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10280 Ayvalık / BALIKESİR

2025-10-13

TEST REPORT

Test id:	2025-0988
Sample id:	SN 42030
Customer:	UMS Medikal
On-site test date:	2025-04-29
Test location:	Postane Mahallesi Emir Sokak No 1 34940 Tuzla / Istanbul Türkei
Test period:	2025-04-29 to 2025-05-02 (Cleaning efficacy) 2025-04-29 to 2025-05-07 (Disinfection efficacy)
Test device:	ENDOWASH Model number: 4102, Serial no.: 2105 4102 0998
Inspector:	Stefan Fehrmann
Test method:	ISO 15883-4 (2018) Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes, SOP 16-004 ISO 15883-5 (2021) Washers - disinfectors - part 5: Test soils and methods for demonstrating cleaning efficacy, SOP 16-008
Information:	none

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Contamination of the test samples

For cleaning performance

Date of contamination:	2025-04-29
Test samples:	2m PTFE-tubes with an inner diameter of 2mm
Test soil for test sample:	Heparinized sheep blood, reactivated with protamine (test soil according to ISO 15883-5). The test soil was provided by the client.
Contamination of the test samples:	20ml the test soil was injected into the test sample with a syringe. In order to achieve the continuity of the test samples, 20ml air are injected. Any excess test soil was removed. The test sample dried horizontally in ambient air conditions for one hour. Each test sample is then pierced with a guide wire so that continuity is guaranteed.
Positive control:	The protein content of an untreated test sample is determined
Drying of the test soil:	1h horizontal at ambient conditions.

For disinfection performance

Date of contamination:	2025-04-29
Test samples	2m PTFE-tubes with an inner diameter of 2mm
Test soil for test sample:	Heparinized sheep blood, batch no. 1471/0500/0117 reactivated with protamine (test soil according to ISO 15883-5) with the test germ *Enterococcus faecium* ATCC 6057
Contamination of the test samples:	20ml the test soil was injected into the test sample with a syringe. In order to achieve the continuity of the test samples, 20ml air are injected. Any excess test soil was removed. The test sample dried horizontally in ambient air conditions for one hour. Each test sample is then pierced with a guide wire so that continuity is guaranteed.
Positive control:	The protein content of an untreated test sample is determined
Drying of the test soil:	1h horizontal at ambient conditions.

General information

Identification of the WD

Trade name:	ENDOWASH
Product name:	Endoscope washer and disinfector device
Model number:	4102
Serial number:	2105 4102 0998
Production date:	21/04/2025

Installed program

Program no.:	Endoscope

Loading positions

Fig. 1: ENDOWASH Model number: 4102, Serial no.: 2105 4102 0998

Test sample	Connection
1	Connections 1 - 2

Overview of the sensors used for testing

Description of the used data loggers

Tab. 1: Used loggers*

Logger	Sensor ID
T1	12662
T2	12663

* = The loggers were provided by the client

Logger positions

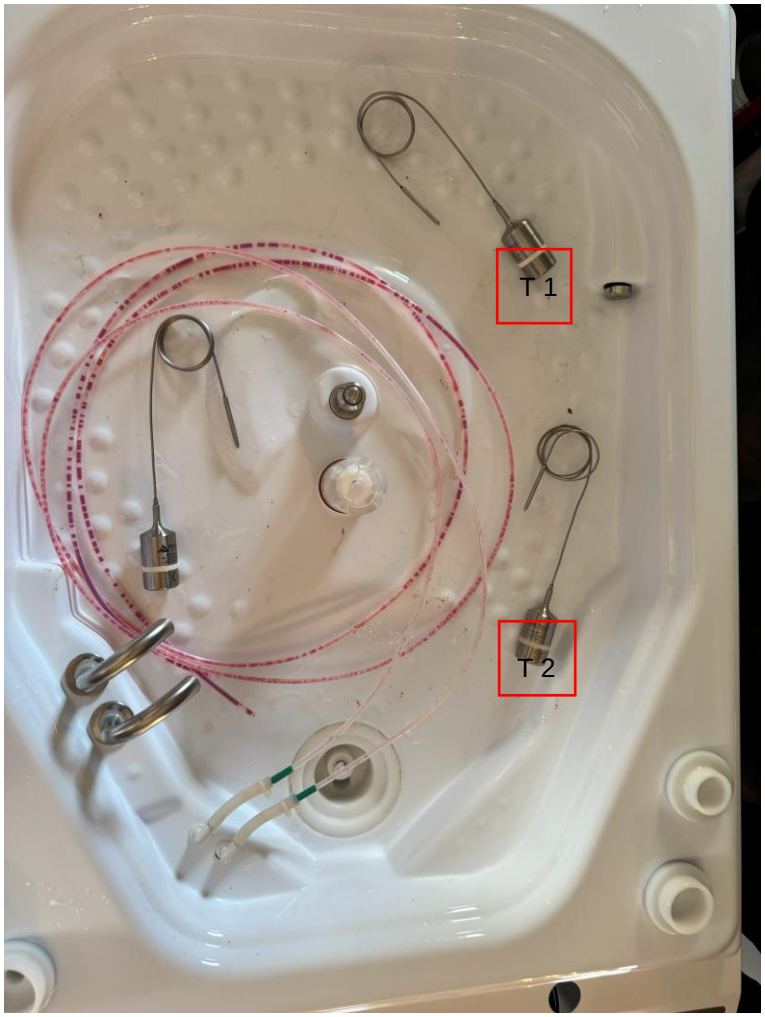

Fig. 2: Logger positions in the chamber

Cleaning product and disinfectant

Tab. 2: Used cleaner and disinfectant.

