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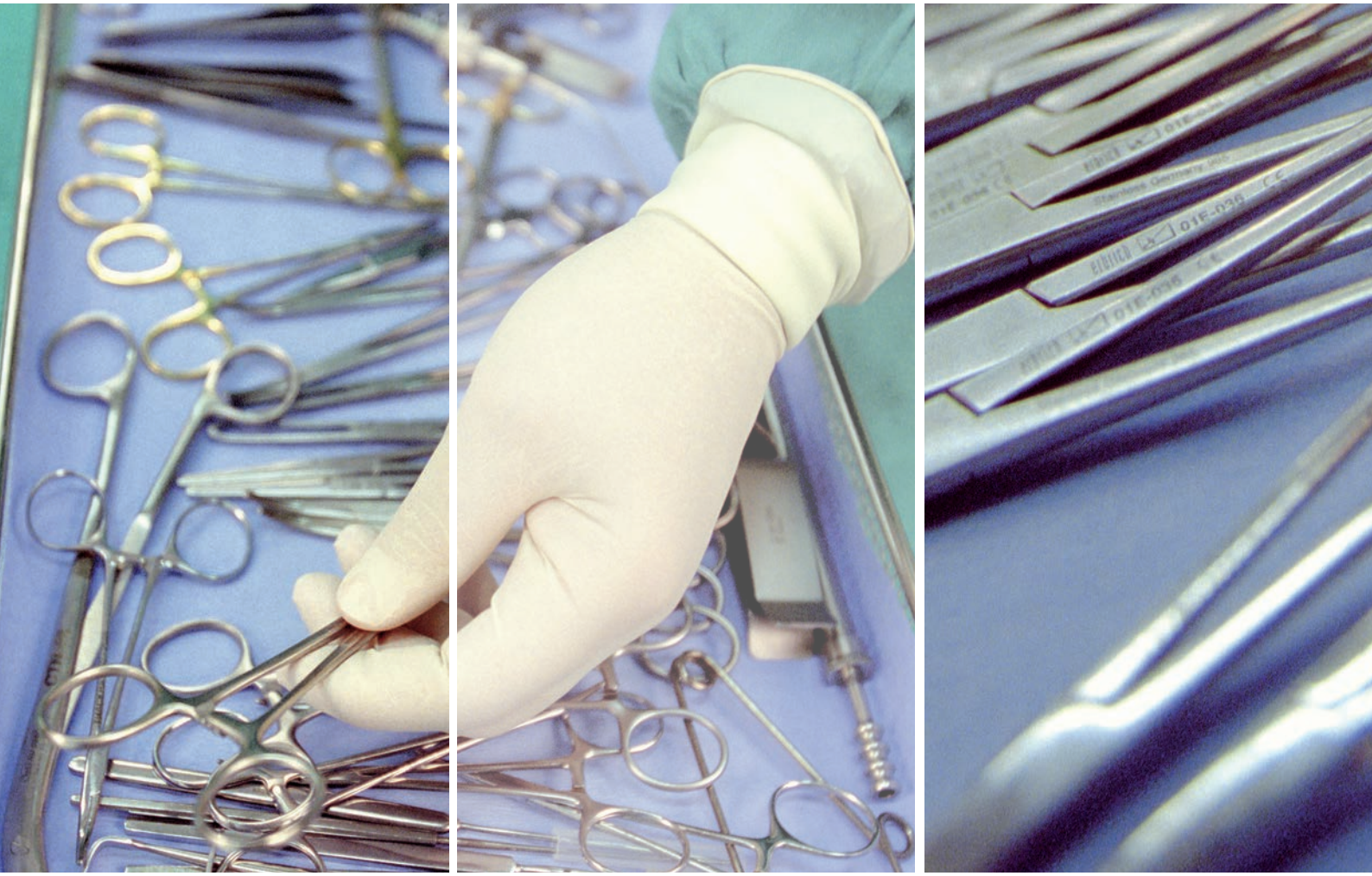

Guideline for validation of manual cleaning and manual chemical disinfection of medical devices

DGSV Deutsche Gesellschaft für Sterilgutversorgung e.V.

DGKH

ARBEITSKREIS INSTRUMENTEN-AUFBEREITUNG

VAH Verbund für Angewandte Hygiene e.V. Desinfektionsmittel-Kommission

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Foreword

Medical devices that should be sterile, or at most have only a low microbial count (disinfected), when used must be processed with validated procedures, while observing the manufacturer's instructions, so as to ensure that the effectiveness of these processes is demonstrated and the safety and health of patients, users or third parties are not compromised.
Apart from the automated cleaning and disinfection process, which should preferably be used, manual cleaning and chemical disinfection process steps are permitted in justified cases and must be validated as parts of the entire process.
Validation of processes, and corresponding standardization of process steps, will not be possible if there is no quality management system in place.
Only through strict adherence to the individual standard operating procedures compiled by the operator and verification that all steps are duly implemented will it be possible to demonstrate quality assurance and reproducibility of the results. This is documented in the validation report.
To understand these interrelationships, both the staff entrusted with processing and the validation personnel need to have extensive knowledge and expertise, which are acquired through qualification (for example as set out in the Qualification Directive of the German Society for Sterile Supply – DGSV e. V.).
Successful conduct of manual cleaning and disinfection was generally not verified in the past. Against that background, and in the light of experiences gained from compilation of guidelines for validation of automated cleaning and disinfection processes, the present Guideline for Validation of Manual Cleaning and Manual Chemical Disinfection has now been compiled. It gives operators/processors, for the first time, information and background legal explanations* on drafting standard operating procedures and their validation.

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**Note: Legal and normative background stated in this guideline are based on application in Germany, following German requirements. If this guideline is applied by processing units in other countries, respective national laws have to be observed.*

1 DGSV: German Society for Sterile Supply
2 AKI: Working Group Instrument Preparation
3 DGKH: German Society for Hospital Hygiene

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Masthead

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Guideline for Validation of Manual Cleaning and Manual Chemical Disinfection of Medical Devices

1 Principles of the Guideline

Quality assurance in medical device (MD) processing is not only a legal obligation, it also has important implications for economic efficiency. Prevention of healthcare-associated (nosocomial) infections is an interdisciplinary challenge for all parties involved. Expert medical device processing is an important component in this regard. The medical devices must be designed to withstand automated and/or manual processing. By assuring process safety, the procedure used must guarantee proper and reproducible processing. The personnel entrusted with processing must have the requisite knowledge and qualifications to ensure proper processing. This Guideline for Validation of Manual Cleaning and Manual Chemical Disinfection (called «manual cleaning and disinfection» in the following) of medical devices disinfected using an immersion method is intended for all establishments in which medical devices are processed for use on humans. The following principles apply for processing:

- The operator is responsible for setting up and maintaining a quality management system.
- The operator is responsible for ensuring that the personnel entrusted with processing have the requisite expertise.
- The operator is responsible for ensuring that validation, performance requalification and periodic routine tests are carried out.
- Preference must be given to automated cleaning and disinfection.
- The acceptance criteria for the efficacy of manual and automated processes are identical.
- «The use of manual processes, when automated processes are available, presupposes that proof of the equivalence of the efficacy of manual and automated processes will have been furnished» [KRINKO/BfArM Recommendation 2012]
- Effective cleaning is a prerequisite for effective disinfection and – if necessary – for subsequent sterilization.

The objectives of the Guideline are as follows:

- Provision of working materials to compile operator-specific standard operating procedures for manual cleaning and disinfection of medical devices tailored to the design of the respective medical device.
- Provision of methods and acceptance criteria for verification of operator-specific standard operating procedures with regard to the cleaning and disinfection results as well as for detection of chemical residues following manual cleaning and chemical disinfection.

1.1 Definitions

Alarm Value
A value which, if exceeded, requires implementation of measures to optimize the process/standard operating procedure, in order to attain/undershoot the guide value

Batch
Medical device or group of medical devices subjected at the same time to a processing procedure

Chemical Disinfection
Reduction of the number of microorganisms in or on an inanimate matrix attained through the irreversible effect of a product on their structure or metabolism to a degree deemed appropriate for a specific purpose (EN 14885)

Chemical Disinfectant
A mixture of one or several biocidal substances used for chemical disinfection

Cleaning
Removal of soils from an object to the extent needed for subsequent processing or the intended use (EN ISO 17664)

Detergent
A substance or mixture of substances that helps to clean medical devices by removing soils

Detergent Disinfectant
A mixture of substances containing detergent as well as disinfectant compounds

Expiry Date
A date on the medical device packaging specifying the date until which the device may be used, assuming it is stored as per the manufacturer's instructions

Guide Value
A value that must not be exceeded in order to complete performance qualification

Gross/Rough Soiling
Visible contamination on medical devices which can be easily removed after using the medical devices. This includes e. g. tissue residues, bone splinters and dental cement.

Hollow Cavity/Lumen in Medical Devices
Medical device which, because of its construction/design, has internal surfaces that do not permit complete visual inspection from the outside

Installation Qualification (IQ)
Process of obtaining and documenting evidence that the organizational, structural and technical prerequisites have been met

Limit Value
A value which, if exceeded, requires immediate process shutdown; the corresponding standard operating procedure must no longer be used.

Manual Chemical Disinfection
Chemical disinfection without using a washer-disinfector

Manual Cleaning
Cleaning without using a washer-disinfector (EN ISO 17664)

Manufacturer/Distributor
Organization or person responsible for construction, manufacture, packaging and labelling of a device before it is placed on the market under his own name, irrespective of whether these activities were conducted by this person himself or by an appointed third party (EN ISO 17664)

Operational Qualification (OQ)
Process of obtaining and documenting evidence that the installed equipment operates within predetermined limits when used in accordance with its operational procedures

Performance Qualification (PQ)
Process of obtaining and documenting evidence that processes were conducted in accordance with the standard operating procedures, thus yielding products that meet the respective specifications

Process
A series of interrelated activities that convert inputs into results (ISO 9000)

Process Chemical
Chemical substances or mixture of substances used for cleaning and/or disinfection of medical devices, such as detergents, disinfectants, care agents, water, etc.

Processor/Operator
An organization or person responsible for performing actions needed to prepare a new or used medical device for its intended use (EN ISO 17664)

Processing
Processing of medical devices, which should be sterile or, at most, have only a low microbial count (disinfected) when used, involves their cleaning, disinfection and sterilization, including associated working steps as well as testing and restoration of functional safety, after use for the purpose of reuse (MPG Section 3 [14])

Product Group/Medical Device Group
Medical devices that are comparable in terms of design and cleaning and disinfection requirements, and for whose cleaning and disinfection one single standard operating procedure can be compiled

Shelf Life of Unused Application Solution of a Disinfectant/Detergent Disinfectant
Period of time during which the proven disinfection efficacy of a ready-to-use solution is preserved, when prepared according to the manufacturer's instructions in the recommended concentration and then left to stand unused, in a covered container, for the time period specified by the manufacturer

Stability of Used Application Solution of a Disinfectant/Detergent Disinfectant
Period of time during which the proven disinfection efficacy of a ready-to-use solution is preserved on repeated use, when prepared according to the manufacturer's instructions in the recommended concentration and then used for the time period specified by the manufacturer

Standardization
The totality of measures taken for harmonization, simplification, classification, limitation or restriction of processes in the form of optimum technical solutions

Standard Operating Procedure
contains a detailed standardized description of how to carry out a task or working step

Validation
A documented process for obtaining, recording and interpreting the results required to establish that a process will consistently yield products complying with predetermined specifications (EN ISO 17664)

Workstation
Structural arrangement and layout equipped with the fittings needed to conduct manual cleaning, rinsing, disinfection and drying

1.2 List of abbreviations

Abbreviation	Explanation
°C	Degree Celsius
AKI	Working Group Instrument Preparation
BAM	Federal Institute for Materials Research and Testing
BCA	Bicinchonic acid
BfArM	Federal Institute for Drugs and Medical Devices
BGBl	Federal Health Gazette
BGR	Rules adopted by the statutory accident insurance institutions
BGV	Guidelines issued by the statutory accident insurance institutions
BiostoffV	Biological Substances Regulation
BSA	Bovine serum albumin
C + D	Cleaning and disinfection
CJD	Creutzfeldt-Jakob disease
cm	Centimetre
cm^2	Centimetre squared
CW	Cold water
dB	Decibel
DGHM	German Society for Hygiene and Microbiology e. V.
DGKH	German Society for Hospital Hygiene e. V.
DGSV	German Society for Sterile Supply e. V.
DIN	German Institute for Standardization e. V.
DVV	German Society for Control of Viral Diseases e. V.
DW	Demineralized water
EN	European standard
ESGE	European Society for Gastrointestinal Endoscopy
ESGENA	European Society of Gastroenterology and Endoscopy Nurses and Associates
EEC	European Economic Community
GMBI	Joint Ministerial Gazette
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HF	High frequency
HIV	Human immunodeficiency virus
IEC/TR	International Electrotechnical Commission/Technical Rules
IfSG	Infection Protection Act
IQ	Installation qualification
ISO	International Organization for Standardization
kHz	Kilohertz
KRINKO	Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute
LAGA 18	State Working Group on Waste Disposal, Implementation Guide 18
LED	Light emitting diode
m^3	Cubic metre
mg	Milligram
MIS	Minimally invasive surgery
min	Minutes
mm	Millimetre

MD	Medical device
mPas	Millipascal
MPBetreibV	Medical Devices Operator Ordinance
MPG	German Medical Devices Act
OP	Operation
OPA	ortho-Phthaldialdehyde
OQ	Operational qualification
PCD	Process Challenge Device
PE	Polyethylene
PPE	Personal protective equipment
PQ	Performance qualification
prEN	Preliminary standard of a European standard
QM	Quality management system
RKI	Robert Koch Institute
SDS	Sodium dodecyl sulphate
SGB	German Code of Social Law
SOP	Standard operating procedure
TMB	Tetramethyl benzidine
TRBA	Technical Regulation on Biological Substances
TrinkwV	Drinking Water Regulation
VAH	Association for Applied Hygiene
vCJD	Variant Creutzfeldt-Jakob disease
VDI e. V.	Association of German Engineers
W	Watt
e. g.	for example
µg	Microgram
µm	Micrometre
µS	Microsiemens

1.3 Using the Guideline

The Guideline consists of an explanatory section as well as of annexes, a test matrix and checklists.

The annexes describe structural prerequisites, test methods and processes. They provide additional information on the respective topic.

Annex 9 «Acceptance criteria for assessment of cleaning efficacy» sets out the currently valid acceptance criteria.

The Test Matrix gives the user tips on how to plan and verify the various validation steps. Details of the recommended test intervals help the processing departments draw up the relevant schedules.

The Checklists have been designed to help the user to verify the different validation steps. Individual checklists can be directly implemented in the processing departments to facilitate planning and conduct of validation and to record the test results.

2 Legal and Normative Background

Medical establishments are obliged to conduct medical device processing in line with the dictates of quality assurance as imposed directly and indirectly by a series of legal acts, regulations, recommendations and standards.

2.1 Legal acts and regulations

All service providers in the healthcare sector are obliged to implement quality assurance measures aimed at improving the outcome quality. To that effect, they must set up an inhouse quality management system and continue to develop this (Sections 135–137 of Book V of the German Code of Social Law).

The Infection Protection Act (IfSG) calls for compilation of Infection Control (Hygiene) Policies. These policies must define parameters for processing, including checks and tests.

The German Medical Devices Act (MPG), which transposed Council Directive 93/42/EEC of 14 June 1993 concerning medical devices into German law, regulates, inter alia, the requirements for functional and hygienic safety of medical devices.

The Medical Devices Operator Ordinance (MPBetreibV) calls for, in Section 4(2), inter alia, validation of processing procedures.

The Drinking Water Regulation defines microbiological and chemical requirements for drinking water.

The Regulation on Health and Safety When Handling Biological Substances (BiostoffV) applies to tasks involving biological substances (pathogens) and must be observed when processing medical devices. It calls for hazard assessment and definition of protective measures for a particular degree of protection.

BiostoffV is supplemented by the Principles of Prevention (BGV A1), this is a document relating to health and safety in the workplace compiled by the Employers' Liability Insurance Association (statutory accident insurance associations), and by Biological Agents in the Healthcare Sector and in the Welfare Services (BGR 250/TRBA 250). It stipulates special precautions and behavioural approaches for healthcare personnel that run the risk of contracting infection from pathogens.

2.2 KRINKO Recommendations

Pursuant to Section 23(3) IfSG, compliance with the relevant state of medical science is assumed if the published KRINKO Recommendations for the respective area are observed.

