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7 February 2020

Ebro Webinar:

Sterilization, Sanitation and Disinfection in the Hospital / Medical Industry

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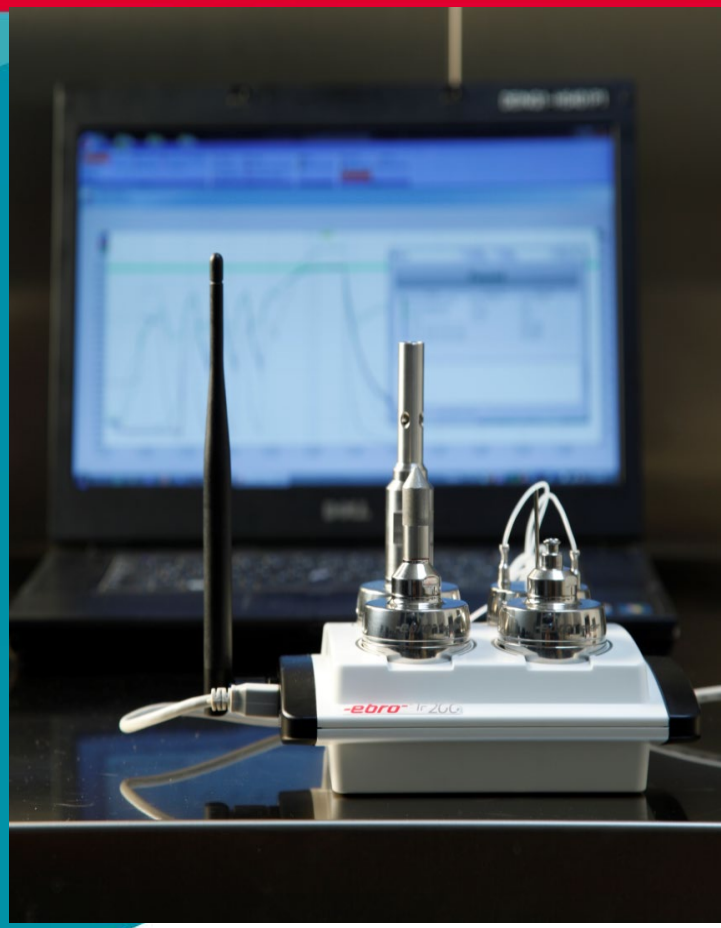
Two Key Requirements in the Hospitals and CSSD:

1. Washing and Disinfection

You Cannot Sterilize What You Cannot Clean (Contaminated Materials)

2. Sterilization

Reduction of Microbial / Bacterial Spores (Sterile Goods)



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Your Xylem Analytics Colleagues and Friends wishing everyone and your families all the best and good health amidst the current COVID19 pandemic

"Life nowadays is not mereley being Alive, but being Well"

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Who is Xylem?

We are one of the world's leading water technology companies

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Bringing together the most progressive brands

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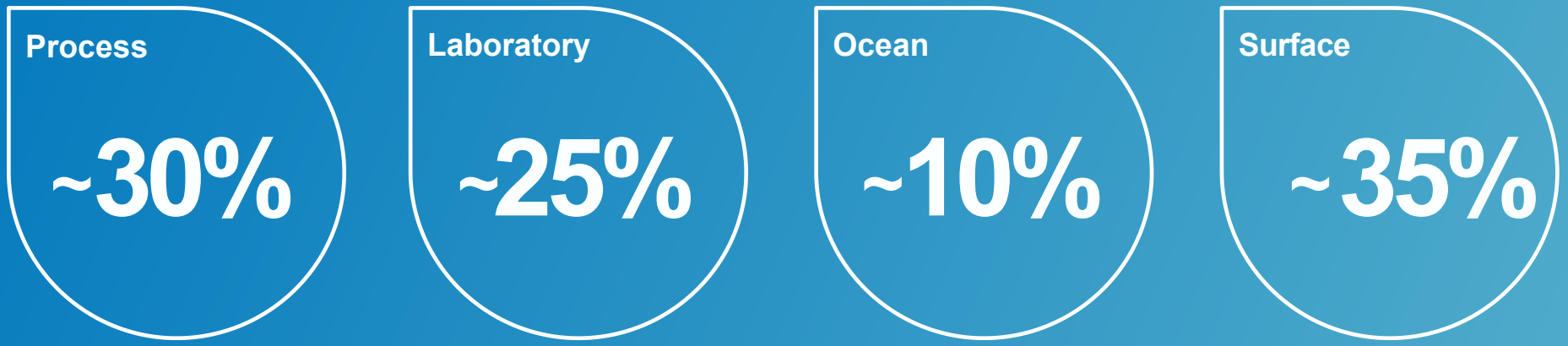
Xylem Analytics Breakdown



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The Hospital **CSSD Workflow

BULK SUPPLY

General Store

Clean Receipt

Wards & Units

Dirty Receipt

OPERATING THEATER
PATIENT ROOMS

Disassembly

Washer + Disinfectors

Instruments

Gloves

Rubberwares

Cotton, Gauze, etc.

Assembly

Inspection

Pre-Sterile Storage

Sterilization

Sterile Storage

Distribution

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** CSSD: Central Sterile Services Department

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The Hospital CSSD Workflow:

"*Where we can provide the solutions*"

Cleaning and Disinfection

- *Reusable MedicalToolds / Equipment*
- *Stainless Steel Surgical and Operation instrumentations*
- *Catheters, IV pumps and crash carts*
- ***Main Target: Endoscopes and other contaminations***

Sterilization

- Especially for "Critical Items" such as any instruments which are introduced into a human blood stream
- ***Main Target: All living and active organisms / Microorganisms***

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7 February 2020

- **Regulation: Standards and Norms**

Standards

- Law of Medical Products
- Medical Products Operator Ordinance Social Law
- Hygiene requirements for conditioning medical products“

The validation of processes in the conditioning of medical products is legally binding.

