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Guideline Compiled by the DGKH, DGSV and AKI for Validation and Routine Monitoring of Automated Cleaning and Disinfection Processes for Heat-Resistant Medical Devices as Well as Advice on Selecting Washer-Disinfectors

DGKH

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Krankenhaushygiene
(German Society for Hospital
Hygiene)

DGSV

Deutsche Gesellschaft
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(German Society for Sterile
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(Working Group Instrument
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Preface to 2nd Edition of Guideline Compiled by DGKH, DGSV and AKI

The automated cleaning and disinfection process is a component of the overall procedure used to decontaminate medical devices.

Compliance with the prescribed specifications and quality assurance measures relating to this step is an indispensable prerequisite for continually assured sterilisation.

Validated decontamination, in line with the dictates of quality assurance, is stipulated by the Medical Devices Directive (MDD) and by the national legislation based on this.

In the past, the paramount importance of standardised cleaning was not fully taken into account or given the attention it deserves.

The aim of this Guideline is thus to bridge this gap. Hence specialists, including operators, are called upon to reappraise their

views and there is a need for qualified personnel and investments. This Guideline is intended as a practical guide to effect this. By no means should it be used as a decision-making source to be invoked to settle disputes with legal consequences. Attention is drawn to the pertinent standards and laws in such cases.

Before its publication, this Guideline for validation of cleaning and disinfection processes was presented at the 10th Congress of the German Society of Sterile Supply (DGSV) in Potsdam and discussed in depth with the experts present. The insights gleaned from the Guideline's first year of application in everyday practice have been taken into account wherever relevant. ♦

The Guideline's team of authors

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1. Principles

Quality assurance in medical device (MD) processing is not only a legal obligation, it has also important implications for economic efficiency. The prevention of nosocomial infections poses an interdisciplinary challenge for all parties involved. The materials and construction of the MDs must be selected to enable automated processing. To assure process safety, the washer-disinfector must guarantee reliable processing. Personnel entrusted with processing must have the requisite knowledge and qualifications to ensure proper processing.

This Guideline is intended for all establishments in which MDs for use on humans are processed.

The following principles apply for processing:

- Automated processing is to be strongly preferred over manual processing, which is to be avoided except where absolutely necessary.
- Efficient cleaning is a precondition for efficient disinfection and, if applicable, for ensuing sterilisation.
- Thermal disinfection processes must be given precedence over chemical disinfection processes.
- The operator is responsible for ensuring that validation and performance requalification are carried out.
- The operator is responsible for conductance of the periodic routine checks defined and documented within the

framework of validation and of performance requalification.

- The operator is responsible for ensuring that personnel entrusted with processing have the requisite expertise.
- The operator is responsible for setting up and maintaining a quality management system.
- If a process parameter is changed (e.g. change of process chemicals, change of programme), performance requalification must be carried out.

2. Legal and Normative Background

Medical device establishments are obliged to conduct medical device processing following the dictates of quality assurance as imposed directly and indirectly by the relevant acts, regulations, standards, directives and recommendations.

2.1 Laws and Directives

All service providers within the healthcare sector are obliged to participate in quality assurance measures aimed at enhancing the quality of the results achieved. To that effect, they must set up an in-house quality management system and continue to develop this (Sections 135–137 of Book V of the German Code of Social Law (Sozialgesetzbuch)). This, of course, holds true for the entire domain of MD processing because a reproducible quality management system can be implemented only on the basis of validated processes.

The Protection against Infection Act (Infektionsschutzgesetz – IfSG) calls for the compilation of Infection Control Plans (Hygiene Plans). Processing, including all control measures and checks, must be defined in these plans.

- The **German Medical Devices Act (Medizinproduktegesetz – MPG)** regulates the requirements for functional and hygienic safety of MDs.
- The **German Medical Devices Operator Ordinance Medizinproduktebetriebsverordnung – MPBetreibV** requires, in Section 4(2), validation of cleaning, disinfection and sterilisation processes.

The “Principles of Prevention” (Grundsätze der Prävention – BGV A1 – this is a document relating to health and safety in the workplace compiled by the Employers’ Liability Insurance Association) and BGR/TRBA 250 “Biological Agents in the Healthcare Sector and in the Welfare Services”

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stipulate special precautions and behavioural approaches for healthcare personnel that run the risk of contracting infection from pathogens. Since automated processing methods are far better able to meet the demands advocated in TRBA for protection of personnel against infection, the introduction of validated automated processing methods ensures that the dictates contained in TRBA are also being fulfilled.

2.2 Standards, Guidelines and Recommendations

Standards, guidelines and recommendations (guidelines and standards) embody the generally accepted stock of scientific knowledge and state of the art.

The RKI recommendations neither have legal character nor do they serve as administrative regulation. They do, however, represent a recommendation based on a consensus reached by specially qualified experts in connection with Federal hearing proceedings.

The standards, directives and recommendations that are important in the context of this present Guideline are:

- The joint recommendation of the RKI and BfArM governing hospital hygiene and infection prevention: "Hygiene requirements for processing medical devices". It calls for quality management as well as for validated processes for processing reusable MDs.
- The standard EN ISO 15883 expresses and defines the requirements for washer-disinfectors as well as for validation of processing procedures in concrete terms.
- DIN EN ISO 17664 specifies the types of information to be provided by the manufacturer for processing medical devices.

3. Scope

This Guideline applies to validation, performance requalification and routine monitoring of processing procedures based on thermal disinfection in washer-disinfectors for heat-resistant MDs pursuant to EN ISO 15883-1 and -2, while additionally taking economic efficiency and practical relevance into account.

By complying with EN ISO 15883-1 and -2 the basic requirements of the Medical Devices Act (MPG) are fulfilled. Only a technical specification (ISO/TS 15883-5) has been published so far with regard to test soils, which does not have the same binding character as the aforementioned standards. This guideline has therefore been compiled to provide a basis for practical quality assurance.

This Guideline is intended for all centres in hospitals and medical practitioners' offices in which MDs for use on humans are processed. It also applies to medical laboratory and pharmaceutical establishments as well as to piercing studios and medical footcare establishments.

The Guideline is valid for both those washer-disinfectors which conform to and which do not conform to the pertinent standards.

In addition, the Guideline is intended as an orientational aid for buying new washer-disinfectors.

4. EN ISO 15883: Structure and Requirements of the Standard

4.1 Basic Requirements

The EN ISO 15883 standard series stipulates general performance requirements for washer-disinfectors and accessories intended for cleaning and disinfection of MDs in medical, dental and pharmaceutical practice. It consists of:

- Part 1: "General requirements, definitions and tests for washer-disinfectors"
- Teil 2: "Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, containers, 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 heat-sensitive endoscopes"
- Part 5: Technical specification "Requirements for test soils"

4.2 Definitions

Acceptance Test

The acceptance test comprises installation qualification and parts of operational qualification. Conductance of this test is a condition for handing over the washer-disinfector from the manufacturer to the operator.

Installation Qualification (IQ)

Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

Operational Qualification (OQ)

Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

Performance Qualification (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.

Note: This means that the cleaning and disinfection process furnishes products that are cleaned, disinfected, rinsed and, if applicable, dried as required by the pertinent standards.

Performance Requalification

Complete or partial repeat of the validation tests (IQ, OQ, PQ) to confirm process reliability.

Process Chemicals

Formulation of chemical compounds intended for use in a washer-disinfector.

Test Instruments (or test devices)

Uncontaminated predefined instruments or devices, e.g. Crile clamp.

Challenge Device

is a test instrument or test device which has been contaminated with a test soil.

Qualification

Qualification is the evaluation or determination that the equipment and its accessories are operational. This is required before a performance qualification can be conducted.

Risk Analysis

Risk analysis investigates potential sources of faults, the probability of faults occurring and the possibility of detecting such faults prior to malfunctioning of equipment. Measures to mitigate faults shall be taken following this evaluation.

Routine Check

The routine check comprises periodic checking and testing of proper function during the time between performance re-qualifications.

Test Device

or test instruments are uncontaminated predefined instruments or devices, e.g. Crile clamp.

Type Test

The manufacturer is responsible for conductance of the type test. It entails a risk analysis to delineate or evaluate the risks and furnish proof that the washer-disinfector complies with EN ISO 15883. This constitutes the basis for compilation of reference data for subsequent tests.

Note: *The tests conducted with test soils provide insight into the probability of achieving this performance in everyday practice for the intended field of application.*

Validation

Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with pre-determined specifications.

For washer-disinfectors validation comprises installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) conducted for equipment which, as documented by the manufacturer, complies with the requirements of the standard.

5. Validation

5.1 Prerequisites for Validation

In order to be able to conduct validation of cleaning and disinfection processes, the operator as well as the manufacturer of the washer-disinfector and of the process chemicals must meet certain preconditions. The complete evaluation of validation can only be conducted if all prerequisites are met.

5.1.1 Structural and Technical Prerequisites at Operator's Premises

Before any other work is undertaken, the constructional and structural prerequisites must be verified and any upgrade carried out. The most important point here is to ensure that the clean area is separated from the decontamination area. The rationale behind this is to ensure that no microorganisms or particles can be transmitted from the decontamination area to the clean area. If the decontamination area cannot be separated from the clean area, suitable organisational measures must be taken to ensure that transmission of airborne/aerosolized microorganisms and particles is minimised. Validation can be conducted only after the washer-disinfector has been installed according to the manufacturer's installation plan, has been connected and is ready for operation and all operating materials of the requisite quality are available.

Checklist 1, "*Structural and Technical Prerequisites at the Operator's Premises*", gives an overview.

5.1.2 Organisational Prerequisites at Operator's Premises

Quality assurance measures are the most important prerequisites to be fulfilled for validation of a cleaning and disinfection process. A quality management system is required.

Before commencing validation, risk evaluation and classification of MDs as per the "Hygiene requirements for processing MDs" formulated by the Robert Koch Institute (RKI) must be carried out.

Checklist 2, "*Organisational Prerequisites at the Operator's Premises*", gives an overview.

5.1.3 Information to be Provided by Washer-Disinfector Manufacturer to Operator

A further prerequisite for validation of a washer-disinfector is that the washer-disinfector manufacturer must provide the operator with certain types of specifications and information.

Checklist 3, "*Information to be Provided by Washer-Disinfector Manufacturer to Operator*", gives an overview.

5.1.4 Information to be Provided by Operator to Washer-Disinfector Manufacturer/Supplier

The operator must provide the following information:

- special requirements for the process as a result of statutory dictates or special factors relating to the items to be processed
- Conditions prevailing at the installation site (see 5.1.1)
- Information from the MD manufacturer relating to processing (EN ISO 17664)
- Quality of the operating materials (e.g. water); information on water qualities is available in Annex 4, "*Water Qualities*".

5.2 Validation

Since the publication of EN ISO 15883, new installations of washer-disinfectors shall place into operation only those washer-disinfectors that have passed a type test per the requirements of EN ISO 15883. This constitutes a precondition for conformity assessment and CE marking of washer-disinfectors pursuant to the Medical Devices Act (MPG), and is checked and confirmed by the Notified Body. Validation of such washer-disinfectors can be conducted without resorting to additional risk analysis for this equipment.

Validation comprises installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). The operator is responsible for ensuring that validation is carried out. This can be done only at the site of use.

Validation may be conducted only by persons who have the requisite expertise by virtue of their specialist training and practical experience as well as their knowledge of the pertinent acts, standards and directives. The persons entrusted with validation must have at their disposal the requisite measurement and test equipment and know which methods to apply. The qualifications necessary for persons entrusted with validation are stated in Annex 1.

Validation must be carried out using recognised methods while observing the dictates of quality assurance.

If processes are to be validated for washer-disinfectors that are already in operation (but which were not subjected to a type test as per EN ISO 15883), extra

tests may be needed. These must be determined for each specific washer-disinfector (see also 5.2.4).

5.2.1 Installation Qualification

Installation qualification is carried out to ensure that

- the washer-disinfector has been properly delivered and installed
- the available utilities meet the specified requirements

The tests and control measures to be carried out as part of installation qualification must be specified, conducted and the results documented.

The tests and control measures to be conducted include but are not limited to the following.

- Verification of the order and delivery (check inventory, in the case of installations already in place):
 - Washer-disinfector (correct design and options)
 - Base/floor-level tank
 - Drying unit
 - Steam condensation/ventilation facility
 - Trolleys for transporting supplies to and from CSSD
 - Loading trolleys/trays, inserts as well as nozzles/adapters
 - Installation plan, operating instructions and any other documentation
- Verification of connections and supplies, bring into line with installation plan
 - Electricity
 - Water hot/cold/demineralised
 - Steam
 - Sanitary drain
 - Exhaust/air removal

Checklist 4, "Installation Qualification", gives an example.

