Examination and validation for washer-disinfectors for flexible endoscopes

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Legal Basis for the Examination and Validation of WD

Basis for the cleaning and disinfection of medical devices for health institutions are the Austrian Medical Device Act (MPG), the ordinance acc. to § 94 MPG, the recommendation of the Robert-Koch-Institute (RKI) „Hygieneic Requirements for the Processing of Medical Devices" and the EN 15883 part 1 - 5.

The examination and validation of cleaning and disinfection methods for the preparation of flexible endoscopes also poses a challenge for testing methods.

The work presented describes a method for the validation of cleaning and disinfection method for the preparation of flexible endoscopes according to EN ISO 15883 part 1 and prEN ISO 15883 part 4.

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Implementation of the Examination

The examination can be structured into the following steps depending on devices and programs to be tested:

- Thermoelectric test for the validation of the temperature sequence in **all** cycles
- thermoelectric test of the Self-disinfection cycle
- Test of the dosage accuracy
- Test of cleaning efficacy
- Microbiological testing of the disinfection efficacy in cycles and part of cycles
- Test of resources (e.g. quality of water supply)
- Chemical and physical test of the final rinse water quality (chamber)
- Microbiological testing of final rinse water quality (chamber)

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Thermoelectric Test: Validation of the Temperature Sequence

Multi-channel process chart recorder (or thermo-logger) with 6 temperature sensors

All programmes used

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Test of the dosage accuracy

The test can be performed volumetric or gravimetric

Gravimetric Test:

- Put the cleaner canister on the scales
- Note the weight
- Read the weight after the dosage is applied
- Calculate the dosage minding the density
- Maximum deviation +/-10 %

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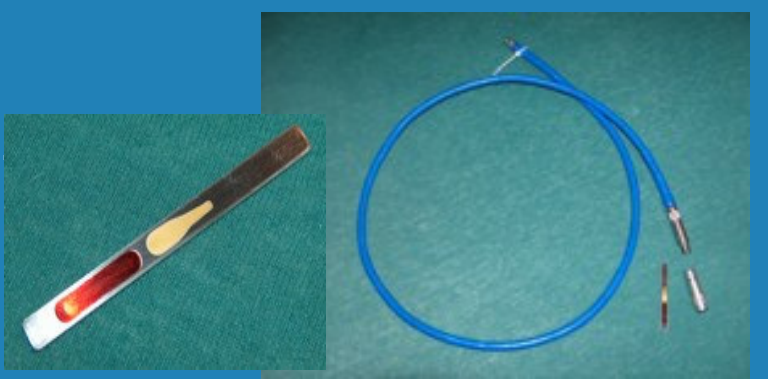
Test of cleaning efficacy of endoscope channels in dummy tests

As test pieces we use Teflon tubes with a lenght of 2000 mm and inner diameters of 2 mm and 1 mm respectively.

To contaminate the test pieces we inject soil (wheat flour, nigrosine, hen‘s egg – according to „MNE Prüfanschmutzung nach Koller„) into the Teflon tubes. After 60 minutes of drying, the tubes are purged with air in order to ensure they are not blocked.

Per tested programme or cycle we prepare one pair of test pieces (1 x 1 mm, 1 x 2 mm inner diameter).

Additionally we perform a flexi-check test (blood and polysaccharide-test contamination).



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Test of disinfection efficacy of endoscope channels in dummy tests

Preparation of metal germ carriers

Small metal plates with a length of 55 mm, a width of 5 mm, and a thickness of 1 mm

Concentration on each plate
10^{10} Enterococcus faecium
(EK) ATCC 6057

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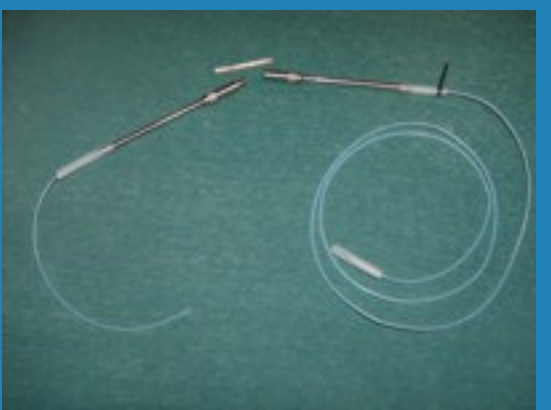
Test of disinfection efficacy of endoscope channels in dummy tests

Preparation of the Test Body

As test piece for the disinfection efficiency we use Teflon tubes with a length of 1500 + 200 mm and an inner diameter of 2 mm and 1 mm and a test chamber (TOSI-Lumcheck) with metal plates, with a suspension of test organisms (Enterococcus faecium ATCC 6057) of 10^{10}.



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Test of disinfection efficacy of endoscope channels in dummy tests

Test cycles:

Cleaning cycle (break after the cleaning stage):

RF: > 4 log step

Complete cycle:

RF: > 9 log step

RF: Reduction factor of the applied test organisms

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Test of water quality

Ressource check (VE-water-inflow)

From the water inflow we take 350 ml water close to the WD.

Acceptance criteria

cfu 37°C: < 20 cfu / ml

Pseudomonas aeruginosa: 0 cfu / 100 ml

Enterococcaceae: 0 cfu / 100 ml

Enterobacteriaceae: 0 cfu / 100 ml

Test of water quality

Final rinse water

Acceptance criteria

cfu 22°C: < 20 cfu / ml

cfu 37°C: < 20 cfu / ml

Pseudomonas aeruginosa: 0 cfu / 100 ml

Enterococcaceae: 0 cfu / 100 ml

Enterobacteriaceae: 0 cfu / 100 ml

Differentiation of germs (cfu 22°C and 37°C):
no Staphylococcus aureus

Results

Cleaning cycle (break after the cleaning stage)

1 mm Dummy:

Reduction factor: 5

2 mm Dummy:

Reduction factor: 6

Complete cycle (1 mm und 2 mm Dummy)

Reduction factor: > 9 log steps

(no detection of the test organisms)

(5 machine types of 4 suppliers)

Summary

The method is suitable according to prEN 15883 part 4 in respect to required reduction factors of test organisms for part and full cycles

Simple and suitable on-site test method

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Thank you for your attention

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