Process chemicals	
BIO RAD ENZYM	Detergent LOT E0425004
BIO RAD POWERFUL PA	Disinfectant LOT PWP0325001

Fig. 3: Used cleaner and disinfectant

Temperature curves

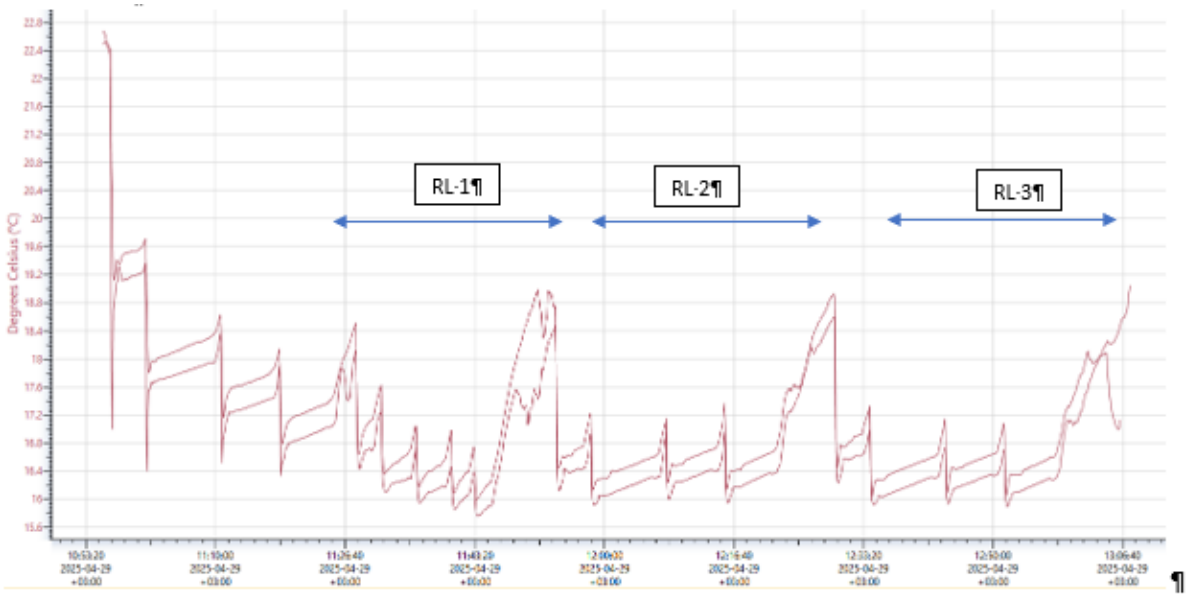

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Fig. 4: Temperature curves, cleaning – run 1 to run 3 from 2025-04-29

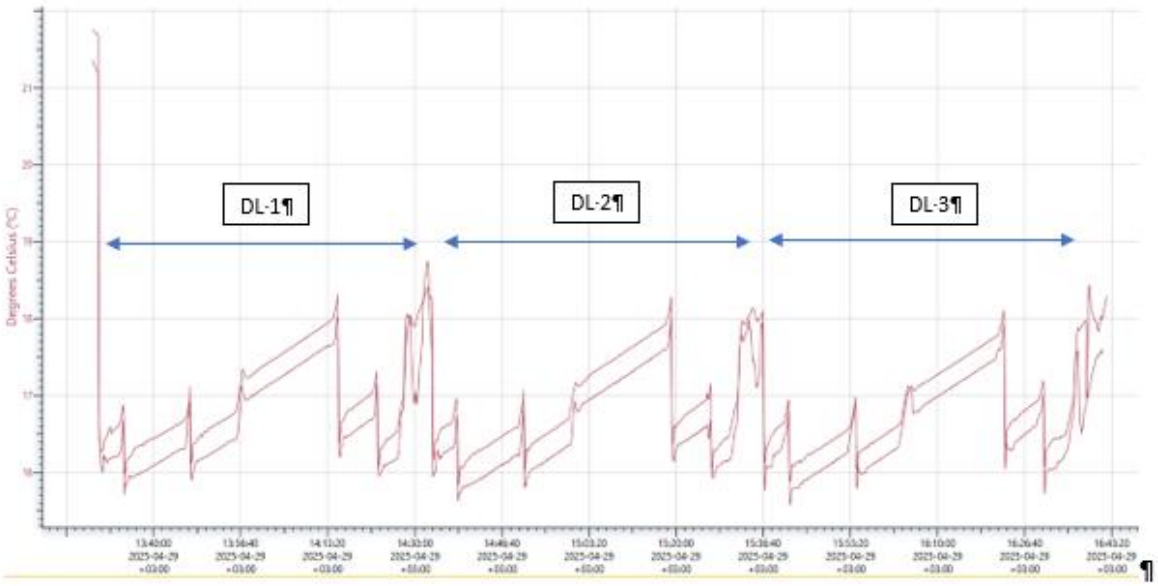

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Fig. 5: Temperature curves, disinfection – run 1 to run 3 from 2025-04-29