Furthermore, pursuant to Section 4(2) MPBetreibV appropriate processing is assumed if the KRINKO/BfArM Recommendation for hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), are observed

This KRINKO/BfArM Recommendation sets out the requirements to be met by the processing procedures. Annex 1 describes «suitable validated processes»: «When processing a MD, the sum of all automated and manual processes involved (the various, mutually complementary processing steps) contribute to achieving the processing goal. Hence, inadequately validated individual steps (processes), as well as failure to observe the standard operating procedures, detract from the processing quality outcome».

In addition, at least the following KRINKO Recommendations must be observed:

- Hygiene requirements for cleaning and disinfection of surfaces
- Requirements for the design, features and operation of decentralized disinfectant dispensers
- Hand disinfection.

2.3 Standards

Standards are anticipated expert opinions on the state of the art. The standards of importance for this Guideline include:

- EN ISO 14971 describes risk management with regard to medical devices
- EN 14885 specifies which claims by disinfectants (spectrum of action) must be substantiated by which European test standards
- EN ISO 17664 is intended for reusable medical devices and single-use devices that are supplied in an unsterile state but must be sterile when used. This standard specifies the information to be provided by the medical device manufacturer for processing medical devices claimed to be resterilizable. This information must include details of safe, val-

idated processing while ensuring that the medical device's functionality is preserved. «A validated process must be specified for manual cleaning. In addition, at least one automated process in a washer-disinfector must be specified, unless the medical device does not lend itself to such a process. If that is the case, a warning should be issued». Information on the manufacturer's instructions are given in Annex 1 «Contents of EN ISO 17664».

2.4 Recommendations

The recommendations of importance for this Guideline are:

- Disinfectants List by the Association for Applied Hygiene (VAH), setting out the chemical disinfection methods tested and deemed effective for prophylactic disinfection and hygienic handwashing.
- Guideline by the German Association for Control of Viral Diseases (DVV) e. V. and the Robert Koch Institute (RKI) describing the methods for testing chemical disinfectants for efficacy against the viruses encountered in human medicine.

3 Scope

This Guideline for Validation of Manual Cleaning and Disinfection of Medical Devices is intended for all centres in hospitals and medical practitioners' offices in which medical devices for use on humans are processed. It also applies for piercing and tattooing studios as well as for podiatry establishments.

The Guideline should be consulted for manual cleaning and disinfection, including manual pre- and re-cleaning in combination with automated cleaning/disinfection processes of all medical devices used on patients. The following are not covered by this Guideline:

- Processing steps such as inspection, care, functional testing, packing, labelling, sterilization, release for use after sterilization, distribution and storage
- Heat-sensitive endoscopes
- Medical devices designated for single use by the manufacturer
- Medical devices excluded by regulation (e. g. by the KRINKO/BfArM Recommendation)
- Medical devices requiring wipe disinfection.

Pursuant to the KRINKO/BfArM Recommendation, for cleaning and disinfection of medical devices belonging to the Critical B group automated cleaning and thermal disinfection must in principle be carried out with validated processes. If substantiated and following risk analysis and evaluation it is revealed that medical devices belonging to the Critical B group lend themselves only to manual cleaning and chemical disinfection, the medical device manufacturer's instructions for validated manual cleaning and disinfection must be observed.

The Guideline does not take account of special aspects of medical device processing in relation to CJD/vCJD.

It is pointed out that a detailed description of all aspects of the accessories needed for manual cleaning and disinfection is outside the scope of this Guideline (e. g. details of the water and air operating pressure needed, compressed air quality), since precise details are not available in the literature or in the manufacturer's instructions.

4 Requirements for processes

Manual cleaning, disinfection, rinse and drying processes must be carried out in a standardized manner. Under no circumstances should the manual processes lead to a poorer outcome compared with that assured by an automated process. This must be demonstrated in the context of validation of standardized manual processes. All steps of manual processes must be performed, verified and recorded by demonstrably qualified personnel.

4.1 Preconditions for standardization

Establishment of a quality management system is a prerequisite for standardization and facilitates organization of working practices. Standard operating procedures for cleaning and disinfection processes also serve as verification standards. The quality of manual cleaning and disinfection is demonstrably assured by defining and implementing suitable test measures as well as by observing the defined acceptance criteria and, if applicable, taking remedial action. Process reproducibility can only be assured if all process participants are appropriately trained.

The operator must draw up standard operating procedures, describing in details all processing steps. Depending on the medical device's intended purpose and use, SOPs must also be compiled for any processing steps prior to and/or after cleaning and disinfection. This applies for testing and operating equipment and systems used during the cleaning and disinfection process (for example an ultrasonic bath/cleaner, stopwatches, dosing equipment).

Note: Standard operating procedures are tailored to a specific process, medical device or workplace. They serve as service instructions for all staff members to ensure that tasks can be demonstrably discharged in a quality-assured and reproducible manner. The individual working steps are commonly presented in flow charts, tables or summarized in short sentences.

To standardize a manual cleaning and disinfection process, the prerequisites described below, at the very least, must be met by the operator and by the manufacturers of the medical devices, accessories (e. g. ultrasonic bath, brushes) and of process chemicals.

4.1.1 Structural, technical and organizational prerequisites at operator's premises

First, the structural and spatial prerequisites are verified and, if necessary, amended. Of paramount importance here is definition of working sequences while taking account of occupational health and safety requirements.

If structural separation of the cleaning/disinfection zone from the clean zone is not possible, by taking appropriate functional and/or organizational measures it must be ensured that transmission of microorganisms and particles is kept to a minimum. Standardization can begin only after the circuit allotted for manual cleaning and disinfection has been properly set up, connected and is operational, and all operating materials of the required quality are available.

An example of the workstation for manual cleaning and disinfection is illustrated in Annex 2 «Workstation – example».

Quality assurance measures are among the organizational prerequisites of vital importance for standardization of manual cleaning and disinfection process. Before standardization can begin, risk assessment must be conducted and the medi-

cal devices classified in accordance with the «Hygiene requirements for processing medical devices» stipulated by the KRINKO/BfArM Recommendation.
Checklist 1 «Organizational prerequisites to be met by operator» (Part A of installation qualification) helps to define the organizational prerequisites at the operator's premises.
Checklist 2 «Structural and technical prerequisites to be met by operator» (Part B of installation qualification) helps to define structural and technical prerequisites at the operator's premises.

4.1.2 Information to be provided by the manufacturers to the operator

A prerequisite for standardization of a manual cleaning and disinfection process is as following: the relevant instructions must have been supplied by the manufacturer of the medical devices, of process chemicals as well as of the equipment and utensils used in the cleaning and disinfection process.

4.1.2.1 Information to be provided by the instrument manufacturers

The instrument manufacturers must provide the operator with processing instructions containing the information set out in EN ISO 17664.
Below is an example of the information that should be given in the manufacturer's instructions for processing medical devices.

- Material compatibility of the medical devices with the process chemicals used, while taking account of the contact time
- Suitability for use in ultrasonic bath
- Requirements for compressed air, if special conditions apply
- Requirements for drying accessories
- Requirements for cleaning and disinfection accessories, if special conditions apply (for example, materials, dimensions and length of brushes for narrow-lumened instruments).

4.1.2.2 Information to be provided by the process chemicals' manufacturers

The process chemicals' manufacturers should provide the operator with, inter alia, the following:

- Safety data sheets
- Use instructions with application recommendations on e.g.:
  - Concentration
  - Contact time
  - Application temperature
- Spectrum of action for disinfectants with information on whether products featured on the VAH List
- Details of amount of residual chemicals tolerated.

4.1.3 Content of standard operating procedures

First, risk assessment and classification of the medical device must be performed. The information in Annex 3 «Determination of a processing procedure» can be consulted to devise a processing procedure.
As a guide to compiling the respective standard operating procedure, while taking account of the circumstances under which the individual steps listed in 4.2.1 – 4.2.10 are carried out by the operator, the flow charts given below by way of example, containing detailed information on the procedures required, can be consulted:

- Annex 4 «Flow chart: Group A instruments»
- Annex 5 «Flow chart: Group B instruments with joints»
- Annex 6 «Flow chart: Group B hollow instruments»

These flow charts set out the requisite steps for manual cleaning and disinfection and serve as a guide for compiling operator-specific standard operating procedures for individual medical devices or medical device groups.
The standard operating procedures must give precise details of the operator-specific procedures, while listing the adjuncts needed, such as for example:

- Process chemicals, contact times, concentrations
- Cleaning accessories (type and dimensions of cleaning brushes)
- Cleaning steps (water quality, water quantity and/or details of cleaning time)
- Drying (non-linting cloths, compressed air quality and quantity, drying cabinet).

4.2 Standardization of the process

Operator-specific, documented, standardized processes (standard operating procedures) must be compiled for all medical devices and medical device groups. Manual cleaning and disinfection processes comprise the working steps listed below and these must be set out in writing. If a medical device that was not available hitherto (new) is to be cleaned and disinfected, it must be decided whether an existing SOP can be used or whether a new SOP has to be compiled.
The decision as to whether this involves a new process can be made by carrying out risk analysis and evaluation. To that effect, the content of existing SOPs are compared with the requirements for cleaning and disinfecting the new medical device.

Note: To reduce the number of process validations needed, changes can be made to the working steps.

4.2.1 Tasks immediately after use

If applicable, additional steps may have to be taken at the medical device point of use in preparation for processing. These include, for example, elimination of gross soiling and flushing of hollow cavities to prevent drying of adherent residues, making it harder to remove them later. Where possible, medical devices should be disassembled as per the manufacturer's instructions. The medical devices should be transported in closed containers, preferably in a dry state, and in timely fashion.

4.2.2 Pre-cleaning

Manual pre-cleaning tasks must be carried out in the cleaning/disinfection zone, while taking account of occupational health and safety regulations.
Pre-cleaning is performed, if necessary, using suitable detergents and/or equipment, such as e. g. an ultrasonic cleaner. This is used to remove soils (for example, heat-fixed coagulation residues, bone residues) which are not eliminated by the ensuing routine automated or manual cleaning steps.

4.2.3 Cleaning

Manual cleaning tasks must be carried out in the cleaning/disinfection zone, while taking account of occupational health and safety regulations.
Manual cleaning is performed with suitable detergents, using the following combination: immersion, brushing, if necessary, use of ultrasound and rinsing.
Cleaning serves to remove soils from the medical device to the extent needed for subsequent processing or for the intended use.

4.2.4 Intermediate rinse
Manual rinsing tasks must be carried out in the cleaning/disinfection zone, while taking account of occupational health and safety regulations.
Rinsing with water serves to remove chemical detergents and, if necessary, adherent residual soils from the medical device. Attention must be paid to ensuring that all external and internal surfaces are rinsed. Moveable parts must be moved while rinsing.

4.2.5 Draining off
Medical devices must be drained off in the cleaning/disinfection zone, while taking account of occupational health and safety regulations.
Medical devices are allowed to drain off to minimize dilution of the disinfectant solution. Therefore the water must have drained off from all the medical device's external and internal surfaces before it is immersed in the disinfectant solution.

4.2.6 Inspection for cleanliness
Medical devices must be inspected for cleanliness in the cleaning/disinfection zone, while taking account of occupational health and safety regulations.
Cleanliness is determined through visual inspection, if necessary, using a magnifying lamp.

4.2.7 Disinfection
Manual disinfection is performed by immersing the medical device in an instrument disinfectant solution, while ensuring complete wetting of all the medical device's internal and external surfaces. When choosing a disinfectant, pay attention to the spectrum of action, concentration and contact time as well as shelf life of the solution.

4.2.8 Final rinse
Rinsing with water serves to remove process chemicals from the medical device. Attention must be paid to ensuring that all external and internal surfaces are rinsed. Moveable parts must be moved while rinsing.

4.2.9 Drying
First, the water must be allowed to drain off from all internal and external surfaces. Then the internal and external surfaces are dried with compressed air, and with clean, low-microbial and non-linting cloths and/or in a drying cabinet.

4.2.10 Documentation and release
Conduct of all cleaning and disinfection substeps must be documented. The various steps and release can be recorded using, for example, the Checklist 3 «Batch documentation» form.
The batch/medical device is released once all the aforementioned manual cleaning and disinfection substeps have been completed and documented.
Depending on the medical device's intended use, the processing procedure may be underpinned by subsequent working steps (functional testing, packing, sterilization, etc.).

5 Validation
«Manual cleaning and disinfection processes, e. g. used for pre-cleaning medical devices or for devices that do not lend themselves to automated cleaning/disinfection (group B) or based on risk analysis, must always be carried out in accordance with documented standard operating procedures, while employing products of proven efficacy as well as agents and methods tailored to the medical device» (1.3 Validation of processing procedures, KRINKO/BfArM Recommendation 2012).
Validation serves to verify and demonstrate reproducibility of standardized manual cleaning and disinfection processes in a particular workstation at the operator's premises. Validation consists of installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).
The «Test Matrix for validation of manual cleaning and disinfection processes» gives an overview of the tests that should be performed for validation and performance requalification as well as routine checks. The Matrix draws attention to further documents.
The validation personnel's qualifications with regard to validation of manual cleaning and disinfection processes is an important aspect of its conduct. Annex 7 «Requirements to be met by validation personnel» describes the basic requirements to be met by the validation personnel (persons and institutions entrusted with conduct of validation).

5.1 Prerequisites
Compilation of an overview plan, setting out at least the following details, is a prerequisite for validation:

- Responsibilities
- Qualification steps (IQ, OQ and PQ)
- Validation release by the operator
- Implementation of measures if validation failed

Checklist 4 «Validation report cover page» can be used to facilitate planning and conduct of validation. It can also be used as a cover page for the validation report.

5.2 Tests as part of validation

5.2.1 Installation qualification (IQ)
Installation qualification is carried out to ensure that the working area and all requisite equipment, working materials/accessories as well as the manual cleaning and disinfection environment are appropriate and properly installed.
The tests and checks performed for installation qualification must be defined, implemented and the results recorded.
It is recommended that the corresponding checklists be used for conduct of IQ. Checklist 1 «Organizational prerequisites to be met by the operator (Part A der installation qualification)» and 2 «Structural and technical prerequisites to be met by operator (Part B of installation qualification)» are given in the annex and can be used as a guide and for documentation.

5.2.2 Operational qualification (OQ)
During operational qualification a check is carried out to ascertain whether all equipment, working materials and accessories are functional and qualified in line with the quality management system. Evidence must be provided that servicing, calibration, functional testing and performance tests as specified in the quality management system have been conducted.
Checklist 5 «Operational qualification» can be used as a guide to operational qualification.

5.2.3 Performance qualification (PQ)
During performance qualification proof must be furnished that following manual cleaning and disinfection reproducibly cleaned and disinfected medical devices are produced in accordance with the respective SOP. Performance qualification must be carried out for SOPs.
Compliance with all parameters set out in the SOPs, e. g. time periods, brushing cycles must be verified and recorded.
The disinfectant efficacy is tested indirectly by investigating the parameters exerting

an influence on the disinfection efficacy. Checklist 6 «Performance qualification» can be consulted for conduct of performance qualification.
The methods used for efficacy testing of cleaning, disinfection, drying and for checking for process chemical residues are described below.

5.2.3.1 Verification of cleaning

5.2.3.1.1 Definition of test instruments

The aim here is to verify how effective each compiled SOP has been implemented for the specified workstation by the appointed personnel.
The cleaning results are verified for non-critical, semi-critical A and critical A medical devices on the basis of instruments contaminated with everyday soils.
If semi-critical B and/or critical B medical devices are processed, proof of cleaning efficacy must be furnished additionally on the basis of Crile clamps contaminated with standardized blood.

5.2.3.1.2 Methods for verification of cleaning

5.2.3.1.2.1 Instruments with everyday soils

Practice-oriented efficacy tests entail checking medical devices of various designs, e. g. with joints and/or lumens, which were contaminated during routine use. Accordingly, the conditions impacting on cleaning when using the instruments, pre-processing handling and the various cleaning additives used are taken into account.
The medical device must be inspected for cleanliness, if necessary, using a magnifying lamp. Medical devices with surfaces not amenable to visual inspection must be checked by means of a semi-quantitative or quantitative protein detection test (see Annex 8 «Verification of cleaning»).
If residues of unknown provenance are detected during visual inspection, protein detection will help to distinguish between soil residues and corrosion. Corrosion is not a criterion on which to base assessment of the cleaning results.

