EXPLORING DIFFERENCES BETWEEN STEAM PENETRATION IN A B&D TEST PACK AND IN A CHANNELLED INSTRUMENT

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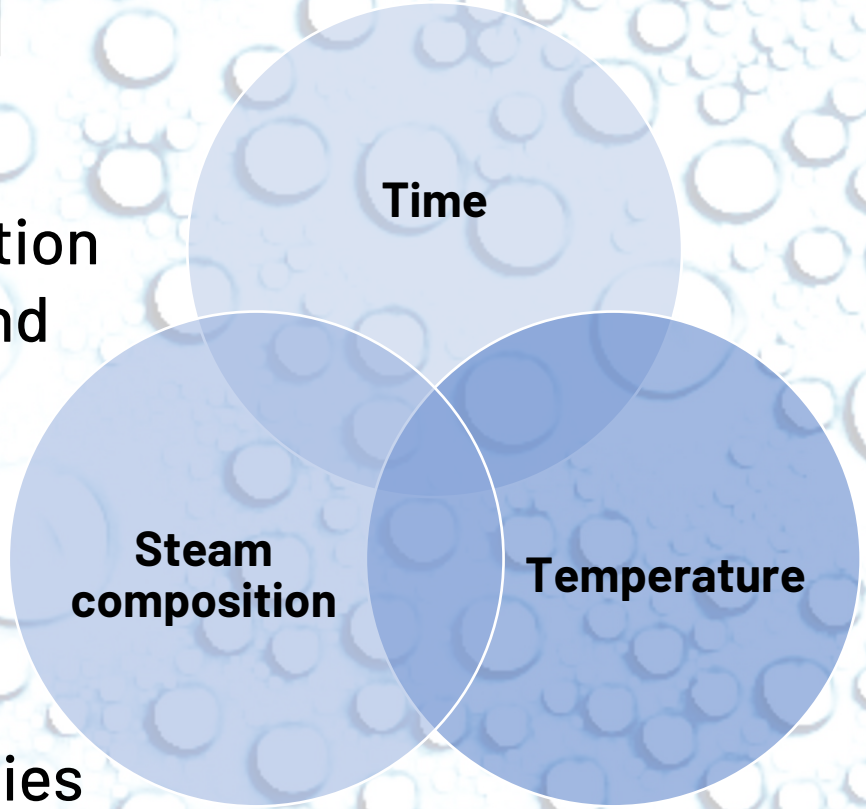
INTRODUCTION

Steam sterilization requires that all surfaces to be processed are exposed long enough to steam sterilization conditions (i.e. defined combination of temperature and time in the presence of sufficient humidity).



According to standards the steam penetration capacities of a sterilizer should be tested with a steam penetration test [ISO 17665:2024].

INTRODUCTION

In the early 1960s Bowie and Dick developed the first steam penetration test.

The original "Huckaback Towel Pack" according to Dr. J. H. Bowie and Mr. J. Dick

[THE BOWIE AND DICK AUTOCLAVE TAPE TEST, The Lancet, (1963), S.586]

This test was further developed and minimum performance requirements are defined in standards [ISO 11140-3, 11140-4, 11140-5].

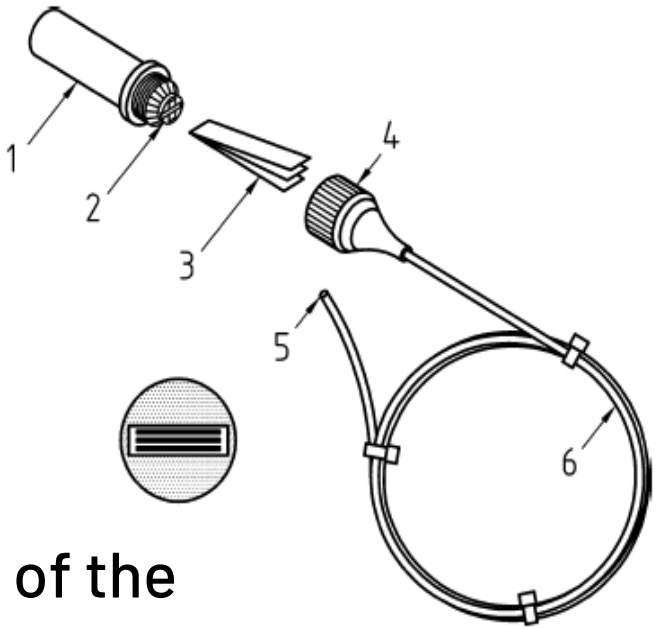
INTRODUCTION

The number of medical devices with channels is increased in last decades and a test for steam penetration in these devices would be very helpful, if not necessary.

INTRODUCTION

Often, proposed Process challenge devices (PCDs) are helix-shaped and are in practice referred to as hollow A, hollow load, helix, or helix shaped PCD.

These test device may look like a channel in a medical device but differ strongly in characteristics.



The PCDs defined in standards and those commercially available could be described as a system of two volumes connected by a narrow channel.

On one end of the channel there is the relatively large volume of the sterilizer, and on the other end the relatively small volume of the receptacle.

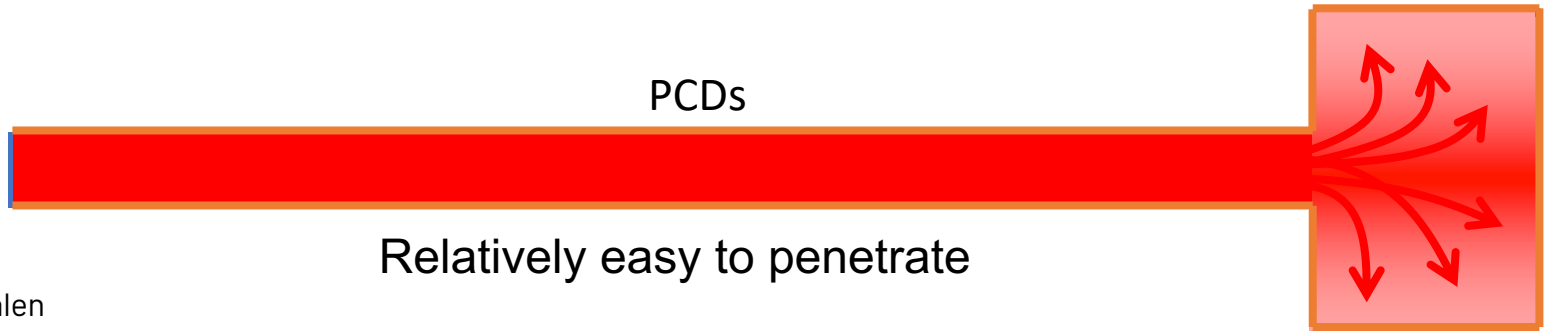
INTRODUCTION

Compared to a channel with a homogeneous radius over its full length, as present in medical devices, PCD systems with communicating volumes have different characteristics.

LUMENED INSTRUMENT

Relatively difficult to penetrate

PCDs



Relatively easy to penetrate

Credit to JPCM van Doornmalen

INTRODUCTION

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Steam penetration in thin-walled channels and helix shaped Process Challenge Devices

J.P.C.M. van Doornmalen Gomez Hoyos*[1,2], K. Kopinga[1]

"Helix devices with chamber do not represent narrow channels without "chambers"

"Hollow A PCD cannot be used to predict the steam penetration in other channels as long as the receptacle is not accurately specified"

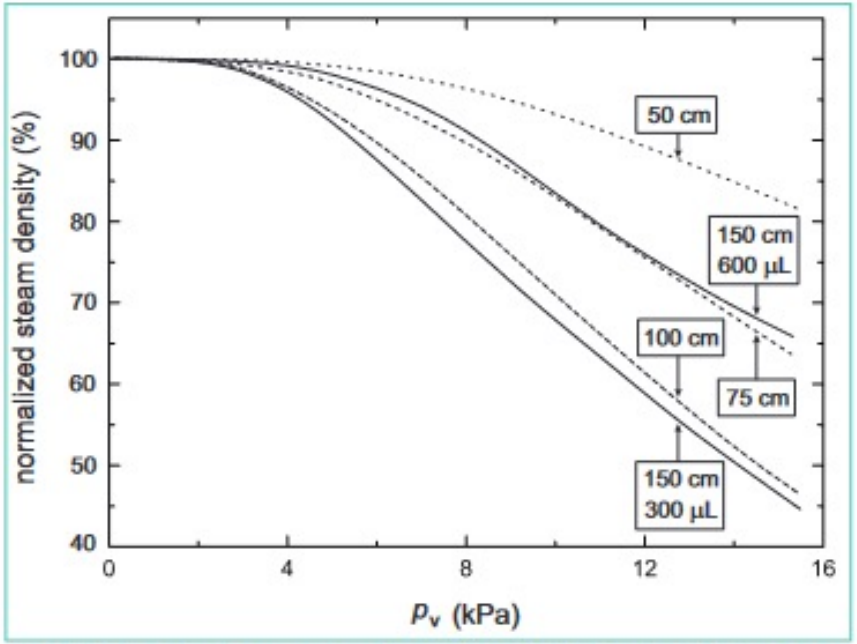

Fig. 5: Calculated vapour density at the start of the sterilization phase (see figures 2 and 3) at the closed end of various channels as a function of the pressure p_v of the vacuum level control points of a generic sterilization process with 4 identical vacuum pulses. The solid curves denote the results for channels with a length of 1.5 m and a diameter of 2 mm connected to a measurement chamber of 300 and 600 µL, respectively. The dashed curves denote the results for channels of 50, 75 and 100 cm without an additional volume at the closed end. The vapour density is normalized to the density of saturated steam of 134 °C.

INTRODUCTION

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Current reference devices for hollow instrument loads as defined in standards are not a valid steam penetration test

S. Esen[1], F. Tessarolo[2], R.J. Hermsen[3] and J.P.C.M. van Doornmalen*[3]

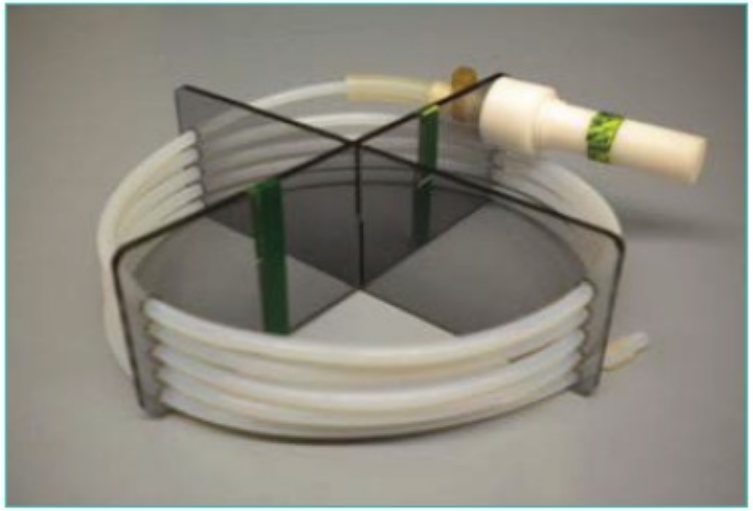


Fig. 1: Hollow A or helix Process Challenge Device as specified in the standards [10,11] and further specified in the TC 198 WG6 documents. The tubing is placed in a holder because tubing bound together may influence the results [16]. In the receptacle a CI can be loaded before use in a process. After a process the CI can be taken out and investigated.

