



World Federation for
Hospital Sterilisation Sciences

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Sterilgutversorgung e.V.

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**Impact of air removal in steam
penetration: a case study**

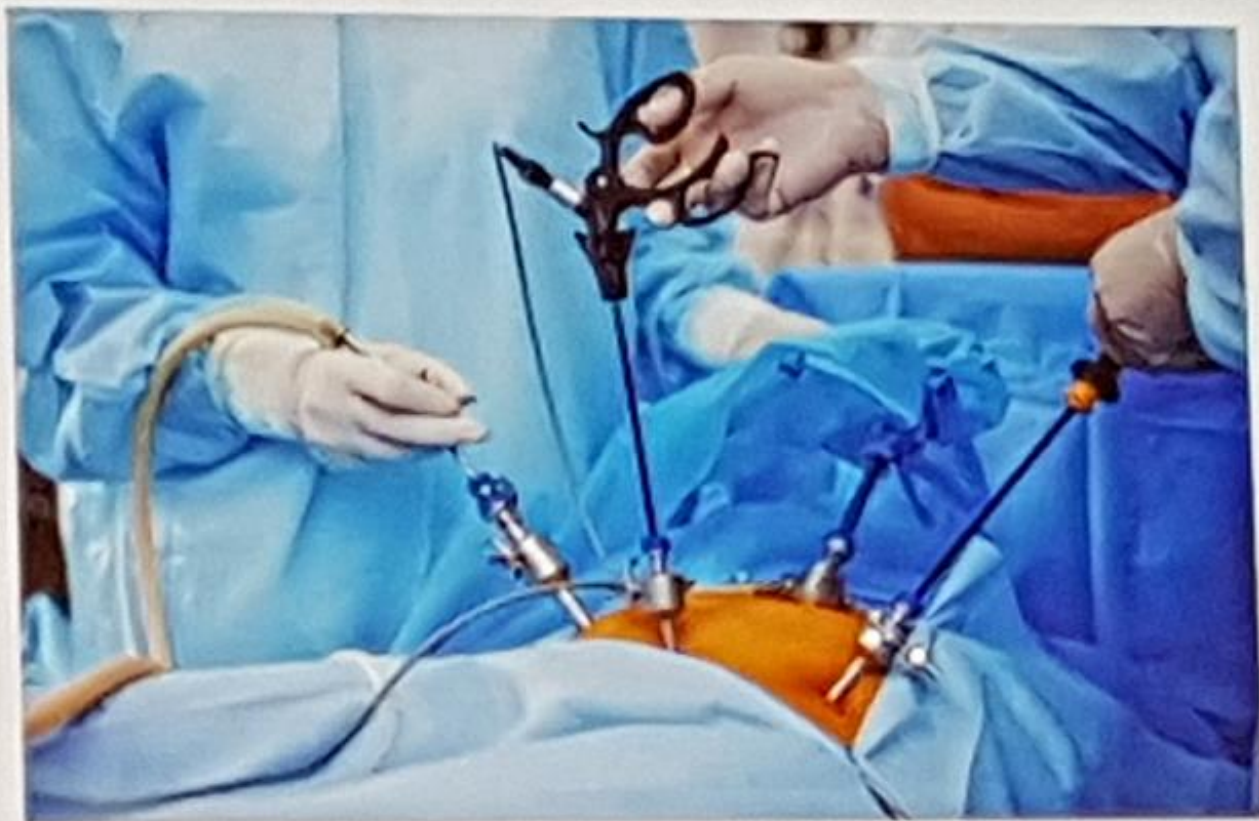
Matias Pilasi P.