5.2.2 Acceptance Test and Parts of Operational Qualification

The acceptance test (see Checklist 5 „Acceptance test and parts of operational qualification“) comprises installation qualification and parts of operational qualification. Tests already conducted within the framework of the acceptance test need not be repeated for the operational qualification if the acceptance test had

been carried out within the preceding 6 weeks.

Operational qualification is carried out to ensure that the washer-disinfector and supplies meet the manufacturers' specifications and the requirements of EN ISO 15883.

The tests and control measures to be carried out as part of operational qualification must be specified, conducted and the results documented.

The tests and control measures to be conducted include but are not limited to those in Checklist 6, "Operational Qualification Tests, Control, Measures".

5.2.3 Performance Qualification

Specification and documentation of the requisite programmes with corresponding process sequences constitute a precondition for performance qualification. The process definition must include the preconditions applicable to cleaning. A detailed description of the process must be given, while also giving a detailed account of the chemical products to be used.

Checklist 7, "Performance Qualification – Define and document programmes", can be consulted as a guide.

As part of performance qualification the cleaning and disinfection programmes specified for the reference loads are checked and the results documented to ensure that, while observing these specifications, reproducible results are continually obtained, i.e. the process must continually meet the given specifications. Each reference load must contain instruments bearing the contaminants typically encountered in routine operation as well as reflecting critical design features. The reference load is to be documented.

Reference loads shall consist of the items processed in the respective establishment. All operators do not need to test all example items if they are not used in the facility. Other reference loads (e.g. mixed loads) can be defined and documented. Any pre-treatment measures, e.g. preliminary cleaning tasks, must be documented.

Examples for medical devices with different degrees and types of contamination:

"Average degree of contamination"

General surgical instruments used for incision surgery in the fields of visceral sur-

gery, urology, gynaecology, ear, nose and throat surgery (ENT, dermatology, paediatric surgery, etc.

"MIS"

Instruments employed in minimally invasive surgery in various disciplines

"Stubborn contaminants"

Instruments used in orthopaedic and/or trauma surgery, craniotomies, etc. These have a heavy load of intraoperative soils, e.g. tissue residues or bone meal; in most cases, drilling systems must also be processed.

"Microinstruments"

Microinstruments used in ophthalmology, neurosurgery, ENT and other disciplines

"Anaesthesia"

Respiratory tubes, respiratory masks and other MDs made of heat-resistant synthetic materials

5.2.3.1 Verification of Cleaning

5.2.3.1.1 Methods for Verification of Cleaning

- use of test devices (Crile clamp) with a defined soil = test device (A) to make a comparison with a defined cleaning performance for loads with surgical instruments
- instruments contaminated in everyday use (B, C, D) for comparison with a practice oriented load (i.e., instruments soiled in real use) and for verification of cleaning for instruments/devices of various designs (e.g., lumened devices).

(A) Test devices

In order to be able to make a comparison with the required minimum performance when carrying out performance qualification on site, the first method adds instruments with a defined soil (prepared as per standard instructions in a qualified laboratory) to the reference load.

However, the test soils and methods to which the standard EN ISO 15883 refers for verification of cleaning of surgical instruments does not list all aspects relating to quantification, standardisation and practical relevance. The authors of this Guideline believe that there is an urgent need to use test soils that can be compared with representative contaminants encountered in everyday practice. Here a

consensus was reached to use heparinised sheep blood, to which protamine sulphate was added as an anticoagulant.

(B) Instruments contaminated in Everyday Use

The practice oriented performance check involves inspection of instruments contaminated in everyday use which are included in the defined reference loads. Accordingly, attention is also paid to the conditions prevailing in the following settings which might have implications for cleaning: in the surgical departments, during transportation of supplies to the CSSD for processing, any pre-cleaning measures and the load.

(C) Hollow Devices

Depending on the type of hollow devices used, the instruments to be evaluated will be jointly selected by the validator and by the operator.

It is advisable to evaluate the instruments that are most difficult to clean. In hollow devices of a modular construction, the innermost lumens will be checked. To effect this, evaluation will be conducted as for instruments contaminated in everyday use (B).

(D) Anaesthesia equipment and other medical devices, which are not used directly on or in humans (e.g. containers, bowls)

Depending on the type of medical device, reference loads and the extent of evaluation will be jointly determined by the validator and by the operator.

5.2.3.1.2 Determination of Reference Loads and Procedure

Each programme used must be tested at least once.

To assure verification of cleaning, at least three batches with the same or different reference loads have to be tested.

Loads including hollow devices (MIs or ophthalmologic instruments) must be tested. For each load, at least three different hollow devices must be tested (e.g. Verress needle, shaft of MIS scissors, suction tube). Annexes 2 and 3 must be observed regarding the procedure for evaluation of hollow devices.

The instruments to be used are those contaminated with everyday soils and are representative of exposure to all prevailing influences (B, C, D).

After the maximum period of time allotted for transportation of used supplies

to the CSSD for processing, the instruments are placed on the loading trolley in a specified loading pattern. While doing this, each medical device will be individually inspected. Any instruments or parts of instruments that are visibly contaminated will be documented (taking digital photos, as applicable) and marked. For each programme run, an additional load with a defined contaminated test instrument (A) is used for each tray, using at least five per programme run. The washer-disinfector cycle will be interrupted just prior to the disinfection step, and the marked instruments and the test instruments will be withdrawn for evaluation and assessment.

Note: To ensure recovery, instruments and test devices may also be withdrawn at the end of the process.

To protect against infection, provision must be made for thermal disinfection of the reference load as well as of the test instruments once the cleaning results have been evaluated.

For information on checking the test devices please consult Annex 2, "Description of Method for Verification of Cleaning", and Checklist 8, "Verification of Cleaning".

5.2.3.1.3 Evaluation

(A) Test devices

The cleaning results obtained for the test instruments are evaluated visually initially, and these results documented. The test instruments must be clean under visual examination. Following this, all test instruments must be checked for protein residues using a protein detection method of at least a semi-quantitative nature (see Annex 2 and 3). If residues of an unclear origin have been detected during the visual evaluation, the protein detection method is used to differentiate between test soil residues and corrosion. Corrosion does not serve as an evaluation criterion.

In practice, the biuret/BCA method can be carried out on site.

Note: In addition to the aforementioned protein-analytical methods for determination of residues, these investigations can also be carried out with other physical/ chemical detection methods able to furnish equally sensitive, quantitative results.

(B) Instruments with Everyday Soils

The cleaning results obtained for marked instruments bearing everyday soils are visually verified and documented. If residues of an unclear origin have been detected during the visual evaluation, protein detection methods may be used to differentiate between test soil residues and corrosion. Corrosion does not serve as an evaluation criterion.

(C) Hollow Devices

For hollow devices, protein detection has to be carried out in the predetermined number of instruments. Each instrument will be photographed as part of the evaluation.

(D) Anaesthesia equipment and other medical devices, which are not used directly on or in humans (e.g. containers, bowls)

In these medical devices, removal of the everyday soils will be visually evaluated.

5.2.3.1.4 Assessment

(A) Acceptance criteria for test instruments

All test devices must be visually free of test soil.

	Protein per test device
Limit value	> 200 µg must not be reached/exceeded
Alarm value	> 100 – ≤ 200 µg
Acceptable value	≤ 100 µg

(B and C) Acceptance criteria for Instruments with Everyday Soils

All instruments must be visually clean.

	Protein per Instrument
Limit value	> 200 µg must not be reached/exceeded
Alarm value	> 100 – ≤ 200 µg
Acceptable value	≤ 100 µg

(D) Acceptance criteria for Anaesthesia equipment and other medical devices, which are not used directly on or in humans (e.g. containers, bowls)

All instruments must be visually clean.

5.2.3.1.5 Measures taken due to Assessment

If performance qualification furnishes different results from those obtained for the type test, a solution must be found by all parties concerned. The causes for these

discrepancies have to be determined and eliminated. Qualification of the problem and its solution have to be documented in the validation protocol.

Visual contamination

Discontinue operation of washer-disinfector immediately for the failed reference load (load configuration). Operation shall be discontinued until performance has been optimised, taking into account all relevant process parameters and before evaluation is repeated. Only after successful cleaning, i.e. removal of all visible contamination, is performance qualification complete.

Exceeding the limit value

Discontinue operation of washer-disinfector immediately for the failed reference load (load configuration). Operation shall be discontinued until performance has been optimised, taking into account all relevant process parameters and before evaluation is repeated. Only after successful cleaning, i.e. removal of all visible contamination, is performance qualification complete.

Reaching the alarm value

Operation of washer-disinfector for the assessed reference load (load configuration) may be continued. Measures to achieve the acceptable value must be immediately determined, implemented and demonstrated by repeat evaluation using test devices. Until then, performance qualification is deemed incomplete.

Note: *If certain trays account for the reaching of the alarm value (e.g. trays with narrow meshes or holes), corrective measures may be limited to these trays.*

Compliance Achievement of the acceptable value

No measures needed.

Checklist 8, "Verification of Cleaning", can be used for documentation purposes.

5.2.3.2 Verification of the Cleaning Pressure

For all test loads the cleaning pressure must be measured and documented throughout the entire process at a designated site within the respective loading trolley (the connection to a cleaning nozzle for hollow instruments is particularly suited to this purpose; it may be necessary to make alterations to the cleaning water supply pipe in the loading trolley). Devia-

tions of $\pm 20\%$ of the mean value must not occur during a process step involving cleaning (precleaning or cleaning cycle). If the WD is equipped with two circulation pumps for cleaning water supply to the loading trolley and integrated cleaning arms, in addition to the measurements carried out on the loading trolley the cleaning pressure must also be measured at either the pump head of the pump supplying the integrated cleaning (rotary) arms or, at least, the rotational speeds of the cleaning arms must be measured and documented. The rotational speeds must be within the range of 25 to 45 revolutions per minute (rpm) and must not deviate by more than ± 5 rpm in the cleaning step used for the various test loads.

Furthermore, the temperatures measured during the cleaning cycle must be within the range of ± 5 K of the set temperatures.

Pressure or rotational speed deviations outside of these limits must be evaluated, and it may be necessary to check the alterations made to the measuring system, prefill the adaptation connection with water, check for entrainment of foam-inducing substances with the instruments because of pretreatment measures, check for adequate precleaning or check and correct the water level used for the cleaning cycles.

5.2.3.3 Verification of Disinfection

Temperature measuring systems complying with the requirements of the pertinent standard (see EN ISO 15883-1, point 6.8) must be used to verify the results obtained for thermal disinfection; these systems must be equipped with facilities for recording the measured values. The sensors are placed between the instruments and near the washer-disinfector's own measuring points. In addition, measuring points must be selected on the load carriers and on the chamber walls. The sites of high risk, i.e. those locations at which the process temperature is reached last, can be found by consulting the type test or previous tests. If the measured values furnished by the temperature sensors do not agree with the values displayed on the washer-disinfector, the reason for these discrepancies must be investigated and eliminated.

It is recommended that at least two cycles

using six sensors in each case or three cycles using four sensors in each case be checked for each reference load.

Please consult Checklist 9, "Positioning of Temperature Sensors", for information on positioning the sensors.

The target values to be reached are based on the A_0 value requirements in conjunction with the specified disinfection temperature with a tolerance of $-0/+5$ K (temperature range). If the A_0 value t is calculated by integration, the sensors' tolerance as well as the permissible temperature deviation of 2 K have to be deducted from the temperature data used in the integration.

The A_0 concept is described in Annex 5, "A₀ Concept of EN ISO 15883".

The temperature profile during the holding time of the temperature dependent process steps has to coincide in two measured cycles within the range of $\pm 2,5$ K.

It is not necessary to verify the disinfection performance with biological indicators since the disinfectant action is assured by the effect of the water temperature for a defined period of time.

5.2.3.4 Verification of Drying

Drying is to be verified for all relevant reference loads. The items processed are removed from the washer-disinfector and placed on an even surface on coloured crepe paper. The moisture contained in the load will be visible on the crepe paper.

For hollow instruments, dry air is blown through the lumen onto a mirror in order to detect residual moisture. The results are to be documented.

Evaluation

Tests in which residual moisture leaks or flows out of the instrument are rejected. Residual moisture is tolerated at contact sites.

Measures to be taken in case of rejection

The goal is technical improvement. If this is not possible, the rejected goods have to be redried.

Performance qualification will be deemed incomplete if any of the results are rejections.

In case of adjustments the drying results have to be reverified within the scope of performance qualification.

5.2.3.5 Verification of Rinsing/Process Chemical Residues

For medical devices that have been processed according to prescribed methods in the washer-disinfector any residual quantities of process chemicals found on the devices after completion of cleaning and disinfection must not pose any toxicological risk. The manufacturer of the process chemicals defines limit values that pose no toxicological risk while taking account of residues of rinse water on the medical device when left in the rinse water.

