Guidelines (draft) for Validation and Routine Monitoring of Process Steps in Automated Cleaning Processes with Thermal Disinfection for Heat-Resistant Medical Devices

as per prEN ISO 15883-1 and prEN ISO 15883-2

Table of Contents

1 Introduction

In Germany, cleaning and disinfection of medical devices is regulated by the German Medical Devices Act (MPG), Medical Devices Operator Ordinance (MP-BetreibV), Recommendation of the Robert Koch-Institute "Hygiene requirements for processing medical devices" and by prEN ISO 15883–1 and prEN ISO 15883–2.

Both the acts and directive call for suitable validated processes to ensure that processed medical devices do not pose any health risks to patients, users or third parties.

The horizontal standard prEN ISO 15883-1 contains basic, internationally agreed requirements, definitions and test methods for the automated cleaning and disinfection processes used for medical devices. This is rounded off by the vertical standard prEN ISO 15883-2 for surgical instruments, anaesthesia utensils, hollow devices and glassware.

This Guideline contains fundamentals for validating processes in washer-disinfectors that conform to the standard as well as instructions for performance testing of washer-disinfectors currently in operation. This Guideline will serve as an orientational guide to those centres entrusted with validation, certification and verification tasks aimed at compliance with MP-BetreibV in respect of automated cleaning and disinfection as a process step in processing medical devices. This Guideline reflects the current stock of knowledge and will be revised and updated to take account of any new developments.

Any suggestions for improving, supplementing or updating the Guideline should be addressed to:

Deutsche Gesellschaft für Krankenhaushygiene e. V./DGKH), Sektion Maschinelle Reinigung und Desinfektion,
e-mail: sigrid_krueger@t-online.de

Classification (e. g. IA, recommended strongly, based on expressive, confirmed experimental clinical and epidemiological studies..., see Hyg Med 2001; 26 [10]: 418) has been effected in accordance with the guidelines of the Centers for Disease Control and Prevention (CDC), Atlanta, USA or of the Robert Koch-Institute (RKI)

2 Area of Application

This Guideline regulates validation of processing sequences in washer-disinfectors – which conform to the standard – for medical devices (MDs) based on prEN ISO 15883–1 and –2 as well as revalidation and routine monitoring of these processes.

In addition, based on prEN ISO 15883 – 1 und –2 the Guideline serves as a guide to performance testing of washer-disinfectors of older design which do not conform to the standard.

It does not cover processing of human waste containers as per prEN ISO 15883-3 or validation of chemicothermal automated processes, e. g. for processing flexible endoscopes.

Attention is drawn to the report compiled by the RKI vCJD Task Force as regards the requirements governing CJD and vCJD. This Guideline will be further elaborated on the working procedures to be observed in respect of CJD and vCJD.

3 Fundamentals

3.1 Legal Aspects and Competences

The operators, e. g. hospitals, doctors' surgeries, etc. processing medical devices (MDs) for their own needs and within the framework of loan or leasing contracts to execute an order, must only use suitable, validated processes (MP-BetreibV Article 4(2); Amended German Medical Devices Act, Article 3(11.2) (1).

Since the coming into force of prEN ISO 15883–1, only washer-disinfectors that have been subjected to a type test as per EN ISO 15883 may be purchased. The washer-disinfector manufacturer furnishes proof that the washer-disinfector conforms to the standard and is suitable for processing the MDs listed.

The Recommendation of the Robert Koch-Institute "Hygiene requirements for processing medical devices" (3), which has been integrated into the amended version of MPBetreibV, calls for implementation of a quality management system that also covers the CSSD and any decentralised processing centres.

Process Selection

Preference should be given to thermal automated processes when processing medical devices. Alternatively, chemothermal processes based on suitable chemical disinfectants can be used for heat-sensitive MDs. A final draft of the vertical standard 15883-4 for validation of processes for processing heat-sensitive MDs, e. g. flexible endoscopes, is not yet available.

3.2 Process Steps

The overall medical device processing cycle at the operator's premises comprises several manual and automated steps (Table 1).

