Validation of washing and disinfection procedures – performance testing

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What does ‘VALIDATION‘ mean?

- According to EN ISO 15883 validation is a documented procedure for obtaining, recording and interpreting the required to establish that a process will consistently yield product complying with predetermined specifications.

- Dr. Kromidas: Validation of a process is a documented qualification for a particular and intended purpose – it’s not a matter to serve as an alibi but to approach the truth.
Why to validate?

The objective of validation is to achieve a high safety standard with reprocessing of medical devices to protect the patients and to provide legal security for those being responsible.
Guidelines compiled jointly by:

AKI
Instrument Reprocessing Working Group

DGKH
German Society for Health-Care Hygiene

DGSV
German Sterile Supplies Society
Ao concept for thermal disinfection parameters

- Ao is defined as time equivalent in seconds at 80°C required to achieve a predetermined level of disinfection.
- Under the presumption (simplification) that the drop in the titre count is linear with respect to the change in temperature, it is possible to calculate the appropriate contact/holding times for other relevant temperatures.
**A₀ values for various applications**

- **A₀ = 600 secs.** (80°C/10 mins. or 90°C/1 min.) for devices coming only in contact with intact skin
- **A₀ = 3000 secs.** (80°C/50 mins. or 90°C/5 mins.) required to deal with highly resistant pathogens (HBV) or high levels of contamination
- **A₀ = 60 secs.** (80°C/1 min. or 75°C - 5 mins.) for containers for human excrements

**Temperature tolerance: -0/+5°C**
Disinfection performance test

Thermal disinfection in accordance with EN ISO 15883, 6.8.2

1 = Next to temperature sensor for automatic controls
2 = Location in which operating temperature is first reached
3 = Location in which operating temperature is reached last
4 (5, 6) = Reference sensors for cabinet temperature

Recommendation: At least two cycles with 6 sensors or 3 cycles with 4 sensors for each load category.
Temperature measurements using data logger
Temperature/pressure monitoring using a logger

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Cleaning performance test

Cleaning tests allow the use of two approaches:

- Test instruments with predefined soiling (A)
- Instruments soiled through practical use (B)
Load pattern has to be appointed
Test soil preparation at laboratory:
Contamination of the haemostatic clamp with 100 µl clottable blood, dried on for 1 hour at 45°C, packed in a bag, evaporated and sealed.
Loading the instruments contaminated by normal use, those are identified to be significantly soiled and intended to be checked for cleaning result after washing.
Washing and thermal disinfection process (Vario)

Testing cleaning efficacy, the cycle shall be run without a disinfection stage (6.10.1. of ISO EN 15883-1)
Visual inspection – non acceptable result
Sampling to enable chemical protein analysis
Elution

Intensive rinsing of the joint area using 1% SDS solution
Test Kit using the semi-quantitative Biuret/BCA detection method
Comparison with the colour chart

- kein Protein: 0 μg/ml
- wenig Protein: ca. 50 μg/ml
- viel Protein: ≥100 μg/ml
Measurement with reflectometer RQflex (VWR)
Sampling with a MIS shaft
Cleaning Test: acceptance criteria

- **Max. permissible value:** Test instruments must be visually clean. In addition to visible cleanliness, a protein content of 200 µg (as bovine serum albumin) per instrument applies as max. permissible value. With values above the WD has to be decommissioned.

- **Alert value:** Values above 100 µg protein (as bovine serum albumin) per instrument demand improvement of performance.

- **Guideline:** Max. 100 µg protein (as bovine serum albumin) per test instrument is acceptable.
In routine you can only refer to the performance testing results if you keep the load pattern
Cleaning and thermal disinfection process
Isothermal wash with alkaline detergent (0.3 %) comparison with demineralized and softened water

% residue protein

- DI-Water
- Soft-Water

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Temperature/pressure monitoring using a logger

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Remaining cleaning problems

Even with optimal design of the Vario-process not all cleaning tasks will be accomplished:
- Incrusted residual blood in difficult accessable areas of instruments (slits, joints)
- After longer drying on times, e.g. after surgery on weekend reprocessing the instruments on Monday
- Denaturation and fixation by antiseptics
- Thermal fixation with HF instruments
Cleaning indicators are not mentioned in EN ISO 15883. The different indicators in the market have different baseless endpoints. TOSI test in a domestic dishwasher gave excellent results.
Oxidative effect of peroxide in a laboratory test

Filter paper method

1. DI-water
2. NaOH solution pH 11
3. Hydrogenperoxide 0.1% 
4. Peroxid 0.1%/ alk. FR pH 11

% Restkontamination
The solution to overcome cleaning problems: Oxivario

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Blood fixated by glutardialdehyde

after Vario after Oxivario process
Coagulation forceps

before

after Oxivario
Colour changes by Oxivario with Titanium implants
Many thanks for your attention!