Routinary & operational tests

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Reference documents

EN 285	→ European Standard for Large Steam Sterilizers
HTM 01-01 (ex CFPP 01-01)	→ Management and decontamination of surgical instruments (medical devices) used in acute care: Part C – Steam sterilization
UNI EN ISO 17665 (replaces UNI EN 554)	→ Sterilization of health care products / Moist heat
EN ISO 11140-3 (replaces EN 867-3)	→ Sterilization of health care products. Chemical indicators. Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

Air leakage test:

Chamber vacuum leak 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 the final vacuum drying phase.

To verify this, we have to carry out the chamber vacuum leak rate test.

Chamber vacuum leak test

"If the sterilization process makes use of a vacuum, an air leakage test shall be carried out at specified intervals."

(Ref. EN ISO 17665.1 – clause 12.1.5)

The air leakage test shall be carried out weekly by a CP (Competent Person).

(Ref. HTM 01-01 Part C)

Chamber vacuum leak test

The pressure is recorded at different time and the test is satisfactory if:

P2 – P1 ≤ 20 mbar

P3 – P2 ≤ 13 mbar

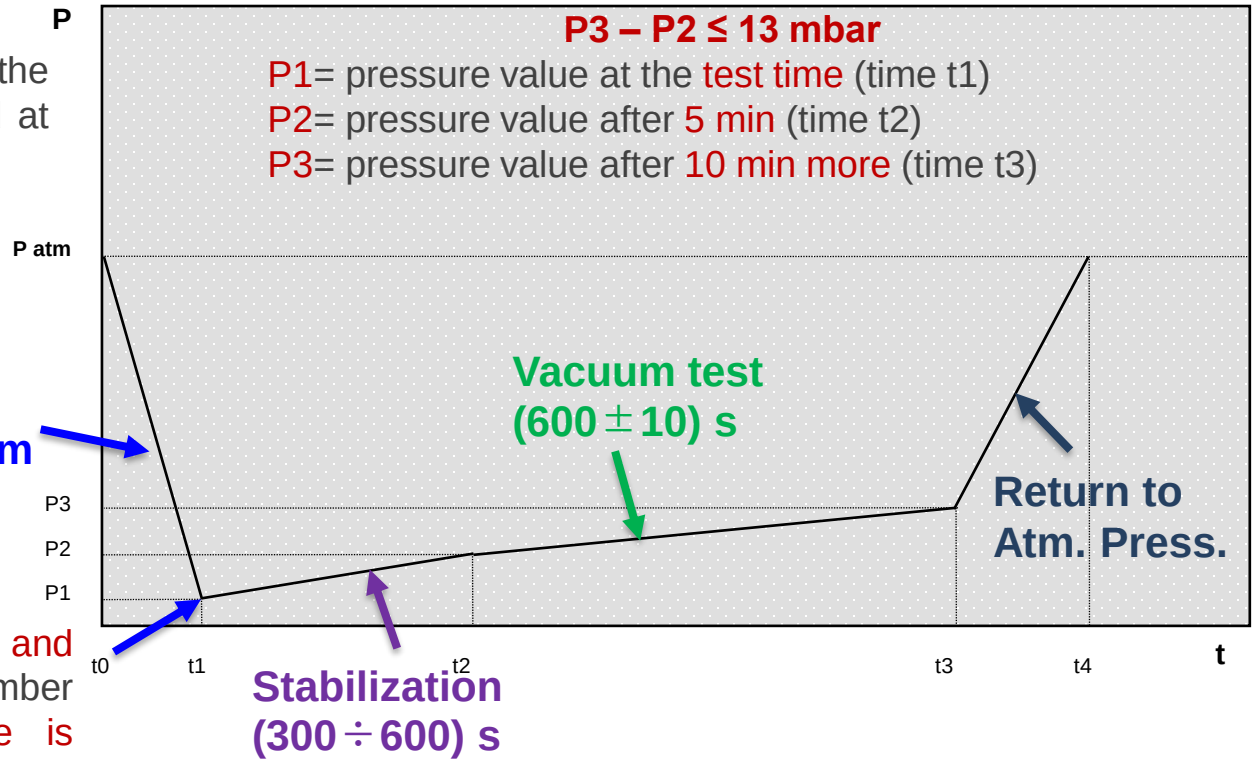
P1= pressure value at the test time (time t1)

P2= pressure value after 5 min (time t2)

P3= pressure value after 10 min more (time t3)

The test is performed when the chamber is thoroughly dry and at a stabilized temperature

The chamber is brought to a vacuum of 70 mbar



The valve between the pump and the chamber is closed, the chamber is isolated and the pressure is recorded over the time (t1, t2, t3)

Chamber vacuum leak test

If P2 – P1 > 20 mbar, probably the test has been performed while the chamber is moist

If P3 – P2 > 13 mbar, the leaks that are evidently present and must be eliminated

Today, most autoclaves have an automatic program for a routine tightness test, which is "analyzed" by the pressure measurement systems of the autoclave itself.
Discrimination capacity not better than 10 mbar → test time is generally increased to 16 minutes and the acceptable tightness loss becomes 20 mbar

Air leakage test:

Chamber pressure leak test

Chamber pressure leak test

It's used for autoclaves that are not equipped with a vacuum pump (counterpressure autoclaves)

It is not standardized and the definition of rational limits are the responsibility of the autoclave user

For tightness testing purposes, the chamber is pressurized by compressed air up to 2 to 3 bar abs

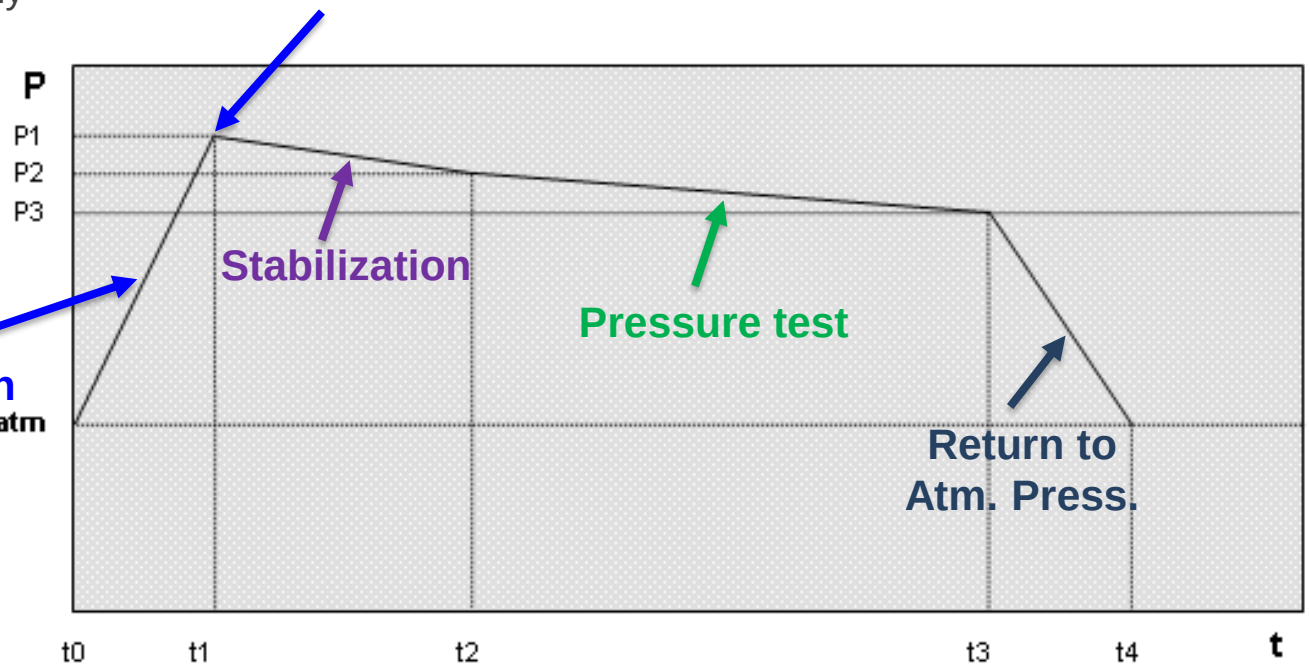
A long stabilization time (up to 30 minutes) is to be foreseen to eliminate the effect of residual pressure loss due to further cooling during the test

