

The German version of this guideline [Bundesgesundheitsbl 2012 • 55:1244–1310] shall be taken as authoritative. No guarantee can be given with respect to the English translation.

Hygiene Requirements for the Reprocessing of Medical Devices

Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices"

This text replaces the corresponding recommendation of 2001, published in the *Bundesgesundheitsblatt* 44 (2001):1115-1126.

Specific aspects, such as the reprocessing of flexible endoscopes and endoscopic accessories, the topic of CJD/vCJD as well as the fleshing out of specific aspects of the central recommendations are discussed in the applicable annexes.

Overview of the annexes

Annex 1

On the term "suitable validated procedures"

Annex 2

Re: Section 2.2.3 Technical-functional safety testing

Annex 3

Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist)

Annex 4

Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (checklist)

Annex 5

Overview of requirements on reprocessing units for medical devices

Annex 6

Staff expertise

Annex 7

Measures for minimising the risk of a transmission of CJD/vCJD through medical devices

Annex 8

Hygiene requirements for the reprocessing of flexible endoscopes and endoscopic accessories

Essential content from the "Recommendations for the supervision of medical device reprocessing" produced by the Working Group on Medical Devices (AGMP), have been taken into account, particularly in some of these applicable annexes.

The recommendations apply, in principle, irrespective of the location where the reprocessing is carried out, both in the inpatient and outpatient sectors. Of decisive importance for the nature and scope of the measures, is the complexity of the medical device as well as its previous use and its use after reprocessing.

The recommendation "Infection prevention in dentistry – requirements for hygiene", published in the *Bundesgesundheitsblatt* 49 (2006):375-394, contains examples to assist with use in practice.

The use of categories of evidence

At this point, one would generally find an overview of the categories of evidence used in the recommendation. However, the hygiene requirements for the reprocessing of medical devices constitute, in some respects, an exception within the framework of the recommendations of the Commission for Hospital Hygiene and Infection Prevention.

It constitutes an area in which recommendations are issued, jointly, by the Commission for Hospital Hygiene and Infection Prevention as well as the Federal Institute for Drugs and Medical Devices. In the case of the reprocessing of medical devices, the established procedures developed experimentally; as a result, the effective cleaning, disinfection and sterilisation derive from the corresponding laboratory tests and technical standards ('best practice'). It is for this reason that these requirements result less from the tests that form the basis for the categories of evidence underlying other recommendations from the Commission for Hospital Hygiene and Infection Prevention and which, in 2010, were once more adjusted to meet the high demands on evidence-based recommendations in medicine (*Bundesgesundheitsblatt* 2010 (53):754-756). As a result, in many cases, the measures described are therefore based on aspects of the continuous activity to secure the necessary, standardisable, reproducible, effective processes to achieve the specifications while, at the same time, guaranteeing the technical-functional safety of the medical device and the documentation of these processes (MPBetreibV). This is highlighted, in the specific context, by the indication 'QM'.

1. General Provisions

Medical devices that are contaminated with pathogens can be a source of infection for humans [1-3]. The use of such medical devices thus requires previous reprocessing, for which defined requirements have been established.

These essentially result from:

- statutory provisions for the protection of patients, users and third parties (e.g. those responsible for reprocessing) (see Appendix A, legal provisions) [4];
- the known limits of methods used for reprocessing [2, 5-25] and
- the necessity to always guarantee that the tried and tested methods are of a constantly high and verifiable quality (quality management, QM.¹) within the context of an established quality management system [26, 27].

The **requirements set out in this document apply to** the reprocessing of medical devices and components of such devices, including accessories, which are intended:

¹ Definition of the use of QM. The abbreviation 'QM' can be found, in this context, in the text, when a described measure serves to assure the quality of reprocessed medical devices or the reprocessing procedures themselves. With a view to the fulfilment of predetermined specifications (in this case, cleanliness, low microbial contamination (the state subsequent to proper disinfection), sterility, function and safety of use) it is closely associated with the definition and objectives of validation.

- to be brought into contact with or inserted into the human body;
- to be used for conveying or banking blood, blood constituents, other body fluids or body tissues or changing the biological or chemical composition thereof, for subsequent use in humans or
- to be used for conveying liquids, gases or other preparations for the purpose of an infusion, reinfusion, perfusion or other administration to or introduction into the human body

Reprocessing normally **comprises** the following individual steps:

- a) proper **preparation (e.g. pre-treatment, collection, pre-cleaning** and, where applicable, **disassembling** the used medical devices and their swift and safe **transportation** to the reprocessing site, while avoiding injuries, contamination and damage,
- b) cleaning, if necessary intermediate rinsing, disinfection, rinsing and drying,
- c) **inspection for cleanliness** and **integrity** (e.g. corrosion, material condition), where appropriate, repetition of step b) and identification, e.g. for the purpose of deciding whether to repeat reprocessing in cases where the number of repetitions is limited,
- d) **maintenance and repair**
- e) **functional testing**

and, if required,

- f) **labelling**

as well as

- g) **packaging**

- h) **and sterilisation.**

Reprocessing ends with the medical device's documented **release** for use (QM, see also 2.2)

Reprocessing before use is also required if the packaging of a medical device, which is sterile in compliance with its intended purpose, has been opened or damaged, and the medical device has not been used, or if a medical device, which is to be used in a sterile state was not delivered in this state in the first place, and is to be reprocessed according to the manufacturer's instructions or if its expiry date has passed (see also 2.1).

The chain of necessary measures must be optimised since weaknesses in one of the aforementioned individual steps can adversely affect the subsequent steps and so compromise the overall result (e.g. improper cleaning which compromises the effectiveness of disinfection or sterilisation) [1-9, 11-25, 28-31].

Therefore, all individual reprocessing steps must be adapted to suit

- the medical device (especially its intended use and function and its construction and materials),
- previous reprocessing and
- previous and subsequent use of the medical device

and must always **guarantee the outcome in a traceable (see documentation) and reproducible manner** by using validated methods.

The reprocessed medical device must be perfectly functional, in line with its **intended use**, and guarantee all **safety-relevant requirements** without restrictions. The entire reprocessing procedure and the reprocessed medical device may not jeopardise the safety of patients, users or third parties.

This further implies that, for reasons of occupational health and safety and to avoid the contamination of other medical devices, contamination of the environment must be minimised as far as possible during reprocessing. This is also the reason why disinfecting cleaning must be performed, if necessary. Surfaces must be disinfected at least once a day and in the event of contamination.

Reprocessing must ensure that the reprocessed medical device poses **no risk to health** when it is subsequently used, specifically focusing on

- infections,
- pyrogenic reactions,
- allergic reactions,
- toxic reactions
- changed technical-functional properties of the medical device.

Reprocessing and the consistent compliance with the requirements imply the installation and maintenance of a quality management system (QM).

Reprocessing must be performed in accordance with accepted engineering practice and take state-of-the-art science and technology into consideration. Regarding reprocessing management, explicit reference is therefore made to the **standards** listed in Annex B (see Annex B: Standards).

1.1 Responsibility

Reprocessing carries with it a great responsibility ("fully controllable risk"). **Due diligence** implies compliance with all of the following requirements. For reasons of **in-house organisation** and the required **quality management, responsibilities** for all reprocessing steps must be specified and documented before medical devices are reprocessed (QM).

Proper and appropriate reprocessing requires the implementation and documentation of a **corresponding risk assessment and classification** of the medical devices to be reprocessed (QM; s. 1.2.1) [26].

On this basis, the person in charge of reprocessing (the operator) shall **specify in writing (see Table 1)**, taking account of the manufacturer's instructions (see DIN EN ISO 17664):

- whether,
- with which methods
- and under what conditions (e.g. rooms, work equipment, staff qualification)

medical devices that are operated within his/her area of responsibility, are reprocessed and stored (QM, Medical Devices Operator Ordinance (MPBetreibV)).

All individual steps involved in the **implementation in practice** of the methods used are to be specified before reprocessing. In this respect, it must be ensured that the persons in charge are indeed able to fulfil their tasks by virtue of their **positions and qualifications** (QM, MPBetreibV; required technical knowledge). A high **level of education** and regular **instructions** are of decisive importance (QM; see also Table 1) [26]. For the required technical knowledge, reference is made to the applicable Annex No. 6 "Staff Expertise" as well as the information resources offered by public corporations and professional societies such as the DGSV (German Society for Sterile Supply).

If reprocessing is carried out by **other parties**, it is advisable to specify the operator's and contractor's rights and obligations as well as the modalities for delivering, returning and reprocessing the medical devices in a written contract. The contractor shall provide evidence of a quality management system which guarantees adherence to the requirements mentioned in this document and must be licensed pursuant to Sections 10 and 25 of the Medical Devices Act (MPG). For the certification of the reprocessing of 'Critical C' medical devices, see also 1.4 and Table 1 (QM).

1.2 Prerequisites for Reprocessing

The prerequisite for reprocessing is that the **product compatibility of the reprocessing methods to be used** (guarantee of the medical device's functional and safety-relevant properties after reprocessing) and their **efficacy** must have been proven within the context of a product/product-group specific test and validation (see also 1.2.2, MPG, MPBetreibV, basic requirements pursuant to 93/42/EEC; QM; DIN EN ISO 17664).

Before purchasing medical devices, it is expedient for the medical devices operator to become informed not only of the medical and functional requirements but also of the relevant reprocessing information available from the medical device manufacturers (pursuant to DIN EN ISO 17664) so as to be able to consider the feasibility of reprocessing and the means and equipment necessary to this end (process chemicals, washer-disinfectors, steriliser etc), and to involve the persons in charge of reprocessing and procurement in the decision-making process (QM).

Before a decision on reprocessing is taken, **in addition to a critical feasibility study**, it must also be examined whether the entire process (also taking into account the **risk** associated with the reprocessing and use of the medical device, and the **cost and effort for validation and quality assurance**) **is economically and ecologically** reasonable. For 'critical C' medical devices, the results of this examination are to be documented (QM).

With regard to the spatial requirements for medical devices reprocessing units, see Annex 5 "Overview of requirements for medical devices reprocessing units" as well as the recommendation "*Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen* (Hygiene requirements for cleaning and disinfecting surfaces)" [32].

1.2.1 Risk Assessment and Classification of Medical Devices before Reprocessing

The person in charge of reprocessing must lay down in writing, for each medical device (if appropriate, for the medical device group):

- **whether, if appropriate how often** and
- with which methods it is to be reprocessed (QM, see Table 1).

The **operator** is responsible for **correctly classifying** the medical devices and for **determining the type and implementation of reprocessing**. The manufacturer's instructions must be followed (MPG; MPBetreibV; see also DIN EN ISO 17664). With a view to the necessary expertise, it is advisable for the person in charge of hygiene and the **person directly responsible for reprocessing** to be included in the process of classifying and determining the type of reprocessing (QM).

In case of doubt regarding classification, the medical device must be assigned to the higher (more critical) risk level (QM). The **suitability** (compliance with the medical device's properties

that are of relevance in terms of functionality and safety) and **efficacy** of the chosen reprocessing method must have been demonstrated previously in tests that are appropriate to the medical device and its risk assessment (MPG, MPBetreibV; DIN EN ISO 17664).

In the course of the **evaluation and selection of the reprocessing methods** which is required due to the need to classify each medical device or group of medical devices:

- the **constructional properties, material characteristics and functional properties** of the medical device, as well as the manufacturer's instructions (see also DIN EN ISO 17664) and
- the **nature of the previous and subsequent use** of the medical device

must be considered as they can affect the efficacy and suitability of methods [2, 5, 7-9, 11, 13-19, 21-23, 28, 30, 33-36].

Considerations regarding the **quantity and type of pathogens** likely to be present on the used medical device and their **resistance** to the reprocessing methods used are decisive for observing the **efficacy limits of the methods envisaged for use** ([2, 4, 7-9, 11-13, 15-25, 35].

Table 1. Risk Assessment and Classification of Medical Devices before Reprocessing

Classification	Medical device	Preparation	Cleaning and Disinfection	Special labelling	Sterilisation	Critical processing steps, Special requirements
Non-critical	e.g. ECG electrodes		X			
Semi-critical A) no special requirements for reprocessing	e.g. speculum	(X)	X		(X)	Disinfection (activity spectrum bactericidal (incl. mycobacteria), fungicidal and virucidal)
B) with stricter requirements for reprocessing	e.g.: flexible endoscope (gastroscope)	X ¹	X		(X ²)	Additionally: see the relevant special Annex No. 8 "Hygiene requirements for the reprocessing of flexible endoscopes and endoscopic accessories"; preferably mechanical/automated washing and disinfection
Critical A) no special requirements for reprocessing	e.g.: retractors	(X)	X		X	Preferably mechanical/automated washing and disinfection (see text No. 1.3) Generally Sterilisation with moist heat
B) with stricter requirements for reprocessing	e.g.: MIS trocar	X ¹	X	(X)	X	Additionally: - Evidence of recognised training completed by the person in charge of reprocessing ⁴

Classification	Medical device	Preparation	Cleaning and Disinfection	Special labelling	Sterilisation	Critical processing steps, Special requirements
						- Generally mechanical/automated washing / thermal disinfection in washer/disinfectors ⁵ (see text No. 1.3) Sterilisation with moist heat
C) with particularly high requirements for reprocessing	e.g.: ERCP catheters	X ¹	X	X	X ³	Suitable sterilisation ³ Additionally: Certification of the quality management system (DIN EN ISO 13485) in conjunction with the recommendation "Hygiene requirements for the reprocessing of medical devices" by a body notified by the competent authority, Risk analysis DIN EN ISO 14971 (see text 1.4)

1 Pre-cleaning also immediately after use

2 If appropriate in the case of endoscopes used in sterile body sites

3 So far, non-thermal sterilisation methods have not consistently proven effective for prion inactivation. This is relevant for medical devices of this group that are intended to come into contact with exposed lymphatic tissue or neural tissue (see also Annex 7).

4 See Annex 6 Staff expertise

5 In all cases, ensuring standardised and reproducible cleaning of evidence-based effectiveness (including internal surfaces)

(X) Optional step

The **risks** posed by reprocessed medical devices are determined:

a) by undesired effects that can arise from

- the previous use,
- previous reprocessing and
- transportation and storage,

as well as

b) from the nature of subsequent use.

Risks can arise, for example, from

- **residues from previous use** (e.g. blood, blood constituents, secretions, excretions and other parts of the body, medicinal products),
- **residues from previous reprocessing** (e.g. **detergents, disinfectants, sterilising products and other agents**, including their reaction products);
- **changes in physical, chemical or functional properties** of the medical device or
- **changes in material condition** (e.g. accelerated material wear, embrittlement and altered surface properties, changes at contact points and joints, e.g. from adhesive bonding, welding, pressing) [5, 14, 37].

Regarding the **nature of subsequent use** and the resulting risk, medical devices can be classified into:

Non-critical medical devices:

Medical devices which only come into contact with intact skin.

Semi-critical medical devices:

Medical devices which come into contact with mucous membranes or pathologically altered skin.

Critical medical devices:

Medical devices for the use of **blood, blood products or other sterile medicinal products/sterile medical devices**, and medical devices that are intended to penetrate the **skin or mucous membranes** and thus come into contact with blood, internal tissues or organs, including wounds (see Table 1) [9, 19, 25].

The **constructional and material-related details** of the product design could necessitate stricter reprocessing requirements. Consequently, it is necessary to specify this classification [6, 9, 10, 19, 28-30, 37].

Semi-critical and critical medical devices can be further divided into those which can be reprocessed **without special requirements (Group A)** or those **needing stricter requirements (Group B)**.

Moreover, a specific group of critical medical devices is subject to particularly strict reprocessing requirements (Group C) (see 1.4 and Table 1).

Medical devices that are subject to stricter reprocessing requirements are medical devices for which:

- **cleaning effectiveness** cannot be directly assessed by means of an inspection (e.g. due to long, narrow, especially terminal lumina, hollow spaces with only one opening (no flushing

but only dilution possible), complex, rough and hard to access surfaces which makes them difficult to clean);

- **reprocessing effects (including transportation)** that affect the safe use or functional safety of the **medical device and its material properties** cannot be excluded (e.g. bend-sensitive medical devices; sensitive surfaces; electronic components / active medical devices) so that, as a result, it requires greater cost and effort to conduct their technical-functional examination,

or

- the **manufacturer has limited the number of uses or reprocessing cycles** to a certain number.

Within the group of critical medical devices, those subject to stricter reprocessing requirements ('critical B') must be further divided into:

- **thermostable** medical devices (i.e. devices that can undergo steam sterilisation at 134°C) 'Critical B' and
- **thermolabile** medical devices (i.e. those that cannot undergo steam sterilisation) 'critical C'.

Owing to the **process-specific** efficacy limits and/or the prerequisites for non-thermal sterilisation methods, **critical** medical devices that cannot undergo steam sterilisation and belong to this group must be classified as **medical devices with especially strict reprocessing requirements (= critical C; see Table 1)** [5, 9-11, 14, 17, 24, 25, 28].

The special reprocessing requirements resulting from this classification (risk assessment) are also outlined in Table 1 so as to give an overview.

Owing to

- the particularly strict requirements for cleaning performance that can only be consistently guaranteed by process engineering,
- the limitations of the sterilisation methods used and
- the need for specific requirements that are to be guaranteed regularly in order to ensure the effectiveness of non-thermal sterilisation methods,

the reprocessing of critical medical devices with especially strict reprocessing requirements ('Critical C', see Table 1) is subject to an external quality control. The latter has to be proven by means of the **certification that the quality management system** is able to guarantee the adherence to these requirements at all times (see also 1.4 and Table 1; QM) [38, 39]

The external certification requirement does not apply if the manufacturer of the medical device has provided concrete information on the use of another specified sterilisation procedure and the use of this procedure has been validated on site with a view to its efficacy.

When carrying out the risk assessment of medical devices for reprocessing, the **critical processing steps** (critical control points) and the corresponding results as well as the **potential hazards** need to be defined (QM). This results in measures for **risk minimisation** and assessment or, if the risks are deemed to be uncontrollable or unacceptable, the decision to forego reprocessing.

In this context, it must also be considered that **effective cleaning** can be rendered impossible by **special uses** (e.g. the use of oily or viscous substances). Particular difficulties arise if medical devices containing hollow spaces are cleaned after they have been used in solid tissue (e.g. drills and screws after use on bones) [40].

Medical devices that are technically difficult to reprocess and the reprocessing of which brings with it a high **risk of injury**, should be given particular attention. In some cases if necessary, as with injection cannulae, reprocessing should be dispensed with (TRBA 250).

Owing to their particular hazard potential, medical devices used for administering **cytostatic or radiopharmaceutical medicines** should also be **barred from reprocessing** (Medicinal Products Act (AMG), Hazardous Substances Ordinance (GefStoffV), Radiation Protection Ordinance (StrlSchV).

Regarding the reprocessing of medical devices that have been used or are intended for use in persons with confirmed or suspected Creutzfeldt-Jacob-Disease (**CJD**) or its variant (**vCJD**), the requirements mentioned in the respective Annex to this Recommendation (Annex 7) shall be adhered to. **Dry heat, ethanol, peracetic acid, formaldehyde and glutaraldehyde have a fixating but not inactivating effect** on TSE pathogens. Of the available sterilisation methods, it was possible to prove a limited effect for vapour sterilisation (134°C, 5-18 minutes) and for certain H₂O₂-based methods [11, 12, 16, 17, 21, 22].

The results of the classification and risk assessment shall be documented (see e.g. Table 1, QM).

1.2.2 Manufacturer's instructions

The marketability of a medical device classified as reusable by the manufacturer also involves the latter's obligation to issue instructions for reprocessing including cleaning, disinfection, rinsing, drying, if appropriate packaging and sterilisation, transport and proper storage, as well as information on risks involved in reprocessing, if appropriate (see footnote ² and DIN EN ISO 17664) (MPG, MPV). This must already be taken into account when purchasing medical devices.

Deviations from the manufacturer's reprocessing instructions must be justified and documented and it must be ensured that the reprocessed medical device's

- operability and thus ability to fulfill its intended purpose, as well as
- its safety in use are fully guaranteed (see also 1.2.1). In consultation with the infection control personnel, procedures must be tested and validated for suitability and efficacy, using methods that are appropriate to the medical device and its risk assessment and classification [39].

Where necessary, in the case of incomplete and/or implausible information in the manufacturer's directions for use, the completion, further elaboration and/or correction of the information must be demanded. In the individual case, it will be necessary to examine whether an incident pursuant to section 2, no. 1 of the Medical Devices Safety Plan Ordinance (MPSV) and, consequently, a notification to the Federal Institute for Drugs and Medical Devices (BfArM) is necessary, pursuant to section 3, subsection 2 of the Medical Devices Safety Plan Ordinance (MPSV).

² Excerpt from COUNCIL DIRECTIVE 93/42/EEC concerning medical devices, Annex I, Section II, 13.6: Where appropriate, the

instructions for use must contain the following particulars:

h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.

If the medical device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;

1.3 Validating Reprocessing Methods/Procedures

Pursuant to Section 4 of the Ordinance on Operators of Medical Devices (MPBetreibV), medical devices that are intended for use in an almost sterile or sterile state must be reprocessed using **appropriate, validated methods** in such a way that the **success** of these methods is **traceable and guaranteed** and the **safety and health** of patients, users and third parties are not endangered (MPBetreibV). In validating the reprocessing methods, the parameters that are necessary for proving that the specific process (individual reprocessing steps, e.g. in cleaning, disinfecting and sterilising medical devices) has been completed in a way which guarantees the fulfilment of the corresponding specifications are also defined (see also Annex 1).

In the foregoing context, these are:

- those **parameters of the medical device** (suitability of the method for the medical device in terms of operability and safety) that must be **guaranteed in order to fulfill the demands of technical-functional safety** and
- the parameters for **guaranteeing effective cleaning, disinfection and sterilisation (cleanliness/low microbial contamination) and sterilisation (sterility) including the maintenance of low microbial contamination or sterility up to the time of use.**

Validation is to be appropriate for the medical device, its risk assessment and classification, and be carried out in accordance with **accepted engineering practice**, (see for example Annex B) taking account of **state-of-the-art science and technology**. The extent of the tests required for validation can be reduced or adapted in keeping with the technical or site-related requirements, if evidence of suitable information from the manufacturer is presented (DIN EN ISO 17664).

Helpful information for the validation of cleaning and disinfection methods and/or sterilisation methods can be found in Annex No. 3. Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist) and No. 4: Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (checklist).

If no **batches of uniform medical devices** can be created, testing must be done within the context of validating the processes necessary for the reprocessing of medical devices that are intended for use in an almost sterile or sterile state using **representative medical devices (test models**, where appropriate). The criteria for selecting test models have to be substantiated and documented.

Full validation of **sterilisation methods** is possible provided that they are used for medical devices that are residue-free after cleaning. This has been addressed in relevant technical rules (see harmonised standards in Annex B).

With regard to **cleaning and disinfection methods**, mechanical/automated methods lend themselves particularly to validation and should be preferred. **Manual cleaning and disinfection methods that are used, for instance, to pre-clean medical devices or for medical devices that cannot be mechanically cleaned/disinfected (Group B), or used based on a risk analysis**, must always be carried out in a validated manner according to **documented standard operating procedures** and using methods and processes tested for efficacy and adapted to the individual medical device (i.e. suitable and compatible with materials) (Medical Devices Act, basic requirements and DIN EN ISO 17664).

The standard operating procedures shall explicitly specify the critical processing steps. These should be taken into account within the framework of periodic testing, in order to provide evidence of the efficacy of the individual measures.

The disadvantages of manual reprocessing consist, above all, in the problem of reproducibility and standardisation, as well as in personnel protection. In any case, standardised and reproducible cleaning with evidence-based effectiveness (for Group B including internal surfaces) must be ensured.

The contents of the standard operating procedures shall address the following prerequisites:

- The procedure has been specified in sufficient detail.
- The specification includes, in particular, a precise description of all steps as well as the technical aids they involve.
- The description of the procedures is to contain – with reference to the technical aids to be used – clearly defined minimum requirements (including admissible tolerances) for the intensities to be used, rinsing and treatment durations, rinsing volumes, number of rinsing steps, etc.
- In the validation process, 'worst-case' aspects are to be used with regard to the conditions specified in the description.

In the case of **mechanical/automated cleaning and disinfection methods**, process engineering can ensure that the **parameters**, e.g. water volumes, water pressure, temperature, dosage of detergents and disinfectants and contact times, which are necessary to achieve **quantifiable cleaning and disinfection results**, are adhered to. The machines' monitoring, control and alarm systems are the prerequisite for ensuring successful cleaning and disinfection and thus reprocessing. Owing to the great importance of cleaning and disinfection results and product-specific determinants, only devices that have successfully undergone type examination can be recommended [29, 41]. It should be noted that the cleaning performance of mechanical/automated methods varies [29, 42] and that performance also depends on careful loading and the use of product-specific connectors (see e.g. errors in connecting hollow instruments or unwanted screening effects). Proper operation is facilitated by corresponding detailed directions from the manufacturer. The training/construction of the operating personnel is therefore essential for the operation of washers/disinfectors as well (MPBetreibV; QM) (see also Annex 3: Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist)).

1.4 Assuring the Quality of the Reprocessing Methods Used

Consistently ensuring reprocessing quality requires expertise [26, 27] and should be guaranteed by means of a quality management system and relevant training in line with this Recommendation (see Annex 6 Expertise; MPBetreibV; QM).

Also for the sake of standardisation and reproducibility, the individual steps involved in the reprocessing methods to be performed according to the medical devices' classification must be specified in **standard operating procedures and operating instructions**, detailing the **tests** required in each case (QM/MPBetreibV).

The quality management system for **reprocessing medical devices with particularly strict reprocessing requirements** ('Critical C', see Table 1) should be **certified** by a **body notified** by the competent authority pursuant to DIN EN 13485 in conjunction with the Hygiene Requirements for the Reprocessing of Medical Devices (QM). Explicit reference is made to risk management based on DIN EN ISO 14971 (see also Annex No. 2 on section 2.2.3. Technical-functional safety testing).

Test and validation reports prepared by laboratories accredited for the relevant methods by the competent authority (see above) can be taken into account for the validation of reprocessing methods within the context of certification.

The external certification requirement does not apply if the manufacturer of the medical device has provided concrete information on the use of another specified sterilisation procedure and the use of this procedure has been validated on site with a view to its efficacy.