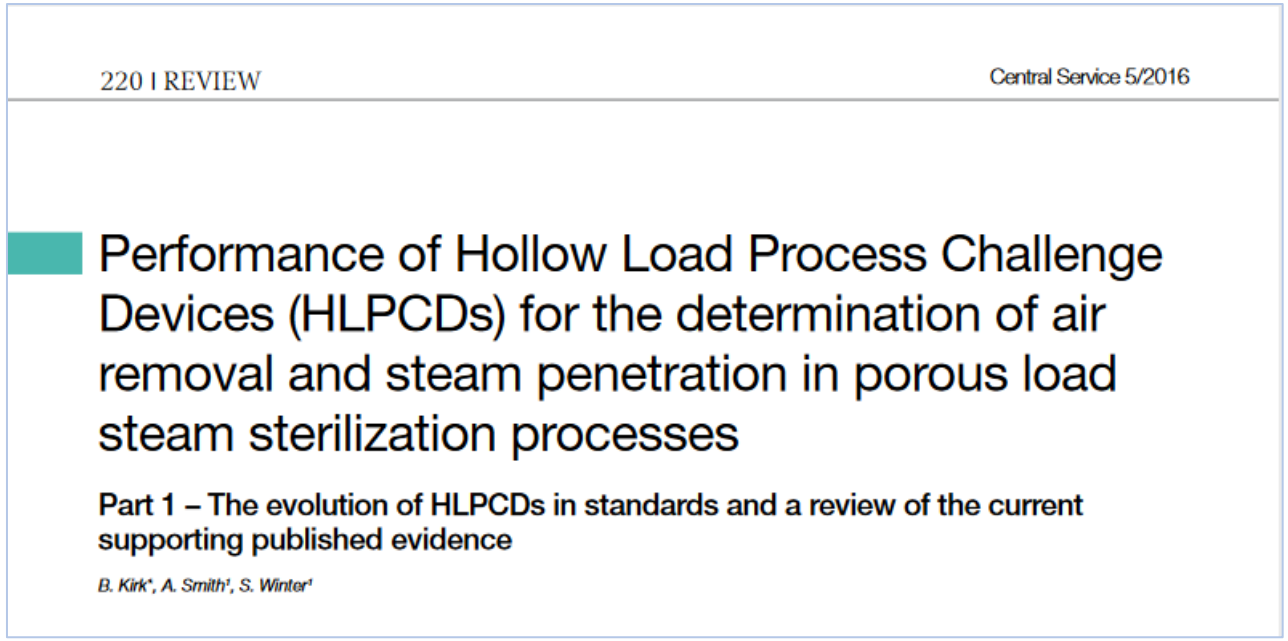
"The used reference PCD is not suitable as steam penetration tests for instruments with narrow channels"

"The reference hollow A PCD tested in this study and the hollow A PCD defined in the standards do not meet the current steam penetration requirement"

INTRODUCTION

"With regard to the apparent acceptance of the HLPCD in EN867-5 into custom and practice for batch monitoring, the literature suggests this may be misleading."

"The rate of pressure change on steam penetration efficacy is a factor which requires further examination, and which is largely ignored by the standards for steam sterilization."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Performance of Hollow Load Process Challenge Devices (HLPCDs) for the determination of air removal and steam penetration in porous load steam sterilization processes

Part 1 – The evolution of HLPCDs in standards and a review of the current supporting published evidence

B. Kirk*, A. Smith†, S. Winter†

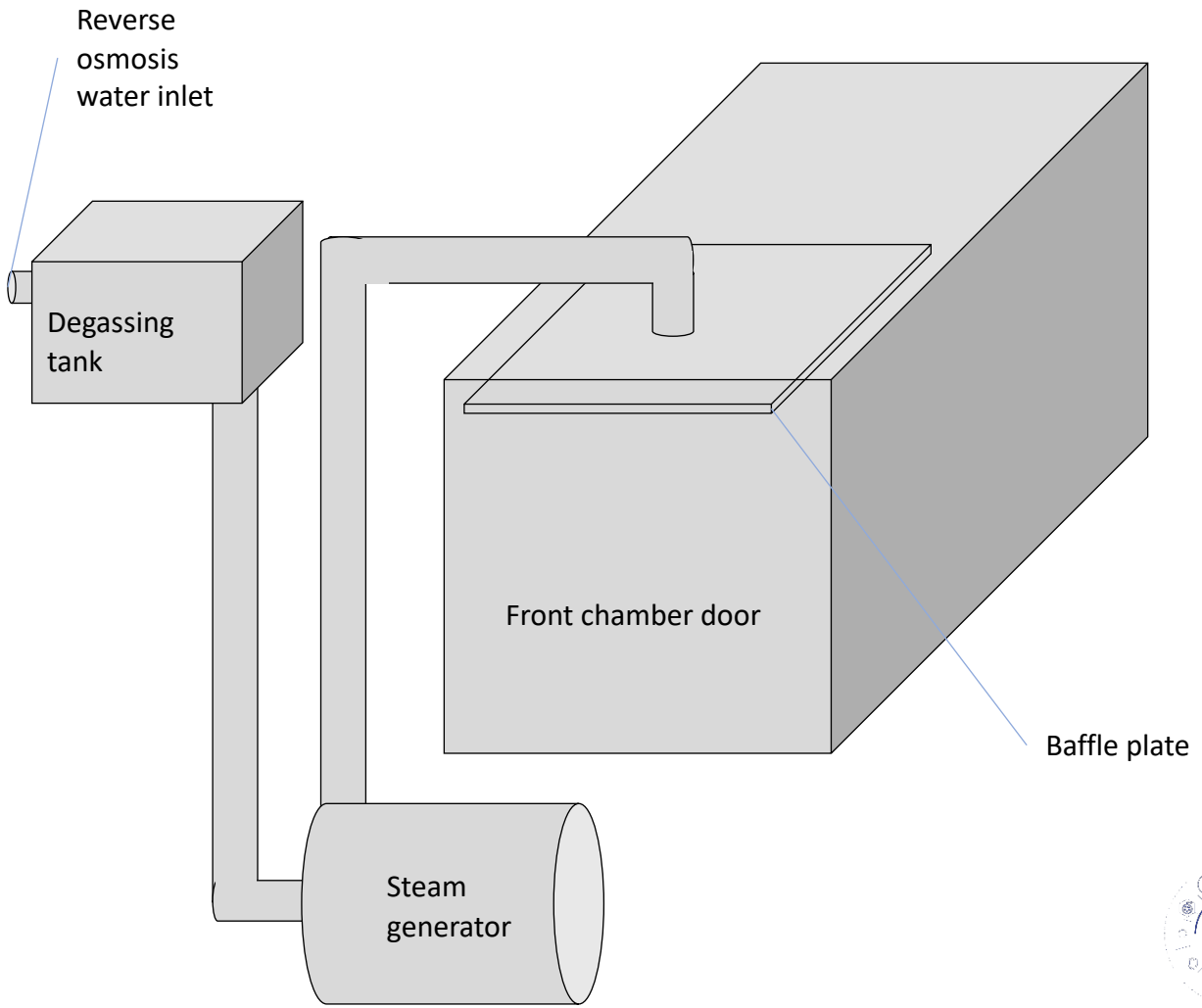
AIM of the study

Explore whether significant differences exist between steam penetration in a (alternative) B&D test pack and in a channel, representative for a channelled instrument.

Provide further insight into differences between steam penetration into porous loads and channelled loads in experimental conditions close to CSSD practice.

METHODS - Sterilizer

Experiments were performed in a 8 units (614 L) commercial sterilizer equipped with a degassing system and fed with osmotic water.

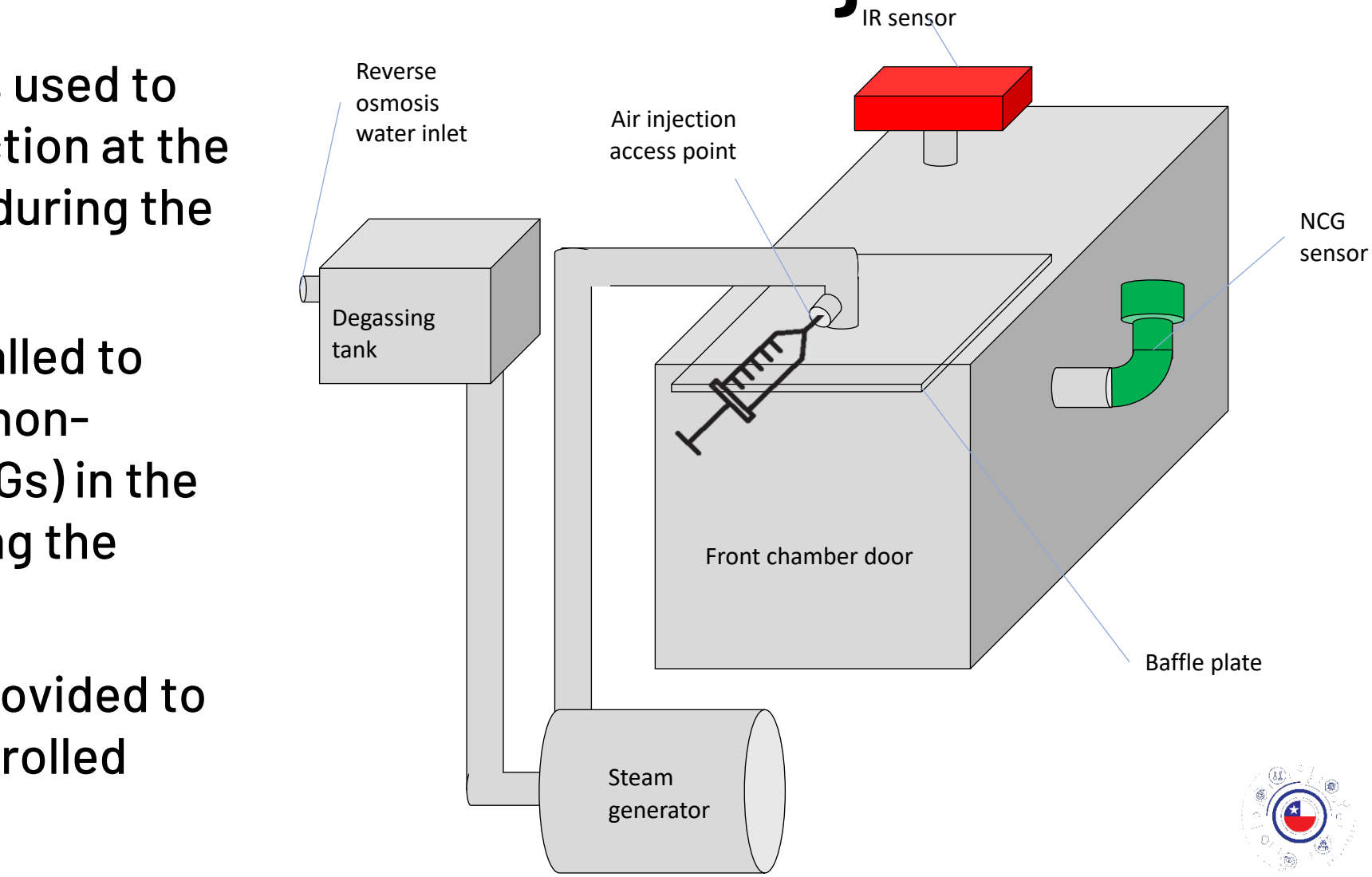


METHODS – Sensors and air injection

An infrared sensor was used to monitor the vapour fraction at the end of 70 cm long tube during the exposure phase.

