The Bowie Dick Test: Electronic Indicator, or Autoclaves with Integrated Test?

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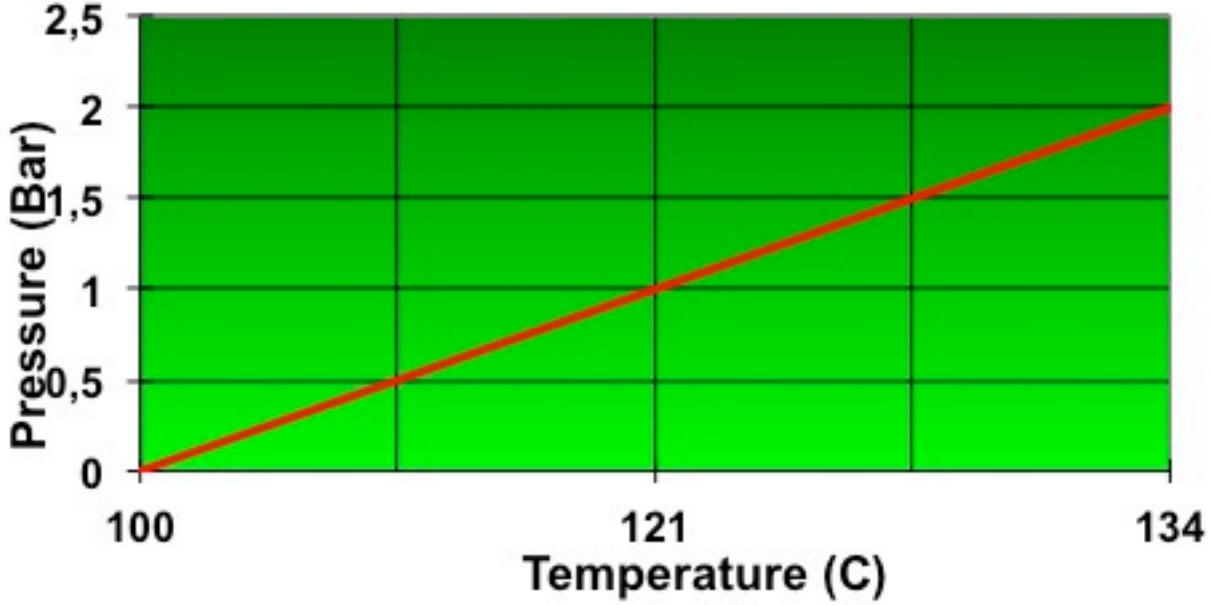
Steam!

Pressure/temperature correlation of saturated steam

Saturated steam follows phase boundary line

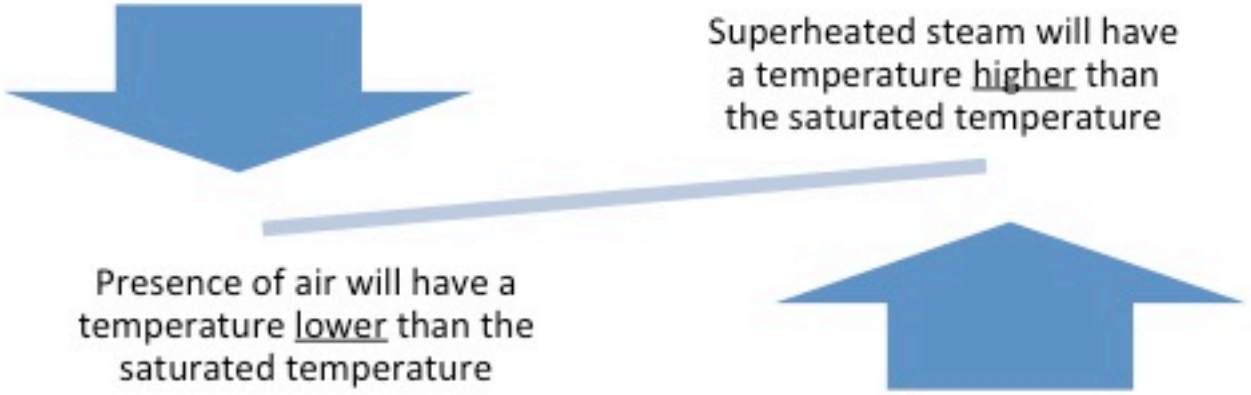


Saturated steam

Saturated steam is steam at equilibrium between the liquid (water) and gas (steam) phases

