

Aspects of Steam Sterilization Process Monitoring:
from Huckaback Towels to ETS and what Standards do and don't cover
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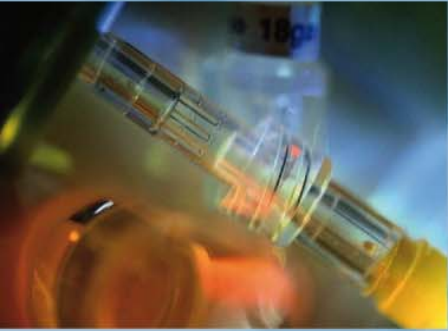


Hollow, porous, solid, ...?
Testing of Steam Sterilizers



Contents

- Basic challenges of steam sterilization and testing principles
- Relevant standards
- Background to commonly used standard steam penetration test
- The hollow PCD
- Outlook

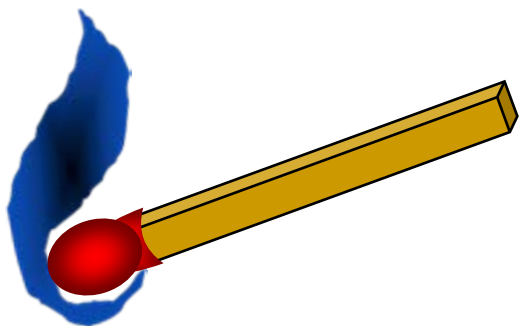


Basic challenges of steam sterilization and testing principles



Why Process Monitoring?

- sterilization is a “special process”
- the result can not be tested on the end product
- a non-destructive, direct check of sterility is impossible



YES --- it burns!

The basic challenge of a steam process

- If you don't get the air out, you can't get the steam in!
- This is why tests for air removal and steam penetration are carried out.
 - *See EN ISO 17665 (EN 554)*

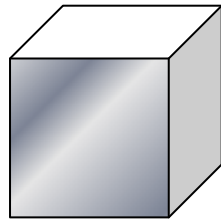
The challenges of a steam process

- Adequate steam penetration
 - *Based on adequate air removal and adequate steam quality*
- To judge steam quality an object is necessary on which the steam can condense - the "condensation point"). By this enough steam is attracted in order to accumulate NCG in such an amount that they are detectable.
- The "condensation point" can be a porous mass
 - *towel pack*
 - *alternative paper based Bowie Dick Test packs*
- or
 - *the challenge tube of the ETS*
 - ...

Load categories and product families

3 major groups of design characteristics:

- Solid

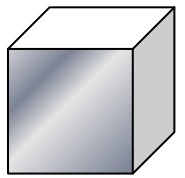


- Porous



- Hollow (or complex?)





Solid

- Typically found in many surgical instruments, e.g. hammer, retracting blades etc.
- Free access of steam to all surfaces
- Main influencing factors: thermal mass, steam quality
- NCG can form an insulating layer on the surface!



Is "solid" easy to sterilize?

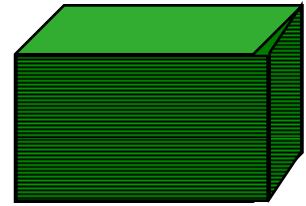
Peter Hooper:

„The inference may be that it is not cannulated, long, intricate instruments that will create operational difficulties. It is the orthopaedic mallet that requires our attention.“

Central Service, 13 2005, 308

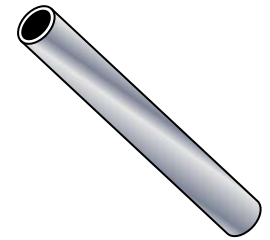


Porous



- Typically found with OR drapes and gowns, swabs and wound dressings
- Main influencing factors:
air removal phase,
steam quality
- Non-equilibrated cellulosic fibres will re-hydrate
(exothermic process resulting in local superheat conditions)





Hollow (or complex?)

- Typically found in many surgical instruments, e.g. MIS
- Variety of “challenges”:
 - *gaps, hinges, hoses, insulation, sliding surfaces, threads*
- Combination(s) of the above increases challenge dramatically
- Main influencing factors:
Air removal phase,
steam quality



Are temperature and pressure loggers enough?

- Kirk¹ has shown that pure physical measurement of pressure and temperature to judge steam quality isn't feasible and practical.
- A "condensation point" is necessary to accumulate non-condensable gases in a sufficient quantity to make a judgement.

