

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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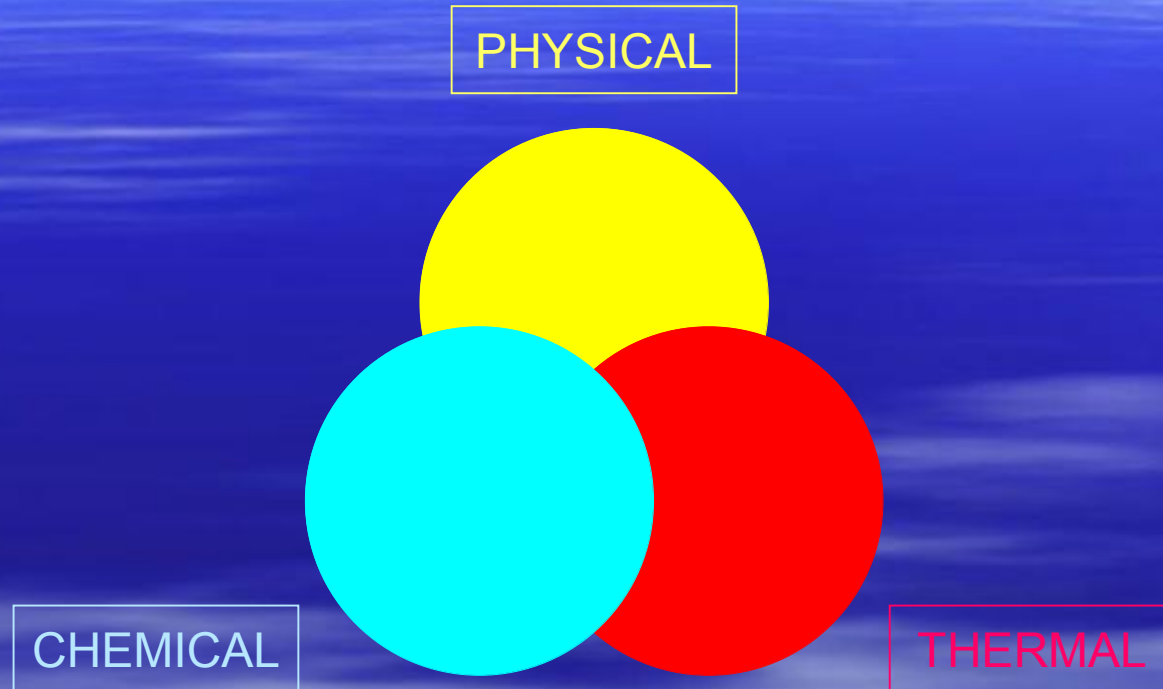
- A_0
 - Equivalent time in seconds at 80°C, delivered by the disinfection process
- **Cleaning**
 - Removal of contamination to the extent necessary for its further processing and intended use
- **Disinfection**
 - Reduction of the number of microorganisms to a level specified as appropriate for handling or use

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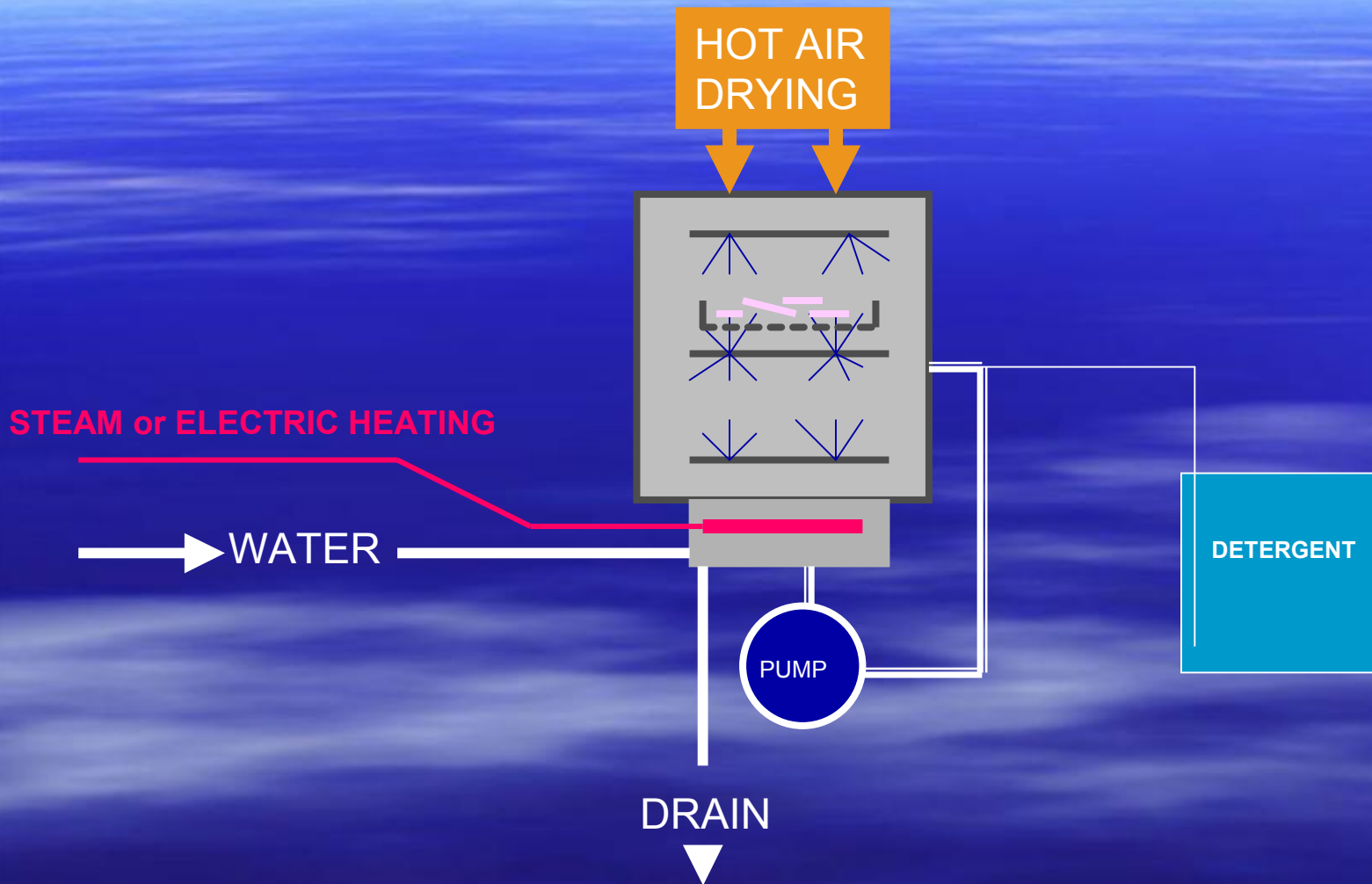
- **Validation**
 - Documented procedure for obtaining, recording and interpreting data required to show that a process will comply consistently with pre-determined specifications

