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RehaWash Systems GmbH
Berliner Straße 104
D- 02943 Weißwasser

2019-04-08

TESTREPORT

Identification number of test laboratory:	SN 27163
Test ID No.:	2019-0483
Tested device:	Waschstraße B 904 D / B 904 D T
Test order:	Performance qualification of the Waschstraße B 904 D / B 904 D T
Customer:	RehaWash Systems GmbH Berliner Straße 104 D- 02943 Weißwasser
Test site:	RehaWash Systems GmbH Berliner Straße 104 D- 02943 Weißwasser
Test period on site:	2019-02-28
Test period:	2019-02-22 to 2019-03-01
Test method:	Validation of the reprocessing processes based on EN ISO 15883-7

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1 General Information

On 2019-02-28, the washer- disinfector type B 904 - D was subjected to a test of cleaning and disinfection and recovery of the test soiling on the basis of DIN ISO TS 15883-5.

1.1 General Information

Manufacturer:	RehaWash Systems GmbH
Type:	Waschstraße B 904 D / B 904 D T
Serial No.:	018/18
Date of manufacturing:	2018-06

1.2 Detergents and Disinfectants

Dosage pump	Process chemicals
Dos. 1	neodisher® MediClean forte (Lot No.: 624294/1218)
Dos. 2	neodisher® MediKlar special (Lot No.: 622618/1218)
Dos. 3	neodisher® Dekonta AF (Lot No.: 622940/1218)

2 Description of the method for KMNE and MNE soiling

2.1 Cleaning performance according to EN 15883-5 Annex C (KMNE[1] - soiling)

2.1.1 Test specimens

Wheelchairs, toilet seats, walkers, decubitus mattresses, bedsteads

2.1.2 Test soil

Mix 600ml of nigrosin suspension (6g of nigrosin powder that has been dissolved in 600ml of lukewarm tap water, stirred constantly and heated up to 80°C) with 800ml of white flour suspension (115g of white flour that has been brought to the boil in 800ml of cold tap water, while being constantly stirred, and then boiled for approx. 3min.).

Just before use, warm up 700g of the flour and nigrosin mix to approx. 35°C then leave to cool. Add the egg yolk and egg white of three medium-sized raw hen's eggs and mix thoroughly (flour, nigrosin and egg mix). If necessary, warm back up to approx. 35°C.

Add approx. 100g of dried potato flakes gradually while stirring until the required consistency is reached. To reach the desired consistency, dip the whisk about 700mm into the mix, beat slowly and then carefully remove. If the mix has the right consistency, it will flow slowly down the metal loop of the whisk and after 10 to 15 seconds, the lumps of mixture remaining on the whisk should have a diameter of 40 to 50mm.

Fill the test specimens with 200 to 300g of test contamination, spread it carefully until a layer of around 2mm thick is reached. This should simulate a normal quantity of stool in the right position.

With a flat brush, spread the test contamination over the entire inner surface of the test specimen so that a layer of around 2mm thick is reached.

[1] KMNE = potato flakes, egg, flour and nigrosin

To simulate heavy soiling of the bedpan, put the test contamination on the outer wall to a thickness of 2mm in places where the bedpan came into contact with the patient's skin, and on the remaining places, including the handle, to a thickness of approx. 1mm.

Leave the test contamination to rest at normal room temperature at normal air humidity for at least 5 minutes, but no longer than 10 minutes.

Immediately after the cleaning phase (before disinfection), the program was stopped and the cleaning and disinfection device (CDD) was removed.

2.1.3 Test procedure

After cleaning the CDD, a sight test of the bedpans was carried out.

2.1.4 Acceptance criteria

The cleaning effect of the CDD is considered to be sufficient if there is no visible residue of the test soil on the test specimen, on either the inner or outer wall.

2.2 Disinfection efficacy

Germ carriers are contaminated with a mixture of *Enterococcus faecium* (ATCC 6057, 48h at 36 ± 1 ° C on BHI agar) and defibrinated sheep blood ($CFU_{E.\ faecium}$ approx. per 10^{10}ml) and then incubated in the incubator at 36 ± 1 ° C for 3h dried with opened lids.

The contaminated germ carriers were attached so that they hang freely in the chamber space and do not rest against the wall, or fixed to the wheelchair.

After the complete wash cycle, the test specimens were removed and transferred immediately to the enrichment culture (5ml CSL).