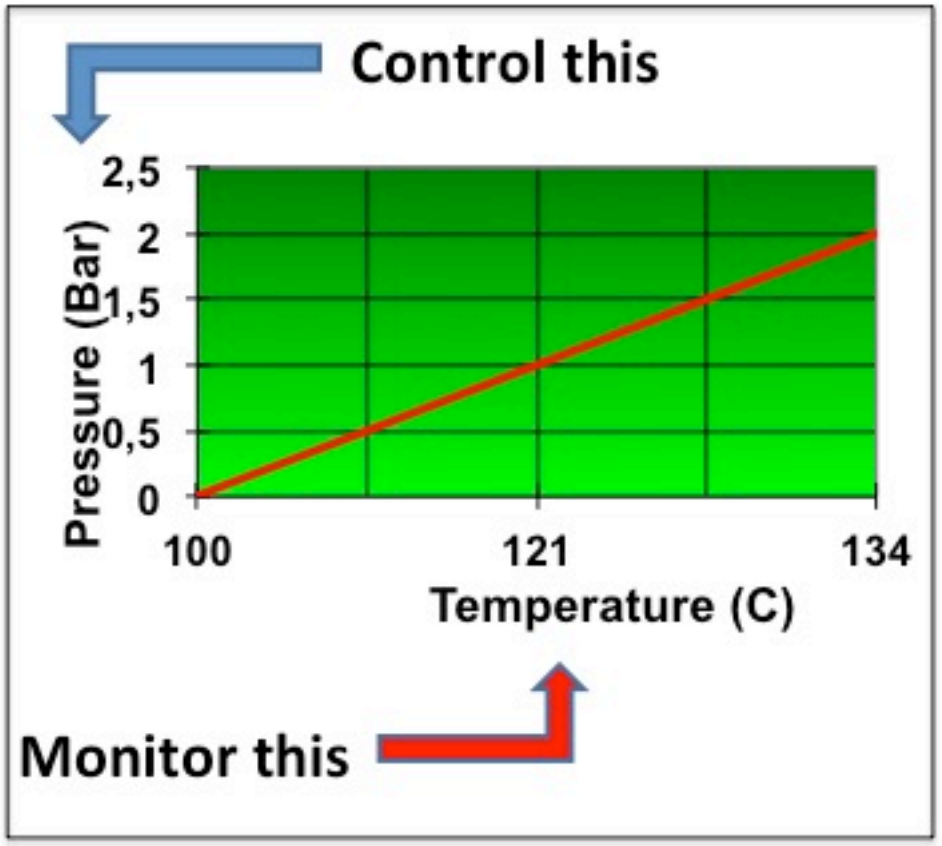
It will have a fixed temperature at a given pressure, unless:

- Steam is superheated
- Air is present



Control of a steam sterilizer

- Steam sterilizers use knowledge of steam properties to control and monitor the process
- PRESSURE of steam is controlled
- TEMPERATURE of load is monitored
  - There is no means (or need) to control presence of moisture
  - **MUST control air**
  - **Bowie Dick test is essential**



WHAT IS THE PROBLEM?

Steam sterilizers

They should be called 'moist heat' sterilizers

If moisture is present, micro-organisms will be killed

- e.g. fluid sterilizers successfully sterilize ampoules containing aqueous fluids

Moist heat at 134 °C is capable of destroying 1 million spores in under 1 minute

Use high energy of steam to heat load rapidly

Using saturated steam (vs. water) will affect the rate of heating, but not microbial lethality

Removal of air

Air is heavier than steam

WHY REMOVE AIR?

