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ANNEX 3

to the

Guideline

for Testing, Validation and Monitoring

of

Automated Cleaning and Disinfection Processes

for Medical Devices

in compliance with

prEN ISO 15883 Parts 1, 2 and 5

Purchasing Washer-Disinfectors

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Please send any suggestions for improving this Guideline or your experiences of implementing it to the following email address:

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TABLE OF CONTENTS:

ANNEX 3 to the Guideline
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Automated Cleaning and Disinfection Processes for Medical Devices

Purchasing Washer-Disinfectors

Compiled by: Testing Committee

1 Purpose and field of application

This part of the Guideline is intended as a means of helping the operator purchase washer-disinfectors (WDs). The following information refers primarily to WDs that comply with Part 2 of standard ÖNORM EN ISO 15883; however, the essential requirements can also be applied to the purchase of endoscope WDs.

The legal, normative and business-management requirements regulating medical device reprocessing stipulate that purchase of suitable WDs be meticulously organised and planned.

2 Purchasing washer-disinfectors

In principle, only WDs that comply with the pertinent standards must be purchased. Evidence of compliance with standard ÖNORM EN ISO 15883 Part 1 and 2 must be provided by the manufacturer.

The opinions of at least the following specialists and specialist departments/bodies must be sought already at the time of compiling the performance catalogue:

- Central Sterile Supply Department (CSSD)
- Engineering Department
- Infection control team
- Health and safety team
- If applicable, department head for the future site of operation

The points to be borne in mind when purchasing WDs must be verified and evaluated before compiling the performance catalogue in respect of the locally prevailing conditions. They contain important information on advance structural preparation, installation, requisite tests and subsequent operation.

For the operator this means that before compiling the performance catalogue for a WD that has been subjected to a type test as per the valid version of standard ÖNORM EN ISO 15883, an in-depth analysis must be carried out; this must take account of the medical devices (MDs) to be reprocessed, the capacity and number of WDs to be used, requirements addressed to outcome quality (e.g. in respect of disinfection performance (disinfectant action) – A_0 concept) and the ambient conditions at the place of operation (see below for details).

Furthermore, the following information must be obtained:

- Reprocessing instructions by the MD manufacturer (ÖNORM EN ISO 17664)
- Instructions by the suppliers of washer-disinfectors
- Instructions by the suppliers of process chemicals
- Instructions by the suppliers of external dosing systems, if applicable
- Instructions by the planning engineers (sanitation, ventilation, statics, etc.), if applicable

2.1 Aspects to be borne in mind when purchasing WDs

2.1.1 Installation conditions

- Space requirements
  - Machine dimensions (L-B-H)
  - Maintenance room / machinery room
  - Access on loading and unloading side, incl. enough space for opening doors
  - Space for loading trolleys, incl. storage space
  - Routes for returning loading trolleys
  - Ventilation /air conditioning (heat, moisture) for WD and workstation (incoming / outgoing air)
  - Space for process chemicals and dosing equipment, incl. storage room (external or internal)
  - Space for process documentation
  - Transport access, incl. transport facility, or access route for delivery of WD (width of gangway, lift capacity)
- Delivery periods
- Installation periods
- Statics at installation site (ceiling/floor tolerances, weight-bearing capacity)
- Effects from / on adjacent rooms
  - Noise level (occupational protection)
  - Electromagnetic fields
  - Risk assessment in respect of potential water damage
  - Scope of structural measures needed
- Costs
- Time investment
- Competences
  - Appointment of competent persons and definition of interfaces

2.1.2 Connection conditions / media

The required operating media as well as the incoming / outgoing connections must be specified:

- Demineralised water (pressure, quality, design specifications)
- Other type of water (pressure, quality, design specifications)
- Compressed air (pressure, quality), if applicable
- Steam supply (pressure, temperature, design specifications), if applicable
- Electricity (cross-sections, fuses, separate electrical circuits)
- Waste water (cross-sections, non-pressurised drain, position and material of waste water system, maximum temperature)
- Proposed process chemicals (based on agreement with supplier of chemicals and the MD manufacturer's instructions) (concrete specifications or description of devices)
- Connections for process chemicals (access to containers and their connections, number of dosing pumps needed)
- Central dosing system advisable?
- Facility for taking samples of operating media? (demineralised water supply pipe, softened water)
- Facility for taking samples of rinse water from tank or drain?
- IT connections (network topology, if applicable, note cable length)
- Emergency Off switch (note position)
- Shut-off values for repair tasks?

