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Guideline compiled by the DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices

5th Edition 2017

DGKH
Deutsche Gesellschaft für Krankenhaushygiene

DGSV
Deutsche Gesellschaft für Sterilgutversorgung

AKI
Arbeitskreis Instrumentenaufbereitung

DGKH

DGSV Deutsche Gesellschaft für Sterilgutversorgung e.V.

ARBEITSKREIS INSTRUMENTEN-AUFBEREITUNG

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Foreword to the 5th Edition of the Guideline compiled by DGKH, DGSV und AKI

The 5th edition of the guideline of DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices replaces the 4th edition from the year 2014. The German Medical Device Act requires in § 8 that the processing of medical products to be used in a sterile or disinfected state is to be carried out in accordance with the manufacturer's instructions using appropriate validated procedures so that the success of the processing can be guaranteed and the safety and health of patients, operators or third parties must not be jeopardized. Validation of the process steps of cleaning and disinfecting of medical devices is an elementary requirement to ensure that the requirements of this regulation are met.
Since the first edition in 2005, the team of authors has continuously developed this document, building on experience and improvements as they have become available and proven. This revised Guideline also implements the requirements of the current version of EN ISO 15883, "Washer Disinfectors", and by this the organizations involved provide an updated implementation. Differences from the 4th edition are provided by the following points:

- The numbering of the Annexes, Information sections, and Checklists is changed due to the removal of some documents
- The Information sections are expanded
- Annex 9, "Measures to Guarantee Cleaning and Disinfection Performance between Initial Startup, Acceptance and Validation" has been removed
- Organizational Requirements for the User have been removed from the text of the Guideline
- Checklist 1, "Constructional and Technical Requirements for the User", has been removed
- Checklist 2, "Organizational Requirements for the User", has been updated
- New Checklist 1, "Organizational Requirements for the User – Information for the Validation Personnel"
- A new Information 2 "Requirements of the user for automated cleaning and disinfection processes" replaces the contents of the old removed Checklists 1 and 2
- Annex 3, "Description of the Methods for Cleaning Efficacy Testing", has been expanded.
- A new Information section 6, "Test Matrix for the Performance Qualification of multiple, identical Washer Disinfectors with the same process chemical supply and utilities", has been added.

The authors will continue to further develop and revise this document to provide support to those involved in the processing of medical devices, to provide support relative to future requirements as they develop.

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Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices

1. Principals of the Guideline

Quality assurance in the processing of medical devices (MP) is not only a legal obligation but also of economic importance. The prevention of nosocomial infections represents an interdisciplinary challenge for all participants. The proper preparation of medical devices is an important building block. The process must allow for a correct and traceable processing in all processing steps by means of documented process reliability. The operator of the facility is fully responsible and must, among other responsibilities, ensure that the personnel responsible for the processing have the necessary knowledge and qualifications for the proper preparation.

This guideline is intended for all institutions in which thermostable medical devices are processed for use on humans. The following principles apply to medical device reprocessing:

- The User has the responsibility to institute and follow a quality management system.
- The User has the responsibility to ensure that the personnel carrying out the instrument processing have the required expertise (for example, Technical Qualification Course 1 of the DGSV).
- The User has the responsibility to carry out validation and requalifications.
- The User is responsible for carrying out periodic routine monitoring, which is defined and documented in the course of validation and in the case of new performance qualification.
- Efficient cleaning is a prerequisite for efficient disinfection, and, if required, also for subsequent sterilization.
- Automated cleaning and disinfection are preferred over manual processes.
- Medical devices should be purchased that can undergo automated cleaning and thermal disinfection.
- Thermal disinfection of thermostable medical devices is preferred over chemical disinfection.

The objectives of the guidelines are:

- Provision of information and documentation for the creation of user-specific standard operating procedures for automated cleaning and thermal disinfection of medical devices based upon the design of the medical devices.
- The provision of methods and acceptance criteria to verify user-specific standard operating procedures regarding the results of automated cleaning and thermal disinfection, as well as the determination of chemical residues after automated cleaning and thermal disinfection.

2. Legal and Normative Background

The User's obligation for application of quality-assurance principles to the reprocessing of medical devices for use in medical facilities arises both directly and indirectly from a series of laws, regulations, recommendations and standards.

2.1 Laws and Regulations

In healthcare, all service providers are obliged to execute quality assurance measures with the aim of improving the quality of results. To this end, they must introduce and continuously develop an in-house quality management system (German Social Law, Book V, §§ 135 – 137).

The German "Infection Protection Act" (Infektionsschutzgesetz – IfSG) requires the development of infection control plans. These plans must include the processing and any necessary controls and tests.

The requirements for the functional and hygienic safety of medical devices are regulated in the German "Medical Devices Act" (MPG), which is the implementation of Council Directive 93/42/EEC of 14 June 1993 for medical devices in German law.

The new European Medical Device Regulation MDR EU2017745 revises the previously-cited European guidelines. The Medical Product Regulation will come into effect no later than early 2020.

The German "Medical Devices Operator Regulations", (MPBetreibV), § 8 paragraph 1 requires, among other things, that processing must be carried out using validated procedures. In der

The German "Drinking Water Ordinance" (TrinkwV) sets out both the microbiological and chemical requirements for drinking water.

The "Ordinance on Safety and Health Protection of Activities with Biological Materials" (German BiostoffV) applies to activities involving biological agents (infectious agents) and must be taken into account when processing medical devices. It calls for the execution of a risk assessment and the definition of protective measures at a specified level of protection.

The BiostoffV is supplemented by the "Principles of Prevention" (DGUV Regulation 1) and TRBA 250 "Biological Agents in Health Care and Welfare Care". These regulations include special precautionary measures and behaviors to be implemented to ensure the health of healthcare personnel, which can be endangered by infectious agents. According to TRBA 250, "automat-

ed cleaning and disinfection" is preferred for the protection of the personnel.

2.2 Recommendations of the KRINKO

- According to § 23 paragraph 3 IfSG, compliance with the state of medical science in this area is presumed, if the published recommendations of the KRINKO have been observed.
- Furthermore, according to § 8, paragraph 2 of the German MPBetreibV, proper processing is assumed if the recommendation of the Commission for Hospital Hygienel and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) "Requirements for infection control in the processing of medical devices" is observed.
- The KRINKO/BfArM recommendation describes the requirements for processing practices. In Annex 1, "appropriate validated procedures" are described: "When processing a medical device, the sum of all the automated and manual processes involved (supplementary individual steps of the preparation) contributes to the achievement of the specific processing goal. To this extent, inadequately-validated individual steps (processes) also have a negative impact on the results of the processing, as does the failure not to observe standard operating procedures."

Relative to personnel and environmental hygiene, the following recommendations of KRINKO must also be observed:

- hand washing and disinfection in the healthcare facilities,
- infection control requirements for cleaning and disinfecting surfaces.

2.3 Standards

Standards are anticipated expertises on the state of the art. Important standards for this guideline are:

- DIN EN ISO 14971 (describes risk management practices and procedures in the handling of medical devices)
- DIN EN ISO 15883 (specifies and defines the performance requirements for Washer-disinfectors as well as the validation of these processes)
- DIN EN ISO 17664:2008 ("specifies information to be provided by the manufacturer for the reprocessing of medical devices if they are to be designated as resterilizable or sterilized by the user.") The required information must contain information on a safe, validated processing procedure under consideration of the necessary performance of the medical device. "A validated procedure for manual cleaning must be indicated. In addition, at least one validated automated procedure using the washer-disinfector must be indicated, unless the medical device is unsuitable for such a procedure. In this case, a warning should be issued." Information on the manufacturer's information can be found in **Information 1 "Contents of EN ISO 17664-2004"**.

3. Scope

The guideline for validation, new performance qualifications, and routine monitoring of thermal disinfection processes in washer-disinfectors is aimed at all facilities where medical devices are prepared for use on humans including piercing and tattoo studios as well as facilities for podiatry.

This guideline was developed based upon EN ISO 15883 (parts 1 and 2) and ISO/TS 15883 (part 5) as well as based upon extensive round-robin studies, from practical experience (Roth and Michels (2005), Michels et al (2013) and with additional attention to cost effectiveness and practice relevance.

Compliance with EN ISO 15883 (Part 1 and 2) provides compliance with the essential requirements of the MDR. A technical specification (ISO/TS 15883, Part 5) has been published as a reference for the requirements for cleaning and the use of test soils. Concrete – quantitative – statements on acceptable and limit values of, for example, residual protein, are not given in part 5. These will be added with the revision of part 5 and its publication as a EN ISO standard.

The recommendations of this Guideline do not refer to medical devices that should be cleaned and disinfected as per the other parts of EN ISO 15883 listed below:

- **Washer-disinfectors – Part 3:** Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (EN ISO 15883-3:2006,
- **Washer-disinfectors – Part 4:** Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (EN ISO 15883-4:2008.
- **Washer-disinfectors – Part 6:** Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical products and healthcare equipment (EN ISO 15883-6: 2016).
- **Washer-Disinfectors – Part 7:** Requirements and test for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (EN ISO 15883-7: 2016).

The following areas are not covered by this guideline:

- Processing of medical devices that are labeled as single-use by the manufacturer.
- Processing of medical devices that require special treatment due to CJD/vCJD.

These guidelines are concerned exclusively with automated washing-disinfection procedures for processing of medical devices. Prerequisites for processing as well as other portions of processing or procedures requiring special validation of their respective processes are not described in these guidelines. These include, for example:

- Constructional considerations and equipment
- Organizational considerations
- Implementation of the requirements for occupational health and safety Instruction, training, advanced training
- Packaging, transport, and storage of medical devices

If manual pre- and post-cleaning steps are necessary in connection with the automated washing and disinfection processes, the German "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices" compiled by DGKH, DGSV and AKI must be followed as well.

4. Structure and Requirements of the Standard EN Iso 15883 "Washer-Disinfectors"

4.1 General Requirements

The EN ISO 15883 series of standards defines general performance requirements for washer-disinfectors and their accessories intended for the cleaning and disinfecting of medical devices in medical, dental, and pharmaceutical practices. It consists of various parts, each providing specific requirements for the design and operation of washer-disinfectors for different types of medical devices.

- Part 1: "General requirements, terms and definitions and tests"
- Part 2: "Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, utensils, glassware, etc."
- Part 3: "Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers"
- Part 4: "Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes"
- Part 5: Technical Specification; "Test soils and methods for demonstrating cleaning efficacy of washer-disinfectors".
- Part 6: "Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment".
- Part 7: "Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment".

As already stated in the Scope chapter, the standards EN ISO 15883-1 and 15883-2 and the Technical Specification ISO/TS 15883-5 are applicable to this Guideline.

4.2 Definitions

Acceptance Test
The Acceptance test includes the installation qualification and parts of the operation qualification. It is the prerequisite for the transfer of the washer-disinfector to the user.

Work Instruction (Standard Operating Procedure)
The Work Instruction contains the detailed standardized description of the execution of an activity or a work step.

Operator
Institution responsible for carrying out the actions necessary to process a new or used medical device for its intended use (EN ISO 17664)

Processing
The preparation for use of medical devices which are intended to be disinfected or sterile. Processing includes cleaning, disinfection, and sterilization (if required), and includes specified work steps, as well as the testing and recertification of their technical and functional safety (MPG § 3, para. 14). Processing may only take place after formal commissioning of the medical device.

A_0 Value
Quantitative measure for thermal disinfection as a time equivalent in seconds at a temperature of 80 °C for microorganisms for which z is 10.

Remark: "Z" is the temperature change in Kelvin, which is required to change the D value by a factor of 10. The D value (decimal reduction value) is the time in minutes at a particular temperature required to kill 90% of a population of a microorganism. "A" is the time equivalent in seconds at 80 °C at which a given disinfecting effect is achieved.

Load
A collective term for describing all goods, equipment and materials that are put into a washer-disinfector at any one time for the purpose of cleaning and disinfecting it by an operating cycle.

Operational Qualification (OQ)
Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures (ISO/TS 11139: 2001, definition 2.24)

Batch
Medical products on a load carrier, which are simultaneously subjected to a washing/disinfecting process in the washer-disinfector

Disinfection
Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use (EN ISO 15883 Part 1, Definition 3.16)

Requalification/Reassessment
Complete or partial repetition of the validation testing (OQ, PQ) to confirm the reliability of the process (EN ISO 15883 Part 1)

Limit Value
Value which, if exceeded, shall result in the immediate stoppage of the process, and the washer-disinfector cannot be used further for this process.

Gross Contamination
Visible soil on medical devices that can be removed from the device immediately after use by means of simple measures. This includes, among others, tissue, bone, and filling materials in dental procedures

Manufacturer/Distributor
Organization or person responsible for the construction, manufacture, packaging, and labeling of a device before it is brought to market, regardless of whether this person or a contracted third party has done this work (EN ISO 17664)

Hollow Bodied/Lumened Medical Devices
Medical devices that contain design or construction features with interior surfaces that cannot be completely viewed from the outside of the deviced

Installation Qualification (IQ)
Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification (ISO/TS 11139:2006, Definition 2.22)

Disinfected
Cleaned and disinfected medical device

Duration of contamination
Time from the beginning of the use of the medical device to the beginning of the processing in the CSSD.

Performance Qualification of Automated Cleaning and Thermal Disinfection (PQ)
Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification (ISO/TS 11139:2001, Definition 2.26)

Note: this qualification testing shall demonstrate that the washing and disinfection processes reliably produce products that have been cleaned, disinfected, undergone final rinse and, as required, dried per the requisite standard.

Product Groups/Medical Device Groups
Medical devices that can be considered equivalent based upon similar design and the requirements of cleaning and disinfection

Process
Set of interrelationships or activities which converts inputs into results (ISO 9000)

Process Chemicals
Chemical products that are specified for use in a washer-disinfector

Test Instruments
Uncontaminated, defined instruments or objects, e.g., Crile Clamps

Test Object
A test instrument or test object that has a test soil applied to it

Qualification
A qualification is the assessment or determination of the suitability of a device and any ancillary equipment for use. This ensures that a performance qualification of the device is possible.

Reference Load
One or more specified loads for a washer-disinfector chosen to provide a worst-case challenge for cleaning and disinfection of medical devices (per EN ISO 17665 part 1)

Cleaner
Substance or mixture of chemical substances for supporting the cleaning of medical devices

Cleaning
Removal of contamination from an item to the extent necessary for further processing or for intended use (EN ISO 17664)

Washer-Disinfector (WD)
Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice (EN ISO 15883 Part 1)

Benchmark
Value that must not be exceeded in order to complete a Performance Qualification

Risk Analysis/Assessment
A process of investigating the possibility of failures, the probability of the occurance of the failure, and the probability of discovery of the failure. Remediation measures are taken based upon the results of the risk assessment

Routine Monitoring
Periodic checking and testing carried out to establish that the operational performance of the washer-disinfector remains within the limits established during validation (EN ISO 15883)

Standardization
All measures taken for unification, simplification, ranking, and limitation or restriction of procedures to create technically-optimal solutions.

Type Test
A type test is the responsibility of the manufacturer. It is a risk analysis for delimiting or assessing the risks and for verifying compliance of a washer-disinfector with EN ISO 15883. This is the basis for the generation of reference data for follow-up tests

Validation of automated cleaning and thermal disinfection processes
A documented procedure for obtaining, recording, and interpreting the results required to demonstrate that a process constantly delivers product that complying with predetermined specifications. For washer-disinfectors, the validation consists of installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) carried out on machines for which documented proof exists for compliance with the requirements of the standard from the device's manufacturer

Warning Range
Range between the benchmark level and the limit value in which measures to optimize the washing-disinfection process must be carried out to return the process to a state in which the benchmark level is no longer exceeded

Note: If the measured values lie in the warning range, the washer-disinfector can still be used. However, the validation cannot be completed until the process values do not exceed the benchmark level.

