## 1. Introduction

During validation of steam sterilization processes some service technicians try to check the successful steam penetration inside hollow devices by temperature measurements.

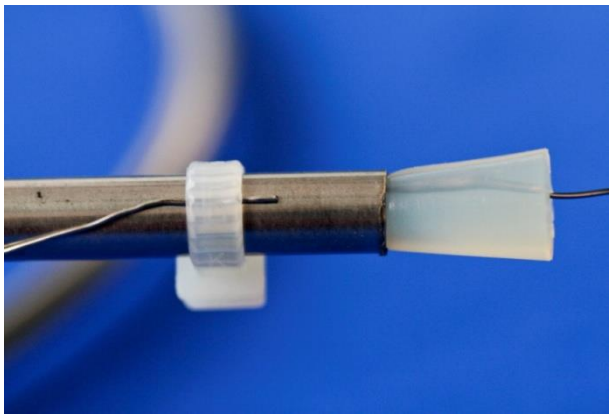
This method is successful to test the steam penetration of porous loads (e.g. BD-cotton pack). However, it is impossible to transfer this approach to hollow metal instruments as demonstrated by the following test procedure.

## 2. Material

Measurements with two different test objects were conducted:

*2.1 Stainless steel tube*

A stainless steel tube of 1 m length with an inner diameter of 6 mm and a wall thickness of 0.5 mm has been sealed with a silicone plug at the end. Behind the silicon plug a biological indicator was placed. The plug was prepared so that a thermocouple element could be inserted and could be fixed to a biological indicator.

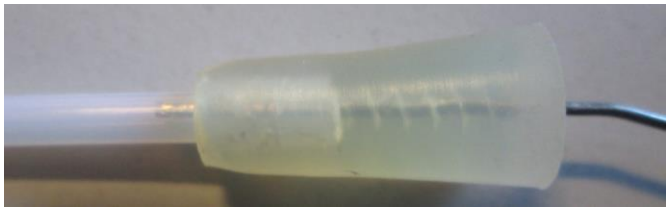


Other thermocouple elements were fixed at the outside wall of the tube and in the free chamber. This way the temperature gradients in the tube, at the outside of the tube and in the sterilizer chamber could be compared.

*Picture 1 Thermo couple elements inside and outside of the tube*

*2.2 Teflon tube*

For this experiment we took a teflon tube of 1.5 m length with an inner diameter of 2mm and a wall thickness of 0.5 mm. These tube dimensions conform to the tube used for hollow load tests according to the standard EN 867-5 (new: EN ISO 11140-6). The tube was sealed with a silicon plug at the end. Behind the silicon plug a biological indicator was placed. The plug was prepared so that a thermocouple element could be inserted and fixed to the biological indicator. The temperature gradient was recorded and compared to the temperature in the sterilizer chamber.



*Picture 2 Thermo couple element in a teflon tube*

2.3 *Biological indicator*
For all tests biological indicators of GKE, *Geob. Stearothermophilus* $10^6$, D-value 1.8 min, lot number 3160471 are used.

## 3 Test procedure

The stainless steel tube, as described above, as well as a process challenge device (PCD) with a teflon tube were tested in a test sterilizer according to DIN EN ISO 11140-4 in a steam sterilization process at 121°C for 15 minutes, but with two different air removal cycles.