¹ B. Kirk, SGSV/EFHSS Conference 2003 Winterthur, CH

What are and why are PCD used

- PCD = Process Challenge Device
- device which challenges a process

process challenge devices object which simulates the **worst case** of conditions for attainment of the specified sterilization conditions within the items to be sterilized

See „Central Service“ 2005/13, 320



Purpose of PCD

- create a (defined) challenge for the sterilant to reach a surface to be sterilized
- the overall kill capabilities of a sterilization process are defined by it's penetration and kill characteristics
- porous loads and torturous paths/tubes are the main designs

Porous is not Hollow!



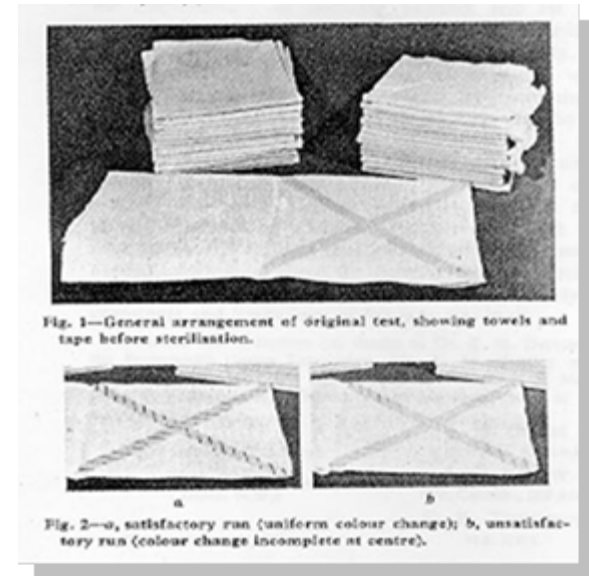
≠



... and vice versa!

The Standard Test Pack – a porous PCD

- more than 40 years experience
 - *Lancet, 1963 Mar 16;1:586-7.*
The Bowie and Dick autoclave tape test,
BOWIE JH, KELSEY JC, THOMPSON GR.
- constant development of standards
 - *(national, EN 285, EN 867-3/4,*
EN ISO 11140:2006)
- constant development of products
 - *disposable, limited reusable,*



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Relevance - The BDT and Your Car

- It is like “kicking the tyre” before you start the engine – a quick basic test for road fitness of the car
- It is like watching the dashboard if no alarming light is on – a reassuring test for safety
- Btw: the German STVO (Straßenverkehrs-Ordnung) requires every driver to check the safety of his car before driving – independently from the TÜV test which needs to be carried out every 2 years (=“ validation”)



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Tubular Test Devices – “hollow PCD”

- more than 30 years experience
 - *S. J. Line and J. K. Pickerell (1973) Journal of Clinical Pathology 26, 716-720*
 - *DIN 58946-13 test device for LTSF sterilization*



Hollow test device for small steam sterilizers*

- EN 867-5** describes a hollow load process challenge device in the form of a PTFE tube (2mm inner diameter, 1.5m long) with an attached a capsule to contain a biological or chemical indicator. This is known as the "Hollow A" PCD.



* EN 13060

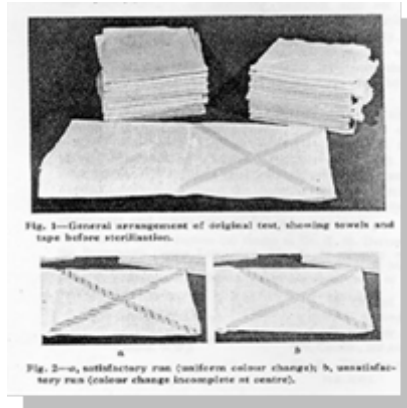
** Currently under revision (2008), will resurface as EN ISO 11140-6

Adoption by EN 285 II

- The “Hollow A” test (EN 867-5) has been adopted as an additional test into EN 285.
- This “Hollow A” replaces the former “Rubber Load Test” of EN 285:1996.
- The Hollow A test complements, but does not replaces the “Bowie Dick Test”!
- According to prEN ISO 17765:2, it shall be carried out at least annually, the Bowie Dick Test shall be carried out on every day the sterilizer is used.

Sterilizer testing using PCD

1950
onwards



Are they “representative” for the items primarily sterilized at their time?

Were/are they intended to be “representative”?