This test is recommended in the case of contaminant loads

Chamber pressure leak test

The test is performed when the chamber is thoroughly dry and at a stabilized temperature

All the valves are closed and the chamber is isolated. The pressure is recorded over the time (t1, t2, t3)



The chamber is pressurized up to 2 to 3 bar abs

Bowie&Dick test

Bowie&Dick test

The Bowie and Dick test is used to demonstrate the complete air removal for the 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 17665.1 – clause 12.1.6)

B&D test: standard test pack

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.

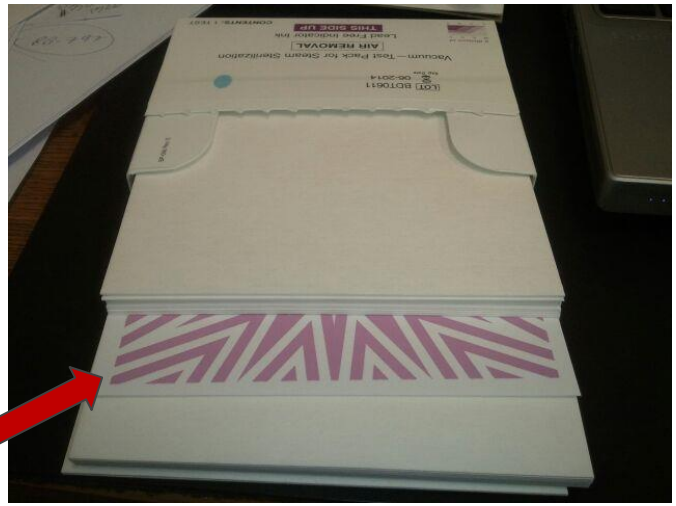
B&D test: standard test pack

Halfway along the height of the stack is inserted 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 11140-3).

Indicator test sheet

B&D test: disposable test pack

We can have problems using the plain cotton sheets, in terms of handling, washing, drying and aeration; therefore, disposable devices are commercially available which simulate the conditions of the described test pack device.



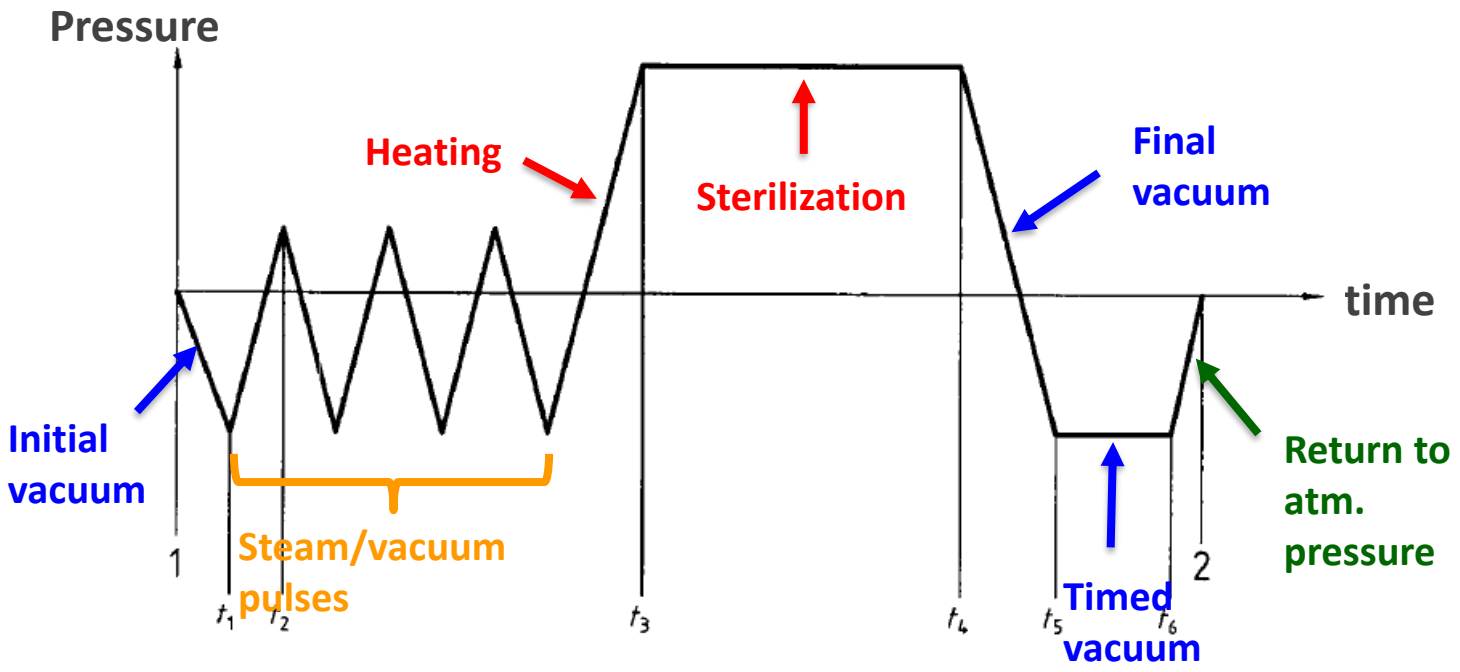
Indicator test sheet

B&D test: procedure

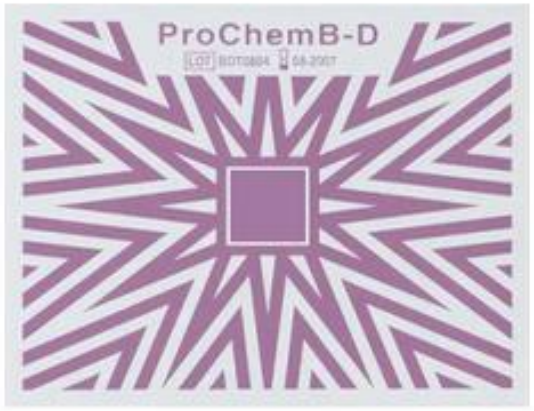
The pack is placed in the empty autoclave and a program is run at 134°C for 3,5 minutes or 121°C for 10 minutes (without any extended drying time)