Reprocessing quality is guaranteed, depending on the cleaning, disinfection and sterilisation method used, by means of:

- a) **validation (consisting of installation, operational and performance qualification)**
- b) **periodic routine tests (e.g. daily)**
- c) **batch-related routine tests**
- d) **metrological monitoring and testing of processing parameters**
- e) maintenance, calibration, if appropriate adjustment, repair and
- f) **periodic process qualification (renewed performance test)**
- g) **event-driven process qualification (performance testing for specific reasons)**

(QM, see also Annex B Standards, as well as the particulars in Annex 3. Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist) and Annex 4: Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (checklist)).

The parameters to be checked can be seen from the instructions for use and the validation protocols/plans.

Periodic process qualifications are to confirm that:

- no undesired changes in processes have occurred over time and prove that
- the parameters specified in the validation protocol/plan are being adhered to (QM). They can, for example, be co-ordinated with the maintenance of the devices used for reprocessing, in order to avoid additional downtimes.

2. Undertaking Reprocessing

2.1 Reprocessing of Unused Medical Devices

These medical devices include:

- **medical devices that have been delivered in an unsterile state but must be used in a sterile state** and which have to be reprocessed before use according to the manufacturer's instructions;
- sterilised medical devices the **packaging of which has been damaged** or opened without the medical device having been used or
- medical devices the **sterile shelf life of which has expired** within the period of time in which safe use of the medical device is possible (expiry date),

without them being used in the meantime, if their design lends itself to reprocessing.

If contamination of or damage to the medical device is ruled out, reprocessing may be limited to repackaging and re-sterilisation, provided that the technical-functional safety of the device is not compromised in the process. In this process, the manufacturer's instructions must be taken into consideration.

The following steps are necessary:

- where appropriate, unpack and **test technical-functional safety** (see also 2.2.3),
- **repack** (see 2.2.4),
- use a suitable **sterilisation method** (see 2.2.5) that, aside from sterilisation, guarantees that the medical device's function is preserved without restriction,
- **labelling** (see 2.2.6)],
- **documentation of reprocessing** (see 2.2.8),
- **release** for use (see 2.2.7).

If contamination **cannot** be excluded and, if appropriate, also where medical devices are delivered in an unsterile state but must be used in a sterile state, these medical devices must also be reprocessed as if they had been used pursuant to Point 2.2, in keeping with the manufacturer's instructions (MPG; MPBetreibV).

2.2 Reprocessing of Used Medical Devices

The following steps are necessary when reprocessing used medical devices:

- proper **preparation (e.g. pre-treatment, collection, pre-cleaning** and, where appropriate, **disassembling) (see 2.2.1)** of used medical devices and their safe **transport** to the reprocessing site in a closed container to avoid damage;
- **cleaning, if necessary intermediate rinsing, disinfection, rinsing and drying** (see 2.2.2);
- **check for cleanliness and integrity of surfaces** (e.g. corrosion, material condition) and, where applicable, identification for the purpose of deciding whether to repeat the reprocessing;
- **maintenance and repair;**
- **technical-functional safety testing** (see 2.2.3);

and, if required,

- **labelling** (see 2.2.6);
- **packaging** (see 2.2.4);
- **and sterilisation** (see 2.2.5).

Reprocessing is concluded with the documented **release** of the medical device for further use or storage (see 2.2.6 and 2.2.7) (QM).

2.2.1 Preparation of Reprocessing, (Pre-treatment, Collection, Pre-cleaning, if appropriate, Disassembling, Temporary Storage and Transport)

The chain of required measures must be optimised as any weakness in a single step (e.g. cleaning) might compromise the overall result. Inadequate results can be the consequence of flaws in any of the individual reprocessing steps, such as the use of unsuitable detergents and disinfectants, faulty use, contaminated disinfection or rinsing liquids, insufficient drying and improper storage [2, 5, 7, 9, 11, 13-17, 19, 22, 23, 28-30]. Therefore, **preparation** (pre-treatment and collection) is normally necessary to ensure that medical devices are reprocessed properly (see also Table 1). In order to avoid compromising the hygienic safety and operability of the reprocessed medical device, particularly when cleaning and disinfection are delayed, the pre-cleaning that is necessary in these cases and, where appropriate, **temporary storage** must meet the following requirements:

- **Gross debris** must be removed from the medical device promptly after use. As far as possible, blood and tissue must be prevented from drying and sticking to the device. This is achieved by specifying adequate methods and procedures (e.g. wiping off outer debris and flushing working channels immediately after use, specifying disposal times), especially to ensure that cleaning performance is not adversely affected (drying and sticking of infectious agents in protective colloids) [11, 13, 23].
- The **pre-cleaning** agents and methods must be adapted to the subsequent reprocessing procedure, especially to preclude adverse effects on subsequent steps (e.g. avoiding fixating methods, such as the use of heat or aldehydes before cleaning; exemptions might be necessary in specific situations for the purpose of infection prevention) [9, 12, 13, 19, 21].
- Chemical, mechanical and physical damage to medical devices due to pre-cleaning, **transportation** or perhaps necessary **temporary storage** (e.g. resulting in the crystallisation of liquid residues) must be ruled out by specifying suitable operational procedures. Corresponding risks (e.g. kinking) are to be taken into account in tests for cleanliness and technical-functional safety (QM).
- Occupational health and safety is to be guaranteed during all preparation stages (collection, pre-cleaning, temporary storage and transportation), e.g. by providing suitable protective clothing, safety goggles, suitable gloves and ensuring good indoor air quality (TRBA 250).

2.2.2 Cleaning, Disinfection, Rinsing and Drying

Only clean medical devices can be sterilised in a reliably effective manner. Cleaning is therefore of paramount importance in the overall reprocessing procedure [9, 11-13, 19, 21, 23, 28, 30].

With respect to **cleaning, disinfection, rinsing and drying**, it is necessary to distinguish between manual and mechanical/automated methods, whereby mechanical/automated methods should be preferred, especially since they are easier to standardise and reproduce and for reasons of occupational health and safety (see also 1.3) [23, 27, 41].

The use of manual processes, given the availability of mechanical/automated processes, presupposes that evidence of the equivalence of the efficacy of manual and mechanical/automated processes has been furnished.

In the case of manual cleaning and disinfection involving possible risks of injury and infection, a non-fixating disinfection of proven efficacy must be performed while observing further **occupational health and safety measures** (e.g. protective clothing, safety goggles, suitable gloves and good indoor air quality) (TRBA 250).

Cleaning, disinfection, rinsing and drying methods must comply with the following requirements.

- In principle, **all external and internal surfaces** must be **accessible** to the detergents and disinfectants used (opening of valves/taps, hinged instruments, avoiding of screening effects, correct connection of hollow instruments). Where appropriate, complex medical devices must be disassembled according to the manufacturer's instructions [9, 10, 19].

Cleaning:

- An **effective cleaning method** must be used which avoids persistent cross-contamination, i.e. cross-contamination relevant to the safe use of the released medical device. The aim of the measures is residue-free cleaning (see above for the cleanliness warning value) to prevent the subsequent disinfection and sterilisation stages from being adversely affected, for example, by blood, secretion or tissue residues [9, 11, 13, 19, 21, 23, 30].
- As in the case of **pre-cleaning**, the procedure **used for (main) cleaning** must be such as to **prevent the fixation** of residues (e.g. tissue residues, blood) to the medical device as this would adversely affect cleaning, disinfection and sterilisation performance (Cat. IB) [2, 8, 9, 14].
- **Alkaline cleaning** is usually very effective at dissolving protein and fat residues and may even have an antimicrobial effect. On the other hand, it might cause adverse material changes. When purchasing medical devices, it is therefore advisable to opt for devices that are also suitable for alkaline cleaning. What is decisive is the **proven cleaning performance** of an agent or method (such as DIN EN ISO **15883**). Also with a view to the problem of unidentified carriers of pathological prion proteins, the aspect of cleaning has a prominent role to play since, on the one hand, the efficacy of inactivation procedures is considerably compromised by prior thermal drying or the use of protein-fixing disinfectants, on the other, a suitable cleaning procedure can lead to a considerable reduction in the burden of prion proteins [8, 16, 22, 44].
- The use of **ultrasound** can increase cleaning performance under certain conditions (see the manufacturer's instructions for validated methods). When using ultrasound, the dosage instructions for the ultrasound-tested detergent/disinfectant in combination with the specified exposure time must be adhered to, in keeping with the manufacturer's instructions. The detergents used are to prevent the reattachment of dissolved material (minimising cross-contamination). Ultrasound is not appropriate for all medical devices (caution is advised, for example, in the case of adhesive bonds or lenses) or is not always effective, especially as a result of insufficient sound transmission in the case of soft or air-filled medical devices. In case of doubt, the manufacturer (of the medical devices to be reprocessed) should be consulted. Special diligence needs to be exercised when loading ultrasonic baths since improper loading can result in poor results (e.g. due to acoustic shadows). For the bath to be fully effective, all components of the medical device must be completely wet by liquid (inside and outside). The ultrasonic transmitter is subject to wear and tear, which causes a reduction in performance. Since ultrasound can raise the temperature of the bath, and this might have negative effects on the medical devices or on the cleaning performance, the operating

temperature is to be controlled by the device [45]. It is advisable to cover ultrasonic baths for reasons of industrial safety (see TRBA 250).

- As the cleaning solution becomes contaminated by organic matter and chemical residues it is to be freshly prepared at least once every working day, and changed promptly in the event of visible contamination, so as to **avoid microbial propagation**, persistent **cross-contamination** and adverse effects on the cleaning results. For the same reasons, and to avoid biofilm formation, the cleaning basin is to undergo thorough mechanical/automated cleaning and disinfection on each working day (QM) [46].

Intermediate rinsing:

- In reprocessing medical devices, it is either obligatory to perform rinsing between cleaning and disinfection to prevent organic material and chemical residues from the previous cleaning from adversely affecting the efficacy of the disinfection, or the manufacturer of the process chemicals can provide proof of sufficient disinfection even without rinsing.

Disinfection:

- The disinfectants used in the final disinfection of semi-critical medical devices must demonstrably be **bactericidal** (including mycobacteria), **fungicidal and virucidal**. The Robert Koch Institute's working group on virucidal activity has published a statement on claims regarding the efficacy of disinfectants (*Arbeitskreis Viruzidie beim RKI [47] 2004*). In this statement, two fields of action are defined – disinfectants with a limited spectrum of virucidal activity (effective against enveloped viruses) and disinfectants with virucidal activity (effective against enveloped and non-enveloped viruses). The working group on virucidal activity recommended the testing method of the German Association for the Control of Virus Diseases (DVV) and the RKI which comprises a suspension test. This testing method was systematically revised in 2005 and supplemented in 2008 and should therefore only be used in the current version (Version 2005: also suitable for use with the exception of the chemo-thermal procedures; see the DVV's website for information) for tests and declarations. This means, in practice, that for a declaration of virucidal efficacy, expert opinions pursuant to the DVV/RKI guideline must include polio virus, adenovirus and SV40.

For *C. difficile*, decontamination using a combination of thorough pre-cleaning and cleaning, as well as instrument disinfection based on glutaraldehyde and peracetic acid, has been found to be effective [48, 49].

- The cleaned and disinfected medical device may not pose any risk of infection when it comes into contact with skin or mucous membranes. **Thermal methods** in washer-disinfectors should be preferred over chemical and chemo-thermal disinfection methods on account of their more reliable efficacy (less residual soiling) [9, 19, 23, 24, 41]. Disinfectants on the list of the Association for Applied Hygiene (VAH) are intended for the manual disinfection of medical devices but not for mechanical/automated disinfection. The efficacy of cleaning/disinfection equipment must therefore be proven by means of expert reports based on mechanical/automated reprocessing conditions (see Annex 3: Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist)).
- As is the case during **pre-cleaning and cleaning, during disinfection**, process control must **prevent the fixation** of residues (e.g. blood, secretions, tissue residues) on the medical device as this would adversely affect cleaning, disinfection and sterilisation performance rates [9, 11, 13, 19, 21, 23, 30].

- Since aldehyde, alcohol, peracetic acid and temperatures > 55°C have fixative properties, cleaning performance in the previous cleaning step must ensure that no relevant protein fixation can occur here [12, 13, 16, 21, 22].
- Effective cleaning and disinfection presupposes compliance with instructions for use, especially as regards **concentrations** and **contact times** [9, 18, 19, 24, 29]. This must be taken into account when **organising the operating cycles** (QM).

Rinsing and drying:

- The build-up of **reaction products and the presence of residues** from used detergents and disinfectants or other process chemicals in quantities that might have adverse health effects (e.g. chemical irritations or allergic reactions) must be avoided. Cleaning and disinfectant solutions must therefore be removed by **intensive renewed rinsing**, down to the limit that the manufacturer deems to be tolerable. The effect of this step depends on the time, temperature and water volume used. Information on tolerable residues, if necessary from the manufacturer, is to be given for all process chemicals, such as neutralisation agents or drying agents, left on the medical device as a result of the procedure. If necessary, the examination procedures used by the process chemicals' manufacturer are to be made available. In the case of eye surgeries, complications at the patient's eye (for example ocular burns) because of alkaline detergent residues must be excluded. Therefore, a standardised and appropriate rinsing with suitable water between uses is of major importance when reprocessing medical devices used in ophthalmology. When washing and disinfecting ophthalmologic devices in a washer-disinfector, a suitable programme should be used to ensure the success of the rinsing operation and to prevent potential burns to the patient's eye due to alkaline detergent residues. In the course of the process validation it must be proven that the alkalinity has been removed.
- The necessary requirements, in terms of microbiological and chemical properties, for water intended for use in the reprocessing of medical devices are to be defined for each specific process. This applies, in particular, to the water used for the **final rinse**.

General requirements:

- In terms of microbiology, the water shall have at least potable water quality [15, 27]. Regarding the subsequent propagation of typical water bacteria (e.g. pseudomonads, legionellae and atypical mycobacteria), please refer to the Recommendations for the reprocessing of flexible endoscopes (Annex 8).

Requirements for final rinse water:

- Absence of potentially pathogenic microorganisms
- Demineralised water is recommended in order to avoid crystallisation on the medical device [9]. In this context, account should be taken of the potential for bacterial contamination depending on the water treatment process used [50-55].

Microbiologically clean water for final rinsing can be produced by suitable water filters. It might be necessary to use water of a higher quality (e.g. purified water (Aqua purificata) or water for injection (Aqua ad iniectabilia) [56]) for certain medical devices (especially those with higher or particularly strict reprocessing requirements) owing to the material properties of the medical device or because of the need to ensure the absence of endotoxins or particles in the case of long and narrow lumina.

- Final rinsing and drying must be performed under conditions that **rule out the re-contamination of disinfected medical devices**. The use of medical compressed air [56] for drying is therefore recommended, as it is fast-acting and effective.

Visual check:

- Only clean medical devices can be safely sterilised [9, 11-13, 19, 21, 23, 28, 30] [9, 11-13, 19, 21, 23, 28, 30] (for the warning value see the footnote under 2.2.2). It is therefore necessary to verify the cleaning effect. After cleaning/disinfection, **no contaminants** (e.g. encrustation, deposits) may be visible on any components of the medical device during visual checks (normal vision or vision corrected to normal) (QM). If need be (e.g. in case of critical medical devices with particularly strict reprocessing requirements = 'Critical C'), optical magnifying aids or appropriate other (e.g. chemical or physical) methods will be required to evaluate cleaning performance.
- If cleaning success cannot be assessed by visual inspection (e.g. due to long, narrow lumina, hollow spaces, such as, for instance, in MIS instruments; 'Critical B and C' medical devices) cleaning must be ensured through process engineering (e.g. by validated, mechanical/automated cleaning methods) and, where applicable, parametric monitoring (see Table 1; Annex 3. Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist), QM). In this context, the difficulty of manual cleaning lies especially in providing proof of reproducible implementation (for example, thorough brush cleaning of endoscopes). Periodic testing of the cleaning performance, above and beyond the thorough implementation of the manual procedures pursuant to the standard operating instructions, is therefore advisable.

2.2.3 Verifying Technical-Functional Safety (see also Annex No. 2 on Section 2.2.3

Technical-functional safety testing)

Guaranteeing the technical-functional safety of a reprocessed medical device is the responsibility of the operator. Simple, safety-relevant functional tests are to be carried out also by the user immediately before use (MPBetreibV).

Technical-functional tests should also be carried out after cleaning, disinfection, rinsing and drying have been completed but prior to sterilisation, especially when maintenance and repair work is being performed (MPBetreibV). The scope and nature of the tests depend on the medical device and are to be defined in the standard operating procedures (QM).

In this respect, no contamination with harmful substances (e.g. toxic care products) or particles (e.g. talc) which would outlast subsequent reprocessing steps may occur (MPBetreibV). Moreover, the care products used (e.g. paraffins according to the European pharmacopeia (Ph.Eur.) [56]) may not adversely affect sterilisation success [9]. For this purpose, the care product manufacturer may have to be consulted.

The tests for cleanliness, integrity and defined technical-functional properties serve to screen out medical devices from which visible residues cannot be removed, even after renewed-cleaning, or where technical-functional deficiencies cannot be remedied (QM). Where

deficiencies are observed, these are to be documented, their source investigated and eliminated.

Effects of the reprocessing procedure on material properties and technical-functional safety tend to be product-specific. They must therefore be verified on an individual basis, declared in the manufacturer's instructions for reprocessing, where appropriate indicating the tests or checks to be carried out after reprocessing, and must be taken into account by the operator in the standard operating procedures, for example, by specifying the target values to be achieved (see also 1.2.2 and 1.3) (MPG; MPBetreibV; QM).

Moreover, maintenance and repair must also be in line with the relevant manufacturer's directions (MPBetreibV).

2.2.4 Packaging

The packaging system normally consists of a sterile barrier system and, if appropriate, a protective wrapping and must be adapted to:

- the sterilisation method used (e.g. enabling sterilisation through suitable sterilant penetration) (see Point 2.2.5);
- the properties of the medical device that is disinfected or is to be sterilised, maintaining its operability (e.g. mechanical protection of sensitive components) as well as
- the intended storage and transportation (taking mechanical stress factors into account).

Air plays only a subordinate role in the re-contamination of cleaned and disinfected medical devices. Consequently, no special requirements are placed on the quality of the air in the packaging area.

The **packaging system** must enable sterilisation and guarantee sterility until use under proper storage conditions; where required, a **sterile goods shelf life** has to be specified (see also instructions of the sterile goods packaging manufacturer). Recontamination of the medical device after it has been reprocessed must be ruled out until it is used (also see Annex B Standards).

Imperviousness of the sealing seams must be proven, at least by means of simple tests in the course of the reprocessing process (see also Annex 4 page 4 "Batch-related Tests – Visual Inspection of Packaging"). This is without prejudice to the obligation to conduct tests immediately before use. The DIN 58953 standard series contains useful information on sterile supplies.

2.2.5 Sterilisation

Basically, sterilisation is conducted subsequent to the thorough cleaning and disinfection of medical devices that is required for reasons of occupational health and safety [9, 11, 13, 21, 23, 24, 28].

A method that is effective and has been validated and verified with a view to its suitability for the medical device must be used for sterilisation (see also Point 1.3) (MPBetreibV). The nature of the sterile goods, their packaging and loading configuration are important determinants of sterilisation success [10, 11, 33, 34, 57].

The use of steam sterilisation at 134 °C is to be preferred as the standard procedure owing to its minimal dependence on influencing factors [9, 24, 25]. Care must be taken to ensure that

the sterilant has access to all external and internal surfaces of the medical device within the sterile packaging (e.g. by thoroughly cleaning all lumina and opening valves or taps). Before any lubricants/sprays (grease, oils) are used, it must be ensured that they will not adversely affect the sterilisation success. These requirements must be taken into account when purchasing the medical devices and the relevant containers (QM).

Hot-air sterilisation (disinfection) can only be considered, according to the current state of technology, for semi-critical A (unpacked) or critical A products (in packaging that is suited to the procedure). Unlike other sterilisation procedures, in the case of hot-air sterilisation, the mass of the goods, their specific heat and specific thermal conductivity, packaging and especially the loading pattern are critical. As a result, the operator must validate the procedure, define and standardise the load (mass of the instruments) and the packaging and consistently document these as well as the observance of the necessary temperature-time relationships [34].

For the purpose of **conducting and monitoring sterilisation**, reference should be made to the corresponding standards (see Annex B Standards) as well as Annex 4: "Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices". Annex 4 provides an overview of the essential components of a validation.

Especially prior to using **low-temperature methods** and in the case of medical devices classified as 'Critical C', the **performance limits** of the methods employed are to be defined, documented and evaluated, taking account of the previous use of the medical device (QM, see also Table 1) [4, 9, 58].

Additionally, the **requirements stipulated by the Hazardous Substances Ordinance and relevant standards** might have to be taken into account (e.g. those for ethylenoxide, formaldehyde or hydrogen peroxide sterilisation) (e.g. TRGS 513).

2.2.6 Labelling

Packaged, reprocessed medical devices are to be accompanied by **information** that enable **safe use**, taking into consideration the level of training and knowledge of the user circle and the complexity of the medical device (MPG).

It must be possible at all times for the user to recognise:

- the **name of the medical device**; this must allow for use-relevant identification (e.g. model, size) if this is not immediately obvious;
- information on the labelling of released medical devices; as well as
- the **release decision** and, where applicable, process indicators;

as well as information that enables a decision to be taken on time-related aspects of safe use of the medical device, such as:

- date of sterilisation and the type of sterilisation method used (**batch number of the sterilisation, sterilisation date**);
- where appropriate, an **expiry date** understood as the manufacturer-indicated date until which safe use is proven to be possible;
- the **sterile goods shelf life**, if it is closer than the expiry date.

Where appropriate (e.g. in the case of medical devices belonging to the 'Critical C' group)

- Specifications for technical-functional testing and safety, **safety instructions, warnings** and other information, which is exclusively present on the original packaging and is relevant for safe use and traceability;
- the **name of the manufacturer** and, where appropriate, **batch or serial number**;

and, when **reprocessing is undertaken by other parties**, additionally

- the name and address of the reprocessing company.

If the manufacturer has specified the number of times a medical device may be reprocessed, the **number and type of completed reprocessing cycles** must also be stated (MPG, QM). This is not necessary in the case of medical devices that are intended for multiple use for which the manufacturer has not specified a maximum number of reprocessing cycles. Pertinent labels can also be attached directly to the medical device using electronic data processing if it is ensured that the number and type of reprocessing cycles performed on the respective medical device are readable when the decision is to be taken on a renewed reprocessing cycle. Such medical devices may only be released if the corresponding product-specific requirements have been complied with (MPG).

The results are to be documented in such a way that traceability to the specific batch (in the case of medical devices in the critical A and critical B groups) or to the specific reprocessed medical device (in the case of medical devices belonging to the critical C group) is guaranteed.

As regards the use of **symbols** for labelling, please refer to the appended standards (see DIN EN 980).

In determining the expiry date, meaning the date until which use is demonstrated to be safe, the possibility of material changes (also possibly caused by the reprocessing method/s) has to be taken into account; in determining the sterile goods shelf life, the type of packaging, transport and storage conditions also have to be factored in.

The user must also be able to identify completion of the process cycle in the case of medical devices the reprocessing cycle of which ends with disinfection (QM).

2.2.7 Release for Use

The reprocessing of medical devices ends with their documented release for use. This is authorised if the process parameters measured during the reprocessing cycle comply with those of the validation reports and includes:

- **implementing and documenting routine checks**;
- verifying and documenting the full and proper implementation of the process (batch-related routine checks and batch documentation);
- **checking the packaging for integrity and dryness**; and
- verifying the labelling (see 2.2.5) (QM).

For reasons of quality management, the persons authorised to approve releases must be specified in writing (QM).

Standard operating procedures must include

- the form in which **the release decision must be documented**,

and

- the **procedure to be followed for process deviations** (QM).

Care is to be taken to ensure the **safe removal** (rinsing and desorption) **of harmful substances** resulting from the reprocessing procedure (e.g. adherence to desorption times) (see Annex Standards, Technical Rules for Hazardous Substances (TRGS) 513). It is only subsequently that the release for use, which must be documented, can be authorised.

2.2.8 Batch documentation

The data on the process parameters measured during reprocessing and the release decision must be documented and reference must be made to the batch and the person authorising the release. They must document that the **reprocessing procedure used was completed according to the standard operating procedures and in compliance with the parameters laid down in the validation protocol** (QM).

Records of the reprocessing of medical devices must be kept for not less than five years. This is to be without prejudice to other legislation on retention periods (e.g. patient documentation). In this context, neither may the original content of an entry be obliterated nor alterations be made which render it impossible to tell if they were made during or after the original entry. Records may also be stored on image or data storage media. It must be ensured that they are accessible and readable during the retention period. The records and protocols must be submitted to the competent authorities on request (MPBetreibV).

3. Transportation and Storage

Transportation and storage may not adversely affect the properties of the reprocessed medical device. The instructions of the manufacturer of the medical device and of the packaging materials must be taken into account when storing reprocessed medical devices (MPBetreibV). Reprocessed medical devices that are used in a sterile state must always be packaged and must be stored in a dustproof, clean, dry and vermin-proof area at room temperature. Storage periods depend on the quality of packaging materials, sealing seam integrity and storage conditions. Depending on these conditions, storage periods over the six month are conceivable.

Almost-sterile (semi-critical) medical devices must be stored under conditions that prevent recontamination during storage.

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Annex A: Laws, Ordinances, Directives

- Council Directive 90/385/EEC of 20 June 1990 relating to implantable medical devices
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
- Medical Devices Act (MPG)
- Ordinance on Medical Devices (MPV)
- Ordinance on Installing, Operating and Using Medical Devices (Medical Devices Operator Ordinance (MPBetreibV))
- Medical Devices Safety Plan Ordinance (MPSV)

Occupational health and environmental protection:

- Biological Agents Regulation (Bio StoffV).
- Ordinance on Occupational Health Care (ArbMedVV)
- Chemicals Act (*Chemikaliengesetz*)
- Hazardous Substances Ordinance (*Gefahrstoffverordnung*)
- Radiation Protection Ordinance (*Strahlenschutzverordnung*)
- Waste Avoidance and Waste Management Act (*Abfallgesetz*)
- Technical Rules for Biological Agents (TRBA) 250
- Technical Rules for Hazardous Substances (TRGS) (300, 401, 440, 513, 525, 555; 900, 905)

Annex B: Standards

If the provisions of the standards referred to are complied with, accepted engineering practice is deemed to be fulfilled. This collection comprises the standards to be observed under aspects of hygiene from which the standards matching the planned reprocessing work must be selected in each case. For testing that serves to ensure technical-functional safety, additional standards may have to be observed, as appropriate.

