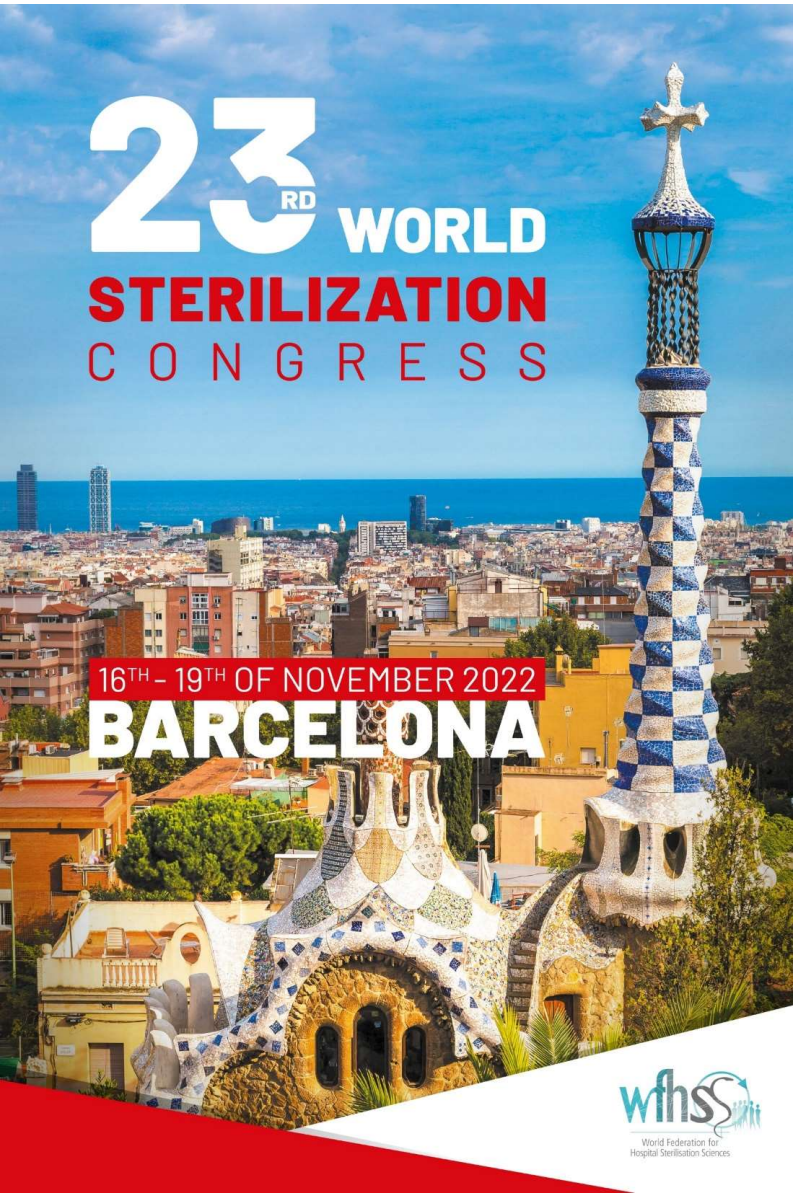

Implementing an evidence based parametric load release for steam sterilisation in practice

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Introduction

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2. Test phase
3. Purchase and implementation phase
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All results and data presented in this presentation are exclusively from our hospital

Questions for you

- ***Which tool do you use to test the steam quality in your sterilizer?***

A) ETS (electronic test-system), or B&D test (bowie and dick, paper version)
B) Helix test
C) BI (biological indicator)
D) NCG sensor