4.3. List of Abbreviations

Abbreviation	Explanation
AA	Standard Operating Procedure
°C	Degrees Celsius
AKI	Working Group Instrument Processing
AEMP (CSSD)	Processing Unit for Medical Devices
BCA	Bicinchoninic acid
BfArM	German State Institute for Drugs and Medical Devices
BiostoffV	German Biomaterials Regulation
BQ	Operational Qualification
BSA	bovine serum albumin
CJK	Creutzfeldt-Jakob Disease
cm	Centimeter
cm^2	Square centimeter
DGKH	German Society for Hospital Hygiene e.V.
DGSV	Germany Society for Sterile Supply e.V.
DGUV	German statutory accident insurance (rules and regulations formerly BGV and BGR)
DIN	German Institute for Standardization e.V.
EN	European Norm
IfSG	German "Infection Protection Act"
IQ	Installation Qualification
ISO	International Organization for Standardization
K	Kelvin
KRINKO	German "Commission for Hospital Infection Control and Prevention" of the Robert Koch Institute
KW	Cold water
LQ (PQ)	Performance Qualification
MIC	Minimally-invasive Surgery
Min	Minutes
MP	Medical Device
MPBetreibV	German "Medical Devices Operator Regulations"
MPG	German "Medical Device Law"
OP	Operation Room
OPA	*ortho*-Phthaldialdehyded
PP	Polypropylene
PSA	Personal Protective Equipment
QM	Quality Management
RKI	Robert Koch-Institut
SDS	Sodium-Dodecyl-Sulfate
SGB	German "Social Code"
TRBA	German "Technical Rules for Biological Agents"
TrinkwV	German "Drinking Water Regulation"
vCJK	Creutzfeldt-Jakob Disease variant

VE	Deionized or demineralized Water
z B.	For example
ZSVA	Central Sterile Processing Department (CSSD)
µg	Microgram
µS	Microsiemens
WD	Washer-disinfector

5. Validation

According to the KRINKO/BfArM Recommendation 2012 (1.3 Validation of the Processing Procedures/Processes), "automatic cleaning and disinfecting processes that are used ... must always be carried out according to documented standard operating procedures and with processes which have been tested for efficacy as well as means attuned to the medical device (i.e., appropriateness for use and material-compatibility)."

The validation is used to verify the performance and to demonstrate the reproducibility of the standardized automated cleaning and disinfecting processes. A validation consists of installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).

Before the washer-disinfector is used for the first time for the preparation of medical devices for use on the patient, the validation must be successfully completed, documented, and evaluated and released by a (responsible) person designated by the user. The examination of the cleaning performance on real instruments, which is necessary as a component of the performance assessment, can be carried out within 4 weeks after the first performance assessment if not possible at an earlier date.

5.1 Prerequisites for the Validation

In order to be able to carry out the validation of a cleaning and disinfecting process, the operator, the manufacturer of the washer-disinfectors, and the manufacturer of the process chemicals must fulfill prerequisites. The overall assessment of the validation of the cleaning and disinfecting process can only be carried out if all prerequisites are fulfilled.

Checklist 1, "Organizational Prerequisites for the Operator – Information for the Validation Personnel", provides an overview.

A prerequisite for the validation is the creation of a validation plan, which must at a minimum contain the following items:

- Responsibilities
- Qualification Steps (IQ, OQ, and PQ)
- Approval of the validation by qualified personnel on operator's side
- Measures to be taken if the validation is not successful
- Establishment and execution of documented routine monitoring by qualified personnel spelled out in the validation report

Annex 1, "Structure and Contents of the Documentation (Validation Folder)", can be used for support during planning and execution of the validation. It can be used as a cover sheet for the validation report.

As an organizational prerequisite for the validation of a cleaning and disinfecting process, quality assurance measures must be in place, with a quality management system required. Information is provided in **Information 2 "Prerequisites for the user for mechanical cleaning and disinfection processes"**. If the assigned checklist is edited by the operator before a validation or before a renewed PQ, he has an overview of the fulfillment or non-fulfillment of required conditions. It is not the task of the validator to check these conditions and measures.

5.1.1 Information Provided by the Washer-Disinfector Manufacturer for the User

As a prerequisite for the validation of a cleaning and disinfecting process, inputs and information from the manufacturer of the washer-disinfector are required and are to be made available to the operator.

Checklist 2, "Information Provided by the Washer-Disinfector Manufacturer for the User", provides an overview.

5.1.2 Information Provided by the User to the Washer-Disinfector Manufacturer/Distributor

The user must provide the following information:

- Special requirements for the washer-disinfector processes based upon official requirements or specialized usage of the products to be processed
- Site-specific conditions
- Requirements in the medical device manufacturer's IFU (EN ISO 17664)
- Qualities of the Process Utilities
  - Water: Information about water qualities can be found in **Information 3 "Chemical Water Quality"**.
  - Process Chemicals: Information concerning process chemicals can be found in Information **4, "Process Chemicals"**.

5.2 Validation Tests

Validation tests shall be carried out in conformity with the requirements for medical devices and per the harmonized standard applicable here, EN ISO 15883. The type test is the prerequisite for the conformity assessment and CE marking of the devices according to the MDR. With type-tested washer-disinfectors, validation is possible without additional device-related risk analysis (exception, for example, washing pressure).

The validation consists of installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). It is the responsibility of the operator to carry out the validation. It can only be carried out at the user site.

Validations may only be carried out by persons who have appropriate expertise. This expertise includes professional training and practical experience, as well as knowledge of the relevant laws, standards and directives. These persons must have the necessary test and measurement equipment and have mastered the validation methods. The qualifications are given in **Annex 2, "Qualifications of the validation personnel"**.

Validations must be carried out using quality-assured methods and in collaboration with the competent personnel of the user. Optimization of the process in advance of or during the validation may be needed to ensure ongoing compliance with the required acceptance criteria. If optimization takes place during the validation, the affected parts of the validation must be completely repeated.

If a process must be validated for a washer-disinfector that is already in use, for which no type test per EN ISO 15883 exists, additional testing must be carried out. This differs for each machine (see **Information 5, "Qualification of Existing, In-Use WDs".**)

5.2.1 Installation Qualification (IQ)

Installation qualification is carried out to ensure that the installation site and all necessary devices, process materials, accessories, as well as the surrounding area are appropriate for automated washing and disinfection, and are correctly installed.
The tests and evaluations required for installation qualification must be agreed in advance of the testing, carried out, and the results documented.
Tests and evaluations to be carried out include, but are not limited to the items in the following list.

- Review of the Accuracy of Ordering and Delivery (for existing installations, documentation of the inventory):
  - Washer-disinfector (manufactured to order specifications)
  - Base/drip tray
  - Drying unit
  - Steam condenser/Ventilation system
  - Load/Unload cart
  - Load carrier, inserts, as well as jets and adapters
  - Installation plan, instructions for use, and other documents
- Review of the connections and utilities, comparison to installation plan:
  - Electrical power
  - Water (cold, warm, DI)
  - Central/decentral chemical dosing system
  - Steam
  - Sanirary drain
  - Exhaust

Checklist 3, "Installation Qualification", provides an example.

5.2.2 Operational Qualification (OQ)

Operational qualification is carried out to ensure that the washer-disinfector connected to the utilities at the use location and operates in accord with the specifications of the manufacturer and the requirements of EN ISO15883. The operational qualification is done to check that all devices, utilities, and accessories function properly and that the qualification is carried out within the context of the user's quality system.
The tests and evaluations required for operational qualification must be agreed in advance of the testing, carried out, and the results documented.
An acceptance test (see **Checklist 4 "Acceptance Testing and Parts of the Operational Qualification"**) includes the installation qualification and portions of the operational qualification. Tests that are executed as part of the acceptance testing are not required to be repeated for the operational qualification, as long as the acceptance testing was not done more than four weeks prior to the operational qualification.
Tests, examinations, and actions to be carried out are described in **Checklist 5 "Operational Qualification: Tests, Observations, Actions".**

5.2.3 Performance Qualification (PQ)

The prerequisite for performance qualification is the definition and documentation of the necessary programs with appropriate procedures. The procedure must include the preconditions for cleaning. The procedure description shall be documented in detail, including details of the chemicals to be used.
In the performance qualification, the defined cleaning and disinfecting programs for operating loads (reference loads) are tested and the results documented, ensuring that reproducible results can be achieved at all times. That is, the process must always meet its specifications. Each reference load shall include instruments with typical in-use contamination, processed after normal pre-treatment steps. The reference load is to be documented. Reference loads are always user-specific. **Checklist 6, "Performance Qualification: Assistance in Selection of Real Instruments"**, is provided to assist in defining the reference loads.

5.2.3.1 Cleaning Tests

To verify that cleaning performance is basically given and reproducible, test objects are used. Real, in-use contaminated instruments from the user and assignet to different product groups are to be represented in this testing. **Annex 3, "Description of the Methods for Cleaning Efficacy Testing"**, provides an overview of this process.

5.2.3.1.1 Test Objects (Crile Clamps) real and in-use soiled instruments

The following test objects and real, in-use soiled instruments must be considered for use in cleaning testing:

– **Test Objects**
In order to establish a defined cleaning performance in the performance qualification on site, contaminated reference test objects (Crile clamps contaminated with test soiling according to the standard operating procedures in a qualified laboratory) are added to the reference load to be tested.
Not all listed test soils and methods referred to in the standard EN ISO 15883 for the cleaning test for surgical instruments are appropriate for this testing as concerns quantifiability, standardizability and practical relevance. From the point of view of the authors of this guideline, it is absolutely necessary to use test soils that are comparable to a representative, in-use contamination. A consensus has been reached here regarding the use of heparinized sheep's blood, which becomes coagulable by the addition of protamine sulfate.

– **Real, in-use soiled instruments**
Real, in-use soiled instruments/medical devices are used to provide a reference for practice-specific loading and for cleaning assessment of differently designed instruments/medical products (product groups). Their use also takes into account of the conditions which influence the cleaning during use in the operating room, the transport, the preparation for processing, the possible preliminary cleaning and the specifics of loading into the washer-disinfector (see **Annex 4 "Cleaning tests for performance qualification (PQ)"**). The purpose of this test is to establish the technically-achievable cleaning limit creating an endpoint measurement. At the present time, a technically feasible value of a maximum of 3 µg of residual protein per cm^2 is used (see literature: Michels et al., 2013). The acceptance criteria are presented in **Annex 5 "Acceptance Criteria for the Assessment of Cleaning Performance"**).

5.2.3.1.2 Specification of the Test Loads and Procedure

Depending on the type of instruments used, the instruments to be tested are jointly agreed by the validator and the operator. It is necessary that the most-difficult instruments as well as those with the longest dwell time are checked for cleaning efficacy. The selection must be justified and documented by the user.
Every program used must be tested at least once. In order to ensure reliable verification of cleaning performance, a total of at

least three process loads with the same or different reference loads must be examined. For further information, see **Annex 4, " Cleaning tests for performance qualification (PQ)"**, and **Information 6, "Test Matrix for the Performance Qualification of multiple, identical Washer-Disinfectors with the same process chemical supply and utilities "**.
Real, used instruments are placed on the load carriers according to the agreed-upon, defined pattern.
Each medical device is individually inspected. Instruments or their parts, which are visually contaminated, are documented (if possible, digital photo) and marked. In each process sequence (batch), one contaminated test object is added per level, with a minimum of five per cycle. In practice, this means at least five Crile clamps per cycle, distributed at all levels of the load carrier. Based upon the results of the type test, the location where the lowest cleaning performance is to be expected shall be tested (refer to Type Test data from the manufacturer). The distribution of the test objects depends on the WD and load being run. This is to be documented at the test site, preferably with a digital photo. The test objects are to be opened to approximately 90°, and placed within the normal instrument loading.
The wash program must be interrupted before the beginning of the thermal disinfection phase (water inflow). At this point, the marked, real, in-use soiled instruments and the test objects are removed for analysis and evaluation. The load is not to be released for use.

WARNING: If the real instruments and test objects can only be removed at the end of the process, it must be ensured that the recoverability of protein is not adversely affected by the disinfection step.
For guidance in carrying out the testing with test objects, refer to **Annex 6, "Cleaning Testing"** and **Checklist 7, "Tests of Cleaning Performance"**.

5.2.3.1.3 Evaluation

– Test Objects
The evaluation of the test objects' cleaning results is initially done visually and documented. Only visibly-clean test objects are subsequently tested for protein residues using a quantitative or semi-quantitative method of protein analysis (see **Annex 4, "Cleaning tests for performance qualification (PQ)"**, **Annex 5, "Acceptance Criteria for the Assessment of Cleaning Performance"**, and **Annex 6, "Cleaning Testing"**.
However, if residuals of an unknown source have been identified during the visual check, a distinction must be made between residual test soil and corrosion. Corrosion is not an assessment criterion. In practice, the Biuret/BCA method can be carried out on site.

– Real In-Use Soiled Instruments
In the assessment, the area of the sampled surfaces shall be taken into consideration (see **Annex 5, "Acceptance Criteria for the Assessment of Cleaning Performance"**). Only visibly-clean instruments are tested for protein residues using a quantitative or semi-quantitative analytical protein detection method (see **Annex 6, "Cleaning Testing"**). If, however, residues of unknown source have been identified during the visual check, a distinction is made between residual soil and corrosion. Corrosion is not an assessment criterion. In practice, the Biuret/BCA method can be carried out on site.
There are currently no clinical data or studies that clearly establish acceptance criteria, or suggest the need to reduce soiling to a certain minimum from which acceptance criteria can be derived. In order to determine acceptance criteria, one must therefore rely on the state of the art and examine what can be achieved reproducibly with today's methods. The principle applies: to meet the optimization requirements, the less residue the better resulting a greater degree of safety. The current state of the art derives from the results of the performance tests on real instruments as well as test objects documented in validation reports.
The basis of the assessment is described in **Annex 5, "Acceptance Criteria for the Assessment of Cleaning Performance"**.

5.2.3.2 Washing Pressure Test
The washing pressure can be generated by one or more circulating pumps.
The washing pressure of the complete process must be measured and documented. This can be done at a test point on the load carrier provided by the washer-disinfector manufacturer, or at other locations, if possible and applicable.
Preferably, the pressure-measurement connection is made to a nozzle connection for device for hollow/lumened instruments or, if not present, to an adapter on the water supply of the load carrier. If filter systems are installed in the load carrier, the connection must be made after the filters. The manufacturer's instructions regarding the pressure level must be observed. The pressure must be within the range specified by the washer-disinfector manufacturer, which has been determined during the type test for the particular load carrier. In the course of the validation, it must be demonstrated that the pressure profile can be reproduced.
Since a reproducible washing pressure is an important criterion for achieving the cleaning result, deviations from the calculated mean value of the respective test load should not be greater than ±20%. The pressure is measured after the water has been introduced until the final purge of the detergent solution. For deviations of more than 20%, a separate documented assessment is necessary.

Note: The observation of the washing pressure is not done for the precleaning phase.

If the washer-disinfector is not equipped with a spray arm monitoring, the spray arms must be checked for free rotation after loading and before unloading of the washer/disinfector. This is done in order to ensure that no objects have impaired the cleaning performance during the wash program by blocking the rinse arms rotation.

5.2.3.3 Test of Temperatures
For the verification of the thermal disinfection performance, external temperature measuring systems must be used that are independent of the washer-disinfector's sensors that have accuracy and resolution as specified in EN ISO 15883-Part 1. The sensors are positioned between the instruments and in the vicinity of the measured points of the washer-disinfector as specified from the type test. In addition, measuring points must be selected on the load carriers and the chamber walls. The positions that are slowest to achieve the process temperature can be determined from the type test or other previous tests as necessary. If the measured values of these temperature sensors do not match the actual values of the WD display, the cause of the differences must be searched for, eliminated, and documented.
The minimum testing requirement is two cycles with six sensors, or three cycles with four sensors.

The suggested measurement positions of the sensors are shown in **Checklist 8, "Positioning of the Temperature Sensors".**
The target temperature values to be achieved for the cleaning stage have a tolerance of 0 to +/- 5 K (cleaning temperature band) relative to the cleaning temperature setpoint.
The target temperature values result from the A_0-value requirements in connection with the disinfection setpoint temperature with a tolerance of 0 to +5 K (disinfection temperature band). If the A_0 value is calculated by integration, the sensor tolerance and the allowable temperature deviation of 2 K must be deducted.
The A_0 concept is described in **Information 7, "The A_0 Concept of EN ISO 15883"**.
The temperature profile during the holding times of the temperature-controlled process stages must be in agreement within ±2.5 K for two measured cycles.

Note: Testing of the disinfection performance with biological indicators is not required, since the disinfection is assured by the effect of the water temperature over a defined time.

5.2.3.4 Drying Test

Drying must be tested for all reference loads. This can be done for simple loads by visual inspection.
If the drying is to be subjected to more accurate testing in narrow instrument features or cavities/lumens, use absorbent paper which contains anhydrous copper (II) sulfate to test this. When in contact with water, the white paper turns blue.
Sections of this indicator paper can be to test dryness as follows. For narrow instrument features pull the strip through the portion of the instrument to be tested. For cavities/lumens, hold the distal end of the hollow instrument at a distance of 50 to 100 mm from the paper and blow through it with compressed air pulses at a moderate pressure from the other end. Blue spots indicate residual water.

Assessment:
Any residual or leaking residual liquid is unacceptable. Residual moisture at contact points is acceptable.

Actions to be taken for unacceptable Residual Water
A technical improvement is to be striven for. If this is not possible, the washed load must be dried for a longer period.
The performance qualification cannot be completed if an unacceptable drying result is obtained.
In the case of an improvement of the drying result, a repeat of the drying test must be carried out.

