MONITORING STEAM PENETRATION IN CHANNELED INSTRUMENTS: AN EVIDENCE-BASED WORST-CASE FOR PRACTICAL SITUATIONS

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Steam sterilization for surgical instruments

- Steam sterilization is recommended as the preferred sterilization method for medical instruments in hospitals.
- **All accessible internal and external surfaces** of the devices should be reached by steam
- **Sterilization conditions** should be achieved and maintained in all space within the sterilizer chamber

[https://www.who.int/infection-prevention/publications/decontamination/en/]
[https://wfhss-guidelines.com/]

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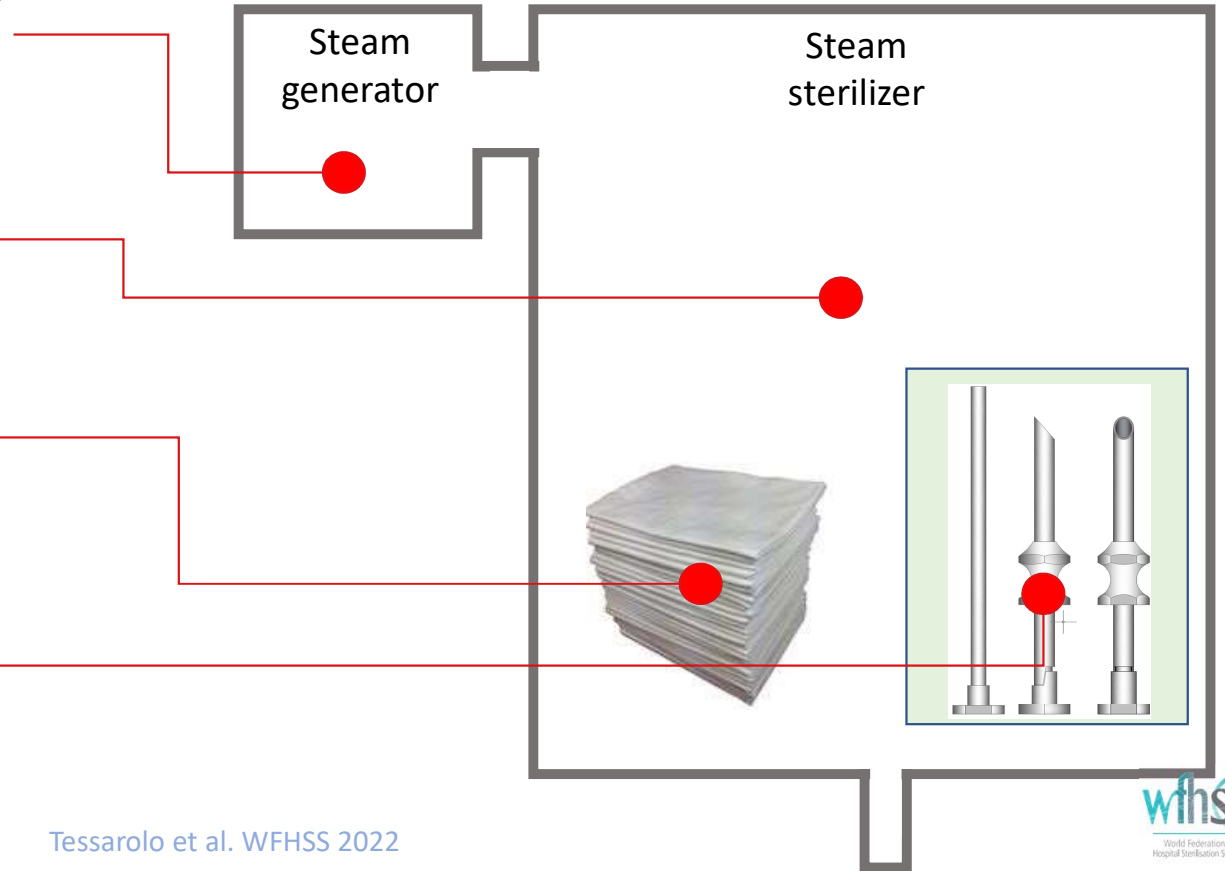
Where to test steam sterilization conditions?

- At the steam generator level (EN 285)
- In the sterilizer chamber (e.g. NCGs sensor)
- Inside a towel pack (ISO 11140)
- Inside pack containing (cannulated) instruments



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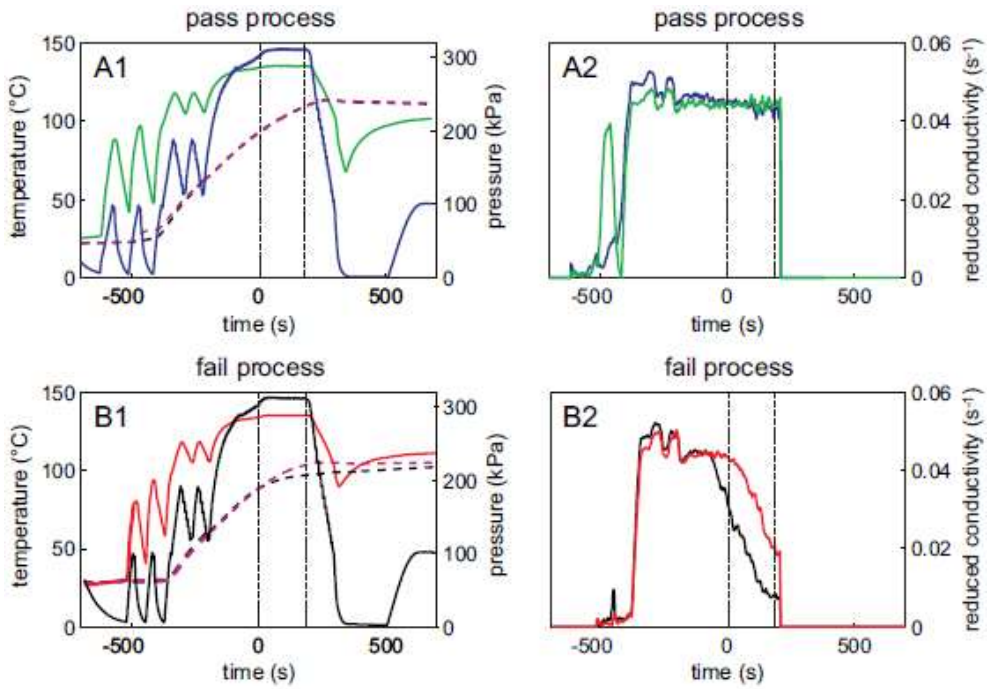
What is known: steam sterilization parameters

Pressure, Temperature and Time are not enough to monitor steam sterilization process

Essential parameters for steam sterilization are:

- Temperature
- Time
- Humidity (steam fraction)



[Central Service 2014;4:250-253]

What is known: surgical instrument design

Surgical instruments can be divided into two main designs (product families):

- Bulky (or massive)
- Channelled (or lumened)

Channelled devices are more critical for steam penetration than massive instruments

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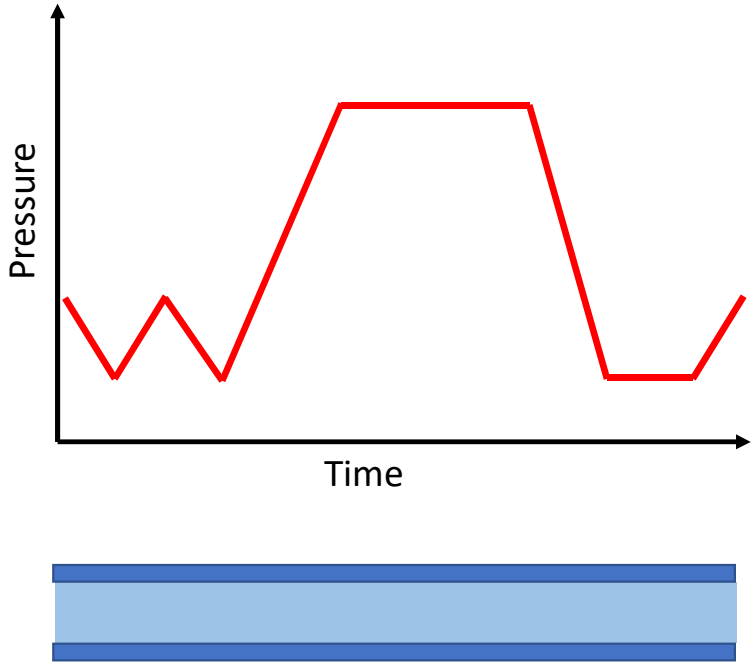
What is known: steam penetration in channels (both ends open)