2.1.3 Operating data

- Select programme in accordance with the medical devices and other devices to be reprocessed, while taking account of the manufacturer's instructions (ÖNORM EN ISO 17664)
- Is the WD suitable for reprocessing the intended MDs?
- Note type and number of suitable loading trolleys (LTs), incl. check if loading trolleys can be reused (optimisation)
- If a type test was carried out as per ÖNORM EN ISO 15883, specify test conditions and any deviations from the standard (see also Chapter 2)
- Consumption data / costs
    - Consumption per programme and cycle:
        - Demineralised water
        - Cold water (CW) and hot water (HW)
        - Electricity
        - Process chemicals
- Maintenance costs
    - Repair costs (request scope of repairs with protocol of contents)
- Costs for installation test

♦ Operating data

- Thermal output during operation in watt
- Mean value and peak value of noise level generated (in dB(A))

2.1.4 Washer-disinfector documentation (to be provided by WD manufacturer)

- Type test documentation (see Chapter 2)
- Factory test documentation
- Installation qualification test report (scope of test and test soils used as per ÖGSV Guideline for testing and monitoring automated cleaning and disinfection processes for medical devices)
- Operating instructions (incl. abridged version)
- Maintenance instructions
- Equipment manual (medical devices' manual)
- Process parameters, incl. permitted tolerances
    - Temperatures
    - Time
    - Dosage data
    - Water quantities
    - Pump pressure
- Requirements for water quality

2.1.5 Process documentation

- Setpoint and actual values for temperature at all relevant process steps
- Setpoint and actual values for dosing process chemicals
- Setpoint and actual values for water quantities
- Serial batch numbers
- Date and time
- Programme number and designation
- Serial number
- Fault signals, showing cause and/or programme phase
- Operator identification, if applicable
- MD identification, if applicable
- Loading rack used, if applicable

2.1.6 Requirements to be met by user

Information to be provided by user:

- Number and capacity of WDs
- Information on available space at machine installation site
- Information on available operating media
- Information on process chemicals needed (pH value, possibly manufacturer)
- Information on type of devices to be reprocessed
    - Any special requirements in terms of water composition (e.g. absence of. endotoxins), If applicable
    - Maximum reprocessing temperature tolerated by heat-sensitive devices (e.g. flexible endoscopes)
- State whether existing LTs are to be used, if applicable,
- Number and type of LTs [e.g. MIS trolleys, number and dimensions of trays (DIN/ISO trays) per LT]
- Information on loading and unloading (e.g. automatic feed-in)
- Type of doors (slide doors, glass doors, etc.)

- Information on local legal regulations (e.g. emission regulations for waste water discharged into sewer system), if applicable

2.1.7 Information to be provided by the manufacturer to the user in addition to that specified in Section 1.1.3 (see also Chapter 3)

- Any preliminary treatment for MDs to be reprocessed, if applicable
- Batch times, taking account of at least the following programme steps: prerinse, cleaning, intermediate rinse, disinfection, drying
- Can utilisation capacity be increased (e.g. through additional programmes and LTs)?
- Is easy, time-optimised and ergonomic operation possible?
- Is easy and ergonomic replacement of process chemicals possible?
- Is it possible to connect MDs in special LTs?
- Can the process be observed (e.g. glass door)?
- Is the WD equipped with cleaning arm sensors?
- Are separate loop control, measurement and logic control mechanisms available?