5.2.3.5 Test for Process Chemical Residues

With proper processing in the washer-disinfector, only toxicologically-safe residual amounts of the process chemicals may remain on the medical devices after completion of the thermal disinfection. Acceptance limits are defined by the manufacturer of process chemicals.
The performance qualification must demonstrate that no process chemical residuals remain above these limits.
The methods or evidence required to determine the residual amounts of the process chemicals depend on the process chemicals used and must be made available by the manufacturer of the process chemicals. See **Information 2, "Process chemicals"**.

5.3 Documentation and Assessment

All data relevant to safety and efficacy of the installation, operation, maintenance, and test of the process must be documented and assessed. It is recommended to use checklists for documentation.
The minimum content of documentation is summarized in **Annex 1, "Structure and Content of the Documentation (Validation Folder)"**.

5.4 Requalification/Reassessment

A repeated performance qualification must be run if:

A) On a periodic basis as defined with validation
EN ISO 15883 recommends the execution of a repeat PQ without specific cause on a yearly basis. If a different interval is chosen, this must be justified.
➔ For the procedure, see **Annex 7, "Requalification (repeat performance qualification) without special reason"**.

B) When routine monitoring of the performance of the washer-disinfector reveal deviations from the validation results.
➔ After remedying the reasons for the deviations, the scope of the new performance qualification/assessment shall be determined by means of a risk analysis in accordance with **Information 8, "Risk Analysis for Existing Washer-Disinfector Installations"**.

C) Introduction of a new medical device with different cleaning and disinfection requirements or a new load carrier, if no equivalence to a tested reference load or validated medical device or loading system can be demonstrated.
➔ The scope of the new performance qualification/assessment shall be determined by means of a risk analysis in accordance with **Information 8, "Risk Analysis for Existing Washer-Disinfector Installations"**.

D) Change in process chemistry.
➔ For determination of the procedure, see **Annex 8, "Event-Driven Requalification (Repeat Performance Qualification) (Process Chemical Change)"**.

E) Following maintenance work that could affect the performance of the washer-disinfector.
The scope of execution of a reassessment must be justified. The assessment of the results, including the justification for the decisions taken, and the extent of the changes to the cleaning and disinfection process or the requirements for the reassessment (if applicable) shall be documented (see **Information 9, "Definitions for Maintenance, Calibration and Adjustment"**).

➔ For the procedure, see **Annex 9, "Event-Driven Requalification (Repeat Performance Qualification) (After Maintenance)"**.
Checklist 11, "Preparation for a requalification (OQ/PQ)", provides guidance for preparation for a repeat OQ/PQ.

5.5 Approval of the Validation Documentation by the User

The user confirms that the execution of the validation has been done per the requirements and order, and has been correctly documented.

Scope and Form of the Approval
The approval covers all type of validation including repeat performance qualification/assessment.
The validation documents must be approved by the user after successful results for all tests. The approval must be carried out according to a method governed by the user's quality management system. The responsibility for the release has to be assumed by a user staff member. The responsibility can be delegated by the user (MPBetreibV § 4).

The validation can only be approved when all prerequisite requirements of the validation are met (see 5.1) and the tested reference load is typical of normal usage of the washer-disinfector.
For tests that have not been evaluated by the validator, the user must confirm in writing that these aspects of testing have been comprehensively fulfilled.

Consequences of the approval of the validation for the user:

- If the tests are documented as "passed": Processing shall be carried out until the next date of the repeat performance qualification/assessment using the conditions tested during the validation.
- If the tests are documented as "failed":
  - Processing with the noncompliant processes must be discontinued.
  - The cause of the noncompliance must be identified and remedied.
  - The processes must be revalidated

6. Routine Monitoring of Washing-Disinfection Processes

Routine monitoring of washing and disinfecting processes is particularly important for ongoing verification of the required quality standards for automated cleaning and disinfection of medical devices being met. The goal is to achieve this through the parametric release, which would make many routine checks unnecessary. If this is not possible (for details, see **Information 5 "Qualification of Existing, In-Use WDs"**), endpoint tests must be carried out at a minimum to ensure the cleaning and disinfecting performance.
The verification of automated cleaning and disinfecting processes includes the parameters related to the washer-disinfector, the utilities supply as well as a visual inspection of the cleaning results on real instruments/medical devices. These results are recorded, documented and evaluated. The documentation is carried out within the framework of the quality management system.
Routine monitoring consists of a combination of daily tests and additional tests.
Special requirements for different medical devices or practice applications must be defined within the scope of quality management in work instructions (e.g., ophthalmology: checking the pH value). Refer to **Information 10, "Measurement of the pH values of the final rinse water for washer-disinfector processes."**
The following information and checklists are intended to be guides and tools.

6.1 Daily Operational Testing

Daily operational tests are to be understood as tests which are to be carried out before the day's use and are to be documented. The use instructions of the washer-disinfector manufacturer must be observed.
Checklist 9 "Daily in-use testing of the washer-disinfector", provides examples.

6.2 Daily Per-cycle Observations

For each batch, check for the free rotation of the spray arms and loading per SOP, such as the appropriate connection of lumened devices, before removing the instruments from the load carrier have to be conducted. Afterwards a visual check of the medical devices (MD) is to be carried out for cleanliness and dryness.
If it is visually determined that certain medical devices have not been cleaned, measures which have been defined in the quality system must be taken.
Per the KRINKO/BfArM recommendations, a cleaning indicator can be used for visual inspection verifying the suitability of the wash program used for the items to be processed: "Tests for Cleanliness (relative to the results for the cleaning indicator, and may be applied to critical B medical devices, for example)".
Since there are no standards for "cleaning indicators" at this time, they are not recommended for routine monitoring.

6.3 Routine Monitoring of the Technical Function

Routine monitoring must be determined by the user on the basis of the actual features of the washer-disinfector. This is set out within the scope of the validation, see **Information 5, "Qualification of Existing, In-Use Devices"**).
A successful cycle sequence of a washer-disinfector depends on temperature and time, water pressure, sufficient dosing of process chemicals and sufficient water level within the washer-disinfector. These parameters must be met with sufficient certainty. Depending on the specific configuration of the washer-disinfector or possibly external equipment (e.g., central dosing devices, independent documentation and monitoring modules), routine monitoring at different time intervals is necessary. Preferably, the parameters specified must be tested and documented independently of the controller and the sensors of the WD (e.g., temperature sensors, pressure transducers). If this is not possible, appropriate monitoring at specified time intervals must be carried out, e.g., protein analysis of test objects after cleaning and before disinfection. These monitoring mesures are determined using a risk analysis. (**Information 8, "Risk Analysis for Existing Washer-Disinfector Installations"**).
If automatic process documentation for each cycle is not available, as documented in the qualification of the WD, manual documentation must be recorded according to SOP's.
The test equipment and test methods must be used and/or carried out by trained personnel according to SOP's.

Note: To minimize the amount of routine monitoring, the WD may be outfitted prior to validation with an independent monitoring modules for pressure, temperature, and dosing that provides automated cycle monitoring.

Checklist 10, "Matrix for creation of a checklist for routine monitoring of the washer-disinfector's technical function", serves as support for the creation of a monitoring plan.

6.4 Periodical Routine Monitoring of Cleaning and Disinfection Performance

EN ISO 15883 part 1 recommends, for example, quarterly monitoring. This testing may be more or less frequent, depending upon the results of a risk analysis (see **Information 8, "Risk Analysis for Existing Washer-Disinfector Installations"**).
Periodic monitoring of the cleaning performance is to be carried out using semi-quantitative and/or qualitative protein determinations in the case of real contaminated medical devices, which appear visually clean but cannot be checked visually on all surfaces (see **Annex 5, "Acceptance Criteria for the Assessment of Cleaning Performance"**).
The instruments to be tested should be of a critical design group. The instruments, as well as their location within the washer-disinfector must be defined within the course of the validation. A checklist for periodic monitoring can be created. All tests must be documented, evaluated, and considered in the subsequent requalification.

When testing the cleaning by means of (semi-)quantitative protein determination, the instruments must be taken out of the washer before the start of thermal disinfection. The process can then be continued without these instruments. The tested instruments can be run in the next load after protein evaluation, or the process can be paused until they have undergone sampling, rinsing and then return to the load carrier, at which point the process may be resumed. The process documentation shall be accompanied by a corresponding test comment. A test with biological indicators is not required as a periodic test.

7. References

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Annex 1: Structure and Content of the Documentation (Validation Folder)

Overview	Initial Validation of a standards-conforming WD RDG	Requalification (Performance Qualification) without special reason	Documentation
COVER SHEET			Must be available as paper documentation
Details of:			
Type of Testing (Validation)	×	×	
User and Installation Location	×	×	
Machine manufacturer, model, serial number, year of manufacture	×	×	
Client	×	×	
Validation company and Validator or Validation Team	×	×	
Results of the validation and established routine tests	×	×	
Details of deviations and deficiencies regarding the WD, the process media, the operation, or the results	×	×	
Summary of the results and evaluation of the deviations	×	×	
Deviations from the current guidelines in execution of the validation			
TABLE OF CONTENTS	×	×	
INFORMATION			May also be available as an electronic document
Notes on standards and laws relative to the tests carried out	×	×	
Certificates for the qualifications of the validators or team carrying out the validation	×	×	
Information on the measuring instruments used including calibration protocols	×	×	
Process chemicals used	×		
Crossreference to manufacturers' instructions for MD processing (EN ISO 17664)	×	If changes	
PREPARATION FOR VALIDATION			
Preliminary validation talk to ensure compliance with the guidelines LL	×	×	
Crossreference for maintenance , calibration and adjustment		×	
Examination of the loading carrier (connections and pressure test)		×	
Examination and evaluation of the release documentation since the last PQ (batches)		×	
Definition of the reference loads	×	×	
SOP for manaul pre-cleaning (or cross reference if appropriate)	×	If changes	
Qualification of in-use WDs that do not meet the current EN ISO 15883 requirements (including description)			
Information on			
Functional examination of the WD and accessories			
Leak-tightness of the WD			
Functional test of the (central) dosing system			
Test plan with acceptance criteria			
WD provisions and accessories			
Utilities, drain and exhaust			

INSTALLATION QUALIFICATION			May also be available as an electronic document
Installation Qualifcation			
OPERATIONAL QUALIFICATION			
Acceptance testing and portions of the operational qualification			
Information on:			
Correctness of the utilities and process media connections	×		
Correctness of the drain and exhaust connections	×		
Functional testing of the WD and its accessories	×		
Leak-tightness of the WD	×		
Functional testing of the (central) dosing system	×		
Test plan with acceptance criteria	×		
PERFORMANCE QUALIFICATION			
see Checklists			
Process details of the programs to be tested	×		
Positioning of the test objects/real instruments	×	×	
Positioning of the temperature sensors (i.e. photo documentation)	×	×	
Description of the washing pressure test	×		
Test objects			
Visual examination/documentation	×	×	
Protein tests/documentation	×	×	
Real instruments			
Visual examination/documentation	×	×	
Protein tests/documentation	×	×	
Water Level Measurements	×		
Documentation of the test results on residual amounts of the process chemicals	×		
Process chemical	×		
Test plan with acceptance criteria	×	×	
Established routine tests	×	×	
Protein test: identification of the method/calibration must be available	×	×	

Annex 2: Qualifications of the validation personnel

1. Introduction

This Annex describes requirements for the qualification of persons and entities carrying out an IQ, OQ and / or PQ in the course of validation. It does not refer to the type tests to be performed by the manufacturer of the RDG according to EN ISO 15883.

2. Responsibility for the validation

The user has the responsibility to use only those processes that have been validated. The validation must be carried out on behalf of the operator by appropriately qualified specialists.

Validations consist of various phases where different qualifications are required. The individual phases are as described in this guideline:

- Installation qualification (IQ
- Operational Qualification (OQ)
- Performance Qualification (PQ) or requalification

3. Requirements for installation qualification

The examination of the completeness of the delivery of the WD with accessories does not require any special qualification. The participation of the user (e.g., facilities engineering) in this test and the confirmation in the documentation are necessary.

The correct installation of the WD according to installation plans/rough-in drawing and the execution of the connections to the utilities like electrical power, process media (steam, compressed air, water), and disposal (drain, exhaust) is to be done by qualified personnel in the respective areas of expertise.

4. Requirements for the operational qualification

Companies or institutions that are contracted to do this testing must be able to demonstrate a quality management system (eg according to ISO 9001 or ISO 13485) as well as technical training and qualification for the WD under test. Direct involvement of the user in the operational qualification is necessary, for example if central dosing systems are to be integrated for process chemicals and/or reverse osmosis plants. The following knowledge and experience must be provided in writing by the persons carrying out the work:

4.1 General knowledge of the relevant laws, standards, and guidelines, etc.

- Medical Device Law, German ‚Medical Devices Operator Regulations'
- KRINKO/BfArM recommendation "Infection Control Requirements for Processing of Medical Devices"
- EN ISO 15883
- Validation Guidelines of the DGKH, DGSV, AKI
- EN ISO 14971 (Risk Analysis)
- BioMaterials Regulations, Hazardous Substances Regulations

Evidence can be provided, for example, by means of special documented validation training courses and/or by proof of successful completion of requisite qualification FK II.

4.2 General knowledge and experience of reprocessing

Parameters that influence reprocessing, for example:

- Water quality
- Process chemicals
- Material and instrument expertise
- Loading of the load carrier
- Process designing/execution
- Operation of the WD
- Basic knowledge in the field of quality management in the processing of medical devices
- Basic knowledge of microbiology and infection control

Acceptable proof of this knowledge can be demonstrated by:

- Requisite qualification FK I and at least 3 years' work as a technical sterilization assistant (TSA) or
- As a medical or service technician employed in this field.

4.3 Technical knowledge of the WD and knowledge of measurement, operation, and control technology (MSR) of the WD

- Knowledge of the WD and knowledge of measurement, operation, and control technology of the WD
- Electrotechnical knowledge for simulations and error recognition in the electrical/electronic equipment
- Measurement technological knowledge and experience
- Proof of electrotechnical training including MSR and experience with the WD under test must be provided. There must be knowledge about the current version of the WD to be tested.

4.4 Knowledge and experience for the execution of process validation

- Process sequences for the reference loads to be tested

The proof can be provided by documented participation in at least 5 validations of reprocessing processes. (References must be provided).

5 Requirements for the initial and repeat performance qualifications

Companies or institutions which are contracted must demonstrate a quality management system (e.g., per ISO 9001 or ISO 13485). The general knowledge and experience for the performance qualification are the same as in the case of the operational qualification (see 4.1 and 4.2) and must be provided in writing by the persons carrying out the work.

- Knowledge of and experience with the measuring instruments used
- Knowledge and experience in the execution of process validation
- Documented capability of conducting sampling and use of testing systems (Biuret, etc.) as well as proof of appropriate training
- Process sequences for the reference loads to be tested

The proof can be provided by documented participation in at least 5 validations of reprocessing processes. (References must be provided).

Annex 3: Description of the Methods for Cleaning Efficacy Testing

1. Contamination of the test objects (Crile artery clamps + test soiling

The test soil used is heparinized sheep's blood, which has been made coagulable using protamine sulfate. The sheep's blood should not be older than one week and shall be stored in a refrigerator until use.

Contamination of the test object must be done in a laboratory that has appropriate quality assurance measures (see below for example). To prepare the test soil for contamination of the instruments, the sheep's blood (for example, Acila GMN®, Möhrfelden) is diluted with 10% twice-distilled water. The sheep's blood solution is made coagulable by addition of a specific amount of protamine sulfate. Each instrument is then inoculated with 100 µl of the solution in the hinge by means of a pipette.

The test objects are then opened and closed five times to achieve an even distribution of the contamination.

After contamination, a maximum of 20 test objects are laid open in a wire basket. It is critical to ensure that the wire basket does not sit upon an absorbent surface, and it is preferred that it sits above the surface. If this is not done, a portion of the test soil can be absorbed, and the test objects will have differing amounts of contamination on them. The wire basket with the test objects within it is placed in a drying cabinet at 45 °C for one hour.

After drying, each test object is closed and placed in an individual polypropylene bag. The polypropylene bag shall have all possible air removed, and shall be sealed closed. Studies have shown that this packaging method permits a shelf life of 14 days with only a small effect on the cleanability of the test object, enabling problem-free shipping of the test objects. A temperature of 20 – 25 °C may not be exceeded for more than one day during storage and transport.

2. Quality Assurance of the Test Objects

To assure the reproducibility of the results, the manufacturer of the test objects must carry out quality assurance measures.

An example of testing the test objects for cleanability and their preparation for reuse follows.

2.1 Cleaning Test

As part of the quality assurance process, the cleanability of the relative to the blood lot used must be studied.

Note: Quality assurance measures must be taken for every type of test object and the production of the test objects.