The column "Sections of the Annex" cross-references the underlying standards and the corresponding sections of the Recommendation. The standards with particular **practical**

relevance are **highlighted in grey** (see also DIN Taschenbücher 169, 263, 265, 469 und 475). This part of the Annex is regularly updated (see also www.named.din.de).

Annex B Standards

Standard harm. under Dir.	Standard	Title	Sections of the Annex
93/42/EEC	DIN EN 285	Sterilization - Steam sterilizers - Large sterilizers <i>(applies up to and including installation qualification)</i>	1.3, 1.4, 2.2.5
93/42/EEC 90/385/EEC 98/79/EC	DIN EN 556-1	Sterilisation von Medizinprodukten – Anforderungen an Medizinprodukte, die als "STERIL" gekennzeichnet werden (Sterilization of medical devices - Requirements for medical devices to be designated "STERILE") Teil 1: Anforderungen an Medizinprodukte, die in der Endpackung sterilisiert wurden (Part 1: Requirements for terminally sterilized medical devices)	1.3, 1.4, 2.2.5
	DIN EN 867-5	Nichtbiologische Systeme für den Gebrauch in Sterilisatoren (Non-biological systems for use in sterilizers) Teil 5: Festlegungen von Indikatorsystemen und Prüfkörpern für die Leistungsprüfung von Klein-Sterilisatoren vom Typ B und vom Typ S (Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilisers Type B and Type S) <i>(Parts 1, 3 and 4 replaced by DIN EN ISO 11140-1, 3 and 4; see also DIN EN ISO 18472)</i>	1.3, 1.4, 2.2.4, 2.2.5
	DIN EN 868	Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte (Packaging for terminally sterilized medical devices) Teil 2: Sterilisierverpackung – Anforderungen und Prüfverfahren (Part 2: Sterilization wrap - Requirements and test methods); Teil 3: Papier zur Herstellung von Papierbeuteln (festgelegt in EN 868-4) und zur Herstellung von Klarsichtbeuteln und -schläuchen (festgelegt in	1.3, 1.4, 2.2.4

Standard harm. under	Standard	Title	Sections of the Annex
		<p>EN 868-5) – Anforderungen und Prüfverfahren (Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods);</p> <p>Teil 4: Papierbeutel – Anforderungen und Prüfverfahren (Part 4: Paper bags - Requirements and test methods);</p> <p>Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösen Materialien und Kunststoff-Verbundfolie – Anforderungen und Prüfverfahren (Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods);</p> <p>Teil 6: Papier für Niedertemperatur-Sterilisationsverfahren – Anforderungen und Prüfverfahren (Part 6: Paper for low temperature sterilization processes - Requirements and test methods);</p> <p>Teil 7: Klebemittelbeschichtetes Papier für Niedertemperatur-Sterilisationsverfahren – Anforderungen und Prüfverfahren (Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods);</p> <p>Teil 8: Wiederverwendbare Sterilisierbehälter für Dampf-Sterilisatoren nach EN 285 – Anforderungen und Prüfverfahren (Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods);</p> <p>Teil 9: Unbeschichtete Faservliesmaterialien aus Polyolefinen – Anforderungen und Prüfverfahren (Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods);</p>	

Standard harm. under	Standard	Title	Sections of the Annex
		Part 10: Teil 10: Klebemittelbeschichtete Faservliesmaterialien aus Polyolefinen – Anforderungen und Prüfverfahren (Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods); (; Part 1 replaced by DIN EN ISO 11607-1)	
93/42/EEC 90/385/EEC 98/79/EC	DIN EN 980	Symbole zur Kennzeichnung von Medizinprodukten (Symbols for use in the labelling of medical devices) (see also Draft 'Entwurf DIN EN ISO 15223-1')	2.2.6
93/42/EEC 90/385/EEC	DIN EN 1041	Bereitstellung von Informationen durch den Hersteller von Medizinprodukten (Information supplied by the manufacturer of medical devices)	2.2.6
93/42/EEC	DIN EN 1422	Sterilisatoren für medizinische Zwecke – Ethylenoxid-Sterilisatoren – Anforderungen und Prüfverfahren (Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and testing)	1.3, 1.4, 2.2 5
93/42/EEC	DIN EN 13060	Dampf-Klein-Sterilisatoren (Small steam sterilizers)	1.3, 1.4, 2.2 5
93/42/EEC	DIN EN 14180	Sterilisatoren für medizinische zwecke – Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren – Anforderungen und Prüfung (Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing) (applies up to and including installation qualification)	1.3, 1.4, 2.2 5
93/42/EEC	DIN EN ISO 25424	Sterilisation von Medizinprodukten – Niedertemperatur-Dampf-Formaldehyd – Anforderungen an die Entwicklung, Validierung und Routineüberwachung von Sterilisationsverfahren für Medizinprodukte (Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for	1.3, 1.4, 2.2.5

Standard harm. under	Standard	Title	Sections of the Annex
		<p>medical devices) (replaces DIN EN 15424)</p>	
<p>93/42/EEC (other than Part 5!)</p>	<p>DIN EN ISO 15883</p>	<p>Reinigungs-Desinfektionsgeräte (Validierung und Betrieb)(Washer-disinfectors (Validation and operation) Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren (Part 1: General requirements, terms and definitions and tests); Teil 2: Anforderungen und Prüfverfahren von Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für chirurgische Instrumente, Anästhesiegeräte, Gefäße, Utensilien, Glasgeräte usw. (Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware etc.); Teil 3: Anforderungen an und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für Behälter für menschliche Ausscheidungen (Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers); Teil 4: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für thermolabile Endoskope (Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes); Teil 5: Prüfanschmutzungen und -verfahren zum Nachweis der Reinigungswirkung (<i>Technische Spezifikation</i>) (Part 5: Test soils and methods for demonstrating cleaning efficacy (technical specification)) Teil 6: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für nicht invasive, nicht kritische</p>	<p>1.3, 1.4, 2.2 2</p>

Standard harm. under	Standard	Title	Sections of the Annex
		Medizinprodukte und Zubehör im Gesundheitswesen.(Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment);	
93/42/EEC 90/385/EEC 98/79/EC	DIN EN ISO 14971	Medizinprodukte – Anwendung des Risikomanagements auf Medizinprodukte (Medical devices - Application of risk management to medical devices)	1.2, 1.3, 2.2.3
93/42/EEC (Parts: 1, 3, 4-7, 9, 11-18) 90/385/EWG (Parts: 1, 4-7, 9, 11-13, 16-18)	DIN EN ISO 10993	Biologische Beurteilung von Medizinprodukten (Biological evaluation of medical devices) Teil 1: Beurteilung und Prüfungen im Rahmen eines Risikomanagementsystems (Part 1: Evaluation and testing within a risk management system) Teil 2: Tierschutzbestimmungen (Part 2: Animal welfare requirements) Teil 3: Prüfungen auf Gentoxizität, Karzinogenität und Reproduktionstoxizität; (Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity); Teil 4: Auswahl von Prüfungen zur Wechselwirkung mit Blut (Part 4: Selection of	1.3, 1.4, 2.2.5, 2.2.8

Standard harm. under	Standard	Title	Sections of the Annex
		<p>tests for interactions with blood);</p> <p>Teil 5: Prüfungen auf In-vitro-Zytotoxizität (Part 5: Tests for in vitro cytotoxicity);</p> <p>Teil 6: Prüfungen auf lokale Effekte nach Implantationen (Part 6: Tests for local effects after implantation);</p> <p>Teil 7: Ethylenoxid-Sterilisationsrückstände (Part 7: Ethylene oxide sterilization residuals);</p> <p>Teil 9: Rahmen zur Identifizierung und Quantifizierung von möglichen Abbauprodukten (Part 9: Framework for identification and quantification of potential degradation products);</p> <p>Teil 10: Prüfungen auf Irritation und Hautsensibilisierung (Part 10: Tests for irritation and skin sensitization);</p> <p>Teil 11: Prüfungen auf systemische Toxizität (Part 11: Tests for systemic toxicity);</p> <p>Teil 12: Probenvorbereitung und Referenzmaterialien (Part 12: Sample preparation and reference materials);</p> <p>Teil 13: Qualitativer und quantitativer Nachweis von Abbauprodukten in Medizinprodukten aus Polymeren (Part 13: Identification and quantification of degradation products from polymeric medical devices);</p> <p>Teil 14: Qualitativer und quantitativer Nachweis von keramischen Abbauprodukten (Part 14: Identification a.quantification of degradation products from ceramics);</p> <p>Teil 15: Qualitativer und quantitativer Nachweis von Abbauprodukten aus Metallen und Legierungen (Part 15: Identification a.quantification of degradation products from metals a. alloys);</p> <p>Teil 16: Entwurf und Auslegung toxikokinetischer Untersuchungen hinsichtlich Abbauprodukten</p>	

Standard harm. under	Standard	Title	Sections of the Annex
		<p>und herauslösbaren Bestandteilen (Part 16: Toxicokinetic study design for degradation products and leachables);</p> <p>Teil 17: Nachweis zulässiger Grenzwerte für herauslösbare Bestandteile (Part 17: Establishment of allowable limits for leachable substances);</p> <p>Teil 18: Chemische Charakterisierung von Werkstoffen (Part 18: Chemical characterization of materials);</p>	
93/42/EEC	DIN EN ISO 11135-1	<p>Sterilisation von Produkten für die Gesundheitsfürsorge – Ethylenoxid – (Sterilization of health care products - Ethylene oxide) Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices)</p> <p><i>(planned to be replaced by DIN EN ISO 11135)</i></p>	1.3, 1.4, 2.2.5
	DIN ISO/TS 11135-2	<p>Sterilisation von Produkten für die Gesundheitsfürsorge – Ethylenoxid – (Sterilization of health care products - Ethylene oxide) Teil 2: Leitfaden zur Anwendung von ISO 11135-1 (Part 2: Guidance on the application of ISO 11135-1)</p> <p>(Attention: Technical specification)</p> <p><i>(planned to be replaced by DIN EN ISO 11135)</i></p>	1.3, 1.4, 2.2.5
93/42/EEC (other than Part 3) 90/385/EEC (other than Part 3)	DIN EN ISO 11137	<p>Sterilisation von Produkten für die Gesundheitsfürsorge – Ethylenoxid – (Sterilization of health care products - Radiation) Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices);</p>	1.3, 2.2.5

Standard harm. under	Standard	Title	Sections of the Annex
		<p>Teil 2: Festsetzung der Sterilisationsdosis (Part 2: Establishing the sterilization dose);</p> <p>Teil 3: Anleitung zu dosimetrischen Aspekten (Part 3: Guidance on dosimetric aspects)</p>	
<p>93/42/EEC (only Part 2 and Part 3)</p> <p>90/385/EEC (only Part 2 and Part 3)</p>	<p>DIN EN ISO 11138</p>	<p>Sterilisation von Produkten für die Gesundheitsfürsorge – Biologische Indikatoren (Sterilization of health care products - Biological indicators)</p> <p>Teil 1: Allgemeine Anforderungen (Part 1: General requirements);</p> <p>Teil 2: Biologische Indikatoren für Sterilisationsverfahren mit Ethylenoxid (Part 2: Biological indicators for ethylene oxide sterilization processes);</p> <p>Teil 3: Biologische Indikatoren für Sterilisationsverfahren mit feuchter Hitze (Part 3: Biological indicators for moist heat sterilization processes);</p> <p>Teil 4: Biologische Indikatoren für Sterilisationsverfahren mit Heißluft (Part 4: Biological indicators for dry heat sterilization processes);</p> <p>Teil 5: Biologische Indikatoren für Sterilisationsverfahren mit Niedertemperatur-Dampf-Formaldehyd (Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes)</p> <p><i>(see also DIN EN ISO 18472)</i></p>	<p>1.3, 1.4, 2.2.5</p>
<p>93/42/EEC (only Part 1 and Part 3)</p> <p>90/385/EEC (only Part 1)</p>	<p>DIN EN ISO 11140</p>	<p>Sterilisation von Produkten für die Gesundheitsfürsorge – Chemische Indikatoren (Sterilization of health care products - Chemical indicators)</p> <p>Teil 1: Allgemeine Anforderungen (Part 1: General requirements);</p>	<p>1.3, 1.4, 2.2.5, 2.2.6</p>

Standard harm. under	Standard	Title	Sections of the Annex
		<p>Teil 3: Indikatorsysteme der Klasse 2 zur Verwendung im Bowie-Dick-Dampfdurchdringungstest (Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test);</p> <p>Teil 4: Indikatoren der Klasse 2, die alternativ zum Bowie- Dick-Test für den Nachweis der Dampfdurchdringung verwendet werden (Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration)</p> <p><i>(see also DIN EN 867-5 and DIN EN ISO 18472)</i></p>	
93/42/EEC 90/385/EEC	DIN EN ISO 11737-1	<p>Sterilisation von Medizinprodukten – Mikrobiologische Verfahren – (Sterilization of medical devices – Microbiological methods)</p> <p>Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (Part 1: Determination of a population of microorganisms on products)</p>	1.2
93/42/EEC 90/385/EEC 98/79/EC	DIN EN ISO 11737-2	<p>Sterilisation von Medizinprodukten – Mikrobiologische Verfahren – (Sterilization of medical devices – Microbiological methods)</p> <p>Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens (Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process)</p>	1.2
93/42/EEC 90/385/EEC 98/79/EC	DIN EN ISO 13485	<p>Medizinprodukte – Qualitätsmanagementsysteme – Anforderungen für regulatorische Zwecke (<i>Zertifizierung</i>)(Medical devices - Quality management systems - Requirements for regulatory purposes)</p>	1.3 1.2 1
	DIN EN ISO 14161	<p>Sterilisation von Produkten für die Gesundheitsfürsorge – Biologische Indikatoren – Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen</p>	1.3, 1.4, 2.2.5

Standard harm. under	Standard	Title	Sections of the Annex
		(Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results)	
93/42/EEC 90/385/EEC 98/79/EC	DIN EN ISO 14937	Sterilisation von Produkten für die Gesundheitsfürsorge – Allgemeine Anforderungen an die Charakterisierung eines sterilisierenden Agens und an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices) <i>(also applies to previously non-standardised methods)</i>	1.3, 1.4, 2.2 5
	DIN EN ISO 15882	Sterilisation von Produkten für die Gesundheitsfürsorge – Chemische Indikatoren – Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen (Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results)	1.3, 1.4, 2.2 5
93/42/EEC (Part 1 and Part 2) 90/385/EEC (only Part 1)	DIN EN ISO 11607	Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte (Packaging for terminally sterilized medical devices) Teil 1: Anforderungen an Materialien, Sterilbarriersysteme und Verpackungssysteme (Part 1: Requirements for materials, sterile barrier systems and packaging systems); Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (Part 2: Validation requirements for forming, sealing and assembly processes) <i>(see also DIN ISO/TS 16775)</i>	1.3, 1.4, 2.2.4
93/42/EEC	DIN EN ISO	Sterilisation von Medizinprodukten – Vom	1.2, 2, 2.2 6

Standard harm. under	Standard	Title	Sections of the Annex
	17664	Hersteller bereitzustellende Informationen für die Aufbereitung von resterilisierbaren Medizinprodukten (Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices)	
93/42/EEC 90/385/EEC	DIN EN ISO 17665-1	Sterilisation von Produkten für die Gesundheitsfürsorge – Feuchte Hitze (Sterilization of health care products – Moist heat) Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices)	1.3, 1.4, 2.2.5
	DIN ISO/TS 17665-2	Sterilisation von Produkten für die Gesundheitsfürsorge – Feuchte Hitze (Sterilization of health care products – Moist heat) Teil 2: Leitfaden für die Anwendung von ISO 17665-1 (Part 2: Guidance on the application of ISO 17665-1) (Attention: Technical specification)	1.3, 1.4, 2.2 5
	DIN EN ISO 18472	Sterilisation von Produkten für die Gesundheitsfürsorge – Biologische und chemische Indikatoren – Prüfausrüstung (Sterilization of health care products - Biological and chemical indicators - Test equipment)	1.3, 1.4, 2.2.5
	DIN 58921	Prüfverfahren zum Nachweis der Eignung eines Medizinproduktsimulators bei der Dampf-Sterilisation – Medizinproduktsimulatorprüfung (Test method to demonstrate the suitability of a medical device simulator during steam sterilisation – Medical device simulator testing)	1.3, 1.4, 2.2.5
	DIN SPEC 58929	Betrieb von Dampf-Klein-Sterilisatoren im Gesundheitswesen – Leitfaden zur Validierung und Routineüberwachung der	1.3 1.4 2.2.5

Standard harm. under	Standard	Title	Sections of the Annex
		Sterilisationsprozesse (Operation of small steam sterilizers in the health-care system - Guidance for validation and routine control of sterilization processes)	
	DIN 58946-7	Sterilisation – Dampf-Sterilisatoren Sterilization – (Steam sterilizers) Teil 7: Bauliche Anforderungen und Anforderungen an Betriebsmittel (Part 7: Requirements on installation and services)	2.2.5
	DIN 58948-7	Sterilisation – Niedertemperatur-Sterilisatoren – (Sterilization - Low temperature sterilizers) Teil 7: Bauliche Anforderungen und Anforderungen an die Betriebsmittel sowie den Betrieb von Ethylenoxid-Sterilisatoren (Part 7: Requirements for the installation and operation of ethylene oxide sterilizers and their supply sources)	1.3, 1.4, 2.2 5
	DIN 58948-17	Sterilisation – Niedertemperatur-Sterilisatoren (Sterilization – Low temperature sterilizers) Teil 17: Bauliche Anforderungen und Anforderungen an die Betriebsmittel sowie den Betrieb von Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren (Part 17: Requirements for the installation and operation of low temperature steam formaldehyde and formaldehyde sterilizers and their supply sources)	1.3, 1.4, 2.2 5
	DIN 58949	Desinfektion – Dampf-Desinfektionsapparate (Disinfection - Steam disinfection apparatus) Teil 1: Begriffe (Part 1: Terminology); Teil 2: Anforderungen (Part 2: Requirements); Teil 3: Prüfung auf Wirksamkeit (Part 3: Efficiency testing); Teil 4: Biologische Indikatoren zur Prüfung auf Wirksamkeit (Part 4: Biological indicators for efficacy tests); Teil 6: Betrieb von Dampf-Desinfektionsapparaten	1.3, 1.4, 2.2 2

Standard harm. under	Standard	Title	Sections of the Annex
		(Operating of steam disinfection apparatus); Teil 7: Bauliche Anforderungen und Anforderungen an die Betriebsmittelversorgung (Part 7: Structural requirements and requirements on service supply)	
	DIN 58952	Sterilisation – Transportkörbe für Sterilbarrieresysteme (Sterilization - Transport baskets for sterile barrier systems) Teil 2: Sterilisierkörbe aus Metall (Part 2: Sterilizing baskets made of metal); Teil 3: Sterilisiersiebschalen für Sterilisiergut aus Metall (Part 3: Instrument trays for sterilizing goods made of metal)	1.3, 1.4, 2.2.4, 2.2.5
	DIN 58953	Sterilisation – Sterilgutversorgung (Sterilization - Sterile supply)(<i>Begriffe, Logistik von sterilen Medizinprodukten, Anwendungstechniken</i>)(<i>Terminology, logistics of sterile medical devices, methods of use</i>) Teil 1: Begriffe (Part 1: Terminology); Teil 6: Prüfung der Keimdichtigkeit von Verpackungsmaterialien für zu sterilisierende Medizinprodukte (Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized); Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und -schläuchen (Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels) Teil 8: Logistik von sterilen Medizinprodukten (Part 8: Logistics of sterile medical devices); Teil 9: Anwendungstechnik von	2.2 4 3

Standard harm. under	Standard	Title	Sections of the Annex
		Sterilisierbehältern (Part 9: Use of sterilization containers)	
93/42/EEC	DIN EN 13795	Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte, für Patienten, Klinikpersonal und Geräte – Allgemeine Anforderungen für Hersteller, Wiederaufbereiter und Produkte, Prüfverfahren und Gebrauchsanforderungen (Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels)	
	DIN EN 15986	Symbol zur Kennzeichnung von Medizinprodukten – Anforderungen zur Kennzeichnung von phthalathaltigen Medizinprodukten (Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates)	2.2.6

Annex B - Standardisation projects

Standard harm. under Dir.	Standardisati on projects	Title	Sections of the Annex
	E DIN 58946-7	Sterilisation – Dampf-Sterilisatoren Sterilization – (Steam sterilizers) Teil 7: Bauliche Voraussetzungen sowie Anforderungen an die Betriebsmittel und den Betrieb von Dampf-Sterilisatoren im Gesundheitswesen (Part 7: Edifical preconditions, requirements for the services and the operation of steam sterilizers)	2.2.5

		used in health care facilities) (Scheduled to replace DIN 58946-7:2004)	
93/42/EEC 90/385/EEC 98/79/EC	E DIN EN ISO 15223-1	Medizinprodukte – Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen (Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied) Teil 1: Allgemeine Anforderungen (Part 1: General requirements) (Scheduled to replace DIN EN 980)	2.2.5
	E DIN EN 15224	Dienstleistungen in der Gesundheitsversorgung – Qualitätsmanagementsysteme – Anforderungen nach EN ISO 9001:2008; Deutsche Fassung FprEN 15224:2012 (Health care services - Quality management systems - Requirements based on EN ISO 9001:2008; German version EN 15224:2012) (Scheduled to replace DIN CEN/TS 15224:2006)	1.3, 1.4, 2.2 2
93/42/EEC 90/385/EEC 98/79/EC	E DIN EN ISO 11135	Sterilisation von Produkten für die Gesundheitsfürsorge – Ethylenoxid – Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices) (Scheduled to replace DIN EN ISO 11135-1 and DIN ISO/TS 11135-2)	1.3, 1.4, 2.2 5
	DIN ISO/TS 16775	Verpackungen für in der Endverpackung sterilisierte Medizinprodukte – Leitfaden für die Anwendung von ISO 11607-1 und ISO 11607- 2 (Packaging for terminally sterilized medical devices – Guidance for the Application of ISO 11607-1 und ISO 11607-2)	1.3 1.4, 2.2.4

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Links:

- FDA. Guidance on enforcement priorities for single-use devices reprocessed by third parties and hospitals.

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107164.htm>) (<http://www.fda.gov/MedicalDevices/default.htm>)

- Device Bulletins and Hazard and Safety Notices der Medicines and Healthcare products Regulatory Agency (MHRA); Executive Agency of the Department of Health, UK.

(<http://www.mhra.gov.uk>)

Annex 1 On the term "suitable validated procedures"

Annex applicable in conjunction with the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices"

Suitable validated procedures as defined in section 4 (2) of the Ordinance on Operators of Medical Devices (*Medizingerätebetriebersverordnung - MPBetreibV*) are procedures that reproducibly produce a defined outcome (especially cleanliness, low germ counts/sterility and functionality) with evidence-based consistency. When reprocessing medical devices, the sum of all of the automated and manual processes involved (complementary, individual reprocessing steps) is instrumental in achieving the defined reprocessing goal.

Consequently, poorly validated individual steps (processes) affect the quality of the reprocessing result in a similarly adverse manner as the failure to observe SOPs.

To ensure process quality and a long-term consistent procedure, the following minimum requirements must be met.

- **Pre-treatment:** Prepare SOP
- **Collection:** Prepare SOP
- **Pre-cleaning:** Prepare SOP
- **Dismantling:** Prepare SOP
- **Cleaning, if necessary pre-rinsing, disinfection:**

In case of manual W/D: Prepare SOP and provide appropriate evidence of their effectiveness

In case of automated W/D: Prepare SOP and carry out process validation (see Annex 3):

Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist)

- **Rinsing, drying:** If manual, prepare SOP. If automated, integrated into the overall process and validated
- **Cleanliness/integrity testing:** Prepare SOP
- **Maintenance/repair:** Prepare SOP
- **Functional testing:** start by preparing SOP, in special cases, process validation is necessary (see Annex 2: re section 2.2.3 Technical-functional safety testing)
- **Packaging** Prepare SOP
- **Sterilisation:** Perform process validation (refer, e.g. to Annex 4: Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (checklist))
- **Labelling** Prepare SOP
- **Documented release:** Prepare SOP
- Prepare SOP governing **Interface arrangements** (e.g. requirements for cleaning and disinfection, handover, transport, storage)
- Prepare SOP for **dealing with deviations/errors**

Annex 2 to section 2.2.3 Technical-functional safety testing

Annex applicable in conjunction with the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices"

The manufacturer has furnished proof that a medical device basically lends itself to reprocessing and reuse in his product-related risk management as stipulated in standard DIN EN ISO 14971 "*Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte*" (Medical devices - Application of risk management to medical devices)" He shall include relevant details on the implementation of reprocessing into the instructions for use (cf standard DIN EN ISO 17664 "*Sterilisation von Medizinprodukten - Vom Hersteller bereitzustellende Informationen für die Aufbereitung von resterilisierbaren Medizinprodukten*" - "Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilisable devices") According to the note in section 1 "*Anwendungsbereich*" (Scope of application) of the standard , the principles of the latter may also be applied to medical devices that will be used after final disinfection (rinsing and drying).

The following shall apply in cases where **medical devices are reprocessed contrary to the manufacturer's specifications**. This can refer to deviations from the established processing regulation and is mandatory for medical devices that are subjected to reprocessing contrary to the manufacturer's specifications. To ensure the medical devices' perfect technical and functional safety, relevant testing parameters shall be included into validation. The term technical and functional safety implies **ensuring that the material properties and functionality** of a reprocessed medical device are not compromised so that it can be used with the necessary level of safety for patients, users and third persons.

The decision to reprocess a concrete medical device shall be based on risk management as specified in standard DIN EN ISO 14971. The requirements set out in standard DIN EN ISO 17664 shall be taken into consideration. Risks shall be identified and analysed in the same way that any risks that might be involved in the development and production of a medical device would be considered and controlled. The following major aspects shall be considered

- aspects relating to the medical device (such as material, construction),
- aspects relating to its use (where is the medical device being used, duration of use, strain during use) and

- cumulative impact of reprocessing.

