EBOOK
PHARMACEUTICAL COLD CHAIN

A guide to confidently managing pharmaceutical cold chains

ZEBRA

Empowering teams with intelligent operations

The pharmaceutical sector innovates relentlessly.

And just as it searches ceaselessly for breakthroughs, so do we to better support our pharmaceutical customers.

We understand the pharma supply chain is increasingly more complex, and legislation more onerous, while there is a pressing demand to expand distribution capacity and handle a higher volume of temperature-sensitive items. We recognize, too, that clinicians, who often work under huge pressure, need better support when making decisions about whether products should be used.

In the following sections, we discuss how to create the environment for intelligent operations: operations that empower your frontline teams with new and better ways of working. Which clearly show clinicians if a vaccine, medicine, medical device, or blood bag has experienced a temperature excursion. That help supply chain operatives accelerate tasks while giving them the insight to make informed decisions, free of uncertainty, as to whether consignments are suitable to be accepted and continue their journey. And which also gives confidence to those people receiving medications at home that their items have arrived within the allowable temperature range.

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Shipping pharmaceutical products from manufacturing to distribution hubs

Imagine a vaccine shipment being dispatched from a vaccine manufacturing site to a regional distribution hub. Pallets, each containing multiple boxes, are loaded into a refrigerated (“reefer”) container for distribution on a journey which may span a region, country, or the globe.

Having access to accurate, immediate temperature data is everything: The manufacturer can protect brand integrity and ensure product quality, while the supply chain team, whether that be the manufacturer’s own or a third-party logistics provider, has the data to verify compliance with temperature control requirements.

That is where our ZS300 Electronic Sensor comes into its own. The compact, robust data logger continually captures temperature status, recording this at intervals you define. It also alerts frontline teams and wider stakeholders if temperature excursions have occurred. With intelligence in hand, your teams are equipped to make quick, accurate, and informed decisions which prioritize the quality of pharmaceutical products. The ZS300 can also be paired over Bluetooth® with the equally compact ZB200 Bridge, or your teams’ mobile devices, to securely stream its data to the cloud. The data can be integrated with your supply chain and warehouse management solutions, where it can be put to work to provide next-best action guidance to your frontline teams.

Small, robust, and easily fixed to items, the ZS300 can record the temperature of pallets, boxes, and even individual products. The granularity of data overcomes any issues with microclimates, especially with shipping or reefer containers which are prone to experiencing varying degrees of temperature in different areas of the container.

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Sending medication directly to people's homes

Pharmacies and clinics are increasingly sending medications directly to people's homes. This creates the need to extend cold chain monitoring beyond the traditional supply chain and into the last mile, with deliveries managed by pharmacies themselves or outsourced to local courier firms.

Ready-to-use indicators are here to help. Zebra TransTracker Shipment Temperature Indicators are durable, single-use cards, which integrate one or more temperature-sensing technologies to monitor heat, freeze, or dual heat / freeze exposures of temperature-sensitive items. The single-use cards are easy to read, irreversible, and typically placed inside secondary packages or shipping boxes.

For the cost of around $2.00, or less, per unit, the indicators remove uncertainty, giving people the confidence that their medicines have been handled in the correct way, while delivering a clear cost benefit to you by significantly reducing the number of re-ship requests or rejected items due to suspected heat or freeze events.

TransTrackers can be branded with your logo, colors, and text, such as customer service contact details. The customization differentiates your service and emphasizes your brand's commitment to quality and patient care.

