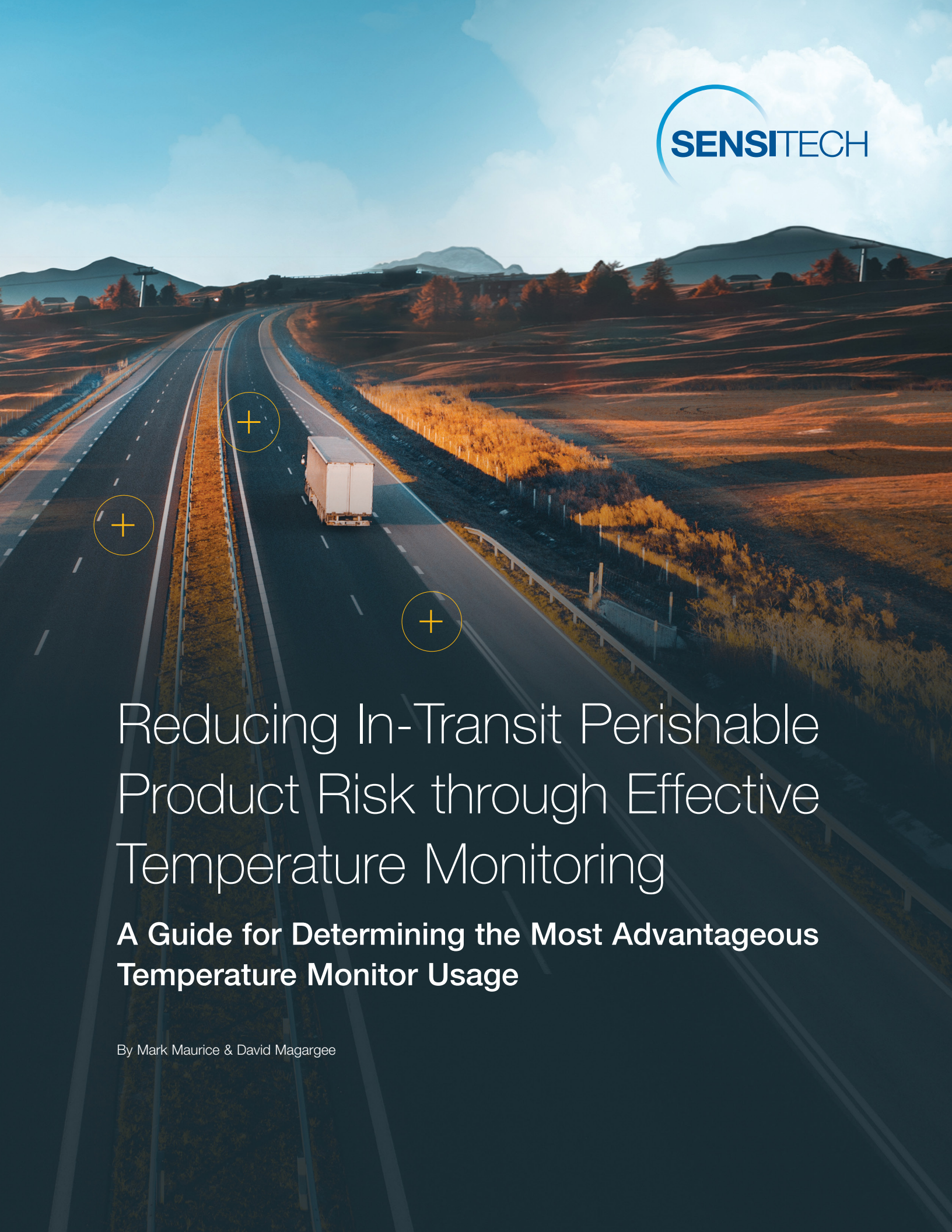

SENSITECH

Reducing In-Transit Perishable Product Risk through Effective Temperature Monitoring

A Guide for Determining the Most Advantageous Temperature Monitor Usage

By Mark Maurice & David Magargee

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Introduction

The temperature-controlled supply chain involves many complex environments, from storage to in-transit. Each has a myriad of factors that could affect the temperature exposure of perishable products and consequently cause significant financial and consumer risk.

To avoid such risks, many life science companies use temperature monitors to alert the responsible parties of potential temperature excursions, above or below the recommended range, that could damage or compromise products while in transit. The temperature data collected from the monitors while in-transit can also be analyzed later to identity the causes of the temperature excursions.

