Validation of manual cleaning and disinfection procedures

„Guideline of DGKH, DGSV and AKI for validated manual cleaning and chemical disinfection of medical devices (GVMCD)“

13th October 2011
The guideline for validated manual cleaning and disinfection is being developed by

**DGKH** - German Society for Hospital Hygiene

[www.dgkh.de](http://www.dgkh.de)

**DGSV** - German Society for Sterile Supply

[www.dgsv-ev.de](http://www.dgsv-ev.de)

**AKI** - Instrument Preparation Working Group

[www.a-k-i.org](http://www.a-k-i.org)
Authors of the guideline

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Outline

Requirements

Objektives and Delimitation
Validation of manual procedures
Results of laboratory tests
Trials in the CSSD (practical field)
Key elements of the guideline
Flowcharts to assist in the drafting of SOP’s in CSSD
Present state of work on the guideline
Outlook
Requirements

for the processing of contaminated medical devices regarding

- hygienic aspects
- biocompatibility and
- technical functionality

resulting from:

- Medical Device Directive
- Medical Device Operators Ordinance
- ISO 17664
- RKI / BfArM recommendation (GER)
Requirements

- Quality Management
- Risk assessment and classification of the medical device
- Detailed definition of the individual processing steps
- Application of validated procedures
Outline

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Objectives of the Guideline

➢ Provision of working materials for the creation of operator-specific SOP’s for manual cleaning and disinfection of medical devices depending on design and classification.

➢ Provision of methods and acceptance criteria to verify the operator-specific SOP’s regarding the results of the cleaning and disinfection as well as for the detection of chemical residues after manual cleaning and chemical disinfection.

➢ Provision of recommendations and materials for carrying out the validation of manual cleaning and chemical disinfection.
Delimitation

The recommendations are intended to include all medical devices used on the patient for treatment with the exception of

- flexible endoscopes,
- instruments which have been classified by the manufacturer as single use instruments,
- medical devices classified “critical C”
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**Definition for Validation**

**ISO TS 11139**

„documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications“

*Can this requirement be fulfilled when carrying out manual procedures?*
Validation of manual procedures?

Examples of manual activities during processing of medical devices

- preparatory measures in the OR
- proper dismantling and disposal
- manual precleaning
- loading of washer-disinfectors
- visual inspection
- maintenance and care
- function control
- Packaging (for sterilization)
- release after sterilization
- **Manual cleaning and disinfection**
Validation of manual procedures?

Requirements for validation of procedures

- basis for the validation of manual cleaning and disinfection is an existing quality management system
- technical requirements
- organizational requirements
- information from the manufacturer,
- medical devices - compliant with DIN EN ISO 17664
- process chemicals
- risk assessment and classification of medical devices
- application of validated detection methods to verify quality characteristics
### Outline

- **Requirements**
- **Objectives and delimitation**
- **Validation of manual procedures**
- **Results of laboratory tests**
- **Trials in the CSSD (practical field)**
- **Key elements of the guideline**
- **Flowcharts to assist in the drafting of SOP’s in CSSD**
- **Present state of work on the guideline**
- **Outlook**
Studies on the manual processing of medical instruments
(exploratory investigation on behalf of the guideline-group of DGKH, DGSV and AKI)

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2: MVZ society for medical care centers GbR Cologne
3: MMM Group, Planegg

Authors in consultation with the guideline-group
Method

Instruments used for testing

<table>
<thead>
<tr>
<th>Surgical instruments</th>
<th>Classification categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>surgical forceps</td>
<td>Critical A</td>
</tr>
<tr>
<td>dissecting forceps</td>
<td>Critical A /semicritical A</td>
</tr>
<tr>
<td>Crile-forceps</td>
<td>Critical B</td>
</tr>
<tr>
<td>Volkman spoons</td>
<td>Critical A</td>
</tr>
</tbody>
</table>
Contaminated instruments

test soil A:

- 9,50 ml heparinized sheep blood (10 % A. bidest.)
- 0,35 ml *Enterococcus faecium* (10⁹ KBE/ml)
- 1,5 I.E./ml Protamin (0,15 ml) added just before soiling
Test procedures

- **Products used for testing**
  - 6 different combined cleaner disinfection products (A, B, C, D, E, F - 1 of the products with surfactants)
  - 5 different cleaners (G, H, I, J, K - 4 with surfactants and one enzymatic cleaner)