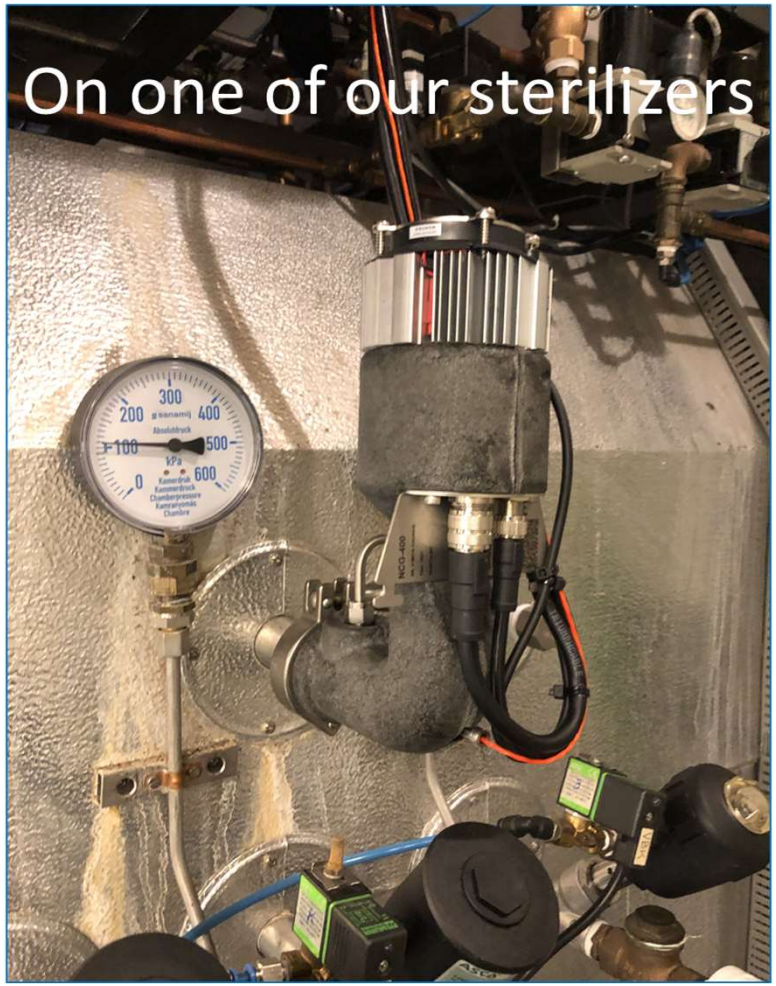
- ***How often do you test the steam quality?***

A) Ones a day
B) More times a day
C) Ones a week
D) Never

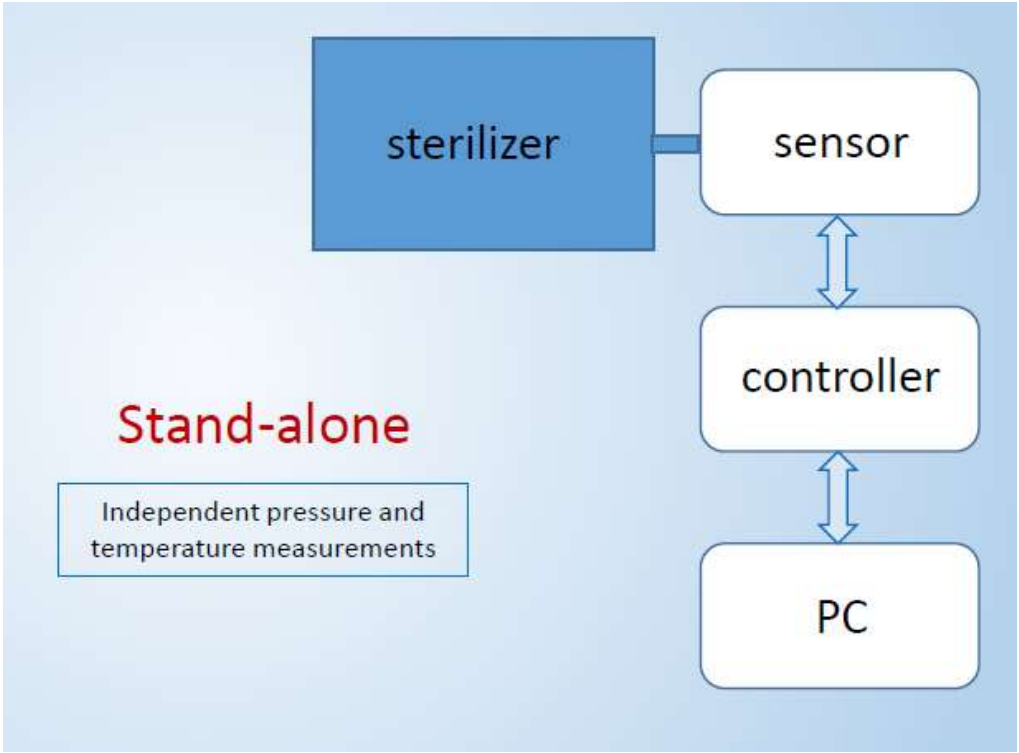
- ***Does this give you the assurance that sterilization conditions will be met in every process?***

