

# ON THE SAFE SIDE WITH VALIDATED PROCESSES

30 YEARS OF EXPERIENCE IN THE PRODUCTION & SERVICE OF DATA LOGGERS



# Validation and process monitoring

Whether monitoring pasteurization units or validating sterilization processes, only **robust, high accuracy data loggers** can meet the standards required for **reliable and reproducible process safety**.

Customers rely on our years of experience to advise them on specifications and relevant regulations and to select the right data loggers for their application

Depending on the process, you can **measure**, **record** and **transmit** the following parameters live to the software:

- Temperatures from -200 °C to +400 °C
- Pressure from 0.1mbar to 10.000 mbar
- Relative humidity from 0 % rH to 100 % rH
- Conductivity from 1 μS/cm to 2000 μS/cm





#### We fulfil your high demands with

- Fast response times of the data loggers
- Pt 1000 sensors and therefore high measuring accuracy
- User-friendly software certified by TÜV Süd
- Fully FDA 21 CFR Part 11 compliant software
- High-quality, user-replaceable batteries
- Food-safe and FDA-compliant stainless steel housing

Thanks to their **ATEX approval** (©EX II 1G), selected loggers can be used in extreme conditions such as explosive atmospheres.

# Data loggers for your requirements



# **Food industry**

- Full water autoclaves
- Spray water autoclaves
- Steam autoclaves
- Pasteurs
- Freezers
- Smoke chambers
- Ovens
- Continuous fryers



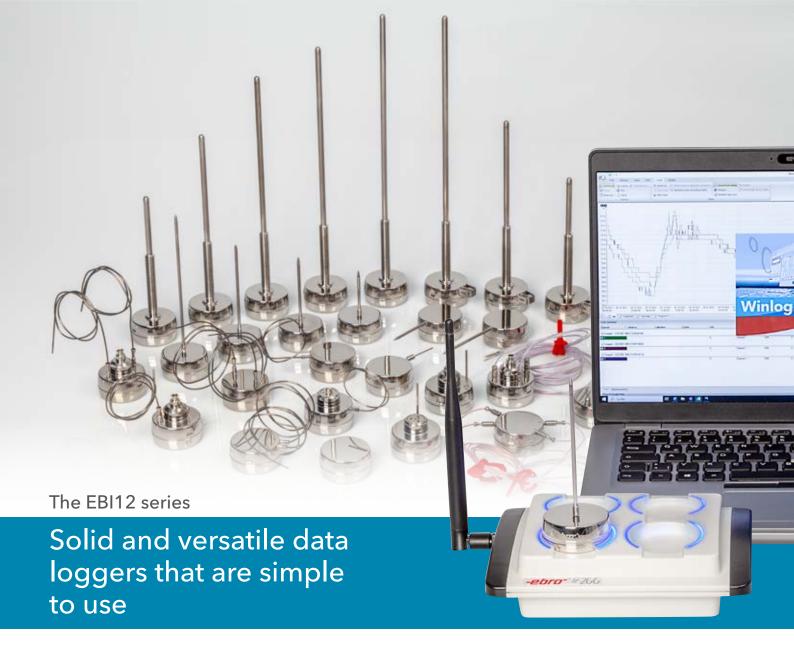
# **Medical Sector**

- Steam sterilizers
- Plasma sterilizers
- FO sterilizers
- Washer-disinfectors
- Washer-disinfectors for endoscopes
- DAC
- Careclave



# **Pharmaceutical Sector**

- Steam sterilizers
- Hot air sterilizers
- EtO sterilizers
- Stability chambers
- Incubators
- Freezers
- Ultra freezers



