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STERİLMED TIBBİ CİHAZLAR
Başkent O.S.B. 18.Cadde No:43
Malıköy-Sincan / ANKARA
TURKEY

02.03.2021

Inspection report U210121

STERİLMED TIBBİ CİHAZLAR

Validation Microbiological tests based on EN ISO 15883-1/2

Ordered by:	Sterilmed Tıbbi Cihazlar Başkent O.S.B. 18.Cadde No:43 Malıköy-Sincan / ANKARA TURKEY	
Date of order:	2021-02-20	
Inspection order:	Validation Microbiological tests based on EN ISO 15883-1/2	
Inspection item:	Manufacturer: Device: Serial number:	STERİLMED Washer Disinfection-SM-DWD-8 SM-DWD-8-2020-001-1
Date of inspection:	2021-02-20	Inspection by:
Inspection period / test period:	2021-02-18 – 2021-02-19; 2021-02-25 to 2021-03-05	
Participants of the inspection:	Mr. Bülent Deveci, UMS Medikal	
Inspection method / test method:	The new performance qualification (PQ) according to EN ISO 15883-1 and EN ISO 15883-2 for the validation and routine monitoring of machine cleaning and disinfection processes for thermostable medical products and the principles of the device selection "	

Digitally signed by Morozov Maria
Date: 2024.02.29 17:02:34 EET
Reason: MoldSign Signature
Location: Moldova

Contents

1 General İnformation

According to the order, the new performance qualification (PQ) according to EN ISO 15883-1: 2012 and EN ISO 15883-2: 2009 has been applied to the Sterilmed SM-DWD-8 (Sn: SM-DWD-8-2020-001-1) cleaning disinfector for the validation between 18.02.2021 - 19.02.2021 And routine monitoring of machine cleaning and disinfection processes for thermostable medical devices and principles of device selection "

All cleaning disinfectors (WD‘s) are supplied with process chemicals via a decentralized dosing device, in the STERİLMED, I&D Alcali with Dr.Schumacher Thermoton N (STERİLMED TIBBİ CİHAZLAR - ANKARA)

2 Basic data and data

Address: Sterilmed Tıbbi Cihazlar
Başkent O.S.B. 18.Cadde No:43
Malıköy-Sincan / ANKARA
TURKEY

Test place: Sterilmed Tıbbi Cihazlar
Başkent O.S.B. 18.Cadde No:43
Malıköy-Sincan / ANKARA
TURKEY

2.1.1 Sketch oft he test place

View: Sterilmed - SM-DWD-8

2.1.2 Information on structural conditions

Dirty and clean area separated:	☒ YES ☐ NO **<u>Instructions:</u>** not _____ Organizational/Hygienic_____ _____ But no spatial separation _____
Return of the loading wagons to the Unclean side:	☒ WD ☐ Lock / Single door ☐ Lock / second door ☐ Opening without closure ☐ Others _____
Reach between the pure and pure side:	☒ No ☐ Opening with possibility of closure ☐ Opening without closure ☐ Others _____

2.1.3 Information on responsibilities of the operator

Specialists for hygiene[1]:	-
Head of the sterilization department[1]:	-

[1] Indication at the time of the examinations..

2.2 Information on the WD and its loading wagon

All data are only valid for programs or loading cars registered during the course validation. Additional programs and loading carts installed or existing are not considered.

2.2.1 Information on the WD

Manufacturer:	STERİLMED
Type:	SM-DWD-8
Device number:	SM-DWD-8-2020-001-1
Construction year:	2020
Condition on delivery[2]:	New
Standort des RDG[3]:	STERİLMED / ANKARA
The internal term Of the RDG:	-
Design of the RDG Type:	☐ Undercounter ☐ Stand / upper table unit ☐ Multi-chamber system (____ chambers) ☒ Others _____
Design of the WD - doors:	☐ Single chamber / Single door ☒ Single chamber / two-door ☐ Multi-chamber system (____ chambers) ☐ Others _____

[2] If any information is relevant / relevant, otherwise "no information ".
[3] Information about the location can include the building section, floor, room number, etc..

Heating:	☒ Electric heating ☐ Steam heating ☐ Heat recovery ☐ Others _____
Type tested according to EN ISO 15883:	☒ Unknown ☐ YES *(If YES, by whom)* _____ _____ **accredited for this exam?** ☐ YES ☒ NO
Loading the RDG via:	☒ Transfer cars ☐ Supply line manually ☐ Supply belt automatically ☐ Others _____
Unloading of the RDG:	☒ Transfer cars ☐ Output belt manually ☐ Output belt automatically ☐ Others _____
Instructions:	Not

2.2.2 Information about loading rack

2.2.2.1 Information about the 5-level rack

Manufacturer:	Sterilmed
Type:	5-level rack
Device number:	-
Use in programs:	• • _____ • _____
Photo / Drawing:	
Instruction:	• **<u>Labeling by the user:</u>** • **<u>Number of carts on site:</u>** • **<u>Number of carts ordered:</u>** <u>Notes:</u> * X is a consecutive number ** Information on the date of the investigations.

2.3 Information on the media supply for the WD

2.3.1 Water supply

Existing water quality:	☒ Cold water ☒ Hot water ☐ Demineralized water ☒ Others __Osmos_____
Water treatment:	_____ _____ _____ _____

2.3.2 Air Supply

Available air quality:	☒ Oil-free compressed air Control of valves, etc. _____ ☐ Medical compressed air _____ ☐ Others _____
Instructions:	Not

2.3.3 Dosage

The product data sheets, if available, are attached to this test report. In any case, the product data sheets are in the customer's documentation.

2.3.3.1 Information on dosage 1

Manufacturer:	I&D Alcali
Product:	I&D Alcali
Dosage sart:	☒ Decentralized dosage ☐ Centralized dosage with intermediate container ☐ Central dosage without intermediate container ☐ Others _____
Removing the container / canister to the WD:	☒ 0.5 to 1.5 m on the same floor ☐ ___ m on over ___ floor (s) ☐ Others _____
Dosage in program:	• _____ • _____
Instructions:	not _____ _____

2.3.3.2 Information on dosage 2

Manufacturer:	Dr.Schumacher
Product:	Dr.Schumacher Thermoton N
Dosage sart:	☒ Decentralized dosage ☐ Centralized dosage with intermediate container ☐ Central dosage without intermediate container ☐ Others _____
Removing the container / canister to the RDG:	☒ 0.5 to 1.5 m on the same floor ☐ ___ m on over ___ floor (s) ☐ Others _____
Dosage in program:	• _____ • _____
Instructions:	Disinfectant quantity determination system not possible

2.4 Program descriptions

All data on programs are based on the program descriptions UMS MEDİKAL LTD. submitted by the client or the data of the batch documentation of the WD manufacturer.

