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Technical Note
ebro EBI 300 Series Dataloggers
June, 2021

Use Of Correct Data Loggers for Vaccines and other Sensitive Pharmaceutical Products

A light at the end of the COVID tunnel comes with distribution challenges. Each vaccination has its own set of management challenges, such as temperature needs and distribution issues. The use of digital data recorders to monitor temperature changes along the vaccine cold chain is vital to the vaccines' effectiveness. Whether you are handling Pfizer, Moderna, AstraZeneca or other sensitive pharmaceutical products, you are going to need quality data loggers to keep a track of the temperature.

We wish to provide you with some important tips while addressing these issues as the COVID-19 crisis continues. With the increasing number of discoveries in the field of immunization, reliable and compliant cold chain monitoring is the key to viable and effective vaccine distribution.

A cold chain relies upon a few important factors such as a professional courier, proper packaging, and a reliable logistic system, that requires optimal control and monitoring.

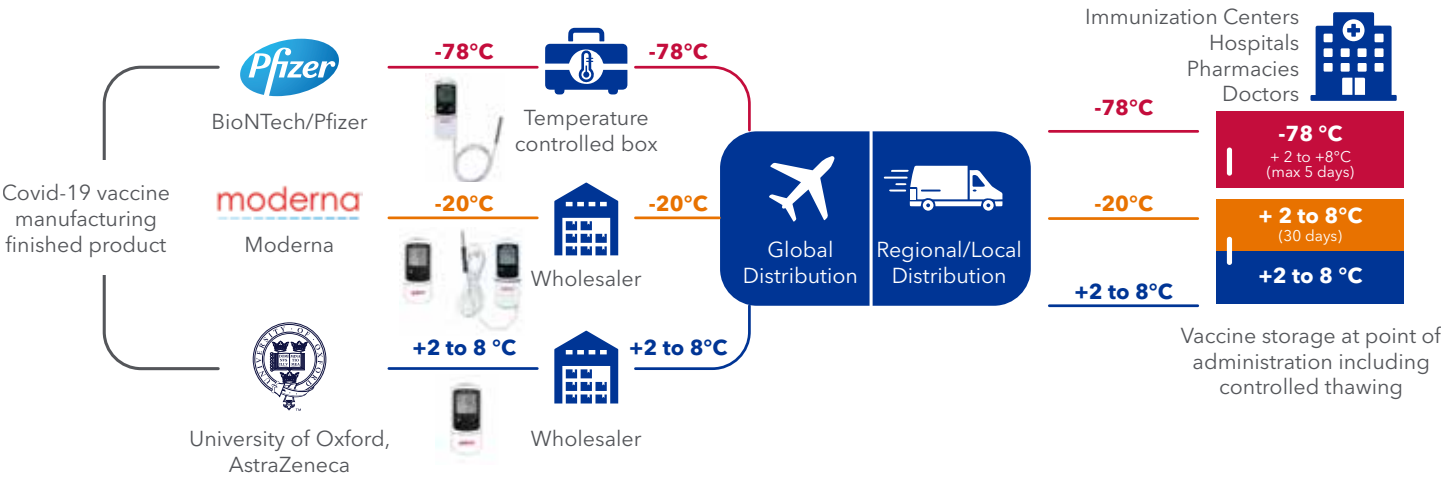
Think about how the vaccines' integrity and efficacy are addressed when the box is sealed and the doors are closed. No one knows what changes occur inside the container and what kind of environment it must face. This is the reason why temperature data loggers are important as they play a crucial role in the transportation and storage process of vaccines.

Here we are going to offer you some useful information to choose the most suitable data logger for cold chain monitoring.

The use of digital data loggers (such as ebro EBI 300 series) to monitor temperature changes along the vaccine cold chain is vital to the vaccines' effectiveness.

-ebro-
a xylem brand

Everything you need for your transportation



There are five key details to consider when choosing a data logger.

1. What is your required temperature range?
2. Where is the logger placed?
3. Who will read out the data?
4. Does it come with a calibration certificate? How to recalibrate it?
5. Is it FDA 21 CFR part 11 compliant?

