



# Pharmaceutical Temperature Monitoring

for Reduced Waste  
and Improved  
Compliance

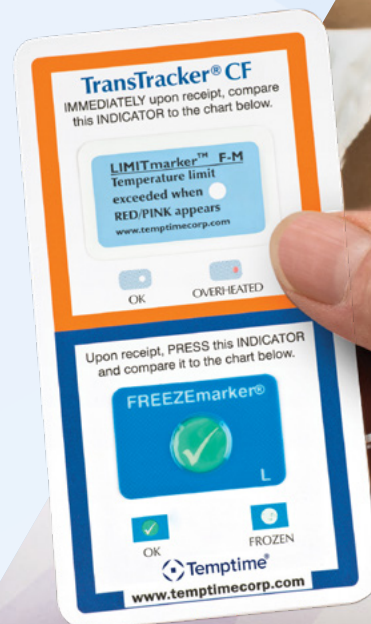


# Storage and distribution of temperature-sensitive pharmaceuticals and biologics

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Cover Photo: Lindsey Darby



## 30 years of innovation

For more than 30 years, Zebra Technologies has been innovating cost-effective temperature monitoring solutions for a wide range of environmentally sensitive medications, biologics, medical devices and other products. Deeply committed to improving public health, we strive to ensure supply chain integrity to protect patients and benefit communities globally.

Since the beginning, our temperature and humidity monitoring devices, manufactured by Temptime, have helped healthcare workers immunize millions of children around the world and extend care to regions previously thought to be unreachable. With products that have Food and Drug Administration (FDA) 510(k) medical device clearances, we are regularly audited by the US-FDA.

Today, Zebra continues to innovate with solutions that provide end-to-end visibility via the Internet of Things (IoT) and cloud-based services. That is why pharmaceutical corporations, biotechnology companies, specialty pharmacies, emergency medical service organizations, blood banks and hospitals use our devices and solutions to help assure compliance to the storage, handling and shipping requirements of hundreds of millions of temperature-sensitive products each year.

Photo: Umit Kartoglu

# Storing and transporting temperature-sensitive pharmaceuticals and biologics

## Evolving Regulatory Oversight

With an ever-changing regulatory landscape, including increased scrutiny around environmental conditions in the storage and transportation of pharmaceuticals, medical devices and biologics, it is imperative to have proven systems and processes in place to meet all requirements. Findings by regulators and/or accrediting agencies that indicate noncompliance can be extremely costly to your organization, your reputation, your brand and your financial performance. High quality, trusted monitoring and temperature indicators that include visual controls are critical to the successful storage and distribution of your organization's valuable product brands.

## Customer Complaints and Patient Safety

Customer satisfaction and product performance are key for establishing brand equity of your pharmaceuticals and biologics. The digital revolution and mainstream use of social media has given people a platform to acclaim or complain about a brand or company in real time and in a potentially viral manner. This is coupled with speed of delivery expectations created by global ecommerce fulfillment companies, resulting in an increasing demand from physicians, health care professionals and patients alike that pharmaceuticals and biologics arrive quickly and within the appropriate temperature range. Proper visual temperature controls included in each package will signal to the customer whether or not the appropriate temperature range has been maintained, giving them added peace of mind.

## Impact on Financial Performance

Successful execution of the shipment process is important for driving high customer satisfaction and brand equity. That is why good quality processes for ensuring proper temperature controls across the entire supply chain—from manufacturing and storage through to distribution—are essential. Having the right temperature monitoring devices and solutions in place can help.



# Complying with temperature monitoring regulations while meeting patients' needs

Qualifying and implementing the appropriate temperature monitoring system can be complicated. There are many different solutions available and very few specifically oriented for pharmaceuticals and biologics. What's more, the data-driven requirements of regulators can be at odds with the less complex needs of the patients.