The detection of *Enterococcus faecium* is carried out by platin 1ml and 0.1ml of the enrichment culture on CSA agar (casein peptone soybean meal peptone agar). The plates are then incubated at 36°C / 48h. Enrichment cultures are liquid incubated at 36 ± 1°C for 1 week.
By platin samples of the enrichment cultures on SBA after 3 days and 1 week, additional testing for growth of the test germs is performed.

3 Results of the cleaning efficacy for KMNE soiling

3.1 Wheelchair

Test date:	2019-02-21
Tested device:	Waschstraße B 904 D / B 904 D T
Charge:	2019-02-21 / 09:02 a.m. and 2019-02-21 / 10:42 a.m.

before

after

Result: Visual inspection shows no residual test soil.

3.2 Decubitus Mattresses

Test date:	2019-02-21
Tested device:	Waschstraße B 904 D / B 904 D T
Charge:	2019-02-21 / 09:38 a.m. and 2019-02-21 / 11:09 a.m.

before: Test specimens with KMNE soiled

after

Result: Visual inspection shows no residual test soil.

3.3 Bedsteads

Test date:	2019-02-21
Tested device:	Waschstraße B 904 D / B 904 D T
Charge:	2019-02-21 / 10:12 a.m. and 2019-02-21 / 11:37 a.m.

before

after

Result: Visual inspection shows no residual test soil.

3.4 Results of the disinfection performance

3.5 Wheelchairs, toilet seats and walkers

Tested device	Waschstraße B 904 D / B 904 D T
Test organism	*Enterococcus faecium* ATCC 6057
Program	Cleaning heavy contamination with disinfection
Charge	2019-02-21 / 12:40 p.m.

Arrangement of the test specimens

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Results

The results of the germ carrier experiments are described in the following tables.

The residual germ content (*Enterococcus faecium* ATCC 6057, averaged value of 2 non-exposed germ carriers controls, was:

[log CFU]/Germ carrier = 8.49

Test specimen	1ml direct	0.1ml direct	Enrichment* [3 / 7 days]	CFU/ Test specimen [log]	Reduction factor (RF) [log]
1	0	0	+ / +	1.00	**> 7.49**
2	0	0	- / -	0.00	**≥ 8.49**
3	0	0	+ / +	1.00	**> 7.49**
4	0	0	+ / +	1.00	**> 7.49**
5	0	0	+ / +	1.00	**> 7.49**
6	0	0	+ / +	1.00	**> 7.49**

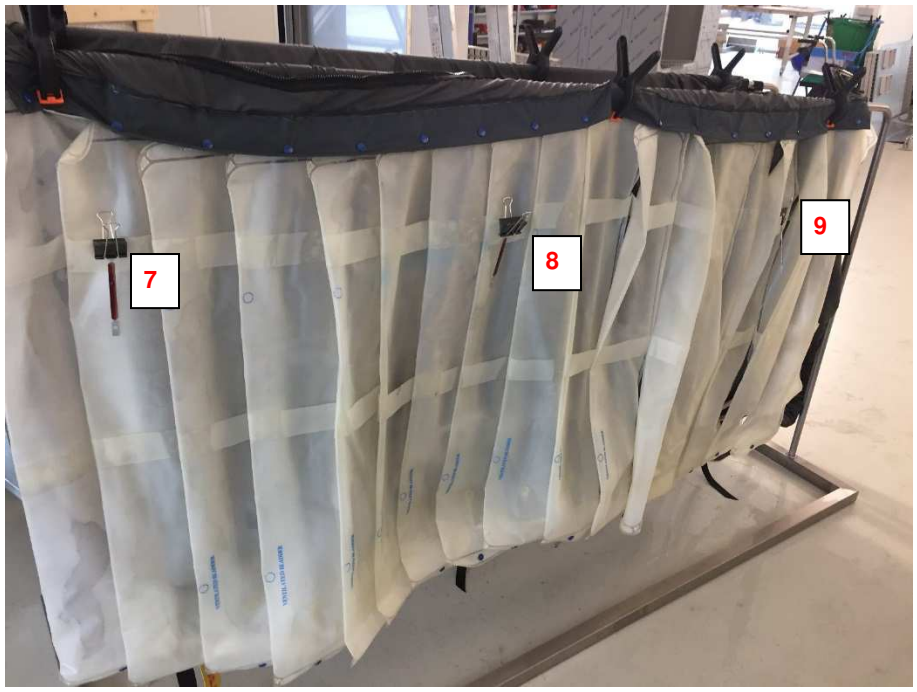
Legend:

