Washer-Disinfectors
EN 15883 and the rôle of the operator

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EN 15883 and the rôle of the operator

- Current status of EN 15883
  - Part 1 General
  - Part 2 Surgical Instrument
  - Part 3 Human waste container
  - Part 4 Endoscope

Further parts?

- Safety requirements IEC 61010-2-045
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- **Introduction**
  - Use only for loads specified by WD manufacturer
  - Validation and periodic testing

- **Scope**
  - Specifies general performance requirements
  - Cleaning and disinfection of RMDs
  - Excludes Laundry, catering and ‘washer-sterilizers’
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- **Definitions**
  - $A_0$
  - Cleaning
  - Disinfection
  - Validation
    - IQ
    - OQ
    - PQ
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- $A_o$
  - Equivalent time in seconds at 80°C, delivered by the disinfection process

- Cleaning
  - Removal of contamination to the extent necessary for its further processing and intended use

- Disinfection
  - Reduction of the number of microorganisms to a level specified as appropriate for handling or use
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- **Validation**
  - Documented procedure for obtaining, recording and interpreting data required to show that a process will comply consistently with pre-determined specifications
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CLEANING IS AN ENERGETIC PROCESS

- Physical
- Chemical
- Thermal
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- PUMP
- DRAIN
- WATER
- STEAM or ELECTRIC HEATING
- HOT AIR DRYING
- DETERGENT
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SERVICES
- Water
- Electricity
- Steam
- etc

ENVIRONMENT
- WD

PROCESS CHEMICALS
- Detergent
- Neutraliser
- Rinse aid

USER
- Maintenance
- Operation
- Testing

MANAGEMENT

ACTIVITIES

/etc
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- **Performance requirements**
  - Any item which has been processed shall have been cleaned, disinfected, rinsed and, when appropriate, dried.

- Cleaning and disinfection is also required for chamber walls and load carriers

- **Automatic process control**

- **Independent monitoring**
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- **Mechanical and process requirements**
  - Leak tight chamber
  - Materials that will not corrode in use
  - Longevity – 10,000 cycles
  - Standard entry port for temperature sensors
  - Control of doors – safety interlocks
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- Mechanical and process requirements
- Spray systems
- Dosing system
  - Reproducibility
  - Low level interlock
- Temperature control
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- Process verification
  - Risk analysis to EN ISO 15971
  - Nature and extent proportionate to risk
- A) Operator verification
- B) Independent Process Record
  - Thermal disinfection time and temperature record
- C) Independent Process Record
  - Process variables critical to cleaning and disinfection
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Testing for conformity

- Type test
- Works test
- Validation
  - Installation qualification
  - Operational qualification
  - Performance qualification
- Routine tests
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- Cleaning efficacy
  - Chamber
  - Load carrier
  - Load
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- Cleaning
  - Removal of test soil
  - Visual examination
  - Residual protein test

- Test soils
  - Existing national methods
  - Need for standard method
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- **Thermal Disinfection**
  - Chamber walls
  - Load carriers
  - Final rinse water tank
  - Load

- **Temperature control**
  - Process stages
  - Over-temperature cut-out
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- **Disinfection**
  - Thermal preferred to chemical

- **Physical monitoring**
  - Time & temperature
  - $A_o > 600$ at temperatures $> 65^\circ C$
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What goods can I process?
What services are required?
What quality of water? At what temperature? At what pressure? What volume?

STEAM or ELECTRIC HEATING
WATER

PUMP
HOT AIR DRYING

How do I select the cycle I want?
Which detergent? How much?

What do the fault codes mean?

DRAIN
DETERGENT
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- **Information to be supplied by WD manufacturer**
  - Installation instruction
  - Process chemicals
  - Instructions for use
  - Maintenance manual

- **Information to be requested from purchaser**
  - Water regulations
  - Type of goods to be processed
  - Accessories required
  - Services available
  - Test soil to be used in testing

- **See also ISO 17664**
  - Information to be provided by device manufacturers
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- The standard
  - Combines equipment requirements and test programmes
  - Is a Major step in worldwide harmonisation
  - Has already triggered many changes
  - Is only the START of an evolutionary process
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- The WDs specified in the standard provide the operator with
  - Fully automated cycles
  - Assurance of product quality
  - Protection from infection hazards
  - Safe operation
  - An improved working environment
Even the most sophisticated equipment is only effective when used by:

- Trained operators who
- Follow the manufacturers instructions
  - WD manufacturer
  - Process chemical manufacturer
  - Re-usable medical device manufacturer
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Nothing in the foreseeable future will replace the need for the skilled vigilance of the technically competent operator.