ZEBRA

Enhance Pharmaceutical and Medical Device Compliance in Shipping and Storage

Zebra electronic Bluetooth® temperature monitoring sensors for pharmaceutical manufacturers, distribution centers and laboratories

Pharmaceutical and medical device companies face several challenges when they transport temperature-sensitive medications and medical devices through the cold chain. Whether shipping from manufacturing plants to distribution centers or company locations, or shipping to end customers, they need proper visibility and monitoring tools to ensure their products stay within acceptable temperature ranges. Exposure to certain temperatures can damage medical devices and reduce medication efficacy, causing failure to meet compliance requirements, lost revenue, and adverse events for consumers who use compromised medications or medical devices.

Objectives

- Increase temperature-monitoring visibility and accuracy
- Speed shipping and storage workflows
- Automate data collection for reporting and analysis
- Improve customer satisfaction and confidence
- Meet regulatory requirements, including 21 CFR Part 11

Challenge

Preconfigured, USB-based temperature sensors increase manual tasks, slow workflows and decision making, inhibit temperature visibility, limit application uses and increase device inventory costs.

Zebra's Solution

Zebra's electronic temperature sensors are wireless, Bluetooth®-enabled devices to give pharmaceutical and medical device companies more monitoring control, smarter access to temperature data, automated and continuous monitoring options and greater management capabilities for every temperature-sensitive shipment through the cold chain.

Other Solutions Slow Workflows

Pharmaceutical and medical device shipping and storage typically rely on preconfigured, USB-based temperature sensors. These sensors introduce unnecessary and preventable risk.

No Confirmation Devices Are Working

Because they are not wireless with Bluetooth capabilities, it's not possible to confirm devices are functioning properly until packages are opened upon receipt or mid-shipment. If devices cannot be detected wirelessly after closing the box there is no way to be assured that the devices were started correctly or didn't fail.

Environmental Integrity Can Be Threatened

Packages must be opened to retrieve devices and download data, thereby threatening the environmental integrity which is critical to product stability.

USB-Based Devices Increase Task Time

Once received, packages must be opened, devices collected and data downloaded physically via USB connection to a computer. The data is often in a PDF format, limiting its use for analysis. It must be emailed to quality-control personnel who will decide to accept or reject the product. This process can take anywhere from 15-30 minutes per package, versus less than a minute per package with a wireless temperature sensor.

Physical Collection Adds Potential for Errors

When workers are busy receiving multiple packages, physical collection of devices greatly increases the potential for errors. Workers can mix up devices during collection, make mistakes in data downloads or misplace devices entirely. The results can cause problematic setbacks in time, reporting and compliance with negative impacts on customer satisfaction.

Preconfigured Devices Limit Applications

Because preconfigured devices allow little to no customization, users are required to purchase different devices for different product temperature requirements, increasing device inventory and overall costs.

Zebra Delivers Visibility

Zebra's electronic temperature sensors are portable, wireless, Bluetooth®-enabled devices to empower pharmaceutical and medical device companies with exceptional visibility and monitoring capabilities to minimize risk.
With mobile connectivity and cloud-based data-sharing, Zebra helps ensure the successful shipment of every temperature-sensitive product.

Automate Data Collection and Reduce Errors

Zebra devices allow you to automatically upload temperature data for immediate, remote access to device data via the cloud. Using a Bluetooth gateway, you can access temperature data after products are packaged to confirm devices are working and shipments are in compliance.

Read Temperatures Through Containers

Zebra devices allow you to retrieve and record temperature data through packing materials, containers and vehicles, making it easier to quickly view temperature data without opening containers or threatening environmental integrity. Not only do you limit products' exposure and help protect product efficacy, you reduce worker hours and speed workflows.

Access Data Mid-Shipment

With USB-based devices, there is no way to check on products mid-shipment without opening containers. Zebra devices, however, allow for immediate temperature readings at any point during shipment by using a Zebra Android™ or iOS mobile computer, smartphone or tablet, or when shipments pass through a Bluetooth gateway at an intermediary point.

Get Alerts About Temperature Excursions

One of the most powerful benefits of Zebra devices is the visibility to the temperature status, whether it be viewing the current status on the EDGEVue Mobile App or through the automated alerts when connected to the cloud. With data in the cloud, your team has better access to the data, whether it be the driver who can make a change when viewing the status in the EDGEVue App, or remote staff when an OCEABridge is installed in a truck and allows automated alerts if temperature excursions occur.

Closed-Loop or Third-Party Delivery

Zebra devices provide visibility for both closed-loop systems and third-party shipping. In closed-loop shipping, company couriers or owned vehicles with company drivers can use

Bluetooth gateways at shipping and recieving ends and Zebra's EDGEVue app and EDGECloud™ services to enable wireless readings and uploads to the cloud. Similarly, third-party shipping companies can be required to download Zebra's EDGEVue app or enable Zebra Bluetooth gateways to take mid-shipment reads for greater continuity in remote visibility.

Improve Receipt and Reduce Errors

Data can automatically be uploaded to the cloud immediately upon entering a receiving dock when using the Bluetooth gateway, or packages can be read using the EDGEVue App on a mobile device which also allows it to be uploaded to the cloud. These options reduce data-collection time to less than a minute per package. Additionally, because devices do not need to be removed from containers, human errors can be reduced and reporting accuracy increased.

Speed Reporting and Trend Analysis

Data in the cloud streamlines data sharing, storage and reporting for compliance. Over time, the data is more easily analyzed for trends to improve operations.

Customize Settings, Reduce Device Inventory

Zebra devices are among the most customizable in the market, giving users a wide range of options and controls over settings, start time, reading intervals and alarm limits.

Application Uses Include Facility Monitoring

Zebra devices can also monitor stationary medication and medical device storage facilities. Once a package is received and placed into storage, the same Bluetooth gateway that uploaded the data upon receipt can also be used to continue to monitor the storage portion of the cold chain and provide real-time alerts. They can be configured in several ways to ensure compliant temperatures for medication storage refrigerators, with all the automated features of data collection and alerts.

Learn more about Zebra's Electronic Temperature Sensors.
Please visit **www.zebra.com/electronictempsensor**

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