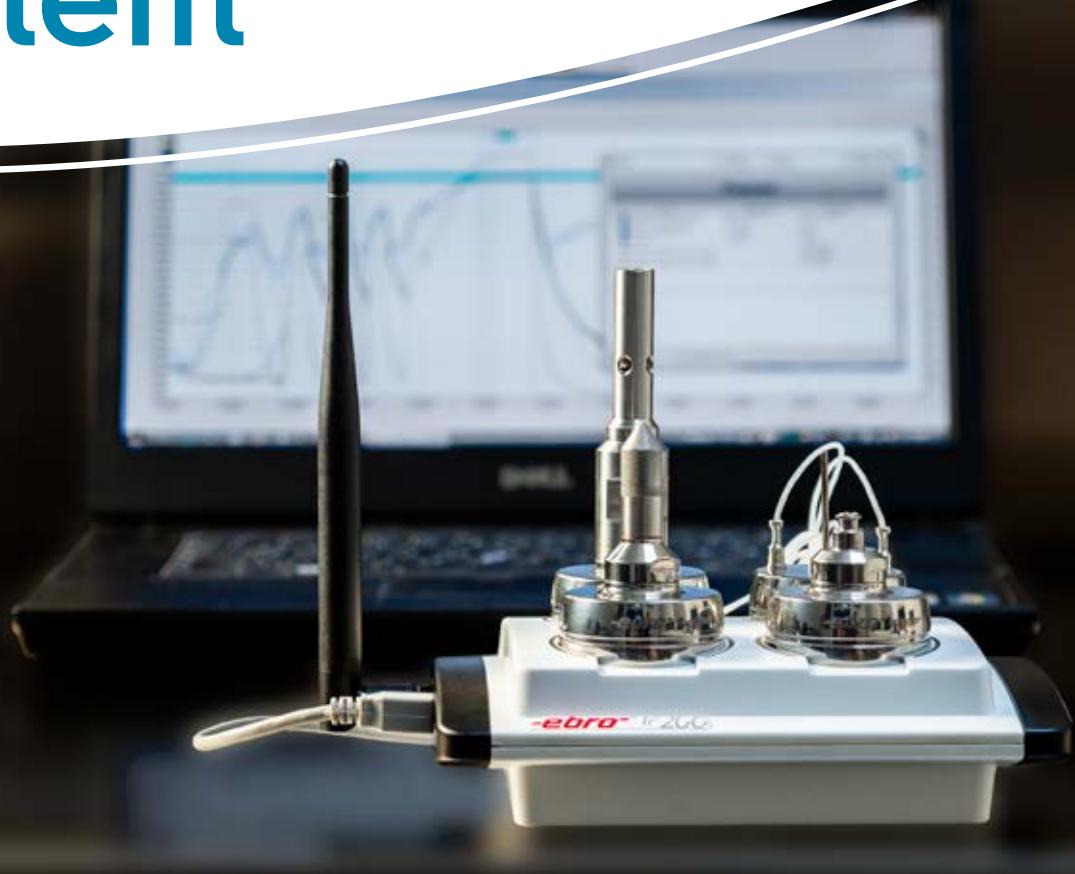


xylem



Professional Data Logger

FOR VALIDATION, ROUTINE CONTROL AND PROCESS MONITORING

MEDICINE

FOOD

PHARMACEUTICAL

LABORATORY

-ebro-
a xylem brand

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



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

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.

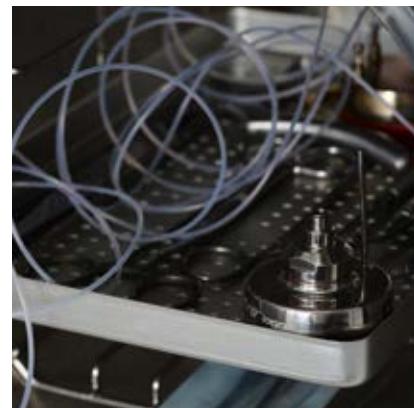
DIN EN ISO 17665	Sterilization of health care products. - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
DIN EN 285	Sterilization - Steam sterilizers - Large sterilizer
DIN EN ISO 15883	Washer disinfectors - General requirements, 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 / Pressure Data Loggers EBI 12 series