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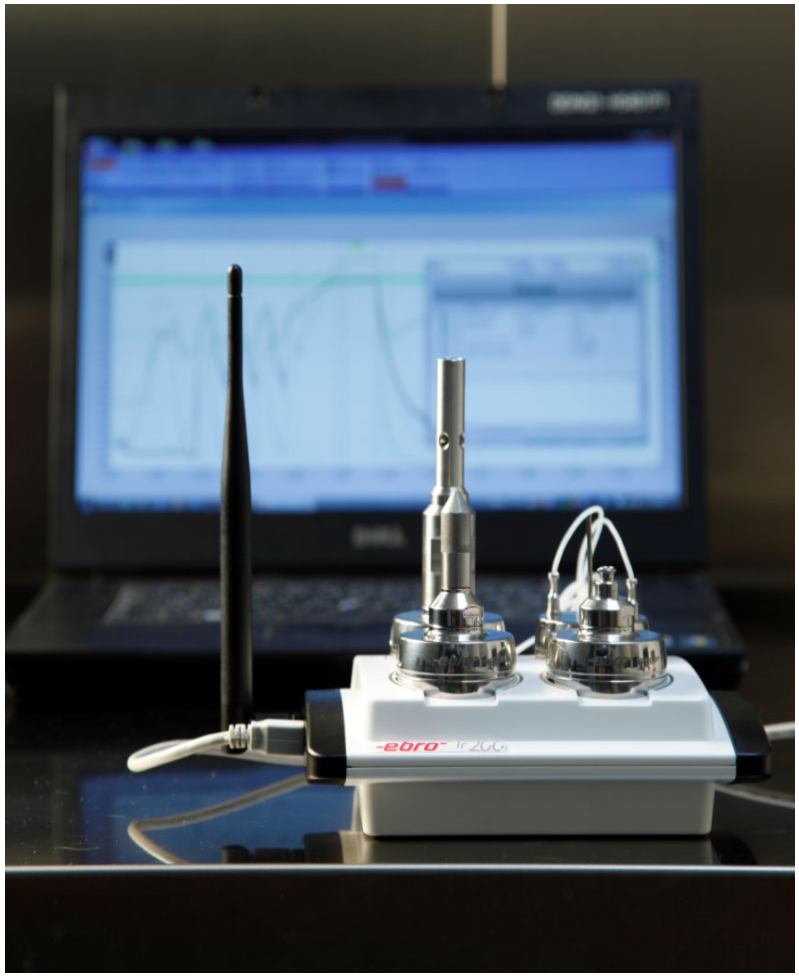
VALIDATION

The essentials of Validation: The **Installation Qualification (IQ)**, the **Operation Qualification (OQ)** and the **Performance Qualification (PQ).**

Validation is a complete presentation and verification of facts, that procedures, processes, equipment, materials, process steps or systems actually lead to the expected results.

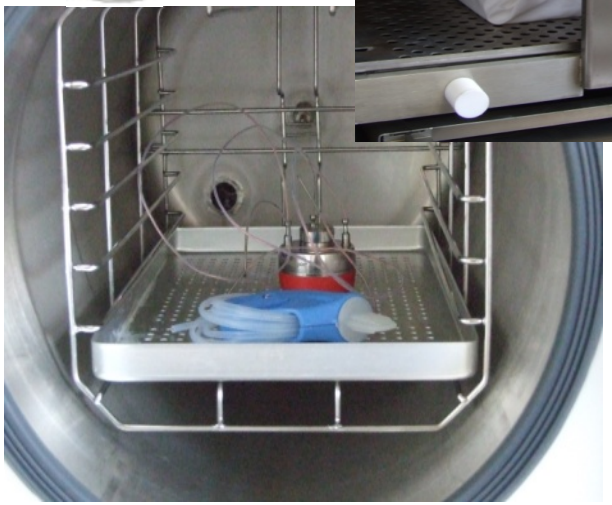
The results are then **summarized** and presented in details in a **validation report**, which helps to evaluate and assess the predetermined acceptance criteria and process optimization objectives



Routine Control

Routine controls are series of periodic verifications to check if the operating performance of the washer-disinfector and the sterilizer meets the limit values that were defined during the validations.

The frequency of performing routine controls depends on the machineries (washer disinfector or sterilizer) and the processes which is solely on the responsibility of the operator and the CSSD manager.



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Validation of washer-disinfector processes with data loggers

"Thermometric" or "Parametric" Method

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Standards and guidelines for washer-disinfector processes:

EN ISO 15883 *routine control and validation of washer-disinfector processes*

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ISO 15883-1
Title: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests

