

21ST 
WORLD
STERILIZATION
CONGRESS



*Steam Sterilization Routine
Monitoring: is it safe to use Type 5
Chemical Indicators as a substitute
to Biological Indicators?”*

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17 / 20 NOVEMBER 2021
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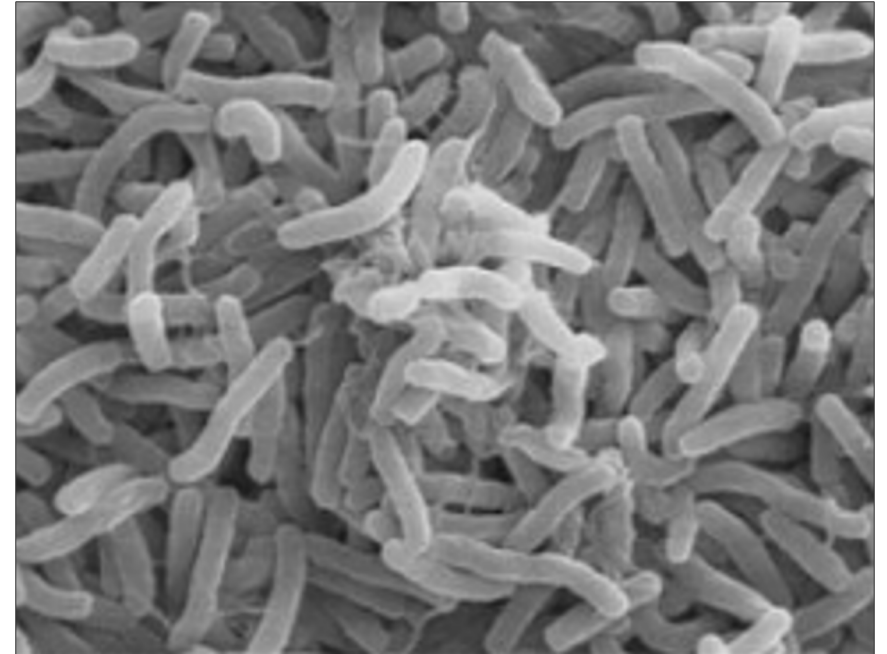
- Introduction
- Background
- Materials and Methods
- Results
- Conclusions

- Chemical and Biological indicators (CIs and BIs) are used in many countries to evaluate steam sterilization processes.
- Some local recommendations requires the use of BIs in certain situations (e.g. for implants release).
- ISO 11140-1 states that Type 5 CIs are equivalent or exceed the performance of BIs described in ISO 11138-1. However, some guidelines do not allow the use of Type 5 CIs as a replacement of BIs.

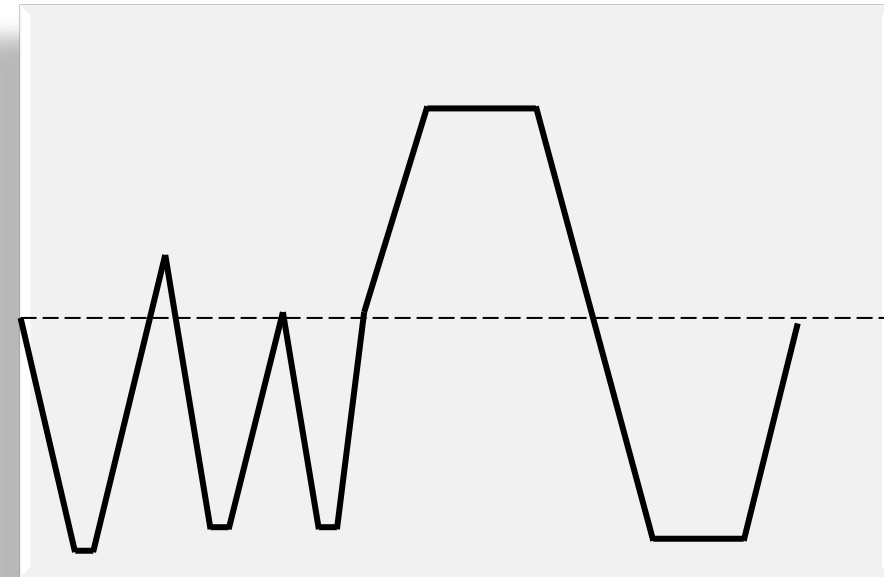


➔ what is the rationale behind this?