Crile clamps are the example provided in the following section:

10 Crile clamps shall be cleaned for each cleaning program using the following processes. Cleaning shall be done on the day after the contamination of the clamps, at the earliest. The position of the clamps in the WD must be defined. The cleaning program must be run in the same WD and same load carrier.

Program 1

- 3 min cold pre-rinse
- Drain
- 10 min cleaning with 0.5% alkaline detergent (pH 10±0.5), wash temperature 70 °C
- 1 min rinse

Fig. 1

- ***Program 2***
- 3 min cold pre-rinse
- Drain
- 5 min cleaning with 0.3% alkaline detergent (pH 10±0.5), wash temperature 55 °C
- 1 min rinse

The evaluation of the results with the Biuret/BCA or modified OPA method must show that the program 1 process resulted in no more than two clamps reached the warning level and the program 2 process resulted in no more than one clamp was over the limit value.

If one deviates from this example quality assurance test, the method shall be qualified and documented in the validation report.

2.2 2.2 Preparation and Care of the Test Objects

The test objects can be reused after a specified preparation in the laboratory.

The test objects may tend to rust, depending upon the material quality of the test object, the duration of blood contact, and the presence of residual SDS solution on

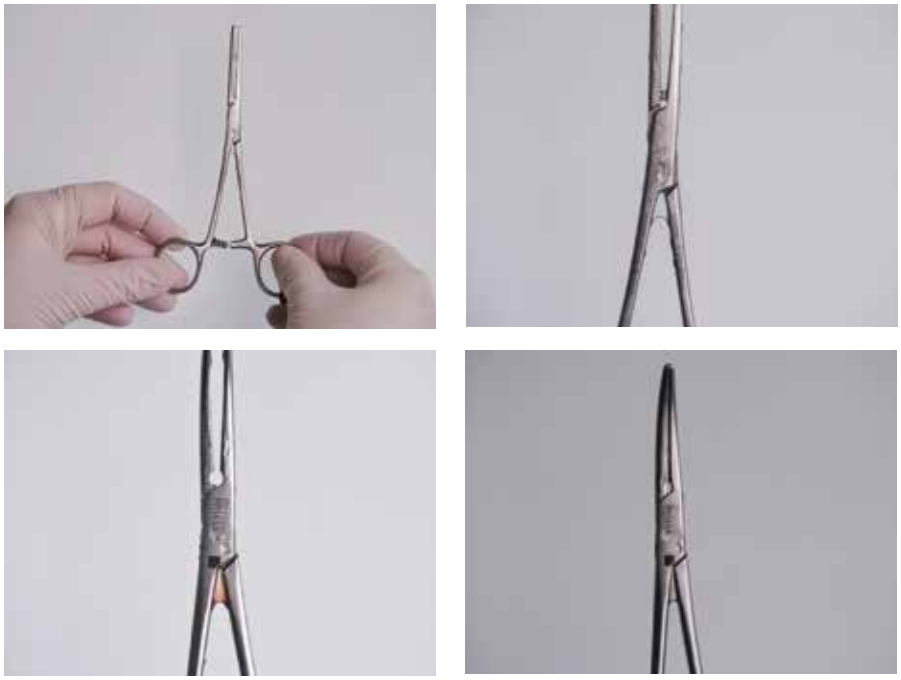


Fig. 2 – 4

them. If the protein test is done using the modified OPA method, rust particles will result in false results. For this reason, it is necessary to thoroughly clean and passivate the test objects after each use.

2.2.1. Basic cleaning for Reuse
30 min sonication in an ultrasonic bath at 70 °C with a 1% alkaline detergent solutio
3 min rinse with DI water

2.2.2. Passivation
30 min sonication at 70 °C in 5% citric acid solution
3 min rinse with DI water

2.3 Cleaning after Passivation
The test objects are processed using the Vario-TD program with alkaline detergent after passivation.

2.4 Care of the Hinges of the Test Objects
A steam-permeable, medical-grade lubricant is applied to the dry test objects. In order to achieve an even distribution of the lubricant, the test objects are opened and closed five times.

2.5 Steam Sterilization
The test objects are then steam sterilized for 3 minutes at 134 °C. The sterilization serves to aid in the even distribution of the lubricant. Packaging of the clamps is only required if the test objects will not be reused immediately. Contamination and packaging are described earlier in this diocument.

3. Execution of the Testing with Test Object, Visual Assessment and Sample Collection

The test objects (A) are placed in the defined test load, see Guideline section 5.2.3.1.

Since the clamps must be removed from the WD before the disinfection phase, waterproof, clean gloves must be worn.

The test objects will be wet after removal from the WD before the disinfection phase. Hold the instrument in its wet state vertically with the working portion perpendicular. Open and close it three times. Look for the presence of coloring or cloudiness in the water droplets at the lower end of the closure for the visual evaluation.
Sample collection for semi-quantitive protein testing is done by rinsing the hinge area with 1% sodium dodecyl sulfate solution (SDS). This is prepared for the testing or can be obtained from an apothecary. For the testing of cleaning processes where the temperature of the cleaning phase of the process was above 60 °C (before the thermal disinfection phase), adjust the pH of the SDS solution to pH 11 with sodium hydroxide. This compensates in part for the temperature-dependent protein denaturing.
For sample taking, each instrument shall be placed into a 50 ml beaker (high form, e.g., Item C123.1, Carl Roth GmbH, Karlsruhe) and 2 ml of the SDS solution pipetted over the hinge area. (Wear gloves!)
Hold the beaker at an angle, and the instrument against the low side of the beaker, so that the instrument is wetted up to just over the hinge. The hinge area shall then be opened and closed five times, opening as far as possible each time. Then the instrument is left in the beaker for 10 minutes and the extraction process repeated two more times using the same solution.
The SDS solution is analyzed semi-quantitatively immediately thereafter.
When carrying out the elution, care must be taken that the 2 ml of the solution is not spilled. This corrupts the sample and the result is unusable!

4. External Examination of the Test Objects

The semi-quantitative protein analysis can be carried out in an external laboratory that is specifically equipped to do this analysis.

Fig. 5

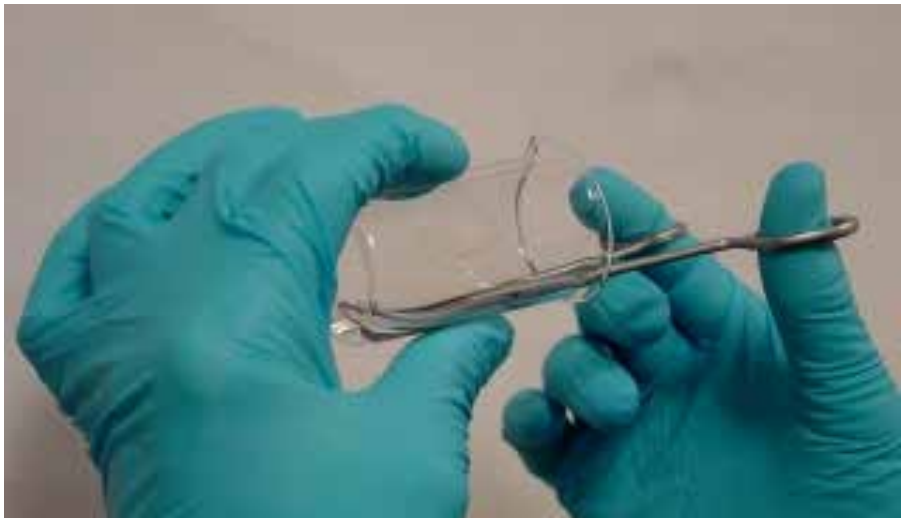


Fig. 6

Method:
After the visual results (digital photo) have been collected, they are documented in **checklist 7 "Tests of cleaning performance"** and the test object is dried on a non-absorbent support at temperatures below 40 °C (in a drying cabinet or a few hours at ambient conditions). The dried test object is packaged in a polypropylene bag and sealed. Together with the checklist 7 it is forwarded for assessment on the following day at the latest.
In order to be able to carry out the investigations in the laboratory immediately, the inspections of the RDG should not be carried out on Thursdays or Fridays.

5. Processing of the Test Objects

After successful sample collection, the test objects are subjected to automated processing, this time including the disinfection step and drying. The clamps are then returned to the provider.

Note: In the period from November 2004 to February 2005, a round-robin study was done for verification of the method, which was carried out in various CSSD's across Germany. The results of this study were published in *Zentralsterilisation* 2005; 13:106–117. ■

Annex 4: Cleaning Tests for Performance Qualification (PQ)

Group	Type of load/medical device	Load carrier	Test runs	Test Objects -visual and protein test	Real, in-use soiled instruments Visual test	Real, in-use soiled instruments Protein test	Documentation	Notes
1	Instruments without hinges or cavities/lumens, completely dismantlable instruments	Specified instrument load carrier	3	Five Crile clamps per load/load carrier level (distributed among the levels of the carrier, mixed in with the instruments)	Five per load, distributed in different carrier levels	semiquantitative	Crile clamps and marked real, in-use soiled instruenmts and their locations (Photo with legend)	Provide the position of the pressure measurement (Photo if possible))
2	Hinged instruments	Specified instrument load carrier	3			Semi-quantitative or quantitative		
3	Shift-Shaft instruments	Specified instrument cart with hollowware connection	3			Yes and at least three hollow/lumened instruments quantitative		
4	Tubular/ hollowware instruments	MIS load carrier	3			Yes and at least three hollow/lumened instruments quantitative		For load carriers with tubing connections, plastic parts may need to be replaced.
5	Microsurgical instruments	Specified instrument carrier with hollowware connection and filter system	3			Yes and three hollow/ lumened instruments quantitative		Pressure measurements after the filter systems. Record the position (Photo if possible)
6	Complex instruments	Specified instrument carrier with hollowware connection	3			Yes and three hollow/ lumened instruments quantitative		
7	Flexible Instruments	Specified instrument carrier with hollowware connection	3			Semi-quantitative and three hollow/lumened instruments quantitative		Position of the pressure measurement (Photo if possible)
8	Utensils (Bowls / Containers)	Specified load carrier	2	None	5 per load	If protein loading is to be expected, qualitative	Photo with legend	Loads with only noncritical instruments does not have to be validated
9	Anaesthesia/ Plastics	Anaesthesia/Tubing Carrier	2			Yes, if protein loading is expected semi-quantitative	Marked real product and their distribution in the load (Photo with legend)	Provide the position of the pressure measurement (Photo if possible)

Instructions for using the information in the table

1. If loads from different groups (eg 1, 2 and 3) are combined and go through an automated process together, the number of test objects remains constant at five (5). However, the real instruments of the different groups must be checked separately.
2. If loads of different groups are cleaned and disinfected with different load carrier types, but the same process sequence, testing of two batches per load carrier type is sufficient.
3. If, in addition to the testing of batches of groups 1–7, loading is carried out with MD of group 8 with a specific load carrier/process, the test of one load/process is sufficient.
4. Multiple WD's identical in construction or model must be fully tested independently.
5. A further reduction in the number and type of studies is possible on the basis of a documented risk analysis and risk assessment if more than two processes and / or loading configurations are checked. The risk analysis and evaluation is usually carried out by the user together with the validator. (see **Information 6 "Test Matrix for Performance Qualification for multiple identical Washer-Disinfectors with the same process, chemical supply and utilities"**)

Annex 5: Acceptance Criteria for the Assessment of Cleaning Performance

The state of the art of automated washer-disinfector performance has improved greatly since previous versions of this guideline. The evaluation of validation data for automated cleaning and disinfecting processes from 2011 to 2012 has shown that the technically-achievable residual protein quantities after cleaning have decreased significantly relative to the acceptance criteria determined in previous studies, both on real soiled instruments and on the Crile clamp test objects.
The acceptance criteria shown in the following sections apply to the execution of testing per **Annex 6 "Cleaning Tests"** in this Guideline.

1. Acceptance Criteria for "Crile Clamp Test Objects"

All test objects must be free of visible test soil. Only visually-clean instruments are to be measured either semi-quantitatively or quantitatively for residual protein.
Residual protein per test object as bovine serum albumin (BSA)

- Upper limit > 150 µg
- Warning level > 80 ≤ µg
- Acceptance Benchmark ≤ 80 µg

2. Acceptance criteria for real instruments

The sample instrument groups are listed in the table "Acceptance Criteria for Real Instruments". The instruments can be assigned to different groups based upon its design. For example, if the inner surfaces of the instrument are accessible after the disassembly and thus visible for cleaning assessment, the assignment is different than for a similar instrument that cannot be disassembled. The individual parts of a dismantlable instrument can be assigned to different groups.
All real instruments must be visually free from contamination. Only visually clean instruments are analyzed semi-quantitatively or quantitatively for protein residues. When assessing the residual amounts of protein, the surface area of the samples shall be estimated and considered in the analysis. For instruments with a calculated surface of more than 50 cm^2, the maximum values given in the following table must not be exceeded. The acceptance criteria obtained with the aim of a residual protein quantity of less than ≤3.3 µg per cm^2 are listed in Table 1 (see following page).

3. Actions to be taken based upon the assessment

Visible Soiling of the Test Object/Real Instrument

Immediate stoppage of processing using this process, this WD process cannot be run again until its processing failure is remediated

Improved practices must be implemented. A requalification of the affected process is required. The performance qualification cannot be completed

Reaching or exceeding the limit value for test objects

Immediate stoppage of processing using this process, this WD process cannot be run again until its processing failure is remediated.

Improved practices must be implemented. A requalification of the affected process is required. The performance qualification cannot be completed.

Value in the warning range for the test object

The affected process can continue to be used, but improved practices must be established and implemented without delay with the aim of reaching the benchmark. The performance qualification cannot be completed.

Value in the warning range for real instruments

The affected process can continue to be used, but improved practices must be established and implemented without delay, or acceptance of the higher residual level should be justified in the context of a risk analysis. The performance qualification cannot be completed.

Benchmark value for test objects/real instruments

No action is required if the benchmark value is observed/not exceeded.

Note:

If the acceptance criteria are exceeded, this must be assessed, e.g., with regard to the location of the instruments in the WD. ■

Table 1: Acceptance Criteria for Real Instruments				
Group	**Examples of the Instrument Type**	**Method**	**Acceptance Level**	**Warning Level**
1	Instruments without hinges or cavities (not hollowware) *Sharp spoons, retractors*	Visual Examination	≤ 3 µg/cm²	> 3 ≤ 6µg/cm²
2	Hinged Instruments *Scissors, Clamps*	At least a semi-quantitative protein measurement after elution in a polypropylene bag)	< 75 µg per Instrument (up to a length of 15 cm) < 100 µg per Instrument (with a length of > 15 cm)	> 75 ≤ 150 µg per Instrument > 100 ≤ 200 µg per Instrument
		Elution analogous to Crile Clamps as test objects for the functional part with a hinge	< 50 µg per Instrument	> 50 ≤ 100 µg per Instrument
3	Shift-shaft instruments*** *Punches, Rongeurs*	Quantitative protein measurement after elution of the entire instrument in a polyproylene bag Partial elution on the functional end in a reagent glass with ultrasonication	< 100 µg per Instrument < 50 µg per Instrument	> 100 ≤ 200 µg per Instrument > 50 ≤ 100 µg per Instrument
4	Hollowware/lumen instruments	Quantitative protein measurement, e.g., the shaft of a dismantlable instrument is sampled from the inside only (flushing of the tube) – Working element isolated for elution, in a closed tube for example. – The jaw and its hinge is eluted in a reagent glass with ultrasonication	< 75 µg per Instrument (up to 4 mm inner diameter) < 100 µg per Instrument shaft tube (greater than 4 mm inner diameter) < 50 µg per functional portion of the instrument < 40 µg per jaw with hinge	> 75 ≤ 150 µg per Instrument > 100 ≤ 200 µg per Instrument > 50 ≤ 100 µg per functional portion of the instrument > 40 ≤ 80 µg per jaw with hingei
5	MIcrosurgical instruments	Quantitative protein measurement after elution of the entire instrument	< 50 µg per Instrument < 20 µg per Instrument (Ophthalmic Instruments)	> 50 ≤ 100 µg per Instrument > 20 ≤ 40 µg per Instrument

*** (non-dismantlable

Annex 6: Cleaning Efficacy Testing

Sampling and protein detection/determination in the test of real in-use soiled instruments

The initial examination of the cleaning results of instruments contaminated in actual use in the course of performance testing and routine testing is carried out by visual inspection after cleaning. A qualitative and/or quantitative determination of the protein must also be carried out in addition to the visual findings.

Protein determination

Sample taking

Samples for analysis are obtained by rinsing the instruments or by rinsing (eluting) the specific areas of the instruments (cavity, joint) to be analyzed with an aqueous rinse solution of 1% by weight of sodium dodecyl sulfate (SDS solution).

Preferably, the sampling is limited to the areas of the instruments which come into contact with the patient tissue and of which a transfer risk primarily arises with reuse. In this way, unacceptable findings caused by including noncritical areas of instruments can be prevented, which would not be objectionable.