General technical specifications: valid for all EBI 12-TP data loggers

Operating temperature: pressure logger	0 °C ... +150 °C (+32 °F ... +302 °F)
Accuracy: temperature	±0.1 °C (0 °C ... +120 °C) ±0.05 °C (+120 °C ... +140 °C) ±0.1 °C (+140 °C ... +150 °C)
Accuracy: pressure	±10 mbar (50 mbar ... 150 mbar) ±10 mbar (2,050 mbar ... 2,250 mbar) ±10 mbar (3,000 mbar ... 3,250 mbar) ±15 mbar (for the remaining measurement range)
Resolution: temperature	0.01 °C
Resolution: pressure	1 mbar
Data memory	Max. 100,000 measurements (total)
Sensor: temperature	Pt 1000, Class A
Sensor: pressure	Piezoresistive pressure sensor (temperature compensated)
Sampling rate	250 ms ... 24 h
Measurement mode	<ul style="list-style-type: none"> • Endless measurement • Measure upon start time • Start immediately until end of memory • Start- / Stop measurement
Storage temperature	0 °C ... +125 °C (+32 °F ... +257 °F)
Maximum operating pressure	Pressure logger: 7 bar (abs)
Minimum operating pressure	Logger with flexible cable probe: 20 mbar (abs)
Time accuracy (24h)	< 5 sec
Battery	Lithium cell, 3.6 V, user replaceable
Dimensions (Ø x H)	48 mm x 32 mm*
Weight	Approximately 120 g *
Housing material	316 L Stainless steel / PEEK
Protection class	IP 68
Certificate	Factory calibration certificate

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



EBI 12-TP222 Temperature / Pressure Data Logger bendable metal probe and Luer-Lock-Connection



Application sample

- Washer disinfectors
- Sterilizer

Technical Data

Measurement range: temperature	0 °C ... +150 °C (+32 °F ... +302 °F)
Measurement range: pressure	1 ... 4,000 mbar
Data memory	2 x 33,400 measurement values
Factory calibration certificate	0 °C, +60 °C and +134 °C 100 mbar and 3100 mbar at +25 °C and 3100 mbar at +134 °C

- 1 external temperature probe, axial, bendable, Ø 1.5 mm
- 1 internal pressure sensor with Luer-Lock-Connection

Type	Description	Part No.
EBI 12-TP222	Needle Length = 500 mm, Luer-Lock-Connection	1340-6653

EBI 12-TP226 Temperature / Pressure Data Logger bendable metal probe



Application sample

- Washer disinfectors
- Sterilizer



Technical Data

Measurement range: temperature	0 °C ... +150 °C (+32 °F ... +302 °F)
Measurement range: pressure	1 ... 4,000 mbar
Data memory	2 x 33,400 measurement values
Factory calibration certificate	0 °C, +60 °C and +134 °C 100 mbar and 3100 mbar at +25 °C and 3100 mbar at +134 °C

Approximately available from Q2 2019

- 1 external temperature probe, axial, bendable, Ø 1.5 mm
- 1 internal pressure sensor
- Small size

Type	Description	Part No.
EBI 12-TP226	Needle Length = 250 mm	1340-6657

EBI 12-TP231 Temperature / Pressure Data Logger rigid metal probe and Luer-Lock-Connection



II1G Ex ia IIC T4 Ga



Application sample

- Washer disinfectors
- Sterilizer
- EtO sterilizer (ATEX type)

Technical Data

Measurement range: temperature (Use in EX Area)	EBI 12-TP231: 0 °C ... +150 °C (+32 °F ... +302 °F) EBI 12-TP231-EX: 0 °C ... +85 °C (+32 °F ... +185 °F)
Measurement range: pressure	1 ... 4,000 mbar
Data memory	2 x 33,400 measurement values
Factory calibration certificate	0 °C, +60 °C and +134 °C 100 mbar and 3100 mbar at +25 °C and 3100 mbar at +134 °C

- 1 external temperature probe, axial, Ø 1.95 mm
- 1 internal pressure sensor with Luer-Lock-Connection

Type	Description	Part No.
EBI 12-TP231	Needle Length = 40 mm	1340-6655
EBI 12-TP231-EX	Needle Length = 40 mm	1340-6655-EX



EBI 12-TP234 Temperature / Pressure Data Logger *tube connection and M 10x1 internal thread*



Application sample

- Drainages

Technical Data

Measurement range: temperature	0 °C ... +150 °C (+32 °F ... +302 °F)
Measurement range: pressure	1 ... 4,000 mbar
Data memory	2 x 33,400 measurement values
Factory calibration certificate	0 °C, +60 °C and +134 °C 100 mbar and 3100 mbar at +25 °C and 3100 mbar at +134 °C

- 1 external temperature probe, axial, Ø 1.95 mm
- 1 internal pressure sensor with tube connection

Type	Description	Part No.
EBI 12-TP234	Needle Length = 40 mm	1340-6652

EBI 12-TP322 Temperature / Pressure Data Logger *bendable metal probes with Luer-Lock-Connection*