Air will insulate the load and prevent attainment of the necessary temperature

- Maximum temperature difference of 2 °C is specified in EN ISO 17665-1
- Insufficient moisture to kill micro-organisms

Air remaining in or on a load will be concentrated

Control of air

Air and other non-condensable gases (NCGs) must be reduced to a level as low as possible

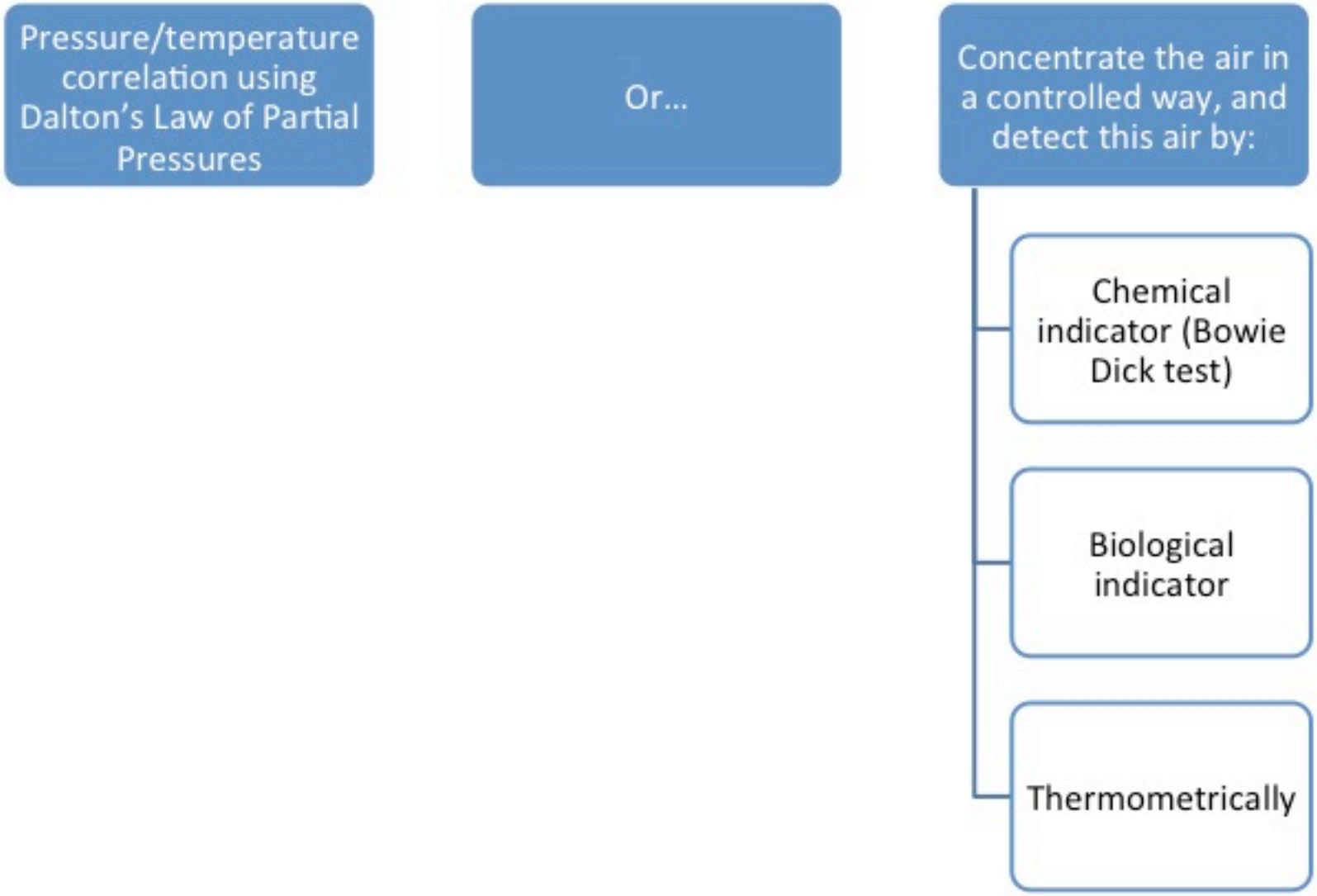
This is done by:

- Minimising amount of NCGs in steam
- Minimising air leaks into chamber

How is this checked?