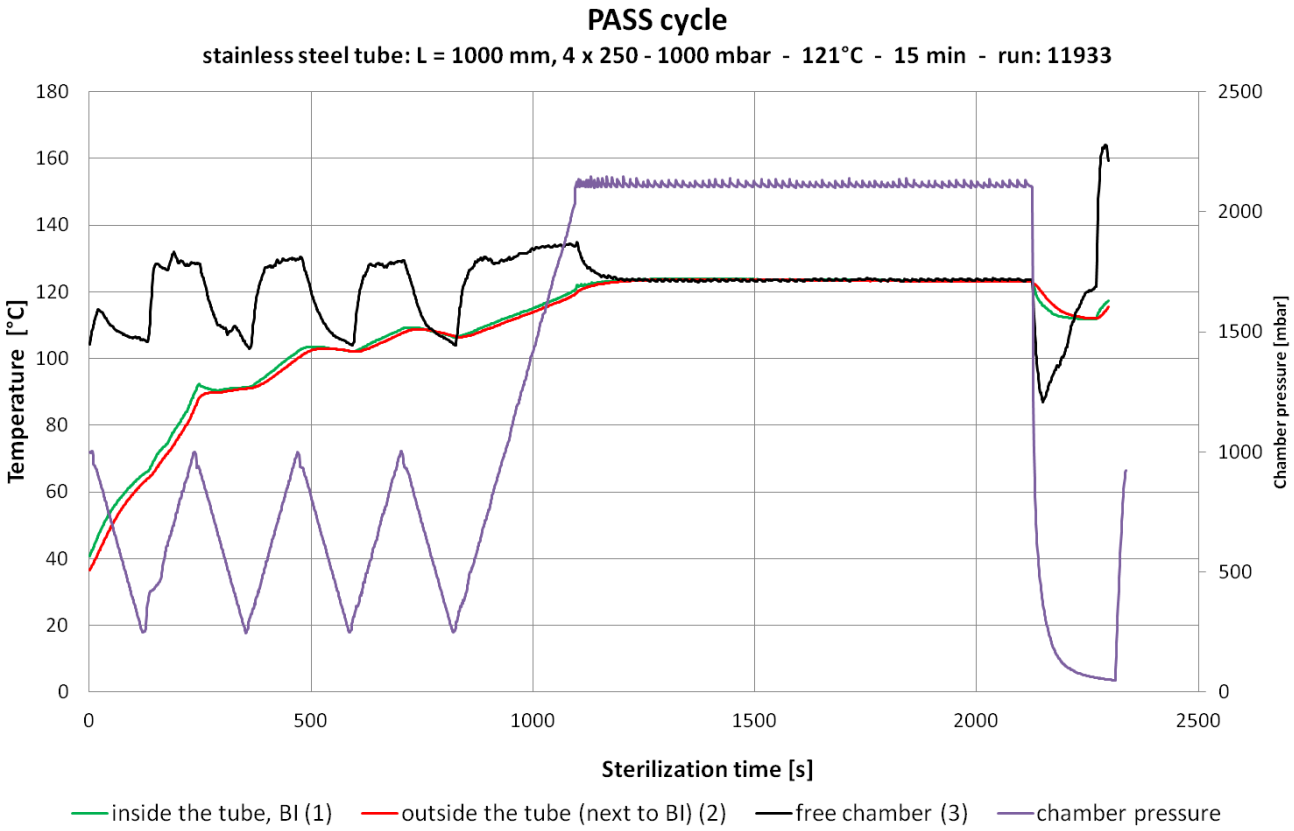
For each PCD as described above two separate sterilization processes have been carried out.

After the sterilization process the biological indicators were taken out of the PCD under aseptic conditions in a laboratory, where they were transferred into a culture medium (TSB) and incubated for 24 hours at 55°C.