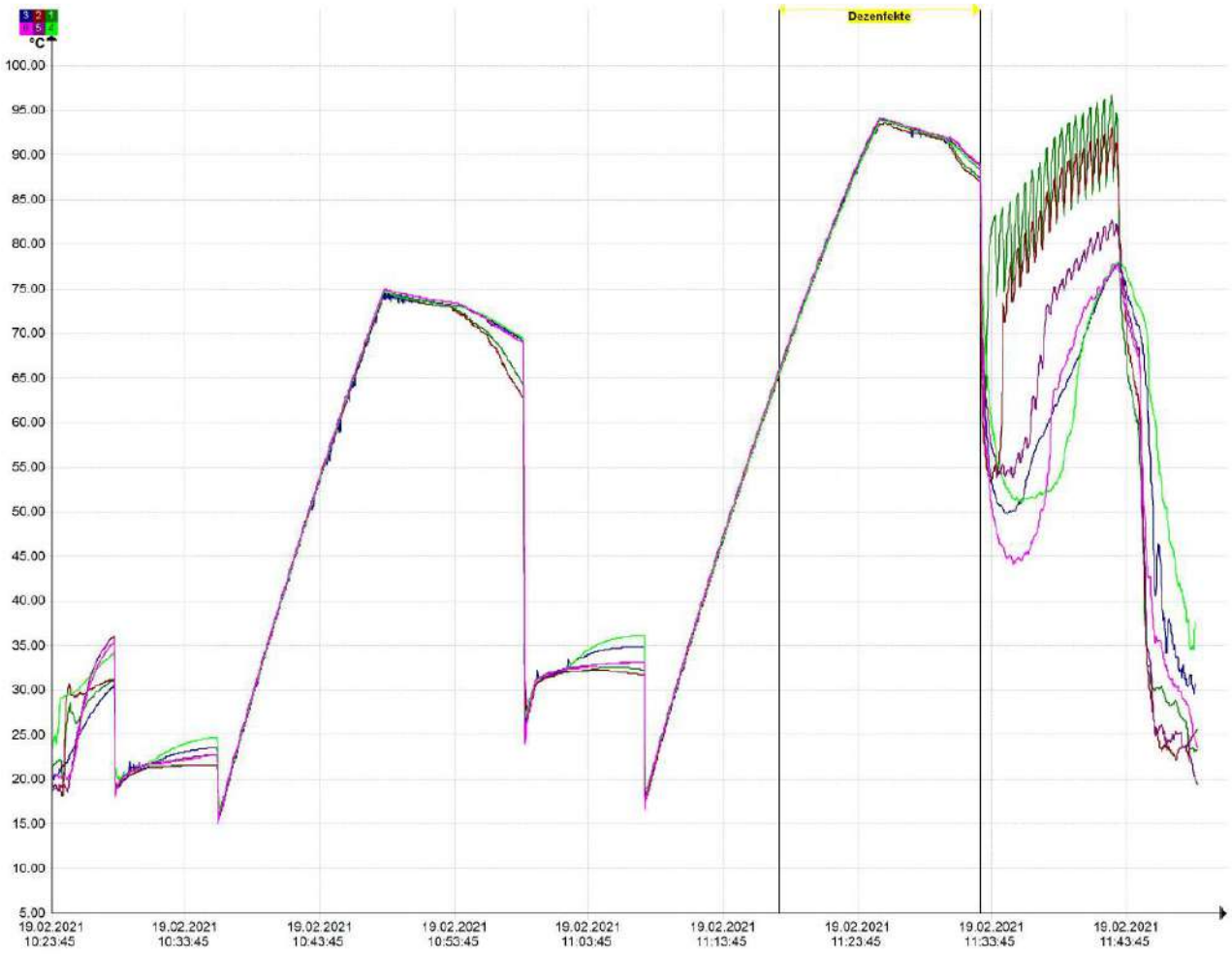
2.4.1 Program

2.4.1.1 Program Description / P1 Standard

Phase	Time	Temperature	Water / air	Dosing line	Cleanser	Concentration
Prerinse 1	2,5 min	30°C	CW (26 Liter)			
Washing 1	5 min	60°C	CW+HW (26 Liter)		Alcali	120 ml
Rinse	2,5 min	30°C	CW+HW+CDW (26 Liter)		Noutrulizane	60 ml
Thermal disinfection Ao-3000	1 min	90°C	Tank 1 (26 Liter)			
Drying	10 min	130°C				

Legend:
CW: Coldwater
HW: Hotwater
CDW: Completely desalinated water

2.4.1.2 Sample curve for the process flow to the program



Note: This is a sample curve that has been provided with additional information. Date and time have no meaning.

2.4.1.3 Comments on the program

Not

2.4.1.4 Notes on possible process-relevant preparatory steps

- At the time of validation = none known

2.5 Description of the test condition of the WD

2.5.1 Information on the installation qualification (IQ = Installation Qualification)

Date of installation qualification:	--
Where can the data for the characterization of the equipment be viewed?	--
Instructions:	Not

2.5.2 Information on the operation qualification (OQ = Operational Qualification)

Date of last operation qualification:	--
Where can the data for the operation qualification be viewed?	--
Instructions:	Not

2.5.3 Performance qualification information (PQ = Performance Qualification)

Date of last operation qualification:	---
Where can the data for the operation qualification be viewed?	In this test report
Instructions:	Not

2.5.4 Information on changes since the last test

Date of change:	--
Type and reason of amendment:	--
Change implemented by:	--
Instructions:	--

2.5.5 Technical and optical condition

Description of the general condition of the RDG when the validation work is started:	New _____ _____ _____ _____
Determinable technical deficiencies[3]:	☒ NO ☐ YES *(if yes, which)* _____ _____
Instructions:	Not

[3] z.B. Visible leaks, defects on loading wagons, wear on rotating arms or spraying systems, etc.

2.6 Information on the batch documentation by the operator

Batch prints in the Getinge CM320 available:	☐ YES (print) ☒ YES (Digital) ☐ NO (No documentation) **Instructions:**
What are the batch expressions ?:	☐ Not specified ☐ Original of the WD manufacturer ☒ Documentation software **Zus.Information about the documentation software:** Manufacturer: Sterilmed® Software: Sterilmed® **Instructions:** Not

Batch printings Part of the test report:	☐ YES ☐ YES, partially ☒ NO *(If NO, comment)* **Instructions:** At the time of validation no documents were handed over.
General note:	

3 Overview of the tests performed during the course of operation and / or service qualification

SM-DWD-8-2020-001-1

Elektro

Instrument

RL Blut
5 Etagen
Wagen

DL (A0)
E.faecium

RL Blut
5 Etagen
Wagen

4 Examinations and results to program

4.1 Overview of the sensors used

See also temperature curves and method descriptions in the appendix.

