

UNDP IRAQ
Renovation of Al-Qayarah General Hospital
Ninawa Governorate - IRAQ

2019-01-17

Inspection report BI 22111

UNDP IRAQ Renovation of Al-Qayarah General Hospital Ninawa Governorate - IRAQ

Examination of disinfection method for porous materials according to RKI, EN 285, DIN 58949-3, EN 12740 and STAATT Level IV

Ordered by:	ETIHAD DIAR ALKEER CO.		
Date of order:	2018-12-16		
Inspection order:	Examination of disinfection method according to RKI, EN 285, DIN 58949-3, EN 12740 and STAATT Level IV		
Inspection item:	UBM Müh.-Medical waste sterilization system; SRN:ARI-550.004		
Date of inspection:	2019-01-17	Inspection by:	Monika Feltgen HygCen Austria GmbH
Inspection period / test period:	2018-12-24 – 2018-12-25; 2019-01-08 – 2019-01-16		
Participants of the inspection:	Bülent Deveci; UMS Medical		
Inspection method:	Examination of disinfection method (134° C for porous materials based on Robert-Koch-Institute (RKI Germany Guideline), EN 285 and DIN 58949-3, EN 12740 and the STAATT Level IV; SOP 21-015		

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1. Basic data

1.1 Data of the sterilizer

Manufacturer:	UMB MÜHENDİSLİK İstasyon Mah. Talat Pasa Cad. Yeni Sanayi Sitesi, 14C-Blok, No.4 Merkez-Edirne TURKEY
Brand name	UMB
Type:	Medical waste sterilization systems
Model	ARI-550
Device - serial number:	ARI-550.004
Chamber volume in [L] without loading:	1250 lt
Weight:	2800 kg
Max. working pressure:	4,5 bar
Max. working temperature:	160°C
Evacuation phase:	3
Year of construction:	2018

1.2 Pictures of the medical waste sterilization plant



 	
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NAME OF THE MACHINE / MAKINE ADI :	Medical Waste Sterilizer / Tıbbi Atık Sterilizasyon Cihazı
TYPE / MODEL :	ARI-550
SERIAL NO / SERİ NUMARASI : A	ARI-550.004
VOLTAGE / VOLTAJ :	380 V
POWER / GÜÇ :	95 kw
CURRENT / AKIM :	120 A
FREQUENCY / FREKANS	50 Hertz
PRODUCTION YEAR / ÜRETİM YILI	2018
LENGHT / BOY	240 cm.
HEIGHT / YÜKSEKLİK	230 cm.
WIDTH / GENİŞLİK	150 cm. (except the wheel)
WEIGHT / AĞIRLIK	2800 kg.

2. Calibration of the equipment used by HygCen (according to EN 17025 accredited testing laboratory)

Calibrated temperature measuring and recording system	
Manufacturer	Ellab Validation Solutions
Type	TrackSense Pro Sysytem
Serial-No.	311408-311413-335871-335876-335843-350321-311768
Class	PT 1000
Calibrated by	Ellab Validation Solutions

Pressure sensor	
Manufacturer	Ellab Validation Solutions
Type	TrackSense Pro Sysytem
Serial-No.	347649
Class	A
Calibrated by	Ellab Validation Solutions

3. Description of Waste

The PCD's and Loggers are became in a cotton bag (red colour) with those the rubbish which are delivered by health centers (see picture), exposes.