Basics

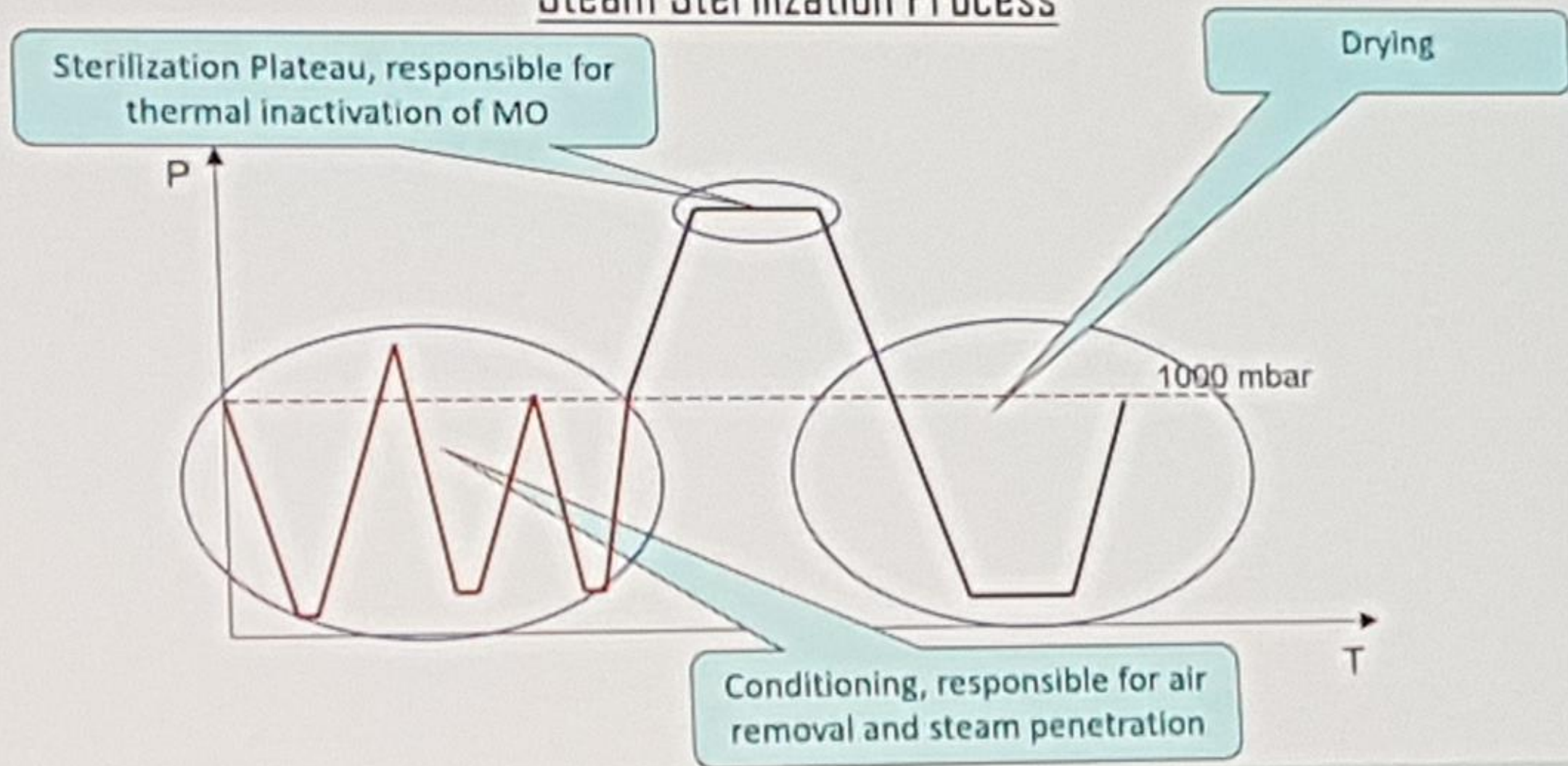
- Sterilization is the killing or irreversible inactivation of all viable micro-organisms.
- For steam sterilization, 3 conditions are needed on the surface of the medical devices for successful sterilization:
 - Time
 - Temperature
 - Moisture (saturated steam conditions)
- The heat transfer coefficient of dry heat is 40 times less in comparison to saturated steam.
- In places where Non Condensable Gases accumulates, a similar situation to dry heat conditions is created, thus time and temperature required for successful sterilization are higher than those for steam sterilization.
- NCG could be present due to the following:
 - ~~Insufficient air removal~~
 - Air leakage into the chamber (in under-pressure conditions, e.g. defective door seal)
 - NCG in the steam