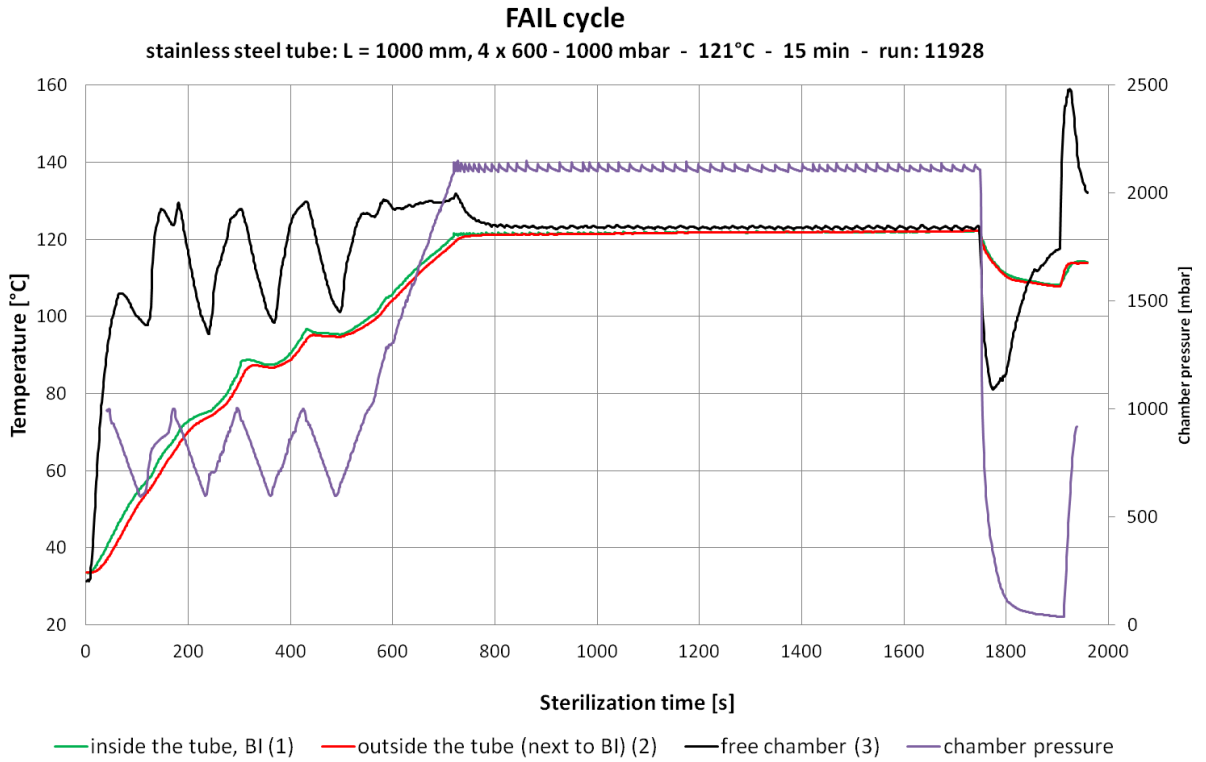
The temperature and the pressure were simultaneously recorded during the complete sterilization process and are documented in the pictures 3-6.

*Test cycle 1 – successful sterilization (PASS):*
An air removal process with 4 x 250 – 1000 mbar was used to reach a successful air removal and steam penetration (see picture 3+5).