*)	= Smear on slanetz-bartley-agar + aeskulin after 3 and 7 days
CFU	= Colony forming units
TS	= Test specimen
RF	= Reduction factor
CSA	= Casein-soybean agar
KBE:	= Number of test microorganisms that can be detected per surface on surface culture
n.c.	= not countable
-	= No turbidity due to germ growth
+	= Turbidity due to germ growth

3.6 Decubitus Mattresses

Tested device	Waschstraße B 904 D / B 904 D T
Test organism	*Enterococcus faecium* ATCC 6057
Program	Cleaning heavy contamination with disinfection
Charge	2019-02-21 / 13:24 p.m.

Arrangement of the test specimens



Results

The results of the germ carrier experiments are described in the following tables.

The residual germ content (*Enterococcus faecium* ATCC 6057, averaged value of 2 non-exposed germ carriers controls, was:

[log CFU]/Germ carrier = 8.49

Test specimen	1ml direct	0.1ml direct	Enrichment* [3 / 7 days]	CFU/ Test specimen [log]	Reduction factor (RF) [log]
7	0	0	- / -	0.00	**≥ 8.49**
8	0	0	- / -	0.00	**≥ 8.49**
9	0	0	- / -	0.00	**≥ 8.49**
10	0	0	- / -	0.00	**≥ 8.49**
11	0	0	- / -	0.00	**≥ 8.49**
12	0	0	- / -	0.00	**≥ 8.49**

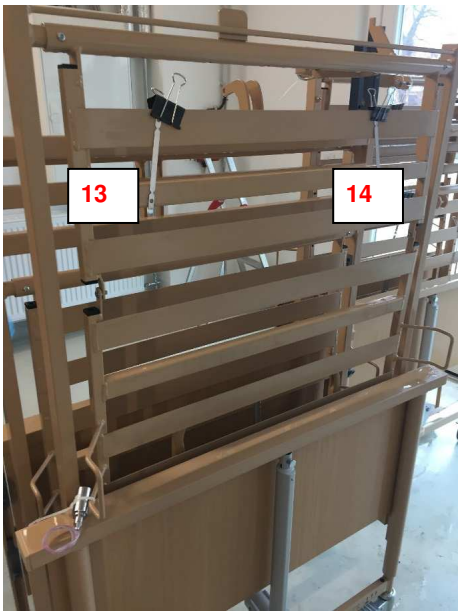
Legend:

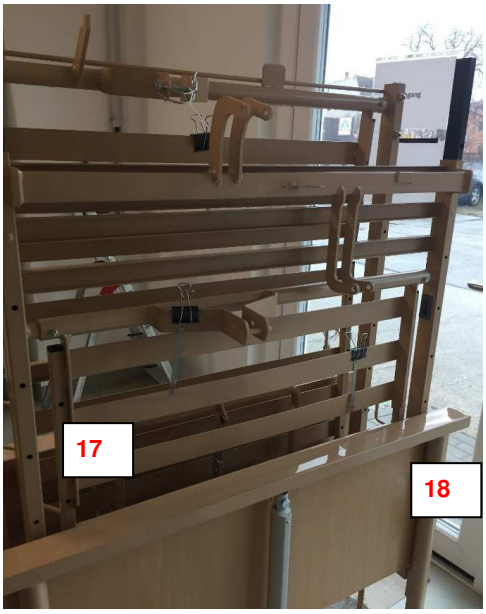
*) = Smear on slanetz-bartley-agar + aeskulin after 3 and 7 days
CFU = Colony forming units
TS = Test specimen
RF = Reduction factor
CSA = Casein-soybean agar
KBE: = Number of test microorganisms that can be detected per surface on surface culture
n.c. = not countable
- = No turbidity due to germ growth
+ = Turbidity due to germ growth

3.7 Bedsteads

Tested device	Waschstraße B 904 D / B 904 D T
Test organism	*Enterococcus faecium* ATCC 6057
Program	Cleaning heavy contamination with disinfection
Charge	2019-02-21 / 14:06 p.m.

