Global Warming of PCD's

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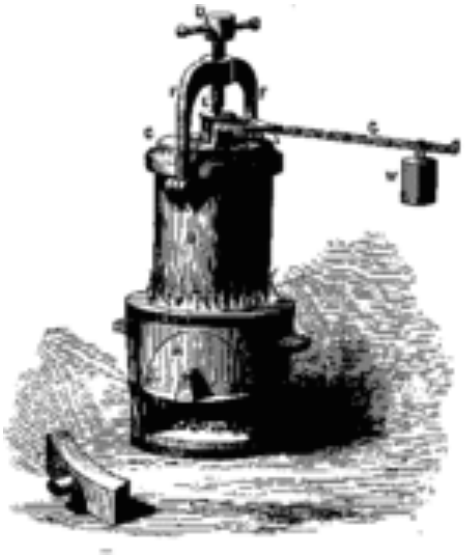
The most dangerous phrase in the language is, "We've always done it this way."
Rear Admiral Grace Hopper
Pioneering Computer Scientist
1906-1992

Sterilisation Historically

- Originated from:
  - Steam sterilizers are derived from domestic food cookers
    - ‘steam digester’ invented in 1679 by Denis Papin 1679 (1647−1712)
  - Chamberlain (1851−1908), working with Louis Pasteur, was the first to use elevated pressure for sterilization purposes (1879)
  - Little happened until world war II
  - 1950 – 1970 research



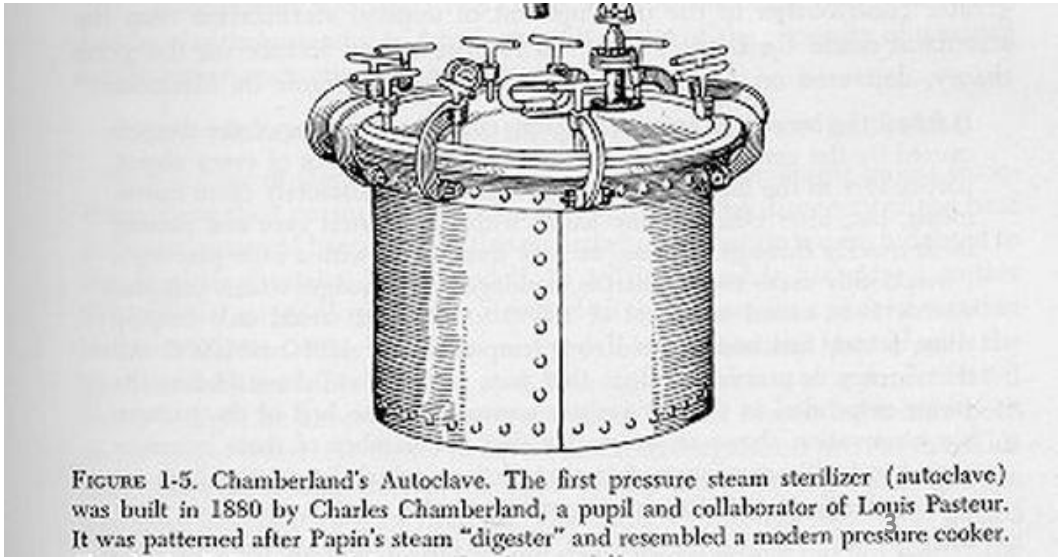


FIGURE 1-5. Chamberland's Autoclave. The first pressure steam sterilizer (autoclave) was built in 1880 by Charles Chamberland, a pupil and collaborator of Louis Pasteur. It was patterned after Papin's steam "digester" and resembled a modern pressure cooker.

First vacuum assisted processes: faster and more reproducible processes

Not clear who was the first to apply vacuum assisted processes

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MODERN APPARATUS FOR STERILISATION

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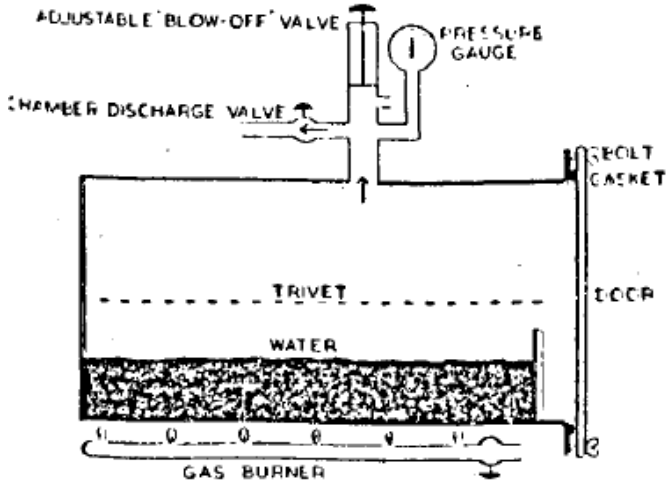


FIG. 2.—19TH CENTURY FORM OF HORIZONTAL AUTOCLAVE (PRESSURE COOKER TYPE)