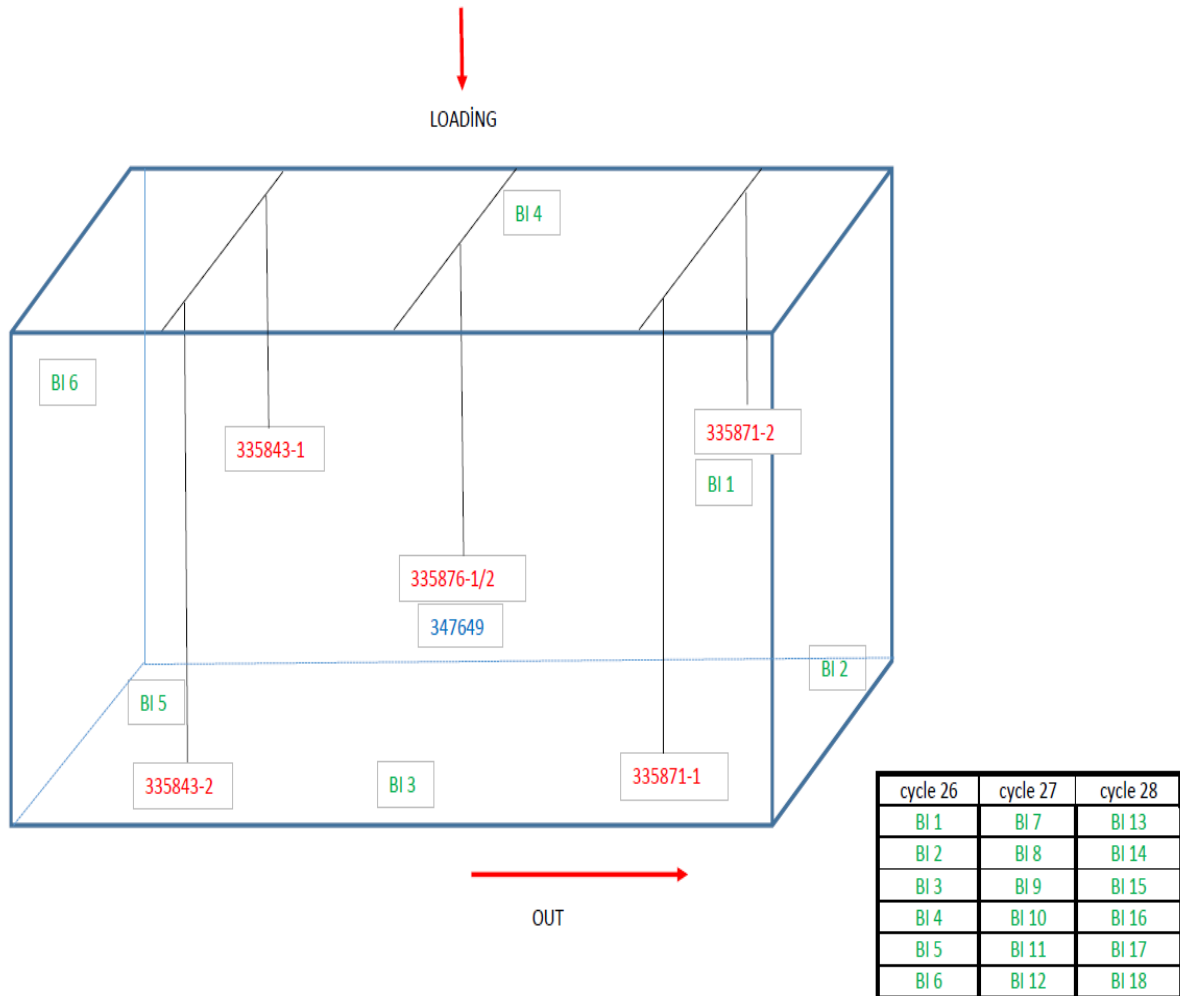
4. Overview of the carried out measurements

Date	Measurement No.	Cycle	Loading	Program No.
24.12.2018	1	24	Chamber profile	MANUEL
25.12.2018	2	26	Small load 1 with porous load (scheme of the loading)	MANUEL
25.12.2018	3	27	Small load 2 with porous load (scheme of the loading)	MANUEL
25.12.2018	4	28	Full load with porous load (scheme of the loading)	MANUEL

5. Schema of the loading

The thermo sensor and Bio-Indicator were so put on with part loading and full loading that we can make a declaration thereby with the help of the measuring results about the whole process. Besides, it was considered because of construction of the Sterilizer the critical areas.

Schema 1: Schema of the small and full loading



5.1 Photos of the carried out check

The arrangement described here of the PCD's and loggers in red color cotton bag was maintained in all loadings.



PCD for Bio indicator



PCD's in cotton bag



Bio Indicators / log.10⁸



Loggers in red color cotton bag



Loggers and Bio ind.in chamber



Dummy loads after sterilization

6. Method description concerning the microbiological indicators

6.1 Preparation

No additional preparation necessary. Spore strips (provided by HygCen) were used.