1970
onwards



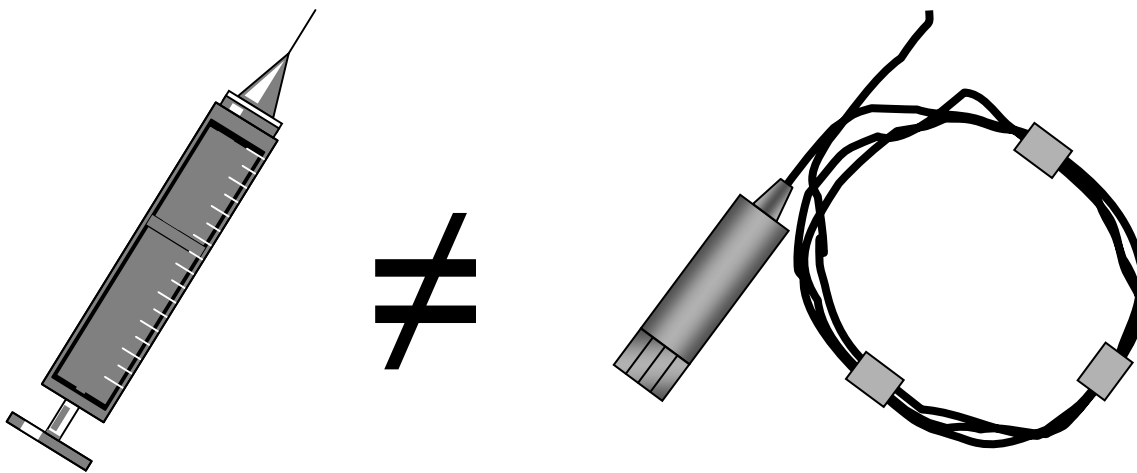
What are the limits of their “representativeness”?

EN ISO 17665 (and EN 554) require every load to be monitored.



“representative”

- PCD’s representativeness is limited
- only a syringe behaves like a syringe



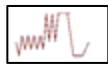
Alternative Product Testing and EN ISO 11140-4

- 3 different types of test cycles are described:

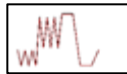
- *Sub-atmospheric*



- *Trans-atmospheric*



- *Super-atmospheric*



- These are “representing” the real cycles found in hospital sterilizers and are used to qualify a BDT product.

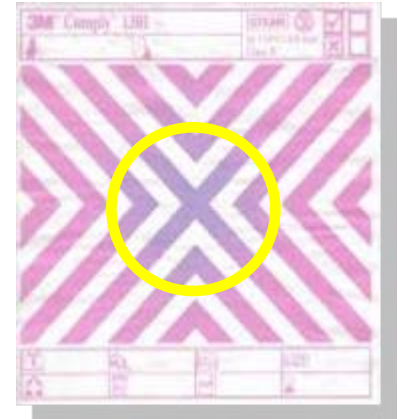
- 3 different failure modes are described:

- *Bad vacuum*

- *Leaks*

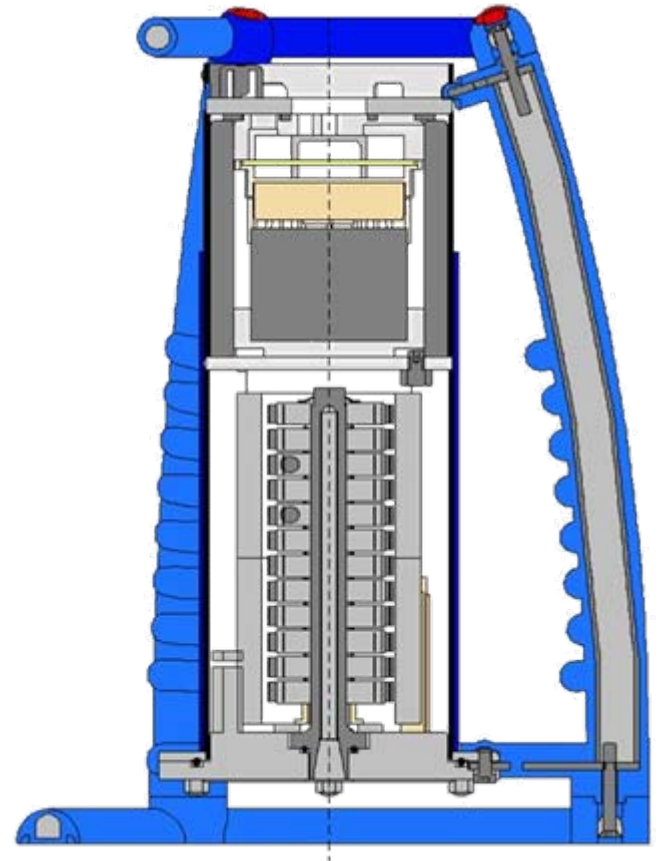
- *Air injection*

- If a BDT product is not suitable for one of these defined cycles, the manufacturer has to state this.