The SDS solution used for elution should be adjusted to pH 11 when using disinfectants with cleaning capability or with instruments with possibly slightly-soluble residues (e.g., cauterization). The pH adjustment should be carried out by means of a 0.1 N sodium hydroxide solution under the control of pH test strips with a graduation of at least 0.5 pH units or by means of a pH meter. The elution should be carried out with the least possible amount of SDS solution.

Intensive rinsing with the SDS is basically carried out three times at intervals of 10 minutes as soaking times.

Methods for protein determination

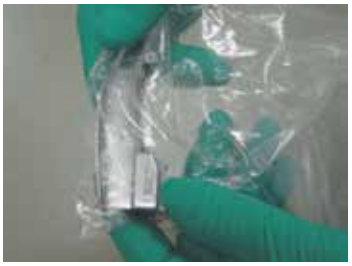
A protein determination after the sampling can be carried out by means of a modified

Example 1: Elution of the surfaces of an instrument in a polypropylene bag with 2–5 ml of SDS solution

Rinsing of possible residual contamination of instruments can be carried out with 2 to 5 ml 1% SDS solution in a suitably large, stable polyproylene (PP) bag in order to obtain an elution sample from the entire instrument. The instrument in the sealed bag is intensively contacted by the SDS and manipulated through the bag. This enables elution of portions of the instrument that are difficult to clean.

Hinged instruments are to be operated within the bag so as to enable contact with the hidden surfaces of the hinge.

Sampling is also possible in hollow-body instruments with large, easily accessible cavities, e.g., trocar sleeves in a suitable polypropylene bag,. The solution can be made to flow through the cavities and thoroughly contact and elute them by tilting the pouch back and forth. The instrument in the pouch must also be turned so that all the internal area are contacted by the eluant solution.



Example 2: Elution of a hinged instrument (partial, critical area) with 2–3 ml of SDS solution

In the case of hinged instruments, the functional area, including the hinge, is usually sampled as a test object, as in the case of the Crile clamps; this requires intensive movement of the joint in the eluant solution.

Example 3: Elution of a shaft tube with 2–5 ml SDS solution

Instruments with narrow lumens can be placed with the distal end in a beaker. They may be held with a lab stand clamp. Using a pipette or a syringe, flush 2–5 ml of the SDS solution through the instrument. Repeat the flush five times using the same eluant solution.

An analogous procedure is also possible by placing the working inserts of dismantlable MIS shaft instruments in a hose of suitable length whose inner diameter is just large enough to allow the inserts to be placed within it, using the hose as the lumen.

A soaking time of 10 minutes between the repeated rinses should be allowed.

OPA method or Biuret/BCA method. Only pH-neutral eluates are stable for an extended period of time and can therefore be sent to an external laboratory for analysis. When using alkaline SDS solutions, cooled transport/shipment is required within 24 hours.
Turbid solutions are not acceptable. Protein determination using a photometric measurement is not possible with such solutions. The cause of a turbid solution must be determined and remediated. Microfiltration using a syringe filter made of regenerated cellulose (pore size 0.2 µm) can be used to remove the cloudiness. However, it is essential to ensure that the separated material remaining on the filter membrane does not contain protein. Membrane filtration must be validated as all of the other steps in protein determination.
Eine Mikrofiltration mittels Spritzenfilter aus regenerierter Cellulose (0,2 µm) kann die Trübung der Probelösung für eine photometrische Messung beseitigen. Es ist jedoch sicherzustellen, dass der Rückstand auf der Membran kein Protein enthält. Die Membranfiltration ist genau wie die anderen Schritte der Proteinbestimmung zu validieren.
The choice of the detection method, its detection range, and its specificity must be appropriate to the acceptance criteria applicable to the instruments or their sampled areas. This applies in particular to the ratio of the total volume of eluate to the partial volume used for protein determination, where the total volume should be as close to the partial volume as is feasible (see also Table 1). Furthermore, it must be considered whether the residues of the process chemicals used have an influence on the chemical detection reaction of the protein determination. Carrying out a negative control is useful (test and evaluate a clean, unsoiled instrument in the load as if it were a real instrument).

Calcuation of the protein content

When calculating the eluted total protein content, the effect of dilution based on the volume of SDS solution used must be taken into account. Thus, the amount of protein found in the partial volume of the eluate must be multiplied by the ratio of total eluate volume/partial volume in order to determine the amount of protein per instrument/portion of the tested instrument. Table 1 illustrates actual results including dilution effects for total protein content of 100 µg or 50 µg from the sampled portion of an instrument appear for different volumes of SDS solution as quantity of protein per ml. ■

Example 4: Extraction Using Sonication

Extraction of the distal gap area of a non-dismountable punch in a test tube using ultrasonication. The instrument should be operated manually during the sonication.

Example 5: Extraction Using a Vortexer

The extraction of complex instruments with a small volume of 2 to 4 ml of 1% SDS solution can be done successfully in a plastic sample tube using a vortexer, An example is the distal functional end of a robotic instrument after removal from the instrument. Typical extraction conditions are 5 vortexings for 15 sec each at 5 min intervals.

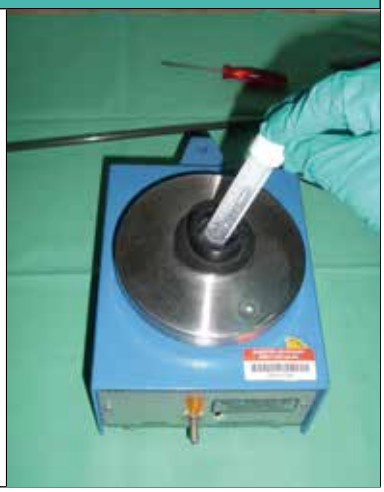


Table 1: Calculation examples for the total amount of protein per area sampled

Total Eluate Volume [ml]	Measured protein content in the partial volume analyzed [µg/ml]	Resultant total protein content for the sampled portion of the instrument [µg]
2	50	100
3	33	100
4	25	100
5	20	100
2	25	50
3	17	50
4	13	50
5	10	50

Annex 7: Requalification (Repeat Performance Qualification) without special reason

Requalification without special cause

This procedure is done so long as there are no changes made in the process that would result in a requalification (PQ) with special reason (e.g., new process chemicals, changed load configuration, process changes). EN ISO 15883-1 recommends an annual requalification.

1. The following confirmations and checklist shall be documented by the user:

a. If all of the load carrier and their couplings to the flushing system have not been checked for a postive confirmation of proper function of the WD, or replaced during maintenance, a test of function including pressure curve testing must have been done no more than six weeks prior to the PQ.

b. If no calibration and no needed adjustments of all sensors of the WD are to be done during the requalification, calibration and any needed adjustments must have been done no longer than six weeks prior to the requalification.

2. The release documentation (batch records) and routine tests since the previous PQ shall be reviewed by the user. The user and validator shall evaluate these records together to develop the scope for the requalification and the measures which are required.

3. At least five test objects (Crile clamps) must be used and tested per WD program.

   For processing of instruments that are considered to be especially critical, a requalification of each instrument type that is used (see **Annex 5, "Table of Acceptance Criteria for Real Instruments"**) is required. At least three instruments of each type, with real, in-use contamination shall be examined visually and tested for residual protein.

   The results shall not show negative deviations relative to the previous validation.

Note:

It is not necessary to examine every program and every load with a new PQ if the performance of the programs/process sequences used has been proven to be satisfactory during the validation.
If it discovered that the original validation is incomplete, the missing tests shall be run, or the need to do so ruled out by a risk analysis.

Over time, primary physical parameters such as water level, pressure, temperature, process chemical dosing, which equally influence all programs and loads, can change. During the testing of the selected programs, deviations in these parameters are expected to become evident. Mechanical changes should normally be discovered during maintenance of the machine and the load carrier.

4. Measured temperature and pressure curves and test results shall be compared to the previous validation. In the case of deviations, the failing program must undergo additional tests and other programs may be included in this testing as well. If the negative deviations remain, the cause must be ascertained and remediated. ■

Annex 8: Event-Driven Requalification (Repeat Performance Qualification) with process chemical change

1. General Information

In principle, the operator must be able to make changes in order to implement technical improvements or innovative process chemicals and program sequences. Events include:

- Modifications or technical modification of the WD which may affect the cleaning performance,
- Introduction of new or modified instruments or new loading systems,
- Introduction of new process programs or modification of process parameters (e.g., temperature, time) which can affect performance,
- Change of process chemistry.

The procedure described below refers exclusively to a repeated performance qualification (PQ) when changing process chemicals. The extent of the new PQ depends on the nature and degree of change. The tests are carried out using the reference loads used during the validation. Modified pre-treatments must be added to the SOP's.

Changes that may require a new PQ are:

a) Detergent: Different type and/or change in concentration/amount
b) Neutralizer: Different type and/ or different concentration/amount or discontinued use
c) Rinse aid/post-wash rinse agent: Different type and/or different concentration/amount or discontinued use. Change in the pre-wash.
d) Water quality

The manufacturer of the new process chemicals must provide all required documentation as required in these Guidelines:

- Product description and recommended dosage
- Safety data sheet
- Methods for verification of the dosing amount/concentration
- Information concerning the toxicological safety of residual process chemicals on medical devices
- Methods for the determination that the remaining chemicals are below the toxicologically safe limit value.

2. Evaluation (sections 3.1-3.4):

- If the test cycles show equivalent or better results than in the previous validation after the change of chemistry, the process is considered to be validated.
- If the test cycles show worse results than in the validation or most recent requalification, a risk analysis must be carried out based upon the results obtained. The need for a change in routine testing has to be evaluated.

3. . Process chemical change

3.1 3.1 Change of detergent

A part of the operational qualification (OQ) must be repeated, this being the error indication for underdosing and empty detergent bottle indication. This must be adjusted for the new chemistry, since these alarms can be influenced by the type and composition of the process chemicals.

Other items to test:

- Accuracy of the dosage
- Residual process chemicals

For change of detergent with no other changes in the process, a pressure test is required, see Guideline section 5.2.3.2. The pressure curve shall be compared to the pressure curve from the previous validation. Major deviations or fluctuations in pressure speak to an unacceptable interaction of the detergent with the washing mechanic.

To check the cleaning performance, reference loads are used as was done in the initial validation. At least two loads shall be run with real contaminated instruments and at least five Crile clamps in the same positions as for the previous validation. The clamps are visually evaluated and subjected to a residual protein test.

Processing of lumen or microsurgical instruments, especially those considered to be especially critical, must also be tested. A minimum of three lumen instruments with real contamination (e.g., Veress needle, shaft of an MIS scissors, suction cannula, as used in the previous validation) shall be visually evaluated and subjected to a residual protein test.

The results are to be compared to the results of the previous validation.

3.2 3.2 Supplement, Change or Discontinued Use of the Neutralizer

If the neutralizer is supplemented, changed, or its use discontinued, one must test that the residual process chemical level is below the limit provided by the process chemical manufacturer.

In addition, the following must be tested:

- Accuracy of dosage

3.3 3.3 Change, Introduction of, or Discontinued Use of a Rinse Aid/Rinse Agent

If a rinse aid/agent is changed, introduced, or its use discontinued, the following tests shall be run:

- Accuracy of dosage

- Drying of surfaces that are difficult to dry
- Materials compatibility with the medical devices being processed.
- Influence on the washing pressure in the individual phases of the program sequence. If a meaningful influence is detected (see above), the tests for cleaning performance must be rerun (e.g., check for an effect of residual rinse aid/agent on the pre-wash/cleaning phase of the next process cycle).
- Certification from the manufacturer of the process chemicals for toxicological safety

3.4 3.4 Change in Water Quality

Since the quality and composition of the water can have a significant influence on the results of the processing, water must also be regarded as a process chemical. In the case of modifications, new PQ testing must be carried out as described in section 3.

In the case of a change in the DI water quality in the range of 3–15 µs, no additional PQ testing must be carried out if the process chemical manufacturer certifies that there is no effect on cleaning or residual levels of process chemicals. ■

Annex 9: Event-Driven Requalification (Repeat Performance Qualification) (after maintenance)

A reassessment of a cleaning and disinfecting process must be carried out after each change to the washer-disinfector (for examples, see below: "Assessment of changes")...
The scope of the reassessment must be justified.
The records of the reassessment shall be kept together with the records of the changes made and the corrective measures taken. These records shall be kept with the machine's validation documents.

Risk Analysis for Changes Made

Every change must be evaluated for its influence upon the cleaning and disinfection process. The changes to be considered, where applicable, include:

a) Exchange of a part, if that exchange can influence a process parameter
b) A change in the washing mechanics in the chamber
c) New or changed software and/or hardware
d) Change of a process parameter
e) A change resulting from maintenance of the supply utilities or process chemical delivery system (see also, **Annex 8: "Requalification (Repeat Performance Qualification) for special reason (process chemical change)"**.

The assessment of the results, the justification for the decisions made, and the extent of the changes in the cleaning and disinfection process or the requirements for re-assessment (if applicable) shall be documented.

Testing and Monitoring of the Process

All calibrations, adjustments, maintanance, and performance qualification must be successfully completed before the WD may be used.

Examples:

1. 1. Exchange of a part, if that exchange can influence a process parameter

Change:
Pump replacement
Possible Results:
Pressure change results in a change in themechanics of the cleaning.
Measures to be taken:
1. Risk analysis and evaluation
2. Obligatory testing with pressure datalogger and comparison to a succcesful PQ
3. Documentation – release

2. A Change in the Washing Mechanic in the Chamber

Change:
Repair/replacement of the rinse arms
Repair/replacement of the rinse arms
Change in the mechanics of the cleaning
Measures to be taken:
1. Risk Analysis and Evaluation
2. Obligatory complete requalification (PQ)
3. Documentation - release

3. New or Changed Software and/or Hardware

Change:
Controller replacement/Printed Circuit Board Replacement/New Software
Repair/replacement of the rinse arms
Program change relative to a successful PQ
Measures to be taken:
1. Risk analysis and evaluation
2. Obligatory complete requalification (PQ) (or for a software change, confirmation by the manufacturer that no significant effect on the process results from the replacement. – For a printed circuit board (A/D), only calibration and adjustment are required.)
3. Documentation – Release

4. Change of a Process Parameter

Change:
Direct (manual change) or indirect (sensor replacement etc.).
Repair/replacement of the rinse arms
Process change (in comparison to the valid previous PQ)
Measures to be taken
1. Risk Analysis and evaluation
2. Obligatory complete requalification (PQ) (or for a sensor replacement, only calibration and adjustment are required.)
3. Documentation Release

5. 5. Change Resulting from Maintenance of Supply Utilities and/or Process Chemical Delivery System

See **Annex 8**: **"Requalification (Repeat Performance Qualification) for special reason (process chemical change)"**.

5. Relationship Between Maintenance and Repeated PQ

New, modern and more economical maintenance concepts are individually tailored to customers, projects and applications. As manufacturers increasingly differentiate between "safety-relevant inspection and maintenance" and "preventive maintenance", this is only possible independent of the normal intervals of requalifications (periodic PQ).
KRINKO/BfArM recommendations, standards, and guidelines have recently been heading more and more in the direction that after each preventative or emergency maintenance activity, a requalification (PQ) must be done (see EN ISO 17665-1, section 12.5.
The above-mentioned points and references justify the abolition of the 4-week deadline. ■

Checklist 1: Organizational Prerequisites for the User – Information for the Validation Personnel			
Requirement	**Present**	**Not present**	**Actions to be taken/observations**
Instructions for use for all medical devices with the manufacturer's instructions (according to EN ISO 17664)			
Risk assessment and classification of the medical devices per the infection control requirements for processing of the RINKO/BfArM			
Description of the reference load to be cleaned and disinfected with photographic and written documentation			
Instructions for use and medical device book of the WD			
Maintenance plan for the WD			
Data sheets for the process chemicals (product data sheets, safety data sheets, instructions for use)			
Description of the entire processing process from start up to documented release (quality management)			
Determination of the maximum time taken to transport used supplies for each load			
Specification of the load for performance qualification and generation of the standard operating procedures for operation			
Specification of responsible parties			
Qualifications of the personnel (e.g., DGSV specialist training course)			
Infection control (hygiene) plan			
Cleaning and disinfection plans			

Checklist 2: Information to be Provided by the Washer-Disinfector Manufacturer to the User			
Requirement	**Present**	**Not present**	**Actions to be taken/observations**
Documented certification of compliance with EN ISO 15883			
Documentation for all additional devices to be used with the washer/ disinfector (e.g., load carrier instructions)			
Process parameter values, e.g., time, temperature, water consumption, water pressure, amount of process chemicals			
Temperature and time for each process step			
Description of the standard programs provided with the washer/disin-fector			
Maintenance scope and intervals			
Process chemicals and their concentrations			
Water quality requirements			
Loading requirements for load carrier, trays and inserts			
Description of adjustment of safety devices			
Responses to processing errors			

Checklist 3: Installation Qualification			
Machine (description/number)			
Location			
Person responsible for the Installation Qualification			
IQ reviewer			
Date of the Test			
Type of machine:		❑ Serial equipment	❑ No
Manufacturer:		Serial No.:	
Type:		Year of manufacture	

Installation Qualification		Documentation of Order and Delivery		
Ordering Information			Delivery Information	Damaged (2)
Article description (1)	Article No.	Quantity ordered	Quantity received	Yes/no

(1) record here if the ordered items were delivered.
(2) record here if the delivered items were visibly damaged upon receipt.