Channelled instruments can contain channels:

- with **both ends open**
- with one end open and one closed

For the channelled instruments with both ends open, the most difficult location for steam penetration is the centre of the inner channel wall



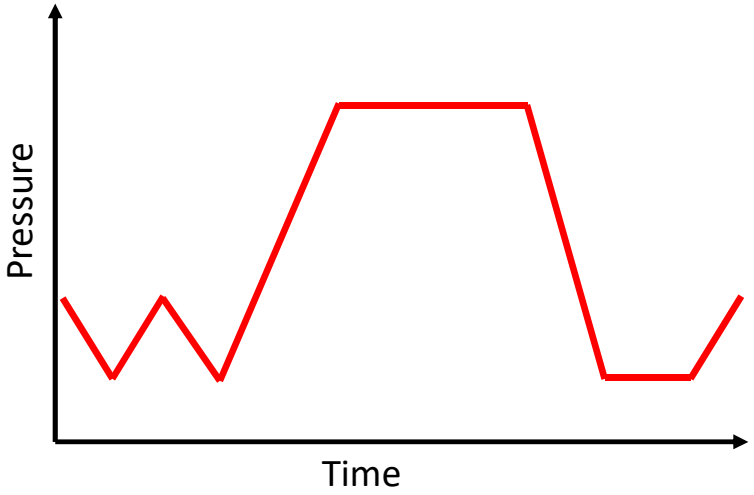
[Journal of Physics D Applied Physics, 2013;46(6):065201]

What is known: steam penetration in channels (single end open)

Channelled instruments can contain channels:

- with both ends open
- with **one open end and one closed**

For the channeled instruments with one end open and one closed, the most difficult location for steam penetration is the inner channel wall at the closed end



[Journal of Physics D Applied Physics, 2013;46(6):065201]

What is known: the most difficult channel in practice

In terms of steam penetration, a channel with both ends open can be represented as a channel of half the length with one end open and one end close.

1 m

50 cm

In the clinical practice the maximum length of steam sterilized channelled instruments is 1 m with both ends open.

Channelled instruments can be represented by a 50 cm long channel with one end open and one end closed.

[Journal of Physics D Applied Physics, 2013;46(6):065201]

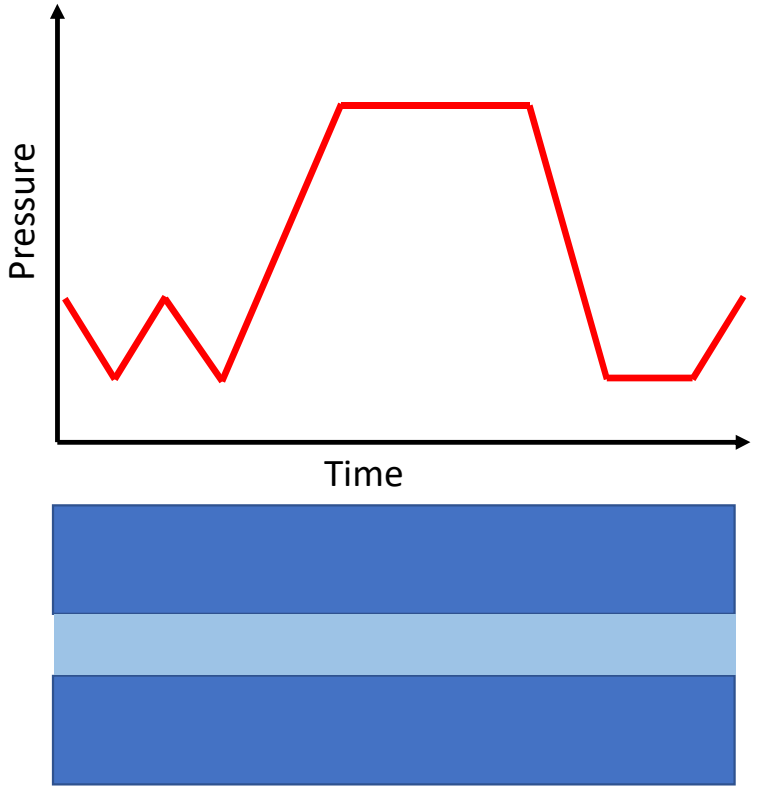
What is known: thin and thick-walled channels

Thin-walled channels

- having a warming up time of the inner wall equal or less than the time required for steam penetration into the channel. The channel is warmed up mainly by steam condensation on the outer surface.

Thick-walled channels:

- are warmed up mainly by steam condensation on the inner channel wall, creating condensate inside the channel.



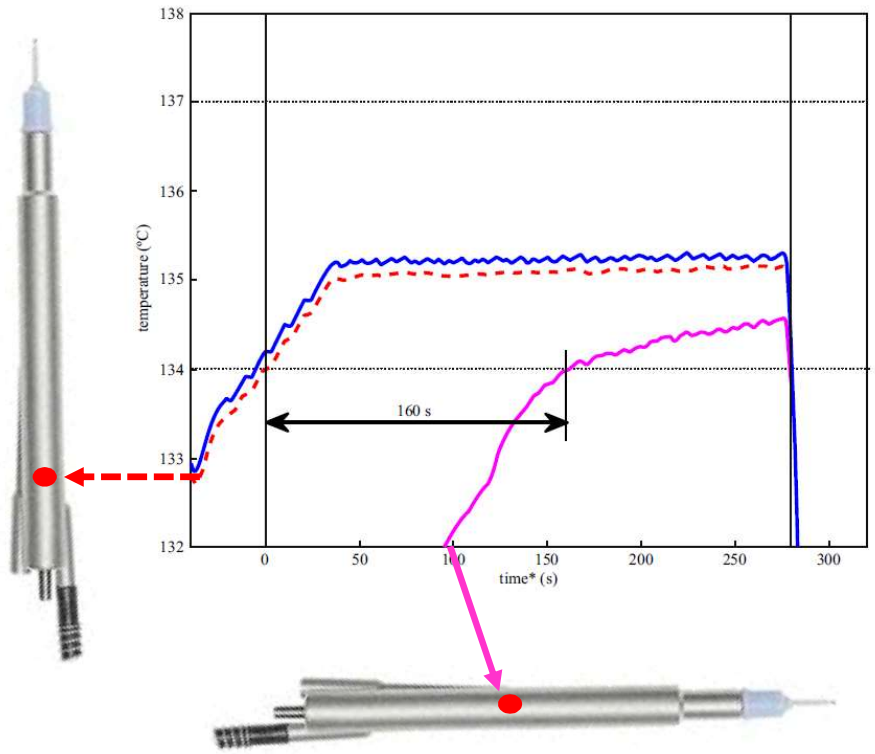
[Journal of Hospital Infection 2015;90:52-58]

What is known: thin and thick-walled channels

Thick walled channels:

- Channel obstruction by water droplets can impair steam penetration into thick walled channels.
- The orientation during steam sterilization should guarantee an effective drainage of the condensate from the open end.

Instruments having thick walled channels need to drain condensate from the channel



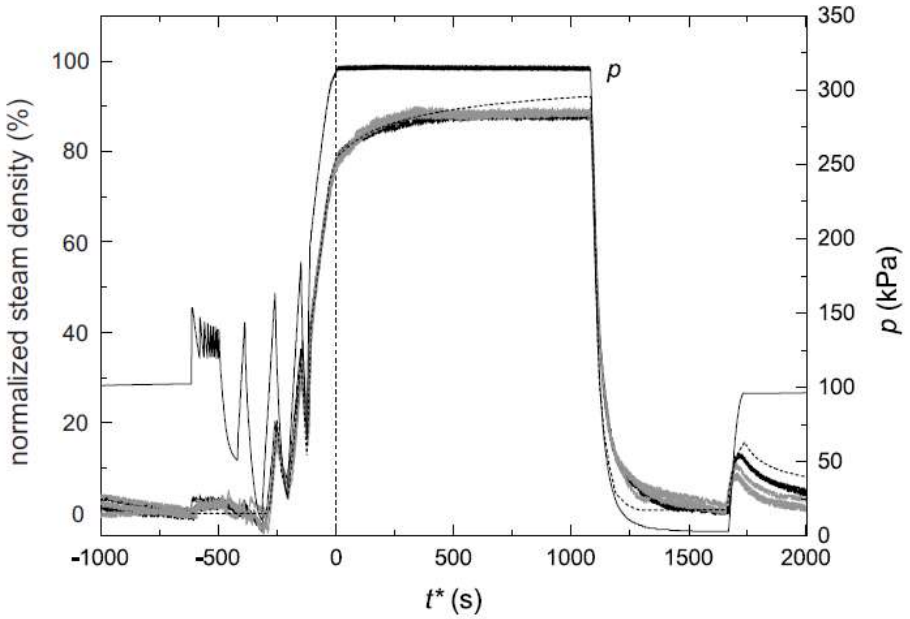
[Journal of Hospital Infection 2015;90:52-58]

What is known: channel diameter

Most of the channels present in medical devices for minimally invasive surgery have a diameter in the range from 1 to 5 mm.