Current Technologies – incorporating the benefits of both

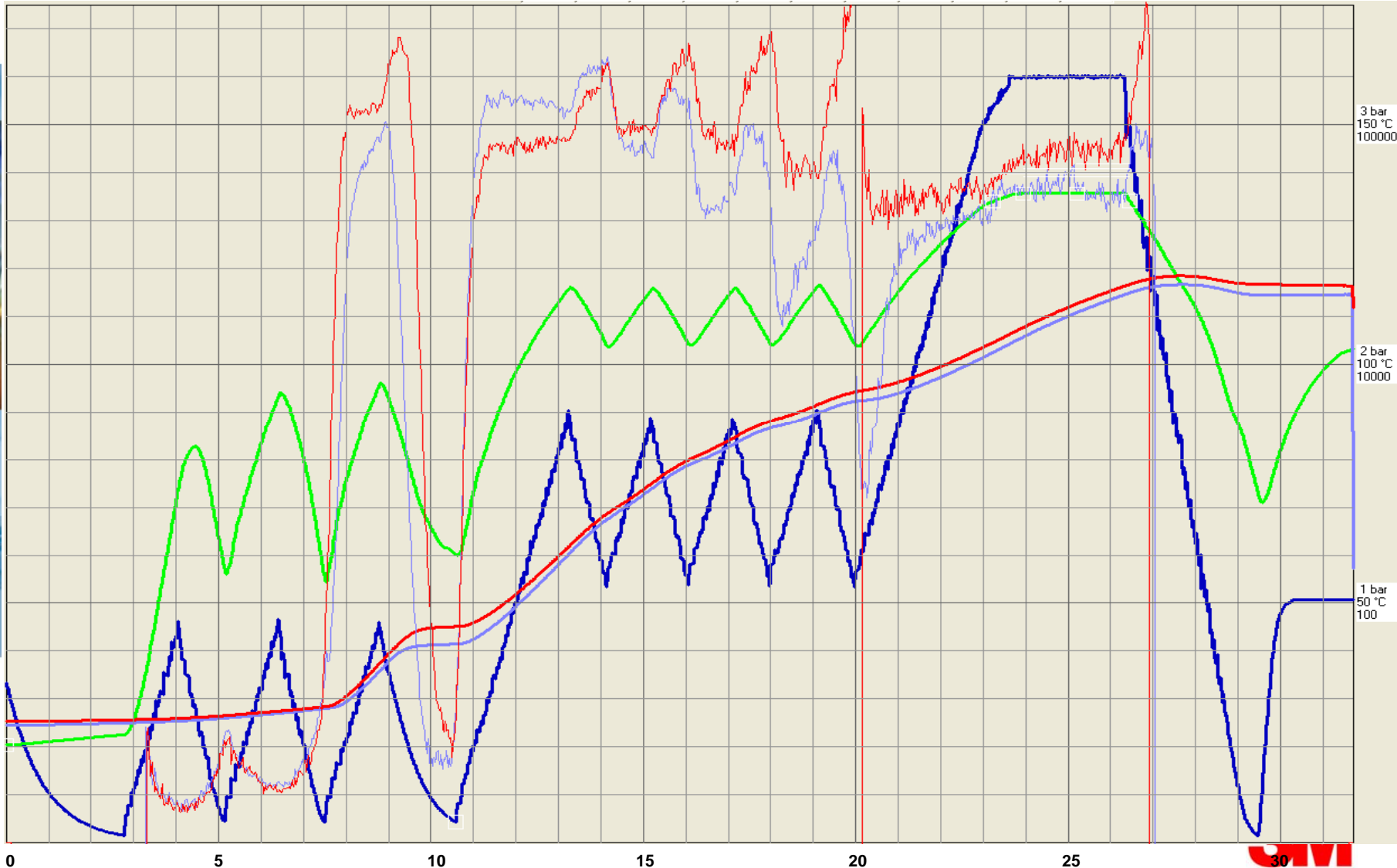
- Physical-electronic test device
 - *based on “condensation load”*
 - *featuring “hollow load”*
 - *calibrated against EN towel pack sensitivity*
 - *non-interpretative result indication*