4.1.1 Description of the used loggers

Bez. internally	Serial no. sensor	Serial no Logger	Description
T 1	EBI 12	19701142	Temperature Logger
T 2	EBI 12	19701143	Temperature Logger
T 3	EBI 12	19701538	Temperature Logger with pressure

Note:

Not

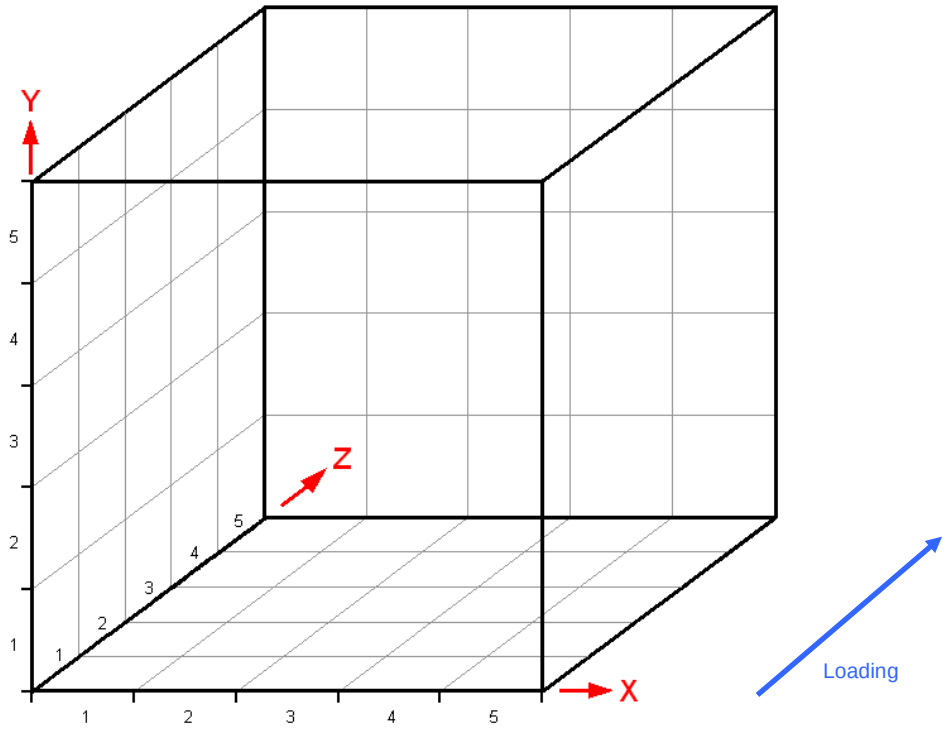
4.1.2 Description of the used readout device

Serial-Nr. Sensor	Article no.	Description
20010222	VQ5-EBIIFXXX	EBRO EBI IF 200

4.1.3 Arrangement of the loggers

In order to be able to define the logger positions independently of the loading cart used, the data on the logger positions with three-dimensional coordinate axes are defined as follows:

- **Starting point:** Unclean side, left, down
- **X- Axis:** Left to right
- **Y- Axis:** From bottom to top
- **Z- Axis:** From the Unclean Side to the Pure Side



Note:

In addition, there can be meaningful photos of the respective loads in the following chapters..

4.1.4 Charge Cycle 1 / 2 / 3 - Electrically heated

Car Type: 5-level -rack (15)
(Chapter 2.2.2)

Test Configuration: Cleaning performance by quantitative protein analysis

Logger (Bez. Intern)		Loggerposition			Comments
		Position X-Axis	Position Y-Axis	Position Z-Axis	
T 1	- 1				
	- 2				
T 2	- 1	3	3	3	
	- 2	3	3	3	
T 3	- 1				
	- 2				

Additional information:

If an exact assignment of the batch number in the documentation system at the inspection time is not possible, the batch is clearly defined with the date and start time.

4.1.5 Charge Cycle 4 / 5 / 6 - Electrically heated

Car type: 5-level rack (15)
(Chapter 2.2.2)

Test Configuration: Disinfecting performance by means of quantitative germ reduction including A0 evaluation

Logger (Bez. Intern) *(Chapter **Hata! B aşvuru kaynağı bulunamadı.**)*		**Loggerposition** *(Chapter **Hata! B aşvuru kaynağı bulunamadı.**)*			**Comments**
		Position X-Axis	**Position Y-Axis**	**Position Z-Axis**	
T 1	**- 1**	5	5	5	
	- 2	5	5	5	
T 2	**- 1**	3	3	3	
	- 2	3	3	3	
TD 3	**- 1**	1	1	1	
	- 2	1	1	1	

Additional information:

If an exact assignment of the batch number in the documentation system at the inspection time is not possible, the batch is clearly defined with the date and start time.

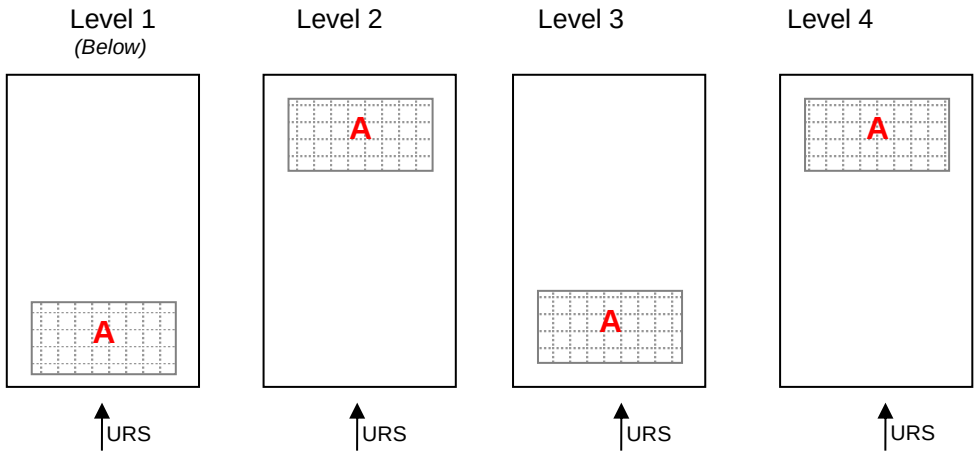
4.2 Effectiveness of cleaning

In all cleaning efficiency tests, the process was interrupted immediately prior to the disinfection phase, except for the assessment of the real contaminated instruments in the customer load, or a program specially programmed for checking the cleaning performance was selected.

4.2.1 Test soiling according to EN 15883-5 Annex A

See description for methodology.

4.2.1.1 Loading Charge Cycle 1 , Cycle 2 and Cycle 3



Legende:

Sieve
A Screen tray position
URS Unclean side

4.2.1.2 Results for Charge Cycle 1

Car type: 5-level rack(15)
(Chapter 2.2.2)

Test configuration: Cleaning performance according to EN 15883-5 Annex A

Level screen position		Number of test specimens				Comments
		Mayo scissors soiled	Mayo scissors With remnants	CRILE terminal soiled	CRILE terminal With remnants	
1	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
2	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
3	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
4	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
Summe		40	0	40	0	
		= 0 %		= 0 %		
		= 0 %				*(acceptance criteria = max. 5%)*

Comments: Not

4.2.1.3 Results for Charge Cycle 2

Car type: 5-level rack(15)
(Chapter 2.2.2)

Test configuration: Cleaning performance according to EN 15883-5 Annex A

Level screen position		Number of test specimens				Comments
		Mayo scissors soiled	Mayo scissors With remnants	CRILE terminal soiled	CRILE terminal With remnants	
1	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
2	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
3	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
4	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
Total		40	0	40	0	
		= 0 %		= 0 %		
		= 0 %				*(acceptance criteria = max. 5%)*

Comments: Not

4.2.1.4 Results for Charge Cycle 3

Car type: 5-level rack(15)
(Chapter 2.2.2)

Test configuration: Cleaning performance according to EN 15883-5 Annex A

Level screen position		Number of test specimens				Comments
		Mayo scissors soiled	Mayo scissors With remnants	CRILE terminal soiled	CRILE terminal With remnants	
1	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
2	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
3	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
4	- A	10	0	10	0	
	--	--	--	--	--	
	--	--	--	--	--	
Total		40	0	40	0	
		= 0 %		= 0 %		
		= 0 %				*(acceptance criteria = max. 5%)*

Comments: Not

4.2.2 Quantitative protein analysis using test specimens

The test specimens are attached to the grid bars using stainless steel wire and pass through the entire process. Since the geometry of the loading trolleys can differ, the exact position of the individual test bodies can best be described by the coordinate assignment, analogous to that of the logger.

