

Guideline

for Testing, Validation and Monitoring

of

Automated Cleaning and Disinfection Processes

for Medical Devices

in compliance with

Standard EN ISO 15883 Part 1, 2 and CEN ISO/TS 15883-5

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Please send any suggestions for improving this Guideline or your experiences on using it to the following email address:

ÖGSV

email: office@oegsv.com

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1 Introduction

Cleaning and disinfection of medical devices (MDs) in / for healthcare establishments is regulated by the Medical Devices Act (MPG), regulation related to Article 94 MPG, Recommendation by the Robert Koch Institute (RKI) “Hygiene requirements for reprocessing medical devices” and by Standard EN ISO 15883 –1, 2 and 5.

This Guideline presupposes that users are familiar with the laws, regulations and directives listed in the References section. Hence these will not be repeated or cited here.

Both the laws and directive stipulate that suitable validated processes be used to ensure that reprocessed medical devices do not pose any hazard to the health of patients, users or third parties. Standard ÖNORM EN ISO 15883-1 contains basic, internationally agreed requirements, definitions and test methods for automated cleaning and disinfection processes for medical devices, which are supplemented by standard ÖNORM EN ISO 15883-2 for surgical instruments, anaesthesia equipment, hollow devices and glassware. The test methods used in the various EU Member States are featured in Part 5.

The Guideline is intended for quality assurance of medical device reprocessing.

The Guideline for testing, validation and routine monitoring of automated cleaning and disinfection processes for medical devices was compiled to assure as far as possible uniform conductance of test/validation activities in Austria.

NOTE: The Guideline differs in some (to an extent important) points from standard ÖNORM EN ISO 15883. This divergence was made, first, to facilitate implementation of the standard requirements, making them more relevant to everyday practice. The differences relate in particular to the number of repeat tests as well as to individual, hitherto not established, tests for which sufficient information is not yet available (e.g. investigation of reprocessed supplies for endotoxin) or for which no guide or limit values are currently defined (e.g. water quality). This divergence can be further explained by the fact that at present in some cases the standard requirements greatly exceed what is currently, or in the near future, possible in Austria. In most European countries WDs are not at all tested, and it appears unlikely that validation of processes can be implemented within the next few years. In Austria, there has been a long tradition of investigating WDs in many institutions, at least after installation or annually, and measures are already underway for validation of automated cleaning and disinfection processes or of the entire reprocessing chain (i.e. including sterilization). The ÖGSV is thus of the opinion that these **viewpoints** are justified and in the interest of patient safety.

The Guideline contains important practical fundamental tips for validation of cleaning and disinfection processes in washer-disinfectors (WDs). In Annex 2 are forms that can be used to record the requisite data in a transparent manner and check all entries. Annex 1 contains instructions on practical conductance of validation.

Thanks to this Guideline, the bodies entrusted with conductance of validation will find it easier to check prerequisites in compliance with the pertinent standards, carry out commissioning as well as

perform measurements for performance qualification, evaluate results and compile a validation report and, if required, evaluate this. For operators the Guideline gives tips on how to prepare for validation.

This Guideline is not intended as an impediment to development of new concepts or technologies. It will be revised as soon as this appears necessary.

2 Scope

This Guideline sets out the principles underlying the validation of cleaning and disinfection processes for medical device washer-disinfectors that comply with standard ÖNORM EN ISO 15883 –1 and –2 as well as for revalidation and routine monitoring of these processes.

Furthermore, it can be used for performance qualification of WDs that are still in operation but do not comply with the pertinent standards.

In general, it is not relevant for reprocessing of human-waste containers since, in the opinion of the ÖGSV, these do not require validation in the strict sense; however, the other steps (tests) described in Chapter 5 are required. Nor does it refer either to validation of chemothermal automated processes as used for reprocessing flexible endoscopes as per prEN ISO 15883-4.

NOTE: However, instructions on testing chemothermal processes are given in Annex 1.

This Guideline is intended as a source of guidance for the bodies entrusted with validation, certification and inspection when verifying compliance with the *Regulation as per Article 94 MPG governing cleaning, disinfection and sterilization of medical devices in or for healthcare institutions* with regard to automated cleaning and disinfection as a partial step of the medical device reprocessing chain.