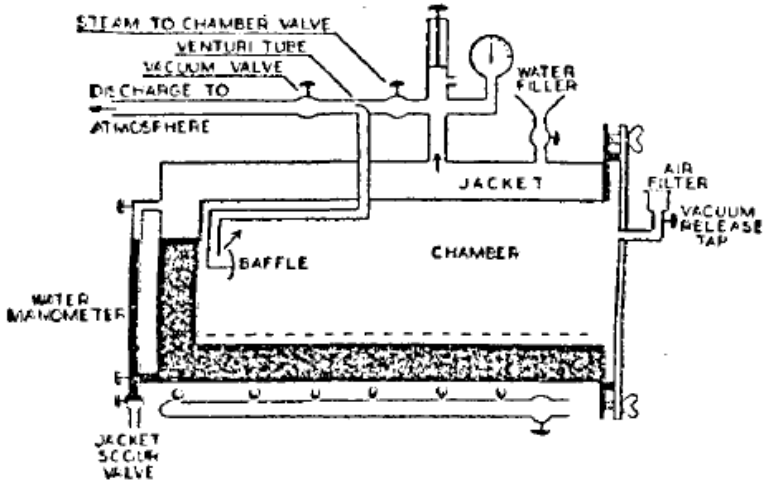


FIG. 3.—END OF 19TH CENTURY FORM OF JACKETED AUTOCLAVE WITH VACUUM ATTACHMENT

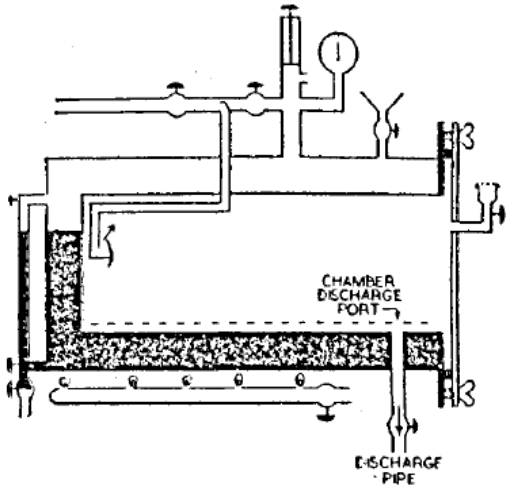


FIG. 4.—DEVELOPMENT OF CHAMBER AIR AND CONDENSATE DISCHARGE BY GRAVITY (1914-18 WAR)

The Technology is old but historically "saved lives”

- Mornington emigration station, South Australia
- Cholera, Plague and Typhoid were that main pathogens
- Autoclave manufactured in 1917

Parametric release and PCD's

- Parametric release is a system of release that gives the assurance that the product has achieved the intended quality(STERILE)
- A Process Challenge Device (PCD) is a test device intended to provide a challenge to the sterilization process that is equal to or greater than the challenge posed by the most difficult item routinely processed. In other words, a PCD is used to confirm that a sterilizer has effectively sterilized ALL items processed in that cycle?

History of Vacuum assisted Sterilisers

- Not clear who was the first to apply vacuum assisted processes
- Reason to apply vacuum:
  - Time
  - Reproducibility of processes
  - Sterilized devices less time to elevated temperatures

Sterilisation conditions established

Current times are first specified in:

- Precht JCH. Tempertur und Leben. Springer Verlag, Berlin, 1955.
- Perkins JJ. Principles and Methods of Sterilization. Charles C Thomas, Springfield (IL), 1956.

Time [min]	Temperature [°C]
2	132
8	125
12	121
18	118
30	116

Experiments performed in aqueous environment

Specified are:

Time – temperature combinations

Pressure is not mentioned!

Working Party on Pressure Steam Sterilizers of the Medical Research Council. Sterilisation by steam under increased pressure. The Lancet, 273:425–435, 1959.

It must be emphasised that this does not mean that only 95% of the air need be removed from the steriliser at the outset, for the steam entering a mass of **cotton** will push the air ahead of it to form a central " bubble " of nearly pure air, which is very slow to diffuse out. Such a bubble will prevent sterilisation of the **dressings** in contact with it.

In summary:

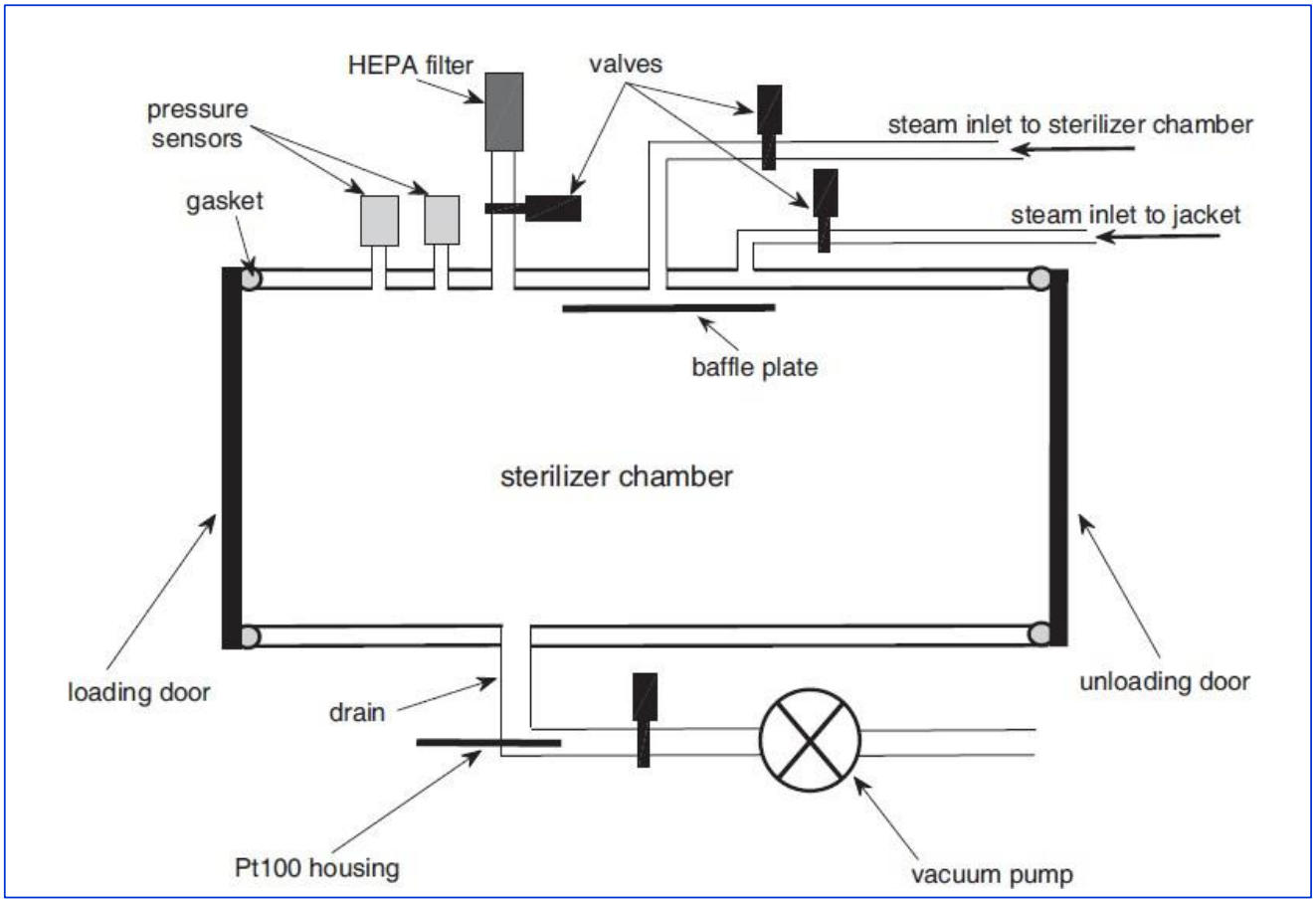
- Time - temperature combinations
- Largely only textiles and non hollow instrument
- Steam composition <u>in</u> the load contains less than 5 % NCGs