A NCG sensor was installed to monitor the amount of non-condensable gases (NCGs) in the sterilizer chamber during the exposure phase.

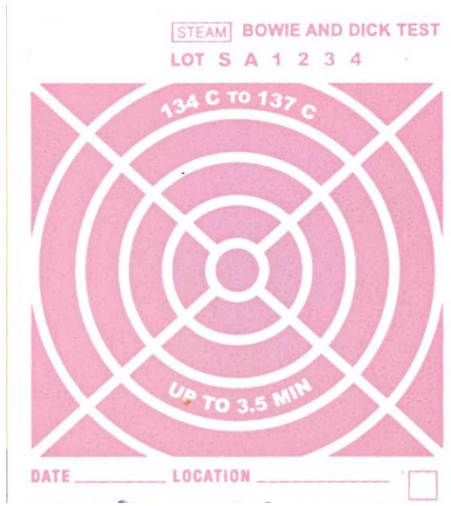
An access point was provided to allow admission of controlled volumes of air.



METHODS – B&D test pack

An alternative B&D test pack (stated values 134°-137°C, 3.5 min) , compliant to ISO 11140-4:2007, was positioned in the chamber in every cycle.

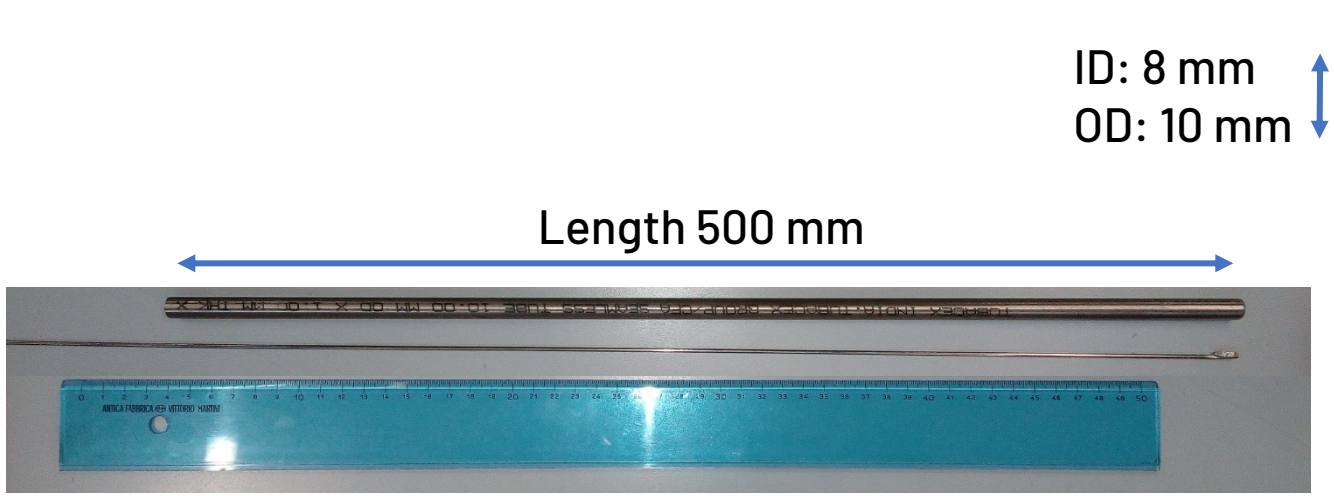
Unexposed or Failed

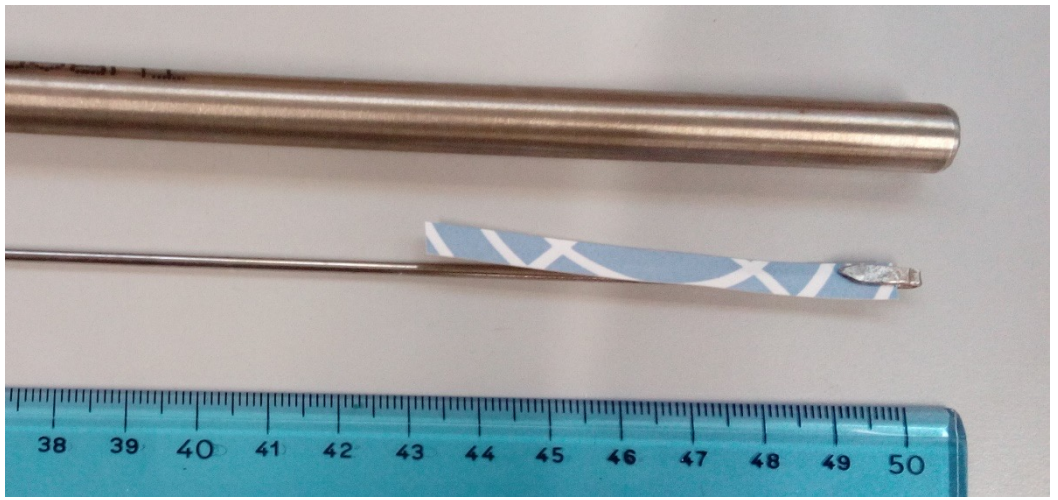


Passed

METHODS – Challenge tube

A chemical indicator (CI) strip, obtained from a new B&D test pack (same brand and lot) was inserted up to the closed end of a stainless-steel challenge tube (8 mm internal diameter, 50 cm long, and with 1 mm thick walls).



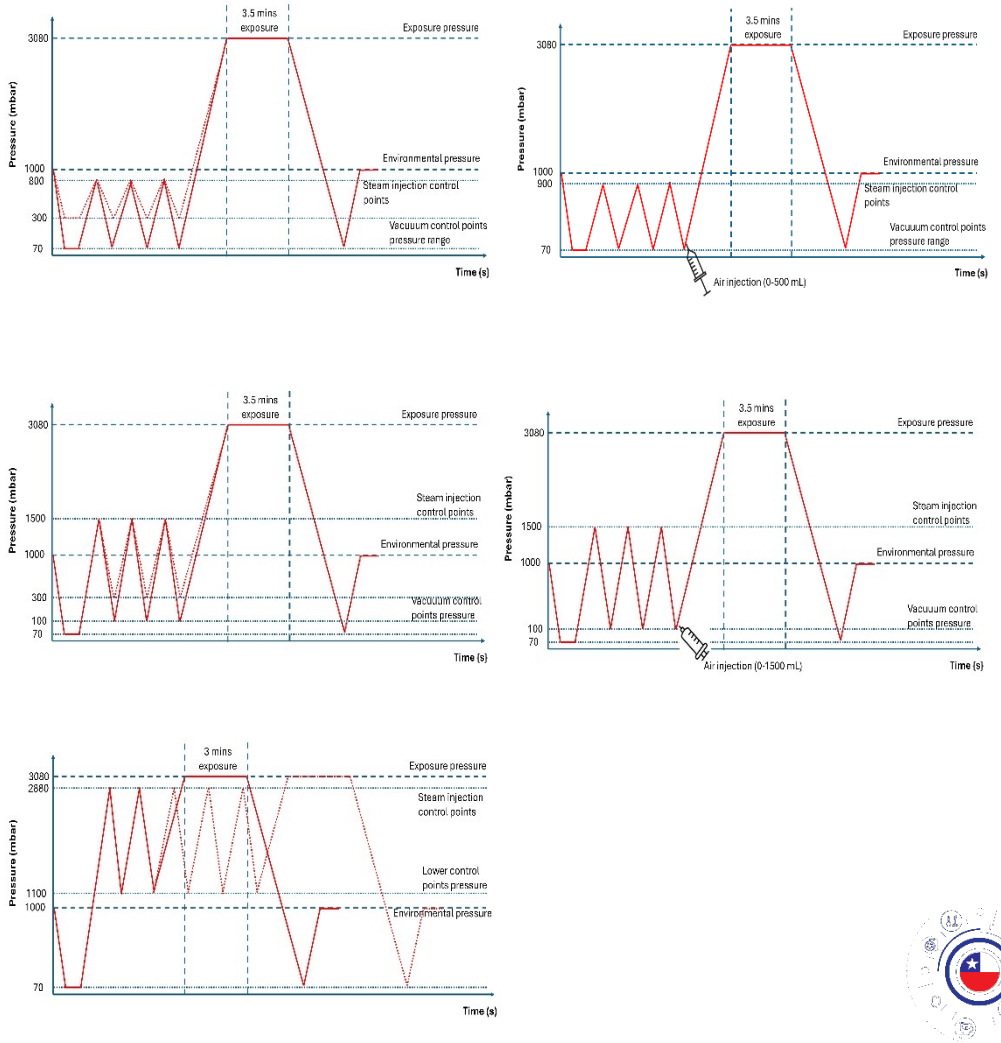


METHODS - Processes

Conditioning:
Sub-atmospheric, trans-atmospheric and supra-atmospheric

NCGs:
Variation of the vacuum point pressure.
Admission of air (0-1500 mL) at the beginning of the come-up ramp.
Variation of the number of pulses in the conditioning phase.

Exposure:
All processes shared a 3.5 minutes-long exposure phase at 134.5°C.