Non Condensable Gases

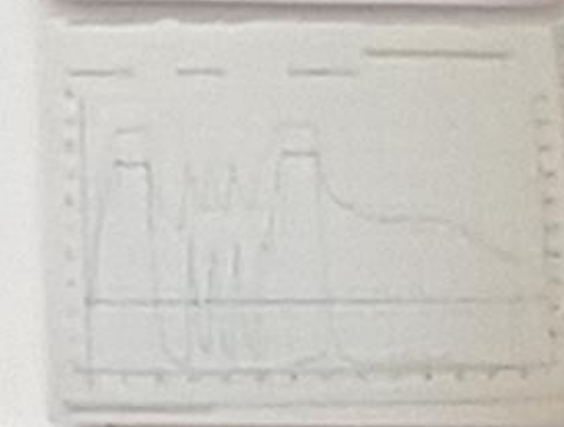
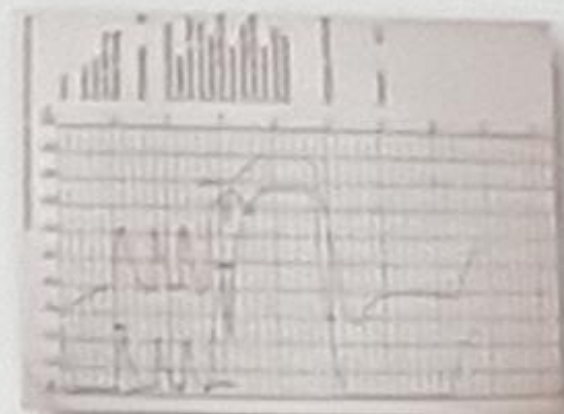
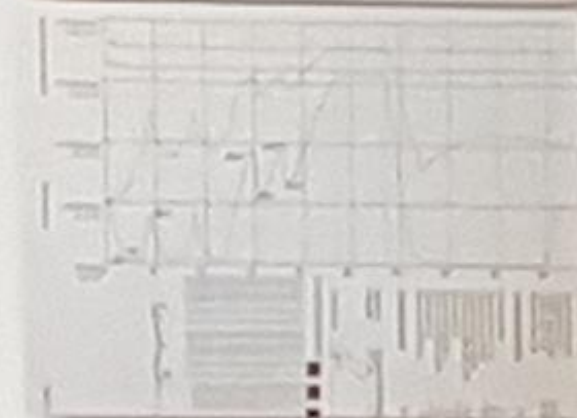
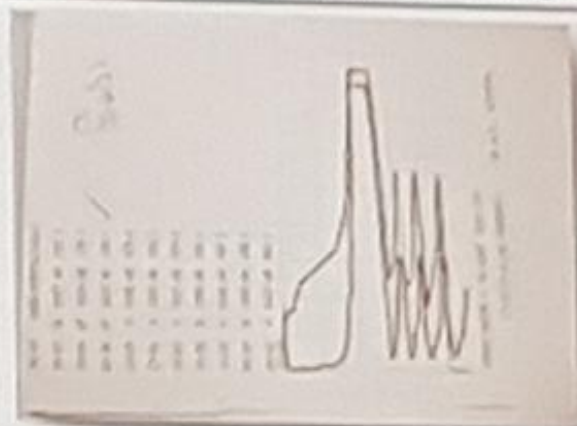
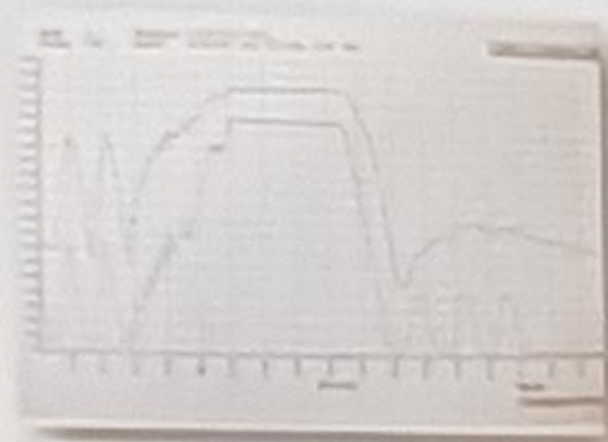
NCG are problematic for porous loads and particularly for hollow instruments used in MIS.



