



EN ISO 9001:2000
Zertifikat Nr. 20 100 52000989

HYGIENE REPORT

on the microbiological and temperature distribution tests

in the

SINTION MICROWAVE DISINFECTOR / STERILIZER

Following the "Examination of Cleaning and Disinfection Devices in Practice"

at the premises of

CMB (Maschinenbau und Handels GmbH)
Plabutscherstrasse 115
8051 Graz

January, 23, 2007



Athanasios Bogiatzis M.D.
Hospital Hygienist
Specialist for Hygiene
and Microbiology

Tamara Savic M.D.
Specialist for Hygiene
and Microbiology

1 TECHNICAL DATA

| | |
|--|---|
| Testing Laboratory: | Institute for Hospital Hygiene and Microbiology, Stiftingtalstraße 14, 8036 Graz, Austria |
| Device: | SINTION |
| Manufacturer: | CMB (Maschinenbau und Handels GmbH) |
| Distribution: | CMB (Maschinenbau und Handels GmbH) |
| Serial Number: | 06-09-001 |
| Outside Dimensions: | W/H/D 849/1180/1120 mm |
| Disinfection Chamber: | Ø = 450 mm, H = 650 mm |
| Weight: | 540 kg |
| Working Frequency: | 2450 MHz |
| Voltage: | 400V, 50 Hertz, 16 A (T) 3 P (400 V) + N + PE |
| Power Consumption: | 8, 7 KW |
| Working Pressure for Disinfection: | 1, 0 bar |
| Working Pressure for Sterilisation: | 2, 0 bar |

The technical data was put at disposal by the manufacturer.

2 EXECUTIVE SUMMARY

2.1 NON SPECIFIED MEDICAL WASTES

The test runs applying SINTION programmes 3 and 4 achieved STAATT Level IV on all test strip positions

2.2 RIGID GEL CONTAINERS

The test run 2.1, applying a not validated program version, partially achieved STAATT Level IV. The microbiological analysis method was only qualitative (growth or non-growth) and does not afford a quantification of the \log_{10} reduction when 6 \log_{10} was not reached.

The microbiological results were obtained in test runs which in subsequent comparison turn out as not having been the optimal choice.

For loads up to 3 pcs. of 2000 ml containers the borderline for meeting STAATT Level IV has to be expected at about 65 minutes, maybe even shorter, if a cycle variant as tested in test run 2.1 could be applied with prolonged holding time.

3 INTRODUCTION

The tests were performed at the CMB factory and guided and microbiologically analyzed by the *INSTITUT FÜR KRANKENHAUSHYGIENE UND MIKROBIOLOGIE Graz*.

Treating rigid containers filled with gel or loose clusters of gel comes out to be a problem of physical restriction. The temperature charts in this test report visualise the fact that the core suffers from a heavy temperature delay as long as the energy only penetrates from the surface. This certainty was to expect out of theoretical cognitions. Therefore mere autoclaving has got no chance to meet STAATT Level III in an acceptable time frame, when a gel body's diameter exceeds a few centimetres.

The SINTION's performance on gel bodies up to 120 mm in diameter and 230 mm in height shows results close to STAATT Level IV, and Level IV can obviously be afforded by a programme adaptation and a slight extension of the holding time if needed at all, as real terms hardly would bring as massive gel bodies as worst case tested.

As a result of the tests it can be said in accordance with the theories of warming, that the diameter of gel bodies increases the time constant of temperature equalization over proportional with increasing diameter. Destroying rigid bodies could aggravate the problem, as the free gel tends to form clusters.

4 AIM OF THE TEST RUNS

The aim was to prove the SINTION's capability to disinfect gel in rigid containers as well as in non specified medical wastes according to State and Territorial Association on Alternate Treatment Technologies (STAATT) Level III. This requires a *Geobacillus stearothermophilus* spores reduction rate of 4 log₁₀.

5 PRINCIPLE OF FUNCTION

The SINTION combines the technique of sterilization by saturated steam with that by microwave-generated heat.

In the first case, the thermal energy is supplied by condensing steam to the surface of the wastes. From there it diffuses into the depth, influenced by thermal conductivity, convection, situation e.g.

In case of heating with microwaves, microwave absorbing materials convert the electromagnetic energy into thermal energy. The electromagnetic field is influenced by geometry, situation of absorbers, dielectric constants e.g. Heating occur into the wastes themselves and heat spreads by thermal conductivity from favoured areas to such in sections of weaker field or shielded ones.