During performance qualification proof must be furnished that, when used as directed, no residual quantities of process chemicals above the defined limit values are found on the medical device or in the rinse water.

The methods employed to elucidate the residual quantities of process chemicals, or furnish requisite proof, will depend on the process chemical used and must be made available by the manufacturer (see Annex 6, "Process Chemicals").

5.2.4 Qualification of Washer-Disinfectors in Operation

For washer-disinfectors already in operation and which do not meet the basic requirements of the standard, but are to be qualified for further operation, a baseline assessment must be carried out. Assessment criteria are:

- Automated/electronic programme control
- Automated error message generation in the event of faults (water quantity, dosage)
- Facilities for calibration of measurement chain
- Temperature display
- Separate sensors for control and monitoring
- Automated dosage facilities
- Monitoring of cleaning pressure

This assessment procedure will enable one to establish whether, on making a reasonable investment, it is possible to carry out a validated cleaning and disinfection process with the current washer-disinfector.

By conducting appropriate risk analysis (see Annex 6, "Risk Analysis") the

scope of the tests (performance qualification) and any supplementary measures, e.g., frequency of routine checks, must be defined. In principle, the same tests are conducted as for those washer-disinfectors that conform to the pertinent standards. But extra tests may be needed (see Checklist 11, "Routine Monitoring of Cleaning and Disinfection Processes").

As a minimum requirement, the following instructions must be observed for evaluation of washer-disinfectors and for the intervals at which routine checks are to be conducted, see also 6.2:

Logic Control

Washer-disinfectors equipped with mechanical/electrical logic control facilities or programme-card logic controls do not meet the requirements of the standard.

In the case of washer-disinfectors with electronic logic controls a check must be carried out to establish whether other measures can be taken to assure compliance with the specified parameters.

Door Locks

If the washer-disinfector is not equipped with a door/operational locking mechanism, the manufacturer/supplier must be contacted to find out whether these can be fitted. If this is not possible, personnel must be instructed and made aware (as documented by the staff member's signature) that the process may be interrupted only after conducting a meticulous check and consulting the responsible parties, while taking account of safety (heat, chemicals, etc.) and assessment of the process status (cleaned?, disinfected?).

Temperature Sensors

If the washer-disinfector is equipped with only one sensor for temperature regulation and monitoring, a weekly or monthly test (depending on frequency of operation) should be carried out using a measuring system that is independent of the washer-disinfector. The frequency of this testing must be determined based on how often the washer-disinfector is operated.

Regulation of Water Level

It is important that a uniform water level be used for each operation in order to maintain the cleaning pressure and the concentration of process chemicals. If this is determined primarily by the flow pressure at the site of use, measures

must be taken to check this, take remedial action if necessary and define regular tests.

Dosage Facilities

If there is no facility for monitoring the level for the supply container, the level must be checked daily as instructed. The dosage volume must be monitored for each cycle, independently of the control facility. Alternatively, external dosage monitoring systems can be retrofitted.

5.3 Documentation and Evaluation

All data and evaluations relating to the safety and effectiveness of the washer-disinfector installation, operation, maintenance and tests must be documented. It is recommended that standardised checklists be used for documentation purposes.

5.4 Performance Requalification

A decision on whether to conduct performance requalification can be taken either on the basis of the data gleaned from validation, after a specified period of time or after making important changes.

Performance requalification must be carried out in the following cases:

- If new medical devices are introduced or devices that must be cleaned or disinfected in a different manner or new loading systems are used for which no equivalence to a validated reference load or to a validated medical device or loading system can be furnished
- If new process parameters, including chemicals, are introduced
- If the washer-disinfector is altered or subjected to technical interventions that could have a bearing on its performance
- If the washer-disinfector performance is unacceptable

The washer-disinfector must undergo a maintenance check as specified by the manufacturer no more than 4 weeks prior to performance requalification, or ideally immediately prior to it.

The exact scope of the tests shall be determined in consultation with the operator after reviewing the documentation and the results obtained for routine checks for the period after the last time performance requalification was carried out.

6. Routine Monitoring of Cleaning and Disinfection Processes

Routine monitoring of cleaning and disinfection processes plays a pivotal role in continually assuring the highest possible quality standards for automated decontamination of medical devices. This goal is intended to be achieved by parametric release, which avoids the need for a lot of routine checks. If this is not possible (for details see 5.2.4), endpoint testing has to be done to assure cleaning and disinfection performance.

Monitoring of cleaning and disinfection processes entails a check of those parameters directly related to the washer-disinfector (WD), of the consumable agents supplied as well as verification of the cleaning results primarily on the basis of visual inspection. These results are recorded, documented and evaluated. This documentation is maintained within the framework of the Quality Management System.

Routine monitoring entails daily operation tests and routine checks.

Any special requirements relating to different medical devices or application domains must be set out in standard operating instructions as dictated by quality management procedures (e.g. ophthalmology: verification of the pH value)

The following information and checklists are intended as a guide and aid in this respect.

6.1 Daily Routine Checks

Daily checks and measures are needed to assure problem-free routine operation of validated processes. The procedures in the WD operating manual supplied by the WD manufacturer must be followed. Checklist 10, "*Daily Operation Tests*", lists examples.

6.2 Routine Checks of Technical Functions

The routine checks must be specified by the operator in line with the technical features of the WD during validation, especially for qualification (see 5.2.4) of equipment which is being operated but does not comply with the pertinent regulations.

Successful execution of programme sequences in a WD depends on the temperature and time, water pressure, adequate dosage of process chemicals and on an adequate water level within the WD. These parameters must reliably meet their specified values. Routine tests are required at different intervals in accordance with the technical features of the WD, or any external equipment connected to it (e.g. central dosage facilities, independent documentation and monitoring modules). Preferably, the specified parameters must be verified and documented independently of the logic controller and associated sensors (e.g. temperature sensors, pressure gauges). If this is not possible, suitable procedures have to be used to check the final result.

If there are no facilities for automatic process documentation of each load based on qualification of equipment, this must be documented manually in standard operating procedures.

The test equipment and methods must be used and implemented, respectively, by trained personnel in accordance with standard operating procedures.

To minimise routine checks, documentation and monitoring modules (e.g. measurement and documentation of pressure, temperature and dosage), which are independent of the logic controller, can be fitted before validation.

See Checklist 11, "Form for compilation of a checklist for routine monitoring of technical function", for compilation of a checklist for routine monitoring of technical function.

6.3 Routine Checks of Cleaning and Drying Performance

In principle, when each medical device is removed from the WD it is visually inspected to ensure that it is clean and dry. If visual inspection is not possible, or limited, appropriate tests and testing intervals must be specified within the framework of the quality management system.

6.4 Routine Checks of Disinfection Performance

It is not necessary to verify the disinfection performance with biological indicators since the disinfectant action is assured by the effect of the water temperature for a defined period of time. This is expressed by the A_0 value (see 5.2.3.3, "Verification of Disinfection").

7. Selecting Washer-Disinfectors

This part of the Guideline is designed to help the operator select a WD. In principle, only WDs that conform to the relevant standards should be purchased.

The medical device decontamination requirements specified in legislation, standards and business management guidelines call for thorough preparations and

detailed planning in order to purchase suitable WDs.

At a minimum, the following experts and departments must be consulted before making any decision to purchase a WD:

- Central Sterile Supply Department
- Engineering Department
- Infection Control Team
- Health and Safety Department

The points outlined in Checklist 12, "Aspects Relating to Procurement of a WD", must be studied and answered before making any purchase, while taking the locally prevailing circumstances into consideration. They contain important instructions for structural preparations, installation, the requisite tests as well as subsequent operation.

This means that the operator must carry out in-depth analysis before making any decision to purchase a WD that has been subjected to a type test as per EN ISO 15883; this analysis must take account of the medical devices (MDs) to be decontaminated, the requirements relating to the results achieved and the operating environment.

Based on the results of the analysis, information must be obtained, while bearing in mind at least the following:

- The MD manufacturer's instructions for decontamination (DIN EN ISO 17664)
- The WD supplier's instructions
- The instructions of the process chemicals' supplier
- Any instructions given by the suppliers of external dosage facilities
- Planning experts, (sanitary, ventilation, structural, etc.)

8. References

- Final Report by vCJD Task Force, Variant Creutzfeld-Jakob Disease (vCJD), Federal Health Gazette (Bundesgesundheitsblatt) 4/2002, S. 376–394.
- Robert Koch-Institut (RKI) Recommendations Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, Bundesgesundheitsblatt (Hygiene Requirements for Processing Medical Devices, Federal Health Gazette) 11/2001 – 44: 1115–1126.
- Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (Association of Scientific Medical Societies): www.awmf-online.de
- DIN EN ISO 14971 – Medical Devices – Applying Risk Management to Medical Devices.
- DIN EN ISO 17664 – Information to be Provided by the Manufacturer for Reprocessing Resterilisable Medical Devices – Requirements.
- EN ISO 15883 Part 1, 2 and ISO/TS 15883-5 – Washer-Disinfectors, Requirements, Definitions and Test Methods.
- Quality Assurance for Processing Medical Devices – Guide to Process Validation for Washer-Disinfectors, Spectaris, German Industry Association for Optical, Medical and Mechatronic Technologies, Large Sterilisers, Cologne, November 2003.
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Official Journal of the European Communities L 169, Volume 36, 12 July 1993.
- Medical Devices Act of 2 August 1994, in the version published on 7 August 2002 (BGBl. I p. 3146)
- Ordinance Governing the Assembly, Operation and Use of Medical Devices – Medical Devices Operator Ordinance – MPBetreibV of 29 June 1998, version published on 21 August 2002 BGBl. p. 3396
- K: Roth; W. Michels: Inter-Hospital Trials to Determine Minimal Cleaning Performance According to the Guideline by DGKH, DGSV and AKI. ZentralSteril 2005; 13: 106–117.

9. Annexes

Annex 1: Qualification Requirements for Persons Entrusted with Validation

1 Introduction

This Annex sets out the qualification requirements to be met by persons and establishments conducting IQ, OQ and/or PQ as part of validation. It does not apply to the type test performed on the manufacturer's premises pursuant to EN ISO 15883.

2 Responsibility for Validation

The operator is responsible for ensuring that only validated processing methods are used. Validation must be conducted on the operator's behalf by suitably qualified specialists.

Validation entails diverse phases calling for different qualifications. As described in this Guideline, these phases are as follows:

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

3 Requirements for Installation Qualification

No particular qualifications are needed to check that the washer-disinfector and all its accessories have been properly delivered. The operator's (e.g. Engineering Department) assistance is needed to check this and confirm its accuracy in the documentation.

Specialist personnel authorised by their respective branches/trades (e.g. certificate as specialist technician) must be entrusted with the task of correctly installing the WD as per the installation plan/original drawings, making the supply (energy, media) and disposal (waste water, exhaust air) connections and providing the associated operating materials (electricity, steam, air, etc).

4 Requirements for Operational Qualification

Companies or institutions entrusted with these tasks, must furnish evidence of a quality management system (e.g. as per ISO 9001 or ISO 13485) as well as of comprehensive training and skills regarding the respective WD. The operator's direct involvement is needed for operational qual-

ification if, for example, central dosing facilities for process chemicals and/or reverse osmosis systems are to be installed.

The persons entrusted with these tasks must provide written evidence of the following:

4.1 General knowledge of relevant legislative acts, standards, regulations, guidelines, etc.

- The German Medical Devices Act (MPG), the Medical Devices Operator Ordinance (MPBetreibV)
- Recommendation by the Robert Koch Institute: "Hygiene requirements for processing medical devices".
- EN ISO 15883
- Guideline for Validation compiled by DGKH, DGSV, AKI
- EN 14971 (risk assessment)
- Biomaterials Regulation, Hazardous Substances Regulation

This proof can be furnished e.g. in the form of certificates documenting participation in special validation training courses and/or in Specialist Training Course II (run by the DGSV for Sterilisation Technical Assistants).

4.2 General knowledge and experience of decontamination processes

Parameters that have an effect on processing, e.g.

- Water quality
- Process chemicals
- Knowledge of materials and instruments
- Stacking the loading trolleys
- Process sequences
- Operating the WD
- Basic knowledge of quality management as regards medical device decontamination
- Basic knowledge of microbiology/hygiene

Proof of the above can be furnished in the form of a Specialist Training Course I certificate and at least 3 years' experience as a Technical Sterilisation Assistant (TSA) or as a medical technician or service engineer in this field.

4.3 Knowledge of equipment and of measurement and control technology with regard to the WD

- Electrotechnical knowledge for simulation and fault recognition in electrical/electronic systems
- Knowledge and experience of measurement technology

Proof must be furnished of training in electrotechnology, incl. measurement and control technology, and of familiarity with the respective type of WD. This must reflect the latest stock of knowledge with regard to the WD to be investigated.

