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

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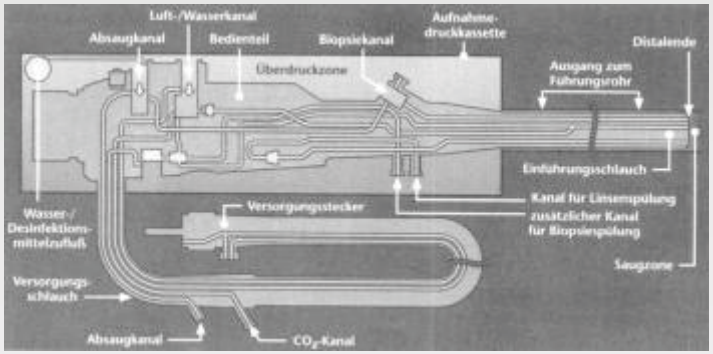
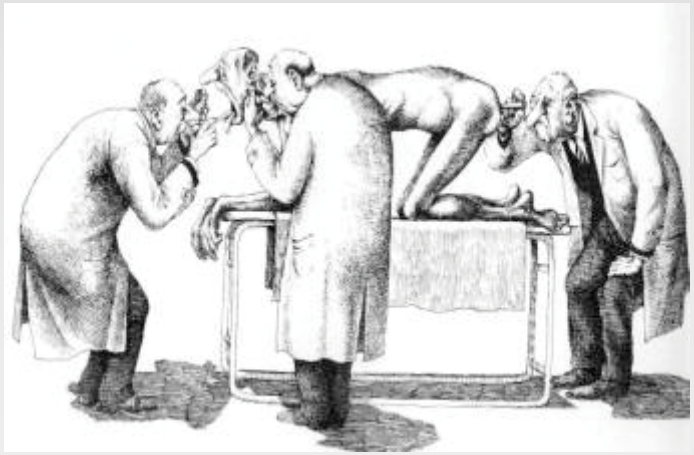
G. Palmisano gespag_center_for_hygiene

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

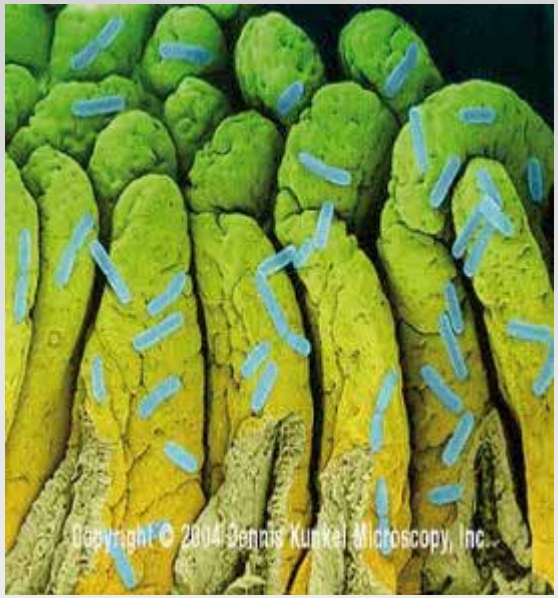


- Practice
  - as many examinations as possible
  - in as less time as possible
  - with as few instruments as possible