1. Temperature Range and Accuracy

Temperature range and accuracy is the first thing to be considered while choosing a data logger. Determine the temperature range of the pharmaceutical product you are handling. For example, BioNtech-Pfizer vaccine should be stored in an ultralow temperature freezer between -80°C and -60°C (-112°F and -76°F). If you have an ultralow temperature freezer (ULT) you need a suitable data logger to regulate its' temperature. However, recently an alternative solution was stated by the US and EU regulator - now vaccines can be stored in a freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. [1]

The total time vaccines are stored at this temperature range should be tracked and should not exceed 2 weeks. Moderna vaccine can be stored in a freezer between -50°C and -15°C (-58°F and 5°F). They can also be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days before vials are punctured. Johnson & Johnson's and AstraZeneca's vaccines are the easiest to transport so far—they can be stored for up to six months between +2 °C and +8 °C (36°F and 46°F) [2], [3] i.e normal refrigeration temperatures. It is important to choose the right data logger based on the required temperature range you need.

Another essential point is accuracy. For monitoring storage conditions for temperature-sensitive products, accuracy up to ±0.5 degrees can be trusted. When selecting a data logger, look for the required specifications and be aware of paying too much for unnecessary features.

2. Placement Of Data Logger

To ensure the ideal storage temperature, there are usually two data loggers used for each carton or container. One should be placed right next to the vaccine, and the second one outside the container. The one inside the box should be placed in the center of the vaccine stock. Ensure the vaccine stock and the temperature sensor are not in direct contact with the ice packs to minimize risk of freezing.

The second data logger outside the box must be placed in a visible location to monitor the storage environmental temperature. The logger should be operational as soon as the product is packaged and continue until it arrives at its destination.

To measure the internal box temperature, it may be necessary to choose a logger with an extension cable because the ultra-low temperature (such as -70°C / -57°F) could freeze all electronics.

For vaccines such as Moderna and AstraZeneca, it is recommended to use a USB-type data logger. They are usually small and thin and easy to position next to the vaccine. Currently, a multiple channel design is available that requires only one logger to measure both the inside and outside temperatures at the same time.

How to Pack Vaccines and Prepare for Transport

1 Frozen cold packs

Place a layer of cold packs to completely cover the bottom of the cooler.
NEVER USE DRY ICE.

2 Vaccines

Layer vaccine boxes directly on top of the frozen cold packs.

3 Buffered probe

Place the buffered probe with the top layer of vaccines.

4 Frozen cold packs

Spread another layer of frozen cold packs to completely cover the vaccines.

5 Bubble wrap

Layer bubble wrap to fill the remaining empty space and close the cooler.

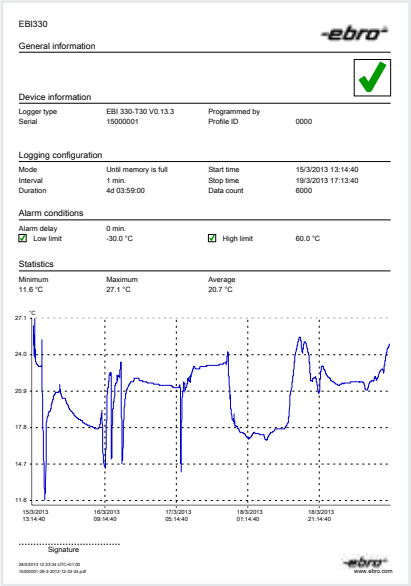
6 Transport log and display

Record the "Time" and "Temperature of vaccine in cooler before departure" on the bottom of transport log. Attach the digital display and transport log carefully to the outside of the cooler. Drive the vaccines to your alternate storage location.

3. Reading The Data

Another important point to consider is, “Who” will read out the logger data and how? Is the receiver from the same country? Some data loggers require a specific read-out interface, others operate with universal interfaces such as via USB.

For a far-away receiver or a distant destination, e.g., international transportation, monitoring may cost much effort considering return shipment and management. Therefore, a one-time-use, disposable data logger may be an ideal and cost-effective solution. There are many new technologies that offer to read out the data such as via bluetooth, Wifi or 5G; however, make sure the data is comprehensive and that there is no risk of data leakage. No matter which technology you choose, the software should be simple to use and generate a PDF report automatically.


