

## Recommendations by the Quality Task Group (86)

# Programme Controls Part 1: Washer-disinfectors with a thermal and chemothermal disinfection cycle

## This recommendation replaces Recommendations 11 and 12, from 2000

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→ **WDs** are supplied for reprocessing the most diverse types of medical devices.

→ **A STANDARD PROGRAMME** is designed to reprocess the vast majority of medical devices.

→ **THE OVERALL RESULTS** depends on the optimal conduct of each process step.

→ **THE PROCESS STEPS** may be executed in a varying order.

1 German Medical Devices Operator Ordinance (MPBetreibV), Section 4, Maintenance: Reprocessing is presumed to have been carried out in accordance with the pertinent regulations if the recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) has been complied with.

### Introduction

→ **WASHER-DISINFECTORS (WDs)** are now a standard feature of any Central Sterile Supply Department (CSSD) and are supplied by manufacturers for reprocessing the most diverse types of medical devices.

A distinction is made between standard washer-disinfectors (WDs) and those endoscope washer-disinfectors (EWDs) used to reprocess heat-sensitive flexible endoscopes. Standards DIN EN ISO 15883 Part 1, Part 2 and Part 4 set out all the technical and operational requirements applicable to WDs and EWDs [1].

In addition to the special programmes reserved for special solutions, there is generally a → **"STANDARD PROGRAMME"** with a thermal disinfection cycle designed to reprocess the vast majority of medical devices (MDs). Such programmes are the same regardless of their make, with often only minor differences such as the duration and number of pre-cleaning and intermediate rinse steps or as regards the duration of the drying cycle. Most WDs are fitted with microprocessor logic controllers and can be customized to meet the respective user's needs.

The programmes take account of the pertinent legal requirements and of the KRINKO/BfArM Recommendation [3]. Accordingly, apart from the requirements governing the cleaning and disinfection efficacy, steps must also be taken to prevent Creutzfeld-Jakob disease (CJD) and variant CJD (vCJD). All reprocessing steps are also subject to patient safety as well as to occupational health and safety (OSH) requirements.

The purpose of this present Recommendation is to give a better understanding of all essential process parameters of automated reprocessing. The most important requirements and their implementation will now be explained below.

### Fundamentals

The programmes available in a WD or EWD are composed of individual process steps. Each of these steps contributes to the overall outcome and must be tailored to the respective circumstances. If conduct of one of these process steps is not optimal, the → **OVERALL RESULTS** may be jeopardized.

The following → **PROCESS STEPS** are available, and the order in which they are executed may vary:

- Pre-cleaning
- Cleaning
- Neutralization
- Rinsing
- Disinfection
- Final rinse (only after chemothermal disinfection)
- Drying

The process chemicals, water quality, temperature, mechanical action (cleaning pressure), exposure time as well as the cleaning and microbiological requirements are important components of the individual process steps.

## I The individual process steps

### Pre-cleaning

The **→ PRE-CLEANING STEP** is designed to reduce the burden of coarse soils, in particular water-soluble substances, e. g. blood. This process step is carried out with cold water (drinking water or demineralized water) to prevent protein denaturation, and normally no chemicals are used.

There are no special requirements as regards the water used. The exposure time must be tailored to the contamination burden. If medical devices with high blood contamination are to be reprocessed or if foam-producing substances were used for pre-cleaning, a second pre-cleaning step may be needed.

### Cleaning

The cleaning step is aimed at removing all contaminants from the medical device. The chemical detergents used are generally alkaline products that may contain, among other things, alkalis, surfactants and/or enzymes. The instructions supplied by the detergent manufacturer must be observed.

To test whether a WD/EWD is able to assure a **→ MINIMUM CLEANING EFFICACY**, visual inspection and tests for protein residues must be carried out at the time of validation. The acceptance criteria are given in the relevant guideline [2].

To assure reproducibility and optimization of this step, the majority of the detergent manufacturers recommend the use of **→ DEMINERALIZED WATER**. The exposure times and temperatures are also generally specified or recommended by the manufacturers. The standard parameters observed for reprocessing critical medical devices pursuant to the KRINKO/ BfArM Recommendation, Annex 7 [3] are generally based on an alkaline detergent at 55°C with 10- minute exposure time.

In line with the "presumption of conformity"<sup>1</sup> and in keeping with the CJD/vCJD prophylaxis requirements, these parameters should be used when defining this process step. If pH-neutral detergents are used, again to comply with CJD/vCJD prophylaxis demands, moist heat sterilization should be prolonged to at least 18 minutes.

### Neutralization

After using an alkaline detergent in the cleaning step, the pH value should be reduced as quickly as possible to a **→ NEUTRAL LEVEL**. To that effect, an equal amount of a neutralizing agent, e. g. based on citric or phosphoric acid, can be added to the first rinse water.

No special requirements apply as regards the quality of the water used. It is advisable to use demineralized water in this process step to prevent the water constituents having any negative impact through entrainment of the cleaning solution.

