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).

| AUTOMATED PROCESSES should be preferred when reprocessing flexible endoscopes. |

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

| ALL PROCESS STEPS contribute to the overall outcome. Optimum performance of each step should therefore be assured. |

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

### Introduction

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 I II, including the supplementary commentaries [7] and DIN EN ISO 15883, Part 1; 4 and 5 must be observed [2].

### 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. 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. 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.

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<tr>
<th>Manual pre-cleaning</th>
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| To pre-clean, coarse soils are removed from the endoscope insertion tube and oper-
ating 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 de-
naturation 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.

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<th>Leakage test</th>
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| 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 in-
structions 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.

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<th>Programme steps</th>
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<td><strong>Pre-cleaning</strong></td>
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| 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 chemi-
cals, is used here to prevent protein denaturation.

<table>
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<th>Cleaning</th>
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| 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 valida-
tion using visual inspection and protein residue tests performed with the tube test model.
ENTRAINMENT of process chemical residues into the chemothermal disinfection step can be avoided by using an intermediate rinse with water or demineralized water.

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

DRIYING must be sufficient to prevent growth of any residual microorganisms.

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].

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.

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.

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.

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.

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 (DGHK), 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 (DGHK), 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.