However, manufacturers and shippers are often unsure of how many monitors to use in order to best protect their products and meet regulatory requirements. Typically, companies use monitors either on a container-level basis, where fewer are needed to assure proper temperature management, or a pallet-level basis, which requires more monitors.

The Sensitech Professional Services Team has collected in-transit temperature data for over 600 storage and transportation temperature management studies for customers. Over the course of these studies, we identified specific temperature monitoring procedures that are considered best practices in an effort to offset the most significant risk factors when it comes to temperature excursions. We also have identified other risk-reducing actions that can help to ensure that products are not compromised.

We have found that when customers follow these practices for an ideal temperature monitoring strategy, they can optimize the temperature management of their in-transit distribution and significantly reduce risk of an excursion. If the majority of the recommendations are followed, fewer monitors are needed; conversely, if a company has not put most of the practices in place, more monitors are optimal.

This guide discusses the difference between container and pallet monitoring, the risk factors associated with temperature excursions and actions that can help reduce risk. There is also a risk assessment check list that can help organizations determine the best temperature monitoring strategy for their particular shipping scenarios.

Note: The scope of the content here is limited to large in-transit shipments of a pallet shipment or larger, with a focus on trucks (lorries), trailers, sea and air containers. For the purposes of this paper, the term 'container' refers to all physical units meeting the guidelines listed. Small parcel shipments have not been considered.

Container-Level Versus Pallet-Level Monitoring

When organizations develop a temperature monitoring strategy, they have the choice to monitor their products at a container or pallet level.

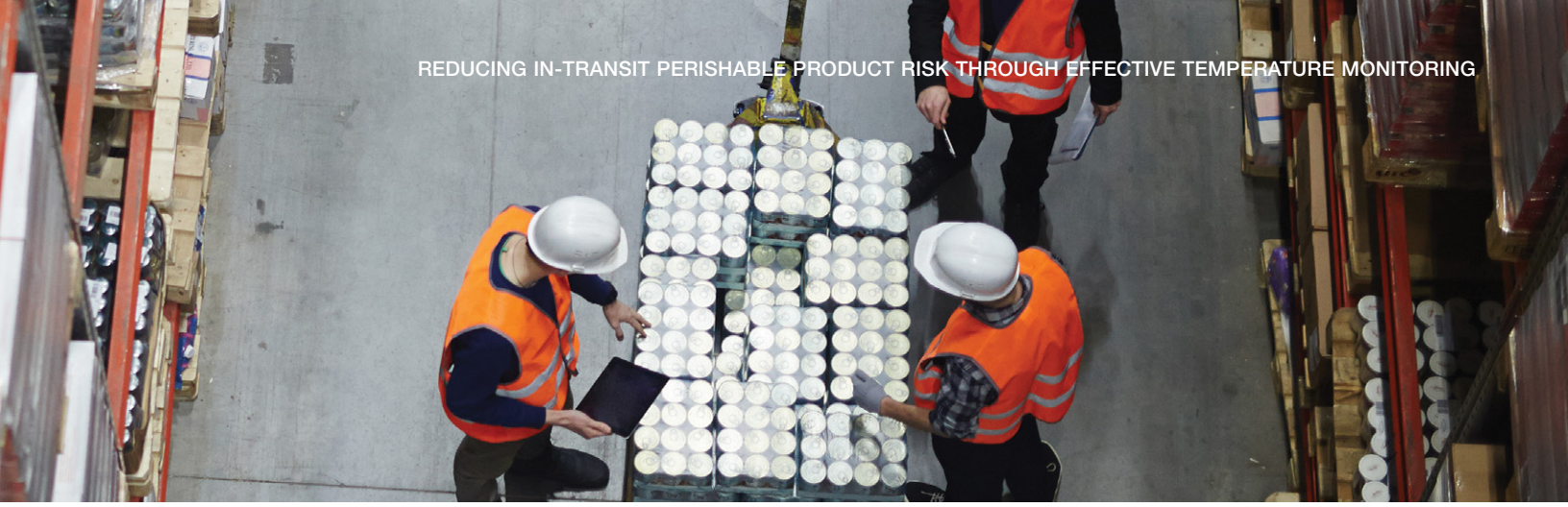
Container monitoring uses a 'bracketing' concept where monitors are placed strategically throughout a container to reliably capture any high or low temperature extremes and identify excursions. If there are no excursions where the monitors are placed, then the temperatures throughout the container are theoretically within acceptable ranges. When more exacting data is desired, a thermal mapping study can identify the specific locations of high and low temperatures within a container to determine if the product temperatures are indeed within acceptable ranges.