Documented Release

The **manual** steps must be conducted using appropriate standard operating procedures (SOPs). Personnel must be suitably trained (in Germany, e. g. have received training as sterilisation assistant as per the guidelines of the German Society for Sterile Supply – DGSV) and briefed.

In some cases it may be necessary to first of all dismantle or pretreat the medical device either because of its complex design or of the difficulty in removing specific residues. Pretreatment steps or automated cleaning steps must not lead to fixation of residues. Residues and any contaminants that have not been removed impede subsequent thermal disinfection.

The **automated** cleaning and disinfection process based on prEN ISO 15883-2 comprises one or several cleaning steps possibly with ultrasound and one thermal disinfection step as well as intermediate and final rinse steps. A defined procedure must be used when loading items into the inserts provided in the washer-disinfectors, e. g. jointed instruments must be opened, tubes and hollow devices connected to corresponding ports, etc. If special inserts are required, the manufacturer must demonstrate their suitability for this operation. They must be available at the operator's premises and included in validation.

No residues – or demonstrably only minute quantities – of body substances, treatment agents, detergents, rinse aids, used to enhance wetting of surfaces, or of water constituents should be present to ensure that the safety of a subsequent sterilisation process and safe use for the patient are not compromised.

Personnel entrusted with processing tasks must be suitably trained (in Germany, e. g. technical sterilisation assistant as per the training guidelines of the German Society for Sterile Supply – DGSV) and briefed, see 4.6.

Table 1:
Overall medical device processing cycle at the operator's premises

Step	manual/ automated
Preliminary tasks (pretreatment, dismantling, precleaning, e. g. in ultrasound bath)	manual
Cleaning, disinfection, rinsing, drying	automated
Inspection for cleanliness and integrity	manual
Maintenance and repair	manual
Functional testing	manual
Packing, possibly with validated equipment	manual/ automated
For critical MDs sterilised with validated processes	automated

3.3 Type Testing Washer-Disinfectors as per prEN ISO 15883-1 and prEN ISO 15883-2

The manufacturer can conduct the type test himself if he disposes of a qualified quality assurance department.

The manufacturer can also have all, or some, of the tests carried out by a suitable accredited test laboratory.

3.3.1 Information to be Provided by the Procurement Centre/Operator to Manufacturer

The procurement centre must inform the manufacturer of the expected performance. This includes the type of medical devices to be processed as well as the requirements governing the disinfection and cleaning performance. The operator can request that provision be made for using the test soils and test methods customarily employed in the respective country (EN ISO 15883 – 1, Annex B).

The manufacturer should obtain information on the composition of piping systems and on the water quality.

3.3.2 Information to be Provided by the Washer-Disinfector/Manufacturer to the Operator

3.3.2.1 Information on Type Testing

It is important for the operator to have the following information on the types tests:

- what water quality is used for each programme step,
- what detergents and additives,
- what dosage quantity and concentration of detergent,
- what programme cycles (temperature, hold time, water volume)
- what test soils,
- what type of loads,
- what type of inserts.

This information must be made available to the operator so that he can make preparations for installation of the washer-disinfector, and then install it properly, conduct operational qualification tests and operate the washer-disinfector.

In concrete terms, standard EN ISO 15883–1, Chapter 8, stipulates that the manufacturer provide the following information (extract):

1. The manufacturer must declare each pretreatment measure to which the MD to be processed in the washer-disinfector is subjected and which might be necessary to achieve the requisite performance (e. g. dismantling, precleaning, etc.).
2. The following parameters must be defined by the manufacturer for each process cycle to be executed:
   2.1. The intended purpose of the washer-disinfector, including any restrictions.
   2.2. The type of MDs to be cleaned and disinfected by the programme. This information must be based on the validation tests conducted for specific MDs or MD families.
   2.3. The chemical substances employed in the process.
   2.4. The values for cycle variables, e. g. time, temperature, water quantity, quantity of chemical substances used in the process, disinfection time / temperature.
   2.5. The maximal deviations of process variables, e. g. pressure, temperature, etc.
3. For each process phase and cycle the manufacturer must specify conditions to be observed to meet the performance requirements.
4. For washer-disinfectors of serial manufacture the manufacturer must specify the customary operating time periods needed for execution of all routine maintenance tasks and the intervals at which they must be conducted.

