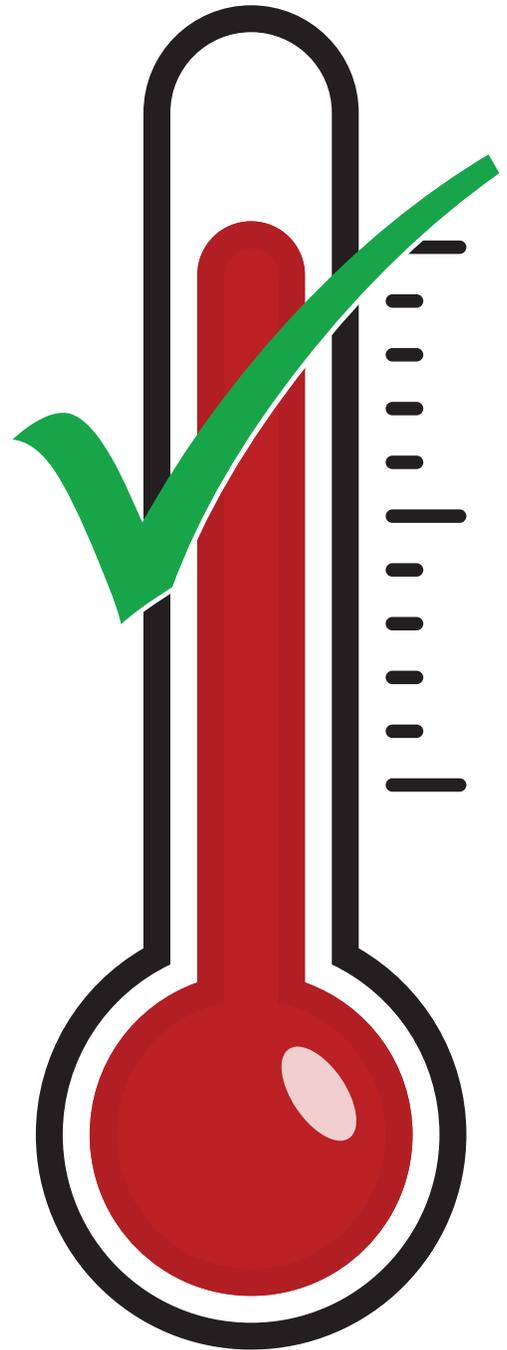
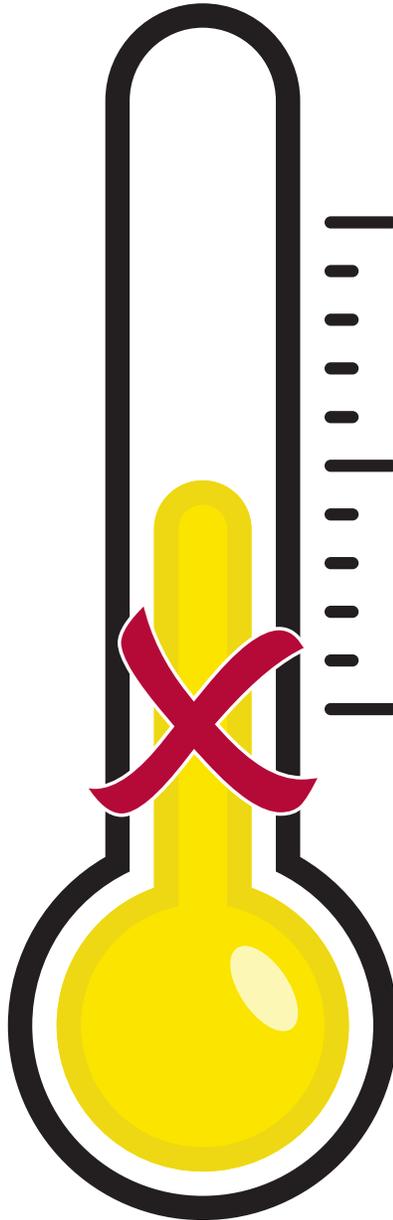
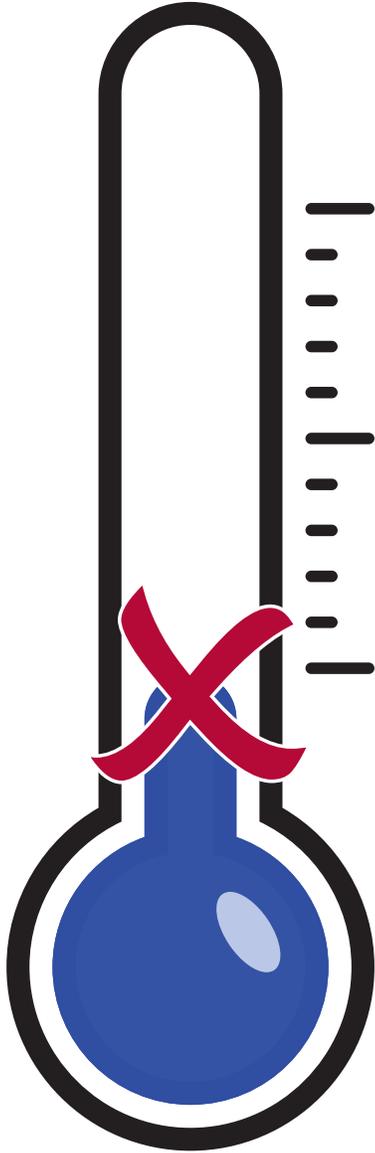