The test is successful if the tracks of ink change uniformly (even in its central regions) their color

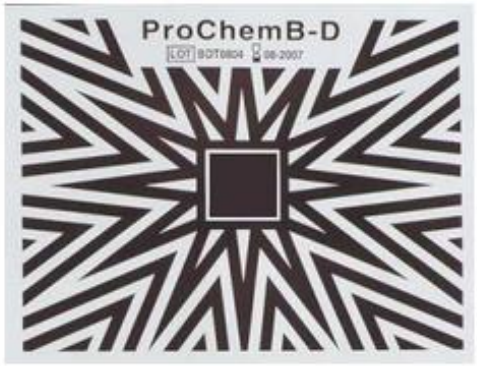
B&D test: cycle



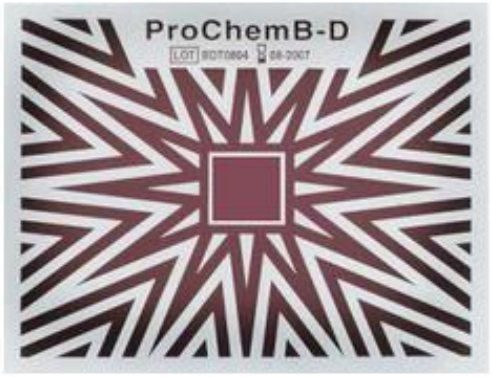
B&D test: result



Unexposed



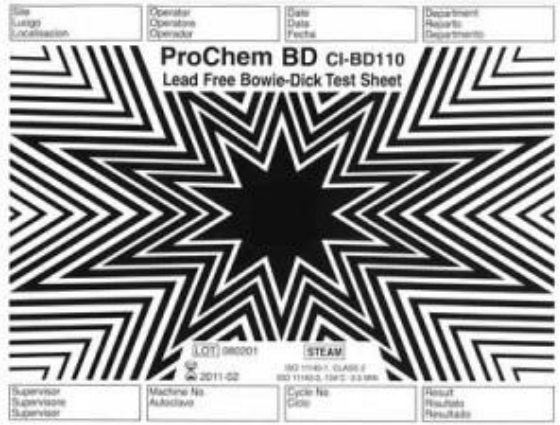
Pass



Fail

B&D test: result

Unexposed



PASS!!

FAIL

B&D test: result

Common causes of failure:

The air has not been extracted completely from the chamber and therefore from the porous load

The steam contained unacceptable quantities of non condensable gases (air or CO_2)

There is a leak in the chamber

B&D test: result

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 tests in order to identify the cause of the failed process.

- ✓ Verify the efficacy of the air removal phases of the tested cycle
- ✓ Conducting an air leak test will identify chamber leaks.
- ✓ A steam-quality test for non-condensable gases will identify this cause of failure

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

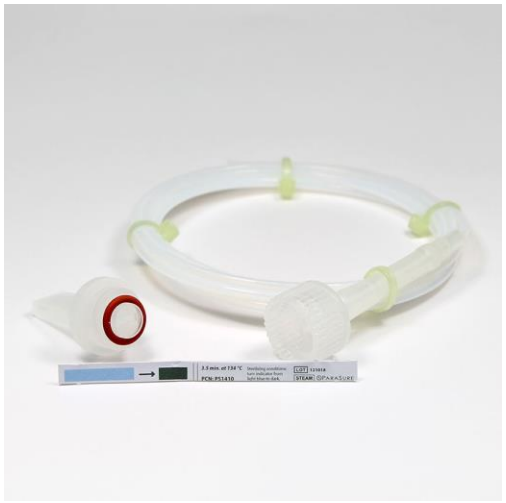
Test device: a tube with a length of 1500 mm, an internal diameter of 2 mm, walls with a thickness of 0.5 mm, connected hermetically to a small cylindrical capsule with an equally hermetic closure; the other end of the tube is open; the material is usually entirely Teflon.

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

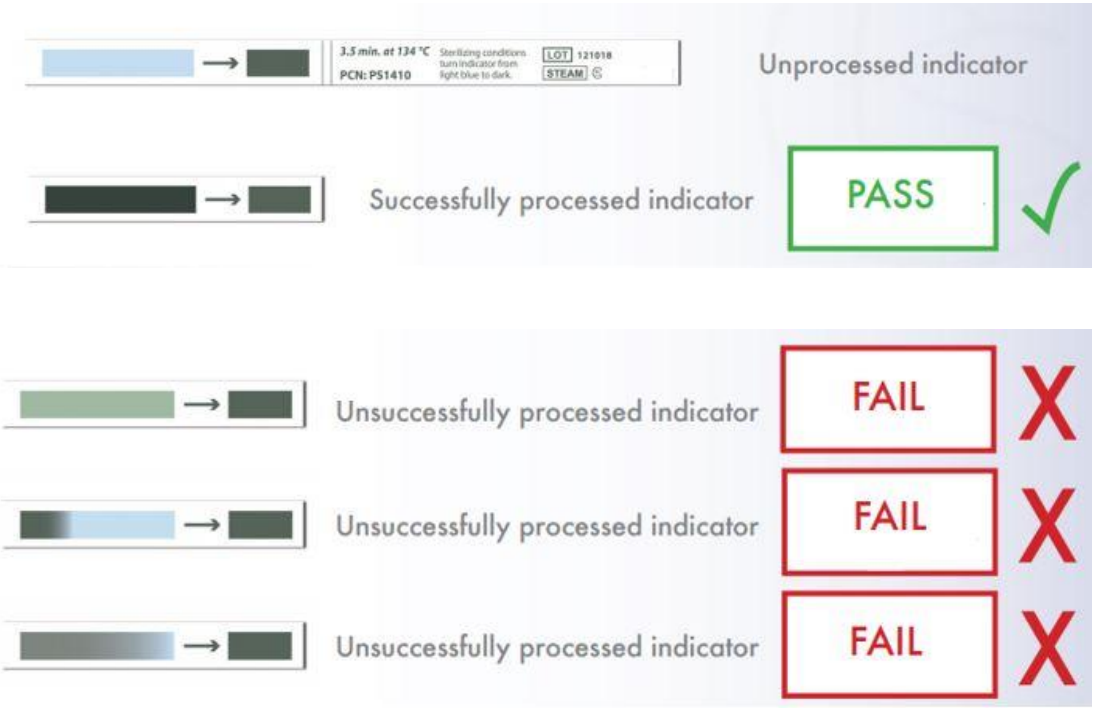
All the material for the Helix Test is commercially available.