Variations in the channel diameter in the range from 0.7 to 5 mm were shown not to significantly affect steam penetration at the start of the sterilization phase.

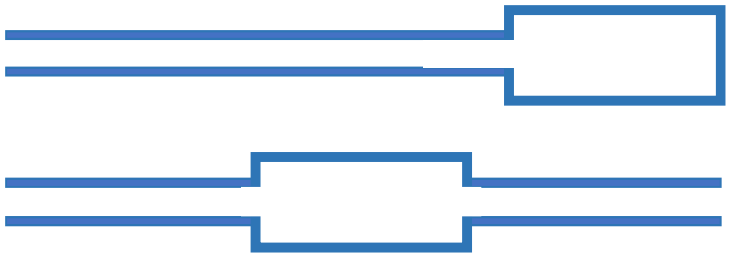
[Journal of Physics D Applied Physics, 2013;46(6):065201]



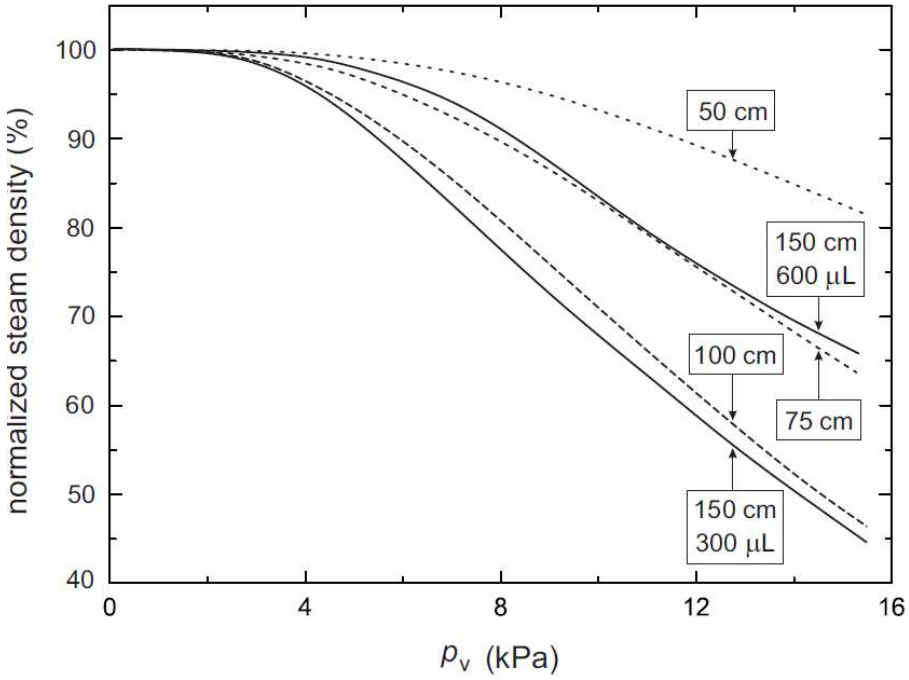
[Central Service 2015;6:429-433]

What is known: channel design

Simulations and experiments showed that having chambers in the channel favour steam penetration into the lumen.



Channels with a constant radius over the full length of the instrument are the most difficult to steam penetrate



[Central Service 2015;6:429-433]

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What is still missing: a worst case for steam penetration in channels

No data are available on the worst case condition for steam penetration in channelled instruments in practical conditions, taking into consideration:

- Wrapping
- Load amount into the pack
- Position of the pack into the sterilizer chamber

AIM of the study

The study was aimed at providing experimental proof that:

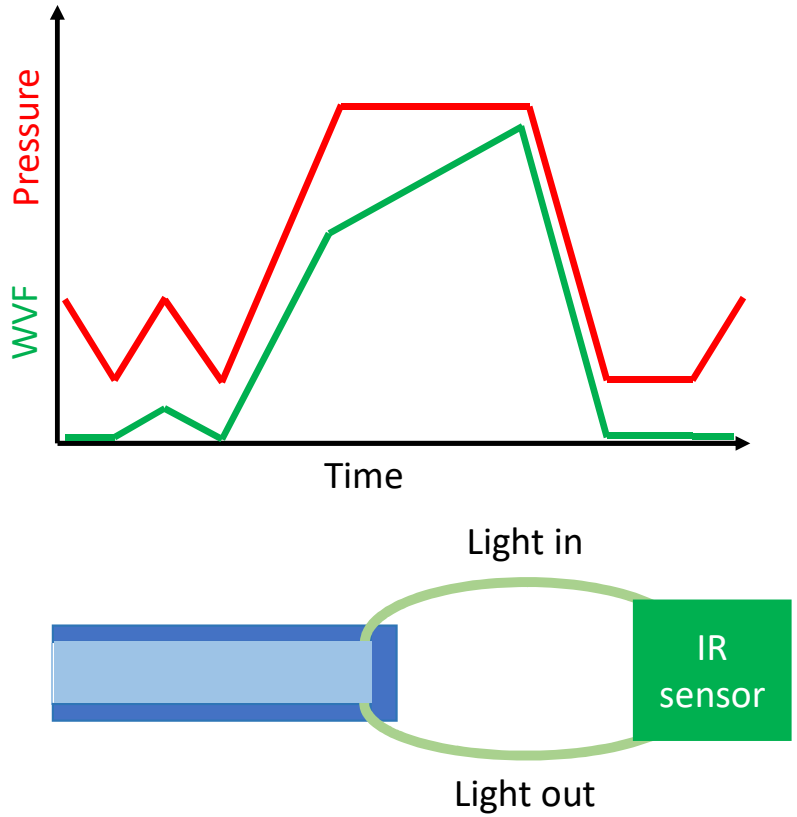
a 70 cm long tube is **the most difficult condition for steam penetration in a load representative for surgical instruments** (channelled and non channelled) **in practical situations**.

MATERIALS AND METHODS

Measuring water vapour fraction using an IR sensor

Allows to measure steam fraction (WVF) at the closed end of a channel in real time during the whole sterilization process.

- Do not affect steam penetration process
- Do not alter channel geometry



[J. Phys. D: Appl. Phys. 2013; 46: 065201]