4.4 Knowledge and experience of conductance of process validation exercises

- Process sequences for the reference loads to be checked

This evidence can be provided in the form of a certificate documenting participation in the validation of decontamination processes (references must be provided) on at least 5 occasions.

5 Requirements for the initial performance qualification as well as for performance requalification

Companies or institutions entrusted with these tasks must provide proof of a quality management system (e.g. as per ISO 9001 or ISO 13485). The general knowledge and experience needed for performance qualification is the same as that required for operational qualification (see 4.1 and 4.2); the parties concerned must provide written proof of this.

- Knowledge and experience of measurement technology relating to the measuring equipment/instruments
- Knowledge and experience in conducting process validation exercises
- Experience with sampling and test systems (Biuret, etc.) (proof of corresponding advanced training courses)
- Process sequences for the reference loads to be investigated

Proof can be furnished in the form of a certificate documenting participation in the validation of decontamination processes (references must be provided) on at least 5 occasions. ♦

Annex 2: Description of Method for Verification of Cleaning

1 Contamination of Test instruments (Crile arterial clamps + Test soil)

The test soil used is heparinised sheep blood rendered coagulable by addition of protamine sulphate. This sheep blood should not be older than one week and must be refrigerated until the time of use.

Contamination of the test instruments must be carried by a qualified laboratory with suitable quality assurance procedures (see example below). To contaminate the instruments, the heparinised sheep blood (Acila GMN®, Möhrfelden) is diluted with 10% double-distilled water. The sheep blood solution is then rendered coagulable by adding 1.5 IU protamine sulphate (Acila GMN®) to each 1 ml blood. Aliquots of 100 µl of this are pipetted into the joint (Fig. 1).

The test instrument is opened and closed five times to ensure uniform distribution of contamination.

After being contaminated, a maximum of 20 test instruments are placed on a perforated or wire-mesh tray in an opened position. Ensure that the tray is placed on a non-absorbent surface and that the bottom of the tray does not contact the surface. Otherwise part of the test soil could drain off by contact with the underlying surface, causing non-uniform contamination of the test instruments. The tray with the test instruments is dried in a drying cabinet for one hour at 45 °C.

Once dry, each test instrument is closed and the instruments are placed separately in a polyethylene (PE) bag. The air must be completely removed from the PE bag with the instrument and this must then be hermetically sealed (investigations have revealed storage of this package for even 14 days exerts only a minimal influence on the cleaning behaviour demonstrated by the test instruments, making it possible to ship contaminated test instruments to remote test sites).

It must be assured that the temperature does not exceed 20–25 °C during transport and storage.

2 Quality Assurance for Process Challenge Devices

Quality assurance measures must be taken by the manufacturer of process challenge devices (PCDs) to assure the reproducibility of results.

Below is an example of how to check the PCDs' cleanability and PCD decontamination for reuse:

2.1 Cleaning Test

As part of the process of quality monitoring a test is conducted to determine the cleaning characteristics of the PCDs relative to the blood challenge used. Batches of clamps, in this example, ten clamps, are cleaned with the following cleaning programmes. Cleaning is carried out, at the earliest, three days after contamination of the clamps. The position of the clamps in the WD must be defined:

Programme 1

- 3 min cold pre-cleaning
- Empty the chamber
- 10 min cleaning with 0.5% alkaline detergent, cleaning temperature 70 °C
- 1 min rinse
- Miele G 7735 washer disinfectant (WD)
- Insertion cart for trays

Programme 2

- 3 min cold pre-cleaning
- Empty the chamber
- 5 min cleaning with 0.3% alkaline detergent, cleaning temperature 55 °C
- 1 min rinse
- Miele G 7735 WD
- Insertion cart for trays

Evaluation of the results with the Biuret or modified OPA method must demonstrate that in the case of programme 1 a maximum of two clamps reach the limit value and that for programme 2 at least one clamp is above the limit value.

2.2 PCD Decontamination and Care

Following decontamination, the PCDs can be reused in the laboratory.

Depending on the quality of the material of which they are made, the PCDs can have a tendency to develop rust because of prolonged exposure to the blood challenge and due to residues of the SDS solution. Rust particles can give rise to false results if protein detection is carried out with the modified OPA method. To prevent this, the PCDs must be thoroughly cleaned and passivated each time they are used.

2.2.1. Thorough Cleaning

- Sonicate the instruments in an ultrasound bath for 30 min at 70 °C using a 1% alkaline detergent
- 3 min rinse with demineralised water

2.2.2. Passivation

- Sonicate for 30 min at 70 °C in 5% citric acid
- 3 min rinse with demineralised water

2.3 Cleaning after Passivation

After cleaning, the PCDs are reprocessed using the Vario TD programme (Miele) with an alkaline detergent or an equivalent process.

2.4 Caring for the PCD Joints

To maintain proper function, a steam-permeable care emulsion is applied to the dry PCD. The PCD is then opened and closed 5 times to ensure uniform distribution of the emulsion.

2.5 Steam Sterilisation

The PCDs then undergo steam sterilisation at 134 °C for 3 min. Sterilisation, too, provides for uniform distribution of the emulsion, which explains why packaging is needed only if the PCDs are not being reused immediately.

See above for contamination and packaging procedures.



Fig. 1

3 Test procedure with test instruments, visual inspection and sampling procedure

The test instruments (A) are assigned to the previously-determined reference loads, see 5.2.3.1 and Checklist 8.2



Since the clamps must be removed from the washer-disinfector before the disinfection step, waterproof, clean gloves must be worn when performing the following tasks.

The test instruments will be wet when withdrawn from the washer-disinfector before the disinfection step. With the functional part pointing vertically upwards, open and close the wet instruments three times. For visual evaluation of the results, the water drop that has collected in the lower closing region is investigated for discoloration or turbidity.

Protein recovery for the semi-quantitative test is effected by rinsing the joint region with 1% sodium dodecyl sulphate solution (SDS). This will either be included in the test kit or must be purchased from a pharmacy. Using sodium hydroxide adjust the pH of the 1% SDS solution to a pH value of 11 when investigating cleaning processes with process steps whose temperature is higher than 60 °C (before thermal disinfection). This compensates somewhat for any reduced recovery that might result from temperature denaturation.

For sample recovery, each instrument is placed in a 50 ml beaker (tall design, e.g. article C123.1, Carl Roth GmbH, Karlsruhe) and 2 millilitres of SDS solution is pipetted over the jointed region (wear gloves!)

The beaker is then positioned obliquely such that the instrument, held against the wall of the beaker, is wetted to just above the joint. The jointed region is then opened as widely as possible and closed five times in the solution. The instrument is then left to stand for 10 minutes in the beaker and the procedure is repeated using the same solution. The procedure is then repeated for a third time.

The SDS solution is then subjected to immediate semi-quantitative analysis.



When carrying out elution make sure that none of the 2 ml solution is spilt. Incorrect working procedures will lead to false results that are of no use!

4 External inspection of the clamps

The semi-quantitative protein detection test can also be conducted in an appropriately equipped, external laboratory.

Procedure

After assessment of visual cleanliness (digital photo if possible) the result is documented in Checklist 8 and the test instrument is dried on a non-absorbent surface at temperatures below 40 °C (in a drying cabinet or for some hours in the surrounding air). Once dry, each test instrument is sealed separately in an airtight PE bag and is sent for evaluation together with Checklist 8 no later than the following day.

To assure that the laboratory tests can be conducted immediately, WD evaluations should not be scheduled for a Thursday or Friday.

5 Processing the Clamps

Following sampling, the clamps are placed in the washer-disinfector for automated processing, continuing on this occasion through to the disinfection and drying steps. The clamps will be sent back to the provider afterwards.

Note: A multicentre trial was carried out from November 2004 to February 2005 to investigate this method in different sterilisation departments throughout Germany. The results of the multicentre trial were published in *Central Service* 2005; 13: 106–117.

6 Visual Inspection and Sample Recovery When Investigating Instruments In Everyday Use

Cleaning of instruments contaminated under everyday use conditions in the OR is verified in principle through visual inspection carried out in the course of routine tests and performance tests. However, chemical protein detection tests should also be conducted to confirm and document the results of visual inspection, in particular, for instruments of intricate design (gap regions, lumens).

Sample recovery is performed by rinsing off or rinsing out instruments or regions of instruments (lumen, joint) with the 1% sodium dodecyl sulphate (SDS) aqueous rinse solution. If temperatures above 60 °C are used, the SDS solution used for elution should also be adjusted to

pH 11. The pH value can also be set in situ in the CSSD using an alkaline, non-surfactant detergent and a pH strip with graduations of at least 0.5 pH units as a control. Any residual contamination on non-complex instruments can be rinsed off in a suitably-sized polyethylene bag using 2 to 5 ml 1% SDS solution so as to collect a sample from the entire instrument surface. The instrument is thoroughly wetted in the sealed bag by manually moving the bag to and fro or by squeezing it firmly. This applies especially to the zones that are difficult to clean. Jointed instruments should be moved in the bag so as to operate the joint, so that the joint, too, is rinsed. In this way it is also possible to recover samples from hollow instruments with large, easily accessible cavities, e.g. trocar sleeves. To and fro movement of the bag provides for flow of the solution, and the hollow instrument must be turned in the bag so that all internal regions are included. Narrow-lumened instruments,



Fig. 2

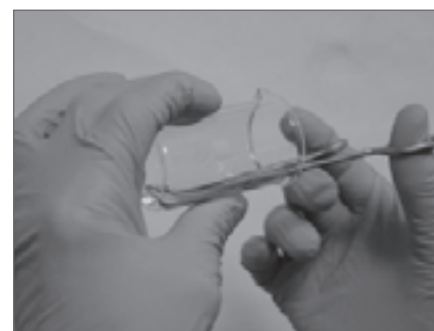


Fig. 3

which have been placed in an upright position in a beaker that is then mounted on a stand and into which 2 – 5 ml SDS solution has been pipetted, can be purged by fitting a disposable syringe at the upper end and by repeatedly siphoning in and emptying out the solution. It is also possible to purge the lumen into the beaker and then recover the solution from there using a pipette, repeating this several times. This can also be done in a suitably long tube using inserts for MIS shaft instruments that can be dismantled. Using such a procedure, it is always possible to recover the sample with only 2 ml SDS solution. It is advisable in principle to allow an interval of between 5 and 15 minutes between the thrice-repeated rinsing steps and the soaking period.

The semi-quantitative protein measurement using the Biuret/BCA method is then to be conducted using the same procedure as described for the test instruments. For calculation purposes, dilution based on the volume of SDS solution used must be taken into account. Accordingly, the quantity of protein recovered per ml eluate must be multiplied by the elution volumes used so as to determine the protein quantity per instrument. Table 1 illustrates how the limit value (200 µg per instrument) as well as the guide value (100 µg per instrument) is converted to µg per ml eluate due to the use of different volumes of SDS solution.

For elution examples using a laryngoscope or shaft tube see Figs. 4 and 5. ♦

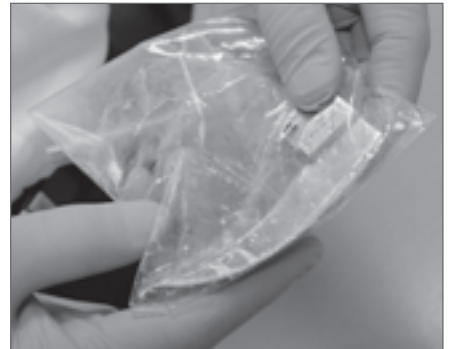


Fig. 4

Protein per instrument [µg]	Volume of 1% SDS for elution [ml]	Biuret/BCA result [µg/ml eluate]
200	2	100
200	3	67
200	4	50
200	5	40
100	2	50
100	3	33
100	4	25
100	5	20

Tab. 1



Fig. 5

Annex 3: Protein Measurement with the Biuret/BCA Method

1 Description of Method

The word "biuret" is derived from the chemical compound carbamoyl urea, whereby "bi" denotes "two" and "uret" is derived from the Latin term "urea". This basic structure of urea is reflected in proteins, with two of these chemical structures forming a blue-violet coordination complex with copper (II) ions in an alkaline solution. In general copper tartrate, the salt of tartaric acid, is used for this reaction, with copper having oxidation level II. Four peptide bonds are coordinated or formed via the nitrogen with the copper ion (Fig. 6). The concentration of the colour complex is measured photometrically at 545 nm. This simple biuret method does not provide for semi-quantitative measurement since it does not give rise to colours that can be clearly differentiated.