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

Hollow load test: test device



Hollow load test: result



Equilibration time

Definition of ET - Historical

EN285/1996:

Clause *3.15* – ***Equilibration time***
"Period which elapses between the attainment of the ***sterilization temperature*** *in the* ***sterilizer chamber*** *and the attainment of the sterilization temperature at all points within the* ***load****."*

As the statement "***in the sterilizer chamber***" was unclear, the definition was modified and has remained unchanged till now:

Definition of ET - Actual

EN285/2015:

Clause 3.10 – ***Equilibration time***
*"Period which elapses between the attainment of the **sterilization temperature** at the **reference measurement point** and the attainment of the sterilization temperature at all points within the **load**."*

Clause 3.24 – ***Reference measurement point***
*"**Point** where the **temperature probe** used for the operating **cycle control is located**."*

Definition of ET - Actual

PDA TR N°1

Glossary:

*"**The period** that **elapses** between **the attainment of the minimum exposure temperature at the reference measurement point (typically the drain)** and the **attainment of the sterilization temperature at all points within the load**. This period is an indication of the ability to properly remove air and heat the load items; consequently, it is typically only evaluated by placing heat penetration probes in porous/hard goods loads."*

Definition of ET – Requirements

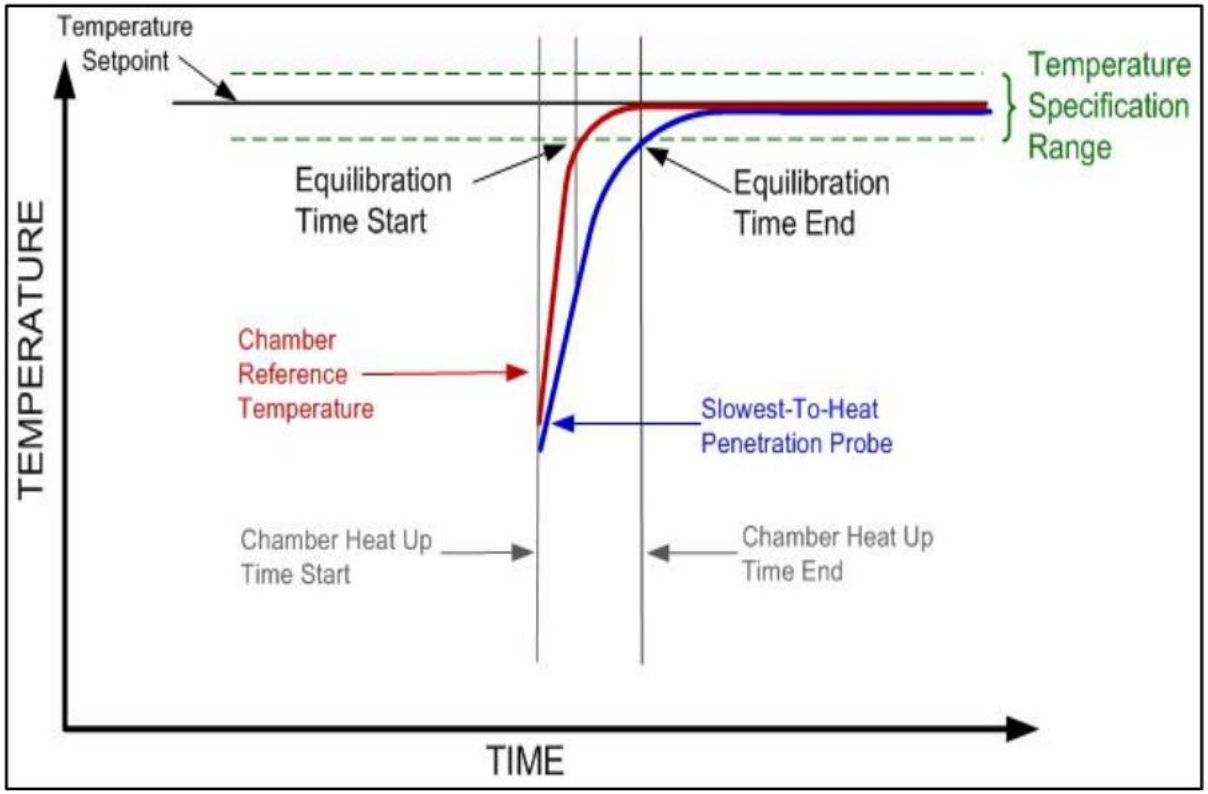
EN285/2015:

Clause 8.2.1.2.1 (Small load) & 8.2.1.3.1 (Full load)
"The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers ."

PAY ATTENTION!!

The requirements for **equilibration time not exceeding 30 (or 15) seconds** are referred to **test loads!!** The requirement on equilibration time duration is part of specification of the sterilizer and has the aim to demonstrate, by mean of **the standard test load**, that the sterilizer is compliant with the Standard.

Equilibration time



ET: conclusions

Equilibration time **is a variable parameter** that **shall be minimized** during the cycle development and **its maximum shall be included** among the **acceptance criteria for any actual sterilization process**.

The following options can be used to reduce the Equilibration time:

- Assure loads are oriented for efficient air removal
- Increase number of steam/vacuum pulses
- Add hold steps during steam/vacuum pulses
- Increase depth of vacuum pulses
- Make longer the heating time

Steam quality test

Non-condensable gases

This test is used to demonstrate that the level of non-condensable gases contained in the steam will not prevent the attainment of sterilization conditions in any part of the sterilizer load.

Non-condensable gases are generally air and air is a poor sterilant compared to steam. As an example, a typical dry-heat sterilization exposure phase lasts upwards of two hours at a temperature of at least 160°C/320°F. Steam sterilization typically is done with exposure phases of 15 minutes at 121°C/250°F or 3.5 minutes at 134°C.

Non-condensable gases

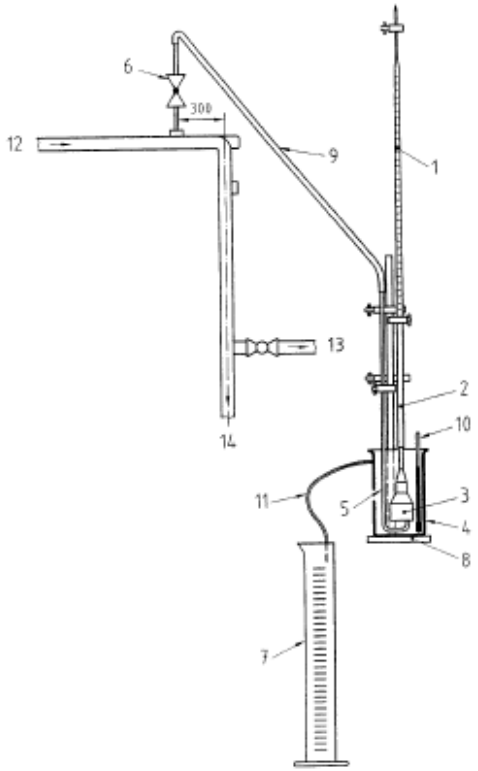
In short, non-condensable gases decrease sterilization efficacy.

The Sterility Assurance Level will be less than expected if non-condensable gas content has increased since product sterility validation.

ACCEPTANCE CRITERIA

The percentage of non-condensable gases in the steam should be less than or equal to 3.5% by volume.

Non-condensable gases



Key

1 50 ml burette	6 needle valve	12 from steam service
2,9 rubber tubing	7 250 ml measuring cylinder	13 to sterilizer
3 funnel with parallel sides	8 burette stand	14 to trap set
4 2 000 ml container	10 temperature measurement system	
5 steam sampling pipe	11 overflow pipe	

Dryness value

This test is used to demonstrate that the level of dryness of the steam will not prevent the attainment of sterilization conditions in any part of the sterilizer load.

