Hauptsitz
Prüfinstitut
HygCen Germany GmbH
Bornhövedstrasse 78
19055 Schwerin

Phone: +49 (0) 385 5682 65
Fax: +49 (0) 385 5682 67
Email: info@hygcen.de
Web: www.hygcen.de

[HYGCEN GERMANY GMBH | BORNHÖVEDSTRASSE 78 | 19055 SCHWERIN]

Sterilmed Medical Elek. Elekt. Otomasyon İnş. San.Ve Dış. Tic. Ltd. Şti.

Baskent OSB 18. Cad. No.43 Malikoy, Sincan / ANKARA

2019-09-11

TEST REPORT

Labor No.:	SN 20321
Product:	Steam sterilizers (540 liter)
Client:	**Sterilmed Medical Elek. Elekt. Otomasyon İnş. San. VeDış. Tic. Ltd. Şti.** Baskent OSB 18. Cad. No.43 Malikoy, Sincan / ANKARA TURKEY
Test place:	**Isparta Devlet Hastanesi** Doğancı Mahallesi, Yokuşbaşı Sokak No:34 ISPARTA / TURKEY
Test periods:	2019-09-11 – 2019-09-12
Tester:	Bülent Deveci
Method:	Thermoelectrical measuring, using the borderlines / requirements given in EN 285 and/or EN ISO 17665

Digitally signed by Morozov Maria
Date: 2024.02.29 17:02:55 EET
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Lungu Ion
Date: 2024.02.29 16:56:14 EET
Reason: MoldSign Signature
Location: Moldova

Content

Appendix

1 General Information

In the period 2019-09-11- 2019-09-12 the measurements (Validation) according to EN 285 and/or EN ISO 17665 for the performance qualification (PQ) of the sterilizer (Type: SMA DSD 540; SNR:2019-006) had been done.

2 Requirements for thermo electrical measuring

2.1 Small load, thermometric (according to EN 285:2006+A2:2009; chapter 16.1)

During the plateau period the temperature measured above the test pack (“antenna”) shall not exceed the temperature measured at the reference measurement point of the sterilizer chamber by more than 5 °C for the first 60 s and 2 °C for the remaining period.

Throughout the holding time the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the test pack and the saturated steam temperature calculated from the measured chamber pressure shall:

- be within the sterilization temperature band (defined Temperature +3 °C);
- not differ from another by more than 2 °C.

The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers.

2.2 Full load, thermometric (according to EN 285:2006+A2:2009; chapter 16.2)

Throughout the holding time the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the good and the saturated steam temperature calculated from the measured chamber pressure shall:

- be within the sterilization temperature band (defined Temperature +3°C);
- not differ from another by more than 2 °C.

The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers.

2.3 Bowie-Dick test (according to EN 285:2006+A2:2009; chapter 17.1)

The used chemical indicator must show a steady color on the whole surface.

2.4 Air leakage test (according to EN 285:2006+A2:2009; chapter 18)

When the sterilizer is tested as described in Clause 18 the rate of pressure rise shall be within the limits specified by the manufacturer and in any case shall be not greater than 0,13 kPa/min (1,3 mbar/min).

2.5 Load dryness (according to EN 285:2006+A2:2009; chapter 20)

Load dryness, small load, textiles:

When the sterilizer is tested as described in 20.1, the mass of the test pack shall not increase by more than 1 %.

Load dryness, full load, textiles:

When the sterilizer is tested as described in 20.2, the mass of the standard test pack shall not increase by more than 1 %.

Load dryness, metal load:

When the sterilizer is tested as described in 20.3, the mass of the test load shall not increase by more than 0,2 %.

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

Calibrated temperature measuring system	
Manufacturer	Ahlborn Meß- und Regelungstechnik GmbH
Type	Pt-100, in Vierleiter-Technik (P05-1)
Serial-No.	Po5-1 / 175 / T26b
Class	Sensor according to class 1/5 DIN
Calibrated by	UMS - TURKAK

Thermometric recording instrument			
Manufacturer	Ahlborn Meß- und Regelungstechnik GmbH		
Type	3290-8 V_5	3290-8 V_5	3290-8 V_5
Serial-No.	9912185 G	9912186 G	9912187 G
Class	--	--	--
Calibrated by	Ahlborn Meß- und Regelungstechnik GmbH		

Temperature sensors	
Manufacturer	Newport Omega
Type	Thermocouple Type K (Outer diameter = 0,5 mm)
Serial-No.	--
Class	1
Calibrated by	HygCen before measuring (see curve in annex **Hata! Başvuru kaynağı bulunamadı.**)

Pressure sensor	
Manufacturer	DruckMesstechnik GmbH
Type	PTX 511-I, 0-4000 mbar absolute
Serial-No.	1824436
Class	0,2 (0,2 % v.E.)
Calibrated by	UMS – TURKAK

Hygrometer	
Manufacturer	ROTRONIC
Type	HP101A-L5-S28X1W
Serial-No.	16720 001
Class	--
Calibrated by	UMS – TURKAK

4 Sterilizers tested

Sterilizer 800 liter	
Manufacturer	Sterilmed
Chamber volume in dm³	540 Liter
Year of production	2019

5 Tested Programs / loadings

☒ **Program „ AIR LEAKAGE TEST“**

- Air leakage test according to EN 285;

☒ **Program „BOWIE DICK TEST“**

- Small load test (standard test pack, according to EN 285; chapter 24.1)

☒ **Program „TEXTILE“**

- Small load textiles
- Full load textiles

☒ **Program „CERRAHİ ALET“**

- Small load instrument
- Full load instrument

6 Thermo electrical measurements – 540 liter

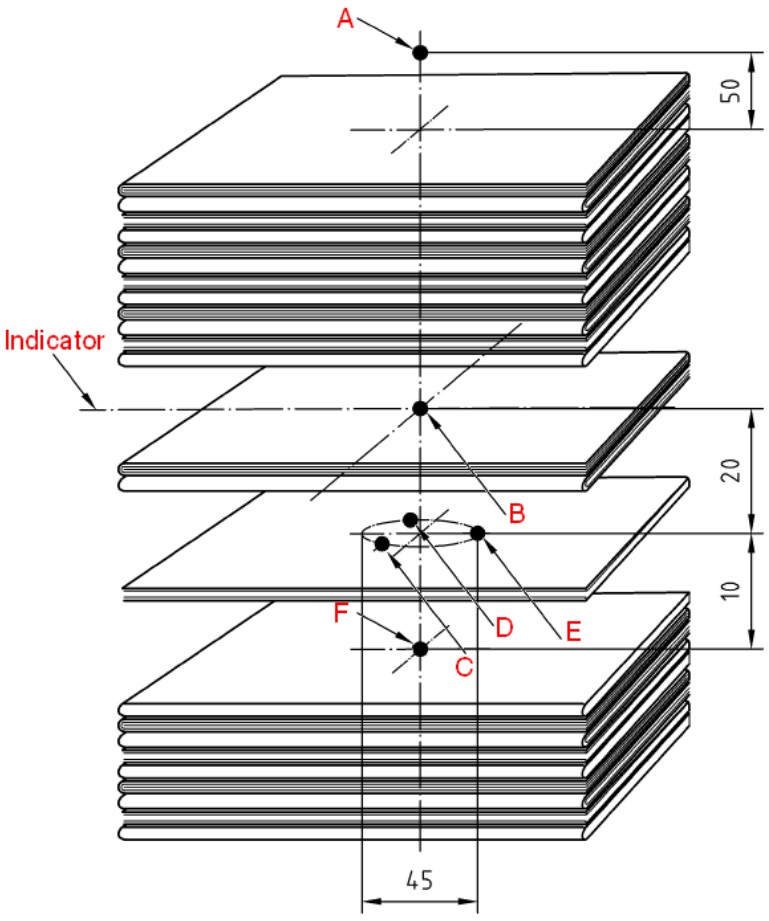
Leakage test after implementing the equipment			
Date: 2019-03-11			
Time	**Measured pressure**		
After stopping vacuum pump	p1	68	mbar
After 5 minutes	p2	71	mbar
After additional 10 minutes	p3	72	mbar
Result = p3 – p2		**1**	**mbar**

6.1 Small load test (Bowie-Dick Test)

Pictures of the loading (exemplary)	
	
Here the relative humidity is measured by a blade sensor (exemplary picture)	In this way the standard test pack was positioned within the chamber. (exemplary picture)