The steps involved in risk management are, *inter alia*, assessment of the identified risks, risk control, acceptance of the overall residual risk.

The medical device-related aspects under consideration that include both the testing of material properties and of function, require relevant product information that can usually be obtained from the manufacturer of the medical device in question. Moreover, relevant, product-related standards must be included in each case.

The parameters of interest in terms of **material properties** that must be considered, if necessary, for risk control purposes in the context of reprocessing validation, can be, for instance:

- surface characteristics
- corrosion resistance
- embrittlement
- breaking, tensile strength
- stability of bonding/contact points
- joint lubrication
- material fatigue
- residues/absorption of process chemicals (such as cleaning, disinfecting and sterilising agents)
- integrity of housings, casings and components.

Considering the broad spectrum of medical devices, differentiated instructions for **functional testing** cannot be provided in full. As a rule, the function(s) ascribed to the device by its manufacturer should be included as test parameters into testing for validation and implementation of reprocessing. As stated above, product-relevant standards should be observed, here, too.

Moreover, the maximum number of reprocessing cycles and the useful life of the reprocessed products should be stipulated and justified based on stability testing.

The reasons for the decision that, based on the performed validation, product-specific reprocessing results in a product that not only reliably meets technical and functional requirements but also satisfies the requirements set out in section 4 subsection (1) of the Medical Devices Act (MPG) should be documented (risk analysis). The instructions

according to Directive 93/42/EEC, Annex I, 13.6h) that the manufacturer must provide with respect to any known product risks in case of reuse should be considered and addressed separately.

Annex 3 Commissioning and operation of washers-disinfectors (WD) for the reprocessing of medical devices (check list)

Applicable Annex to the Recommendation from the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

Documentation of the WD's suitability

Characteristic	Documentation by	Documentation in
Type approval test (DIN EN ISO 15883), in-plant testing	Manufacturer (CE marking)	Instruction manual
Suitability for reprocessing of the concrete medical devices of category semi-critical A/B or critical A/B		
Required accessory equipment e.g. for medical devices of category semi-critical or critical (e.g. special connectors/nozzles, mobile units,...)		

Suitability of the installation site and operating materials documented by the operator

Characteristic	Documentation by	Documentation in
Installation room and installation type (e.g. front loading, front and rear-opening devices)	Operator in co-operation with service provider/service technician, validator, as appropriate	e.g. room data sheet, technical documents
ambient conditions (aim: discharge of thermal and chemical loads; e.g. fume extraction, ventilation)		
electric supply		
water supply, waste water (aim: adequate water supply, smooth drainage)		
water quality (e.g. drinking water, deionized water)		
matching the process chemicals used to the processing method in the WD: Process temperatures ph-value, water hardness material compatibility	operator, following the instructions of the process chemicals' manufacturer	product fact sheets safety data sheets SOP/ working instructions
acceptance inspection: installation qualification (IQ)	operator in co-operation with	validation report with

Characteristic	Documentation by	Documentation in
<ul style="list-style-type: none"> • checking order scope against scope of delivery • proper installation • checking of connections, supply lines and media quality, compliance with installation plan instructions • empty chamber profile • test run with test load • check of engineered safety devices • handover of operating and maintenance instructions • instruction in operating the device and guidance on malfunctions • installation and handover record <p>Operational Qualification (OQ)</p> <ul style="list-style-type: none"> • operating conditions and operating materials during the test • positioning of sensors • disinfection conditions (suitability of the load carrier and load, temperature control function) • doors and locking mechanism • dosage of chemicals • water quality • check for freely draining pipework • check calibration of measuring instruments • correctness of the process cycle • reproducibility • fault indication 	<p>manufacturer (checklists included in the guidelines of by the DGKH-DGSV-AKI, such as List 4/Installation Qualification, lists 5 and 6/Operational Qualification</p>	<p>product data sheets, recorder printouts, photo documentation</p>

Documentation of both the WD's performance and the instruction of the operation staff in the proper **operation of the WD**

Characteristic	Documentation by	Documentation in
operating instructions	manufacturer	operating instructions
Overview and risk classification of the MD to be reprocessed acc. to No. 1.2.1 of the Recommendations of the RKI and the BfArM	operator	operator document

Characteristic	Documentation by	Documentation in
description of the medical devices/configurations being used: description of <u>all</u> use-relevant loading configurations and identifying the MD that are the most difficult to clean and disinfect (stating the reasons why)	operator considering the manufacturer's instructions validator, as appropriate	operator document with photos
stating the maximum interval between the end of use and start of the cleaning process	operator	operator document

<p>suitability of operation parameters</p> <p>Performance Qualification (PQ)</p> <ul style="list-style-type: none"> List of loading patterns matched to tested WD programmes operating conditions and operating materials during test function of the spraying system as appropriate, logging of flushing pressure positioning of sensors effectiveness of cleaning¹ (test and real loading incl. chamber walls and load carriers) description of disinfection conditions disinfection effectiveness [□] (incl. chamber walls, load carriers, boiler, tanks) drying effectiveness[□] process residues dosage of chemicals 	operator considering manufacturer's instructions in co-operation with qualified validator	validation report with product data sheets, recorder printouts, photo documentation as appropriate evidence of equivalence
<p>specifications for in-process controls:</p> <ul style="list-style-type: none"> if appropriate, selection of a suitable process challenge device: surface, fissure, lumen PCD frequency of PCD use (in case of stable process flow, in case of complaints, in case of operational malfunction) processes to validate the cleaning result, residual protein determination (specify sufficiently sensitive methodology) 	operator referring to the validation report	operator document

¹ alternatively:

Evidence of efficiency for specific loads / configurations and device types furnished by a recognised test laboratory with evidence of equivalence of the concrete loads and specification of suitable PCD

regular instruction of operating staff	operator	training document (training content, participants, trainer)
servicing: maintenance, if necessary repair and repeat performance qualification for specific reasons	manufacturer or service provider, operator	instruction manual (chapter on maintenance and repair documentation)

Tests to be performed every working day

Characteristic	Documentation by	Documentation in
visual check (e.g. chamber, flushing arms, connectors, sealings, mesh trays)	operator in line with manufacturer's instructions	test record and check list
functional testing of movable parts		
filling level chemicals container, daily use rates		
if necessary additional tests, based on the validation results		

batch-related testing

Characteristic	documentation through	Documentation in
load consistent with configuration as validated	operator	batch record and release record
suitability of the programme applied		
documentation of the relevant process parameters. <ul style="list-style-type: none"> • dosage of chemicals • process cycle (time) • Process temperatures • where appropriate flushing pressure (flushing ensured) 		
visual check of the load items:		

Characteristic	documentation through	Documentation in
<ul style="list-style-type: none"> cleanliness (if appropriate referring to a cleaning indicator, e.g. for critical B medical devices) integrity dryness, residual moisture 		

clearance

Characteristic	Documentation by	Documentation in
authorisation list: <ul style="list-style-type: none"> authorisation basis list of authorised persons 	operator	evidence of qualification, name list
release criteria (see also tests above)	operator	release record
approach and , if appropriate, reasons for release in case of deviations from the regular process flow	operator	release record

periodical testing and approach in case of deviations from the regular process flow and relevant framework conditions

Characteristic	Documentation by	Documentation in
determining the due dates of periodic tests (repeat performance assessment, see performance qualification) , if appropriate coordinated with maintenance when determining testing intervals, process stability history shall be taken into consideration	operator and validator considering manufacturer's instructions, if appropriate calling in the hygienist	validation report
scope of testing		

Annex 4 Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (check list)

Applicable Annex to the Recommendation from the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

Documentation of **steriliser suitability**

Characteristic	documentation through	Documentation in
type test (DIN EN 13060), factory test	manufacturer (CE marking)	instruction manual
process type specification: Type B: for packaged and unpackaged massive products, hollow-ware Type A and porous products Type N: for unpackaged massive products Type S: for products according to manufacturer's instructions		

Documentation of **suitability of the installation site and operating materials** kept by the operator
The suitability of the installation site and operating materials shall be documented by the operator

Characteristic	documentation through	documentation in
installation room (room function, e.g. sterilisation room, processing room) , installation type (table-top device, fitted device) and ambient conditions (climate, wall clearance - to avoid overheating-)	operator in co-operation with service provider /service technician, if appropriate validator	e.g. room book, technical documents
electric supply		
water supply (water connection, tank without direct connection) and waste water management (sewage, waste steam/vapours)		
feed water quality DIN EN 13060, Annex C		
acceptance inspection: <ul style="list-style-type: none"> • Installation Qualification (IQ): <ul style="list-style-type: none"> ○ scope of the order checked against 	operator in co-operation with manufacturer	directions for use and maintenance

Characteristic	documentation through	documentation in
<p style="text-align: center;">scope of delivery</p> <ul style="list-style-type: none"> ○ proper installation ○ vacuum test, empty chamber test ○ test run with test load ○ check of engineered safety devices ○ handover of operating and maintenance instructions ○ instruction in operating the device and guidance on malfunctions ○ installation and handover record <ul style="list-style-type: none"> ● Operational Qualification (OQ) <ul style="list-style-type: none"> ○ process evaluation system (DIN EN 13060, Annex B) ○ process flow test with defined load (most difficult to sterilise medical devices and packages) ○ test of air removal and steam penetration by means of suitable PCD (hollow device) ○ test of the error detection system as specified by the manufacturer ○ documentation of the results in a qualification report ○ data and test results provided by the manufacturer must be taken into consideration 		<p>installation and handover certificate, validation report with recorder printouts and photo documentation</p>
<p>sterile goods packaging:</p> <ul style="list-style-type: none"> ● packaging in line with DIN EN 868-2 and following parts as well as DIN EN ISO 11607-1 ● heat sealers: <ul style="list-style-type: none"> ○ critical process parameters are temperature and contact pressure ○ sealing seam width must be at least 6 mm ○ minimum distance between sealing seam and MD must be 3 cm ○ operating instructions / directions for 	<p>operator in co-operation with manufacturer</p>	<p>operator document operating instructions / directions for use, instruction manual</p>

Characteristic	documentation through	documentation in
<p>use must be available</p> <ul style="list-style-type: none"> ○ suitability of the method as stated by the manufacturer of the heat sealer or sterile barrier system ○ routine checks comprise <ul style="list-style-type: none"> ➤ ink test or seal check ➤ sealing seam strength / peel strength ➤ critical parameters 		

documentation of steriliser performance and instruction of operating staff in the proper operation of the steriliser

Characteristic	documentation through	Documentation in
operating instructions (see installation and handover record)	manufacturer	operating instructions
risk classification of the MD to be sterilised in line with RKI-BfArM recommendation (if appropriate, pooled into product groups)	operator	operator document
description of the medical devices/configurations being used: description of <u>all</u> loading configurations incl. the "most challenging" load(s) (stating appropriate reasons) □	operator considering the manufacturer's instructions	operator document with photos as appropriate evidence of equivalence
suitability of operation parameters Performance Qualification (PQ)⁴ <ul style="list-style-type: none"> • determination and documentation of test loads incl. proof of equivalence 	operator in co-operation with qualified validator	validation report with product data sheets,

¹ Alternatively: Evidence of effectiveness for specific loads / configurations and device types furnished by a certified test laboratory with evidence of equivalence of the concrete loads and specification of suitable PCD

Characteristic	documentation through	Documentation in
<ul style="list-style-type: none"> • evidence of test load sterilisation as stipulated in DIN EN ISO 17665-1 and DIN SPEC 58929 <ul style="list-style-type: none"> ◦ if appropriate, testing of partial cycles, if parametric testing is not sufficient • measurement of pressure and temperature profile at the critical points within the load through an independent calibrated measurement system (e.g. logger) • microbiological testing in places that do not allow physical measurement 		recorder printouts, photo documentation
<p>specifications for in-process controls:</p> <ul style="list-style-type: none"> • evidence of effective sterilisation parameters by means of batch record and/or process evaluation system (DIN EN 13060, Annex B) • selection of PCD in case of hollow device sterilisation (see also (DIN EN 13060, Annex A) • for the selection of chemical indicators see below "specific guidance on the use of chemical indicators" 	operator referring to the validation report	operator document
regular instruction of operating staff	operator	training document (training content, participants, trainer)
servicing: maintenance, if necessary repair and repeat performance qualification for specific reasons	manufacturer or service provider, operator	instruction manual (chapter on maintenance and repair documentation)

Tests to be performed each working day

Characteristic	documentation through	Documentation in
visual checks of <ul style="list-style-type: none"> • chamber and sealings • feed water container, feed water • cooling water, if appropriate 	operator in line with manufacturer's instructions	test record and check list
functional testing <ul style="list-style-type: none"> • vacuum test, if appropriate • steam penetration test with suitable PCD, if appropriate • logger (e.g. printer) 		

batch-related testing

Characteristic	documentation through	Documentation in
load consistent with configuration as validated	operator	batch record and release record
Checking for complete and proper process cycle <ul style="list-style-type: none"> • checking and documentation of the treatment indicator result (cl. 1) • checking and documentation of process parameters (readings of process parameters, if appropriate process evaluation system) • checking and documentation of the process indicator result <ul style="list-style-type: none"> ○ critical A: without PCD (cl. 5) ○ critical B: with PCD, e.g. helix test (cl.2) 		
visual check of the packaging: <ul style="list-style-type: none"> • dryness • integrity • sealing seam integrity • complete labelling 		

release

Characteristic	documentation through	Documentation in
authorisation list: <ul style="list-style-type: none">• authorisation basis• list of authorised persons	operator	evidence of qualifications, name list
release criteria	operator	release record
approach and , if appropriate, reasons for release in case of deviations from the regular process flow	operator	release record

periodical testing and procedure in case of deviations from the regular process flow and relevant framework conditions

Characteristic	documentation through	Documentation in
determining the due dates of periodic tests (repeat performance assessment, see performance qualification) , if appropriate coordinated with maintenance	operator and validator considering manufacturer's	validation report
scope of testing	instructions, if appropriate calling in the hygienist	

Appendix to Annex 4

Guidance on the use of biological and chemical indicators

Sterile medical devices (MD) cannot be visually distinguished from non-sterile devices. Neither physical measurements, nor biological or chemical indicators can, on their own, prove that the devices subjected to the sterilisation process have been successfully sterilised or are sterile.

Therefore, sterilisation procedures must be validated (see 1.3; Annex 1). However, successful validation alone does not ensure that sterilisation requirements are actually met during routine operation, too. In addition to changes in loading patterns, packaging or the goods used, other factors that the operator may not notice or not identify as problematic due to ignorance, may also affect the process. Therefore, suitable routine monitoring must be carried out (see DIN EN ISO 14937 chapter 10), to ensure that the validated procedure will be applied consistently. In doing so, the manufacturer's instructions for use (e.g. fitness for purpose, positioning and interpretation) of the systems selected must be observed to avoid misleading results. The results

of biological and chemical indicators must be documented without delay. Indicators need not be retained.

For steam sterilisation procedures, too, sterilisation conditions can change during routine operation (see DIN EN ISO 17665-1 chapters 10 and 11). Temperature and pressure patterns over time can be monitored and documented with relative ease through the measuring instruments that are installed in the steriliser. In the context of release, achievement of the physical parameters **established** and documented during validation must be confirmed, among other things.

Biological and/or chemical indicators complement physical measurements.

Specific guidance on the use of biological indicators

The requirement for sterilisers to be checked by means of bioindicators every half year or after 400 batches derives from an older chapter, "Inspection", of the meanwhile completely withdrawn DIN 58946-6 on the operation of large-scale steam sterilisers. The applicable successor standard DIN EN ISO 17665-1 (related guidance DIN EN ISO 17665-2), that incorporates a broader scope of application, including small scale sterilisers, no longer contains this specific requirement. For performance assessment, this standard says that also microbiological methods, whereby the biological indicators must be affixed to the medical device or the medical device is directly inoculated with the biological indicators, are eligible for complementing physical measurements. The informative annexes C and D to this standard stress that, for microbiological testing, the points in the medical device be selected that are hardest to reach by the sterilant under the required conditions. Like standard DIN EN 285 for large-scale steam sterilisers, DIN EN 13060 for small steam sterilisers does not address requirements for validation and routine monitoring.

Biological indicators are not suited for assessing the retention time that must be ensured because, in most sterilisation cycles, it exceeds the time it takes to inactivate the bioindicators. This requires physical measurements. Both the heating phase it takes to reach the retention time and the subsequent cooling phase at temperatures higher than 100°C contribute to inactivation. With steam sterilisation for instance, bioindicators are inactivated after a few seconds at 134°C and, as a result, do not allow any conclusions to be drawn regarding the requisite retention time of 3 to 18 minutes (required for prions).

Consequently, while the complementary use of biological indicators can make sense, they are no substitute for validation.

For the selection, use and interpretation of results of biological indicators pursuant to the standard series DIN EN ISO 11138, guidance DIN EN ISO 14161 is available.

Specific guidance on the use of chemical indicators

Chemical indicators are mainly used to

1. distinguish between sterilised and non-sterilised products (process indicator)

and

2. for the steam penetration test
as well as internal indicators.

Chemical indicators show a visible change (e.g. colour change) when exposed to defined values of the critical variables during the sterilisation process (product information). Poorly changing chemical indicators can flag up risks in connection with the use of a sterilisation process (e.g. absence of the sterilant): for instance, chemical indicators can reliably distinguish between saturated steam and air of the same temperature. This is because accumulations of non-condensable gases (NCG, such as air) prevent steam sterilisation.

Part 1 of DIN EN ISO 11140 distinguishes between several classes of chemical indicators with different tasks. However, this classification is no hierarchical rating (no "better" or "worse"). Class 1 process indicators must be used to distinguish goods that are not yet sterilised from treated ones. Properly responding process indicators show that the packaging was exposed to conditions that are only present in a steriliser.

Indicators used in packages or mesh trays can flag the position of vulnerable points and/or confirm that the stipulated values of the critical variables (product information) were reached at these points.

Class 2 indicator systems are needed for special tests that are required in standards governing sterilisers, they are made up of a process challenge device (PCD) and the indicator. According to DIN EN ISO 17665-1, 12.1.6, a steam penetration test (e.g. Bowie-Dick-Test) must be conducted each day before using the steriliser, when air is being removed from the sterilising chamber to allow quick and even penetration of the steam into the steriliser load.

Chemical indicators for testing steam penetration are standardised in parts 3 and 4 of DIN EN ISO 11140. Chemical indicator systems for testing air removal and steam penetration in small steam sterilisers are standardised in part 5 of DIN EN 867.

Process challenge devices have been developed to each simulate a specific challenge to steam penetration in a sterilisation process. The challenge level is matched to the type of sterilisation process. There is no one universal PCD that is suitable for all process types and purposes. DIN EN 285 and DIN EN 13060 each define several different process challenge devices. These process challenge devices do not represent specific products.

The challenge level of class 2 indicators results from the combination of the chemical indicator and the PCD components. Each variation, e.g. the use of another indicator, can lead to malfunctions going undetected. Therefore, components may only be combined as intended by the manufacturer. This also applies to systems with reusable process challenge devices.

A medical device simulator (MDS) only shows that air removal and steam penetration are sufficient for the specific medical device. A medical device simulator (MDS) is not intended to test the sterilisation process and does not provide any sound evidence that the product simulated by the MDS has actually been sterilised. A MDS can usually be used instead of the

specific medical device for the **intended/defined** purpose in the performance assessment.

Evidence of suitability of a MDS is described in DIN 58921 .

In steam sterilisation, for instance, non-condensable gases in the steam and transient leaks can occur unexpectedly. Such malfunctions are only detected through periodic testing (e.g. "Bowie-Dick Test), if they happen to occur while the test is ongoing.

An error warning system that is used in every sterilisation cycle ("batch control") can consist of a process challenge device and a physical or chemical detector. General recommendations for the use of error warning systems can not now be issued since there are no generally accepted methods for verifying their performance/efficiency (relevant standard project/work item proposal is under preparation).

For the selection, use and interpretation of results of chemical indicators, guidance DIN EN ISO 15882 is available.

Annex 5 Overview of requirements for reprocessing units for medical devices

Annex applicable in conjunction with the Recommendation from the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

reprocessing unit category	A	B	C
classification of MD to be reprocessed up to	semi-critical A, critical A	semi-critical B, critical B	critical C
examples of use of reprocessed MD	dressing changes, dental/medical examination and treatment ⁽¹⁾	invasive procedures/surgery, endoscopy	invasive procedures/surgery using MDs of group critical C or their reprocessing for other establishments
examples of establishments concerned	doctors' surgeries ⁽²⁾ , dental surgeries ⁽¹⁾	ambulatory surgery centres, dental surgeries, endoscopy, hospitals	selected hospitals, reprocessing units for other establishments ⁽⁴⁾
structural and functional requirements	designated area ⁽⁵⁾ segregated dirty/clean/storage zones (temporal separation possible)	designated reprocessing rooms ^{(3),(5)} segregated dirty/clean/storage areas	- separate dirty/clean/storage rooms ⁽³⁾ - - specific requirements depending on the technical effort required
examples of technical equipment	depending on reprocessing profile (for the use of washer-disinfectors and small steam sterilisers see annexes 3 and 4) ultrasonic cleaner, if appropriate	depending on reprocessing profile washer-disinfectors endoscope washer-disinfectors ultrasonic cleaner sealer appropriate testing instruments appropriate steriliser water treatment facility, if appropriate	depending on reprocessing profile (endoscope) washer-disinfectors ultrasonic cleaner sealer appropriate testing instruments devices for specific sterilisation processes water treatment facility

(The relevant provisions concerning health and safety at work are also applicable.)

Annex 6 **Subject knowledge of staff**

Annex applicable in conjunction with the Recommendation from the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

Requirements regarding the subject knowledge of staff in charge of the reprocessing in reprocessing units according to category A and B (see annex 5)

The subject knowledge about the reprocessing of medical devices (section 4 subsection 3 of the German Medical Devices Operator Ordinance) includes:

- fundamentals of instrumentation (department-specific, if applicable)
- knowledge of hygiene/microbiology (including transmission routes)
- Risk assessment and classification of medical devices according to the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices".
- Priorities governing reprocessing:
 - appropriate preparation (pre-treatment, collection, pre-cleaning, disassembling)
 - cleaning, disinfection, rinsing and drying
 - verifying the cleanness and intactness
 - maintenance and repair
 - functional tests
 - labelling
 - packaging and sterilisation
 - documented approval of medical devices for use/storage
- spatial and organisational aspects of reprocessing
- development of procedure and working instructions for reprocessing
- knowledge of the law (Act on Medical Devices, German Medical Devices Operator Ordinance, Biological Agents Ordinance)

A person is considered qualified if **evidence of education or training** in a relevant medical profession which covers these topics as part of the framework curricula can be provided and if this education or training has been successfully completed. If some topics have only been

partly covered or not addressed at all as part of the education or training, this knowledge has to be supplemented or updated through adequate training.

A specialist training is necessary if there is **no evidence of education or training** in a relevant medical profession - this could be based on the specialist training courses according to the qualification frameworks of the German Society for Sterile Supply or covered through training by associations of medical professions or public institutions.

Furthermore, public bodies and scientific societies, such as the German Society for Sterile Supply, provide information about the requirements regarding subject knowledge.

Annex 7 Measure for minimising the risk of a transmission of CJD/vCJD through medical devices

Applicable annex to the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices".

Introduction

The sporadic Creutzfeldt-Jakob Disease (CJD) occurs at a prevalence rate of 1-2 cases per one million population per year, making it a rare disease in humans. Nevertheless, the transmission of CJD through contaminated medical devices has been reported in individual cases. Furthermore, the disease is usually fatal. The occurrence of a new, BSE-linked variant of CJD (vCJD) in humans also means that this topic has to be specifically addressed because the pathogens show a high tolerance against usual reprocessing procedures for medical devices [1-3].

Information about the epidemiological and pathogenetic background can be found in Beekes 2010 [1] and up-to-date data about the prevalence of CJD/vCJD can be accessed under www.rki.de > Infektionsschutz > Infektions- und Krankenhaushygiene > Themen von A-Z > CJK/vCJK (in German only).

CJD has a long incubation period which is not known for each individual case. Patients in the asymptomatic stage of a progressing CJD, i.e. who have continuously multiplying pathological prion proteins (PrP^{TSE}) [4] in their body while not yet showing any clinical symptoms can present a currently neither identifiable nor quantifiable risk for iatrogenic transmission of TSE pathogens. Another factor are cases where invasive surgery is being performed and where the disease pattern or the genetic or other risk (see 1.1) has not been recognised as such.

The aim of the measures described hereafter is to minimise the risk of human-to-human transmission for all forms of transmissible spongiform encephalopathies (TSEs), including the variant CJD (vCJD) through contaminated medical devices.

According to what has been established above, the measures can be divided into

- 1) measures in case of an identifiable (or presumed) risk (i.e. diagnosis of potential or clinically probable CJD/vCJD or a rapidly progressing dementia) (procedure I) or
- 2) measures in the case of no identifiable risk (procedure II).

(also see table I)

The risk of transmission through appropriately reprocessed medical devices which have been used on asymptomatic or unidentified carriers is currently not objectively quantifiable but considered low by all estimations [1] and generally depends on:

- a) the prevalence of the illness in the general population and
- b) the co-occurrence of

- a previous contamination of a medical device (intervention on pathogen-infected tissues of an asymptomatic or unidentified carrier of CJD/vCJD),
- the incomplete removal (decontamination) or inactivation of the CJD/vCJD pathogen through cleaning/disinfection and, if applicable, sterilisation of the instruments used during the intervention and
- the use of a medical device that is still contaminated (contagious) on the next patient, resulting in transmission, whereby the probability of an infection not only depends on the residual pathogen load on the medical device but also on the susceptibility of the tissue into which the TSE pathogens are being inserted.

Main parameters of the risk analysis and risk evaluation also include knowledge of

- the pathogen load of different tissues [5],
- the effectiveness of different decontamination and inactivation procedures (also see table 2)

and

- the initial protein burden on the used surgical or endoscopic instruments (see table 3).

The deduction of risk minimisation measures is also based on these considerations.