Ideally, the dryness value is 1.0 (i.e. perfectly dry steam with no liquid water content.) Normally, the dryness value is less than 1.0.

Dryness value

If the steam is TOO WET:

- it has a lower enthalpy and delivers a lower amount of heat to the load to be sterilized: this results in a longer duration of the process
- it wets the products much more than necessary and makes more difficult or even impossible the final drying: the permanence in the time of the sterile condition can become uncertain

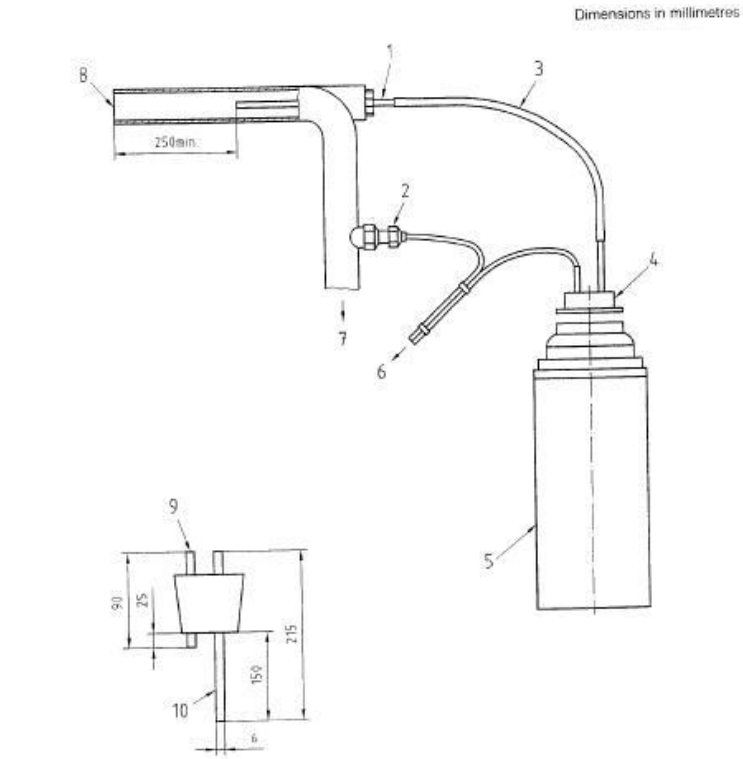
Dryness value

A dryness level down to 90% is considered acceptable for laboratory autoclaves, however, steam below this value is considered to be wet steam.
If the steam is wet the expected Sterility Assurance Level is probably not being achieved.

ACCEPTANCE CRITERIA

The dryness value of the saturated steam must be equal/higher than 0,95

Dryness value



Key

1 pitot tube
2 temperature sensor entry gland
3 rubber tubing
4 rubber bung assembly
5 one-litre Dewar flask
6 to temperature measuring instrument
7 to sterilizer
8 from steam service
9 pipe for thermocouple and vent
10 sample pipe

Superheat

The steam is sampled in free expansion into ambient air.

The maximum temperature measured at a precise location in the jet is the temperature upon which the superheat analysis is based.

When the temperature and moisture content do not match up, two things can happen:

1. If the moisture content is higher than saturation for the temperature, wet loads occur;
2. When the moisture content is lower than saturation for the temperature, the condition is called superheat.

Superheat

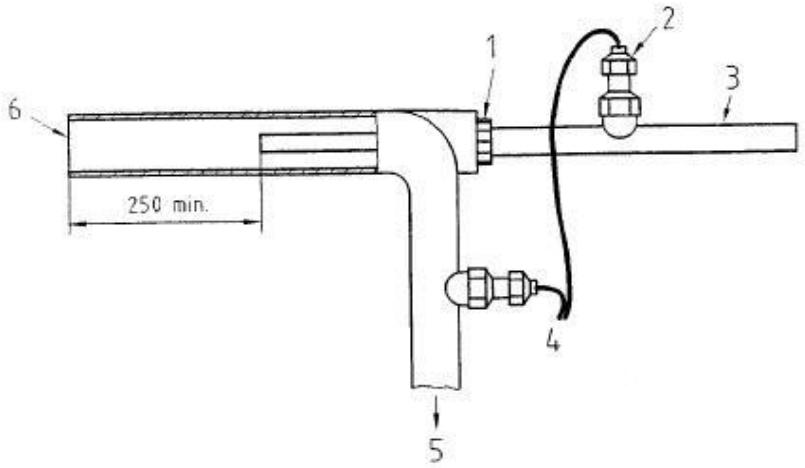
In superheat, the steam is too dry and its energy content is too high, this may damage heat-sensitive products. It makes uncertain the presence of water in its liquid state on the surface of hard / porous loads: this means the risk of not satisfying one of the basic conditions for the sterilization by moist heat.

ACCEPTANCE CRITERIA

The amount of superheat present in the steam should be no more than 25 degrees Kelvin (~25 degrees Celsius) above the temperature in free expansion into atmosphere at the current atmospheric pressure.

Superheat

Dimensions in millimetres



Key

1	pitot tube	4	to temperature measuring instrument
2	temperature sensor fitting	5	to sterilizer
3	expansion tube	6	from steam service

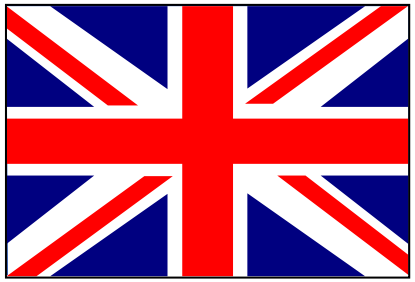
Air Detector System

What is the air detector?

EN285: (Not mandatory)

An air detector can be fitted to a sterilizer 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 sterilization cycle are sufficient to cause the sterilizing process to be of uncertain efficacy.

What is the air detector?



HTM 01-01:

An air detector is fitted to certain sterilizers that employ vacuum as a means of removing air from the load before sterilization.

It is required for porous load sterilizers.

It is used to determine whether any air or non-condensable gas present in the chamber is sufficient to impair the sterilizing process.

The air detector should cause a fault to be indicated if the amount of air or gas in the chamber at the start of the plateau period is sufficient to depress the temperature in the centre of the load more than 2ºC below the temperature in the active chamber discharge.