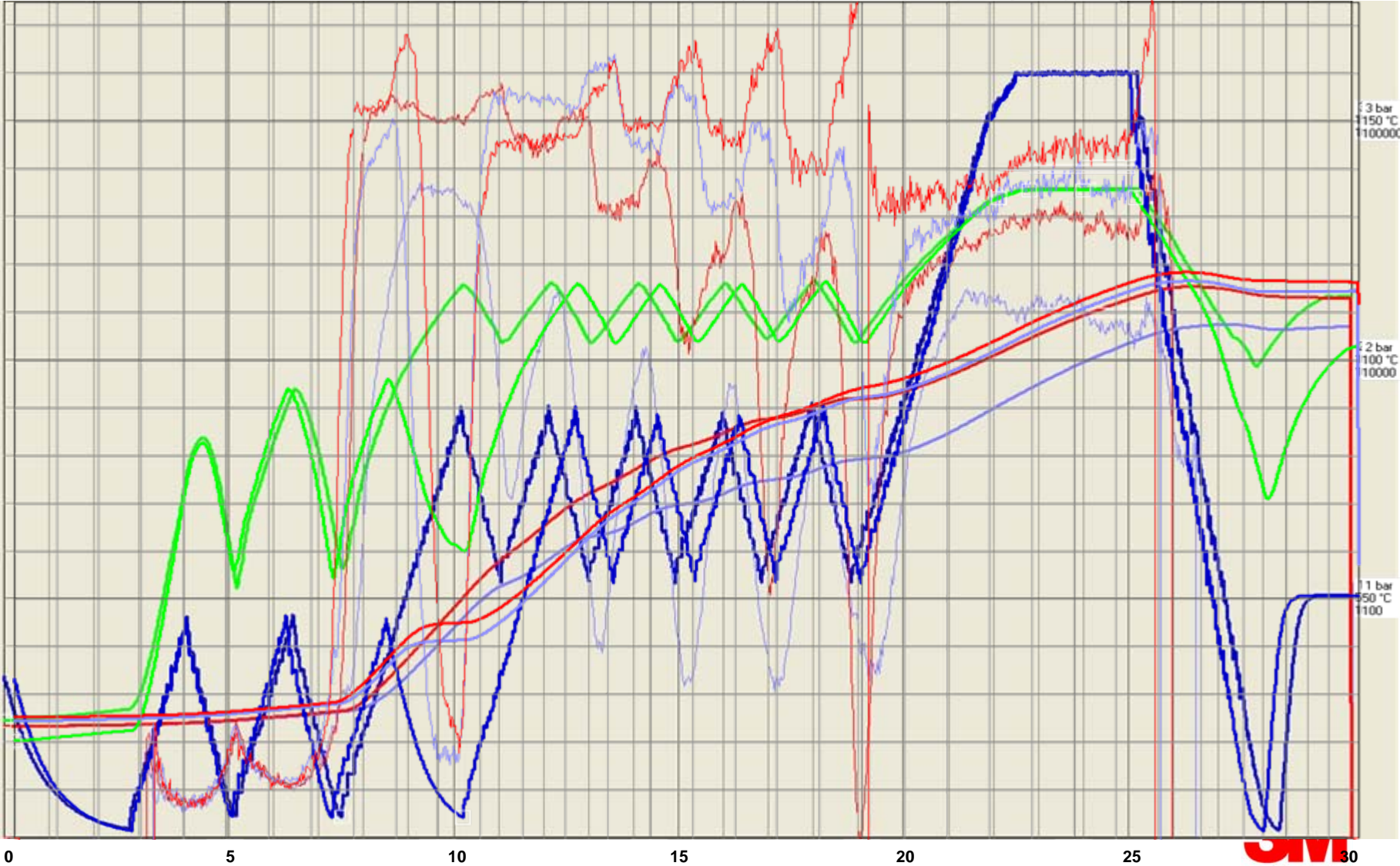
Cycle from UK replicated in 3M research sterilizer 1



Super atmospheric pulse converted to sub atmospheric



Cycle improvement easily visible



Outlook I

- Solid, hollow and porous items are and will be part of sterilizer loads
- Various PCD to represent “product families”, e.g. a porous one plus a hollow one ... ???
- Performance requirements (sensitivity level to detect failures) need to be defined for batch monitoring/load release/...
- Key question: What is the critical fail they need to detect?

Outlook II

The user is responsible to prove his processes are safe:

- by validation and appropriate routine control mechanisms based on current (local) laws and applicable standards
- based on common sense and science

- Standards do not replace own thinking!