Protocol	List of the technical documents for the WD and its accessories		
Type/title	Present and complete yes/no	Document No./ Material No.	Storage location
Installation plan I (Machine)			
Installation plan II (floor-level tank)			
Installation plan III (other)			
Electrical drawings			
Instructions for Use (WD)			
Instructions for Use (Other)			
Operating Manual and Programming Manual			
Device Book per MPBetreibV			

No. (1)	Remarks/deviations/complaints	Influence on:		Deviation resolved/ corrected
		Performance Result (2)	IQ/OQ	Date/signature

(1) Enter the number of the remark/deviation/complaint.

(2) Record the influence on the performance result as none, low, medium, or large. Record the internal departments or contracted firms who carried out and verified the on-site installation of the utilities for the washer/disinfector and accessories.

On-site Installation	Internal department or name and address of the contracted installer
Electrical installation (1) Power supply and potential equalization	
Steam	
Water connections (1)	
Drain connection	
Vent/exhaust air	
Cooling circuit	
Central supply of process chemicals	

(1) If the installation was carried out by multiple internal departments or contractors, these are to be listed in the notes.

WD and acessories(1)	Internal department or name and address of the authorized installer	Date
Washer-disinfector		
Accessories		

(1) The physical installation of the washer/disinfector and any accessories were carried out by the listed internal departments or the authorized installer.

Record the internal department or contractor who connected the washer/disinfector to the utilities.

Connection to installed utilities	Internal Department or name and address of the contracted installer	Date
Electrical installation (1) Power supply and potential equalization		
Steam		
Water connections (1)		
Drain connection		
Vent/exhaust air		
Cooling circuit		
Central supply of process chemicals		

(1) If the installation was carried out by multiple internal departments or contractors, these are to be listed in the Notes.

Checklist 4: Acceptance Test and Parts of Operational Qualification

SPECTARIS	Acceptance Test Washer-Disinfectors	Page 1 of 3

WD type:	Serial No.:
Date:	Manufacturer:
Operator:	
Location:	
Field of use	

1. Visual Inspection			Comments
Housing	❑ ok	❑ not ok	
Chamber	❑ ok	❑ not ok	
Door region/seals	❑ ok	❑ not ok	
Load carriers/trays	❑ ok	❑ not ok	
Dosage equipment	❑ ok	❑ not ok	

2. 2. Functional Tests			Comments
Water level	❑ ok	❑ not ok	
Cold water	❑ ok	❑ not ok	
Warm water	❑ ok	❑ not ok	
Demineralized water	❑ ok	❑ not ok	
Spray arms	❑ ok	❑ not ok	
Dosage system	❑ ok	❑ not ok	
Load carrier docking	❑ ok	❑ not ok	
Steam	❑ ok	❑ not ok	
Condensate removal	❑ ok	❑ not ok	
Electrical connection	❑ ok	❑ not ok	
Compressed air	❑ ok	❑ not ok	
Exhaust	❑ ok	❑ not ok	
Drain	❑ ok	❑ not ok	

Thermoelectrical Measurements:
Test of the disinfection parameters, e.g., 80 °C – 10 min or 90 °C – 5 min,
measured temperature (0/+5 °C) and time at disinfection temperature base on a programme

Programme checked/ designation:			
Temperature _____ °C	❑ ok	❑ not ok	
Time _____ min	❑ ok	❑ not ok	

SPECTARIS	Acceptance Test Washer-Disinfectors	Page 2 of 3

3. 3. Built-in detergent dosing system

Dosing pump 1	
Product/description	
Manufacturer	
Dosage (g/l)	
Dosing device	

Dosing pump 2	
Product/description	
Manufacturer	
Dosage (g/l)	
Dosing device	

Dosing pump 3	
Product/description	
Manufacturer	
Dosage (g/l)	
Dosing device	

Dosing pump 4	
Product/description	
Manufacturer	
Dosage (g/l)	
Dosing device	

4. 4. Ancillary equipment

Description:	❑ ok	❑ not ok	
Description:	❑ ok	❑ not ok	

SPECTARIS	Acceptance Test Washer-Disinfectors	Page 3 of 3

5. 5. The following persons act as operating and use instructors:

	Name	Signature
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Place::	Date:
Signature/Client:	Title:
Signature/service person:	Title:

Checklist 5: Operational Qualification: Tests, Observations, Actions			
Requirement	**Setpoint**	**Actual value**	**Actions/observation**
Function: Cold water inlet, capacity			
Function: Warm water inlet, capacity			
Function: Demineralized water inlet, capacity			
Agreement of displays with measurements (if displays are present)			
Function: Heating rate, observance of temperature			
Agreement of displays with measurements (if displays are present)			
Sensor calibration/adjustment (sensor cleaning solution 1)			
Sensor calibration/adjustment (sensor cleaning solution 2)			
Sensor calibration (drying air)			

Requirement	**ok**	**not ok**	**Actions/observations**
Piping system leakage test			
Door leakage test			
Check of the chamber drainage (degree of emptying)			
Filter check before suction by the circulation pump (clean, leak-tight)			
Functional check of the spray arms (free rotation, RPM)			
Functional check of the jets/nozzles ➔ visual for drainage of solutions			
Functional check of error messages			
Functional check of connections ➔ load carrier to water supply			
Functional check of the drying system ➔ blower performance			
Functional check of exhaust ➔ avoidance of condensate backflow			
Unlocking/opening of the doors only after the process is complete			
No program start with a door open			

Checklist 5: Operational Qualification: Tests, Observations, Actions			
Requirement	**ok**	**not ok**	**Actions/observations**
Door on removal side opens only after an error-free process execution			
Functional check of alarm if chemical dosage is too small			
Functional check of alarm if a chemical supply is empty			
Functional check of alarm if there is a temperature sensor failure			
Functional check of alarm if the chemical dosage is interrupted			
Functional check of alarm if a sensor cable breaks or there is a short circuit in the sensor			

Requirement	**Name**	**Observation**
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		
Definition of all customer-specific programs		

Checklist 6: Performance Qualification: Assistance in Selection of Real Instruments

This form is to be used as an aid to the determination of the required processes in connection with **Annex 4 "Cleaning tests for performance qualification (PQ)"** *and* **Annex 5 "Acceptance Criteria for the Assessment of Cleaning Performance".**

Measurement quality	**Criterion**		**Criterion**		**Criterion**		**Criterion**		**Conclusions**
Material properties	Stainless steel	❑	Aluminum	❑	Titanium	❑	Plastics	❑	Thermolabile MD require a chemical-thermal disinfection and are not in the scope of this Guideline
	Thermostabile	❑	Thermolabile	❑			Other:	❑	
Visible degree of soiling of the instruments	Low	❑	Heavy	❑	Very heavy	❑		❑	Cleaning outcomes must be tested in the PQ
Difficult to remove soils	Bone meal	❑	Medicines/ Residual disinfectants	❑	Tissue residue	❑	Other:	❑	Cleaning outcomes must be tested in the PQ
Duration between use and processing (WD)	< 1 hour	❑	< 6 hours	❑	< 12 hours	❑	> 12 hours	❑	Performance qualification to be done after the maximum duration after use.
Precleaning	Assured by SOP	❑	Carried out by the user	❑	Carried out in an AEMP	❑	Automated precleaning	❑	If a criterion is not checked, the precleaning must be assured by the organization practices.
Load carrier	Universal	❑	Microsurgical instruments	❑	MIS instruments	❑	Anesthesia materials	❑	A reference load must be specified and tested if the program phases are not identical.

Checklist 7: Tests of Cleaning Performance

Evaluation of the cleaning performance is carried out with defined test objects (Crile clamps) and real contaminated instruments/medical devices. When using test objects, these must be placed within the normal load. The distribution of the clamps is dependent on the WD and the load, and is to be defined on site and documented (digital photo). The test objects have to be open to approx. 90 °.

The process is interrupted before the thermal disinfection step. The test objects and real instruments are removed and examined visually for cleanliness. Gloves are to be worn when removing and handling the instruments and test objects. ■

Example for an evaluation table for test objects

No.	Code No.	Position	Visual cleanliness	Benchmark value <80 µg	Warning range 80 – 150 µg	Limit value >150 µg	Assessment

Real instruments evaluated on site are to be reprocessed in the WD. If real instruments and test objects are being sent to a laboratory for evaluation, they shall be labeled as such and packed for shipment.

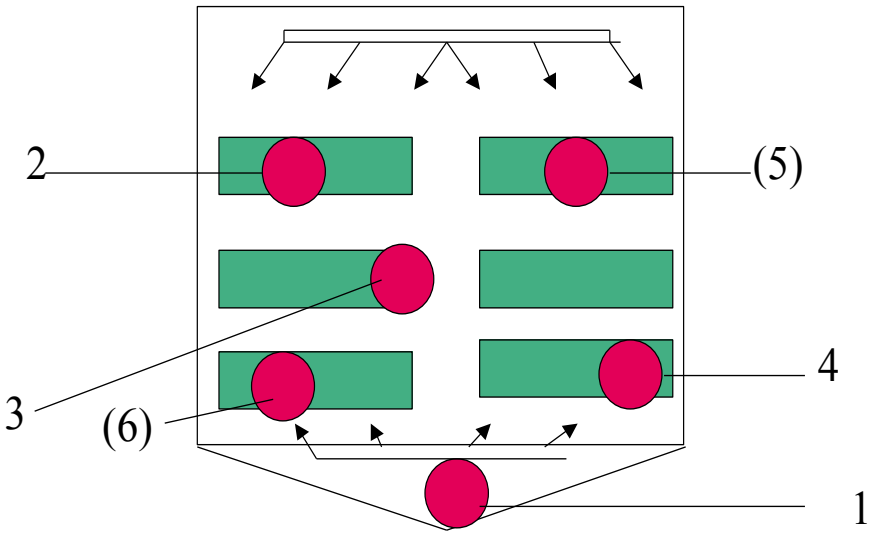
Example of an evaluation table for real instruments

No.	MD	Product family group	Position	Visual Cleanliness	Estimated surface area	Value	Benchmark level for the product family	Assessment

Real instruments evaluated on site are to be reprocessed in the WD. If real instruments and test objects are being sent to a laboratory for evaluation, they shall be labeled as such and packed for shipment.

Checklist 8: Positioning of the temperature sensors

Thermal disinfection per EN ISO 15883 – 1, 6.8.2



1 = adjacent to the temperature sensor for process control
2 = location where the temperature is reached most quickly
3 = location where the temperature is reached most slowly
4 (5, 6) = reference measurement sensors for the chamber temperature

Recommended measurements are two cycles with six sensors or three cycles with four sensors to test each load category

Checklist 9: Daily in-use testing of the washer/disinfector

Identification of the CSSD

washer/disinfector No. Month:	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.
Filters (sieve filter) coarse/fine																
Pump sump																
Spray arms/spray jets/nozzles																
Load carrier																
Load carrier connection																
Connections/adapters/blind plugs																
Rollers																
Load carrier recognition																
Visual check of the washer/disinfector inside and outside																
Door gasket																
Further daily checks specified in the instructions for use																
Demineralized water quality (conductivity)																
Signature of the staff member																
	17.	18.	19.	20.	21.	22.	23.	24.	25.	26.	27.	28.	29.	30.	31.	
Filters (sieve filter) coarse/fine																
Pump sump																
Spray arms/spray jets/nozzles																
Load carrier																
Load carrier connection																
Connections/adapters/blind plugs																
Rollers																
Load carrier recognition																
Visual check of the washer/disinfector inside and outside																
Door gasket																
Further daily checks specified in the instructions for use																
Demineralized water quality (conductivity)																
Signature of the staff member																

Description of the items in the checklist "Daily in-use testing of the washer/disinfector before starting work"	
Filters (sieve filter) coarse/fine	Cleaning of all filters and check of their function
Pump sump	Check and cleaning, removal of small parts, e.g., scalpel blades, needles, etc., observing all workplace safety requirements
Spray arms/spray jets/nozzles	Check to assure free and even rotation in the WD and on the load carrier Check the jets/nozzles for blockages and remove any found/clean them
Load carrier	
– Connection to the WD	Ensure correct function of the coupling of the load carrier to the washer/disinfector plumbing
– Connections/adapters/blind plugs	Check all Luer-Lock, tubing connections, blind plugs and jets/nozzles on the load carrier for proper function and completeness
– Rollers	Check for proper function and completeness
– Load carrier recognition	Check coding, if available
Visual examination of the washer/disinfector inside and outside	Examination of the wash chamber for cleanliness and deposits (e.g., lime, silicate, rust)
Door gasket	Check the door gasket for leaks and cleanliness
Further daily checks specified in the instructions for use	Per the recommendations of the manufacturer
Demineralized water quality (conductivity)	Daily conductivity measurement, maximum value 15 µS/cm
Signature of the staff member	Signature or mark of the responsible staff member
In order to ensure a smooth operation, a check of the levels in the storage containers by visual inspection is necessary (built-in containers, single canisters, dosing system require different procedures).	

Checklist 10: Matrix for creation of a checklist for routine monitoring of the washer/disinfector's technical function					
1 Temperature and time-and/or A0 observation via data logger testing	daily use*	2 weeks	3 months	6 months	Annually**
1a WD with temperature documentation: actual values with separate sensors recorded independent of the control system					×
1b WD with temperature documentation: actual values with separate sensors recorded, not independent of the control system				×	
1c WD with temperature documentation: actual values without separate sensors			×		
1d WD without temperature documentation or only with a set point indication	×				
2 Pressure monitoring/additional tests: e.g., pressure measurement or spray arm rotational rate	per load	2 weeks	3 months	6 months	Annually**
2a WD with pressure documentation: with actual value monitoring					×
2b WD without pressure documentation: with actual values monitoring				×	
2c WD without pressure documentation: without actual value monitoring	×				
3 Dosage monitoring/additional test: e.g., dosage amount or conductivity monitoring	daily use*	2 weeks	3 months	6 months	Annually**
3a WD with dosage amount documentation: actual value monitoring independent of the control system				×	
3b WD with dosage amount documentation: actual value monitoring not independent of the control system			×		
3c WD without dosage amount documentation: without monitoring		×			
4 Water level monitoring/additional test: e.g., manual water level measurement	daily use*	2 weeks	3 months	6 months	Annually**
4a WD with volume-controlled water inlet					×
4b WD with level-controlled water inlet				×	
4c WD with time-controlled water inlet		×			

* daily use means 1 x per workday

** can also be carried out in an annual requalification (PQ). Further explanation of the matrix entries are found on the next page.

Explanation of the entries in the matrix for routine check of the WD's technical function

The following notes are intended to provide assistance for the assignment of tests for the existing WD in the matrix and provide explanations:

1) Temperature and time and / or Ao value monitoring by additional data logger check
Depending on the WD's internal monitoring equipment (see variants 1a – 1d), temperature measurements throughout the cycle are required in addition to the internal device monitoring and documentation. This can be done with a temperature data logger.

1a) WD with temperature documentation: actual values with separate sensors recorded independent of the control system
In this variant, the actual values of the WD's process data is recorded with an additional temperature sensor (real temperature measurement), and is equipped with an independent monitoring module. In addition, the holding time is documented.

1b)) WD with temperature documentation: actual values with separate sensors recorded not independent of the control system
In this variant, the actual values of the WD's process data is recorded with an additional temperature sensor (real temperature measurement), and is not equipped with an independent control module. In addition, the temperature values and holding time is documented. In this variant, there is the possibility that an error in the machine controller, which is used for both process control and execution, and documentation, is not recognized. Therefore, shorter intervals are required for the routine check than for variant 1a.

1c) WD with temperature documentation: Actual values without separate sensors
In this variant, the WD is not equipped with an additional temperature sensor, but actual values (real temperature measurement) are recorded. The WD has no monitoring unit independent of the controller. The temperature values and the holding time are documented. In this variant, there is the possibility that an error in the machine controller, which is used for both process control and execution, and documentation, cannot be detected. Therefore, shorter intervals are required for the routine check than for variant 1a and 1b.

