Validation of cleaning and disinfecting processes in WDs: Implementation of the ÖGSV-Guideline

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preferably automated thermal processes
- Washer-disinfector

Within the procurement of new instruments suitability for an automated process should be a determining criterion
Automated cleaning and disinfection

Cleaning efficacy depends on:

- kind of MD
- kind of contamination
- professional loading (right position, no overloading, no obstruction of the moving parts etc.)
- correct service (e.g. cleaning of nozzle and sieves)
- cleaning process in WD (mechanics, chemicals, time, temperature)
Influencing factors – cleaning efficacy

detergents
dosing
water quality
dosing temperature
foam performance

pump pressure
conveying quantity
chamber geometry
flow conditions
Washing arms
trays
water quantity
dosing temperature
foam performance

heating up

Pre rinse
Cleaning
Last rinse

cleaning

last rinse
ÖNORM EN 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 container
Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes

Part 5: **CEN ISO/TS 15883-5**: Test soils and methods für demonstrating cleaning efficacy
Validation

“Documented procedure for obtaining, recording and interpreting data required to show, that a process will comply consistently with predetermined specifications”

Validation should confirm the conformity of the processes in the WD with the given specifications as well as the qualification of the process for the MDs used on site

ÖNORM EN 15883: Validation = entire programme, consisting of
- Installation qualification (IQ),
- Operation qualification (OQ) and
- Performance qualification (PQ)
Validation of reprocessing is the verification of the process being suitable for defined products in defined packages and load configurations to meet the intended efficacy reproducible under the conditions on site (i.e. is able to bear clean, disinfected and - if applicable - sterile products)
ÖGSV-guideline to validation
www.oegsv.com

- describes principles for validation, revalidation and routine control of reprocessing in WDs meeting the standard
- also applicable to non-conform WDs

- **Text of guideline**
- **Annex 1:** Test method und contents
- **Annex 2:** Report
  - Part 1: Commissioning protocol
  - Part 2: Test protocol for OQ and PQ
- **Annex 3:** Procurement
Preconditions for validation

- structural requirements
- qualification of staff
- adequate quality assurance/quality management
- risk evaluation and classification of MD and MD-groups
- technical minimum requirements for WDs
- supply of resources (e.g. demin. water)
Operative Preconditions

- organisation chart
- information of the WD manufacturer (e.g. calibration protocols, program specifications)
- instruction manual for the WD
- instructions of the MD manufacturer for reprocessing
- information of the manufacturer of the process chemicals
- load configurations
- standard instructions for all steps of reprocessing
- risk classification according RKI
- operation journal
- hygiene plan (incl. Cleaning/disinfection-plan)
- maintenance plan
- routine control plan
- evidence of qualification resp. education
- Criteria for product release and -documentation
Minimum requirements for WD

- Automatic cycle (freely programmable programmes)
- Adjustable temperature display
- Automatic dosing of chemicals
- Permanent fault indication
- Cycle counter (or documented control system)
- Process documentation (minimum: temperature / time parameters as actual values, date, time)
- Suitable load carriers for MIS instruments, anesthetic equipment, if applicable
<table>
<thead>
<tr>
<th>VALIDATION</th>
<th>Type test / Works test</th>
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<tbody>
<tr>
<td></td>
<td>Installation Qualification (IQ)</td>
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<tr>
<td></td>
<td>Operation Qualification (OQ)</td>
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<td></td>
<td>technical inspection</td>
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<td>hygienic inspection</td>
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<td></td>
<td>Commissioning</td>
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<td></td>
<td>(Assessment of structural, technical preconditions (if applicable: repetition of specific tests of OQ))</td>
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<td></td>
<td>Performance Qualification</td>
</tr>
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<td>Routine control and annual revalidation (re-qualification)</td>
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</tbody>
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RDG nach prEN ISO 15883-1

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Installationsprüfung

Betriebsprüfung
(technische Abnahmeprüfung, hygienische Abnahmeprüfung)

Kommissionierung
(Kontrolle der Rahmenbedingungen, ggf. Nachholung der Betriebsprüfungen)

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Lesungsprüfung

jährliche Revalidierung
(erneute Leistungsprüfung)

nein

Mindestanforderungen erfüllt?
(siehe 5.3)

Gerät austauschen oder nachrüsten!

