18 years’ experience with performance qualification

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Situation in Germany for hospitals

Legal requirements: Quality Management since 2000
Normative requirements: Following ISO 15883 since 2006

ISO 15883-1:2006(E)

Table A.1 — Summary of test programmes for WDs

Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
1 Cleaning efficacy							
1.1 Chamber	4.2.1.1	6.10.2	X	B	X	B	B
1.2 Load carrier	5.1.10	6.10.2	X	B	X	B	B
1.3 Load	4.2.1.1	6.10.2	X	B	X	B	X(Q)
		6.10.3 (visual)	B	B	B	X	X(D)
		6.10.3 (Annex C)			O	X	O
2 Thermometric							
2.1 Thermal disinfection							
— Chamber walls	4.3.1.2, 4.3.1.3, 4.3.3.2 and 5.9.2	6.8.3	X	X	O	X	O
— Load carrier	4.3.1.1, 4.3.1.3	6.8.2	X	X	X	B	O
— Final rinse water tank	5.3.2.5						
— Load	4.3.1.1, 4.3.1.3, 4.3.3.1, 5.9.1						
2.2 Temperature control							
— Rate of rise	4.1.4						
— Flushing stage	4.2.2						
— Washing stage	4.2.3						
2.3 Over-temperature cut-out	5.8.3						
2.4 Chemical disinfection[a]							
— Chamber walls and load carrier	4.3.2						
— Calorifier and tanks	4.3.3						
— Load	5.3.2.3						
	4.3.2, 4.3.3						
3 Load dryness	4.5.1, 4.5.2						
4 Fluid emission							
— Chamber leak proof	5.1.7, 5.1.8						

ISO 15883-1:2006(E)

Table A.1 *(continued)*

Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
13 Trollets							
13.1 Alignment	5.28.2	6.7.2	X	B	B	B	B
14 Operating cycle							
14.1 Spray system	5.6	6.10	X	X	X	X	X
	5.6.4	verified by 1, 2.1 and 2.2 of Table A.1	X	B	B	B	B
14.2 Reproducibility	5.9.1 c)	6.8.2	X	X	X	O	O
	5.9.2 d)	6.8.3	X	X	X	O	O
14.3 Fault indication	5.22.1	6.3.5	X	X	X	B	O

X recommended

B not recommended

O optional test which can be requested by the purchaser or user

v verification of calibration at the value(s) of interest for the particular instrument e.g. the disinfection temperature

Q quarterly test interval, W weekly test interval, D daily test interval

The tests included in this table assume that all necessary installation qualification checks and tests (see 6.1.3.2) have been completed satisfactorily.

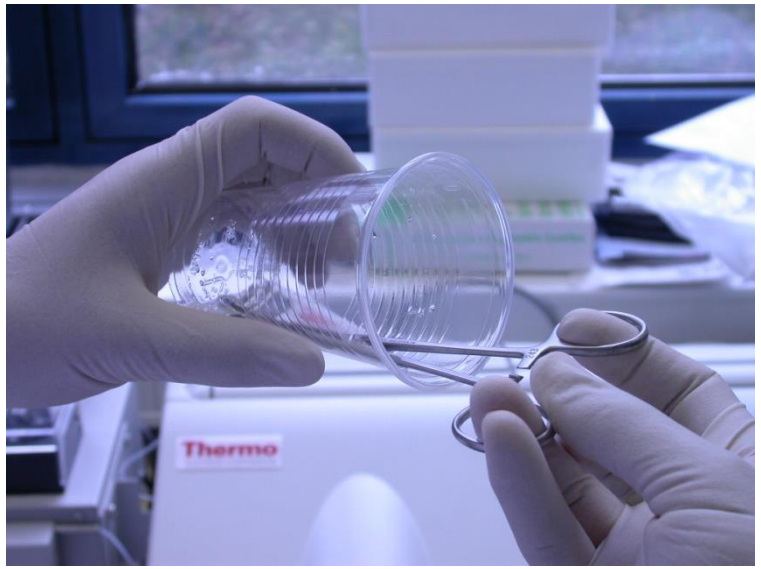
Optional tests may be carried out at discretion or may be required by local regulation.