3.3.2.2 Information on Installation of the Washer-Disinfector

Furthermore, the standard specifies the information required for proper installation (not given here).

3.3.2.3 Documentation Supplied with the Washer-Disinfector

When the washer-disinfector is delivered, the manufacturer must hand over the following to the purchaser:

1. Operating Instructions in the form of an abridged manual that must contain at least documentary proof of compliance with standard EN ISO 15883 as well as
   Area of application
   Type of load
   Loading configuration
   Correct loading sequence
   Total volume of chamber
   Applicable pressure, permitted operating pressure and permitted temperature
   Description of the existing cleaning and disinfection cycles
   Description of the logic control and recorder units
   Description and adjustment of safety devices
   Instructions on malfunctioning
   Instructions for rinsing and disinfection of the washer-disinfector
   Instructions for cleaning the sheathing
2. Chamber dimensions and usable volume
3. Loading volume
4. Description of the washer-disinfector cycle or cycles (this should include a diagram depicting the operational sequences of all equipment units as well as the process variables regulating each phase, e. g. timepoint, when temperature is reached)
5. Information on matters of relevance to operating safety
6. Maintenance manual with the following information:
   Maintenance tests and intervals at which they are to be carried out,
   electrotechnical connection diagrams and pipe layout,
   overview of the hydraulics and pipe layout, dead space in pipes,
   the processes recommended for cleaning all supply lines and valves,
   a complete list of spare parts,
   a list of the special tools needed for maintenance and testing of the washer-disinfector,
   the type of warranties given,
   a list of the customer service centres,
   troubleshooting instructions for locating and eliminating the causes of malfunctioning

When carrying out the type test, the manufacturer must take account of the countries in which his washer-disinfector is to be operated. This is because at the time of validation the operator might demand compliance with national recommendations (e. g. A_0 = 3000 for disinfection performance in Germany and Austria) as well as the use of the test soils and test methods customarily employed in the respective country (standard EN ISO 15883-1, Annex B).

3.4 Cleaning

The term 'cleaning' denotes the removal (or reduction) of all existing contaminants to a specified final level. Recontamination of sterile supplies through entrainment or the use of an inappropriate quality of rinse water or dead spaces that are too large must be ruled out.

Removal is underpinned by the interaction of temperature, hold time and mechanical exposure to the cleaning solution and can be achieved by a combination of pre-rinses and main rinse. Manual pretreatment tasks are necessary for certain medical devices. When carrying out cleaning it must be borne in mind that some contaminant components are soluble in cold water (native blood), while others must be emulsified or disintegrated.

The most important positive and negative parameters of influence include

- mechanical effects (spray system, water quantity, water pressure, etc.)
- chemical effects (detergents, additives, concentration, temperature, adverse effects mediated by water constituents, reaction with residues)
- thermal effects (underpinning disintegrating and solubilising action)
- blockage of detergent components, e. g. by the hardening constituents of the water
- protein coagulation due to fixing treatment agents or heat exposure
- sufficiently long hold times for swelling, disintegration, hydrolysis or enzymatic decomposition
- avoidance of recontamination by providing for good anti-redeposition power

Paramount importance is ascribed to the mechanical cleaning performance. The spray system must be capable of conveying the water in a sufficient quantity and under sufficient pressure to all the inner and outer surfaces of the medical devices being cleaned. This must be demonstrated by resorting to the qualitative and quantitative tests stipulated in standard EN ISO 15883–1. If other methods are employed, proof of their equivalence or superiority must be furnished.

3.4.1 Cleaners

There is a choice of the following types of cleaners for automated cleaning of medical devices:

- Alkaline cleaners pH >10
- Alkaline cleaners pH <10
- Neutral detergents
- Cleaners with oxidizing components
- Detergents or cleaners with enzymes

Within these groups, too, cleaners may show different levels of cleaning action. Preferably, alkaline cleaners with a pH value > 10 should be used in the use solution as they provide for better and quicker protein disintegration and lipid emulsification. However, the pH value alone is no indicator of a good cleaning action because other components of the cleaners can be co-determinants of cleaning performance. For instance, a diluted sodium hydroxide solution with pH value >10 is not a suitable cleaner because of its poor anti-redeposition power and inadequate elimination of residual hardness.