A) Yes
B) No

The NCG sensor



Real time measurement of steam quality in every sterilization process



The NCG sensor

What are NCGs?
NCGs are non- condensable gasses
For example: nitrogen, oxygen, carbon dioxide, argon

Why are they important to measure?

- To create sterilization conditions in the sterilizer you need saturated steam. Non condensable gasses are part of the steam and they have to be measured to determine if they affect the steam composition. (Quality)
- Non- condensable gasses reduce steam heat transfer during sterilization.

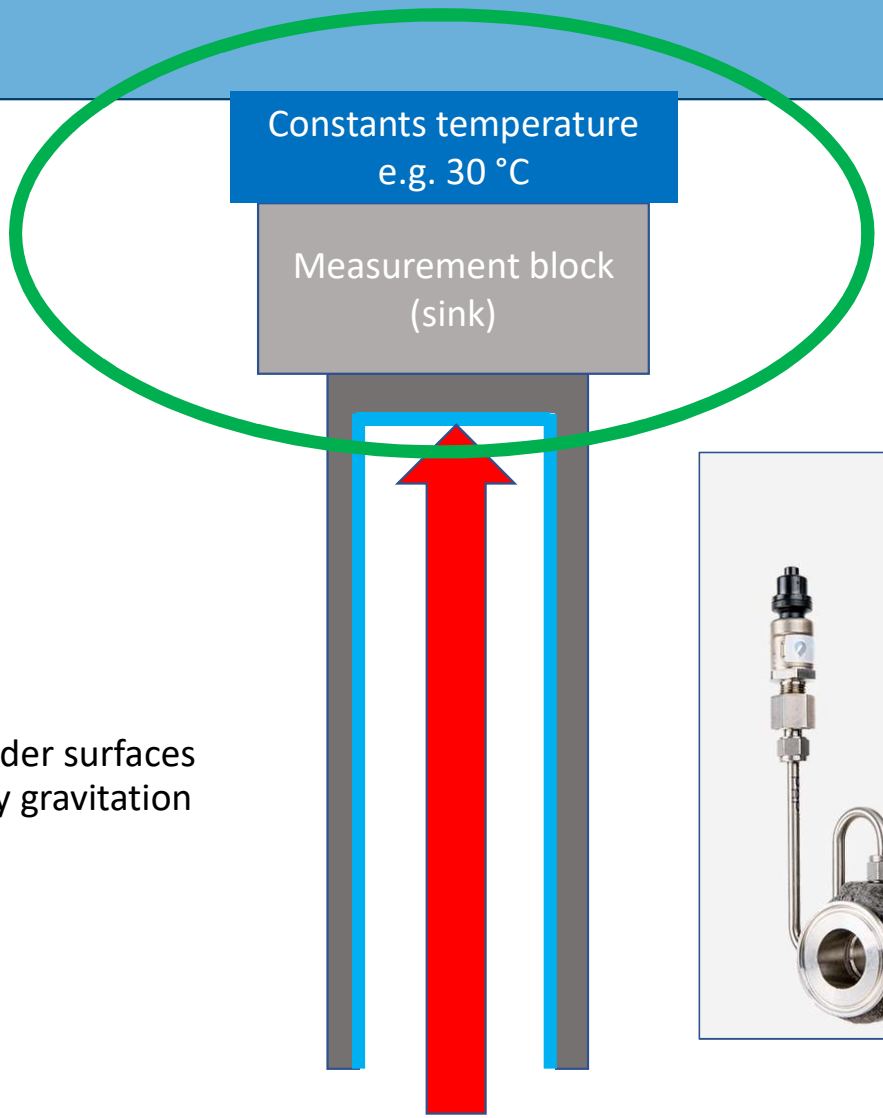
Our sterilizers cannot measure the NCG fraction by themselves. They only measure time, pressure and temperature.

