

Thank you for interest!

Do you want more information for the food sector or the medical/pharmaceutical sector?



Food sector



Medical / Pharmaceutical sector



Content

1) Product information Food sector.....	3
a) TÜV-Software Certificate 2023	22
b) TÜV-ISO9001-Certificate_2023	23
c) Accreditation_DIN EN ISO_IEC 17025	24
d) Installation Winlog.validation	28
e) Catalog Professional Data Loggers	31
2) Product information Medical / Pharmaceutical sector.....	12
f) TÜV-Software Certificate 2023	22
g) TÜV-ISO9001-Certificate_2023	23
h) Accreditation_DIN EN ISO_IEC 17025.....	24
i) Installation Winlog.validation	28
k) Content IQOQ V2.12 Winlog.validation	30
l) Catalog Professional Data Loggers	31



Product information

Food sector

EBI 11 & EBI 12 SERIES DATA LOGGERS

Content

1) Introduction.....	1
2) Product description of the EBI 11 and EBI 12 data loggers.....	1
3) Selection of the correct ebro® software	2
Winlog.pro - The reliable all-rounder	2
Winlog.validation - The specialized software for validation and routine control	3
4) Commissioning the data loggers.....	3
5) Calibration and servicing.....	4
6) Training courses and seminars.....	5
7) ebro® / Xylem - a certified service provider	5
8) Further contact with our field service	6

Product information

EBI 11 and EBI 12 data loggers

1) Introduction

Thank you for your interest in our products. With this document we would like to give you an overview of the possibilities and requirements of our EBI 11 and EBI 12 data loggers. With this, you will have an overview of the possibilities and be aware of all the prerequisites for smooth functionality.

2) Product description of the EBI 11 and EBI 12 data loggers

The ebro® EBI 11 Series and EBI 12 Series data loggers are characterized by their high accuracy and robustness. Depending on the logger type you can benefit from:

- temperatures from **-200 °C to +400 °C**
- pressure from **0.1 mbar to 10.000 mbar**,
- relative humidity from **0 % rH to 100 % rH** and
- conductivity from **1 µS/cm to 2000 µS/cm**

These values can be measured, recorded, and transmitted live to the software. This makes them perfectly suited for the following food industry applications, for example:

- Pasteurization processes
- Temperature control
- Sterilization processes
- Beverage and canning production
- Recording during food production

Data is transmitted wirelessly to the data logger, which in turn must be connected to your computer via USB.

Product information

EBI 11 and EBI 12 data loggers

3) Selection of the correct ebro® software

When working with our data loggers, we provide you with two high-quality software solutions.

Winlog.pro - The reliable all-rounder

Winlog.pro is perfect for **programming several loggers together** and visualizing them together on an overview after the measurement.

Further advantages are:

- Easy installation and programming of the data loggers;
- Determination of process-critical parameters such as pasteurization unit, F-value automatically possible
- Extensive and customized reporting and choice between
 - o a **compact** report
 - o a **detailed** report or
 - o a **tabular report** of the measured values
- Insertion of own company logo possible
- Data export to Microsoft Excel® and to PDF
- Integration of pictures and graphics possible
- Wireless operation of the loggers enables real-time viewing of the data
- FDA CFR 21 Part 11 compliant

Product information

EBI 11 and EBI 12 data loggers

Winlog.validation – The specialized software for validation and routine control

The TÜV-certified Winlog.validation software is suitable for programming and reading out the ebro® data loggers as well as for evaluating the measured values. It is a powerful reporting and evaluation software for the high demands of validation and qualification.

4) Commissioning the data loggers

The commissioning of the data loggers includes the following activities:

- **Installation** of the correct Winlog software on your computer or network.
- **Checking the compatibility** of the installed drivers with the existing requirements.
- **Training of the employees** on the use of the Winlog software.

Product information

EBI 11 and EBI 12 data loggers

5) Calibration and servicing

The ebro® data loggers are always delivered with a **factory calibration certificate**. The function and the tolerances stated in the technical specifications are guaranteed. Factory calibration is carried out with traceable standards.

In addition, we offer **calibration according to ISO 9000** as well as accredited **calibration according to DIN EN ISO/IEC 17025 (DAkkS)** for your requirements in our certified calibration laboratories. This is required by modern quality assurance systems such as QS 9000 or regulations such as EU GMP or FDA. Simply get in touch with us to arrange calibration or servicing.

We recommend an annual calibration for temperature and pressure.

On request, we will be happy to include you in the free ebro® calibration reminder service.

Service and maintenance work is carried out by experienced service staff in our service department in Weilheim. For optimal processing of your order, simply fill out the corresponding [service order form](#).

You can find our service order on our homepage:



Product information

EBI 11 and EBI 12 data loggers

6) Training courses and seminars

Technical and regulatory requirements are constantly increasing and so is the increased demand for training and workshops. Through our training and conference rooms, including the associated **laboratories and industry-compliant equipment**, we offer you optimal opportunities to exchange ideas with our **experts** and stay up to date with the latest technology in practical demonstrations.

Our speakers are experts in their respective fields. The aim of the seminars is to achieve a safe handling of the measurement technology and software.

If you would like to attend one of our seminars please contact us with the name of the seminar, the date you wish to visit and how many in your party. You can find more information on our homepage under [Training](#).

7) ebro® / Xylem - a certified service provider

It's very important to us that our products and services conform to the highest standards. Through continuous development and improvement, we regularly certify our products and software in accordance with valid standards. The **following certificates** are relevant to ebro® products at point of purchase:

- ISO 9001:2015 Certificate ebro/ Xylem
- Accreditation according to DIN EN ISO/IEC 17025:2018
- EC declarations of conformity
- TÜV certificate of the Winlog.validation software on DIN ISO/IEC 25051:2014, DIN EN ISO 9241-110:2020 and FDA 21 CFR part 11

Product information

EBI 11 and EBI 12 data loggers

8) Further contact with our field service

Of course, not all questions can be fully answered within this document. Should you require further assistance or product demonstrations then please contact us and we'll be happy to help.

