Testing, Validation and Routine Control in Processing of flexible Endoscopes in Austria

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The Problem

- **Processing**
  - thermolabile
  - stressed by use and processing
  - high bioburden
  - long, narrow lumina
  - hardly accessible parts
  - poor (no) possibilities for visual control of cleanliness

- **Practice**
  - as many examinations as possible
  - in as less time as possible
  - with as few instruments as possible
Bioburden of flexible Endoscopes

- After examination:
  Up to $10^{10}$ cfu/ channel

- After processing:
  $\leq 10$ cfu / channel
  RF $\geq 9$ log (full cycle)
Rules and Regulations

- Austrian Medical Device Act
- Planned Ordinance for the Hygienic Management of Medical Devices
- Guideline of the Federal Ministry of Health concerning the Processing of Endoscopes
- ÖNORM EN ISO 15883-1 and –4, ISO /TC 15883-5
Planned Ordinance for the Hygienic Management of Medical Devices in/for Health Care Institutions under § 94 Medical Device Act
The Ordinance requires:

- Working acc. to the state of the scientific and technical knowledge
- Determination of responsibilities
- Determination of processes
- Categorisation of Medical Products into Risk Groups following RKI
- Documentation
- Quality assurance for all relevant processes
- Validated processes:
  - Installation Qualification, Operational Qualification, Process Qualification, Routine Control
- Qualification of the staff
- Automatic processing of type B MP
Categorisation of Medical Products into Risk Groups following RKI

Uncritical
(contact with intact skin only)

A (without special requirements)
(simple construction, no cavities)

B (elevated requirements)
complex construction, cavities

C (especially high requirements)
like critical B, additionally no steam sterilisation possible

Semicritical
(contact with mucosa or pathological modified skin)

A
simple construction, no cavities

B
complex construction, cavities

Critical
(penetration of skin or mucosa)
Situation in Austria

- About 470,000 Gastro- and Colonoscopies / Year
- Hospitals: Processing exclusively in WDs
- Resident doctors: only about 30% automatic processing
## Annex 2: AEMP (PUMP)-Categorisation

<table>
<thead>
<tr>
<th>AEMP-Category</th>
<th>I</th>
<th>II</th>
<th>III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MP to be processed</strong></td>
<td>Uncritical, semicritical A, critical A, hand- and angle pieces</td>
<td>Uncritical, semicritical A, B, critical A</td>
<td>all risk groups</td>
</tr>
<tr>
<td><strong>QM</strong></td>
<td>Adequate Q-Assurance</td>
<td>QM acc. to ONR 112069 and RKI resp.</td>
<td>QM-System according to EN ISO 13485</td>
</tr>
<tr>
<td><strong>Edificial Requirements</strong></td>
<td>Seperate area/ preferable seperation of zones in unclean/clean/sterile</td>
<td>separate processing room / seperation of zones in unclean/clean/sterile</td>
<td>Seperate premises Seperation of unclean/clean/sterile rooms</td>
</tr>
<tr>
<td><strong>Qualification of the Staff</strong></td>
<td>Director and agency: Q-course 1</td>
<td>Director and agency: Q-course 2</td>
<td>Director and agency: Q-course 3</td>
</tr>
<tr>
<td></td>
<td>Staff : Q-course 1</td>
<td>Staff : Q-course 1</td>
<td>Staff : Q-course 1</td>
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</tbody>
</table>
PUMP II

- Separate Room
- Separation of Zones
- "One way"
- WD
- Steriliser acc. to EN 13060
EN ISO 15883 Part 1-5: Washer Disinfectors

- Part 1: General Requirements, Definitions and Tests
- Part 5: Test Methods (in Revision)
Testing, Validation and Routine Control
OEGSV Guideline for Testing, Validation and Control of automatic Cleaning and Disinfection Procedures of flexible Endoscopes

in accordance with EN ISO 15883-1, -4 and CEN ISO/TS 15883-5
(October 2008)

www.oegsv.com
WD-flexible Endoscopes

- Programme Sequence
  - Pre Rinsing
  - Cleaning
  - Intermediate Rinsing
  - Disinfection (Glutaraldehyde, Peracetic acid)
  - Final Rinsing
  - Drying (Purging)
Type/Works Test (Manufacturer)

- **Type test:**
  - Series of tests to be carried out with every new type of WD-E
    - should be demanded before purchase

- **Works test:**
  - Series of tests to be carried out before distribution of a machine
Validation

- Shall ascertain the accordance of the process to the specifications as well as the adequacy of the procedure for the processing of the used MPs
- EN ISO 15883: Validation = Complete program consisting of
  - Installation Qualification,
  - Operational Qualification and
  - Performance Qualification
IQ /OQ

- **IQ:**
  - Control, if the WD is delivered according to tendering, that it is supplied with the required resources and safe for use

- **OQ:**
  - technical approval (in combination with IQ)
  - hygienic approval
Commissioning

Control of:

• Constructural requirements (PUMP-Concept)
• Technical requirements (WD + accessories)
• Supply of recourses (z.B. deionised water)
• Qualification of director and staff
• Quality assurance and
• In case of first validation of processes in an already operated WD: OQ
The „Heart of Validation“: Hygienic Approvement as part of OQ