Working principle

Working principle I

What happens in the measurement block?

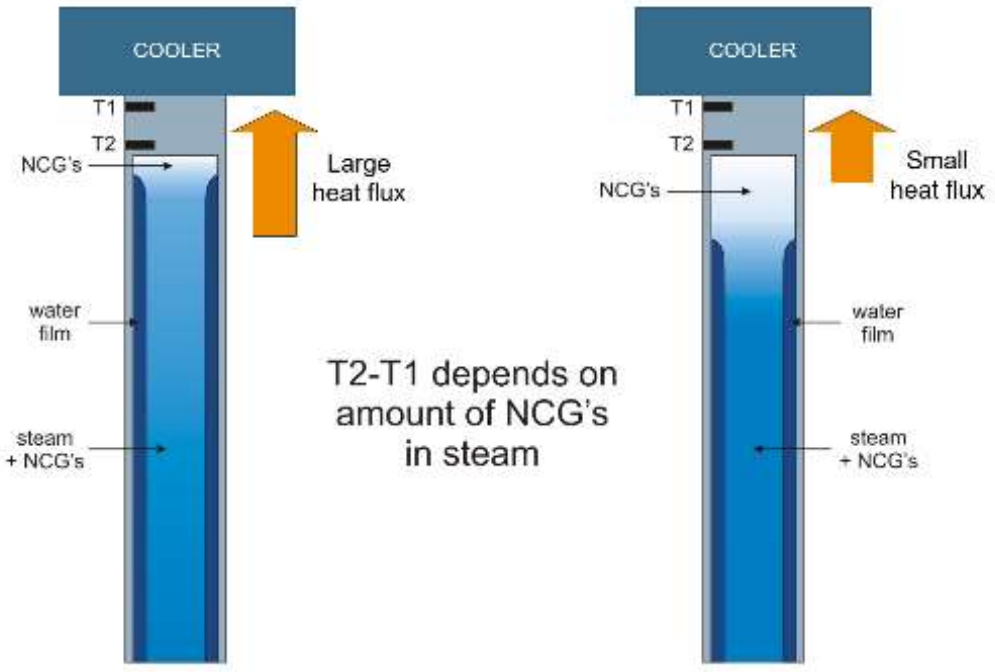
1. Steam comes in the tube
2. Steam condenses on the colder surfaces
3. Condense leaves the tube by gravitation



Working principle 3

Working principle III

Heat transfer depends on the steam composition



Test phase

That's theory! But how does it work in practice?

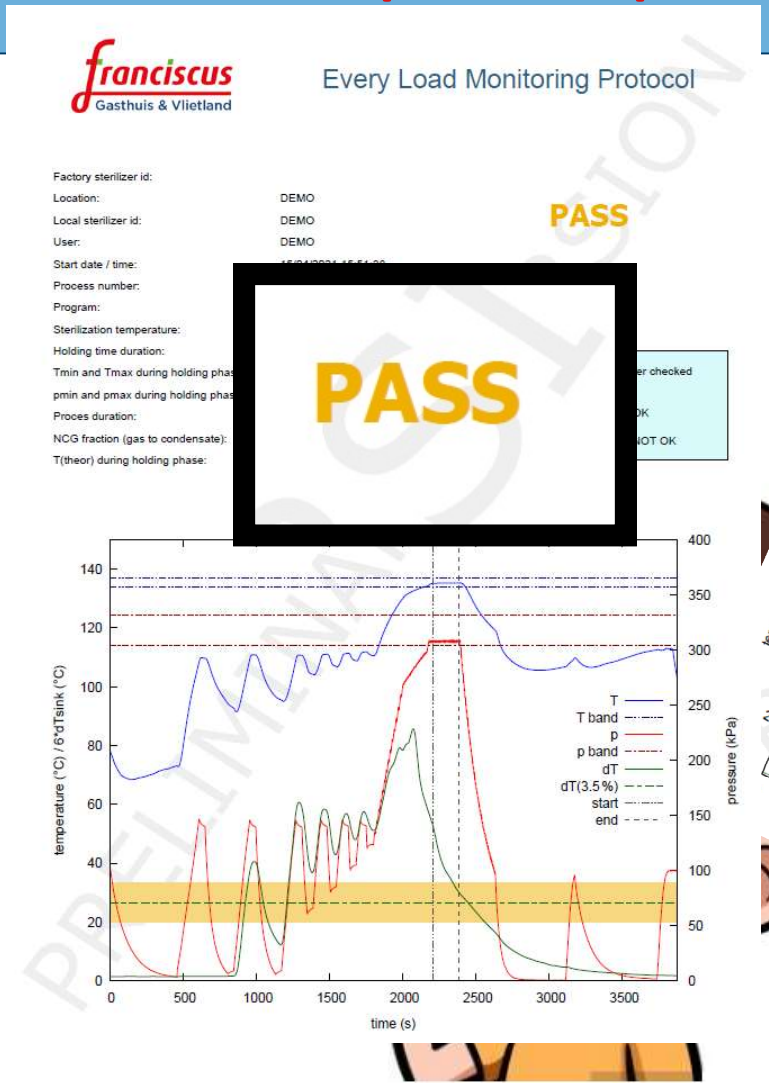
- Test setup for one week with one sterilizer in May 2021
- Test setup with prototype NCG sensor