2.1.8 Project development

The following must be observed for project development:

- Does the capacity of the WDs to be purchased plus existing WDs cover needs?
- Can all equipment be purchased from a single source or must different suppliers be contacted?
- Drawings of intended project?
- Constructional inspections by supplier?
- Delivery periods?
- Installation periods?
- Restricted use during the installation phase?
- Time for installation qualification
- Time for operational qualification
- Time for performance qualification, if applicable
- Time reserve for actual operation

3 Information from the type test needed for installation qualification/validation

To assure the success of installation qualification and validation, certain data from the type test must be made available. If the entire document is not provided, at least a summary of the following data is required:

- Machine type: proof that all parts of the equipment and configurations correspond to those subjected to the type test or evidence that any changes made will not affect the results obtained in the type test
- As per which version of EN ISO 15883 was the type test conducted?
- Respective test body
- Date of type test

3.1 Verification of the cleaning performance

The following data are needed:

- Number of tests
- Interruption of programme at which process step
- Programme specifications
- Process chemicals used (batch numbers)
  - Dosage (specified and measured values)
- Water quality and water quantity used (for each process step)
- Pump pressure (specified and, If applicable, measured values at pump output)
- Loading rack (exact description or drawing)
- Any aids used (e.g. spacers for nozzles, plugs for unused connections)
- Test load :
  - Number and type of test instruments or process challenge devices
  - For MIS instruments: length, internal and external diameter and material of dummies or tubes
- Test soil and test method
  - Drying time
- Results of optical inspection
- If applicable, results of protein detection test after cleaning (description of method)
- Recorded and documented process data (documentation system)
- Evaluation
- If applicable, any operating or loading restrictions than can be concluded from the test results

3.2 Verification of the thermal disinfection performance

The following data are needed:

- Number of tests
- Programme specifications
- Processes (specified temperature / time correlation in respect of required A0 value)
- Loading rack (exact description or drawing)
- Test load
- Number and position of temperature sensors or loggers
- Measurement results (analogue or digital printout of measured data)
- Comparison of WD and documentation data with measuring system data
- Recorded and documented process data (documentation system)
- Evaluation
- If applicable, any operating or loading restrictions than can be concluded from the test results

3.3 If applicable, verification of chemical/chemothermal disinfection performance

The following data are needed:

- Number of tests
- Programme specifications
- Disinfectants
- Dosage
- Test method
    - Test organisms used (possibly, with soil used)
    - Number and type of germ carriers used
    - Baseline microbial count, recovery rate and reduction factors
- Recorded and documented process data (documentation system)
- Evaluation
- If applicable, any operating or loading restrictions than can be concluded from the test results

4 WD features recommended by the ÖGSV

The following recommendations are based on the experiences of users and of the engineers entrusted with testing automated cleaning and disinfection processes. Attention is drawn to the fact that the recommendations reflect the current state of the art. They cannot, of course predict or take account of future developments. The aim of the present assessment is to assist users in evaluating the WD features when making a purchase, and promote transparency within this product range.

The following breakdown was primarily governed by hygiene considerations and patient safety as well as in some cases by user friendliness.

To ensure that this information is kept as topical as possible, it will be updated and revised at regular intervals by an ÖGSV team of experts. The authors welcome suggestions from users, test engineers and interested parties.

4.1 Features which, based on experiences hitherto, have proved to be mainly useful

- Hygiene test programmes involving deliberate interruption of the cycle before the disinfection step or facility for manual cycle interruption and manual opening of machine door
- Hygiene test programmes involving deliberate interruption of the cycle before pumping off the last rinse water or facility for manual cycle interruption and manual opening of machine door
- Rotary arms and water-supply pipes to the loading trolley that can be easily dismantled (without implement, if possible,) and are amenable to visual inspection and easy to clean
- Glass doors
- Chamber lighting (optional)
- Lever for loading trolleys
- Rotary arm sensors
- Access facility for external measurement of pump pressure
- Perfect fit of fine filter in the WD exhaust air opening
- Facility to enable engineer to easily modify programme sequences (any number of programme steps as required, any time and temperature settings)

- External steam heating to shorten the heating-up time and permit more flexible organisation of cycles
- Sampling taps on water pipes as closely as possible to WD
- Sampling taps on circulation system
- Temperature display
- Printout of specified and actual values for process chemicals' consumption
- Printout of specified and actual values for water consumption
- Printout of specified and actual values for temperatures reached
- Display and printout of pump pressure

4.2 Features which could tend to negatively impact on the quality and safety of reprocessing procedures

- Reprocessing cycles that have no preliminary rinse step
- Reprocessing cycles that have no water-exchange facility between the cleaning and disinfection step
- Reprocessing cycles that have no intermediate rinse step between the cleaning and disinfection step
- Programmes with reduced water consumption
- Programmes with non-modifiable programme sequences

5 List of authors

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