METHODS – Load amount

Load amount included:

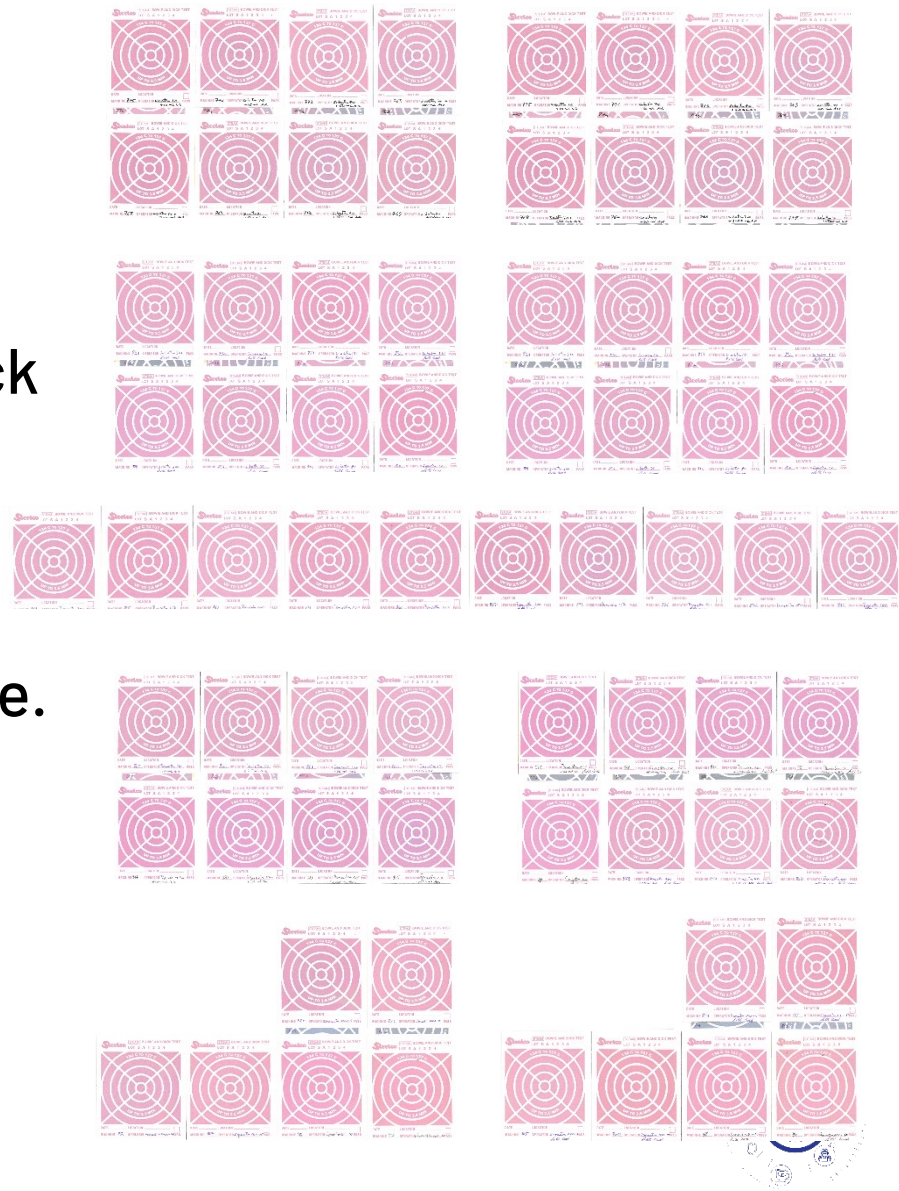
- empty chamber (only B&D test pack and challenge tube)
- full load (8 nets of 15 kg metallic unwrapped load each + B&D test pack and challenge tube).

No additional load

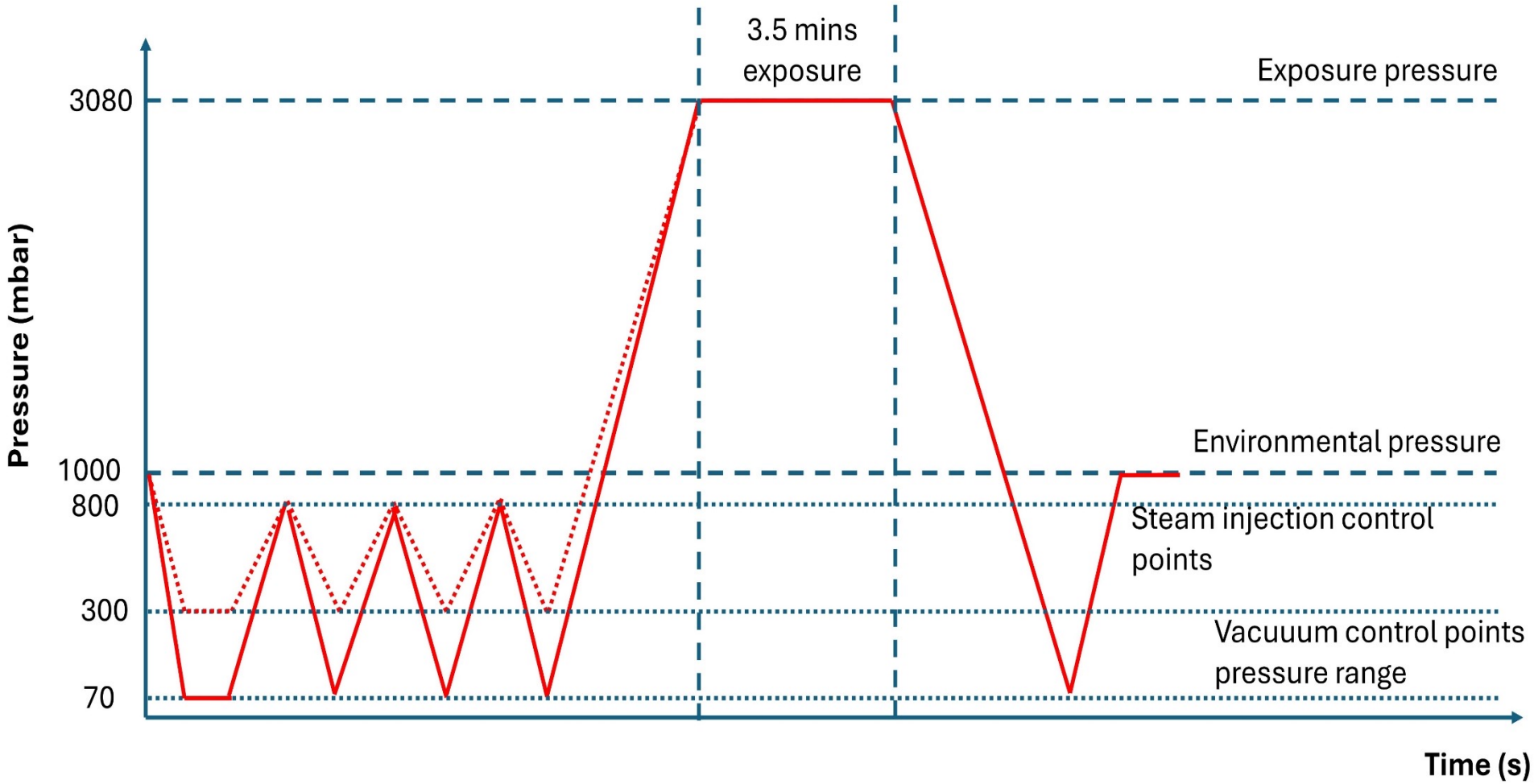
Full load (120 kg SS + loading trolley)

RESULTS

- A total of 76 combinations of processes and loads were tested.
- All processes resulted in a pass of the B&D test pack
- Only sub-atmospheric and trans-atmospheric processes with deep vacuum points or a limited amount of injected air resulted in a colour change of the CI positioned in the 50 cm long challenge tube.
- Supra-atmospheric processes never produced a colour change of the CI in the challenge tube, regardless of the number of pulses in the preconditioning phase (tested up to a max of 40 pulses).



RESULTS: Sub-Atm – Vacuum variation

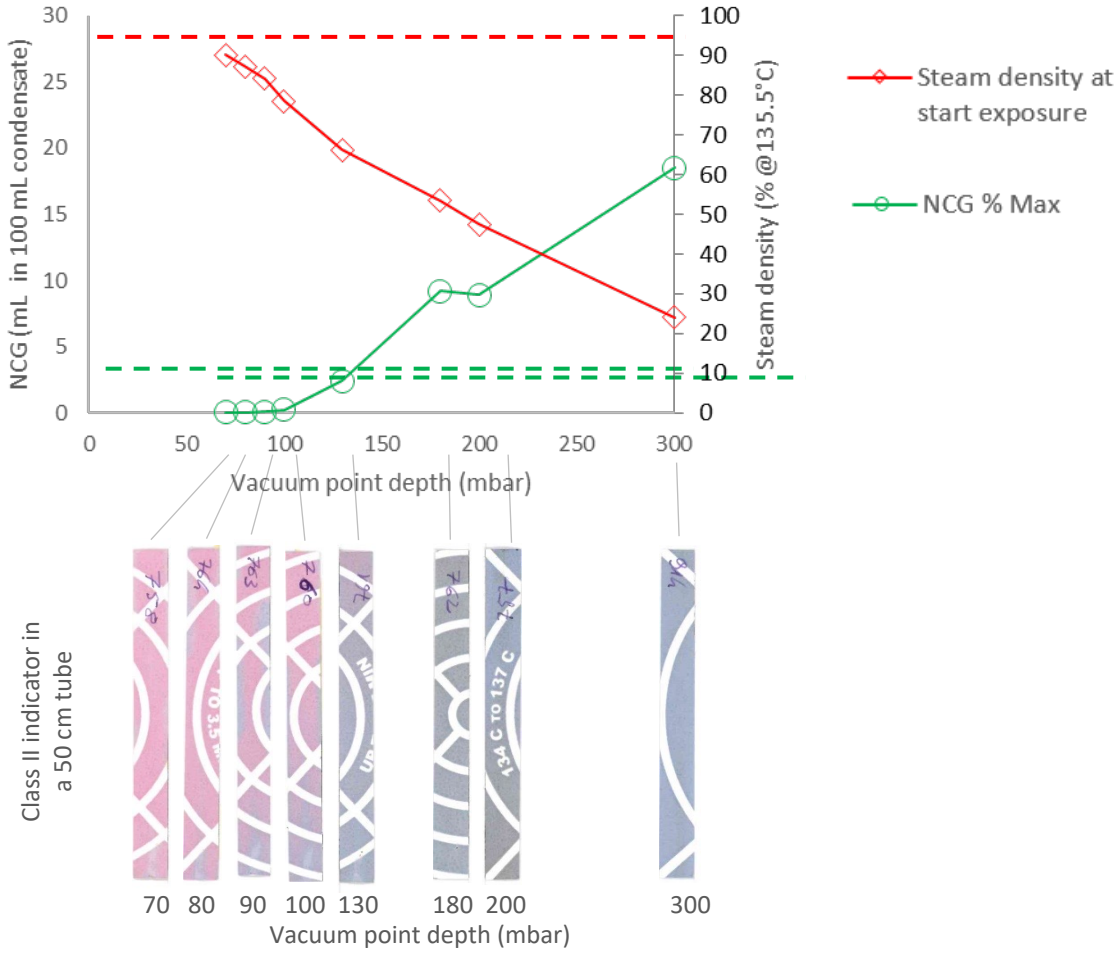


The conditioning phase included only sub-atmospheric pulses.