ISO 15883-2
Title: Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

ISO 15883-3
Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

ISO 15883-4
Title: Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

ISO 15883-5
Title: Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy

ISO 15883-6
Title: Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

ISO 15883-7
Title: Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment

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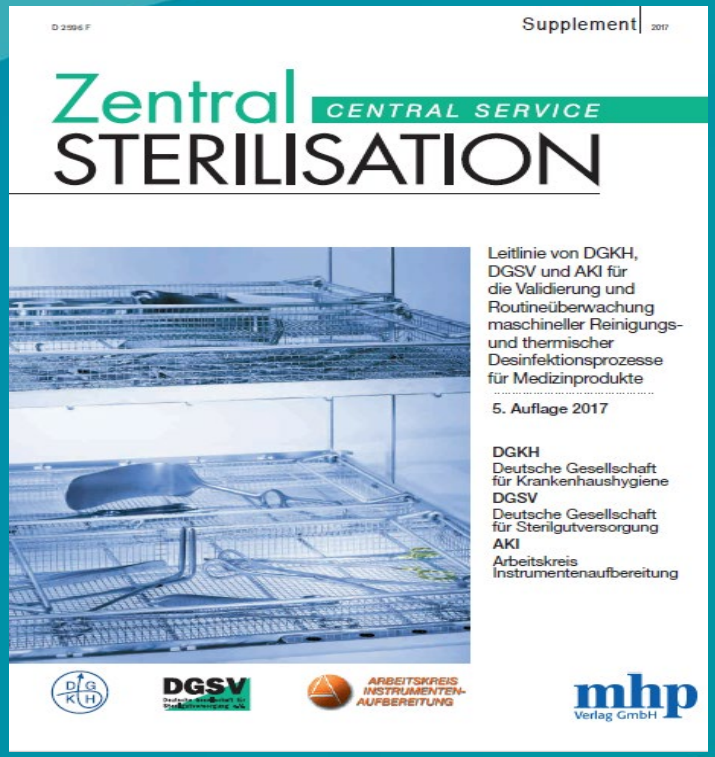
Guideline applies for the validation and the repeated performance evaluation of conditioning processes with thermal disinfection in washer-disinfector devices for thermostabile medical products (MP) following the guideline EN ISO 15883-1/-2 and -5

It relates to washer-disinfectors as compliant or non-compliant to the guidelinse for conditioning of medical products in all facilities in stationary and established sectors.



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Technical requirements for the equipment of washer-disinfectors

1. Washer-disinfector device

- Cleaning programs
- Disinfection programs
- Rinse water circulation

2. Loading

- Arrangement towards the rinsing mechanics
- Rinsing dead zones
- hollow spaces

3. Equipment

- Water
- Steam
- Compressed air
- Energy supply

Technical requirements for the equipment of washer-disinfectors

4. Process chemicals

- Detergents
- Disinfectants
- Neutralization agents
- Rinsing agents

5. Instrument design

- Materials
- Joints
- Hollow spaces

6. Load carrier

- Rotating arms
- Instrument holders
- Spray nozzles

Validation of the thermal process in washer-disinfector

Common concerns towards cleaning efficiency and thermal disinfection

1. How does the temperature curve evolve during the cleaning step?
2. What is the final temperature that is reached and how long is this temperature held?
3. What system-related pressure does occur during the separate phases?
4. Which temperature do the instruments reach?
5. How long is the maximum value held?
6. What is the resulting **A_0 value?**

$$A_0 = \sum 10^{\frac{(T-80)}{Z}} \cdot \Delta t$$

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What is essential for the validation?

Temperature increase and hold time during the cleaning steps and thermal disinfection
A_0 value

- Pressure changes
- pH value during rinsing
- Conductance influent water
- Conductance last rinsing water before draining
- Temperature during the disinfection

Qualification

Installation Qualification (IQ)

- the washer-disinfector and its accessories are properly supplied and duly installed with the correct connections, fixtures and peripherals

Operation Qualification (OQ) ensures that

- the equipment of the washer-disinfector and the media supply comply with the manufacturer specifications as well as with the requirements of EN ISO 15883

Performance Qualification (PQ) comprises the thorough evaluation of the ff:

- Cleaning performance
- The adequate removal of process chemicals
- Adequacy of the disinfection process
- Evaluation of the Drying Process

Technical requirements for the equipment of washer-disinfectors

Control and monitoring of:

- Water volume
- Dosage
- pH values
- T emperature during cleaning and thermal disinfection

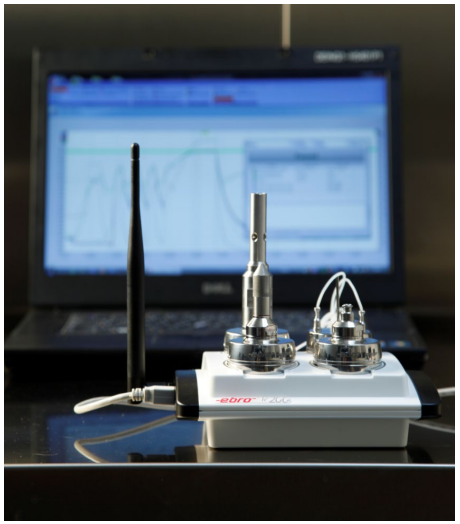
Control and monitoring of:

- Pressure
- Perfusion of Lumina (e.g.: MIC)
- Water quality
- Conductance by the end of the last rinsing

The A0-concept

The formula for the A-value calculation is:

$$A_0 = \sum 10^{\frac{(T-80)}{Z}} \cdot \Delta t$$



A_0: is the A-value when Z is 10 ° C

t: the exposure time of humid heat above 65° C, expressed in degree Celcius

T: the temperature of the loading in degree Celsius

Z: value depending on the kind of microorganisms, giving the temperature change in ° C that is needed to change the decimal reduction value by the factor 10 (postulated with 10)

Haltezeit		Temperatur	A_0-Wert
min	s	°C	
1	–	80	60
–	6	90	60
10	–	80	600
100	–	70	600
1	–	90	600
1	–	93	1 200

