Wireless: The Future of Temperature Monitoring

Pharmacists are widely acknowledged to be “the drug experts,” regularly intervening to ensure the safety and effectiveness of pharmacotherapy. But if the integrity of those drugs suffers because they are stored outside of a recommended temperature range, all those efforts can go for naught.

That’s partly why so many regulatory agencies are taking a harder look at how health systems and other stakeholders monitor the temperature of products in warehouse or other storage locations.

The U.S. Pharmacopeia (USP), for example, urges that “a suitable number of temperature-recording devices” be placed in pharmacies’ refrigerators and freezers, with recording systems to log and track temperatures, and alarm systems that alert staff to temperature excursions. Whether those systems are wireless is partly a function of cost and location in the supply chain, according to Rafik Bishara, PhD, a technical advisor and former director of quality knowledge management and technical support for Eli Lilly and Company.

“Real-time wireless temperature monitoring may be cost-prohibitive in most cases at this point for last-mile shipping of pharmaceuticals, but it’s becoming more and more important in warehouses and storage within the pharmacy, as well as during shipment of large pallets,” Dr. Bishara said. In such settings, “if you have live data, you can quickly correct the situation when you have a temperature or humidity excursion, rather than finding out about it a few hours or days too late. And with experience and volume, the prices should go down.”
Moreover, with their automatic data logging and audit trail, wireless systems can reduce the amount of employee time spent on documentation for regulatory and accrediting bodies, he added.

Here’s what’s new from three different players in the pharmacy temperature monitoring field.

**Temptime**

New Jersey–based Temptime’s EDGE suite of sensors provides wireless temperature tracking, mobile connectivity and data sharing for temperature performance monitoring. With Bluetooth wireless technology, performance is monitored and tracked on a smartphone or mobile device, with data stored in the cloud, using the company’s proprietary EDGEVue app and EDGECloud services.

“Using low-energy Bluetooth, we can penetrate most drug packages, interrogate the wireless data logger inside, and get a true reading without opening it up and exposing it to the environmental temperature outside the package,” said Chris Caulfield, the vice president of global customer development.

![Temptime's EDGE suite of sensors provides wireless temperature tracking, mobile connectivity and data sharing.](image-url)
In pallet shipping, the monitors can be paired with a gateway known as EDGEBridge, which can interrogate all the wireless data loggers as they enter or exit a warehouse. “The gateway automatically grabs all the data monitoring information and sends it to the cloud, increasing productivity while decreasing the human element,” Mr. Caulfield said. “Typically today, someone has to go and retrieve the data logger, putting the product in quarantine until they find it and decide to accept or not accept the delivery. This technology allows you to make evaluation of acceptance of that material immediately upon delivery.”

For real-time facility monitoring, Temptime’s systems deploy a long-range communications network that can be put in place for each facility, using one “mothership” receiver to connect to as many as 800 temperature and humidity sensors, placed within a connectivity range of up to 10 miles line of sight. “This reduces the infrastructure you have to install to monitor a substantially sized facility, or multiple facilities within that distance,” said Mark Eppedio, the senior product manager. “There are also multiple layers of encryption, meeting all regulatory requirements.”

Cost: $1,500 for one EDGEBridge system plus one sensor data logger; $5,000 for the warehouse-based “mothership” receiver, plus $300 to $500 per sensor for in-facility monitoring. Individual prices decrease based on volume.

Phononic

Based in North Carolina, Phononic sells Evolve compressor-free refrigerators with temperature, air and glycol monitoring directly embedded in the units. “There are two ways to monitor,” explained Jerilin Kenney, the company’s vice president and general manager of life sciences and health care. “The first is through local memory. The system logs data to a flash memory drive, and you can extract your temperature conditions along with any alarm events over at least 30 days. The second option uses an embedded Wi-Fi device to transmit that data securely to our cloud environment. The user can download their data through an internet portal and receive email alerts of excursion or alarm events.”
An Evolve refrigeration unit (Phononic), shown on the far right counter top, features integrated temperature monitoring and audible alarms.

Pharmacies can define excursion limits at each unit and transmit them to the cloud. Each account can have as many assigned users as needed, who can set their own preferences for excursion notifications. “Any alerts triggered are digitally received on the user interface, and then recorded and documented in either local memory or the cloud, giving you an auditable data log,” Ms. Kenney said.

Phononic is working with multiple pharmacies, medication rooms and clinics in health care systems, she noted. “It’s a solution for pharmacies to have both local and remote temperature monitoring without a significant overhead investment at each location.”

Cost: Approximately $2,500 for the smaller refrigeration unit and $4,000 for the larger. Monitoring is $250 per year per unit. Individual MSRP is reduced with the purchase of multiple units and monitoring subscriptions.

Primex

Wisconsin-based Primex manufactures wireless environmental monitoring systems for a wide range of industries. Its PrimexTEMP wireless temperature sensors are linked to a proprietary system called OneVue, which uses Amazon Web Services to process more than 480 million sensor updates each day.
“It’s a completely cloud-based monitoring solution designed for mass scalability, which fits perfectly in the pharmacy world,” said Primex General Manager Mike O’Brien. “The sensor device, which is the brains of the local monitoring capability, connects with the cloud via Wi-Fi, PoE or a standard Ethernet connection. That device has a couple of ports for probes, which connect into the sensor device. The probes are mounted inside the refrigerator or freezer and inserted into a bottle containing a glycol or wax solution that emulates the contents for monitoring, rather than ambient air.”

The sensors regularly log and report temperatures, and when an excursion from predefined ranges occurs. When there is a temperature excursion, the cloud-based system sends out alerts based on user preferences. “You can ask for email, SMS text or voice call alerts—or all three,” Mr. O’Brien said. “Users can also configure alert rules that specify who gets notified of an excursion depending on the time and location.”

All of this is documented in a time-stamped record, which identifies the person who reviewed the temperature excursion. The user also can add comments, documenting what led to the excursion and what was done to mitigate it. “That’s extremely important for the FDA and regulatory agencies,” Mr. O’Brien said.

All of the probes employ CertiTrak Calibration Certification Tracking, which links a unique certificate to each individual probe. The certificate provides data required for compliance with CDC guidelines and other authorities having jurisdiction. “We only use RTD [resistance temperature detector] platinum probes, which have the highest accuracy and the least amount of drift over time,” Mr. O’Brien said. “The sensors are solid-state, and the probes all store information about when they were put into service and when they were calibrated. Instead of looking at a spreadsheet to maintain data on when your probes went into service and need to be calibrated or changed, our system tracks it all and takes the burden off the end user.”

Cost: Approximately $50 per probe and $200 per sensor unit.

—Gina Shaw