

Wireless Data Logger EBI 10 for Validation

PROCESS VALIDATION ACCORDING TO ISO 17665 / ISO 15883



MEDICAL | CSSD

Only 3 Easy Steps ...ebro[®] Validation systems



Quick and easy validation

The ebro Winlog validation system is a combination of high accuracy dataloggers and powerful reporting and evaluation software.

The system consists of:

EBI series Data Loggers:

Datalogger to measure and record process conditions (temperature, pressure, time).

Measurement systems:

TÜV validation, FDA 21 CFR Part 11 conform, IQ / OQ documentation, allows evaluation according to international standards (EN 285, ISO 17665, ISO 15883)

Winlog.validation

Easy-to-use software for programming, evaluation, calibration and report generation.

WE have the solutions to meet YOUR validation and measurement requirements!

Use ebro® systems to validate:

Steam-sterilizers - washer-disinfectors - freeze dryers - warehouses - cold rooms - dry heat sterilizers - refrigerators - freezers - incubators - shipment studies ...

Finlog.validation Software for Validation



- > Very user friendly
- > Tamper-proof software
- > Detects and checks all relevant stages (cleaning, disinfection and sterilization process)
- > Automatic determination of all relevant parameters (e.g. A_0 -value, F_0 -value)
- > Professional process evaluation with an unambiguous result (passed / failed)
- > Display and print out of all temperature and pressure curves
- > FDA 21 CFR Part 11 conform

System requirements

Processor speed (CPU) with at least 1 GHz, 1 GB working storage, 5 GB free hard disc storage, USB (Universal Serial Bus), Microsoft Windows XP®, Windows Vista® (64 Bit) or Windows 7®

Winlog.validation

An evaluation software for data loggers, specifically designed for validation of washerdisinfectors and steam-sterilizers in central sterilization departments. Most process flows during daily routine checks and annual validation are handled automatically.

Winlog.validation



Process validation via EBI 10 Data Logger



EBI 10-T471 Temperature Data Logger

- > 2 channel
- > axial probes
- > probe: 1.2 mm diameter





Maximum Flexibility

Technical Data

Type Sensors Temperature measurement range Pressure measurement range Temperature resolution Pressure resolution Temperature accuracy Pressure accuracy Memory Sampling rate Measurement mode

Battery Size Housing material Protection class



EBI 10-T671 Temperature Data Logger > 4 channel

- > axial probes
- > probe: 1.2 mm diameter
- > probe length: 1,200 mm



IP 68 (NEMA 6)

Cable Logger EBI 10-T and EBI 10-TP

2, 3 or 4 (probes are factory replaceable)

1 mbar ... 4,000 mbar (0.015 psi ... 58 psi)

endless, start / stop time, start immediately, start immediately until end of memory

-50 °C ... +150 °C (-58 °F ... +302 °F)

0.025° C (0.045 °F)

1 mbar (0.015 psi)

0.1° C (0.045 °F)

10 mbar (0.15 psi)

250 ms ... 24 h

3.6 V (exchangeable)

48 mm x 48 mm x 24 mm

stainless steel (V4A) / PEEK

100,000 measurements (Total)

EBI 10-TP452 Temperature / Pressure Data Logger > 4 channel > axial probes > probe: 1.2 mm diameter > probe length: 1,200 mm



Winlog

EBI 10-TP453 Temperature / Pressure Data Logger > 4 channel > axial probes

- > probe: 1.2 mm diameter
- > probe length: 1,200 mm
- > Luerlock connector

Accessories EBI 10 Cable Logger



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Probe AL 171 PT1000 PTEE coated

PTFE coated Probe length = 3 cm Probe diameter = 1.2 mm Cable length = 1,200 mm



Process validation in washer-disinfectors and steam steam-sterilizers

Temperature and pressure loggers complying with the requirements of the standard EN ISO 15883-1 must be used during the process validation in washer-disinfectors.

The sensors are placed between the instruments and in proximity to the washer-disinfector's own measurement points. In addition, measurement points must be selected on the load carriers and on the chamber walls of the washer-disinfectors. The risk sites, i.e. those locations at which the process temperature is last reached must be identified by consulting the type test or previous tests. It is recommended that at least two cycles using six sensors in each case or three cycles using four sensors in each case be checked for each reference load. The use of biological indicators as a substitute for thermometric testing is not acceptable (EN 15883-1, 6.8.1).

ebro[®] Validation Set SL 2000

Temperature and pressure monitoring, process validation of washer-disinfector

Set contains:

- 1 x Temperature/Pressure Data Logger EBI 10-TP231 Luerlock
- 3 x Temperature Data Logger EBI 10-T441
- 1 x Interface IF 200
- 1 x Software Winlog.validation
- 1 x pH-tester PHX 800
- 1 x TDS 3 Conductivity tester
- 1 x AL 130 Aluminum Case EBI TAK ALU

Description	Туре	Part No.
Temperature Data Logger, 2 channel, L = 1,200 mm	EBI 10-T471	1340-6144
Temperature Data Logger, 4 channel, L = 1,200 mm	EBI 10-T671	1340-6145
Temperature / Pressure Data Logger, 4 channel, L = 1,200 mm	EBI 10-TP452	1340-6146
Temperature / Pressure Data Logger Luerlock, 4 channel, L = 1,200 mm	EBI 10-TP453	1340-6147

Process validation in steam-sterilizers

Laws and Standards

Various laws and standards call for appropriate validated processes in order to avoid hazards for patients and hospital staff emanating from processed medical products. These regulations are based on the standards ISO EN 17665, EN 285 (steam-sterilizers), or pr DIN 58929 / DIN EN 13060 (small steam-sterilizers) as well as ISO 15883 (washer-disinfectors).

The aim of the technical validation process is to provide a documented verification that each particular steam-sterilizer supplies the sterilization results required. Thermoelectric measurements are crucial for the validation process.

Small Steam-sterilizer Set SL 3000

for process validation in small steam-sterilizers

Set contains:

- 1 x EBI 10-TP452 Temperature / Pressure Logger
- 1 x Interface IF 200
- 1 x Software Winlog.validation
- 1 x AL 101 Silicone protection box
- 1 x Carrying case

According to pr DIN 58929 as well as EN 13060 a minimum of 3 temperature sensors and 1 pressure sensor is required for the process validation (PQ) in small steam-sterilizers.

ebro[®] Steam-sterilizer Set SL 3100

for process validation in steam-sterilizers

Set contains:

- 5 x EBI 10-T471 Temperature Data Logger
- 1 x EBI 10-TP452 Temperature / Pressure Logger
- 1 x Interface IF 200
- 1 x Software Winlog.validation
- 1 x AL 112 Antenna
- 1 x AL 150 lead-through for antenna
- 1 x PHX 800 pH-tester
- 1 x TDS 3 Conductivity tester
- 5 x AL 107 Silicone protection box
- 1 x AL 101 Silicone protection box
- 1 x AL 130 Carrying case

According to ISO 17665 as well as EN 285 a minimum of 12 temperature sensors and 1 pressure sensor is recommended for the process validation (PQ) in steam-sterilizers.

Description	Туре	Part No.
Validation Set for Washer-disinfectors	SL 2000	1340-6072
Validation Set for Small Steam-sterilizers	SL 3000	1340-6079
Validation Set for Steam-sterilizers	SL 3100	1340-6080





ebro[®] Electronic GmbH

Peringerstraße 10 • D-85055 Ingolstadt Tel. +49 (0) 841 - 9 54 78-0 Fax +49 (0) 841 - 9 54 78-80 Internet: www.ebro.com e-Mail: info@ebro.com