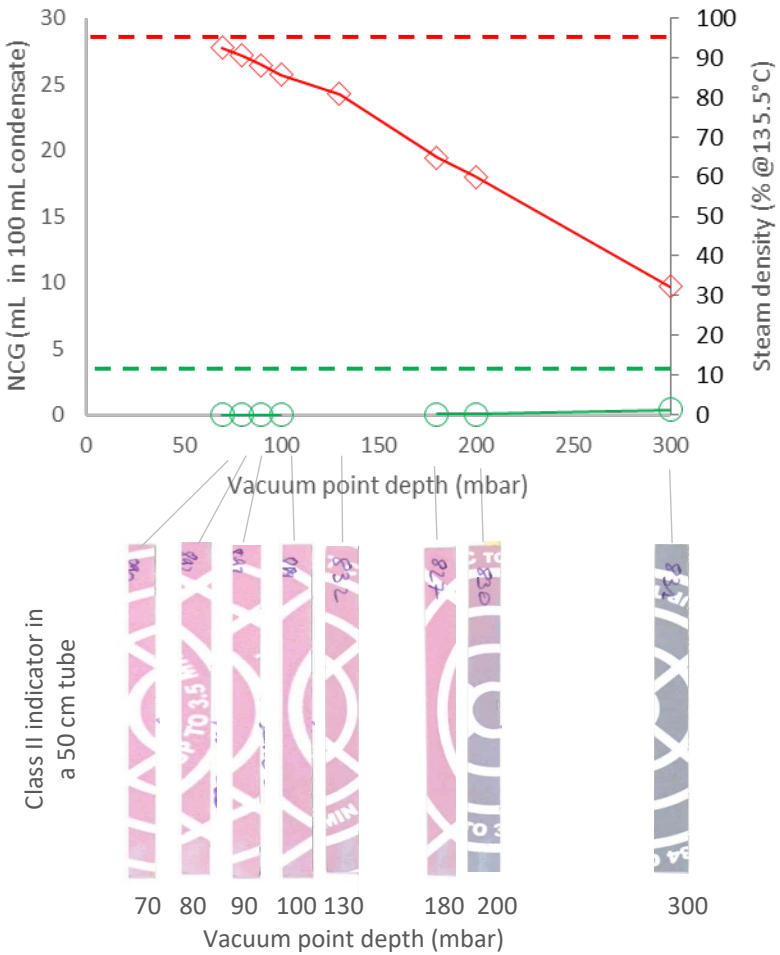
The vacuum control point pressure was varied between 70 and 300 mbar

RESULTS: Sub-Atm – Vacuum variation

Empty load



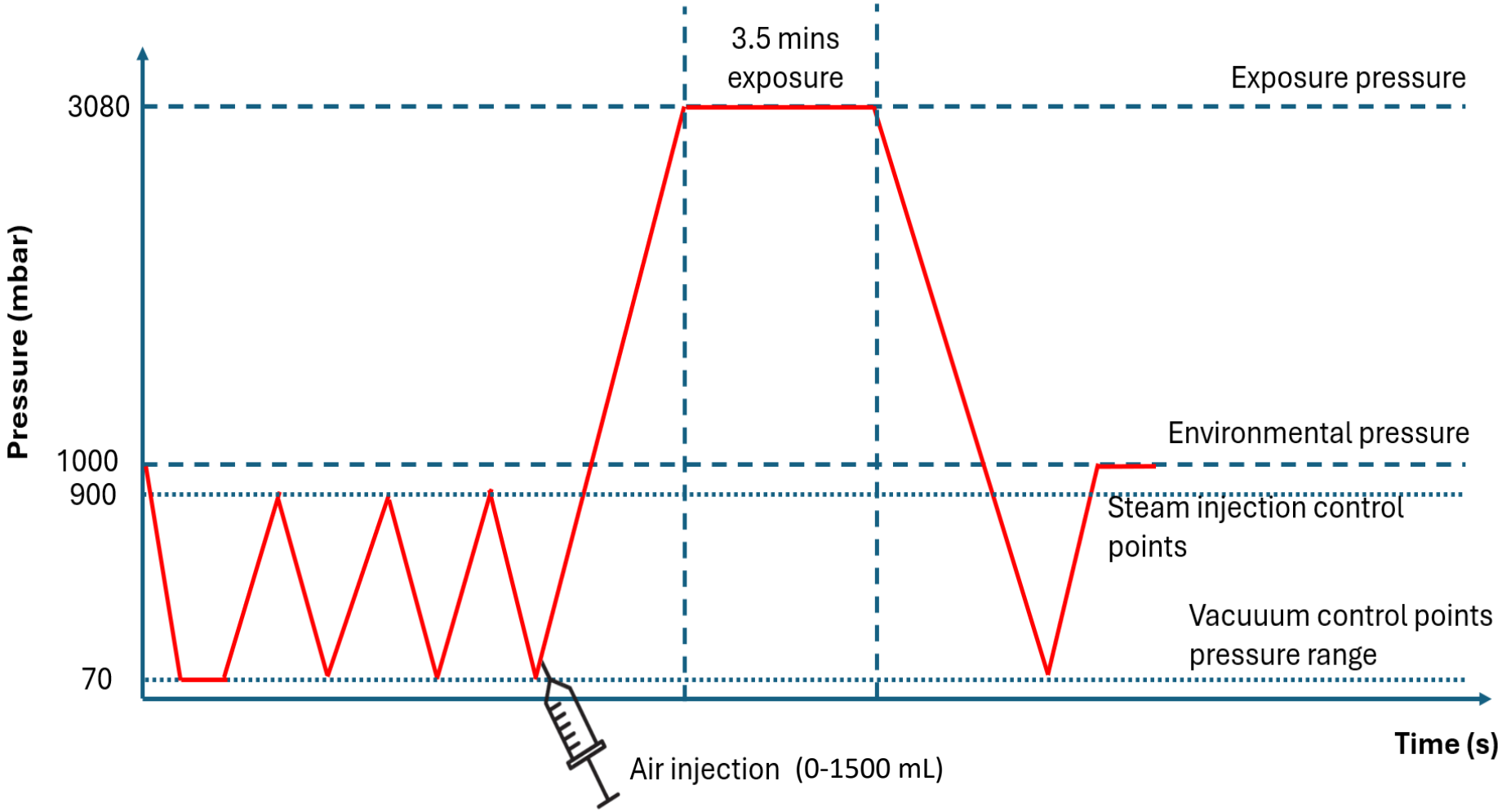
Full load



Not all CI strips turned pink, showing conditions at the end of the challenge tube were different from B&D pack.

The worse the vacuum, the worse the steam penetration in channels.

RESULTS: Sub-Atm- Air admission

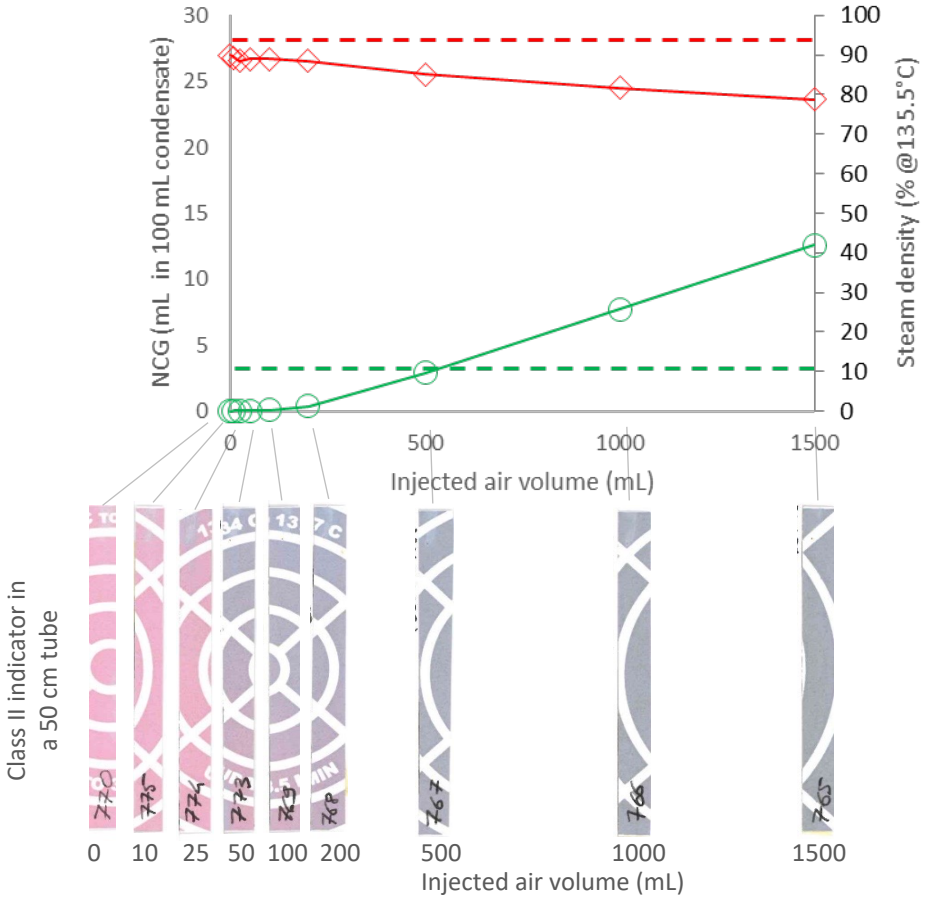


The conditioning phase included only sub-atmospheric pulses with vacuum control point pressure set at 70 mbar

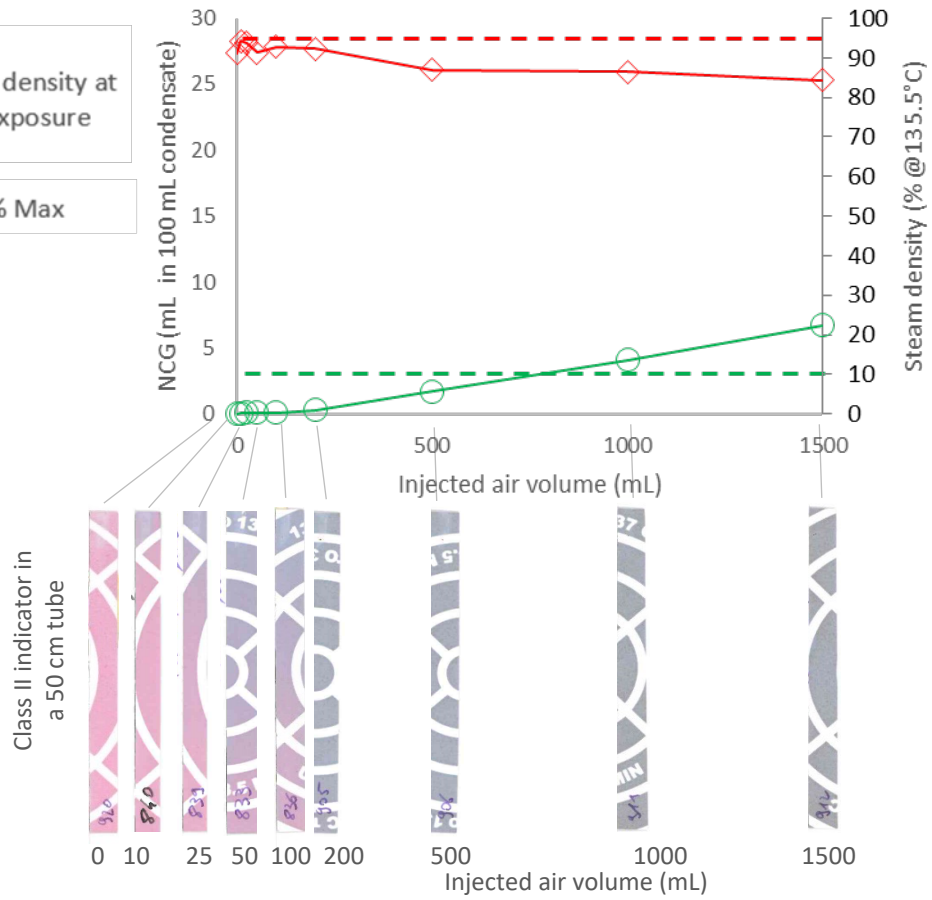
A volume (0-1500 mL) of air was admitted at the start of the come-up ramp.