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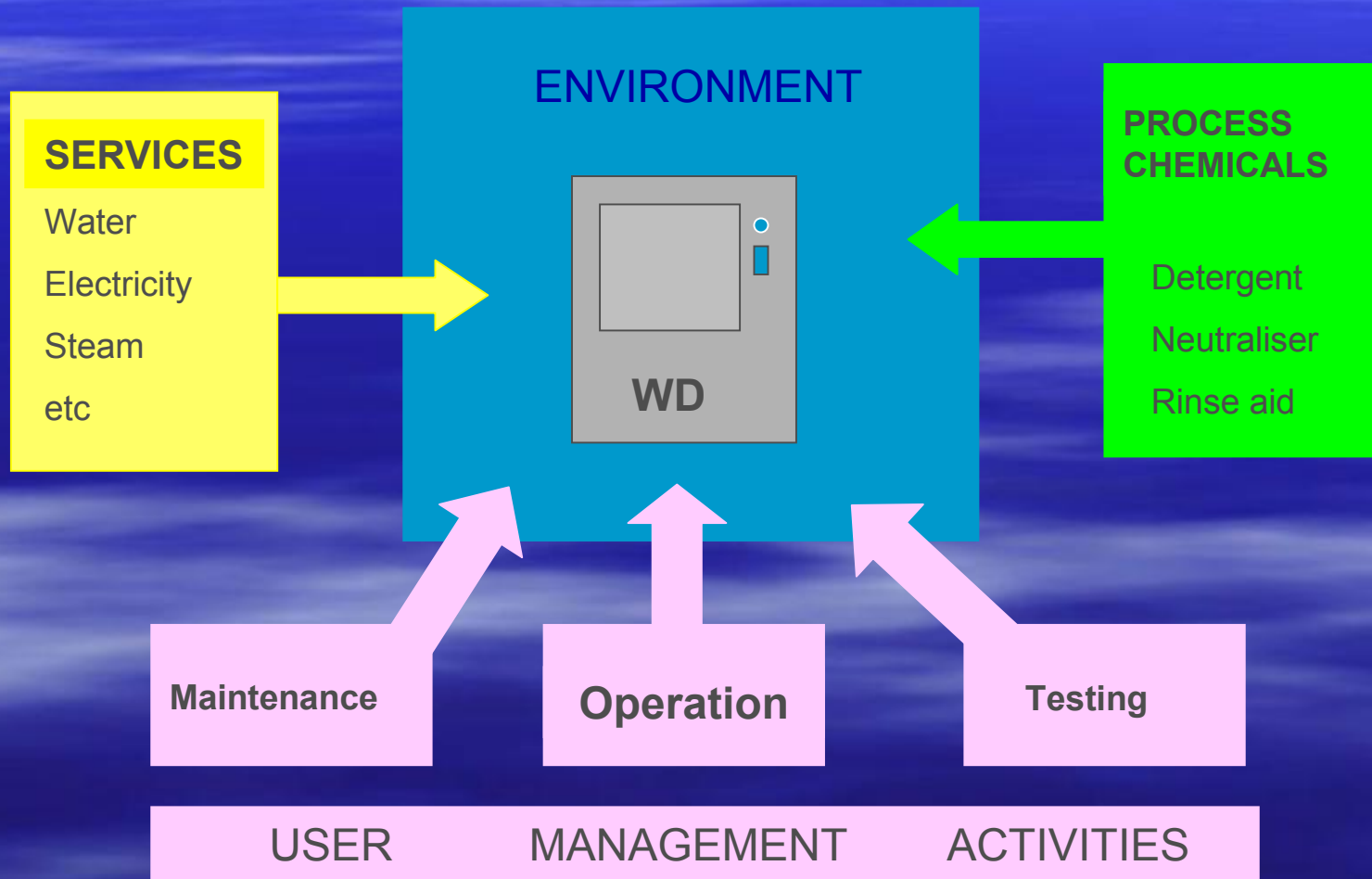
CLEANING IS AN ENERGETIC PROCESS



