

Revision 01

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Short report¹ of hygiene examination for HySeDi GmbH

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Hygiene examination with the involvement of the MD2.7 Efficiency determination of manual Disinfection Processes for Medical devices and reusable Medical Instruments.

Washbasin „Medi_Sink“



Figure 1: Washbasin „Medi_Sink“

Period of examination:

11-Dec-2024 to 12-Jan-2025

In a systematic study², hygiene-relevant properties of the above-mentioned washbasin were examined:

¹ Results are reported in a simplified manner in accordance with DIN EN ISO/IEC 17025 Section 7.8.1.3.

² Due to the lack of normative requirements, the sampling procedures were defined specifically for this purpose. The evaluation of the microbiological samples was carried out according to the accredited method MD2.7.

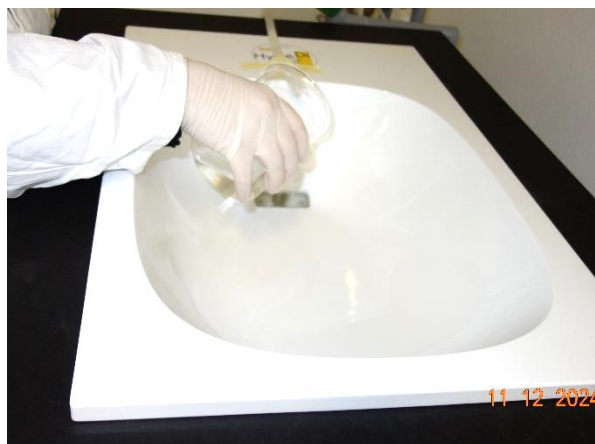
The aerosol formation during the rinsing process was microbiologically examined on 11-Dec-2024 with *E. coli* and *P. aeruginosa* and the examination with *P. aeruginosa* was performed again on 10-Jan-2025 with change in the positioning of the air sampler.

Examination / Specification	Description of the examination	Results																				
Aerosol formation <u>Test germs:</u> - <i>E. coli</i> - <i>P. aeruginosa</i>	- 400 ml of sterile demineralized water was placed in the siphon. 0.4 ml of test suspension per germ were inoculated into the siphon, so that the concentration of 1×10^6 cfu/ml was present in the siphon. - Starting of the water tap and simultaneous start of the air sampler (100L). - Use of selective agar plates for air microbial collection - 4 contact agar plates were sampled after the rinsing process. - Quantitative Evaluation	<u>CFU values of the selective agar plates before rinsing</u> <i>E. coli:</i> 0 <i>P. aeruginosa:</i> 0 <u>CFU values of the selective agar plates after rinsing</u> <i>E. coli:</i> 0 <i>P. aeruginosa:</i> 0 <u>CFU values of the contact agar plates</u> <table border="1"> <thead> <tr> <th colspan="2"><i>E. coli:</i></th> <th colspan="2"><i>P. aeruginosa</i></th> </tr> </thead> <tbody> <tr> <td>Location 1</td> <td>0</td> <td>Location 1</td> <td>0</td> </tr> <tr> <td>Location 2</td> <td>0</td> <td>Location 2</td> <td>0</td> </tr> <tr> <td>Location 3</td> <td>0</td> <td>Location 3</td> <td>0</td> </tr> <tr> <td>Location 4</td> <td>0</td> <td>Location 4</td> <td>0</td> </tr> </tbody> </table>	<i>E. coli:</i>		<i>P. aeruginosa</i>		Location 1	0	Location 1	0	Location 2	0	Location 2	0	Location 3	0	Location 3	0	Location 4	0	Location 4	0
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Aerosol Measurement during flushing					
Sample No.	Date of examination	Location of Inoculation	Air volume [L]	CFU / Plate	Log ₁₀ CFU/ in Siphon
1 (<i>E.c.</i>)	11-Dec-2024	1	100	0	>7
2 (<i>P.a.</i>)	10-Jan-2025	1	100	0	>7

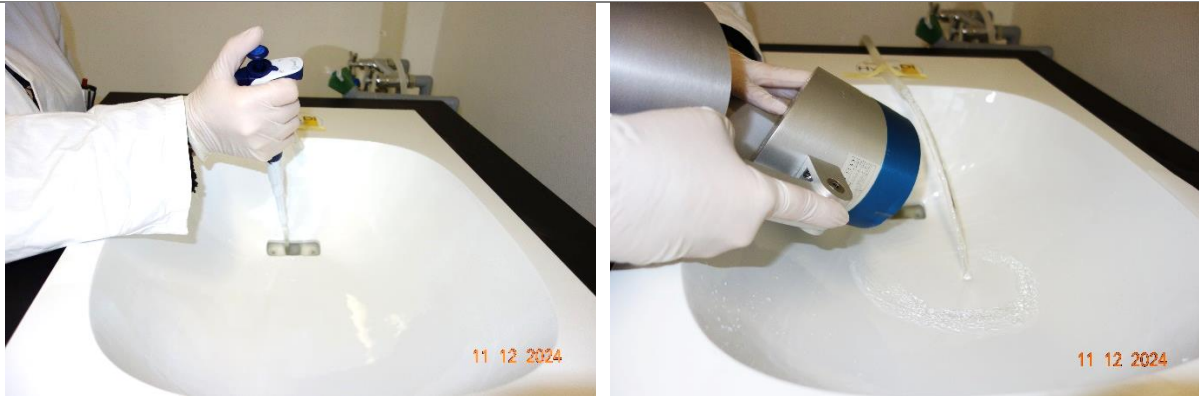
Photographic representation of the inoculation and aerosol measurement:

Filling the siphon with sterile demineralized water

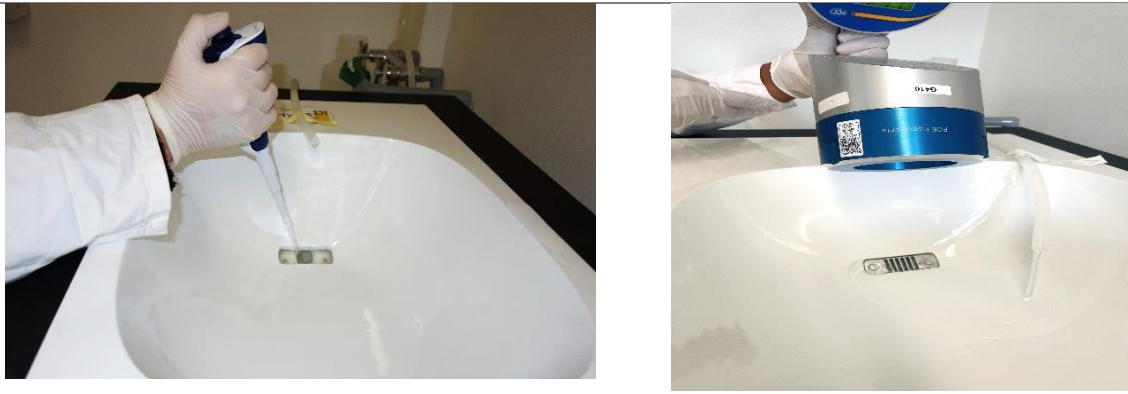


Inoculation of the siphon with the test germ and aerosol measurement

E. coli



P. aeruginosa



Subsequent sampling of the washbasin with contact plates



SMP GmbH

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In 2013, a significant proportion of the test methods were accredited as a test laboratory in accordance with DIN EN ISO/IEC 17025. The currently accredited methods can be found in the accreditation certificate D-PL-17769-01-00.

M. Sc. Ramadevi Padmanabhan
Tübingen, 16-Jan-2025