1d) WD without temperature documentation or only with a set point indication
If an WD only documents or displays values (values or warning signals) that are not actually measured, but instead are stored as fixed values in the controller (these values are called set points), then this documentation represents a significantly lower safety standard than variants 1a – 1c. The routine check is therefore to be carried out on a daily basis.

2) Pressure monitoring/additional tests: e.g., pressure measurement or spray arm rotational rate
The pump pressure is a process-relevant parameter for the cleaning efficacy, and must be checked. Additional checks are necessary depending on the internal monitoring equipment of the WD (see variants 2a – 2c). This can be done with a suitable pressure data logger or a built-in rotational speed monitor for the spray arms. If this is not possible, appropriate end product checks are to be carried out.

2a) WD with pressure documentation: with actual value monitoring
In this variant, the WD is equipped with a pressure switch or pressure transducer which records actual values (real measurement of the pump pressure). In addition, the pump pressure is documented in the relevant process sections.

2b) WD without pressure documentation: with actual values monitoring
In this variant, the WD is equipped with a pressure switch which monitors a predetermined minimum pressure. Here, there is the possibility that an error in cycle execution is not detected. There is no documentation as in variant 2a. Therefore, shorter intervals are required for the routine check than for variant 2a.

2c) WD without pressure documentation: without actual value monitoring
The pump pressure and thus the cleaning efficacy is not checked. Therefore, a routine check of each load is required. The batch-related control is necessary, since the foaming can occur in individual loads and cause pressure drop (e.g., surfactant overdose).

3) Dose monitoring/additional test: e.g., dose amount or conductivity monitoring
Dosing and the dosing quantity are process-relevant parameters that has to be checked. Depending on the internal monitoring equipment of the WD (see variants 3a - 3c) additional checks may be necessary. This can be done by checking the conductance of the detergent/water solution or by measuring, the volume f chemical delivered. Alternatively, a manual check (collection of sample volumes) is to be carried out...

3a) WD with dosage amount documentation: actual value monitoring independent of the control system
In this variant, the WD is equipped with a dosage-measuring device or equivalent sensor that measures and records the actual values by means of a system independent of the WD controller.

3b) RWD with dosage amount documentation: actual value monitoring not independent of the control system
In this variant, the WD is equipped with a dosage-measuring device or equivalent sensor that measures the actual values. The WD has no independent monitoring unit. In this variant, there is the possibility that an error in the machine controller, which is used for both process control and execution, and documentation, is not recognized. Therefore, shorter intervals are required for the routine check than for variant

3c) WD without dosage amount documentation: without monitoring
In this variant, there is no measurement of the dosage. The routine check should therefore be carried out every two weeks.

4) Water level monitoring/additional test: e.g., manual water level measurement
The water level is a process-relevant parameter, which must be checked. Depending on the reliability and accuracy of the WD measuring and control system, addi-

tional checks, such as manual water level measurements, are necessary at defined time intervals.

4a) WD with volume monitoring for water inflow

Water inflow with volumetric monitoring provides, as a rule, the most accurate delivery means and the highest level of process reliability.

4b) WD with level control for water inflow

Water inflow with a level control is significantly more reliable than a timed-flow control system, but more susceptible to error than a volume monitoring system.

4c) WD with timed water inflow control

The amount of water delivered by a timed-flow control system is dependent upon the pressure of the incoming water and can vary greatly. Routine tests must be done on a every second week.

Checklist 11: Preparation for a Requalification (OQ/PQ)			
Executed by the operator	**on.....**		
Question	**Answer**	**interval-driven requalification***	**event-driven requalification****
Are there new instruments that do not fall into the previously validated instrument groups?			
Was there a change in the area of process chemicals?			
Are changes in the area of process chemicals planned?			
Has there been a failure of water quality to meet the existing requirements?			
Are there changes in the process execution?			
Were there changes in the load carrier(s) or is a new load carrier expected to be put into use?			
Are changes in the loading pattern expected?			
Have there been failures to achieve the desired cleaning performance that cannot be traced to human error?			
Have the results of the evaluation of routine monitoring been considered?			
When was the last calibration and adjustment of the measurement chain carried out?			
When was the last load carrier check carried out per Annex 7?			
Were maintenance and repair measures per § 7 MPBetreibV carried out by persons with a qualification certification per § 4 MPBetreibV?			
Have there been error messages or process failure notifications on the load records?			
Other issues, e.g. audit findings or inspection issues?			

* **Without special reason (interval-driven requalification → For procedure, see Annex 7, requalification "repeat performance qualification"** without special reason

** **For special reason (event-driven requalification) → For procedure, see Annex 8, "Requalification (Repeat Performance Qualification) for special reason (process chemical change"**

Information 1: Contents of DIN EN ISO 17664-2004

Manufacturers of medical devices must make the following information availabl:	
Processing Step	**Description**
Preparation at point of use	If needed, information on: • Transport containers • Instrument holding systems • Maximum time between use and cleaning • Precleaning • Requirements during transport
Preparations prior to cleaning	Some medical devices require preparatory measures prior to cleaning. For example: • Requirements for covering/capping of connections • Dismantling • Leak testing • Manual precleaning with brushes or pre-rinse with a cleaning pistol
Cleaning	If needed, information on: • Accessories for the cleaning process • Concentration of the cleaning process chemical • Exposure time for the cleaning process chemistry • Water quality • Limits and monitoring for chemical residuals on the medical devices • Limits for temperature, solution concentration and exposure time • Applicable techniques, including rinsing
Disinfection	If needed, information on: • Accessories for the disinfection process • Concentration of the process chemicals for disinfection • Exposure time for the process chemicals • Water quality • Limits and monitoring of chemical residuals on the medical devices • Limits for temperature, solution concentration, exposure time • Applicable techniques, including rinsing
Drying	If needed, information on: • Accessories for the drying process • Maximum temperature and exposure time for the product • Technical data for the drying medium used • Applicable techniques
Inspection, Maintenance, and Testing	If needed, information on: • Procedure for adjustment/calibration of the medical device • Oil, lubricant or other instrument care products • Performance capability criteria to ensure safe usage • Assembly of the medical device • Spare parts-procedure for replacement • Special tools • Visual inspection • Maintenance intervals
Packaging	If needed, information on: • Special packaging and storage processes during and after sterilization. These must be compatible with the sterilization process.
Sterilization	At least one validated process. Moist-heat sterilization is preferred.
Storage	Restrictions on storage conditions or storage time must be indicated if needed
If a medical device can only be processed for a limited number of times, the manufacturer must provide this information, for example, frequency of processing cycles or other information that defines the time or cycle count at which medical device may no longer be used safely.	

Information 2: Requirements of the operator for mechanical cleaning and disinfection processes including checklist

Processing of medical devices is to be carried out using specific, validated processes (see § 8 Medical Device Ordinance , KRINKO-/BfArM recommendation). This applies to medical devices that are to be delivered for use in either a disinfected (low microbial level) or sterile state.
These requirements apply regardless of the location of the processing and the application of the medical devices.

The obligation to exercise due care is only met when the legal requirements for these processes are met by the operator.
The requirements for reprocessing of medical devices requires establishment of structural, process and results quality assurance (implementation of, at least, an internal quality management system).
The reprocessing procedures for all medical devices that are reprocessed must be suitable to the needs of the medical device.

The basis for this are the manufacturer's instructions for reprocessing (IFU).
Additional issues to consider are, for example, the workplace conditions and capabilities and the abilities of the personnel.
The following checklist gives examples of the aspects of cleaning and disinfection processes that must be taken into account and documented.

Checklist for Information 2 : Requirements for the operator for validation of mechanical cleaning and disinfection processes-informative examples				
Executed by the operator	**on .....**			
Requirement		**Present**	**Not present**	**Actions/Observations**
Requirement				
Physical separation between the cleaning/disinfection area and the packing and sterilization area				
Return capability between the packing and sterilization area and the cleaning/disinfection area (e.g., return/pass-through window)				
Changing area for changing into reprocessing clothing, protected storage for reprocessing clothing				
Separate clothing for cleaning/disinfection area and packing/sterilization area				
Fixtures for handwashing and hand disinfection	Changing area, toilet, break room, cleaning/ disinfection area			
Hand disinfection chemical dispenser, easily reached, near the packaging area	Packing and Sterilization Area			
Break room				
air conditioning per DIN 1946-4				
air conditioning plant per VDI 6022				
Manufacturer's instructions for processing for all products (per DIN EN ISO 17664)				
Risk assessment and classification of each medical device per KRINKO/ BfArM recommendations including provision of the method of processing				
Documentation of load release (Quality management)				
Assurance of compliance with the maximum processing cycle parameters per the medical device manufacturer's instructions				
Records of the maximum duration of contamination (time between procedure and the beginning of processing)				
Standard Operating Procedures (SOP's) for all processing activities (Quality Management) including precleaning, transport, storage				

Checklist for Information 2 (Continuation)			
Requirement	**Present**	**Not present**	**Actions/Observations**
Standard Operating Procedures (SOP's) for all processing activities (Quality Management) including precleaning, transport, storage			
Infection control plan for CSSD/Reprocessing including personnel hygiene and infection control, health and safety at work (Quality Management)			
Cleaning and Disinfection Plans			
Workplace cleaning and infection control: Establishment of the observations/tests and their schedule			
Establishment of responsibilities (Quality Management) by the operator for: – Commissioning of validation – Preparation of the validation – Validation attendance – Release of the validation report			
Establishment of responsibilities (Quality Management) by the operator for: – Head and deputy head of CSSD/RUMED = Named persons responsible for the processing of medical devices – Qualifications of staff in the CSSD/RUMED – Process steps releases – Release of infection control plan – Release of standard operating procedures			
Internal staff training (Quality Management)			
Continuing education for ……..... (Quality Management)			
Internal orientation of staff members (Quality Management)			
Contract, in cases of processing for third parties			
Use instructions and medical device books for the washer/disinfector and load carriers			
equipment maintenance plan for the washer/disinfector, load carriers, and accessories			
Data sheets for the process chemicals (product data sheets, safety data sheets, instructions for use)			

Information 3: Chemical Water Quality

Water is an important medium in MD processing and is therefore a deciding factor for a good processing result, both in manual and automated processes. The water quality can influence the lifetime of the materials being processed.

The total dissolved solids measurement provides an indication of the total amount of dissolved residues in the water. A total dissolved solids level that is too high can lead to undesired residuals on the load and in the WD. This aspect is especially critical in the final rinse; thus the use of demineralized water is recommended.

This recommendation also applies to manual processing. If tap water is used for the final rinse in manual processing, manual drying must take place immediately after the final rinse, to avoid possible residuals being dried onto the instruments.

Section 6.4.2 of DIN EN ISO 15883-1 describes a test of the composition of the final rinse water. However, no requirements or limiting values are defined. It is recommended in the scope of the validation of the cleaning and disinfection process, that the type of water be documented that is used for pre-rinse, cleaning and intermediate rinse phases.

Obtaining a water analysis from the water supply company can be an easy way to obtain information about the drinking water used. If the water is treated further inhouse, a chemical analysis at the delivery point is recommended.

The quantities total hardness, total dissolved solids, and chloride content should be measured because of their effects on the pre-rinse, cleaning and intermediate rinse phases of the process.

The following upper limits should be observed for softened water:

- Total Hardness: < 3°dH (< 0,5 mmol CaO/l)
- Total Dissolved Solids: < 500 mg/l
- Chloride level: < 100 mg/l
- pH value: 5 – 8

Use of acidic process chemicals with water with a chloride content of less than 100 mg/l can result in pitting on chrome-steel instruments. In these case, an upper limit of < 50 mg/l chloride is recommended.

Process optimization of the pre-rinse, cleaning, and intermediate rinse phases is best done using demineralized water or at least softened water. Use of demineralized water in the final rinse phase for both manual and automated processing results in spot-free processed goods.

The water quality requirement for pure steam generators is specified in in DIN EN 285, Annex B, Table B1. These can be used as the requirements for demineralized water used in manual and automated cleaning. An accepted deviation from these values for manual and automated cleaning is a conductivity of maximum 15 µS/cm.

The AKI brochure (www.a-k-i.org) provides detailed information and guidance concerning water quality and examination of staining, spotting, etc. ■

Information 4: Process Chemicals

General

Process chemicals for processing of medical devices must be developed, tested and manufactured under the applicable European Medical Device Regulation. Cleaners and lubricants are classified as Class I medical devices, which is signified by a CE mark on the labeling

Process chemicals with disinfection activity are classified in Europe as Class IIa or Class IIb medical devices, which is signified by a CE mark with a four-digit number to identify the certifying Notified Body.

In the development phase of the products, the manufacturer of the process chemicals must specify the composition of the products with regard to the product actions to be achieved, such as, e.g., cleaning performance, disinfecting efficacy, or instrument care properties. The manufacturer must also take into account the product's compatibility with the materials used for the manufacture of the instruments as well as the biocompatibility of possible residues with human tissue at the place of use of the instrument. Material compatibility is usually demonstrated by the manufacturer of the process chemicals in cooperation with the manufacturers of instruments. Biocompatibility of any residues remaining on the medical devices is to be tested and evaluated following DIN EN ISO 10993 "Biological Evaluation of Medical Devices".

Optimum effectiveness and material compatibility of the process chemicals, as well as biocompatibility of any residues remaining on the medical devices, are only guaranteed under the conditions recommended by the manufacturer. The use conditions must be described in detail by the manufacturer, in a detailed product description document, to be made accessible to and to be absolutely observed by the user. Particular attention should be paid to the exact concentration of the process chemicals in use dilution as used in the WD, the working temperature, and the duration of application of the application solution to the medical device.

The product description must include by safety data sheets. Additional items in the product description can include methods for verifying the concentration of the use dilution of the product solution, acceptance limits for process chemical residuals remaining on the medical devices and for the residual quantities in the final rinse water as well as analytical methods for the determination of these residual quantities which are to be made available by the manufacturer.

At the request of the user, the manufacturer can provide confirmation of material compatibility, efficacy, and ecological characteristics, as well as information on the biocompatibility of residual process chemicals.

The safety data sheet lists hazardous substances in the process chemicals and their potential hazards, and provides recommended protective measures for safe handling. These recommendations must be observed by the user.

The ingredients of different process chemicals could influence each other's activity. For this reason, the combination of different process chemicals should only be carried out per the recommendations of the manufacturer. In addition, special attention must be given to the thorough rinsing between cleaning and thermal disinfection.

Process Chemical Types

Pretreatment Agents

Pretreatment agents can be cleaners, corrosion protection agents, or, possibly, antimicrobial, bacteriostatic, or other disinfectant agent. These are used before manual or automated cleaning and disinfection, for example, as a foam spray, an agent to maintain humidification of instruments while in transit from point of use to the CSSD, etc.

Detergents

The use of detergents serves to reduce contamination on a medical device to such an extent as is necessary for further treatment or application.

Detergents are used for both manual and automated processing. The available types of detergents are:

- pH-neutral, enzymatic detergents
- mildly alkaline detergents with enzymes
- alkaline detergents without surfactants
- alkaline detergents with surfactants
- detergents with antimicrobial activity (combined detergents and disinfectants)

Neutralization Agents

Neutralizing agents are typically based upon citric or phosphoric acid. They are used in automated cleaning after the alkaline detergent cleaning phase, dosed into the rinse water, and serve to neutralize the alkalinity of residual detergent and to improve rinsing removal of the detergent.

Final rinse aids

are added into the final rinsing water of a machine process in order to achieve a

better and faster drying. The active ingredients contained in the final rinse aid reduce the interfacial tension of the rinse water and thus minimize adhering residual moisture.

Post-Processing Solutions

Post-processing solutions for metal surgical instruments are used to lubricate rubbing metal surfaces that must be oiled. They are composed of Paraffinum Perliquidum and emulsifiers. Other post-processing solutions, for anesthesia utensils, for example, can be made of silicone oils.

Concentration Determination

Compliance of the user with the concentration of a cleaner or the concentration/exposure time specified by the manufacturer is essential for successful use of the process chemicals.

In order to check the concentration of process chemicals, the manufacturer of the process chemicals must provide appropriate analytical methods.

Determination of Residual Process Chemicals

In order to ensure the compatibility of the processed medical products in interaction with human tissue, the manufacturer of the process chemicals specifies limit values for the residual amounts of these substances on the medical product.

These limit values are determined by the process chemical manufacturer in the course of biocompatibility studies following DIN EN ISO 10993.

In order to verify the compliance with these limit values in the context of the verification per SOP's and in routine checks, instructions and analytical methods must be provided by the manufacturer of the process chemicals.