For instance, specialty pharmacies seeking Utilization Review Accreditation Commission (URAC) accreditation or participation in some Pharmacy Benefit Manager (PBM) networks are required to provide proof that temperatures are maintained from the time medication leaves the pharmacy until it is delivered to the patient. This often requires in-depth package performance qualification testing twice a year to verify that packing materials can adequately keep medications within the appropriate temperature range in both cold and warm weather. Similarly, to qualify for the Commission on Accreditation of Ambulance Services (CAAS) or the Commission on Accreditation of Medical Transport Systems (CAMTS), Emergency Medical Service (EMS) providers must show compliance with temperature guidelines mapped out by the United States Pharmacopeia (USP). More and more, state regulations are also requiring that EMS providers put systems in place to monitor the temperature of the medications they store and carry.

The bottom line is that there is no one size fits all solution, but choosing the right partner with the right portfolio of solutions can help you meet both regulatory and patient demands.



# Identifying the temperature compliance of pharmaceuticals and biologics during shipping and storage

An essential part of delivering quality patient care is making sure that medications remain within the appropriate temperature range, and the right temperature monitoring processes and devices can enhance and grow your brand. Onsite, this typically means an environmental monitoring system that records temperatures in the medication storage environment 24/7. While very important, it operates at a micro scale, providing visibility into what is happening in the facility.

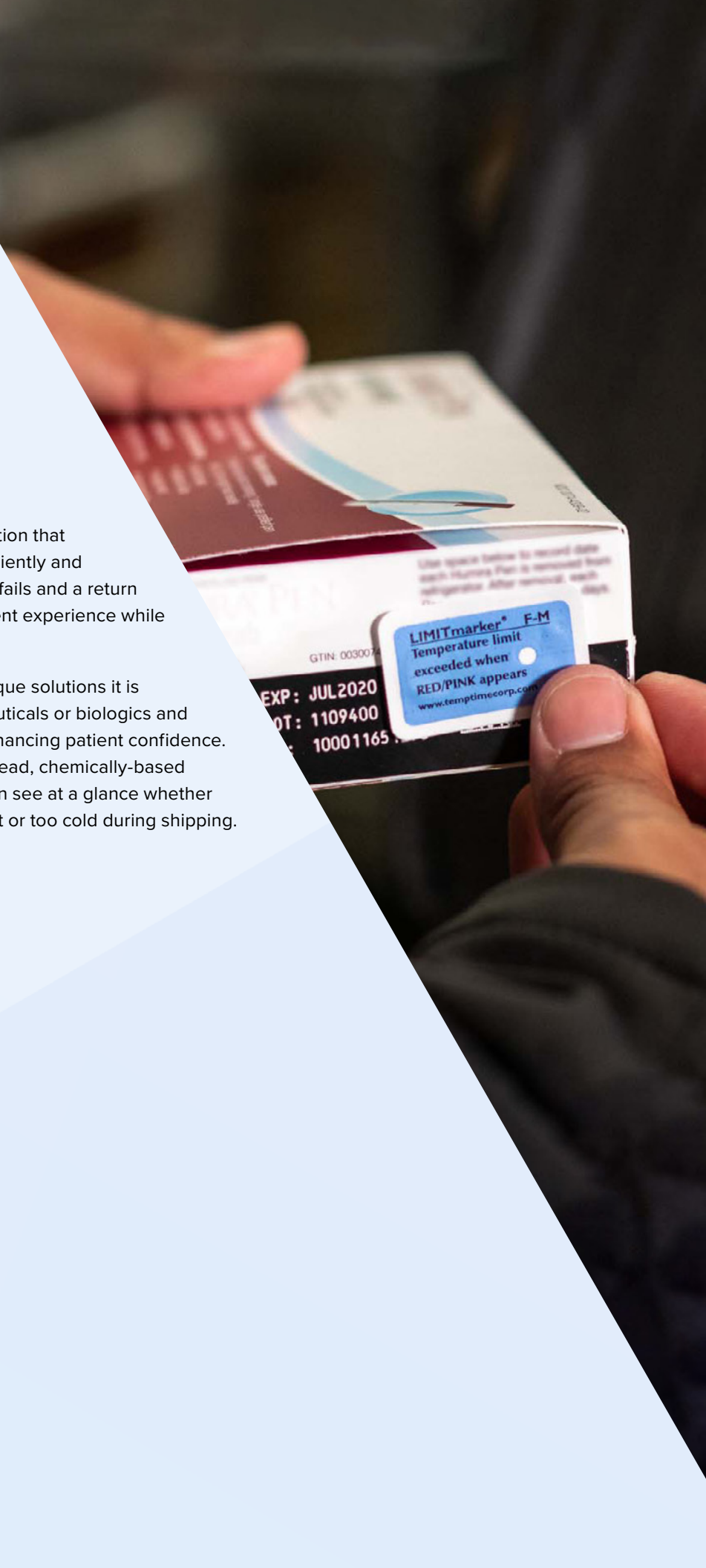
With advancements in environmental sensing technologies, manufacturers have the ability to capture information and data throughout the supply chain—right up until the last mile. These temperature and humidity monitoring devices are easily integrated into your existing systems and range from low-cost, chemically-based, single-use indicators to sophisticated data-driven electronic sensors equipped with Bluetooth® capabilities and cloud-based data storage to thermal labels with integrated visual sensors.