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Attachments food sector

a)	TÜV-Software Certificate 2023 .	22
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e)	Catalog Professional Data Loggers	31



Click here to return to the
product information for the food sector



Are you also interested in the
medical/pharma sector?

Click here to go to the **product information**
for the **medical/pharma sector**





Product information Medical & Pharmaceutical

EBI 11 & EBI 12 SERIES DATA LOGGERS

Content

1) Introduction	1
2) Product description of the EBI 11 and EBI 12 data loggers	1
3) Selection of the correct ebro® software.....	2
Winlog.pro - The reliable all-rounder	2
Winlog.validation - The specialized software for validation and routine control ..	3
4) Commissioning the data loggers.....	4
5) Qualification of the data logger system	4
Implementation of the IQ/OQ by the customer	4
Acquiring the IQ/OQ as a service	5
6) Calibration and Servicing.....	5
7) Training courses and seminars.....	6
8) ebro® / Xylem - a certified service provider	6
9) Further contact with our field service	7

Product information

EBI 11 und EBI 12 data loggers

1) Introduction

Thank you for your interest in our products. With this document we would like to give you an overview of the possibilities and requirements of our EBI 11 and EBI 12 data loggers. With this, you will have an overview of the possibilities and be aware of all the prerequisites for smooth functionality.

In addition, we recommend that you summarize the GMP requirements relevant to you in a specification sheet and send it to us. This way we can respond exactly to your specifications and send you back a signed specification sheet.

2) Product description of the EBI 11 and EBI 12 data loggers

The ebro® EBI 11 Series and EBI 12 Series data loggers are characterized by their high accuracy and robustness. Depending on the logger type you can benefit from:

- temperatures from **-200 °C to +400 °C**
- pressure from **0.1 mbar to 10.000 mbar**,
- relative humidity from **0 % rH to 100 % rH** and
- conductivity from **1 µS/cm to 2000 µS/cm**

These values can be measured, recorded, and transmitted live to the software. This makes them perfectly suitable for the following medical and pharmaceutical applications:

- **Sterilization processes** (steam, EtO, H₂O₂, hot air)
- **Reprocessing processes** in hospitals and at doctors' practices
- **Qualification** of equipment and validation of processes
- **Washer-disinfectors** (WDs)
- **Bowie Dick tests** according to EN 285 / DIN EN ISO 17665

Even special cases including use in explosive atmospheres can be solved thanks to the **ATEX approval** of selected loggers

Product information

EBI 11 und EBI 12 data loggers

Data is transmitted wirelessly to the data logger, which in turn must be connected to your computer via USB.

3) Selection of the correct ebro® software

When working with our data loggers, we provide you with two high-quality software solutions.

Winlog.pro - The reliable all-rounder

The **21 CFR part 11 compliant** Winlog.pro is perfect for programming your loggers and visualising them together on an overview after the measurement. In addition, calculations can be performed afterwards and further information such as the **MKT value, the A0 or the F0 value** can be displayed. The data can be easily exported as a PDF or Excel file.

Product information

EBI 11 und EBI 12 data loggers

Winlog.validation – The specialized software for validation and routine control

The **TÜV-certified** Winlog.validation software is suitable for programming and reading out the ebro® data loggers and for evaluating the measured values. It is a powerful reporting and evaluation software for the high demands of validation and qualification in pharmacy and medicine.

- Central user administration can be stored in the local network.
- Automatic recognition of process cycles and report generation
- Automatic user-defined calculations
- Creation of user-defined templates for specific equipment and thermal processes
- FDA 21 CFR Part 11 compliance
- IQ / OQ documentation for software qualification included.
- Automatic evaluation of validation processes



Product information

EBI 11 und EBI 12 data loggers

4) Commissioning the data loggers

The commissioning of the data loggers includes the following activities:

- **Installation** of the selected **software** on your computer or network.
- **Checking the compatibility** of the installed drivers with the existing requirements
- **Training** of the employees on the use of the Winlog software

In order to guarantee the error-free functionality of the data loggers and the corresponding interface, the correct communication files and drivers must be installed and the system requirements listed in the installation manual of the software must be fulfilled.

5) Qualification of the data logger system

We are happy to support you in the design qualification of your data logger system. It is best to contact us at an early stage so that we can help with the correct definition of your specifications in your URS. With regard to IQ and OQ activities, we offer two options:

Implementation of the IQ/OQ by the customer

ebro®, Xylem brand, will provide you with the IQ/OQ documentation. After a review by the customer and an explanation of the test points, the documentation must be entered into your quality management system. In support of this, an on-site appointment can be arranged for the training of your employees by a specialist from ebro/ Xylem. In this case, the qualification activities are carried out exclusively by one of your employees.

Product information

EBI 11 und EBI 12 data loggers

Acquiring the IQ/OQ as a service

In addition to the documents mentioned above, the **test points** are processed by an employee of ebro/ Xylem. Depending on the size of the acquired system, this takes approximately one working day. A contact person from the customer side should be available on site during the execution to be able to solve any questions promptly. The release of the report remains your responsibility.

The subsequent PQ and CSV should be carried out by the customer. Of course, we are also available here with our expertise to answer any questions you may have.

6) Calibration and Servicing

The ebro® data loggers are always delivered with a **factory calibration certificate**. The function and the tolerances stated in the technical specifications are guaranteed. Factory calibration is carried out with traceable standards.