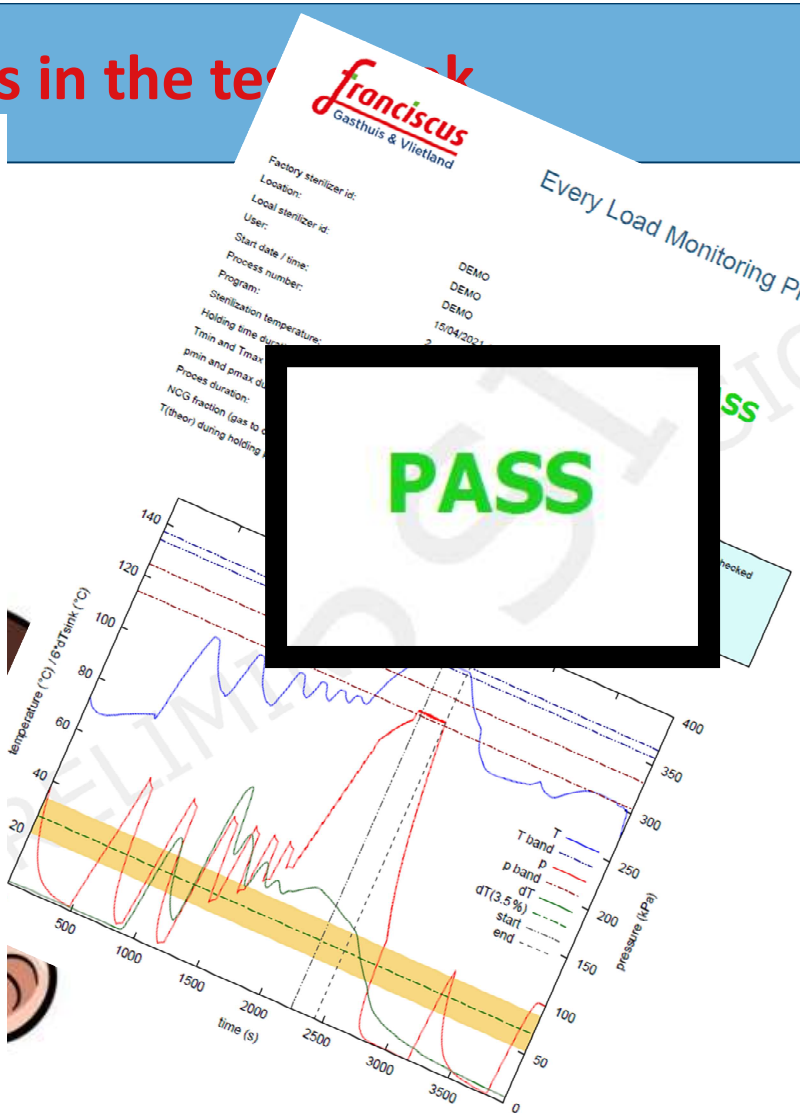
Our experience during that week:

- Test equipment was easy to install
- Stand-alone version, with normal paper printer
- Reports are easy to read and to assess
- Employees of the CSSD were very interested
- Every sterilization process is different! Even in the same sterilizer.