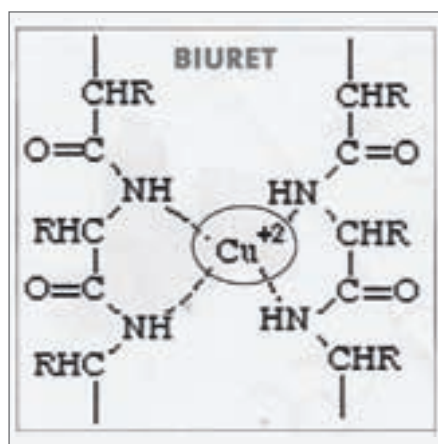


Fig. 6: Structure of the copper (II) protein complex

It is easy to perform the biuret method but there are a few interference factors, with anionic surfactants such as SDS (sodium dodecyl sulphate) and also sugar, e.g. saccharose, playing an important role, since an SDS solution is used for sample recovery and saccharose is present in mucus. This detracts from the precision of quantitative measurements.

The optimal protein concentration of the measurement solution is between 0.5 mg/ml and 10 mg/ml and is thus suitable for use in various areas for identification of protein solutions, for example in clinical chemistry of blood products. But it can also be used to measure solutions with <math><500 \mu\text{g/ml}</math>, if proper pre-treatment is carried out.

Modification of the biuret method, known as the BCA method, results in a significant increase in sensitivity so that protein quantities in the μg region can be reliably detected. This abbreviation "BCA" is derived from the chemical compound bicinchoninic acid. Under alkaline conditions this method uses a copper (II) sulphate or copper (II) nitrate reagent that is reduced by proteins to copper (I). Then copper (I) together with BCA forms a grey-green colour complex whose concentration can be photometrically measured at 562 nm (quantitative).

The detection reaction is a function of the macromolecular structure of the proteins present, the number of peptide bonds and the proportion of the amino acids cysteine, cystine, tyrosine and tryptophan. In the presence of protein, a green copper (II) complex is formed with the BCA in this reaction (Fig. 7). As the protein content in the sample rises, so the colour

changes from grey-green to a red-violet colour. This colour also serves to describe the result: green denoting cleanliness and red/violet inadequate cleaning. The reaction is a function of time and temperature, and the incubation instructions provided for the commercially available reagent kits used for this method must be observed and absolutely complied with. It must be borne in mind that incubation at 60°C for 30 minutes produces more precise results. But incubation at 37°C or for a longer period of time at room temperature is adequate for semi-quantitative measurements.

2 Semi-Quantitative Test Kits

Based on the BCA method there are commercially available semi-quantitative test kits that are used as a swabbing method (with a swab), such as Pro-TECT, M or Konica Swab "N" Check. The latter is not available at present, which is regrettable since this provided for detection not only with a swab but also directly with an SDS eluate solution, so that one could choose between these two methods of sample recovery. Measurement with an SDS eluate sample is possible with the BCA Protein Assay Kit, made by Pierce, and can be obtained from the supplier VWR (Fig. 8). Here one must first of all set the concentrations and reference colours using the bovine serum albumin (BSA) solution supplied, in accordance with the relevant concentration range and the incubation conditions selected. Preference should be given to incubation at 60°C for 30 minutes for the concentration range 5 to $250 \mu\text{g/ml}$.

A further kit is the (Miele) Test Kit containing coordinated reagents, including a concentrate of the SDS rinse solution. This Test Kit is based on a combination of the biuret and BCA reaction, where 1 ml of the SDS sample solution is added to a bottle with reagent A, which contains an alkaline solution with a defined concentration of copper (II) salt. The copper (II) reacts with the proteins in the sample solution, giving rise to a copper (II) protein complex as seen in Figure 6, but does not produce a visible change in colour. The specified reaction time of at least 6 minutes but no more than 7 minutes must be observed. The copper (II) quantity that has not reacted with protein by that time is reduced by

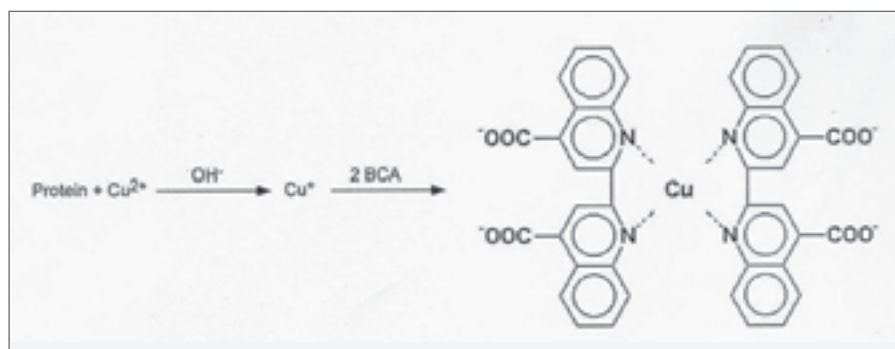


Fig. 7: Formation of the copper (I)-BCA complex

addition of a powder-based reagent B (ascorbic acid) to copper (I). By adding two drops of reagent C, containing BCA, the complex illustrated in Figure 7 is formed. If no protein is present in the sample solution, the entire amount of copper (II) is reduced to copper (I), giving rise to the BCA colour complex at a high concentration. The more protein in the sample solution, the greater the amount of copper (II) that will be bound to protein leaving less copper (I) to be found in the solution after reduction, and the colour complex is formed at a lower concentration. As such, the greater the amount of protein, the lower the intensity of the colour complex, resulting in a colourless reaction product in the presence of high protein quantities. The colour results must be evaluated immediately for this method since otherwise the BCA will also react with the copper (I) reduced by proteins, thus assuming a red/violet colour. This would incorrectly suggest better protein elimination than is actually the case.

3 Interfering Substances in the Biuret/BCA Methods

Every method based on chemical detection reactions is subject to interferences. It is important to understand these and

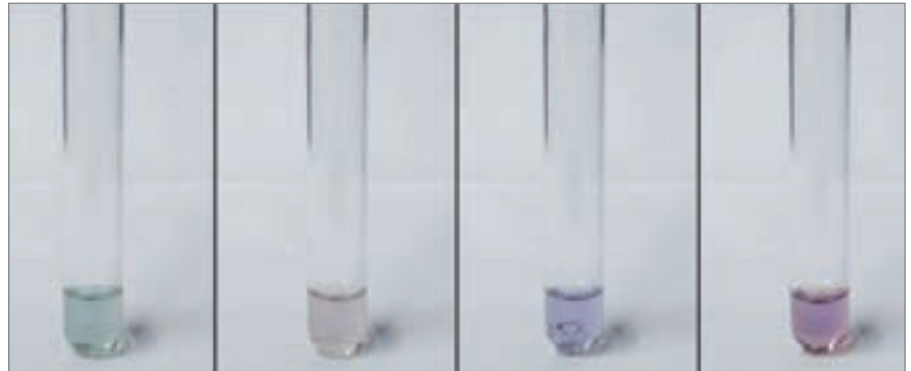


Fig. 8: Colour result of the BCA reaction (manufacturer: Pierce) with protein solutions in the concentrations 5 µg/ml, 50 µg/ml, 100 µg/ml and 125 µg/ml BSA

their relevance as far as false-positive or negative results are concerned must be borne in mind.

In the case of instruments containing brass, copper can go into solution during sample recovery, thus falsifying the measurement reaction. The BCA method is not affected by anionic surfactants in the same way as the biuret method is, hence SDS elution has no effect on results. The sugar saccharose in mucus affects the BCA method in the same way as it does the biuret method, reducing sensitivity. Fur-

thermore, hydrogen peroxide (oxidative cleaning processes), iron ions (instrument corrosion) and lipids (instruments such as intramedullary reamers) in the sample solution can give rise to interference, although this is of less relevance in semi-quantitative measurements when compared with quantitative measurements. If such interference substances are present in significant concentrations, the situation should be carefully assessed and additional measurements that are not subject to such influences carried out. ♦

Annex 4: Water Quality

Because of the volume required, water is an important medium for (medical device) processing and in any automated cleaning process it thus constitutes a vital factor for ensuring that good cleaning results are obtained. The water quality can have implications for the service life of the processed supplies depending on the respective item. The salt content of the water used for the final rinse phase can give rise to undesirable residues on the processed supplies or even cause material damage. Fully demineralised water is therefore recommended for the final rinse step.

EN ISO 15883, Part 1, Chapter 6.4.2 gives a procedure for checking the composition of the final rinse water.

It is recommended that at the time of validation of the cleaning and disinfection process the water quality used for pre-cleaning, cleaning and intermediate steps be documented too. This can be accomplished by having the water supply company conduct an analysis of the water.

For these process steps, attention must be paid in particular to the total hardness, total salt content and chloride content.

The following values are recommended as minimum requirements:

Total hardness: < 3°dH (< 0,5 mmol CaO/l)

Total salt: < 500 mg / l

Chloride content: < 100 mg / l

pH value: 5 – 8

For process optimisation, the use of fully demineralised or at least of softened water is recommended for pre-rinsing, cleaning and intermediate rinsing steps.

The use of salt-free or fully demineralised water for the final rinse step assures clean, spotless goods. Chapter 6.4.2.2 of prEN ISO 15883 – Part 1 lists the critical parameters. EN 285, Annex B, Table B1, lists values for the boiler water of a steam steriliser. This water quality can be recommended for the final rinse step for automated instrument processing.

The following values are recommended as a guide:

Conductivity: $\leq 5 \mu\text{S}/\text{cm}$

pH value: 5 – 7

Total hardness: $\leq 0,02 \text{ mmol CaO}/\text{l}$

Salt content: $\leq 10 \text{ mg}/\text{l}$

Phosphate: (as P_2O_5) $\leq 0,5 \text{ mg}/\text{l}$

Silicate: (as SiO_2) $\leq 1 \text{ mg}/\text{l}$

Chloride: $\leq 2 \text{ mg}/\text{l}$

Note: No recommendation can currently be given regarding endotoxin detection.

At present, elucidation of the microbiological quality of the water used for cleaning or of the bacterial endotoxin load is not required for processing procedures with thermal disinfection. ◆

Annex 5: The A_0 Concept of EN ISO 15883

For thermal processes, the degree of disinfection is preferentially established through parametric calculation. The F value concept, which is used for sterilisation, has therefore been applied to the washer-disinfector and included as the "A₀ value concept" in the standard DIN EN ISO 15883.

When using a moist heat disinfection process it is expected that over a certain period of time a particular temperature will exert a predictable lethal effect on vegetative forms of microorganisms. The lower temperature limit has been determined at 65 °C.

The key criterion for the required temperature is the heat resistance (thermo-resistance) of the present microorganisms present, which is expressed as the D value.

Terms

A Equivalent time in seconds, at a temperature of 80 °C, required to achieve a specified disinfectant effect.

A₀ value lethality expressed in terms of the equivalent time in seconds at a temperature of 80 °C delivered by that process to the medical device with reference to microorganisms possessing a z value of 10.

z value Temperature change required to change the D value by a factor of 10.

D value Decimal reduction value; indicates the time, in minutes, required to reduce by a factor of 10 a population of cells at a given reference temperature, thus corresponding to a 90 % lethality rate.

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

A₀ is the value at which z equals 10 °C

t is the chosen time interval in seconds

T is the temperature within the load in ° Celsius.

Calculation using this formula is normally done by the logger software after the data has been transferred from the logger to the PC.

If the A₀ value is calculated at a lower temperature value, it must be borne in mind that a lower temperature limit of 65 °C has been specified for the integration because at temperatures of less than 65 °C the z and the D values can change drastically for thermophilic organisms. Numerous microorganisms can actively replicate at temperatures below 55 °C.

A₀ values required

The A₀ value that must be reached will depend on the type and number of microorganisms found on the contaminated MDs and will also be determined by subsequent treatment measures or subsequent use. The operator is responsible for achievement of the A₀ value. It is determined in cooperation with the responsible infection control team.

A₀ value of 3000

According to the RKI, an A₀ value of 3000 should be employed for MDs that are, or could be, contaminated with heat-resistant viruses, e.g. hepatitis B virus. This can be achieved by exposure to hot water, e.g. at 90 °C for 5 min, on the surfaces of the medical devices. As a standard approach, automated decontamination should be con-

ducted with an A₀ value of 3000 since the number and type of microorganisms found on the medical devices to be processed are unknown and can vary greatly.

Furthermore, in the case of MDs for which subsequent sterilisation is required, for health and safety reasons, e.g. safety when assembling/inspecting/packing MDs, inactivation of pathogens, incl. HBV, must be assured*.

A₀ values of 600

The use of an A₀ value of 600 is viewed as a minimum requirement for non-critical MDs, i.e. MDs coming into contact with only intact skin. A further precondition for using the A₀ value of 600 is that the only contamination encountered should be of vegetative bacterial or fungal origin, corresponding to spectrum of action A as per the definition in the "List of disinfectants and disinfection procedures tested and approved by the Robert Koch Institute, Federal Health Gazette 1/2003".

