Recommendations by the Quality Task Group (89)

Programme Controls Part 2: Endoscope washer-disinfectors with chemothermal disinfection

T. Appel, P. Bröcheler, D. Diedrich, S. Fiedler, A. Forster, A. Jones, M. Kamer, S. Krüger, E. Schmidt, C. Schmid, M. Schreiner, U. Zimmermann; Gast: U. Beilenhoff (DEGEA)

E-mail: qualitaet@dgsv-ev.de

This recommendation is Part 2 of Recommendation No. 86 by the Quality Task Group entitled Programme Controls. These two recommendations replace Recommendation Nos. 11 and 12 (2000).

Introduction

➜ AUTOMATED PROCESSES should be preferred when reprocessing flexible endoscopes.

Flexible endoscopes are preferably reprocessed with **➜ AUTOMATED PROCESSES**, while paying attention to thorough manual pre-cleaning. The automated sequence of programme cycles assures reproducibility of the individual steps of the programme. Another major advantage is that in each batch fresh water and fresh process chemicals are dispensed thus pre-empting any decline in the cleaning and disinfectant efficacy resulting from repeated use. To ensure that all channels are properly flushed, the endoscopes must be connected to their designated connectors in the Endoscope Washer-Disinfector **➜ (EWD)**, used for flexible endoscopes, as specified in the manufacturer's instructions. The KRINKO/ BfArM Recommendation "Hygiene requirements for reprocessing medical devices", 2012, Annex 8 [1], including the supplementary commentaries [7] and DIN EN ISO 15883, Part 1; 4 and 5 must be observed [2].

➜ IN THE EWD flexible endoscopes must be connected to their designated connectors as specified in the manufacturer's instructions.

Fundamentals

The EWD is equipped with either fixed programmes or with a range of modifiable programmes. The programmes used consist of individual process steps, each of which contributes to the overall outcome. If performance of any of these **➜ PROCESS STEPS** is suboptimal, the overall results could be jeopardized.

➜ ALL PROCESS STEPS contribute to the overall outcome. and optimum performance of each step should therefore be assured.

The following process steps are available:

- Pre-cleaning (optional)
- Cleaning
- Intermediate rinse (optional)
- Chemothermal disinfection
- Intermediate rinse (optional)
- Final rinse
- Drying (optional)

The chief determinants in the process steps are the process chemicals, water quality, temperatures, mechanical action (lumen purging), exposure times as well as specific cleaning and microbiological requirements.

➜ THE ENTIRE REPROCESSING TIME has to be taken into account.

In general, operators want to have the shortest possible automated programme cycle time, even while having to take account of the **➜ ENTIRE REPROCESSING TIME**, i. e. manual pre-cleaning and automated programme sequences.

The manual component of reprocessing makes an important contribution to the quality of the overall outcome. Two guidelines are available for validation of the manual and automated parts of the reprocessing process [3] and [4].

The validation guideline for EWDs [4] should be consulted for details of the chemico-physical water quality (e.g. <3°d) as well as the instructions provided by manufacturer of the respective process chemicals. The microbiological water quality should be at least that of drinking water.

Manual pre-cleaning

To pre-clean, coarse soils are removed from the endoscope insertion tube and operating unit as well as from the entire channel system. This is done by first purging and flushing already in the endoscopy suite unit, followed by manual cleaning, including cleaning with a brush, of all accessible channels in the reprocessing unit. In addition to removing coarse soils, this pre-cleaning measure also includes a patency test of all channels. Functional testing is rounded off with a leakage test. To prevent protein denaturation it is advisable to use the same non-fixing process chemicals for ➜ **REMOVING COARSE SOILS** in the endoscopy suite unit as well as in the reprocessing unit. Reprocessing immediately after use is urgently recommended.

➜ **WHEN REMOVING COARSE SOILS** the same non-fixing process chemicals should be used in the endoscopy suite unit as well as in the reprocessing unit.

Leakage test

If there were to be any leaks or perforations, the flexible endoscope would come into contact with the process chemicals and this could cause serious damage.
The leakage test is performed in accordance with the endoscope manufacturer's instructions before the beginning of manual reprocessing at the endoscopy unit either in the form of a

- manual test or an
- automated leakage test in the EWD, but this must be completed before contact with the load and process chemicals [2]

Since leaks occasionally go undetected in manual tests, or perforations can occur also during an automated process, in the interest of safety it would be advisable to perform, in addition to the manual test, an ➜ **AUTOMATED TEST** in the EWD and interrupt the process in the event of a pressure drop.

➜ **AN AUTOMATED LEAKAGE TEST** should be performed in the EWD in addition to the manual test.