If a company chooses to monitor at a pallet level, temperature monitors are placed on each pallet, or subdivision, of a shipment. More monitors would be used with this approach as compared to monitoring the container units. Pallet monitoring increases the granularity of the temperature data collection and mitigates the risk of missing a temperature excursion in a specific location in the container. It also allows a company to understand what specific pallets may have been materially affected during a temperature excursion.

The decision as to how to monitor a shipment is affected by:

- The amount of risk the product is exposed to while in transit
- Any compliance and regulatory mandates that a company is obligated to follow
- Shipment value
- Insurance requirements

After assessing the risk factors and the actions that reduce risk discussed below, companies can determine the level of monitoring that is most appropriate.



Common Factors that Cause Temperature Excursions

As noted earlier, different environments in the supply chain can potentially expose products to temperature excursions. The following factors are some of the most common causes of temperature variations while products are in transit:

Transportation units

For purposes of this section, a transportation unit refers to any equipment that houses temperature-sensitive products while in transit. This includes, but is not limited to, trucks and containers equipped with refrigeration (reefer) units, active or passive pallet shipping units, and containers designed for air and sea travel.

Transportation units that are not properly functioning can increase the risk of temperature excursions. Here are several criteria companies can use to assess the proper functioning of a transportation unit:

AGE

As transportation units and reefer systems age, the risk of a breakdown or damage to the unit increases. Aging units therefore present more risk to temperature-sensitive products.

MAINTENANCE

Proper maintenance is critical to ensure the optimal operation of active units. A regularly scheduled and documented preventive maintenance inspection is critical to identifying and avoiding issues that may lead to equipment failures, especially in older units.

INSULATION

Some studies indicate there is as much as a 20 percent reduction in insulation in units that have been in use for five to seven years. Therefore, older reefer units have to work harder to keep optimal temperatures, which results in greater wear and higher risk of product damage.

UNIT COLOR

Darker-colored units absorb more solar energy than lighter or reflective ones. The absorption of solar energy in darker units can increase the cooling capacity required.

UNIT CONDITION

Damage to the structure of the unit or to the temperature controlling equipment from everyday use or other events can decrease the efficiency of the unit and cause temperature excursions.

Route planning

Depending on the mode of transport, shipping routes can vary widely, as can the temperatures on the routes, consequently affecting the temperatures inside the transportation units and of the products. For instance, a truck, lorry or trailer traveling through North America would be exposed to warmer temperatures in summers and colder ones in winters. Seaports vary in their standard unplug times, so the amount of time a container is unplugged and the reefer unit is off could affect the product's temperature. Specifying use of a generator set to keep the unit running while on land is recommended. Similarly, airports, cargo handlers, freight forwarders and airlines all have different standards, which could impact the handling and tarmac time of shipments. With knowledge of the route conditions for a specific shipment while in transit, organizations can put controls in place for any potential temperature variances to reduce risk.

Load pattern

Load patterns that allow for proper airflow and reduce product shifting are optimal, as they can help maintain an ideal temperature distribution within the unit.

In trucks and trailers, a common practice is to wall load product, meaning pallets are in contact with the walls of the transportation unit to prevent shifting. However, this can cause conduction of heat or cold directly into the product, which can go undetected, especially if there is not a temperature monitor nearby. The ideal method is centerline loading in which pallets are placed in such a way that there is airflow between the product and the walls of the trailer.

Similarly, trailers should not be loaded above a certain height, usually designated by a line on the trailer wall. Loading above the line can compromise the performance of the unit and lead to temperature excursions that may or may not be detected.

Loading and unloading

Products typically have a designated amount of time out-of-refrigeration (TOOR) and acceptable temperature variations before compromises and damage occur during the loading and unloading processes.

For instance, reefer units are designed to maintain interior temperatures, not reduce the temperature of products. Therefore, if a product is loaded too warm, the reefer unit will need to work harder to compensate, resulting in an increase in the number of defrost cycles and in the time it takes for the unit to reduce the temperature to one within specification.

