

Air Detectors

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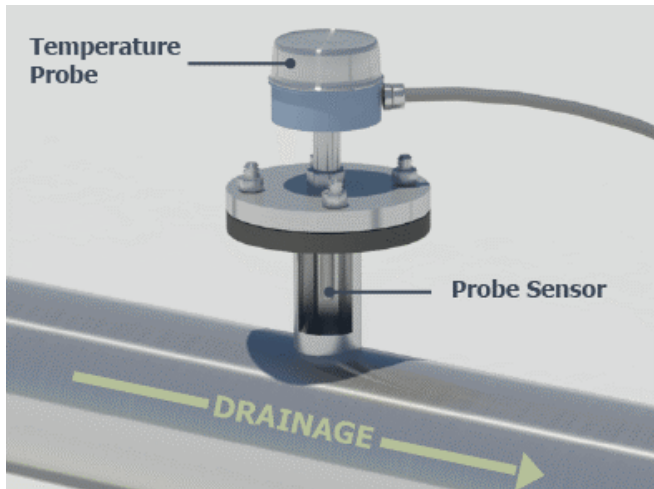
Agenda

- **Introduction**
Air Detectors
- **Annex 1**
Bowie & Dick vs Air Detectors
- **Practical considerations**
Set up and Testing

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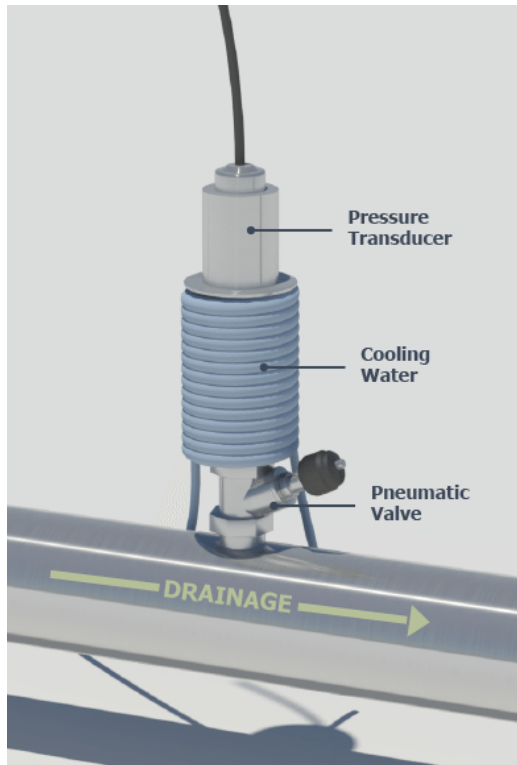
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Temperature Type Air Detectors



- In its simplest form an air detector is a temperature probe located in a tube attached to the drain line or chamber of the autoclave.
- A temperature set point is set on the HMI to check the temperature using the air detector probe. Once this temperature is achieved post air removal and during heat up a temperature reading is taken from the air detector probe.
- If air is present in the chamber, air will collect in the tube where the temperature probe is located.
- If the temperature is less than the temperature of saturated steam at this pressure the system will alarm, as this indicates that air is present in the steam and that saturated steam conditions have not been met.

Pressure Type Air Detectors



- The second type of Air Detector is the pressure-based Air Detector or the condensing Air Detector.
- Similarly, to the temperature-based Air Detector, these are located in a tube in the drain line of the autoclave. In this case a pressure transducer is connected to the tube.
- However, this tube is capable of isolating itself from the drain, usually using a pneumatic valve, and are fitted with a jacket capable of supplying cooling water to the outside of the tube.
- A sample of steam is collected post the air removal phase by isolating the tube from the drain. The cooling water condenses the steam, as this steam condenses it should produce a vacuum on the Pressure transducer.
- The level of this vacuum indicates if air is present in this sample, as air is a non-condensable gas a small vacuum would indicate that there is air present that cannot be condensed by the cooling water, however a larger vacuum indicates that saturated steam is present in the tube and all the contents of the sample have been condensed. A pressure set point is set on the HMI to check the pressure using the air detector sensor.

Air Detectors and Bowie & Dick Tests

An **air detector** is an **optional provision** which when set and tested according to this European Standard will routinely challenge the operating cycle and register a pass/failure. **Other methods** for routinely assessing specific performance aspects can be used, such as **chemical** or biological **indicators**, providing their performance is determined and verified using validated test procedures.