#### **General technical specifications of the EBI 12 series**

| Operating temperature:                | Temperature logger: -90 °C to +150 °C*                                    |
|---------------------------------------|---|
| -   · · · · · · · · · · · · · · · · · | Radio mode: -30 °C to +150 °C   |
| Measuring range:                      | Temperature: -200 °C to +400 °C   |
|                                       | Pressure: 1mbar to 4.000 mbar   |
|                                       | Relative Humidity: 0 % rH to 100 % rH                                     |
|                                       | Conductivity: 1 μS/cm to 2000 μS/cm                                       |
| Accuracy:                             | Temperature: ± 0,1 °C (0 °C to +120 °C)*, ± 0,05 °C (+120 °C to +140 °C)* |
|                                       | Pressure: ± 15 mbar (151 mbar to 2.049 mbar)*                             |
|                                       | Relative Humidity: ± 2 % rH, non-condensing at +25 °C*                    |
|                                       | Conductivity: $\pm$ 0,5 $\mu$ S/cm (1 $\mu$ S/cm to 20 $\mu$ S/cm)*       |
| Resolution:                           | Temperature: 0,01 °C  |
|                                       | Pressure: 1 mbar  |
|                                       | Relative Humidity: 0,1 % rH   |
|                                       | Conductivity: 0,1 µS/cm   |
| Sensor:                               | Temperature: Pt 1000, class A   |
|                                       | Pressure: Piezoresistive pressure sensor (temperature compensated)        |
|                                       | Relative Humidity: Capacitive   |
|                                       | Conductivity: Conductivity electrode                                      |
| Measuring interval:                   | 250 ms to 24 hrs.*  |
| Protection rating:                    | IP68  |
| + F 1:(((                             |   |

<sup>\*</sup> For different specifications, please refer to the product descriptions.



#### General technical specifications of the EBI 11 series

Operating temperature: Temperature logger: -30 °C to +150 °C\*

Measuring range: Temperature: -30 °C to +150°C

Pressure: 1mbar to 10.000 mbar

Accuracy: Temperature:  $\pm 0,1 \,^{\circ}\text{C} \, (0 \,^{\circ}\text{C to } +150 \,^{\circ}\text{C})$ 

Pressure: ±15 mbar (0 to 4.000 mbar)

Resolution: Temperature: 0,01 °C

Pressure: 1 mbar

Sensor: Temperature: Pt 1000, class A

Pressure: Piezoresistive pressure sensor (temperature compensated)

Measuring interval: 1 s to 24 hrs.

Protection rating: IP68

<sup>\*</sup> For different specifications, please refer to the product descriptions.

# Starter kits and data logger sets Standard applications for temperature measurement

- For a quick start
- Further loggers can be easily integrated
- Sets can be configured for selected processes if required



#### Starter-Kit for EBI 12 SK 6200

- 1 x temperature data logger EBI 12-T237
- 4-fold interface IF 200
- Software Winlog.pro
- 4 point calibration certificate (-20 °C, 0 °C, +60 °C and +134 °C)
- Additional EBI 12 data loggers can be integrated



#### Starter-Kit for EBI 11 SK 6100

- 1 x Mini temperature logger EBI 11-T210, needle length: 20 mm
- 4-fold interface IF 300
- Software Winlog.pro
- 3 point calibration certificate (0 °C, +60 °C and +134 °C)
- Additional EBI 11 data loggers can be integrated



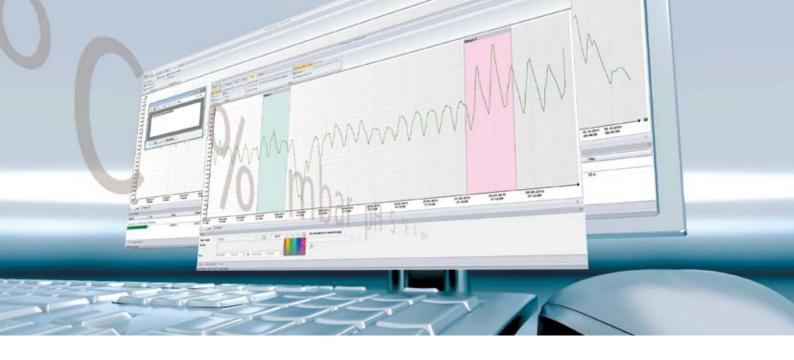
#### EBI 12 Validation SL 3111

- 5 x EBI 12-T441 temperature data logger
- 1 x EBI 12-TP226 temperature / pressure data logger with silicone protection box AL 101
- 4-fold interface EBI IF 200 with USB connection and antenna
- Winlog.validation evaluation software
- Carrying case "SYSTAINER"



#### Bowie&Dick Logger-Set EBI 16 SL 1521

- 1 x Bowie&Dick-Test EBI 16
- Interface EBI IF 150
- Software Winlog.med
- Carrying case "SYSTAINER"



# **Winlog.validation** - The specialized software for validation and routine control

The Winlog.validation software, certified by the TÜV, is designed for programming and reading of ebro® data loggers as well as for automatic evaluation of the measured values. A powerful reporting and evaluation tool for the high demands of validation and qualification in pharmacy and medicine.