RESULTS: Sub-Atm- Air admission

Empty load

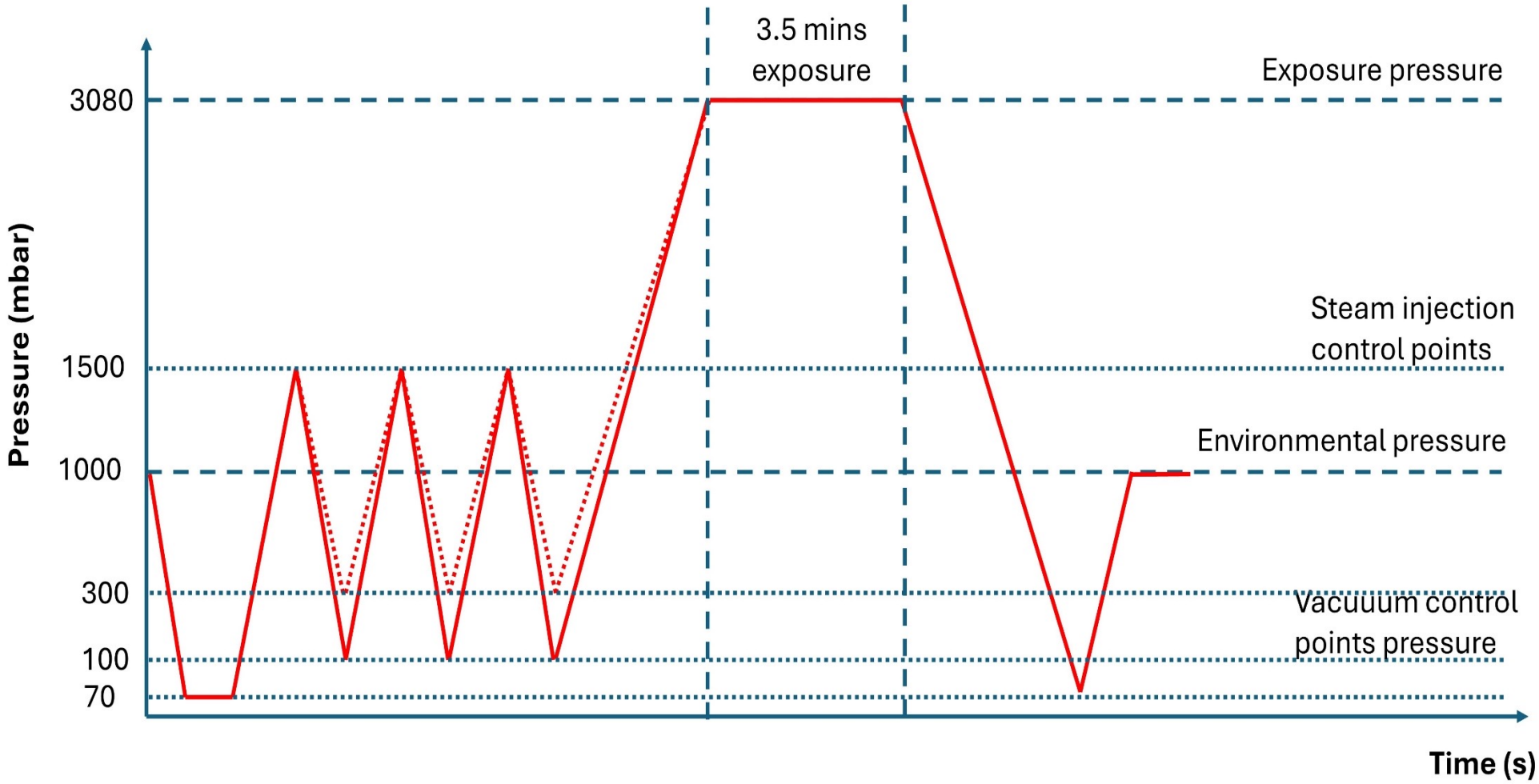


Full load



The higher the admitted air volume, the worse the steam penetration in channels.

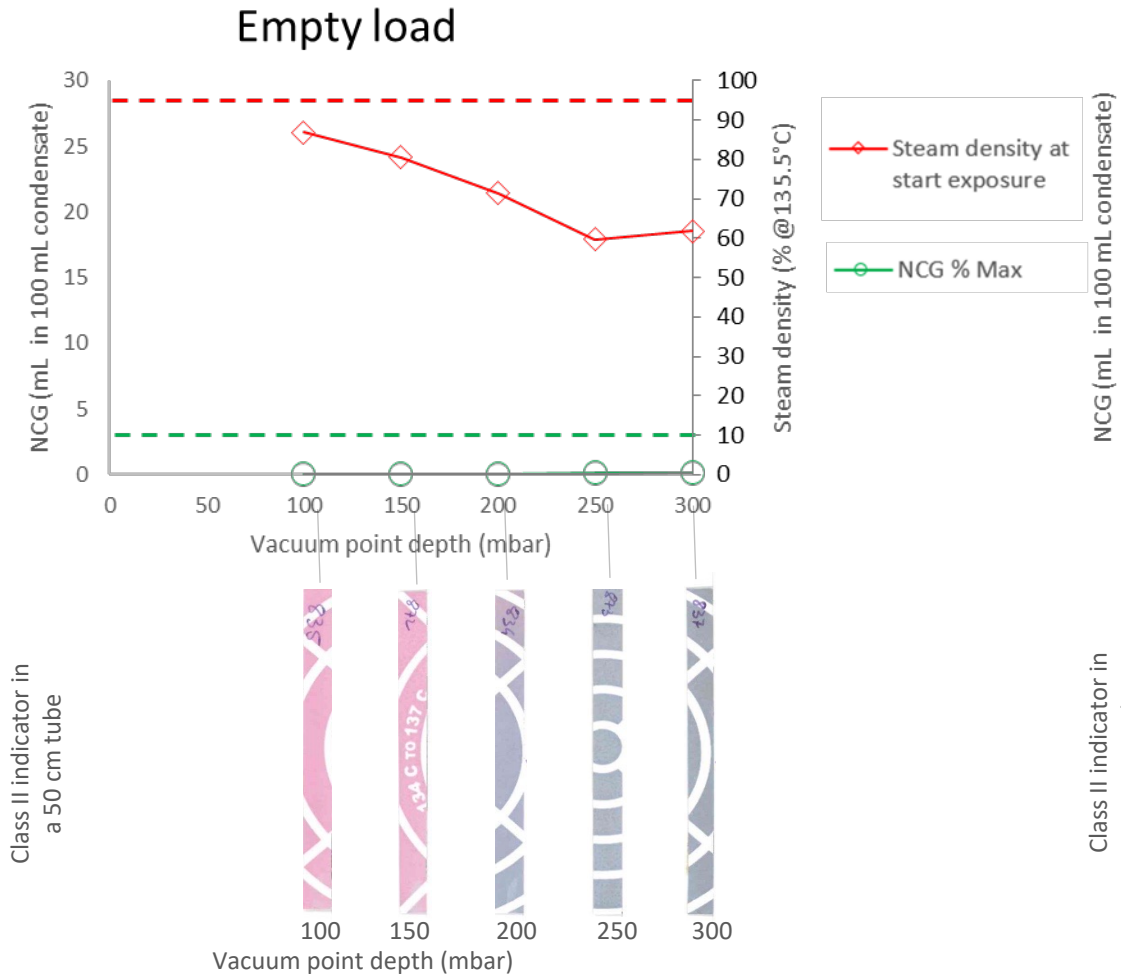
RESULTS: Trans-Atm- Vacuum variation

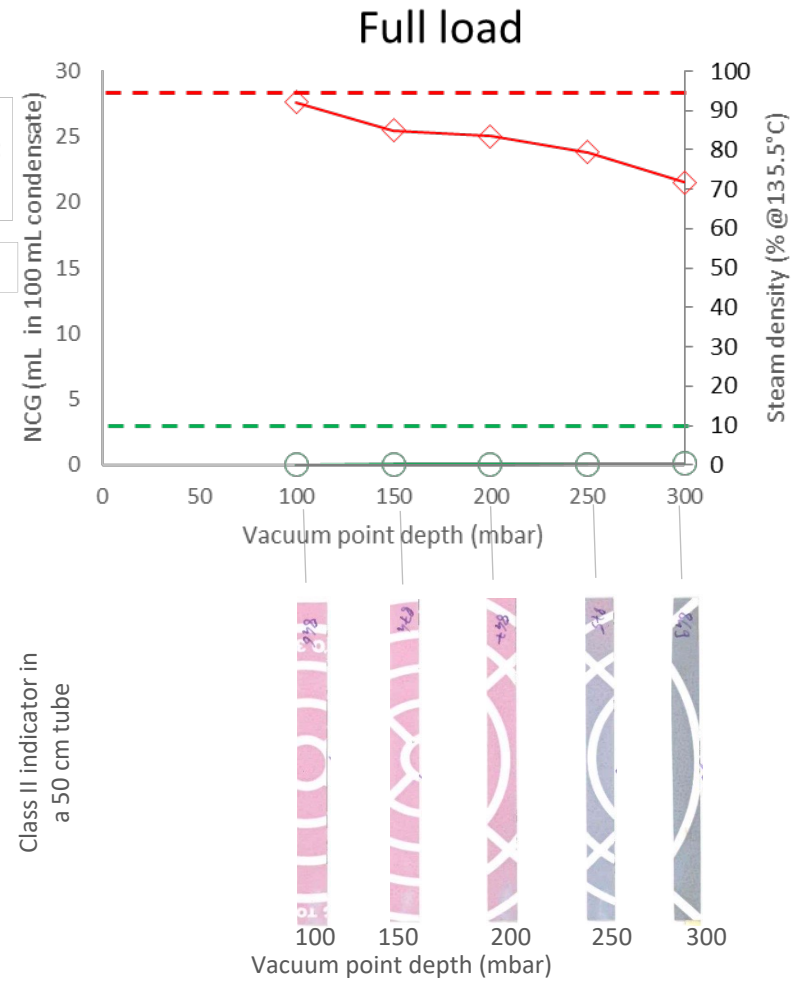


The conditioning phase included trans-atmospheric pulses.