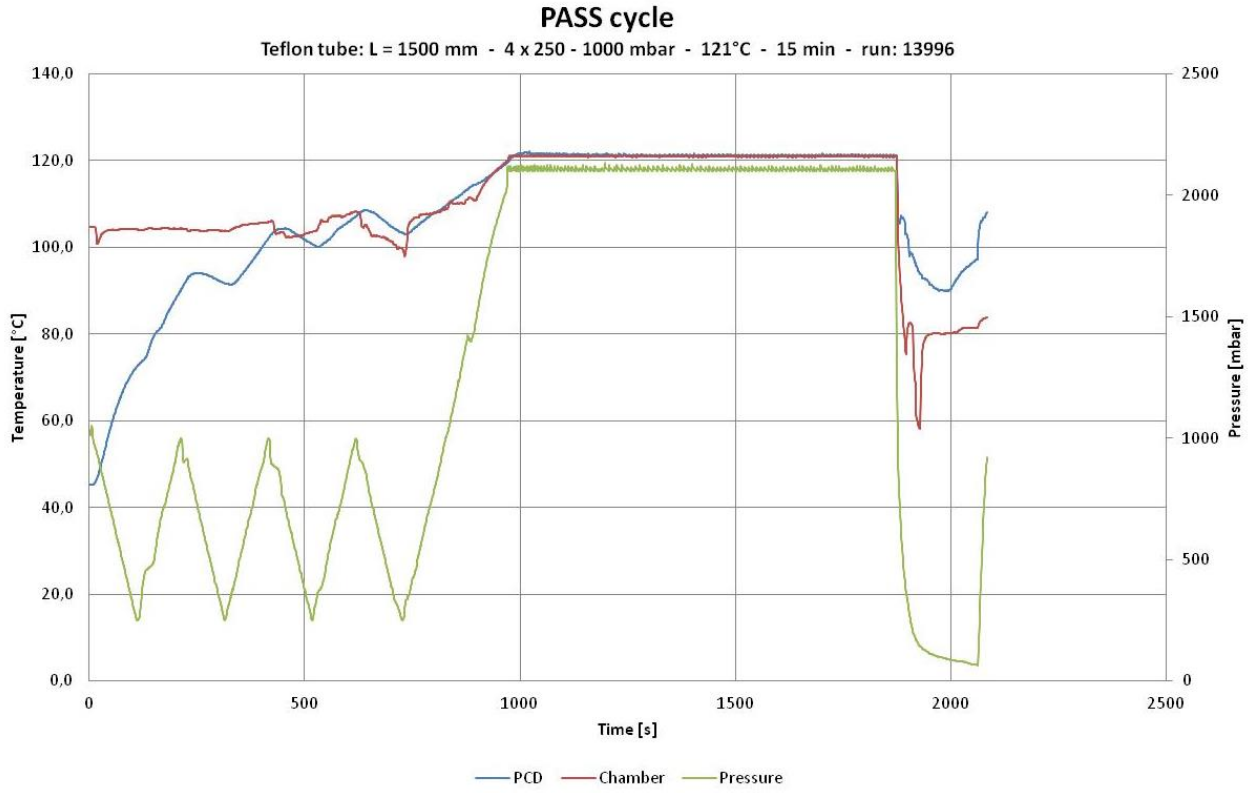
*Test cycle 2 – unsuccessful sterilization (FAIL)*:
An air removal process with 4 x 600 – 1000 mbar was used to simulate an unsuccessful air removal and steam penetration (see picture 4-6).