- Periodic (daily?) leak rate test
- Bowie Dick test at commencement of each day
- Internal chemical indicators in each load item, plus:
  - In UK, Ireland & Australia: air detector fitted to the sterilizer

Detecting presence of air in steam



BOWIE DICK TEST

Bowie Dick test, yesterday & today

The original towel pack was described by Bowie and Dick in 1963:

- Bowie, J.H., Kelsey, J.C. and Thompson, G.R., *Lancet*, i, (1963), p. 586

The origins of this test form a key part of OQ of steam sterilizers:

- EN 285:2015, Sterilization — Steam sterilizers — Large sterilizers, Small load thermometric test, clause 16.1

Current performance requirements for the Bowie Dick test are given in EN ISO 11140-4

Why perform a Bowie Dick test?

Requirement of EN ISO 17665-1

Sterilization of health care products – moist heat
Requirements for the development, validation and routine control of a sterilization process for medical devices

- 12.1.6 'If the sterilization process relies on the removal of air…a steam penetration test shall be carried out each day'

Electronic Bowie Dick tests

Many commercial products available

- There are no product standards. Why?

EN ISO 11140-4

- Sterilization of health care products – Chemical indicators – Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration

4.1. The requirements of ISO 11140-1 apply

- Sterilization of health care products – Chemical indicators – Part 1: General requirements

6.1. The indicator, when tested in combination with the test load specified by the manufacturer, shall show a uniform colour change complying with 5.1 c)…

5.1 c) the indicator system shall have a difference in relative reflectance density of not less than 0.3 between the colour …

Principle of the steam penetration test

Test MUST be conducted in an otherwise empty chamber

Other load items will cause preferential mass flow of steam to condensation sites

- In this case, test sensitivity will be reduced

Biological indicator

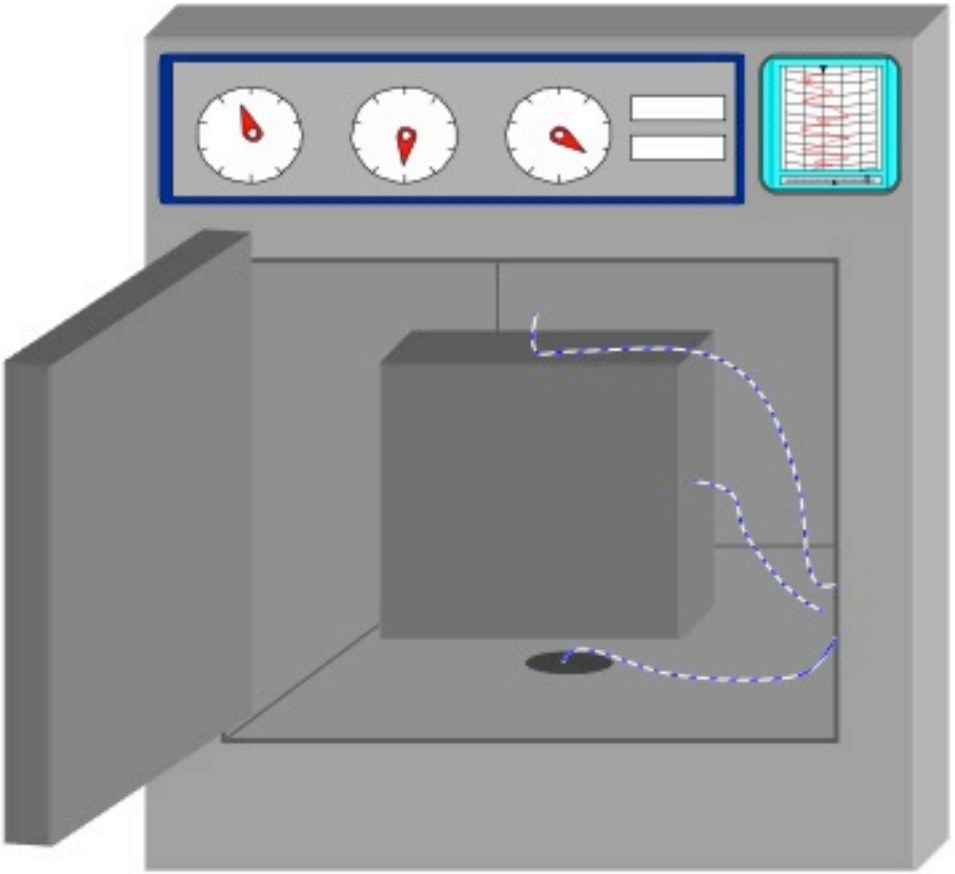
Biological indicators can be used within a towel pack