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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

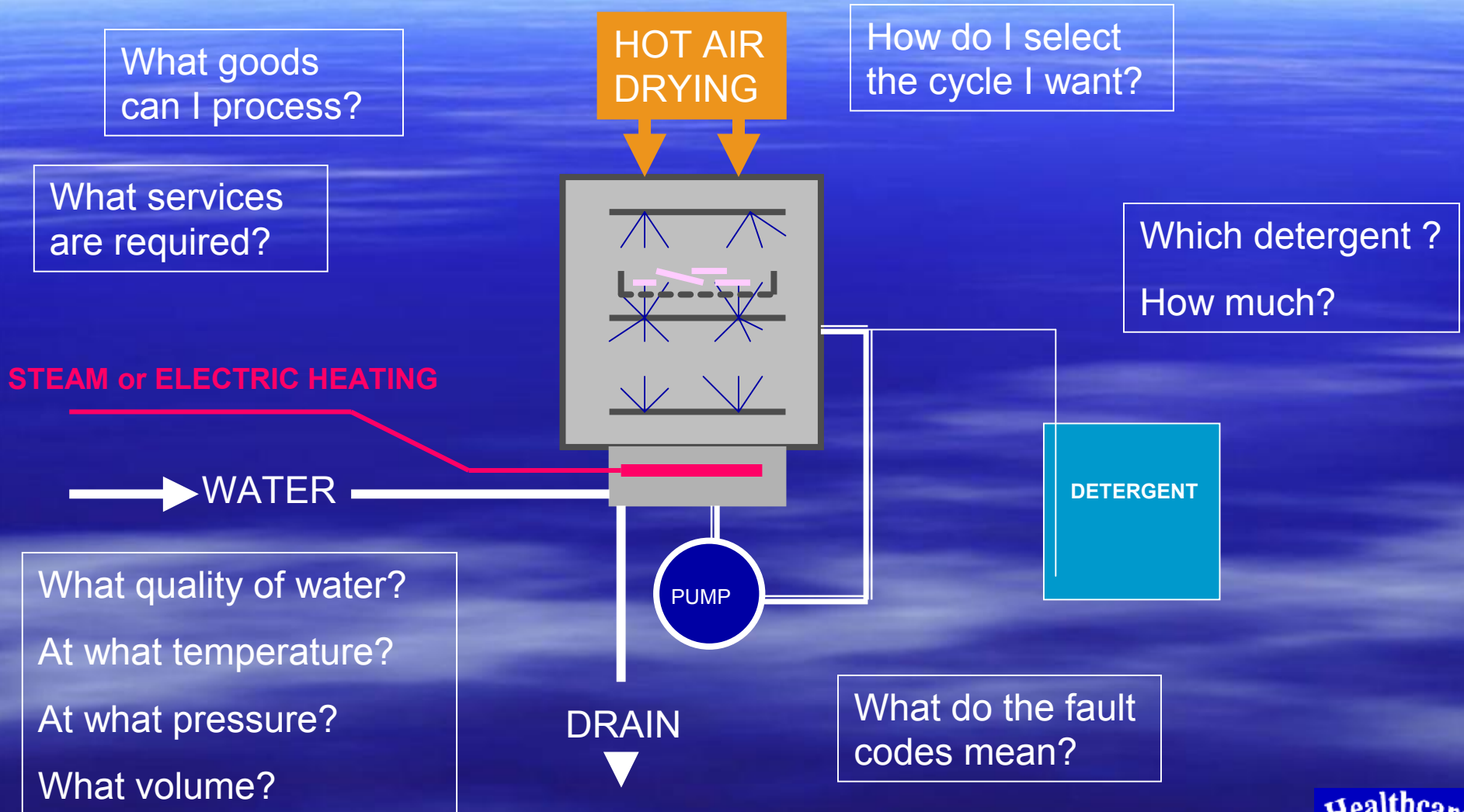
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- **Thermal Disinfection**
 - Chamber walls
 - Load carriers
 - Final rinse water tank
 - Load
- **Temperature control**
 - Process stages
 - Over-temperature cut-out

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- **Disinfection**
 - Thermal preferred to chemical
- **Physical monitoring**
 - Time & temperature
 - $A_0 > 600$ at temperatures $> 65^{\circ}\text{C}$

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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

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- BUT,

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.