The vacuum control point pressure was varied between 100 and 300 mbar

RESULTS: Trans-Atm- Vacuum variation

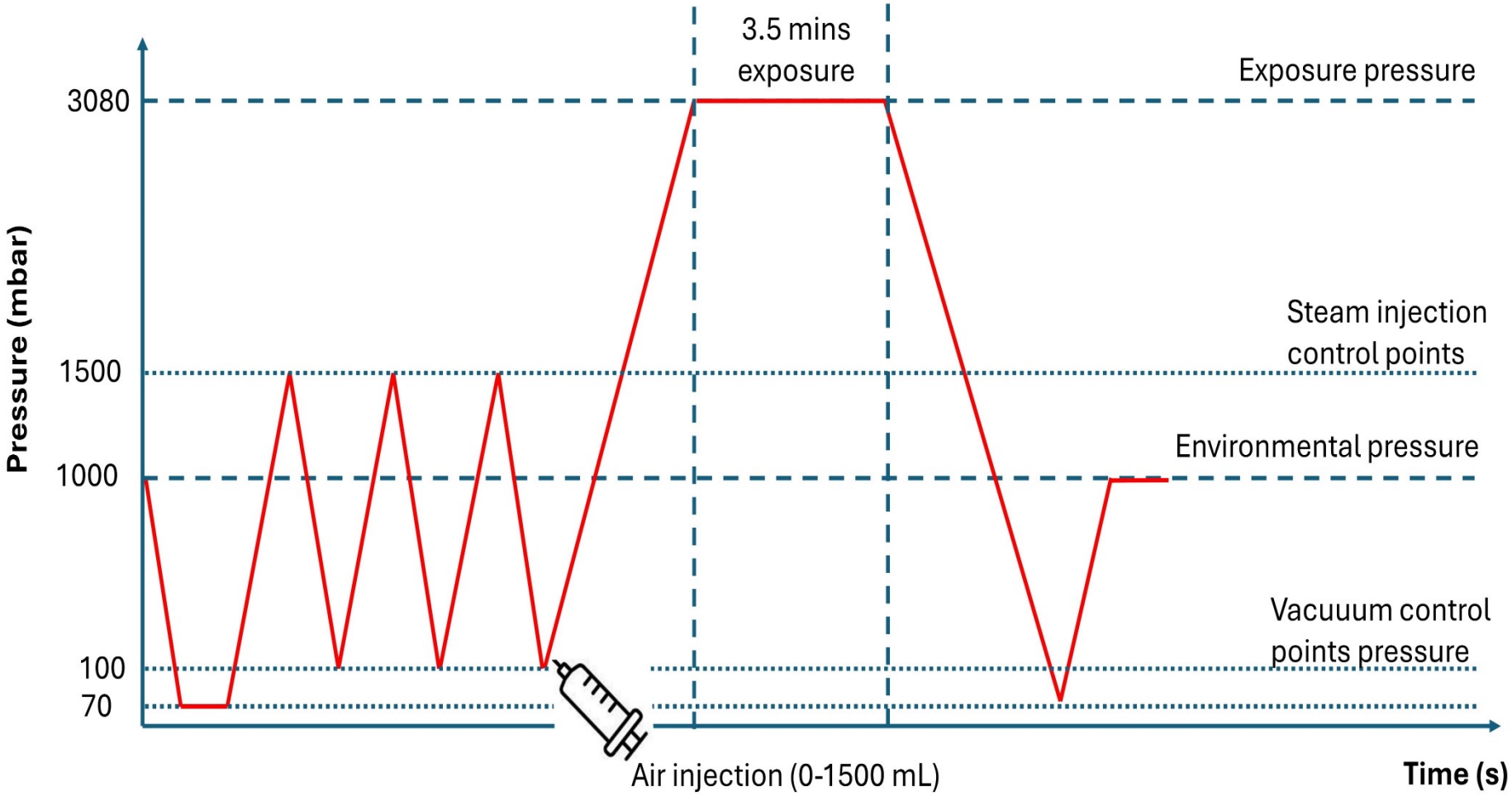




Not all CI strips turned pink colour, despite low amount of NCGs in the exposure phase.

The worse the vacuum, the worse the steam penetration in channels.

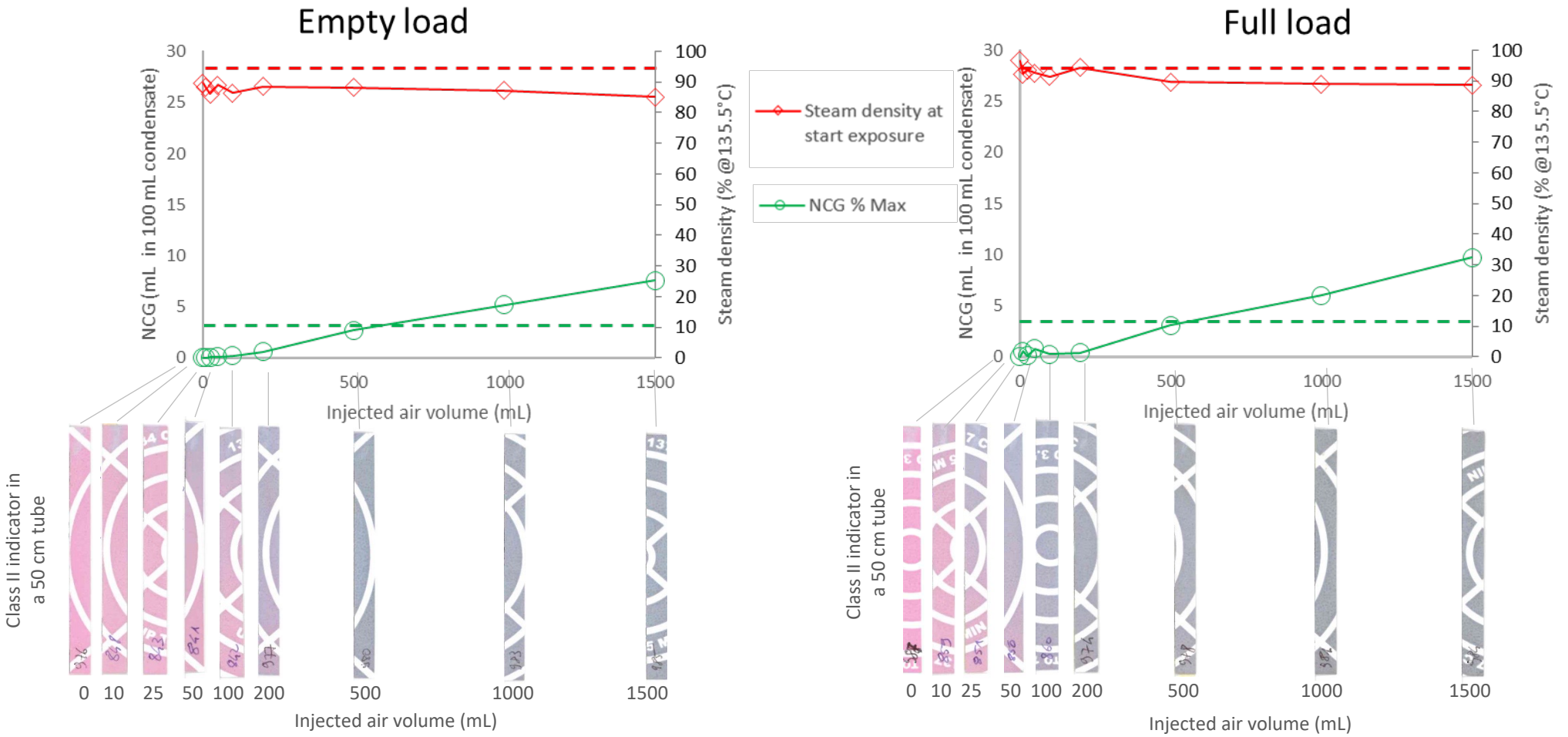
RESULTS: Trans-Atm- Air admission



The conditioning phase included trans-atmospheric pulses with vacuum control point pressure set at 100 mbar

A volume (0-1500 mL) of air was admitted at the start of the come-up ramp.

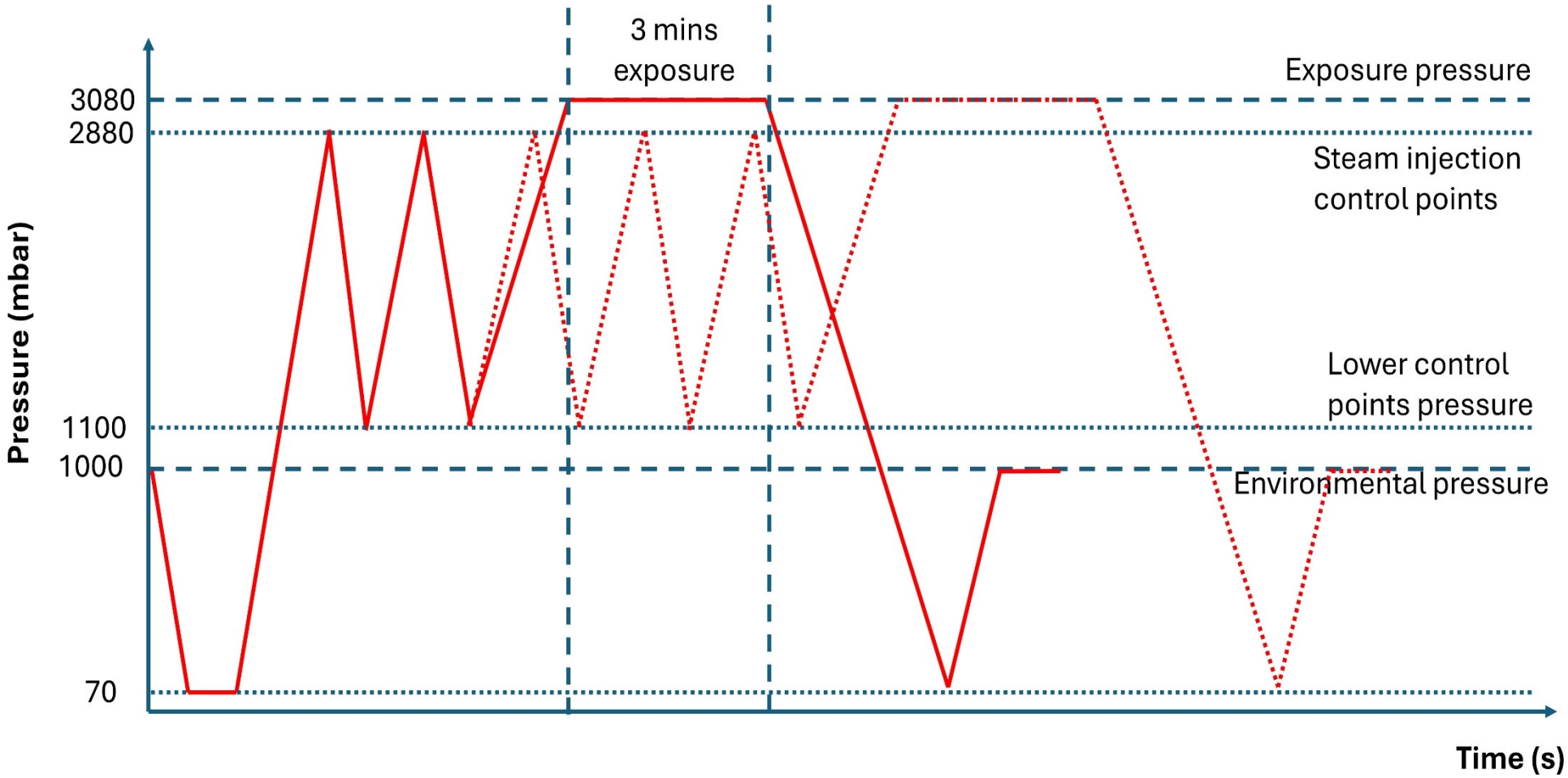
RESULTS: Trans-Atm- Air admission



The higher the admitted air volume, the worse the steam penetration in channels.