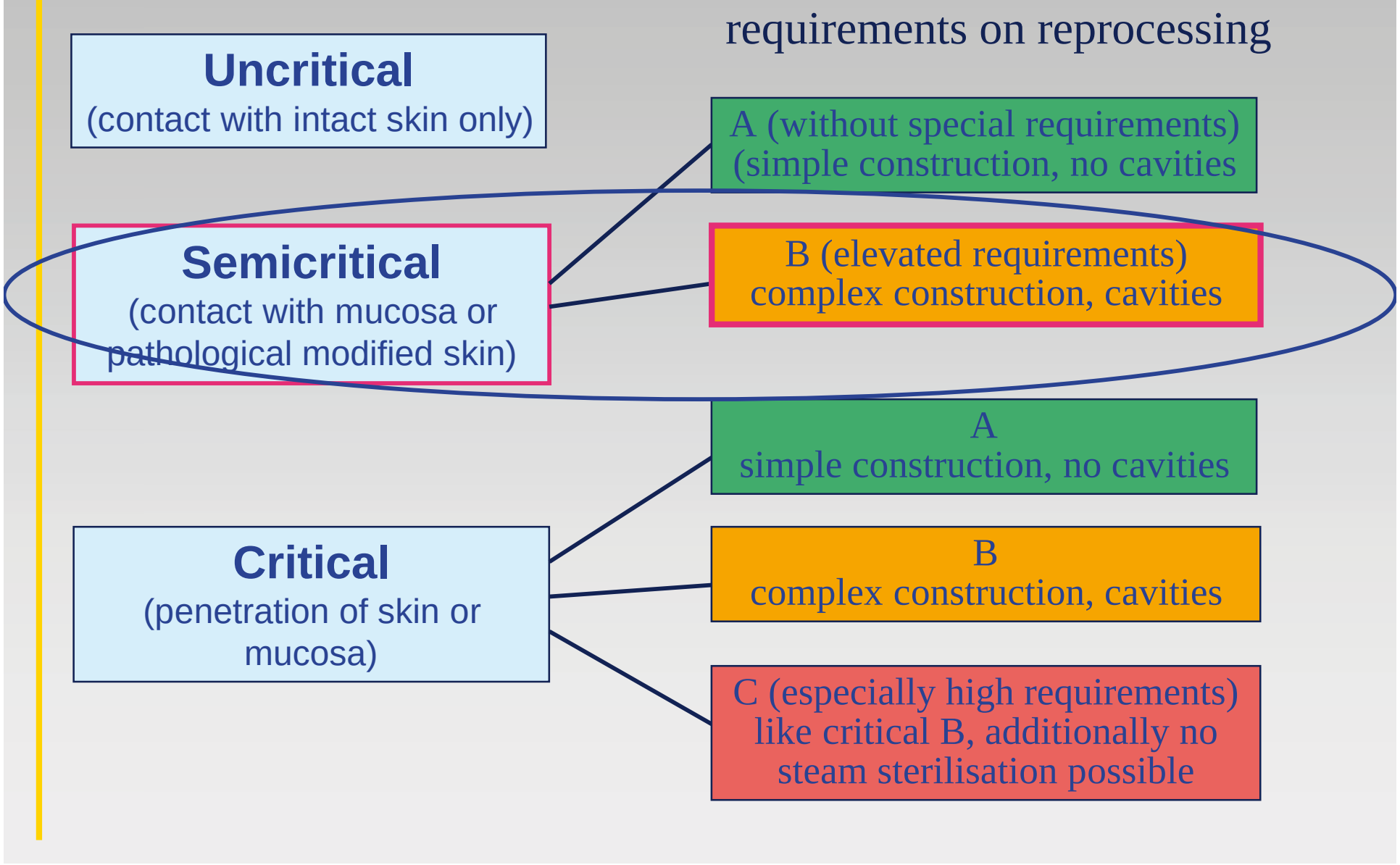
Bioburden of flexible Endoscopes

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



- After processing:
  ≤ 10 cfu / channel
- ➪RF ≥ 9 log (full cycle)

