EN ISO 15883 – A Milestone?

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- EN ISO 15883 has cast its shadows before it
  - Manufacturer: Adjustment of WDs to the requirements of the standard
  - Inspectors: Adjustment of test methods, developing of guidelines
  - User: Taking account of the provisions of the standard in their calls for tenders.
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- CEN TC 102 /WG 8
  - Approx. 10 years of exhausting work on the standards
  - Interests of the member countries and their representatives respectively (WD-manufacturers, hygienists)
  - Critics: No users, not all countries represented
  - Parts 1, 2, 3 and 5: valid standard worldwide
  - Finished for more than one year but still not published (?)
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- **Part 1:** General requirements, definitions and tests
- **Part 2:** Requirements and tests for washer disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment hollowware, utensils, glassware etc. (= „WDs for instruments“)
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- **Part 3**: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (= „bedpan-washers“)
- **Part 4**: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (= „WDs for Endoscopes“)
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„Special case“ ISO/TS 15883-5: Test soils and methods for demonstrating cleaning efficacy

- Task of CEN to work out uniform test methods could not be finished by now
- (Nearly) every country has its own test method (AT, DE, FR, NL, SE, UK, US)
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Scope

- General requirements on WDs and accessories
- Cleaning and disinfection of reusable medical devices used in the context of medical, dental, pharmaceutical and veterinary practice.
- Not for laundry washing machines and dishwashers
- (in Austria: A₀-concept for this purpose integrated as well)
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- Part 1:
  - Technical (safety-, electrical) requirements
  - Performance Requirements to be demonstrated in the course of
    - Type-and works test
    - Validation: IQ, OQ, PQ
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- Type test:
  - Different views concerning scope and contents
  - ÖGSV- guideline on testing, validation and routine control of cleaning-disinfection processes for medical products – Annex 3: Procurement
    - Contents of the type test, which have to be available before IQ and OQ
    - Planned: List of WDs with corresponding type tests
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General requirements

- Cleaning efficacy shall be demonstrated by use of a test method given in ISO/TS 15883-5
- Preference must be given to thermal disinfection.
- The chamber shall be disinfected as well (single chamber devices)
- Means shall be provided to verify and/or record the attainment of the specified process conditions.
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- General requirements (2)
  - The manufacturer shall give information about the **process chemicals** to be used and the **water quality**
  - **Prerinsing** should be carried out with water below 45 °C
  - The concentration of the **process chemicals** has to be lowered to a level, which was stated by the manufacturer to be safe
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- **Process verification** (depending on risk)
  1. Indication only (e.g. bedpan washers)
  2. Recording of disinfection parameters only
     - (e.g. WDs for instruments, if cleaning efficacy can be verified visually)
  3. Recording of Cleaning *and* disinfection parameters
     - MP, which are used without further treatment (e.g. endoscopes)
     - or cleaning efficacy cannot be verified visually (e.g. MIS-instruments)
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- Thermal Disinfection
  - Meeting the specified temperatures and holding times – or -
  - Equivalent lethal effect ($A_0$-concept)
  - Disinfection temperature band:
    Specified temperature – 0 /+5 °C
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- $A_0$ - concept
  - $A_0$-value = time in seconds at 80 °C to produce a given disinfection effect, when $z = 10^*$
    - $A_0 = \sum 10^{(T-80/z)} \Delta t$
    - $t = A_0/10^{(T-80/z)}$

$z$ = Temperature change, which is required to change the D-value by a factor of 1 log

** D-value: Time in minutes at a given temperature to lower the germ count by a factor of 1 log
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- Which $A_0$-value has to be achieved depends on the expected species and count of microorganisms on the MP as well as further treatments and the intended use.

- Proposed $A_0$-values for:
  - „Critical“ MP acc. to RKI (e.g. surgical Instr.): 3000
  - „Semicritical“ MP (e.g. anesthetic equipment): 600
  - „None-critical“ MP (e.g. bedpans): 60
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<table>
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<th>Process Temp (°C)</th>
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<th>Holding time for $A_0=600$ (semicritical MP)</th>
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</table>
Part 4: WDs for endoscopes

- ÖGSV: Guideline for testing, validation and routine control of cleaning and disinfection processes for flexible endoscopes: Under construction

- To be considered when purchasing a new machine:
  - Rinse step between cleaning and disinfection
  - Single channel cleaning (no pressurized chamber machines)
  - Single channel monitoring (?)
  - Traceability (documentation)
YES!

Despite the barrage of criticism addressed to the various parts of the standard, this can on the whole be viewed as a milestone in the field of medical device decontamination, which will contribute to the standardisation, comparability and quality assurance in the field of medical devices’ decontamination and thus to patient safety.
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Thank you for your attention!!!

ÖGSV-wfhss-Kongress Baden/ Austria