

# Recommendations by the Quality Task Group (29): Verification of the Performance of Washer-Disinfectors Used for Thermal Disinfection

## Verification of the Cleaning Performance

Washers-disinfectors must carry out the following tasks:

<b>Pre-cleaning</b>	reduce the amount of contaminants and detach water-soluble residues	→ <b>PRECLEANING</b> should be effected with cold water
<b>Cleaning</b>	clean all inner and outer surfaces to achieve clean medical devices	→ <b>DETERGENT</b> determines the water temperature
<b>Neutralisation</b>	will depend on the type of detergent used	
<b>Intermediate rinse</b>	rinses off all residues of chemicals to ensure that no residues remain on the medical devices	
<b>Disinfection</b>	thermal disinfection in the A or A+B <sup>1</sup> spectra of action, in accordance with the → <b>A<sub>0</sub> CONCEPT 600 – 3000<sup>2</sup></b>	→ <b>A<sub>0</sub> 600</b> for uncritical MDs <b>A<sub>0</sub> 300</b> for semi-critical and critical MDs
<b>Drying</b>	dries all inner and outer surfaces	

Important preconditions for impeccable process sequences:

- optimal, specified water quantity, quality and pressure
- proper functioning of rotary arms and nozzles (spray pattern)
- optimal concentration of detergent and controlled dosage
- correctly set temperatures and hold times

Standard prEN ISO 15883-1 + 15883-2 stipulates that a validated process must make provision for monitoring these parameters. Modern washer-disinfectors are only to an extent, or not at all, equipped with fault indicators, displays or computerized interfaces for this purpose. Therefore standardised processes can be assured only by carrying out regular checks.

In general, the cleaning process entails a cold precleaning cycle, followed by a cleaning step using a suitable detergent. At the end of these phases, the medical device must be → **CLEAN**, otherwise reliable thermal disinfection cannot be performed.

There are various methods of evaluating the cleaning outcome, which are applied during routine checks, while verifying cleaning efficacy as part of validation or during revalidation.

### 1. Visual inspection of medical devices

The medical devices are subjected to visual inspection, possibly with the aid of a magnifier. Haemoglobin residues can be easily detected, but this is not true for colourless residues (e.g. mucous and sera). Lumened medical devices are only partially amenable to inspection for cleaning.

- **Is cleanliness**
- visible?
  - measurable?
  - reproducible?

### Test methods

Can be they conducted in practice?

<sup>1</sup> from: The List of Disinfectants and Processes Approved and tested by the Robert Koch Institute. On using the agents and methods listed below, their microbiological spectrum of action must be borne in mind. Letters are used to denote the spectra of action, e.g.

A: for inactivation of vegetative bacteria, incl. mycobacteria as well as fungi, incl. fungal spores

B: suitable for inactivation of viruses

<sup>2</sup> See internet page of DGSV (German Society for Sterile Supply) at <http://www.dgsv-ev.de> and pages 251 – 258

## 2. Checking for protein residues

Individual medical devices can be subjected to spot checks for protein residues. The standard cites two methods of doing so:

- 2.1 Protein residues can be stained with → **NINHYDRIN**. This method represents a qualitative test that reacts very sensitively to certain proteins, but less so to others. Reproducibility of results is scarcely possible.
- 2.2 The → **OPA METHOD** is a very precise method. But it calls for a special photometer as well as trained laboratory personnel, hence is hardly practicable in everyday routine operations.

A third method is available for on site examination. However, the standard does not list it yet. This is the → **BIURET METHOD** for protein detection. Suitable sets are commercially available.

## 3. Test soils and process challenge devices

The cleaning efficacy and the spray pattern, i.e. the distribution of the spray jets in the cleaning chamber, are tested with test soils. In this respect, the Standardisation Committee has taken on test soils and test methods that have proved themselves over many years as well as nationally standardised test soils and test methods.

- 3.1 In Germany the following test soils, which are also being employed for biological indicators, are used: defibrinated sheep blood, semolina and egg yolk. These test soils can also be used to verify the cleaning performance without test organisms. It is also possible to use them as biological indicators as per the dictates of the Robert Koch Institute, but they are intended primarily for verification of the disinfection results.

The results produced by the various test soils and methods cited in the standard are not comparable.

- 3.2. To check the spray pattern and hence also the cleaning efficacy in various locations of the washer-disinfector, standardised cleaning indicators (TOSI gap process challenge device – PCD) are used in many countries. Here a test soil that is similar to blood such as albumin, haemoglobin and fibrin is applied.

Following a suggestion by the Robert Koch Institute (RKI) – and using these cleaning indicators – members of the German Society for Hospital Hygiene (DGKH) and of the German Society for Sterile Supply (DGSV) conducted a multi-centre trial in various central service sterilisation departments (CSSDs).

This revealed that processes comprising well-defined parameters and → **FUNCTIONAL WASHER-DISINFECTORS** will result in optical cleanliness of these indicators. But if these preconditions are not met, test soil residues will be visible. If haemoglobin can be detected, this means that a PCD was not adequately flushed at this site. A salient feature was that gap PCDs in some washer-disinfectors with a defined load were optically clean at some locations, but not in others. Therefore the user should check the washer-disinfector and process, accordingly, and optimise these if necessary.

The results of this multi-centre trial will be published shortly.

Regarding the verification of thermal disinfection please refer to Recommendation no. 14 in *Central Service* issue no. 6/2000 or to the DGSV website at [www.dgsv-ev.de](http://www.dgsv-ev.de).

### Test methods

What information do they provide?

→ **NINHYDRIN** stains protein residues

→ **THE OPA METHOD** is particularly precise

→ **THE BIURET METHOD** is going to be listed in the standard

→ **FUNCTIONAL WASHER-DISINFECTORS**  
see checklist, *Central Service* 3/2003