3.4.2 Checking the Cleaning Performance

Parametric monitoring of water quantity per process step, temperature, hold time, water pressure, lumen patency, spray system and dosage quantities constitute an indispensable base for validation, but does not suffice on its own. The visual inspection description in the standard does not provide for detection of transparent residues or of residues located in lumens that are not, or only poorly, amenable to inspection. Hence additional quantitative checks of the cleaning performance must be carried out on a regular basis. The frequency of routine tests is recommended in table 2 of the standard, but these intervals can be shortened by the operator or supplemented with other tests.

The cleaning performance can be verified by means of test models (Annex B in EN ISO 15883-1 test soil, methods and evaluation). Preference must be given to the use of standardised, quantitatively assessable test models as they yield reproducible results.

The instructions given by the detergent manufacturer on dosage, optimal use temperature and hold time must be observed. Likewise, the instructions on the storage temperature and shelf lives of treatment agents in a sealed, closed and opened state must absolutely be observed.

3.5 Disinfection

3.5.1 Inprocess Checks and Thermologgers

Based on the standard, the thermal disinfection performance of a washer-disinfector is verified only by measuring temperature and hold-time values on the chamber walls, inserts and sterile supplies. Recourse is had here to the measured values of thermocouples integrated into the washer-disinfector, e. g. in the cleaning chamber walls and in the vicinity of the outflow water. One thermal measuring system is used for process control, a further measuring system for displaying the process data and faults (inprocess checks). Additionally, temperature measurements must be carried out at the time of validation using calibrated thermologgers that function independently of the washer-disinfector and are positioned at specific locations among the medical devices. These positions can be consulted in the type test documentation and indicate the locations at which the setpoint temperature is last reached. These data must be compared with display data or printouts obtained for the in-process checks. The thermologger data shall be decisive in the event of any deviations.

The standard stipulates that as a routine measure, too, washer-disinfector-independent measurements be conducted at least every four months.

For parametric definition of the disinfectant action, the F value concept has been applied to washer-disinfectors and enshrined in the standard as an A value concept.

3.5.2 The A_0 Concept in prEN ISO 15883-1

On using a moist heat disinfection process it can be expected that over a certain period of time a temperature will generate a predictable lethality effect against microorganisms that have been cultured according to standardised methods. Corresponding exposure temperatures and time periods can be calculated assuming the presence of particularly heat-resistant microorganisms in numbers in excess of those likely to be encountered on the medical devices to be processed. Standard EN ISO 15883 introduces the term A_0 for moist heat disinfection (thermal disinfection).

"A" is defined as the equivalent time in seconds at 80 °C needed to produce a given disinfection effect.

If the specified temperature is 80 °C and the z value is 10, the term A_0 is employed.

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

What A_0 value must be obtained will depend on the type and number of pathogens on the contaminated medical devices as well as on the subsequent further treatment or subsequent use.

Here an agreement must be reached with the competent hospital infection control officer.

The use of an A_0 value of 600 is deemed to be a minimum requirement for uncritical medical devices, i. e. medical devices that only come into contact with intact skin. A further precondition is that only slight microbial contamination but no heat-resistant pathogenic microorganisms be present. An A_0 value of 600 can be achieved at 80 °C over 10 min, of 90 °C over 1 min or of 70 °C over 100 min.

An A_0 value of at least 3000 must be employed for medical devices contaminated with heat-resistant viruses, e. g. hepatitis B virus. This can be achieved by exposure to hot water, e. g. at 90 °C provided that the MD can tolerate this temperature for a duration of at least 5 min. For critical medical devices the Robert Koch-Institute recommends thermal disinfection with an A_0 value of at least 3000 in accordance with the A B spectrum of action. This A_0 value must be complied with if the presence of pathogens endowed with a high heat resistance profile can be assumed.