5.2.3.1.2.2 Process challenge devices

Crile clamps, with a defined quantity of a test soil produced in a qualified laboratory, are used as process challenge devices (PCDs) (as set out in the DGKH, DGSV and AKI Guideline for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices as well as advice on selecting washer-disinfectors; 3rd edition, 2008. *Central Service* 16; Suppl 2 [published in German only]). These PCDs are manually cleaned in order to attain a value during cleaning performance which will serve as a reference parameter for the cleaning efficacy.
The PCD is inspected for cleanliness, if necessary using a magnifying lamp.
Visually clean PCDs are then checked for protein residues using one of the methods described in Annex 8 «Verification of cleanliness».

5.2.3.1.3 Procedure

To demonstrate reproducibility, manual cleaning must be carried at least thrice for each standard operating procedure during performance qualification for instruments with everyday soils as well as for the PCDs. Details of the number of instruments with everyday soils and PCDs to be tested are given in the «Test Matrix for validation of manual cleaning and disinfection processes». If several persons are involved in cleaning, the instruments with everyday soils and PCDs must be divided up among these persons.
The instruments with everyday soils should be contaminated during use in a «real-world setting», while exposed to all particular conditions of influence. Certain instruments or parts thereof, which are visibly contaminated, are selected and documented (possibly with photos). On expiry of the maximum time allotted by the specific operator for pre-processing handling after use/drying, the instruments should be cleaned manually in accordance with the corresponding SOP.

5.2.3.1.4 Assessment

All instruments and/or PCDs must be visibly clean. Quantitative or semi-quantitative testing is performed only for visibly clean instruments and PCDs.
The binding criteria and values specified in Annex 9 «Acceptance criteria for assessment of cleaning efficacy» must be observed. The acceptance criteria are based on the results of selected validation examples of cleaning and disinfection processes.
The acceptance criteria have been amended in the light of the five-year experiences gained from implementation of the «DGKH, DGSV and AKI Guideline for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices as well as advice on selecting washer-disinfectors» from 2008. They are also based on the evaluation of validation results for automated cleaning and disinfection processes from 2011 – 2012 (Michels W, Roth K, Eibl R: Assessment of cleaning efficacy based on the protein-surface relationship. *Central Service* 2013; 21: 208–211). This led to a reduction in some cases of the alarm, limit and guide values compared to the aforementioned 2008 guideline. The acceptance criteria will be critically reviewed after one year's experience by the authors of both guidelines and amended, if necessary.

5.2.3.2 Verification of disinfection

Disinfection efficacy as set out in the standard operating procedure is tested indirectly. The prerequisites for successful disinfection are as follows:

- Successful verification of cleaning as per 5.2.3.1
- Selection of a suitable disinfectant endowed with the spectrum of action needed to meet the respective requirements (see Annex 10 «Process chemicals»).
- Selection of water of the right quality (see Annex 11 «Chemical water quality»)
- Observance of the concentration-time relationship specified for the disinfectant
- Complete immersion of the medical device and thorough wetting of all the medical device's internal and external surfaces with the disinfectant solution.

The following indirect tests should therefore be performed to verify disinfection:

- Successful cleaning as per 5.2.3.1
- Verification of disinfectant measurement accuracy (see Chapter 7.5. Dosing equipment)
- Verification of disinfectant solution preparation
- Verification of timekeeping accessories
- Compliance with, and documentation of, the temperature range required for efficacy as specified by the manufacturer.

If the disinfectant is to be used for more than one day, the procedures specified in Annex 10 «Process chemicals» should be observed for validation.

5.2.3.3 Verification of drying

Drying efficacy is tested directly on executing the working steps as per the standard operating procedure. The dried medical device is placed on a flat surface on coloured crepe paper. Any remaining moisture will be visible on the crepe paper. In the case of hollow instruments, dry air is blown through the lumen onto a mirror in order to detect any residual moisture. The results must be recorded. An objection must be made if any residual liquid emerges. Objections must be documented. An improved method must be devised for conduct of the drying step and rechecked after execution. The standard operating procedures for drying must be amended accordingly. The procedures and results must be recorded.

5.2.3.4 Inspection for process chemical residues

Once processing has been completed as per the standard operating procedure, compliance with the limit values, specified by the process chemicals' manufacturers with respect to the residual amounts of process chemicals tolerated on the medical device, must be assured.

These limit values are dependent on both the composition of the process chemicals and the nature and duration of medical device application, i. e. several limit values may be specified for a single process chemical.

At the time of verifying the standard operating procedure, evidence must be produced that the residual amount of process chemicals on the medical device after processing does not exceed the defined limit value.

The methods, or evidence, needed to ascertain the residual amount of process chemicals will depend on the process chemicals employed and must be supplied by the manufacturer of the process chemicals.

5.3 Overall assessment of results

All results obtained during validation are documented and evaluated. If isolated divergent or borderline results are obtained in one or several tests, overall assessment of all process performance results is recommended.

If validation yields results that meet the requirements, the time point for performance requalification is set. Annual testing is seen as a benchmark value that can be under- or overshot in justified cases.

Furthermore, the nature and scope of routine tests shall be based on the validation tests (see Chapter 6).

If validation yields results that do not meet the requirements, all parties involved must endeavour to identify the reason for this failure. Such reasons must be recorded. The existing problem must be qualified and potential solutions documented in the test report. If necessary, partial processes must be modified and retested.

5.4 Documentation

The validation procedure and results must be documented in a summary report. The verified standard operating procedures as well as the checklists and protocols (if applicable, also photos) used for validation serve as evidence and should be enclosed in an annex to the report. The report must also include evaluation of the results.

The report must contain at least the following:

- Cover page of validation report
- Evidence of conduct of validation (for example, completed checklists)
- Evaluation of results
- Documentation of objections
- Details of specified measures, their implementation and results
- Release of validation report
- Definition of routine test schedules
- Definition of requalification schedules
- Evidence of validation personnel's qualifications.

Validation of manual cleaning and disinfection is complete once the validation report has been endorsed by the validation personnel and this validation report released by the operator.

5.5 Performance requalification

When defining performance requalification intervals, the same procedure as for automated cleaning and disinfection should be used.

EN ISO 15883-1 recommends for normal operation annual performance requalification of the process. Any deviations from this annual interval must be underpinned through risk management. A prerequisite for conduct of annual performance qualification once again for no specific reason is that no changes must have been made that would have warranted performance qualification for a specific reason.

Evidence must be provided that servicing, calibration, functional testing and performance tests as specified in the quality management system have been conducted. In addition, the release documentation and routine checks conducted since validation or the last performance qualification must be jointly verified and evaluated by the operator and validation personnel. On that basis they can infer the scope of performance requalification.

For performance requalification certain parts of installation qualification (IQ) and operational qualification (OQ) can be omitted if no changes have been made. Not all changes warrant process performance requalification. But in principle documented evaluation of such a change is needed. If requalification is then deemed unnecessary, this must be documented and substantiated.

It must be ensured that the documents used for performance requalification meet the current requirements. Checklists must be updated if necessary.

5.5.1 Performance requalification for no specific reason

Performance requalification is conducted as scheduled

- in general after one year if no changes have been made to the workstation, process chemicals and/or other factors affecting the process.

Scheduled performance requalification serves as evidence that the cleaning and disinfection process is still within the admissible limits ascertained during validation (IQ, OQ and PQ). In this respect, only performance qualification (PQ) needs to be conducted in general. That since validation no changes have been made to the process chemicals, accessories or standard operating procedures must be confirmed in the report on performance requalification.

5.5.2 Performance requalification for a specific reason

Performance requalification for a specific reason is conducted

- for example if changes are made to process chemicals, accessories and standard operating procedures
- if new medical devices are to be cleaned and disinfected according to a new standard operating procedure.

For performance requalification for a specific reason the potential impact of changes on the process results must first be ascertained. The corresponding result must be recorded. Based on that, the scope of performance requalification for a specific reason must be defined and recorded in for each individual case. This documentation sets out the test procedure. Accordingly, for example if changes are made to the process chemicals, operational qualification (OQ) and performance qualification (PQ) must be fully or partially repeated; if changes are made to the (manual) workstation, installation qualification (IQ) must be repeated, at least in part.

6 Definition of routine tests for cleaning and disinfection processes

Routine tests are defined at the time of validation. This is to ensure that any changes occurring in the processes will be detected in a timely manner before adversely affecting the processes such that they can no longer meet the applicable requirements. Examples of such routine tests include:

- Visual inspection of cleaning
- Tests to demonstrate cleanliness of the medical device
  - Commercially available qualitative or semi-quantitative methods for detection of residual proteins
  - If blood is the main soil to be eliminated, semi-quantitative haemoglobin tests based on the pseudoperoxidase reaction can also be used.
- Check of pH value (for example, for ophthalmologic instruments)
- Measurement of conductivity of the final rinse water
- Visual inspection of the cleaning/disinfection bath
- Temperature measurement
- Supervision of employees discharging tasks by observing them do so.

Intervals (for example, daily, weekly, monthly and acceptance values must be defined for the stipulated routine tests, including remedial action if a test was negative. The routine test results must be recorded.

Critical process parameters must be monitored and documented on a routine basis. In practice various methods have been identified to that effect, e. g.:

- Handwritten records
- Connection of manual cleaning and disinfection to an electronic documentation system.

Routine monitoring of cleaning and disinfection processes is ascribed special importance for assuring continuous and comparable quality of manual processing steps for medical devices. The aim is to assure, on the basis of defined release criteria, continuous control of manual process steps and thus establish a routine monitoring system. The test methods adopted as routine checks must be set out in writing and must be performed by personnel who have the requisite expertise.
Checklist 7 «Daily routine checks of manual workstation» specifies, for example, the scope of daily tests before start-up.
The «Test Matrix validation of manual cleaning and disinfection processes» contains basic details for conduct of periodic routine checks.
The results must be documented and must meet the requirements. If that is not the case, remedial measures must be defined and immediately implemented.

7 Procurement

The following points must be borne in mind when purchasing the necessary equipment, utensils and process chemicals.

7.1 Ultrasound to supplement cleaning

Ultrasound can be used to supplement cleaning in medical device processing. It can be used for pre-cleaning, cleaning and for re-cleaning. When procuring an ultrasonic cleaner (bath), make sure the manufacturer has provided information on performance verification.
Details of the following, in particular, must be provided:

- Checking filling level
- Temperature check
- Positioning the medical devices
- Using accessories (for example, cleaning systems)
- Instrument storage systems.

When using ultrasound, take account of the instructions supplied by the manufacturers of the medical devices to be processed, the process chemicals and ultrasonic bath. Annex 12 «Ultrasound to supplement cleaning» contains information on ultrasonic cleaning.

7.2 Steamers

Steamers are not recommended because of the high risk of infection faced by personnel since effective protection cannot be assured without extensive measures. The steam generated by the steamer dislodges soil particles from contaminated medical devices. Embedded microbes can be dislodged and spread as airborne aerosols.

7.3 Cleaning accessories

The composition of the cleaning accessories should be such that, when used as intended, the medical devices to be cleaned will not be damaged. Under no circumstances should metal brushes be used since they could damage, for example, the passive layers or coatings.
Preference should be given to cleaning accessories that tolerate automated processes or to single-use cleaning accessories. The accessories should be processed such that damage (for example, scratches) can be avoided.
To clean instruments with hollow cavities, the medical device manufacturer must give details of dimensions (diameter and length) and/or recommend suitable brushes.

7.4 Compressed air pistols/water pistols

Cleaning, rinsing and drying of medical devices may be carried out, if necessary, with water or compressed air pistol. All system components generating compressed air must meet the state of the art. Annex 13 «Using water and compressed air pistols» gives an overview of using water and compressed air for manual cleaning and disinfection.

7.5 Dosing equipment

For chemical disinfection observance of the minimum concentration, as well as of temperature and contact time, is an essential prerequisite for disinfectant efficacy. Accordingly, the dosing systems and adjuncts used for disinfectants are of paramount importance, in particular their dosage accuracy.
Inadequate disinfectant solution concentrations, especially if prepared in contaminated containers and kept for a long time, can be a source of infection, in particular, due to colonization by Gram-negative bacteria (Enterobacteria, pseudomonads). Precise disinfectant dosage is a prerequisite for effective disinfection and preven-

tion of microbial selection and, accordingly, of disinfectant tolerance.
The following can be used for dosage of disinfectant concentrates:

- Graduated measuring aids mounted externally or integrated into the packaging
- Dosing aid mounted on or in the packaging
- Decentralized disinfectant dispensers.

The operator is responsible in principle for implementing measures to ensure dosage accuracy as well as for assuring occupational health and safety. Information on dosing systems can be consulted in Annex 14 «Dosing systems for disinfectants».

7.6 Process chemicals (including water)

The quality of the process water required will depend on the respective application. In general, drinking water is used to prepare manual cleaning/disinfection baths. Besides, the instructions supplied by the manufacturer of the chemical additives must be observed. Demineralized water (10 to 25 µS/cm) should be used for the final rinse for medical devices to avoid deposit formation. More detailed information on the chemical quality of the process water is given in Annex 11 «Chemical water quality». The composition of the final rinse water must not adversely affect the microbiological quality of the medical device.
Information on purchasing chemical additives for cleaning and disinfection can be consulted in Chapter 4.1.2.2 «Information to be provided by the process chemicals' manufacturers» as well as in Annex 10 «Process chemicals».

7.7 Drying cabinets

If drying cabinets are used to dry medical devices, it must be ensured that the internally circulating air has been filtered. Only cleaned and disinfected medical devices may be placed for drying in a drying cabinet, otherwise there is a danger of microbial growth. In Germany, drying cabinets are rarely used for medical device processing and must be reviewed by the responsible infection control specialist.

8 References

Legal acts and regulations

Book V of the German Code of Social Law (V) – Statutory Health Insurance Fund – Article 1 of the Act of 20 December 1988 (Federal Law Gazette I p. 2477), last amended by Art. 2(G) of 20 February 2013 (Federal Law Gazette I. 277)

Legal act for prevention and control of infectious diseases in humans (Infection Protection Act – IfSG) of 20 July 2000 (Federal Law Gazette I p. 1045), amended by Article 5(2) of legal act of 20 April 2013 (Federal Law Gazette I p. 868)

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Official Journal of the European Communities; ABl. L 169, Volume 36, 12 July 1993

Medical Devices Act (German Medical Devices Act – MPG) of 2 August in the version published on 7 August 2002 (Federal Law Gazette I p. 3146), last amended by Article 11 of the legal act of 19 October 2012 (Federal Law Gazette I p. 2192)

Regulation on installation, operation and use of medical devices (Medical Devices Operator Ordinance – MPBetreibV) of 29 June 1998 in the version published on 21 August 2002 (Federal Law Gazette I p. 3396), lasted amended by Article 4 of legal act of 29 July 2009 (Federal Law Gazette I p. 2326)

Regulation on the quality of water for human use (Drinking Water Regulation – TrinkwV 2001) of 21 May 2001 (Federal Law Gazette I p. 959), in the version published on 28 November 2011 (Federal Law Gazette I p. 2370), last amended by Article 1 of regulation of 5 December 2012 (Federal Law Gazette I p. 2562)

Regulation on safety and health protection when handling biological substances (Biological Substances Regulation – BioStoffV) of 27 January 1999 (Federal Law Gazette. I p. 50), superseded by Reg. 805-3-13 of 15 July 2013 I 2514 (BioStoffV)

Regulation on of health and safety in the workplace (BGV A1) Accident Prevention Regulation: Principles of prevention of 1 January 2004

Technical rules for biological substances; Biological substances in healthcare and welfare settings (TRBA 250) of November 2003, Amendment and Supplement July 2006 (Federal Work Gazette 7-2006, p. 193) Supplement April 2007 (Joint Ministerial Gazette No. 25 of 27 July 2007, p. 720), last amended and supplemented November 2007 (Joint Ministerial Gazette No 4 of 14 February 2008, p. 83), Amendment and Supplement April 2012, Joint Ministerial Gazette No. 15-20 of 25. April 2012, p. 380–382.

KRINKO Recommendations

Hygiene requirements for processing medical devices. Recommendation by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices)BfArM) Federal Health Gazette – Health Research– Health Protection (2012) 55: 1244–1310.

Hygiene requirements for cleaning and disinfection of surfaces. Recommendation by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI). Federal Health Gazette – Health Research– Health Protection (2004) 47: 51–61.

Requirements for the design, features and operation of decentralized disinfectant dispensers for hand disinfection. Directive by the Federal Institute for Materials Research and Testing, Robert Koch Institute and the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI). Federal Health Gazette – Health Research– Health Protection (2004) 47: 67–72.

Hand hygiene. Memorandum by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI). Federal Health Gazette – Health Research– Health Protection (2000) 43: 230–233.