Carrier or freight forwarder services

Before engaging with a carrier or freight forwarder, it is advisable to fully understand what services and capabilities they offer and if they can adequately manage the temperature requirements of a specific product. Considerations that can be explored with vendors are: years in business, number of employees, familiarity with the mode and route, equipment maintenance records, standard operating procedures and quality agreements.

Partial load (less than a truckload)

If a company allows for partial load shipments, it could negatively impact the temperature of products during shipping. For instance, temperature excursions may occur from the transport, loading or unloading of other products, particularly if they are not temperature sensitive.

Chutes

If a trailer or lorry is used, there is a need for proper airflow through the unit to ensure temperature management in the rear of the unit. A chute is often installed from the reefer unit to the back of the transport unit to ensure greater airflow.

Other risk-related considerations

In addition to the above factors involved in the actual transporting of shipments, there are others that contribute to a temperature monitoring strategy, including:

Compliance regulations and guidance

There are several guidelines and mandatory compliance regulations that Life Sciences companies must follow when shipping products such as pharmaceuticals or medical devices.

For instance, USP is an industry organization that works with government agencies and regulatory authorities to provide guidelines for the global supply of drugs. USP <659> is a legally mandated requirement overseen by the U.S. Food and Drug Administration (FDA) that offers guidance on packaging and storage of pharmaceuticals. USP <1079> has guidelines for storage and shipping practices. Following the guidance of standards such as these and others in the industry, helps further ensure the avoidance of temperature excursions.

Shipment value

The value of the goods in a shipment can also impact the amount of risk and consequently, a company's temperature monitoring strategy and the use of more, rather than fewer, temperature monitors. For instance, if products are extremely high in value, such as those with an immediate impact on saving lives or ones with unique regulatory requirements, the use of more monitors is advisable. The same goes for products that are difficult or nearly impossible to replace after being damaged by a temperature excursion, or those with abnormally high replacement costs.

Insurance requirements

Many insurance companies establish policy premium rates based on a risk assessment. Adherence to the best practices here would show insurance companies how a company intends to reduce or avoid temperature excursions and help reduce insurance costs.

Best Practices and Other Risk-Reducing Actions

The following are best practices and other actions that companies can take to further reduce risk in the supply chain.

SOPs, documentation and training

A key best practice to reduce the risk of temperature excursions is to establish standard operating procedures (SOPs). SOPs should define how a shipment is handled in regards to proper temperature management while in transit from one end of the supply chain to the other. Everyone that is responsible for maintaining the quality of the product and proper temperatures while in transit should be given and trained on the SOPs.

The documentation for SOPs may include, but is not limited to, quality agreements, service agreements, work instructions, procedures, work guides and job aides. These documents should not only define how temperatures should be maintained during the shipping processes, but also provide specific guidelines for the condition and use of equipment, load patterns, pre-shipment checks and any other factors or procedures that occur during the shipping process.

By clearly defining and documenting SOPs, organizations can better ensure that they are followed consistently and are repeatable. Without them in place, temperature variations can occur more easily, lowering a company's confidence in consistency of temperatures throughout a container and increasing the risk potential.

Pre-shipment checks

Another best practice is to conduct a pre-shipment check. If anything of concern arises during the check, then the issues can be resolved before the transportation unit leaves.

The following are recommendations for what to include in the checklist:

Verification of driver information:

- What is the driver's name and contact information?
- What route is the driver taking?

Unit and reefer system assessment (not all questions may be applicable):

- What is the age of the reefer system?
- When was the last preventive maintenance inspection? Were any required or recommended repairs completed?
- Is the unit clean and free of debris and odors?
- Do the doors seal securely? Are there any leaks that allow hot or cold air into the load area?
- Are the water drain tubes closed?
- Is the set point of the reefer at the proper temperature?
- Has the reefer unit been programmed to the proper setting, such as continuous mode?
- Is there any damage to the trailer, or any punctures to the unit's surface, that can damage the insulation or create hot or cold spots?
- Has the unit been pre-cooled and, if so, for how long? Are the temperatures within the unit consistent in three separate locations?
- Has the product been pre-cooled or stored at the appropriate temperature?
- Will the unit be travelling on any non-standard, new or especially challenging lanes?
- Has the load pattern been established?
- Have the calibrations and thermal mappings been completed on the unit or family?

