SpotSee™

Global. Connected. Condition Monitoring.

Protecting Medical Devices in Transit

Protecting Medical Devices in Transit

For medical devices, even sitting on the shelf can be risky. As medical devices become more sophisticated, they also often become more sensitive to environmental conditions like temperature fluctuation, impacts, and vibrations. While packaging engineers do their best to design and test methods to protect devices, supply chain experts should take additional steps to understand and monitor the actual conditions these devices experience.

The simple step of adding an environmental monitor to a shipment removes supply chain decisions from the theoretical constructs of laboratory testing and grounds them in reality. Life scientists might liken this approach to the difference between in silico (computer models) testing and in vivo (in the body) testing. Both are valuable, but in silico testing relies upon models that can never account for every possible variable, while in vivo testing subjects devices to the conditions in a complete, actual organism. When applied to the medical device supply chain, testing labs can model only a limited number of conditions, and few can subject their packages to nearly all of them at once.

In contrast, real-world monitoring provides data from the actual conditions packages encounter. This monitoring isn't a replacement for testing labs, of course, but it provides real-world data and combinations of factors that lab testing may not consider. Just as importantly, it provides a starting point for the initial packaging testing and an opportunity to improve upon the existing situation.

The Challenge

Medical devices are a rapidly growing market that encompasses a broad range of items. In 2000, the World Health Organization (WHO) estimated that 1.5 million different types of medical devices were available throughout the world, representing a $145 billion market. By 2017, that market exceeded $521 billion and is projected to reach $674 billion by 2022. The U.S. share represented 40 percent of the global market in 2015.

The other challenge is the variety of items classified as medical devices. The term covers a broad range of items, including diagnostics kits, diagnostic ultrasound products, mass spectrometer-based systems, x-ray machines, and medical lasers, as well as wearable devices and wheelchairs.

Some of those devices require special handling. For example, many reagents for diagnostic kits are temperature controlled and need refrigeration. Temperature excursions may alter their chemistry and, therefore, the reliability of their results. Likewise, hardware devices with electronic controls (such as pacemakers) may be damaged by vibrations and drop shocks that may break delicate circuitry, crack ceramics, or affect calibration.

Temperature

Recommended storage temperatures vary by assay. For example, some assays that determine the total nitrogen content of water recommend storage at 15–25 °C, while another assay for nitrate analysis recommends storage at 2–8 °C. An assay for human IgG Kappa recommends storage at or below -20°C, while a CD32 binding assay recommends storage at -80°C.

Depending on the assay and the transportation lane, ice, dry ice, or active cooling systems may be used. The challenge with ice and dry ice cooling methods is ensuring – and documenting – that the assays maintained the correct temperature throughout transit. This is particularly difficult when re-icing is required during long journeys. A shipment from San Diego to Bahrain, for example, may be re-iced in New York and London and arrive at the proper temperature. But without monitoring, there's no way to prove temperatures were maintained properly.

> *"As medical devices become more sophisticated, they also often become more sensitive to environmental conditions like temperature fluctuations and jolts and vibrations."*

Temperatures fluctuate during shipping. Several studies conducted during the past many years all indicate that temperatures may vary noticeably throughout shipment and also by position in the vehicle or container. Consequently, positioning matters. Temperatures fluctuate depending on nearness to outer walls, insulation gaps, how cargo is loaded, where it is loaded, mode of transportation, and air flow inside containers and cargo holds.

Michigan State University's School of Packaging studied differentials in temperature and air pressure for multiple FedEx flights. The greatest temperature differential – one flight between East Lansing, MI and San Luis Obispo, CA – had a minimum temperature of 7.8°C and a maximum of 25.9°C. Most of the flights, however, recorded differences of less than five degrees.

Several years ago JAL Cargo published the air temperatures for the cargo compartments of its passenger and cargo planes. At the time, the main deck cargo compartment temperature could be set by the pilot between 2°C and 18°C. When it couldn't be set, it ranged between 21° and 27°C. In the front belly compartment, temperatures can't be set and ranged from 2°C to 7°C. In the rear belly compartment, set temperatures could range from -6°C to 14°C. When temperatures couldn't be set, they ranged between 16°C and 30°C. Humidity was typically 20 percent. Since gathering this data, JAL(and other airlines have upgraded their fleets to handle temperature-sensitive cargo.

Tarmac time matters, too. A study published by the American Society of Agricultural and Biological Engineers tracked six international temperature-sensitive shipments and found that half of those shipments sat on the tarmac for more than 11 hours, which increase their temperature an average of 13°C.

Truck and train temperatures fluctuate, too. Temperature monitors on batteries being shipped from California to Florida recorded temperatures from 20°C to 55°C on the top of the pallet. Sensors inside the boxes ranged from 24°C to 35°C.

A 2008 German study of a shipment that began in Hamburg in June and reached Singapore in August found air temperatures in the initial truck and rail stage of the journey ranged from 12°C to 43°C before goods were transferred to a ship. Air temperatures peaked at 47°C in Singapore Harbor, where temperatures inside the packaging averaged 50°C.