Standards

EN ISO 15883 – Washer-disinfectors

Part 1: General requirements, definitions and tests; 2009

Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthesia equipment, bowls, receivers, utensils, glassware, etc.; 2009

Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers; 2009

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes; 2009

Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment; 2011

ISO/TS 15883 – Washer-disinfectors Part 5; Test soils and methods for demonstrating cleaning efficacy; 2006

EN ISO 14971 –Medical devices – Application of risk management to medical devices; 2012

EN 14885 – Chemical disinfectant and antiseptics – Application of European standards for chemical disinfectant and antiseptics; 2007

EN ISO 17664 – Sterilization of medical devices – Information to be provided by the manufacturer for processing resterilizable medical devices; 2004

EN ISO 9000 – Quality management systems – Fundamentals and vocabulary; 2005

* GHUP: Association for Hygiene, Environmental Medicine and Prevention

** BVÖGD: Federal Association of Public Health Physicians

*** DGHM: German Society for Hygiene and Microbiology

Recommendations and guidelines

VAH Disinfectants List – Status: 2 April 2013: List compiled by the Disinfectants Commission of the Association for Applied Hygiene (VAH) e. V. in cooperation with the following specialist societies/professional associations: DGHM, DGKH, GHUP* and BVÖGD**, and on the basis of the standard methods of the DGHM*** for testing chemical disinfection processes, and processes deemed effective for prophylactic disinfection and hygienic hand washing. Wiesbaden: mhp-Verlag; 2013

Guideline by the German Association for Control of Viral Diseases (DVV) e. V. and the Robert Koch Institute (RKI) describing the methods for testing chemical disinfectants for efficacy against the viruses encountered in human medicine – version of 1 August 2008. Federal Health Gazette – Health Research – Health Protection (2008) 51: 937–945.

Guideline by the German Society for Hospital Hygiene (DGKH), German Society for Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices as well as advice on selecting washer-disinfectors, 3rd edition, 2008. Central Service 16; Suppl. 2 (published in German only)

Qualification directive by the German Society for Sterile Supply (DGSV e. V). and the Swiss Society for Sterile Supplies (SGSV); compiled by members of the Education Committee of the DGSV and adopted on 23/06/2012 by the Education Committee and the Board of Directors:
http://www.dgsv-ev.de/conpresso/_data/20120623_43.BA-Sitzung_Qualifizierungsrichtlinie_der_DGSV_verabschiedet.

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Annex 1: Contents of EN ISO 17664-2004

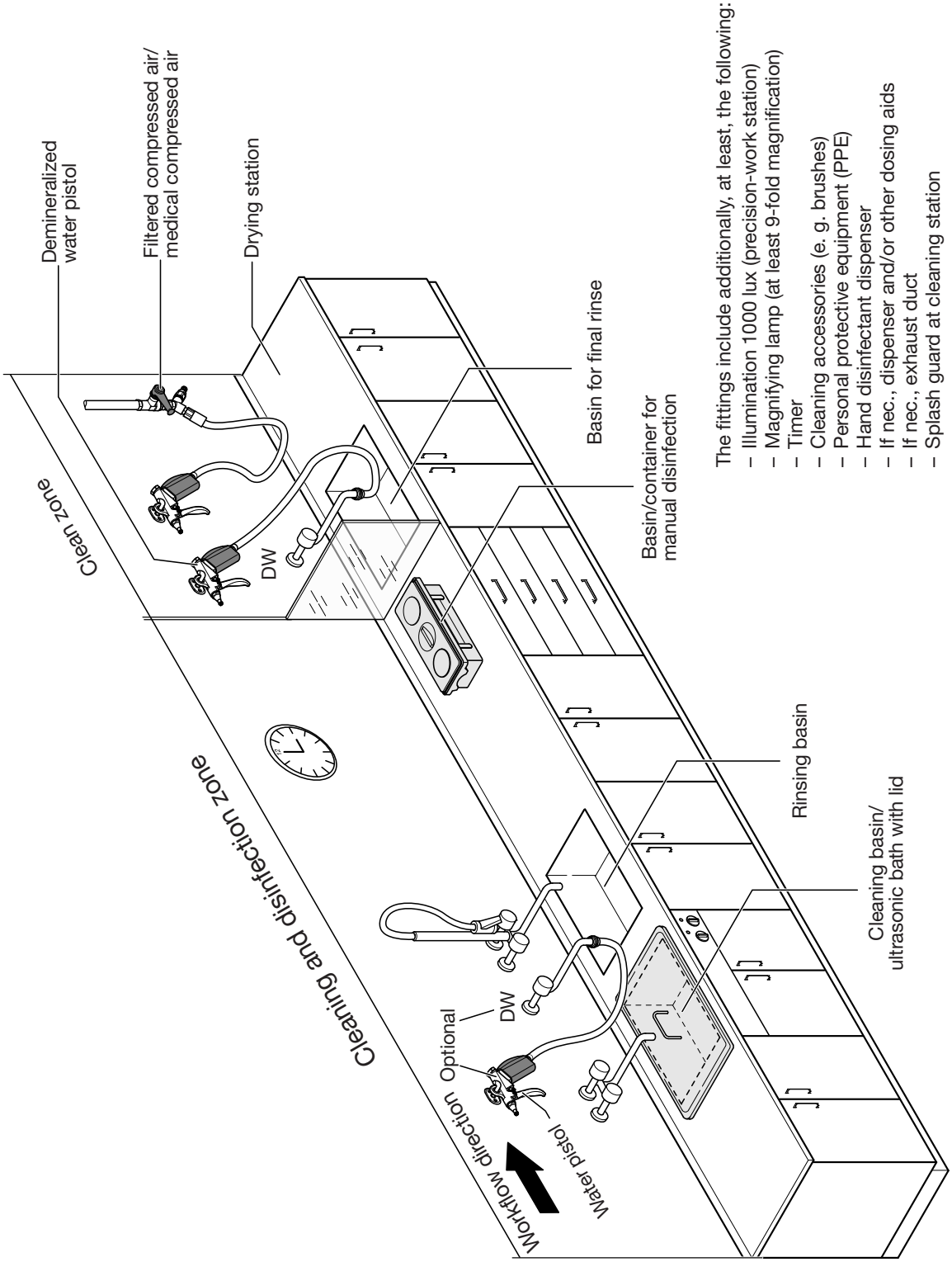
The following information must be provided by the medical device manufacturer:

Process step	Description
Preparation at the point of use	If necessary, information on: – Transport containers – Retaining systems – Maximum time interval between use and cleaning – Pre-cleaning – Transport requirements
Preparation for cleaning	Preparatory measures may be needed for certain medical devices, such as e. g.: – Requirements for covering/closing ports – Disassembly – Leak tests – Manual pre-cleaning by brushing or first rinsing with cleaning pistol
Cleaning	If required, information on: – Accessories for the cleaning process – Concentration of chemical additives for cleaning – Contact time of chemical additives – Water quality – Limit values and monitoring of chemical residues on the medical device – Limit values for temperature, concentration of solutions, contact time used – Methods, including rinsing, to be used
Disinfection	If required, information on: – Accessories for the disinfection process – Concentration of chemical additives for disinfection – Contact time of chemical additives – Water quality – Limit values and monitoring of chemical residues on the medical device – Limit values for temperature, concentration of solutions, contact time used – Methods, including rinsing, to be used
Drying	If required, information on: – Accessories for the drying process – Maximum temperature and contact time for device – Technical data for drying medium used – Methods to be used
Inspection, maintenance and testing	If required, information on: – Methods for adjustment/calibration of the medical device – Oil, lubricant or other care agents – Efficacy criteria to assure safe use – Assembling the medical device – Spare parts – details of replacement – Special tools – Visual inspection – Maintenance cycles
Packaging	If necessary, information on: – Special packaging and storage methods during and after sterilization. These must be compatible with the sterilization process.
Sterilization	At least one validated process. Preference must be given to moist heat sterilization.
Storage	Any restrictions related to storage conditions or shelf life must be specified.

If there are restrictions on the number of times a medical device can be reprocessed, the manufacturer must provide details of these, such as e.g. number of reprocessing cycles permitted or other information on the time point from which safe use is no long assured.

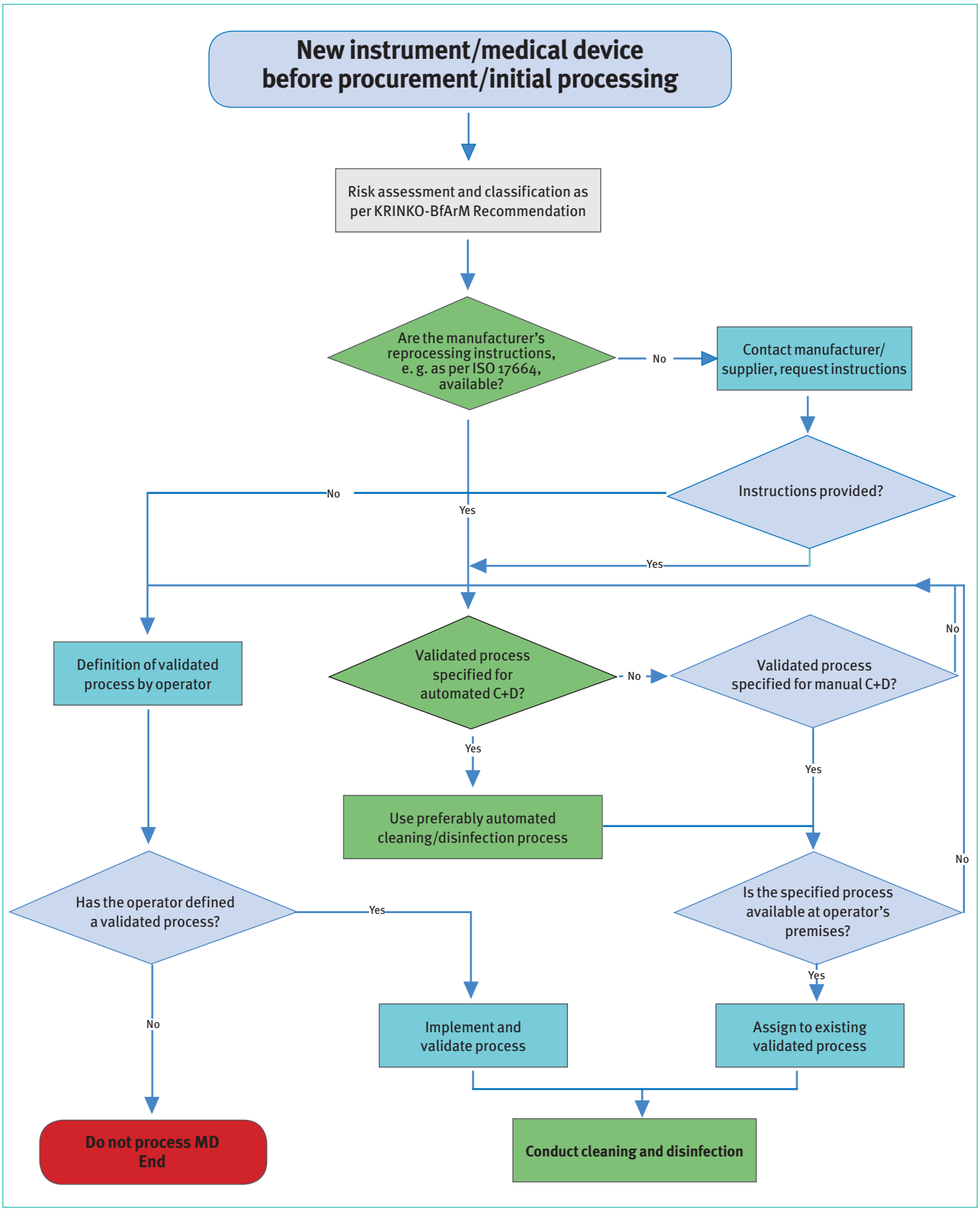
Annex 2: Workstation – example

Ideal workstation

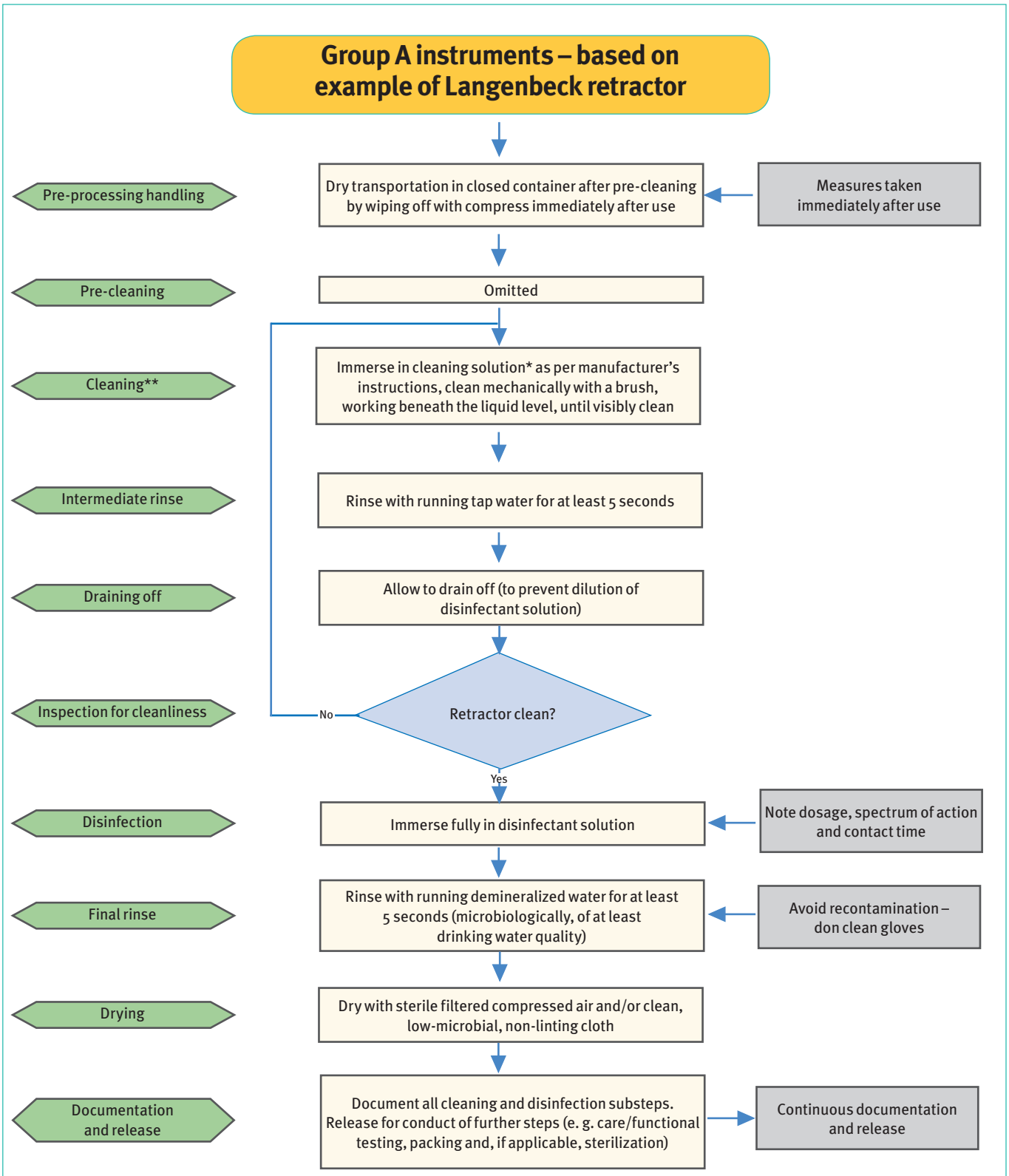


The fittings include additionally, at least, the following:
- Illumination 1000 lux (precision-work station)
- Magnifying lamp (at least 9-fold magnification)
- Timer
- Cleaning accessories (e. g. brushes)
- Personal protective equipment (PPE)
- Hand disinfectant dispenser
- If nec., dispenser and/or other dosing aids
- If nec., exhaust duct
- Splash guard at cleaning station