Similar concept to the Bowie Dick test, but using a biological indicator

Can also be used within a pre-assembled challenge pack

Thermometrically

- Thermocouples can be used inside a towel pack
- Small load thermometric test (EN 285)



CAN WE USE BUILT-IN STERILIZER TEST DEVICE?

Do we mean an air detector?

BS 3970:1966 – British standard for steam sterilizers

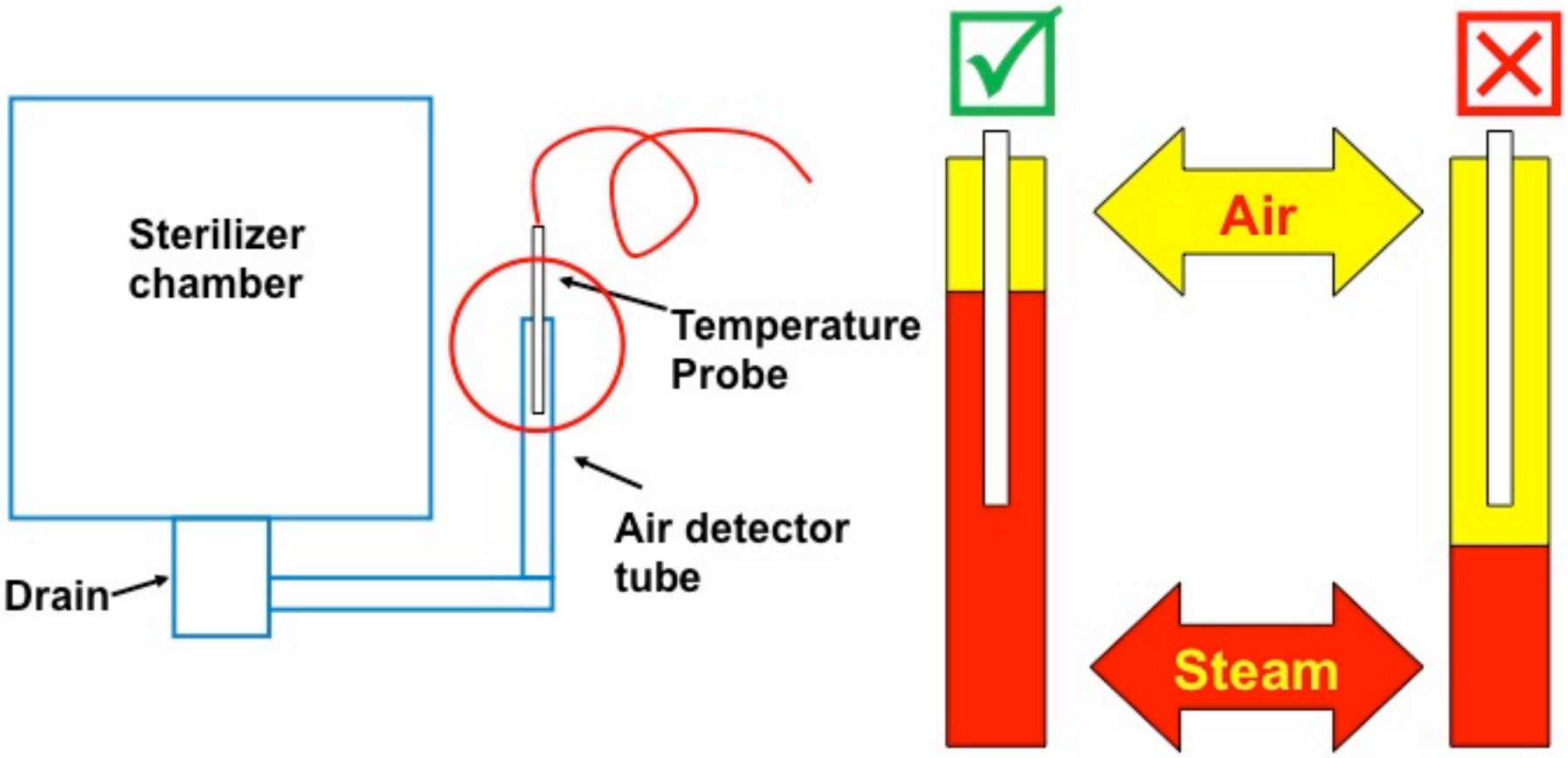
Amended in August 1969 to include a requirement for an 'air detector' to monitor every cycle