In addition, we offer **calibration according to ISO 9000** as well as accredited calibration according to **DIN EN ISO/IEC 17025 (DAkkS)** for your requirements in our certified calibration laboratories. This is required by modern quality assurance systems such as QS 9000 or regulations such as EU GMP or FDA. Simply get in touch with us to arrange calibration or servicing.

We recommend an annual calibration for temperature and pressure and a semi-annual calibration for humidity. On request, we will be happy to include you in the free ebro calibration reminder service.

Service and maintenance work is carried out by experienced service staff in our service department in Weilheim. For optimal processing of your order, simply fill out the corresponding [service order form](#)

You can find our service order on our homepage:



Product information

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7) Training courses and seminars

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If you would like to attend one of our seminars please contact us with the name of the seminar, the date you wish to visit and how many in your party. You can find more information on our homepage under [Training](#).

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Attachments Medical / Pharmaceutical sector

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Click here for the **product info food sector**





Product Service

CERTIFICATE

No. Z2 096885 0008 Rev. 00

Holder of Certificate: **Xylem Analytics Germany GmbH**
Peringerstr. 10
85055 Ingolstadt
GERMANY

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: DIN ISO/IEC 25051:2014 (Functionality)
DIN EN ISO 9241-110:2020 (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. This certificate is valid until the listed date, unless it is cancelled earlier. All applicable requirements of the testing and certification regulations of TÜV SÜD Group have to be complied. For details see: www.tuvsud.com/ps-cert

Test report no.: 713306791

Valid until: 2024-08-31

Date, 2023-10-13

(Tuan Khai Hoang)



Management Service

CERTIFICATE

Certificate Registration No.: **12 100 17506 TMS** / Order No.: **70018126**

**The Certification Body
of TÜV SÜD Management Service GmbH**

certifies that the organization



Xylem Analytics Germany GmbH

**Am Achalaich 11
82362 Weilheim
Germany**

for the scope

**Development, production marketing, sales and service of
physical-chemical measurement and analysis systems, validated data logging
systems, portable instruments, controllers and explosion-protected sensors and
portable measuring instruments Equipment protection by intrinsic safety "i"**

including the sites see enclosure

has established and applies a Quality Management System.

An audit was performed and has furnished proof
that the requirements according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2023-08-12** until **2026-08-11**.

Fred Wenke
Head of Certification Body
Munich, 2023-07-25

Page 1 of 2



Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the calibration laboratory

Xylem Analytics Germany GmbH
Am Achalaich 11, 82362 Weilheim

is competent under the terms of DIN EN ISO/IEC 17025:2018 to carry out calibrations in the following fields:

Thermodynamic quantities

Temperature quantities

- Resistance thermometers
- Thermocouples
- Direct reading thermometers
- Temperature transmitters, data loggers

Humidity quantities

- Devices for relative humidity

Mechanical quantities

- Pressure

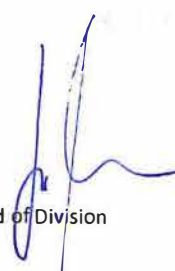
The accreditation certificate shall only apply in connection with the notice of accreditation of 10.12.2021 with the accreditation number D-K-20615-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 2 pages.

Registration number of the certificate: **D-K-20615-01-00**

Berlin,
10.12.2021

Dr Heike Manke
Head of Division

Translation issued:
10.12.2021



Head of Division

*The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH <https://www.dakks.de/en/content/accredited-bodies-dakks>.*

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

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Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The publication of extracts of the accreditation certificate is subject to the prior written approval by Deutsche Akkreditierungsstelle GmbH (DAkkS). Exempted is the unchanged form of separate disseminations of the cover sheet by the conformity assessment body mentioned overleaf.

No impression shall be made that the accreditation also extends to fields beyond the scope of accreditation attested by DAkkS.

The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). DAkkS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:

EA: www.european-accreditation.org

ILAC: www.ilac.org

IAF: www.iaf.nu

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-K-20615-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 10.12.2021

Date of issue 10.12.2021

Holder of certificate:

**Xylem Analytics Germany GmbH
Am Achalaich 11, 82362 Weilheim**

Calibration in the fields:

Thermodynamic quantities

Temperature quantities

- Resistance thermometers
- Thermocouples
- Direct reading thermometers
- Temperature transmitters, data loggers

Humidity quantities

- Devices for relative humidity

Mechanical quantities

- Pressure

The calibration laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use calibration standards or equivalent calibration procedures listed here with different issue dates.

The calibration laboratory maintains a current list of all calibration standards / equivalent calibration procedures within the flexible scope of accreditation.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of calibration laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

The certificate together with the annex reflects the status as indicated by the date of issue.

The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH <https://www.dakks.de/en/content/accredited-bodies-dakks>.

Abbreviations used: see last page

Page 1 of 2

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Permanent Laboratory
Calibration and Measurement Capabilities (CMC)

Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Temperature Resistance thermometers; direct reading thermometers and data loggers with resistance sensor	0 °C	In bath with deionized iced water DKD-R 5-1:2018	15 mK	Deionized water (conductivity < 5 µS/cm)
	0,01 °C	Triple point of water DKD-R 5-1:2018	10 mK	Calibration at fixed point temperatures
	–90 °C to –35 °C	In stirred liquid bath DKD-R 5-1:2018	50 mK	Comparison with standard resistance thermometer
	> –35 °C to 250 °C		30 mK	
Base metal thermocouples, direct reading thermometers and data loggers with thermocouple sensor	–85 °C to 200 °C	In stirred liquid bath DKD-R 5-3:2018	0,3 K	Comparison with standard resistance thermometer
	> 200 °C to 250 °C		0,5 K	
Relative humidity Hygrometers and transmitters	10 % to 30 %	“Two-pressure” humidity generator, temperature range: 5 °C to 70 °C DKD-R 5-8:2019	0,3 %	Comparison with reference dew point mirror and reference thermometer Measurement uncertainty expressed in relative humidity
	> 30 % to 70 %		0,6 %	
	> 70 % to 95 %		0,9 %	
Pressure Absolute pressure p_{abs}	0 bar to 5 bar	DKD-R 6-1:2014	0,62 mbar	Pressure medium: Gas
	> 5 bar to 25 bar		2,0 mbar	