The application of appropriate and adequately sensitive methods is essential here. For example, the measurement of the electrical conductivity of the final rinse water may not be sensitive enough to detect residual process chemicals that contain substances that do not release ions (i.e. nonionic surfactants). ■

Information 5: Qualification of Existing In-Use Devices

For existing WDs that do not comply with the equipment requirements DIN EN ISO 15883, but are to be qualified for further use, analysis of the current state of the equipment must be carried out. At a minimum, this includes the following:

- Automatic/electronic program control
- Automatic error notifications (amount of water, dosing)
- Can the measurement equipment be calibrated?
- Temperature displays
- Separate sensors for control and monitoring
- Automatic dosing
- Rinse pressure measurement

The results of the analysis of the current state of the equipment must be evaluated. The evaluation provides information as to the capability of the WD to be qualified, to provide a validated cleaning and disinfection process.

A risk analysis following **Information 8 "Risk Analysis for Existing WD Installations"** is to be carried out to determine the scope of the testing (Performance Qualification) as well as additional measures such as the frequency of routine testing. Basically, the same tests must be carried out as for WDs that conform to DIN EN ISO 15883. Additional routine tests can be required, see **Checklist 10 "Matrix for creation of a checklist of routine testing of the WD's technical function"**. For complete information on evaluation of the WD and the frequency of routine tests, see sections 6.3 and 6.4. The following points are provided as examples of the required tests:

Machine Controller

WDs with electro-mechanical or program card controllers do not fulfill the requirements of the standard. For WDs with electro-mechanical controllers, one must demonstrate that control within process parameter limits is possible by other means and can be successfully executed on a repeated basis.

Door Lock

If the WD does not have a door/operational locking system, the manufacturer should be consulted concerning a retrofit. It that is not possible, personnel must be trained (with signature confirmation) that a process interruption may only be carried out after a thorough examination of the current state of the cycle and, if needed, supervisory personnel. Any process interruption must take safety (heat, chemicals, etc.) and the process status (cleaned, disinfected?) into account.

Temperature Sensors

If the WD uses a single sensor for process control and monitoring of the temperature, a weekly or monthly test with an independent measurement system is sensible, with testing frequency depending upon the frequency of use of the WD.

Water Level Regulation

Maintaining a repeatable water level in each use of the WD is important for repeatable rinse pressure and concentration of the process chemicals. If this is dependent upon the building's water pressure (i.e., a timed delivery of water to the chamber), measures to ensure repeatable water level must be taken, either retrofit the WD with an actual level controller or carry out regular tests of the water level reached.

Dosage

If there is no level monitoring for the chemical supply containers, the chemical level must be checked daily. The dosing volume must be observed by a system that is independent of the machine controller on every cycle. Alternatively, external dosage surveillance systems can be installed. ■

Information 6: Test Matrix for Performance Qualification of multiple, identical Washer Disinfectors with the same process chemical supply

Annex 4, "Cleaning tests for performance qualification (PQ)" specifies which cleaning tests are to be used depending upon the loading patterns and medical device types.
In practice, there is often the possibility for consolidated testing, as stated in instruction 5 of Annex 4, "A further reduction in the number and type of studies is possible on the basis of a documented risk analysis and risk assessment if more than two processes and/or loading configurations are checked. The risk analysis and asessment is usually carried out by the operator together with the validator". The use of risk analysis and assessment enables this consolidation without reduction of the quality of the Performance Qualification.
Here are a few recommendations and instructions:

1. The validity of the performance test of the processes in the WD to be tested must be demonstrated. This is done preferentially for the most-difficult program and load by repeating the test twice. Deviations from this are not permissible.
2. Processes with identical process phases can be tested as one. This also applies to use of different amounts of water in specified process phases. The requirement here is that the same process chemicals and concentrations are applied. The load is selected to be the one for which cleaning is considered most critical.
3. If the washer/disinfector uses load carriers with different numbers of levels (1, 2, 3, 4, or 5 levels) with the same wash program, the PQ can be run for the load carrier configuration in which the rinse pressure is the lowest (normally the one with the most levels). The type testing of the manufacturer will provide indication of this. The remaining load carriers will only be tested for rinse functionality (rise pressure, spray arm revolutions per minute).
4. If multiple identical washer/disinfectors, i.e. identical types are to be tested, the number of loads tested may be reduced, subject to the following conditions:

- Identical program execution for similar load carriers and loading patterns.
- Identical process chemicals and concentrations
- All washer/disinfectors are installed in the same area of the building
- All washer/disinfectors are connected to the same utilities and process chemical supplies

Instructions:

- At least three loads must be tested in each washer/disinfector, of which at least two loads must contain critical instruments (group 2-7).
- Allocation and frequency of testing of load carriers and loading patterns must be based on the results of risk assessment of the cleaning of medical devices.

The following example allocation may be used for five or 10 washer/disinfector units installed in the same part of a building

Overview – Example for 5 washer/disinfectors								
Programs for the following medical device types		Allocation of the test loads					Test loads per program	Remarks
		WD 1	WD 2	WD 3	WD 4	WD 5		
1	Instruments with/without hinges and without hollow spaces	1	1	1			3	Load carrier with the lowest pressure (type test of the WD manufacturer)
2	Shift-shaft instruments/tubular shaft/ instruments with hollow spaces		1	1	1	1	4	
3	Microsurgical instruments with filter	1			1	1	3	
4	Anaesthsia equipment/plastics	1	1	1			3	
5	Utensils/bowls/containers (1/2 and 1 STU)				1	1	2	
	PQ loads per WD	**3**	**3**	**3**	**3**	**3**		

Overview-Example for 10 washer/disinfectors												
Programs for the following medical device types		Allocation of the test loads									Test loads per program	remarks
		WD 1	WD 2	WD 3	WD 4	WD 5	WD 6	WD 7	WD 8	WD 9	WD 10	
1	Instruments with/without hinges and without hollow spaces	1	1	1			1	1	1	1	1	8	Load carrier with the lowest pressure (type test of the WD manufacturer)
2	Shift-shaft instruments/tubular shaft/ instruments with hollow spaces			1	1	1	1	1	1	1	1	8	
3	Microsurgical instruments with filter	1	1		1	1				1	1	6	
4	Anaesthsia equipment/plastics	1	1	1	1							4	
5	Utensils/bowls/containers (1/2 and 1 STU)					1	1	1	1			4	
	PQ loads per WD	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**		

Information 7: A_0 Value Concept of DIN EN ISO 15883

In thermal processes, the disinfection efficacy can be determined parametrically. To do this, the F-value concept used in moist heat sterilization has been adapted to moist heat washer-disinfector processes and incorporated into the standard, DIN EN ISO 15883 as the A_0 Value concept.

It is expected that in a moist heat disinfection process, application of a specified temperature over a specified time will provide a predictable lethality against vegetative microorganisms. A minimum temperature of 65 °C is specified for this model. The critical criterion for the required temperature effect is the heat resistance (thermal resistance) of the microorganisms present. This is expressed as the D value.

Explanations/notes on the Ao value in relation of temperature and time

Holding Time		Temperature	A_0 value
Minutes	Seconds	(°C)	
100	6.000	70	600
10	600	80	600
1	60	90	600
50	3.000	80	3.000
5	300	90	3.000

Terms

A: Time equivalent in seconds at 80 °C at which the required disinfection efficacy is achieved

A_0 value: Inactivation as a time equivalent in seconds at 80 °C transmitted to the product by the process, relating to microorganisms for which z = 10

z value: Temperature change in Kelvin needed to change the D-value by a factor of 10.

D value: Decimal reduction value, time in minutes at a specified temperature that is required to inactivate 90% of a population of a microorganism.

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

The calculation of this formula is usually done by logger software after reading the data from the logger into the PC. A_0 is the value at which z = 10, t is the selected time interval in seconds, T is the temperature in the load in degrees Celsius.

If the A_0 value is calculated at a low temperature, it must be noted that a lower temperature limit of 65 °C has been set for the integration because the z- and the D-values can change dramatically for thermophilic organisms at temperatures below 65 °C. A variety of microorganisms can actively replicate at temperatures under 55 °C.

Required A_0 Values

The A_0 value to be achieved depends on the type and number of microorganisms on the contaminated medical devices as well as on its subsequent further treatments and/or the subsequent use. The operator is responsible for ensuring that the requisite A_0 value be realized. The decision is made in cooperation with the infection control consultant responsible for the healthcare institution.

A_0 value 3000

In the case of medical devices that are or can be contaminated with heat-resistant viruses (usually medical devices of the semi-critical and critical groups), e.g., hepatitis B virus (HBV) an A_0 value of 3000 is to be applied per the RKI. This can be achieved by the effect of hot water, for example at 90 °C. for 5 min. on the surfaces of the medical devices. Since the number and type of microorganisms on the medical device which is being treated cannot be known, and can also be very different, automated decontamination should always be carried out with an A_0 value of 3,000. The killing or inactivation of pathogens, including HBV, must also be ensured for medical devices for which subsequent sterilization is necessary, for reasons of personnel protection (e.g., safety during assembly/testing/packaging). *

A_0 value of 600

The application of an A_0 value of 600 is regarded as the minimum in non-critical medical devices, i.e., medical devices that only come into contact with intact skin. A prerequisite for the application of the A_0 value of 600 is also that only a contamination with vegetative bacteria and fungi is present, which corresponds to the activity range A of the definitions in the RKI list.

* In the RKI list, the longer exposure time of 10 min. is used for activity range B (see RKI list). The procedures set out there have been established to provide generally-applicable disinfecting measures. These are intended to be comprehensively effective and to provide an additional safety margin against previously unknown pathogens.

Information 8: Risk Analysis for Existing Washer/Disinfector Installations

A risk analysis is designed to identify and evaluate potential hazards. The assessment includes estimation of the probabilities of discovery and occurrence. A formal risk analysis is required for an estimation of risk, its acceptability, and the need for determination of means for its reduction and minimization. In the context of this guideline, risk analysis relates exclusively to process safety. The basic procedure of risk analysis is standardized, but each specific case must be analyzed individually. Various methods of risk analysis are known. One is described in DIN EN ISO 14971.
The following example is based on the structure described in DIN EN ISO 14971.

Risk analysis: Identify hazards/estimate risks for each hazard

For the following example: "missing pressure monitoring and documentation" this is demonstrated in a step-by-step manner.

What can happen?

– Unnoticed rinse pressure drop due to foaming substances (like too much blood on the instruments, carryover of precleaning chemicals, residual chemistry from a previous cycle, etc.) resulting in irreproducible or erratic rinse mechanics and impingement.
– Unacceptable cleaning and disinfection result

Risk asessment:

– Is this risk acceptable, or is it required to install risk reduction measures?
– The risk that results from a negative deviation to the rinse mechanics and impingement must be minimized. A simple heat pressure switch does not compensate for this risk. Minimization measures are required!

Minimization measures can be either implemented in machine design or by training. Design solutions are to be preferred.

– Test if a retrofit is technically possible and economically justifiable
  • The retrofit is economically justifiable and possible
  • The retrofit is not possible with justifiable means

a) For washer/disinfectors with windowed doors, and the load is only cleaned by the spray arm, with no hollow instruments in the load:
  • Documented training as well as written instructions on how to visually monitor the spray arm activity
  • Instructions to monitor every load affixed to the washer/disinfector-
  • A positive result of the monitoring is to be documented for every load.
  • Pressure check has to be carried out every two weeks.

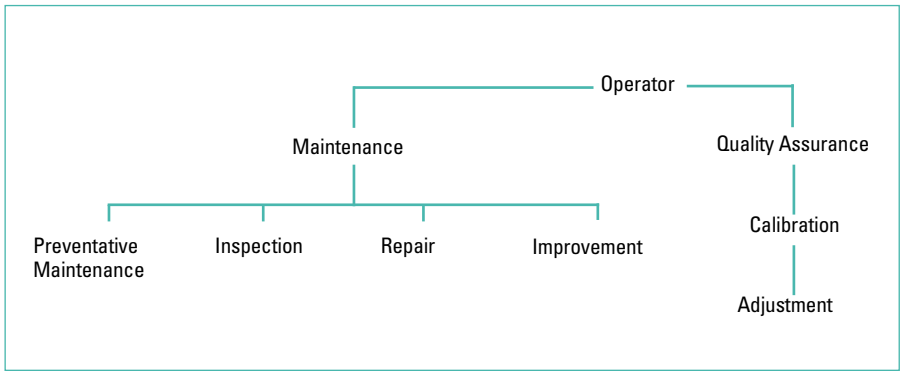
b) If hollow instruments are being processed and/or there is no window in the door:
  • The rinse pressure is to be measured and recorded by an independent measurement system, e.g., datalogger in a representative location (e.g., on a connection for a hollow instrument on the load carrier)
  • The staff members must have documented training and instruction in the measurement procedure.

Risk control:

Evaluate the adequacy of the measures taken to reduce the risk. The newly installed measures must not lead to any other hazard. ■

Information 9: Definitions for Maintenance, Calibration and Adjustment

Maintenance includes various elements, which are defined below. The operator is responsible for the maintenance.



Maintenance (DIN 31051: Preventative Maintenance – Inspection – Repair – Improvement)

Combination of all technical and administrative measures as well as measures of the operator during the life cycle of a WD to maintain the functional state or the return the WD into functional state so that they can fulfill the required function.

Service

Measures for delaying the decomposition of the existing wear stock (wear), caused by chemical and/or physical processes, friction, corrosion, fatigue, aging, cavitation, fracture and so on.
Wear is unavoidable. Preventive measures (such as inspections and maintenance) are carried out in order to take action before an error occurs. These activities can be time-based. However, strategies are also used that are based on other criteria (such as maturities, unit numbers). A typical example is the change of the dosing hoses at fixed intervals.

Inspection

Documented measures for the identification and assessment of the actual state of the WD, including the recommendation of measures to be implemented for future use.

Repair

Measures for the return of an WD to its functional state, except of improvements, such as software updates or structural changes.es.

Improvement

Combination of all technical and administrative measures as well as measures to increase the functional reliability of a WD without changing the required function. An improvement, for example with the aim of eliminating weakness, does not lead to a change in the function.

Calibration/Adjustment (DIN 1319 – 1)

Calibration

Activities for identifying the relationship between the output values of a measuring device or a measuring system or the values represented by a measuring graduation or by a reference material and the associated values of a measured variable determined under normal conditions under specified conditions.

Note:

The result of a calibration can be recorded in a document, which is also called calibration certificate or calibration report.

Adjustment

Adjusting and calibrating a measuring device to eliminate systematic measurement deviations as far as is necessary for the intended application.

Remarks/explanations for practical operators:

Calibration does not affect the measuring device or the measuring chain.
During the adjustment, an intervention is made, which permanently changes the measuring device or the measuring chain.
The calibration values are always to be adjusted so that the calibration values do not have to be added manually for each release according to physical parameters (temperature / pressure), especially if the deviations are significant!
Calibration and adjustment are instruments of quality management and quality assurance. Therefore, they are not automatically part of the maintenance (inspection, maintenance, repair). ■

Information 10: Measurement of the pH values of the final rinse water for washer/disinfector processes

In over 85% of washer/disinfectors in German CSSD's demineralized water is already used in the cleaning phases of the cycles. In the final rinse, this rises to a level of over 95%. The quality of this demineralized water is specified as having a maximum conductivity of 15 µS/cm. In many CSSD's, the quality is much higher, with conductivities of <5 µS/cm.

In the framework of validation and performance qualification, the degree of carryover of process chemicals into the final rinse must be tested in order to assure that the remaining amounts on the medical devices after the rinse cycle are within acceptable limits (see **Information 4: "Process Chemicals"**). Process chemical manufacturers provide acceptance limits for conductivity for each specific product. These acceptance limits are set based upon toxicological testing that shows them to have no toxicological effect on instrument use when not exceeded in the final rinse water. The difference between the conductivity of the demineralized water used in the process phase and the conductivity of the final rinse water at the end of a complete process with normal instrument loading is the quantity to be assessed for compliance.

The pH value of the final rinse water is often measured. The pH value of demineralized water with a conductivity of <10 µS/cm has no meaning, and is no measure of the quality of demineriled water. pH measurements require the presence of ions in the water, and thus is inaccurate at low conductivities. This is true for both electrode measurements as well as for pH paper and dipstick testing.

pH measurements are used, in particular, for the processing of ophthalmological instruments in processes with alkaline cleaners. Corneal or ocular damage due to alkaline etching occurs only at concentrations in the range of > 0.05 N sodium hydroxide solution, where the conductance is already very much greater than 100 µS/cm (endnote 1). Large carryovers of this magnitude are not possible in the washer/disinfector in the case of a correctly executed process, but are limited possible in narrow cannulae due to blockage by particles in the wash water. Instruments of this type can be checked for residual detergent by blowing through them with medical-grade compressed air onto pH paper or pH stick. This procedure has been shown to result in a correct indication (endnote 2) in potentially harmful concentrations. ■

1. Bolkova A, Cejkova J. Relationship between various concentrations of NaOH and metabolic effects in experimentally burned rabbit cornea. Graefe's Arch Clin Exp Ophthalmol 1984; 222: 86–89
2. Personal communication, Merck Millipore Lab Essentials