See description for methodology.

4.2.3 Loading Schema / Photo to Charge Cycle 1 / 2 / 3

Cart type: 5-level rack(15)
(Chapter 2.2.2)

Test configuration: Cleaning performance according to EN 15883-5 Annex A

specimen No. / Batch			Test specimen position *(Chapter **Hata! Başvuru kaynağı bulunamadı.**)*			Comments
			Position X-Axis	Position Y-Axis	Position Z-Axis	
1	20		2,3,4	5	1	Defibrinated sheep's blood
21	40		2,3,4	4	5	Defibrinated sheep's blood
41	60		2,3,4	3	1	Defibrinated sheep's blood
61	80		2,3,4	2	5	Defibrinated sheep's blood

4.2.3.1 Results for Charge Cycle 1 / 2

Control of test specimens	Average µg Asp./PK	log µg Asp./PK
defibr. sheep blood	5.467,14	3,74

Charge Cycle 1

Specimen No	Rehearse-Designation	Rehearse-number	Average µg Asp./PK	Standard Dev.	Extent of stripping	log µg Asp./PK	RF µg Asp./PK
1 to 5	defibr. sheep blood	5	3,40	1,67	99,94	0,53	3,21

Charge Cycle 2

Specimen No	Rehearse-Designation	Rehearse-number	Average µg Asp./PK	Standard Dev.	Extent of stripping	log µg Asp./PK	RF µg Asp./PK
1 to 5	defibr. sheep blood	5	3,40	1,67	99,94	0,53	3,21

Charge Cycle 3

Specimen No	Rehearse-Designation	Rehearse-number	Average µg Asp./PK	Standard Dev.	Extent of stripping	log µg Asp./PK	RF µg Asp./PK
1 to 5	defibr. sheep blood	5	3,40	1,67	99,94	0,53	3,21

Legend:
Asp = aspartic acid
PK = test specimen
RF = reduction factor

Rating:
RF ≥ 3.0 log very good cleaning performance
RF <3.0 and ≥ 2.5 log good cleaning performance
RF <2.5 and ≥ 1.5 log sufficient cleaning power

4.3 Effectiveness of disinfection

4.3.1 Quantitative testing by germ carrier

The test specimens are attached to the grid bars using stainless steel wire and pass through the entire process. Since the geometry of the loading trolleys can differ, the exact position of the individual test bodies can best be described by the coordinate assignment, analogous to that of the logger. The test seed used is E. faecium (ATCC 6057).

4.3.1.1 Loading Schema Charge Cycle 4

Cart type: 5-level rack(15)
(Chapter 2.2.2)

Test configuration: Disinfecting performance

Specimen No	Test specimen position			Comments
	Position X-Axis	Position Y-Axis	Position Z-Axis	
1	5	5	1	
2	5	5	5	
3	1	5	5	
4	1	5	1	
5	3	5	3	

4.3.1.2 Report to Charge Cycle 4

Cart type: 5-level rack (15)
(Chapter 2.2.2)

Test Configuration: Disinfecting performance by means of quantitative germ reduction

Control No.	KBE / Specimen	Average [log]
Control 1	1,5 x 10^8	1,5x10^8

Specimen No.	Position	Enrichment* [3 / 7 Meet]	KBE to CSA	Reduction factor (RF) [log]
1	See loading sketch	- / -	< 100	≥ $1,5x10^8$
2	See loading sketch	- / -	< 100	≥ $1,5x10^8$
3	See loading sketch	- / -	< 100	≥ $1,5x10^8$
4	See loading sketch	- / -	< 100	≥ $1,5x10^8$
5	See loading sketch	- / -	< 100	≥ $1,5x10^8$

Legend:
*)Smear on Slanetz-Bartley agar after 3 and 7 days
KBE = Colon-forming units
PK = Test specimen
RF = Reduction factor

4.3.1.3 Loading Schema Charge Cycle 5 - with user load

Cart type: 5-level rack(15)
(Chapter 2.2.2)

Test configuration: Disinfecting performance

Specimen No	Test specimen position *(Chapter **Hata! Başvuru kaynağı bulunamadı.**)*			Comments
	Position X-Axis	Position Y-Axis	Position Z-Axis	
6	5	5	1	
7	5	5	5	
8	1	5	5	
9	1	5	1	
10	3	5	3	

4.3.1.4 Report to Charge Cycle 5 - with user load

Cart type: 5-level rack (15)
(Chapter 2.2.2)

Test Configuration: Disinfecting performance by means of quantitative germ reduction

Control No.	KBE / Specimen	Average [log]
Control 1	1,5 x 10^8	$1,5x10^8$

Specimen No.	Position	Enrichment* [3 / 7 Meet]	KBE to CSA	Reduction factor (RF) [log]
6	See loading sketch	- / -	< 100	≥ $1,5x10^8$
7	See loading sketch	- / -	< 100	≥ $1,5x10^8$
8	See loading sketch	- / -	< 100	≥ $1,5x10^8$
9	See loading sketch	- / -	< 100	≥ $1,5x10^8$
10	See loading sketch	- / -	< 100	≥ $1,5x10^8$

Legend:
*)Smear on Slanetz-Bartley agar after 3 and 7 days
KBE = Colon-forming units
PK = Test specimen
RF = Reduction factor

4.3.1.5 Loading Schema Charge Cycle 6

Cart type: 5-level rack(15)
(Chapter 2.2.2)

Test configuration: Disinfecting performance – A0

Specimen No	Test specimen position *(Chapter **Hata! Başvuru kaynağı bulunamadı.**)*			Comments
	Position X-Axis	Position Y-Axis	Position Z-Axis	
11	5	5	1	
12	5	5	5	
13	1	5	5	
14	1	5	1	
15	3	5	3	

4.3.1.6 Report to Charge Cycle 6

Cart type: 5-level rack (15)
(Chapter 2.2.2)

Test Configuration: Disinfecting performance by means of quantitative germ reduction – A0