Manufacturer:	HygCen GmbH
Bacteria strain:	<i>Geobacillus stearothermophilus</i> ATCC 7953
Population of spores:	$1,2 \times 10^8$ cfu / ml
Recultivated population from test specimens:	8.9×10^8 cfu per spore strips

6.2 Description of the cultivation and calculation

After exposure the bio-indicators were exposed in 5ml of TSB (Tryptone Soya Broth) and sterile glass beads and mixed for 5 minutes. 100 μ l and 1000 μ l were subcultured on TSA (Tryptone Soya Agar).

These TSA plates and the TSB (enrichment cultures) were incubated at $55^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 7 days. After this incubation colonies of *Geobacillus stearothermophilus* ATCC 7953 were counted. The TSB was analysed for the test bacteria.

The determination of bacterial spores of not exposed bio-indicators, so-called positive controls, took place three times per type of bio-indicator.

The calculation of the logarithmic reduction factors based on the usual formula:

$$\text{Reduction factor } \lg = \bar{x} \text{ cfu } \lg_{(\text{positive control})} - \text{cfu } \lg_{(\text{sample})}$$

7. Results of Microbiological test

In the check were taken with part small loading No.1-6 and full loading No.7-14 tests.

7.1 Positions and Results of the microbiological indicators *SMALL Loading – 1 (with 50 liter load) / cycle:26*

Biological indicator		mean value [lg]
cfu [lg]		
Control 1	8.90	8.91
Control 2	8.90	
Control 3	8.94	

Sample No.	0.1 direct	Enrichment* [3 / 7 days]	Reduction factor [lg]
1	0	- / -	≥ 8.91
2	0	- / -	≥ 8.91
3	0	- / -	≥ 8.91
4	0	- / -	≥ 8.91
5	0	- / -	≥ 8.91
6	0	- / -	≥ 8.91

Legend:

- + clouding as a result of growth of germs
- no growth of germs
- *) Sub cultivation on TSA after 7 days

7.2 Positions and Results of the microbiological indicators SMALL Loading – 2 (with 100 liter load)/ cycle:27

Biological indicator		mean value
cfu [lg]		[lg]
Control 1	8.90	8.91
Control 2	8.90	
Control 3	8.94	

Sample No.	0.1 direct	Enrichment* [3 / 7 days]	Reduction factor [lg]
7	0	- / -	≥ 8.91
8	0	- / -	≥ 8.91
9	0	- / -	≥ 8.91
10	0	- / -	≥ 8.91
11	0	- / -	≥ 8.91
12	0	- / -	≥ 8.91

Legend:

- + clouding as a result of growth of germs
- no growth of germs
- *) Sub cultivation on TSA after 7 days

7.3 Positions and Results of the microbiological indicators FULL Loading - (with 200 liter load) / cycle:28

Biological indicator		mean value [lg]
cfu	[lg]	
Control 1	8.90	8.91
Control 2	8.90	
Control 3	8.94	

Sample No.	0.1 direct	Enrichment* [3 / 7 days]	Reduction factor [lg]
13	0	- / -	≥ 8.91
14	0	- / -	≥ 8.91
15	0	- / -	≥ 8.91
16	0	- / -	≥ 8.91
17	0	- / -	≥ 8.91
18	0	- / -	≥ 8.91

Legend:

- + clouding as a result of growth of germs
- no growth of germs
- *) Sub cultivation on TSA after 7 days

8. Conclusion

According to the results of the testings performed it can be confirmed, that the Medical waste sterilization system container, SRN:ARI-550.004 manufactured by UMB Mühendislik passed all microbiological and thermo-electrical tests with biological indicators (10^9) and is in conformity to the German standard DIN 58949-3 as well as the requirements of German RKI Guideline for Waste and also of STAATT Level IV (Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites, mycobacteria and of *B. stearothermophilus* spores at 6 log₁₀ reduction or greater).

Archiving: A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.

Reference: The test results refer exclusively to the mentioned test piece. Extractions of this report only with a written permission of the HygCen Austria GmbH.

A handwritten signature in blue ink, appearing to be 'H.-P. Werner', written in a cursive style.