Fedegari Air Detector System

History:

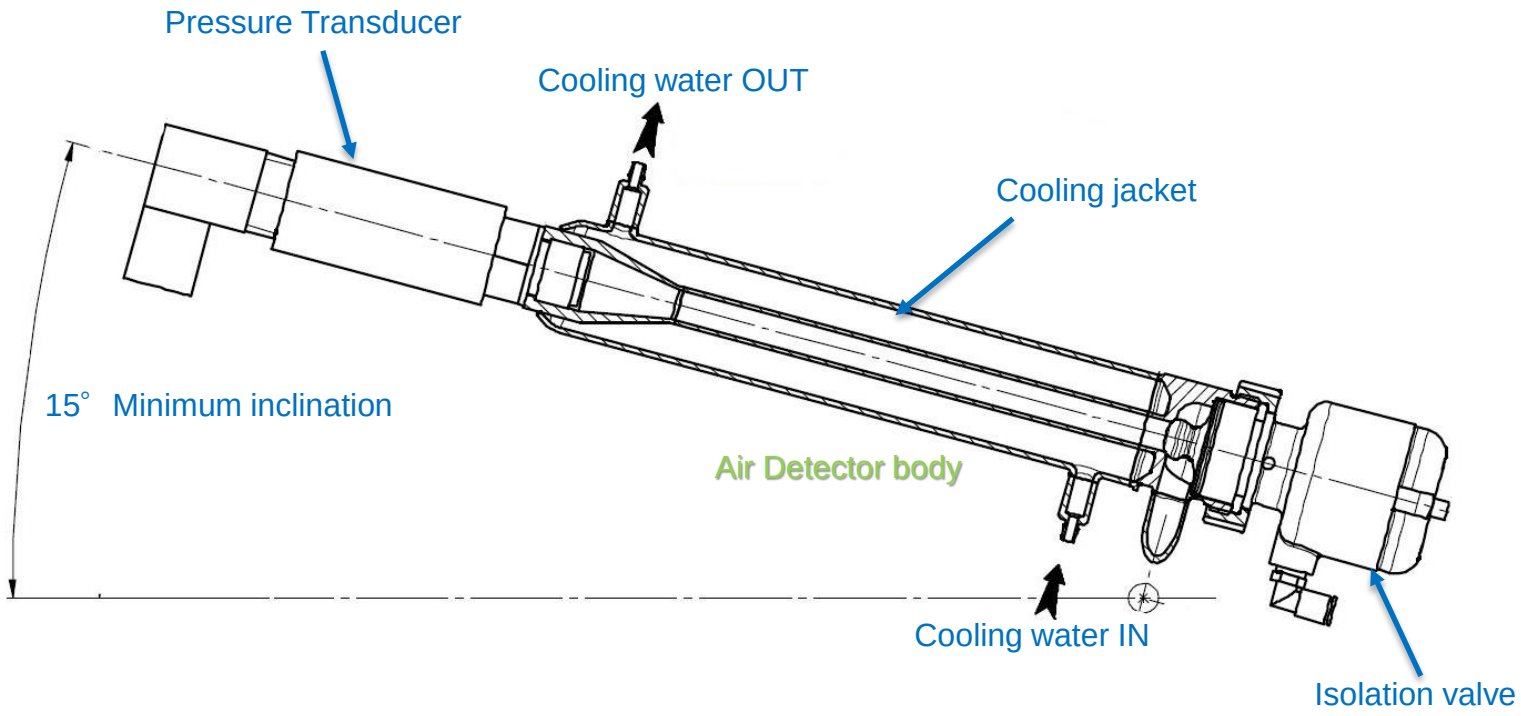
Fedegari "Air Detector System" (ADS) arises from an idea of Mr. Oates (DHSS, for Speywood Lab.s) and it was developed, in 1982-83, to satisfy the requirements of the UK Market and in particular the HTM10(*) requirements relevant to porous materials.

(*) Note: followed by the HTM2010 then by the CFPP 01-01 and now by HTM 01-01

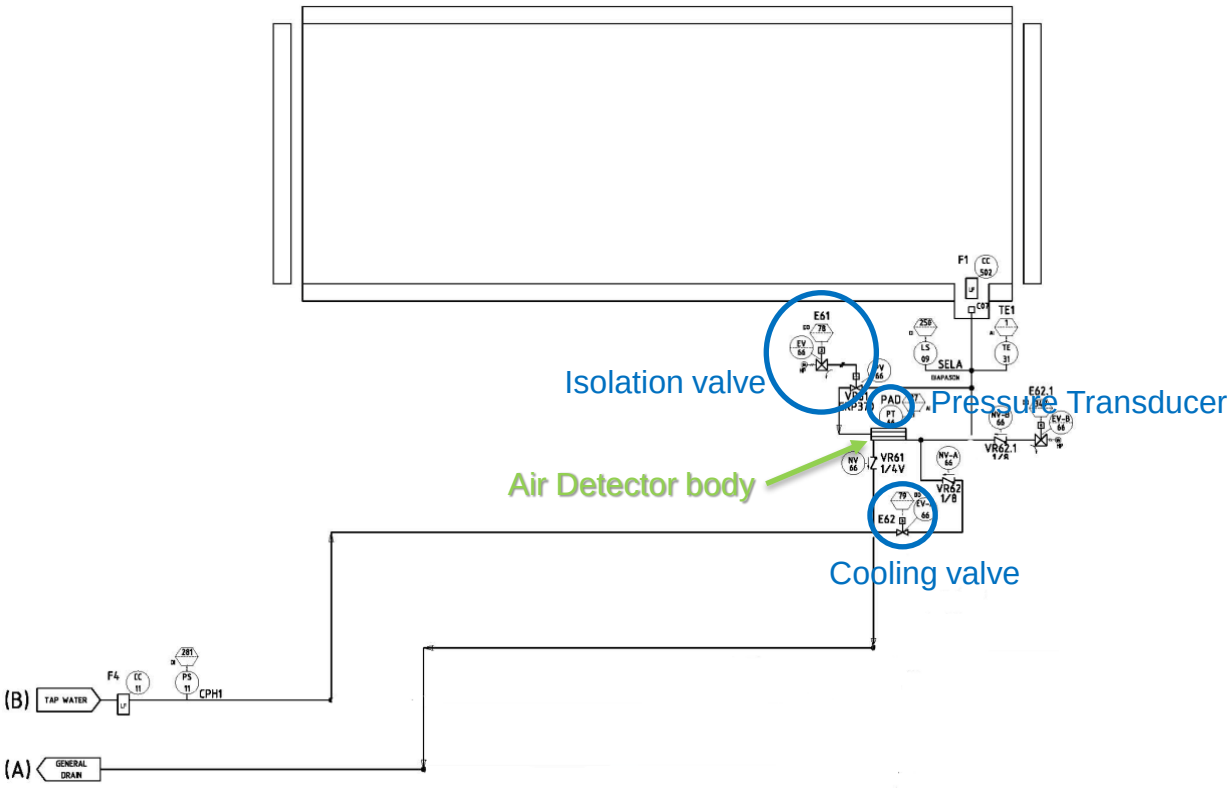
Fedegari Air Detector System

The ADS considers different "Pressure values" generated in the system as a result of a cooling effect.
These different values of Pressure mainly depend on the AIR that has been trapped in the ADS pipe.