Test intervals suggested are given for guidance only. Individual programmes of routine tests should be defined on the basis of a risk analysis, taking into account the conditions and reliability of the WD, the extent of independent monitoring of each cycle and the use to which the WD is put.

a Applied only to WDs employing chemical disinfection with controlled temperatures.

b No need to be repeated when reliable data are already available; the data may be provided by the user.

Tests according to the German Guideline



Method is described in ISO/TS 15883-5; 2005

- Annex A
- Annex M

Extraction with SDS-solution

Evaluation with either

- Modified OPA method

or

- BCA method

German Guideline requirements in 2005: alert level **100** µg/device

Results of round robin test in 2005: 6 of 18 w/d failed

Review of the year 2012 by analyzing the data of

4122 crile clamps:
- 2% have been in the range of 75 to 100 µg
- 4% in the range of 50 – 75 µg
- 94% beneath 50 µg

3780 real used instruments:
- 12% have been in the range of 75 to 100 µg
- 6% in the range of 50 – 75 µg
- 82% beneath 50 µg

786 real used MIS-instruments:
- 1% have been over 100 µg,
- 2% have been in the range of 75 to 100 µg
- 1% in the range of 50 – 75 µg
- 96% beneath 50 µg

Assessment of cleaning efficacy based on the protein-surface relationship; Michels; Roth; Eibl; Central Service 2013; 212- 213

German Guideline requirements since 2015: alert level **80** µg/device

2015-2022

159.500 crile clamps have been evaluated

- 2015: 3 % over the acceptance criterion of 80 µg,
- 2016: 1.6% over the acceptance criterion of 80 µg
- 2017 to 2022: in average of the year the failure rate was going down to 0.5 %.

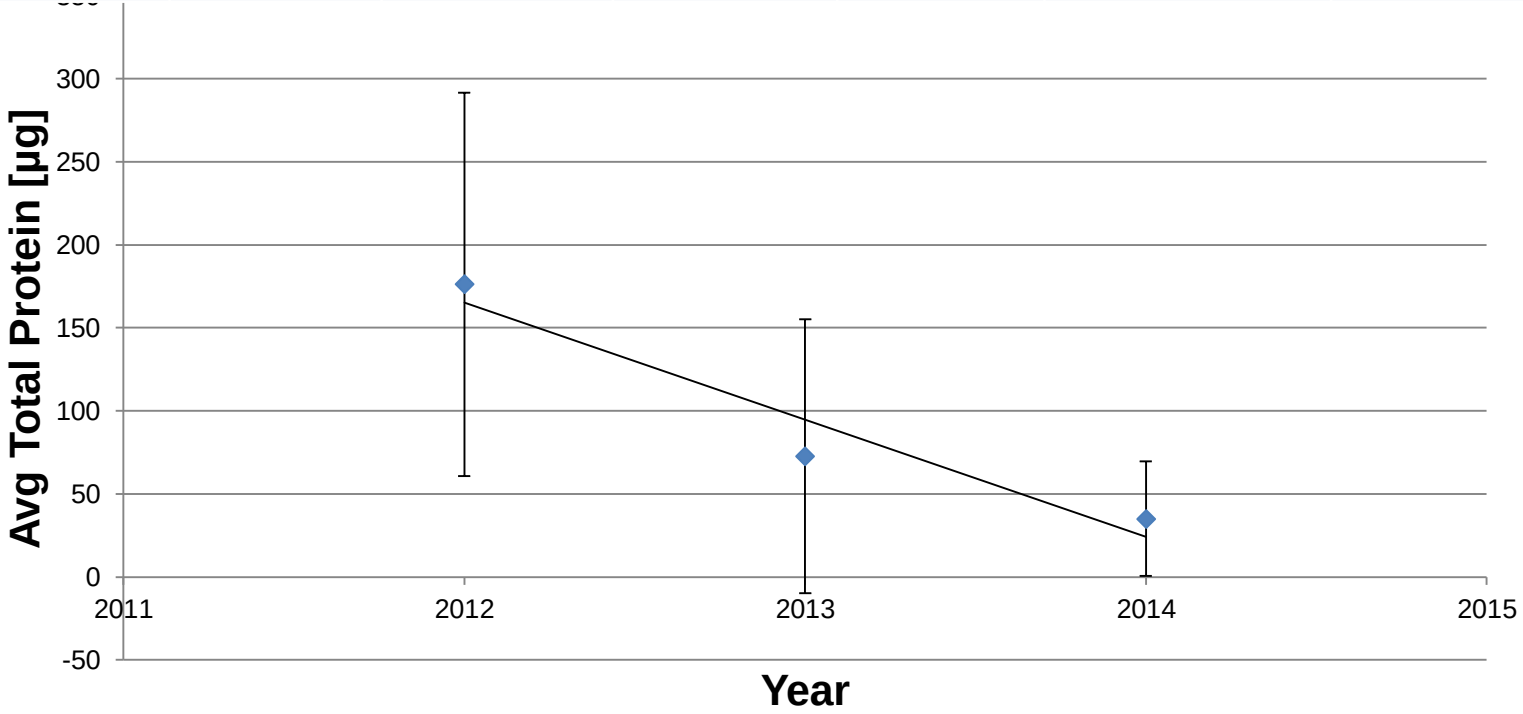
121.313 real used instruments have been evaluated