Steam Sterilization Process



Different Steam Sterilization Processes



There are more than 50 different cycles / processes which are supposed to achieve requirements of EN 285!

Steam penetration - case study in 9 different hospitals

- Materials and Methods

PCD N°	HPR [cm ²]	PCD tube dimension		Colour change of Chemical Indicator
		Length [m]	Diameter [mm]	
1	3,0	1,5	2	■ ■ ■ ■
2	4,5	1,5	3	■ ■ ■ ■ ■
3	5,0	1,0	5	■ ■ ■ ■ ■
4	6,0	3,0	2	■ ■ ■ ■ ■
5	6,0	1,5	4	■ ■ ■ ■ ■
6	9,0	4,5	2	■ ■ ■ ■ ■
7	9,0	3,0	3	■ ■ ■ ■ ■
8	10,0	2,0	5	■ ■ ■ ■ ■
9	12,0	3,0	4	■ ■ ■ ■ ■
10	15,0	3,0	5	■ ■ ■ ■ ■

EN 867-5
EN 285



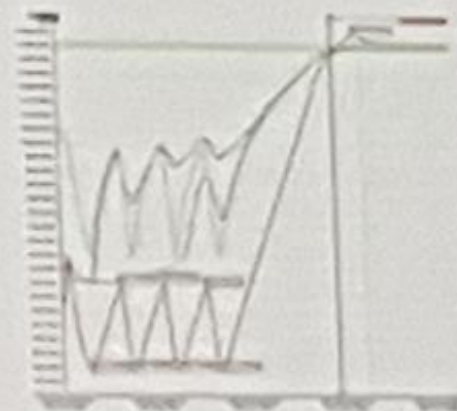
Before exposure to sterilization conditions:



After exposure to sterilization conditions:



121°C, 15 min
134°C, 3 min



Steam penetration - case study in 9 different hospitals

- Results classified by Hospital and Sterilizer manufacturer

Manufacturer	Pass Result PCD	No Pass Result PCD	Hospital
A	1,2,3,4,5,6,7,8,9,10		Hospital 1
B	1,2,3,4,5,6,7,8	9, 10	Hospital 2
C	1,2,3,4,5,6,7,8,9	10	Hospital 3
D	1	2,3,4,5,6,7,8,9,10	Hospital 4
D	1	2,3,4,5,6,7,8,9,10	Hospital 5
E	1,2,3,4,5,6,7	8,9, 10	Hospital 6
F	1,2,3,4,5,6,7,8,9,10		Hospital 7
G	1,2,3,4,5,6,7,8	9, 10	Hospital 8
H	1	2,3,4,5,6,7,8,9,10	Hospital 8
H	1	2,3,4,5,6,7,8,9,10	Hospital 2
I	-	1,2,3,4,5,6,7,8,9,10	Hospital 9

Steam penetration - case study in 9 different hospitals

- Pressure profile Sterilizer A passing all 10 PCDs

Sterilizer A (mbar)



PCD- No.	PCD-longitud de tubo [m]	Diámetro interno [mm]	HPR* [cm]	Campos de colores del indicador químico
1	1.5	2	30	BI BI BI BI BI
2	1.5	3	45	BI BI BI BI BI
3	1.0	5	50	BI BI BI BI BI
4	3.0	2	60	BI BI BI BI BI
5	1.5	4	60	BI BI BI BI BI
6	4.5	2	90	BI BI BI BI BI
7	3.0	3	90	BI BI BI BI BI
8	2.0	5	100	BI BI BI BI BI
9	3.0	4	120	BI BI BI BI BI
10	3.0	5	150	BI BI BI BI BI

BI = negative
CI = pass

Steam penetration - case study in 9 different hospitals

- Pressure profile Sterilizer F passing all 10 PCDs



PCD-No.	PCD-tube length [m]	Inner Diameter [mm]	HPR* [cm ²]	Colour change of chemical indicator
1	1.5	2	30	BI
2	1.5	3	45	BI
3	1.0	5	50	BI
4	3.0	2	60	BI
5	1.5	4	60	BI
6	4.5	2	90	BI
7	3.0	3	90	BI
8	2.0	5	100	BI
9	3.0	4	120	BI
10	3.0	5	150	BI

