Libero. New dimensions.
The independent PDF Data Logger.

BERLINGER & CO. AG

LIBERO redefines cold chain monitoring

What if there was only one single device necessary for the monitoring of temperature sensitive goods during transportation, and what if this device could produce reports on any PC anywhere in the world without the need for any specific software. Would this not considerably simplify the cold chain monitoring process and reduce costs? It would be much easier to launch this system, to train the users and further more, no software validation at the destination would be necessary. This device called PDF Data Logger exists. After transportation it can be plugged into the USB port of any PC and automatically generates a report in a format (Adobe® PDF/A) that can be read everywhere without any problems. Elpro Libero, the worlds first PDF Logger® compliant with the new ISO standard ISO-19005-1 for Document Management heralds a new area of cold chain monitoring.

Conventional cold chain monitoring

Daily, thousands of temperature sensitive pharmaceutical products are being shipped at temperatures between 2° to 8°C. Data loggers accompany most of them in order to securely retrace climate conditions during transportation.

In general, the pre-programmed data loggers are placed with the goods in a suitable position. Then after transportation, the data loggers are unpacked and analyzed by means of specific software. This software produces a report including graphics for the duration of the journey that is often sent back to the sender for review. The sender is then able to make a judgment on the condition of the goods and provide authority to use. Up until now, neither the software, nor the data file nor the analysis reports were standardized. The various systems (local PC, Internet, RFID) were not compatible with each other and generated incompatible file formats as no international standard was established.

This makes long-term preservation of data and reports challenging.

With conventional systems, the following items are essential but are huge factors contributing to the overall cost.

- System introduction including user training
- Installation and maintenance of the analysis software (up-date roll-outs, end user support)
- Generation of individual standard operating procedures (SOP)
- Qualification of software and interface (IQ/OQ)
- Secure compliance with GLP/GMP and FDA Standard 21 CFR Part 11
- Archiving and long-term preservation of data

The total cost of ownership or cost efficiency will be made up of a combination of all the above.

INCREASE OF COST EFFICIENCY THANKS TO LIBERO, THE PDF LOGGER®

Libero automatically and independently establishes a PDF file using the measurement data and generates the pre-defined analysis report. As soon as the Data Logger is plugged into the USB port, the file is ready to be e-mailed, stored on the company network, printed or simply viewed. Thanks to this breakthrough concept, the introduction and training requirements are considerably reduced.

The sender of the goods is also able to determine how the report will look at the destination by pre-configuring the format before shipment. The benefit is having a standardized or uniform report worldwide. With the unique feature of not needing to install any additional software, IQ/OQ do not apply for the receiver and the user training becomes minimal.

Further enhancement to the cost effectiveness of Libero is provided by allowing individual reports to be generated for each stage of a multi-stage journey. This feature is available by utilizing the TRANSIT and ARRIVED functionality at the beginning and end of each stage of the journey. In this way, the receiver will only see a report for the part of the journey that is relevant to him. The Data Logger will however continue monitoring in the background even after a destination is reached and the ARRIVED status activated. This data is stored as part of the raw data in the secure format and embedded in the PDF file.

Start check mark
by pressing
the TRANSIT-Button

End check mark
by pressing
the ARRIVED-Button

The synergy of Data Logger and Adobe® PDF format

A NEW INTERNATIONAL STANDARD
ISO 19005-1 DOCUMENT MANAGEMENT

ELPRO's solution for a straightforward cold chain monitoring is based on a new ISO standard for PDF files.
ISO 19005-1 Document Management: Standardized file format PDF/A for electronic documents for long term archiving

ASSURED QUALITY

- PDF/A is an ISO approved standard
- Alarm indicator conforms with WHO standards
- Supports compliance with FDA standard 21 CFR part 11
- Validation certificate and IQ/OQ documents

TECHNICAL SPECIFICATIONS

- **Ti1/Ti1-L:** Multiple use, 400 days/3 years
  Ti1-S: Single use, 100 days
- Memory capacity: 16'000 data points
- Large, multifunctional display
- Measuring range: -35°C to +70°C
- Accuracy: ± 0.2°C (-10°C to +25°C)
- Alarm: 2 limit values or 5 alarm ranges
- Dimensions: Ti1/Ti1-S: 95 x 40 x 12 mm
  Ti1-L: 102 x 40 x 19 mm
- Weight: Ti1/Ti1-S: 40 g; Ti1-L: 45 g
- PDF file generator
- Detailed evaluation of raw data is possible with elproLOG evaluation software

UNIQUE FEATURES

- All in one: Data Logger and PDF file generator
- No software at destination
- Simple application and quick decision making
- No cable or interface necessary
- Full control thanks to worldwide standardized analysis reports

ANALYSIS REPORT ADOBE® PDF/A

- The PDF/A file has a pre-defined structure that may be customized
- No wrong manipulations possible
- Simple display and print-out
- Can immediately be sent to any destination

The built-in PDF generator automatically creates an analysis report with all relevant data.

The analysis report in the form of a PDF file can either be saved locally or on a company-own network, printed or sent by email. All raw data is tamper-proof embedded in the PDF file. (Detailed analysis with elproLOG software possible)

LIBERO is connected to the USB port of any PC

EXPLANATION OF ICONS

Temperature measurement

USB stick for PC | Report as PDF file

IP protective class

Conformity with FDA Standard 21 CFR Part 11

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