BS EN 285:2015 Introduction

Air Detectors and Bowie & Dick Tests

An **air detector** can be fitted to a sterilizer and used to determine whether the non-condensable gases contained in the steam delivered to the sterilizer and the **air remaining after the air removal stage** of the operating cycle are **sufficient to cause the sterilizing process to be of uncertain efficacy.**

BS EN 285:2015 (19.1)

Air Detectors and Bowie & Dick Tests

The **Bowie and Dick test** was conceived as a test for successful air removal for vacuum porous load sterilizers. A successful Bowie and Dick test indicates rapid and even penetration of steam into the standard test pack or reduced test pack. **Retention of air within the pack** due to

- Inefficient air removal stage,
- Air leak during the operating cycle,
- The presence of NCGs in the steam supply.

are circumstances which can lead to fail result for the test.

BS EN 285:2015 (17.1)

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Bowie & Dick Test vs Air Detectors Annex 1

Annex 1

The Rules Governing Medicinal Products in the
European Union
Volume 4 EU Guidelines for Good Manufacturing
Practice for Medicinal Products for Human and
Veterinary Use

Brussels, 22.8.2022
C(2022) 5938 final

Annex 1 (2008)

85. For effective sterilization the whole of the material must be subjected to the required treatment and the process should be designed to ensure that this is achieved.

92. Sufficient time must be allowed for the whole of the load to reach the required temperature before measurement of the sterilizing time-period is commenced. This time must be determined for each type of load to be processed.

95. All parts of the load should be in contact with the sterilizing agent at the required temperature for the required time.

Annex 1 (2022)

8.61 There should be adequate assurance of air removal prior to and during sterilization when the sterilization process includes air purging (e.g., porous autoclave loads, lyophilizer chambers).

For autoclaves, this should include an **air removal test cycle** (normally performed on a daily basis) **or** the use of an **air detector system**.

Loads to be sterilized should be designed to support effective air removal and be free draining to prevent the build-up of condensate.

Annex 1 (2008)

Annex 1 (2008) did not provide a detailed explanation of how to ensure adequate air removal from the load, in fact it only alluded to this fact through text such as: -

- All parts of the load should be in contact with the sterilizing agent
- *Air is not the sterilizing agent, so we need to ensure we remove the air*
- For effective sterilization, the whole of the material must be subjected to the required treatment.
- *Air is not part of the required treatment, so we need to ensure we remove the air*

Annex 1 (2022)

Annex 1 (2022) provides a far more detailed requirement for the detection of air in the load.

- 8.61 There should be adequate assurance of air removal prior to and during sterilization when the sterilization process includes air purging
- *If vacuum is employed in the process, there needs to be assurance of air removal*
- 8.61 For autoclaves, this should include an **air removal test cycle** (normally performed on a daily basis) **OR** the use of an **air detector system**
- *This is a significant change in the pharmacopeia, previously it was standard practice to perform a ‘air removal test cycle’ with a ‘Bowie&Dick’ type test pack’, the use of air detectors were somewhat optional considering the text in the introduction of EN285:2015 ‘An air detector is an optional provision which when set and tested according to this European Standard will routinely challenge the operating cycle and register a pass/failure’*
- **Now we have a significant change in that the new Annex 1 allows for either an ‘air removal test cycle’ or an ‘Air Detector’ system to be used in order to provide the required assurance of air removal prior to sterilization.**

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Air Detector Test – Small Load

8.2.4.2 When tested as described in 19.2 an air detector shall cause a fault to be indicated if the volume of air or other non-condensable gases retained or introduced into the sterilizer chamber during the air removal and steam admission of the operating cycle causes a difference in temperature of more than 2K.

This difference is evaluated between the lowest measured temperature in a standard test pack (see 23.1) or reduced pack (see 23.2) and the temperature measured at the reference measurement point of the sterilizer chamber at the commencement of the equilibration time.

Air Detector Test – Small Load

23.1 Standard Test Pack

23.1.1 This test pack is used to check that, at the levels at which the cycle parameters are set, rapid and even penetration of steam into the pack is attained.

It is used for the Bowie and Dick test, the small load test, **air detector tests**, load dryness test, textiles and can be used with other materials to form a full load.

