![ELPRO]

LIBERO ITS – Innovative multi-level Indicator with wireless readout technology

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1.   What is innovative about LIBERO ITS?

LIBERO ITS is the world's first (machine-)readable electronic indicator on box level. We combine knowledge on customer needs with state-of-the-art photonics to build an "ELPRO-compatible product".

2.   What are the technical specifications of LIBERO ITS?

The technical specifications are available on the [ELPRO website](#) (Link Tec Specs)

3.   How long can LIBERO ITS run?

LIBERO ITS is designed to monitor pharmaceuticals over its complete lifetime of up to 5 years.

4.   What are the stability budget configurations on the LIBERO ITS?

ELPRO offers some standard configuration options (see [ELPRO website](#)). In addition the temperature thresholds or alarm delay times and alarm types can be defined by the customer when placing an order.

5.   How can I read and document LIBERO ITS?

The status (OK or ALARM) can be read visually by pressing the button at any time. In order to document the status one needs a smartphone and the app installed.

6.   What are the cost for the Smartphone App and where is it available?

A basic version of the Smartphone App is available for free in the App Store (iOS) and the Google Play Store (Android). If you want to have a more private and controlled setting, we can also come-up with a customer specific private version of the App.

7.   Can LIBERO ITS be read out more than once?

Yes. LIBERO ITS can be read out multiple times during operation. Thanks to the documentation capability, LIBERO ITS is the ideal device for continuous temperature monitoring and calculating remaining stability budget along the entire supply chain.

8.   Can I reuse or reconfigure LIBERO ITS?

No. LIBERO ITS is a convenient, cost-effective, single-use electronic monitoring devices, programmed with a customer-specific profile during the manufacturing process. The devices are designed for limited operation life and are not reprogrammable.

we prove it.

9.   Can LIBERO ITS be stopped?

Yes. There is a configuration option available with a stop button feature.

10.   Can LIBERO ITS record a measurement row?

No, LIBERO ITS is no data logger but an indicator. Means: it is not storing the measurement row but just the statistics, events and status - very similar to LIBERO CI.

11.   Does LIBERO ITS provide additional statistics and information?

Yes. LIBERO ITS provides alarm status and statistics for each zone

- Allowed Time, Total Time, Number of Excursion, Longest Excursion, Alarm Status

   as well as configuration details such as

- Profile ID, Logging interval

   and logging results

- Highest and lowest Temperature including timestamp, Time of first alarm, Start and Stop Time as well as Read out time

12.   Can I add specific information to the LIBERO ITS after readout?

Yes. After read-out, shipping or product specific information can be added in the Smartphone App.

13.   What technology is used to download the data from the LIBERO ITS to the Smartphone App?

We use photonics (optical communication) to transmit the data. The LIBERO ITS communicates via LED- flicker. The Smartphone App uses the camera to film the LED-flicker and translates into clear text (alarm status, statistics and events).

14.   Would we be able to re-assess reports with new stability budget?

Yes, a re-assessment with the same alarm limits but different times per zone is possible in the liberoMANAGER cloud database.

15.   What battery is used in LIBERO ITS?

LIBERO ITS uses a button cell battery type. This avoids customs delays and dangerous goods label requirements per IATA's 2017 Dangerous Goods Regulations' 58th Edition.

16.   How did ELPRO validate the performance of LIBERO ITS?

The LIBERO ITS is developed and fully validated by ELPRO following the guideline "GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems". By following the GAMP5 guidelines, the development and validation process is transparent and conforms to the international standard.

17.   How does ELPRO verify the performance of produced LIBERO ITS?

ELPRO performs a 100% temperature calibration of all sensors plus a 100% functional test during assembling. Calibration standards are calibrated by an ISO/IEC 17025 accredited laboratory and are traceable to ISO/IEC 17025, and/or national/international standards (equivalent to NIST, UKAS, DKD).

we prove it.