* In the "List of disinfectants and disinfection procedures tested and approved by the Robert Koch Institute, Federal Health Gazette 1/2003", the longer exposure time of 10 min/93 °C continues to be used for spectrum of action B, as the procedures listed here are intended for statutorily mandated disinfection measures. These are thought to have a broad spectrum of action and also provide an additional safety reserve against hitherto unknown pathogens.

Holding time		Temperature (°C)	A ₀ value
minutes	seconds		
100	6000	70	600
10	600	80	600
1	60	90	600
50	3000	80	3000
5	300	90	3000

Tab. 2: Explanations/notes on the A₀ value and its temperature and time dependence

Annex 6: Process Chemicals

The process chemicals normally needed when processing medical devices with thermal disinfection include detergents, neutralisation agents and rinse aids. These chemicals are used in the cleaning step and in the optional, ensuing neutralisation step. The rinse steps that follow generally use water for intermediate rinsing and a final thermal disinfection rinse. Rinse aids can be used in the final rinse. These process chemicals are classified as medical devices and their manufacturers must furnish proof of conformity pursuant to the medical device directive 93/42.

The manufacturer of process chemicals must provide the following documentation to enable validation:

- Product description with recommended dosage
- Safety data sheet
- Method for verification of dosage
- Information on toxicological safety of any process chemical residues on the medical devices
- Method for furnishing proof of toxicological safety of residual quantities of the process chemicals used, e.g. in the final rinse step.

Theoretical Residues of Process chemicals with 5% Entrainment of Cleaning Solution					
Cleaning steps	Pre-cleaning	Cleaning	Neutralisation	Intermediate rinse	Final rinse
Detergent (vol-%)		0,5	0,025	0,00125	0,0000625
Detergent (ppm)		5000	250	12,5	0,625
Neutralizing agent (vol-%)			0,3	0,015	0,00075
Neutralizing agent (ppm)			3000	150	7,5
Theoretical Residues of Process chemicals with 10% Entrainment of Cleaning Solution					
Cleaning steps	Pre-cleaning	Cleaning	Neutralisation	Intermediate rinse	Final rinse
Detergent (vol-%)		0,5	0,05	0,005	0,0005
Detergent (ppm)		5000	500	50	5
Neutralizing agent (vol-%)			0,3	0,03	0,003
Neutralizing agent (ppm)			3000	300	30

Tab. 3

Detergents

A distinction is made between alkaline and neutral detergents.

Neutral detergents generally contain non-ionic, low-foam surfactants, and may or may not include an enzyme.

When carrying out processing pursuant to the recommendations of the vCJD Task Force as per the RKI vCJD Recommendation, the pH value of the deter-

gent solution must be more than 10 (published in the Federal Health Gazette "Bundesgesundheitsblatt", April 2002).

Neutralisation Agents

These products are based on citric or phosphorous acids. Those products based on phosphorous acid are more acidic, but are deemed to damage certain sterile supplies.

Rinse Aids

Rinse aids are based on surfactants and reduce the boundary surface tension of the rinse water, thus providing for improved drying. Proof must be furnished that residues remaining on the surface of the MD pose no toxicological risk.

Dosage and Detection of Residues

In general, dosage is calculated by measuring the volume of the process chemicals in litres. In cases where the concentration of the alkaline detergent and neutralisation agents must be known, a simple analytical method based on titration with acids and bases has been provided. The concentration of neutral detergents can only be checked by analysis of the contents (e.g. surfactants) in a laboratory.

When processing medical devices, it must be ensured that any residues of process chemicals reaching the final rinse

step pose no toxicological risk. This is assured by ensuring delivery of the exact dosage as per the manufacturer's instructions, providing for adequate rinsing steps and proper loading of loading trolleys. When using alkaline detergents, this can be easily checked on site on the basis of measuring the electrical conductivity. Electrical conductivity of the final rinse water is compared to that of the process water used for the final rinse step, taking into account the conductivity values for acceptable residues in the final rinse water provided by the process chemical manufacturer.

See table 3 for example calculations on chemical residues levels to be expected at 5% or 10% carry-over of the rinse water:

The table shows that even if the neutralisation reaction occurring for the prod-

uct combination "alkaline detergent"/"neutralizing agent" is disregarded, the residues in ppm for the assumed initial concentration of 0.5% for detergents and 0.3% for neutralising agent are very low.

More accurate checks can be carried out by analytical investigations, as specified by the manufacturer of the process chemicals.

Recommended Investigations

- Dosage (specified in ml/l or vol.-%):
- Check regularly or after placing in operation in the relevant areas, e.g. by measuring actual delivered dosage
- As part of performance requalification by measuring the capacity in litres or by means of analysis
- Process chemical residues ◆

Annex 7: Risk Analysis of WDs in Operation

A risk analysis is intended as a means of anticipating and evaluating potential risks. This evaluation also takes into account the probability of such a risk being detected and the probability of it occurring. Risk analysis provides an estimate of the likelihood of the risk occurring and how it can be reduced and minimised by taking appropriate measures.

Within the meaning of this Guideline, risk analysis refers exclusively to process safety.

Conductance of risk analysis must always be tailored to a specific situation, although it is possible to standardise the fundamental approach taken. Various methods are employed for risk analysis, as described in DIN EN ISO 14971.

The following example is based on the structure described in DIN EN ISO 14971.

Risk analysis: Identification of hazards/estimate risk posed by each hazard

The various steps involved in this procedure are portrayed using as an example: "no door locking mechanism".

What could happen?

- Premature interruption, incomplete programme run
- Unsatisfactory cleaning and disinfection results

Risk evaluation:

- Can the risk be justified or must measures be taken?
- The risk posed by interruption/discontinuation of the programme because of no door locking mechanism must be minimised. Measures must be taken!

The measures taken can be of a constructive or informative nature, with preference being given to constructive measures.

- Check whether retrofitting is technically possible and economically feasible
 - Retrofitting is economically feasible and possible
 - Retrofitting is not possible with justifiable investment
- Documented training using written working procedures

- Affix warning sign to washer-disinfector

Assuming that, in conformance with the quality management system, only trained staff are employed in the CSSD and that in addition a warning sign is displayed (notice: "Caution! Open Only When Programme Finished!"), the risk will be adequately reduced. The remaining risk (e.g. wilful infringement) is acceptable.

Risk verification:

- Evaluates whether the measures taken are adequately effective and are thus able to reduce the risk. The newly implemented measures must not give rise to any further hazard. ◆

Masthead

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10. Checklists

Checklist 1: Structural and Technical Prerequisites at the Operator's Premises

Requirement	Available	Not available	Measures/Remarks
Information on existing water quality			
Odour interceptor at outlet from floor-level tank			
Ventilation in servicing room (especially for tunnel washers)			
Room temperature in servicing room less than 50°C			
Exhaust air outlet is temperature resistant			
Condensate drain can tolerate temperatures up to 100°C			
Shut-off valve and dirt trap at steam connection			
Shut-valve at demineralised-water connection			
Shut-off valve and dirt trap at cold-water connection			
Shut-off valve and dirt trap at hot-water connection			
Main electrical switch in immediate vicinity of washer-disinfector			
Structural separation between clean side and decontamination area			
Facilities (such as a hatch) for handing back supplies, e.g. to reclean MDs that are still dirty)			
Staff transfer area between clean side and decontamination area			
Enough space in decontamination area for storage of the MDs to be processed			
Safe, protected and easily accessible place for process chemicals (observe storage temperature)			
Facilities for handwashing and hand disinfection (washbasin and wall dispenser)	In decontamination area		
Hand disinfectant dispenser	In clean area		
Hand disinfectant dispenser	In staff transfer area		

Checklist 2: Organisational Prerequisites at Operator's Premises

Requirement	Available	Not available	Measures/Remarks
Operating Manual for MDs with processing instructions for all devices (as per DIN EN ISO 17664)			
Risk evaluation and classification of MDs as per the hygiene requirements formulated by the RKI for processing MDs			
Description of reference loads to be cleaned and disinfected, with related documentation (photo)			
Operating Manuals and medical device handbooks for the washer-disinfectors			
Servicing and installation plans for the washer-disinfectors			
Data sheets for the process chemicals (product instruction sheets, safety data sheets, operating instructions)			
Description of the entire processing procedure from beginning to documented release (quality management)			
Calculation of maximum time taken to transport used supplies for each load			
Specify load for performance qualification and then draft the standard operating procedures (SOPs) needed for operation			
Define competencies			
Make provision for staff qualifications (e.g. DGSV specialist training course)			
Infection control (hygiene) plan			
Cleaning and disinfection plans			

Checklist 3: Information to be Provided by Washer-Disinfector Manufacturer to Operator

Requirement	Available	Not available	Measures/Remarks
Documented proof of compliance with EN ISO 15883			
Type of products that can be cleaned/disinfected with the programmes			
Ancillary equipment to be used			
Values defined for process parameters, e.g., time, temperature, water quantity, water pressure, quantity of process chemicals			
Temperature and time relating to process steps			
Description of specified standard programmes and of deviations permitted from the process parameters			
Scope of servicing tasks and servicing intervals			
Process chemicals and their concentrations			
Requirements for water qualities			
Loading specifications for loading trolleys, trays and inserts			
Description of control and display equipment			
Description of settings for safety devices			
Procedure in the event of malfunctioning			

Checklist 4: Installation Qualification

Washer-disinfector (designation/number)			
Location			
Person responsible for overall qualification			
Other IQ inspectors			
Test date			
Type of machine:		<input type="checkbox"/> Serial equipment	<input type="checkbox"/> no
Manufacturer:		Serial No.:	
Type:		Year of manufacture:	

Installation qualification			Documentation of scope of order and delivery	
Scope of order			Scope of delivery	Damaged ²⁾
Article description ¹⁾	Article No.	Quantity	Quantity supplied	Yes/no

- whether the articles ordered were supplied is documented.
- whether the articles show external damage is documented.

Protocol	List of technical documents for washer-disinfector and ancillary equipment		
Type/title	Available and complete yes/no	Document No./ Material No.	Storage place
Installation plan I (machine)			
Installation plan II (floor-level tank)			
Installation plan III (miscellaneous)			
Wiring diagrams			
Operating Manual (washer-disinfector)			
Operating Manual (miscellaneous)			
Operating and programming manual			
Equipment manual as per <i>MPBetreibV</i>			

No. ¹⁾	Remarks/deviations/objections	Influence exerted on:		Deviation eliminated, corrected
		Performance outcome ²⁾	IQ/OQ	Date/signature

- Enter the number of the remark/deviation/objection under No.
- Specify what influence exerted on as none, slight, moderate or severe

The names of the inhouse departments or specialist firms that carried out and tested installation of the washer-disinfector and of ancillary equipment at the operator's premises are documented here.

Installation at operator's premises	Name of the inhouse department/name and address of specialist firm
Electrical installation ²⁾	
Voltage supply and potential equalisation (if required)	
Steam	
Water installation ¹⁾	
Waste water installation	
Exhaust air/air removal	
Cooling circuit	
Central supply of process chemicals	

2) if installation is carried out by several inhouse departments or specialist firms, the others must be listed in the Remarks column.


Washer-disinfector and ancillary equipment	Name of the inhouse department/authorised specialist firm	Date
Washer-disinfector		
Ancillary equipment		


1) the washer-disinfector and any ancillary equipment available were installed by the inhouse department or specialist firm named here.

The names of the inhouse departments or specialist firms that made the electrical connections for the washer-disinfector and ancillary equipment at the operator's premises are documented here.

Connection to installation at operator's premises	Name of the inhouse department/name and address of specialist firm	Date
Electrical installation ¹⁾ voltage supply and potential equalisation (if required)		
Steam		
Water installation ¹⁾		
Waste water installation		
Exhaust air/ventilation		
Cooling circuit		
Central supply of process chemicals		

1) if installation is carried out by several inhouse departments or specialist firms, the others must be listed in the Remarks column.

