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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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## 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 (*Medizingerätebetriebsverordnung - 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.