## Choosing the Right Temperature Monitoring Solution



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Globally, pharmaceutical regulators are becoming attuned to cold chain issues as biologics, vaccines, and other temperature-sensitive products are commercialized for a global clientele. Many regulators now recommend including temperature monitoring technology in every cold chain shipment. Controlled-temperature shipping is increasingly important in the food, chemical, and aerospace industries, too, to ensure that their products are handled at optimum temperatures to ensure they last as long as they should.

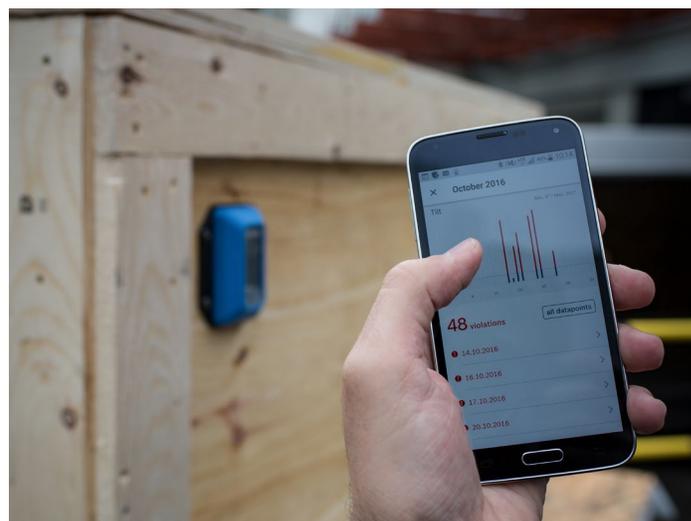
Documenting chain of custody for temperature-sensitive products enhances regulatory assurance and alerts shippers to conditions affecting products' shelf lives and efficacy. Knowing whether, when, and where temperature excursions occurred helps shippers ensure safe products, thereby protecting their clients as well as their own reputations. Temperature monitoring also assigns accountability when excursions occur.

Solutions range from inexpensive indicators that alert shippers to mishandling to sophisticated monitors and data recorders that pinpoint when, where, and for how long excursions occurred. Companies, therefore, can match the technology to their needs.

### Data Loggers

Electronic recorders, sometimes called data loggers, collect information continuously. They measure and record such parameters as temperature, and humidity. The devices can be programmed to trigger alarms at specific damage boundaries – when products become either too hot or too cold – for single or multiple events.

Typically, data from these monitors can be downloaded either directly from the device or wirelessly, enabling analysis and documentation of when damage may have occurred so responsibility can be determined. The latest technologies can be as small as a matchbook, yet read data wirelessly without anyone ever opening the packaging. This is a huge advantage for quality control and customs inspections because this maintains an unbroken chain of



custody by letting shipments remain in qualified, unopened, packaging. In contrast, opening the shipping packaging introduces unknown conditions into the cold chain. Data recorders are best used for high-value shipments and challenging shipping lanes. They are particularly important for large crates or reefers using active cooling systems that are subject to mechanical failure and human error. Their use is limited by memory capacity and battery life, particularly during multi-week transits.