It is not valid for removal and / or destabilisation of prions. For the requirements to be called upon in the event of occurrence, or suspected occurrence, of Creutzfeld-Jacob disease (CJD) or variant CJD (vCJD), please consult the report compiled by the vCJD Task Force at the Robert Koch Institute (RKI)K (www.rki.de).

3 Legal aspects

Operators, e.g. hospitals, doctors' surgeries, etc. that reprocesses MDs for their own use or do so subject to subcontracting or leasing contracts must use suitable validation processes (MPG Article 93, regulation on Article 94).

With the coming into force of Austrian standard ÖNORM EN ISO 15883–1, only WDs that have passed a type test pursuant to ÖNORM EN ISO15883 may be purchased (placed in operation). The WD manufacturer furnishes proof of conformity with the standard and of suitability for reprocessing the MDs listed in the specification. In the future, this requirement will be met through the CE mark. (WDs are Class II medical devices and, as such, must be subjected to a conformity assessment procedure carried by a Notified Body before being placed on the market.)

The RKI recommendation “Hygiene requirements for reprocessing medical devices” as well as the forthcoming regulation on Article 94 MPG stipulate implementation of quality assurance measures. For Category III CSSDs this QM system should be based on the harmonised international standard ÖNORM EN ISO 13485 (see Tab. 3).

4 Explanations on ÖNORM EN ISO 15883-1

4.1 The A_0 concept in ÖNORM EN ISO 15883-1

In ÖNORM EN ISO 15883-1 the F value concept used in sterilisation has been applied to thermal disinfection in WDs, and incorporated into the standard as the A_0 value concept. The disinfectant action of thermal disinfection processes is expressed in terms of A_0 values.

A_0 is defined as the equivalent time in seconds at 80 °C during which a specified disinfectant action is reached.

If the z value = 10, the term A_0 is used.

$$A_0 = \sum 10^{(T - 80) / z} \cdot \Delta t$$

t = selected time interval in seconds

T = temperature of load in °C.

The z value is the increase in temperature in °C needed to change the D value for a particular microorganism by a factor of 10. (The D value is the time in seconds needed at a particular temperature to reduce a population of particular microorganisms by a factor of 10.)

The A_0 value of a moist heat disinfection process is the lethality expressed in terms of the equivalent time in seconds at a temperature of 80 °C delivered by that process to the medical device with reference to microorganisms possessing a z value of 10.

Which A_0 value must be reached depends on the type and number of microorganisms expected on the medical devices to be reprocessed as well as on subsequent treatments (e.g. sterilisation) or the subsequent use.

The medical devices must be assigned to different classes as per the RKI recommendation (see Fig. 2).

The A_0 values to be reached are defined by the infection control team or the hospital infection control specialist, however, the following recommendations apply in principle:

An A_0 value of 60 is considered to be a minimum for non-critical medical devices (as per RKI classification), i.e. for medical devices coming into contact only with intact skin (e.g. bedpans).

An A_0 value of 600 is deemed to suffice for semi-critical MDs if it can be assumed that a only low microbial count is present and that no heat-resistant pathogenic microorganisms are expected.

For all critical medical devices that could be contaminated with heat-resistant microorganisms, e.g. hepatitis B viruses, and come into contact during use with physiologically sterile body cavities or with blood, the Robert Koch Institute recommends thermal disinfection with an A_0 value of at least 3000 as per the AB spectrum of action.

This can be achieved for example with hot water at 90 °C, provided that the surface of the medical devices is able to reach (and tolerate) this temperature for at least 5 min.

