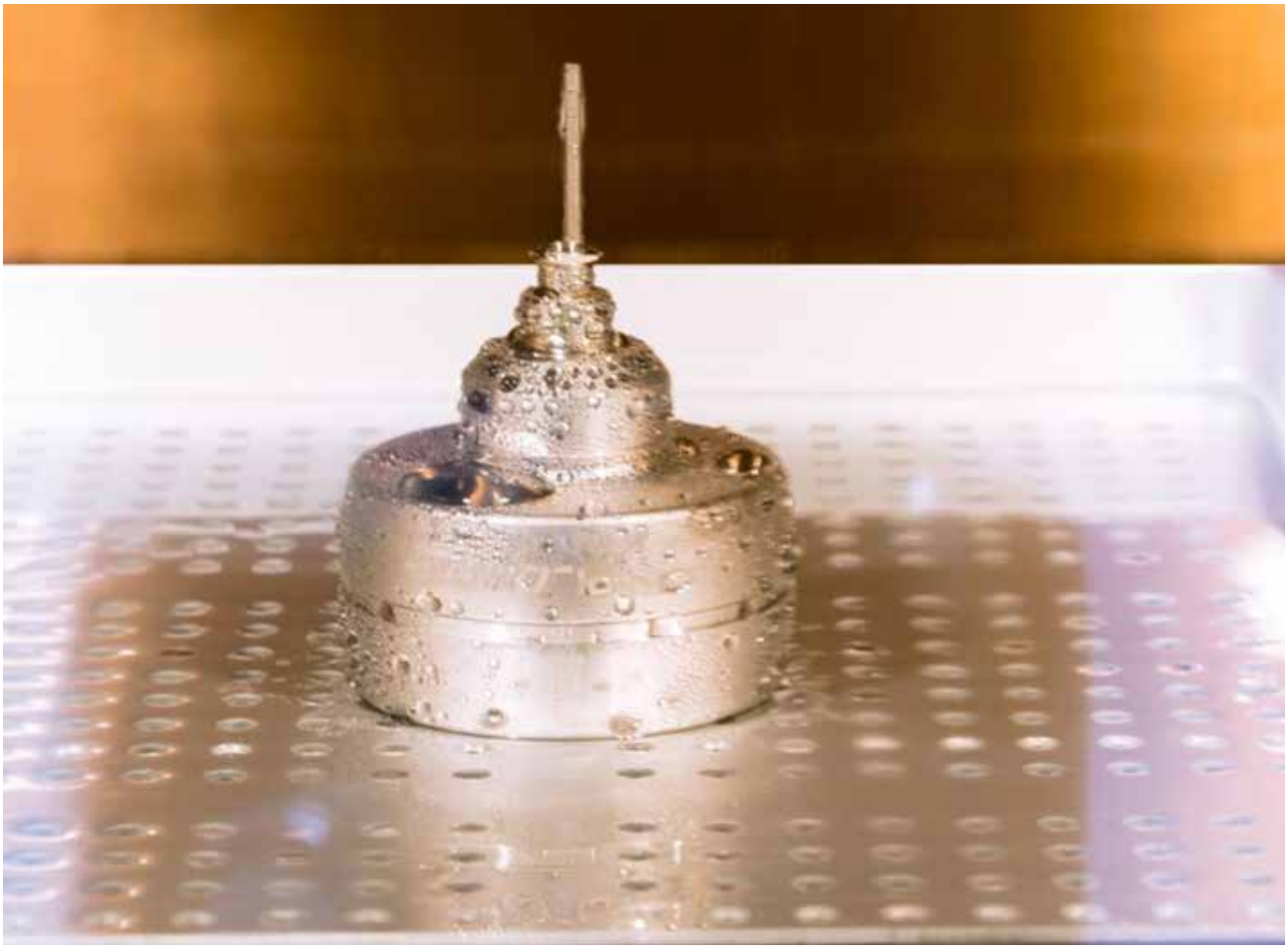
EBI 12 – The new data logger generation

- High quality stainless steel housing
- Application range from -90 °C to 150 °C
- High temperature accuracy up to 0.05 °C
- Extended temperature measurement range -200 °C to +400 °C
- Pressure measurement up to 4,000 mbar
- Precision pressure measurement 0.1 mbar
- High pressure accuracy up to 0.25 mbar
- Humidity measurement from 0% rH to 100% rH
- Conductivity measurement 1 to 2,000 µS/cm
- Radio mode for real-time monitoring
- ATEX approved
- Full compatibility Interface EBI IF-100, EBI IF-150 and EBI IF-200
- Full compatibility to Winlog software



-ebro- a xylem brand
Xylem Analytics Germany Sales GmbH & Co. KG, ebro
Peringerstr. 10 · 85055 Ingolstadt, Germany · Phone +49 841 95478-0 · Fax +49 841 95478-80 · Email: ebro@xyleminc.com · **www.ebro.com**

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 control

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

Room Monitoring and Process control

Description:

- Highly accurate temperature, pressure and humidity data loggers
- Standard temperature and humidity data loggers with automatic PDF report generation
- Wireless system to monitor temperature and humidity
- Multichannel Thermo Couple temperature data loggers

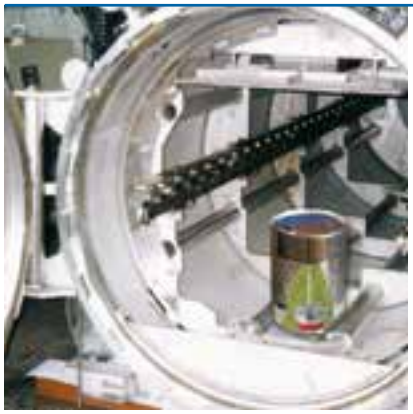
Applications:

- Room monitoring
- Transport and storage monitoring
- Clean room and freezer monitoring

Logger systems

and accessories for Process monitoring, Routine control and Validation

Food



Applications

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

Medical

- Steam Sterilization
- Washer disinfectors / bedpan washers
- H_2O_2-, LTSF- and EtO- Sterilization
- Depyrogenation / heat tunnel
- Incubators
- Refrigerators / Freezers / Cooling Rooms
- Stability Chambers

Pharmaceutical

- Steam-,H_2O_2 and EtO- Sterilization
- Washer disinfectors
- Depyrogenation / heat tunnel
- Lyophilization
- Incubators
- Refridgerators / 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

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 device and 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 94/9 / EC. 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) (German: Device Protection Level) 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.

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TÜV certified evaluation software Winlog.med and Winlog.validation

With the Winlog.med / Winlog.validation we offer a TÜV certified, FDA 21 CRF 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.


CERTIFICATE

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