6.1.1 Small load test (BOWIE DICK TEST / cycle 113)

Position of the temperature sensors			
No.	**Position**	**No.**	**Position**
1	Reference in DRAIN	**11**	On sheet 18
2	On sheet 4	**12**	On sheet 21
3	On sheet 7	**13**	Not present
4	Not present	**14**	On sheet 24
5	On sheet 10 - Position **F**	**15**	Not present
6	On sheet 12 - Position **E**	**16**	Not present
7	Not Present	**17**	On sheet 24
8	On sheet 12 - Position **D**	**18**	Position **A** (“antenna”)
9	On sheet 12 - Position **C**	**19**	Not present
10	On sheet 15 - Position **B**	**20**	Not present



Amount of textiles:

30 sheets + wrapping sheet

Mass:

Before:	6839,5 g
After:	6904,5 g
➔ Difference:	0,95 %

Humidity:

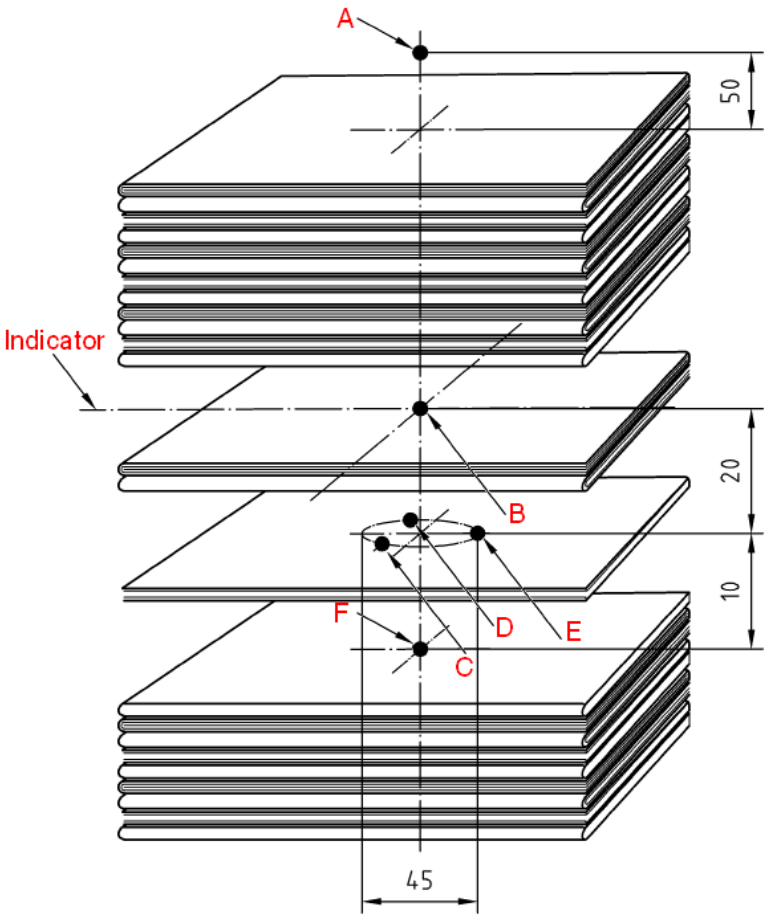
Before:	34,4%

Results

Equilibration time [≤ 15 seconds]:	0 seconds
Mass increase [≤ 1,0 %]:	0,95 %
Indicator [compl. color change]:	Color changed completely

6.1.2 Small load test (BOWIE DICK TEST / cycle 114)

Position of the temperature sensors			
No.	**Position**	**No.**	**Position**
1	Reference in DRAIN	**11**	Not present
2	On sheet 4	**12**	On sheet 21
3	On sheet 7	**13**	Not present
4	Not present	**14**	On sheet 24
5	On sheet 10 - Position **F**	**15**	Not present
6	On sheet 12 - Position **E**	**16**	On sheet 18
7	Not Present	**17**	On sheet 24
8	On sheet 12 - Position **D**	**18**	Position **A** (“antenna”)
9	On sheet 12 - Position **C**	**19**	Not present
10	On sheet 15 - Position **B**	**20**	Not present



Amount of textiles:

30 sheets + wrapping sheet

Mass:

Before: 6818,0 g
After: 6880,5 g

➔ Difference: 0,91 %

Humidity:

Before: 37,4%

Results

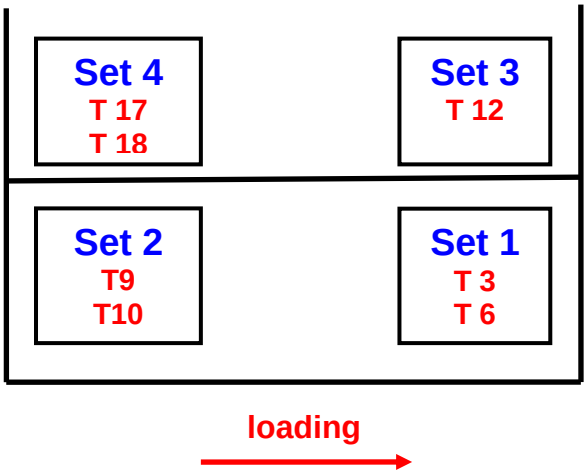
Equilibration time [≤ 15 seconds]: 0 seconds
Mass increase [≤ 1,0 %]: 0,91 %
Indicator [compl. color change]: Color changed completely

6.1.3 Small load textiles-2 (134 C STANDART / cycle 118)

Pictures of the loading textilies (exemplary)	
	
	

Pictures of the loading (exemplary)

Drain T1



Position of the temperature sensors

No.	Position	No.	Position
1	Reference in DRAIN	11	Not present
2	Not present	12	Set 3
3	Set 1	13	Not present
4	Not present	14	Not present
5	Not present	15	Not present
6	Set 1	16	Not present
7	Not present	17	Set 4
8	Not present	18	Set 4
9	Set 2	19	Not present
10	Set 2	20	Not present

Information of the load

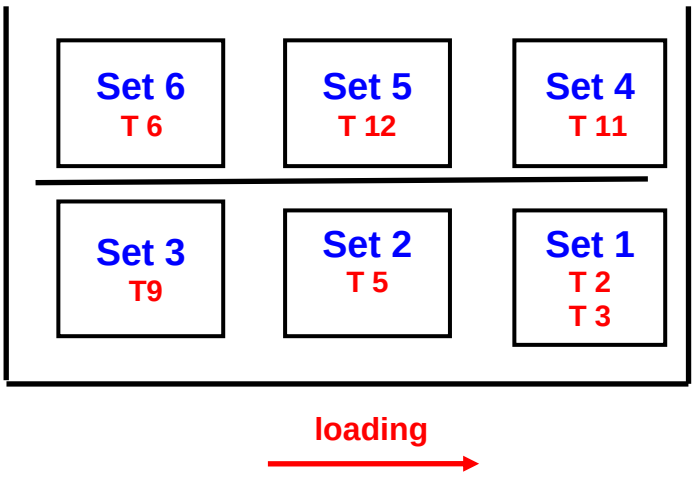
Set No	Relative humidity	Mass before	Mass after	Diff. [%]	Description
1	26,3	6419,5	6436,5	0,26	Set 1
2	22,9	6579,5	6608,5	0,44	Set 2
3	27,6	6545,5	6569,5	0,37	Set 3
4	28,9	6236,5	6275,5	0,63	Set 4

Results

Equilibration time [≤ 15 seconds]: 0 seconds
Mass increase [≤ 1,0 %]: all sets ≤ 1,0 %

6.1.4 Full load textiles- 1 (134 C Tekstil / cycle 117)

Picture (exemplary) / scheme of the loading



Position of the temperature sensors

No.	Position	No.	Position
1	Reference in DRAIN	11	Set 4
2	Set 1	12	Set 5
3	Set 1	13	Not present
4	Not present	14	Not present
5	Set 2	15	Not present
6	Set 6	16	Not present
7	Not present	17	Not present
8	Not present	18	Not present
9	Set 3	19	Not present
10	Not present	20	Not present

Information of the load

Set No	Relative humidity	Mass before	Mass after	Diff. [%]	Description
1	27,1	6421,5	6443,0	0,33	Set 1
2	26,3	6427,0	6453,0	0,40	Set 2
3	22,9	6693,5	6738,0	0,66	Set 3
4	23,6	1246,0	1250,0	0,32	Set 4
5	24,7	1270,5	1274,5	0,31	Set 5
6	25,8	980,0	985,5	0,56	Set 6