Process temp.	Exposure time for $A_0=3000$ (critical MDs)		Exposure time for $A_0=600$ (semi-critical MDs)		Exposure time for $A_0=60$ (non-critical MDs)	
	sec	min	sec	min	sec	min
65	94868	1581.1	18974	316.2	1897	31.6
70	30000	500.0	6000	100.0	600	10.0
75	9487	158.1	1897	31.6	190	3.2
80	3000	50.0	600	10.0	60	1.0
85	949	15.8	190	3.2	19	0.3
87	599	10.0	120	2.0	12	0.2
90	300	5.0	60	1.0	6	0.1
93	150	2.5	30	0.5	3	0.1
95	95	1.6	19	0.3	2	0.03

Tab.1: Temperatures and exposure times for thermal disinfection of medical devices as per the A_0 concept

5 Validation

Validation in the context of European standardisation is understood to mean a documented procedure for furnishing, recording and interpreting the requisite results, in order to demonstrate that a process continually meets the given specifications.

Validation should thus verify conformance of the WD processes with the given specifications as well as the suitability of the process for reprocessing the MDs used on site. The proof that a process continually meets the given specifications can be furnished only by the reproducibility of the process sequence.

In ÖNORM EN ISO 15883-1 validation is considered to be a complete programme comprising installation qualification, operational qualification and performance qualification.

Type test/ factory test			
VALIDIERUNG	Installation qualification		
	Operational qualification	Technical acceptance	
		Hygienic acceptance	
	validation in a narrower sense	Commissioning (verification of framework conditions, technical preconditions, repeat individual operational qualification tests, if necessary)	
		Performance qualification	
Routine inspection (monitoring) and annual revalidation (performance requalification)			

Tab. 2: Summary of the various tests

VALIDATION

Validation in a narrower sense

Since ÖNORM EN ISO 15883 is an equipment standard that only touches on the framework conditions for validation (and validation itself), some additional information is given below.

5.1 Type test

The manufacturer is responsible for the type test, which is divided into a technical and an hygienic part. These partial tests should be preferably conducted by independent technical / infection control experts or accredited test bodies. The test reports should be made available to the operator before

making any purchase. For the information from the type test needed for installation qualification/validation please consult Chapter 2, Annex 3 of this Guideline.

5.2 Validation sequence (see Fig.1)

5.2.1 Preconditions (framework conditions) for validation

The following preconditions must be met before conductance of validation (see also Annex 2):

- Structural preconditions (as per Table 3)
- Management and staff qualifications (as per Table 3)
- Risk evaluation and risk classification of the MDs or MD groups to be reprocessed (see Fig. 2)
- Technical preconditions to be met by WDs (see Section 5.3)
- Appropriate supply of operating media (e.g. demineralised water)
- Appropriate quality assurance measures (as per Table 3)

The following documentation, at least, must be available for validation:

- Written specifications on the structure of the Central Sterile Supply Department (CSSD), showing the responsible/ competent persons (e.g. in the form of an organigramme)
- Information provided by the WD manufacturer for the operator (as per ÖNORM EN ISO 15883), e.g. operating instructions, calibration protocols, programme specifications
- The MD manufacturer's reprocessing instructions (if they can be supplied)
- Information provided by the manufacturer of process chemicals (e.g. on dosing, safety sheets)
- Loading configurations
- Standard operating procedures for all reprocessing steps
- Operating logbook
- Infection control policy (incl. cleaning/disinfection policy)
- Servicing schedule
- Routine inspection schedule
- Proof of qualifications and training
- Release criteria and documentation

5.2.2 Installation qualification

During installation qualification a check is conducted to establish whether the WD was delivered and installed as per the contractual terms and that all operating media were supplied and the machine can be safely operated. This is a purely technical test. The manufacturer must make provision for, and document, installation qualification once the machine has been supplied and connected. The technical part of operational qualification can be carried out at the same time as installation qualification.

5.2.3 Operational qualification

5.2.3.1 Technical acceptance

Unless otherwise contractually agreed, this is to be conducted by the manufacturer together with a technical expert appointed by the respective institution

- Inspection of the supplied documentation and the type test documents as per Annex 3
- Doors and locks
- Escape of liquids or gases
- Operating media supplies
- Safety techniques
- Design (e.g. solder seams)
- Display and recording equipment (measurement precision of instruments, calibration)
- Automatic transport mechanisms, if applicable
- Check of other technical specifications (e.g. as per tender)

5.2.3.2 Hygienic acceptance

The results of installation qualification and the technical acceptance test should be available before the start of the hygiene acceptance test .

