

## Recommendations by the Quality Task Group (71)

# Reprocessing ophthalmologic medical devices (Part 2)

### 1. General

In **→ OPHTHALMOLOGY** many microsurgical instruments are used which because of their intricate geometry must be classified as critical B medical devices. The Robert Koch Institute (RKI) stipulates that validated, automated cleaning and disinfection be used for critical B medical devices [1]. This means that precleaning at the site of use, as described in Part 1 (Recommendation 70), should preferably be followed by automated reprocessing in a washer-disinfector (WD). If these medical devices (MDs) as well as critical A MDs and semi-critical MDs tolerate automated cleaning with thermal disinfection without any material damage, these MDs, too, are reprocessed in a WD. Studies (see Part 1) have shown that most MDs tolerate **→ ALKALINE DETERGENTS** well; of importance is to ensure that all chemical residues are rinsed off, using a validated controlled rinse method.

The instructions supplied by the manufacturers of the instruments as well as of the process chemicals must be observed.

A further important point is «correct» **→ POSITIONING** of the microsurgical instruments to, first, prevent material damage and, second, ensure that the cleaning solution will be able to gain access to them and that they can be rinsed off as well as possible. There are a number of supports and knob mats that can be used to that effect.

For **→ HEAT-SENSITIVE MDs** the manufacturers recommend manual cleaning and disinfection. The latter is based on the instructions set out in standard operating procedures (SOPs) which, strictly speaking, cannot be validated since they do not constitute a documented process. A point to consider is whether such MDs could not be replaced by devices that do lend themselves to automated reprocessing, because manual cleaning and disinfection is an onerous and time-consuming task that requires well-trained and conscientious personnel.

The belief that manual cleaning and disinfection are faster is often attributable to failure to comply with the specified steps needed, e. g. brushing, thorough rinsing, frequent changing of the disinfectant solution, inspection for residues, etc.

### 2. Reprocessing

The instructions supplied by the manufacturers of the instrument as well as of the process chemicals must be observed. In principle, personnel protection measures must be assured.

#### 2.1 Requirements for manual pretreatment

If the instrument manufacturer has specified manual pretreatment, detergents or disinfectant detergents can be used.

#### 2.2 Requirements for automated cleaning and disinfection

Cleaning and disinfection of ophthalmologic MDs should be performed in **→ SEPARATE WDs**, which if possible should be equipped with suitable filter systems. If separate WDs are not available, by taking appropriate measures or using special rinse programmes, e. g. a blank load, it must be ensured that particle entrainment from previous cleaning processes is avoided.

Automated processes are **→ VALIDATED** as per EN ISO 15883, while taking account of national requirements, e. g. as per the Guideline compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) [2]. Thermal disinfection should be performed  $A_0 = 3000$ .

**→ IN OPHTHALMOLOGY** many microsurgical instruments are used which must be classified as critical B medical devices.

**→ ALKALINE DETERGENTS** are tolerated well by most MDs.

**→ POSITIONING** is important to prevent material damage and to ensure thorough cleaning.

**→ FOR HEAT-SENSITIVE MDs** manual cleaning and disinfection according to SOPs is recommended. They should be replaced by MDs that lend themselves to automated reprocessing if possible.

**→ SEPARATE WDs** should be used for ophthalmologic instruments.

**→ VALIDATION** of automated processes is performed according to EN ISO 15883.

→ **INSPECTION FOR PROTEIN RESIDUES** must also be performed on patient-used instruments.

→ **REGARDING THE GUIDE VALUES FOR PROTEIN RESIDUES** an amendment in relation to the instrument surface ( $\mu\text{g Protein}/\text{cm}^2$ ) is currently discussed.

→ **RINSING** of process chemical residues must be done thoroughly in ophthalmologic instruments.

→ **A ROUTINE CHECK FOR ALKALINE RESIDUES** is recommended for each batch of lumened MDs. The use of pH strips has proved useful.

→ **FOR MANUAL DRYING** medical compressed air with pressure regulation must be used.

→ **MANUAL CLEANING AND DISINFECTION** are subject to the same quality assurance requirements as automated reprocessing.

→ **A GUIDELINE FOR STANDARDISATION OF MANUAL CLEANING AND DISINFECTION** is currently being compiled.

### 2.3 Verification of the cleaning performance/protein measurement

At the time of validation of an automated cleaning and disinfection process, Crile clamps are used to verify the minimum cleaning performance (using process challenge devices based on the DGKH, DGSV, AKI Guideline). The guide value specified is max. 100  $\mu\text{g}$  protein/instrument. In addition, instruments used on a patient must be inspected for → **PROTEIN RESIDUES** after reprocessing.

The application of such a high guide value must be critically reappraised in the case of ophthalmologic instruments because of their small surface. In some countries the guide value is given in  $\mu\text{g protein}/\text{cm}^2$  instrument surface. In Germany there is now talk of amending the → **GUIDE VALUES** in line with the instrument surface.

In one study instruments that had been used on a patient were inspected before cleaning using the BCA/biuret method. This revealed that the protein quantities measured before cleaning were mostly below the guide value of 100  $\mu\text{g}/\text{instrument}$  set out in the Guideline [3].

### 2.4 Rinsing

The residues of process chemicals must be → **RINSED** off thoroughly so that the patient will not suffer any harm because of any residues left. The manufacturer of process chemicals must provide instructions and a test method to that effect. This applies for both alkaline and neutral treatment agents.

To be on the safe side, it is advisable to repeat the rinse step.

In addition to the tests described in the Guideline, it is recommended that for each batch a → **ROUTINE CHECK** be carried out for alkaline residues in lumened MDs, especially cannulas. The use of pH strips, with 0.5 gradations, has proved useful in this respect. Using medical compressed air, liquid residues are expelled onto the pH strips. The values indicated by the pH strips should concord with the pH values of the final rinse water taken at the time of the most recent performance qualification.

### 2.5 Drying

The drying effect will depend on the MD, loading rack and loading pattern. For subsequent → **MANUAL DRYING**, medical compressed air must be used. It must be possible to regulate the pressure to avoid damaging the instruments, e. g. phaco-handpieces (note manufacturer's instructions). Patency can be checked at the same time. In this way any particles that, for example, had been introduced by the cleaning process into lumens and rinse/suction handpieces can be removed. The method described above to measure the pH value can also be used.

If necessary, use ear protection equipment for compressed air drying.

## 3. Requirements for manual cleaning and disinfection

In principle → **MANUAL CLEANING AND DISINFECTION** of instruments are subject to the same quality assurance requirements as automated reprocessing. Attention is drawn to the fact that for MDs belonging to the «critical B» class (covered surfaces and lumened instruments), the RKI has specified that in principle automated cleaning and disinfection be used.

Just as for automated procedures, so for manual tasks, too, all steps must be set out in standard operating procedures and their execution documented.

A → **GUIDELINE FOR STANDARDISATION OF MANUAL CLEANING AND DISINFECTION** of medical devices is being currently compiled by the DGSV, DGKH and AKI. This Guideline will describe all steps of the cleaning and disinfection process, including drying and handing over the MDs to the clean area of the Central Sterile Supply Unit (CSSD). The Guideline will also feature test methods for the various process steps as well as recommendations for the manual reprocessing circuit and checklists.

### Remark

Part 3 will contain flow charts compiled by the working group «Guideline for standardisation of manual cleaning and chemical disinfection» as well as advice on procurement of new medical devices and references.