Minimum requirements to A0-values

A0-value 60 (300) bedpan washer-disinfector

A0-value 600 uncritical medical products

A0-Value 600 critical medical products
according to ISO 15883

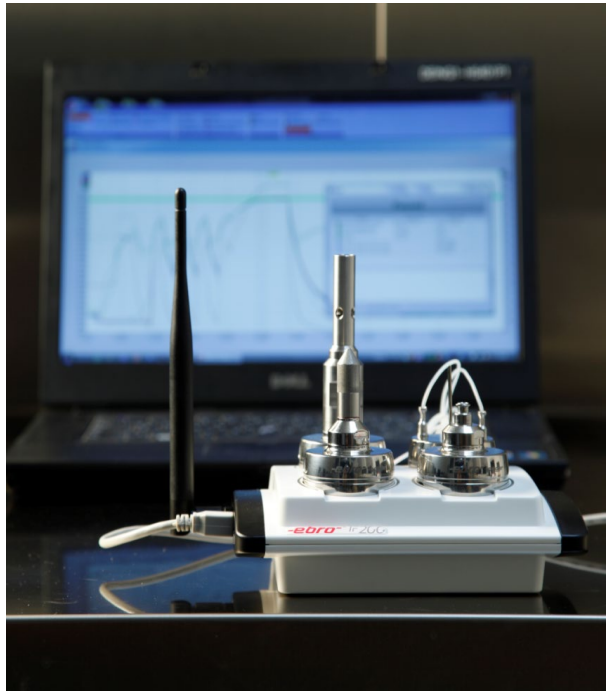
A0-value 3000 critical medical products
recommend by Robert Koch Institute Germany

The Robert Koch Institute recommends a thermal disinfection with an A0-value of at least 3000 for all critical medical products.

Validation of processes with thermal disinfection

Positioning of the temperature sensors:

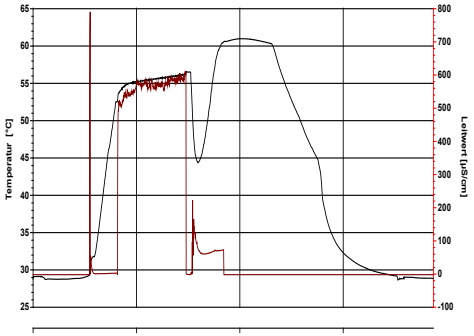
1. Between the loading or the instruments respectively
2. Reference position of the washer-disinfectors
3. Registration device of the washer-disinfector
4. Risk areas (please refer to the type test for further information)



It is recommended to check a minimum of
2 cycles with 6 measuring points, or **3 cycles with 4 measuring points** for each loading category.

Sufficient **water pressure** is precondition for the functioning of the spraying system. A pressure loss already occurs due to the proteins rinsed and dissolved from the medical products and after adding several cleaners.

Rinsing of all process chemicals / Verification by µS measurement



The washer-disinfector manufacturer needs to be informed by the manufacturer of the chemicals about all requirements for a safe handling, data of maximum permissible residual concentrations on the products and the proof procedure used for determining the process residues.

It is important to measure the **conductance in the last rinsing**.

pH measurement

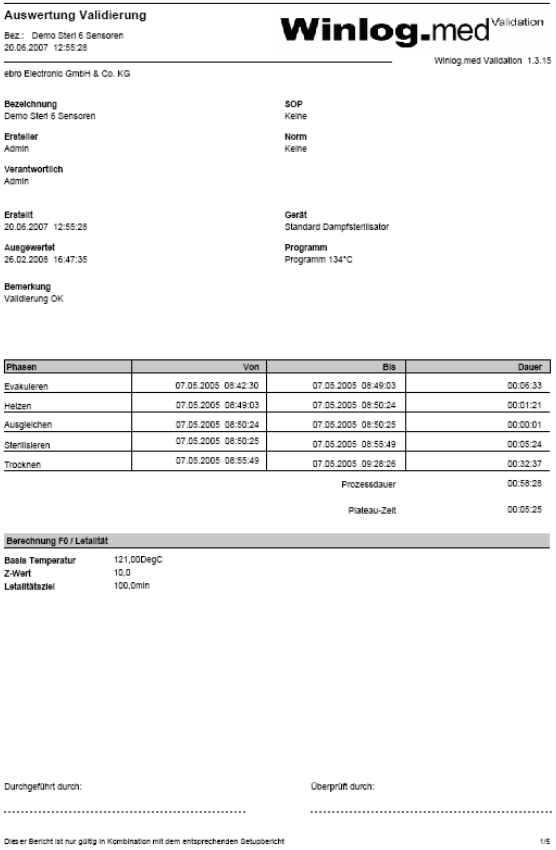
- Temperature-compensated **pH-loggers** that were adjusted with buffer solutions are used at operating temperature for the permanent recording of pH-values in the detergent solution.

- Alternatively you can use **temperature-compensated pH-measuring devices**

- **approximately pH 10 for the alkaline cleaning** according to the RKI guideline

- The n**eutralization in the first rinsing and the pH-value in the last rinsing can also be measured (pH 5-7**), but the better result you will measure with the conductivity datalogger

Validation report of washer-disinfector processes



Auswertung Validierung

Bez.: Demo Sterl 6 Sensoren
20.06.2007 12:55:28

Winlog.med Validation

Winlog.med Validation 1.3.15

ebro Electronic GmbH & Co. KG

Bezeichnung
Demo Sterl 6 Sensoren

Ersteller
Admin

Verantwortlich
Admin

Erstellt
20.06.2007 12:55:28

Ausgewertet
26.02.2008 16:47:35

Bemerkung
Validierung OK

SOP
Keine

Norm
Keine

Gerät
Standard Dampfsterilisator

Programm
Programm 134°C

Phasen	Von	Bis	Dauer
Evakuieren	07.05.2005 08:42:30	07.05.2005 08:49:03	00:06:33
Heizen	07.05.2005 08:49:03	07.05.2005 08:50:24	00:01:21
Ausgleichen	07.05.2005 08:50:24	07.05.2005 08:50:25	00:00:01
Sterilisieren	07.05.2005 08:50:25	07.05.2005 08:55:49	00:05:24
Trocknen	07.05.2005 08:55:49	07.05.2005 09:28:26	00:32:37
		Prozessdauer	00:58:28
		Plateau-Zeit	00:05:25