Annex 3: Determination of a processing procedure



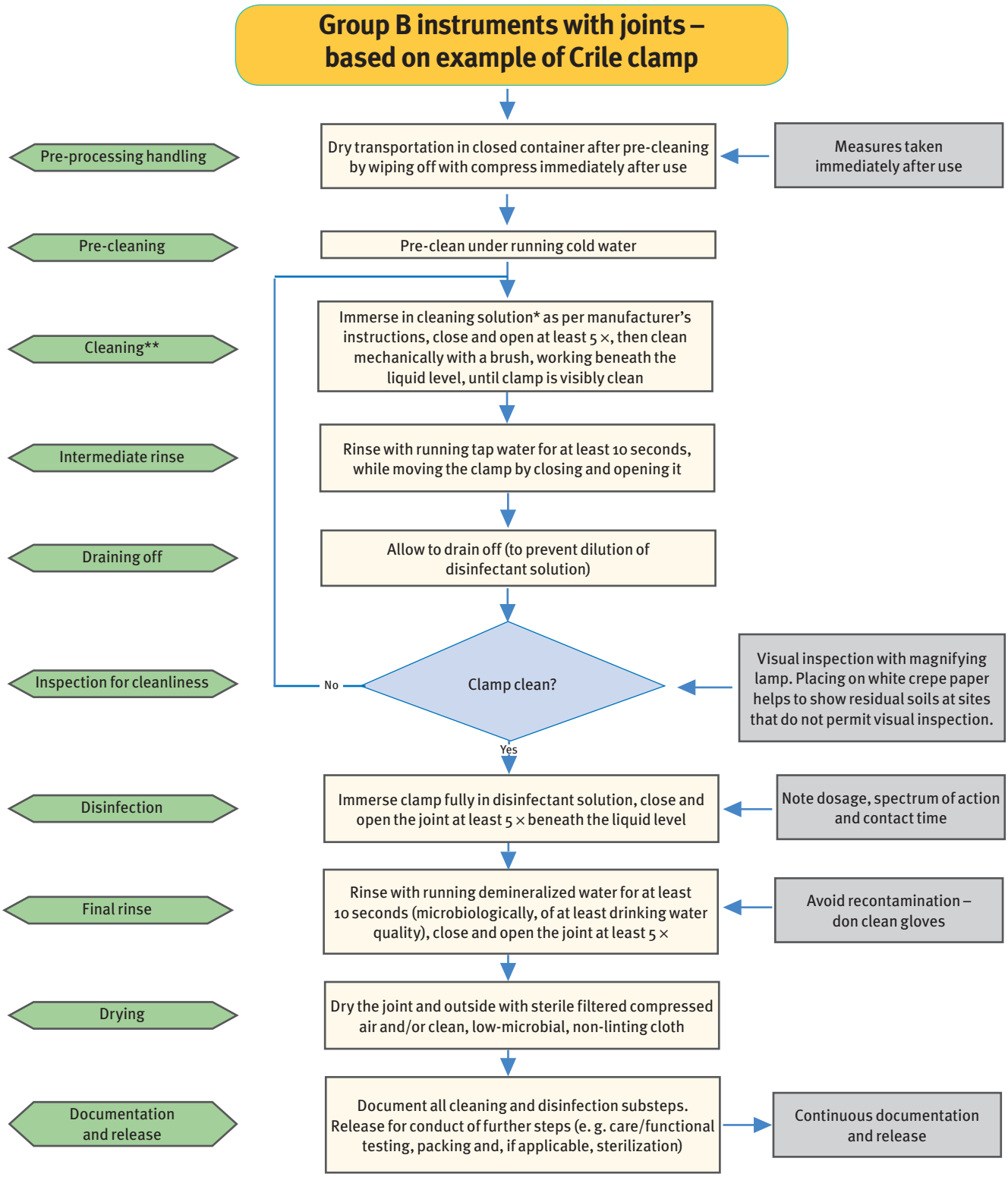
Annex 4: Flow chart: Group A instruments



* Instead of a cleaning solution, a combined, non-fixing detergent/disinfectant can be used.

** Cleaning can also be performed in an ultrasonic bath.

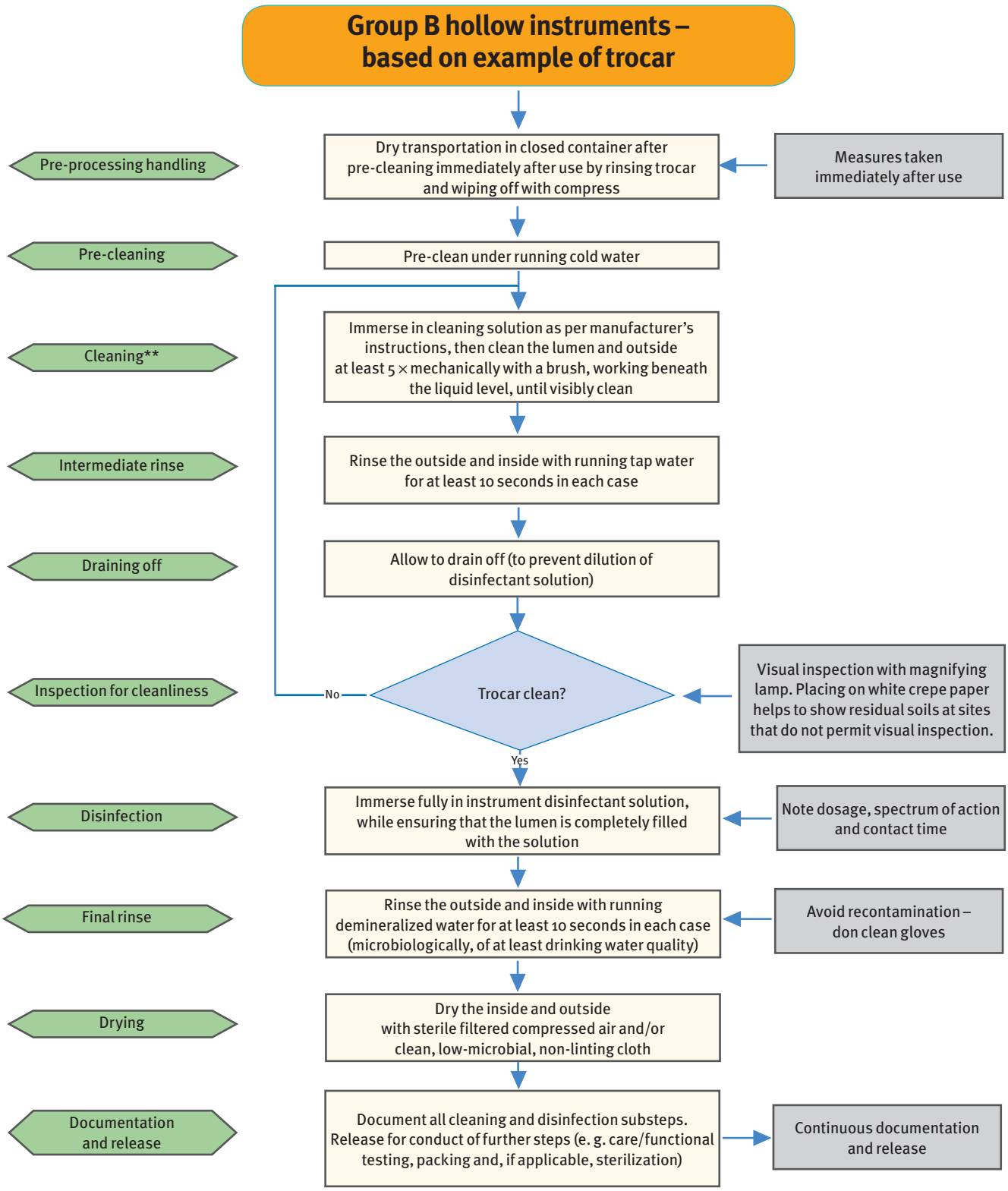
Annex 5: Flow chart: Group B instruments with joints



* Instead of a cleaning solution, a combined, non-fixing detergent/disinfectant can be used.

** Cleaning can also be performed in an ultrasonic bath.

Annex 6: Flow chart: Group B hollow instruments



* Instead of a cleaning solution, a combined, non-fixing detergent/disinfectant can be used.

** Cleaning can also be performed in an ultrasonic bath.

Annex 7: Qualifications needed by validation personnel

1 Introduction

This annex describes requirements regarding the qualifications needed by the personnel and establishments that, when validating manual cleaning and chemical disinfection of medical devices, conduct installation qualification (IQ), operational qualification (OQ) and/or performance qualification (PQ). It does not apply to the type tests carried out by the medical device manufacturer when testing the reprocessing procedure.

2 Responsibility for validation

The operator bears responsibility for ensuring that only validated processing procedures are used. Validation must be conducted on behalf of the operator by appropriately qualified experts.

Validation consists of various phases for which different qualifications are required. The different phases, as described in this Guideline, are as follows:

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

3 Requirements for installation qualification and operational qualification

The persons entrusted with conduct of validation (validation engineers) must provide written evidence that they possess the following knowledge and experience:

General knowledge of relevant legal acts, standards, directives, guidelines, etc.

- Biological Substances Regulation, Hazardous Substances Regulation
- EN ISO 14971 (risk assessment)
- EN ISO 17664
- KRINKO/BfArM Recommendation: «Hygiene requirements for processing medical devices» (2012)
- German Medical Devices Act (MPG), German Medical Devices Operator Ordinance (MPBetreibV)
- German Technical Regulation on Biological Substances (TRBA 250)
- Validation Guideline compiled by the German Society for Hospital Hygiene (DGKH), German Society for Sterile Supply (DGSV), Working Group Instrument Preparation (AKI).

General knowledge and experience of processing medical devices

- Basic knowledge of hygiene (infection control)/microbiology
- Theoretical knowledge of testing and listing disinfectants
- Knowledge of materials and instrumentation
- Process chemicals.

The persons entrusted with conduct of validation should also demonstrate knowledge of quality management and validation of medical device processing.

Proof of the requisite knowledge can be provided through:

- Certificate – Specialist Course II as per the qualification directive of the DGSV e. V. (or similar) and
- Certificate of attendance at a validation course as per the qualification directive of the DGSV e. V. (or similar) and/or
- Certificate of attendance at a quality management course in the healthcare sector (or similar).

Just like the contract awarder, so the firms or institutions awarded the contract must provide evidence of having in place a quality management system (e. g. pursuant to EN ISO 9001 or EN ISO 13485).

4 Requirements for initial performance qualification as well as performance requalification

The general knowledge and experience required for performance qualification are the same as for installation and operational qualification and written evidence must be provided by the persons entrusted with these tasks. Moreover, knowledge of the following must be demonstrated:

- Experience of sampling
- Experience of text systems for verification of cleaning (e. g. biuret, haemoglobin test)
- Knowledge and experience of analytical determination of process chemicals.

The person responsible for validation may subcontract various parts of performance qualification to a third party. Appointed companies, institutions or laboratories must provide proof that they have in place a quality management system (e. g. pursuant to EN ISO 9001 or EN ISO 17025).

5 References

Hygiene requirements for processing medical devices. Recommendation by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices BfArM) Federal Health Gazette – Health Research - Health Protection (2012) 55: 1244–1310.

Regulation on safety and health protection when handling biological substances (Biological Substances Regulation – BioStoffV) of 27 January 1999 (Federal Law Gazette. I p. 50), amended by Reg. 805-3-13 of 15 July 2013 I 2514 (BioStoffV)

German Medical Devices Act (MPG) of 2 August in the version published on 7 August 2002 (Federal Law Gazette I p. 3146), last amended by Article 11 of the Act of 19 October 2012 (Federal Law Gazette. I p. 2192)

Regulation on installation, operation and use of medical devices (Medical Devices Operator Ordinance MPBetreibV) of 29 June 1998 in the version published on 21 August 2002 (Federal Law Gazette. I p. 3396), last amended by Article 4 of the Act of 29 July 2009 (Federal Law Gazette. I p 2326)

Regulation on protection against hazardous substances (Hazardous Substances Regulation – GefStoffV) of 23 December 2004 (Federal Law Gazette. I p 3758), last amended on 18 December 2008 (Federal Law Gazette. I p 2768)

Technical Regulation on Biological Substances; Biological substances in the health and welfare sector (TRBA 250) of November 2003, amended and supplemented in July 2006 (Federal Work Gazette 7-2006, p 193) Supplement April 2007 (Joint Ministerial Gazette (GMBI) No. 25 of 27 July 2007, p 720), last amended and supplemented in November 2007 (Joint Ministerial Gazette No. 4 of 14 February 2008, p 83), Amendment and Supplement of April 2012, Joint Ministerial Gazette No. 15–20 of 25 April 2012, p 380–382.

Guideline by the German Society for Hospital Hygiene (DGKH),German Society for Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices as well as advice on selecting washer-disinfectors, 3rd edition, 2008. Central Service (2008) 16; Suppl. 2 (published in German only)

EN ISO 9001 – 1st Amendment - Quality management systems – Requirements; 2008

EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes; 2012

EN ISO 14971 – Medical devices – Application of risk management to medical devices; 2012

EN ISO/IEC 17025 2nd Amendment – General requirements for the competence of testing and calibration laboratories; 2005

EN ISO 17664 – Sterilization of medical devices – Information to be provided by the manufacturer for processing resterilizable medical devices; 2004.

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Annex 8: Verification of cleaning

1 Sampling and protein detection/determination based on inspection of instruments with everyday soils (i. e. contaminated from «real-world» use)

The cleaning efficacy is initially verified through visual inspection of instruments, contaminated during routine use, by means of performance qualification and routine tests following cleaning. As a supplementary measure and to gain an objective view of the visual results, qualitative and/or quantitative protein determination must also be carried out.

2 Protein determination

2.1 Sampling

Sampling is performed by rinsing off/flushing out the instruments or parts of the instruments (cavity, joint) with an aqueous rinse solution containing a 1% weight-increasing agent, sodium dodecyl sulphate (SDS).

Sampling is preferably confined to those areas coming into contact with the patient's tissues, and which pose the greatest transmission risk. This helps to avoid obtaining unacceptable results to which no objection would have to be made. That would be the case if the results obtained were to be extrapolated to include also the non-critical instrument parts.

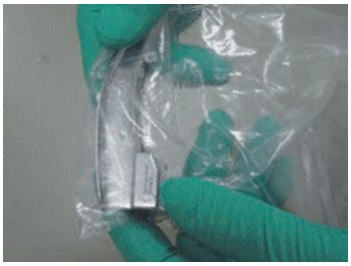
When using detergent disinfectants, the SDS solution used for elution should be set to pH 11. The pH value should be set using 0.1 N sodium hydroxide solution and pH strips with a graduation of at least 0.5 or by means of a pH meter. Elution should be carried out with as little SDS solution as possible.

2.2 Methods for protein determination

A modified OPA method or biuret/BCA method can be used for protein determination after sampling. Only pH-neutral eluates will prove stable over a long period of time and are thus suitable for analysis

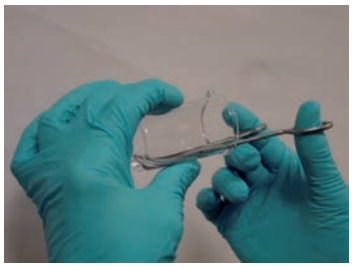
Example 1: Elution of instrument surfaces in a PE bag with 2–5 ml SDS solution

Any residual soils present on instruments can be rinsed off with 2 to 5 ml 1% SDS solution in a suitably sized stable polyethylene (PE) bag to obtain a sample from the entire instrument surface. Inside the sealed bag the instrument is intensively wetted, and mechanically processed, by moving/swivelling manually within the bag. This applies, in particular, to areas that are difficult to clean.
Joint instruments must be moved in the bag such that the gap regions are included.
Hollow instruments, e. g. trocar sheaths, which have large easily accessible cavities, can also be sampled in a suitable PE bag. By intensively inclining the bag to and fro, the solution can be introduced into the cavities, while also turning the instrument in the bag so that all areas are covered.



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

For joint instruments, the working end, including joint, is normally sampled in the same way as Crile clamp PCDs.



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

Instruments with narrow lumens can be flushed into a beaker with 2–5 ml SDS solution using a pipette or syringe (while secured on a stand, if necessary). This solution is then recovered and the procedure repeated 5 ×.
A similar procedure can also be used to elute, into a tube of suitable length, the working elements of dismantable MIS shaft instruments.
It is advisable in principle to allow an interval of 10 minutes for soaking between each test repetition.

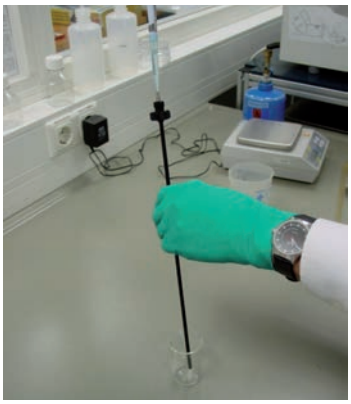


Table 1: Calculation examples for the entire protein quantity per sampled surface

Total eluate volume [ml]	Protein content measured in partial volumes [µg/ml]	Yields protein per sampled surface [µg]
2	50	100
3	33	100
4	25	100
5	20	100
2	25	50
3	17	50
4	13	50
5	10	50

in an external laboratory. If alkaline SDS solutions are used, they must be analysed on site.
Turbid sample solutions are not acceptable and do not lend themselves to protein determination. The sampled instrument will be deemed to have been inadequately cleaned or inadequately rinsed. The reasons must be elucidated.
The choice of detection method, detection range and specificity must be tailored to the acceptance criteria governing the instruments or the sampled areas. This is particularly true for the ratio between the entire eluate volume and the partial volume, used for protein determination (see also Table 1). Another point to determine is whether the residues of the process chemicals used exert an influence on the chemical detection reaction underlying protein determination.