BI = negative

CI = pass

Steam penetration - case study in 9 different hospitals

- Pressure profile Sterilizer H passing 1 PCDs

Sterilizer H

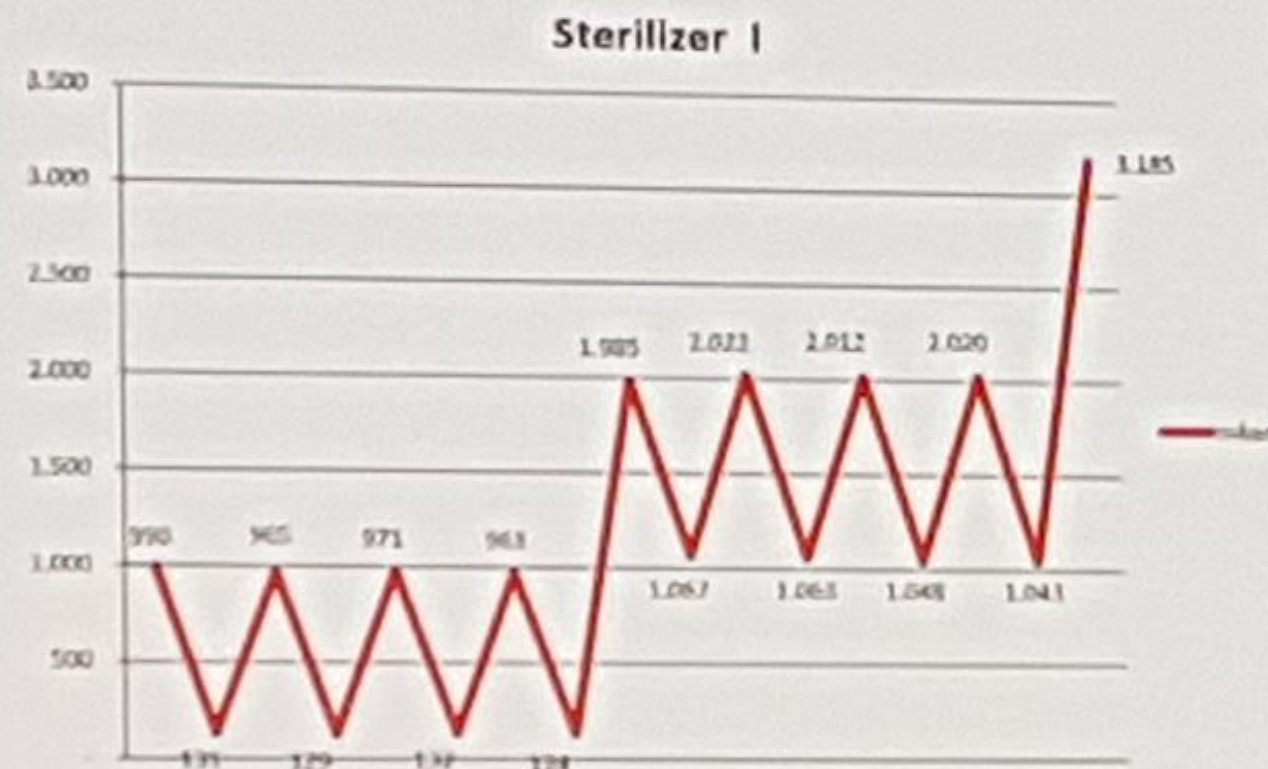


PCD-No.	PCD-tube length [m]	Inner Diameter [mm]	MPR [cm ²]	Colour change of chemical indicator
1	1.5	2	30	Bl
2	1.5	3	45	Bl
3	1.0	5	50	Bl
4	3.0	2	60	Cl
5	1.5	4	60	Cl
6	4.5	2	90	Cl
7	3.0	3	90	Cl
8	2.0	5	100	Cl
9	3.0	4	120	Cl
10	3.0	5	150	Cl