Steam sterilisation conditions (from literature)

- Steam: high amount of water vapour, low amount of NCGs
  - On all locations in load NCG < 5%
  - In the steriliser chamber (free space) << 5 %

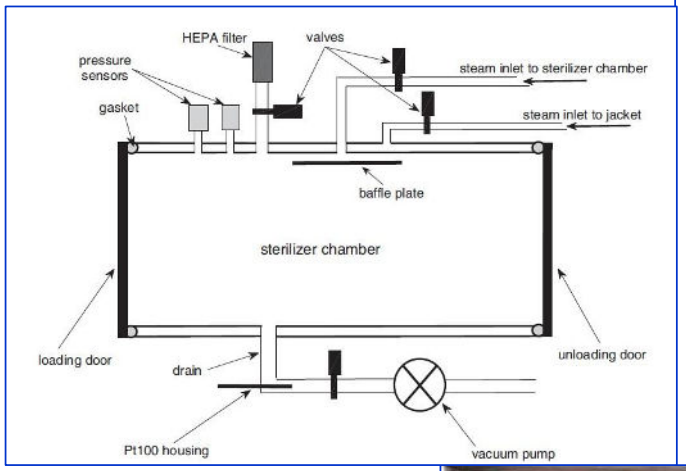
- Aimed time - temperature combination
  - On all locations in the load.
  - This is what most PCD's are aiming to prove Time, Temperature and air removal

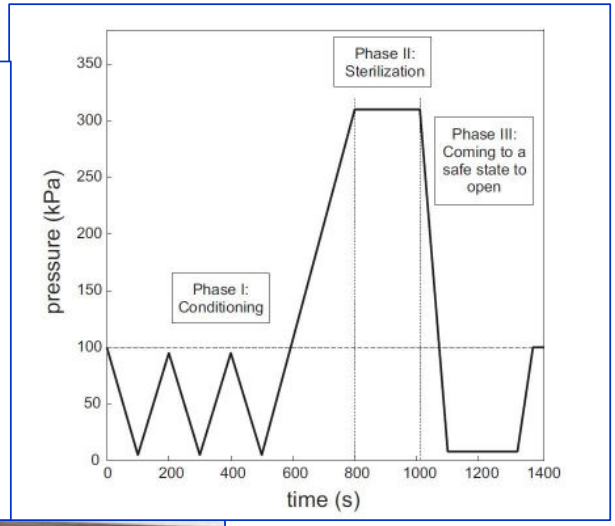
Current sterilisers with on-board gadgets(IMS etc)



Appendages are here handled as part of the sterilizer.
E.g., steam supply and vacuum pump
Note . Could be integral Steam Generator/Boiler

Essential MEASURING components in compliance with EN285(2015)
1:Air detector/Equivalent:
2:condense sampling points
3:Independent Management System
4:Integrated device proving air removal
5:Independent steam penetration device
6: 4D Sensors(interfaced with traceability
7:Energy sustainability
8:Remote monitoring
9: Capuchino/Coffee maker





Success of a process:

- Steriliser
  - Includes Services such as:
    - Steam supply
    - Vacuum pump(chilled)
    - Support Engineering
    - Proven Validation(IQ/OQ/PQ)
- Process
- Load
- Loading pattern
- Wrapping