3 Calculation of the protein content

When calculating the total eluted protein content, dilution based on the volume of the SDS solution used must be taken into account. Accordingly, the protein amount detected in the partial eluate volume must be extrapolated to the total eluate volume to determine the protein amount per instrument/sampled instrument area.
Table 1 explains how protein amounts of 100 µg or 50 µg detected in the sampled instrument area change, in terms of the protein amount per ml eluate, because of using different volumes of SDS solution.

Annex 9: Acceptance criteria for assessment of cleaning efficacy

The acceptance criteria given below are based on the evaluation results from validation of automated cleaning and disinfection processes from 2011 – 2012 (Michels W, Roth K, Eibl R: Assessment of cleaning efficacy based on the protein-surface relationship. Central Service 2013; 21: 212–215).

1 Acceptance criteria for instruments with everyday soils

All instruments must be visibly clean. Semi-quantitative or quantitative testing for protein residues is performed only for visibly clean instruments.
The estimated size of the sampled surfaces must be included in evaluation. With the aim of obtaining a residual protein quantity of up to 3 µg per cm², the following acceptance criteria are obtained (see Table).

2 Acceptance criteria for process challenge devices

All process challenge devices (PCDs) must be visibly free of test soils. Semi-quantitative or quantitative testing for protein residues is performed only for visibly clean instruments. Protein per PCD as bovine serum albumin (BSA):
Limit value: > 150 µg must not be reached /exceeded
Alarm value: > 80 ≤ 150 µg
Guide value: ≤ 80 µg

3 Measures based on assessment

Visual contamination of instruments with everyday soils/PCDs
Shut down the process immediately; the corresponding standard operating proce-

Group	Model Instruments	Methodology	Guide Value
1	Instruments without joint and without cavity: sharp spoon, wound retractor	Visual inspection	< 10–15 µg/per 4–5 cm²
2	Instruments with joint: scissors, clamps	At least semi-quantitative protein detection after elution in PE bag	< 75 µg per instrument (up to a length of 15 cm) < 100 µg per instrument (for a length of more than 15 cm)
		Elute as for Crile clamp PCD, but using only the working end with joint	< 50 µg per instrument
3	Sliding-shaft instruments: punches, rongeurs	Quantitative protein detection after elution of the entire instrument in PE bag	< 100 µg per instrument
		Partial elution of working end into test tube, supplemented by ultrasound	< 50 µg per instrument
4	Instruments with cavity (tubular instruments): MIS instruments	Quantitative protein detection e. g. shaft of a dismantable instrument, only interior sampled (flush out):	< 75 µg per instrument (up to 4 mm internal diameter) < 100 µg per instrument Schaftrohr (more than 4 mm internal diameter)
		Working elements separately (e. g. eluted in tube closed at both ends)	< 50 µg per working element
		Only jaw region with joint in test tube, supplemented by ultrasound	< 40 µg per jaw region with joint
5	MIS instruments	Quantitative protein detection after elution of entire instrument	< 50 µg per instrument < 20 µg per instrument (ophthalmology instruments)

dure (SOP) must no longer be used. Amend SOP and reassess the process.
Performance qualification is deemed to have not been completed so far.

Limit value for PCDs
Shut down the process immediately; SOP must no longer be used. Amend SOP and reassess the process.
Performance qualification is deemed to have not been completed so far.

Alarm value for PCDs
SOP can continue to be used, but improvements must be immediately defined and implemented in order to try and attain the guide value.
Performance qualification is deemed to have not been completed so far.

Guide value for PCDs/instruments with everyday soils
If the guide value is observed, no measures are needed.
If the guide value is exceeded in the case of instruments with everyday soils, the SOP must be amended or acceptance of the higher value justified on the basis of risk analysis.

Annex 10: Process chemicals

1 General

The process chemicals used for medical device reprocessing in Europe must be developed, tested and manufactured pursuant to the European Medical Devices Directive 93/42/EEC.

Detergents and care agents are grouped as class I medical devices, as indicated by a CE mark on the label.

Process chemicals with a disinfectant action are grouped in Europe as class II a or II b medical devices, as indicated by a CE mark in addition to a four-digit number denoting the responsible «Notified Body».

During the development phase, the manufacturer of the process chemicals must ensure that the product formulations are tailored to the intended use, e. g. cleaning efficacy, disinfection efficacy or care characteristics, while taking account of their compatibility with instrument materials and biocompatibility of any residues with human tissues at the site of instrument use. Material compatibility is generally demonstrated as a collaborative measure on the part of the manufacturers of the process chemicals and of the instruments. Biocompatibility must, if necessary, be investigated and evaluated pursuant to EN ISO 10993 «Biological assessment of medical devices».

Optimum efficacy, material compatibility and biocompatibility of process chemicals are assured only subject to the application conditions recommended by the manufacturer. The application conditions must be set out in detail in the corresponding product description documentation by the manufacturer and made available to the user. The latter must scrupulously observe these recommendations, in particular, the exact concentration of process chemicals in the use solution, operating temperature as well as the contact time of application solution on the medical device.

The product description is supplemented by safety data sheets. Furthermore, the manufacturer can also provide information on:

- methods for verification of the concentration of the use solution
- limit values for the maximum residual quantities on the medical devices or tolerable residual amounts in the rinse water
- details of methods to determine such residual amounts.

If requested by the user, the manufacturer can provide confirmation of material compatibility, efficacy, ecological characteristics and tolerable residues of process chemicals.

Hazardous substances as well as any potential dangers when handling the chemicals, and corresponding protective measures, are described in a safety data sheet. The user must take note of these.

The constituent substances of different process chemicals can interact with each other. For example, a detergent surfactant can have a negative effect on disinfectant efficacy if small quantities of the detergent are carried over into the disinfectant solution. For that reason, different process chemicals can be combined only while taking account of the manufacturer's recommendations. Special attention must be paid to thorough rinsing between cleaning and disinfection. Mutual compatibility of the products must be assured and, if necessary, demonstrated and confirmed by the manufacturer.

2 Types of process chemicals

2.1 Pre-processing agents

Pre-processing agents may be detergents or antimicrobial, e. g. bactericidal or bacteriostatic, products used prior to manual or, preferably, automated cleaning and disinfection, e. g. as a foam spray or a product for wet transportation of medical devices after use.

For practical reasons and to preserve the value of the medical devices to be processed, it is recommended that they be transported in a dry state after use and without employing pre-processing agents for intervals up to six hours between use and processing.

2.2 Detergents

Detergents are used to reduce the contamination burden on a medical device to the extent needed for subsequent processing or use.

Detergents are used for both manual and automated processing. Essentially, a distinction is made between

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

For detergents with disinfectant action, the minimum requirements are for demonstrated bactericidal, levurocidal (effective against yeasts) and limited virucidal efficacy under the use conditions (concentration, contact time, temperature). The values obtained for the concentration and contact time under high organic load (dirty conditions) in tests based on German or European test methodologies must be used.

Antimicrobial substances with protein-fixing characteristics should not be used for combined cleaning and disinfection.

2.3 Disinfectants

Disinfectants are used in both manual and automated reprocessing for final disinfection of heat-sensitive medical devices, e.g. flexible endoscopes. Disinfectants contain microbicidal substances, or mixtures, and reduce the number of colony forming units of microorganisms on a medical device to the extent needed for further reprocessing or use.

2.3.1 Disinfectant requirements

The requirements for the disinfectant spectrum of action are determined by the type of processing cycle used.

If the medical devices are sterilized after disinfection, the disinfectant solution should be endowed with at least bactericidal, levurocidal and limited virucidal action (i.e. effective against enveloped viruses, such as HBV, HCV, HIV).

If the disinfectant step is not followed by sterilization, the disinfectants should have at least bactericidal, levurocidal, tuberculocidal and virucidal (enveloped and non-enveloped viruses) action. Furthermore, fungicidal, mycobactericidal and sporcidal efficacy may be required in justified cases.

Note: In this respect, the Guideline differs from the KRINKO/BfArM Recommendation «Hygiene requirements for processing medical devices». However, this divergence is in compliance with the European strategies implemented in the harmonized EN standards for testing disinfectants in CEN TC 216 (Technical Committee for Chemical Disinfectants and Antiseptics) and in the recommendations by the Association of Applied Hygiene (VAH).

The recommendations by the Association of Applied Hygiene (VAH) or the German Association for Control of Viral Diseases (DVV) can be used to test the efficacy of disinfectants.

If fungicidal or sporicidal efficacy is deemed necessary, the choice of test organisms can differ from the test organisms prescribed by the standards, and efficacy tested against the pathogen of relevance in the respective situation (e. g. spores of *Clostridium difficile* instead of *Bacillus cereus* and *Bacillus subtilis*).

Since the medical devices to be disinfected will already have been cleaned, the concentration and contact time values obtained on testing a disinfectant under a low organic load (clean conditions) can be used.

2.3.2 Disinfectant substances

Disinfectant substances differ in accordance with their chemical structure with regard to

- the mechanism of action against microorganisms, and accordingly, to their spectrum of action,
- compatibility with medical devices to be processed and
- interaction with the constituent substances of body fluids, such as protein.

These give rise to different recommendations for the disinfectant substances used depending on the post-disinfection processing steps.

If the disinfection step is not followed by sterilization, antimicrobial substances from the group of oxidizing substances and aldehydes should be preferably used. Their action is generated by undergoing chemical reactions with the microorganisms. Examples from the aldehyde group of substances include glutaraldehyde or ortho-phthaldialdehyde. Examples from the oxidizing substance group are hydrogen peroxide, peracetic acid and their salts and hypochlorous acids.

If the medical devices are sterilized after disinfection, a broader range of substances can be used for disinfection. Apart from the substances mentioned above, there are substances from the group of quaternary ammonium compounds, guanidine compounds and amines. At room temperature, and in the absence of additional formulations, these substances do not possess the spectrum of action needed for disinfection if not followed by sterilization.

2.4 Care agents

Care agents for surgical instruments whose metal friction surfaces must be lubricated consist of paraffinum perliquidum and emulsifiers. Other care agents, e. g. used for anaesthesia utensils, can also be based on silicone oil.

3 Determination of concentrations

For process chemicals to be used successfully, it is essential that the detergent concentration and concentration/disinfectant contact time specified by the manufacturer be observed. For that reason, the concentrations must be determined when verifying the standard operating procedures used for manual cleaning and disinfection of medical devices as well as when testing processes at the time of validation and for routine checks.

To verify the concentration of process chemicals the respective detergent or disinfectant manufacturer must provide instructions and/or methods to that effect.

If the manufacturer of the detergents or disinfectants used for manual cleaning and disinfection has provided information on stability and/or shelf life of the detergent/disinfectant solution exceeding one day, and if the solution is to be used for more than one day, this longer stability and/or shelf life must be checked when verifying the standard operating procedure, while taking account of the conditions prevailing at the respective site. Corresponding instructions and methods must be made available by the manufacturer of the process chemicals. When testing the shelf life the maximum contamination load, e. g. blood, expected under practical conditions must also be taken into account.

4 Determination of the residual amounts of process chemicals

The manufacturer of process chemicals must set limit values for the residual amount of process chemicals tolerated on the medical device after the final rinse.

Guides and analytical methods are supplied by the manufacturers of process chemicals to check that the limit values are being observed when verifying standard operating procedures and during routine checks.

5 References

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Official Journal of the European Communities; ABl. L 169, Volume 36, 12 July 1993

Hygiene requirements for processing medical devices. Recommendation by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch-Institute (RKI) and by Federal Institute for Drugs and Medical Devices (BfArM) Federal Health Gazette – Health Research – Health Protection (2012) 55: 1244–1310.

EN ISO 10993 – Biological assessment of medical devices

VAH Disinfectants List – Status: 2 April 2013: List compiled by the Disinfectants Commission of the Association for Applied Hygiene (VAH) e. V. in cooperation with the following specialist societies/professional associations DGHM*, DGKH, GHUP** and BVÖGD***, and on the basis of the standard methods of the DGHM for testing chemical disinfection processes, and processes deemed effective for prophylactic disinfection and hygienic hand washing. Wiesbaden: mhp-Verlag; 2013

* DGHM: German Society for Hygiene and Microbiology

** GHUP: Association for Hygiene, Environmental Medicine and Prevention

*** BVÖGD: Federal Association of Public Health Physicians

Annex 11: Chemical water quality

Water is an important medium in the medical device processing procedure and is therefore a decisive factor for assuring good results for each process step. Besides, the water quality can help to preserve the value of the reprocessed items.
The dissolved water constituents, known as «evaporation residues», can result in undesirable residues on or in the reprocessed supplies. This is important, in particular for the final rinse, therefore demineralized water is recommended.
When validating the cleaning and disinfection process, it is recommended that the water qualities also used for pre-cleaning, cleaning, intermediate rinse and disinfection be evaluated and documented. This task could be facilitated by having a water supply company carry out water analysis. Chemical analysis is recommended for treated water. The requirements specified by the manufacturer for the chemical water quality must be taken into account. The use of demineralized water for the final rinse will assure stain-free reprocessed supplies.
The limit values recommended in EN 285, Annex B, Table B1 for the feed water quality used for pure steam generation in steam sterilizers can also be incorporated into the requirements for the demineralized water used for automated and manual cleaning and disinfection. However, as opposed to the information given in EN 285, an electrical conductivity value of around 15 µS/cm is adequate for demineralized water.
Detailed information on water quality as well as on investigating discolorations, marks, etc. can be found in the «Instrument Preparation» Brochure (Red or Yellow Brochure) compiled by the Working Group Instrument Preparation (AKI).

References

EN 285: Sterilization – Steam Sterilizers – Large Sterilizers, 2009

Instrument reprocessing – Reprocessing of instruments to retain value (2012) 10th Edition

Instrument reprocessing in dental practice – How to do it right. Working Group Instrument Preparation (2011) 4th Edition

Annex 12: Ultrasound to supplement cleaning

1 Equipment technology/ design of ultrasonic baths

In ultrasonic baths piezoelectric transducers are used to generate ultrasound that converts high frequency (HF) electrical power supplied by a generator into mechanical alternating power with corresponding movement amplitude. Via the transducers, which are generally placed externally at the bottom or at the side of the ultrasonic bath, this mechanical, high-frequency movement is transmitted directly to the bath liquid and, as such, used to clean the instrument surfaces.

The transducers are operated at frequencies in the low ultrasonic-frequency range between 25 kHz and 50 kHz, mainly at 35 kHz. To avoid differences in cleaning arising from standing waves in the bath, the operating frequency is allowed to fluctuate/sweep automatically in a narrow range.

An ultrasonic bath for (pre-) cleaning consists essentially of four components:

- Stainless steel oscillation tank, fitted with ultrasound transducers. For flush-mounted equipment, this is mainly a soldered plate, 2 mm thick (for example Material No. 1.4571); for compact equipment it is made of a thinner, deep-drawn material (e. g. Material No. 1.4301).
- HF Generator generally equipped with an operator panel that is mounted at the front in the case of flush-mounted equipment; this is incorporated into the housing in the case of compact machines.
- Stainless steel basket – possibly with rack – for accommodating the instruments
- A lid to protect against contamination, evaporation and aerosols as well as for noise dampening.

The basic layout of compact and flush-mounted equipment is illustrated in Fig 1. Ultrasonic baths fitted with special accessories for (pre-) cleaning MIS instruments are also available. They have special adapter facilities for suction and/or rinse operation.