Contingency plans

One of the greatest challenges in the supply chain is being prepared for the unknown circumstances that may – or may not – arise. Contingency plans for any kind of event that could negatively impact the temperature of products while in-transit can significantly help reduce risk. Warehouse operations, transportation operations, quality, finance, third-party logistics, carriers and freight forwarders each should define possible unforeseen occurrences and have alternative plans in place.

Here are some examples where a contingency plan would be helpful:

- If an approved carrier unexpectedly cannot take on a specific shipment, is there a plan in place that allows for another approved carrier to step in?
- Are there alternative plans for when a vehicle breaks down?
- Is there a plan to increase the number or placement of temperature monitors if a temperature excursion occurs?
- Does the driver know who to contact if excursions or other problems occur with the transportation unit?

Studies and historical data

Manufacturers, carriers and freight forwarders can conduct studies using temperature monitors to identify temperature variations in transport units or on routes.

As mentioned, thermal mapping studies are one of the best ways to identify how many monitors should be used to reduce the risk of temperature excursions. A thermal mapping study will track temperature change and can provide a quantitative assessment of the number of monitors needed on similar shipments based on an analysis of route, carrier, freight forwarder and equipment data.

A stability study can determine the allowable temperatures and times to complete the load and unload procedures before excursions may occur. Such a study would define stability budgets, or the ideal parameters, for factors such as dock temperatures, trailer temperatures, reefer status (on or off), loading dock product staging and the distance between where the product is stored and the transportation unit. By understanding and controlling these factors, product temperatures can be better managed and aligned with the stability budgets for time and temperature.

Shipping studies and route analyses can also help identify, document and mitigate areas of risk as well.

These studies also provide critical information for shipment and temperature monitoring SOPs. Additionally, they can help identify problem areas and necessary corrective actions and ultimately reduce risk of excursions.

Self-Assessed Risk Calculation

The questionnaire below lists all the factors that can cause temperature excursions, other risk factors and the actions that can help reduce risk.

It can be used as a simple, preliminary way for companies to assess risk and determine whether container-level (and fewer temperature monitors) or pallet-level (and more monitors) should be used for shipping their products.

Assessing Risk in a Temperature Monitoring Strategy

Temperature Excursion Factors	Assessment	Yes	No
Transportation units	Are your containers and temperature controlling equipment in good working order?		
Load pattern	Is your product center loaded and are there allowances for airflow?		
Loading and unloading	Did you build proper load and unload processes into your overall stability budget and is there a way to know if you meet or exceed that budget?		
Route planning	Do you know the route your product is taking and if the proper temperature controls are in place for it?		
Carrier or freight forwarder services	Do you know your vendors' capabilities and can you trust them with your product?		
Partial loads	Is your product shipping with other products that may be loaded or unloaded while in transit?		
Other Risk-Related Considerations			
Compliance regulations and guidance	Does everyone in your supply chain comply with mandatory regulations and voluntary compliance for industry requirements such as USP <659> and USP <1079>?		
Shipment value	Is your product of high value to your company and to your end users that it would require greater monitoring?		
Insurance requirements	Does your insurance policy require any special procedures for risk reduction?		
Best Practices and Other Risk-Reducing Actions			
SOPs, documentation and training	Do you have SOPs defined and documented for maintaining proper temperatures throughout the supply chain? Is everyone trained on these?		
Pre-shipment checks	Did you do a pre-check on the equipment and are there clear communication pathways with the driver?		
Contingency plans	Do you have defined contingency plans in place for unforeseen situations? Can you manage excursions that come with loading and unloading of partial loads or from along the route?		
Studies and historical data	Do you conduct studies and monitor temperature variations to identify areas on routes that may be of risk due to temperature excursions?		
Total answers			

Risk Calculation:

- "Yes" for the majority of answers: Container-level monitoring is the best option.
- One or two "no" answers: Container-level monitoring can be considered.
- Three or more "no" answers: Pallet-level monitoring is the best option.

Risk Calculation Overview

The following pages contain examples of how answering the questionnaire could drive decisions on which temperature monitoring approach is most effective, given a company's specific circumstances and the degree of risk involved in a particular shipment.