Temperature monitoring for consumers

A range of TransTracker Shipment Temperature Indicators are available as follows:

Temperature indicator	Response temperatures	Response time
TransTracker CD **Dual freeze / heat quick response temperature monitoring**	Heat: 40°C Freeze: 0°C / -1°C / -6°C (±2°C)	Heat: Quick response within 15 minutes Freeze: Within 30 minutes
TransTracker C **Freeze event indicator**	0°C / -1°C / -6°C (±2°C)	Freeze: Within 30 minutes
TransTracker CF **Dual monitoring for heat excursion or freeze event for a short period of time**	Heat: 17.5°C / 25°C / 31°C Freeze: 0°C / -1°C / -6°C (±2°C)	Heat: Within 2 hours Freeze: Within 30 minutes
Transtracker D **Quick response heat indicator**	Heat: 40°C	Heat: Quick response within 15 minutes
Transtracker F **Time delay heat threshold indicator**	9°C, 17.5°C, 25°C, 31°C	Heat: within two hours

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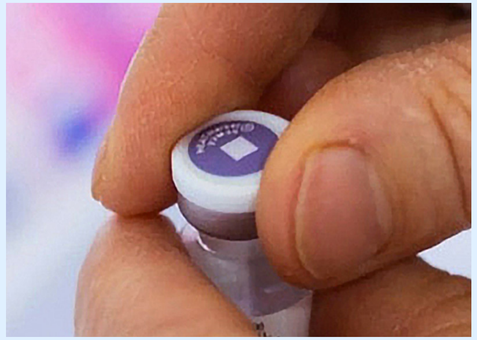
Monitoring vaccines from manufacturers to the end user



Vaccines must be monitored for temperature excursions, from the production line to the moment of immunization. Our vaccine vial monitors (VVMs) are small, self-adhesive devices engineered for this task. The monitors undergo clear color changes when experiencing temperature excursions beyond the predetermined levels. They help enable healthcare professionals to make immediate and informed decisions about whether a vaccine can be used.

Immediate decisions at the point of care

HEATmarker VVM, LIMITmarker, FREEZEmarker, and TransTracker with LIMITmarker are ready-to-use, self-adhesive, and easy-to-understand indicators which may be attached to the primary package or secondary package by the vaccine manufacturer.

- **HEATmarker VVM:** HEATmarker VVMs are small devices coated onto flexible labels that allow application to curved individual units of temperature-sensitive vaccines. With HEATmarker, you identify the combined effects of heat exposure over time, with a range of options that align to your product's stability profile. HEATmarker VVM is a WHO pre-qualified device.

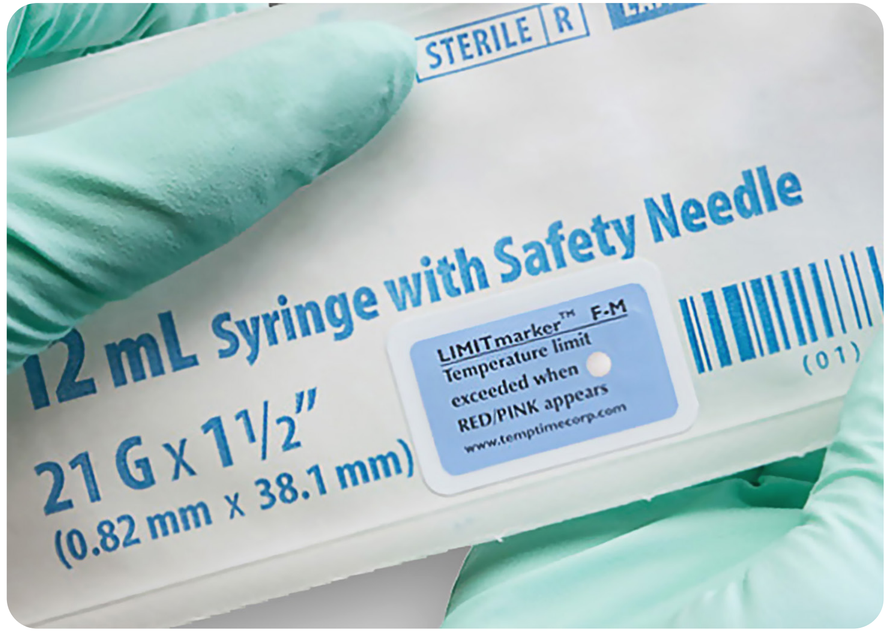
- **FREEZEmarker:** FREEZEmarker is a self-adhesive, single-use freeze indicator that can be applied directly to product surfaces or packaging. FREEZEmarkers provide a visual warning within 30 minutes of a freeze event. FREEZEmarker is a WHO pre-qualified device.