Unless otherwise contractually agreed, hygienic acceptance is to be organised by the manufacturer while preferably appointing an independent infection control (hygiene) expert. If the results of installation and operational qualification are positive (technical and hygiene acceptance tests), the preconditions for acceptance of the WD by the respective institution will have been met. Unless otherwise contractually agreed, the manufacturer cannot be held liable for any problems occurring during performance qualification, imputable to the MDs to be reprocessed or to the loading patterns,

The nature and scope of operational qualification are described in Annex 1.

For operators who (for whatever reason) are unable to conduct validation of all reprocessing steps the process is temporarily terminated after installation and operational qualification. However, in such cases, too, annual routine inspection preferably by an independent test body is required.

5.2.4 Process validation (in a narrower sense)

5.2.4.1 Commissioning

Reproducible compliance with the requirements does not depend exclusively on the WD, but also for instance on the structural situation, organisational measures, staff qualifications, manual steps, etc. For that reason certain structural, operational and organisational preconditions must be met before validation can be conducted in the stricter sense of this Guideline. The operator is therefore called upon to ensure that the minimum requirements listed in Table 3 or in Section 5.2.1 for the different

Central Sterile Supply Department categories are met. Compliance with these requirements is checked within the framework of commissioning.

If operational qualification had been carried more than 3 months previously and validation included “old equipment” (see below) that does not meet the pertinent standards, parts of operational qualification are carried out at the time of commissioning. The scope of testing needed for commissioning is outlined in the column “operational qualification/ commissioning” in Tab. 1, Annex 1.

5.2.4.2 Performance qualification

During performance qualification the cleaning performance of the process is verified when reprocessing everyday MDs harbouring the most difficult to remove soils. Other tests need not be repeated unless operational qualification had been conducted more than 3 months previously.

The scope and methodology of the tests to be performed are given in Annex 1.

NOTE: deviation from ÖNORM EN ISO 15883-1: the cleaning performance is assessed after a full cycle.