Berechnung F0 / Letalität

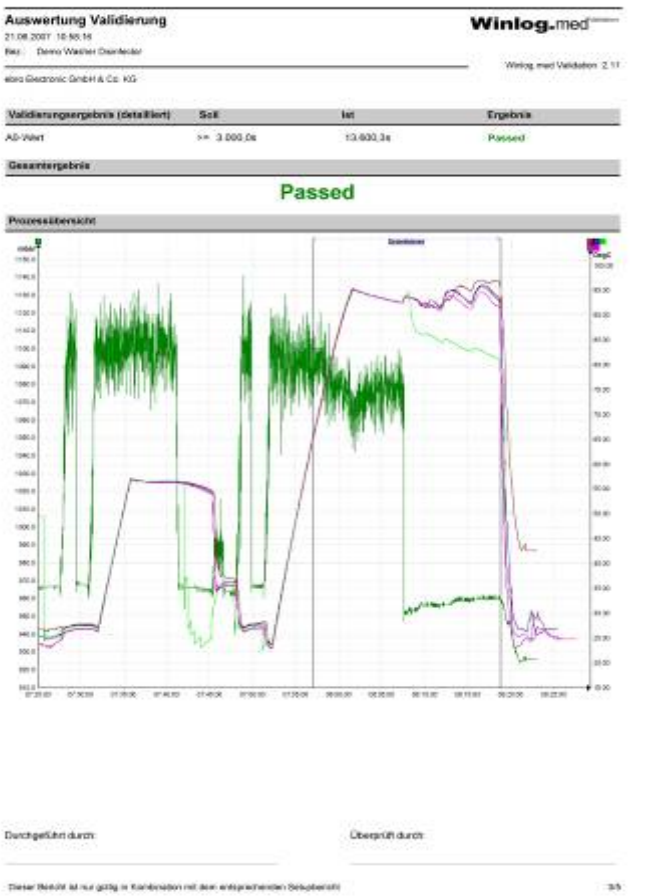
Basis Temperatur 121,00DegC
Z-Wert 10,0
Letalitätsziel 100,0min

Durchgeführt durch:

Überprüft durch:

Dieser Bericht ist nur gültig in Kombination mit dem entsprechenden Setupbericht

1/5



Auswertung Validierung

Winlog.med

Validierungsergebnis (detailliert) | **Soll** | **Ist** | **Ergebnis**

A0-Wert | >= 3.000,0s | 13.600,3s | Passed

Gesamtergebnis

Passed

Prozessübersicht

Durchgeführt durch:

Überprüft durch:

3/5

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Validation of Steam Sterilizers

"Thermometric" Method

Characteristic ISO 17665

ISO 17665 is kept very open.

ISO 17665 does not require compliance of the temperature band or plateau time. It must be verified that the required F0 value is reached in all positions under saturated steam conditions.

According to ISO 17665, also processes of older sterilizers that are not compliant to the standard EN 285, EN 13060 can be validated

An annual validation cannot specifically be explained, but typical annual re-qualification is necessary (ISO 17665-2 part 12.4). The time interval depends on the risk evaluation as well as the procedure stability.

Conclusion:

The requirements to the performance of the validation have increased. A high level of expertise is required in order to be able to perform a validation of a sterilization procedure technically correct.

Important preconditions for a sterilization

Validated cleaning and disinfection processes

Proper drying

Maintenance of instruments

Validated packing

Maintained sterilizer

Correct loading

Correct program selection

Validated sterilization process

Routine control of the processes

Validation as per EN ISO 17665

Validation

Commissioning:

- **IQ:** Check the installation

- **OQ**: Check the specification

  Check the equipment

Performance Qualification:

PQ: Physical evaluation

Microbiological evaluation

Preparation for the validation of the sterilization process

Charge composition:

Sterile goods (textile, instruments, MIC, orthopaedics)

Packing (containers, paper, fleece, foil, other packings)

Weight (heavy textile, heavy instruments, cage loading, separate objects)

Reference loading (compose, weigh)

Important: All sample loadings must be documented and photographed.

Sequence and setup of the Operation Qualification (OQ)

1. General information
2. Summary of the results and deviations / defects

3. Preconditions for the Operation Qualification

- Programs meant for validation
- Collect medical products for the reference loading
- Record medical products in packing lists
- Record the test configuration

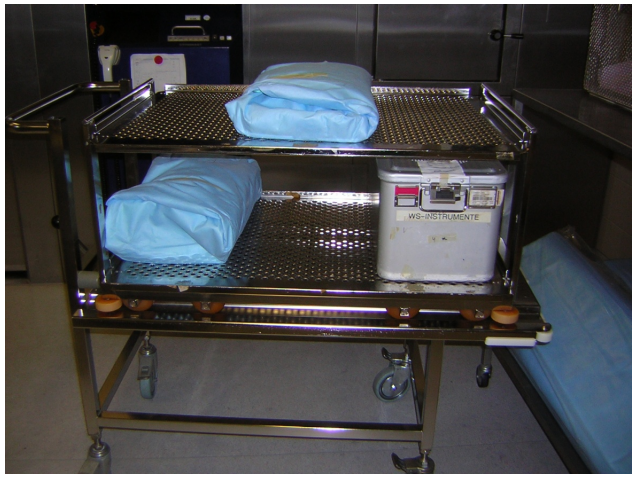
4. Checks

- Conductivity of the feed water
- Vacuum test
- BD-test and/or Helix-test
- Empty chamber profile
- Thermometric check with partial loading
- Thermometric check with full loading

Sequence and setup of the Performance Qualification (PQ)