- A publication from 2005¹ states that only BIs reacts under superheated steam, however mix of conditions (SCBIs, PCDs, different populations and D values).
- Equivalence of BIs and Type 5 CIs according to ISO 11140-1 is based on a minimum:
 - D-value of 1,5 min.
 - Population of 10^5 CFU
 - z-value greater than 6
- Type 5 steam indicators should not show a pass result when exposed to dry heat at $140^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 30 min. ± 1 (ISO 11140-1, clause 11.7).



- Critical values of steam sterilization are:
 - Temperature
 - Time
 - Moisture (saturated steam)
- The heat transfer coefficient of dry heat is 40 times less in comparison to saturated steam.
- Big challenge of steam sterilization is air removal.
- Superheated steam has a similar effect as dry heat.



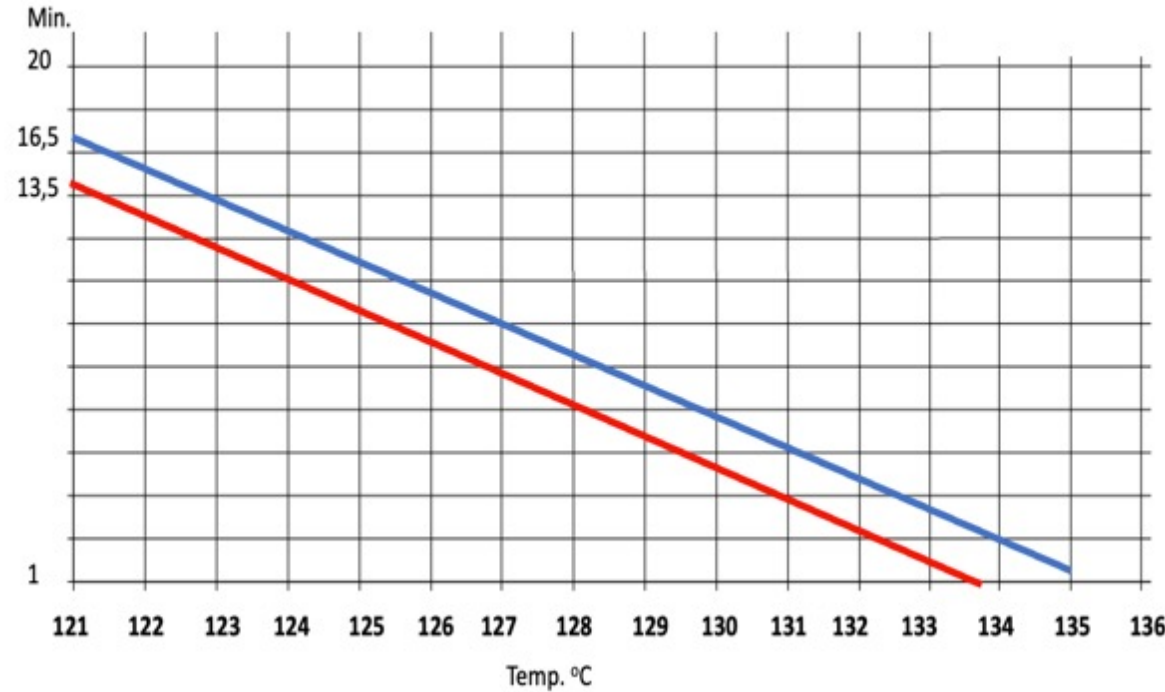
Equivalence between BI and Type 5 CI

ISO 11138-1, BIs:

- Min. Survival time = 4,5 min. @ 121°C
- Min. Kill time = 13,5 min. @ 121°C

ISO 11140-1, Type 5 CIs:

- Min. fail time: 14 min @ 121°C
- Min. pass time: 16,5 min @ 121°C

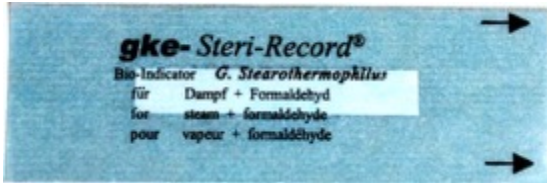


Set of 9 PCDs

PCD-No.	PCD-length [m]	Internal diameter [mm]
1	0,25	5
2	0,50	5
3	0,75	5
4	1,0	5
5	2,0	5
6	3,0	5
7	4,0	5
8	5,0	5
9	6,0	5



Spore Strips



Germ: *G. stearothermophilus*

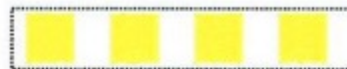
Population: 10^5 CFU

D_{121} value: 1,6 minutes

z value: 7,7 °C

Chemical Indicator

Before exposure:



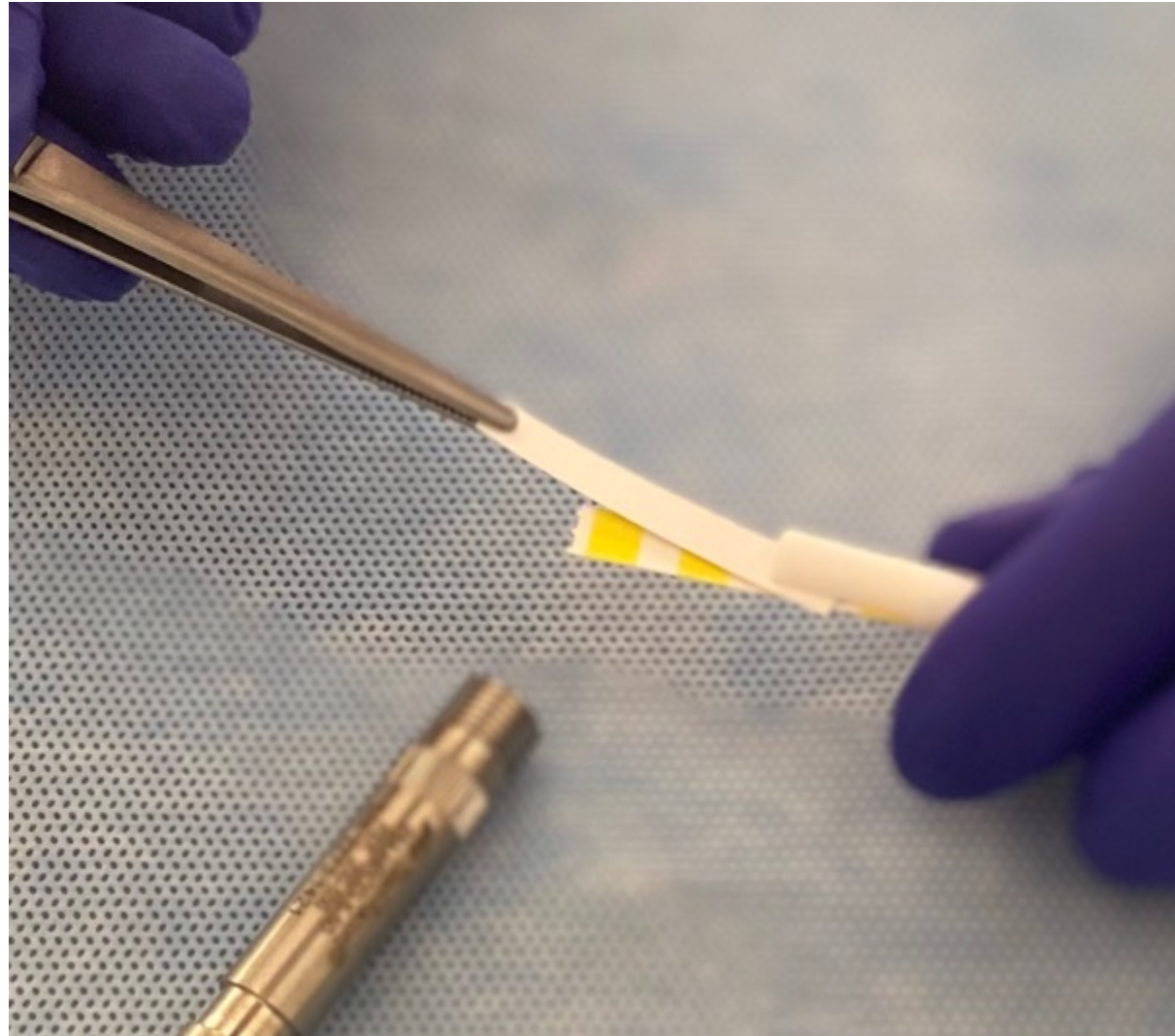
After exposure:



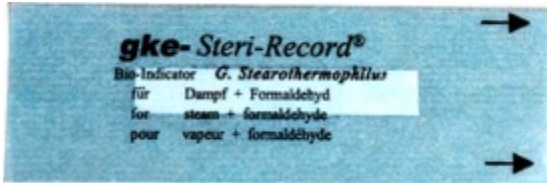
Stated Value (SV):

121°C, 15 min.

134°C, 3 min.