The main absorbing material in the SINTION is water molecules.

6 METHODS AND MATERIALS

6.1 MICROBIOLOGICAL EFFICACY TESTING

6.1.1 Materials

Spore probes containing *Geobacillus stearothermophilus* ATCC 7953 (population: 3, 3 x 10⁵), *Bacillus atrophaeus* ATCC 9372 (population: 2, 7 x 10⁶) Lot 54 2501, Exp 07/07 and were used throughout this test. They were used in form of strips.

6.1.2 Culture Agents

As culture agents were used Trypticase Soy Broth Bouillon of the manufacturer Becton & Dickinson, lot number: 5292193 and expiry date: 2007-04-13.

6.2 Temperature recording

The used temperature recording equipment was:

- 3 pcs. Thermocouples type K
- Extension wires to data logger
- Data logger Fluke HYDRA Series 2-2645 A
- Laptop with recorder software

The data logger in common with the thermocouples was calibrated on 2006-04-19 by

Sensotech Mess- und Regeltechnik
Kalsdorfer Straße 48
A-8073 Feldkirchen

and the results journalized in TESTO Kalibrierschein Calibration No. 038116

TEST LOADS

6.2.1 Test Load A

Test load A was used to approve the SINTION's competency to disinfect non specific clinical waste according to STAATT Level III. Programme 3 and 4 was used.

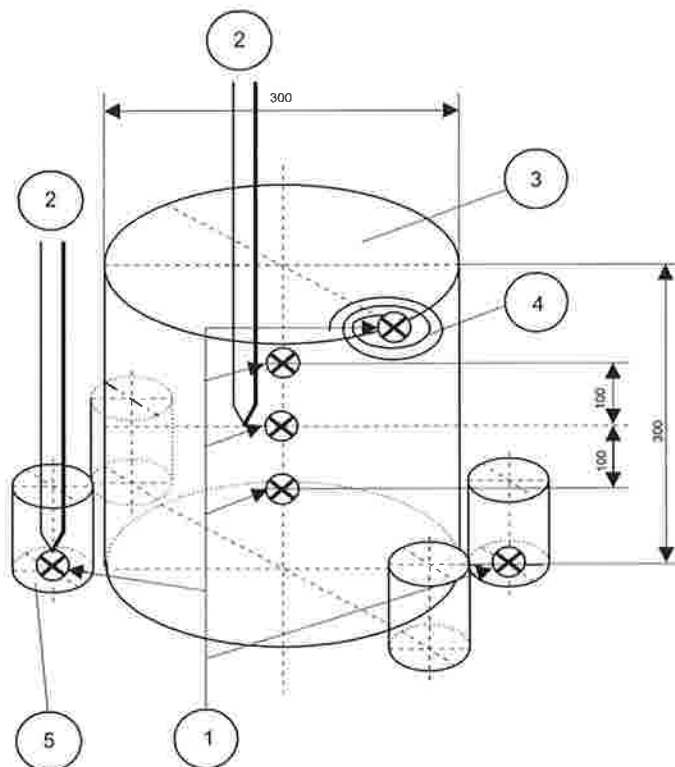


Figure 6-1: Drawing Load A

1. Spore Strip
2. Thermocouple in center of cellulose packing
3. Thermocouple in glass bottle
4. Cellulose packing
5. Hollow body
6. 500 ml glass bottles, \varnothing 120 mm x 230 mm



Figure 6-2: Load A

6.2.2 Test Load B

Test load B was used to approve the SINTION's competency to disinfect gel in smaller rigid containers according to STAATT Level III.

Verna gel absorbent powder was used as the solidifying agent (Verna care, Folds Road, Bolton BL 2 2TX). Each sachet solidifies 350 ml, therefore 1, 5 sachets were used in a full 500 ml container.

The containers were placed on the bottom of the treatment chamber. Three of them had been filled with jelly. Into the empty fourth one the thermocouples and spore strips fixed on delicate pillars of 1-mm-NiCr-wire were placed and then the container doped with 1, 5 sachets of Verna gel and filled with water.