Results

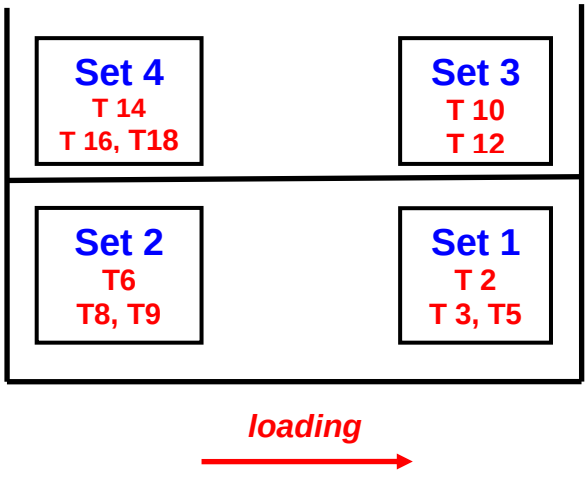
Equilibration time [≤ 15 seconds]: 0 seconds

Mass increase [≤ 0,2 %]: all sets ≤ 1,0 %

6.1.5 Small load instrument-2 (134 C Cerrahi / cycle 116)

Pictures of the loading instrument (exemplary)	
	
	

Picture (exemplary) / scheme of the loading



Position of the temperature sensors			
No.	**Position**	**No.**	**Position**
1	Reference in DRAIN	**11**	Not present
2	Set 1	**12**	Set 3
3	Set 1	**13**	Not present
4	Not present	**14**	Set 4
5	Set 1	**15**	Not present
6	Set 2	**16**	Set 4
7	Not present	**17**	Not present
8	Set 2	**18**	Set 4
9	Set 2	**19**	Not present
10	Set 3	**20**	Not present

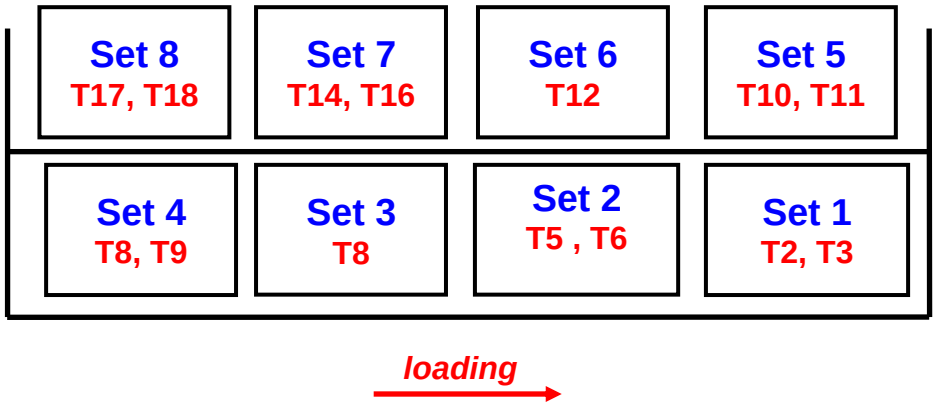
Information of the load					
Set No	**Relative humidity**	**Mass before**	**Mass after**	**Diff. [%]**	**Description**
1	36,8	3300,5	3295,5	-0,15	Set 1
2	42,4	5366,5	5357,5	-0,17	Set 2
3	38,1	7325,5	7338,0	0,17	Set 3
4	33,8	7254,0	7265,0	0,15	Set 4

Results

Equilibration time [≤ 15 seconds]: 0 seconds
Mass increase [≤ 0,2 %]: all sets ≤ 0,2 %

6.1.6 Full load instrument (134 C Cerrahi / cycle 115)

Picture (exemplary) / scheme of the loading



Position of the temperature sensors

No.	Position	No.	Position
1	Reference in DRAIN	**11**	Set 5
2	Set 1	**12**	Set 6
3	Set 1	**13**	Not present
4	Not present	**14**	Set 7
5	Set 2	**15**	Not present
6	Set 2	**16**	Set 8
7	Not present	**17**	Set 8
8	Set 3	**18**	Set 8
9	Set 4	**19**	Not present
10	Set 4	**20**	Not present

Information of the load

Set No	Relative humidity	Mass before	Mass after	Diff. [%]	Description
1	36,8	3313,0	3300,5	-0,38	Set 1
2	42,4	5386,0	5368,5	-0,32	Set 2
3	38,1	4515,0	4506,5	-0,19	Set 3
4	33,8	7335,5	7325,5	-0,14	Set 4
5	36,1	7266,5	7254,0	-0,17	Set 5
6	32,0	4833,0	4828,0	-0,10	Set 6
7	32,6	7016,0	7010,5	-0,08	Set 7
8	31,7	8024,5	8027,5	0,04	Set 8

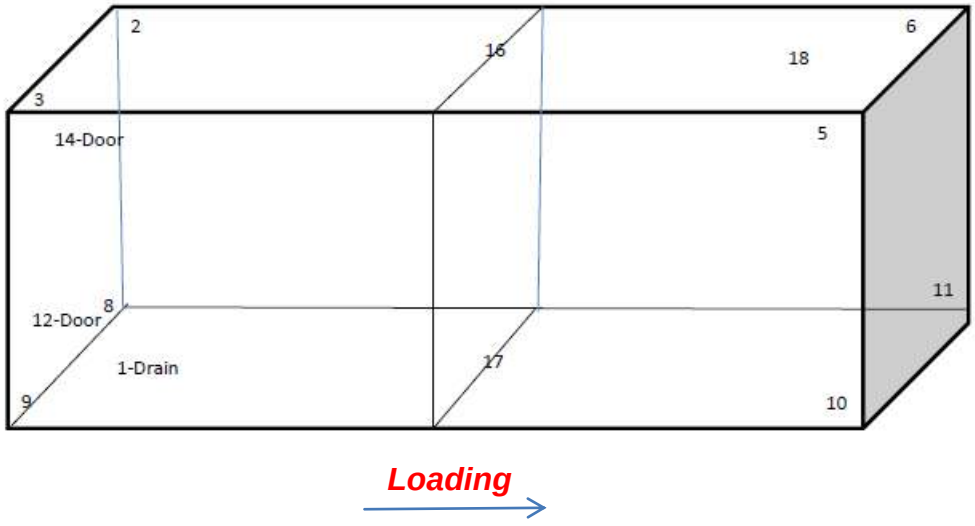
Results

Equilibration time [≤ 15 seconds]: 1 seconds

Mass increase [≤ 0,2 %]: all sets ≤ 0,2 %

6.1.7 Empty chamber + PCDs (Bowie Dick / cycle 119)

Pictures of the loading (exemplary)



Position of the temperature sensors			
No.	**Position**	**No.**	**Position**
1	Reference in DRAIN	**11**	Not present
2	Not present	**12**	Front / middle/ down
3	Front right up	**13**	Not present
4	Not present	**14**	Front / middle/ up
5	Back / right / up	**15**	Not present
6	Back / left / up	**16**	middle / up
7	Not present	**17**	Back / middle / down
8	Back / right / down	**18**	Back / middle / up
9	Front / right / down	**19**	Not present
10	Back / right / down	**20**	Not present

Results

Equilibration time [≤ 15 seconds]: 1 seconds

6 different PCDs, loaded with chemical indicators:

Indicator [compl. color change]: Color changed completely Ø 2mm max. 3,0m
Color changed completely Ø 2mm max. 4,5m
Color changed completely Ø 3mm max. 3,0m
Color changed completely Ø 4mm max. 3,0m
Color changed completely Ø 5mm max. 2,0m
Color changed completely Ø 5mm max. 3,0m

7 Conclusion

According to the results Sterilmed can be confirmed, that the types / sizes of steam sterilizers tested are conform to EN 285 and/or EN 17665.

This is also valid for all types / sizes of steam sterilizers, build in the same way of the exemplary tested sterilizers, within the chamber sizes from 540 liter.