### Rinse/intermediate rinse steps

To ensure that no residues of the chemical products used will linger on the medical devices, an additional "rinse/ intermediate rinse step" is used to reduce any such residues to at least a value specified by the manufacturer.

**→ DEMINERALIZED WATER** must be used to assure a successful outcome. Demineralized water has a twofold benefit: it has a high affinity for absorption of the water constituents and, for its part, introduces very few constituents to the water during reprocessing.

If ophthalmology instruments are to be reprocessed, a second rinse step may be needed to ensure that all residues of alkaline and other process chemicals are eliminated from the medical devices and enhance patient safety.

### Disinfection

#### Thermal

The final cleaning step also serves for thermal disinfection.

**→ THERMAL DISINFECTION** should be given preference for all heat-resistant medical devices. Disinfection helps to reduce the number of microorganisms adhering to a medical device. Temperatures of at least 80°C, and the appropriate exposure time, are used for thermal disinfection.

The  $A_0$  value concept has been introduced as the parameter to uphold disinfectant efficacy. The  $A_0$  value concept is described in detail in standard DIN EN ISO 15883 Part 1 and in the pertinent guideline [2].

**→ THE PRE-CLEANING STEP** is designed to reduce the burden of coarse soils – normally without using chemicals.

**→ THE MINIMUM CLEANING EFFICACY** has to be tested during validation.

**→ THE USE OF DEMINERALIZED WATER** is recommended for the cleaning step.

**→ FOR NEUTRALIZATION** of alkaline detergents, a neutralizing agent based on citric or phosphoric acid is added.

**→ DEMINERALIZED WATER** must be used to assure a successful outcome of the rinse step.

**→ DURING THERMAL DISINFECTION** on observing an exposure time of around five minutes, an  $A_0$  value of at least 3000 can be obtained.

Temperatures of around 90 °C tend to be used in routine practice and, on observing an exposure time of around five minutes, an  $A_0$  value of at least 3000 can be obtained. That parameter assures the requisite bactericidal, fungicidal as well as extensive virucidal efficacy.

The use of demineralized water is obligatory for this process step so as to, among other things, prevent staining and chloride-induced pitting corrosion.

#### Chemothermal

A chemothermal programme can also be incorporated into a WD used to reprocess heat-sensitive MDs. However, temperatures > 65 °C should not be used to avoid damage to the instrument materials, hence the  $A_0$  value concept cannot be applied.

Therefore in this process step microbial reduction is assured by adding a → **DISINFECTANT** suitable for automated reprocessing. Successful chemical disinfection is determined essentially by compliance with the parameters specified by the disinfectant manufacturer. These parameters include, in particular, the temperature, concentration and exposure time. The disinfectants used are based on aldehydes or peracetic acid. In compliance with the KRINKO/BfArM Recommendation [3], the disinfectants used in routine practice must be endowed with bactericidal, fungicidal as well as extensive virucidal efficacy. The disinfectant manufacturers must be in possession of expert opinions issued as per the by provisions of the German Association for Applied Hygiene (VAH) and the German Association for Control of Viral Diseases (DVV) / Robert Koch Institute (RKI), status 2008.

→ **A DISINFECTANT** assures microbial reduction if temperatures above 65 °C cannot be used to avoid damage in heat-sensitive MDs.

→ **AFTER CHEMOTHERMAL DISINFECTION** a rinse step is required preferably using demineralized water.

#### Final rinse

A rinse after the disinfection step is needed only following → **CHEMOTHERMAL DISINFECTION** and is designed to ensure that any remaining disinfectant residues will be reduced to a value specified by the manufacturer. To that effect, demineralized water should be used preferably, since stringent microbiological requirements must be observed to prevent recontamination of the MDs.

#### Drying

Provision must be made for adequate drying following automated reprocessing. If hot air is used, a HEPA filter must be fitted to prevent recontamination of the MDs. Any → **RESIDUAL MOISTURE** can have a negative impact on subsequent process steps, e. g. sterilization. Even in the case of MDs that are not sterilized residual moisture may have adverse effects since any microorganisms present can grow in a moist environment and present a risk to patients.

→ **RESIDUAL MOISTURE** can have a negative impact on subsequent process steps.

If synthetic materials are not properly dried, additional measures must be taken.

## References

- [1] EN ISO 15883 Washer-disinfectors – Part 1: General requirements, terms and definitions and tests  
EN ISO 15883 Washer-disinfectors – Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthesia equipment, bowls, receivers, utensils, glassware, etc.  
EN ISO 15883 Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
- [2] Guideline for validation and routine monitoring of automated cleaning and disinfection of heat-resistant medical devices as well as advice on selecting washer-disinfectors, compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI), issued in 2008
- [3] KRINKO/BfArM Recommendation: Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), issued in 2012

#### Examples of process sequences

1. pH curve on using an alkaline detergent without adding a neutralizing agent
2. pH curve on using an alkaline detergent and adding a neutralizing agent