- 2015 to 2022: 1.2% over the acceptance criterion of 80 µg
  0.35 % > 100 µg

Robotic instruments

Summary Statistics of Performance Qualification Testing at 28 Hospitals in Germany

Year	N	Total Protein [µg]		Number		
		Ave	SD	<100µg	100-199µg	>=200µg
2012	61	176,3	115,4	19	21	21
2013	89	72,7	82,4	73	13	3
2014	73	35,1	34,5	70	2	1



Wallace, Wille, Roth, Hubert; Central Service 2015; 23:182-87

Robotic instruments

Performance qualification data from SMP on hospital used devices

		Type I		Type II		Xi + Si 8mm			
Year	Tested Devices (all families)	Xi 8mm	Si 8mm	Xi 8mm	Si 8mm	results over 100 µg (excluded from AVG)	N	AVG [µg]	SD [µg]
2016	38	9	12	0	9	-	30	31,7	8,8
2017	57	13	5	21	13	440; 153	50	32,1	16,3
2018	80	33	6	16	21	114; 124	74	37,2	17,0
2019	140	55	6	49	25	137; 119; 407; 265; 121	130	31,9	14,1
2020	128	53	8	62	5	151; 138; 108; 101; 126; 122	122	33,8	15,3
2021	113	26	4	76	4	-	110	29,1	17,9
2022	124	56	4	51	11	110; 103; 136; 103	98	31,6	18,8
		245	45	275	88				
Total	680	653				~96%			

Conclusion

- Identification of Problems
- Analysis
- Improvement of Processes
- Ongoing Monitoring

Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices
https://www.dgsv-ev.de/wp-content/uploads/2022/03/MHP_ZS-Supplement-ENG-2017_E-Paper.pdf

Publications:

- Assessment of cleaning efficacy based on the protein-surface relationship; Michels; Roth; Eibl; Central Service 2013; 212- 213
- Results of Performance Qualification Testing on Clinically-Used daVinci EndoWrist Instruments at Hospitals in Germany; Wallace, Wille, Roth, Hubert; Central Service 2015; 23:182-87

Presentations:

- https://wfhss.com/downloads/Barcelona-2022/221117_Thursday/Session_04/Conference11-Seekamp_Karen-Statistical_evaluation_of_protein_levels_of_test_objects.pdf

- https://wfhss.com/downloads/Barcelona-2022/221117_Thursday/Session_03/Conference08-Roth_Klaus-Cleaning_of_robotic_instruments.pdf