4 Validation of Processes in Washer-Disinfectors as per prEN ISO 15883

4.1 Fundamentals

Validation of an automated cleaning and disinfection process with thermal disinfection is conducted at the operator's premises, prior to which the washer-disinfector must have been subjected to type testing as per EN ISO 15883. The type test lists the medical devices with corresponding inserts, supports, connections, etc. (load configurations) for which the manufacturer has declared the washer-disinfector suitable and has furnished proof of such.

Validation verifies whether the washer-disinfector processes conform to the given specifications and the type test data.

4.2 Scope of Validation and Competences

Validation comprises:

- Installation qualification (IQ) after connecting the washer-disinfector; the manufacturer is responsible for this
- Operational qualification (OQ) with verification of the cleaning and disinfection performance and of the programme cycles; the manufacturer is responsible for this
- Performance qualification (PQ) taking account of the items to be processed at the operator's premises and of the treatment agents used; the operator is responsible for this

4.3 Prerequisites for Validation

The following documentation must be available before commencing validation:

- Information provided by the manufacturer to the operator with
  - Manufacturer's Operating Instructions and / or medical device manual,
  - Maintenance plan, loading configurations
- Classification of the MDs to be processed based on risk assessment (RKI)
- MD manufacturer's processing instructions
- Information provided by the manufacturer of the chemical substances used in the process
- Pretreatment of specified device groups acc. to standard operating procedures (SOPs)
- Loading codes
- Operational logbook
- Plan for routine checks
- Documentary proof of training

4.4 Conductance of Validation

Validation must only be carried out by persons who by virtue of their training and practical activities in the field of cleaning and disinfection and of their knowledge of the pertinent laws, standards and directives have the requisite expertise. Persons entrusted with validation must have at their disposal the necessary measurement technology and chemico-

technical facilities and be conversant with the procedures involved. These persons should enlist the cooperation of accredited laboratories for any supplementary microbiological tests.

In Germany, accreditation can be given by the Central State Office for Health Protection in Respect of Drugs and Medical Devices in Bonn – ZLG) or by other Notified Bodies.

Validation must be initiated by the operator.

The manufacturer's instructions for dismantling MDs and fitting the inserts and connections, choice of chemical treatment agents and temperatures (prEN ISO 17664) as well as the water quality must be borne in mind.

The operator need not use the treatment agents employed in the type test. Accordingly, it may be necessary to modify the programme sequences and/or the concentrations of the cleaners to achieve the final results required.

The parameters of influence to be observed in order to achieve good process results are listed below.

The following parameters affect validation of automated cleaning processes:

- Design of the washer-disinfector and its inserts
- Load
- Programme cycles set
- Chemical treatment agents (concentration, dosage precision, the temperature chosen for detergent type, hold time and water quality)
- MD contaminants typically encountered during operation with regard to quantity, type and extent of dried-on substances
- MD design and materials
- Patency of lumened instruments

The following parameters affect validation of automated thermal disinfection processes:

- Design of the washer-disinfector and possible loads
- Programme cycles set
- Temperature
- Hold time
- Spray pattern, i. e. exposure of all MDs to the cleaning solution so that the requisite temperature and hold times are observed on all inner and outer surfaces
- Cleanliness of MDs
- MD design and materials, possibly with lumens

4.4.1 Installation Qualification

Installation qualification is a documented process to demonstrate that the washer-disinfector complies with the specifications.

Measurements and tests to be conducted:

- Temperature-time curves
- Patency measurements of cleaning system and lumened instruments
- Ports for lumened instruments
- Doors and seals
- Process cycles/spray pattern
- Dosage precision
- Leakage of liquids or gases
- Air quality
- Drying

4.4.2 Operational Qualification

Operational qualification is a documented process to demonstrate that the washer-disinfector, as it has been installed, complies with the specifications.

Test loads must be specified and defined for the measurements and tests to be conducted (tests that are in addition to the IQ are printed in bold):

- **Cleaning action**
- **Water quality**
- **Measurement precision**
- **Piping systems**
- Temperature-time curves
- Doors and seals
- Process cycle / spray pattern
- Dosage precision
- Leakage of liquids or gases
- Air quality

Recourse can be had to the type test data for these purposes. The measuring equipment used for the inprocess checks and for the independent measurements must be calibrated.