EBI330

General information

Device information

Logger type	EBI 330-T30 V0.13.3	Programmed by	
Serial	15000001	Profile ID	0000

Logging configuration

Mode	Until memory is full	Start time	15/3/2013 13:14:40
Interval	1 min.	Stop time	19/3/2013 17:13:40
Duration	4d 03:59:00	Data count	6000

Alarm conditions

Alarm delay	0 min.		
☑ Low limit	-30.0 °C	☑ High limit	60.0 °C

Statistics

Minimum	Maximum	Average
11.6 °C	27.1 °C	20.7 °C

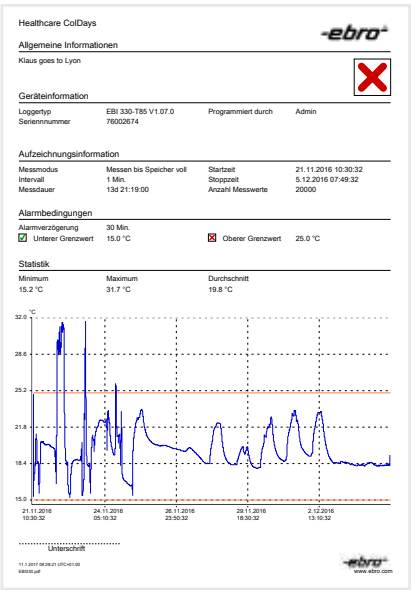
°C
27.1
24.0
20.9
17.8
14.7
11.6
15/3/2013 13:14:40
16/3/2013 09:14:40
17/3/2013 05:14:40
18/3/2013 01:14:40
18/3/2013 21:14:40

Signature

4. Recalibration and Calibration Certificates

The WHO (World Health Organization) recommends sending your temperature monitoring devices and control sensors for calibration every one or two years. A proper calibration report proves the accuracy of a data logger by testing the instrument according to an internationally recognized standard for calibration and traceability. Purchase a data logger that has a calibration certificate. Since every temperature monitoring equipment loses efficiency over time with increasing use, write a plan beforehand for the recalibration before its due date. One alternative solution is to work with single-use disposable data loggers.

Another solution is to use sensor-replaceable data loggers. Such products include disposable plug-in sensors which have a unique corresponding serial number. This type of device including the replaceable sensors is usually delivered to you with their calibration certificate.


Healthcare ColDays

Allgemeine Informationen

Klaus goes to Lyon

Geräteinformation

Loggertyp	EBI 330-T85 V1.07.0	Programmiert durch	Admin
Seriennummer	76002674		

Aufzeichnungsinformation

Messmodus	Messen bis Speicher voll	Startzeit	21.11.2016 10:30:32
Intervall	1 Min.	Stoppzeit	5.12.2016 07:49:32
Messdauer	13d 21:19:00	Anzahl Messwerte	20000

Alarmbedingungen

Alarmverzögerung	30 Min.		
☑ Unterer Grenzwert	15.0 °C	☒ Oberer Grenzwert	25.0 °C

Statistik

Minimum	Maximum	Durchschnitt
15.2 °C	31.7 °C	19.8 °C

°C
32.0
28.6
25.2
21.8
18.4
15.0
21.11.2016 10:30:32
24.11.2016 05:10:32
26.11.2016 23:50:32
29.11.2016 18:30:32
2.12.2016 13:10:32

Unterschrift

Disposable, one-time use, pre-calibrate data logger

Plug-in type sensor and it’s calibration report

Unique corresponding serial number

Calibration certificate

5. FDA 21 CFR Part 11 Compliance

Since there are various brands for data loggers, manufacturers might use many different types of data acquisition and analysis software packages.
However, one of the most important criteria for selecting a data logger is whether it is FDA 21 CFR Part 11 compliant or not.

FDA 21 CFR Part 11

What does "FDA 21 CFR Part 11" mean?

A specific focus of FDA 21 CFR is Part 11. It includes the use of electronic records and electronic signatures. For companies that rely on digital data for monitoring their goods, especially those within the pharmaceutical, food, and healthcare sectors, ensuring 21 CFR Part 11 compliance is essential. Under the 21 CFR Part 11 law, system entry needs to be controlled by a unique login and password for every user. It has also mentioned the "Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records." Choose a data logger with compliant software that will assure data security and audit logs in the relevant areas.

We hope the above 5 tips will help you choose the right data loggers. If you need support with your data logger and monitoring plans, please contact us – we will be happy to guide you with your cold chain process and setup.

References

[1] U.S. Food & Drug Administration, "Coronavirus (COVID-19) Update: FDA Allows More Flexible Storage, Transportation Conditions for Pfizer-BioNTech COVID-19 Vaccine", https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer, 2021

[2] CDC., "Quick Reference Guide for Healthcare Professionals", https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf, 2021

[3] AstraZeneca, "AstraZeneca COVID-19 Vaccine (AZD1222)", https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/02-COVID-Villafana.pdf, 2021