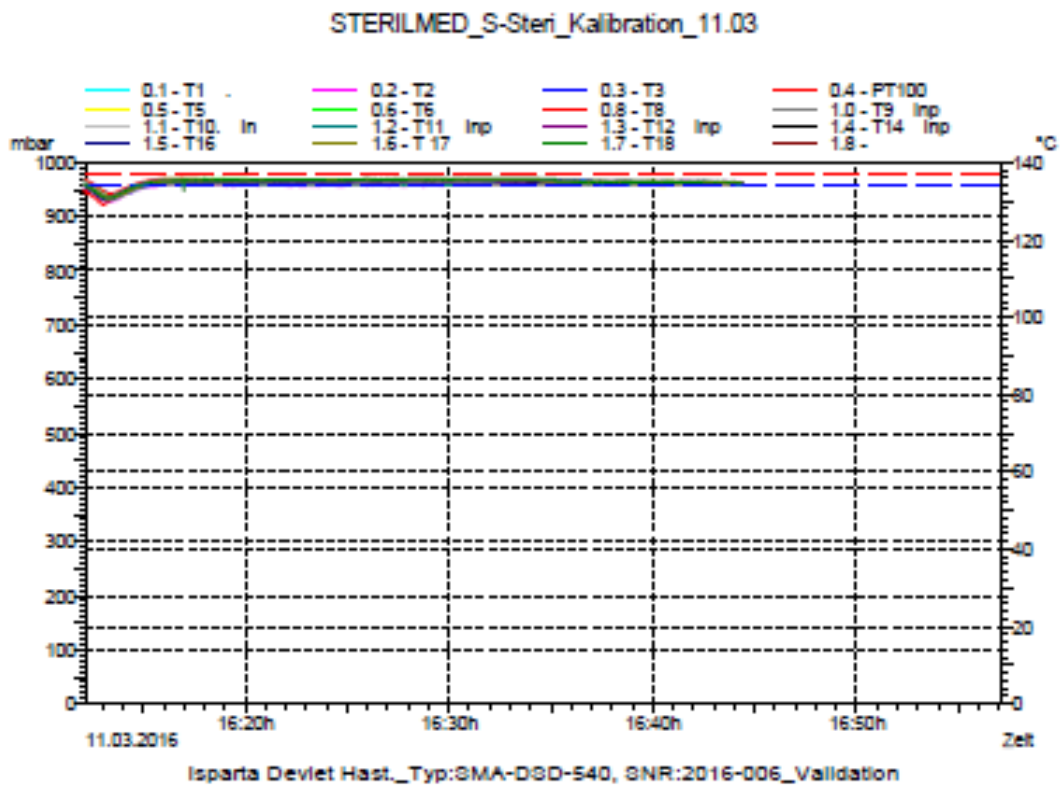
Archiving: A copy of this report is kept together with the raw data in the archive of HygCen GmbH.

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

Prof. Dr. med. H.-P. Werner
Manager of scientific-technical affairs

Monika Feltgen
Department manager

Appendix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0.2 - T2
0.3 - T3
0.4 - PT100
0.5 - T5
0.6 - T6
0.8 - T8
1.0 - T9 Inp
1.1 - T10. In
1.2 - T11 Inp
1.3 - T12 Inp
1.4 - T14 Inp
1.5 - T16
1.6 - T 17
1.7 - T18
1.8 -
mbar
°C
1000
900
800
700
600
500
400
300
200
100
0
140
120
100
80
60
40
20
0
16:20h
16:30h
16:40h
16:50h
11.03.2016
Zeit
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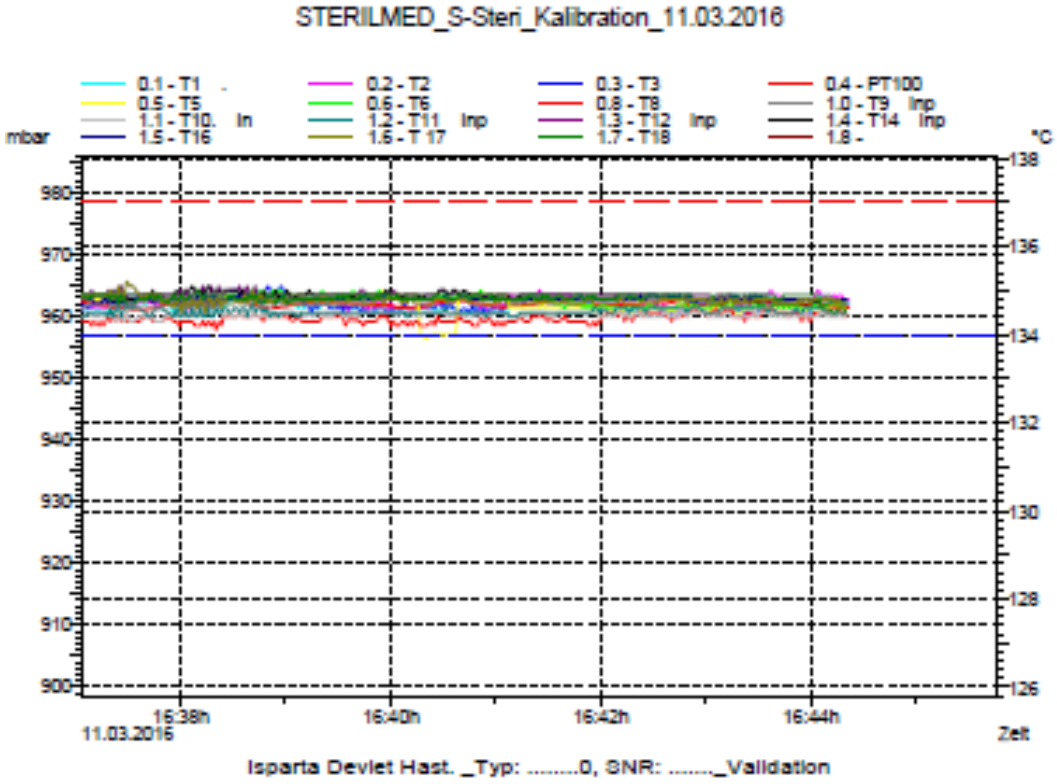
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0.1 - T1
0.2 - T2
0.3 - T3
0.4 - PT100
0.5 - T5
0.6 - T6
0.8 - T8
1.0 - T9 Inp
1.1 - T10. In
1.2 - T11 Inp
1.3 - T12 Inp
1.4 - T14 Inp
1.5 - T16
1.6 - T 17
1.7 - T18
1.8 -
mbar
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980
970
960
950
940
930
920
910
900
138
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16:38h
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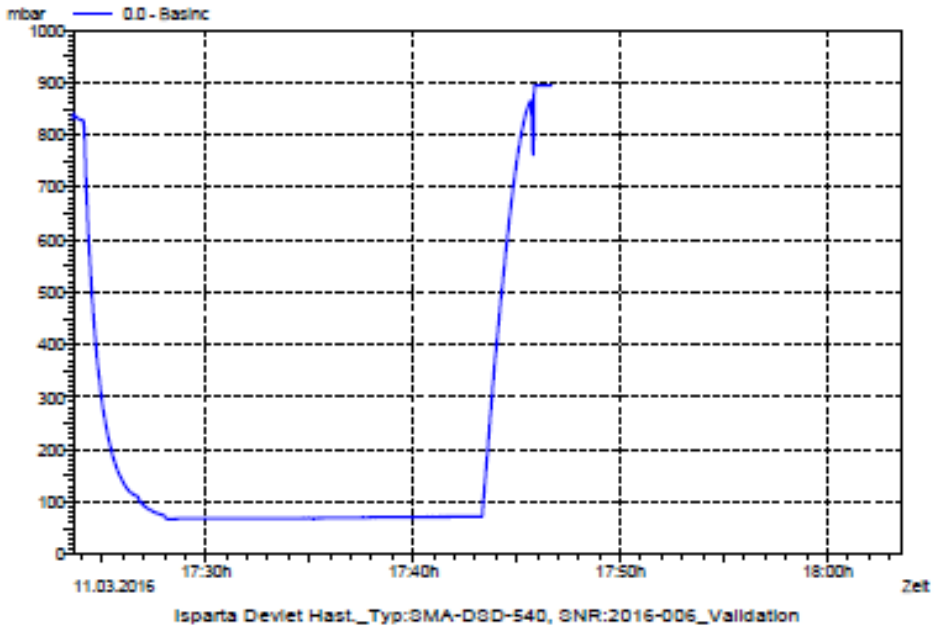