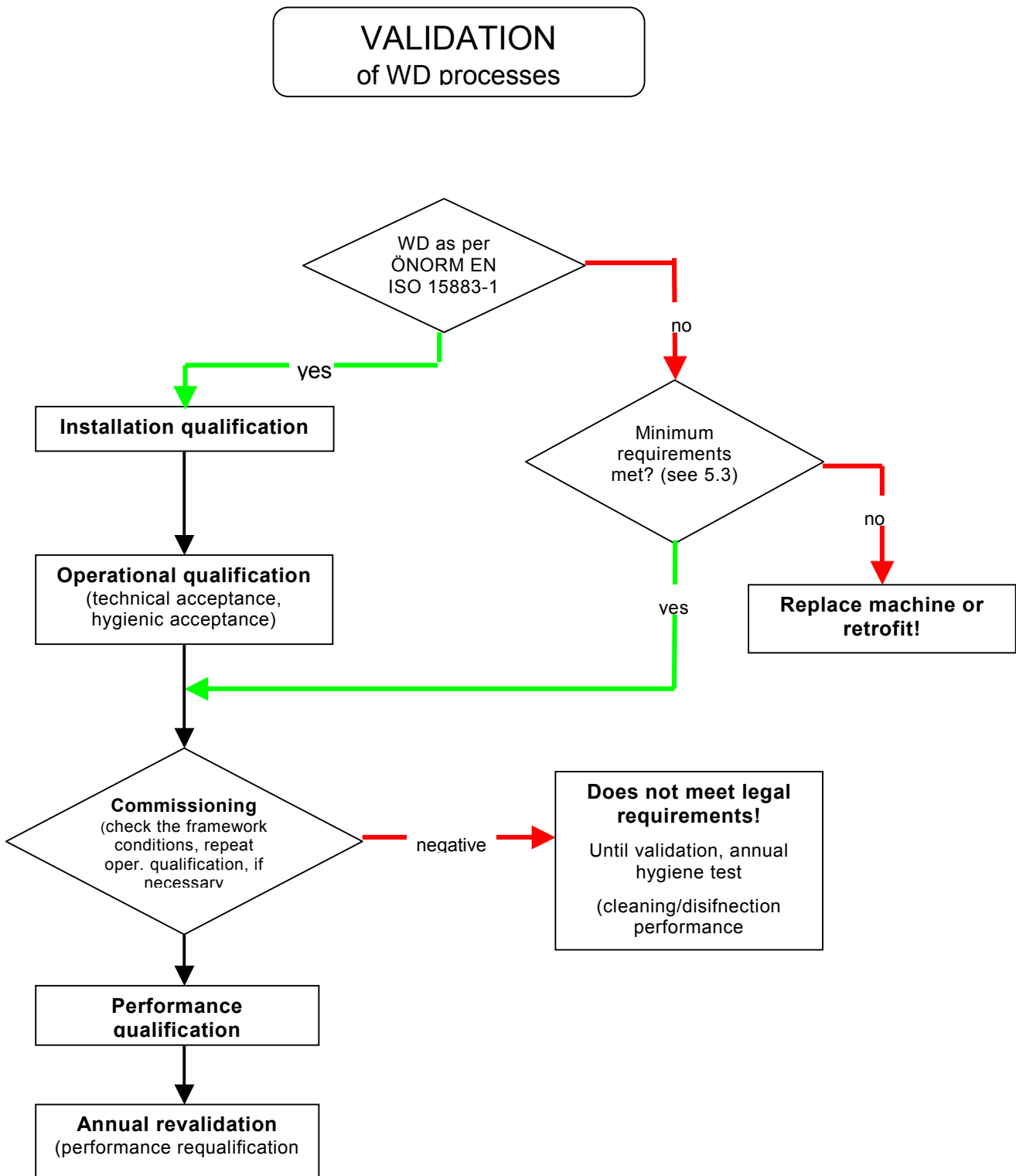


Fig. 1: Flow chart on validation sequences

5.3 Validation of cleaning and disinfection processes commissioned before ÖNORM EN ISO 15883 –1 came into force

For WDs already in operation before ÖNORM EN ISO 15883-1 came into force, often installation and operational qualification will not have been carried out (see Fig. 1), hence in such cases validation begins with (earlier missed, and possibly restricted) operational qualification.

The following minimum requirements must be met by the WD as a precondition for process validation:

- Automatic process sequence (freely programmable programmes)
- (Adjustable) temperature displays
- Automatic dosing of process chemicals (these should be volumetrically verifiable)
- Continuous fault signalling if faulty programme cycle (inadequate water supply, temperature too low in disinfection phase, inadequate supply of process chemicals)
- Batch counter (or documented control system)
- Process documentation (mind. temperature/time variables as ACTUAL values, date, time)
- Appropriate inserts for hollow devices (MS, AN), if necessary

To meet the requirements, one must clarify with the WD manufacturer whether retrofitting is possible.

5.4 Documentation

The forms in Annex 2 can be used to record the results of operational and performance qualification as well as for revalidation for the test report.

The test report must feature the signature of the person responsible for testing, evaluation of results and overall assessment as well as of the institution's responsible person.

If the WD operator is a manufacturer and person placing MDs on the market within the meaning of MPG, validation must be evaluated by a Notified Body within the framework of the conformity assessment procedure.

5.5 Revalidation

At least once yearly revalidation must be conducted in the form of performance requalification as well as of restricted operational qualification using standard test methods. The scope of testing is outlined in Table 1, Annex 1.

Furthermore, performance or operational requalification must be carried out if important technical changes or repairs have been made, e.g. change of operating media (e.g. water) or reprocessing agents (chemicals), different loading racks used, major changes to the load, etc. It is not mandatory if the results of routine checks deviate significantly from the set points since in such cases checks,

adjustments or repairs should first of all be carried out by the engineering department. Following that, a repeat test may be needed.

6 Routine inspections

Standard operating procedures must be in place for all test methods used for routine inspections.