Examples of reports in the tec k

Exciting about what to expect!





Purchase and (technical) preparations

We were convinced!!

To start with:
- Investment application
- Business case

Required disciplines in our hospital:
- ICMT
- Technical and maintenance department
- CSSD

Further preparations:
- How and where can the NCG sensor be connected to the sterilizer?
- Where do we place the controller and computer (without screen)?
- Are all the necessary requirements present (sockets and data points)?
- Where and how to view process data? Digital or printed?
- Where and how to store process data?
- A remote connection with the manufacturer is required to accomplish an adequate approach by malfunctions

Implementation phase

Installation:
25th and 26th of April 2022

Test phase of NCG sensors on all sterilizers and preparing for official start

Official start of the load release by NCG sensor:
4th of July 2022

What did we do before we could start?

1. Ensure everyone has access to the process data
2. Updating protocols
3. Training of CSSD employees
4. Start of working with te system. Providing guidance for CSSD employees in assessing the plots and load release process by using a key- user
5. Monitoring results of all sterilizers and load release by employees
6. Making trend analysis of results

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Data report

Example of an *correct process*, a *process with warning* and an *incorrect process* in our sterilizers based on the amount of NCGs

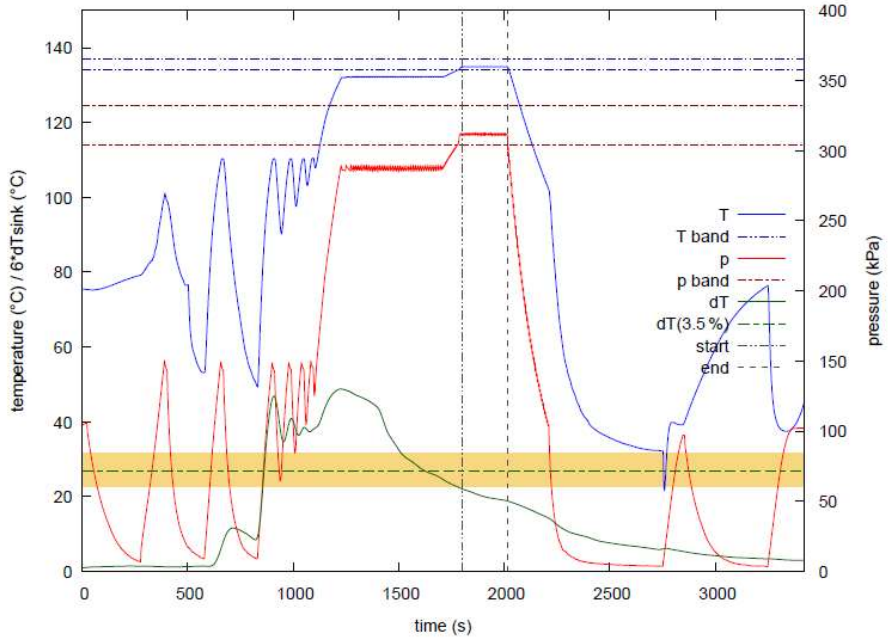
Factory sterilizer id:	id01
Location:	Vlietland
Local sterilizer id:	ster01
User:	CSA
Start date / time:	10/10/2022 13:20:08
Process number:	659
Program:	134 °C standard
Sterilization temperature:	134.9 °C
Holding time duration:	03:50 (mm:ss)
Tmin and Tmax during holding phase:	134.6 / 135.0 °C
pmin and pmax during holding phase:	308.6 / 309.7 kPa
Proces duration:	01:00:25 (hh:mm:ss)
NCG fraction (gas to condensate):	0.01 % (min) - 0.01 % (max)
T(theor) during holding phase:	134.6 °C

Orange PASSes and FAILs are also possible when temperature or pressure is not right

Factory sterilizer id:	id03
Location:	Gasthuis
Local sterilizer id:	ster03
User:	CSA
Start date / time:	11/07/2022 10:25:54
Process number:	343
Program:	134 °C standard
Sterilization temperature:	134.9 °C
Holding time duration:	03:33 (mm:ss)
Tmin and Tmax during holding phase:	134.8 / 134.9 °C
pmin and pmax during holding phase:	311.2 / 311.7 kPa
Proces duration:	00:56:02 (hh:mm:ss)
NCG fraction (gas to condensate):	4.5 % (min) - 6.3 % (max) ***
T(theor) during holding phase:	134.8 °C