No major impact on NCG by load amount.

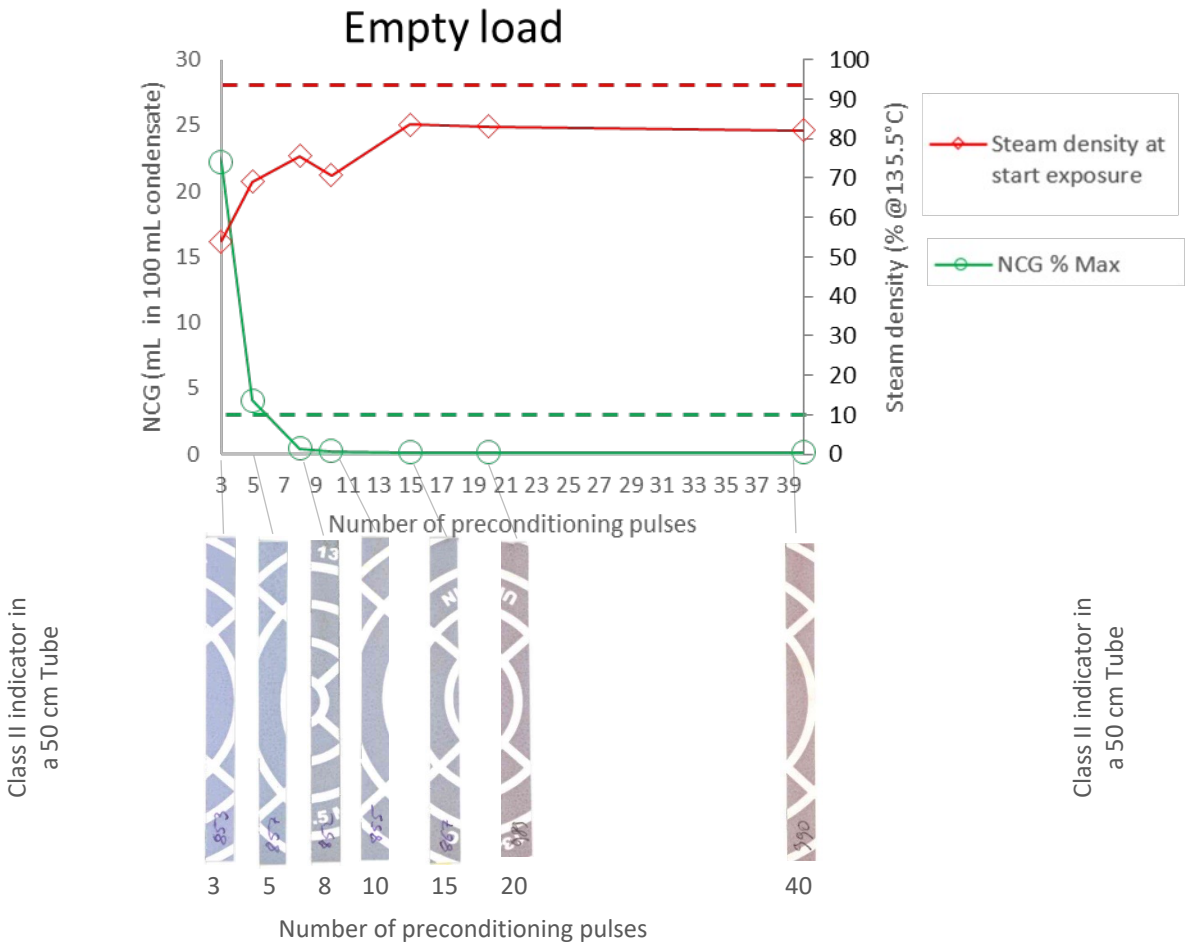
RESULTS: Supra-Atm- Pulse number variation

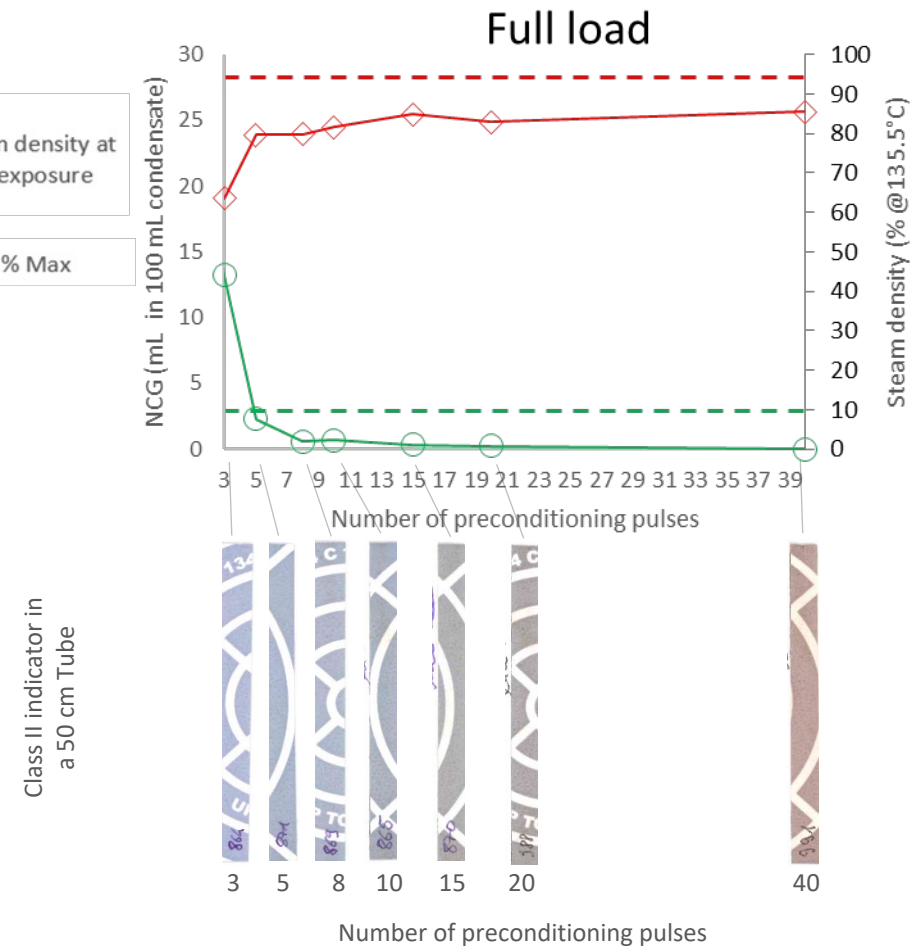


The conditioning phase included supra-atmospheric pulses within 1100 and 2880 mbar.

The number of supra atmospheric pulses was varied from 3 to 40.

RESULTS: Supra-Atm- Pulse number variation





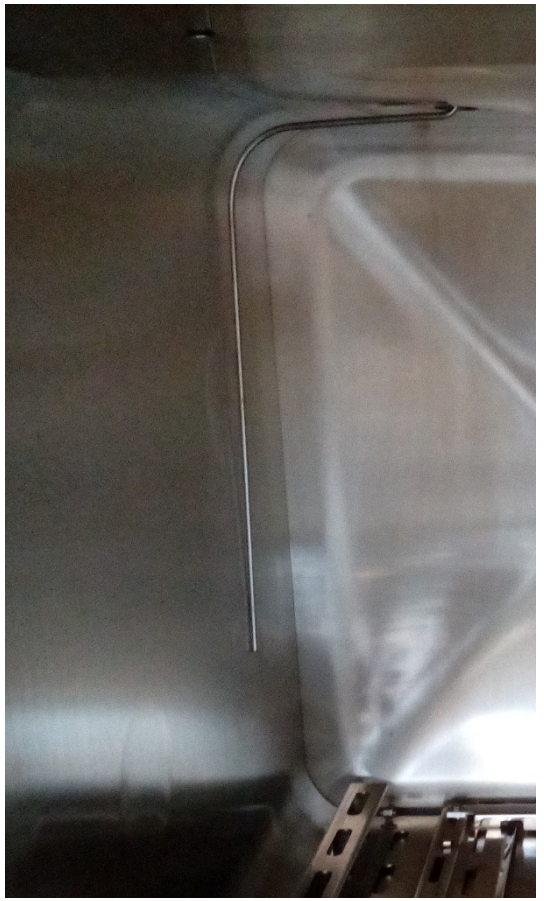
CIs did not turn pink, although NCGs in the chamber were effectively reduced when using a high number of supra-atm pulses.

RESULTS – NCGs in the sterilizer chamber

- NCG sensor data documented that the deeper the vacuum points in the conditioning phase the lower the amount of NCGs in the exposure phase.
- Air injections in the come-up ramp also elevated NCGs amount in the exposure phase.
- Supra-atmospheric processes resulted in a low content of NCGs in the sterilizer chamber only when several pulses were used.

RESULTS – Vapour fraction in the 70 cm challenge tube

- IR sensor detected higher vapour fractions when deeper values of vacuum points were achieved, and no air was injected.
- Supra-atmospheric processes never resulted in high vapour fractions despite low NCG amounts in the chamber.
- In general, the higher the load amount the higher the vapour fraction in the 70 cm long tube connected to the sensor.



CONCLUSIONS

B&D test pack does not provide relevant information about steam penetration in channelled loads.

Channels (even with relatively large diameter, e.g. 8mm, and limited length, e.g. 50cm) are challenging to be penetrated by steam and demand for:

- low amounts of NCGs in the sterilizer chamber
- effective air removal in the conditioning phase (e.g. multiple deep vacuum points during sub-atmospheric or trans-atmospheric conditioning).

Steam penetration in channels cannot be obtained using supra-atmospheric conditioning within a time interval compatible with CSSD production.

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