

# Use Of Correct Data Loggers for Vaccines and other Sensitive Pharmaceutical Products 對疫苗和其他敏感藥品使用正確的數據記錄器

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. COVID隧道盡頭的一盞燈帶來了配送挑戰。每種疫苗都有其自身的管理挑戰，例如溫度需求和配送問題。使用數位式數據記錄器來監測疫苗冷鏈中的溫度變化對於疫苗的有效性至關重要。無論您是在處理輝瑞、莫德納、阿斯利康還是其他敏感的醫藥產品，您都需要高質量的數據記錄儀來追蹤溫度。

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. 隨著 COVID-19 持續的危機，我們希望在解決這些問題的同時為您提供一些重要提示。隨著免疫領域的發現越來越多，可靠且合規的冷鏈監測是可行且有效的疫苗配送的關鍵。

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. 冷鏈依賴於一些重要因素，例如專業的快遞、適當的包裝和可靠的物流系統，這些都需要最佳控制和監控。

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. 想一想在盒子密封和門關閉時如何解決疫苗的完整性和有效性問題。沒有人知道容器內部發生了什麼變化，它必面對什麼樣的環境。這就是為什麼溫度數據記錄器很重要的原因，因為它們在疫苗的運輸和儲存過程中起著至關重要的作用。

Here we are going to offer you some useful information to choose the most suitable data logger for cold chain monitoring. 在這裡，我們將為您提供一些有用的信息，以選擇最適合冷鏈監控的數據記錄器。



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. 使用數字數據記錄器（例如 ebro EBI 300 系列）來監測疫苗冷鏈中的溫度變化對於疫苗的有效性至關重要。

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## Everything you need for your transportation 運輸所需的一切



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

選擇數據記錄器時需要考慮五個關鍵細節。

1. What is your required temperature range? 您需要的溫度範圍是多少？
2. Where is the logger placed? 記錄器放在哪裡？
3. Who will read out the data? 誰來讀出數據？
4. Does it come with a calibration certificate? How to recalibrate it? 是否附有校準證書？如何重新校準？
5. Is it FDA 21 CFR part 11 compliant? 是否符合 FDA 21 CFR part 11？

#### 1. Temperature Range and Accuracy 溫度範圍和精度

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] 選擇數據記錄器時首先要考慮溫度範圍和精度。確定您處理的藥品的溫度範圍。例如，BioNtech-Pfizer 疫苗應儲存在 -80°C 和 -60°C (-112°F 和 -76°F) 之間的超低溫冰箱中。如果您有超低溫冰箱 (ULT)，則需要合適的數據記錄器來調節其溫度。然而，最近美國和歐盟監管機構提出了一種替代解決方案——現在疫苗可以儲存在 -25°C 至 -15°C (-13°F 至 5°F) 最多 2 週。[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. 疫苗在此溫度範圍內儲存的總時間應進行追蹤，不應超過 2 週。莫德納疫苗可以儲存在 -50°C 至 -15°C (-58°F 至 5°F) 的冰櫃中。他們能也可存放在 2°C 至 8°C (36°F 至 46°F) 的冰櫃中在小瓶被刺破之前最多 30 天。強生和阿斯利康的疫苗是迄今為止最容易運輸的——它們可以在 +2°C 和 +8°C (36°F 和 46°F) 之間最多儲存六個月 [2]，[3] 即正常的冷藏溫度。基於您所需溫度範圍選擇對的數據記錄器很重要。

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. 另一個關鍵點是準確性。用於監控存儲條件對於溫度敏感產品，精度可達 ±0.5 度值得信賴。選擇數據記錄器時，請尋找所需的規格並注意為不必要的功能支付太多費用。



## 2. Placement Of Data Logger 數據記錄器的放置

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. 為確保理想的存儲溫度，每個紙箱或容器**通常使用兩個數據記錄器**。一個應該放在疫苗旁邊，第二個放在容器外面。盒子裡的那個應該放在疫苗儲備的中央。確保疫苗儲備和溫度傳感器不與冰袋直接接觸，以最大程度地降低凍結風險。

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. 箱外的第二個數據記錄器必須放置在可見的位置，以監控存儲環境溫度。產品包裝後，記錄儀應立即運行，並繼續運行直至到達目的地。

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  $-70^{\circ}\text{C}$  /  $-57^{\circ}\text{F}$ ) could freeze all electronics. 要測量箱內溫度，可能需要選擇帶有延長線的記錄儀，因為超低溫（例如  $-70^{\circ}\text{C}$  /  $-57^{\circ}\text{F}$ ）可能會凍結所有電子設備。

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. 對於 Moderna 和 AstraZeneca 等疫苗，建議使用 USB 類型的數據記錄器。它們通常小而薄，易於放置在疫苗旁邊。目前，可以使用多通道設計，只需一個記錄器即可同時測量內部和外部溫度。

### How to Pack Vaccines and Prepare for Transport 如何包裝疫苗和準備運輸



#### 1 Frozen cold packs 冷凍冷藏袋



Place a layer of cold packs to completely cover the bottom of the cooler. NEVER USE DRY ICE. 放置一層冷袋以完全覆蓋冷卻器的底部。切勿使用乾冰。

#### 2 Vaccines 疫苗



Layer vaccine boxes directly on top of the frozen cold packs. 將疫苗盒直接放在冷凍冷藏袋的頂部。

#### 3 Buffered probe 緩衝探針



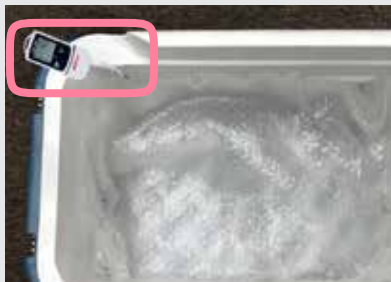
Place the buffered probe with the top layer of vaccines. 將緩衝探針放在疫苗的頂層。