Results of the quantitative cleaning performance

Test date: 2025-04-29 to 2025-05-02

Tab. 3: Positive controls

Sample No.	Dilution factor	Extinction*	Test sample [µg BSA/TS]
Positive control	1:10	0.672	**7 4187.6**

Tab. 4: Results for the test samples

Sample No.	Optically visible soiling	Extinction [340nm]	Visual clean - / +	Test sample [µg BSA/TS]	Test sample [µg BSA/cm²]**	Criteria
1-1	negative	0.000	-	0.00	**0.00**	**Pass**
1-2	negative	0.020	-	36.80	**0.29**	**Pass**
2-1	negative	0.018	-	33.10	**0.26**	**Pass**
2-2	negative	0.007	-	12.90	**0.10**	**Pass**
3-1	negative	0.004	-	7.40	**0.06**	**Pass**
3-1	negative	0.005	-	9.20	**0.07**	**Pass**

Legend:

BSA	Bovine serum albumin
bdl	below detection limit
n.a.	not available
neg	Results negative
RF	Reduction factor
TS	Test sample
*	Extinction at 340nm (OPA)
**	The inner surface of the PTFE-tube is 125.00 cm^2
+	Blood residue visibly recognisable
-	No recognisable blood residue visible

Requirements for reprocessed test samples according EN ISO 15883-5:2021

1. Acceptance criteria: visual clean

2. Acceptance criteria:
   Alert level: ≥ 3µg / cm^2
   Action level: ≥ 6,4µg / cm^2

Results for quantitative disinfection performance

Test germ: *Enterococcus faecium* ATCC 6057
Test period: 2025-04-29 to 2025-05-07

Tab. 5: Results of the positive control

Sample No.	Culture medium	CFU [CFU/ml]	CFU / TS [lg]	Mean value
Positive control 1	TSA	$1.80x10^9$	**9.26**	**9.17**
Positive control 2	TSA	$1.10x10^9$	**9.04**	
Positive control 3	TSA	$1.60x10^9$	**9.20**	

Tab. 6: Results for the test samples

Device	Run	Sample	CFU/TS [ml]	Enrichment* [3 / 7 days]	CFU/TS [lg]	RF [lg]	Criteria
Endowash 4102	1	4.1	0.00	- / -	0.00	**≥9.17**	**Pass**
		4.2	0.00	- / -	0.00	**≥9.17**	**Pass**
	2	5.1	0.00	- / -	0.00	**≥9.17**	**Pass**
		5.2	0.00	- / -	0.00	**≥9.17**	**Pass**
	3	6.1	0.00	- / -	0.00	**≥9.17**	**Pass**
		6.2	0.00	- / -	0.00	**≥9.17**	**Pass**

Tab. 7: Results for the final rinse water

Sample id	Device	CFU / 100ml	Criteria*
SN 42030 I	Endowash Model number 4102	0	Pass

Legend:

CFU = Colony forming units
RF = Reduction factor
TS = Test sample
* = <10 cfu /100ml and no germs found *Pseudomonas aeruginosa*
+ = Enrichment after 7 days

Summary

Conclusion: The cleaning and disinfection performance test of ENDOWASH Model number: 4102, Serial no.: 2105 4102 0998 was performed according to DIN EN ISO 15883-4.

Evidence of residual soiling was obtained qualitatively by means of optical inspection and by way of a quantitative protein analysis of the SDS eluate using the modified OPA method.
After the cleaning process the test samples were visibly clean.
The required value for the residual protein content of lower 6.4µg/cm^2 per test sample was fulfilled with the tested process.

The results show a reduction of the test germ *Enterococcus faecium* by ≥9.17 steps for all tested samples.

The required reduction factor for *Enterococcus faecium* for high level disinfection of ≥9lg steps was maintained.

Archiving: **A copy of the test report will be kept together with the raw data in the contractor´s archive.**

Note: The test results refer only to the named test samples. Reproduction of any part of this report requires the written permission of HygCen Germany GmbH.

Test report history

Ref.	Date of issue	Comment	Approved by
001	2025-05-26	-	Stefan Fehrmann
002	2025-06-03	The address on the 1st page of the test report has been corrected.	Stefan Fehrmann
003	2025-10-13	The device's serial number was changed in the conclusion. Additionally, the soiling date and the test period were adjusted.	Stefan Fehrmann

This test report replaces the test report PB2025-0988_SN42030 REV002 dated 2025-06-06. The original test report is therefore not valid.

Schwerin, 2025-10-13

DocuSigned by:

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Stefan Fehrmann
Division Manager
Hygiene Technology