Control No.	KBE / Specimen	Average [log]
Control 1	1,5 x 10^8	1,5x10^8

Specimen No.	Position	Enrichment* [3 / 7 Meet]	KBE to CSA	Reduction factor (RF) [log]
11	See loading sketch	- / -	< 100	≥ 1,5x10^8
12	See loading sketch	- / -	< 100	≥ 1,5x10^8
13	See loading sketch	- / -	< 100	≥ 1,5x10^8
14	See loading sketch	- / -	< 100	≥ 1,5x10^8

Legend:
*)Smear on Slanetz-Bartley agar after 3 and 7 days
KBE = Colon-forming units
PK = Test specimen
RF = Reduction factor

4.3.2 Thermoelectric measurement including A0 evaluation

Charge Nr.	A_0-Valeu (calculated)[5]	A_0-Valeu (specification)
6	8317 s	> 3000 s

[5] *Die Angaben beziehen sich auf den Logger mit dem niedrigsten A_0-Wert und sind abgerundet auf die nächste glatte Zahl!*

4.4 Effectiveness of drying

Since the dryness of the medical products prepared in the RDG is very much dependent on the respective medical device itself and the placement on the loading carrier, the test for dryness within the framework of the validation is only for the purpose of documenting the actual condition.

Inadequate drying results do not necessarily lead to a verification, but can be adapted by the operator, together with the service technician who is knowledgeable for the RDG, by extending the drying phase.

4.4.1 Evaluation of the In the test loads

All tested within the scope of the test loads had sufficient drying.

4.4.2 Assessment of in real customer load

The verified customer loading shows sufficient drying.

4.5 Chemical dosage

The dosage is checked at regular intervals by the client or the chemical supplier.

The meaningfulness of the permissible metering monitoring is not assessed by HygCen since it was set by the manufacturer and EN ISO 15883-1 under point 5.7.5 defines: "The manufacturer must determine the accuracy and repeatability of the control of the volume addition of each installed dosing system."

4.5.1 Dosage 1

The results showed no deviations from the set limit.

4.5.2 Dosage 2

Not use

4.5.3 Dosage 3

Not use

4.6 Absence of process residues

The absence of process chemicals was tested by measuring the conductivity of the final rinsing water. Thus, on the one hand, the electrical conductivity of the used tapping water quality is checked and then increased by the limit value of the respective chemistry prescribed by the manufacturer of the chemicals.

An examination of real medical devices was not part of the order and was not carried out.

4.6.1 Limits of the manufacturer of the process chemicals.

Dos. Nr.:	Chemistry	Manufacturer's limit [5]
1	I&D Alcali Dr.Schumacher Thermoton N	See documents Customer

[5] *Alle Angaben sind Herstellerangaben und werden hier nur angewendet!*

4.6.2 Results

All conducted conductivity measurements gave values within the limits set by the manufacturer

4.7 Reproducibility

The reproducibility of the process based on the physical data can be confirmed by the data loggers running in all batches and the evaluation of the corresponding curves (see appendix).

Since a quantitative analysis of standardized test specimens has also been carried out during the validation, reproducibility of the process can also be confirmed based on protein depletion.

5 Summary / Evaluation

5.1 Short Summary

Cleaning performance: (Qualitative, quantitative and real pollution)	☒ OK	☐ Not OK (NOK)	**Comment / Restriction:** Not
Disinfection performance: (Quantitative and A0 value calculation)	☒ OK	☐ Not OK (NOK)	**Comment / Restriction:** Not
Desiccation: (Visual inspection)	☒ OK	☐ Not OK (NOK)	**Comment / Restriction:** Not
Recommendation of the next checkmaker:	03/2022		**Comment / Restriction:** • Not

5.2 Evaluation of program

It can be confirmed that the cleaning performance of the tested program meets the requirements.

It can be confirmed that the tested program has a disinfection performance against E. faecium greater than $1{,}5x10^8$ log. The calculated A0 value was above the requirements.

Safe processing of the tested medical device types on the corresponding loading cart in this program can be confirmed.

Archiving: A copy of the report is kept together with the raw data in the archives of the contractor.

Reference: The test results refer exclusively to the test object mentioned. Reproduction of this report only with written permission of UMS Medikal Test.

Signature of the person responsible for the assessment and preparation of the report:

İbrahim ÇILDIR
Şirket Müdürü

Bülent DEVECİ
Laboratuvar Müdürü

Signature of the person responsible for acceptance in the establishment:

_____

(Ort / Datum / Stempel)

6 Appendix

6.1 Methods Description

6.1.1 Quantifiable cleaning performance

6.1.1.1 Specimen

The test material used was standard cotton. The material was pre-washed, rinsed and dried. Then test pieces with a diameter of 12 mm were punched out and used for soiling.

6.1.1.2 Test soil

Blood for the test specimens
The defibrinated sheep blood used was obtained from Fiebig Nutrient Technology. The maximum duration of use was 2 weeks. (The freshly collected sheep blood is then gently shaken to produce the resulting fibrin fibers by means of filtration and the filtrate - defibrinated sheep blood - can then be stored for 3 weeks.

6.1.1.3 Detection methods

The basis for the protein detection of the test soiling is the modified OPA method. In the presence of a thiol component, o-phtaldialdehyde "OPA" reacts with free NH2 groups of the blood proteins - terminal □- and terminal □-amino groups - to fluorescent substances which can be detected photometrically. In the case of protein hydrolysates, all free primary amines are accessible. As a result, the detection limit decreases by a factor of about 10. For the protein analysis, all samples were therefore digested with an acidic hydrolysis.

6.1.2 Cleaning performance according to EN 15883-5 Annex A

The cleaning performance is checked after cleaning, H. The process is aborted after the cleaning step.

6.1.2.1 Test pieces

Surgical instruments with joints (single-ended shears and clamps with extended joints in the ratio 1: 1) on standard sieve trays (WxHxT = 300 x 600 x 70 mm), with 20 instruments positioned per sieve tray.

6.1.2.2 Test soil

Heparinized sheep blood is brought to room temperature, and 0.15 ml protamine is added to each 10 ml each in a corresponding vessel. The test soiling is applied to joints and corrugated surfaces under ambient conditions with a brush.
The soiled joint instruments are distributed to the sieve trays (10 joints of MAYO-shears and 10 pieces of CRILE-clamps) each approximately 20 pieces (joints approximately 90 °) and positioned on the loading cart according to the loading procedure. All instruments were prepared and positioned within 30 minutes.

The soiled instruments are left on the sieves for approx. 30 min in the presence of ambient temperature and air humidity. Thereafter, each instrument and tray is checked for excess test contamination (e.g., blood clot> 5mm on the bottom, clogged screen apertures), which, if present, are removed with an absorbent pad or the like. Subsequently, the instruments are positioned with the other side upwards on a different sieve tray and left to dry for at least 30 minutes but at most 60 minutes.

The amount of test soiling is calculated according to the regulations of the ÖGSV, 0.05% per 10 liters of water. Example: For a water volume of 40 liters / filling 20ml of blood must be used.
Immediately after the cleaning phase (before disinfection) the program is interrupted and the RD unit is discharged.