- **Test designs**
  - 8 different designs were tested
Disinfection
Brush cleaning

Neutralisation
# Test results

## manual processing of surgical forceps

<table>
<thead>
<tr>
<th>Test design</th>
<th>processing steps</th>
<th>Product</th>
<th>Ig RF</th>
<th>Ig RF (1. disinfection)</th>
<th>Ig RF (after 2nd rinsing)</th>
<th>Ig RF (after 1st rinsing)</th>
</tr>
</thead>
<tbody>
<tr>
<td>III a</td>
<td><strong>wet disposal B</strong> (15 min RT) – disinfection (15 min) brushing (2 min) – rinsing under water (30 sec)</td>
<td>C</td>
<td>6,45</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D</td>
<td>6,75</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>IV a</td>
<td><strong>dry disposal B</strong> (60 min 20°C) – rinsing under water (30 sec) – Enzymatic cleaner (10 min), brushing (2 min) – rinsing under water (30 sec) – disinfection (15 min) – clear rinsing</td>
<td>J + C</td>
<td>5,45</td>
<td>–</td>
<td>3,11</td>
<td>0,15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>J + D</td>
<td>6,77</td>
<td>–</td>
<td>2,42</td>
<td>0,64</td>
</tr>
<tr>
<td>VI</td>
<td><strong>dry disposal B</strong> (60 min 20°C) – disinfection (15 min) brushing (2 min) – rinsing under water (30 sec) – disinfection (15 min) – clear rinsing</td>
<td>D</td>
<td>6,18</td>
<td>4,14</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>
## Test results

### Manual processing of Crile-forceps

<table>
<thead>
<tr>
<th>Test design</th>
<th>processing steps</th>
<th>Product</th>
<th>Ig RF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>dry disposal A (60 min 45°C) – disinfection 15 min</td>
<td>A</td>
<td>0,91</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B</td>
<td>0,96</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>1,89</td>
</tr>
<tr>
<td>IIIa</td>
<td>wet disposal B (15 min RT) – disinfection (15 min) brushing (2 min) – rinsing under water (30 sec)</td>
<td>C</td>
<td>2,02</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D</td>
<td>3,40</td>
</tr>
</tbody>
</table>
# Test results

## Manual processing of Crile-forceps

<table>
<thead>
<tr>
<th>Test design</th>
<th>processing steps</th>
<th>Product</th>
<th>Ig RF</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV a</td>
<td><strong>Dry disposal B</strong> (60 min 20°C) – rinsing under water (30 sec) – Enzymatic cleaner (10 min), brushing (2 min) – rinsing under water (30 sec) – disinfection (15 min) – clear rinsing</td>
<td>J + C</td>
<td>4,62</td>
</tr>
<tr>
<td></td>
<td></td>
<td>J + D</td>
<td>5,59</td>
</tr>
<tr>
<td>VI</td>
<td><strong>Dry disposal B</strong> (60 min 20°C) – disinfection (15 min), brushing (2 min) – rinsing under water (30 sec) – disinfection (15 min) – clear rinsing</td>
<td>D</td>
<td>3,81</td>
</tr>
<tr>
<td></td>
<td></td>
<td>F (with surfactants)</td>
<td>6,13</td>
</tr>
</tbody>
</table>
Test design following the steps on the flow chart

1. **Disposal**
   - Dry in a closed container
   - Pre-cleaning immediately after use by wiping it with a swab at the operating table

2. **If necessary pre-rinsing**
   - Pre-rinsing under running cold water

3. **Cleaning**
   - Insert in cleaning solution* according to the manufacturer's instructions, open and close at least 5 times and then clean mechanically with a brush under the water level until the medical device is visually clean
   - Rinse with running tap water for at least 10 seconds, whilst opening and closing the joint of the instrument

4. **Draining**
   - Drain (to avoid the dilution of the disinfectant)

5. **Disinfection**
   - Complete immersion in instrument disinfection solution, opening and closing of the joint below liquid level at least 5 times
   - Complete immersion in instrument disinfection solution, opening and closing of the joint below liquid level at least 5 times

6. **Final rinsing**
   - Rinse under running demineralized water for at least 10 seconds (at least microbiological quality of drinking water), at least 5 times opening and closing of the joint

7. **Drying**
   - Dry the inside and outside of instrument with sterile filtered compressed air and/ or clean, germ-free, lint-free cloth