Prof. Dr. med. H.-P. Werner
Technical Manager
Inspector

Annex: I

Diagram 1: Small load – 1 / cycle: 26

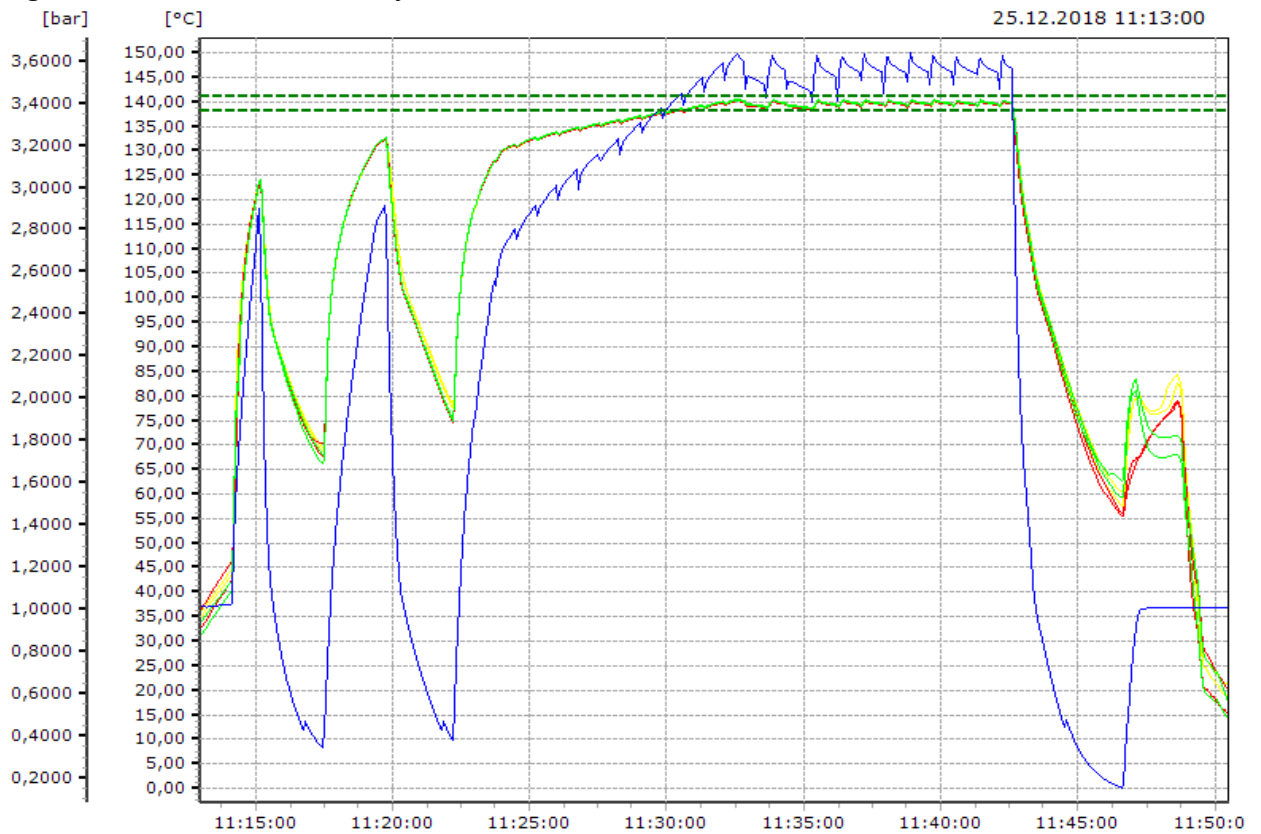


Diagram 2: Small load – 2 / cycle: 27

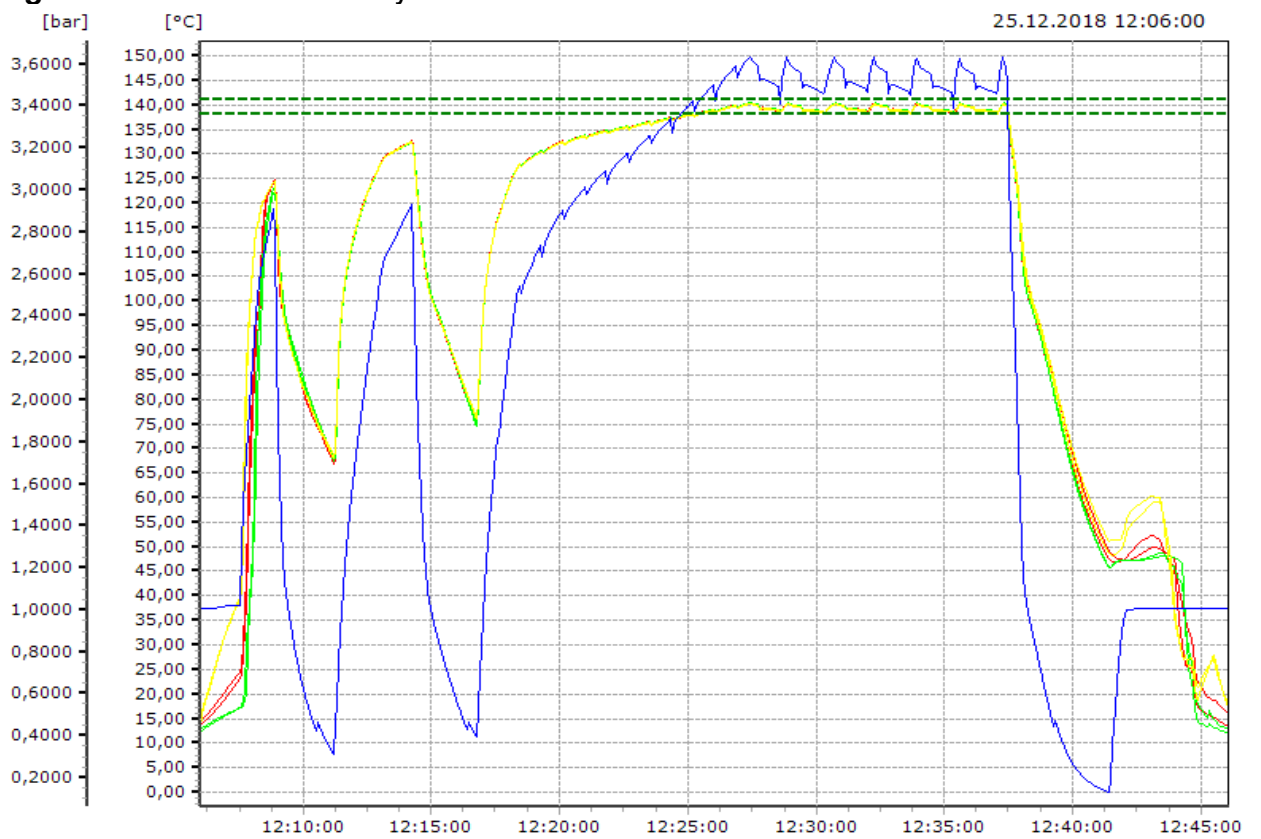