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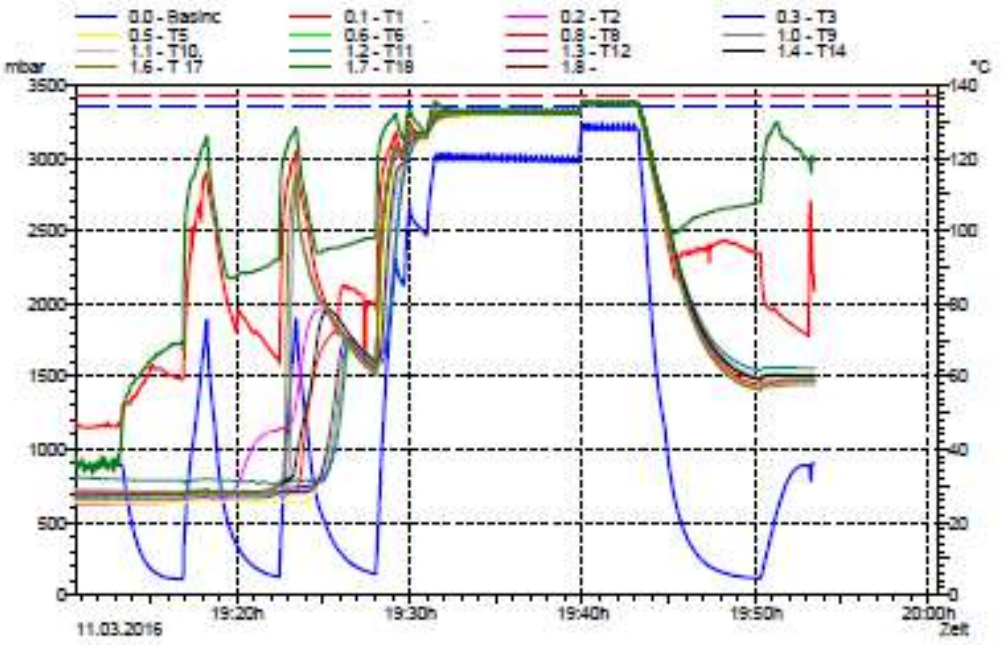

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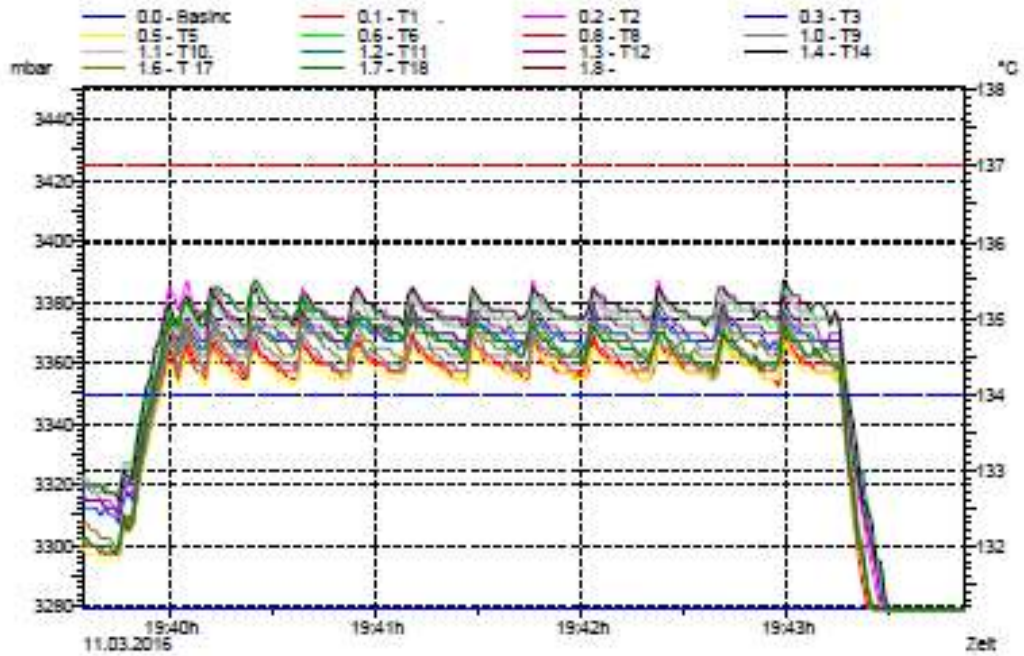

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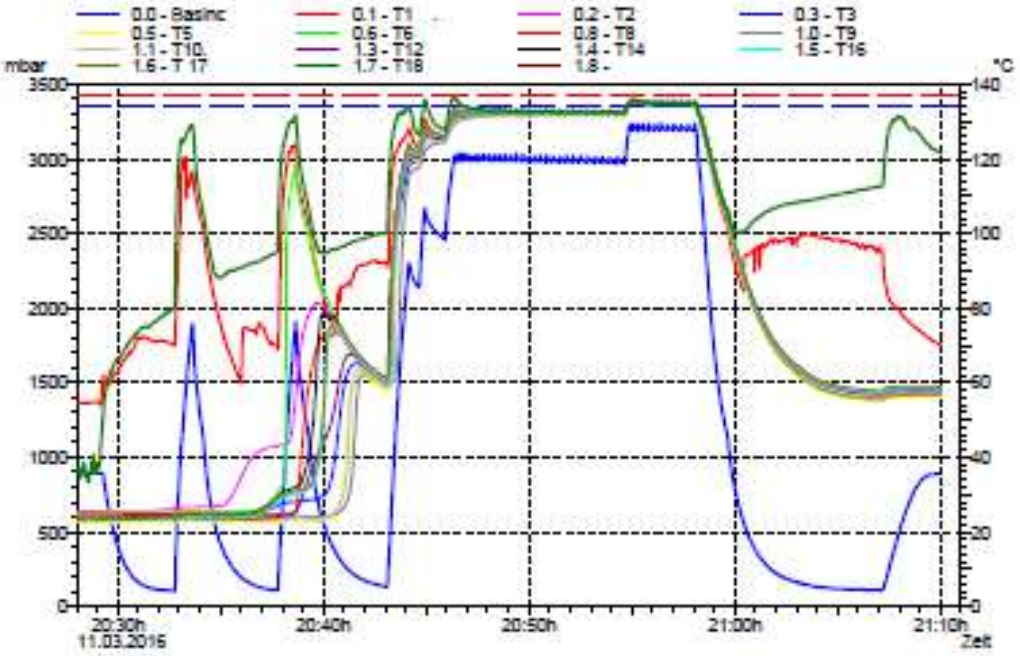

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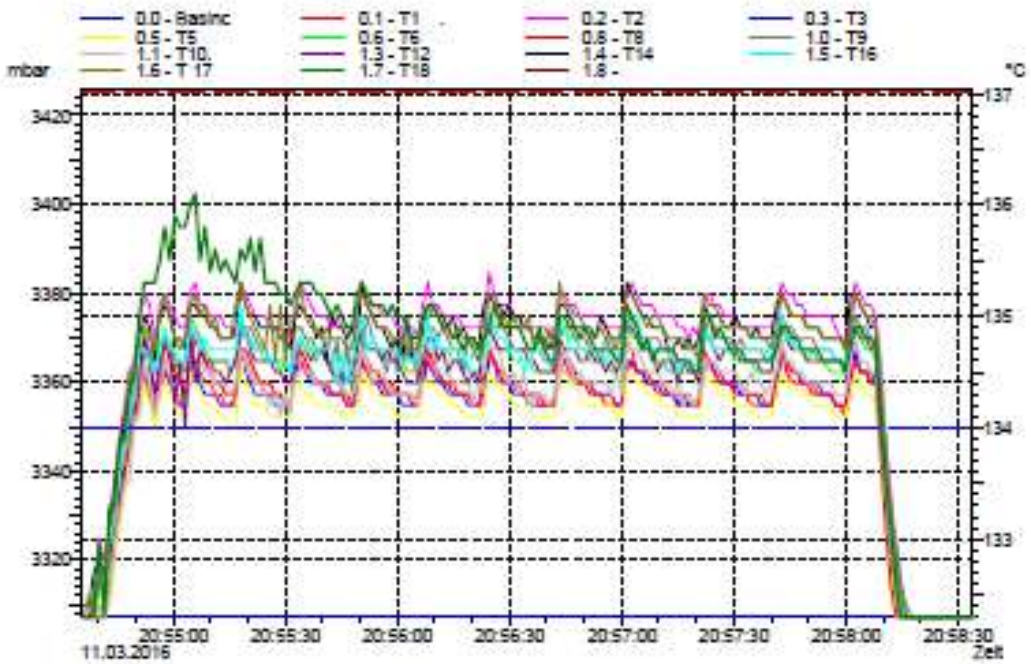