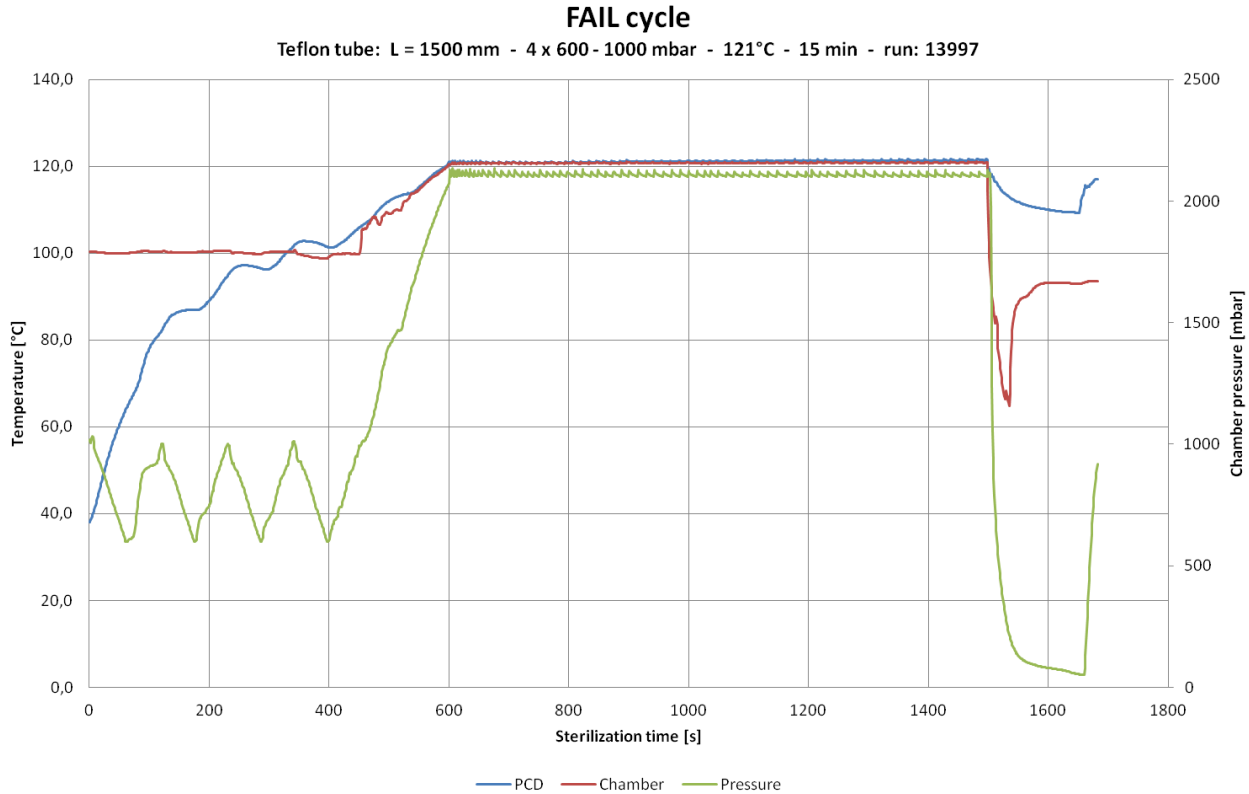

*Picture 3 Temperature gradient of the PASS sterilization process with inactivated biological indicator in stainless steel tube*




*Picture 4 Temperature gradient of the FAIL sterilization process with active biological indicator in stainless steel tube*




*Picture 5 Temperature gradient of the PASS sterilization process with inactive biological indicator in Teflon tube*




*Picture 6 Temperature gradient of FAIL sterilization process with active biological indicators in Teflon tube*

## 4 Test results

In test cycle 1 the biological indicators were completely inactivated after incubation time of 24 hours. There was no growth. That means there was a successful air removal process in both PCDs and the sterility inside of the PCD at the most difficult place could be confirmed.

In test cycle 2 the biological indicators of both process challenge devices grew already after 5 hours incubation time. That means the air removal and the steam penetration of both process challenge devices in this air removal process was not successful.

## 5 Conclusions

In the pictures 3-6 the temperature-time diagrams with the different PCDs and air removal procedures are demonstrated. Temperature sensors were placed inside and outside the PCDs and in addition the temperature was measured in the free chamber. The results of all 4 tests show that the temperature during the plateau period of all sensors evens out to 121°C without any temperature difference between the sensor inside the PCD and outside of the PCD.

Since there was obviously no steam penetration and the biological indicators showed growth in the two tests with insufficient air removal, no sterilization happened there. However, the sensors did not show any temperature difference there.

Similar measurements are carried out in cotton packs where temperature sensors are placed inside of the cotton pack and in the free chamber. Because of the large volumes in cotton packs and the good insulation a temperature difference between chamber and cotton pack is visible during insufficient air removal. Vice versa the conclusion is drawn that the sterilization inside the cotton packs was successful if there is no temperature difference visible.

In contrast the test hollow lumen shows that without any temperature difference between inside and outside of the PCD no air removal has taken place. Therefore thermo-electric measurements cannot be used to check steam penetration in hollow devices.

Comparing thermo-electric measurements in cotton packs and in hollow devices, the extreme volume differences of less than 1 ml in hollow devices and of several 100 ml in cotton packs are the reason that in cotton packs with large inner volume convection between steam and air can occur, while in tiny lumens convection is not possible. Therefore thermo-electric measurements in hollow devices cannot provide any information about a successful sterilization process.