For risk management purposes, it is essential to identify

- a) people at risk (risk groups 1.1) and**
- b) high-risk interventions (high-risk surgery 1.2).**

1.1 Risk groups

People at risk of CJD/vCJD can be divided into the following risk groups:

risk groups (I-V):

- I. Patients suffering from vCJD or suspected to suffer from the disease (possible or clinically probable vCJD).
- II*. Patients suffering from CJD or suspected to suffer from the disease (possible or clinically probable CJD).
- III. Relatives of a CJD patient (in risk group II or who has died of CJD) (unless a genetic form of the disease has been ruled out for the relatives concerned).
- IV. Recipients of (non-recombinant) human growth hormone and cornea or dura mater transplants.
- V. Patient with a rapidly progressing disease of the central nervous system of unknown origin, with or without dementia and without concrete suspicion of CJD.
- VI. Any other person

(* This includes sporadic, genetic and iatrogenic CJD as well as other human forms of TSE such as Gerstmann-Sträussler-Scheinker syndrome and sporadic fatal/fatal familial insomnia).

1.2 High-risk tissues or high-risk surgery

Due to the distribution pattern of the pathological prion protein in the human system, interventions have to be classified into the following high-risk interventions [5]:

high-risk interventions (a-e; differentiated by the pathogen load of the affected tissue and the presence of CJD or vCJD):

- a) Neurosurgery involving the central nervous system (brain, spinal cord, optic nerve) as well as interventions involving the dorsal root or trigeminal ganglia, inner ear, pituitary gland or the olfactory region of the nasal mucosa;
 - b) Eye surgery (posterior segment of the eye: retina and optic nerve); (as well as cornea transplants and surgery using cornea transplants¹)
 - c) other surgical interventions contact to high-risk tissue (ENT, olfactory epithelium)
 - d) lumbar puncture for taking samples of cerebrospinal fluid (usually irrelevant as disposable products are generally used)
 - e) in the case of vCJD: also surgery on lymphatic tissues, such as for example tonsillectomy, splenectomy, appendectomy, surgery of the terminal ileum, lymphadenectomy, lymph gland biopsy, bone marrow surgery (for example in orthopaedic or trauma surgery).
- Blood is only to be considered a specified risk material in cases of vCJD.

1.3 Risk management

- ▶ *Before each invasive procedure, the patient should be checked for signs of possible or clinically probable CJD/vCJD in order to be able to take specific preventive measures if necessary. These measures become necessary if the pathogen load on the medical devices to be used exceeds the cleaning/decontamination/inactivation performance of the routine reprocessing procedures in place. This should be particularly kept in mind for neuro- and eye surgery as well as ENT- or oral surgery (see 1.2) because of the pathogen distribution in the body.*
- ▶ *A case is considered as suspected CJD if the patient shows symptoms of a neurological multi-systemic disease that is quickly progressing. A recent history of cortical visual impairment can for example be a concrete reason for suspicion. Ophthalmological symptoms are the most common neurological initial manifestations of CJD [6]!*

Typical scenario:

- a) At the onset, the patient is suddenly no longer able to read the newspaper; in this case, signs of cortical visual impairment should be checked: Pictures appear no longer to be square/rectangular, tile joints in bathroom/kitchen do not seem straight, colours changed,

¹ It is not the cadaveric-donor cornea which presents a risk but the cross-contamination of the cornea from retinal tissue when extracting the graft.

distances cannot be gauged anymore (mostly men report that they can suddenly no longer drive a car).

b) An initially mild dementia rapidly worsens, so that within days/the previous month the patient's forgetfulness considerably worsens or he or she has additionally developed disorientation, apraxia, lessened ability to speak or ataxia.

In the case of patients with clinically suspected CJD/vCJD, it might prove useful to delay the intervention/endoscopy by approx. 5 days to allow a more precise risk assessment. If the patient's neurological condition has noticeably worsened within a short period of time and without any other apparent cause this is suggestive of CJD.

► *Every physician involved - that is to say both the referring physician as well as the physician carrying out the intervention - is obliged to verify with each patient whether the current clinical picture is suggestive of suspected human TSE. For elective interventions on patients with suspected CJD, a neurologist should be consulted before the examination and the execution of the intervention planned accordingly. If a consultation is not possible beforehand due to the urgency of the examination, it should be carried out under the conditions of procedure I (identifiable risk, see below). If necessary, the medical devices (for example endoscope) can be stored/quarantined after the examination until the suspicion of CJD has been confirmed/ruled out (see 1.3.2.1).*

1.3.1 Procedure in case of no identifiable risk (procedure II), general measures for the reprocessing of medical devices to avoid the transmission of pathological prion protein (best practice)

► For interventions on high-risk tissues (see 1.2 a) -d)) **single-use medical devices** should be used, if possible. This includes

- scalpels,
- biopsy needles and cannulae, medical devices for spinal anaesthesia and nerve conduction blocks,
- bone drills and bone screws that might be exposed to the central nervous system or cerebrospinal fluid.

► **Reprocessable medical devices** fall into thermostable and thermolabile medical devices (for example flexible endoscopes).

General measures for avoiding a transmission of pathological prion proteins through medical devices will be described hereafter. Specific aspects of the reprocessing of flexible endoscopes will be discussed further below. The reprocessing recommendations for

thermostable surgical instruments also apply to rigid endoscopes which can be steam-sterilised.

► *The reprocessing of medical devices should always be undertaken in compliance with the common recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention and the Federal Institute for Drugs and Medical Devices "Hygiene Requirements for Reprocessing Medical Devices" in the latest applicable version and combine at least two procedures which are also (at least partially) suitable for the decontamination or inactivation of prions (see table 2 [7]).*

These procedures include for example:

- pre-cleaning and cleaning
- appropriate (chemo-thermal, if applicable) disinfection
- sterilisation with proven effectiveness against prions (also see table 2 and the ANSM list (www.ansm.sante.fr)).

1.3.1.1 Pre-cleaning and cleaning

► *Appropriate measures have to be taken to prevent excessive drying of residual tissue and blood on the inner and outer surfaces of medical devices. This can for example be achieved by optimising the disposal times and by avoiding influences that lead to protein fixation (for example the presence of high temperatures or certain disinfectants) as well as through pre-cleaning of the medical devices immediately after use on the patient.*

► *The cleaning performance proven in each case (also see the specifications concerning the validation of cleaning and disinfecting procedures) is decisive when assessing the suitability of a cleaning process (also see table 3).*

► *Based on current knowledge, reprocessing in an alkaline environment is preferable in terms of cleaning performance (the proven cleaning performance is always decisive). The capacity of a detergent to inactivate prions is most likely with pH-values > 10 and a soaking time of more than 10 minutes under elevated, but not protein-fixing temperatures (for example 55 °C). However, claims that a product can inactivate prions must be evidence-based (see for example list of the ANSM [7,8]).*

► *Generally, no problems are to be expected when using alkaline cleaning processes on medical devices made of stainless steel. In the case of medical devices containing other materials, information on the material compatibility of the detergent should be obtained from the manufacturer and an appropriate procedure with a high cleaning performance chosen.*

► *In the case of eye surgeries, complications at the patient's eye (for example ocular burns) due to alkaline detergent residues must be excluded. Therefore, a standardised and appropriate pre-rinsing with suitable water between uses is of major importance when reprocessing medical devices used in ophthalmology. When washing and disinfecting ophthalmologic devices in a washer-disinfector, a suitable programme should be used to ensure the success of the rinsing process and to prevent potential ocular burns of the patient's eye due to alkaline detergent residues. The removal of alkalinity has to be proven in the course of the process validation.*

1.3.1.2 (Chemo-thermal) disinfection

► *It is recalled that chemical (for example aldehydes, alcohols, peracetic acid) or thermal processes during the reprocessing in the washer-disinfector (for example thermal disinfection, drying) can affect the anti-prion effectiveness of the following process steps (for example sterilisation). Pre-cleaning and cleaning ahead of potential chemical or thermal protein fixation is therefore of utmost importance. This is another reason why the use of appropriate detergents constitutes an advantage.*

1.3.1.3 Sterilisation

a) Steam sterilisation

► *Steam sterilisation at a temperature of 134 °C with a hold time of at least 5 minutes is recommended for sterilisation, as long as a pre-treatment (pre-cleaning, cleaning, disinfection) has been carried out as described above [9].*

► *Medical devices which cannot be reliably or safely reprocessed (for example because of the danger of ocular burns when performing surgery on the eye) in a washer-disinfector using a cleaning stage with an at least partially prion-inactivating or prion-decontaminating effect and which are intended to come into contact with high-risk (prion) tissue (for example high-risk surgery a,b,c) can, if possible, undergo a different standardised and documented cleaning procedure, followed by steam sterilisation at 134 °C with a hold time of 18 minutes. If this is not possible either, a suitable reprocessing procedure has to be developed and laid down in detail or, if necessary, reprocessing be dispensed with [6].*

b) Alternative reprocessing procedures for thermolabile medical devices

► *The development of more and more complex medical devices for invasive procedures using different materials requires the development of new reprocessing procedures (particularly in the sectors of ophthalmology, ENT, dental, oral and maxillo-facial surgery as well as surgery on the central nervous system and the spine). Over the last years, various partially prion-decontaminating reprocessing procedures have been developed (see for example the ANSM list [10-17]). Certain H₂O₂-based sterilisation procedures for example can - at least partially - inactivate the TSE infectivity on those outer and inner surfaces of medical devices which can be reached by the sterilising agent [10-17]. The effectiveness of this procedure depends, inter alia, on the pre-treatment of the medical devices, the type and nature of the potentially contaminated surfaces, the concentration of H₂O₂ on the surfaces to be treated as well as on the type of load (partial load/full load). Before application, it has to be verified if reliable data are available, according to which the effectiveness of the procedure has been successfully tested under real-life or comparable conditions (goods to be sterilised, bioburden, pre-treatment, sterilising parameters relevant to the effectiveness) (see for example ANSM list, [10-17]).*

1.3.2 Procedure in case of an identifiable risk (procedure I) (prion-specific safety measures)

► *If the suspicion of a possible or clinically probable CJD/vCJD (see 1.3) has been raised **prior** to an invasive procedure or if a procedure (including endoscopic interventions) has to be performed on a patient with suspected possible or clinically probable CJD/vCJD, the indication should be carefully reassessed and a risk-mitigating approach identified accordingly. If the indication for a surgery persists, the following measures might be taken:*

► *Prion precautions have to be taken for the following combinations of risk groups and high-risk interventions:*

- *For risk group I (suspected vCJD, see 1.1) the measures listed below are required for all invasive procedures (see 1.2).*
- *For risk group II (suspected CJD, see 1.1) and III - V, the measures listed below are required for high-risk procedures a-d (see 1.2 procedures on the central nervous system, eye, olfactory epithelium, cerebrospinal fluid).*

The following prion precautions are advisable in this context:

► *Whenever possible and justifiable under surgical considerations, **disposables** should be used for invasive surgery on patients with definite, clinically probable or possible (v)CJD. These are to be discarded and incinerated after use in line with EWC code 18 01 03.*

► *If the use of disposables is not possible, the surgery should be planned in advance to enable identification, after careful consideration, of the medical devices that can be safely reprocessed after use. All other medical devices must be discarded and incinerated after use in line with EWC code 18 01 03.*

► *The medical devices that can be safely reprocessed thanks to their design and material characteristics (for example thermostable medical devices "critical A"), have to undergo **appropriate pre-cleaning** observing occupational health and safety regulations (see 1.3.1.1). According to WHO guidelines, NaOH, NaOCl and guanidinium thiocyanate can be considered for initial prion decontamination. For practical reasons, the pre-cleaning has to be done in a suitable basin, which has to be suitably disinfected or discarded after use. The instruments used for pre-cleaning (for example brushes) have to be discarded and incinerated in line with EWC code 18 01 03.*

► ***After pre-cleaning** and rinsing in water, the instruments are separately and mechanically cleaned in a validated, prion-effective cleaning process and, if necessary, disinfected in a suitable, non-fixating, chemo-thermal disinfection process. Thermal drying should not be carried out since it might*

affect the following sterilisation process. Afterwards, the washer disinfectant should run on an empty cycle.

► Alternatively (for example in the case of unclear neurological diagnosis, for example risk groups III-V), the medical device can be stored under suitable conditions after separate pre-cleaning and rinsing until the diagnosis has been established. If **CJD/vCJD has been ruled out**, a common reprocessing procedure (procedure II) can take place.

► In cases of **suspected vCJD**, all invasive medical devices (critical medical devices and semi-critical instruments contaminated with tissue (for example biopsy channel)) are to be regarded as potentially contaminated with Prp^{TSE}. If these medical devices are not discarded, they can be stored until the diagnosis has been established (see table 1).

1.3.2.1 Storage of medical devices

► The storage of medical devices until the confirmation or exclusion of the diagnosis should be carefully planned and centralised (for example in the central sterile services department (CSSD)). The suspected diagnosis has to be documented on a form (accompanying certificate for medical devices) by the physician in charge. One copy has to accompany the stored instruments, a second copy has to be filed in the patient record and a third copy should be sent to the hospital hygienist/the person in charge of hygiene. The dry instruments are put onto mesh trays in an alkali-resistant container (for example V4A steel, DIN material number: 1.4401) with a tightly closing lid or a suitable disposable container which can be steam sterilised. To this end, the container has to be permanently and clearly labelled (for example: medical device with suspected prion contamination, do not use).

The following rules apply when storing devices:

- Disposables should be screened out beforehand and put in a safe container for incineration as waste (EWC code 18 01 03.),
- gross debris has to be removed from the medical devices that might be reprocessed later on, strictly observing occupational health and safety regulations (also see suitable pre-cleaning),
- avoid injuries at all costs,
- do not overload containers and sieves,
- sort instruments and place with open joints or hinges,
- make sure containers are securely closed (for example sealed on both sides) and
- confirm the handing over of the container to the CSSD/the reprocessor

on the accompanying certificate.

► *Pending the establishment of the diagnosis (CJD/vCJD confirmed, inconclusive or safely ruled out), the instrumentation has to remain at a designated location under the responsibility of a designated person. The diagnosis has to be communicated in writing by the physician in charge and has to be documented on the accompanying certificate. Because of the complexity of the problem to be solved, it is recommended to inform the responsible hospital hygienist about the process. In the case of a confirmed or definitely inconclusive diagnosis (CJD/vCJD), the semi-critical or critical medical devices used (see "Hygiene Requirements for the Reprocessing Medical Devices") are safely discarded through incineration (EWC 18 01 03) (or reprocessed using prion precautions (if justifiable in the context of CJD)).*

► *If CJD/vCJD has been safely ruled out, the instruments can be reprocessed as usual in accordance with the "Hygiene Requirements for the Reprocessing Medical Devices" (also see annex Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation).*

1.4 Use of flexible endoscopes in relation to CJD/vCJD

a) Procedure in case of no identifiable risk (procedure II)

Flexible endoscopes are frequently used in modern medicine, for example when a PEG is placed. Precisely patients for whom this procedure is indicated also include some who suffer from dementia. If careful history-taking (see 1.3) cannot clarify the issue further, it has to be ensured nevertheless that patients who are examined afterwards are not exposed to any risk and that no other medical devices are cross-contaminated as a result of (invasive) medical devices being used on those patients. This is the purpose of the Recommendations to the "Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation".

Some important aspects have to be reiterated here:

► *In the interest of traceability, a documentation of the endoscope used should be done for every patient.*

► *The pre-cleaning is an essential step in the reprocessing of medical devices and of flexible endoscopes, in particular. Inappropriate pre-cleaning or brushing of the channels in a cleaning solution which is used for several endoscopes without replacing it, can pose the risk of cross-contamination of other medical devices. From this point of view, the following procedure is always recommended after the completion of endoscopy:*

- ▶ *Immediately after the end of the examination, the instrument channel as well as all other channels of the instrument have to be thoroughly flushed with water and the inserted part of the endoscope has to be cleaned with a disposable cloth from the outside in order to wipe off gross debris.*

- ▶ *Without allowing the debris to dry, the device has to be placed in an immersion tray/a basin for pre-cleaning with a suitable and effective detergent and the channels need to be thoroughly flushed whilst paying attention to staff protection (see table 2; 1.3.1.1). Cleaning brushes used (flexible brushes, hand brushes and toothbrushes) have to be cleaned in an ultrasonic bath and subsequently disinfected after each use. After cleaning and disinfecting, the brushes have to be stored in a dry place that is safe from contamination at the end of each working day. The cleaning solution is contaminated with organic matter and chemical residues and a new solution has to be prepared at least each new working day while paying attention to occupational health and safety. In the case of visible debris or contamination by faecal matter on an endoscope, the cleaning solution must be changed immediately. The cleaning basin must undergo thorough mechanical cleaning and disinfection at the end of each working day.*

- ▶ *The pre-cleaning tray should also undergo wipe cleaning with an appropriate detergent.*

- ▶ *After a thorough pre-cleaning, the endoscope is further reprocessed according to the general recommendations for the reprocessing of flexible endoscopes.*

A current risk assessment by a commission of experts from the United Kingdom (UK) concludes that endoscopes used in the upper or lower gastrointestinal tract presented only a low risk of relevant contamination with pathological prion proteins, as long as they were not used invasively (for example as long as no biopsies were being performed) or used on patients with vCJD. Endoscopes used in ENT or in neurosurgery (high-risk surgery a, b, c and e) are assumed to have a higher potential pathogen load (MDA DB 2002(05) with Annex A1 and F) [18, 19].

A risk-adjusted use of flexible endoscopes will therefore be based on the following considerations:

b) Patients with confirmed CJD/vCJD and patients with suspected or an elevated risk of CJD/vCJD (risk groups I-V), (procedure in case of an identifiable risk, procedure I)

- ▶ *Flexible endoscopes in neurosurgery, oral surgery and otorhinolaryngology*

- For neurological-neurosurgical interventions as well as ENT or oral interventions with possible exposure to the olfactory epithelium, flexible endoscopes should not be used on patients with CJD/vCJD or suspected CJD/vCJD if medically acceptable. If it has to be used, it should be withdrawn from circulation after use (see 1.3.2.1). Further steps have to be assessed individually for each case.

► Flexible endoscopes in gastroenterology, pulmonology, intensive care and urology

- Endoscopes which have been used in areas other than otorhinolaryngology, oral or neurosurgery on patients with suspected CJD/vCJD should be withdrawn from circulation (quarantined) until further notice (see 1.3.2.1) after having been pre-cleaned (see 1.3.1.1). The decision whether or not they can be reprocessed will be made at a later stage.
- The endoscope or the endoscope channel might be contaminated when extracting biopsies or during other invasive procedures (for example through lymphatic tissue when performing polypectomy in the terminal ileum).
- If the suspicion of CJD persists, reprocessing should not be undertaken.
- In case of suspected CJD (risk group II), endoscopes may be reprocessed after endoscopic procedures in the fields of gastroenterology, pulmonology, intensive care and urology if extra care is taken and if the additional precautions listed above concerning additional instrumentation and cleaning brushes are observed.
- Aldehyde disinfectants with fixating properties (such as glutaraldehyde or OPA) can stabilise and fixate prions. Disinfectants with fixating properties should not be used when reprocessing flexible endoscopes that have been used on patients with suspected CJD.

► Additional Endoscopic Instrumentation

- Brushes that have been used to clean the endoscope channels should be discarded after use and disposed of (EWC code 18 01 03)
- When undertaking a biopsy, disposable biopsy forceps have to be used which have to be discarded and disposed of after use (EWC code 18 01 03).
- After a biopsy, the biopsy port cap must be discarded and disposed of before reprocessing the endoscope (EWC code 18 01 03).

1.5 Staff protection

Concerning staff protection, explicit reference is made to the Technical Regulation for Biological Agents, TRBA 250 and the Committee for Biological Agents (ABAS) decision 603.

In order to render this recommendation more practicable, some measures are only briefly mentioned, such as wearing a liquid tight apron or coat, an appropriate protection of the mucosa from splashes (for example a mouth and nose cover/safety goggles) and double layer gloves as well as using liquid tight surgical drapes when performing invasive procedures.

In the daily (basic) care of patients with (v)CJD, no special measures that go beyond standard hygiene are necessary, unless they are required because of other (different) diagnoses. The precautions put in place against HIV, hepatitis B and C can be considered effective.

1.5.1 Measures after unprotected exposure to pathogenic material

According to ABAS decision No 603:

In the event of cuts or needlesticks involving exposure to pathogenic material, free bleeding should be encouraged, the wound region rinsed under running water and the treated wound region treated with 1M NaOH (if necessary with a mull or cotton pad soaked in the solution in order to protect uncontaminated areas of skin) for 5-10 minutes. Afterwards, the area should be thoroughly rinsed under running water for a second time.

In case of skin contamination (no visible wounds), the respective area has to be thoroughly rinsed under cold water first, then treated with 1M NaOH as described above and then again thoroughly rinsed with water.

Mechanical irritation of bruised or contaminated areas of skin (for example scrubbing with a brush) should be avoided.

Solutions for wound treatment have to be stored separately and replaced every three months (stability of NaOH).

A physician might be consulted for further treatment after the emergency measures have been taken. In case of invasive contamination, mucosal contamination (i.e. eyes) or peroral contamination with materials which contain human TSE agents, the decision of whether an immunosuppressive therapy or other measures could be advisable as further prophylactic steps

has to be made after a comprehensive consultation with an experienced physician and a careful risk-benefit assessment.

PLEASE NOTE: NaOH solutions should be kept in closed containers.

1.6 Disposal of waste that has been contaminated with pathogenic tissue (see 1.2)

This waste has to be collected and incinerated according to EWC code 18 01 03.

All other waste resulting from caring for patients with CJD/vCJD has to be collected and disposed of according to EWC code 18 01 04.

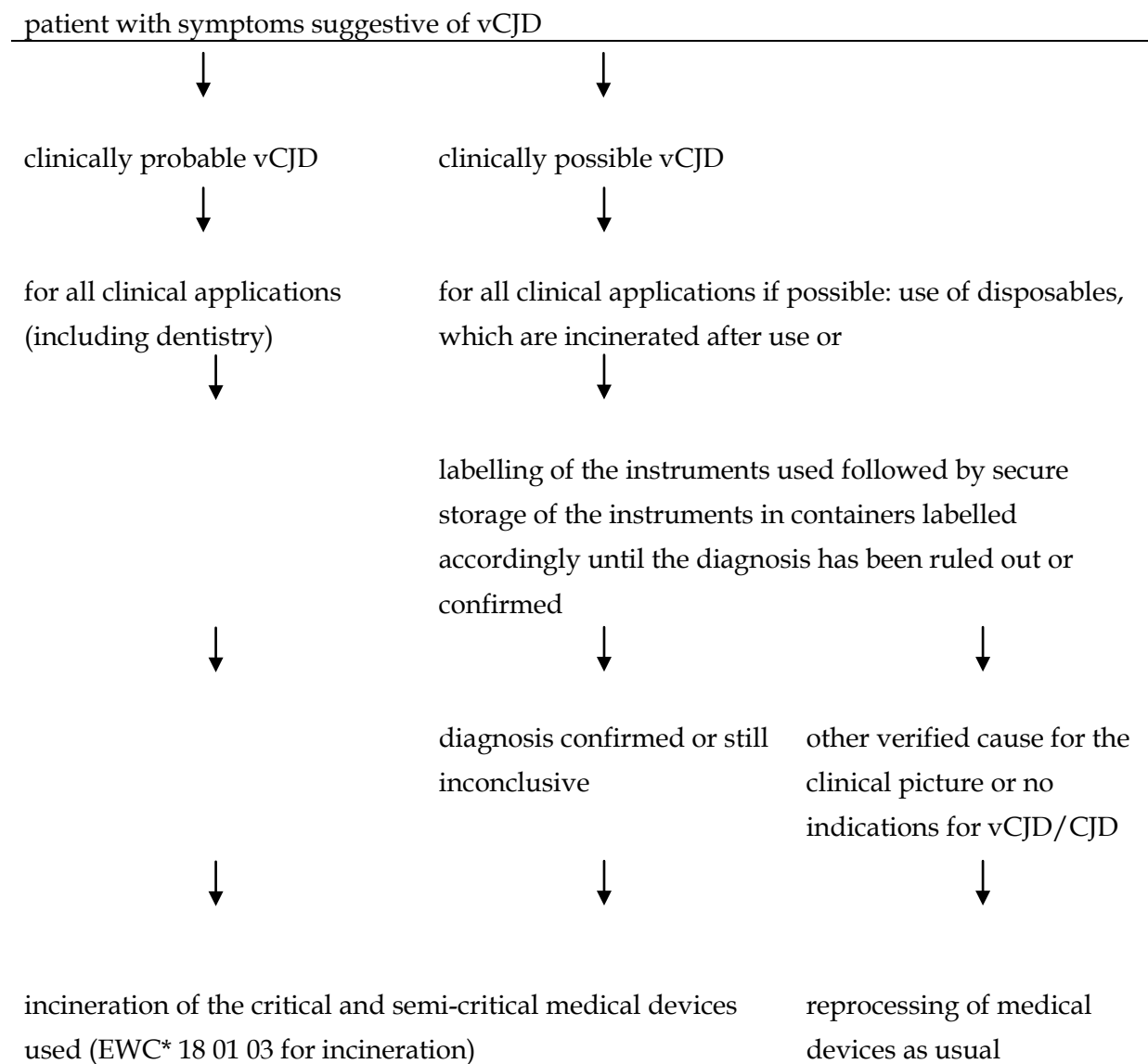
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Table 1

Recommendation for the handling of medical devices used in elective surgery on patients with clinically probable or possible vCJD in accordance with the generally accepted criteria for differential diagnosis of CJD, vCJD, Alzheimer's and depression with cortical visual impairment, peripheral dysaesthesias or myoclonic seizures



* Waste code according to the European Waste Catalogue

Table 2

Effectiveness of different procedures to decontaminate instruments or inactivate prions when reprocessing medical devices

At least partially effective procedures/agents	ineffective or fixating procedures/agents
<ul style="list-style-type: none">- carefully validated (particularly alkaline) cleaning* (see also 1.3.1.1)- 1 M NaOH* (40 g / l minimum 1 h at 20 °C)- 2.5 - 5 % NaOCl* (minimum 1 h at 20 °C; minimum 20 000 ppm chlorine content)- ≥ 4 M GITC* (minimum 30 min at 20 °C)- steam sterilisation (minimum 5 min at 134°C)- H₂O₂ (certain procedures, see also 1.3.1.3)	<ul style="list-style-type: none">- alcohol- aldehydes, formaldehyde gas- ethylene oxide gas- iodophors- HCl- dry heat- UV radiation- ionising radiation- peracetic acid

* It is recalled that the devices must be thoroughly rinsed in order to remove harmful residues.