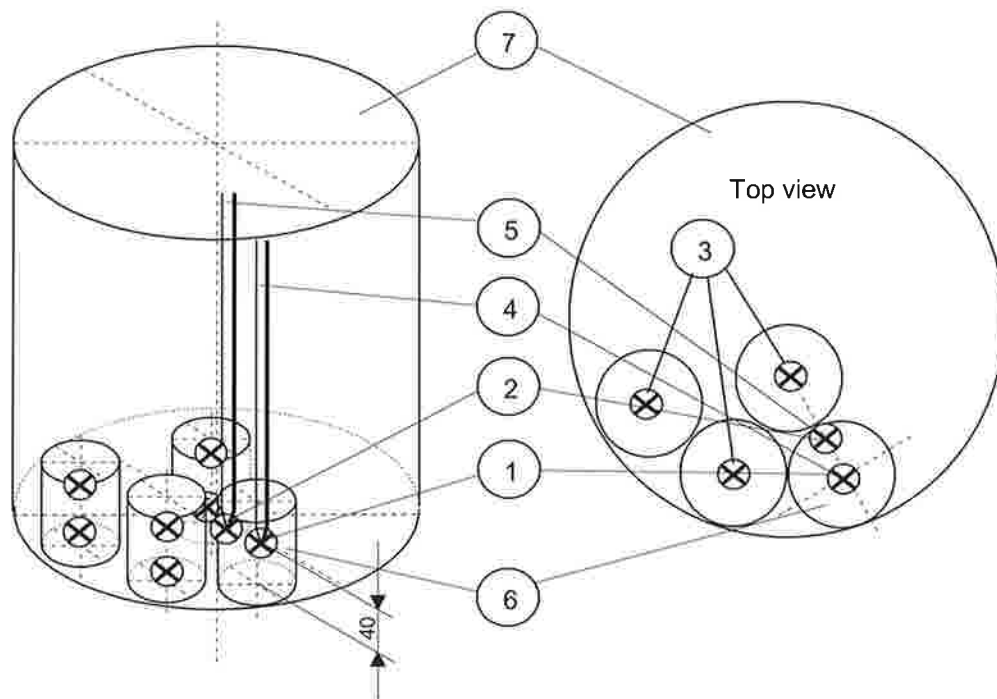


Figure 6-3: Draft Load B

1. Spore strip in centreline
2. Spore strip in near-mantle layer
3. Two spore strips, one 40mm and the second 80 mm above bottom
4. Thermocouple in centreline
5. Thermocouple in near-mantle layer
6. 500 ml polypropylene container, Ø 70 mm x 140 mm
7. Treatment chamber

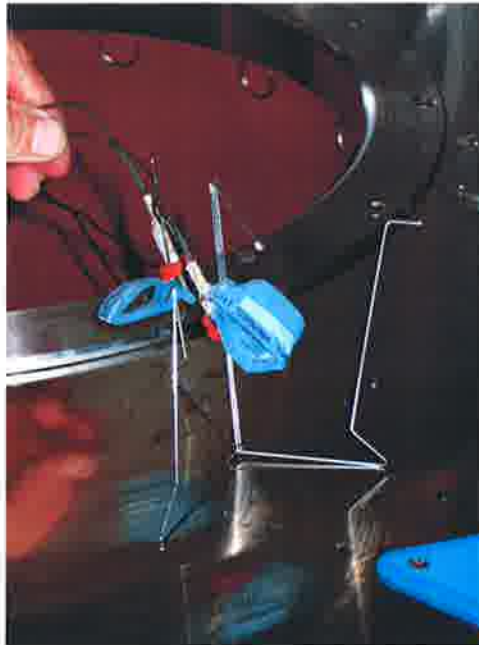


Figure 6-5: Fixation

7 TEST RUNS

7.1 TEST RUN SERIAL 1

7.1.1 Test Run 1.1

Test run parameters:

Test Load A
SINTION programme 3 (validated for disinfection)

***** SINTION 1.1 ** CMB-Austria *****
Ser.Nr.: 06/09/001 Charge: 000023

Betriebsparameter:
VD=2 BD= 2.10 bar (121' C) HZ=0360 sec
p(V1)=0.15 bar p(D1)=1.20 bar
p(V2)=0.30 bar p(D2)=2.10 bar

Datum: 06-11-20
Start: 11:52 Ende: 12:20 Dauer: 27:51
effektive HZ: 0603 sec
----- DESINFEKTION OK -----

Test Run 1.2

Test runs parameters:

Test Load A
SINTION programme 4 (validated for sterilization))

```
***** SINTION 1.1 ** CMB-Austria *****  
Ser. No. 06/09/001      load: 000027
```

```
operation parameter  
VS=2  OP= 2.90 bar (132' C)  HT=0360 sec  
p(V1)=0.15 bar             p(S1)=1.20 bar  
p(V2)=0.30 bar             p(S2)=2.90 bar
```

```
date: 06-11-20  
start: 14:33   end: 15:11   dura.: 37:27  
holding time:      1404 sec  
----- STERILIZATION OK -----
```

7.1.2 Test Run 2.1

Test run parameters:

Test Load B without spore strips
SINTION programme 5

- VD 2
- p(V1) 0,15 bar_{abs}
- p(S1) 1,25 bar_{abs}
- p(V2) 0,30 bar_{abs}
- p(S2) 2,70 bar_{abs}
- OP 2,70 bar_{abs}
- Temp 130 °C
- HT 1800 sec

8 MICROBIOLOGICAL TESTS

8.1 Test Load A

On the Test Load A was used the Program 3 and 4.

8.1.1 Program 3

| Sterilization time in Min. | Charge time in Min. | Position of Spore strips | ° C | Bio indicator | Growth |
|----------------------------|---------------------|---------------------------------------|-----|---------------|--------|
| 6 | 27:51 | spore strip loose | 121 | 1 | no |
| 6 | 27:51 | in center of cellulose packing | 121 | 2 | no |
| 6 | 27:51 | in glass bottle with H ₂ O | 121 | 3 | no |
| 6 | 27:51 | in hollow body | 121 | 4 | no |
| 6 | 27:51 | in glass bottle with H ₂ O | 121 | 5 | no |

8.1.2 Program 4

| Sterilization time in Min. | Charge time in Min. | Position of Spore strips | ° C | Bio indicator | Growth |
|----------------------------|---------------------|---------------------------------------|-----|---------------|--------|
| 6 | 30:22 | spore strip loose | 134 | 6 | no |
| 6 | 30:22 | in center of cellulose packing | 134 | 7 | no |
| 6 | 30:22 | in glass bottle with H ₂ O | 134 | 8 | no |
| 6 | 30:22 | in hollow body | 134 | 9 | no |
| 6 | 30:22 | in glass bottle with H ₂ O | 134 | 10 | no |

8.2 Test Load B

On the Test Load B was used the Program 5

8.2.1 Program 5

| Sterilization time in Min. | Charge time in Min. | Position of Spore strips | ° C | Bio indicator | Growth |
|----------------------------|---------------------|--------------------------|-----|---------------|--------|
| 30 | 65 | in centreline | 130 | 11 | no |
| 30 | 65 | in near-mantle layer | 130 | 12 | no |
| 30 | 65 | 40 mm above bottom | 130 | 13 | no |
| 30 | 65 | 80 mm above bottom | 130 | 14 | no |

9 CONCLUSION

On the basis of microbiological tests according to State and Territorial Association on Alternate Treatment Technologies (STAATT) Level III and IV is SINTION appropriate

to disinfect non specified medical wastes (STAATT Level IV)
and
to disinfect gel in rigid containers (STAATT Level III)



Graz on January, 23. 2007

The Examiner:

Athanasios Bogiatzis, M.D.
Specialist for Hygiene and Microbiology
Head of Institute

Tamara Savic, M.D.
Specialist for Hygiene and Microbiology



Nr.9367/06

Mikrobiologischer Befund vom 28.11.2006

Einsender:

CMB Christoph group

Plabutscherstraße 115, 8051 Graz

Prot.Nr.: **47978-47982**

Eingegangen: **21.11.2006**

Proben abgenommen am/von: Stegmüller Wolfgang

| Nr. | Abt./Zi. | Art ³⁾ | Bezeichnung der Probe | KBE ¹⁾ | Befund ²⁾ |
|-------|----------|-------------------|---|-------------------|----------------------|
| 47978 | | StD | Versuch 1, Sintion 1.1 0609001, Programm 3, 121° C, Bio 1 | 0 | ohne Keimwachstum |
| 47979 | | StD | Versuch 1, Sintion 1.1 0609001, Programm 3, 121° C, Bio 2 | 0 | ohne Keimwachstum |
| 47980 | | StD | Versuch 1, Sintion 1.1 0609001, Programm 3, 121° C, Bio 3 | 0 | ohne Keimwachstum |
| 47981 | | StD | Versuch 1, Sintion 1.1 0609001, Programm 3, 121° C, Bio 4 | 0 | ohne Keimwachstum |
| 47982 | | StD | Versuch 1, Sintion 1.1 0609001, Programm 3, 121° C, Bio 5 | 0 | ohne Keimwachstum |
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¹⁾ KBE = Kolonienbildende Einheiten; ~ = bewachsen; n.a. = nicht auszählbar; n.w. = nicht auswertbar; ²⁾ aer. = aerobe; K.n. = Koagulase negative