- *'A device capable of detecting the presence of air in sufficient quantity to prevent…sterilizing conditions …shall be fitted to form part of the automatic control'*

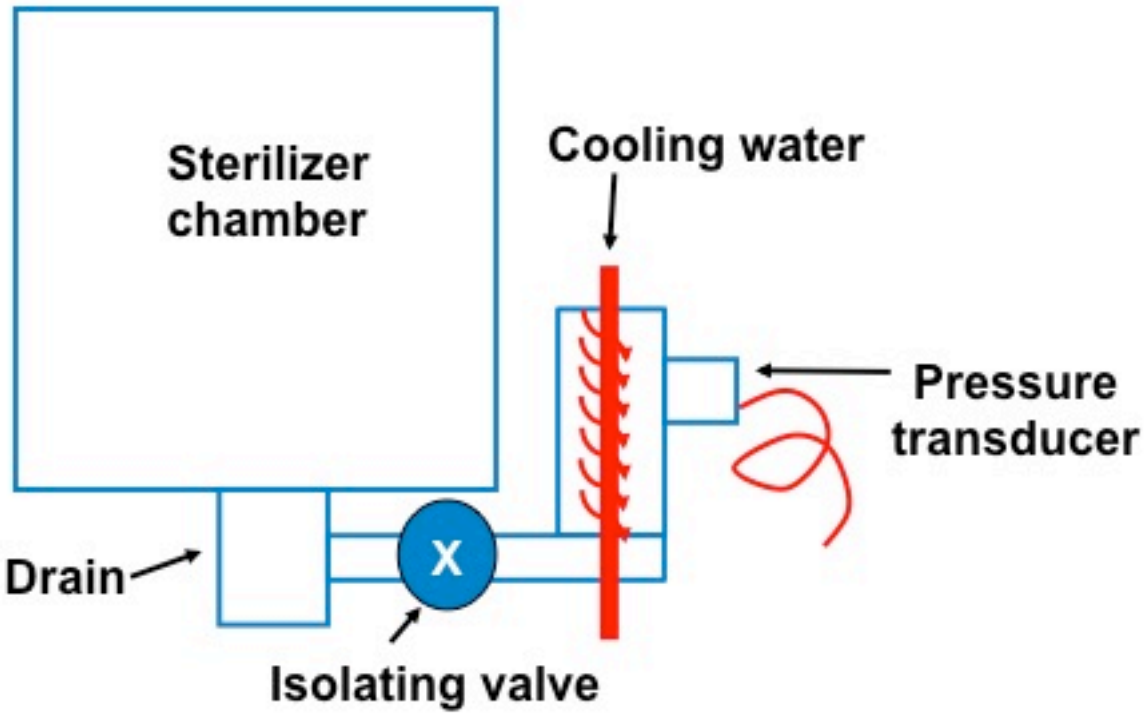
There are 3 ways in which air detectors can operate:

- 'Thermometric' air detectors
- 'Partial Pressure' air detectors
- 'Condensate' air detectors

