Wireless Data Logger System

FOR THERMAL PROCESS VALIDATION

MEDICAL / CSSD / PHARMACEUTICAL / FOOD

-ebro-
a xylem brand

Flexible Data Logger System

For Thermal Validations

ebro offers a flexible measurement and documentation system for validating many different thermal processes. This reliable system includes easy to use data loggers placed directly in the process and software to evaluate the processes.

EBI 11 mini data logger

EBI 10 wireless data logger

Process Validation With Temperature And Pressure Data Loggers Across Many Applications In:

Medical Sector

- Washer-disinfectors
- Washer-disinfectors for endoscopes
- Bed pan washers
- Steam sterilizers
- Blood banks
- Medicine refrigerators
- Laboratories
- Freezers

Pharmaceutical Industry

- Steam sterilization
- Stability chambers
- Cold storage
- Validation of store houses
- Incubators
- Laboratories
- Freezers

Food Industry

- Retorts
- Pasteurization
- Spiral-cooker / cooler
- Transport facilities
- Freezers
- Refrigerators
- Smoke chambers
- Ovens
- Full water autoclaves

Benefits Of The System

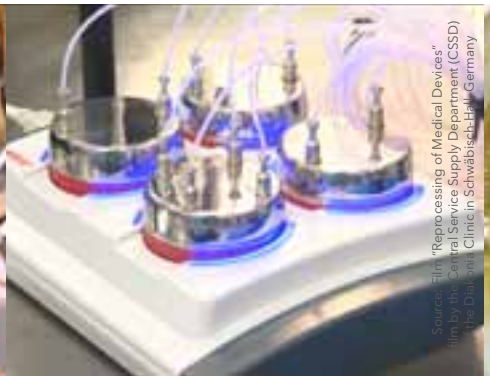
- Full automatic and tamper-proof FDA CFR 21 Part 11 compliant validations
- Broad range of wireless data loggers for all applications
- Highly flexible temperature wire probes (individually replaceable sensors)
- High accuracy PT 1000 temperature sensors
- High accuracy of up to ±0.1°C
- TÜV Industrial Services certified system
- 2-year warranty

CERTIFICATE

The Entire System Conforms With The Following Standards

- FDA 21 CFR Part 11
- EN 17025
- ISO 15883
- ISO 17665
- EN 285 / EN 13060
- EN 12830
- GAMP 5
- DIN 58929

Source: Film "Reprocessing of Medical Devices" a film by the Central Service Supply Department (CSSD) of the Diakonia Clinic in Schwäbisch Hall, Germany



Source: Film "Reprocessing of Medical Devices" a film by the Central Service Supply Department (CSSD) of the Diakonia Clinic in Schwäbisch Hall, Germany

The Perfect Solution For Your Applications

To fit each of your specific processes, ebro offers a wide variety of EBI 10 temperature and pressure data loggers in many different configurations. For example you have the choice of internal sensors, rigid metal probes, bendable metal probes, fully flexible cable probes, Luer-Lock or tube connection.

EBI 10 Wireless Data Loggers

- ✓ Very flexible wire probes
- ✓ Fast temperature sensors
- ✓ Wireless transmission possible in certain applications

Technical Data

Temperature measurement range	
Temperature data loggers	-85 °C … +400 °C (depending on logger type)
Temperature-pressure data loggers	0 °C … +150 °C
Temperature accuracy	±0.1 °C (0 °C to +140 °C)
Pressure measurement range	1 mbar … 4000 mbar
Pressure accuracy	±10 mbar
Dimensions (Ø x h)	48 mm x 14 mm (without probes)

Integrated sensor | Rigid metal probes | Bendable metal probes | Flexible wire probes | Luer-Lock connection | Tube connection

For our complete range of EBI 10 data loggers, please have a look in our full catalog.

Talk to us and we will help you select the logger that fits your application perfectly:

+49 841 95478-0

The Perfect Solution For Tight Spaces

For temperature and pressure measurements in tight spaces, ebro offers the EBI 11 mini data loggers. Many configurations are available to suit your application, including internal sensor, rigid metal probe, bendable metal probe, Luer-Lock connection or threaded connection versions.

EBI 11 Mini Data Loggers

- ✓ Designed for tight spaces, e.g. in small steam sterilizers, bottles, cans or bags
- ✓ Pressure measurement up to 10 bar

Technical Data

Temperature measurement range	0 °C … +150 °C
Temperature accuracy	±0.1 °C
Pressure measurement range	1 mbar … 10000 mbar
Pressure accuracy	±15 mbar (0 mbar … 4000 mbar)
Dimensions (Ø x h)	16,5 mm x 24 mm (without probe)

Integrated (pressure) sensor

Rigid metal probe

Bendable metal probe

Luer-Lock connection

M5 thread connection

Accessories and Sets

For EBI 10

SL 3100 Complete Validation Set

With the ebro SL 3100 data logger set, you are fully prepared to validate your steam sterilizer processes according to ISO 17665 as well as your processes in washer-disinfectors and washer-disinfectors for endoscopes according to ISO 15883.