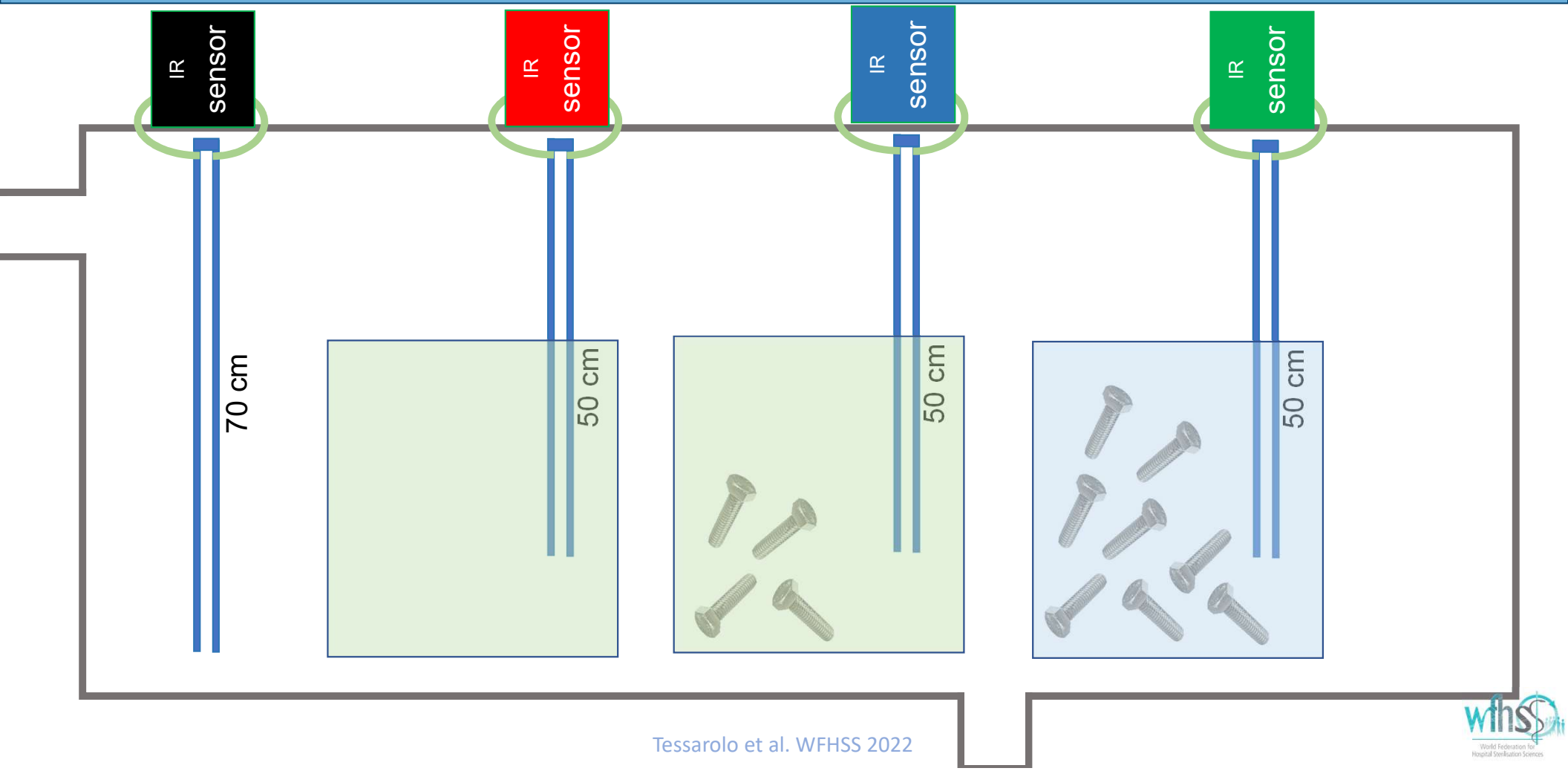
Research question

"During the exposure phase of a sterilization process, is the water wapour fraction measured by an IR sensor equipped with a 70 cm long tube lower than the steam fraction at the closed end of a 50 cm channelled device inside a pack?"

This question should be tested in practical conditions characterized by different combinations of:

- wrapping
- load amount in the pack
- different pack positions into the sterilizer chamber

Study protocol in a nutshell



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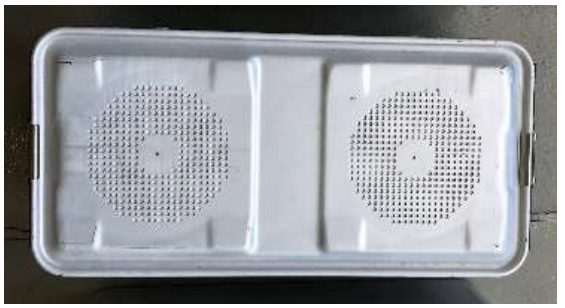
Experimental variables 1/3

Wrapping

- Crepe
  double wrapping
- SMS
  single wrap using double layer foils
- Pouch
  double
- Container
  large volume with paper filters



Experimental variables 2/3

Pack Load

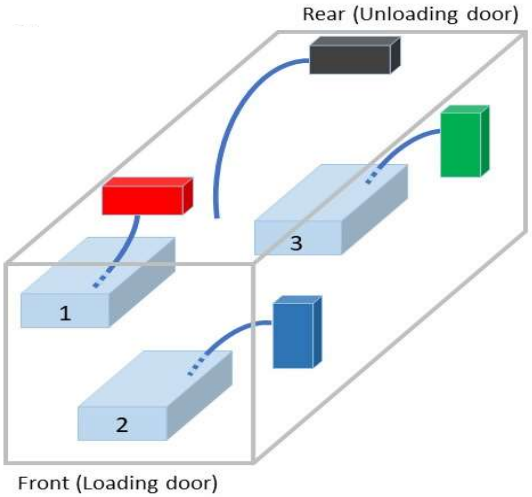
- No load but the open end of the channel
  - 0 Kg
- half load amount
  - 7.5 Kg of steel for SMS, crepe and containers;
  - 0.2 Kg of steel for pouches
- full load amount
  - 15 Kg of steel for SMS, crepe and containers;
  - 0.4 Kg of steel for pouches