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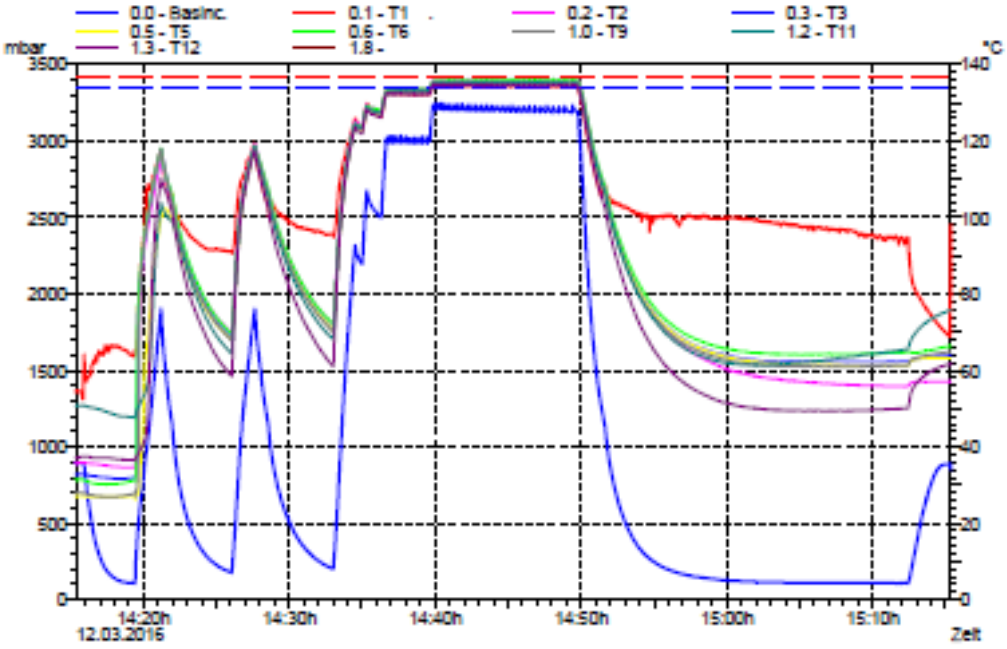

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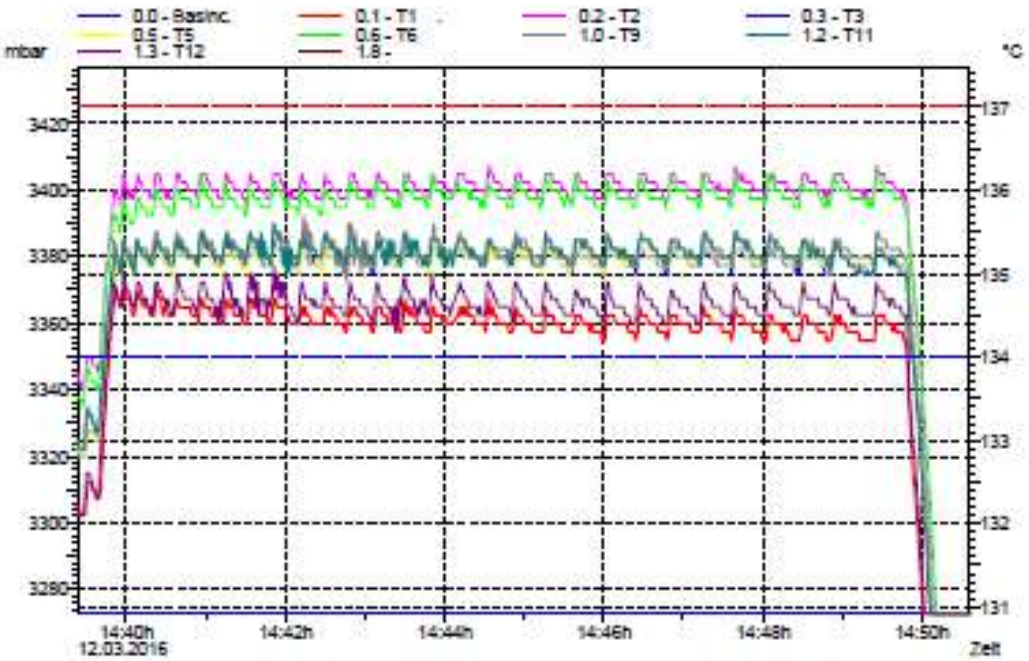

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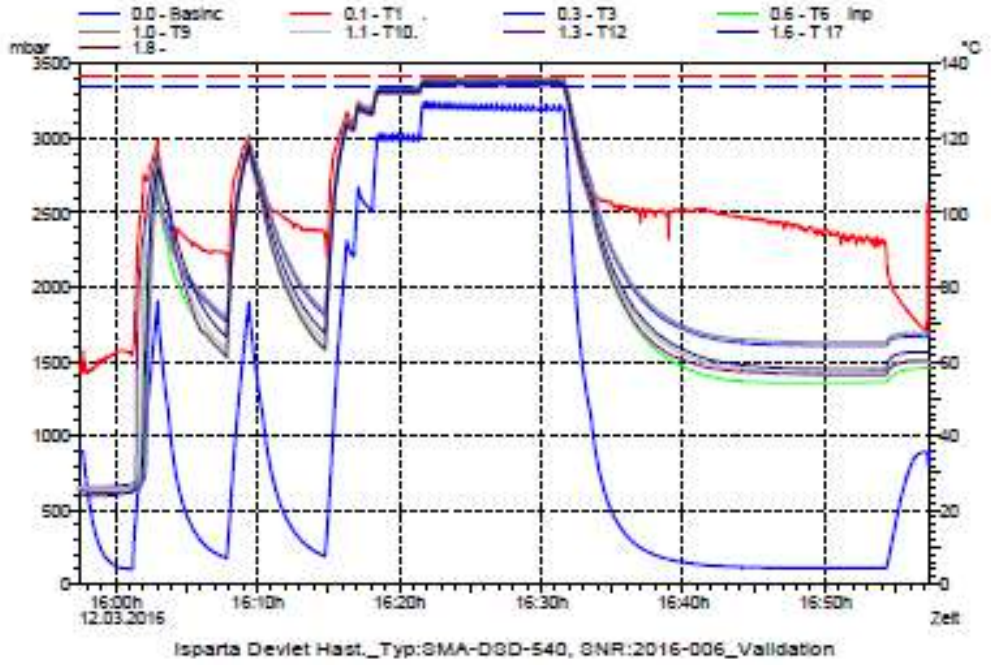

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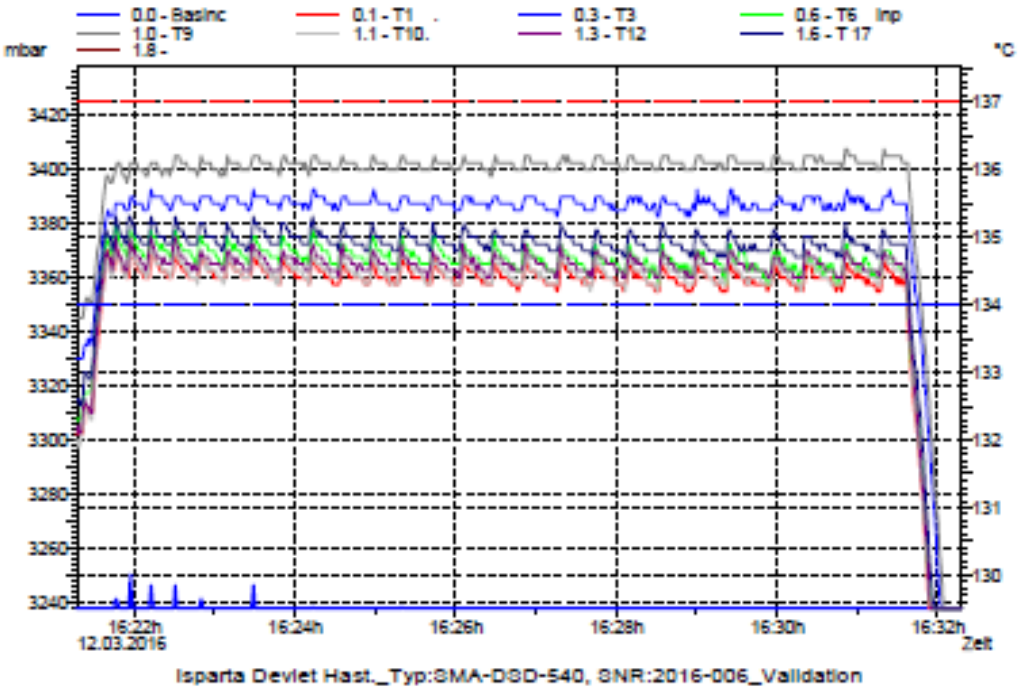