Diagram 3: Full load / cycle: 28

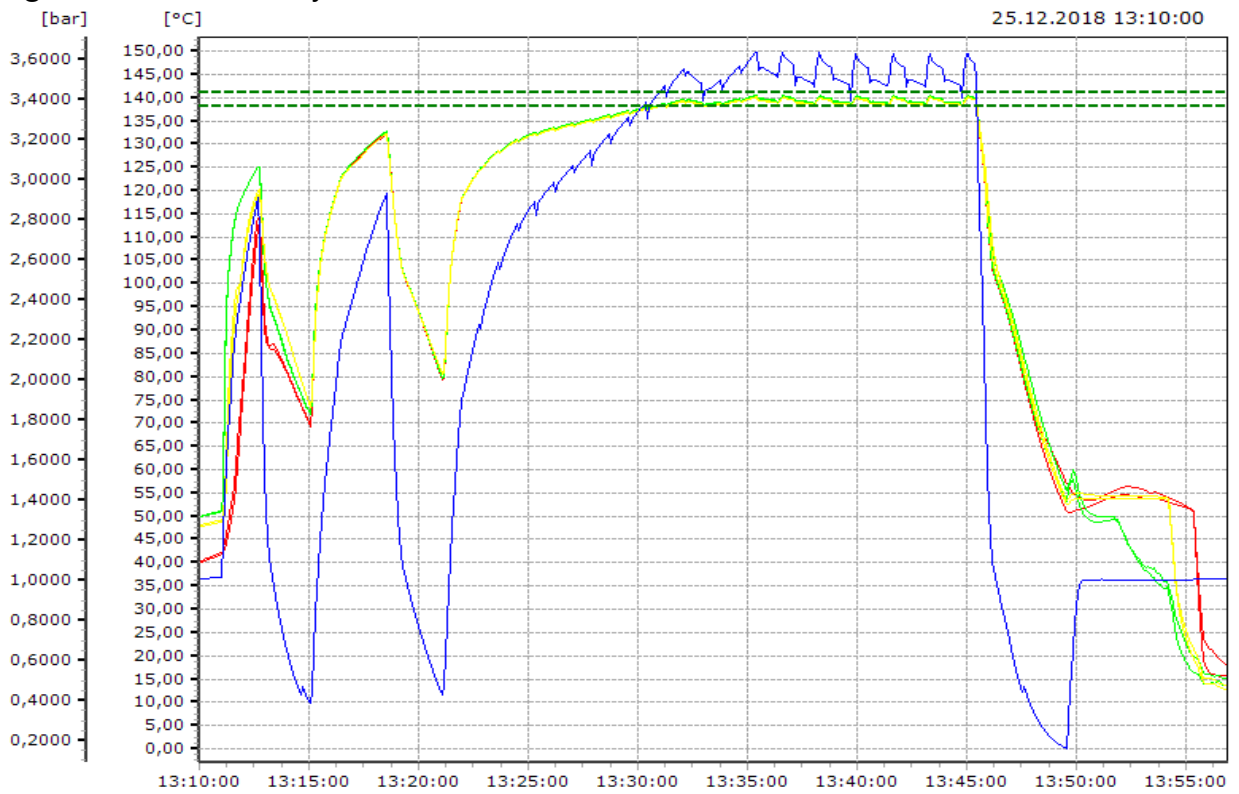
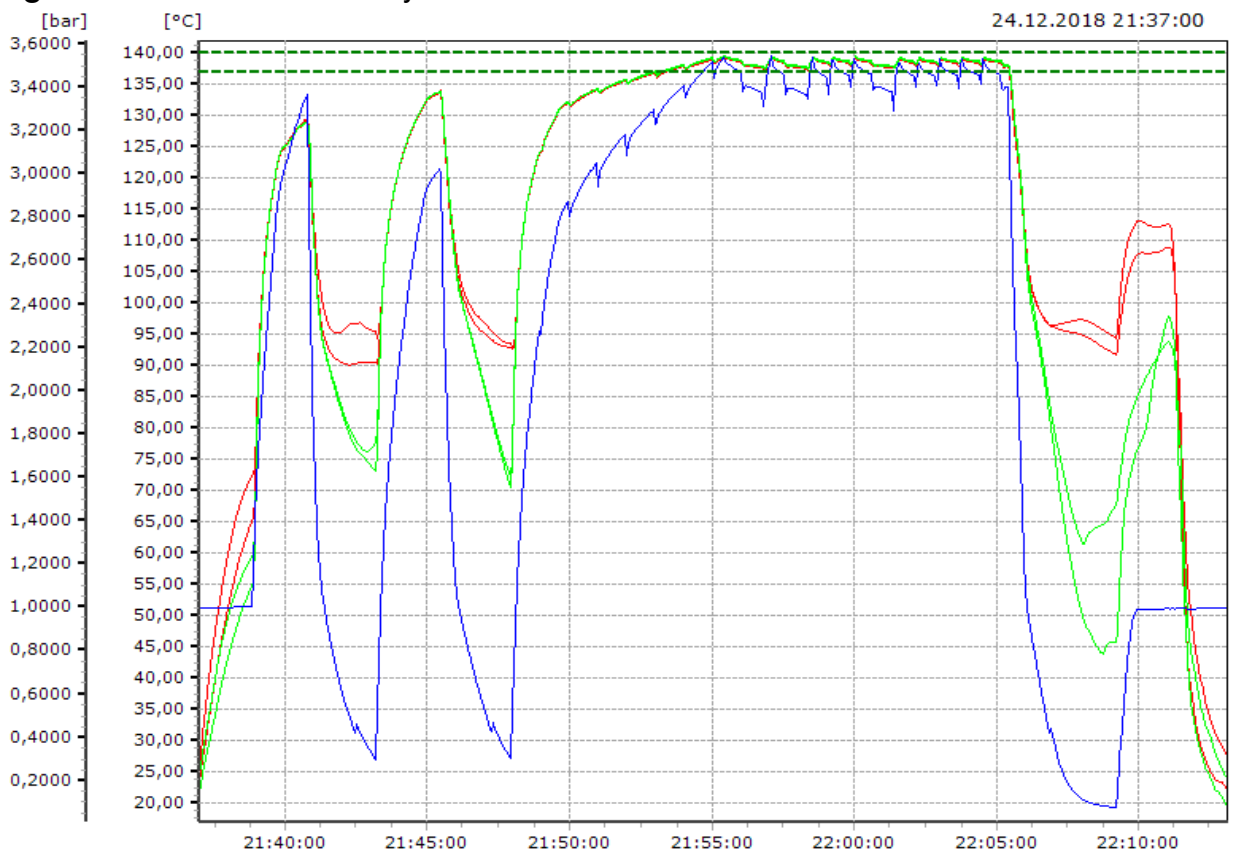