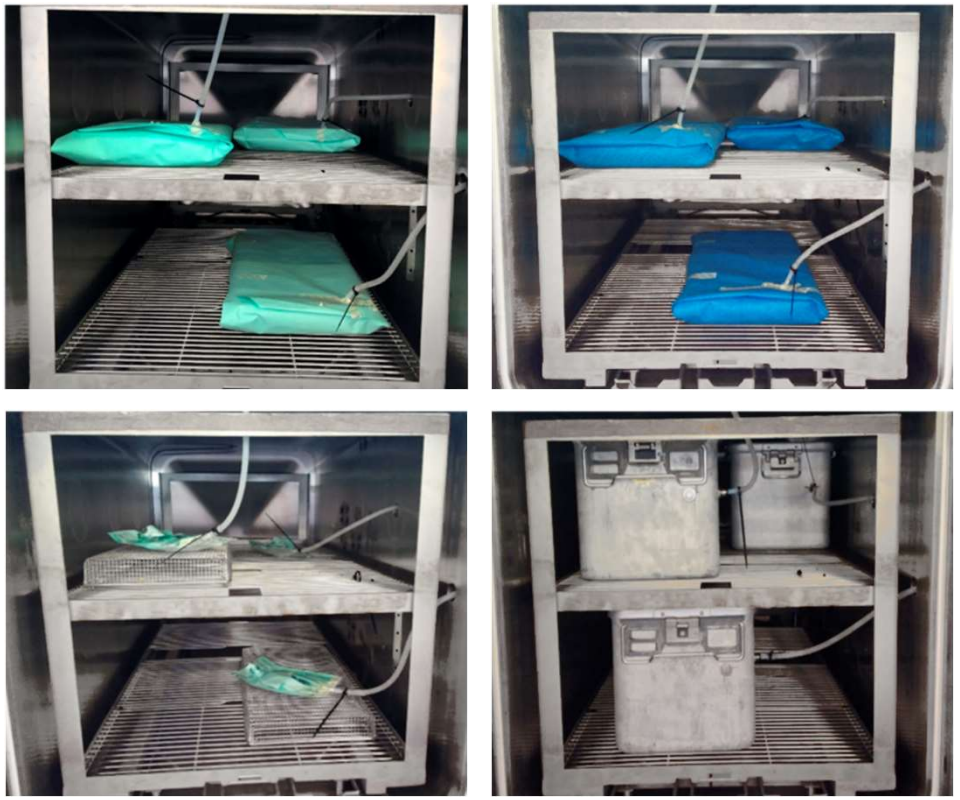



Experimental variables 3/3

Pack position into the sterilizer

- in the front upper level
- in the back upper level
- in the front lower level





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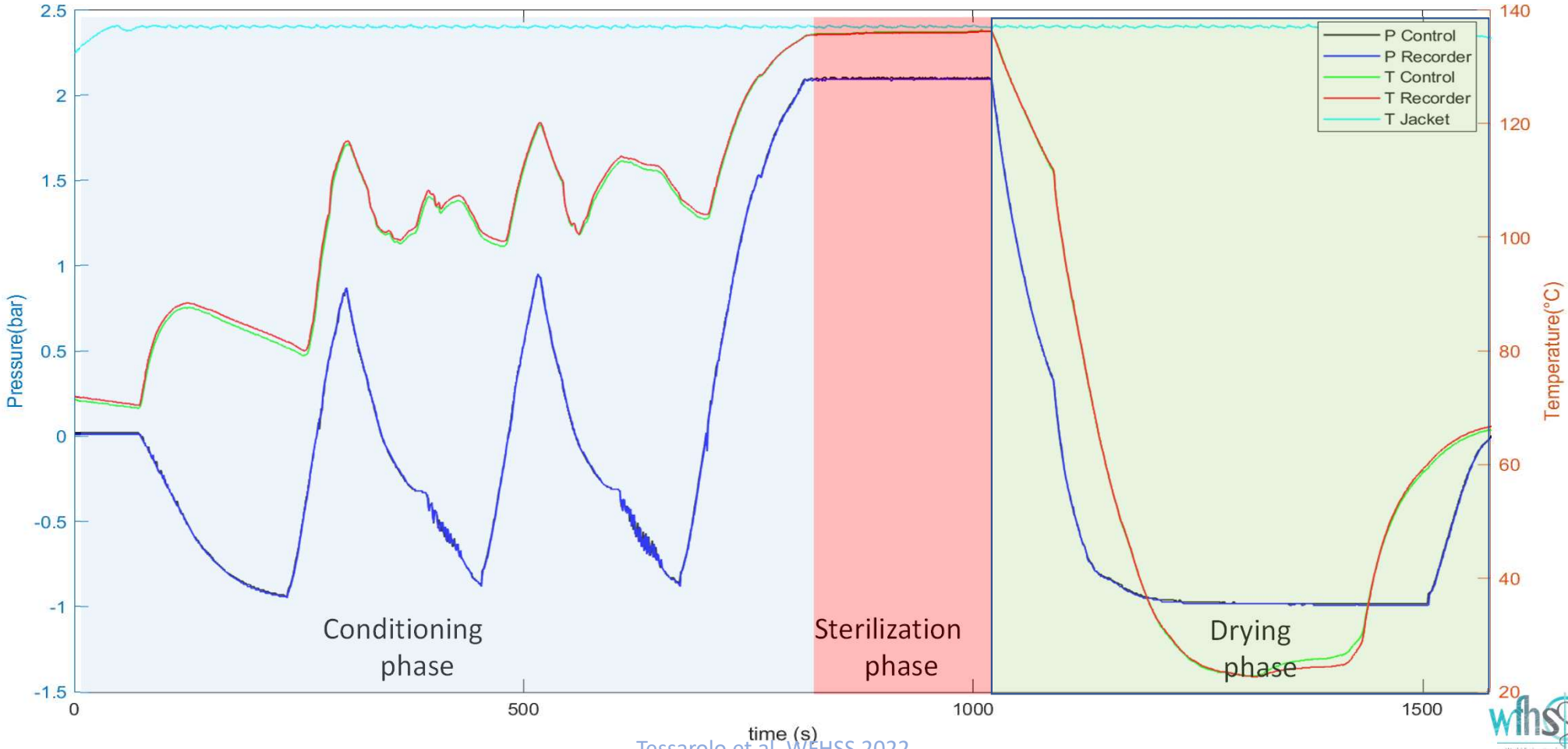
The steam sterilization process



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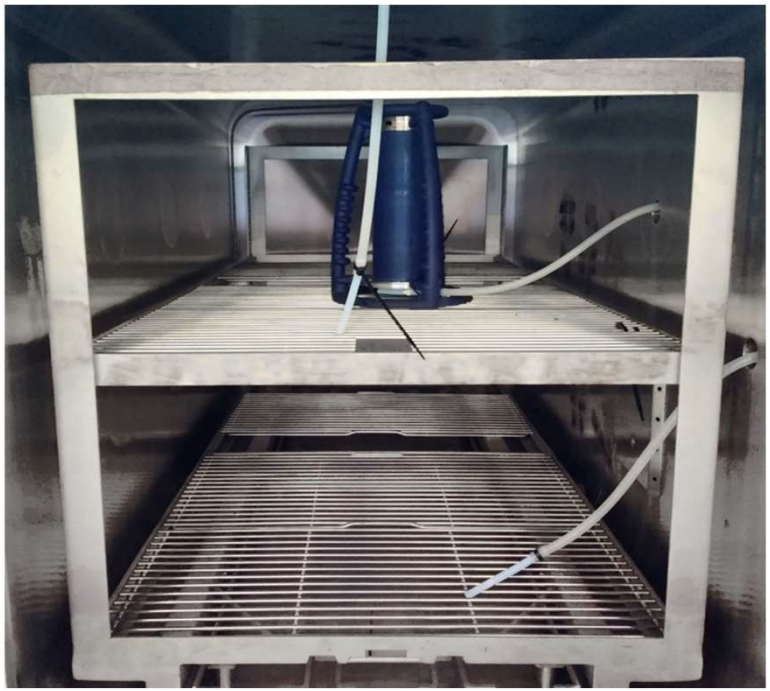
The sterilizer

Eight units steam sterilizer equipped with built-in steam generator and water degassing system.

At the start of each experimental day, the sterilizer performed:

- a warming up cycle to warm up the sterilizer chamber
- an air leakage test
- a Bowie & Dick (B&D) test in accordance to ISO 17665-1 [ISO 17665-1:2006]



RESULTS

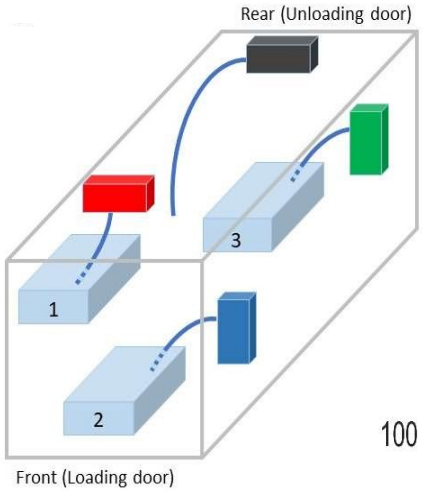
Performed experiments

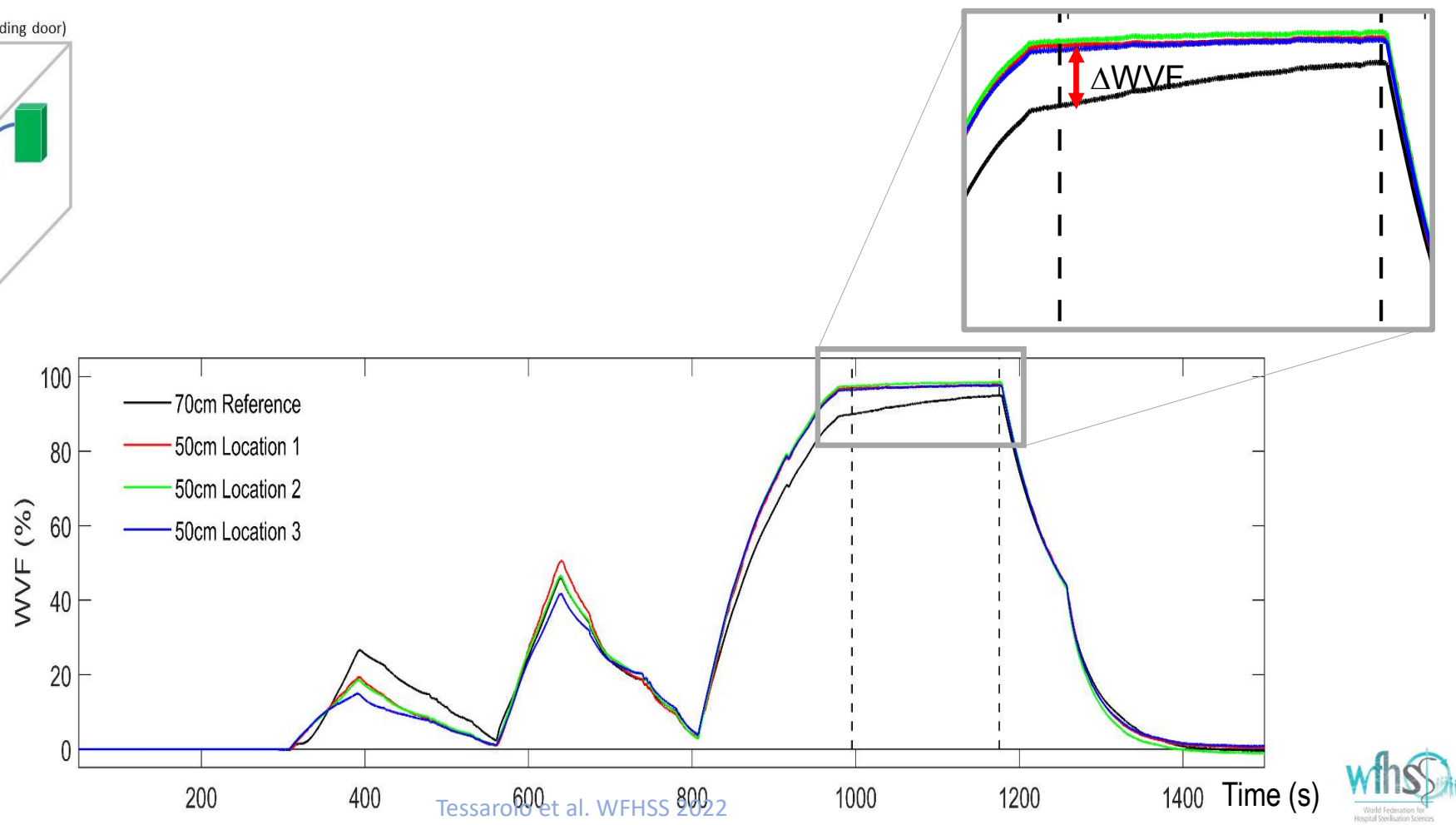
A total of **180 experimental datasets** obtained from 60 sterilization processes covering the combination of:

- 4 wrappings
- 3 load amounts in pack
- 3 locations in the sterilizer chamber

5 replicates per each condition.

