Washer-Disinfectors - Effectiveness and Quality Assurance

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Reprocessing of Medical Devices

The reprocessing of reusable Medical Devices (MDs) which are to be used disinfected or sterile is defined as:

The Cleaning, Disinfection and Sterilization (where required) after use (including the necessary workflow) as well as the testing and reconstitution of the technical and functional safety.
Aims of Reprocessing

• Reprocessing must assure that there is no risk for the patient coming from the MD in the sense of:
  • Infections
  • Pyrogenetic reactions
  • Allergic reactions
  • Toxic reactions
  • Changed quality characteristics
These requirements call for:

• Implementation of a Quality Management System

• Validation of the processes

• Qualified staff

• Compliance with the state of the scientific and technical knowledge (standards, guidelines of scientific associations)
  
  • e.g. wfhss guideline No. 4
WFHSS guidelines

- **No. 01**
  Tests/Checks after Maintenance/Repairs of WDs and Sterilizers

- **No. 02**
  Check List for Procurement of Medical Devices pursuant to EN ISO 17664:2004

- **No. 03**
  Requirements for Reprocessing Units for Medical Devices (RUMEDs) in Healthcare Establishments

- **No. 04**
  Reprocessing of Medical Devices in/for Healthcare Establishments

- **More to come…**

  www.wfhss.com > wfhss guidelines
WFHSS guidelines

- **WFHSS Recommendation**
  Validation of Decontamination Processes

- **WFHSS Guideline No. 01**
  Tests/checks after maintenance/repairs

- **WFHSS Guideline No. 02**
  Check List for Procurement of Medical Devices pursuant to EN ISO 17664:2004
  - [WFHSS Guideline No. 02](#)
    Check List for Procurement of Medical Devices pursuant to EN ISO 17664:2004
    [MS-Word Version]

- **WFHSS Guideline No. 03**
  Requirements for Reprocessing Units for Medical Devices (RUMEDs) in Healthcare Establishments

- **WFHSS Guideline No. 04**
  Reprocessing of Medical Devices in/for Healthcare Establishments
Reprocessing of Medical Devices

- Preferably automatic thermal processes, i.e.
  - Washer – Disinfectors (WDs)

- When purchasing new MDs the suitability for automatic reprocessing should be a very important factor

(see wfhss guideline No. 2)
The advantages of using WDs

- Better reproducibility
- Less possibilities for mistakes
- Facilitation and higher safety for workers
  - Less exposure to chemicals
- High safety by thermal disinfection
- Less danger of recontamination
- Better traceability
- Easier documentation
- etc.
Automatic Cleaning and Disinfection

- The cleaning efficacy of the process is essential and depending on:
  - Type of MD
  - Type of soiling
  - Adequate loading
  - Adequate maintenance
  - Cleaning programme in the WD
  - Chemistry used
Factors Influencing the Cleaning Efficacy

Chemistry
- Cleaner
- Dosing
- Dosing temperature
- Water-quality
- Foaming

Mechanics
- Pump pressure (Foaming)
- Chamber design
- Flow conditions
- Spray arms
- Trays
- Water amount

Time
- Prerinsing
- Cleaning

Temperature
- Prerinsing
- Cleaning
ISO 15883 Part 1-5
Washer Disinfectors

- **Part 1**: General requirements, definitions and tests
- **Part 2**: Requirements and tests for washer disinfectors employing thermal disinfection for **surgical instruments**, **anaesthetic equipment**, **hollowware**, **utensils**, **glassware**, etc.
- **Part 3**: Requirements and tests for washer disinfectors employing thermal disinfection for **human waste containers** (bed pan washers)
ISO 15883 Part 1-5
Washer Disinfectors

- **Part 4**: Requirements and tests for washer disinfectors employing chemical disinfection for thermolabile endoscopes
- **Part 5**: CEN ISO/TS 15883-5: Test soils and methods for demonstrating cleaning efficacy
- **Part 6** (WDs for non critical, non invasive MDs): to come
Thermal Disinfection

- Is sufficient if:
  - The defined temperature and holding time is achieved on all surfaces of the load or
  - The equivalent $A_0$ value is achieved

- Disinfection temperature band
  - Defined disinfection temperature $-0 /+5$ K
A₀-Concept

A₀-Value = Specifies the relation between temperature and exposure time to achieve a defined inactivation of microorganisms (MO)

In Theory!
**A₀-Concept**

**BUT**
- Deduction not proved by experimental investigations
- Up to now only few studies available on thermal resistance of vegetative bacteria and the suitability of the A₀ concept
- Data partly contradictory

**AND**
- Microorganisms do not behave as the formula expects it from them!
- Maybe someone forgot to explain the A₀-formula to the bacteria?
A₀-Concept

Is there a need to limit the time for inactivation of microorganisms on Medical Devices to the minimum?
The principle of overkill procedures should be retained for sterilisation as well as for disinfection of MDs.

This procedure assures a certain robustness of the reprocessing treatment of MDs under difficult conditions.
Sorry…

So please don’t believe everything which is in a standard!

We have to think and to be careful!

e.g. in Austria the $A_0$ concept is limited to temperatures above 80 °C until more data are available
There would be hardly a problem, IF:

1) Type tests according to the standards were conducted (by independent accredited test labs) prior to marketing
Type testing

Ad 1)

- Obviously the simple presence of a standard is not enough to guarantee good machines.

- Findings during type testing
  - e.g. WD-E: 1mm channel not rinsed at all

The first principal theorem of technical hygiene: first test, then sell!
There would be hardly a problem, IF:

2) There were more independent test laboratories with specific expertise in the field of reprocessing

3) The WDs were tested prior to use and the processes were validated on site
Validation in other words

- Validation is the evidence that the reprocessing process for MDs is able to achieve the intended effect reproducible under the operating conditions on site, for defined items in the given type of packing and loading, that means:
  - Generating clean, disinfected and sterile products respectively

Type testing and validation by manufacturers/distributers - Quality assurance?
Test Laboratories and Validation

Ad 2 and 3)

- Problems arising during OQ and PQ
  - e.g. delayed release or dismanteled WDs
  - due to not meeting the requirements for cleaning efficacy

We need more independent test laboratories for validation!
There would be hardly a problem, IF:

4) There was a standard for cleaners for WDs

5) Manufacturers of cleaning/disinfecting agents could prove their claims of perfect performance of their products by independent expert’s reports
Missing standard for cleaners

Ad 4) and 5)

• Nearly hundreds of standards for reprocessing, except for cleaners
• No way to compare cleaners for the user
• There might be differences between lots

Have a look at the chemistry
(and eventually the load carrier and the water quality)!
There would be hardly a problem, IF:

6) The staff on site was trained specifically and thus accordingly qualified

(see wfhss education program)
Trained personell

Ad 6)
- Inadequate handling
- Overloading, inappropriate loading of MIS instruments

Trained personell is essential for reprocessing medical devices at a high level!
There would be hardly a problem, IF:

7) A quality management system was implemented in the reprocessing units for medical devices (RUMED)

(see wfhss guideline No. 3 and 4)
Quality Management

Ad 7)

e.g.

- Standard Operating Procedures
- Maintenance plan
- Routine control system

A living QM System is essential for reprocessing medical devices at a high level, guaranteeing the minimum risk for the patient!

Institut für angewandte Hygiene
What we need

1. Type-tested machines
2. Independent test laboratories
3. Good (and tested) cleaners
4. Trained personell
5. Quality management system
THANK YOU for your attention!