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nicht gesetzeskonform!
bis zur Validierung jährliche Hygieneprüfung (Reinigungs-/Disinfektionswirkung)
**Type test/ Works test** (Manufacturer)

**Type test:**
- Sequence of tests to determine process parameters for a certain type of WD

**Works test:**
- Sequence of tests, carried out on a single WD at the manufacturing site to provide evidence of the accordance with its specification
Installation Qualification (responsibility of the manufacturer)
- Inspection, if the WD was delivered, installed and supplied with resources according to the contract and the device is safe for operation

Operation Qualification (responsibility of the manufacturer)
- technical inspection (evtl. in combination with IQ)
- hygienic inspection
Checking of:

- documentation
- doors and interlocks
- resources supply
- safety features and equipment (e.g. doors and interlocks)
- construction (finish) (e.g. welded seams)
- display and recording instrumentation (calibration)
- if applicable: further technical specifications (e.g. in accordance with tendering)
Hygienic Inspection

- In responsibility of the manufacturer
- preferably independent hygiene expert
- in case of positive result of IQ and OQ the preconditions for taking-over of the device by the institution is given

For problems during PQ due to MDs or load configuration used on site, the manufacturer is out of responsibility, unless there exist other contract details.

- **Cleaning efficacy**
  (standard soiling)
  - Chamber (KMNE)
  - load carrier (KMNE)
  - load (3x)
    (MNE, reactivated sheep blood)

- **Disinfection efficacy**, temperature control, reproducibility (thermoelectric)
  - chamber walls
  - load carriers
  - load

- **Accuracy of display/recording**
- dosing accuracy
- **water quality**
  - softened water
  - deionised water
  - last rinse water
    - chemical/physical
      - pH, conductivity, hardness, Chlorine
    - (bacteriological)

- **Water quality**
  - softened water
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Test method surgical instruments

- Test soil: reactivated sheep blood
- Application of TS with brush
  - Critical spots (joints)
- Drying app. 2 x 30 min (upside down)
- Interruption after Cleaning!
- Repetition 3 x
Evaluation surgical instruments

_evaluation_

- Visual check
- Protein detection (if necessary)

Criteria for acceptance
- Max. 5% of soiled instruments may show residual soiling
- Protein detection: within acceptance criteria
  (20 µg/Instrument)
Validation

Commissioning:
- technical, operational and organisational preconditions as well as documentation is checked

Performance Qualification:
- the process is checked for its efficacy and reproducibility,
- that means....
Cleaning efficacy is tested under real conditions with:

- the MD to be reprocessed
- the specified load configurations (preferably worst case)
- the specified program sequence
- the available resources
- the chosen detergents
- evaluation by protein detection tests limit: 20 µg/instrument
Practicability of the Austrian test method

- Easy to accomplish
- Soiling on-site
- Analysis (visual control) possible without further effort
- Faults/deficiencies/problems (e.g. dosing of detergents, insufficient water quantity etc.) can be detected and solved – followed by a control survey
Problems in practice

- chamber geometry
- washing arms (construction/velocity)
- pump pressure (foam performance)
- water quantity
- load carrier (condition of water flow)
- trays
- detergents (high-/low-alkaline/neutral)
- foam performance
- dosing temperature
- dosing quantity
- dosing pumps (-tubes)
- water quality
The evaluation of the Austrian test method for WD-testing (especially for surgical instruments) showed, that it is suitable for an adequate process assessment.

The averaged results are confident indicators for the efficacy of the tested cleaning process.
Compliance with the 5% limit guarantees satisfying cleaning results during routine operation.

Protein detection tests on instruments with real contamination show consistently results below the defined acceptance criteria of 20 µg/instrument.

Good repeatability.
Reproducibility of the Test Method

Instrumente mit Restverschmutzung (Gesamtzahl 120)

relative Summenhäufigkeit in %

Binomialverteilung
Obergrenze (95 %)
Untergrenz (95 %)
empirische Σ Werte
The implementation of new test methods (e.g. the new Austrian one) is an important part of the quality improvement in the field of reprocessing of medical devices and is finally able to help raising patient safety.
Thank you for your attention!