# Financial benefits of using temperature monitoring devices and systems

Distribution models are developed with the expectation that pharmaceuticals and biologics will be delivered efficiently and effectively with consistency. Every time the process fails and a return or reship is required, this negatively affects the patient experience while costing your company money.

Many organizations have found that through our unique solutions it is possible to significantly reduce returns of pharmaceuticals or biologics and realize a competitive advantage in the market by enhancing patient confidence. For instance, by including inexpensive and easy-to-read, chemically-based indicators in each medication package – patients can see at a glance whether biologics or pharmaceuticals have not gotten too hot or too cold during shipping.



# The future of temperature monitoring

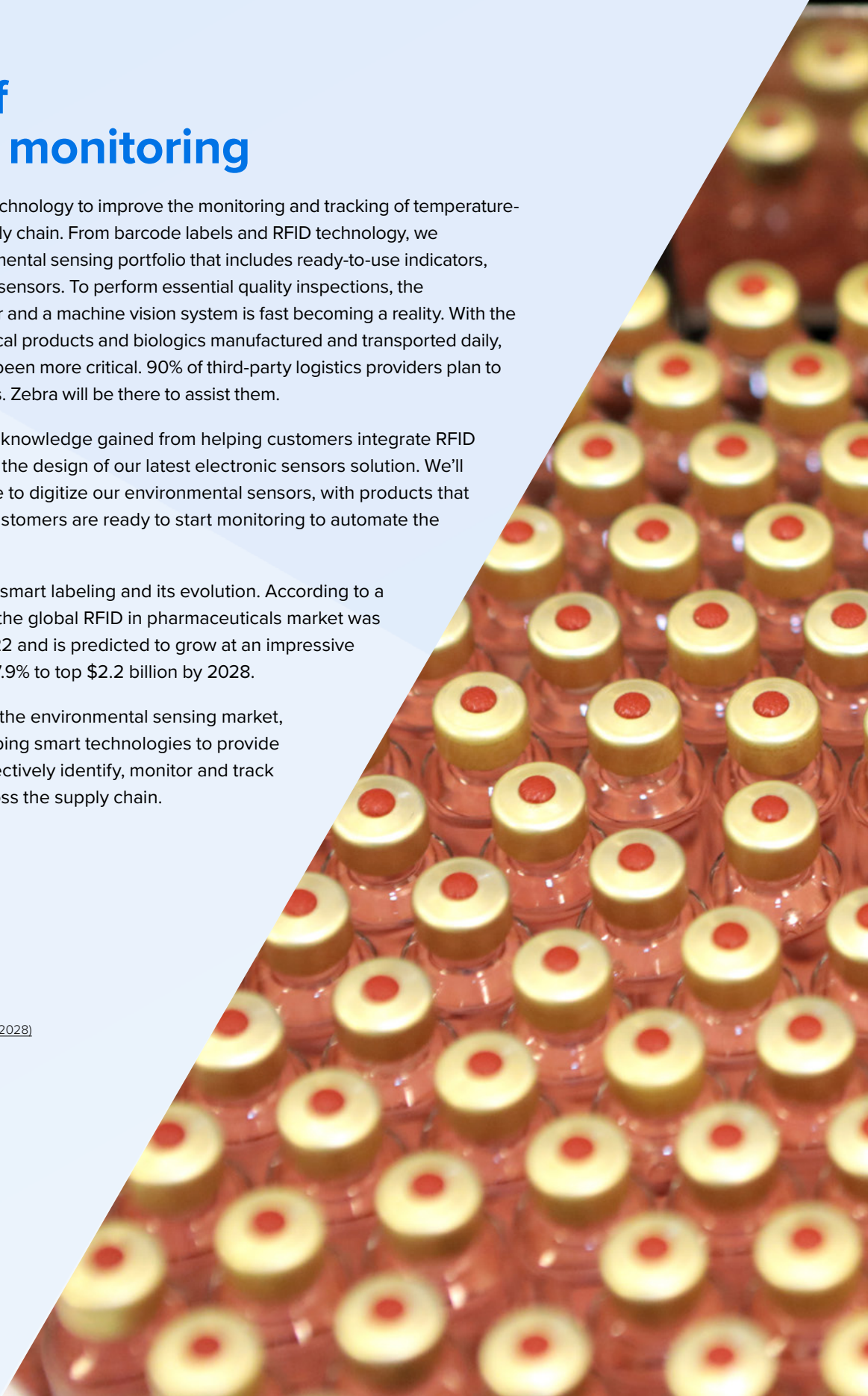
Zebra is continuously advancing technology to improve the monitoring and tracking of temperature-sensitive products across the supply chain. From barcode labels and RFID technology, we expanded our reach to an environmental sensing portfolio that includes ready-to-use indicators, printable indicators and electronic sensors. To perform essential quality inspections, the combination of a printable indicator and a machine vision system is fast becoming a reality. With the increasing number of pharmaceutical products and biologics manufactured and transported daily, the need for innovation has never been more critical. 90% of third-party logistics providers plan to expand their cold chain capabilities. Zebra will be there to assist them.