Categorisation of Medical Products into Risk Groups following RKI



Situation in Austria

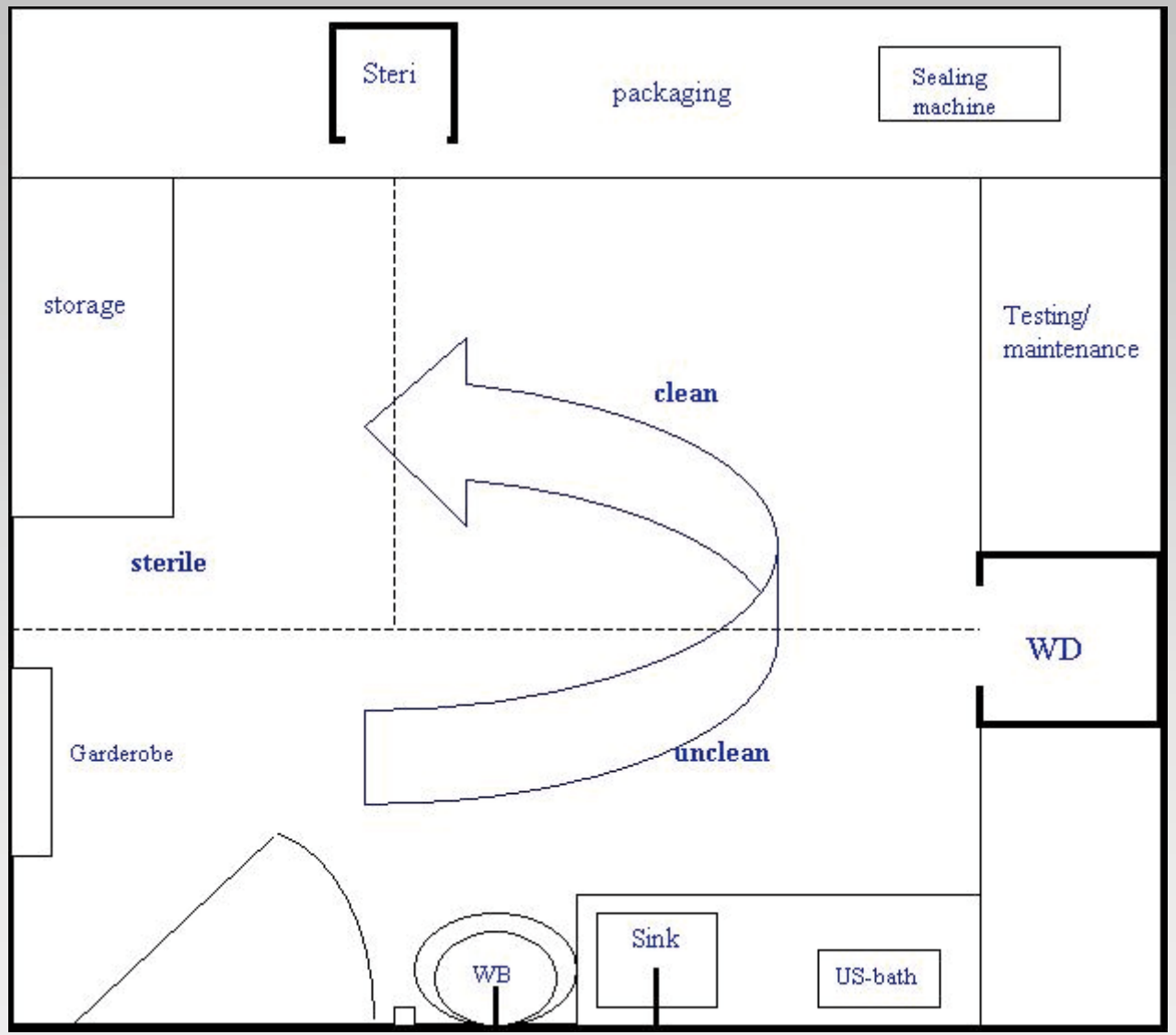
- About 470.000 Gastro- and Colonoscopies / Year
- Hospitals: Processing exclusively in WDs
- Resident doctors: only about 30% automatic processing

Annex 2: AEMP (PUMP)-Categorisation

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

PUMP II

- Seperate Room
- Seperation 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 4: Requirements and Tests for WDs for flexible Endoscopes (WD-E): August 2008
- Part 5: Test Methods (in Revision)