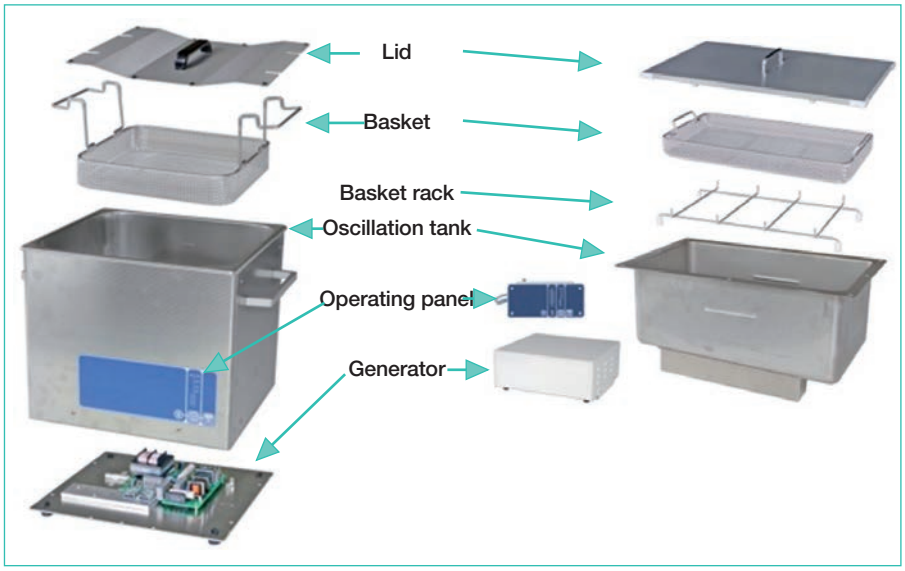


Fig. 1: Components and layout of an ultrasonic bath

The ultrasonic bath should be fitted with a thermometer to prevent protein coagulation because of excessively high temperatures.

The performance of an ultrasonic bath depends on the bath size, or bath volume, and is generally between 80 W and 1,000 W. Ultrasonic baths cannot normally be heated.

2 Ultrasonic function and activity – cavitation

When low-frequency ultrasound is introduced into liquids, the ensuing stretching and compression gradients produce microscopically small bubbles in the µm range, which implode within seconds. This activity is known as cavitation. The «hissing» sound generated in an ultrasonic bath signals the formation of such bubbles and is known as «acoustic white noise». The cavitation sound can be perceived as unpleasant or loud; as from 85 dB (AU) – Measurement pursuant to VDI Guideline 3766 – noise level protective measures are needed.

The cavitation intensity in the ultrasonic bath is affected by various parameters and is also determined by characteristics of the bath solution (e. g. temperature, viscosity). The magnitude and energy of the cavitation bubbles are largely dependent on the ultrasonic frequency. As the frequency rises, so the time available for formation of a cavitation bubble is reduced. At the same time, the power and, as such, the effect of the bubbles becomes weaker, whereas the incidence of bubble formation rises in line with the reduced effect. Intense cavitation activity can be attained only with a low ultrasonic frequency, e. g. of around 35 kHz. The number and distribution of cavitation bubbles depend on the total ultrasonic en-

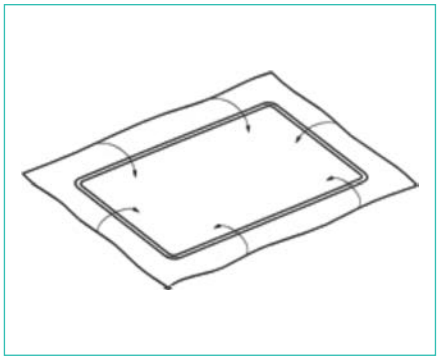


Fig. 2: Aluminium foil spread out on wire frame

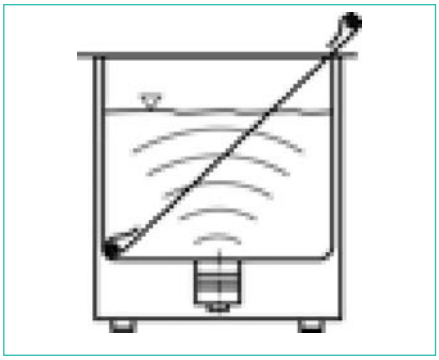


Fig. 3: Placing the frame in the ultrasonic bath

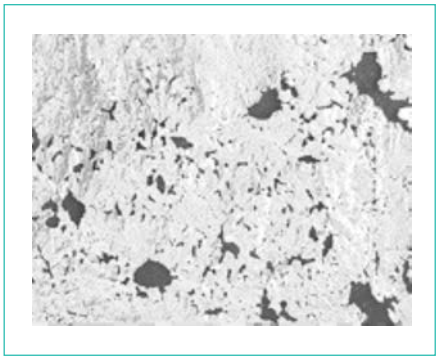


Fig. 4: Example of a perforation image after sonication

ergy introduced into the liquid, i.e. from the number and distribution of the transducers fitted to the ultrasonic bath.
The effect of an imploding cavitation bubble in the liquid can be compared with a «micro pneumatic drill», which blasts off adhering residues from the instrument surfaces. One reason for this effect is that when these energy-rich bubbles implode liquid jets are formed, going on to hit against the surface at several times the speed of sound. Apart from this mechanical component, the micro currents arising in this turbulent environment surrounding the cavitation bubbles contribute to the detachment action. Three points must be taken into account to generate effective cavitation and, hence, cleaning action on the instrument surfaces:

- A process chemical agent can be added to the bath liquid, helping to reduce the surface tension of the bath liquid. High surface tension results in cavitation generated mainly on the bottom of the bath instead of on the instrument surfaces.
- The bath liquid must be degassed before placing instruments in it. Freshly prepared solutions, in particular, have a high gas content which must first be expelled through cavitation. To that effect, before using the bath each day the empty bath should be switched on and operated without a load for 10 up to 20 min, depending on the bath volume. A low noise level following degassing does not signal declining ultrasonic activity, but rather the end of the degassing phase and, as such, enhanced ultrasonic activity.
- Ultrasound heats the bath liquid. There is a marked rise in temperature as sonication continues with the lid fitted. To prevent protein denaturation, the temperature of the ultrasonic bath should not exceed 55 °C.

3 Using ultrasonic baths

A high contamination burden in the bath solution will reduce the cleaning effect, while increasing cavitation erosion. The solution should therefore be replenished at least daily.
If the ultrasonic bath is used for chemical disinfection, the use concentrations and contact times specified in the VAH List shall apply. But the processes must be explicitly recommended by the manufacturer for such use.

4 Installation and functional testing before commissioning

Already before assembling or installing the ultrasonic bath, the following must be noted:

- The installation site must be decided for the ultrasonic bath such that the drain cock (if present) is accessible and the solution can be easily drained off.
- The ultrasonic bath must be connected via a grounded socket outlet to the power supply.
- If baths have a drain, ensure the drain cock is shut.
- Fill the bath to the level mark with the appropriate bath liquid.
- Commissioning:
  - Using a mechanical timer or digital operating keys, pre-select the time and switch on the ultrasound.
  - Corresponding signal lamps, or LEDs, signals active ultrasonic operation.
  - With operation active, the characteristic cavitation noise can be heard and if the bath liquid is clear, the rising small bubbles can be observed in the basin.

5 Testing and routine checks

Regular performance qualification of the ultrasonic bath is required at the time of validating manual cleaning and disinfection.
To ensure proper functioning of an ultrasonic bath it is advisable to check for effective ultrasonic action in the bath liquid. This can be done on the basis of the international technical regulation IEC/TR 60886:1987-03 as well as per the manufacturer's specifications with the «foil test»(Fig. 2 – 4).
To that effect, a thin aluminium foil that is spread out on a wire frame is diagonally placed in the full bath and then sonicated for a set time (e. g. 3 min). Reproducible conditions must be observed when carrying out this test.
Following visual inspection of the partially perforated/eroded foil, it is possible to draw conclusions about the intensity and distribution of cavitation in the ultrasonic bath. The ultrasonic performance is verified by repeating the test. Photographic documentation of foil perforation serves as a reference result for subsequent periodic testing. The foil test should be carried out at least quarterly (note the manufacturer's instructions). The IEC foil test is deemed to be a reliable test method that reflects everyday conditions.
Rinse the bath thoroughly with water after the foil test to prevent detached aluminium particles from being spread to the instruments.

6 General use instructions

- The ultrasonic bath operating instructions and process chemicals' product information sheets must be observed.
- Likewise, the information provided by the medical device manufacturer on material compatibility with ultrasound must be noted.
- For elastic objects, e. g. medical devices made of rubber, latex and silicone rubber, the ultrasonic activity is greatly dampened by the material's flexibility.

7 Special use instructions

- Always fill bath to filling level. When preparing the solution, use active detergent, non-protein-fixing process chemicals, and observe the specified dosage / concentrations.
- Degas freshly prepared bath liquids.
- Place instruments gently in the basket and not directly on the bottom of the bath. Open joint instruments (forceps, scissors, etc.) beforehand. Position delicate instruments apart from each other in the basket, in particular the cutting jaw parts of scissors and forceps, to protect them against damage.
- Connect hollow (lumened) instruments, depending on device type, to special suction and/or rinse adapters or place them obliquely so that air bubbles can escape from their cavities and the lumen will be filled with liquid.
- Do not place instruments on top of each other, and avoid spray shadowing.
- Ensure that the medical devices in ultrasonic bath are completely covered by the solution and/or filled with solution.
- Each day after draining /replenishing the bath solution, clean mechanically and, if necessary, disinfect the ultrasonic bath.
- Observe the occupational safety and safety regulations.

Annex 13: Using water and compressed air pistols

If a water pistol is used for the final rinse with demineralized water, filter systems must be fitted for hygiene reasons to prevent any microbiological recontamination from the demineralized water.
If compressed air is used for drying the cleaned and disinfected medical devices, this must be virtually free of oil (0.1mg/m^3) and must not adversely affect the microbiological condition of the medical device. The KRINKO/BfArM Recommendation specifies use of medical compressed air.
Water and compressed air pistols must be designed such that, when properly used, the medical devices to be rinsed /flushed will not be damaged. For medical devices which, as per the manufacturer's instructions may only be treated with suitable water/air pressure, an appropriate pressure reducing device must be connected upstream for the respective pistols.
In principle, the same pistols used for the manual pre-cleaning, cleaning or re-cleaning steps (all pre-disinfection steps) should not be used for rinsing and drying the disinfected medical devices.
If there is no other option but to use the same pistols, these must be cleaned and disinfected before using them for the disinfected medical devices to prevent recontamination.
Preference should be given to pistols and pistol accessories that can be reprocessed in a washer-disinfector. The manufacturer's reprocessing instructions must be available. The pistols and accessories must be cleaned and disinfected at the end of each working day.
The pistols must have been released for the particular application by their manufacturer, and information provided on adapter dimensions, as applicable.

Annex 14: Dispenser systems for disinfectants

1 Decentralized dispensers

The requirements for the design, features and operation of decentralized disinfectant dispensers are set out in the KRINKO Recommendation «Requirements for the design, features and operation of decentralized disinfectant dispensers». Apart from general dispenser requirements, the aforementioned recommendation specifies requirements for the design, features and operation of disinfectant dispensers, which are not described here in detail.
One major difference versus the tests carried out up till 2004, devised by the Federal Institute for Materials Research and Testing (known as the BAM Tests), is that testing as per the above guideline may be carried out only by specially accredited test laboratories (EN ISO/IEC 17025). Furthermore, as regards the dose accuracy, it was revealed that the extent to which disinfectants proved suitable for use in such dispensers was essentially determined by their viscosity. Today, it is no longer necessary to test each disinfectant in each dispenser, as was customary when using the BAM test method.

The user should note the following:

- Preference should be given to decentralized disinfectant dispensers over manual or central dispensers.
- Decentralized disinfectant dispensers must meet the «Requirements for design, features and operation of decentralized disinfectants dispensers» as specified by the RKI and BAM. Proof that the respective dispensers have undergone type tests in line with these requirements must be furnished by the dispenser manufacturer, on the basis

of a certificate issued by the accredited test laboratory.

- It must be ensured that in terms of viscosity the disinfectants meet the dispenser requirements. The former BAM Tests had shown that disinfectants with a high viscosity (> 50 mPas) had given rise in some cases to faulty dispenser operation. It was possible to use disinfectants with a viscosity of < 50 mPas without problem in the dispensers. For disinfectants with a viscosity > 50 mPas, as per the RKI Recommendation a special test is needed and this must be prescribed by the disinfectant manufacturer.
- The disinfectant manufacturer must issue a certificate confirming that his product is compatible with the materials used in the product-conveying parts of the dispenser.
- Once the dispenser has been installed at the point of use, it must be tested by the manufacturer or his representative to ensure its safety and that the concentration of the use solution is within the tolerance limits.
- The dispenser must be serviced at least annually, while also checking the concentration.
- When replacing the product, all dispenser pipes conveying the product must be rinsed with water and then the concentration of the use solution checked. If necessary, the assistance of the disinfectant and dispenser manufacturers must be sought.
- The minimum dosage quantity must be noted when using the dispenser.
- Occupational health and safety regulations (e. g. use of personal protective equipment) must be observed when replacing containers for chemicals.

2 Central dosing systems

In the past many hospitals installed central (chemical) disinfectant dosing systems mainly for surface disinfection. These were systems from which the application solutions had to be transported over long distances to the various sampling points. Today, such systems are used less commonly because of the risk of contamination of the use solution in the pipes and of the formation of concentration gradients at sampling points that were not regularly in use.

3 Graduated measuring beakers

Appropriate disinfectant doses can be dispensed by means of graduated measuring beakers integrated into the packaging or external beakers. One disadvantage of using external measuring beakers is the direct contact with the disinfectant concentrate. Mistakes can be made when dispensing a precise concentration of the use solution or when calculating the ratio of disinfectant quantity to water as well as in provision of the correct amount of water.
Standard operation procedures must precisely define the individual dose dispensing steps, including the device to be used to that effect, define the type of documentation to be used as well the requisite occupational health and safety measures. The operator must provide appropriate personal protective equipment, such as chemically resistant gloves and goggles.
The operator is responsible for taking measures to ensure dose accuracy and occupational health and safety.

4 Dispensers on or in packaging

Dispensers installed on packaging (hand dispenser pumps) have the drawback that over time dispensing accuracy can change. The amount of disinfectant concentrate dispensed must definitely be checked regularly, preferably at the end of each working day, and recorded.
Non-graduated dispenser devices (e. g. dispenser bottles) integrated into the packaging have the disadvantage that, depending how full the packaging is and on the inclination angle when dispensing, the amount dispensed can vary.
Errors can also be made when calculating and using the correct amount of water. Precise standard operating procedures as well as education and training of staff are needed to achieve as far as possible precise dosage of the disinfectant concentrate and the disinfectant concentration in the use solution.

5 References

EN ISO/IEC 17025 Amendment 2 – General requirements for the competence of test and calibration laboratories; 2005

Guideline by the Federal Institute for Materials Research and Testing, of the Robert Koch Institute and the Commission for Hospital Hygiene and Infection Prevention. Requirements for design, features and operation of decentralized disinfectants dispensers. Federal Health Gazette – Health Research – Health Protection (2004) 47: 67–72.

Checkliste 1: Organizational prerequisites to be met by operator (Part A of installation qualification)

Test Object	Requirement	Available		Check ok		Measures/Remarks
		Yes	No	Yes	No	
Medical devices (instruments)	List of medical devices to be manually processed					
	Operating instructions					
	Processing instructions					
	Risk assessment and classification for processing					
Cleaning equipment (ultrasonic baths, dosing equipment, steamers, etc.)	Operating instructions					
	Medical device manuals/equipment manuals					
	Servicing and maintenance schedules					
Accessories, utensils and adjuncts (e. g. brushes, adapters, timers, water pistols, dosing aids, water filters)	List of accessories and materials					
	Operating instructions/processing instructions					
	Servicing and maintenance schedules					
Documentation on process chemicals (detergents/ disinfectants)	Product description					
	Safety data sheets					
	Instructions for use					
Quality management	Infection control policy, incl.					
	Waste disposal policy					
	Cleaning and disinfection policy for the workstation					
	Confirmation of course attendance by staff					
Contact person for validation engineer and responsibilities at operator's premises	for appointment					
	for monitoring of validation					
	for release of the validation report					

Checklist 2: Structural and technical prerequisites to be met by operator (Part B of installation qualification)

Test Object	Requirement	Available		Check ok		Measures/Remarks
		Yes	No	Yes	No	
Water connections	Incoming cold water supply					
	Incoming hot water supply					
	Incoming demineralized water supply					
	Perlator					
	Dirt trap					
Exhaust duct	Exhaust connection					
Compressed air	Technical compressed air					
	Medical compressed air					
Electrical engineering	Power connection					
	Network connection					
Illumination	Illumination 1000 lux					
	Magnifying lamp (9-fold)					
Workstation areas Adequate work surfaces Fittings	Separation of working zones					
	for cleaning					
	for disinfection					
	for final rinse and drying					
	Cleaning basin					
	Ultrasound basin (qualified ultrasound)					
	Cleaning basin/ultrasonic basin (qualified ultrasound)					
	Rinse basin					
	Basin/container for manual disinfection					

Checklist 2 (continued): Structural and technical prerequisites to be met by operator (Part B der installation qualification)

Test Object	Requirement	Available		Check ok		Measures/Remarks
		Yes	No	Yes	No	
Equipment	Lids for basins and baths					
	Qualified water pistol					
	Sprinkler					
	Tap					
	Timer					
	Splash guard					
	Qualified demineralized water pistol					
	Qualified medical compressed air pistol					
	Basin for final rinse					
	Qualified dosing equipment					
	Dosing aids (e. g. measuring beaker) with dosing instructions					
	Disinfectants/process chemicals					
	Hand washbasin as per German Technical Regulation on Biological Substances (TRBA 250)					
	Personal protective equipment (PPE) and storage facilities					
	Cleaning accessories and storage facilities for accessories					
	Waste containers as per German State Working Group for Waste Disposal (LAGA 18)					
	Drying cabinet					
Other equipment	Spatial separation of cleaning/disinfection area from area allotted for, if appl., final disinfection and drying					

Checklist 3: Batch documentation

Working steps conducted as per standard operating procedure (SOP) must be documented with employee's initials for each manually cleaned and disinfected batch/medical device.