Bl = negative
Cl = pass

Steam penetration - case study in 9 different hospitals

- Pressure profile Sterilizer I passing 0 PCDs



PCD-No.	PCD-longitud de tubo [m]	Diámetro interno [mm]	HPR* [cm ²]	Cambio de colores del indicador químico
1	1.5	2	30	BI
2	1.5	3	45	BI
3	1.0	5	50	BI
4	3.0	2	60	BI
5	1.5	4	65	BI
6	4.5	2	90	BI
7	3.0	3	90	BI
8	2.0	5	100	BI
9	3.0	4	120	BI
10	3.0	5	150	BI

BI = negative
CI = pass

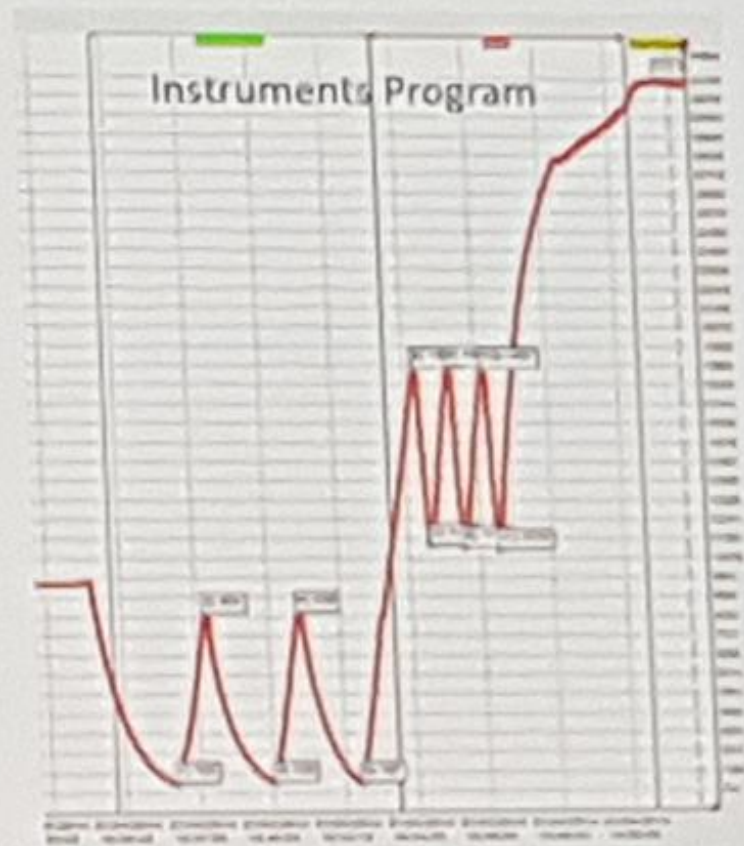
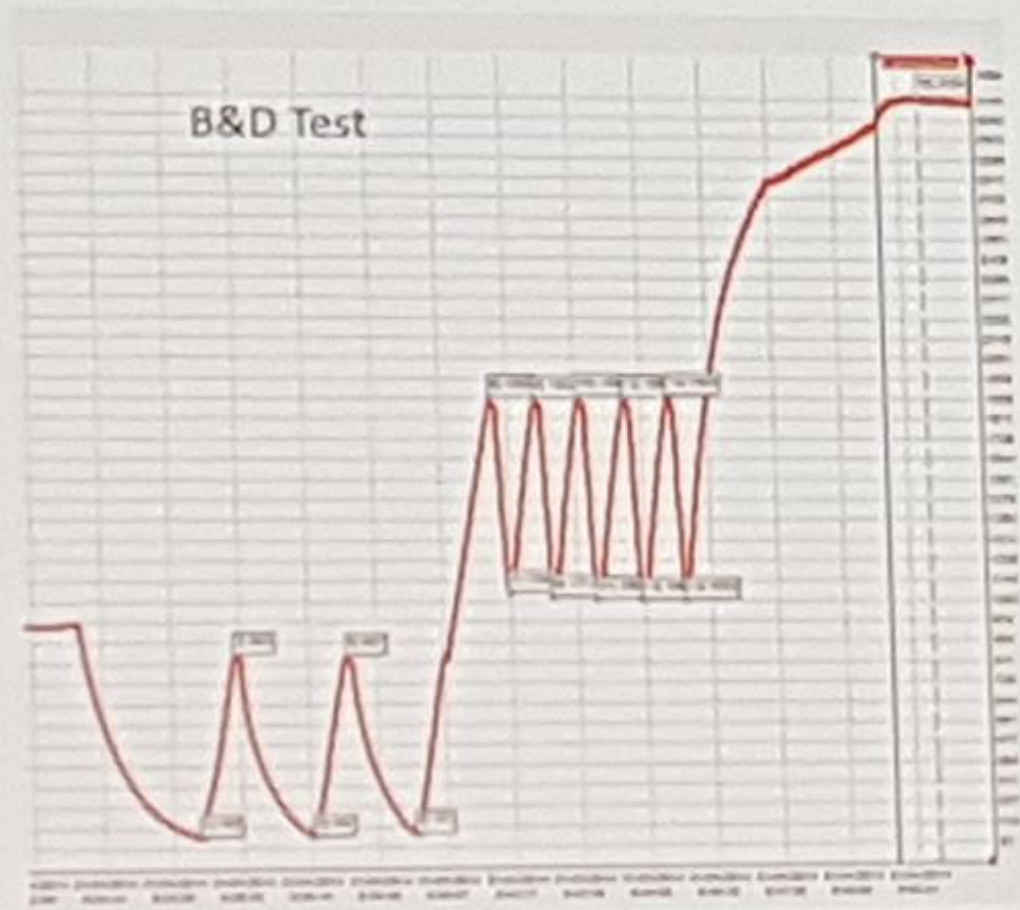
Additional Findings