Therefore, data recorders should have the ability to conserve batteries to enable at least 30 percent longer life than the expected shipping and storage duration to minimize the risk of data loss towards the end of the journey. Because battery life is diminished by constant use, it is more efficient to record data periodically.

## Choosing the Right Temperature Monitoring Solution



For example, the [SpotBot BLE](#), made by Spotsee in partnership with Bosch, measures temperature, humidity, tilt, and shock every 10 minutes. It has a battery life of up to two years, making it robust enough to use during multiple transits.

### Data Monitors

Like data recorders, data monitors can track temperature, humidity, and impact but, in contrast, only report excursions from predefined thresholds. This extends battery life by up to 12 months and allows shippers to make Data monitors' small size makes them easy to insert into shipments without changing the packaging.

Temperature data monitors are best used to ensure that product stability data after shipping matches the data before shipping. Their data also can be correlated with transit records to determine when and where single or multiple excursions occurred, and to indicate time and temperature for mixed-product loads.

The [Log-ic Temperature Recorder](#) has a battery life of up to three years. It focuses solely on temperature and can store up to 4,000 logged data points and 16 million histogram points to provide a detailed look at shipping conditions.

Because data monitors are less expensive than data recorders they are good solutions for last mile transport.

### Chemical and Mechanical Indicators

Indicators identify excursions visually, changing color when



single or multiple temperature thresholds are passed. For example, an indicator may be activated if the product temperatures become either too hot or too cold, based upon a user's predefined parameters.

Indicators work in a wide range of conditions, including frozen and deep frozen (-75°C and below) shipping. They are moisture- and tamper-resistant, irreversible, and are highly accurate. They can be activated at any point during the packaging and shipping process, sometimes without any preconditioning required.

Indicators are inexpensive, making them good candidates for smaller packages that often are non-returnable and non-recyclable. They typically are accurate to +/- 1°C.

Indicators like the Spotsee [ColdMark and WarmMark](#) are available for a range of temperatures. They change color when the temperature threshold is breached,, making excursions instantly noticeable. The WarmMark Duo records temperature excursions above 10°C and their duration, and also notes when temperatures exceed 34°C, thus helping the product's users to more accurately calculate the product's useable life. Chemical indicators don't use batteries and have a shelf-life of one to three years, so can be purchased in bulk and stored. They may be mounted on the product, inside the packaging, or on the packaging. While internal mounting shows environmental conditions inside the packaging, external mounting provides a visible deterrent to mishandling. Both provide a permanent exposure record.

# Choosing the Right Temperature Monitoring Solution

## Combinations

Indicators often are combined with data monitors or recorders, providing a double layer of protection. Temperature indicators also can be combined with impact indicators, either in one product (the Spotsee SpotBot BLE) or as multiple products. This makes them particularly valuable for products like wine, pharmaceuticals,

or chemicals, which can be harmed by temperature excursions as well as by impacts that may break seals or crack vials or bottles.

Of course, not every product requires a high-tech solution. Choosing technology based upon the product and its risks can contain costs while still providing assurance – and proof – of how product actually were handled.



### SpotBot BLE

The device was created in partnership with Bosch to make the supply chain transparent. Once attached to the shipment, the SpotBot BLE measures and records temperature, humidity, tilt, and shock, with the data visualized through the SpotBot BLE app. The limits of each parameter can be individually configured, and any violation is traceable and assignable.

### LOGIC Temperature Recorder

Designed to be low-cost and help optimize the cold chain by alerting manufacturers, handlers and shippers when a product has been exposed to temperature conditions beyond a specified threshold. All LOGIC units are water resistant (NEMA 4) recorders with USB in addition to integrated wireless capability that allows for fast data downloads.

### WarmMark

Single-use, ascending time-temperature indicator which alerts users of exposure to unacceptable temperature conditions.

### ColdMark

A single-use descending temperature indicator, is designed to help shippers identify and correct gaps in their cold chain. The ColdMark turns from clear to violet when the temperature goes below a predetermined threshold.

[Contact Spotsee to choose the best temperature monitoring device for your application.](#)