Routine inspection of reprocessing procedures should be conducted regularly using tests that are easy to implement. These tests must be noted in a routine inspection schedule, and the test results should be continuously recorded.

It is recommended that those test methods to be used for routine inspection be integrated into validation and revalidation so that suitable acceptance criteria can be defined.

The test methods used during routine inspection must be carried out by staff with the requisite expertise.

The minimum results (set points) to be assured must be defined. If such results are not obtained, measures must be stipulated and immediately implemented to eliminate the shortcomings.

The operator defines the scope and frequency of the various tests as well as the number and positions of e.g. indicators. The following recommendations can be used as a guide to that effect:

6.1 Recommendations for routine inspection

(see also Annex 1, Tab. 1)

6.1.1 Cleaning performance:

- Visual inspection for cleanliness of each batch
- Spot checks based on protein detection tests (e.g. biuret reaction as per Annex E of ÖNORM EN ISO 15883-1) (at least once weekly after reprocessing MDs belonging to the semi-critical B and critical B and C risk groups).
- Verification of cleaning performance with cleaning indicators, as necessary (e.g. TOSI gap PCDs) at regular intervals.

6.1.2 Disinfectant action:

- Verification of compliance with the disinfection parameters for each load, by comparing ACTUAL and SET POINT values (parametric release based on batch documentation)
- Use of machine-independent temperature loggers (recommended quarterly in high risk areas)

6.1.3 Water quality

- Verification of conductivity of demineralised water (weekly)
- Inspection for turbidity (weekly)

7 Management and staff qualifications

The minimum requirements listed in Table 3, or those set out in regulation on Article 94 MPG apply here.

8 Legal basis, standards

1. Medical Devices Act (MPG): Federal Gazette. 1996/657
2. Regulation on Article 94 MPG governing cleaning, disinfection and sterilisation of medical devices in, or for, healthcare institutions (in preparation)
3. ÖNORM EN ISO 15883-1: Washer-disinfectors – General requirements, definitions and tests. Final draft July 2003.
4. ÖNORM EN ISO 15883-2: Washer-disinfectors – Requirements for and testing washer-disinfectors employing thermal disinfection for surgical instruments, anaesthesia equipment, bowls, dishes, receivers, utensils, glassware, etc. Final draft November 2003.
5. ÖNORM EN ISO 13485: Quality assurance systems - Medical devices – Special requirements for application of EN ISO 9001
6. EN ISO 14971 Application of risk management to medical devices
7. ÖNORM EN ISO 17664 Sterilization von medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

9 List of authors

V. Buchrieser, M. Gehrler, H. Getreuer, W. Koller, P. Lachner, C. Lass-Flörl, T. Miorini, H. Mittermayer, A. Percht, M. Suchomel

10 Abbreviations

MD	Medical device
WD	Washer-disinfector
RKI	Robert Koch Institute
ÖGSV	Austrian Society for Sterile Supplies
CSSD	Central Sterile Supply Department

11 References

British Standard 2745: 1993. Washer-disinfectors for medical purposes Part 3. Specification for washer-disinfectors except those used for processing human-waste containers and laundry. British Standards Institution, London. ISBN 0 580 21545 8.

Bundesgesetzblatt Jahrgang 1998 Teil I Nr. 42, 1998 (D): Verordnung über das Errichten, Betreiben und Anwenden von medical devices (Medical devices-Betreiberverordnung - MPBetreibV)

C. Höller, S. Krüger, H. Martiny und R. Zschaler (Hrsg.): Qualitätssicherung von Reinigungs- und Desinfektionsprozessen, Anforderungen, Prüfmethode, Dokumentation, Bezugsquellen, Behr's Verlag Hamburg, 1994.

Deutsche Gesellschaft für Krankenhaushygiene (DGKH): Guidelinene Entwurf: validation und Routineüberwachung von Prozessabläufen bei maschinellen Reinigungsverfahren mit thermischer Desinfektion für thermostabile Medical devices. Zentr Steril 2003 11: 242-250.

Früh B., Pfeifer M.: Effiziente Überprüfung der Reinigungswirkung in Reinigungs-/Desinfektionsgeräten im Routinebetrieb. Zentr Steril 2002; 11 (1): 41-52.