Abbreviations used:

CMC	Calibration and measurement capabilities
DKD-R	Calibration Guide of Deutscher Kalibrierdienst (DKD), published by the Physikalisch-Technischen Bundesanstalt

¹⁾ The expanded uncertainties according to EA-4/02 M:2013 are part of CMC and are the best measurement uncertainties within accreditation. They have a coverage probability of approximately 95 % and have a coverage factor of $k = 2$ unless stated otherwise. Uncertainties without unit are relative uncertainties referring to the measurement value unless stated otherwise.

Winlog.validation

Installation

System requirements

Operating system

Windows 8, Windows 10, Windows 11.
for 32 and 64 bit.

PC hardware

- Prozessor (CPU) minimum 1.6 GHz Dual Core (32 bit or 64 bit)
- main memory minimum 2 GB at 32 bit, 4 GB at 64 bit
- 4 GB free hard disc memory
- Screen solution: 1280 x 768 Pixel
- USB port 1.1 or better

Display

- Minimum screen solution: 1280 x 768
- Default view (100 %)
- Screen resolutions, which are similar to the minimum screen resolution, but the ratio of horizontal and vertical values are different (e.g. 1366x768), we recommend to use the Windows-style view "Windows - Classic"

Winlog.validation

IQOQ V2.12

Content

Objective

This document contains the following lists:

- The software versions this IQOQ is valid for
- All files that are part of this IQOQ

Valid for software versions

Winlog.validation V4.0

Documents

IQ_1340-2287_0212 Winlog.val - TC000 – IQ.docx

OQ_1340-2287_0212 Winlog.val - TC001 – First software start.docx

OQ_1340-2287_0212 Winlog.val - TC002 – Login and user settings.docx

OQ_1340-2287_0212 Winlog.val - TC003 – Routine test.docx

OQ_1340-2287_0212 Winlog.val - TC004 – Database.docx

OQ_1340-2287_0212 Winlog.val - TC005 – Reports.docx

OQ_1340-2287_0212 Winlog.val - TC006 – Maintenance.docx

OQ_1340-2287_0212 Winlog.val - TC007 – Validation.docx

RA and Functional Overview V2.12.xlsx

xylem



Professional Data Loggers

FOR VALIDATION, ROUTINE CONTROL AND PROCESS MONITORING

MEDICINE

FOOD

PHARMACEUTICAL

LABORATORY

-ebro-
a xylem brand

KompetenzCentrum ebro®

Combining theory and hands on work is the basis for the successful concept for our trainings, webinars, and workshops. Our speakers are experts in their specialized fields. The aim of all seminars is that all participants will receive a sound knowledge of the hardware and software.

Seminar program and LIVE webinars 2022

Medical market

- Routine controls in the RUMED in the hospital
- Validation of reprocessing processes in the hospital
- Validation of preparation processes in the Sector, e.g. DAC (Sirona), Careclave (Melag)
- Temperature monitoring in the hospital (radio monitoring system EBI 25)

Pharmaceutical market

- Refreshing GMP regulations
- Cold chain monitoring & mapping
- Qualification and validation in the pharmaceutical field
- Computer software validation

Food market

- Cold chain monitoring
- Pasteurization process monitoring
- Measuring devices for HACCP monitoring
- Training for food inspectors



You can find the current program on our homepage
<https://www.ebro.com/en/company/further-education.html>



Overview of
current DATES for
SEMINARS and
WEBINARS

Data Logger from the EBI 12 series



EBI 12-T222

The logger reacts very quickly on temperature changes caused by the small and fast probe. It is therefore ideally suited for temperature measurement during process validation.

Technical details on page 15



EBI 12-T237

The data logger can be used in several measurement applications in the food and pharmaceutical industries. For example in stability chambers, retort sterilization and in pasteurization tunnels.

Technical details on page 12



EBI 12-TP237

This data logger is used for simple pressure checks in pipelines as well as in the washer-disinfectors or even steam sterilizers.

Technical details on page 22



EBI 12-T26x

The new bottle loggers with a temperature probe are characterized by their robustness and easy handling. With the M10 thread, they can easily be attached to the bottle adapter and the probe can be brought into the optimal position for measurement.

Technical details on page 13

Data Loggers

ebro® offers data loggers for many different applications:



Operation and Process qualification

Description:

- Highly accurate temperature, pressure, humidity and conductivity data loggers for thermal validation processes
- Wide range of probe types and configurations
- Wireless data loggers for real time monitoring
- Data loggers for low space

Applications:

- Process validation in steam sterilizers, autoclaves, in the production of canning, a.s.o.
- Process validation in washer-disinfectors and washer-disinfectors for endoscopes
- F_0 -value and A_0 -value calculation
- Process validation in low temperature sterilizers such as EtO, LTSF and H_2O_2

Routine control / Mapping

Description:

- Highly accurate temperature, pressure, humidity and conductivity data loggers for thermal process control
- Electronic Bowie&Dick-Test according to ISO 17665 and EN 285 / EN 13060
- Data loggers for low space
- Data loggers for regular process controls

Applications:

- Routine control in steam sterilizers and autoclaves
- Routine control in washer-disinfectors and washer-disinfectors for endoscopes
- Routine control at canning
- Mapping

