

# **Compliance Q & A**

# PharmaWatch™ Sensors for Backup and Emergency Transport

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### Scope

Recent amendments to CDC guidance have included a recommendation to utilize at least one backup device at each Location where vaccines and/or similar inventory are being monitored.

This document describes the use of a PharmaWatch™ SNEXT sensor with display to accommodate this recommendation.

## Q and A

#### **Question:**

What does the new CDC guidance recommend for backup devices?

#### **Answer:**

The CDC's "June 2016 Storage Handling and Toolkit" guidance has recommended the following:

"At least one backup DDL [Digital Data Logger] in case a primary device malfunctions or is out for calibration testing (make sure the backup device has a different calibration testing schedule than the primary device so it is available when the primary device is being tested)

CDC recommends DDLs with the following characteristics:

- Detachable probe in a thermal buffered material (e.g., glycol, glass beads, sand, Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature indicator
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user"

#### **Question:**

Can I use a PharmaWatch™ device to meet the recommendations in the new guidance?

#### Answer:

Yes, PharmaWatch™ SNEXT sensors may be utilized to help comply with this recommendation. However, setup and use of a PharmaWatch™ sensor as a backup device is different than a standard continuous use sensor.

#### **Question:**

How do I request a backup PharmaWatch™ sensor for my site?

#### **Answer:**

PharmaWatch™ Sensors may be ordered from your PharmaWatch™ Account Executive or from PharmaWatch™ Support Services by email <a href="mailto:support@ameri-pharma.com">support@ameri-pharma.com</a> or phone at 888-234-5157.

#### **Question:**

How do I setup my new sensor for use as a backup device?

#### **Answer:**

- 1. When filling out your enrollment form, be sure to name the new Zone as a backup device (e.g. "Clinic 3 BU") and fill in the alert range for where it will be used for backup (e.g. refrigerator or freezer).
- 2. After receiving the new sensor, power it on and connect it to an A/C power source in a Location where staff will access it when needed.
  - (**Note**: it may be preferable to have the backup probe in a storage unit so it is preconditioned within alert tolerances when needed.)
- 3. Leave the sensor running for one week while the Validation report is prepared.
- 4. After the report is delivered, use the web portal to place and keep the Zone "Out of Service" until needed. Keep the sensor charging, connected to the wi-fi and ready to be deployed.

(**Note:** leaving the sensor out of service will disable all alerts. Periodically verify the sensor is reporting to the Portal and ready for deployment.)

#### **Question:**

How do I use my backup device when needed?

#### **Answer:**

- 1. Unplug the sensor from the A/C power source and install the sensor probe in the storage unit requiring the backup device.
- 2. Reset the sensor display "min-max" by pressing the wi-fi button then selecting it again and holding it down for 5 seconds.
- 3. On the web portal Dashboard view, use the "Place in Service" button for the backup Zone. This will enable all alerts (if Wi-Fi is connected!).
- 4. The sensor battery will last up to 7 days on power allowing for data to be collected and transmitted (if Wi-Fi is available) or data to be stored for when the connection resumes (if Wi-Fi is offline, e.g. power outage).

#### **Question:**

Can I use a PharmaWatch™ sensor as a backup and for emergency transport?

#### **Answer:**

Yes, however PharmaWatch™ SNEXT model sensor radios have a limited battery life that may be affected by cold environments and are not ruggedized for continuous transport use (e.g. not designed for drops or heavy vibrations).

If using for emergency transport:

- Keep sensor radio outside of storage environments (e.g. in a pocket or sleeve on transport cooler, then run probe into storage cooler).
- Be sure radio was connected to A/C power and fully charged prior to transport (e.g. LED charge light blinking).
- The CDC 2016 guidance recommends the probe and buffer be "pre-cooled" for 5 hours prior to transport.
- **Important:** return the radio to a location with the same Wi-Fi settings as the origin location to have the data recorded during transport uploaded to the web portal!

#### **References:**

2016 Vaccine Storage and Handling Toolkit <a href="https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf">https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf</a>

2016 Packing Vaccines for Transport during Emergencies <a href="https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf">https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf</a>