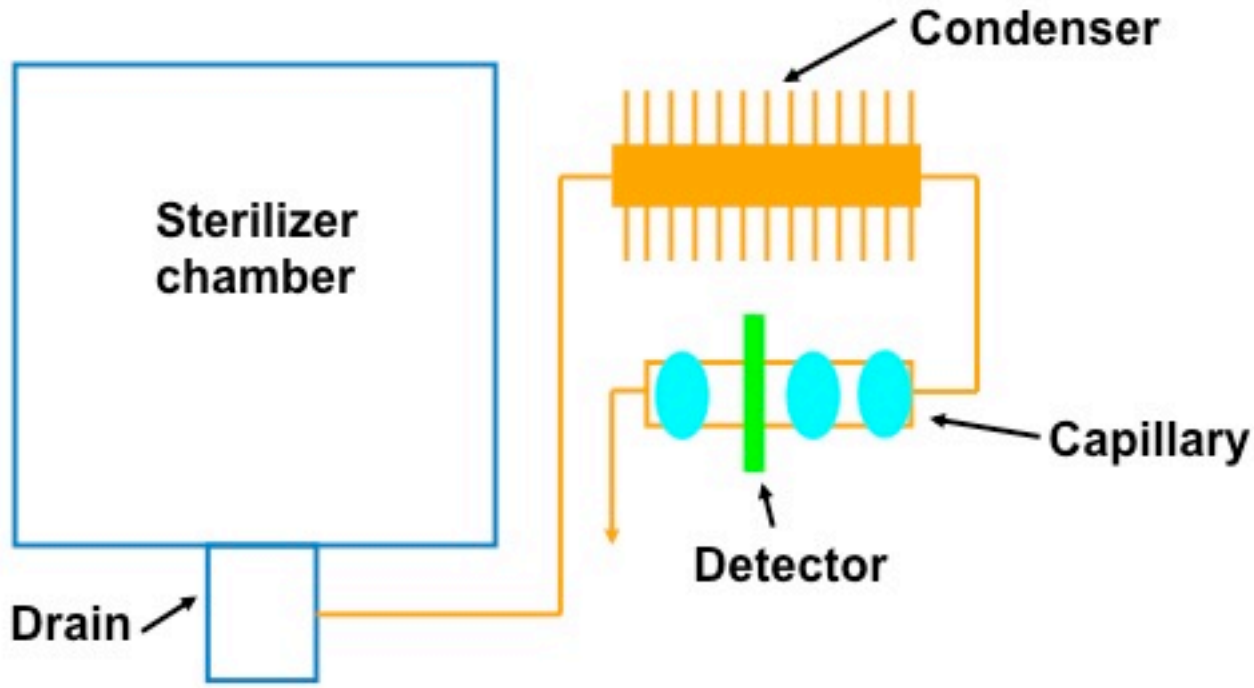
Thermometric air detector



Partial pressure air detector



‘Condensate’ air detector



Sensitivity of air detectors

The 3 types of air detector vary in sensitivity

Performance is dependant upon how they are calibrated

Influenced significantly by:

- Air leak position
- Load size & type
- Chamber size

Air detectors are not perfect!

Air detectors do monitor every cycle, although not as accurately as a Bowie Dick test

Don’t forget pack monitoring!

- Use of internal indicators ensures monitoring of steam penetration in actual loads

Regulation (EU) 2017/745 (MDR)

- There are currently 3 Medical Device Directives in EU
  - 93/42/EEC+2007/47/EC – General MDD
  - 90/385/EEC - Active Implantable MDD (AIMDD)
  - 98/79/EC - In Vitro Diagnostic MDD (IVDMDD)
- The EU MDD Directives have been extensively redrafted as the EU Medical Device Regulations
  - Regulation (EU) 2017/745 concerning Medical Devices and Active Implantable Medical Devices
  - Regulation (EU) 2017/746 concerns In Vitro Diagnostic Devices
- The EU Parliament approved the final text of the EU Device Regulations on 25th May 2017
  - 3 or 5 year transition –
  - 2017/745 (MDR) combines the MDD with the AIMDD - has to be fully implemented (date of application) by 26th May 2020
  - 2017/746 (IVDR) replaces the IVD - has to be fully implemented (date of application) by 26th May 2022