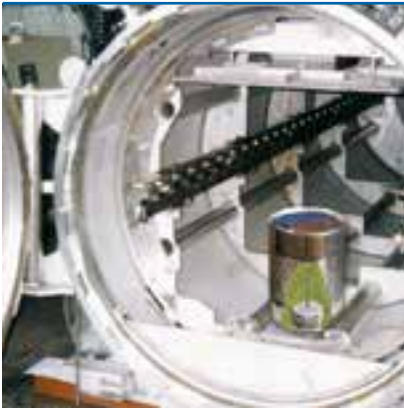


Logger systems

and accessories for Process monitoring, Routine control and Validation



Food



Applications

- Autoclaves / Sterilizers / Pasteurization Processes
- Continuous Fryers
- Lyophilization
- Hydrostatic Retorts
- Refrigerators / Freezers / Cooling Rooms
- Smokehouse
- Cooker / Cooler (Reel and Spiral)



Medical



- Steam Sterilization
- Washer disinfectors / bedpan washers
- H₂O₂-, LTSF- and EtO- Sterilization
- Depyrogenation / heat tunnel
- Incubators
- Refrigerators / Freezers / Cooling Rooms
- Stability Chambers



Pharmaceutical



- Steam-, H₂O₂ and EtO- Sterilization
- Washer disinfectors
- Depyrogenation / heat tunnel
- Lyophilization
- Incubators
- Refrigerators / Freezers / Cooling Rooms
- Climatic Test Chambers / Stability Chambers

Products



EBI 11 Series



EBI 12 Series



EBI 310 Series



EBI 25 Series



EBI 40



EBI 11 Series



EBI 12 Series



EBI 16



EBI 310 Series



EBI 25 Series



EBI 40



EBI 11 Series



EBI 12 Series



EBI 16



EBI 310 Series



EBI 25 Series



EBI 40

Process monitoring, Routine Control and Validation easy and safe

Process Validation

Is a reproducible proof that a process permanently generates the required results.

Validation is a clear demonstration that processes, equipment, materials, work steps or systems actually lead to the expected results.

Routine Control

Routine control is a regular test to determine the performance of the equipment. It is the verification that the limits are in accordance to the validation.

The frequency depends on the device and the process.

Continuous Process Monitoring

The continuous process check as a validated status during the commercial manufacturing process ensures that the ongoing process remains under continuous control. The recognition of unplanned deviations from the plan is indispensable to the achievement of the set objectives and the conformity with the requirements.

EX Area

Hazardous areas (except for mining)

The categories 1 to 3 are classified according to the ATEX Directive 2014/34/EU. The letter "G" stands for gas. In the IEC 60079-0 for electrical components and devices, and thus for approvals according to the IECEx scheme, Equipment Protection Levels (EPL) are defined.

Devices according to Category 1G or EPL Ga

Devices must be designed in such a way as to ensure a very high degree of safety. Devices of this category must also ensure the required degree of safety even in the case of infrequent disturbances. Even if there are two faults on the unit, ignition must not occur. They may be used in Zone 0 (Category 1G).

Requirement for reprocessing of medical devices

Reprocessing of medical devices coming to an intended application as low-germ or sterile is to perform. By using the manufacturer's instructions with suitable validated process and procedures, that the success of this procedure is reproducible and do not endanger the safety and health of patients, user and third parties.

Data Logger Systems

ebro® is specialist for measuring systems for flexible and reliable measurement and documentation systems for routine control and validation of various thermal processes in the medical field, the pharmaceutical and the food industry.

Our product range covers easy to use data loggers of the EBI 12 and EBI 11 series, which are placed directly in the process. An intuitive, TÜV certified software to routine testing or validation of processes assists to evaluate your process data.

In addition, we offer you the certified EBI 16 system to perform the daily Bowie&Dick-test with a clear „fail“ or „passed“ result.

TÜV certified evaluation software Winlog.med and Winlog.validation

With the Winlog.med / Winlog.validation we offer a TÜV certified, FDA 21 CFR Part 11 compliant software. The system is characterized by high data security. The automatic evaluation of the process is possible as well as the manual evaluation.

The software offers the possibility to create user defined evaluations. So it is possible to create individual process parameters and test criteria.



Conformance

Our systems are compliant with the relevant standards and guidelines.

DIN EN ISO 17665	Sterilization of health care products. - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
DIN EN 285	Sterilization - Steam sterilizers - Large sterilizer
DIN EN ISO 15883	Washer disinfectors - General requirements, terms and definitions and tests
DIN EN 13060	Small steam sterilizers
DIN SPEC 58929	Operation of small steam sterilizers in health care - Guidelines for validation and routine monitoring of sterilization processes
DIN EN ISO 11135	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
DIN EN ISO 25424	Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices.
DIN EN ISO 11140-4	Sterilization of health care products - Chemical indicators - Class 2 indicators as an alternative to the Bowie&Dick-type test for detection of steam penetration.
DIN EN ISO 9241	Ergonomics of human-system interaction: Dialogue principles
DIN 12880	Electrical laboratory equipment - heaters and incubators
DIN EN ISO 13408-3	Aseptic processing of healthcare products -- Part 3: Lyophilization
DIN EN ISO 14937	Sterilization of healthcare products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.
ISO/IEC 25051	Software engineering -- Systems and software Quality Requirements and Evaluation (SQuaRE) -- Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing
FDA 21 CFR Part 11	Is the part of the FDA regulations about electronic records and electronic signatures, specifies the criteria under which electronic records and electronic signatures can be considered trustworthy and reliable as a paper document
FDA 21 CFR Part 210-211	Defines minimum requirements for the methods to be dispatched in the manufacture, processing, packaging and warehousing of drugs and vaccine and distribution and controls to be used.
Guidelines	Guidelines from DGKH, DGSV and AKI for the validation and routine monitoring of machine cleaning and thermal disinfection processes for medical devices
Recommendations	DGKH recommendations for validation and routine monitoring of sterilization processes with moist heat for medical devices