	Acceptance Test Washer-Disinfectors	Page 2 of 3
<p>3. Machine-Integrated Dosage Facility</p> <p>Dosage facility 1</p> <p>Product/designation: _____</p> <p>Manufacturer: _____</p> <p>Dosage qty. (g/l): _____</p> <p>Dosage device: _____</p> <p>Dosage facility 2</p> <p>Product/designation: _____</p> <p>Manufacturer: _____</p> <p>Dosage qty. (g/l): _____</p> <p>Dosage device: _____</p> <p>Dosage facility 3</p> <p>Product/designation: _____</p> <p>Manufacturer: _____</p> <p>Dosage qty. (g/l): _____</p> <p>Dosage device: _____</p> <p>Dosage facility 4</p> <p>Product/designation: _____</p> <p>Manufacturer: _____</p> <p>Dosage qty. (g/l): _____</p> <p>Dosage device: _____</p>		
<p>4. Ancillary Equipment</p> <p>Designation: <input type="checkbox"/> ok <input type="checkbox"/> not ok _____</p> <p>_____</p> <p>Designation: <input type="checkbox"/> ok <input type="checkbox"/> not ok _____</p> <p>_____</p>		

 SPECTARIS	Acceptance Test Washer-Disinfectors	Page 3 of 3																																	
<p>5. The following persons act as operating and use instructors</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Name</th> <th style="width: 50%;">Signature</th> </tr> </thead> <tbody> <tr><td>1.</td><td></td><td></td></tr> <tr><td>2.</td><td></td><td></td></tr> <tr><td>3.</td><td></td><td></td></tr> <tr><td>4.</td><td></td><td></td></tr> <tr><td>5.</td><td></td><td></td></tr> <tr><td>6.</td><td></td><td></td></tr> <tr><td>7.</td><td></td><td></td></tr> <tr><td>8.</td><td></td><td></td></tr> <tr><td>9.</td><td></td><td></td></tr> <tr><td>10.</td><td></td><td></td></tr> </tbody> </table>				Name	Signature	1.			2.			3.			4.			5.			6.			7.			8.			9.			10.		
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Checklist 6: Operational Qualification "Tests, Control Measures"

Requirement	Set point	Not Ok	Actual State	Measures/Remarks
Cold water inlet function, filling capacity				
Hot water inlet function, filling capacity				
Demineralised water inlet function, filling capacity				
Agreement between display – measurement (if display fitted)				
Heating gradient function, observance of temperature				
Agreement between display – measurement (if display fitted)				
Calibrate sensors (cleaning solution 1)				
Calibrate sensors (cleaning solution 2)				
Calibrate sensors (drying air)				
Requirement	OK	Not Ok	Measures/Remarks	
Piping system leakage test				
Door leakage test				
Drain check (degree of emptying)				
Filter check before circulation pump suction (clean, airtight)				
Rotary arm functional check (rotary function, rpm)				
Nozzle functional check > visual inspection for drainage of cleaning solution				
Connections functional check > loading trolley connected to supply				
Dryer functional check > blower output				
Air removal functional check > avoidance of condensate reflux				
Unlock/open doors only at process end				
Programme does not start if doors open				

Checklist 6: Operational Qualification, Page 2

Requirement	Ok	Not Ok	Measures/Remarks
Door on removal side opens only after problem free operation complete			
Alarm message functional check in the event of underdosage			
Alarm message functional check if chemical products used up			
Alarm message functional check for temperature sensors			
Fault message functional check in the event of dosage fault			
Alarm message functional check in the event of sensor short circuit or cable breakage			

Requirement	Name	Remarks
Specification of all client-specific programmes		
Specification of all client-specific programmes		
Specification of all client-specific programmes		
Specification of all client-specific programmes		
Specification of all client-specific programmes		
Specification of all client-specific programmes		
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Specification of all client-specific programmes		
Specification of all client-specific programmes		

Checklist 7: Performance Qualification: Specify and Document Programmes

This form is intended as an aid for specification of the requisite programmes. The programmes are specified on Page 2

Check point	Criterion	Criterion	Criterion	Criterion	Conclusion				
MDS to be processed (note manufacturers instructions pursuant to DIN EN ISO 17664)	Instruments following incision surgery/ Containers, lids	<input type="checkbox"/>	MIS instruments / rigid endoscopes	<input type="checkbox"/>	Microinstruments	<input type="checkbox"/>	The number of programmes will depend on the type of MDS to be processed		
	With spirals, e.g. forceps	<input type="checkbox"/>	Drilling shafts / compressed air tubes	<input type="checkbox"/>	Motor handpieces	<input type="checkbox"/>			
MDS that are difficult to clean	< 1 mm	<input type="checkbox"/>	≥ 3 mm	<input type="checkbox"/>	≥ 5 mm	<input type="checkbox"/>	Optics	<input type="checkbox"/>	Must be checked at the time of PQ
Hollow devices/lumens, tubes	Stainless steel	<input type="checkbox"/>	Aluminium	<input type="checkbox"/>	Titanium	<input type="checkbox"/>	Synthetics	<input type="checkbox"/>	Chemithermal disinfection is needed for heat-sensitive MDS; these items are outside the scope of this Guideline
	Heat resistant	<input type="checkbox"/>	Heat sensitive	<input type="checkbox"/>		<input type="checkbox"/>	Miscellaneous:	<input type="checkbox"/>	
Material composition	Slight	<input type="checkbox"/>	Heavy	<input type="checkbox"/>	Very heavy	<input type="checkbox"/>		<input type="checkbox"/>	The cleaning outcome must be checked at the time of PQ
	Bone meal	<input type="checkbox"/>	Medicinal product/ disinfectant residues	<input type="checkbox"/>	Tissue residues	<input type="checkbox"/>	Miscellaneous:	<input type="checkbox"/>	The cleaning outcome must be checked at the time of PQ
Contaminants that are difficult to solubilise	< 1 hour	<input type="checkbox"/>	< 6 hours	<input type="checkbox"/>	< 12 hours	<input type="checkbox"/>	> 12 hours	<input type="checkbox"/>	Performance qualification must be conducted after the maximal time needed to transport used supplies to CSSD
	Assured by means of SOPs	<input type="checkbox"/>	Is carried out by user	<input type="checkbox"/>	Is carried out in CSSD	<input type="checkbox"/>	Automated precleaning	<input type="checkbox"/>	
Precleaning	Universal	<input type="checkbox"/>	Microinstruments	<input type="checkbox"/>	MIS instruments	<input type="checkbox"/>	Anaesthesia equipment	<input type="checkbox"/>	If a criterion is not ticked (checked), provision must be made for organising precleaning
	Container	<input type="checkbox"/>	Bulky items	<input type="checkbox"/>	Miscellaneous:	<input type="checkbox"/>	Miscellaneous:	<input type="checkbox"/>	
Loading trolley		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	Specify and check reference load if programme steps are not identical
		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	

Checklist 7, page 2: Specification of Programmes to be Tested

The following programmes are specified after compiling the form.
In the case of programmes that differ only in terms of duration, the shortest programme can be checked

Loading trolley	Prog. Desig.	Preclean		Clean			Intermediate Rinse	Neutralisation	Disinfection		Drying	
		Time min	Temp °C	Time min	Temp °C	Detergent %			Number	Chemicals	Time min	Temp °C

Verification of cleaning performance according to 5.2.3.1

Instruments, general												
MIS												
Microinstruments												
Other programmes												

Verification of cleaning performance through visual inspection

Containers if appl.												
Anaesth. equipment												

Cannot be validated (disinfection before cleaning); used only for epidemics

BGA ¹ programme pursuant to Section 18 IfSG ²	Disinfection Detergents		Temp °C	Time min	Rinse Number	Neutralisation		Drying	
	Time min	Temp °C				Chemicals	Time min	Temp °C	

¹ programme devised by former German Federal Health Office

² Protection against Infection Act

Checklist 8: Verification of Cleaning

8.1 Technical Data

Establishment:	Address:
Department:	
Contact person:	
Telephone number:	

Washer-disinfector type/manufacturer:			
Number of levels in insert trolley:		Number of DIN trays per level:	
Programme designation:			
Cold precleaning	Duration		
Cleaning	Product		
Temperature	Duration	pH value: (as specified by manufacturer)	
Neutralisation	Product		
Temperature	Duration	pH value: (as specified by manufacturer)	
Intermediate rinses	Duration		

Programme can be interrupted before thermal disinfection: yes no

Dataloggers available (printout enclosed): yes no

Digital photo facilities: yes no

Clean, waterproof gloves must be worn when removing the test instruments from the washer-disinfector before the disinfection step and for any further tasks.

The test instruments will be wet and should not be dried when removed from the washer-disinfector before the disinfection step. With the functional part pointing vertically upwards, open and close the wet instrument three times. For visual evaluation of cleaning results, the water drops that have collected in the joint region are investigated for discoloration or turbidity.

8.2 Positioning the Test Instruments when Loading the Trays

The test instruments are opened to approx. 90 ° for cleaning.

Top:	Level 4	Additional level	Batch 1	Batch 2	Batch 3
			1	11	21
			2	12	22
Middle:	Level 3	Additional level			
			3	13	23
			4	14	24
			5	15	25
Middle:	Level 2	WD with one level			
			6	16	26
			7	17	27
			8	18	28
Bottom:	Level 1	WD with one level			
			9	19	29
			10	20	30

One level WD		
Bat. 1	Bat. 2	Bat. 3
1	6	11
2	7	12

One level WD		
Bat. 1	Bat. 2	Bat. 3
3	8	13
4	9	14
5	10	15

The process is interrupted immediately before start of disinfection.

Test instruments are removed while wearing clean, waterproof gloves and checked as specified.

If the insert trolley has e.g. only 2 levels, level 2 is the top level. If there are more than 4 levels, the load must be adapted accordingly, using the column "Additional level" in the form. In machines with only one cleaning level, position 5 instruments as shown in the grey levels. Distribute the test instruments as uniformly as possible among the levels available. Please mark any discrepant position.

8.3 Visual Inspection of Cleaned Test Instruments

Batch 1		Test instruments as per:		Result Protein Detection		
(use 1–5 for batch 1 for one-level WD)	Code	Visual Result	Acceptable value 100 µg	Alarm value > 100 µg – 200 µg	Limit value > 200 µg	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Batch 2		Test instruments as per:		Result Protein Detection		
(use 6–10 for batch 2 for one-level WD)	Code	Visual Result	Acceptable value 100 µg	Alarm value > 100 µg – 200 µg	Limit value > 200 µg	
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

Batch 3		Test instruments as per:		Result Protein Detection		
(use 11–15 for batch 3 for one-level WD)	Code	Visual Result	Acceptable value 100 µg	Alarm value > 100 µg – 200 µg	Limit value > 200 µg	
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						

Note: Enter the visual inspection results obtained for one-level washer-disinfector under numbers 1–15 (see grey area).

8.4 Visual Inspection of Instruments in Daily Use

Batch 1		Test instruments as per:		Result Protein Detection		
(use 1–5 for batch 1 for one-level WD)	Code	Visual Result	Acceptable value 100 µg	Alarm value > 100 µg – 200 µg	Limit value > 200 µg	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

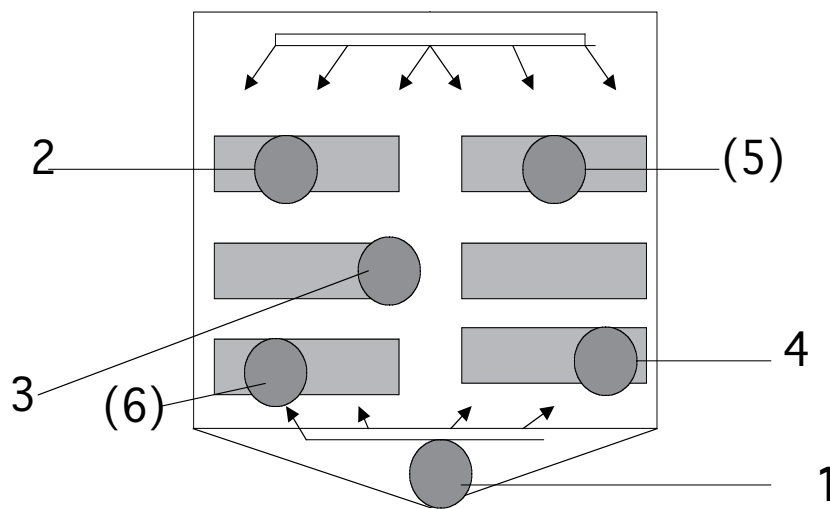
Batch 2		Test instruments as per:		Result Protein Detection		
(use 6–10 for batch 2 for one-level WD)	Code	Visual Result	Acceptable value 100 µg	Alarm value > 100 µg – 200 µg	Limit value > 200 µg	
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

Batch 3		Test instruments as per:		Result Protein Detection		
(use 11–15 for batch 3 for one-level WD)	Code	Visual Result	Acceptable value 100 µg	Alarm value > 100 µg – 200 µg	Limit value > 200 µg	
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						

Note: Enter the visual inspection results obtained for one-level washer-disinfector under numbers 1–15 (see grey area).

Checklist 9: Positioning Temperature Sensors

**Thermal Disinfection Based on
EN ISO 15883, 6.8.2**



1 = contiguous with temperature sensor for automatic control

2 = site at which temperature is reached most quickly

3 = site at which temperature is reached most slowly

4 (5, 6) = reference sensor for chamber temperature

It is recommended that at least two cycles, each with 6 sensors, or three cycles, each with 4 sensors, respectively, be checked for each load type.