Zebra's expertise in RFID, and the knowledge gained from helping customers integrate RFID into their workflows, has informed the design of our latest electronic sensors solution. We'll continue to leverage this expertise to digitize our environmental sensors, with products that can be activated only when our customers are ready to start monitoring to automate the capture of sensor information.

RFID is also an important factor in smart labeling and its evolution. According to a report by Future Market Insights\*, the global RFID in pharmaceuticals market was worth more than \$1.4 billion in 2022 and is predicted to grow at an impressive compound annual growth rate of 7.9% to top \$2.2 billion by 2028.

We are expanding our portfolio in the environmental sensing market, and we intend to continue developing smart technologies to provide advanced layers of visibility to effectively identify, monitor and track pharmaceutical and biologics across the supply chain.

\*RFID in Pharmaceuticals Market Outlook (2022-2028)





## Case studies

Increase customer satisfaction, meet evolving regulations and improve financial performance through the proper storage and transportation of medical products.

### Maintaining Medication Temperature Is Key to Patient Treatment

Preveon Specialty, who opened their doors in just 2017, used Zebra's temperature monitoring devices to boost patient satisfaction in our case study [Delivering Peace of Mind with Every Specialty Medication](#). You'll also learn how they built on this success to gather information for URAC and ACHC accreditations and have confidence in the efficacy of the medications that they provide to their patients.

### Best Practices and Lessons Learned for US Specialty Care

Specialty pharmacies provide service and support to patients with complex medical conditions throughout the country. Along with this privilege comes the enormous responsibility of making sure these patients receive medications that are safe and stable to use. US Specialty Care (USSC) takes this responsibility seriously and has performed extensive tests in partnership with Zebra to develop cost-effective solutions to overcome the everyday challenges of shipping temperature-sensitive medications. Read more in this white paper, [Safeguarding the Integrity of Medications: Shipping Matters](#), by Marlette Oelofsen, CSP, Pharmacist in Charge for USSC.

### Thermal Shipping Technologies: The Cold Hard Facts

We asked an independent testing lab to source the five most commonly used packaging technologies used by specialty pharmacies and evaluate their performance against a commonly used testing standard and the packaging manufacturer's own claims. In short, the outcome of this study and the data developed still hold true as many specialty pharmacies continue to purchase and use these same packaging technologies today. Read the white paper on [Developing Good Distribution Practices at the Specialty Pharmacy](#).

Learn more about Environmental Sensing Solutions at  
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