Application sample

- Washer disinfectors
- Sterilizer

Technical Data

Measurement range: temperature	0 °C ... +150 °C (+32 °F ... +302 °F)
Measurement range: pressure	1 ... 4,000 mbar
Data memory	3 x 25,000 measurement values
Factory calibration certificate	0 °C, +60 °C and +134 °C 100 mbar and 3100 mbar at +25 °C and 3100 mbar at +134 °C

- 2 external temperature probes, axial, bendable, Ø 1.5 mm
- 1 internal pressure sensor with Luer-Lock-Connection

Type	Description	Part No.
EBI 12-TP322	Luer-Lock-Connection	1340-6664

EBI 12-TP422 Temperature / Pressure Data Logger bendable metal probes with Luer-Lock-Connection



Application sample

- Washer disinfectors
- Sterilizer

Technical Data

Measurement range: temperature	0 °C ... +150 °C (+32 °F ... +302 °F)
Measurement range: pressure	1 ... 4,000 mbar
Data memory	4 x 20,000 measurement values
Factory calibration certificate	0 °C, +60 °C and +134 °C 100 mbar and 3100 mbar at +25 °C and 3100 mbar at +134 °C

- 3 external temperature probes, axial, bendable, Ø 1.5 mm
- 1 internal pressure sensor with Luer-Lock-Connection

Type	Description	Part No.
EBI 12-TP422	Needle Length = 500 mm, Luer-Lock-Connection	1340-6662

EBI 12-TP45X Temperature / Pressure Data Logger flexible cable probes with Luer-Lock-Connection



Application sample

- Sterilization

Technical Data

Measurement range: temperature	0 °C ... +150 °C (+32 °F ... +302 °F)
Measurement range: pressure	1 ... 4,000 mbar
Data memory	4 x 20,000 measurement values
Factory calibration certificate	0 °C, +60 °C and +134 °C 100 mbar and 3100 mbar at +25 °C and 3100 mbar at +134 °C

- 3 external temperature probes, axial, flexible, Ø 1.2 mm
- 1 internal pressure sensor with Luer-Lock-Connection

Type	Description	Part No.
EBI 12-TP451	Cable Length = 600 mm, Luer-Lock-Connection	1340-6643
EBI 12-TP453	Cable Length = 1,200 mm, Luer-Lock-Connection	1340-6647

EBI 12-TP460 Temperature / Pressure Data Logger flexible cable probes



- 3 external temperature probes, radial, Ø 1.2 mm
- 1 internal pressure sensor

Application sample

- In limited spaces e.g. in containers

Technical Data

Measurement range: temperature 0 °C ... +150 °C (+32 °F ... +302 °F)

Measurement range: pressure 1 ... 4,000 mbar

Data memory 4 x 20,000 measurement values

Factory calibration certificate 0 °C, +60 °C and +134 °C
100 mbar and 3100 mbar at +25 °C and
3100 mbar at +134 °C

Type	Description	Part No.
EBI 12-TP460	Cable Length = 600 mm	1340-6648

EBI 12-TPX9X Precision Pressure Logger high precision pressure measurement down to 0.1 mbar



In the process of H₂O₂ Sterilizers a very precise pressure measurement is necessary. The system works with pressures down to 1 mbar abs. A Highly accurate pressure data logger is necessary caused by the very low pressure nearly by vacuum.



Not for use in steam sterilizer



- 1 internal or 1 external temperature sensor, Ø 1.95 mm
- 1 internal pressure sensor

Technical Data

Measurement range: temperature 0 °C ... +85 °C (+32 °F ... +185 °F)

Measurement range: pressure 0.1 ... 1,050 mbar (0.1 ... 788 Torr)

Accuracy: temperature ±0.1 °C

Accuracy: pressure ± 0.25 mbar (0.1 mbar ... 50 mbar)
± 5% of measured value (50 mbar ... 100 mbar)
± 1% FS (100 mbar ... 1,050 mbar)

Resolution: temperature 0.01 °C

Resolution: pressure 0.1 mbar

Data memory TP190: 50,000 measurement values
TP290: 2 x 33,400 measurement values

Sensor: temperature Pt 1000

Sensor: pressure Piezoresistive pressure sensor

Measurement cycle 250 ms ... 24 hours

Measurement mode

- Endless measurement immediately
- Start / Stop measurement
- Measure immediately until end of memory

Operating temperature 0 °C ... +85 °C

Max. operating pressure 2,000 mbar (abs.)