When to use container-level monitoring

For an organization that is more established and practiced at sending bulk loads of products, container-level monitoring is typically recommended. This type of company typically has a good understanding and documentation of best practices, with study data to support unexpected temperature variations in the container.

On the following page is an example of how a company might fill out this questionnaire and determine container-level monitoring would be the best option. Despite the shipment being of higher than normal value and at additional risk for delay, diversion or temperature extremes, it's apparent that this company understands temperature variations and knows how to control them. Because the temperatures in the containers are typically consistent, the company could place monitors at two of the hottest and coldest positions in the container as identified in a shipping or temperature mapping study.

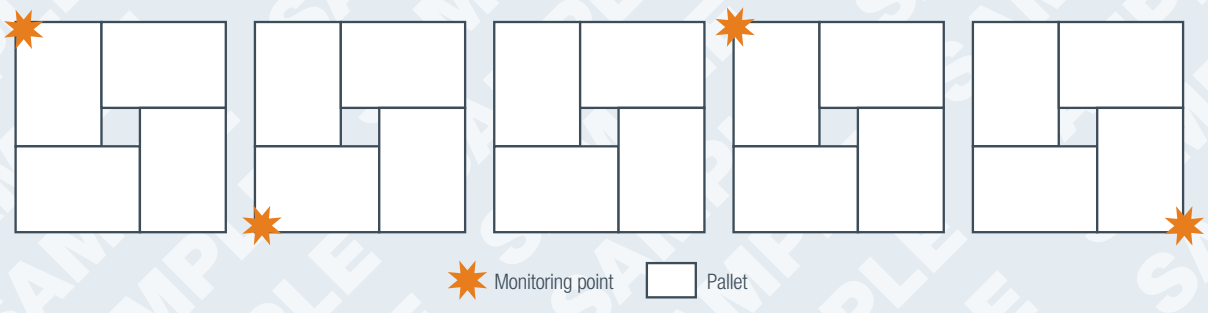
Assessing Risk in a Temperature Monitoring Strategy

Temperature Excursion Factors	Assessment	Yes	No
Transportation units	Are your containers and temperature controlling equipment in good working order?	✓	
Load pattern	Is your product center loaded and are there allowances for airflow?	✓	
Loading and unloading	Did you build proper load and unload processes into your overall stability budget and is there a way to know if you meet or exceed that budget?	✓	
Route planning	Do you know the route your product is taking and if the proper temperature controls are in place for it?		✓
Carrier or freight forwarder services	Do you know your vendors' capabilities and can you trust them with your product?	✓	
Partial loads	Is your product shipping with other products that may be loaded or unloaded while in transit?	✓	
Other Risk-Related Considerations			
Compliance regulations and guidance	Does everyone in your supply chain comply with mandatory regulations and voluntary compliance for industry requirements such as USP <659> and USP <1079>?	✓	
Shipment value	Is your product of high value to your company and to your end users that it would require greater monitoring?		✓
Insurance requirements	Does your insurance policy require any special procedures for risk reduction?	✓	
Best Practices and Other Risk-Reducing Actions			
SOPs, documentation and training	Do you have SOPs defined and documented for maintaining proper temperatures throughout the supply chain? Is everyone trained on these?	✓	
Pre-shipment checks	Did you do a pre-check on the equipment and are there clear communication pathways with the driver?	✓	
Contingency plans	Do you have defined contingency plans in place for unforeseen situations? Can you manage excursions that come with loading and unloading of partial loads or from along the route?	✓	
Studies and historical data	Do you conduct studies and monitor temperature variations to identify areas on routes that may be of risk due to temperature excursions?	✓	
Total answers		11	2

Risk Calculation:

- "Yes" for the majority of answers: Container-level monitoring is the best option.
- One or two "no" answers: Container-level monitoring can be considered.
- Three or more "no" answers: Pallet-level monitoring is the best option.

This is a diagram of what a typical container-level monitoring strategy would look like.



When to use pallet-level monitoring

If an organization is relatively new to sending bulk loads of products, pallet-level monitoring is typically more appropriate. The sample questionnaire on the following page is for a company that is shipping a relatively large quantity of product, which makes the shipment value an important factor in decision-making. Its quality systems are not as robust as the mature company in the previous example. The company does not have a full understanding of the distribution and variation of temperature within the shipping container, nor does it have any proven consistency for SOPs, documentation and training.