#### 4 Frozen cold packs 冷凍冷藏袋



Spread another layer of frozen cold packs to completely cover the vaccines. 再鋪上一層冷凍冷藏袋以完全覆蓋疫苗。

#### 5 Bubble wrap 泡泡棉



Layer bubble wrap to fill the remaining empty space and close the cooler. 鋪上一層泡泡棉以填充剩餘的空間並關閉冷卻器。

#### 6 Transport log and display 運輸日誌和顯示



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. 在運輸日誌底部記錄"出發前冷藏箱中疫苗的時間"和"溫度"。小心地將數字顯示器和運輸日誌貼在冷卻器的外面。將疫苗運送到您的備用存儲位置。



3. Reading The Data 讀取數據

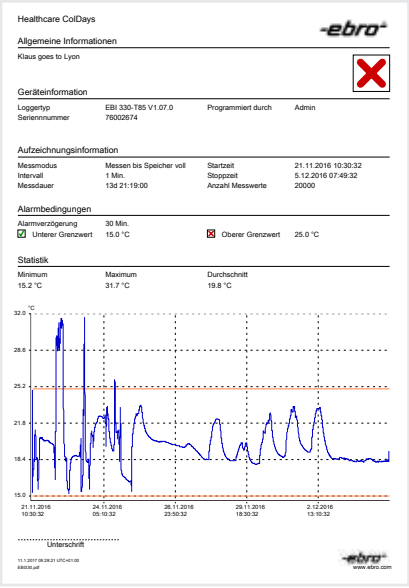
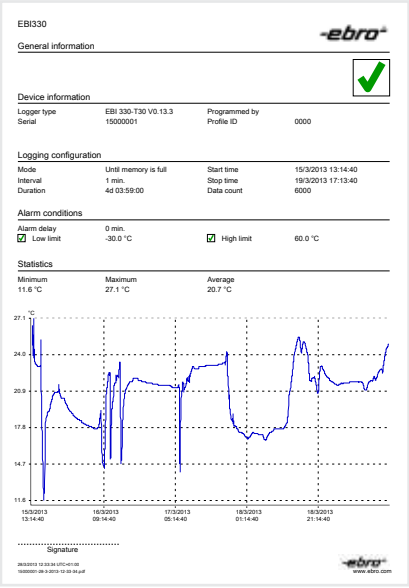
Another important point to consider is, “Who” will read out the logger data and how? Is the receiver from the same country? Some data loggers require a specific read-out interface, others operate with universal interfaces such as via USB. 另一個需要考慮的重點是，“誰”將讀取記錄器數據以及如何讀取？收貨人是同一個國家的嗎？一些數據記錄器需要一個特定的讀出界面，其他的則使用通用界面，例如通過 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. 對於遠方的接收方或遠方的目的地，例如國際運輸，考慮到回運和管理，監控可能會花費很多精力。因此，一次性使用的一次性數據記錄器可能是一種理想且經濟高效的解決方案。有許多新技術可以通過藍牙、Wifi 或 5G 等方式讀取數據；但是，請確保數據全面且不存在數據洩露風險。無論您選擇哪種技術，該軟件都應該易於使用並自動生成 PDF 報告。

4. Recalibration and Calibration Certificates 重新校準和校准證書

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. WHO（世界衛生組織）建議每隔一兩年發送一次您的溫度監測設備和控制傳感器進行校準。正確的校準報告通過根據國際公認的校準和可追溯性標準測試儀器來證明數據記錄器的準確性。購買具有校准證書的數據記錄器。由於每個溫度監測設備都會隨著使用量的增加而隨著時間的推移而降低效率，因此請在到期日之前提前製定重新校準計劃。一種替代解決方案是使用一次性數據記錄器。

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. 另一種解決方案是使用傳感器可更換的數據記錄器。此類產品包括具有唯一對應序列號的一次性插入式傳感器。此類設備（包括可更換傳感器）通常會隨校准證書一起交付給您。



Disposable, one-time use, pre-calibrate data logger 一次性、一次性使用、預校准數據記錄器



Plug-in type sensor and it's calibration report 插入式傳感器及其校準報告



Unique corresponding serial number 唯一對應的序列號



Calibration certificate 校准證書

## 5. FDA 21 CFR Part 11 Compliance FDA 21 CFR Part 11 合規性

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. 由於數據記錄器有多種品牌，製造商可能會使用許多不同類型的數據採集和分析軟體包。然而，選擇數據記錄器的最重要標準之一是它是否符合 FDA 21 CFR Part 11。

### What does “FDA 21 CFR Part 11” mean? “FDA 21 CFR Part 11”是什麼意思？

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. FDA 21 CFR 的一個具體重點是第 11 部分。它包括電子記錄和電子簽名的使用。對於依賴數字數據來監控其商品的公司，尤其是製藥、食品和醫療保健行業的公司，確保符合 21 CFR 第 11 部分至關重要。根據 21 CFR Part 11 法律，系統入口需要由每個用戶的唯一登錄名和密碼控制。它還提到“使用安全的、電腦生成的、帶時間戳的審計追蹤來獨立記錄操作員條目的日期和時間以及創建、修改或刪除電子記錄的操作。”選擇帶有合規軟體的數據記錄器，以確保相關領域的數據安全和審計日誌。



FDA 21 CFR Part 11

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. 我們希望以上 5 條提示能幫助您選擇合適的數據記錄儀。如果您需要有關數據記錄器和監控計劃的支持，請聯繫我們——我們很樂意指導您進行冷鏈流程和設置。

## References 參考文獻

- [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

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