Battery Lithium cell, 3.6 V, user replaceable

Dimensions (D x H) 48 mm x 35 mm

Housing material 316 L Stainless steel / PEEK

Protection class IP 68

Factory calibration certificate 0 °C and +60 °C
<=0.5 mbar, 50 mbar at +25 °C and
<=0.5 mbar, 10 mbar, 50 mbar at +60 °C

Type	Description	Part No.
EBI 12-TP190	Internal temp. sensor	1340-6665
EBI 12-TP290	Needle Length = 40 mm	1340-6666

Accessories and Interface-Sets



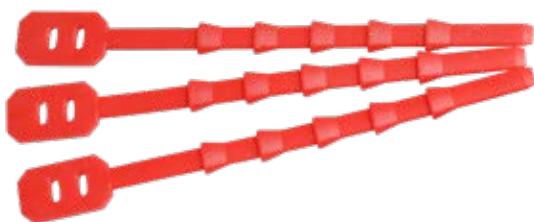
Battery replacement set AL 120
for EBI 12
Consisting of 3 batteries, 6 O-rings with
grease and opening tool EBI 12



AL 121 opening tool EBI 12
To open the data loggers e.g. for battery
change



AL 122 eyelet ring EBI 12
For securing the EBI 12 data loggers in
process



AL 190 Silicone cable strap
To hold the flexible cable probes of the EBI 12 data loggers



Holding clamps probes
To hold the flexible cable probes of the EBI 12 data loggers.



Silicone protection box

- Protects EBI 12 Data Loggers against heat peaks
- Protects EBI 12 Data Loggers against mechanical damage
- Extends the life of EBI 12 Data Loggers

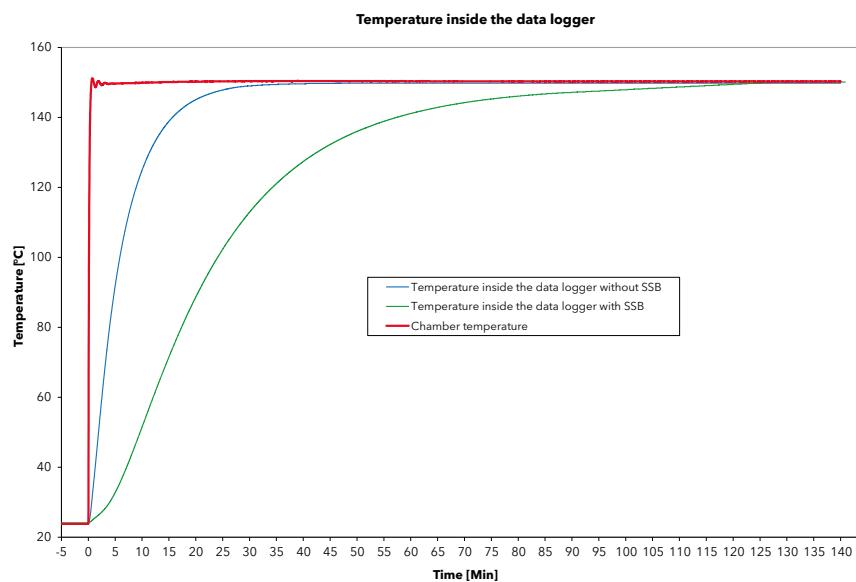


Silicone protection box AL 101
for e.g.
EBI 12-TP222,
EBI 12-TP322,
EBI 12-TP422 and
EBI 12-TP45x

Ø 78 mm,
Height: 50 mm

Silicone protection box AL 107
for e.g.
EBI 12-T24x,
EBI 12-T441,
EBI 12-T67x und
EBI 12-T471

Ø 78 mm,
Height: 44 mm



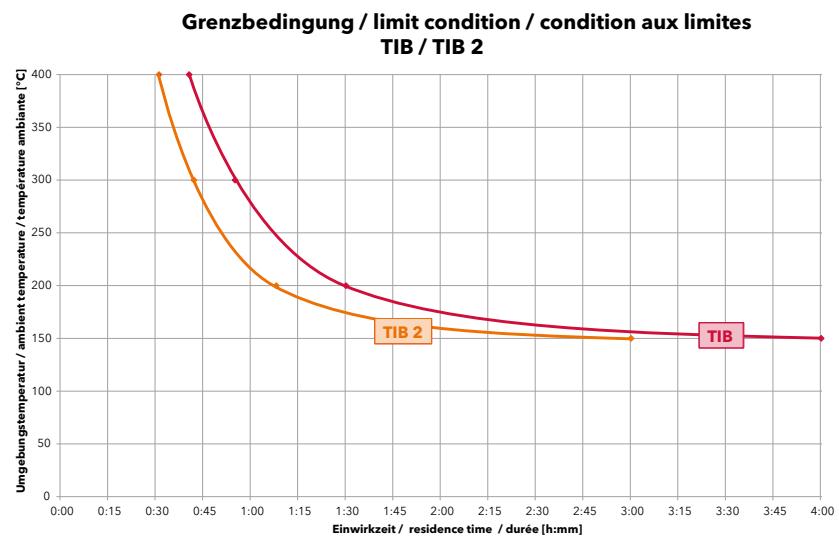
Thermal Insulation Boxes

- Usable from +150 °C ... +400 °C
- Thermal protection of data loggers
- Stainless steel