6.1.2.3 Detection methods

After cleansing in the cleaning / disinfecting device, the instruments are visually inspected, each individual instrument being examined by opening and closing joints. The number of clean (no eye corrected for normal visual acuity and normal blood light) and non-clean instruments are counted and documented.

6.1.2.4 Acceptance criteria

The cleaning process is considered to be satisfactory for simple surgical instruments if:

- at least 95% of the test bodies have no residual soiling

- if appropriate, the residual protein content <20 µg / test specimen or within the acceptance criteria stated by the manufacturer.

6.1.3 Disinfection performance

The respective process was completed completely to determine the disinfecting performance.

6.1.3.1 Test pieces

Stainless steel metal grid with a slightly textured fabric surface and a mesh width of 50 µm. The material is cut into strips of 0.5 x 3.0 cm, provided with a hole for hanging and degreased with 80% ethanol.

6.1.3.2 Test soils

The test soiling consists of a mixture of E. faecium (ATCC 6057, 48 h at 36□1 ° C grown on BHI agar) and defibrinated sheep blood (KBE E. faecium approx. 108 / ml). The stainless steel metal grids are contaminated with 0.05 µL of test soiling and then dried for 3 h under laminar flow. The contaminated germ carriers required for the respective experiment were placed on a 0.5 mm thick wire between the grid bars.

6.1.3.3 Detection methods

After the purification / disinfection procedure, the germ carriers were removed and immediately transferred to the enrichment culture (10 ml CSL).

E. faecium is detected by sputtering on CSA (casein peptone soyamehl peptone agar, standard medium for bacteria detection) and incubation at 36 ° C / 48h. The enrichment cultures are incubated at 36 ° -1 ° C. for 1 week. By sprouting the enrichment cultures on Slanetz Bartley Agar after 3 days and 1 week an additional check is carried out on growth of the test germs. The results are marked in the table with "+" for growth and "-" for no growth. A reduction factor (log) is then calculated with respect to the initial contamination (positive controls).

6.1.4 Temperature

Thermal data loggers from the company ebro Electronic GmbH (Ingolstadt / Germany) and the company ellab GmbH (Denmark) are used for checking the flotation temperatures. These are programmed and then positioned at the appropriate location.
The data processing of the ebro loggers is carried out with the software WINLOG 2000 or Winlog.med Validation from Ebro.
The measurement data processing of the ellab loggers is carried out with the software ellab ValSuite Pro.

6.1.5 A0 value determination

Thermal data loggers from the company ebro Electronic GmbH (Ingolstadt / Germany) and the company ellab GmbH (Bockel / Germany) are distributed on the respective slide-in car and a complete process is started.
The evaluation software WINLOG 2000 or Winlog.med Validation from Ebro or the software ellab ValSuite Pro. was used to evaluate the curves and calculate the A0 value.

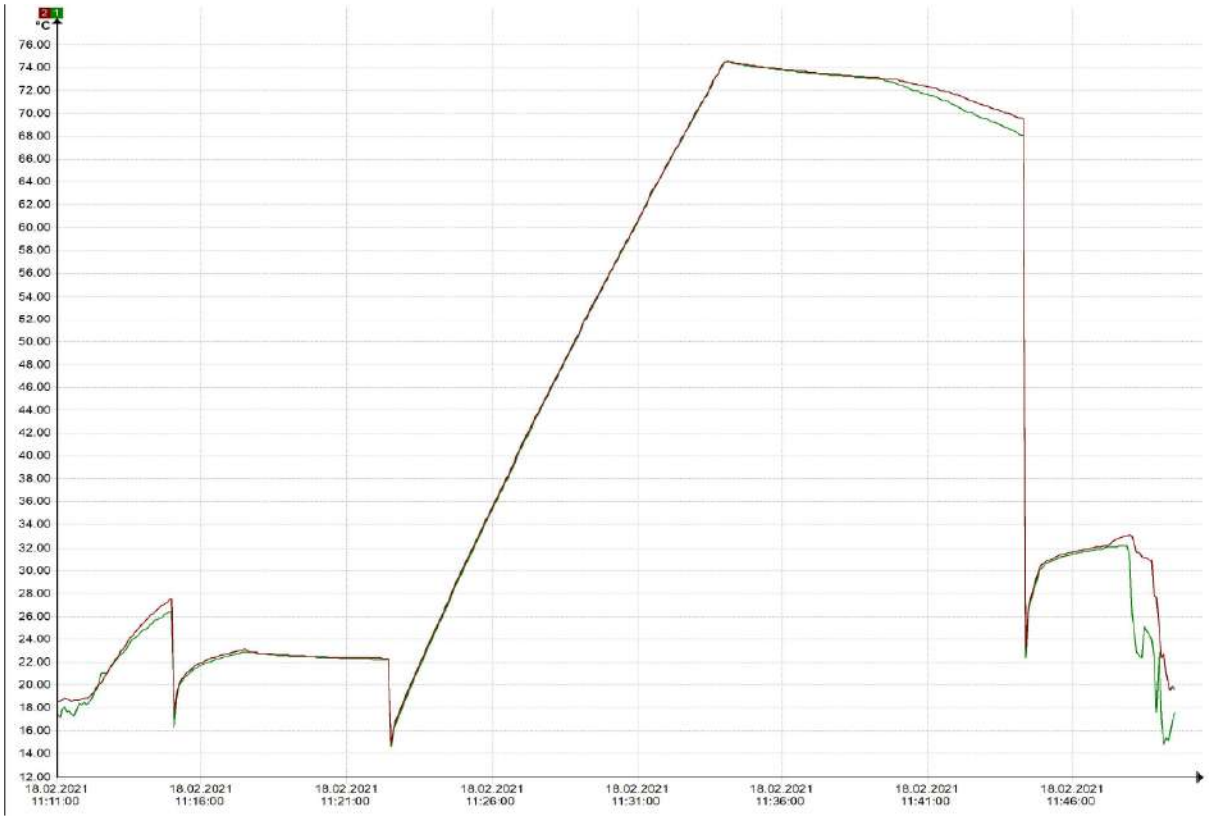
Definition:
The standard specifies the variable A0 in seconds. The A0 value is a measure of the effectiveness of thermal disinfection as a function of temperature and disinfection time. Mathematically, this dependence is described with the integral of the temperature over time.

An A0 value of 600 s is sufficient for the thermal disinfection of surgical instruments which only come into contact with the intact skin (e.g., anesthetic material), as well as thermal disinfection of the RDG.