As far as possible, typical loads used in routine operation should be employed during operational qualification instead of dummies to determine the cleaning action.

4.4.3 Performance Qualification

Performance qualification furnishes documentary proof that the washer-disinfector, as it has been installed and is being operated in accordance with the process sequences, continually complies with the specified criteria and thus produces devices that meet the requirements.

This means that the washer-disinfector continually processes medical devices of the requisite standard.

Reference loads that are characteristic of those loads encountered in routine operation must be specified and defined for the measurements and tests to be conducted (tests that are in addition to the OQ are printed in bold):

- **Disinfectant action**
- **Residues**
- **Suitability of the load supports/inserts/connections**
- **Patency measurements of cleaning system and lumened instruments**
- **Ports for lumened instruments**
- Cleaning action
- Temperature-time curves
- Drying
- Process cycle/spray pattern

In line with the loads typically encountered in routine operation, test loads must be specified for MDs selected at the operator's premises, e. g. general surgical instruments, minimally invasive instruments, anaesthesia utensils, containers, etc.

Patency of lumened MDs is of paramount importance both for cleaning and disinfection.

The MDs available to the operator are used.

The programme sequences must be set in accordance with the expected extent of residues and dried-on substances on the MDs.

The treatment agents, e. g. detergents or cleaners, must be used in accordance with the manufacturer's instructions. On completion of the programme, residues of any agents should be present only in such minute quantities that when the medical device is put to its intended use, it is not expected to pose any health risk. Proof must be furnished by the manufacturer of the treatment agents, while specifying the test methods and acquisition limits.

The water quality must comply with the manufacturer's specifications, unless water of another quality produces equally good results.

Standard prEN ISO 15883-1 first of all calls for testing with the test soils chosen by the operator and using the corresponding method (Chapter 6.8 Test 1; Annex B). The aim here is to furnish proof that the process is capable of removing this soil from the MDs, the washer-disinfector walls and inserts. This is determined either by means of visual inspection or using the method described. If this test is suc-

cessful, the washer-disinfector is then investigated using three loads typically encountered in routine operation (test 2). Cleanliness is assessed by visual inspection. In addition, spot checks for protein detection can be carried out; these methods are described in Annex E.

The test soils and methods are not, necessarily, comparable with each other. For example, it may be much more difficult to remove the test soil customarily used in a particular country (i.e. the national test soil) than that soil used in the type test.

The same test soils or standardised cleaning indicators can be used to elucidate the spray pattern. If these are not mentioned in the standard, proof of their suitability must be furnished.

To check the thermal disinfectant action, thermologgers must be positioned at the risk sites among the MDs and in the vicinity of the measuring points on the washer-disinfector. The risk sites, i.e. those sites at which the process temperature is last reached, can be consulted in the documentation relating to the type test or to previous tests. Otherwise, they must be determined during the performance test. If the measured values of the thermologgers do not agree with the values obtained for the washer-disinfector inprocess checks and displays, the thermologger measured values shall be decisive.

The recommended positions are shown in figure 1

The drying action, if this is part of the washer-disinfector performance, is assessed by visual inspection.

The water quality, supply of operating materials, type and quantity of items to be cleaned and disinfected as well as loading of the inserts (loading configurations) and if applicable any pretreatment measures (dismantling, ultrasound, etc.) must be specified in special standard operating procedures (SOPs) and documented on forms. They must be checked regularly and updated as necessary.

Pretreatment measures, loading patterns, programme sequences and detergents must not be changed so as to ensure that the goal of validation is reached, i.e. to demonstrate that a process constantly produces clean and disinfected medical devices. Revalidation must be repeated following any major changes.

Proof must be furnished of the power, efficiency and reproducibility of the test methods used for the type test, validation at the operator's premises and for routine tests.

4.4.4 Commissioning

Commissioning furnishes proof and documents that the equipment has been delivered and installed to specification and that it meets the requirements within the given limits.

The results of the installation qualification and operational qualification tests as per EN ISO 15883 –1 and EN ISO 15883 – 2 must be available.