1. General information
2. Summary of the results and deviations / defects
3. Preconditions for the Performance Qualification
4. Checks
   - BD-test => only for large sterilizers
   - Three times product check
   - Proof of product compatibility
   - Proof of protection from recontamination
   - Proof of the identification ability
5. Determination of routine controls

Validation of processes in steam sterilizers



Thermometric check of the partial loading using dataloggers

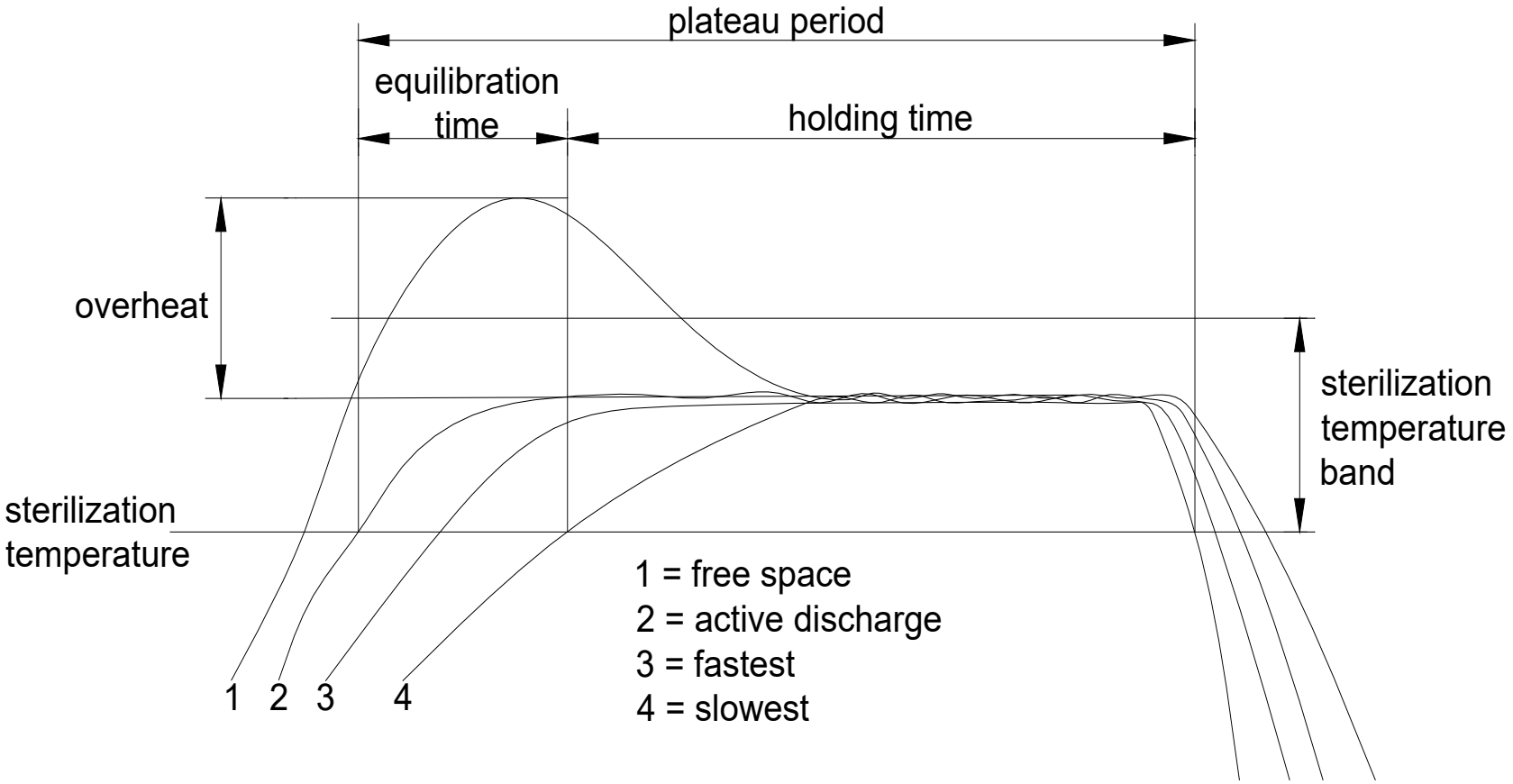
Thermometric check of the full loading using dataloggers

Validation of processes in steam sterilizers

Must be conducted or performed only by authorized personnel

Knowledgeable about the Regulations, the Standards and the Norms

Interpretation of the thermometric measurement



Reaching the sterilization conditions

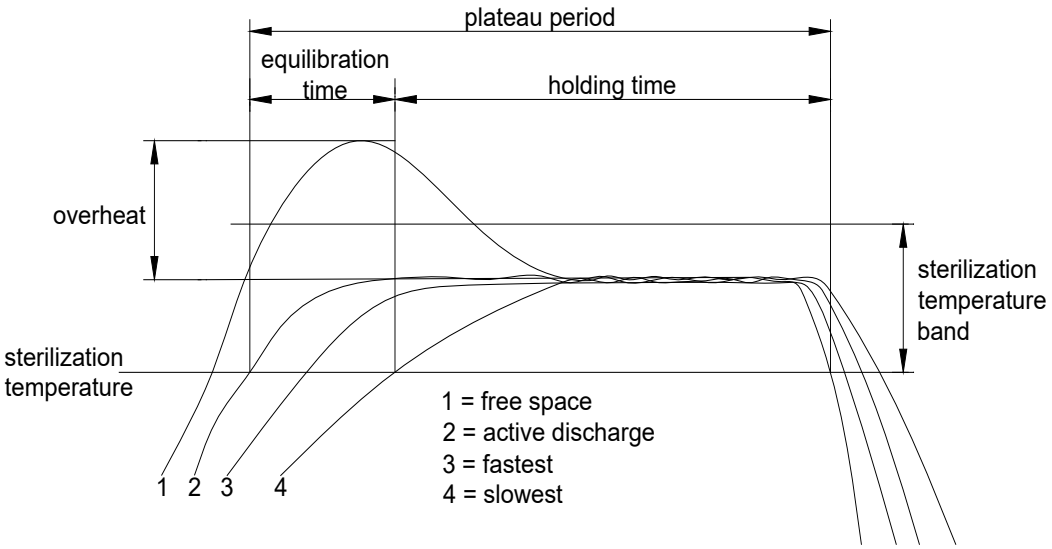
The existence of saturated steam in the usable area and within the loading can be considered as reached, if all temperatures measured in the usable area and within the loading during the hold time:

- are not below the sterilization temperature
- are not more than 3K (large sterilizer and small since 2016) / 4 K (small sterilizer before 2016) above the sterilization temperature
- do not diverge by more than 2° C
- equilibration time 15 s to 800 liter, 30 s for larger sterilizers
- minimum hold times 121 ° C for 15 min; 126 ° C for 10 min; 134 ° C for 3 min
- F_0-Value minimum15 min

The saturated steam temperature that is calculated with the measured pressure is to be considered as measured temperature.

Interpretation of the thermometric measurement

The compensation time / equilibration time is the period of time between reaching the sterilization temperature in the sterilization chamber (reference measuring point in the coldest point) and reaching the sterilization temperature in all points of the loading. The equilibration time may not exceed 15 s for sterilizers up to 800 l or 30 s for larger sterilizers.



Measuring values outside the tolerances

What measures need to be taken in case the results to not correspond to the specifications?

1. Check if the loading is correct?
2. Positioning of the measuring sensors
3. Repeated calibration of the measuring system
4. Adjust process parameters by manufacturer or service company (e.g. confining / chamber pressure, pressure period)
5. Alternative medical products? (materials, construction)

SOP

Operating instruction

Step-by-step instruction

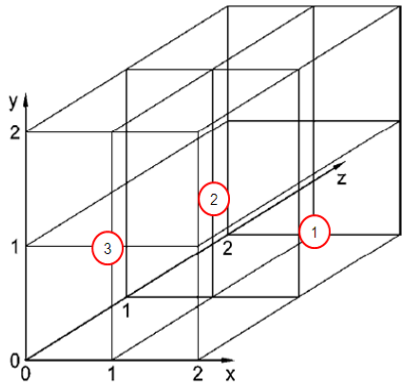
Explanations and examples for completing the paperwork

Advice for positioning of the sensors

Integration in the software Winlog.validation

Separate parts are explained(IQ, OQ, PQ)

- Revalidation
- Shortened validation



1: Referenzmessstelle
2: Mittig im Kammerinnenraum
3: In Türnähe

Requirements for the measuring technology as per EN 285 / ISO 17665

Temperature-compensated pressure sensor

Measuring rate ≤1 s

Measuring range of the pressure measuring device: 0 to 4 bar (0 to 400 kPa)

Resolution: 0.04 bar (4 kPa)

Accuracy of the pressure measuring device ± 0.5 % of the measuring range, as long as the environment temperature is (20 ± 3°C)

The device must have a valid certificate

Calibration according to manufacturer instructions, traceable to a national standard (e.g. DKD), (DIN EN 285 Pt. 26.5)

Validation of the thermal process in washer-disinfector and sterilizer

Suitable data logger

EBI 12 pressure logger with 1.95 mm rigid probe with luerlock

EBI 12 pressure logger with 1.5 mm flex probe with luerlock

EBI 11 temperature logger with 1.95 mm rigid probes

EBI 11 temperature logger with 1.5 mm flex probes

Validation of the thermal process in washer-disinfector and sterilizer

Suitable data logger

EBI 12 temperature logger with 1.5 mm flex probes radial and axial

EBI 12 temperature logger with 1.2 mm cable probes radial and axial

EBI 12 pressure logger with 1.2 mm cable probe, radial without luerlock and axial with luerlock

EBI 11 pressure logger with luerlock and without luerlock

Validation of the thermal process in washer-disinfector

Suitable conductivity logger for measuring the last rinsing

Conductivity logger for washer-disinfector

Measurement range: 0 … +125° C
0 … 2000µs/cm

Accuracy: ±0,1° C
±0,5µs/cm

Not suitable for Sterilizers

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Validation of the thermal process in Plasma sterilizers

Suitable temperature / pressure logger for measuring in Plasma sterilizer H_2O_2

- Low pressure and temperature logger
  EBI 12 TP 190
- Measurement range: 0 … +85°C
  0 … 1050mbar
- Accuracy: ±0,05°C
  ±0,25mbar
- Part number: 1340-6665
- Not suitable in steam sterilizer

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Routine control and validation of the thermal process in steam sterilizer

Suitable electronic BD-Test for steam sterilizers

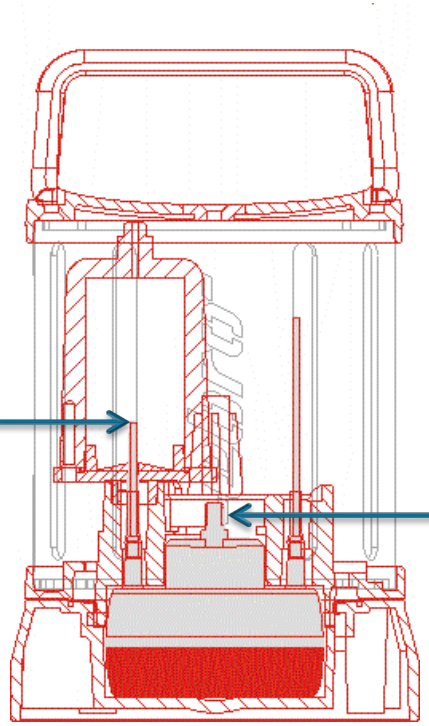
EBI 16 – Electronic Bowie&Dick Test

- Exact and independent measurement of the steam penetration
- Exact, reproducible result „passed/not passed“
- 1000 cycles
- Electronic data logger function
- Certified according to EN ISO 11140-4 by an independent laboratory

Validation and Routine Control
EBI 16 Set For Routine Monitoring In Hospitals

The EBI 16 is a steam penetration test to check the sterilization quality during the exposure time.