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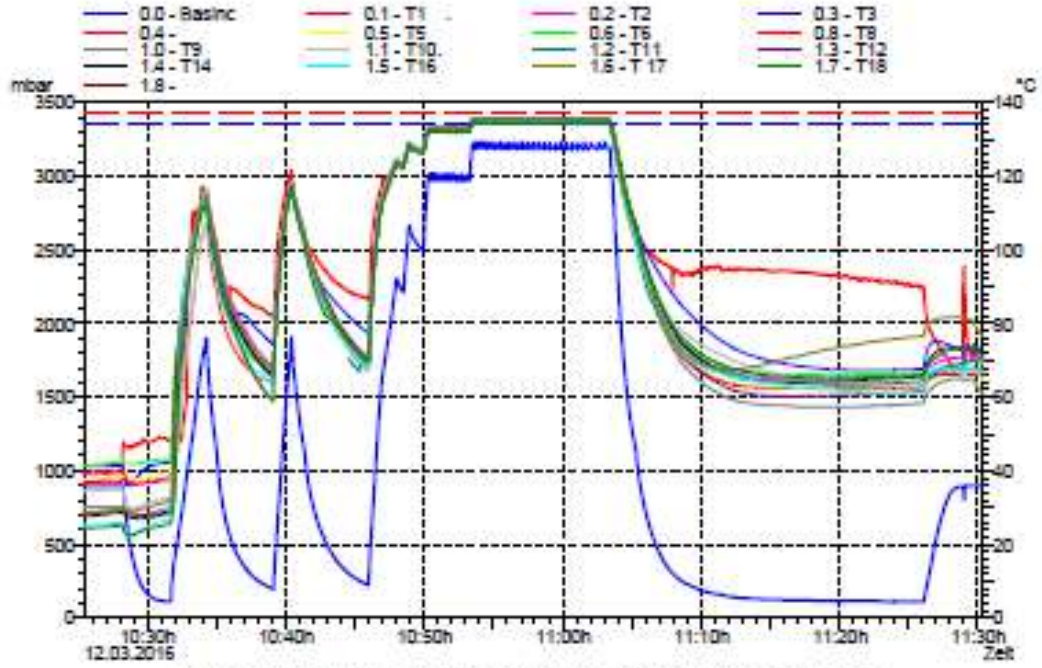

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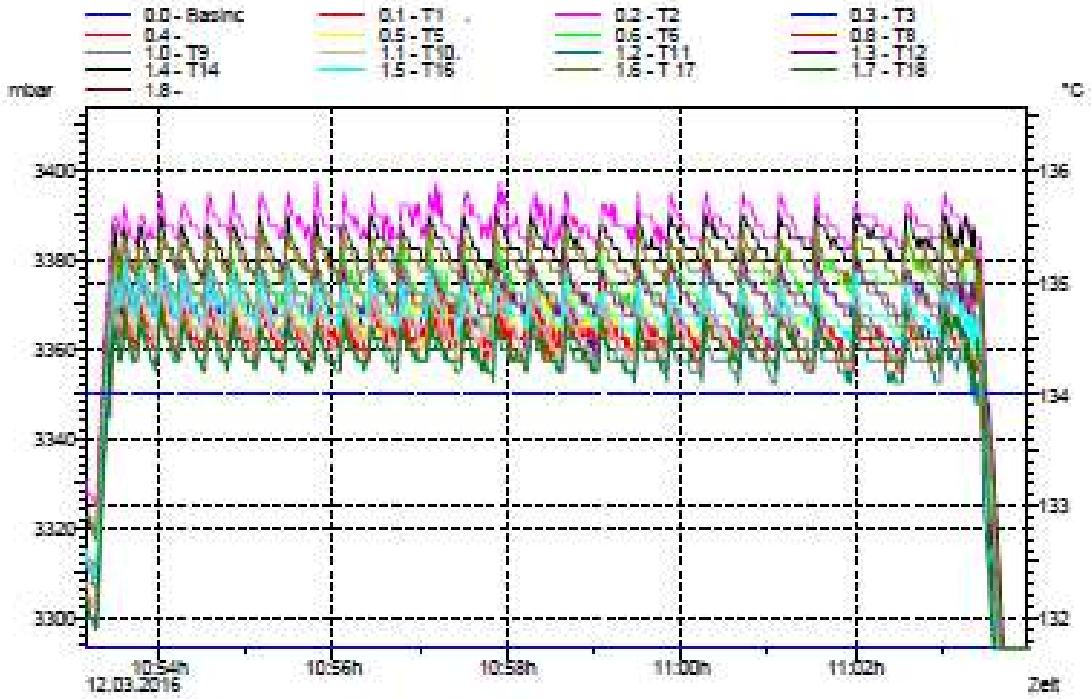
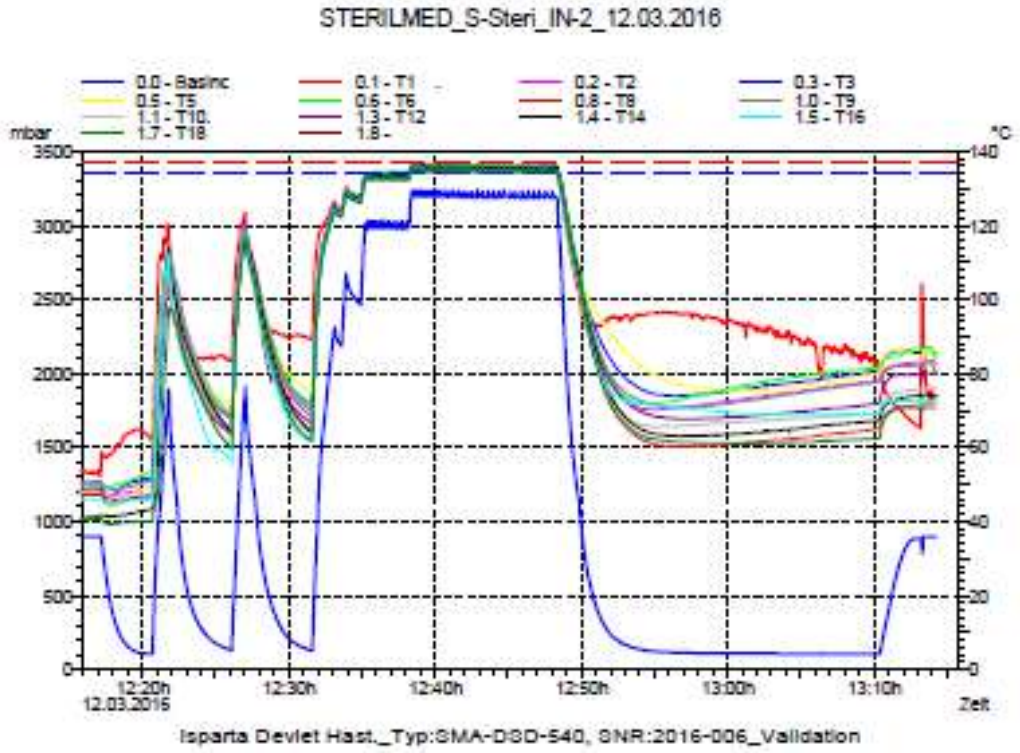
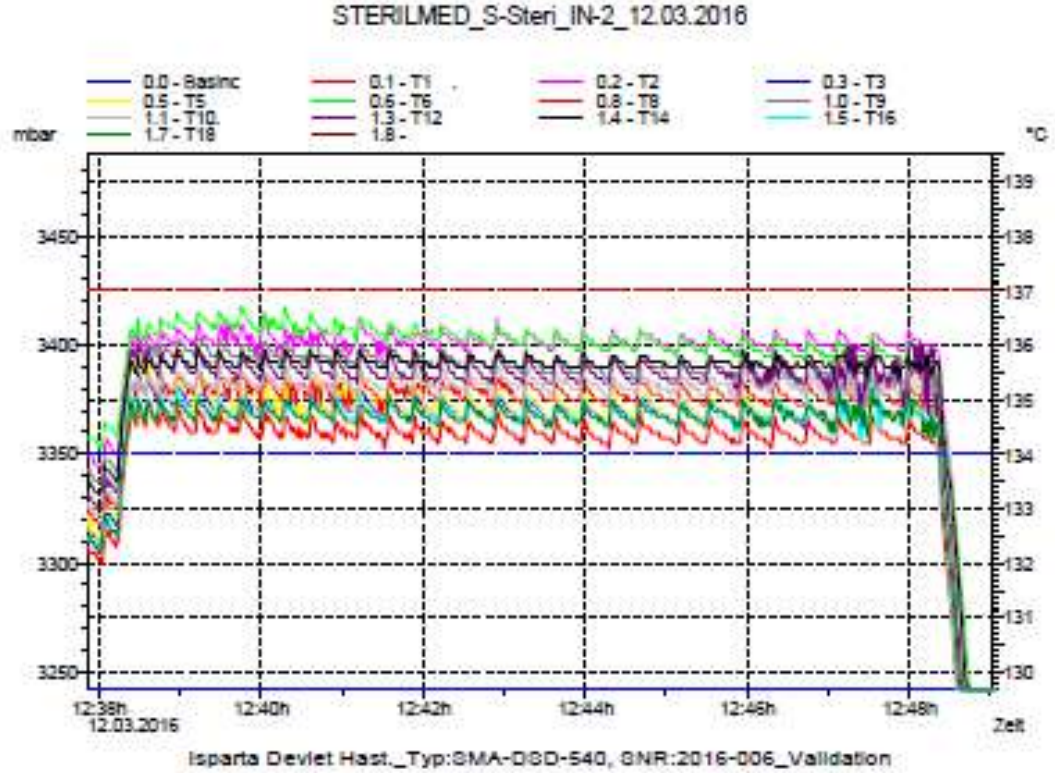
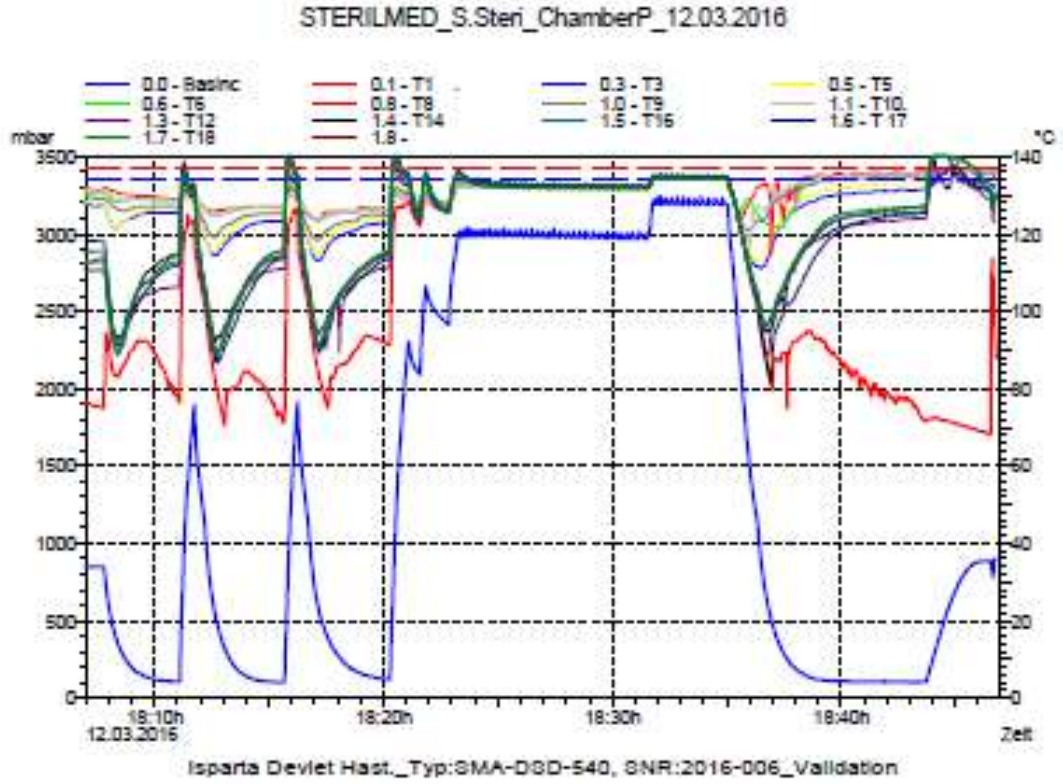
STERILMED_S.Steri_IN-1_12.03.2016