Diagram 4 : Chamber Test / cycle: 24



Annex: II

STERIL_ID: 24
 24.12.2018 - 21:37
 OPERAT_START
 21:38 PRE-HEAT:0 START
 0,0 bar - 100 C
 21:40 PRE-VACC:1 START
 21:42 PRE-HEAT:1 START
 0,-8 bar - 98 C
 21:45 PRE-VACC:2 START
 21:47 PRE-STERIL_START
 STERIL_START

TIME	BAR	TEMP
21:55	2,5	137 C
21:56	2,3	137 C
21:57	2,4	137 C
21:58	2,4	136 C
21:59	2,4	137 C
22:0	2,4	137 C
22:1	2,3	136 C
22:2	2,4	137 C
22:3	2,4	137 C
22:4	2,3	137 C
22:5	STEAM DISCH	START
22:5	VACCUUM	START
22:8	AIRING	START
22:10	OPERAT	FINISH

eye. 26
 11:13 PRE-HEAT:0 START
 0,0 bar - 102 C
 11:14 PRE-VACC:1 START
 11:17 PRE-HEAT:1 START
 0,-8 bar - 101 C
 11:19 PRE-VACC:2 START
 11:21 PRE-STERIL_START
 STERIL_START

TIME	BAR	TEMP
11:32	2,6	137 C
11:33	2,4	137 C
11:34	2,4	137 C
11:35	2,5	136 C
11:36	2,5	137 C
11:37	2,5	137 C
11:38	2,5	137 C
11:39	2,4	137 C
11:40	2,5	137 C
11:41	2,5	137 C
11:42	STEAM DISCH	START
11:43	VACCUUM	START
11:46	AIRING	START
11:47	OPERAT	FINISH

STERIL_ID: 27
 25.12.2018 - 12:6
 OPERAT_START
 12:7 PRE-HEAT:0 START
 0,0 bar - 98 C
 12:8 PRE-VACC:1 START
 12:11 PRE-HEAT:1 START
 0,-8 bar - 97 C
 12:14 PRE-VACC:2 START
 12:16 PRE-STERIL_START
 STERIL_START

TIME	BAR	TEMP
12:27	2,6	137 C
12:28	2,4	137 C
12:29	2,4	137 C
12:30	2,5	137 C
12:31	2,4	137 C
12:32	2,5	137 C
12:33	2,4	137 C
12:34	2,5	137 C
12:35	2,5	137 C
12:36	2,4	137 C
12:37	STEAM DISCH	START
12:37	VACCUUM	START
12:41	AIRING	START
12:42	OPERAT	FINISH

STERIL_ID: 28
 25.12.2018 - 13:9
 OPERAT_START
 13:10 PRE-HEAT:0 START
 0,0 bar - 95 C
 13:12 PRE-VACC:1 START
 13:14 PRE-HEAT:1 START
 0,-7 bar - 93 C
 13:18 PRE-VACC:2 START
 13:20 PRE-STERIL_START
 STERIL_START

TIME	BAR	TEMP
13:35	2,6	137 C
13:36	2,5	137 C
13:37	2,4	137 C
13:38	2,5	137 C
13:39	2,4	137 C
13:40	2,5	137 C
13:41	2,4	137 C
13:42	2,4	137 C
13:43	2,5	137 C
13:44	2,4	137 C
13:45	STEAM DISCH	START
13:45	VACCUUM	START
13:49	AIRING	START
13:50	OPERAT	FINISH