Testing, Validation and Routine Control

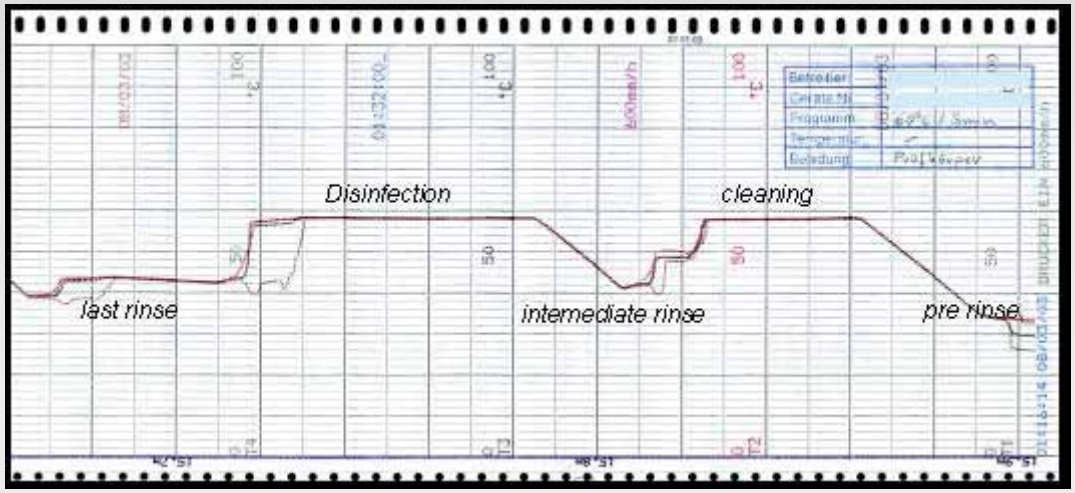
OEGSV Guideline for Testing, Validation and Control of automatic Cleaning and Disinfection Procedures of flexible Endoscopes

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

www.oegsv.com

WD-flexible Endoscopes

- Program 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
  - **I**nstallation **Q**ualification,
  - **O**perational **Q**ualification and
  - **P**erformance **Q**ualification

IQ /OQ

- IQ:
  - Control, if the WD is delivered according to tendering, that it is supplied with the required recources and safe for use
- OQ:
  - technical approvement (in combination with IQ)
  - hygienic approvement

Commissioning

Control of:

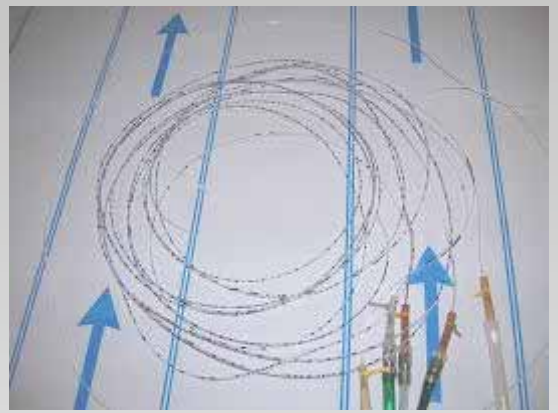
- Constructural requirements (PUMP-Concept)
- Technical reuirements (WD + accessories)
- Supply of recources (z.B. deionised water)
- Qualification of director and staff
- Quality assurance and
- In case of first validation of processes in an already operated WD: OQ

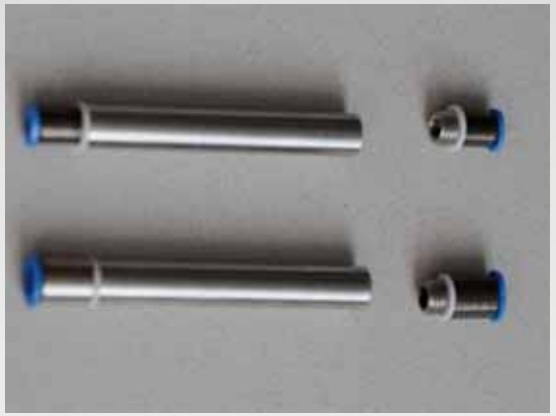
The „Heart of Validation“: Hygienic Approvement

- **Cleaning efficacy**
  - Chamber, load carrier
  - Channels
- **Disinfection efficacy (total germ reduction)**
  - Channells
  - 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 lenght, Inner diameter 1, 2 and 4 mm
  - simulating the endoscope channels
- **Test soil:**
  - cleaning indicators
- **Testing:**
  - Connection to nozzles
  - Interruption of the programme before disinfection
- **Acceptance criteria:**
  - No visible residues