8. **Transfer**
   - Transfer instrument to packaging zone

9. **Documentation**
   - Further steps will follow for release to use (e.g. care / functional testing, packaging, sterilization, if necessary)

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*instead of a cleaning solution a combined cleaning / disinfecting solution can be used
** the cleaning can be performed with ultrasound

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WFHSS Congress, Anke Carter & Dr. Jürgen Gebel

October 2011
## Test results

### Manual processing of Volkmann spoons

<table>
<thead>
<tr>
<th>Test design</th>
<th>processing steps</th>
<th>product</th>
<th>Ig RF</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIII</td>
<td><strong>dry disposal B</strong> (60 min 20°C) – rinsing under water (30 sec) – Enzymatic cleaner (10 min), brushing (2 min) – rinsing under water (30 sec) – disinfection (15 min) – clear rinsing</td>
<td>D</td>
<td>7.29</td>
</tr>
<tr>
<td></td>
<td></td>
<td>F (with surfactants)</td>
<td>7.29</td>
</tr>
</tbody>
</table>
Summary of results of laboratory tests

- Instruments of category "critical B" have, compared to "semi-critical A" and "critical A" instruments, a significantly higher demand for cleaning and disinfection.

- **Different** Standard Operating Procedures (SOPs) are needed for instruments of different design.

- Manufacturers of instruments have to provide detailed processing recommendations.

- There was a large variation in results depending on the processing procedures, thus a standardization of procedures is urgently needed.

- Independent testing of the combination „instrument – processing procedures“ is highly recommended.
Outline

- Requirements
- Objectives and delimitation
- Validation of manual procedures
- Results of laboratory tests
- Trials in the CSSD (practical field)
- Key elements of the guideline
- Flowcharts to assist in the drafting of SOP’s in CSSD
- Present state of work on the guideline
- Outlook
Trials in CSSD

- Trials without standard operating procedure (SOP)
  - 10 CSSDs participated in the first trial
  - Cleaning and disinfecting Crile forceps
    - following their own standards
    - using their own chemicals
    - using their own cleaning equipment (e.g. brushes)

- Trials with a provided standard operating procedure (SOP)
  - 9 CSSDs participated in the second trial
  - Cleaning and disinfecting Crile forceps
    - following instructions stated in the SOP
    - using their own chemicals
    - using their own cleaning equipment (e.g. brushes)
Results of practical trials in CSSD

Following own SOP

Following SOP provided by guideline working group

µg Protein/Prüfkörper
Results of practical trials in CSSD with ultrasonic treatment

\[ \mu g \text{ Protein/crile forceps} \]

Published: Central Service, 18. year, 2010: Pages 36-39
Summary of field tests in the CSSD's

- Results of field tests with well-trained personnel are comparable with those of a non-validated test of WD's with the same specimens (CSSD 2005)
- Manual cleaning and disinfection takes a lot of staff time (8-15 minutes /instrument)
- Optimization potential through standardization and validation of the processes is apparent
- Manual processing using ultrasound shows very good results
Outline

Requirements

Objectives and delimitation

Validation of manual procedures

Results of laboratory tests

Trials in the CSSD (practical field)

Key elements of the guideline

Flowcharts to assist in the drafting of SOP’s in CSSD

Present state of work on the guideline

Outlook
Key elements of the guideline

- Legal and normative requirements
- Definitions of terms
- Prerequisites for the standardization
- Flowcharts to assist in the creation of SOP’s depending on the design and classification of the medical device and the contamination
- Test methods for the verification of SOP’s including those for the sub-steps of manual cleaning and chemical disinfection
- Conduction and working materials needed for the validation
Outline

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Flowcharts to assist in the drafting of SOP’s in CSSD

Present state of work on the guideline

Outlook
3 Flowcharts in the guideline

- 3 flowcharts were developed with the following purposes:
  - Support for CSSD staff when writing SOPs for manual cleaning and disinfection.
  - The flowcharts cannot replace SOPs as some criteria important for the procedure are not included, i.e.:
    - chemicals for cleaning and disinfection
    - detailed design of instruments
    - details about the equipment used for cleaning the instruments
- Flowchart for instruments without joints or lumen.
- Flowchart for instruments with joints.
- Flowchart for instruments with hollow tube /lumen.
Surgical instruments without joints and hollow tubes (Volkmann Spoon)