Temperature sensor inside chamber



Pressure is measured and converted into the theoretical steam temperature

The difference between both temperatures is checked

Software winlog.validation

CERTIFICATE

No. Z2 16 08 96885 001

Holder of Certificate: Xylem Analytics Germany GmbH
Pentgarstr. 16
85055 Ingolstadt
GERMANY

Production Facility(ies): 96885

Certification Mark:

Product: Application Software

Model(s): Data logger systems: Winlog.validation, Winlog.med

Parameters: Data logger system to read and process data for routine control and validation applications in the field of medicine, pharmacy and food

Tested according to: TÜV SÜD Product Service testing principles based on
- ISO/IEC 25051:2014 (Functionality)
- DIN EN ISO 9241-110:2008 (Usability)
- FDA 21 CFR Part 11

The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. It is not permitted to alter the certification mark in any way. In addition the certification holder must not transfer the certificate to third parties. See also notes overleaf.

Test report no.: 028-713094780/000

Valid until: 2017-08-31

Date, 2016-08-11

Page 1 of 1

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 證書 證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Evaluation software Winlog. Validation

Software for validating washer-disinfector and steam sterilizer processes as per DIN EN 15883, EN ISO 17665 and pr DIN 58929

FDA 21 CFR Part 11 compliant software (needed in the pharmaceutical industry)

Validated by TÜV Munich

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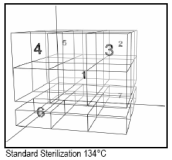
Validation report for sterilization processes

Validation Report

Winlog.med Validation 1.1.3.0

ebro Electronic GmbH & Co. KG
Steri Demo
02.02.2007 09:44:50

Standard Sterilizer



Standard Sterilization 134°C

Name	Steri Demo
Creator	Administrator
Responsible	GB
Remark	Sterilisation demo
SOP	None
Norm	None
Created	02.02.2007 09:44:50
Temperatuer-Loggers	5
Pressure-Loggers	1
Humidity-Loggers	0

Cycles	Evacuate	Heat	Equilibrate	Sterilize	Dry
From	22.01.2007 10:30:00	22.01.2007 10:50:01	22.01.2007 10:52:50	22.01.2007 10:52:59	22.01.2007 10:56:28
To	22.01.2007 10:50:01	22.01.2007 10:52:50	22.01.2007 10:52:59	22.01.2007 10:56:28	22.01.2007 11:30:00
Duration	00:20:01	00:02:49	00:00:09	00:03:29	00:33:32

Plateau-time	00:03:38
Process-time	01:00:00

Lethality / F0

Base-Temperature	121,1 °C
Z-Value	10,00

Loggers in process	Last calibration date
10046501	Refer to certificate
10084369	Refer to certificate
10084372	Refer to certificate
10084373	Refer to certificate
10084377	Refer to certificate
10289545	Refer to certificate

Executed by :

Verified by :

Channels marked with "*" will be ignored for this validation

Validation Report

Winlog.med Validation 1.1.3.0

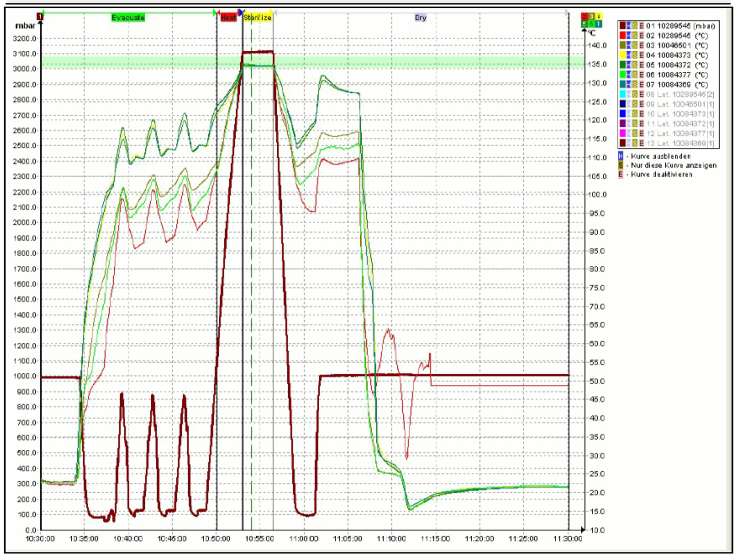
ebro Electronic GmbH & Co. KG
Steri Demo
02.02.2007 09:44:50

Validation results (detail)	Nominal	Actual	Result
Lethality target / F0	>= 5,0m	97,3m	Passed
Temperature band	<= 3,0K	<= 3,0K	Passed
Max. Fluctuation (Sterilization)	<= 1,0K	0,4K	Passed
Max. Variance (Sterilization)	<= 2,0K	0,6K	Passed
Max. Equilibration time	<= 15s	9s	Passed
Min. Sterilization time	>= 150s	209s	Passed

Overal validation result

Passed

Process overview



Executed by :

Verified by :

Channels marked with "*" willl be ignored for this validation

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Let's Solve Water

June 12, 2019

Thank you!

-ebro-
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