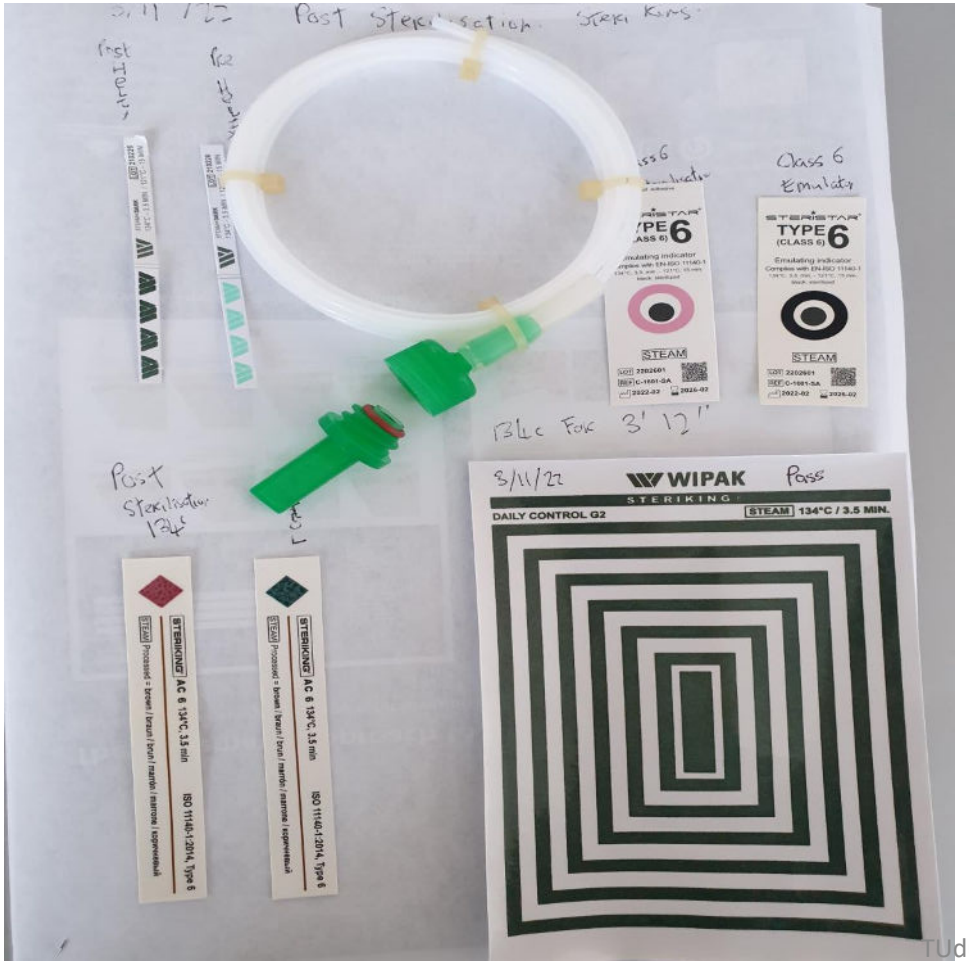
Process Challenge Device>Device challenge

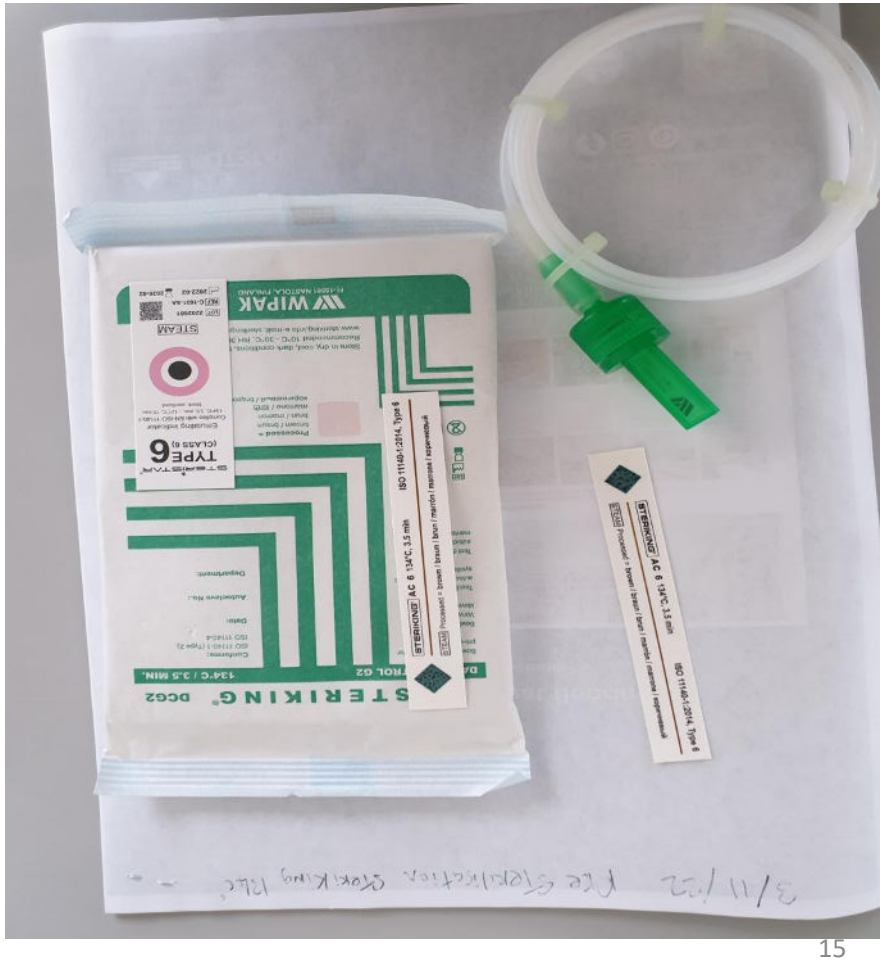
Many instructions for use (IFU) and ISO Standards that were once short and easy to understand are now rigorous, time intensive, and difficult to measure.

This increase in complexity in IFUs/ISO's, tied with other environmental challenges such as staffing shortages, changing guidelines, and lack of control over the operating room's pre-cleaning quality, makes staying compliant with IFUs more difficult than ever. Robotic, Ophthalmic ,Ocular laparoscopic and Intricate MIS sets.