Date/Time	Batch No./MD	SOP	Pre-cleaning	Cleaning	Intermediate rinse	Draining Off	Disinfection	Final rinse	Drying	Release

Checklist 4: Validation report cover page

- ❑ Validation
- ❑ Performance requalification (at regular intervals, generally annually)
- ❑ Performance requalification for specific reason (e. g. new MD, new standard operating procedure)

a) Responsibilities

Name of institution	
Location	
Inspectors (name of persons and, if appl., of company entrusted with validation)	
Person responsible for overall tests (operator)	

b) Qualification steps

Installation qualification (IQ)	❑ conducted	
	❑ already conducted during validation on _____	
	❑ passed	❑ failed
	Date/signature:	
Operational qualification (OQ)	❑ conducted	
	❑ already conducted during validation on _____	
	❑ passed	❑ failed
	Date/signature:	
Performance qualification (PQ)	❑ conducted	
	❑ passed	❑ failed
	Date/signature:	

c) Validation release by operator

- ❑ All parts of validation passed
- ❑ Following parts of validation failed (specify as annex):
- ❑ Measures were defined and recorded

Name/date/signature _____

d) Implementing measures when validation failed

- ❑ Defined measures were conducted (see annex)
- ❑ Requisite tests were repeated (see annex)
- ❑ Validation successfully completed
- ❑ Definition of performance requalification

Date: _____

Name/signature of operator _____

Checklist 5: Operational qualification

** All equipment used must be qualified in line with the quality management system in place (calibration, servicing, functional testing and, if appl., performance qualification)*

Test Object	Requirement	Available		Check ok		Measures/Remarks
		Yes	No	Yes	No	
Water	Quality as per Drinking Water Regulation					
Demineralized water	Conductivity value ≈ 15 µS /cm					
Detergent	As specified by MD manufacturer					
	CE mark					
	Product suitable for intended purpose (cover page)					
	Material compatibility assured and, if appl., confirmed by MD manufacturer					
Detergent with disinfectant action	Requisite spectrum of action covered					
	CE mark					
	Product suitable for intended purpose (cover page)					
	Material compatibility assured and, if appl., confirmed by MD manufacturer					
Disinfectants	Requisite spectrum of action covered					
	CE mark					
	Product suitable for intended purpose (cover page)					
	Material compatibility assured and, if appl., confirmed by MD manufacturer					
Cleaning solution	Standard operating procedure (SOP) for preparation of cleaning solution					
Disinfectant solution	Standard operating procedure for preparation of disinfectant solution					
Dosing aids for manual dosage	Graduations easily visible; dosing aid cleaned and disinfected as per standard operating procedure					
Dosing equipment	Qualification available as per QM regulation*					

Checklist 5 (continued): Operational qualification

** All equipment used must be qualified in line with the quality management system in place (calibration, servicing, functional testing and, if appl., performance qualification)*

Test Object	Requirement	Available		Check ok		Measures/Remarks
		Yes	No	Yes	No	
Ultrasound scanner	Qualification available as per QM regulation*					
Compressed air pistols/ water pistols	Qualification available as per QM regulation*					
Timers	Qualification available as per QM regulation*					
Accessories, utensils and adjuncts (e.g. brushes, adapters, water filters, cloths)	Specify suitable accessories					
	Standard operating procedure for using accessories					
Surfaces of manual processing circuit	Intact; cleaned and disinfected as per cleaning/ disinfection policy					
Taps (water, air) in manual processing circuit	Functional testing; cleaned and disinfected as per cleaning/disinfection policy					
Personal protective equipment	Specification of occupational health and safety					
	PPE properly used by staff					
Illumination	1000 lux					
Magnifying lamp	At least 9-fold magnification					

Checklist 6: Performance qualification

Designation of SOP for the medical device/MD group:

Test	Method	Requirement	Requirement met		Process Step Objective
			Yes	No	
Pre-processing handling (if appl., disassemble, handling, pre-clean immediately after use, transport)	Visual inspection of results on entry into Processing Dept.	as per SOP			Pre-processing handling of medical device as described in SOP
Manual pre-cleaning	Check	as per SOP			Visual inspection and comparison with specifications of SOP
Cleaning solution	Check preparation of cleaning solution (observe procedure, if necessary specify concentration)	as per SOP			Properly prepared cleaning solution
Cleaning, including intermediate rinse and draining off	Observe procedure (if necessary, measure various process parameters)	as per SOP			Proper conduct of cleaning and intermediate rinse, avoidance of excessive dilution of disinfectant solution
Cleaning results for Crile clamps	Verification of cleaning Chapter 5.2.3.1.2.2	Acceptance values as per Annex 9 Acceptance criteria for assessment of cleaning efficacy			Adequate cleaning efficacy
Cleaning results for instruments with everyday soils	Verification of cleaning Chapter 5.2.3.1.2.1	Acceptance values as per Annex 9 Acceptance criteria for assessment of cleaning efficacy			Adequate cleaning efficacy
Disinfectant solution	Check preparation of disinfectant solution (observe procedure, if necessary, specify concentration)	as per SOP			Properly prepared disinfectant solution
Disinfection, including final rinse and drying	Observe disinfection procedure (if necessary, measure process parameters)	as per SOP; indirect verification of disinfection Chapter 5.2.3.2			Adequate disinfection efficacy
	Determine amount of residual chemicals on PCD (Crile clamp)	as per SOP and manufacturer's instructions, Chapter 5.2.3.4			Assurance that the amount of residual process chemicals specified by the manufacturer for the medical device has been observed
	Inspect for residual moisture	as per SOP; verification of drying, Chapter 5.2.3.3			Adequate drying
Batch documentation and release	Check documentation	as per Checklist 3 Batch documentation			Continuous reproducibility of cleaning and disinfection process

Checklist 7: Daily routine checks of manual workstation

Record remarks separately

Test Object	Calendar Week/Year:							Calendar Week/Year:						
	Mon	Tue	Wed	Thur	Fri	Sat	Sun	Mon	Tue	Wed	Thur	Fri	Sat	Sun
Entire workstation														
Cleaning + disinfection policy implemented														
Ultrasonic basin														
Bath clean, empty, lid in order														
Filling level of solution, dose quantity, process chemicals														
Functional capability of timer														
Functional capability of thermo-meter														
Tray rack, spacers														
Placed in operation as per SOP														
Exhaust cleanliness and function														
Basin/container for cleaning														
Bath/basin cleaned and disinfec-ted, lid in order														
Water quantity, detergent quantity														
Timer function														
Basin/container for rinsing														
Bath/basin cleaned and disinfected														
Demineralized water/cold water supply														
Sprinkler head cleaned and disinfected														

Checklist 7 (continued): Daily routine checks of manual workstation

Record remarks separately

Test Object	Calendar Week/Year:							Calendar Week/Year:						
	Mon	Tue	Wed	Thur	Fri	Sat	Sun	Mon	Tue	Wed	Thur	Fri	Sat	Sun
Basin/container for disinfection														
Bath/basin cleaned and disinfected, lid in order														
Water quantity, disinfectant quantity														
Timer function														
Water pistol (pre-cleaning)														
Check demineralized water/cold water supply														
Cleaning + disinfection policy implemented														
Water pistol (final rinse)														
Filter fitted and service life checked														
Check of demineralized water														
Compressed air pistol at drying station														
Cleanliness, function														
Cleaning + disinfection policy implemented														
Final rinse basin														
Bath/basin cleaned and disinfected														
Demineralized water supply cleaned and disinfected														
Cleaning accessories (e. g. brushes)														
Cleaned and disinfected														
Magnifying lamp														
Cleanliness, function														
Signature/initials														

Test matrix: Validation of manual cleaning and disinfection processes

Test Object	Test Requirement		Number of Tests					
Designation	Criteria	See guideline/ document	Validation Installation qualification	Validation Operational qualification	Validation Performance qualification	Performance requalification for no specific reason	Performance requalification for a specific reason	Routine check
Structural separation or division into zones	Installation suitable for intended purpose	CL* 1 and 2 (* = Checklist)	1 × after installation			omitted	a. × b. × c. ○ d. ○	omitted
Personnel qualifications	Demonstrably qualified to conduct manual cleaning and disinfection; records of instructions available	MPBetreibV, CL 1	1 × after installation			Verification	a. ○ b. ○ c. × d. ×	omitted
Installation of workstation at operator's premises	Installation suitable for carrying out manual cleaning and disinfection	Annex 2 CL 2	1 × after installation			Verification	a. × b. × c. ○ d. ○	omitted
Ultrasound	Equipment manufacturer's instructions, operator requirements	Annex 12 QM CL 2 CL 5	1 × after installation	1 × after installation	3 ×	1 ×	a. ○ b. × c. ○ d. ○	CL 7 as per SOP
Dosing equipment/dosing aids	Equipment manufacturer's instructions, operator requirements	Annex 14 QM CL 2 CL 5	1 × after installation	1 × after installation	1 ×	Annual calibration	a. × b. × c. ○ d. ○	
Drying cabinet	Medical device and equipment manufacturer's instructions, operator requirements	QM CL 2 CL 5	1 × after installation	1 × after installation	1 ×	1 ×	a. ○ b. ○ c. × d. ○	
Other equipment for cleaning and/or disinfection	Medical device and equipment manufacturer's instructions, operator requirements	QM CL 2 CL 5	1 × after installation	1 × after installation	1 ×	1 ×	a. ○ b. ○ c. × d. ○	
Media supply (e. g. water, compressed air)	Medical device and equipment manufacturer's requirements, operator requirements	Annex 11, Annex 13, CL 2, CL 5	1 ×	1 ×	omitted	1 ×	a. ○ b. × c. ○ d. ○	CL 7
Detergents, disinfectants	Medical device and process chemicals' manufacturer's instructions, CE mark	Annex 10 CL 1, CL 5	1 ×	1 ×	omitted	1 ×	a. ○ b. × c. × d. ○	CL 7

For no specific reason: Based on 1st validation and routine tests
For specific reason: a. Structural changes to processing circuit b. Change of media supply c. New SOP d. New staff
× = required ○ = not required

Test matrix (continued): Validation of manual cleaning and disinfection processes

Test Object	Test Requirement		Number of Tests					
Designation	Criteria	See guideline/ document	Validation Installation qualification	Validation Operational qualification	Validation Performance qualification	Performance requalification for no specific reason	Performance requalification for a specific reason	Routine check
Accessories for cleaning and disinfection	Medical device and accessory manufacturer's instructions, operator requirements	CL 1, CL 2 CL 5	1 ×	1 ×	omitted	1 ×	a. ○ b. ○ c. × d. ○	CL 7
New SOP	Medical device manufacturer's instructions, CE mark, operator requirements (risk analysis)	Annex 1 – 6, Annex 8 CL 1 CL 5 CL 6	omitted	omitted	3 ×	1 ×	a. ○ b. × c. ○ d. ×	as specified at the time of validation
Measures immediately after use MD disposal for processing	MD disposal for processing as per SOP		omitted	omitted	1 × per SOP but at least 3 ×	1 × per SOP	a. ○ b. ○ c. × d. ○	as specified at the time of validation
Pre-cleaning	Compliance with SOP specifications		omitted	omitted	1 × per SOP but at least 3 ×	1 × per SOP	a. ○ b. ○ c. × d. ○	as specified at the time of validation
Cleaning solution	Compliance with SOP specifications		omitted	omitted	1 × per SOP but at least 3 ×	1 × per SOP	a. ○ b. × c. if appl. × d. ×	as specified at the time of validation
Conduct of cleaning	Compliance with SOP specifications		omitted	omitted	1 × per SOP but at least 3 ×	1 × per SOP	a. ○ b. ○ c. × d. ×	as specified at the time of validation
PCD cleaning result for semi-critical and critical B MDs	Acceptance values as per Annex 9	5.2.3.1	omitted	omitted	3 × 3 Crile clamps	1 Crile clamp per SOP but at least 3 Crile clamps	a. ○ b. × c. ○ d. ×	as specified at the time of validation

For no specific reason: Based on 1st validation and routine tests
For specific reason: a. Structural changes to processing circuit b. Change of media supply c. New SOP d. New staff
× = required ○ = not required

Test matrix (continued): Validation of manual cleaning and disinfection processes

Test Object	Test Requirement		Number of Tests					
Designation	**Criteria**	**See guideline/ document**	**Validation Installation qualification**	**Validation Operational qualification**	**Validation Performance qualification**	**Performance requalification for no specific reason**	**Performance requalification for a specific reason**	**Routine check**
Cleaning result for instruments with everyday soils, in the case of semi-critical and critical B MDs	Acceptance values as per Annex 9	5.2.3.1	omitted	omitted	3 × per SOP but at least 3 instruments	3 × per SOP but at least 3 instruments	a. ○ b. × c. ○ d. ×	as specified at the time of validation
Cleaning result for instruments with everyday soils, in the case of non-critical, semi-critical and critical A MDs	Acceptance values as per Annex 9	5.2.3.1	omitted	omitted	3 × per SOP but at least 9 instruments	3 × per SOP but at least 3 instruments	a. ○ b. × c. ○ d. ×	as specified at the time of validation
Disinfectant solution	Compliance with SOP specifications	5.2.3.2	omitted	omitted	1 × per SOP but at least 3 ×	1 × per SOP but at least 3 ×	a. ○ b. × c. ○ d. ×	as specified at the time of validation
Disinfection, including final rinse and drying	Observe disinfection process	5.2.3.2	omitted	omitted	3 × per SOP	1 × per SOP	a. ○ b. × c. ○ d. ×	as specified at the time of validation
	Measure residual chemicals on PCD (Crile clamp)	5.2.3.4	omitted	omitted	3 × per SOP	1 × per SOP	a. ○ b. × c. ○ d. ×	as specified at the time of validation
	Check for residual moisture	5.2.3.3	omitted	omitted	3 × per SOP	1 × per SOP	a. ○ b. × c. ○ d. ×	as specified at the time of validation
Documentation and release	Complete documentation and release	4.2.10 CL 3	omitted	omitted	depending on task	depending on task	a. × b. × c. × d. ×	as specified at the time of validation

For no specific reason: Based on 1st validation and routine tests
For specific reason: a. Structural changes to processing circuit b. Change of media supply c. New SOP d. New staff
× = required ○ = not required

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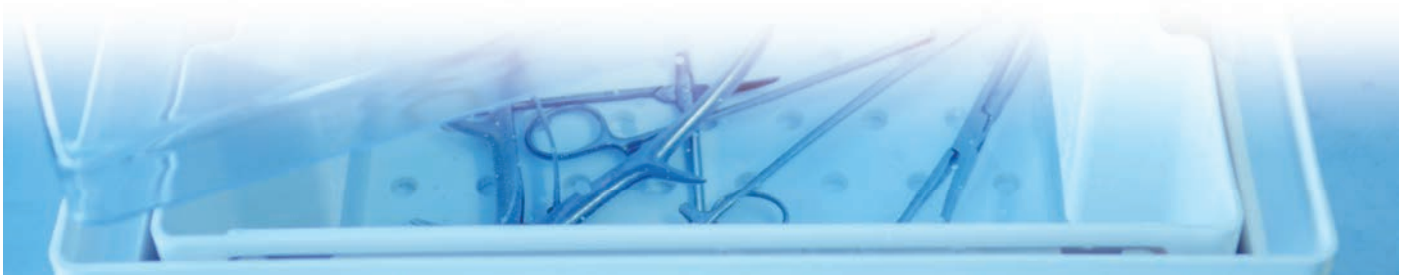

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