FAIL

☐ Process number checked
☐ Load release OK
Load release NOT OK



Practical case

Casus:

- 7 sterilizers (same size, brand, age)
- They all have different results each process
- 2 of 7 sterilizers have noticeably different results

1. One sterilizer has orange PASSes and some time later a lot of FAILS because of NCGs which are too high
2. One sterilizer has very often orange PASSes, more than green PASSes

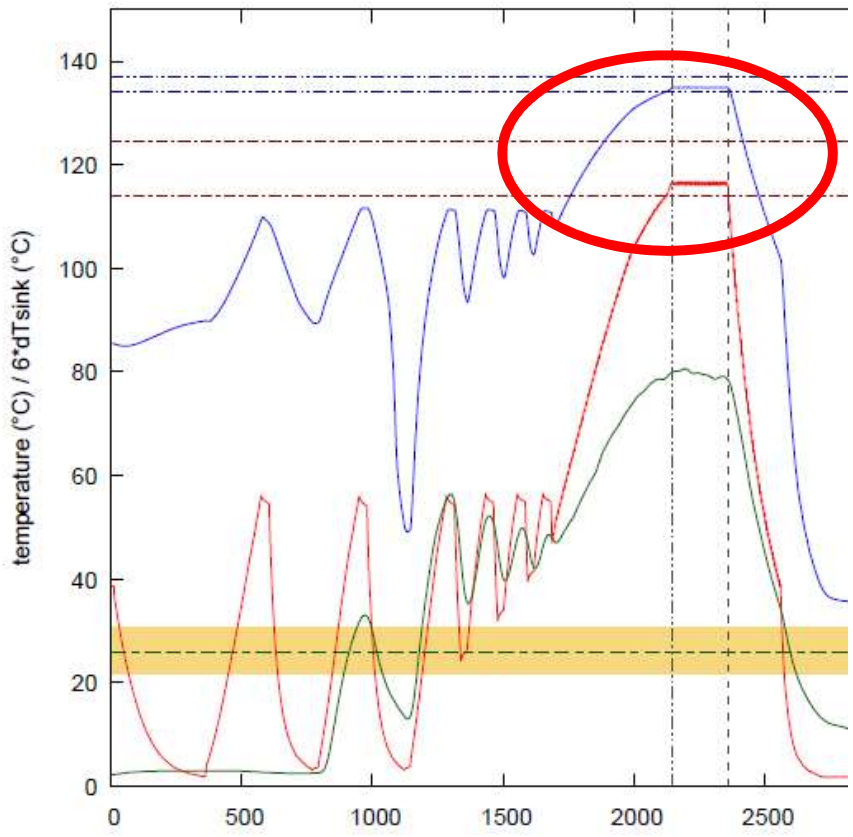
In both situations; the pressure, temperature and time were correct. But the steam quality was inadequate.

What dit we do?