Air Detector Test – Small Load

19.2.2.9 Carry out an operating cycle, but during the air removal stage admit air to the sterilizer chamber by means of the metering device. Control the rate of entry of the air so that, at the start of the plateau period, the lowest temperature measured within the test pack is not more than 2 K lower than the temperature measured at the reference measurement point.

Air Detector Test – Small Load

19.2.2.12 Carry out an operating cycle and check that a fault is indicated either during or at the end of the operating cycle.

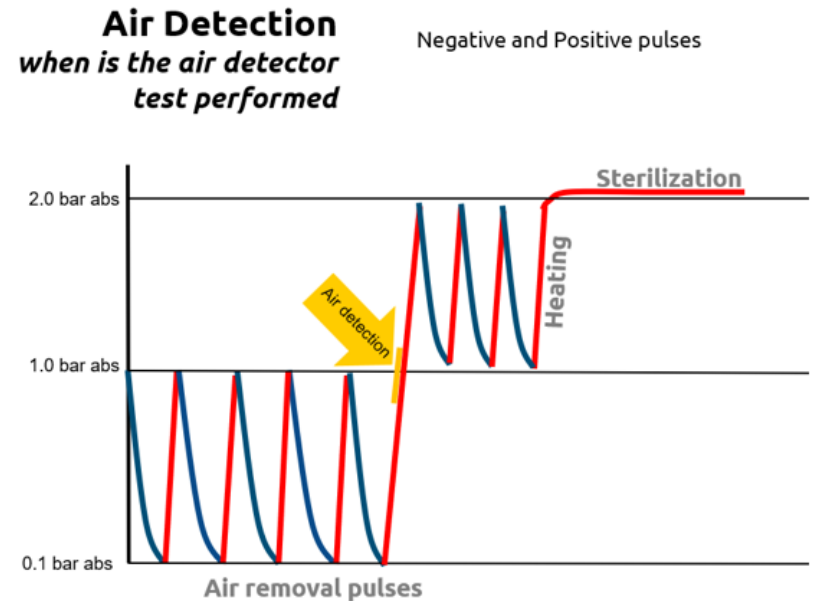
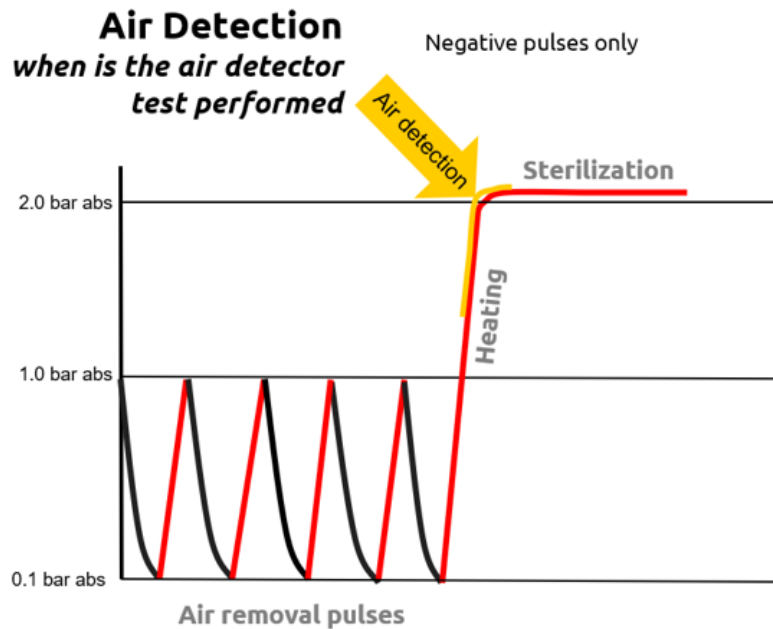
Air Detector Function Test

19.4.1 The air detector function test is used to provide assurance that the setting of the air detector remains valid.

The Test

- Prepare a Test pack as described in 23.1
- Set the metering device to the setting determined during the air detector test, small load
- Carry out an operating cycle
- At the end of the operating cycle check for compliance with the requirement specified in 8.2.4.4. (*When the sterilizer is tested as described in 19.4 the test result shall be regarded as satisfactory if a fault is indicated.*)

Air Detectors using Negative and Positive air removal pulses



Thank you!