Temperature data loggers of EBI 12 series

General technical specifications for EBI 12 T series

Operating temperature: logger	-90 °C ... +150 °C (-130 °F ... +302 °F)*
Operating temperature: radio operation	-30 °C ... +150 °C (-22 °F ... +302 °F)
Temperature accuracy	± 1.5 °C (-200 °C ... -90 °C)* ± 0.5 °C (-90 °C ... -40 °C)* ± 0.2 °C (-40 °C ... 0 °C)* ± 0.1 °C (0 °C ... +120 °C)* ± 0.05 °C (+120 °C ... +140 °C)* ± 0.1 °C (+140 °C ... +150 °C)* ± 0.5 °C (+150 °C ... +250 °C)* ± 0.8 °C (+250 °C ... +400 °C)*
Time accuracy at 25 °C	< 5 sec (24 h)
Temperature resolution	0.01 °C
Sensor	Pt 1000, Class A
Interval	250 ms ... 24 hours.*
Measurement mode	• Endless measurement • Start / stop measurement • Measure upon start temperature • Start immediately until end of memory
Storage temperature	-20 °C ... +70 °C (-4 °F ... +158 °F)
Maximum operating pressure	Temperature logger 10 bar (abs), 4 bar (abs) with flexible cable probes
Minimum operating pressure	Logger with flexible cable probe 20 mbar (abs)
Battery	Lithium cell, 3.6 V, user replaceable
Dimensions (Ø x H)	48 mm x 24 mm**
Weight	Approximately 110 g **
Housing material	316 L Stainless steel / PEEK
Protection class	IP68
Certificate	Factory calibration certificate

* Deviating specifications can be found in the product descriptions.

** Dimensions and weight may be different depending on the type.

Product lines



Data loggers with this symbol have flexible or bendable temperature sensors or, in addition to temperature, can also log other measurands such as pressure, humidity, conductivity. The measured values can be transmitted via radio mode. Field of applications for the data logger of the EBI 12 series are: medicine, pharmaceuticals, food & beverages, as well as industry.

Temperature data loggers with this symbol have usually rigid temperature probes. They are characterized by their easy handling and robustness. Data loggers in this line of products have good accuracy and data memory. Most data loggers have a mounting thread for easy fixation.

The data logger can be used in several measurement applications in the food and pharmaceutical industries. For example in stability chambers, retort sterilization and in paste station tunnels.



Set SI 1100

for EBI 12 and EBI 11

- 2-port Interface IF 100
- Software Winlog.pro
- USB connection
- Colored LEDs signaling programming, readout and incorrect development



Set SI 1200

for EBI 12

- 4-port Interface IF 200
- Software Winlog.pro
- USB connection
- Colored LEDs signaling programming, readout and incorrect development
- Includes antenna



Set SI 2100

for EBI 12 and EBI 11

- 2-port Interface IF 100
- Software Winlog.med
- USB connection
- Colored LEDs signaling programming, readout and incorrect development



Set SI 2110

for EBI 12

- 4-port Interface IF 200
- Software Winlog.med
- USB connection
- Colored LEDs signaling programming, readout and incorrect development
- Includes antenna



Set SI 2150

for EBI 12 and EBI 16

- 1-port Interface IF 150
- Software Winlog.med
- USB connection
- Colored LEDs signaling programming, readout and incorrect development



Set SI 3200

for EBI 12

- 4-port Interface IF 200
- Software Winlog.validation
- USB connection
- Colored LEDs signaling programming, readout and incorrect development
- Includes antenna



AL 112

for IF100 and IF 200

- Developed for real time monitoring
- AL 112 is a cable with 3 m length
- Antenna placement in the field of the door seal of a sterilizer or washer-disinfector
- Antenna steam-tight
- It is possible by a sealing to introduce it in the chamber



**Can adapter set
EBI DA-Set**

With this adapter set you can fix the data loggers at cans or plastic bags. Designed for data loggers of the EBI 12 series with axial, radial or external probes. Hereby you assure the use to ensure proper probes placement.



Can adapter EBI DA
for bottle loggers
(see page 14)



Bottle adapter EBI FL-S
silicone
for bottle loggers
(see page 14)



Grommets for sensor fixing EBI NI-140
Allows precise fixation of the logger sensor, with a 3 mm diameter, in cans and glasses.



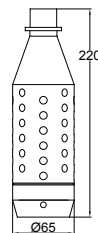
Compression fitting EBI KV-3
Allows exact positioning of the logger sensor, with a diameter of 3 mm, in glasses (lid).



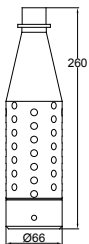
Dummy bottle

Please find EBI 12-T23X Temperature data logger from page 12.

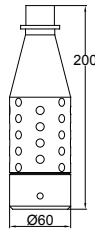
The dummy bottles can be screwed to the ground. This allows the EBI 12 to be positioned within the bottle.