Table 3

Important parameters and assumptions, as used for risk assessment [20]

parameter	comment	ID ₅₀	(CJD)	(vCJD)
			central nervous system/eye	tonsils
			ID ₅₀	ID ₅₀
average initial load of organic material on an instrument	10 mg	10 ⁷	10 ⁶	
decontamination (cleaning/ disinfection)	decimating factor (or remaining infectivity)		(100 to 10 µg)	
	first cleaning	10 ^{-2 bis -3}		
	further cleaning cycles	10 ^{0 bis -2}	10 ⁵ to 10 ⁴	10 ⁴ to 10 ³
inactivation (sterilisation)	decimating factor (or remaining infectivity)			
	first-time sterilisation	10 ^{-3 bis -6}	0 to 10 ²	0 to 10 ¹
	further sterilisation	10 ^{0 bis -3}		
percentage of material transmitted during a single procedure	time-dependent? if applicable completely in the case of implants	10 ^{0 bis -1}	0 to 10 ²	0 to 10 ¹
average number used during an intervention	on average for all surgeries	20	0 to 10 ³	0 to 10 ²
	tonsillectomies	12		

According to these theoretical considerations, a protein load of < 100 µg / instrument after cleaning and an inactivation performance of at least 10⁻⁴ ID₅₀ for sterilisation should be aimed for.

Appendix 1 to annex 7: Information on the pool of endoscopes at the University Medical Center Göttingen

A pool of endoscopes for patients with possible or probable sporadic or hereditary CJD has been established in Germany (in cooperation with different manufacturers). Endoscopes can be requested from this pool of instruments (gastrosopes and coloscopes) for specific interventions on CJD patients (see 1.3.2.3). Subsequently, the endoscopes used are centrally reprocessed.

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This centre dispatches the endoscopes, reprocesses them according to specific guidelines and disposes of them, if necessary. The rental costs of such endoscopes have to be borne by the user. The endoscopic accessories used (for example material used in PEGs, injection needles, catheters) are to be considered as disposables and have to be disposed of and incinerated according to EWC 18 01 03. The reprocessing of endoscopes is done using guanidinium thiocyanate (see table 2).

First, the endoscope is flushed thoroughly and the outside wiped with a cleaning cloth after use on the patient (see 1.3.1.1 and 1.3.2). Ideally, it should be placed in 4 M guanidinium thiocyanate solution immediately afterwards (see table 2).

No pre-treatment with a fixative should be undertaken before decontaminating the endoscope in guanidinium thiocyanate, i.e. the device should not be immersed in an aldehyde solution or in an alcoholic solution beforehand.

Residues of alcoholic solutions should not be introduced into the guanidinium thiocyanate solution as alcohol affects the effectiveness of guanidinium thiocyanate as a chaotropic salt. Also, acid residues should not be introduced into the guanidinium thiocyanate solution as they can release cyanides.

Guanidinium thiocyanate (GITC)

The decontamination with guanidinium thiocyanate represents the first step in the reprocessing procedure. GITC is being used as a 4 molar solution because a renaturation of pathological prion proteins was no longer detectable experimentally in a molar concentration of 3 or over. When handling the solution, the following safety precautions should be observed: the solution may not be ingested orally or inhaled; contact can cause skin, eye and respiratory tract irritation. Adding acids to the guanidinium thiocyanate can cause a release of cyanides. Laboratory gloves and a protective gown have to be worn as a consequence and ingestion of the solution, inhalation or contact with eyes, skin and respiratory tract has to be avoided.

Reprocessing procedure

The reprocessing of endoscopes should be done in a suitable basin for practical reasons (see 1.3.1.1). This makes it possible to only use 4-5 l 4 M guanidinium thiocyanate. The solution has to be poured into the basin and the device immersed therein. After the immersion, every channel of the device has to be flushed separately with a standard disposable syringe or the solution has to be aspirated through the channel and cleaned with a cleaning brush that is suitable for the width of the channel. Every channel has to be passable. Afterwards, the device should be left to soak in the guanidinium thiocyanate solution for 30 min. After a second flushing and brushing of the channels, the device has to be soaked in the guanidinium thiocyanate solution for another 30 min, so that the overall treatment time amounts to 60 min (table 2).

The guanidinium thiocyanate solution has to be carefully washed off the device after the exposure time. The device can only be damaged if the solution, which has a high molarity, crystallises out on the device and if the resulting crystals cause a mechanical damage to plastic components when the device or parts of the device are being moved.

The guanidinium thiocyanate solution has a shelf-life of several months. It must be protected from light. The terms of disposal should be discussed in the hospital. Disposal down the drain can cause serious environmental damage.

The disposal of the rinse water from rinsing the endoscope down the drain is not problematic. Afterwards, the endoscope should be cleaned and disinfected in a washer-disinfector using the standard cleaning programme for endoscopes.

Additional information on the internet

For further reading also see www.rki.de > Infektionsschutz > Infektions- und Krankenhaushygiene > Themen von A-Z > Informationen zu CJK/vCJK) (in German only).

Annex 8 Hygiene requirements for the reprocessing of flexible endoscopes and endoscopic accessories

Applicable annex to the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices".

This text replaces the corresponding recommendation of 2002, published in the *Bundesgesundheitsblatt* 45:395-411.

1 Introduction and background

1.1 Infection risk

Endoscopy-related transmission of microorganisms is sparsely documented [1-11]. A literature survey suggests that from 1966-1992, endoscopic examinations of the upper gastrointestinal tract were described as sources of 180 cases of viral or bacterial transmission that led to, in some cases fatal, infections [11]. The majority of these transmissions was due to inadequate washing and disinfection measures neglecting current reprocessing guidelines [11].

The infection risk varies both with the type of endoscopic intervention and the patient's disposition (e.g. underlying illness, individual anatomical features) and the pathogens' properties [1-9, 11].

1.2 Microorganisms involved

Endoscopy and endoscopic accessories are known to transmit viruses (e.g. hepatitis B [12], hepatitis C [13-15], HIV [16, 17]), bacteria (e.g. salmonellas [18-21], mycobacteria [22-24], pseudomonas [25-33], *Helicobacter pylori* [34-37]), protozoans (e.g.. *Cryptosporidium* [38, 39]), fungi [40, 41] and helminths (e.g. *Strongyloides* [42]).

1.3 The problem of prion transmission

So far, the risk of endoscopic interventions transmitting prion-associated diseases (TSE) has eluded quantification, not least because of the low prevalence rates of this disease. No cases have been described so far [43, 44]. For the management of patients with Creutzfeldt-Jakob Disease (CJD) we refer to the recommendations of the Robert Koch Institute (RKI) [45, 46]. In the light of epidemiological findings on prion-associated diseases [47], British experts [48, 49] and the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute [50] recently revised and updated the recommendations for the prevention of prion-associated diseases.

1.4 Relevant sources and causes of infection and transmission mechanisms

Due to their special design features, flexible endoscopes [11] and endoscopic accessories are classified as medical devices with higher reprocessing requirements (see also [51]).

Patients with a florid infection, excretors (e.g. of salmonellas) or carriers of infectious agents (e.g. hepatitis B or C, HIV infection), are a potential source of infection for the next patients to be examined [4] (Tab. 1). Since a patient's carrier status may be unknown, each patient must be considered a potential carrier.

Microbial contamination can affect the outer casing and canal system of the endoscope, the lens rinsing system including the rinsing solution and accessories (e.g. biopsy forceps, snares) [1-4, 9, 11]. Correctly reprocessed endoscopes and instruments may be recontaminated if they are not stored properly or during transport (Diagram 1).

Diagram 1

Endoscopy-related sources and causes of infection (from [4], modified)

Infection or carrier status of the previously examined patient

patient with known florid infectious disease, e.g.:

salmonellosis

Helicobacter pylori-associated gastritis/ulcer

hepatitis B or C

tuberculosis

clostridium difficile colitis

opportunistic pathogens in immunocompromised patients (mycobacterium avium, cryptosporidium parvum)

patients with asymptomatic infection or carrier status, e.g.:

Salmonella excretors

carrier of viral hepatitis B or C

Flaws of the reprocessing methods used

use of unsuitable detergents or disinfectants;

incompatible detergents or disinfectants

inadequate concentration of or contact time to the used detergents and disinfectants

contaminated detergents or disinfectants

excessive idle time

contaminated dosing system

contaminated tubing systems, receptacles or washer-disinfectors;

use of contaminated tap water or non-sterile distilled water as a rinsing solution;

fixation of organic matter and encrustation of microorganisms.

Flaws or special design features of the endoscope's channel system

e.g. narrow lumens or branched channels or channels which are not accessible for brush cleaning (e.g. rinsing channel, Albarran channel), defective or hard-to-clean caps for biopsy channels

formation of a microbial biofilm in the endoscope channels

leak in the instrument channel with entry of microorganisms into the interior of the endoscope

Flaws of endoscopic accessories and the lens rinsing system

improperly reprocessed accessories (biopsy forceps, snares etc.)

contaminated tap water or non-sterile distilled water for filling the water bottle

improper reprocessing leads to the formation of a microbial biofilm in the bottle or the connecting tube of the water bottle.

Flaws in endoscope storage and transport

inadequate drying after reprocessing (multiplication of typical water-borne bacteria such as *Pseudomonas* spp., *Legionella* spp. in case of residual moisture in endoscope channels)

storage or transportation of the endoscope in the dispatch case
storage without protection against recontamination (e.g. endoscopes hanging openly in the examination room) or unprotected transportation of endoscopes (e.g. to off-site examinations) there is no documented evidence that low germ counts can be maintained in case of storage in an endoscope cabinet for more than 14 days (see also chapter "Storage and transport of flexible endoscopes")

2 General problems and objectives

2.1 Objectives

Since endoscopy-related infections can usually be avoided, all infection prevention measures must be consistently implemented. These recommendations aim to describe suitable and time-tested measures of preventing infection transmission. Pursuant to section 4, subs. 2 of the German Medical Devices Operator Ordinance (MPBetreibV), cleaning, disinfection and sterilisation of medical devices must be performed using suitable validated methods and considering the manufacturer's instructions. Moreover, traceability of the processes is to be documented so as to achieve the desired process outcome and not least for regulatory control. With regard to the reprocessing of rigid endoscopes and accessories, reference is also made to the joint recommendations of the Commission for Hospital Hygiene and Infection Prevention and the Federal Institute for Drugs and Medical Devices "Hygiene Requirements for the Reprocessing of Medical Devices" [51].

The recommendations of this document apply to all gastroenterological, pulmonological and ORL examinations involving flexible endoscopes, irrespective of whether the endoscopic examination is performed in hospitals, private clinics or surgeries (outpatient centres) etc. Generally, they also apply to cytoscopies using flexible endoscopes, although these are invasive interventions into a physiologically uncolonised bodily cavity [50, 52]. In this context, the specifications in the Annex should be followed. Whether or not the current recommendations also apply to endoscopes used in NOTES (natural orifice transluminal endoscopic surgery) is not yet unequivocally established and requires further investigation [53, 54]

Reprocessing must always be performed by trained staff and in a room specifically equipped for this purpose (with a clean and an unclean area) (see also "Hygiene Requirements for the Constructional-Functional Design and Instrumental Equipment of Endoscopy Units"). Translating these recommendations into actual practice is a responsibility shared by all of those working in endoscopy.

These recommendations were drafted on the basis of various guidelines from German-speaking countries and the international field [55-71] as well as the results of scientific investigations [72-79]. They were informed by the guidelines of the German Society for Digestive and Metabolic Diseases (DGVS) [68] and the guidelines of other European [56-58, 60, 61, 69-71] and American professional societies [55, 59] including the multi-society guideline [65, 66] as well as those of the Gastroenterological Society of Australia and the WGO [67]. The recommendations must be updated in the light of new findings.

The "Hygiene Requirements for the Reprocessing of Medical Devices and Endoscopic Accessories" are based on the U.S. American Spaulding Classification and the risk assessment in the Commission's recommendation "Hygiene Requirements for the

Reprocessing of Medical Devices" [51]. Instruments that penetrate tissue or are inserted into sterile hollow organs must be sterile; instruments that come into contact with intact mucosa, must be disinfected [80, 81].

2.2. Cleaning

The purpose of cleaning endoscopes and endoscopic accessories is to remove organic matter and pharmaceutical drugs, leaving as little residue as possible, since these can adversely affect disinfection or sterilisation results [51, 82]. During subsequent disinfection, any microorganisms that remain attached – other than bacterial spores – are killed and/or inactivated to such an extent that the disinfected medical device poses no infection risk when it comes into contact with skin or mucous membranes. For sterilisation, validated physical or physical-chemical methods are employed, which kill or inactivate all microorganisms (including bacterial spores) present on or in the instrument.

Solutions made of surface-active, non-foaming substances (tensides), enzymatic detergents or solutions which have been proven to clean and disinfect in a combined action, are used for pre-cleaning and cleaning flexible endoscopes [55, 56, 58-60, 66-71, 83-85]. Aldehydes and peracetic acid are associated with protein fixation [86 - 88] and are therefore not recommended as cleaning agents.

While alkaline cleaning is highly effective in dissolving protein and fat residues and has a high microbial efficacy; it can cause adverse material changes. Manufacturers' instructions on material compatibility have to be observed. While the various cleaning agents differ in terms of efficacy, [89-94], individual substances have not been conclusively proven to be superior to others.

2.3. Disinfection

Throughout the world, aldehyde solutions or peracetic acid are almost exclusively used for disinfecting (after non-fixating cleaning) flexible endoscopes and endoscopic accessories, owing to their broad-spectrum effectiveness and efficacy [55, 56, 58-60, 66-71, 80, 81]. Other disinfectants (e.g. isopropanol 70%, iodine-containing preparations, quaternary ammonium compounds, chlorhexidine) have gaps in the required spectrum of activity [1, 3, 83-85]. Further disinfectants, e.g. amine derivatives, or oxidation-based disinfectants or electrolysed acid water (EAW) have been tested for the automated reprocessing of flexible endoscopes [95-101].

Disinfectants tested for manual reprocessing are included in the lists of the German Association for Applied Hygiene (VAH) [102] and the Robert Koch Institute [103]. For automated reprocessing, there is currently no list of disinfectants and disinfection methods

that have tested effective. Consequently, only detergents and disinfectants may be used whose suitability and effectiveness have been tested and stated in expert reports provided by the manufacturers of the preparations and/or devices. Basically, only disinfectants with evidence-based antibacterial, antiviral and fungicidal efficacy may be used.

For *C. difficile*, decontamination using a combination of diligent pre-cleaning and cleaning as well as instrument disinfection based on glutaraldehyde and peracetic acid has been found to be effective [80, 104, 105].

2.4 Sterilisation of Endoscopic Accessories

Endoscopic accessories that penetrate mucous membranes (e.g. biopsy forceps, papillotomes and snares), must be sterilised in the context of reprocessing [51, 55, 70, 71, 74, 75, 78].

In case of single-use instruments (e.g. disposable papillotomes, forceps and snares) sterility is guaranteed by the manufacturer. Successful sterilisation of reusable accessories must be ensured by the operator (e.g. outpatient or inpatient endoscopy departments/sterilisation department of hospitals/reprocessing companies) in a traceable manner [51, 77].

Hypodermic needles (e.g. for sclerotherapy of oesophageal varices or injection therapy for bleeding lesions) must always be used as disposable products because the reprocessing of hypodermic needles that are contaminated with blood is fraught with technical difficulties and implies high injury and infection risks [51, 70].

Endoscopic accessories for use in therapeutic interventions on bile ducts or pancreatic ducts, must be sterile. Balloon catheters are thermolabile medical devices of the “Critical C” group [51], which can only be reprocessed – if this is possible at all – in compliance with particularly strict requirements. The “European Society of Gastrointestinal Endoscopy” expressly discourages their reuse [70].

The water bottle and connecting tube must also be reprocessed on each working day in order to avoid contaminations caused by rinsing solutions (see below) [106].

2.5 Instrumental Equipment and Staff Requirements

The number of endoscopes, endoscopic accessories (e.g. biopsy forceps, polypectomy snares) and equipment for cleaning and disinfecting endoscopes that are to be kept ready for use depends on the examination spectrum and frequency, the number and qualifications of endoscopy physicians and assistive personnel, wear and tear of the equipment, use in emergency medical service and time needed for correct hygienic reprocessing [107].

As regards the “Hygiene Requirements for the Constructional-Functional Design and Instrumental Equipment of Endoscopy Units”, reference is made to the relevant recommendations of the Commission for Hospital Hygiene and Infection Prevention [108].

well as other recommendations for the constructional-functional design and equipment of endoscopy units [109-112] ,

The quality and diligence in reprocessing flexible endoscopes critically depend on staff qualification and motivation. In the interest of quality assurance, initial and continuing training tailored to the specific range of activities is essential.

Pursuant to section 2 of the German Medical Devices Operator Ordinance (*MPBetreibV*), medical devices may only be used by persons who have the required training, knowledge and experience for this work (subs. 2), and the operator may only assign such persons to this work (subs. 4), [113] . The curriculum recommended for medical assistants and doctor's assistants to acquire this expertise, would be modelled on the DEGEA's (German Society for Endoscopy Professions) technical seminar on the "Reprocessing of Endoscopes".

In hospital endoscopy departments where endoscopic therapy interventions are conducted, an appropriate share (e.g. 50%) of the endoscopy staff must have completed specialist further training in line with the recommendations of the ESGENA (European Society of Gastroenterology and Endoscopy Nurses and Associates) [114, 115] that can be completed, for instance, in courses offered by the DEGEA. An appropriate option for medical assistants and doctor's assistants in surgeries would be further training programmes and courses offered by the DEGEA and several Land medical associations.

Regular hygiene and subject-specific training courses for all staff working in an outpatient or inpatient endoscopy unit shall be held and documented pursuant to section 2 of the Ordinance on Operators of Medical Devices (*MPBetreibV*) [113], section 12 of the the Biological Agents Ordinance (*BioStoffV*) and No. 5 of the Technical Rules for Biological Materials (*TRBA*) 250 [116] .

Pursuant to section 36 of the Protection Against Infection Act (*IfSG*), in-house infection control protocols have to be specified in hygiene plans.

Close cooperation with infection control personnel (e.g. hospital hygienist, infection prevention nurse, hospital physician in charge of hygiene) is recommended.

3 Principles and Implementation of Flexible Endoscope Reprocessing

A distinction is made between manual reprocessing, semi-automated reprocessing and automated reprocessing methods in endoscope washer-disinfectors (EWDs) (Table 1), the latter additionally falling into chemical and chemo-thermal methods. For practical guidance on implementing manual and automated reprocessing of flexible endoscopes, reference is made to the checklists provided in Appendix 1

In principle, endoscopes can be properly reprocessed both by manual and automated methods [106, 117-121]. Manual reprocessing poses health risks for staff (infection and allergy risks) and ties up human resources. Since manual reprocessing does not fully satisfy

demands for reprocessing methods to be standardised and validated, manual methods must always be implemented in line with documented standard instructions and using methods that have been tested for effectiveness. Since reprocessing in a closed system (EWD) facilitates reprocessing and standardises the reprocessing method, automated reprocessing should be preferred [51, 106]. Moreover, it provides traceable reprocessing records. The methods in endoscope washer-disinfectors (EWDs) [117, 118, 122-129] normally comprise an integrated leak test, treatment of water for final rinsing (thermal or UV disinfection, sterile filtration) and the documentation of successful reprocessing and/or detailed failure reports. EWDs are medical devices and must thus comply with the general requirements of the Medical Devices Act. A European standard on the requirements and tests for EWD has been published [130]. More detailed information is included in the guideline on the validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes (*Leitlinie zur Validierung maschineller Reinigungs-Desinfektionsprozesse zur Aufbereitung thermolabiler Endoskope*) [131], recently published by various professional societies, see also Annex 3, "Inbetriebnahme und Betrieb von Reinigungs-Desinfektionsgeräten (RDG) zur Aufbereitung von Medizinprodukten (Checkliste)".

For hygiene reasons, preference should be given to endoscope washer-disinfectors (EWDs), in which the water used for final rinsing is disinfected by heating and is subsequently cooled, in order to prevent the endoscopes being recontaminated, e.g. by *Pseudomonas* spp., *Legionella* spp. or atypical mycobacteria [106, 132-134]. Regarding EWDs which use sterile filtration of tap water [133, 135-139] or water from distilled water equipment to obtain treated water for final rinsing, the upstream sterile filter must be changed regularly as per the manufacturer's instructions. Regarding EWDs with UV disinfection (sometimes combined with three minutes' thermal treatment of rinsing water [at 60°C]), the UV disinfection plant must be maintained regularly according to the manufacturer's instructions so as to prevent possible errors when the rinsing water is disinfected.

Table 1

Overview of the various endoscope reprocessing methods

	Manual, if appropriate semi-automated	Automated
Pre-cleaning:	Immediately after the examination in the examination room: Wipe the endoscope's outer casing and flush the channels	
Brush cleaning of endoscope channels	Thorough manual cleaning in the reprocessing room (use a disinfected brush matching each channel size!)	
Flush with cleaning solution	Manually in the reprocessing room	in the EWD
Disinfection	Immerse free from air bubbles Flush with disinfectant solution	in the EWD

	Manual, if appropriate semi-automated	Automated
Final Rinsing	In the reprocessing room	in the EWD
Drying	Manually in the reprocessing room (forced air-drying)	in the EWD

3.1. Pre-cleaning

The endoscope must be precleaned immediately after the endoscopic examination has been concluded, ensuring staff protection measures, while the device is still connected to the light source and suction pump. The aim is to prevent organic matter and chemical residues from drying in the channel system or on outer components of the endoscope, and prevent contamination of the environment [4, 140, 141].

The insertion shaft of the endoscope must be wiped down with a lint-free disposable cloth immediately after the endoscopic examination

The distal end of the endoscope must subsequently be immersed in a container with cleaning solution; all accessible channels must be flushed and sucked through with the cleaning solution several times to prevent the formation of incrustations in the channels which cannot be removed later on [86].

The endoscope must then be detached from the light source, lens rinsing system and suction tube, transported into the reprocessing room and placed in a basin containing cleaning solution.

The used endoscope is transported to the reprocessing room in a closed container (e.g. a basin with a lid) in order to avoid contamination of the environment.

3.2. Cleaning

All further reprocessing steps are undertaken in the unclean area of a separate reprocessing room since surfaces may become contaminated by splashes as the used endoscope is being cleaned.

All cleaning steps, especially brushing of endoscope channels, must be done below the liquid's surface in the cleaning basin in order to avoid splashes of contaminated liquids [70].

The working surfaces in the reprocessing room and the examination room must be cleaned and disinfected with surface disinfectants of proven efficacy, e.g. those listed by the VAH [102] each working day, and promptly in the event of visible contamination.

Since the effectiveness of subsequent disinfection is not guaranteed in case of inadequate cleaning [51, 80-82, 87, 142, 143], thorough cleaning of the endoscope is the prerequisite for correct reprocessing. As in the case of pre-cleaning, the procedure used for (main) cleaning must be such as to prevent the fixation of residues (e.g. tissue residues, blood). Thorough manual brushing of endoscope channels can reduce bacterial counts by up to 4 log values

[65, 72, 97]. Thorough manual brushing of the channels is also indispensable for removing parasites/parasite cysts. The currently used disinfectants do not consistently [39] or adequately inactivate parasite cysts [38, 144].

Generally, all accessible channels of the endoscope must be thoroughly cleaned by hand with a disinfected cleaning brush (of the channel-appropriate size recommended by the manufacturer) unless otherwise specified by the endoscope and/or EWD manufacturer. In mechanical brush cleaning, a flexible cleaning brush must be passed through each accessible channel several times until the brush is free from debris. The brushes shall match the respective channel diameter.

After brush cleaning, the channel systems must be flushed with water of drinking water quality. The residual water must be purged from the channels using forced air or an air-filled syringe to avoid the possibility of subsequent interactions of the cleaning solution with the disinfectant solution or dilutions of the disinfectant solution

Used cleaning brushes (flexible brushes, hand brushes and toothbrushes) have to be cleaned in an ultrasonic bath and subsequently disinfected after each use. At the end of the day and after cleaning and disinfection, they must be stored in a dry place and protected against contamination.

Since the cleaning solution is contaminated with organic matter and chemical residues, a new solution has to be prepared at least each new working day while paying attention to health and safety at work. In the case of visible debris or contamination by faecal matter on an endoscope, the cleaning solution must be changed immediately. The cleaning basin must undergo thorough mechanical cleaning and disinfection at the end of each working day.

3.3. Disinfection

Disinfection efficacy can be adversely affected by inadequate cleaning [80, 82, 87, 142] and incompatibilities between detergent residues and disinfectants. Disinfectants with proven efficacy are provided in the VAH's list [102] for the manual disinfection of medical instruments. For automated disinfection, the efficacy of disinfectants must be proven by expert reports provided by the manufacturer.

Throughout the world, aldehydes are considered as benchmark active substances for the hygienic reprocessing of flexible endoscopes [55-64, 66-71, 83, 84]. The use of aldehydes carries health risks and contact with skin and mucous membranes and exposure to vapours can cause irritation of the mucous membranes and allergic reactions in endoscopy staff [145-147].

Only disinfectants with proven bactericidal, virucidal and fungicidal efficacy may be used. The concentrations and contact times of the disinfectants indicated by the manufacturers must be followed precisely.

In case of manual and semi-automated reprocessing, the date on which the disinfectant solution was prepared must be stated, e.g. on the basin. However, in case of visible contamination (clouding), the disinfectant solution must be renewed earlier as per the manufacturers' instructions.

In case of manual and semi-automated reprocessing, all accessible endoscope channels must be filled with a disinfectant solution in such a way that no air bubbles are formed.

Disinfection basins must be thoroughly mechanically cleaned and disinfected when changing disinfectant solutions.

Baths for instrument disinfection shall be covered (airborne contamination, environmental contamination) [70].