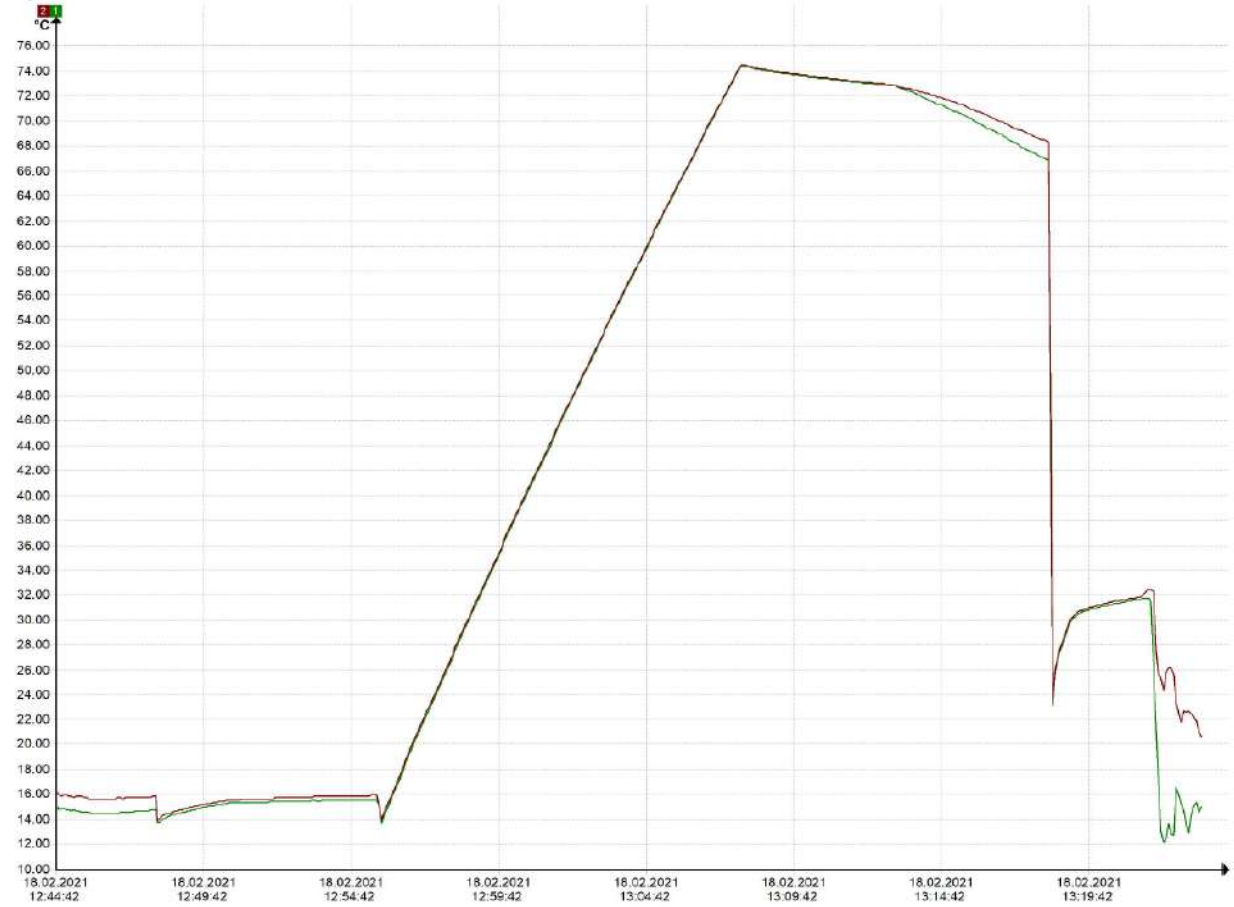
An A0 value of 3000 s is required to inactivate temperature-resistant microorganisms (e.g., HBV) or large amounts of organic stress (bioburden) (e.g., MIC instruments).