Fedegari Air Detector System

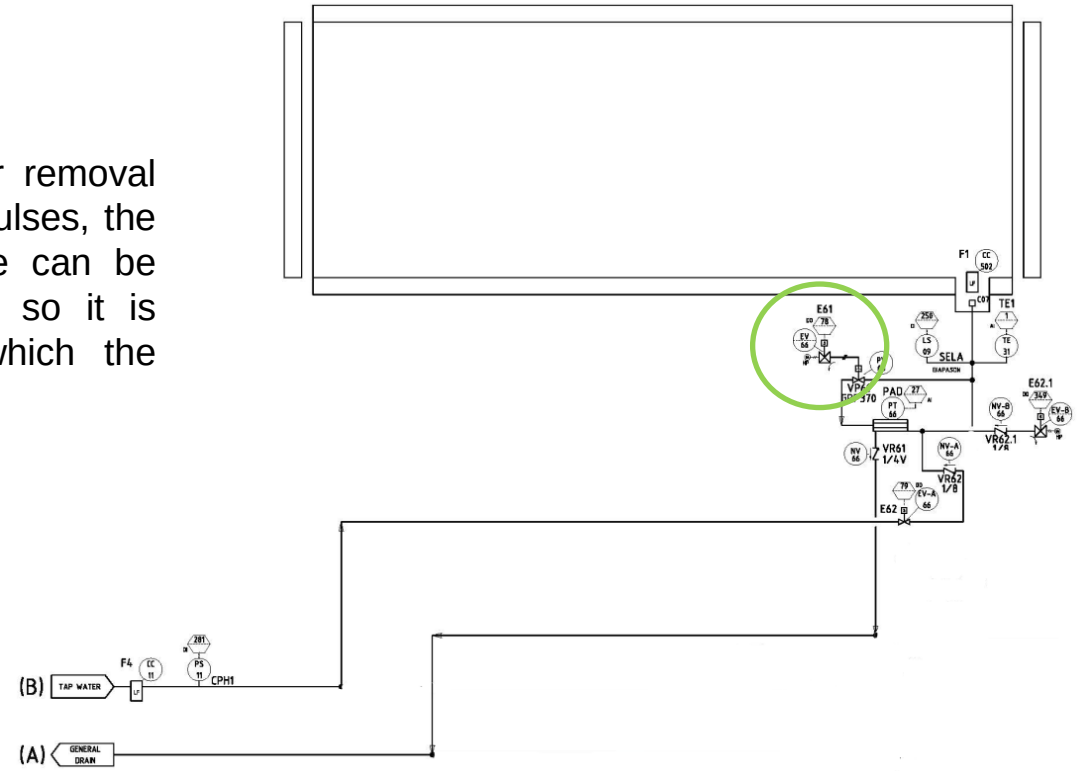


Fedegari Air Detector System



Fedegari Air Detector System

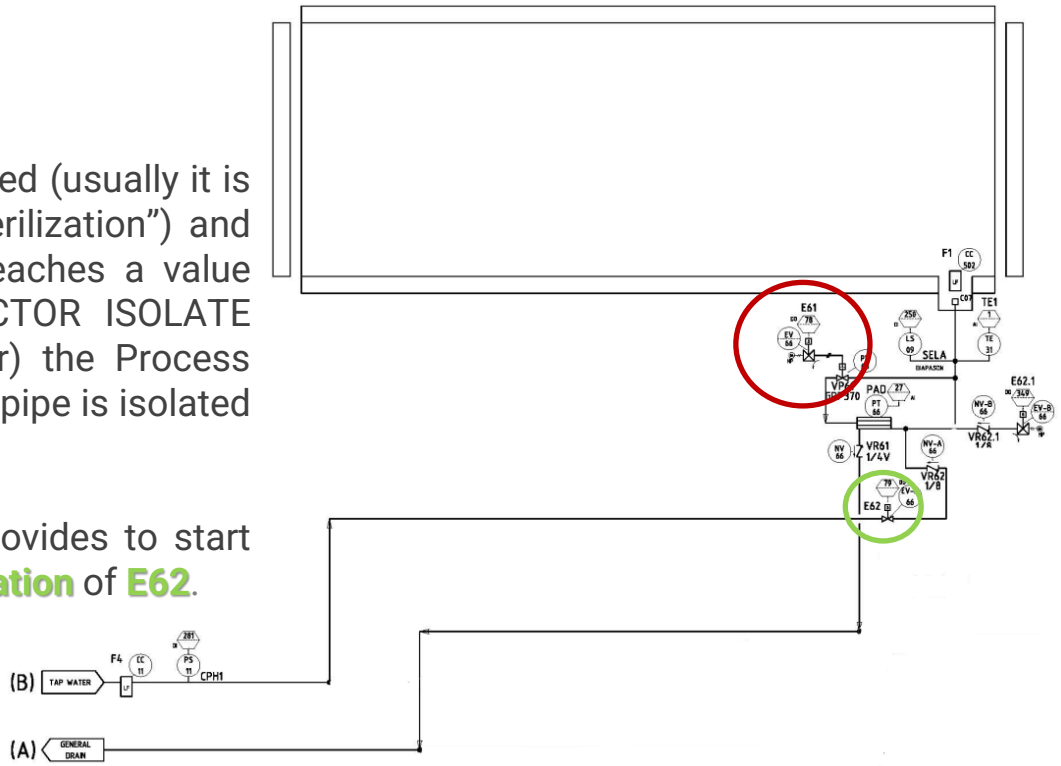
When the Autoclave performs the Air removal phases, through vacuum and steam pulses, the **E61 is activated** and the **ADS** pipe can be considered as part of the chamber, so it is subject to the same Process to which the Chamber is subject.



Fedegari Air Detector System

While Steam injection phase is performed (usually it is the final “Heating” just before the “Sterilization”) and when the Pressure in the Chamber reaches a value prefixed by the User as “AIR DETECTOR ISOLATE PRESSURE” (i.e. a program parameter) the Process Controller **deactivates E61**, so, the **ADS** pipe is isolated from the Chamber.

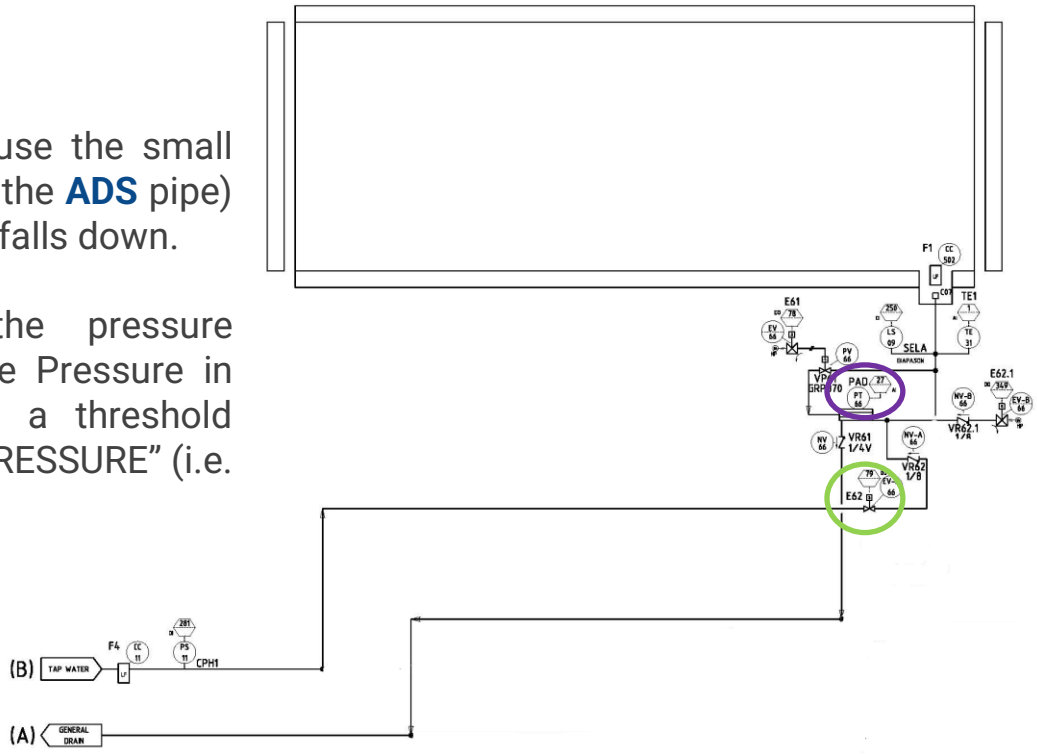
The Process Controller immediately provides to start cooling of the system through the **activation** of **E62**.