Therefore, it is apparent that a higher density of monitoring would reduce risk for this company. Pallet-level monitoring would give the company assurance that, in the case of excursions, it can explore the temperature variations of the various loads, or partial loads, and then make the correct accept or reject decisions.

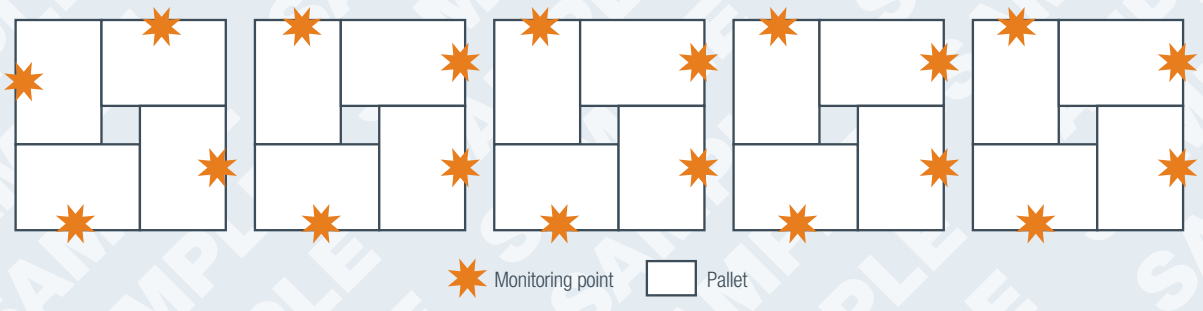
Assessing Risk in a Temperature Monitoring Strategy

Temperature Excursion Factors	Assessment	Yes	No
Transportation units	Are your containers and temperature controlling equipment in good working order?		✓
Load pattern	Is your product center loaded and are there allowances for airflow?		✓
Loading and unloading	Did you build proper load and unload processes into your overall stability budget and is there a way to know if you meet or exceed that budget?		✓
Route planning	Do you know the route your product is taking and if the proper temperature controls are in place for it?	✓	
Carrier or freight forwarder services	Do you know your vendors' capabilities and can you trust them with your product?		✓
Partial loads	Is your product shipping with other products that may be loaded or unloaded while in transit?		✓
Other Risk-Related Considerations			
Compliance regulations and guidance	Does everyone in your supply chain comply with mandatory regulations and voluntary compliance for industry requirements such as USP <659> and USP <1079>?	✓	
Shipment value	Is your product of high value to your company and to your end users that it would require greater monitoring?		✓
Insurance requirements	Does your insurance policy require any special procedures for risk reduction?	✓	
Best Practices and Other Risk-Reducing Actions			
SOPs, documentation and training	Do you have SOPs defined and documented for maintaining proper temperatures throughout the supply chain? Is everyone trained on these?		✓
Pre-shipment checks	Did you do a pre-check on the equipment and are there clear communication pathways with the driver?		✓
Contingency plans	Do you have defined contingency plans in place for unforeseen situations? Can you manage excursions that come with loading and unloading of partial loads or from along the route?		✓
Studies and historical data	Do you conduct studies and monitor temperature variations to identify areas on routes that may be of risk due to temperature excursions?		✓
Total answers		4	9

Risk Calculation:

- "Yes" for the majority of answers: Container-level monitoring is the best option.
- One or two "no" answers: Container-level monitoring can be considered.
- Three or more "no" answers: Pallet-level monitoring is the best option.

This diagram provides an example of pallet-level monitoring.