- **Cleaning efficacy**
  - Chamber, load carrier
  - Channels

- **Disinfection efficacy (total germ reduction)**
  - Channels
  - Outer surfaces: Bioindicators

- **Temperature regulation**
  - thermoelectric measurements

- **Accuracy of display/printout**

- **Dosing accuracy**

- **Water quality**
  - softened water
  - deionised water
  - last rinse water
    - chemical-physical
    - bacteriological
Cleaning efficacy „Dummy-Test“

- **Test pieces:**
  - Teflon tubes of 3.5 m length, Inner diameter 1, 2 and 4 mm
  - simulating the endoscope channels

- **Test soil:**
  - MNE = Mehkleister, Nigrosinlösung, Ei (wheat flour, Nigrosine, Hen’s egg)
  - Drying time: 1 hour

- **Testing:**
  - Connection to nozzles
  - Interruption of the programme before disinfection

- **Acceptance criteria:**
  - No visible residues
Testing of „Total Bacterial Reduction“

- **Microbiological Test:**
  - Same test pieces and Test soil as for cleaning test
  - Alternative: Use of Endoscope dummies and bio indicators

- **Test organism:**
  - *Enterococcus faecium* (ATCC 6057), Initial bacterial count ~ $10^{10}$ cfu/ml

- **Testing:**
  - Full cycle (interruption before drying)
Testing of „Total Bacterial Reduction“ (2)

**Analysis:**
- Rinsing with inhibitory fluid (NaCl)
- Performing of dilution series and plating on agar plates
- Optional: Filling of tubes with Kanamycin Agar

**Calculation of reduction factors:**
- $\text{RF (log)} = \log \text{cfu control} - \log \text{cfu test pieces}$

**Acceptance criteria:**
- Total RF $\geq 9$
Additional tests

• Cleaning/disinfection of outer surfaces: Bioindicators

• Thermoelectric control of process parameters

• Control of dosing

• Physical and bacteriological analysis of the last rinse water
Performance Qualification

- Tests on real endoscopes
  - Rinsing of channels
    - Bacteriological analysis: AC < 10 cfu/ml
  - Protein detection of outer surfaces (hardly accessible spots) and biopsy channel with swabs
    - AC Outer surface: < 20 µg/ instrument
    - AC Biopsy channel: < 100 µg/ channel
Routine control *(in the course of validation)*

- **Each cycle**
  - Visual control for cleanliness
  - Control of programme parameters

- **Weekly tests**
  - Tests for protein residuals *(in implementation)*
  - Use of cleaning indicators
  - Conductivity of deionised water *(if applicable)*

- **Quarterly (at least yearly)**
  - Bacteriological tests on rinsing fluids of channels and last rinse water
Routine control *(actual situation)*

Each used endoscope should be tested once a year!

- **Sampling** (hand disinfection, non touch technique!)
  - **Rinsing fluid**: sterile physiological NaCl-solution
    - 20 ml per channel, drawn in sterile tubes
    - Biopsy channel: to be rinsed by sterile syringe
    - Air/water channel: to be rinsed by use of „water bottle“
    - Additional channels (Bowden control, Jet channel etc.)
Routine control *(actual situation)* (2)

- **Sampling**
  - Swabs from critical spots (e.g. Albarran lever)
  - Last rinse water (e.g. „hygiene programme“ – not to be used in routine!)

- **Processing after sampling** (evtl. only rinsing and drying)

- **Rapid transport to the bacteriological laboratory**
Acceptance criteria / Actions to be taken

- Total bacterial count $\leq 10$ cfu/ml
- *E. coli*, Enterococci, Enterobacteria: not detectable
  - poor cleaning/ disinfection
- *P. aeruginosa*, Pseudomonas sp.: not detectable
  - poor rinsing/ drying
- Other relevant pathogens (e.g. *S. aureus*): not detectable
  - poor storage conditions/ hand hygiene
- Testing of WD-E (cleaning/disinfection efficacy, dosing etc.)
- Testing of water supply quality (e.g. deionised water) / drying /storage
  - Self disinfection cycle?
- Instruction of staff/ checking storage conditions
Cleaning indicators

- Optional during validation
- Recommended as routine control
- Do not replace validation of the process
- Do not replace periodic testing of the WD
Summary

- MD Act: Validation is essential
- Ordinance under §94 MDA: coming soon (hopefully)
- OEGSV-guideline for validation of endocope reprocessing: already available
- EN ISO 15883 part 4: released
- That means: Working on Preparation for validation
  - Implementation of adequate QM-System (working instructions etc.)
  - Upgrading or new acquisition of WD-E
  - Implementing routine controls
  - Qualification of the staff
  - Documentation etc.
www.oegsv.com/guidelines

- Risk categorisation of MD
- Guideline for the Validation of CD Processes (surgical instruments)
- Annex 3: Acquisition of WDs
- Guideline for the Validation of CD Processes for flexible Endoscopes
- Obligatory intermediate rinsing for WD-E
Where is the real problem?

„..the endoscopist tends to see the hole of the patient but not the whole patient...and tends to see the whole instrument ..but not the hole in the instrument...“

Thank you for your attention!