Checklist 10: Daily Routine Checks of WD

Name of Central Sterile Supply Dept./CSSD	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.
WD No.:																
Month:																
Filters (tray filter) coarse/fine																
Pump well																
Rotary arms/cleaning nozzles																
Loading trolleys																
Connection																
Connections/adapters/dummy plugs																
Rollers																
Loading trolley inspection																
WD internal/external inspection																
Door seals																
Other daily checks specified in the Operating Manual																
Demin. water quality (check conductivity)																
Staff member's signature																
	17.	18.	19.	20.	21.	22.	23.	24.	25.	26.	27.	28.	29.	30.	31.	
Filters (tray filter) coarse/fine																
Pump well																
Rotary arms/cleaning nozzles																
Loading trolleys																
Connection																
Connections/adapters/dummy plugs																
Rollers																
Loading trolley inspection																
WD internal/external inspection																
Door seals																
Other daily checks specified in the Operating Manual																
Demin. water quality (check conductivity)																
Staff member's signature																

Details of the various items covered in the Checklist "Daily Routine Checks of WD"

Filters (tray filter) coarse/fine	Clean all filters and check integrity and fit
Pump well	Check and clean, remove small parts, e.g. scalpel blades, needles, etc. while complying with occupational safety requirements
Rotary arms/cleaning nozzles	Check for unimpeded and uniform rotation within the WD and on the loading trolleys. Check nozzles for any blockages and clean if necessary
Loading trolleys	
– Connection	Correct connection of loading trolleys in WD
– Connections/adapters/dummy plugs, nozzles	Check Luer locks and hose connections, dummy plugs and nozzles on the loading trolleys for correct functioning and completeness
– Rollers	Check for correct functioning and completeness
– Loading trolley identification	Check coding, if available
Visual inspection of WD internal/external	Check inside area for cleanliness and deposits (e.g. lime, silicates, rust)
Door seals	Check condition of door seals, cleanliness and leaks
Other daily checks specified in the Operating Manual	As per manufacturer's instructions
Demin. water quality (check conductivity)	Daily conductivity value measurement, 15 µS/cm should not be exceeded
Staff member's signature	Responsible staff member's initials
To assure problem-free operation, it must be possible to visually check the levels of storage containers (a different approach is needed for integrated containers, individual canisters, dosage facilities).	

Checklist 1 1: Matrix for Compilation of a Checklist for Routine Monitoring of Technical Functions

	Daily op. test *	2 weeks	3 months	6 months	annually**
1 Temperature and time monitoring by means of additional testing with data loggers					
1a WD with temperature documentation: actual value with separate sensors/logic-controller-independent measurement				X	X
1b WD with temperature documentation: actual value with separate sensors/logic-controller-dependent measurement			X		
1c WD with temperature documentation: actual value without separate sensors	X				
1d WD without temperature documentation or only with set point display					
2 Pressure monitoring/additional testing: e.g. pressure measurement or cleaning arm rotational speed	Per load	2 weeks	3 months	6 months	annually**
2a WD with pressure documentation: with monitoring of actual values					X
2b WD without pressure documentation: with monitoring of actual values			X		
2c WD without pressure documentation: without monitoring of actual values	X				
3 Dosage quantity monitoring/additional testing: e.g. monitoring of quantity or conductivity value	Daily op. test*	2 weeks	3 months	6 months	annually**
3a WD with dosage quantity documentation: monitoring of actual values / independent of logic controller			X		
3b WD with dosage quantity documentation: monitoring of actual values / dependent on logic controller		X			
3c WD without dosage quantity documentation: no control					
4 Water level monitoring/additional testing e.g. manual measurement of water level	Daily op. test*	2 weeks	3 months	6 months	annually**
4a WD with volume-controlled water inflow				X	
4b WD with level-controlled water inflow		X			
4c WD with time-controlled water inflow					

* daily operation test means 1 x per working day

** can also be carried out within the framework of performance requalification

Further explanations for this matrix are given on the following pages

Key to Matrix for Routine Monitoring of Technical Functions

The following instructions and remarks are a guide for assignment of the existing WD to the matrix:

1 Temperature and time or A_0 value monitoring by additional testing with data loggers

Depending on the technical features (see Models 1a – 1d), temperature measurements are required over a specified period of time in addition to the monitoring and documentation activities carried out in the WD. A data logger can be used for this.

1a WD with temperature documentation: actual value with separate sensors/logic-controller-independent measurement

In this model the WD is fitted with an additional temperature sensor that records the actual values (real temperature measurement) and has an independent logic controller module. In addition, the temperature values are recorded and the holding time verified.

1b WD with temperature documentation: actual value with separate sensors/logic-controller-dependent measurement

In this model the WD is fitted with an additional temperature sensor that records the actual values (real temperature measurement) but has no independent logic controller module. In addition, the temperature values and holding time are recorded. In this model there is a risk that a fault in the common logic controller, which is used for loop control and documentation, will not be detected. Therefore shorter intervals are needed for routine checks than in the case of Model 1a.

1c WD with temperature documentation: actual value without separate sensor

In this model the WD has no additional temperature sensor but the actual values (real temperature measurement) are recorded. The WD has no independent logic controller module. The temperature values and hold time are recorded. In this model there is a risk that a fault in the common logic controller or in the common temperature sensor, which are used for loop control and documentation, will

not be detected. Therefore shorter intervals are needed for routine checks than in the case of Model 1a and 1b.

1d WD without temperature documentation or only with set point display

When a WD only documents or displays values (values or alarm signals) that are not actually measured but rather only copied into the logic controller as fixed values (such values are known as "set point values"), this type of documentation is of a considerably lower safety standard than that of Models 1a – 1c. Therefore a routine check must be carried out each working day.

2 Pressure monitoring/additional testing: e.g. pressure measurement of the cleaning arm rotational speed

The wash pump pressure and hence the mechanical cleaning action constitute process-relevant parameters that must be verified. Depending on the technical features of the WD (see Models 2a – 2c) additional checks are necessary. This can be accomplished with a suitable data logger or by continually monitoring the cleaning arm rotational speed. If this is not possible, corresponding endpoint testing must be carried out.

2a WD with pressure documentation: monitoring of actual values

In this model the WD is equipped with a pressure switch that indicates achievement of a required minimum pressure or a pressure gauge that measures the actual values (real measurement of the wash pump pressure). In addition, the wash pump pressure is documented in the relevant process cycles.

2b WD without pressure documentation: with monitoring of actual values

In this model the WD is equipped with a pressure switch that monitors a specified minimum pressure. In this model there is a risk that a fault in the common logic controller will not be detected. There is no documentation as in Model 2a. Therefore shorter intervals are needed for routine checks than in the case of Model 2a.

2c WD without pressure documentation: without monitoring of actual values

The pump pressure and hence the cleaning mechanical action is not monitored. Therefore a routine check is needed for each load. Batch-related control is needed since foam formation can be seen in certain loads, leading to a drop in pressure (e.g. entrainment of surfactants).

3 Dosage quantity monitoring/additional testing: e.g. monitoring of quantity or conductivity value

The dosage function and dosage quantity are process-relevant parameters that must be monitored. Depending on the technical features of the WD (see Models 3a – 3c) additional checks are needed. These can be carried out by monitoring the conductivity value of the dosed solution or by volumetric measurement. Alternatively, manual checks (measurement of volume injected) are to be carried out.

3a WD with dosage quantity documentation: monitoring of actual values/independently of logic controller

In this model the WD is equipped with a dosimeter or equivalent sensor which measures the actual values as well as with an independent logic controller module. The measured values are documented.

3b with dosage quantity documentation: monitoring of actual values/dependent on logic controller

In this model the WD is equipped with a dosimeter or equivalent sensor which measures the actual values. The WD has no independent logic controller module. The measured values are documented. In this model there is a risk that a fault in the common logic controller, which is used for loop control and documentation, will not be detected. Therefore shorter intervals are needed for routine checks than in the case of Model 3a.

3c WD without dosage quantity documentation: no control

In this model there is no facility for dosage monitoring. Therefore routine checks must be carried out every two weeks.

4 Water Level Monitoring/Additional Testing e.g. manual measurement of water level

The water level is a process-critical parameter that must be monitored. Depending on the technical aspects and precision of the WD's measurement and control functions, additional checks are needed at defined intervals, such as e.g. manual measurement of water level.

4a WD with volume-controlled water inflow

Volume-controlled water inflow as a rule confers the highest degree of precision and safety.

4b WD with level-controlled water inflow

Level-controlled water inflow is considerably more reliable than time-controlled water inflow, but is more prone to inter-

ference than volume-controlled water inflow.

4c WD with time-controlled water inflow

The water level in time-controlled water inflow is dependent on the prevailing water pressure and can vary accordingly. Hence routine checks must be conducted very two weeks. ◆

Checklist 12: Matrix for Selecting WDs

1. Installation Conditions		2.6	Connections for process chemicals (access to the containers and their connections, note number of dosage pumps required)	4. User's Requirements	
1.1.	Space requirement			4.1.	Is the capacity of the intended WD (and existing WDs) economical?
1.1.1	Machine size (L-W-D)			4.1.1.	Observe load times
1.1.2	Maintenance room/Aggregate room	2.7	Is a central dosage facility advisable?	4.1.2.	Number of WDs
1.1.3	Access from loading/unloading side			4.1.3.	Number and type of LTs (e.g. MIS trolleys, number of trays per LT)
1.1.4	Space for loading trolleys (LTs), incl. storage space	2.8	Is there provision for sampling the water used for cleaning?	4.2.	Can decontamination be conducted as per the medical device manufacturer's instructions in the WDs to be purchased (DIN EN ISO 17664)?
1.1.5	Returning LTs	2.9	IT connections (network topology, note cable lengths, as necessary)	4.3.	Can utilisation be expanded by means of additional programmes and LTs
1.1.6	Air circulation/air-conditioning unit (heat, moisture) for WD and workstation (supply air)	3. Operation-Related Data		4.4.	Is easy, time-optimised and ergonomic operation possible?
1.1.7	Space for process chemicals and dosage facilities, incl storage space (external or internal)	3.1	Programme selection in accordance with medical devices and other items to be decontaminated, while taking account of the manufacturer's instructions (DIN EN ISO 17664)	4.4.1.	Loading and unloading
1.1.8	Space for process documentation			4.4.2.	Supply of process chemicals' containers
1.1.9	Transportation openings or space for WD	3.1.1	Is the WD suitable for decontamination of the respective MDs	4.4.3.	Making connections for special LTs
1.2	Statical conditions at installation site (ceiling load/ floor load, load-bearing capacity)	3.1.2	Note type and number of suitable loading trolleys (LTs), incl. examining possibility of further use for existing LTs	4.4.4.	Process observation/Easy release possible?
1.3	Influence exerted by/on adjacent room(s)	3.2	If a type test has been conducted as per EN ISO 15883, list the test conditions	4.4.4.1.	Glass door
1.3.1	Noise level (occupational safety)			4.4.4.2.	Cleaning arm sensors
1.3.2	Electromagnetic fields	3.3	Consumption data/costs	4.4.4.3.	Printout and display of all parameters relating to the process
1.3.3	Risk evaluation in respect of potential water damage	3.3.1	Consumption per programme and load	4.4.4.4.	Alarm messages
1.4	Scope of structural measures required	3.3.1.1	Demineralised water	4.4.4.5.	Separation of loop control and measuring sensors and logic controllers
1.4.1	Costs	3.3.1.2	Cold water (CW) and hot water (HW)	5. Project Management	
1.4.2	Time investment	3.3.1.3	Electricity	5.1.	Everything possible from a single source, or interfaces to different subdistributors
1.4.3	Competencies	3.3.1.4	Proposed process chemicals (in consultation with the supplier of chemical agents and based on the MD manufacturer's instructions)	5.2.	Draft designs
2. Connection Conditions/ Consumable Agents		3.3.2	Maintenance costs	5.3.	Design – inspection by contractors
Connection conditions for consumable agents are specified by the WD supplier, e.g.:		3.3.2.1	Maintenance costs (request scope of maintenance, with a protocol of contents)	5.4.	Delivery times
2.1	Demineralised water (pressure, quality, quality, output)	3.3.2.2	Inspection costs (request scope of inspection, with a protocol of contents)	5.5.	Installation periods
2.2	Other factors relating to water (pressure, quality, output)	3.3.2.3	As per DIN 31050 "Maintenance", as applicable	5.6.	Restricted use during the installation phase
2.3	Compressed air (pressure, quality)			5.7.	Acceptance tests
2.4	Electricity (diameters, fuse protection)			5.7.1.	Acceptance as per Spectaris "Acceptance Protocol"
2.5	Waste water (diameters, non-pressurised flow, position and material of the waste water system)			5.7.2.	Installation qualification
				5.7.3.	Operation qualification
				5.8.	Performance qualification ◆

Notes

Notes

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