6.2 Temperature curves

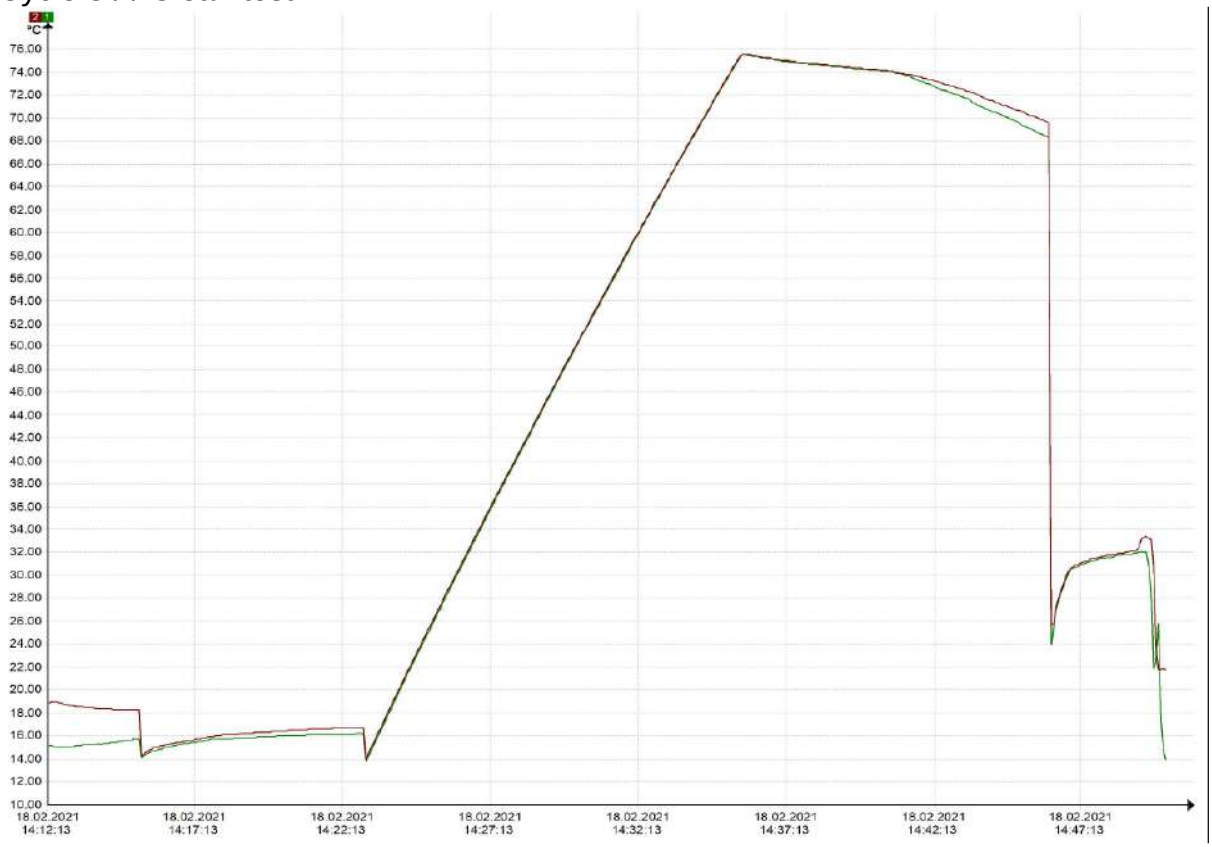
Cycle 1 / Clean test



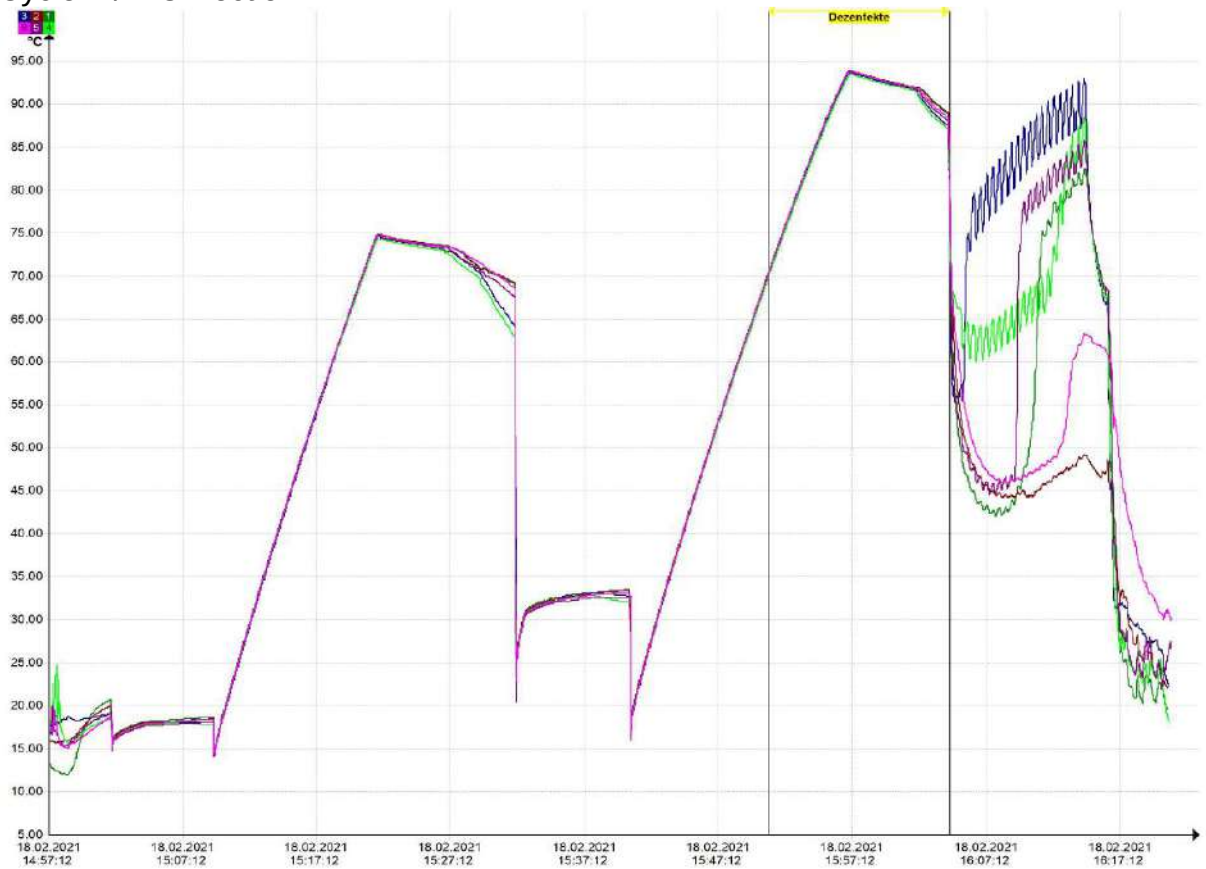
Cycle 2 / Clean test instruments and chamber



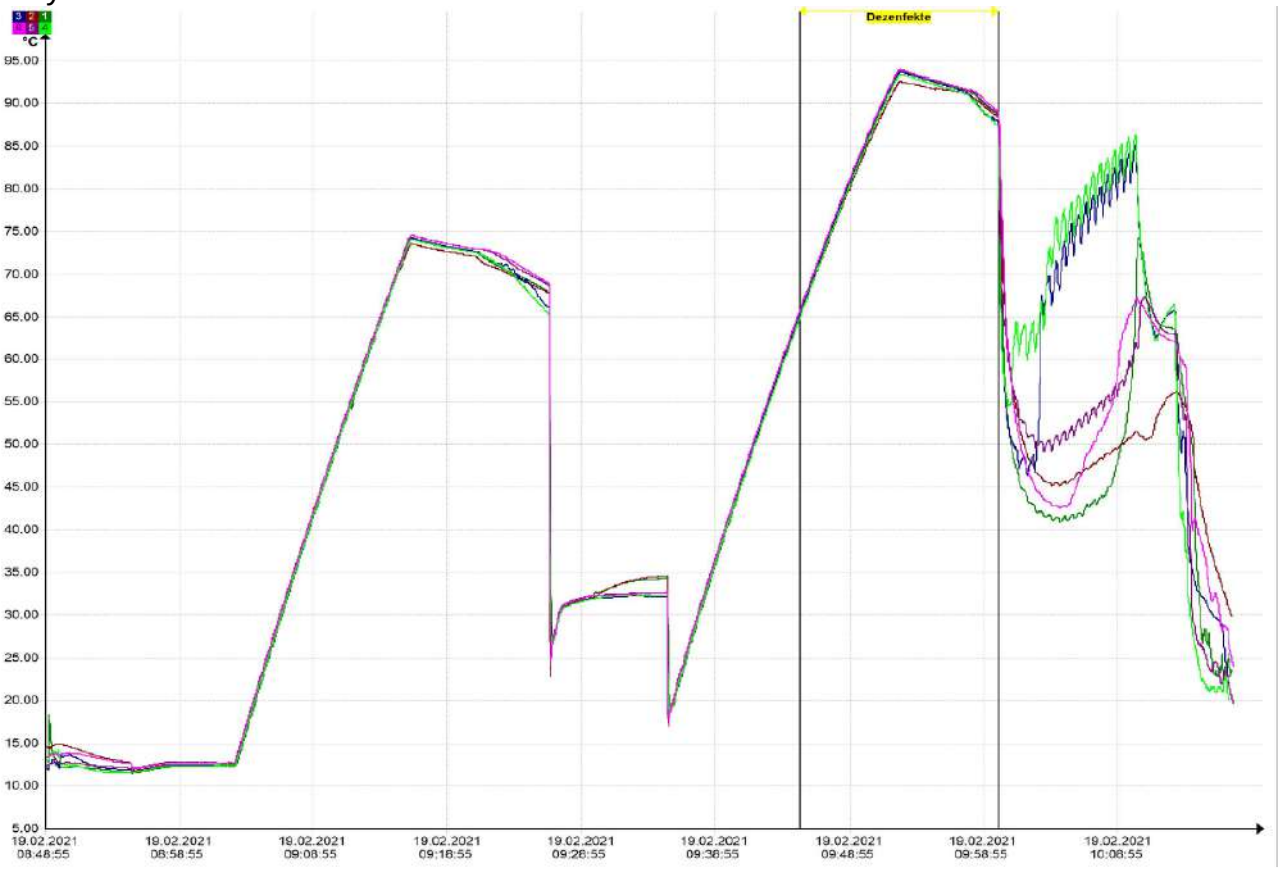
Cycle 3 / / Clean test



Cycle 4 / Disinfection 1



Cycle 5 / Disinfection 2 -User load



Cycle 6 / Disinfection 3- A0