1. In 6 of the 9 hospitals, it was found that the air removal phase of the sterilizers had totally different settings for the production cycle in comparison to the B60 cycle (i.e. with less vacuum pulses, or with different pressure switching points). Moreover, at the six places where this phenomenon was found, it could also be observed that the air removal phase of the B60 cycle had a better performance in penetration than the air removal phase of the production cycle. This is not according to EN 285.

EN 285: (the test cycle) "shall have the same air removal stage as the one used for the operating cycle used for production".

Additional Findings

- Hospital 2 / Sterilizer H (B&D Test v/s Instruments Program)



Additional Findings

- Hospital 2 / Sterilizer H (B&D Test v/s Instruments Program)

B&D Test

PCD-No.	PCD-tube length [m]	Inner Diameter [mm]	HPR* [cm ³]	Colour change of chemical indicator
1	1.5	2	30	
2	1.5	3	45	
3	1.0	5	50	
4	3.0	2	60	
5	1.5	4	60	
6	4.5	2	90	
7	3.0	3	90	
8	2.0	5	100	
9	3.0	4	120	
10	3.0	5	150	

BI= negative

CI= pass

PCD = 6

Instruments Program

PCD-No.	PCD-tube length [m]	Inner Diameter [mm]	HPR* [cm ³]	Colour change of chemical indicator
1	1.5	2	30	
2	1.5	3	45	
3	1.0	5	50	
4	3.0	2	60	
5	1.5	4	60	
6	4.5	2	90	
7	3.0	3	90	
8	2.0	5	100	
9	3.0	4	120	
10	3.0	5	150	