- Central user management storable in the local network
- Automatic recognition of process cycles and report generation
- Automatic user defined calculations
- Creation of user-defined templates for specific devices and thermal processes
- Automatic evaluation of validation processes
- FDA 21 CFR Part 11 conformity
- IQ / OQ documentation for software qualification included

# Winlog.pro - The reliable all-rounder

Winlog.pro is perfect for programming multiple loggers and displaying them together in one overview after measurement.

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



## Certified service provider

It is very important to us at ebro, a Xylem brand that you receive high quality service and verifiably qualified measuring devices.

Therefore, we are regularly certified and continuously improve our software and products in accordance with the currently valid standards.

The following certificates demonstrate the standard you receive when you purchase our products, proving the quality and reliability of ebro, a Xylem brand.

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

#### Ebro data loggers comply with the following standards and regulations

| 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 sterilizers   |
| DIN EN ISO 15883   | Washer-disinfectors, test methods   |
| DIN EN 13060       | Small steam sterilizers   |
| DIN EN ISO 11140-4 | Sterilization of medical devices - Class 2- indicators used as an alternative to the Bowie&Dick test for detection of steam penetration   |
| FDA 21 CFR Part 11 | Is the part of FDA regulations on electronic records and electronic signatures, establishes the criteria under which electronic records and electronic signatures can be considered trustworthy and reliable, like a paper document |
| EU GMP Guidelines  | Annex 1 of the EU GMP Guideline "Manufacture of Sterile Medicinal Products"   |
| ISO 22000:2018     | International standard for food safety management systems. It is based on the PDCA cycle and is orientated towards the principles of HACCP.   |







# DAKAS Akkreditierung ( ZERTIFIKAT Die Zertifizierungsstelle der TÜV SÜD Management Service GmbH bescheinigt, dass die Unternehmen xylem Analytics Germany Sales GmbH & Co. KG In: Nati-Bireogle-Bix 1 - 82392 Weithairs - Deutschland Xylem Analytics Germany GmbH Nati-Bireogle-Bix 1 - 82392 Weithairs - Deutschland Nati-Bireogle-Bix 1 - 82392 Weitham - Deutschland Hattenbergelt: 10 - 95122 Mainz - Deutschland Hattenbergelt: 10 - 95122 Mainz - Deutschland ISO 9001:2015

Product Complesses Management Microbin, 22 07 2020

## Our service includes

- Calibration according to ISO and DAkkS Germany (equivalent to UKAS for the UK)
- International service and field service
- 30 years of experience in sales and service of sterilization loggers.
- IQ & OQ support thanks to documentation and service
- Customized training offers in the Centre of Competence



# Centre of Competence

Seminars - Webinars - Workshops

You can find our current training program at www.ebro.com

tion, we will be happy to assist you: seminare@ebro.com



### Calibration

ebro® data loggers are supplied with a factory calibration certificate. The function and the tolerances specified in the technical specifications are guaranteed. This factory calibration is performed with traceable factory standards.

In addition, we offer calibration according to ISO 9000 ff as well as accredited calibration according to DIN EN ISO/IEC 17025 (DAkkS) 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. Please do not hesitate to contact us. For pressure and temperature an annual calibration is recommended.

Service and maintenance activities are carried out in our service department in Weilheim by experienced service technicians.





# Service agreements

Maintenance contracts offer customers numerous benefits when it comes to ensuring the continued performance and smooth functioning of their products or equipment:

- Benefit from our accredited calibration laboratories
- Service staff specifically trained on the loggers used
- Long-term planning reliability leads to a basis of trust and better cost models
- Shorter lead times reduce downtime



# Even more flexible - with the rental logger service

Our rental loggers offer a practical and cost-effective solution for temporary measurement and monitoring tasks. Instead of purchasing expensive loggers, these devices can be rented for a defined period of time.

This approach offers a variety of advantages:

- Calibrated data loggers available on demand
- Loggers can be used for the duration of your project
- Used data loggers do not have to be listed in your measuring point list

By using this service, organizations can save time and resources while ensuring they have the right tools to achieve their monitoring objectives.



## 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





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