The issue also extends to warehousing. Although many carriers are developing temperature controlled warehouses or storage areas at major hubs, they are not yet ubiquitous. In a warehouse, medical devices may experience temperature fluctuations based upon their storage location. For example, racks along a south-facing wall are warmer than those on the north walls, and higher vertical positions may be warmer than lower racks. Time of day, season, and proximity to outside doors and loading docks also affect temperature. Temperature sensors placed at intervals along a grid, top to bottom, left to right and forward to back can provide a heat map of the warehouse, helping warehouse managers determine the safest locations for temperature-sensitive medical devices.

Vibration and Impact

Many components in medical devices may be damaged by vibrations. Photomultiplier tubes (PMT) used in industrial hygiene monitors, for example, use glass vacuum tube constructions that may break if the device is dropped or jolted. Guide wires and vascular implants may be damaged by ultrasonic cleaning, which triggers vibrations and causes material fatigue. Equipment designed for hospital use may experience similar failures when used in environments like mobile field hospitals or during air evacuations, where vibrations may break seals on sterile equipment. Vibrations and inertial forces experienced during flight are among the reasons.

In a lab, the calibration of extremely sensitive medical equipment may be harmed by vibrations generated by other lab equipment, by technicians walking in the lab, and even by equipment outside the immediate laboratory or building. Although packaging materials are used to attenuate vibrations during transit, they are not always effective. Every cushioning material has a frequency at which it amplifies vibrations and subjects the item to more damaging vibrations than the transportation vibrations alone. Frequencies lower than the packaging's amplification range are transmitted unchanged, while frequencies higher than the amplification range are dampened. Vibration frequencies that match the packaging's amplification range, therefore, are the most damaging.

During shipment, the risks increase as products are subjected to the impacts of aircraft hitting runways, jolts of train coupling and even normal road vibrations as goods are trucked to final destinations. Even warehouse conveyor belts transmit vibrations Additional threats are posed by other packages as they shift during transportation, creating friction points or causing shocks that may damage packaging and its contents. Frequent abrasion, for example, may break a packaging barrier, like a blister pack, and adversely affect sterility. Temperature excursions may affect the effectiveness of preservatives in compounds or change the chemical composition of reagents used in test kits. Environmental conditions, therefore, may hinder the ability of devices to perform properly.

Even when sitting in a warehouse, medical devices may be subjected to drop shocks and impacts on the loading dock, or from forklifts that occasionally clip corners.

Testing

The range of potential damage makes packaging testing imperative. The FDA advises using the International Safe Transit Association Standards for medical device packaging. Device manufacturers typically test packaging materials in a packaging lab before committing to a shipping method. The goal is to ensure the packaging can withstand the broad

extent of shipping conditions, including vibrations, shocks, and temperature extremes.

When designing packaging lab tests, ensure that they account for not just for average conditions, but also extremes. For example, temperature tests should include not just the highest recorded temperatures in a region, but the effects of packaging that may make those temperatures even hotter – dark shipping containers or the use of the clear plastic pallet protectors, for example. That testing approach should include vibrations, too, because rough roads, rails, forklifts, and even internally-mounted racks and other packages add to the vibrations a product experiences during transit.

Also test packaging against intentional mishandling to determine the effect of unusual circumstances. For example, a 2013 YouTube video shows a shocking example of package mishandling at the Guangzhou airport, in which a cargo handler tosses packages toward the conveyor belt, watches them bounce and hit the tarmac, and hurls them again. Additional examples abound.

Laboratory testing is a good initial test for package integrity, but it's also important to monitor products under actual shipping and storage conditions. Laboratory testing can't produce a comprehensive range and combinations of real-world hazards, their magnitudes, or frequency of occurrence. With real-world monitoring, shippers learn the actual conditions and can correlate them to any damage or changes in their conditions or functionality.

Monitoring

Monitoring solutions are available to meet every need and budget. Options are available that provide continuous monitoring and record and report multiple threshold incidents for temperature and impact, or that simply indicate threshold excursions. Sophisticated solutions are even available that incorporate impact, temperature, and other parameters for more comprehensive insights into conditions throughout the supply chain.

Whether monitors are deployed during shipping, storage, or in a healthcare setting, they provide valuable evidence managers can use to prioritize equipment damage checks. These solutions also help create a baseline for supply chain analysis and enable a basis of comparison when evaluating packaging, logistics providers, transportation lanes, and storage facilities.

Contact Spotsee to learn more about using data monitors to manage risks to your shipments of medical devices.

ShockLog 298

Monitors and records shock, vibration, and environmental conditions experienced by any type of structure or equipment, whether in use, in transit, or in storage. With the capacity to record data for 870 events and 262,000-time slots, the device alerts you whenever damage may have occurred so you can respond promptly.

SpotBot Cellular

SpotBot Cellular reduces the high cost of global supply chain damage through a real-time, damage-monitoring device and service. SpotBot helps supply chain managers, forwarders, truckers, quality and plant managers easily see where and when impact or temperature damage occurs and the severity of the damage from anywhere in the world through the SpotSee Cloud. The service enables subscribers to stop damaged shipments early and address damage issues as they happen. It even works inside most refrigerated containers. SpotBot features best in class impact monitoring, generating accurate data on impacts up to 65G which is four times (4X) the range of the next best competitor.

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.

Speak with a SpotSee logistics expert and explore our full line of supply chain products.