The SL 3100 set consists of:

- 5 temperature data loggers
- 1 temperature / pressure data logger
- IF 200 4-port Interface with USB connection and antenna
- Winlog.validation software

EBI TIB Thermal Isolation Box For Data Logger Protection

For measurement temperatures between +150 °C and +400 °C, the EBI TIB thermal isolation box is required.

The EBI-TIB will protect the logger for a period of time depending on the process temperature.

Please contact us for more information.

SI 3200 Interface Set

- IF 200 4-port Interface with USB connection and antenna: colored LEDs signaling programming and read out of the data loggers
- Winlog.validation software

AL 103 Battery Exchange Set

Contains 3 O-rings with grease, battery, changing tools, cross slot screw driver, screw and instruction manual

AL 104 Battery Set

Contains 3 batteries and 3 O-rings with grease

For EBI 11

SI 3300 Interface Set

- IF 300 4-port interface with USB connection: colored LEDs signaling programming and read out of the data loggers
- Winlog.validation software

AL 114 Can / Bag Adapter Set

For placing the EBI 11 data loggers in cans or bags

AL 115 Bottle Adapter Set

For placing the EBI 11 data loggers in bottles

AL 113 Battery Exchange Set

Suitable for 3 battery exchanges; Contains 6 batteries, 3 O-rings and changing tools

Please ask us about additional sets or have a look at our full catalogue for more information!

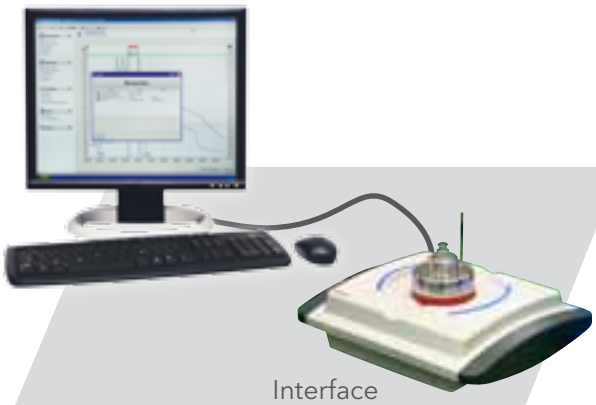
Functional Principle

Programming The Data Loggers

With Winlog.validation Software.

During start up, you can create a simple, reusable, custom template containing all parameters (sampling rate, measurement type, limits, etc) for the specific validation being performed.

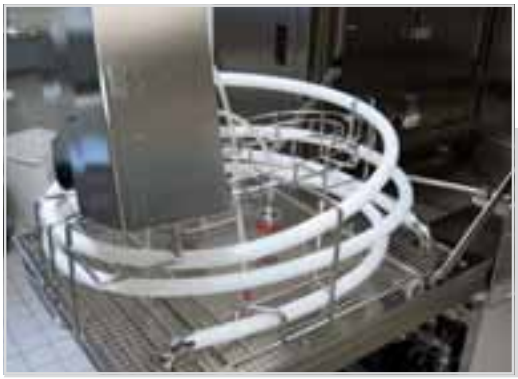
After that, just place the loggers into the interface (read out device) and follow the instructions of the software. The loggers will be programmed and then are ready for the use in the process.



Interface

Measurement During The Process

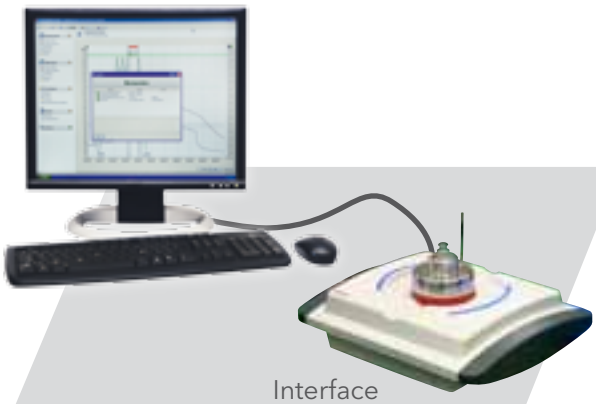
Place the EBI 10 wireless data logger, e.g. in a washer-disinfector for endoscopes:



Place the EBI 11 mini data logger, e.g. in a food autoclave:

Automatic Data Evaluation

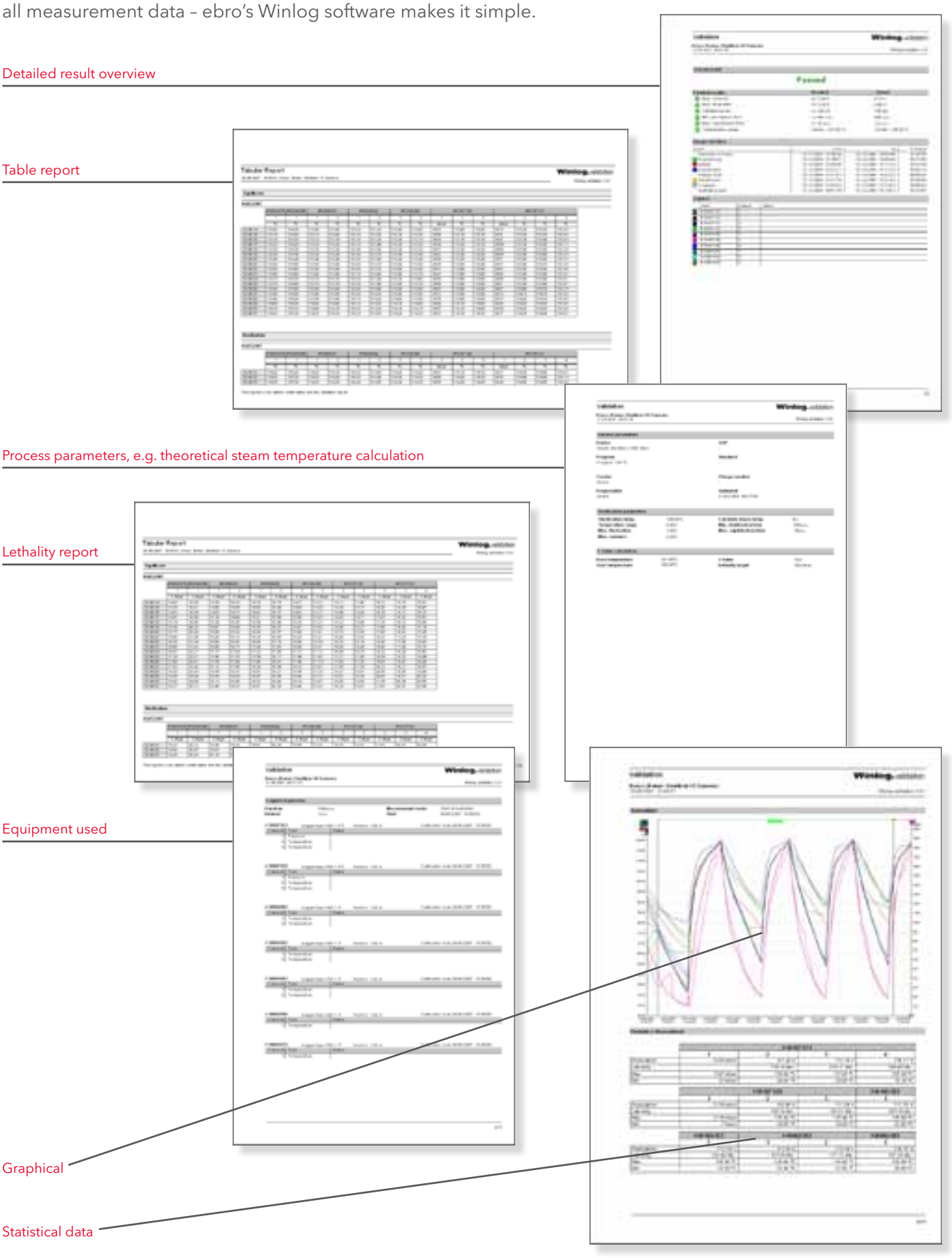
When the measurement is complete, place the loggers in the interface for readout. The software will automatically provide a clear “pass” / “fail” result of your validation report.



Interface

Flexible Report Generation

Whether you need a short process report or a table report with all measurement data – ebro's Winlog software makes it simple.



Winlog.validation Software

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Z2 12 08 10638 037

Holder of Certificate: ebro Electronic GmbH
Peringerstr. 10
86055 Ingolstadt
GERMANY

Production Facility(ies): 10638

Certification Mark:

Product: Application Software

Model(s): Data logger systems: Winlog.validation, Winlog.med in combination with data logger EBI-10, EBI-11, EBI-15

Parameters: Data logger system to read and process data used in the branches medicine and pharmacy

Tested according to: TÜV SÜD Product Service testing principles based on:
- DIN EN ISO 9241-110:2006 (Usability)
- DIN ISO/IEC 25051:2008 (Functionality)
- 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.: 028-713003285-000

Valid until: 2013-03-18

Date, 2012-08-01 (Ina Zumbruch)

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

Winlog.validation is an easy to use tool for data logger programming, data evaluation and results storage in accordance with the current validation norms.

The software will automatically create a clear "pass"/"fail" evaluation of your validation results. In addition, it offers the flexibility of many different possibilities for clear data presentation and creating reports according to your requirements.

Security According To FDA 21 CFR Part 11

The Winlog.validation software conforms with FDA 21 CFR Part 11.

Our Services For You

At ebro service is more than just a word – ebro offers solution according to customer wishes.

Service And Calibrations

ebro offers a calibration service for temperature, pressure and relative humidity by our accredited DAkkS laboratory

Training

Validation and software trainings on request

IQ/OQ Documentation According To GAMP

System IQ/OQ documentation according to GAMP guidelines is available. On request, we can send you a technician who performs the system IQ/OQ with you on-site.

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