- **TransTracker with LIMITmarker:** TransTracker cards with integrated LIMITmarker technology are available with quick indication (up to 15 minutes) and delayed indication (up to 2 hours). The TransTracker card can be customized with your branding and consumer information specific to your use case.

- **LIMITmarker:** LIMITmarker is a threshold indicator that comes in a range of options, all of which are small self-adhesive labels and include:

  - LIMITmarker I-K, I-C, and I-P provide quick indication and clear visual alert, within 15 minutes, if there has been a heat excursion above the predetermined temperature profile. The threshold indicators can be fixed to individual units to monitor products from manufacture, and through the cold chain.

  - LIMITmarker F – these time-delayed threshold heat indicators reach their endpoints within 2 hours when exposed to temperatures above and beyond the threshold temperature.



Over 12 billion

(and counting)

Zebra has shipped over 12 billion vaccine vial monitors (VVMs), which have been used to improve the lives of 1.2 billion children worldwide.

Layering oversight for your shipments

Our electronic sensors, activatable indicators, and ready-to-use indicators complement one another to optimize the actionable intelligence available to your teams. Take, for example, a vaccine shipment. ZS300 Electronic Sensors can be utilized in transit and warehouses to monitor shipping containers and reefers, along with storage environments, while activatable temperature monitors might also be used at pallet level, and VVMs at item level.

This layering of temperature monitoring technology provides reassurance (and evidence) that every aspect of an individual item's journey has been managed the correct way.

If a temperature alert is triggered by an electronic data logger within a container, for example, operatives can quickly check the next level down in the cargo to see if an entire pallet has been affected, or if boxes of products within that pallet, or even individual items, could perhaps be salvaged.

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Confident management of blood stocks

Managing blood stocks is demanding for busy teams who are juggling tasks, especially when blood bags are removed and returned to refrigeration or transported between destinations.

Our Safe-T-Vue® blood bag indicators reduce the stress by providing a clear visual indication of blood that has been exposed to potentially damaging heat. The activatable and self-adhesive indicators are attached directly to bags, showing a non-reversible color change to alert doctors, nurses, and clinicians of potentially damaging heat exposure. Two categories of Safe-T-Vue blood bag indicators are available:

Safe-T-Vue 6: Attaches directly to blood bags during refrigerated storage or transit. The indicator changes color from white to red if the blood has reached or exceeded 6°C.

Safe-T-Vue 10: Helps maintain quality control during temporary storage or transport, changing color from white to red when the 10°C indication temperature has been reached or exceeded.

Your trusted partner

Whether it's frontline supply chain teams or trained clinicians, working in a remote region with vaccines that have traveled a long distance, asking them to make decisions as to whether pharmaceutical products should be used adds to the pressures they face. And if there is any uncertainty in their minds, the easiest, and understandable, decision is to consign items to waste.

Our range of environmental sensors, which are cost-effective and easy to use, fundamentally change how frontline teams work. The teams are empowered by scientifically proven devices, which provide clear visual confirmation of whether pharmaceutical items have experienced temperature excursions. The insight informs decisions that protect product quality, reduce waste, and drive down costly reshipments.

We have a wide range of temperature-sensing capabilities and can customize products to specific requirements.

For more information, visit: www.zebra.com/environmental-sensors

Assured ISO 9001 certification

Quality is everything. As a leader in temperature-sensitive supply chain solutions, Zebra holds ISO 9001 certification and follows processes that satisfy the most recently adopted global quality management standards. All Zebra temperature monitoring devices are manufactured to meet the highest ISO standards, and our Safe-T-Vue blood bag indicator is a US FDA-cleared medical device.

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