Arrangement of the test specimens





Results

The results of the germ carrier experiments are described in the following tables.

The residual germ content (*Enterococcus faecium* ATCC 6057, averaged value of 2 non-exposed germ carriers controls, was:

[log CFU]/Germ carrier = 8.49

Test specimen	1ml direct	0.1ml direct	Enrichment* [3 / 7 days]	CFU/ Test specimen [log]	Reduction factor (RF) [log]
13	0	0	- / -	0.00	**≥ 8.49**
14	0	0	- / -	0.00	**≥ 8.49**
15	0	0	- / -	0.00	**≥ 8.49**
16	0	0	- / -	0.00	**≥ 8.49**
17	0	0	- / -	0.00	**≥ 8.49**
18	0	0	- / -	0.00	**≥ 8.49**

Legend:

*) = Smear on slanetz-bartley-agar + aeskulin after 3 and 7 days
CFU = Colony forming units
TS = Test specimen
RF = Reduction factor
CSA = Casein-soybean agar
KBE: = Number of test microorganisms that can be detected per surface on surface culture
n.c. = not countable
- = No turbidity due to germ growth
+ = Turbidity due to germ growth

3.8 Chemical dosing

The dosing quantities are checked at regular intervals by the client.

HygCen does not assess the usefulness of the permitted metering monitoring, as this has been set by the manufacturer. This is in accordance with EN ISO 15883-1 point 5.7.5: "*The manufacturer shall determine the accuracy and repeatability of the volume addition control of each installed metering system.*"

3.8.1 Dosage 1

Batch 2019-02-21 / 09:02 a.m.:	Should be:	400ml
	Is:	421g (1.07g/cm³ ➔393.5ml)
Batch 2019-02-21 / 09:38 a.m.:	Should be:	400ml
	Is:	426ml (1.07g/cm³ ➔398.2ml)
Batch 2019-02-21 / 11:37 a.m.:	Should be:	400ml
	Is:	411ml (1.07g/cm³ ➔384.1ml)

3.8.2 Dosage 3

Batch 2019-02-21 / 12:40 p.m.:	Should be:	400ml
	Is:	403ml (1.02g/cm³ ➔395.1ml)
Batch 2019-02-21 / 13:24 p.m.:	Should be:	400ml
	Is:	399ml (1.02g/cm³ ➔391.2ml)
Batch 2019-02-21 / 14:06 p.m.:	Should be:	400ml
	Is:	401ml (1.02g/cm³ ➔393.2ml)

3.9 Results of the microbiological check of the last rinse water

Lfd. No.	Place of acceptance or material	CFU/ GKZ	Culture medium	Microbiological Differentiation	Rating ok / nok	Remark
I	0.1ml 1.0ml	3 4	CSA CSA	-	ok	
II	0.1ml 1.0ml	0 7	CSA CSA	-	ok	
III	0.1ml 1.0ml	0 0	CSA CSA	-	ok	

Legend

CFU: Colony forming units
n.c.: not countable
CSA: Casein-soybean agar
ENDO ENDO-Agar

BA: Blood agar
SBA: Slanetz Bartley Agar
SAB: Sabouraud – 4% Glucose – Agar (Nährboden für Hefen und Schimmelpilze)
CSA-I: CSA + Additives for inactivation ev. of disinfectant residues
CN: CN-Agar (Culture medium for pseudomonads)
GKZ: Bioburden

Rating environment
(Note also depending on the type of sample and the location of the sample)
< 10 KBE = ok
10 – 25 KBE = satisfying
25 – 35 KBE = sufficient
> 35 KBE = inadequate

A: Surface impression
B: Personal investigation
C: Fluid inspection
D: Airbone measurement / SAS 200 liers and/or 1000 liters
E: Airborne germ / sedimentation 1 hour
F: Bio-Burden determination
G: Covering sample

o. k. OK
n.o.k. Not OK

Review of swabs
- no proof
+ < 50 CFU
++ 50 – 300 CFU
+++ > 300 CFU

4 Summary

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* of more than 8.49log for all tested products.

A safe processing of the tested medical device types on the corresponding load wagon using this program can be confirmed.

Archiving: A copy of the report is to be stored with the raw data in the client's archives.

Note: The test results refer only to the stated test item. Excerpts of this report may only be reproduced with the written consent of HygCen Germany GmbH.

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Medical products

Stefan Fehrmann
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