Qualitative overview of steam fraction results





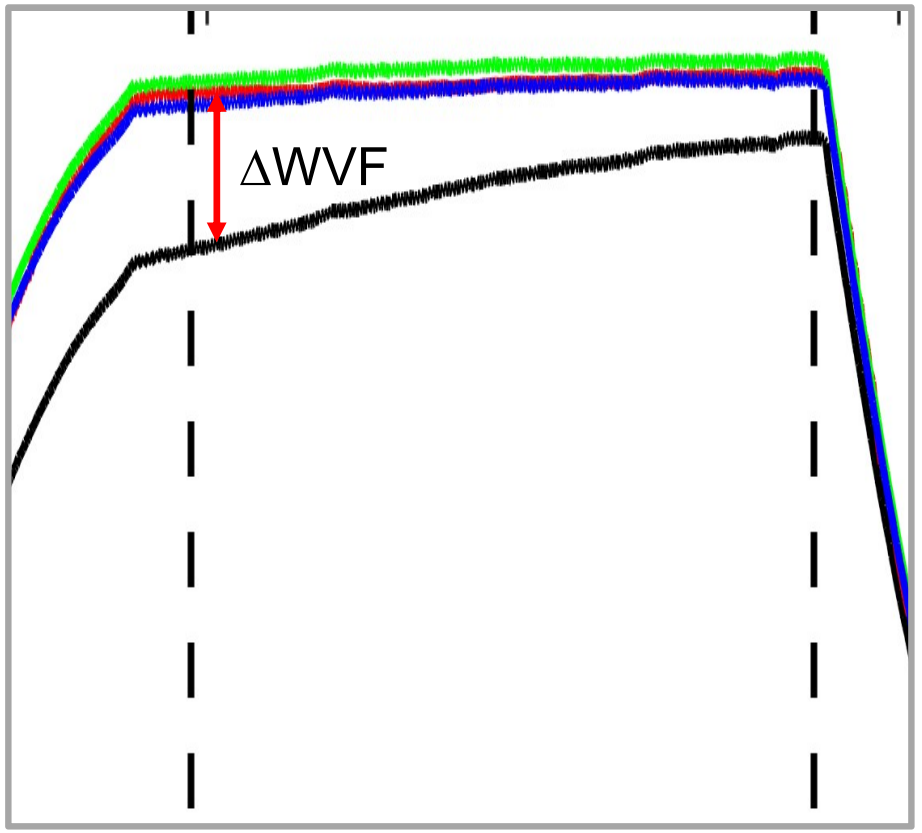
Identification of the worst case for steam penetration

$\Delta WVF = WVF_{50\ cm} - WVF_{70\ cm}$

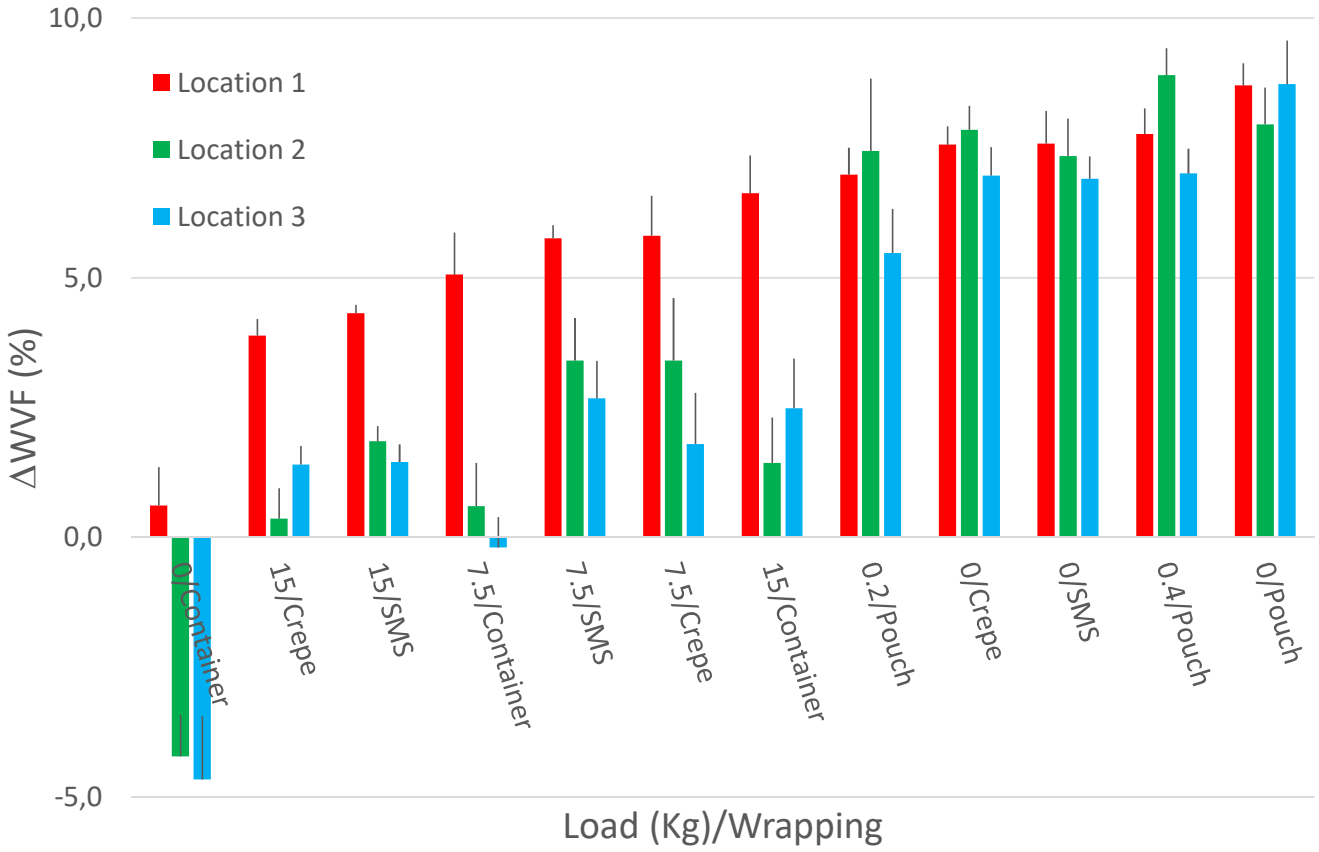
$\Delta WVF > 0$: the steam fraction in the 70 cm tube is lower than in the 50 cm packed channelled instrument

$\Delta WVF < 0$: the steam fraction in the 70 cm tube is higher than in the 50 cm packed channelled instrument

$\Delta WVF > 0$ for any wrapping/load/position
→ 70 cm tube is the worst case



Quantitative analysis at the start of exposure phase



Steam penetration in channels is affected by wrapping, load in the pack and position in the sterilizer.