Programme steps

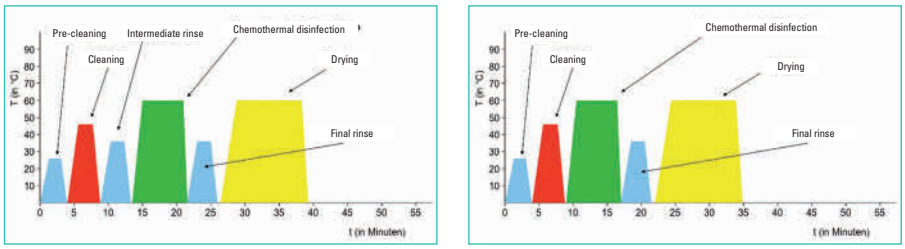
Pre-cleaning

This pre-cleaning measure targets those areas not accessible to manual pre-cleaning, e. g. the operating unit and jet channel. Cold water, without any fixing process chemicals, is used here to prevent protein denaturation.

Cleaning

The cleaning process step is aimed at removing any soils still adhering to the medical device. The detergents used are suitable pH-neutral or mildly alkaline products. The instructions supplied by the detergent manufacturer must be observed
To test the ➜ **MINIMUM CLEANING EFFICACY** visual inspection and protein residue tests are performed with the tube test model at the time of validation. The methods and acceptance can be consulted in the Validation Guideline for EWD [4].
This step is generally carried out in the temperature range between 35 and max. 60 °C with a 3–5 min exposure time.

➜ **MINIMUM CLEANING EFFICACY** should be determined at the time of validation using visual inspection and protein residue tests performed with the tube test model .



Typical process diagram: chemothermal reprocessing cycle with or without intermediate rinse

Rinse/intermediate rinse steps

To ensure that no residues of the chemical products used will linger on the medical devices or be entrained into the ensuing disinfection step, an intermediate rinse step with water or demineralized water is often recommended. This can be omitted to save time if the manufacturer of the respective process chemicals can certify that ➜ **ENTRAINMENT** of any such products will not negatively impact chemothermal disinfection [2].

➜ **ENTRAINMENT** of process chemical residues into the chemothermal disinfection step can be avoided by using an intermediate rinse with water or demineralized water.

Chemothermal disinfection

Since flexible endoscopes are heat sensitive (thermolabile) and tolerate temperatures of only up to 60 °C, thermal disinfection is not permitted. Instead, chemothermal disinfection is used. The following criteria apply:

The disinfectant must lend itself to use in an EWD, must not generate any foam and must be effective within the selected temperature range.

The disinfectant must be compatible with the detergent.

The disinfectant muss be able to generate the required microbicidal action, i.e. be endowed with bactericidal (incl. against mycobacteria), fungicidal and viricudal (Krinko/BfArM Recommendation) activity. The manufacturer of the process chemicals must be in possession of the relevant expert opinions attesting to virucidal activity in accordance with the provisions of the DVV/RKI, 2008 [5, 6].

The disinfectants generally used are based on aldehydes or peracetic acid. The respective expert opinions should be consulted for details of the temperature, exposure time and concentration specified by the manufacturer.

Intermediate rinse

The intermediate rinse step helps to reduce the residues of the process chemicals used so that the limit values prescribed by the manufacturer are safely complied with in the final rinse.

To prevent microbiological recontamination of flexible endoscopes, water of an appropriate quality must be used (e. g. Sterifilter, UV lamp, boiler).

Final rinse

In the final rinse step the residues of the process chemicals used are further reduced so that the limit values prescribed by the manufacturer are safely complied with.

To prevent microbiological recontamination of flexible endoscopes, the ➜ **WATER** used for the final rinse must also be of irreproachable microbiological quality (e. g. Sterifilter, UV lamp, boiler).

➜ **THE WATER** used for the final rinse must be of irreproachable microbiological quality to prevent microbiological recontamination of flexible endoscopes.

100 ml samples of the final rinse water must be free of legionellae, Pseudomonas aeruginosa and mycobacteria and contain altogether fewer than 10 cfu/100 ml (see guideline, Annex 11) [4].

Drying

Flexible endoscopes must be properly ➜ **DRIED** before they are stored since any residual microorganisms could grow in a moist environment and present a danger to patients.

➜ **DRYING** must be sufficient to prevent growth of any residual microorganisms.

References

1 KRINKO-BfArM Recommendation "Hygiene requirements for reprocessing medical devices", 2012
2 DIN EN ISO 15883 Washer-disinfectors – Part 1: General requirements, terms and definitions and tests; Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes; ISO/TS 15883-5: Test soils and methods for demonstrating cleaning efficacy
3 Guideline for validation of manual cleaning and manual chemical disinfection of medical devices, 2013, compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI)
4 Guideline for validation of automated cleaning and disinfection processes for reprocessing thermolabile (heat-sensitive) endoscopes, 2011, compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI)
5 Guideline compiled by the German Association for Control of Viral Diseases (DVV): Quantitative testing of virucidal efficacy of chemical disinfectants on non-porous surfaces. HygMed 2012; 37–3.
6 Guideline compiled by the DVV and by the RKI on testing of virucidal efficacy of chemical disinfectants in human medicine. Federal Health Gazette 2008, 51, 937–945.
7 Commentary on Annex 8 "Hygiene requirements for reprocessing flexible endoscopes and endoscopic accessories" from the recommendation "Hygiene requirements for reprocessing medical devices" Epidem. Bulletin 15 July 2013, No. 28