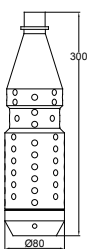
Dummy C



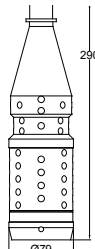
Dummy 0,5 l



Dummy E



Dummy 1 l



Dummy 0,7 l

Type	Description	Part No.
SI 1100	Set: Interface EBI IF 100 and Software Winlog.pro	1340-6061
SI 1200	Set: Interface EBI IF 200 and Software Winlog.pro	1340-6062
SI 2100	Set: Interface EBI IF 100 and Software Winlog.med	1340-6064
SI 2110	Set: Interface EBI IF 200 and Software Winlog.med	1340-6095
SI 2150	Set: Interface EBI IF 150 and Software Winlog.med	1340-6193
SI 3200	Set: Interface EBI IF 200 and Software Winlog. validation	1340-6068
AL 101	Silicone protection box for EBI 12 Pressure Data Logger	1340-6021
AL 102	Silicone protection box for EBI 12 Temperature Data Logger with 2 radial probes	1340-6022
AL 104	Battery Set for EBI 12	1100-0118
AL 106	Silicone protection box for EBI 12 Temperature Data Logger with 1 radial probe	1340-6023
AL 107	Silicone protection box for EBI 12 Temperature Data Logger with axial probes	1340-6024
AL 111	Replacement antenna for Interface EBI-IF 200	1340-6006
AL 112	Antenna steam sterilizer	1340-6007
AL 120	Battery Replacement Set incl. opening Tool for EBI 12	1100-0130
AL 121	Battery change tool (2 parts) EBI 12	1100-0131
AL 122	Eyelet ring EBI 12	1248-0122
AL 123	Standard connector for EBI 12 Pressure data logger	1248-0123
AL 124	Tube connector for EBI 12 Pressure data logger	1248-0124
AL 125	Luer-Lock connector for EBI 12 Pressure data logger	1248-0125
AL 132	Flow adapter for EBI 12-TC 230	1248-0132
AL 190	Silicone cable strap set, consisting of 10 pcs.	1248-0190
AL 285	Logger-Check	1248-0285
EBI TIB2	Thermal Insulation box 160 mm x 160 mm x 60 mm	1340-1892
EBI DA	Can adapter for bottle loggers	1340-1963
EBI DA-Set	Can adapter set for bottle loggers	1340-1984
EBI FL-S	Bottle adapter, silicone	1340-1961
EBI NI-140	Grommets for sensor fixing up to +140 °C (100 pieces)	1340-1988
EBI KV-3	Compression fitting	1340-2005
Dummy C	Dummy Bottle POM 220 mm x 65 mm	1340-2255
Dummy 0,5L	Dummy Bottle POM 0,5 l	1340-2256
Dummy E	Dummy Bottle POM 200 mm x 60 mm	1340-2257
Dummy 1L	Dummy Bottle POM 1 l	1340-2258
Dummy 0,7L	Dummy Bottle POM 0,7 l	1340-2259

Mini Temperature Data Loggers EBI 11 Series

General technical specifications: valid for all EBI 11-T logger types

Operating temperature	-30 °C ... +150 °C (-22 °F ... +302 °F)
Accuracy	±0.2 °C (-30 °C ... +0 °C) ±0.1 °C (0 °C ... +150 °C)
Time accuracy (24h)	< 5 sec
Resolution: temperature	0.01 °C
Data memory	15,000 measurements (total)
Sensor	Pt 1000, Class A
Sampling rate	1 sec ... 24 h
Measurement mode	• Endless measurement • Start / Stop measurement • Measure upon start time • Start immediately until end of memory
Storage temperature	-20 °C ... +70 °C (-4 °F ... +158 °F)
Max. operating pressure	20 bar (abs.)
Battery	Lithium button cell, 2 x BR1225 A, 3V, replaceable
Dimensions (Ø x H)	16,5 mm x 24 mm*
Weight	Approximately 45 g *
Housing material	Stainless Steel (V4A)
Protection class	IP68
Certificate	Factory calibration certificate
* Dimensions and weight may be different depending on the type.	

Product lines



Data loggers with this symbol are characterized by their very small size. For this reason, they are used in the smallest of spaces, for example to control pasteurization in bottles or to carry out thermal tests in small sterilizers.



Data loggers with this symbol are characterized by their very small size. That is why they are very popular with food manufacturers for testing the effects of temperature during pasteurization.

Validation, Routine and Process control sets

Due to the different requirements for the process control, the routine control and validation of processes, there are different sets at ebro®.

As an example, applications for the different sets are clearly displayed in the table. So, it is possible to choose the set suitable for your application at a glance.

	SL 1011	SL 1521	SL 2002	SL 3001	SL 3101	SL 3111	SL 3302	SL 4021	SL 4102	SL 4121
	1250-1011	1250-1521	1250-2002	1250-3001	1250-3101	1250-3111	1250-3302	1250-4021	1250-4102	1250-4121
Routine control in										
Bedpan washer	✓		✓		✓	✓				
Washer disinfectant			✓		✓	✓	✓			
Endoscope washer disinfectant			✓		✓	✓	✓			
Sterilizer < 60 l		BD *	✓	✓	✓	✓	✓			
Sterilizer > 60 l		BD *	✓	✓	✓	✓	✓			
Validation of Processes in										
Washer disinfectant			✓		✓	✓	✓			
Endoscope washer disinfectant			✓		✓	✓	✓			
Sterilizer < 60 l			✓	✓	✓	✓	✓			
Sterilizer > 60 l					✓	✓				
DAC Universal							✓			
Process control in										
Pasteurization cans								✓		
Pasteurization bottles									✓	✓

* Bowie&Dick-Test

Data Logger Sets



Complete Data Logger Sets for Process control and Monitoring, for Routine Control, Mapping and Acceptable Quality Limit (AQL)

Description:

- Data Loggers with evaluation software and extensive equipment
- FDA 21 CFR Part 11 conform software

Applications:

- Process control, Monitoring and routine control in steam sterilizers, washer disinfectors, washer disinfectors for endoscopes as well as bedpan washers.
- Implementation of the electronic Bowie&Dick-Test.
- Process and routine control of pasteurization and bottle cleaning processes
- Process and routine control in cooking processes
- Process and routine control in other thermal processes in the food, pharma or medical sector

Advantages:

- Fully automatic and tamper-proof evaluation
- Individual evaluation by user-defined evaluations
- Wide range of wireless data loggers for different applications
- Highly flexible temperature cable probe
- High precision Pt 1000 temperature sensors
- High accuracy up to ± 0.05 °C
- TÜV certified, FDA 21 CFR Part 11 conform software
- 2 years warranty





Complete Data Logger Sets for Operation and Process Qualification

Description:

- Data Loggers for validation with evaluation software and extensive equipment
 - TÜV certified
 - FDA 21 CFR Part 11 conform software
-

Applications:

- Operation and Process Qualification in pasteurization and bottle cleaning processes.
 - Operation and Process Qualification in steam sterilizers, washer disinfectors, washer disinfectors for endoscopes as well as DAC-Universal
 - Operation and Process Qualification in cooking processes
 - Operation and Process Qualification in other thermal processes in the food, pharma or medical sector
-

Advantages:

- Fully automatic and tamper-proof evaluation
 - Individual evaluation by user-defined evaluations
 - Wide range of wireless data loggers for different applications
 - Highly flexible temperature cable probe
 - High precision Pt 1000 temperature sensors
 - High accuracy up to ± 0.05 °C
 - TÜV certified, FDA 21 CFR Part 11 conform software
 - 2 years warranty
-

Data acquisition in the event of an accident



For the standard-compliant operation of washer-disinfectors, the recording of all process faults in each individual batch is mandatory. If this cannot be ensured, the operator must switch to another independent test method or take his RUMED or parts of it out of operation.

A simple possibility of batch control is offered by the following product compilation, which should not be missing in any RUMED. As part of an average concept, the use of data loggers can ensure standard-compliant monitoring and the RUMED can continue to operate.

Your Benefits are:

- Normative reprocessing despite average through independent measuring system
- No network infrastructure required, as data acquisition and evaluation takes place on a single workstation computer
- Calibrated measuring system
- TÜV certified evaluation software



Depending on the size of the RUMED but of course also based on the risk assessment, one or more such sets should be available.

An accident set should contain the following:

Type	Description	Part No.
EBI 12-TP237	For measuring the temperature and rinsing pressure in the WD. It can also be used in the steam sterilizer.	1340-6658
SI 2150	Software and interface set, consisting of the Winlog.med software with IF 150 interface.	1340-6193
AL 101	Silicone protection box	1340-6021
TDS-3	For checking the water quality of the last rinsing water, measurement of conductivity	1340-5831
PHX 800	For checking the water quality of the last rinse water, measuring the pH value	1340-5800
AL 128	Storage and transport case	1248-0128
AL 1100	Foam insert	1248-1100

Proposal for a pasteurization set in combination with the EBI 11 Mini Data Logger



Targeted heating of food can extend the shelf life.

Regular control and documentation of the temperature in pasteurization and freeze-drying processes is crucial for the quality and safety of the food to be preserved. The food hygiene regulations require the recording of pasteurization temperatures and times. The ideal data loggers for this application are the data loggers of the EBI 11 family.



Proposal for a pasteurization set:

- 1 x EBI 11-T210 Mini temperature data logger, needle length: 20 mm
- AL 114 can adapter set
- SI 1100 Software & interface set, consisting of Winlog.pro software and IF 100
- AL 128 Carrying case „SYSTEMER“
- AL 1103 Foam insert



Type	Description	Part No.
EBI 11-T210	Mini Temperature Data Logger	1340-6260
SI 1100	Set: Interface EBI IF 100 and Software Winlog.pro	1340-6061
AL 128	Carrying Case	1248-0128
AL 1103	Inlay for EBI 11, EBI 12 and interface	1248-1103

Our Services for You

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

For us, Service means more than the usual software hotline, calibration service, repairs, etc. We are dedicated to understanding the needs of our customers and offering them the best possible solutions.

It makes no difference if you need to have a handheld instrument repaired or a thermometer calibrated - we are glad to be of service. Just call!

Repairs & Calibration

Tel.: +49 841 95478-55
Fax: + 49 841 95478-80
E-Mail: ebro@xylem.com

Service and Calibrations

We are happy to perform your calibration for temperature, pressure and relative humidity in our accredited DAkkS laboratory for you. Please just contact us.

IQ / OQ Documentation

Of course, you will receive an IQ / OQ documentation of the system according to the GAMP guidelines.

Maintenance, Fieldservice & Calibration at customers location

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Our service

for quality and safety



- Repair & Maintenance
- Equipment hire
- ISO or DAkkS calibration
for temperature/pressure/humidity
- Temperature Mapping
- Software Hotline
- Trainings



For us, service means more than just repair, rental equipment and calibration service - it means real "service to the customer".

In close cooperation with you, we are looking for the optimal solutions.

Our service order forms



Our training offers



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Technical product details are available
in the entire catalog
"Professional Data Loggers":



If you would like to receive additional samples of our catalogs, please send us your requirements by e-mail to ebro@xylem.com.



Xylem | 'zīləm|

- 1) The tissue in plants that brings water upward from the roots;
- 2) a leading global water technology company.

We're a global team unified in a common purpose: creating advanced technology solutions to the world's water challenges. Developing new technologies that will improve the way water is used, conserved, and re-used in the future is central to our work. Our products and services move, treat, analyze, monitor and return water to the environment, in public utility, industrial, residential and commercial building services settings. Xylem also provides a leading portfolio of smart metering, network technologies and advanced analytics solutions for water, electric and gas utilities. In more than 150 countries, we have strong, long-standing relationships with customers who know us for our powerful combination of leading product brands and applications expertise with a strong focus on developing comprehensive, sustainable solutions.

For more information on how Xylem can help you, go to www.xylem.com

-ebro-[®]



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/ebro.ingolstadt



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