Testing of „Total Bacterial Reduction“

- **Microbiological Test:**
  - 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:**
  - Transfer of bio indicators to solution with neutralizers for disinfecting agents
  - Membranfiltration and plating filters on agar plates
- **Calculation of reduction factors:**
  - RF (log) = log cfu control - log cfu test pieces
- **Acceptance criteria:**
  - Total RF ≥ 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 endocopes
  - 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 lot
  - 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

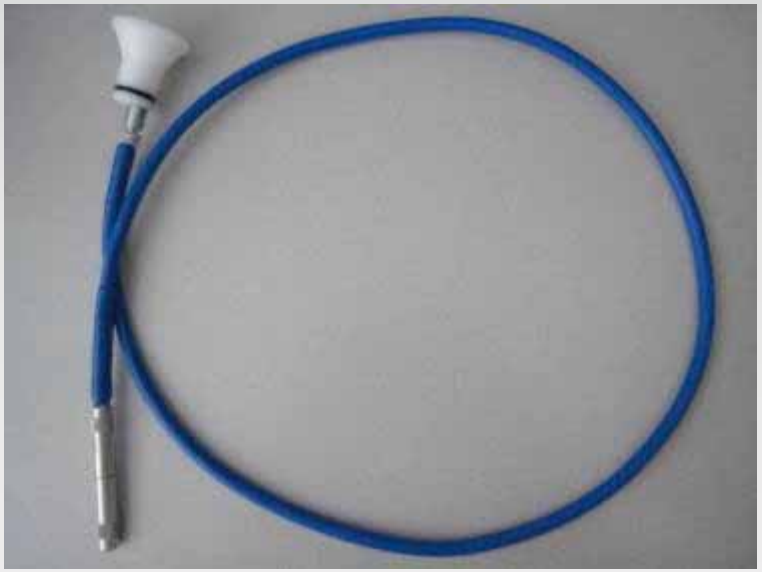
Acceptance criteria / Actions to be taken

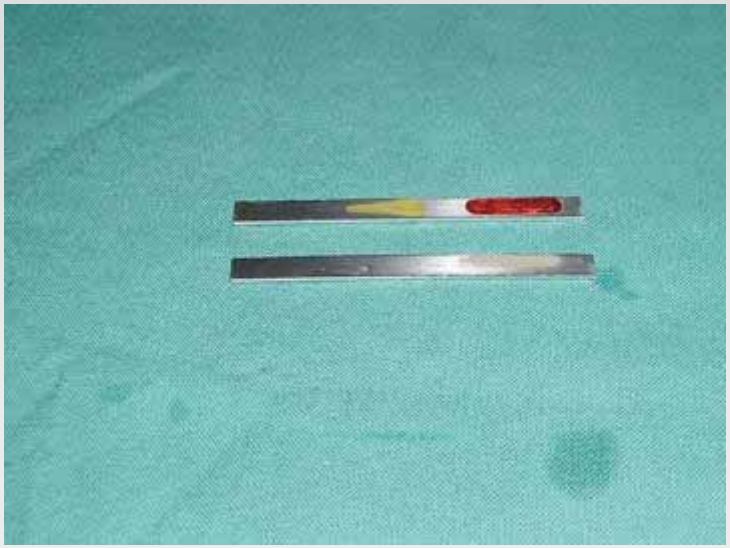
- Total bacterial count ≤ 10 cfu / ml
- *E. coli*, Enterococci, Enterobacteria: not detectable
  - poor cleaning / disinfection
- *P. aeruginosa*, Pseudomonas sp.: not detectable
  - poor rinsing / drying
- Other relevant pathogens (e.g. *S. aureus*): not detectable
  - poor storage conditions / hand hygiene

- Testing of WD-E (cleaning/disinfection efficacy, dosing etc.)
- Testing of water supply quality (e.g. deionised water) / drying /storage
- Instruction of staff / checking storage conditions

Cleaning indicators

- Can be used as part of 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
- OEGSV-guideline for validation of endoscope reprocessing
- EN ISO 15883 part 4
- That means: Working on Preparation for validation
  - Implementation of adequate QM-System (work 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**
- **Annex 3: Aquisition 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…“

fine