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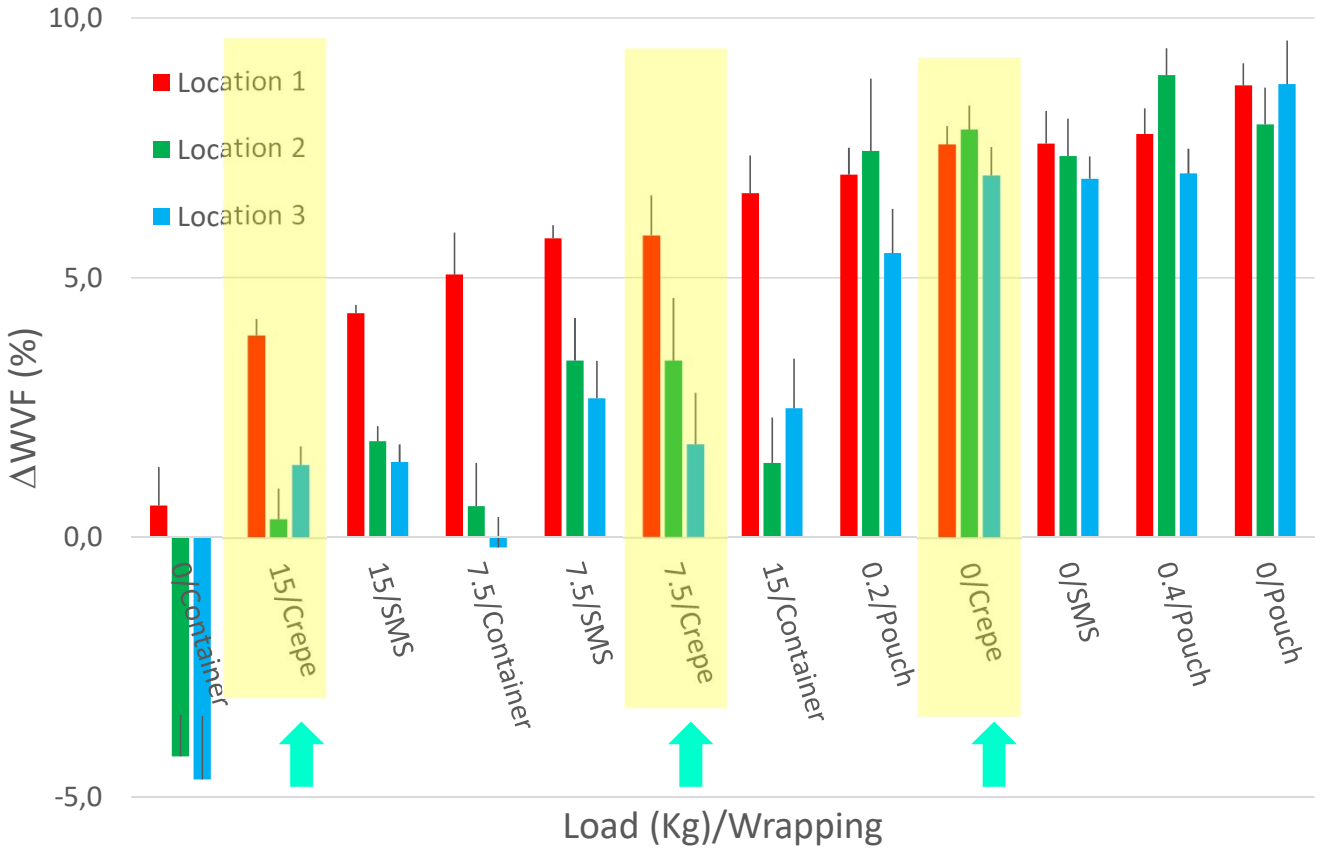
Quantitative analysis at the start of exposure phase



For soft packs (crepe, SMS), the higher the load into the pack, the lower the steam penetration

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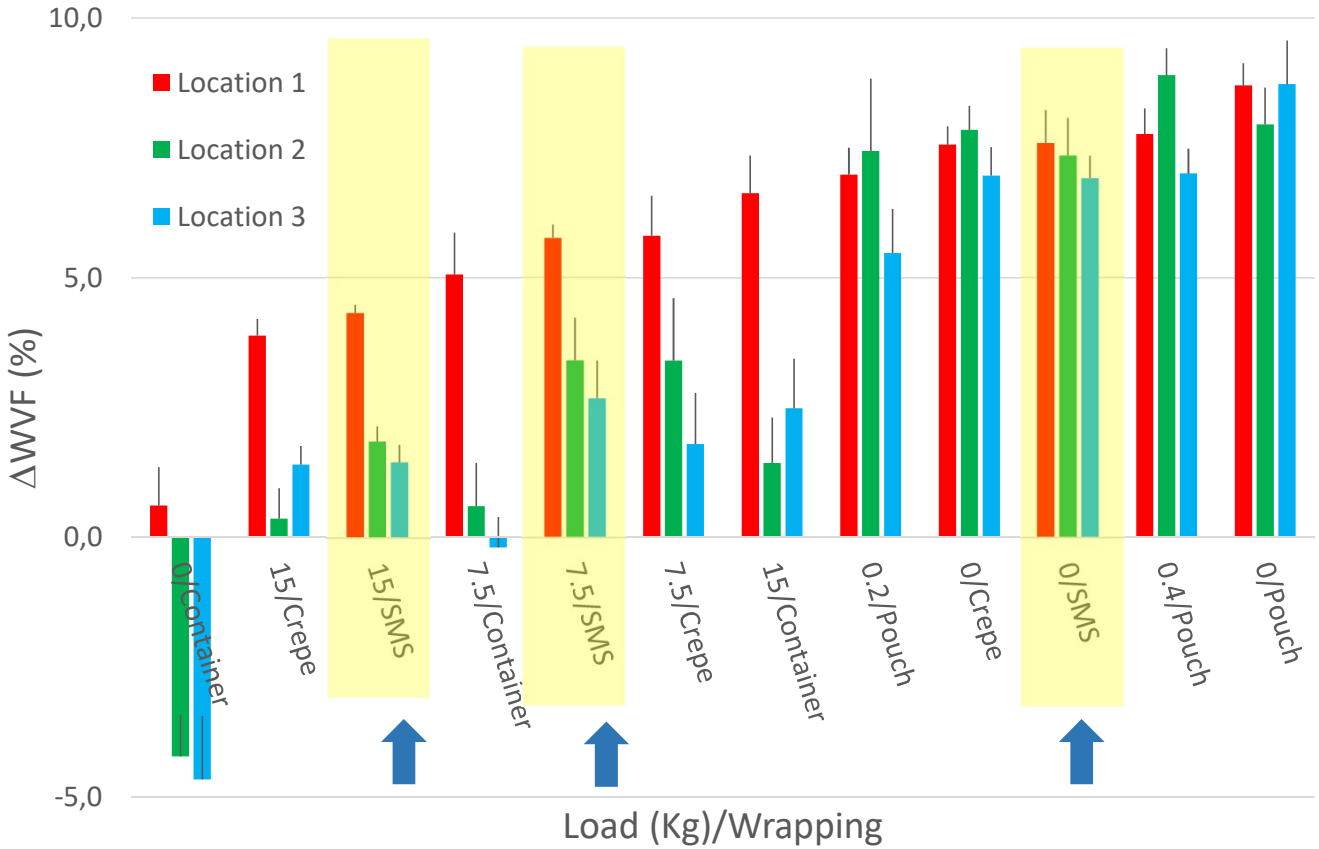
Quantitative analysis at the start of exposure phase