Spore Strips



Germ: *G. stearothermophilus*

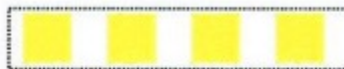
Population: 10^5

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z value: 7,7 °C

Chemical Indicator

Before exposure:



After exposure:



Stated Value (SV):

121°C, 15 min

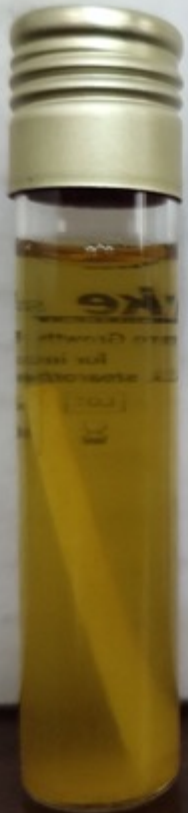
134°C, 3 min



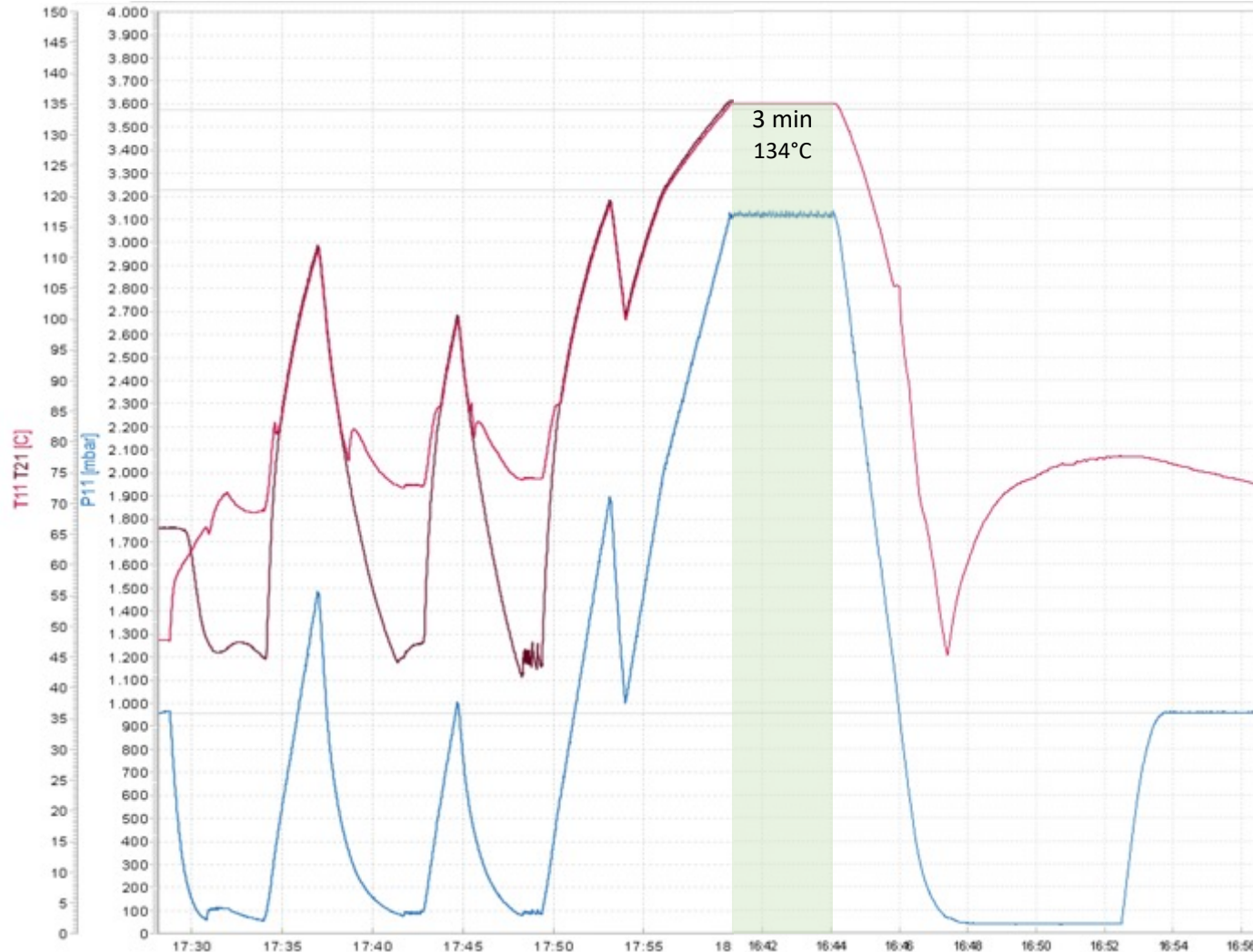
7 days incubation

Growth

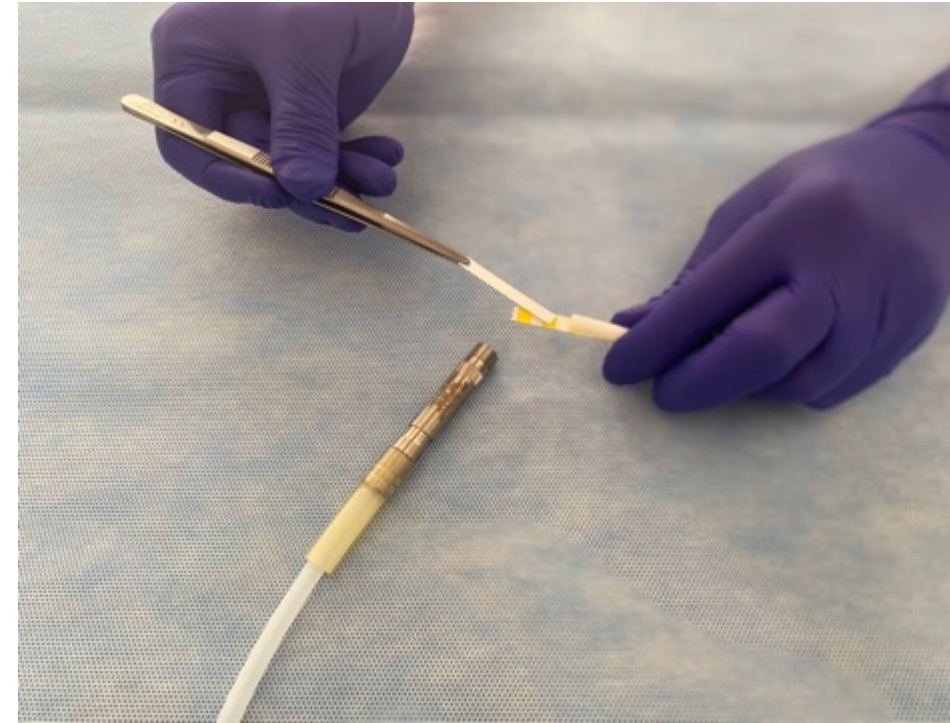
No Growth



Standard Hospital Steam Sterilizer with modified/marginal cycle



- 3 repetitions of the modified cycle were performed, each with all the 9 PCDs containing the spore strips (BIs) and Type 5 CIs at the same location.
- 1 additional run as a Control Group with the standard cycle with the highest air removal performance.
- CIs were evaluated immediately after removing them from the PCD whereas the spore strips (BIs) were incubated in growth media for 7 days.



Results

PCD-No.	PCD-length [m]	Internal diameter [mm]	Run 1		Run 2		Run 3		Control Group	
			BI	CI	BI	CI	BI	CI	BI	CI
1	0,25	5	NG	PASS	NG	PASS	NG	PASS	NG	PASS
2	0,50	5	NG	PASS	NG	PASS	NG	PASS	NG	PASS
3	0,75	5	NG	PASS	NG	PASS	NG	PASS	NG	PASS
4	1,0	5	NG	PASS	NG	PASS	NG	PASS	NG	PASS
5	2,0	5	NG	FAIL	NG	FAIL	NG	FAIL	NG	PASS
6	3,0	5	G	FAIL	G	FAIL	G	FAIL	NG	PASS
7	4,0	5	G	FAIL	G	FAIL	G	FAIL	NG	PASS