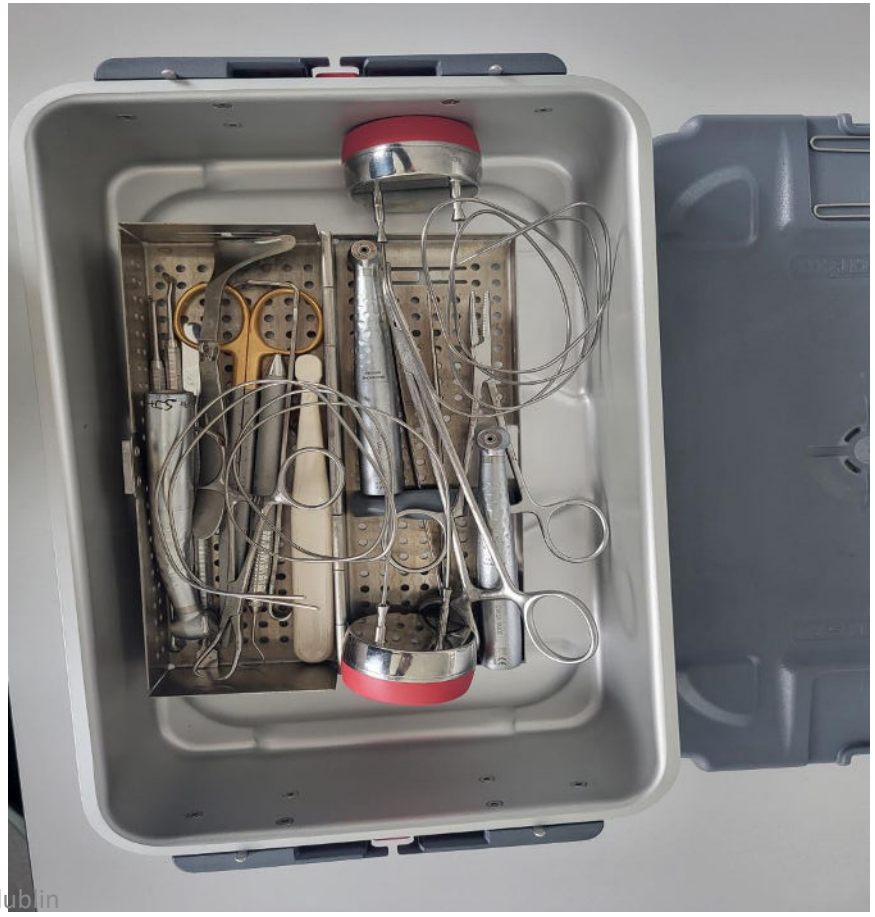
So Much Guidance ,like a Rainstorm of Standards

What do we mean by PCD's?





PCD’s in Sets to Compare and Contrast.



Does the PCD guarantee 100% sterile load?

This is the Job of the PCD/BI's

- A PCD is designed to be more challenging for the parameters to be met compared to the other packages inside the sterilizer.
- In other words, if the PCD passes then all the other packages have most certainly met the parameters of sterilization.(Time, Temperature, Pressure and saturated steam (<3.5% per 100ml condense?)
- A PCD is a quality assurance device offering a challenge to the testing of sterilization to regularly monitor the validity of sterilization(EN 285:2016)

How does a PCD Pass

- That is answered by what is placed inside the PCD.
- There must be a measurable component placed inside every PCD(CI/BI (*G.Stearothermopilus*) .
- An evidence-based and scientifically proven testing apparatus is used to react to sterilization variables
- There are two scientific tests placed inside the PCD, a chemical indicator (CI) and a biological indicator (BI).
- PCD stated parameters should be achieved(challenge > than the most difficult to sterilise item?

Are these results Reliable, Repeatable and consistent?

	**Sufficient temperature, time and steam penetratic**
	**Insufficient air removal and steam penetration**
	**Temperature achieved, but no air removal and no steam penetration**
	Insufficient temperature, no air removal and no steam penetration

Is the PCD a false positive or False negative?

- A false positive is an outcome where the test incorrectly predict a positive outcome!

1. 134 C for 3.5 minutes and sterilisation achieved
2. The test result (PCD) incorrectly classifies the result as positive (sterilisation parameters achieved) when this is not confirmed

- A false negative is an outcome where the test incorrectly predict a negative outcome!

1. 134 C for 3.5 minutes and sterilisation achieved
2. The test result (PCD) incorrectly indicates the condition being tested for is not present when the condition (sterilisation) parameters is confirmed.

In Surface Steam Sterilization There is a Fundamental Problem

If you don't get the air out (*of the chamber and load*)……..

……youcan't get the steam in !