EU MDR

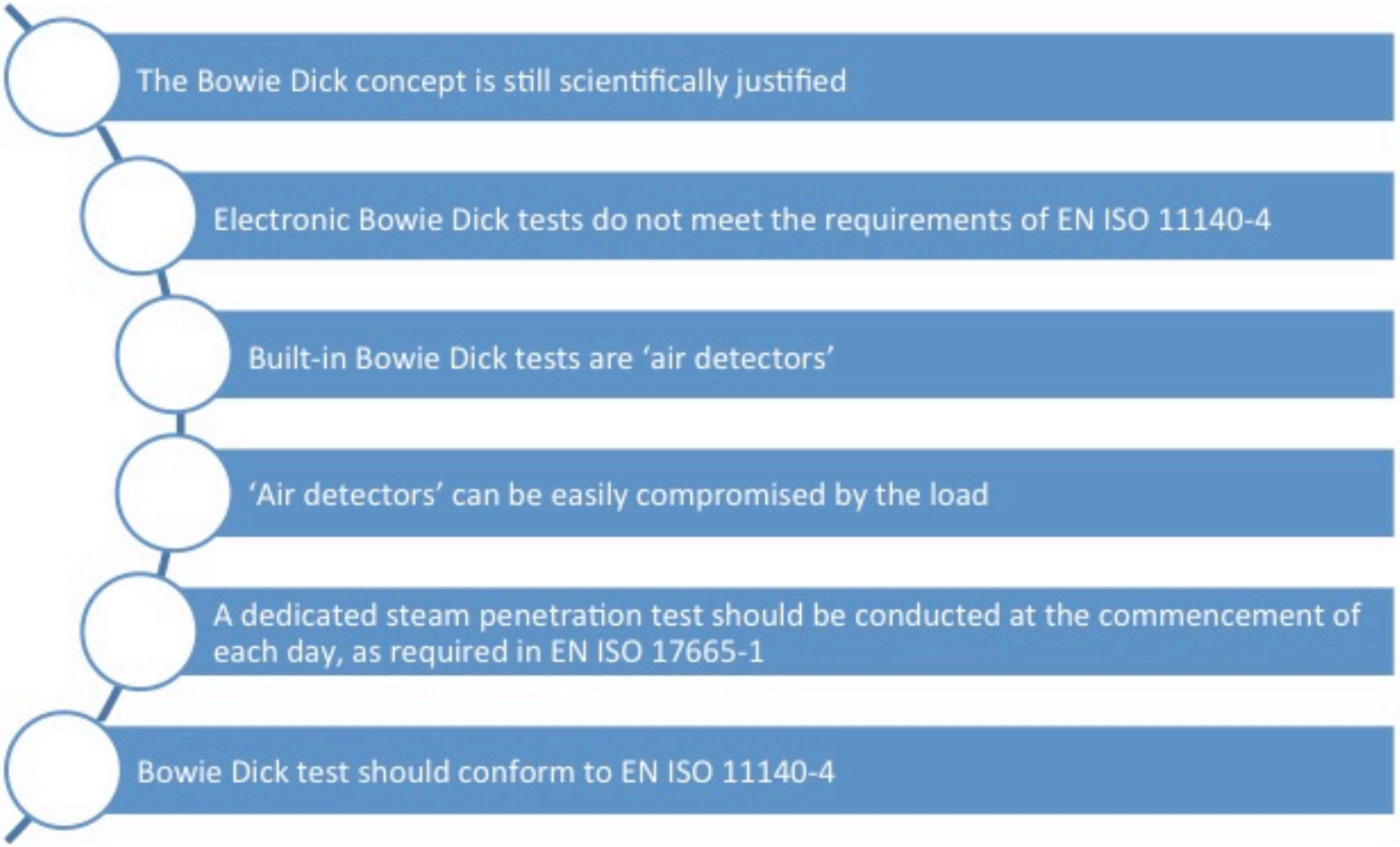
Very significant changes in EU law

Scope of MDR is greater and includes new devices

- Chemical Indicators are now within the scope of the EU MDR

Existing devices will need to conform to new regulation

Conclusion


The Bowie Dick concept is still scientifically justified
Electronic Bowie Dick tests do not meet the requirements of EN ISO 11140-4
Built-in Bowie Dick tests are 'air detectors'
'Air detectors' can be easily compromised by the load
A dedicated steam penetration test should be conducted at the commencement of each day, as required in EN ISO 17665-1
Bowie Dick test should conform to EN ISO 11140-4

Thank You!