4.4.5 Qualification of Management

The management of a Central Sterile Supply Department (CSSD) must have undergone appropriate training. In Germany, the CSSD management must be trained in accordance with the training guidelines of the German Society for Sterile Supply (DGSV) and must have completed Specialist Training Course III, or at least Specialist Training Course II.

In Hamburg, training based on the training criteria of the Senate of the Free and Hanseatic City of Hamburg is recognised.

4.4.6 Revalidation

Revalidation is required at least once each year. The scope of testing will depend on the performance test and on the information provided by the washer-disinfector manufacturer.

Revalidation is intended as a means of confirming that the washer-disinfector is functioning in accordance with its specifications.

It corresponds to the performance qualification and should be conducted each year.

Performance qualification must always be repeated if any major technical changes or repairs have been carried out, e. g. a change of detergent, use of other inserts, etc. It is also necessary if the results of the routine checks deviate considerably from the setpoint values or from the data acquisitioned during the performance qualification.

4.5 Performance Testing of Washer-Disinfectors that Do Not Conform to EN ISO 15883

For washer-disinfectors which are already in operation and are to be upgraded to meet standard requirements for further operation, only the performance qualification tests can be carried out.

The following are minimal prerequisites for standardisation of the process:

1. Automatic programme cycles (as far as possible, freely programmable programmes)
2. (Adjustable) temperature displays
3. Automatic dosage of detergent
4. Error signalling in the event of malfunctioning programme sequence (with type of fault, e. g. water shortage, temperature undershot, shortage of treatment agent, malfunctioning of dosage pump, low water pressure, etc.)
5. Compilation of a catalogue by the operator, possibly in cooperation with the washer-disinfector manufacturer's customer service department, including measures needed for further impeccable operation, e. g. detection of shortage of treatment agent
6. Cycle counters (possibly also manual)
7. Suitable inserts for lumened instruments (MIS, AN), patency test

Independent measurements must be carried out at regular intervals, e. g.

- Thermologgers must be positioned at special locations among the sterile supplies to check the disinfectant action
- Cleaning indicators must be used to check the spray pattern and the cleaning action
- Biological indicators as specified by the RKI must be used for microbiological tests

All results must be documented.

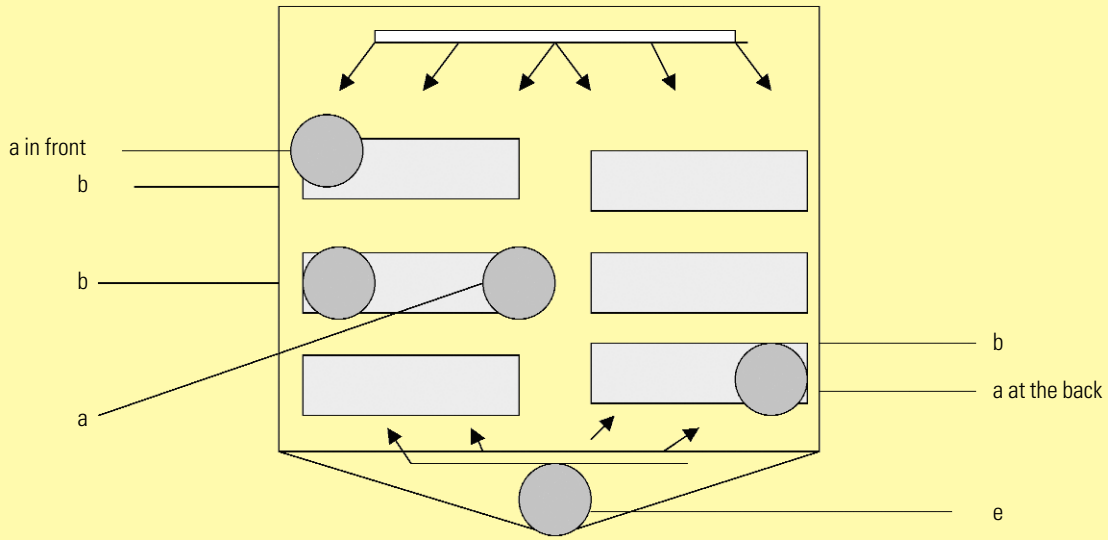
If the washer-disinfector does not meet these prerequisites, process reproducibility is not assured and standardisation is not possible.

