Large Sterilizers

ISO 14937:2009 – Sterilization of heath care products – generation requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

ISO 17665-1:2006 – Sterilization of health care products – moist heat

ISO 11139:2008 – Sterilization of health care products - vocabulary

Steam Quality References - Other

HTM 01-01 Part C

HTM2010 and HTM2031 – UK Hospitals

cGMP (Orange Guide) – EU Pharma

AAMI ST79 – US Hospitals

Australian/New Zealand Standard 1410

ISPE Baseline guide for steam and water

PDA Technical Report No.1 and 48

The Tests

There are three steam quality tests required by the regulations

- Dryness Fraction
- Non-condensable gases
- Superheat

The Tests

There are three steam quality tests required by the regulations

- Dryness Fraction
  - ≥0.95
- Non-condensable gases
  - ≤3.5%
- Superheat
  - ≤25°C

Dryness Fraction

The accurate measurement of the percentage of moisture content in the steam is difficult, and the traditional methods, where constant steam flow is required, are not suitable for sterilizers. This test should be regarded not as a measuring of the true content of moisture in the steam, but as a method by which the provision of acceptable steam quality can be demonstrated.

Dryness Fraction

If the steam is ‘wet’, i.e. less that the expected ‘dryness fraction’

- Wet packaging – bacterial growth can occur through wet wrapping and packaging.
- Wet steam has less energy than dry steam (it’s already condensed have already released it’s latent heat.

Non-condensable gases

Non-condensable gases (NCGs) are defined as gases which cannot be liquified by compression under the range of conditions of temperature and pressure used during the sterilization process. Low levels of NCGs contained in steam supplied to sterilizers can markedly affect the performance of the sterilizer and efficacy of the process, cause chamber overheat and lead to inconsistencies in the performance of the air detector and failure of the Bowie-Dick test.

The major NCGs are air and carbon dioxide

Superheat

Superheated steam is an unsuitable medium for moist heat sterilization and can cause failure to sterilize, scorching of textiles and paper and rapid deterioration of rubber. Superheat conditions within eh load and chamber may result from adiabatic expansion, exothermic reaction or both.

Superheating arising from exothermic reaction may occur during sterilization as a result of rehydration of exceptionally dry hygroscopic material (particularly cellulose fibres such as cotton and paper)

Thank you.