**Disposal**
- Dry in a closed container
- precleaning immediately after use by wiping it with a swab at the operating table

**if necessary pre-rinsing**
- Not necessary

**Cleaning**
- insert in cleaning solution* according to the manufacturer's instructions, clean mechanically with a brush underneath the water level until the medical device is visually clean

**Intermediate rinsing**
- Rinsing with running tap water for at least 10 seconds

**Draining**
- Drain (to avoid the dilution of the disinfectant)

**Disinfection**
- Complete immersion in instrument disinfection solution

**Final rinsing**
- Rinse under running demineralized water for at least 10 seconds (at least microbiological quality of drinking water)

**Drying**
- dry the inside and outside of instrument with sterile filtered compressed air and / or clean, germ-free, lint-free cloth

**Transfer**
- Transfer instrument to packaging zone

**Documentation**
- Further steps will follow for release to use (e.g., care / functional testing, packaging, sterilization, if necessary)

*instead of a cleaning solution a combined cleaning/ disinfecting solution can be used
** the cleaning can be performed with ultrasound
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Surgical instruments with joints (Crile forceps)

Disposal

Dry in a closed container pre-cleaning immediately after use by wiping it with a swab at the operating table.

if necessary pre-rinsing

Pre-rinsing under running cold water

Cleaning**

insert in cleaning solution* according to the manufacturer’s instructions, open and close at least 5 times and then clean mechanically with a brush underneath the water level until the medical device is visually clean.

Intermediate rinsing

Rinsing with running tap water for at least 10 seconds, whilst opening and closing the joint of the instrument.

Draining

Drain (to avoid the dilution of the disinfectant)

Disinfection

Complete immersion in instrument disinfection solution, opening and closing of the joint below liquid level at least 5 times.

Final rinsing

Rinse under running demineralized water for at least 10 seconds (at least microbiological quality of drinking water), at least 5 times opening and closing of the joint.

Drying

dry the inside and outside of instrument with sterile filtered compressed air and/or clean, germ-free, lint-free cloth.

Transfer

Transfer instrument to packaging zone

Documentation

Further steps will follow for release to use (eg care/functional testing, packaging, sterilization, if necessary).

*instead of a cleaning solution a combined cleaning/disinfecting solution can be used

**the cleaning can be performed with ultrasound

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Hollow tube instruments (i.e. Suction tube, trocar)

Disposal
Dry in a closed container immediately after use by wiping it with a swab at the operating table

if necessary pre-rinsing
Pre-rinsing under running cold water

Cleaning**
Insert in cleaning solution* according to the manufacturer’s instructions, clean mechanically with a brush underneath the water level until the medical device is visually clean

Intermediate rinsing
Rinsing with running tap water for at least 10 seconds, rinse the inner lumen of instrument for at least 10 seconds

Disinfection
Complete immersion in instrument disinfection solution, opening and closing of the joint below liquid level at least 5 times

Final rinsing
Rinse under running demineralized water for at least 10 seconds (at least microbiological quality of drinking water), rinse also the inner lumen for at least 10 seconds

Drying
Dry the inside and outside of instrument with sterile filtered compressed air and/or clean, germ-free, lint-free cloth

Transfer
Transfer instrument to packaging zone

Documentation
Further steps will follow for release to use (e.g. care/functional testing, packaging, sterilization, if necessary)

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Dry in a closed container immediately after use by wiping it with a swab at the operating table

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Disinfection
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Drying
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Documentation
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Key elements of the guideline

Flowcharts to assist in the drafting of SOP’s in CSSD

Present state of work on the guideline

Outlook
Present state of work on key elements of the guideline

- Legal and normative basis
  - Developed largely
- Definitions of terms
  - Developed largely
- Requirements for Standardization
  - Developed largely
- Flowcharts to assist in the creation of SOPs, depending on the design of the medical device
  - Three flow diagrams were developed
- Test recommendations for verification of SOPs for the individual steps of manual cleaning and chemical disinfection
  - Developed largely
- Conduct and working material for the validation
  - Developed largely
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Present state of work on the guideline

Outlook
Outlook

- Completion of work on the guideline: Q4 / 2011
- Editing of the guideline: Q1 / 2012
- Publication of the guideline: Q2 / 2012

For further details about the Study at Bonn University, please contact Dr. Jürgen Gebel at Juergen.Gebel@ukb.uni-bonn.de
Thank You very much for your attention!