Thermal insulation boxes EBI TIB and EBI TIB 2

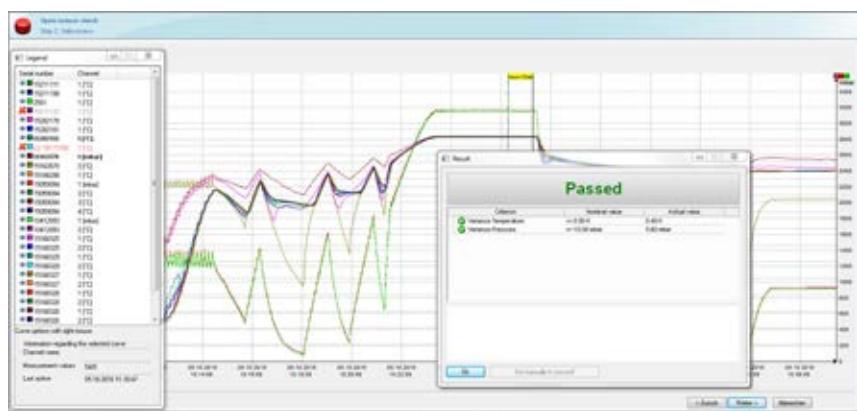
- for EBI 12-T221 and EBI 12-T421
- EBI TIB: 160 mm x 160 mm x 82 mm
- EBI TIB 2: 160 mm x 160 mm x 60 mm



AL 285 Logger-Check

For thermal measuring system control in steam sterilizer

In combination with the software Winlog.validation the AL 285 offers you a simple, on site functional check of the measuring channels.



EN ISO 17665-1, paragraph 9.1.4

Verification of the calibration value of the measuring instrument that is used for the validation of the sterilization process at process condition.

- Easy and reproducible test with automatic generation of reports.
- The tests are stored permanently in the database



**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
- Includes antenna

**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
- Includes antenna

**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 lenght
- 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 mounting of the logger sensor in cans and glass.



Compression fitting EBI KV-3
Allows precise mounting of the logger sensor in glass (caps).

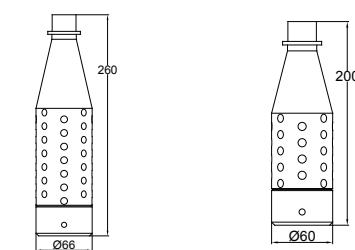
Dummy bottle

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

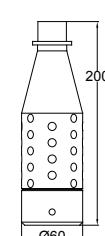


Dummy C

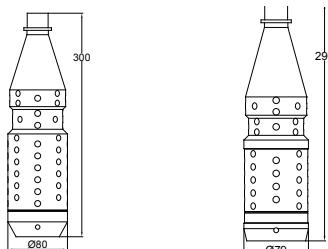
The dummy bottles can be screwed to the ground. This allows the EBI 12 to be positioned within the bottle.



Dummy 0,5 l



Dummy E



Dummy 1 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 120	Battery change set for EBI 12	1100-0130
AL 121	Battery change tool (2 parts) EBI 12	1100-0131
AL 122	Eyelet ring EBI 12	1100-0132
AL 104	Battery set for EBI 12	1100-0118
AL 107	Silicone protection box for EBI 12 Temperature Data Logger	1340-6024
AL 112	Antenna steam sterilizer	1340-6007
AL 190	Silicone cable strap set, consisting of 10 pcs.	1248-0190
AL 285	Logger-Check	1248-0285
Clamp	Holding clamps for probes	1340-0005
EBI TIB	Thermal Isolation box, 160 x 160 x 82 mm	1340-1894
EBI TIB 2	Thermal Isolation box, 160 x 160 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 220x65mm	1340-2255
Dummy 0,5L	Dummy Bottle POM 0,5l	1340-2256
Dummy E	Dummy Bottle POM 200x60mm	1340-2257
Dummy 1L	Dummy Bottle POM 1l	1340-2258
Dummy 0,7L	Dummy Bottle POM 0,7l	1340-2259