Fedegari Air Detector System

The cooling effect is very quick (because the small volume and mass of the fluid trapped in the **ADS** pipe) and the pressure in the **ADS** pipe quickly falls down.

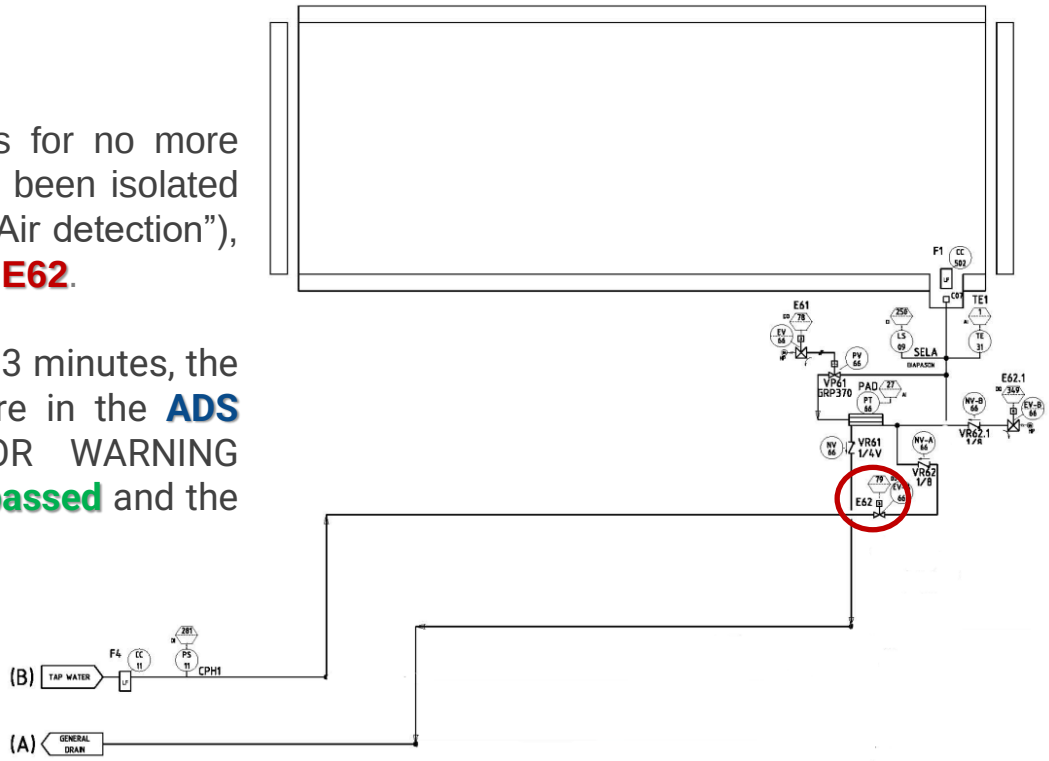
The Process Controller, through the pressure transducer **PAD**, continuously reads the Pressure in the **ADS** pipe and compares it with a threshold prefixed as “AIR DETECTOR WARNING PRESSURE” (i.e. a program parameter).



Fedegari Air Detector System

The cooling of the **ADS** pipe proceeds for no more than 3 minutes since the **ADS** pipe has been isolated (i.e. the maximum allowed time for the “Air detection”), then the Process Controller **deactivates E62**.

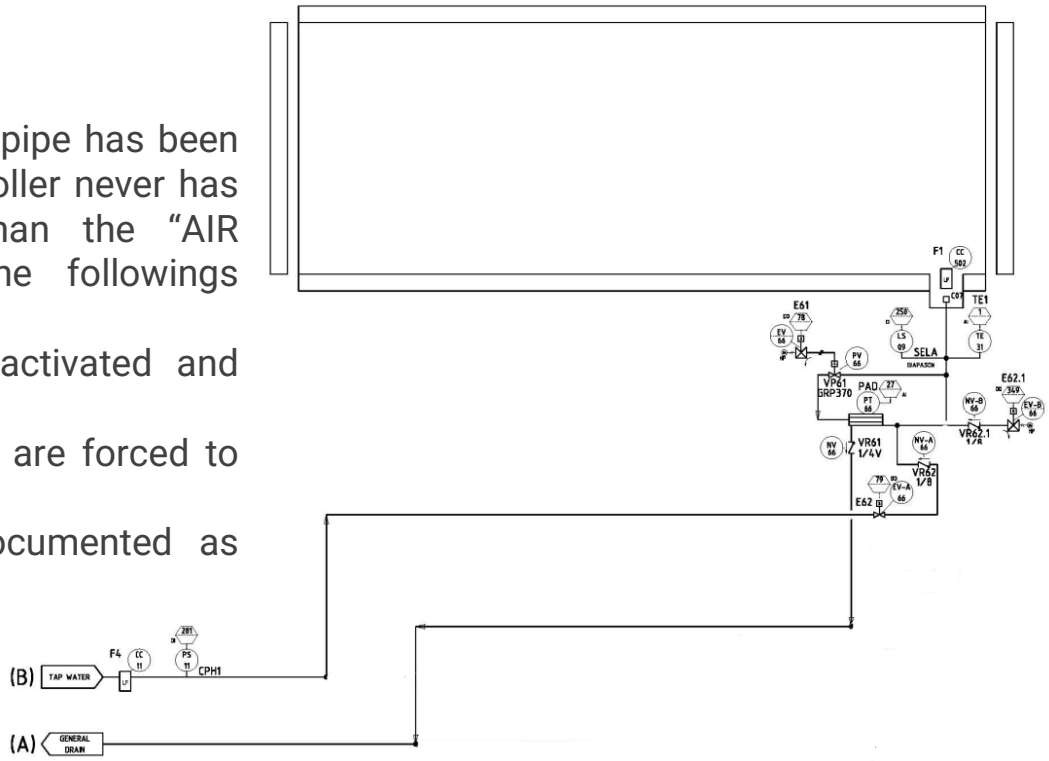
If, at least one time within the aforesaid 3 minutes, the Process Controller detects the Pressure in the **ADS** pipe less than the “AIR DETECTOR WARNING PRESSURE” the “**Air Detection Test**” **is passed** and the Program can proceed regularly.



Fedegari Air Detector System

Else, if within 3 minutes since the **ADS** pipe has been isolated and cooled, the Process Controller never has detected the **ADS** Pressure less than the "AIR DETECTOR WARNING PRESSURE" the followings occur:

- The "**AIR DETECTOR ALARM**" is activated and printed;
- Heating and/or Sterilization Phases are forced to completion;
- Sterilization is considered and documented as "Failed".



Thank you

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