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RehaWash Systems GmbH  
Berliner Strasse 104  
02943 Weißwasser



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2011-07-28

# TEST REPORT

**SN - No.:** SN 12205

**Product:** Washer-disinfector  
RehaWash type 313

**Test definitions:** Contamination of products with test soils for testing  
cleaning and disinfection and recovery of the test  
soil in accordance with DIN ISO TS 15883-5, SOP  
19-002

**Place of test:** RehaWash Systems GmbH  
Berliner Strasse 104  
02943 Weißwasser

**Testing period:** 2011-06-24 –2011-07-10

**Examiner:** Monika Feltgen

## 1 General Information

At 2011-06-24 the washer-disinfector (wheelchairs) type 313 was tested about the cleaning and disinfection and recovery of the test soil in accordance with DIN ISO TS 15883-5.

## 2 General data

General data for identification of the WD.

### 2.1 Identification of the WD

<b>Customer:</b>	RehaWasch type 313
<b>Type:</b>	single-chamber-machine 1-door

### 2.2 Programs for validation

1. program 3 3 minutes cleaning
2. program 7 7 minutes cleaning
3. disinfection 1%

### 2.3 Detergent and disinfectant

Metering	Process chemicals	Dosage
Dos. 1	Indumat 5400 VW	200 ml/50L
Dos. 2	Indumat 4300	150 ml/50L
Dos. 3	Antifect ff (disinfectant)	450 ml/50L

### **3 Method description**

#### **3.1 KMNE<sup>1</sup> - contamination (visual inspection)**

The KMNE-contamination consists of the following ingredients:

- flour paste
- aqueous, 1%ige nigrosine solution
- raw egg
- potato flakes

The ingredients are processed according to the specifications, so that a spreadable „black broth“ is created.

To determine the cleaning efficiency the product (wheelchair) is coated with the KMNE-contamination using a brush, so that an area remains visible besides.

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Koller W.: Reinigung und Desinfektion von Essgeschirr, Instrumenten und Ausscheidungsbehältern im Krankenhaus. Wien: Verlag Dieter Göschl, 1981.

### **3.2 Disinfection efficiency**

The germ carriers are soiled with a mixture of *E. faecium* (ATCC 6057, 48 h at  $36 \pm 1$  °C on BHI-Agar grown) and defibrinated sheep blood (cfu<sub>*E. faecium*</sub> appr.  $10^{10}$ /ml) contaminated and dried in an incubator with open lids at  $36 \pm 1$  °C for 3 h.

The contaminated germ carriers had been attached so that they hang freely in the chamber room and did not touch the wall, therefore attached to the wheelchair.

After termination of the washing process the test samples with the germ carriers are removed and the germ carriers are immediately transferred into the enrichment culture (5 ml TSB/TSHC).

Detection of *E. faecium* by spreading out onto TSA (Tryptone-Soy-Agar) and incubating at 36°C for 48h. The enrichment cultures are incubated at  $36 \pm 1$  °C for 1 week. By spreading out from the enrichment cultures on SBA after 3 days and 1 week on additional check of growth of the test germ is done.

#### Controls

Determination of protein content, control values

	<b>Single value [lg]</b>	<b>Mean value [lg]</b>
Control 1	8,34 / carrier	8,41 / carrier
Control 2	8,41 / carrier	
Control 3	8,47 / carrier	

## **Results of the cleaning efficiency with KMNE-contamination**

### **3.2.1 Program 3 batch 1**

Distribution of contamination:



There were appr. **120g KMNE<sup>2</sup>** (mixed according to the original recipe) distributed on the wheelchair.

After mixing of the KMNE contamination, the wheelchair was soiled and after 30 minutes the program started.

**After the process, no residual contamination was observed.**

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Koller W.: Reinigung und Desinfektion von Essgeschirr, Instrumenten und Ausscheidungsbehältern im Krankenhaus. Wien: Verlag Dieter Göschl, 1981.

### 3.2.2 Program 7 batch 2

#### Distribution of contamination:



There were appr. **120g KMNE<sup>3</sup>** (mixed according to the original recipe) distributed on the wheelchair.

After mixing of the KMNE contamination, the wheelchair was soiled and after 30 minutes the program started.

**After the process, no residual contamination was observed.**

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Koller W.: Reinigung und Desinfektion von Essgeschirr, Instrumenten und Ausscheidungsbehältern im Krankenhaus. Wien: Verlag Dieter Göschl, 1981.

### 3.3 Results of the disinfection efficiency with *E. faecium*

#### Program disinfection 1%; batch 3 and 4

Logger positions / distribution of test pieces:



	Logger position / Logger-No.		
	①	②	③
wheelchair	B2		
front up		B1	
back up			T5

**Results program 3 batch 3:**

Sample designation	Sample number	Reduction factor (RF)
		lg
defibr. sheep blood + E. faecium	1 to 10	≥ 8,41

**Results program 3 batch 4:**

Sample designation	Sample number	Reduction factor (RF)
		lg
defibr. sheep blood + E. faecium	11 to 20	≥ 8,41



#### 4 Result of the chemical verification in last rinsing water

The water sample was taken during the „final rinse“ of disinfection 1%.

Batch	pH- value	Temp.	Conductivity
3	7,94	27,6 °C	774 µS

The water sample was taken during the „final rinse“ of disinfection 1%.

Batch	pH- value	Temp.	Conductivity
4	7,85	28 °C	855 µS

#### 5 Result of the microbiological verification in last rinsing water

Batch	Device / program name	cfu / TBC	Culture medium	Microbiol. differentiation chemistry	Comment
4	disinfection 1%	< 10/ml	TSA		
		< 10/ml	ENDO		
		< 10/ml	SBA		
5	disinfection 1%	< 10/ml	TSA		
		< 10/ml	ENDO		
		< 10/ml	SBA		

**Reference:** < 10/ml cfu = No evidence of microorganisms.

legend:

cfu: colony forming units  
TBC Total bacterial count  
n.c.: not countable  
TSA: Tryptone-Soy-Agar  
ENDO ENDO-Agar

## 6 Summary

Testing of the cleaning efficiency of the washer-disinfector according to ISO / TS 15883-5 with KMNE-contamination in a visually control. It can be confirmed, that the cleaning efficiency of the tested programs 3 and 7 is sufficient.

The used test loading of the test location showed no visual contamination after the test.

It can also be confirmed that in the tested program disinfection 1% the disinfection efficiency against *E. faecium* is bigger than 8 lg.

In the final rinsing water could no microorganisms could be detected.

In the final rinsing water, no chemical residues had been detected

The temperature monitoring with thermocouple data logger confirm the specified temperature profiles by the manufacturer.

### Summarizing results of the validation

Cleaning efficiency:      sufficient              no restriction

Disinfection efficiency:    agreed                      no restriction

Final rinsing water:        agreed                      no restriction

The result can be considered for the RheaWash product family type 313, B 309 and B 904.

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

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



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## **Annex**

I.	Logger curves for the tested programs	12 pages
II.	Product data sheets	15 pages
III.	Program sequence RehaWash	1 page