As the ambient air in the reprocessing room is likely to become polluted with disinfectant vapours [146, 147], sufficient ventilation or a separate extraction system must be provided for reasons of health and safety at work [55, 70]

3.4 Final Rinsing for Removing Disinfectant Residues

Residues of disinfectant solutions in the endoscope can trigger chemical irritations and allergic mucosal reactions in the subsequent patient [148-150]. A fresh volume of water of impeccable microbiological quality must be used for rinsing disinfectant residues off each piece. Using tap water or non-sterile distilled water is inadequate since these tend to be microbially contaminated (e.g. *Pseudomonas* spp., *Legionella* spp., atyp. mycobacteria). This can cause recontamination of properly disinfected endoscopes and channel systems [106]. Inadequate drying of the endoscope can cause the bacterial count to increase during storage [151].

The disinfectant solution must be carefully removed by intensive re-rinsing of the channels and outer casing of the endoscope

For final rinsing, water must be used that is microbiologically potable and free from facultative pathogenic microorganisms. A sufficient quantity of microbiologically impeccable water for final rinsing can be produced by sterile water filters [139]. The guideline of the "Association for Professionals in Infection Control and Epidemiology" (APIC-Guideline [55]) recommends the use of sterile water for final rinsing.

In case of automated reprocessing in EWDs, the water for final rinsing is disinfected by heating, undergoes sterile filtration or is disinfected by UV radiation – depending on the device type. Therefore, automated reprocessing is safer with regard to the microbiological quality of the water used for final rinsing, another reason why it should be preferred over

manual and semi-automated reprocessing [106]. Automated reprocessing in appliances which disinfect the water for final rinsing water by heating it is considered the safest method, and is to be preferred

If endoscopes used for examining not microbially colonised body sites (e.g. bronchoscopes or side-viewing duodenoscopes for ERCP) are manually reprocessed, sterile water must be used for final rinsing [55]

3.5 Drying

When flexible endoscopes are not dried appropriately, microorganisms can multiply in the residual moisture, e.g. the endoscope's channel system, during storage, and represent a source of infection for subsequent patients [25-28, 30, 31, 33]. Therefore, attempts should be made to achieve complete drying [151, 152]. It has not been clarified if additionally rinsing channels with isopropanol 70% increases the effectiveness of drying and thus minimises pseudomonad problems [25, 106, 151-154].

In case of manual cleaning, all accessible channels of the endoscope must be thoroughly blown dry with air prior to storage. The use of forced air (up to not more than 0.5 bar) is recommended

For manual and semi-automated reprocessing, channels can be additionally rinsed with isopropanol 70% for additional disinfection and improved drying of the endoscope channels [153].

In case of automated reprocessing and insufficient channel drying, the corresponding programme step in the EWD must be prolonged [106, 151].

3.6 Documentation and Release of Reprocessing Cycles

Modern EWD register the device number of the endoscope to be reprocessed and automatically document the parameters that are relevant for reprocessing so that the process quality of a given reprocessing cycle can be retraced at any time. For manual reprocessing, disinfectant concentration, contact time and final rinsing with sterile-filtrated water shall be documented.

Whereas medical devices that are subject to sterilisation, must be formally released on reprocessing [51], the identification of reprocessed endoscopes and formal release routines - other than computer-based procedures in large interdisciplinary endoscopy units [155] cannot be implemented in everyday clinical practice in surgeries and small hospitals without substantial paperwork. For pragmatic purposes, a reprocessed endoscope that, on removal from an EWD has been directly taken to an examination room and connected to a

processor or has had its channels blown dry and subsequently been hung in the endoscope cabinet (without suction and rinse buttons) shall be deemed to be released. Release for storage or use shall be specified in SOP and the reprocessing date documented (e.g. by means of date labels)

Endoscopes/endoscope accessories are matched to patients within the context of patient records.

3.7 Storing and Transporting Flexible Endoscopes

If endoscopes are stored horizontally and the endoscope channels have not sufficiently dried, stagnation zones with residual moisture might develop. In recent years, studies have shown that a properly reprocessed endoscope that is stored hanging in an endoscope cabinet remains sterile 7 to 14 days following reprocessing [156-159]. There is no documented evidence of sterility after longer storage. Whereas the updated multi-societies guideline published by the relevant American specialised societies concludes that storage intervals of 10 to 14 days are safe for reprocessed endoscopes [65], the current Australian guideline recommends that gastroscopes and colonoscopes be stored for not more than 72 hours and duodenoscopes and bronchoscopes for not more than 12 hours [64].

Endoscopes should preferably be stored hanging in a closed endoscope cabinet and close to the workplace. Reprocessed endoscopes can be stored in an endoscope cabinet for up to 14 days. For maximum safety, rarely used endoscopes, such as duodenoscopes and devices reprocessed more than 14 days ago shall be reprocessed again before patient use.

Endoscopes used for interventions in not microbially colonised body sites (e.g. intraoperative endoscopy or cholangioscopy), are to be sterilised with gas (ethylene oxide or formaldehyde) or with equivalent methods in sterile goods packaging, and, after appropriate desorption, are to be stored in a closed cabinet in such a way that they are protected against contamination

The transport of reprocessed endoscopes to other hospital departments (OP, ICU, geriatrics, etc.) via public corridors and lifts implies the risk of recontamination.

For endoscopic examinations outside the endoscopy unit (e.g. the intensive care unit) the endoscope is to be transported in suitable, closed containers and protected against contamination.

Storing endoscopes or transporting them to off-site examinations in the endoscope case is not permitted. The endoscope case may only be used for shipping a defective device to the manufacturer for repair

3.8 Sterilisation of Endoscopic Accessories

The water bottle is to be filled with sterile water when being used [106]. After usage and on each working day, the water bottle and the connecting tube are to be at least disinfected, preferably sterilised, and subsequently dried and stored in such a way that they are protected against contamination. Suction systems including adapter and tube connections, must be cleaned and disinfected on each working day, and must be stored in a dry place and in such a way as to ensure they are protected against contamination between working days.

The utmost care is required for cleaning endoscopic accessories (e.g. biopsy forceps, polypectomy snares and sphincterotomes). Examinations under laboratory conditions with radioactively contaminated endoscopic accessories have detected weaknesses in cleaning [142]. Misdiagnoses due to inadequately cleaned biopsy forceps (e.g. the previously examined patient's biopsy material having been fixated with glutaraldehyde) have been described in literature [160].

Biopsy forceps to be reprocessed must be brushed thoroughly and with great care in order to avoid injuries and infections (e.g. hepatitis C [14]). Staff should wear cut-resistant gloves for protection. As instruments that penetrate mucous membranes, biopsy forceps must imperatively be sterilised [51, 55, 70, 80, 81].

Great importance should be attached to standardised processes when cleaning biopsy forceps and snares since otherwise, subsequent disinfection and sterilisation cannot be ensured [53, 89]

Endoscopic accessories should be cleaned in a cleaning solution and/or non-fixating disinfectant solution, observing personal protection. Manufacturers' instructions on concentration and contact time must be followed. The used solution shall be non-foaming, and be demonstrably suitable for both manual cleaning and cleaning in an ultrasonic bath [70].

The cleaning solution in the ultrasonic bath has to be changed at least every working day, and several times a day in the event of visible contamination

The basket of the ultrasonic device must be sufficiently large and deep to guarantee full immersion of instruments. The ultrasonic basket may not be overloaded with dismantled and pre-cleaned instruments but must be loaded in a way that avoids acoustic shadows that compromise the effectiveness of ultrasonic waves [70].

The temperature range recommended by the manufacturers of enzymatic cleaning solutions must be adhered to. Since ultrasonic cleaning may involve increases in the temperature of the bath, it must be ensured that the optimum temperature is not exceeded when using an enzymatic cleaning solution. The temperature in the ultrasonic bath should be monitored and adjusted by the device itself. The use of ultrasonic baths with an operating frequency of 30–50 kHz is recommended.

For disinfecting additional accessories, thermal methods should be preferred on account of their more reliable efficacy compared with chemical or chemo-thermal methods [51].

As the disinfectants listed by the VAH are intended for manual but not automated disinfection, the manufacturer must prove the efficacy of automated disinfection by expert reports. For the practical implementation of reprocessing – especially sterilisation – of endoscopic accessories, reference is made to the “Hygiene Requirements for the Reprocessing of Medical Devices” of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch-Institute and the checklists provided as Appendix 2.

4. Quality Assurance of Hygienic Reprocessing

Possible microbial contaminations on the endoscope and endoscopic accessories as well as the resultant risk of infection for patients and staff make it indispensable to check the quality of reprocessing of flexible endoscopes and endoscopic accessories at regular intervals [61, 63, 64, 161-164]. Multi-centre studies in the late 1980s/early 90s revealed that hygienic reprocessing of endoscopes did not follow the recommendations of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute or the gastroenterological societies in almost half of cases [165-168] and that contaminated devices were used in endoscopy owing to inadequate reprocessing methods. Although there is no data that directly prove that regular microbiological quality checks of endoscope reprocessing can lower the risk of endoscopy-related transmission of infectious agents, the multi-society guideline of the relevant American specialised societies reject microbiological surveillance as not evidence-based [65, 66]. Conversely, it has been shown that regular microbiological checks along the lines of a feedback improve the implementation of hygienically correct procedures for endoscope reprocessing [169] and that outside quality assurance within the framework of the bowel cancer screening programme [170] that was launched in 2002 has clearly lowered the number of complaints over endoscope reprocessing throughout Germany [171]. Hygiene and microbiological checks must be established in all endoscopy units in hospitals and surgeries in order to detect and overcome vulnerabilities in reprocessing [61, 63, 64, 106, 161-164]. The quality of automated reprocessing in washer-disinfectors (EWDs) must also be checked [123-125, 128, 129]. Test procedures using dummies (PCDs made of 2 m long teflon tubes, inner lumen 2 mm, contaminated with enterococcus faecium) were developed for type tests to enable standardised checks of EWD effectiveness (process quality) [129, 130]. Corresponding checks of relevant process parameters (e.g. dosage of cleaning and disinfecting agents, water volume, temperature, flushing pressure and time) shall be carried out within the context of the annual maintenance and check of the performance qualification and, as appropriate, within the context of revalidation.

Outcome quality of reprocessing is to be monitored by regular microbiological checks of the endoscopes [61, 63, 64, 106, 161-164].

Process quality of reprocessing is to be monitored by an annual maintenance and check of the performance qualification of a standard-compliant EWD [131].

So long as the checks of performance-determining process parameters carried out in the context of annual maintenance and performance qualification conform with the relevant parameters of the standard-compliant EWD, are congruent with the results of periodic microbiological testing and there are no signs suggesting a functional impairment of the EWD, the intervals between performance qualifications may be extended.

This notwithstanding, revalidation is mandatory after process-determining repairs or software updates and/or changes to detergents and disinfectants other than those used in the type approval test.

Although the demand for standardised automated reprocessing methods for medical devices [51] is justified and specialised societies, the Arbeitskreis Instrumenten-Aufbereitung - AKI (Working Group on Instrument Reprocessing) and the manufacturers of EWD accordingly focus on technologically verifiable processes [131], it must be underscored that thermolabile endoscopes can also be properly reprocessed manually (see above) and that the verification of process parameters alone cannot identify endoscope defects that affect the disinfection outcome (e.g. cracks or leaks in the endoscope channels that can eventually contaminate the endoscope's interior) With regard to endoscope reprocessing, therefore, the tried and tested practice of combining checks of an EWD'S process quality (annual maintenance and performance qualification check) with the monitoring of outcome quality (microbiological cultures) is upheld.

Practical advice on the implementation of hygiene and microbiological checks of endoscope reprocessing is given in Annex 3. The microbiological checks should cover the endoscope's instrument/suction channel and air-water/rinse channel. With duodenoscopes, the hollow spaces of the Albarran channel must also be checked (e.g. by swabbing laterally of the Albarran lever or by flushing the elevator wire channel). Microbiological checks of the lens rinsing system are required as well [106].

If contaminations are detected in reprocessed endoscopes that suggest recontamination of the final rinse water, microbiological checks of the final rinse water of the endoscope washer-disinfectors (EWDs) are recommended. Checking the reprocessing method in the EWD with contaminated PCDs (see above) is only advisable, for example, after invasive repairs [129, 131].

Hygiene monitoring and checks of the reprocessing standards in endoscopy units are the responsibility of the hospital or surgery's head physician within the framework of quality assurance. In hospitals, this task can be delegated to the head physician of the endoscopy unit, the hospital hygienist or the physician in charge of hygiene.

The measures taken for cleaning, disinfection and sterilisation are to be documented in accordance with the provisions of the Medical Devices Operator Ordinance (MPBetreibV) [113], e.g. by means of an endoscopy hygiene plan.

Know-how on the hygienic reprocessing of flexible endoscopes and measures to avoid nosocomial infections must be updated through regular training sessions (section 2 of the Medical Devices Operator Ordinance (MPBetreibV) [113], section 12 of the Biological Agents Ordinance (BioStoffV) [172]). Close cooperation between endoscopy physicians, endoscopy staff and hospital hygienists, infection prevention nurse and the physician in charge of hygiene is the prerequisite for successful quality management [113].

5 Measures for Protecting Staff

Among occupational risks, the risk of infection plays a major role for staff working in an endoscopy department [173]. Transmission of some pathogens, such as mycobacteria, may be air-borne. Hepatitis B, hepatitis C and HI viruses for example, may be transmitted through exposure of broken skin to blood-tainted saliva. Conceivably, *Helicobacter pylori* might be transmitted via contact with secretions. So far, studies on the seroprevalence of antibodies against *H. pylori* [174- 1761] have been inconclusive on whether the infection risk is higher in endoscopy units. Enteritis pathogens, hepatitis A viruses and cryptosporidia can be transmitted through exposure to faecal matter. HBV, HCV and HIV are the major blood-borne microorganisms transmitted via, e.g. a needlestick injury or injury with biopsy forceps. The risk of infection from a needlestick injury is 30% for hepatitis B, 3% for hepatitis C and approximately 0.3% for HIV [177]. Among occupational risks for endoscopy staff, the risk of allergies must be considered in addition to the risk of infection. As many as 30% of endoscopy staff are affected by an aldehyde allergy in the course of their career [147]. The risk of latex sensitisation must be considered as well.

With regard to the measures to be taken for health and safety at work, the field of endoscopy is subject to the Biological Agents Ordinance (BioStoffV) [172]. It requires the preparation of a risk assessment and identification of the necessary measures based on this assessment (sections 7 *et seqq.* BioStoffV). The activities in this field are normally unspecific activities of protection level 2. Regarding the exposure to hazardous chemical substances (e.g. disinfectants), the specifications of the Hazardous Substances Ordinance (*Gefahrstoffverordnung*) and the accident prevention regulations must be followed

Pursuant to section 15 (1) of the *BioStoffV*, the employer shall ensure that employees undergo occupational health examinations and information as stipulated in Part 2 of the Annex to the Ordinance on Occupational Healthcare (*ArbMedVV*) [178] before they start working with biological agents. Examinations must be repeated regularly and must be offered at the end of employment. Pursuant to Part 2 of the Annex to the *ArbMedVV*, a preventive occupational health care appointment must be offered to employees working with biological agents of risk group 3, before they start working and afterwards at regular intervals. The same applies for activities involving biological agents in risk group 2 unless they are not likely to lead to any adverse health effects according to the risk assessment and given the protective measures taken. Pursuant to Part 2 of the Annex to the *ArbMedVV*, employees who might be exposed to biological agents must be offered vaccination if an effective vaccine is available (e.g. HBV). The exact procedure is described in the *ArbMedVV*. Additional measures have to be stipulated in operating instructions in accordance with risk assessments. Regarding possible personal protection measures in endoscopy, reference is also made to the recommendations and advice listed in Annex 4.

These recommendations were drafted in 2002 on an honorary basis and without any interference from commercial interest groups, on behalf of the Commission for Hospital Hygiene and Infection Prevention by O. Leiß (Wiesbaden) (Chair of the working Group), U. Beilenhoff (Mainz), K. Euler (Erlangen), E. Kern-Waechter (Angelbachtal), A. Iffland-Pape (Wiesbaden), L. Bader (Munich), M. Pietsch (Mainz), M. Jung (Mainz), J. F. Riemann (Ludwigshafen), G. Unger (Bad Elster), and have been approved by the members of the Commission for Hospital Hygiene and Infection Prevention. .

The recommendations were updated in 2012 on an honorary basis and without any interference from commercial interest groups under the leadership of O. Leiß (Mainz) on behalf of the Commission for Hospital Hygiene and Infection Prevention and the Federal Institute for Drugs and Medical Devices.

Appendix 1: Checklist for manual (to a certain extend with mechanical support, if applicable) and automated reprocessing of endoscopes

A. Manual reprocessing of endoscopes

1. Pre-cleaning

Pre-clean immediately after the examination.

When removing the endoscope after the examination, immediately wipe the inserted part with a disposable cloth in order to clean off gross debris.

Immerse the distal end into a container with cleaning solution, alternately depress the suction valve and the air/water valve (use cleaning valve if possible). Purge cleaning solution and air through the endoscope channels and, while doing so, check the channels for patency and operability. A cleaning time of at least 20 seconds and a volume of at least 200 ml can be used as a guideline.

Finally, air-purge channels.

Disconnect the endoscope from the lens irrigation system, connecting tube, suction tube and light source and

transfer to the reprocessing room (transport in a closed container/basin with a lid).

2 Leak test

Apply water protection cap to protect electrical contacts in case of video endoscopes.

Immerse the endoscope in a basin with cleaning solution.

Remove all valves and distal cap and immerse in the cleaning solution.

Carry out leak test according to the manufacturer's instructions.

If the endoscope fails the leak test (perforation shown), do not attempt to further reprocess the endoscope. The outer casing must be wiped with instrument disinfectant and/or isopropanol 70 % (if approved by the endoscope manufacturer). The channels must be dried with compressed air. The endoscope must be wrapped in a protective film sheath, packaged in the dispatch case and transferred to the service centre with the note "leaky, not disinfected".

3. Manual Cleaning

Prepare cleaning solution according to the manufacturer's instructions.

Fully immerse the endoscope in the cleaning solution after the leak test.

Carry out all cleaning steps below the liquid's surface in order to avoid splash-back with contaminated liquid.

Clean outer casing of the endoscope with a lint-free disposable cloth.

Clean channel and valve openings, distal end and control components with a soft brush.

In case of duodenoscopes, move the Albarran lever into its central position and clean with an adequate soft brush from all sides.

For mechanical brush cleaning, repeatedly brush all accessible channel systems with an adequate disinfected flexible cleaning brush until the brush is free from debris when pulled through. Clean all valves and distal caps with a soft brush.

Connect all channels with device-specific adapters and fluid adapters and flush through with cleaning solution in order to remove all dissolved particles.

Clean cleaning brushes and disinfect together with the endoscope.

4. Rinsing off the cleaning solution

Place the endoscope and accessories (valves and cleaning brushes) in a basin containing clean tap water and flush all channels so as to remove detergent.

Air-purge all channels until unblocked.

5. Disinfection

Fully immerse cleaned endoscope and accessories into the disinfectant solution.

Fill all channels, device-specific adapters and fluid adapters with disinfectant solution so that all air bubbles are expelled.

Remove fluid adapters below the liquid's surface.

Cover the basin with a close-sealing lid.

Ensure that concentration and contact time of the disinfectant are adhered to closely, according to the manufacturer's instructions.

The date when the disinfectant solution was prepared has to be stated, for example on the basin.

Disinfection basins must be thoroughly mechanically cleaned and disinfected before they are changed.

6. Final Rinsing

Remove endoscope and accessories from the disinfectant solution wearing fresh disposable gloves.

Air-purge channels until unblocked.

Immerse disinfected endoscope and accessories in a basin/bath with microbiologically pure/sterile water; using fresh water for each device.

Rinse the endoscope's outer surfaces and flush all channels thoroughly with microbiologically pure/sterile water.

Rinse valves until water runs clear.

7. Drying and Storage

Subsequently carefully blow-dry all channels with compressed air.

Dry the endoscope's outer casing with a disposable cloth.

Perform functional test of the endoscope.

Afterwards, the endoscope can be used again for examining the next patient.

Store the endoscope dry and dust-free in a special endoscope cabinet, preferably hanging it up.

Store valves in a dry and dust-free place.

Store the endoscope without inserted valves.

The cleaning brushes used (flexible brushes, hand brushes and toothbrushes) have to be cleaned in an ultrasonic bath and subsequently disinfected after each use. After cleaning and disinfecting, the brushes have to be stored in a dry place that is safe from contamination at the end of each working day.

Since the cleaning solution is polluted with organic matter and chemical residues, a new solution has to be prepared at least each new working day while paying attention to health and safety at work. In the case of visible debris or contamination by faecal matter on an endoscope, the cleaning solution must be changed immediately. The cleaning basin must undergo thorough mechanical cleaning and disinfection at the end of each working day.

B. Manual reprocessing of endoscopes, partly with mechanical assistance

1. Pre-cleaning

Pre-clean immediately after the examination.

When removing the endoscope after the examination, immediately wipe the inserted part with a disposable cloth in order to clean off gross debris.

Immerse the distal end into a container with cleaning solution, alternately depress the suction valve and the air/water valve (use cleaning valve if possible). Purge cleaning solution and air through the endoscope channels and, while doing so, check the channels for patency and operability. A cleaning time of at least 20 seconds and a volume of at least 200 ml can be used as a guideline.

Finally, air-purge channels.

Disconnect the endoscope from the lens irrigation system, connecting tube, suction tube and light source and

transfer to the reprocessing room (transport in a closed container/basin with a lid).

2 Leak test

Apply water protection cap to protect electrical contacts in case of video endoscopes.

Immerse the endoscope in a basin with cleaning solution.

Remove all valves and distal cap and immerse in the cleaning solution.

Carry out leak test according to the manufacturer's instructions.

If the endoscope fails the leak test (perforation shown), do not attempt to further reprocess the endoscope. The outer casing must be wiped with instrument disinfectant and/or isopropanol 70 % (if approved by the endoscope manufacturer). The channels must be dried with compressed air. The endoscope must be wrapped in a protective film sheath, packaged in the dispatch case and transferred to the service centre with the note "leaky, not disinfected".

3. Manual Cleaning

Prepare cleaning solution according to the manufacturer's instructions.

Fully immerse the endoscope in the cleaning solution after the leak test.

Carry out all cleaning steps below the liquid's surface in order to avoid splash-back with contaminated liquid.

Clean outer casing of the endoscope with a lint-free disposable cloth.

Clean channel and valve openings, distal end and control components with a soft brush.

In case of duodenoscopes, move the Albarran lever into its central position and clean with an adequate soft brush from all sides.

For mechanical brush cleaning, repeatedly brush all accessible channel systems with an adequate disinfected flexible cleaning brush until the brush is free from debris when pulled through. Clean all valves and distal caps with a soft brush.

Connect all channels with device-specific adapters and fluid adapters and flush through with cleaning solution in order to remove all dissolved particles.

Clean cleaning brushes and disinfect together with the endoscope.

4. Rinsing off the cleaning solution

Place the endoscope and accessories (valves and cleaning brushes) in a basin containing clean tap water and flush all channels so as to remove detergent.

Air-purge all channels until unblocked.

5. Connection with disinfectant pump

Immerse clean endoscope with all accessories in a disinfection bath/basin.

All channels must be correctly connected to the tube and pump system with device-specific adapters and fluid adapters.

Cover the bath/basin with a matching lid.

Start the programme cycle.

Ensure that concentration and contact time of the disinfectant solution are adhered to closely, according to the manufacturer's instructions.

The date when the disinfectant solution was prepared has to be stated, for example on the bath/basin.

Some disinfectant pumps can, in addition to the disinfection step, also be used for the final rinsing and drying.

6. Final Rinsing

Remove endoscope and accessories from the disinfectant solution wearing fresh disposable gloves.

Air-purge channels until unblocked.

Immerse disinfected endoscope and accessories in a basin/bath with microbiologically pure/sterile water; using fresh water for each device.

Rinse the endoscope's outer surfaces and flush all channels thoroughly with microbiologically pure/sterile water.

Rinse valves until water runs clear.

7. Drying and Storage

Remove endoscope.

Subsequently carefully blow-dry all channels with compressed air.

Dry the endoscope's outer casing with a disposable cloth.

Perform functional test of the endoscope.

Afterwards, the endoscope can be used again for examining the next patient.

Store the endoscope dry and dust-free in a special endoscope cabinet, preferably hanging it up.

Store valves in a dry and dust-free place.

Store the endoscope without inserted valves.

The cleaning brushes used (flexible brushes, hand brushes and toothbrushes) have to be cleaned in an ultrasonic bath and subsequently disinfected after each use. After cleaning and disinfecting, the brushes they have to be stored in a dry place that is safe from contamination at the end of each working day.

Since the cleaning solution is polluted with organic matter and chemical residues, a new solution has to be prepared at least each new working day while paying attention to health and safety at work. In the case of visible debris or contamination by faecal matter on an endoscope, the cleaning solution must be changed immediately. The cleaning basin must undergo thorough mechanical cleaning and disinfection at the end of each working day.

8. Reprocessing of the disinfectant pump and accessories

Clean, disinfect and, as far as possible, thoroughly dry immersion basin and tube system after use at the end of each working day.

Renew the disinfectant solution in the tank of the device according to the manufacturer's instructions (dependent on the number of disinfection processes, idle time or debris).

Empty water tank and canister after use and dry thoroughly at the end of each working day.

Avoid standing residual water.

Renew sterile water filters according to the manufacturer's instructions, if appropriate.

Equipment support must conduct regular maintenance according to the manufacturer's instructions (e.g. once a year).

C. Automated Endoscope Reprocessing in Washer-Disinfectors

1. Pre-cleaning

Pre-clean immediately after the examination.

When removing the endoscope after the examination, immediately wipe the inserted part with a disposable cloth in order to clean off gross debris.

Immerse the distal end into a container with cleaning solution, alternately depress the suction valve and the air/water valve (use cleaning valve if possible). Purge cleaning solution and air through the endoscope channels and, while doing so, check the channels for patency and operability. A cleaning time of at least 20 seconds and a volume of at least 200 ml can be used as a guideline.

Finally, air-purge channels.

Disconnect the endoscope from the lens irrigation system, connecting tube, suction tube and light source and transfer to the reprocessing room (transport in a closed container/bath/basin with a lid).

2 Leak test

Apply water protection cap to protect electrical contacts in case of video endoscopes.

Immerse the endoscope in a basin with cleaning solution.

