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 (gastroscopes 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 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 seewww.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 infectionand 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, excreters (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 rinsingsystem 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 examinedpatient

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 excreters

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 tothe used detergents and disinfectants

contaminated detergents or disinfectants

excessive idle time

contaminated dosing system

contaminated tubing systems, receptacles orwasher-disinfectors;

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

fixation of organic matter and encrustation of microorganisms.

Flaws or special design features of the endoscope'schannel system

e.g. narrow lumens or branched channels or channelswhich 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 endoscopechannels

leak in the instrument channel with entry of microorganismsinto the interior of the endoscope

Flaws of endoscopic accessories and the lensrinsing system

improperly reprocessed accessories (biopsy forceps,snares etc.)

contaminated tap water or non-sterile distilled waterfor 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 endoscopechannels)

storage or transportation of the endoscope in thedispatch case
storage without protection against recontamination(e.g. endoscopes hanging openly in the examinationroom) 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 andtime-tested measures of preventing infection transmission. Pursuant to section 4, subs. 2 of the German MedicalDevices Operator Ordinance (MPBetreibV), cleaning,disinfection and sterilisation of medical devices must beperformed 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 forregulatory 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 allgastroenterological, 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 translumenal 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 ofEndoscopy 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 indissolving protein and fat residues and has a highmicrobial efficacy; it can cause adverse materialchanges. 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 conclusivelyproven to be superior to others.

2.3. Disinfection

Throughout the world, aldehyde solutions or peracetic acid are almost exclusively used for disinfecting (after non-fixatingcleaning) flexible endoscopes and endoscopicaccessories, owing to their broad-spectrumeffectiveness and efficacy [55, 56, 58-60, 66-71, 80, 81]. Other disinfectants (e.g. isopropanol 70%, iodine-containingpreparations, 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 cleaningand 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 assistivepersonnel, wear and tear of the equipment, use in emergencymedical 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].as

well as other recommendations for the constructional-functional design and equipment of endoscopy units [109-112] ,
The quality and diligence in reprocessing flexible endoscopescritically 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 DevicesOperator Ordinance (MPBetreibV), medical devicesmay only be used by persons who have the required training, knowledge and experience for this work (subs. 2), and theoperator 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 InfectionAct (IfSG), in-house infection control protocols have to be specified in hygiene plans.
Close cooperation with infection control personnel (e.g. hospitalhygienist, infection prevention nurse, hospital physician in chargeof hygiene) is recommended.

3 Principles and Implementation of Flexible Endoscope Reprocessing
A distinction is made between manual reprocessing, semi-automated reprocessing and automated reprocessingmethods 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 reprocessingmethod, 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 toendoscope washer-disinfectors (EWDs), in which thewater used for final rinsing is disinfected by heating andis subsequently cooled, in order to prevent the endoscopesbeing recontaminated, e.g. by *Pseudomonasspp., 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 afterthe 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 downwith a lint-free disposable cloth immediately after theendoscopic 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 thelight 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 reprocessingroom in a closed container (e.g. a basin witha 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 EWDmanufacturer.
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 theVAH'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, virucidaland 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 isinadequate 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 microbiologicallypotable 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 thesafest method, and is to be preferred

If endoscopes used for examining not microbially colonised body sites (e.g.bronchoscopes or side-viewing duodenoscopesfor ERCP) are manually reprocessed, sterile watermust 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 channelswith isopropanol 70% increases the effectiveness of dryingand 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 0.5bar) 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

processer 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 endoscopechannels have not sufficiently dried, stagnationzones 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 (ethylenoxide 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 whenbeing 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 mustbe 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 endoscopicaccessories (e.g. biopsy forceps, polypectomy snaresand 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 biopsymaterial having been fixated with glutaraldehyde) havebeen 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 manufacturersof 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 andInfection Prevention at the Robert Koch-Institute andthe 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 arerequired 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 withcontaminated PCDs (see above) is only advisable, for example, after invasive repairs [129, 131].