8	5,0	5	G	FAIL	G	FAIL	G	FAIL	NG	PASS
9	6,0	5	G	FAIL	G	FAIL	G	FAIL	NG	PASS

G = Growth

NG = No Growth

Results

Esterilización: Temp. 134 °C Tiempo de exposición 3 min 18

PCD-No.	PCD-longitud de tubo [m]	Diametro interno [mm]	HPR* [cm ²]	Cambio de colores del indicador químico
1	0,25	5	12,5	-
2	0,5	5	25	-
3	0,75	5	37,5	-
4	1,0	5	50	-
5	2,0	5	100	-
6	3,0	5	150	+
7	4,0	5	200	+
8	5,0	5	250	+
9	6,0	5	300	+

- The results suggests that in fact Type 5 CIs complying with ISO 11140-1 are more demanding than BIs under the presence of Non condensable gases.
- Type 5 CIs can then be a safe and cost-effective alternative for BIs.
- Proper routine monitoring should be defined during the process validation and must represent at least the same challenge as the real load.



- Schneider et al. Performance of various steam sterilization indicators under optimum and sub-optimum exposure conditions. AJIC. 2005 Jun;33(5 Suppl. 2):S55-67.
- ISO 11138-1. Sterilization of health care products – Biological indicators – Part 1: General requirements
- ISO 11140-1. Sterilization of health care products – Chemical indicators – Part 1: General requirements



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THANKS FOR YOUR
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