Remove all valves and distal cap and immerse in the cleaning solution.

Carry out leak test according to the manufacturer's instructions.

If the endoscope fails the leak test (perforation shown), do not attempt to further reprocess the endoscope. The outer casing must be wiped with instrument disinfectant and/or isopropanol 70 % (if approved by the endoscope manufacturer). The channels must be dried with compressed air. The endoscope must be wrapped in a protective film sheath, packaged in the dispatch case and transferred to the service centre with the note "leaky, not disinfected".

3. Manual Cleaning

Prepare cleaning solution according to the manufacturer's instructions.

Fully immerse the endoscope in the cleaning solution after the leak test.

Carry out all cleaning steps below the liquid's surface in order to avoid splash-back with contaminated liquid.

Clean outer casing of the endoscope with a lint-free disposable cloth.

Clean channel and valve openings, distal end and control components with a soft brush.

In case of duodenoscopes, move the Albarran lever into its central position and clean with an adequate soft brush from all sides.

For mechanical brush cleaning, repeatedly brush all accessible channel systems with an adequate disinfected flexible cleaning brush until the brush is free from debris when pulled through. Clean all valves and distal caps with a soft brush.

Connect all channels with device-specific adapters and fluid adapters and flush through with cleaning solution in order to remove all dissolved particles.

Clean cleaning brushes and disinfect together with the endoscope.

4. Rinsing off the cleaning solution

Place the endoscope and accessories (valves and cleaning brushes) in a basin containing clean tap water and flush all channels so as to remove detergent.

Air-purge all channels until unblocked.

5. Loading of washer-disinfectors (EWDs)

Place cleaned endoscope in the cleaning basket of the EWD according to the manufacturer's instructions; where applicable, connect the endoscope to the corresponding system.

Place accessories (e.g. valves, distal caps, cleaning brushes) in the accessories basket.

Insert the cleaning basket in the EWD, close the door, select a programme and start the EWD.

Removing the Endoscope from the EWD

Remove endoscope with disinfected hands or fresh disposable gloves.

Perform functional test of the endoscope.

If necessary, air-purge electrical contacts and channel systems.

Afterwards, the endoscope can be used again for examining the next patient.

Store the endoscope dry and dust-free in a special endoscope cabinet, preferably hanging it up. Store valves dry and dust-free.

Store the endoscope without inserted valves.

The cleaning brushes used (flexible brushes, hand brushes and toothbrushes) have to be cleaned in an ultrasonic bath and subsequently disinfected after each use. After cleaning and disinfecting, the brushes they have to be stored in a dry place that is safe from contamination at the end of each working day.

Since the cleaning solution is polluted with organic matter and chemical residues, a new solution has to be prepared at least each new working day while paying attention to health and safety at work. In the case of visible debris or contamination by faecal matter on an endoscope, the cleaning solution must be changed immediately. The cleaning basin must undergo thorough mechanical cleaning and disinfection at the end of each working day.

Appendix 2: Check lists for the Sterilisation of Endoscopic Accessories

1. Cleaning

Wipe off gross debris with a soft cloth soaked in a cleaning solution.

Disassemble accessories as far as possible and immerse them into the cleaning solution.

Ensure that concentration and contact time of the cleaning solution are adhered to closely, according to the manufacturer's instructions.

The cleaning solution should be a non-foaming solution which is suitable for manual as well as ultrasonic cleaning.

The cleaning solution should be changed at least once a day or immediately in the case of visible debris.

The outer surface of the individual instrument components should be cleaned with a soft cloth, sponge and an appropriate soft, disinfected brush.

Perform brushing and all subsequent cleaning steps under the surface of the liquid, in order to avoid splashes of contaminated liquid.

The cleaning solution has to be injected through all accessible channels and cavities to remove secretions and tissue remnants.

Remove instruments from the cleaning solution.

2. Ultrasonic cleaning

The basket of the ultrasonic cleaner must be sufficiently large and deep to enable full immersion of instruments.

Fill the basket of the ultrasonic cleaner with the disassembled instruments.

Ultrasonic "shadows"/dead spaces that cannot be reached by ultrasonic waves should be avoided. As a consequence, do not overload the basket.

Accessories such as biopsy forceps and polypectomy snares have to be placed in the basket with the cups of the biopsy forceps open (secured with clip) and the snares coiled with a diameter of at least 15–20 cm.

All channels and cavities must be filled with a disinfectant solution in such a way that no air bubbles are formed.

Seal the ultrasonic cleaner with a lid.

Leave the instruments in the ultrasonic cleaner for the contact time recommended by the manufacturer.

Take instruments out of ultrasonic cleaner.

Purge all channels with air in order to remove any remaining liquid.

3. Rinsing off the cleaning solution

Immerse the accessories into a basin with clean tap water, using fresh tap water for every rinsing procedure.

Flush all channels completely and thoroughly with water.

Thoroughly rinse outer surfaces of the instruments with tap water.

Take instruments out of the water.

Air-purge all channels in order to remove rinse water residues.

4. Disinfection

Soak cleaned instruments in a tray with disinfectant solution.

Fill all channels/lumina with a disinfectant solution in such a way that no air bubbles are formed.

Cover the bath with the matching lid.

Ensure that concentration and contact time of the disinfectant are adhered to, according to the manufacturer's instructions.

Remove instruments/instrument parts from the disinfectant solution with new disposable gloves.

5. Neutralisation/Rinsing

Immerse accessories in a basin/bath with microbiologically impeccable/sterile water; use fresh water for each accessory.

Thoroughly rinse the instruments and all channels with water in order to remove disinfectant residues.

Take instruments out of the water.

6. Drying and functional tests

Dry outer surfaces with a lint free cloth and compressed air.

Dry all channels thoroughly using compressed air.

Reassemble instruments and verify the correct functioning.

7. Sterilisation

Wrap instruments in adequate sterile goods packaging.

Select the appropriate sterilisation procedure for thermostable or thermolabile instruments according to the manufacturer's instructions and the national legal provisions and recommendations (steam sterilisation in the steriliser is recommended) [39].

After the sterilisation, check the sterile packaging for any damage and verify the sterilisation indicators.

8. Storage

Sterilised instruments have to be stored in sterile packaging in a closed cupboard, protected from dust, humidity and temperature variations.

Reprocessing of endoscopic accessories in washer-disinfectors (EWDs)

1. Cleaning

As described for the manual reprocessing.

2. Ultrasonic cleaning

As described for the manual reprocessing.

3. Rinsing off the cleaning solution

As described for the manual reprocessing.

4. Loading of the washer-disinfector (EWD)

Load cleaning basket or immersion basin of the appliance according to the manufacturer's instructions.

Connect tubes and channels to ensure complete and thorough irrigation of all lumina. The specific features of the device model must be taken into account.

Handles, wire coils, or guidewires must be fitted into a special basket.

5. Automated disinfection

Close device, select and start the cycle.

After the cycle has finished, verify whether all stages of the programme have been completed and whether all control parameters have been fulfilled.

Open washer-disinfector and remove accessories with disinfected hands or new disposable gloves.

Dry tubes and channels with compressed air; where appropriate, dry instruments with a lint-free cloth.

6. Functional test and maintenance of instruments

Reassemble instruments and verify the correct functioning.

Only apply instrument care products if necessary as they can adversely affect the sterilisation result [39].

7. Sterilisation

Wrap instruments in adequate sterile packaging.

Select an appropriate sterilisation procedure for thermostable or thermolabile instruments according to the manufacturer's instructions and the national legal provisions (steam sterilisation in the steriliser is recommended) [39].

After the sterilisation, check the sterile packaging for any damage and verify the sterilisation indicators.

8. Storage

Sterilised instruments have to be stored in sterile packaging in a closed cupboard, protected from dust, humidity and temperature variations.

Appendix 3: Details on hygienic-microbiological checks of the reprocessing of endoscopes

Measures to ensure the quality of the reprocessing of endoscopes include periodic microbiological checks of endoscopes. If several endoscopes are being used, at least one endoscope of each type and a total of at least two endoscopes which have been reprocessed using the same procedure have to be extracted at each examination date.

It would be desirable to perform a microbiological check on every endoscope in use at least once a year. A microbiological check of endoscopes is also advisable after repairs.

Sampling frequency

Quarterly tests are recommended (especially for manual or semi-automated reprocessing). The testing interval may be extended to semi-annual (especially in the case of automated, chemothermal reprocessing in EWDs) if the results of several endoscope tests gave no cause for complaint. In case of unfavourable results, re-examinations at short notice may be necessary until the repairs have been completed.

Sampling Scope and Implementation

The following methods are currently used for microbiological surveillance of endoscopes:

Flushing of endoscope channels,

Swab tests of points of the endoscope which are difficult to reach during cleaning and disinfection (e.g. endoscope's distal end, recess behind the Albarran lever of duodenoscopes),

"Sponge test" (Pulling a piece of foam through the instrument channel).

Data of the endoscopes checked (i.e. type and number) has to be recorded. A sterile physiological saline solution should preferably be used as a flushing liquid. It is advisable to add adequate disinfectant neutralisers to inactivate any detergent and disinfectant residues in the endoscope. The "sponge test" is rather a visual check for macroscopically discernible debris in the instrument channel of the endoscope and cannot be generally recommended as a method for microbiological checks. Contamination of the endoscope and mixing up of samples of different sampling points must be avoided when samples are taken. Hands must be disinfected hygienically before samples are taken. After sampling, a second reprocessing of the endoscopes examined might be necessary (e.g. re-rinsing and drying of the channels). The specifications of the testing laboratory must be followed.

Flushing of endoscope channels:

Flushing liquid: 20 ml per channel, collect in an adequate laboratory vessel whilst ensuring sterility.

Of all accessible channels (instrument channel and air/water channel), at least one channel, preferably the instrument channel, must be examined.

Where appropriate, an examination of the air/water channel is recommended in addition to the compulsory examination of a liquid sample taken from the lens irrigation system (bottle and connecting tube, prepared as for patient examinations).

The suction channel can optionally be examined by sucking flushing liquid into a tracheal suction set that is interconnected at the plug.

Liquid samples must be transported to the laboratory and processed without delay. The samples should be cooled if longer transportation time is to be expected.

How to take swabs of parts of the endoscope which are critical with regard to reprocessing:

Wet sterile swab with physiological saline solution.

Collect a swab sample on the surface of the area to be examined.

Place swab in adequate medium, transport to the laboratory and process without delay.

Only laboratories with experience in the hygienic-microbiological field should be employed to undertake endoscope checks; they then evaluate the findings and offer advice in case of deficiencies.

Hygienic-Microbiological Requirements of Endoscope Testing (Evaluation of Test Results)

No detection of *Escherichia coli*, other enterobacteriaceae or enterococci as indicators of insufficient cleaning or disinfection.

No detection of *Pseudomonas aeruginosa*, other pseudomonads or nonfermenters as indicators of insufficient final rinsing or drying.

No detection of hygiene-relevant pathogens, such as *Staphylococcus aureus*, as indicators of, for example, contamination of the endoscope after reprocessing because of poor storage or inadequate hand hygiene of staff.

No detection of viridans streptococci as an indicator of contamination with pharyngeal flora in case of endoscopes which are used for examining microbially uncontaminated areas of the upper gastrointestinal tract or respiratory tract (e.g. bronchoscopes or side-viewing duodenoscopes for ERCP).

It is advisable to quantify the detected germ load. The guideline for the Total Viable Count is ≤ 1 CFU per ml liquid sample (20 ml; if the above-mentioned microbiological-qualitative requirements are adhered to).

General reference is made to the "The Microbiology Procedures Quality Standards" by DGHM (German Society for Hygiene and Microbiology) concerning sample processing, examination method and germ differentiation. Membrane filtration of 10 ml samples is one of the recommended examination methods for flushing liquids (culture at 37°C). Agar culture in dilution series or pouring method are recommended for determining the bacterial count. There is a lack of experience regarding the suitability of immersion culture media for endoscopes flushing liquids.

If the above-mentioned requirements are not met during the periodic endoscope inspection regarding the quality of the reprocessing process, the sub-steps of the reprocessing method

which are subject to complaint must be critically examined and shortcomings must be corrected. Examining devices which serve for reprocessing endoscopes, e.g. EWDs or a semi-automatic machines, might be required.

Concerning the examination of reprocessing devices, reference is made to the forthcoming DIN EN 15883 for washer-disinfectors (validation and operation). Test blocks (“dummies”) with test debris and germ load with *Enterococcus faecium* (ATCC 6057) can be used as bioindicators [81].

Determining the process quality of reprocessing equipment is necessary in order to validate type tests of standard EWDs and recently set-up devices (installation and operational qualification) and during annual maintenance and performance qualifications [131]. After method-interfering repairs, updates to the software with changes to the process cycle or when changing the detergent or disinfectant used for the type test, an additional second performance qualification is mandatory. Periodic testing of the microbiological quality of the final rinse water is especially recommended when semi-automatic machines are used for endoscope reprocessing (same laboratory methodology and requirements as for flushing liquids from endoscope channels).

Appendix 4: Guidance on Staff Protection in Endoscopy

1. General measures

General hygiene measures [179-182] including hand hygiene measures [134, 183-185] must be strictly observed in order to prevent hospital-acquired infections and avoid health damages caused by disinfectants.

The skin and mucous membranes should not come directly into contact with blood or other bodily fluids. In order to prevent injuries, adequate measures must be taken (Accident Prevention Regulation) [186]).

2. Protection against Contamination

During endoscopy, physicians and assisting endoscope staff have to wear nursing scrubs, disposable gloves and, where appropriate, surgical masks and protective gowns to avoid contamination [140, 141].

In addition, surgical masks and goggles have to be worn when treating patients where spurting of blood or bodily secretions is likely (e.g. emergency endoscopy in the event of upper GI bleeding) and in case of patients with contagious diseases (tuberculosis, hepatitis B or C, HIV). Staff must always wear dust masks (FFP2 masks) in case of bronchoscopy on patients with open tuberculosis of the respiratory tract. Surgical masks do not provide any protection against inhaling aerosols which contain microorganisms.

Cut-resistant gloves and liquid-proof, long-sleeve protective gowns/nursing scrubs and plastic aprons, surgical masks and goggles have to be worn during endoscope reprocessing in order to avoid possible contact of skin and mucous membrane with pathogens of nosocomial infections.

After each patient, the surface of the area near the patient (e.g. examination table) has to be thoroughly disinfected and, where appropriate, the floor has to be disinfected after contamination. Endoscopic examinations of airborne infectious patients should be carried out at the end of the work programme.

3. Protection against Injuries

Since needlestick injuries are by far the most frequent cause of exposure to hepatitis viruses or HIV in the medical field, protective measures against injuries are particularly important (Accident Prevention Regulation [186]).

Breakproof and puncture-proof containers must be used for safely disposing of pointed, sharp, potentially contaminated objects, such as hypodermic needles.

Used needles must not be put back into their plastic cover and must not be bent or snapped [177] but must be disposed of immediately, i.e. without passing them on to endoscope staff, in a break- and puncture-proof container at hand.

Injuries must be avoided when dealing with biopsy forceps. Manual cleaning of biopsy forceps, especially those with spikes, must therefore be performed thoroughly and with the

utmost care – a hepatitis C transmission due to an injury with biopsy forceps has been described [14].

The necessary rules of conduct after a needlestick injury and current recommendations for post-exposure prophylaxis [186] must be familiar to all those working in outpatient and inpatient endoscopy departments and must be implemented immediately if required.

4. Infection Protection through Vaccination

As hepatitis B is still the most frequent infectious disease in people working in healthcare [173], all nursing staff, doctor's assistants and physicians working in endoscopy should be actively vaccinated against hepatitis B.

The vaccination success of the primary immunisation has to be verified four to eight weeks after the third vaccination by checking the anti-HBs titer. If the anti-HBs value is below 100 IE/l after primary immunisation, another vaccination (one dose) has to be administered immediately, and a subsequent check-up has to be carried out.

In case of an anti-HBs value above 100 IE/l, a booster (one dose) has to be administered after ten years (recommendations of the standing committee on vaccination (STIKO) [187]).

If possible and for insurance reasons, the hepatitis B and C as well as the HIV-status should be documented before duty is taken up in an endoscopy department [4]. It should be documented in writing if a hepatitis B vaccination is refused.

5. Reducing the Aldehyde Load

Skin contact with aldehydic disinfectants and inhalation of aldehyde vapours must be avoided.

Cut-resistant gloves and liquid-proof gowns must be worn when cleaning and manually reprocessing endoscopes.

Basins for disinfecting instruments must be covered. Flexible endoscopes and endoscopic accessories should preferably be disinfected in the closed system of a washer-disinfector in order to protect staff from exposure to the disinfectant [70].

Endoscopes must be reprocessed in a separate reprocessing room that can be ventilated easily and must not be used for other purposes (storage, changing room, common room).

Appendix 5: Cross References to Other Legal Provisions and Recommendations to which the present Recommendations relate

Aspect	Cross reference	Source
Reprocessing in general	German Medical Devices Operator Ordinance (MPBetreibV) of 29 July 2009 RKI Recommendations for the Reprocessing Medical Devices	MPBetreibV BGBl I, page 2326 [113] <i>Bundesgesundheitsbl.</i> 2012 in print [51]
Sterility	RKI Recommendations for the Reprocessing Medical Devices	<i>Bundesgesundheitsbl.</i> 2012 in print [51]
Disinfectants	German Hazardous substances legislation (GefStoffV) of 28 July 2011 Manufacturers' instructions List of the VAH List of the RKI	GefStoffV <i>Bundesgesundheitsbl.</i> I p. 1622 [188] [102] [103]
Requirements for Endoscope Washer-Disinfectors (EWDs)	EN ISO 15 883-1 Recommendations of the working group on Endoscopy	[125, 129, 130] Höller/Krüger/Martiny/Zschaler: Überprüfung von RGD im prakt. Betrieb.
Documentation requirements	German Medical Devices Operator Ordinance (MPBetreibV) of 29 June 1998, 29 July 2009	<i>Bundesgesundheitsbl.</i> I p. 2326 section 9, subsection 2 MPBetreibV [113]
Prion diseases	Memoranda of the RKI Final report of the vCJK task-force at the RKI Annex 7: Measure for minimising the risk of a transmission of CJD/vCJD through medical devices to the "Hygiene Requirements for the Reprocessing of Medical Devices"	<i>Bundesgesundheitsbl.</i> 1998; 41: 279-285 [45-49, 189]
Health and safety at work	German Biological Agents Regulations (BioStoffV) of 18 December 2008 section 7ff. (BioStoffV) German Accident Prevention regulations (UVV)	<i>Bundesgesundheitsbl.</i> I, page 2768 [172] [186]

Aspect	Cross reference	Source
	Regulation on preventive occupational medicine (ArbMedVV)	[178]
Staff protection	Recommendations on vaccinations	Regulation on preventive occupational medicine (ArbMedVV) [178] recommendations of STIKO [187]

These recommendations were drafted on an honorary basis and without any interference of commercial interest groups, on behalf of the Commission for Hospital Hygiene and Infection Prevention by O. Leiß (Wiesbaden) (Chair of the working Group), U. Beilenhoff (Mainz), K. Euler (Erlangen), E. Kern-Waechter (Angelbachtal), A. Iffland-Pape (Wiesbaden), L. Bader (Munich), M. Pietsch (Mainz), M. Jung (Mainz), J. F. Riemann (Ludwigshafen), G. Unger (Bad Elster), and have been approved by the members of the Commission for Hospital Hygiene and Infection Prevention.

The recommendations were updated in 2012 on an honorary basis and without any interference from commercial interest groups under the leadership of O. Leiß (Mainz) on behalf of the Commission for Hospital Hygiene and Infection Prevention and the Federal Institute for Drugs and Medical Devices.

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Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers;
Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
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Appendix 6:

On reprocessing flexible cystoscopes and bronchoscopes

Commentary of the Commission for Hospital Hygiene and Infection Prevention, the Federal Institute for Drugs and Medical Devices and the RKI

In accordance with the "Hygiene Requirements for Reprocessing Medical Devices" [1], flexible cystoscopes and bronchoscopes which are being used for diagnostic purposes have to be considered as "semi-critical B" medical devices, which are – unlike i.e. colonoscopes – being used in sterile bodily cavities or pushed into normally sterile areas of the bronchus. This requires lower germ counts (sterility; see table 1, index 2 of the recommendation) [1]. The regular passage through the physiologically colonised urethra or the pharynx and the trachea and the limited possibilities to sterilise flexible endoscopes have led to numerous inquiries of users and prompted these detailed explanations as an appendix to the recommendation.

A flexible cystoscopy is a diagnostic measure which, compared to the use of rigid cystoscopes that can be steam sterilised, is considerably more gentle for patients. However, adequate methods of sterilisation (i.e. EO sterilisation) are only available in very few facilities. In view of the above and considering the available information on infection risk and the efficiency of adequate disinfection procedures, the reprocessing of flexible endoscopes used in cystoscopy has been assessed separately. Consequently, the reprocessing of flexible endoscopes used in cystoscopy without final sterilisation seems justifiable under the condition that suitable measures for cleaning, disinfection and re-rinsing are being implemented according to written-down standard working instructions. This evaluation holds equally true for bronchoscopes. In this context, we would also like to point to the "Hygiene Requirements for the Reprocessing of Medical Devices and Additional Endoscopic Instrumentation" [2] and the recommendation "Hygiene Requirements for the Constructional-Functional Design and Instrumental Equipment of Endoscopy Units" [3].

In this context, **disinfection and re-rinsing** need to be outlined separately. **Instrument disinfectants with CE marking and based on glutaraldehyde, orthophthaldialdehyde or peracetic acid** [4] which have been proven effective against bacteria, including mycobacteria (testing should include *M. avium*) and viruses (declared as "virucide", see working group "viruzidal activity" 2004) [5] and which have been designed for this field of application by the manufacturer are suitable for the final disinfection. We emphasise the need for a thorough prior cleaning because of possible impairment of the effect due to debris from the preceding use on a patient [4, 6, 7]. Reference is further made to the instructions of the

endoscope manufacturer as laid down in the manual on the material compatibility of specific medicinal products with the endoscopes.

Specific formulas (that is medicinal products which contain for example glutardialdehyde in a nonionic surfactant solution, peracetic acid salts in a buffer solution) can deviate from the pure active substance solutions in their characteristics relevant to the application (i.e. effect, material compatibility, stability). Instructions on pure active substance solutions can therefore only serve as a guideline and have to be completed with the specifications of a disinfectant by the manufacturer. While the substances listed above have proven to work well, there are no recommendations for specific methods such as "electrolysed" or "super-oxidised" water yet [8-11].

All outer and inner surfaces of the endoscope have to be re-rinsed with suitable sterile or sterile-filtrated water after the disinfection. This step in the reprocessing procedure has to ensure that the endoscope and the patient do not suffer any damages because of residues from the previous treatment and prevent that the endoscope is re-contaminated. If the reprocessing is not carried out immediately before using the endoscope, it has to be stored in a dry place and in such a way as to prevent contamination.

In order to ensure consistent quality of the effective procedure, preference should be given to automated procedures. As a minimum standard, the implementation has to be carried out according to standard working guidelines put down in writing and by suitably trained staff. Interventions in areas of the urogenital system which are in close proximity to the bladder have to be carried out using sterile medical devices. Concerning the reprocessing of endoscopic accessories, reference is made to the recommendation "Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation " [2].

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Appendix 7:

Reprocessing of Ultrasound Probes for use in Gynaecology

Joint statement of the Federal Institute for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI). The BfArM and RKI were informed by health offices and gynaecologists about the issue of insufficient reprocessing of ultrasound probes for transvaginal use in everyday practice. According to them, it is common use to put a latex cover over these ultrasonic probes as the only protective measure and to discard the cover after the examination. This procedure is not in line with the required diligence that is necessary when reprocessing semicritical medical devices according to the joint recommendation [\[1\]](#) of the BfArM and the Commission for Hospital Hygiene and Infection Prevention at the RKI and constitutes a violation of the required patient and user safety. When handling the cover, smear infections or cross-contamination cannot be ruled out. Therefore, the probe has to be disinfected after each examination (after removing the cover) so as to kill bacteria, fungi and viruses[\[2\]](#).

According to the essential requirements for medical devices (Council Directive 93/42/EEC, Annex 1, section 13.6), the instructions for use must contain information on the appropriate processes to allow reuse if the device is reusable. Manufacturers of ultrasonic probes for transvaginal use are therefore obliged to provide, together with the instructions for use, information on at least one effective and material compatible disinfection procedure with the above-mentioned spectrum of activity. The effectiveness when using recognised methods has to be proven by expert opinions.

The additional use of a cover during the examination shall remain unaffected by this requirement. Due to current events, we would like to point out that we consider instructions in a manual concerning the alternative use of disinfectants or covers which emphasise that the latter procedure has no impact on the material aging process and therefore increases the durability of a product as a deception under the required user and patient safety as these instructions indirectly recommend to refrain from a disinfection.

In a letter dated 21 January 2005, manufacturers of ultrasonic probes for use in gynaecology were asked to immediately take action if the user information on transvaginal use of ultrasonic probes were not in line with the requirements listed above. The manuals should be changed immediately and the users should be provided with the necessary information in a suitable way and as quickly as possible.

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Appendix 8:

Reprocessing of ultrasonic probes with mucous membrane contact

More information about the Joint statement of the Federal Institute for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI) of 17 February 2005:

After the publication of the Joint statement of the Federal Institute for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI) on the Reprocessing of Ultrasound Probes for use in Gynaecology ([Recommendation of 17.02.2005](#); in German), we were told by representatives from different medical fields that the sometimes insufficient information by the manufacturer on the reprocessing of ultrasonic probes as well as uncertainties concerning the required procedure for the users is not limited to the transvaginal use but consists a general problem for the application of probes with mucous membrane contact.

Once again, we have written to manufacturers of ultrasonic probes and associations of manufacturers of medical devices and asked them, if they haven't already done so, to immediately include at least one effective and material compatible disinfection procedure that kills bacteria, fungi and viruses into the manual and to provide the necessary information on disinfection to the users of these ultrasonic probes as quickly as possible.

Additionally we would like to draw your attention to the fact that, while paying attention to the manufacturers' instructions, the operator or user bears responsibility for the correct reprocessing of medical devices and their proper application that does not put the safety and health of patients, users or third parties at risk.

If you have any questions concerning reference number 4306/05, please contact:

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