Grangl, F., Miorini, T., Buchrieser, V.: Vergleichende Untersuchungen verschiedener Prüfanschmutzungen zur Bewertung der Reinigungsleistung von Reinigungs-/Desinfektionsgeräten. Präsentation anlässlich des DOSCH-Symposiums der ÖGHMP Kitzbühel, 3.Juni 2003,

Haase B: Wie sauber muss eine Oberfläche sein? Reinheitsanforderungen an Metalloberflächen. JOT 1997; 4: 52-57

Health Technical Memorandum 2030 Washer-disinfectors. Validation and verification. The Stationery Office, London. 1997 ISBN 0-11-322071-5.

Hurrell, David: A0-Konzept, presented at the Dublin meeting in September 1996 and reviewed and developed at a seminar held by TC102 in Berlin in April 1997.

Koller W., Reinigung und Desinfektion von Eßgeschirr, Instrumenten und Ausscheidungsbehältern im Krankenhaus; Grundlagen - Verfahren – Prüfung

Krüger S: Überprüfung der Reinigungswirkung in Dekontaminationsanlagen. Teil 1 Zentr Steril 1997, 333-344; Teil 2 Zentr Steril 1999, 180-188

Martiny H., Krüger S: Die Rolle der Reinigung bei der Aufbereitung von medical devices. Zentr Steril 2002; 10 Suppl. 2: 15-18.

Michels W, Fengler Th, Pahlke H, Frister H: Anforderungen an die Reinigung bei der Instrumentenaufbereitung. Hrh.-Hyg. + Inf. Verh 2000; 22: 45-49.

Michels W, Frister H, Fengler T, Pahlke H: Überprüfung der Instrumentenreinigung und Normierung der Leistungsanforderungen an Reinigungs- Desinfektionsautomaten. Krh.-Hyg + Inf.verh. 2001; 23: 39-42.

Michels W, Frister H., Pahlke H., Fery R.: Überprüfung der Reinigung minimalinvasiver Instrumente nach maschineller Dekontamination. Hyg Med 1996, 324-330

Miorini, T., Buchrieser, V.: Erweitertes österreichisches Prüfverfahren zur Bewertung der Reinigungsleistung von Reinigungs-/Desinfektionsgeräten. Präsentation anlässlich des DOSCH-Symposiums der ÖGHMP Kitzbühel, 3.Juni 2003,

Miorini, T., Grangl, F., Buchrieser, V.: Entwicklung und Evaluierung einer neuen Prüfmethode zur Prüfung der Reinigungswirkung von Reinigungs-/Desinfektionsgeräten für chirurgische Instrumente, Teil 1: Methodenentwicklung. Zentr Steril 2004; 12 (3):181-184.

Miorini, T., Grangl, F., Buchrieser, V.: Entwicklung und Evaluierung der österreichischen Prüfmethode zur Prüfung der Reinigungswirkung von Reinigungs-/Desinfektionsgeräten für chirurgische Instrumente, Teil 1: Evaluierungsuntersuchungen. Zentr Steril 2006; 14 (4):263 - 274.

Pfeifer M: Standardisierte Testanschmutzung Blut 1: Zusammensetzung, Herstellung, Anwendung. Zentr Steril 1998; 6: 381-385.

Reichl R, Roth K, Heeg P, Bueß G F : Anforderungen an Waschdesinfektionsautomaten für chirurgische Instrumente. Zentr Steril 1999; 234-239

Richtlinie des Bundesgesundheitsamtes zur Prüfung von thermischen Desinfektionsverfahren in Reinigungsautomaten. Bundesgesundheitsblatt 1980, 23, 364-367.

Robert Koch Institut (RKI): „Anforderungen an die Hygiene bei der Aufbereitung von medical devices“ Bundesgesundheitsbl 2001 44: 1115-1126.

Schrader G, Görisch G.: Die Grenzen der Instrumentenreinigung unter dem Eindruck der Datenlage zur vCJK-Gefahr. Hyg Med 2003; 28 (7-8): 306-309.