Isparta Devlet Hast._Typ:SMA-DSD-540, SNR:2016-006_Validation


STERILMED_S-Steri_IN-2_12.03.2016
0.0 - Basinc
0.1 - T1
0.2 - T2
0.3 - T3
0.5 - T5
0.6 - T6
0.8 - T8
1.0 - T9
1.1 - T10.
1.3 - T12
1.4 - T14
1.5 - T16
1.7 - T18
1.8 -
mbar
°C
3500
3000
2500
2000
1500
1000
500
0
140
120
100
80
60
40
20
0
12:20h
12.03.2016
12:30h
12:40h
12:50h
13:00h
13:10h
Zeit
Isparta Devlet Hast._Typ:SMA-DSD-540, SNR:2016-006_Validation


STERILMED_S-Steri_IN-2_12.03.2016
0.0 - Basinc
0.1 - T1
0.2 - T2
0.3 - T3
0.5 - T5
0.6 - T6
0.8 - T8
1.0 - T9
1.1 - T10.
1.3 - T12
1.4 - T14
1.5 - T16
1.7 - T18
1.8 -
mbar
°C
3450
3400
3350
3300
3250
139
138
137
136
135
134
133
132
131
130
12:38h
12.03.2016
12:40h
12:42h
12:44h
12:46h
12:48h
Zeit
Isparta Devlet Hast._Typ:SMA-DSD-540, SNR:2016-006_Validation


STERILMED_S.Steri_ChamberP_12.03.2016
0.0 - Basinc
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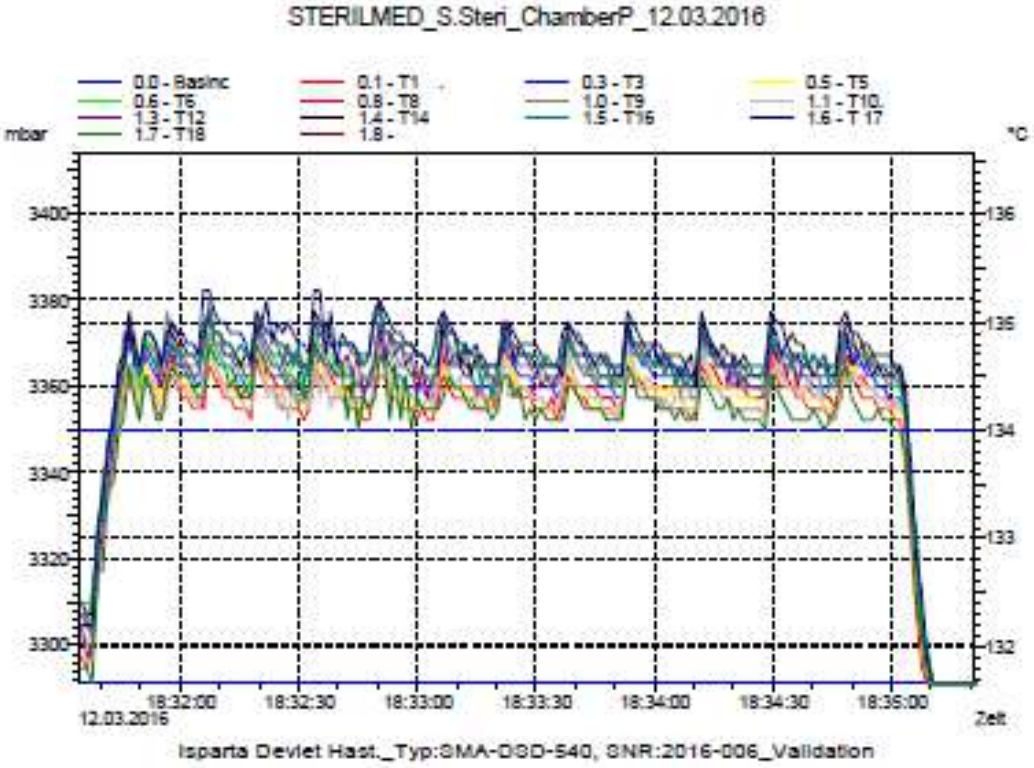
0.3 - T3
0.5 - T5
0.6 - T6
0.8 - T8
1.0 - T9
1.1 - T10
1.3 - T12
1.4 - T14
1.5 - T16
1.6 - T 17
1.7 - T18
1.8 -
mbar
°C
3500
3000
2500
2000
1500
1000
500
0
140
120
100
80
60
40
20
0
18:10h
12.03.2016
18:20h
18:30h
18:40h
Zeit
Isparta Devlet Hast._Typ:SMA-DSD-540, SNR:2016-006_Validation


STERILMED_S.Steri_ChamberP_12.03.2016
0.0 - Basinc
0.1 - T1
0.3 - T3
0.5 - T5
0.6 - T6
0.8 - T8
1.0 - T9
1.1 - T10
1.3 - T12
1.4 - T14
1.5 - T16
1.6 - T 17
1.7 - T18
1.8 -
mbar
°C
3400
3380
3360
3340
3320
3300
136
135
134
133
132
18:32:00
12.03.2016
18:32:30
18:33:00
18:33:30
18:34:00
18:34:30
18:35:00
Zeit
Isparta Devlet Hast._Typ:SMA-DSD-540, SNR:2016-006_Validation