What we need to monitor and how to ensure effective sterilization

Moist Heat Sterilization Process Variables

- Time
- Temperature
- Moisture

INSIDE A PCD

Monitoring Sensors

Physical Indicators

Respond to the absence of air or detect presence of moisture

Chemical Indicators

Respond to defined process parameters

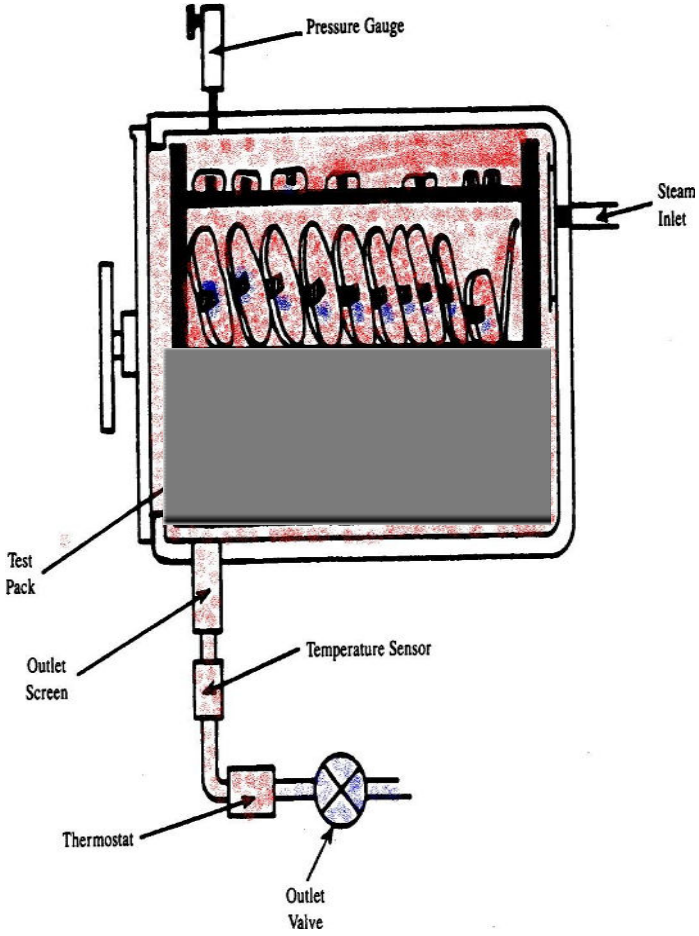
Biological Indicators

Respond to all process variables and demonstrate kill

Will the PCD alert issues in Porous Loads?

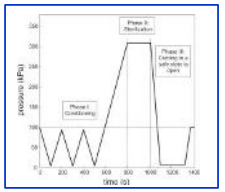
Were Residual Air Locates in Packs and.

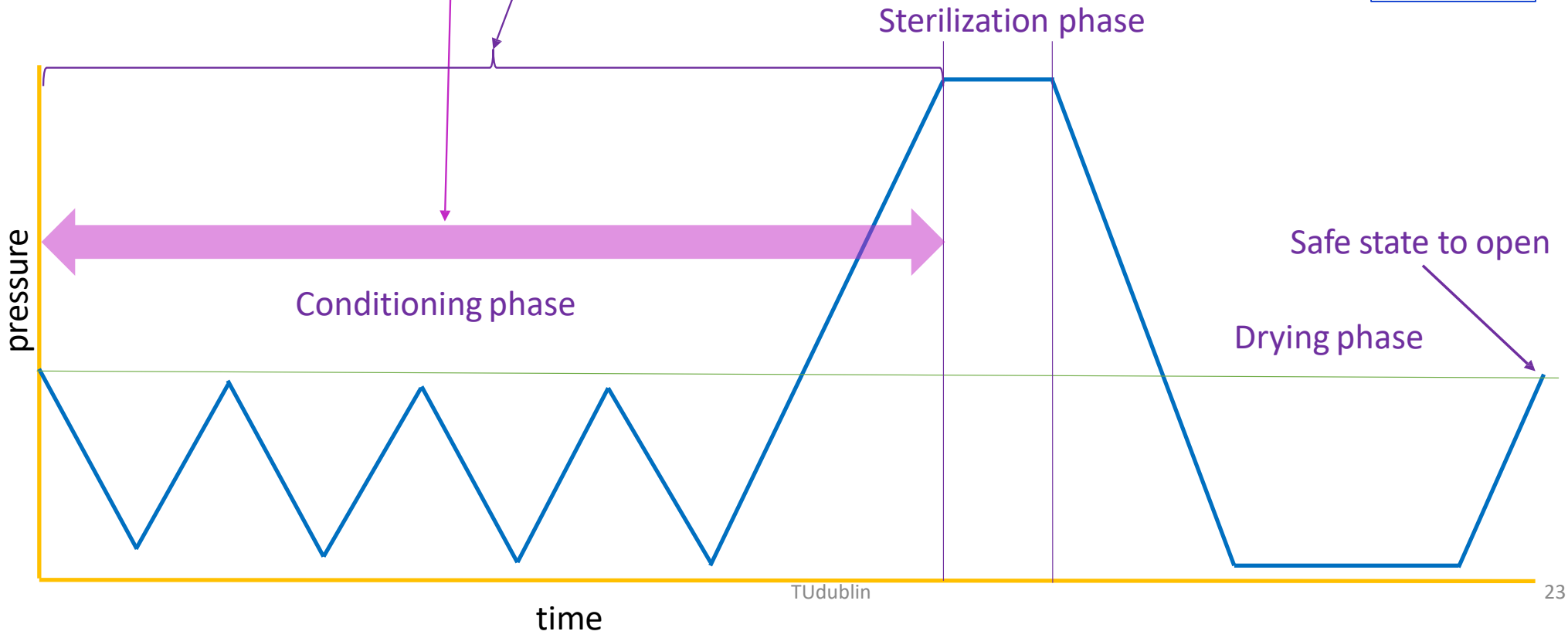
- Prevents steam penetration.
- Resulting in incomplete sterilization.
- Same applies to lumened instruments.



