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 andsterilisation are to be documented in accordancewith the provisions of the Medical Devices OperatorOrdinance (MPBetreibV) [113], e.g. by means of anendoscopy 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 OperatorOrdinance (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 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.* Bio StoffV). 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 SubstancesOrdinance (*Gefahrstoffverordnung*) and the accident prevention regulations must be followed

Pursuant to section 15 (1) of the *BioStoffV*, theemployer 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 beoffered 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 recommendationsand 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] *Bundesgesundheitsbl.* 2012 in print [51]
Sterility	RKI Recommendations for the Reprocessing Medical Devices	*Bundesgesundheitsbl* 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 *Bundesgesundheitsbl.* 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	*Bundesgesundheitsbl.* 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"	*Bundesgesundheitsbl.* 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)	*Bundesgesundheitsbl.* 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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