The Best Plan? Assess Risk and Follow Best Practices

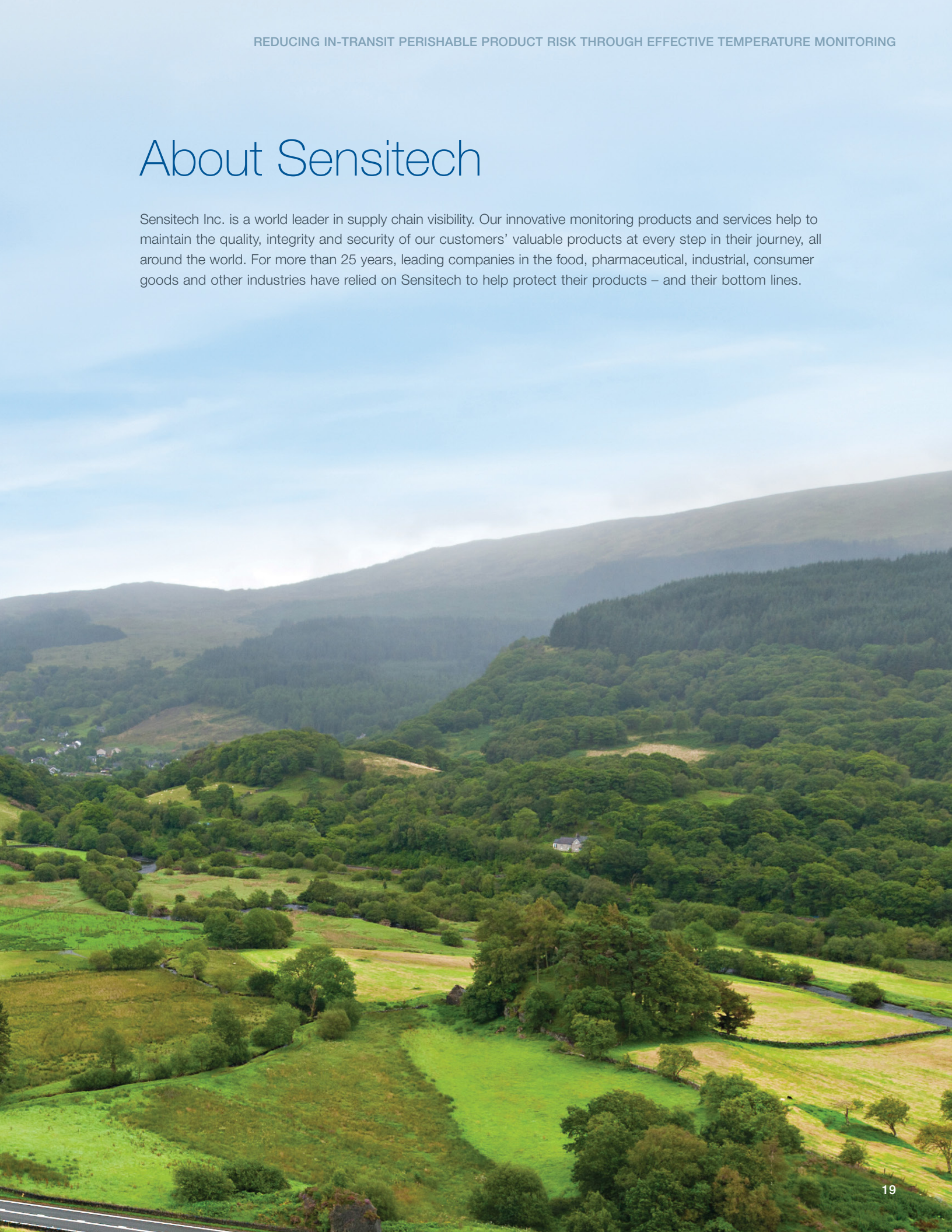
Developing a plan to understand and manage risk and the associated costs is a key step in an overall logistics plan. Both risk and costs can be reduced by following the right temperature monitoring management strategy.

Adherence to the guidance in this paper will help determine whether container-level or pallet-level monitoring would be best for your product. Consequently, it will also affect the quantity of temperature monitors needed, as greater temperature variability could increase the need for more monitoring locations. If the procedures are followed closely, then fewer monitors will be needed.

Partnering with a team that has experience in assessing risk and measuring temperature monitoring gaps is a good step in creating a detailed risk assessment. Benchmarking what other companies have created is another great step that will also save time. The best practice procedures outlined here should be included in your risk assessment. Once these factors are understood, the correct temperature monitor quantity and placement plans can be determined.

About Sensitech

Sensitech Inc. is a world leader in supply chain visibility. Our innovative monitoring products and services help to maintain the quality, integrity and security of our customers' valuable products at every step in their journey, all around the world. For more than 25 years, leading companies in the food, pharmaceutical, industrial, consumer goods and other industries have relied on Sensitech to help protect their products – and their bottom lines.



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Sensitech Inc. • Global Headquarters • 800 Cummings Center • Suite 258X • Beverly, MA 01915-6197
1-800-843-8367 • +1-978-927-7033 • Fax: +1-978-921-2112 • clientservices@sensitech.com