Sterilisation phases

- Convection
- Diffusion
- Condensation





Sterilization is affected by small changes

Sterilizer (lack of vacuum cooling water)

Process (wrong cycle chosen)

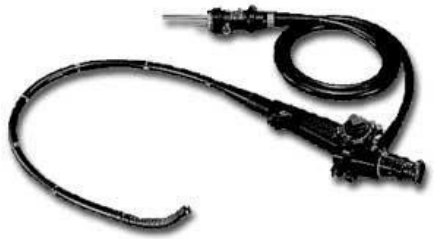
Load (new set, not validated)

Loading pattern (Heavy sets on top, light sets on bottom)

Wrapping (Micro Biological Barrier) (Humid load effect tape adhesion)

Change:

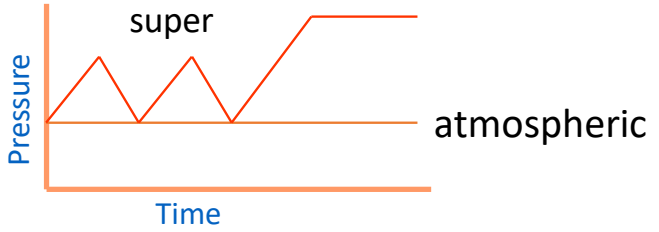
Load from non hollow instruments to hollow instruments

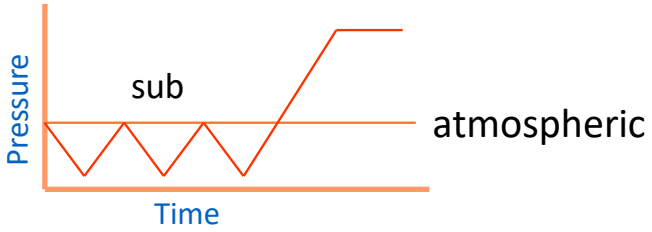


Action:

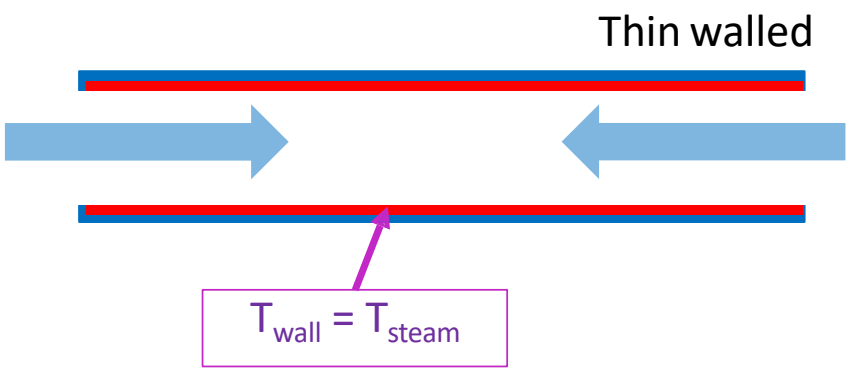
To establish steam sterilization conditions on all surfaces

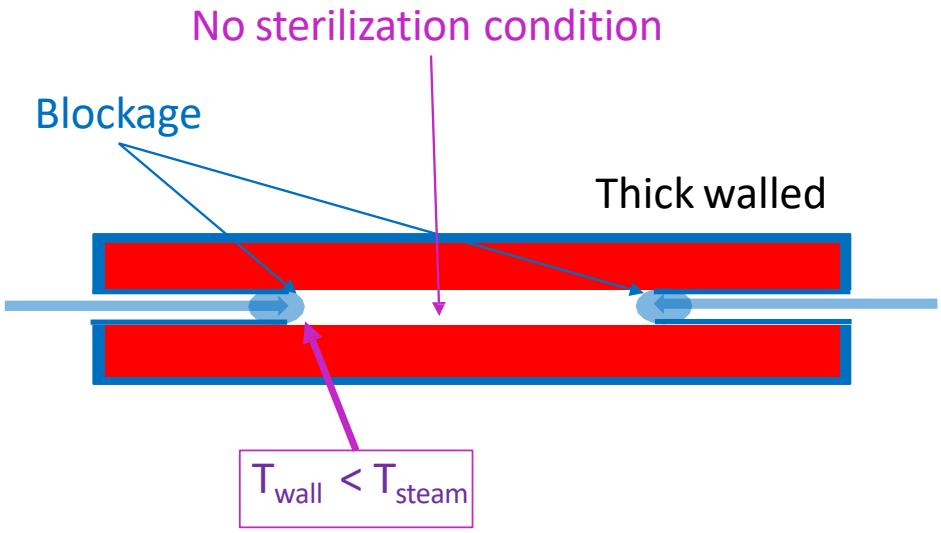
Process from gravity to fractionated vacuum process

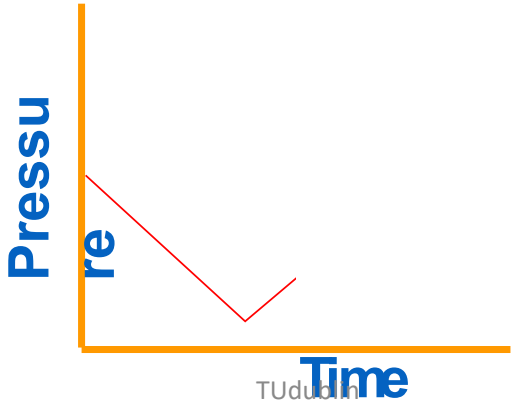




Difficult instrument for air removal







What the Standards say, e.g.: 134 °C process (EN285:2015 and ISO17665-1:2006)

location						*EN*285: 2015 *clause no*
In chamber in load	134 °C	≤	*T*	≤	137 °C	
In chamber free space			*NCG*	≤ 3.5 % V_{NCGs}	$V_{100\,ml\ condensate}$	8.1 and 13.3.1
In load			*Water vapour*	≥ 92 % $V_{Water\ vapor}$	$V_{100\,ml\ steam}$	8.2
			t	≥	180 *s*	
Load dry after the process						(ISO17665-1:2006)

We want every cycle with Time, Pressure, Temperature and NCG'S

1:We want every cycle with Time, Pressure, Temperature and NCG'S measured?