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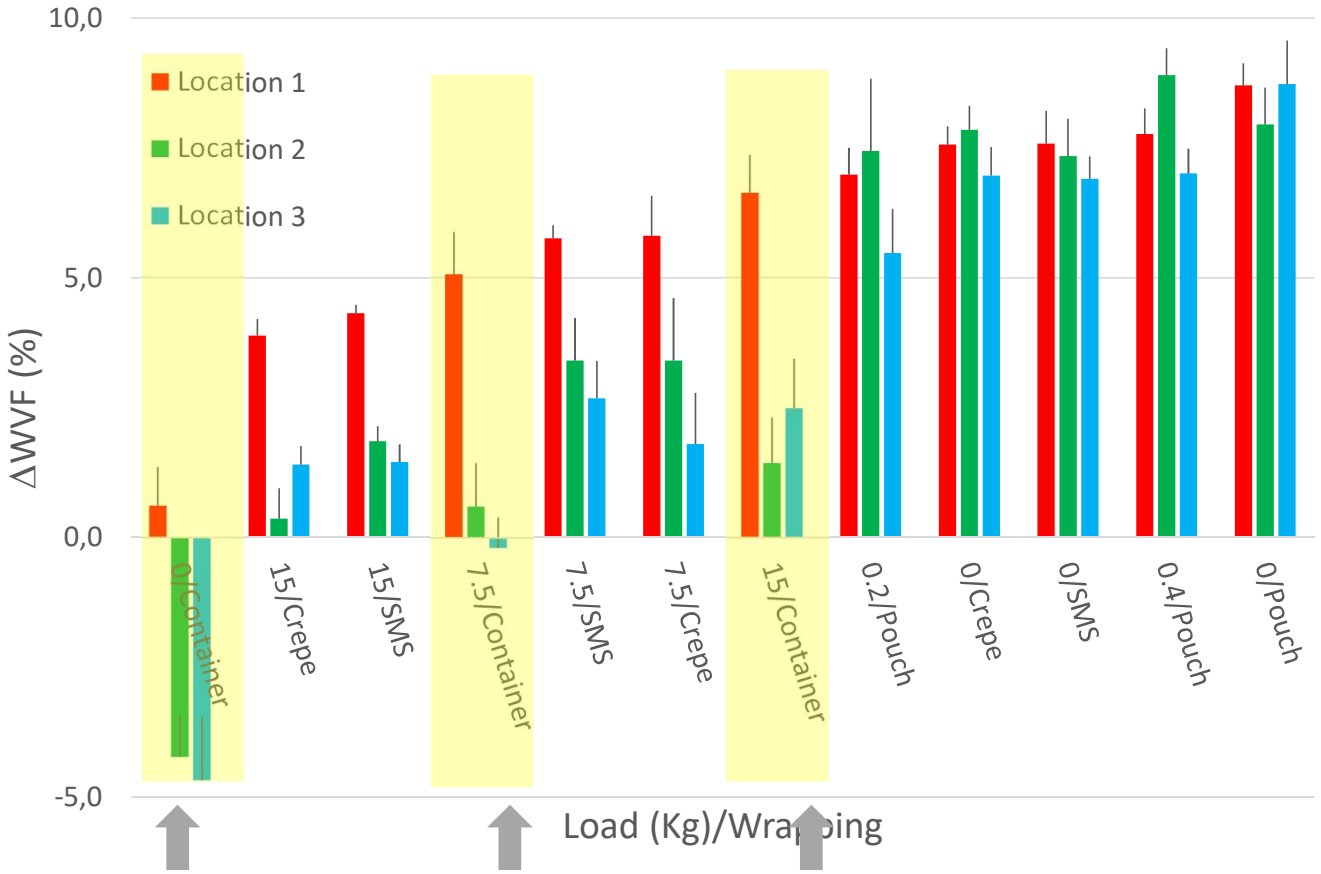

For rigid packing system (containers), the higher the load into the pack, the higher the steam penetration

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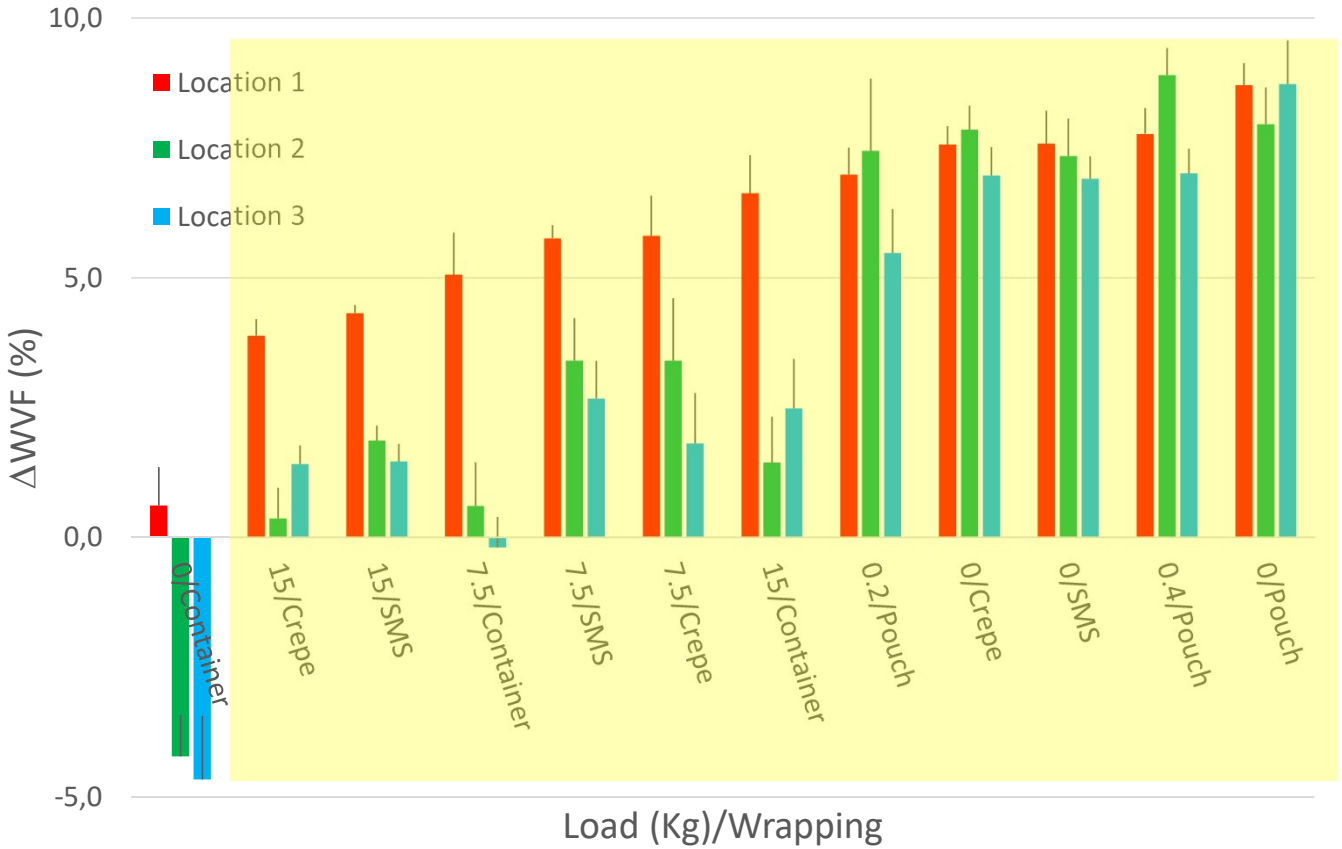
Quantitative analysis at the start of exposure phase



All tested wrapping/load combinations (but the 0/container) showed higher steam penetration in the 50 cm tube in the pack than in the 70 cm tube

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Conclusions 1/2

Measuring water vapour fraction (or NCGs) in channels is key to properly sterilize channeled instruments in a sterilizer.

Experimental data showed:

- Steam penetration (in channels) is affected by packaging/wrapping systems.

- The amount of load inside the pack is a non negligible driver for steam penetration (in channels).

Conclusions 2/2

The worst case for steam penetration in channelled instruments can be represented by an unwrapped 70 cm long tube.

A steam fraction sensor equipped with this tube can be used as a **steam penetration test** in a steam sterilizer to allow **process monitoring** of **massive** and **channelled instruments loads**.

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  Data collection
- Michela Masè,
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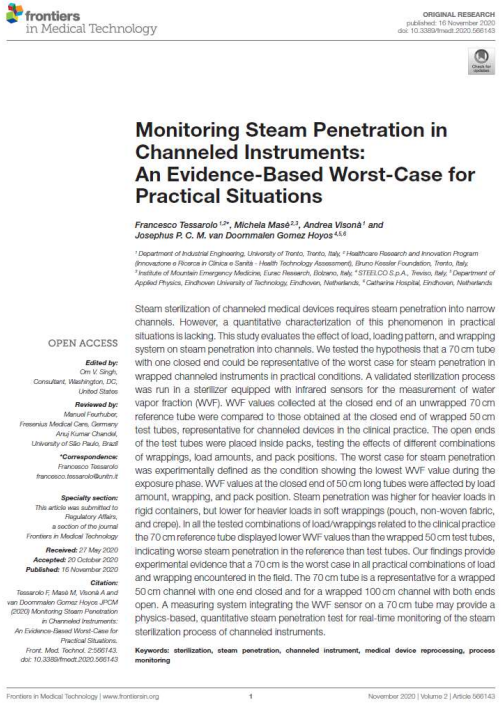
- Joost van Doornmalen
  experimental design and results discussion
- Lorenzo Bellotto & Pieraldo Croppo
  technical support



frontiers in Medical Technology

ORIGINAL RESEARCH

Monitoring Steam Penetration in Channeled Instruments: An Evidence-Based Worst-Case for Practical Situations

OPEN ACCESS

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Open access paper available at:
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