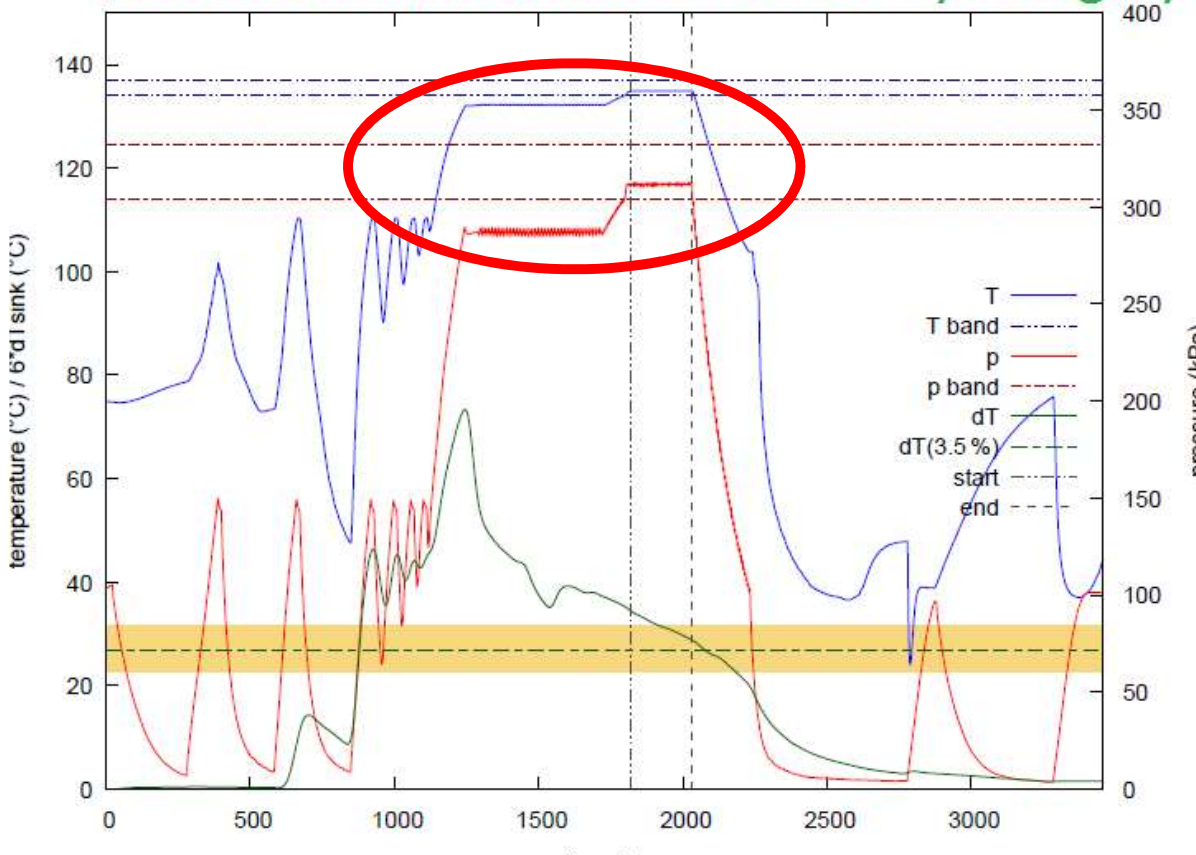
- Maintenance! But that didn't solve the problem…
- Need for deeper research in the sterilizer system
- We found out that the program itself is the cause of the appearance of NCGs (it was amended in the past because of eye instruments: phaco hand pieces)

Practical case

Normal instrument process



Process for instruments used for eye surgery



Added Values

Our experience

- You do not need to run test programs in the morning in an empty sterilizer before you can start sterilizing instruments . (that's what we normally do in the Netherlands) (it save a lot of time and purchase costs)
  - steam penetration test
  - vacuum leakage test

- The NCG sensor gives more assurance about steam conditions in every sterilization process. (patients safety,)

- Trend analysis provide insight into the performance of the sterilizers. (higher quality)

- It is possible to carry out more targeted maintenance, and in some cases, to prevent worse defects. (Anticipating maintenance, preventing sterilizer failure)

- Validation of sterilizers might be performed in less measurements. (Financial savings)

Evidence Based tool; the sensor is developed according to scientific papers and adapted to the Standard. EN285

See the next slide: More information

Experiences CSSD employees

https://youtu.be/uOcohjHsFJ0

More information

Reference literature and documentation:

- *Parametric release with measurements of steam sterilisation parameters: temperature, steam composition and time.* ResearchGate (April, 2022) . https://www.researchgate.net/publication/360110647_Parametric_release_with_measurements_of_steam_sterilisation_parameters_temperature_steam_composition_and_time

- *Steam sterilisation criteria according to EN 285:2015.* Zentralsterilisation - Central Service 28(2020-1):51-54 (PDF) Steam sterilisation according to EN 285:2015 (researchgate.net)

- *NCG meting maakt tijdrovende tests overbodig.* Sterilisatievereniging Nederland, Parametric Release. PR-nummer-71-juni-2022.pdf (sterilisatievereniging.nl) (July 2022) (in Dutch)

- Manuscript *Improving parametric load release for steam sterilisation* submitted for publication to the Journal of Hospital Infection

The End

THANK YOU
for your
ATTENTION!