2:Summary printout measure NCG at 0.41%→0.75%

3:For optimal steam penetration and processing results, steam should be "saturated" and consist of a Dryness factor not<95%/per/volume

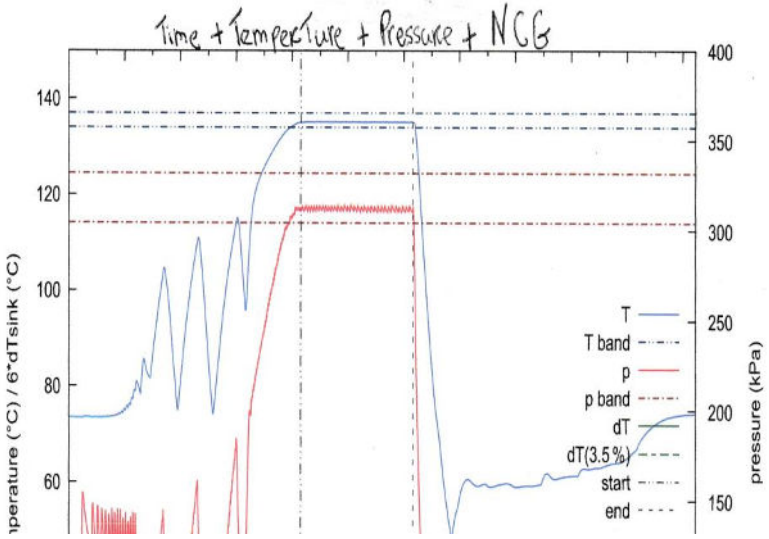
Local sterilizer id:	ster01
User:	TEST VESSEL
Start date / time:	2022/09/12 13:39:56
Process number:	27
Program:	134 °C TEST VESSEL
Sterilization temperature:	135.1 °C
Holding time duration:	04:01 (mm:ss)
Tmin and Tmax during holding phase:	135.0 / 135.2 °C
pmin and pmax during holding phase:	311.1 / 312.6 kPa
Proces duration:	00:21:28 (hh:mm:ss)
NCG fraction (gas to condensate):	0.41 % (min) - 0.75 % (max)
T(theor) during holding phase:	134.9 °C

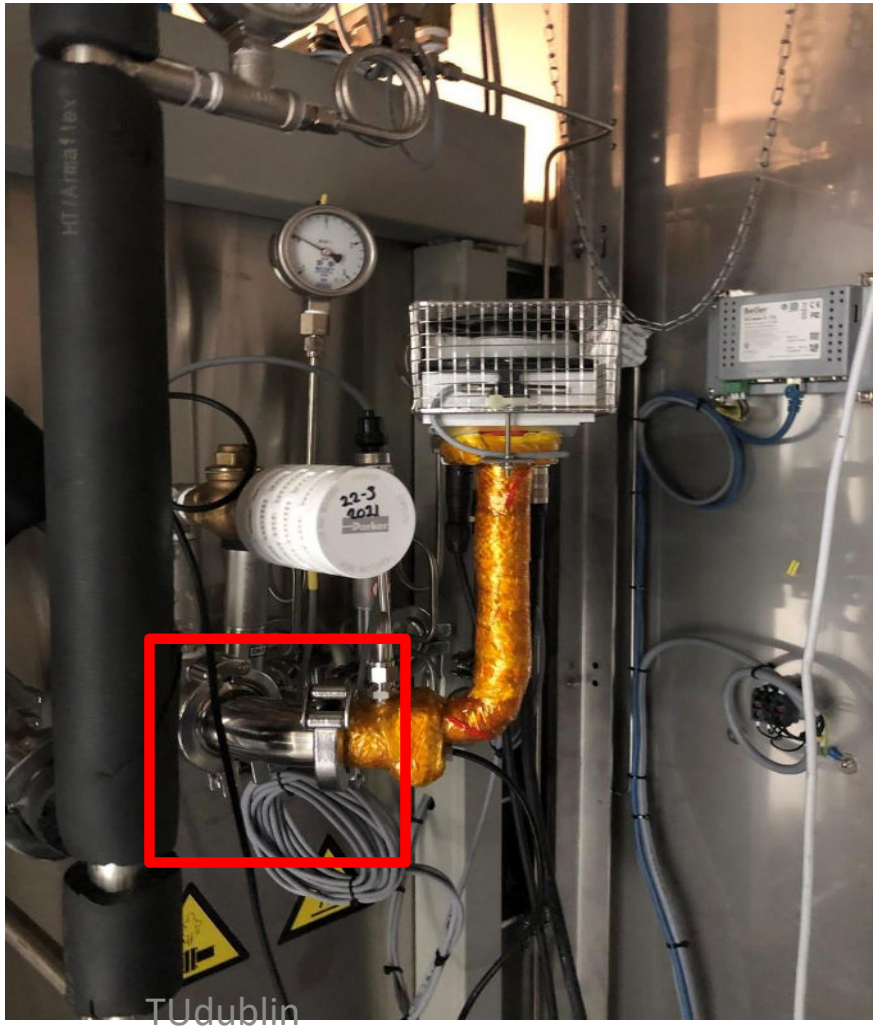
PASS

☐ Process number checked

☐ Load release OK

☐ Load release NOT OK





Preferred method
Direct on the chamber which does not interfere with calibration
1:NEED A SILVER BULLET
2: May already exist but needs widespread Testing
3: EN/ISO Working party need to consider alternative technologies

Summary of PCD’s and solutions

- There needs to be something physically inside the sterilizer to alert us that the sterilization cycle met the three sterilization parameters (time, temperature, and pressure and no NCG’s).
- Even better if it exceeded all mandated process parameters.
- Conclusion The applied parametric release method for every load leads to a higher safety for staff and patients in hospitals, more insight in steam sterilization, reduction of the use of resources an increased sustainability.