BI= negative

CI= pass

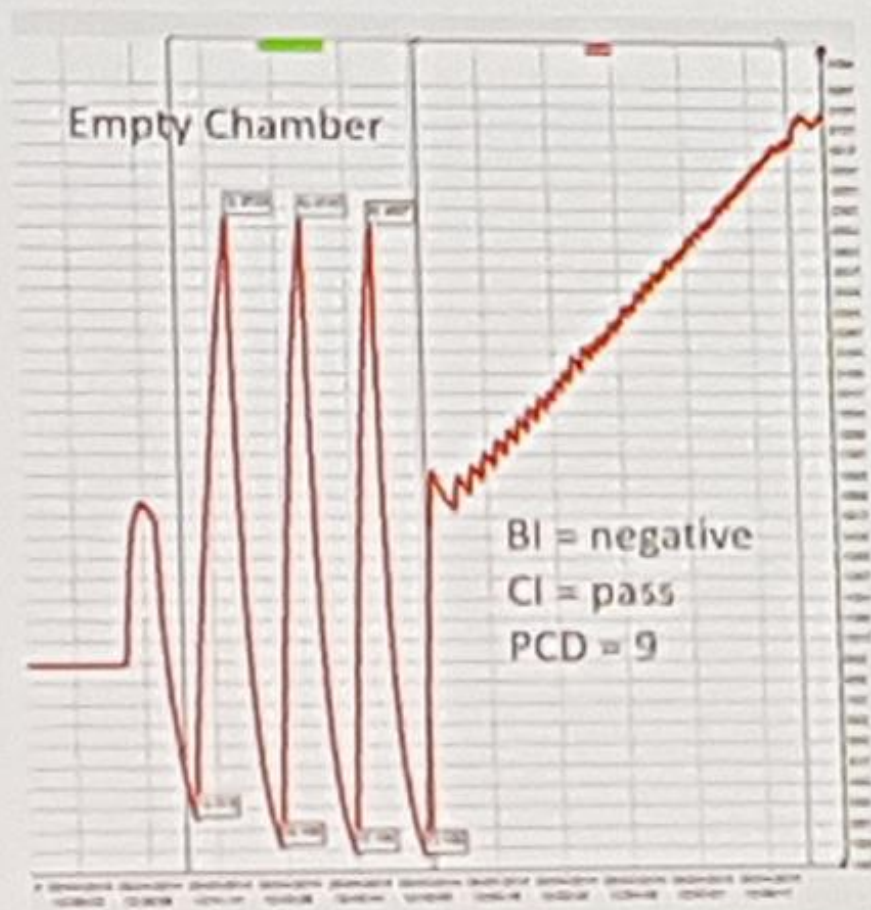
PCD = 1

Additional Findings

2. At two hospitals (Hospitals 4 and 5) where the same sterilizer is installed (from manufacturer D) a significant difference in the air removal phase was found for the same sterilization program but depending on the sterilizer load. So, when there was no load, the sterilizer had a better performance than when it was fully loaded (better vacuum points and a better result on the PCOs).

Additional Findings

- Hospital 4 and 5 / Sterilizer D (with and without load)



Additional Findings

- Hospital 4 and 5 / Sterilizer D (with and without load)

Empty Chamber

PCD- Nº.	PCD-longitud de tubo [m]	Diametro interno [mm]	HPR* [cm ²]	Cambio de colores del indicador químico
1	1.5	2	30	BI
2	1.5	3	45	CI
3	1.0	5	50	CI
4	3.0	2	60	CI
5	1.5	4	60	CI
6	4.5	2	90	CI
7	3.0	3	90	CI
8	2.0	5	100	CI
9	3.0	4	120	CI
10	3.0	5	150	CI

BI = negative
CI = pass
PCD = 9

Full Chamber

PCD- Nº.	PCD-longitud de tubo [m]	Diametro interno [mm]	HPR* [cm ²]	Cambio de colores del indicador químico
1	1.5	2	30	BI
2	1.5	3	45	CI
3	1.0	5	50	CI
4	3.0	2	60	CI
5	1.5	4	60	CI
6	4.5	2	90	CI
7	3.0	3	90	CI
8	2.0	5	100	CI
9	3.0	4	120	CI
10	3.0	5	150	CI

BI = negative
CI = pass
PCD = 1

Conclusions

1. The air removal has a direct impact on the steam penetration of hollow instruments and therefore affects directly the sterilization result.
2. Chemical and Biological Indicators that are not used in combination with a high penetration resistance PCD, do not provide results that represent sterilization conditions inside complex instruments.
3. New standards should have specific requirements for air removal phases.
4. Without validation, different cycle performances cannot be detected.
5. The required steam penetration has to be adapted to the requirement of the load.

Conclusions

6. The best practice for a safe result should be:
- Validation of the sterilization process according to ISO 17665-1.
 - Proper choosing of routine monitoring.

Conclusions

6. The best practice for a safe result should be:
- Validation of the sterilization process according to ISO 17665-1.
 - Proper choosing of routine monitoring.
 - Batch release in accordance to the validated procedure.

References

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THANKS FOR YOUR ATTENTION