4.6 Documentation

Protocols are compiled on forms together with the results of installation, operational and performance qualification testing as well as of revalidation.

The protocol bears the signature of the persons responsible for evaluation of the results and for overall assessment as well as of the person responsible for acceptance of the protocol within the organisation.

If the washer-disinfector operator is deemed to place medical devices on the market within the meaning of MPG, evaluation must be conducted by a Notified Body within the scope of a conformity assessment procedure.



a = diagonally, three thermologgers
b = on at least three levels, three thermologgers
c = point at which the temperature is reaches slowest?, see type testing
d = point at which the temperature is reached fastest?, see type testing
e = adjacent to temperature sensor for automatically control
f = process sensor?, see declaration of manufacturer
a = reference sensor for chamber temperature?, see declaration of manufacturer

Fig. 1: Thermal Disinfection as per prEN ISO 15883, 6.8.2

5 Routine Checks

For routine checks the operator must formulate a concept with regular checks to verify whether impeccable functioning of the washer-disinfector is still assured. In doing so, the recommendations of prEN ISO 15883 (table 2) must be borne in mind. Tests that are endowed with sufficient power and can be conducted as a routine measure and provide information on deviations as well as on microbiological investigations, e. g. with biological indicators, can be integrated.

It is recommended that additional checks, which are to be used for routine monitoring, be integrated already at the time of validation and revalidation in order to demonstrate correlation with other methods.

A routine control concept can include:

- Temperature-time curves
- Visual inspection for cleanliness
- Cleaning tests with cleaning indicators, inter alia, test soils as per Annex B
- Verification of the spray pattern
- Testing with biological indicators
- Spot checks for protein residues
- Checking of water quality

The test methods designated as routine control measures must be properly carried out by personnel with the necessary expertise.

The test results must be endowed with sufficient power.

The minimum results (setpoint values) to be achieved must conform to the provisions enshrined in the pertinent legislation, the standard and the RKI Recommendation. In the event of non-compliance, measures must be formulated for elimination of faults and immediately implemented.

SOPs must be available for all test methods. The results must be documented.

The operator is responsible for drawing up a routine check plan. He determines the scope and frequency of the individual tests as well as the quantity and positioning of indicators. Pertinent recommendations, such as those of the DGSV, can serve as a guide here.

6 Annexes and Remarks

6.1 Definitions

6.2. Legal Fundamentals, Standards, Directives, Recommendations

German Medical Devices Act
Medical Devices Operator Ordinance
Recommendation of the Robert Koch Institute "Hygiene requirements for processing medical devices"
prEN ISO 15883
prEN ISO 17664
Book V of the German Code of Social Law

6.3. List of Authors

H. Martiny, D. Bobyk, T. Linner, H. Henn, A. Carter (on behalf of the DGSV), A. Jones (on behalf of the DGSV), A. Kramer, H.-P. Werner, C. Weitze, P. Kober, T. Miorini
Coordination: S. Krüger

6.4. References (enclosed later)

6.5 Abbrevations

CSSD	Central Service Supply Department
DGSV	German Society for Sterile Supply
MD	Medical Device
RKI	Robert Koch-Institut
SOPs	Standard operating procedures

The assignment of categories, the references and, if necessary, any other diagrams are still considered and inserted.

7 Questionnaire

1. Have risk assessment and classification of all medical devices to be processed been conducted?
2. Has the manufacturer provided all the information required for processing?
3. Are standard operating procedures available for all manual steps?
4. Have CSSD management personnel been trained as sterile supply assistants?
5. Are there workplace descriptions for all personnel?
6. Have all personnel been briefed?
7. Do all personnel undergo regular training?
8. Is further improvement of qualifications planned?
9. Are all measures documented?
10. Have the steam sterilisation processes already been validated?
11. Have the persons entrusted with release of sterile supplies been designated?
12. Has a quality management system been implemented? Being planned?