³⁾ AK = Abklatsch; AS = Abstrich, LKM = Luftkeimmessung; Sed = Sedimentationsplatte; StD = Bioindikator-Dampf; StG = Bioindikator-Gas; StH = Bioindikator-Heißluft; E = Endoskopspülwasser; IFL = Infusionslösung; TK = Thrombozytenkonzentrat; TZ = Transfusionszwischenfall; H2O = Wasser; SN = Säuglingsnahrung; DM = Desinfektionsmittellösung; P = Personaluntersuchung; Div. = Diverses

Bemerkung/Beurteilung: (Unauffällige Ergebnisse sind in Normalschrift, auffällige in **Fettdruck** angeführt)

- Das Ergebnis entspricht den Vorgaben!
- Das Ergebnis entspricht **NICHT** den Vorgaben!
- Wiederholung erbeten!
- Reinigungs- und/oder Desinfektionsmaßnahmen überprüfen!
- Der geprüfte Sterilisator kann unter den bei der Prüfung vorliegenden Bedingungen weiter betrieben werden!
- Der geprüfte Sterilisator kann unter den bei der Prüfung vorliegenden Bedingungen **NICHT** weiter betrieben werden!
- Befund telefonisch mitgeteilt am



i.A.

Prim. Dr. A. Bogiatzis



Nr.9368/06

Mikrobiologischer Befund vom 28.11.2006

Einsender:

CMB Christoph group

Plabutscherstraße 115, 8051 Graz

Proben abgenommen am/von: Stegmüller Wolfgang

Prot.Nr.: **47983-47987**

Eingegangen: **21.11.2006**

| Nr. | Abt./Zi. | Art ³⁾ | Bezeichnung der Probe | KBE ¹⁾ | Befund ²⁾ |
|-------|----------|-------------------|---|-------------------|----------------------|
| 47983 | | StD | Versuch 2, Sinton 1.1 0609001, Programm 4 (Sterilisation), 134° C, Bio 6 | 0 | ohne Keimwachstum |
| 47984 | | StD | Versuch 2, Sinton 1.1 0609001, Programm 4 (Sterilisation), 134° C, Bio 7 | 0 | ohne Keimwachstum |
| 47985 | | StD | Versuch 2, Sinton 1.1 0609001, Programm 4 (Sterilisation), 134° C, Bio 8 | 0 | ohne Keimwachstum |
| 47986 | | StD | Versuch 2, Sinton 1.1 0609001, Programm 4 (Sterilisation), 134° C, Bio 9 | 0 | ohne Keimwachstum |
| 47987 | | StD | Versuch 2, Sinton 1.1 0609001, Programm 4 (Sterilisation), 134° C, Bio 10 | 0 | ohne Keimwachstum |
| | | | | | |
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- Befund telefonisch mitgeteilt am
-

i.A. 
 Prim. Dr. A. Bogiatzis



Nr.9449/06

Mikrobiologischer Befund vom 29.11.2006

Einsender:

CMB Christoph group

Plabutscherstraße 115, 8051 Graz

Prot.Nr.: **48393-48396**

Eingegangen: **22.11.2006**

Proben abgenommen am/von:

| Nr. | Abt./Zi. | Art ³⁾ | Bezeichnung der Probe | KBE ¹⁾ | Befund ²⁾ |
|-------|----------|-------------------|--|-------------------|----------------------|
| 48393 | | StD | Versuch 7, Sintion 1.1, 5, 1800, 130° C, li./u, Bio 11 | 0 | ohne Keimwachstum |
| 48394 | | StD | Versuch 7, Sintion 1.1, 5, 1800, 130° C, li./u, Bio 12 | 0 | ohne Keimwachstum |
| 48395 | | StD | Versuch 7, Sintion 1.1, 5, 1800, 130° C, li./u, Bio 13 | 0 | ohne Keimwachstum |
| 48396 | | StD | Versuch 7, Sintion 1.1, 5, 1800, 130° C, li./u, Bio 14 | 0 | ohne Keimwachstum |
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