

The Centers for Disease Control and Prevention (CDC) has developed guidance for storage and handling of vaccines. To see the current guidance issued by the CDC, view the <u>Vaccine Storage and Handling Toolkit</u>.

### **Key Points:**

- CDC recommends that practices maintain a calibrated, temperature monitoring device (data logger) and manually record temperatures in each unit containing Vaccines For Children (VFC) vaccines. This should be done twice daily.
- Data loggers have many different features. CDC recommendations are below, but call your VFC coordinator to learn what is required in your state.
- Consider a phone-enabled or internet-aware alarm to alert you by phone/internet anytime temperature excursions occur. Multiple people should be on the notification list to ensure the best chance that appropriate action is taken to correct the problem.

### It is recommended that your data logger have the following functionality:

- Hi/Lo auditory alarm for out-of-range temperatures;
- Displays current temperature, as well as the minimum and maximum temperatures recorded since last manual recording of temperature (values must be visible from outside of the vaccine storage unit);
- Low battery indicator;
- Accuracy of +/- 0.5 degrees C (+/-1 degrees F) as certified by a current Certificate of Traceability and Calibration.
  - Certificates may last 1-2 years.
  - Speak to your VFC coordinator for your options. It may be cheaper to purchase a new device, or they can discuss acceptable testing laboratories.);
- Records continuously with memory storage of at least one month of data\* (no less than 4,000 readings);
- Data recording loops when memory is full.\* (Remember to download and transfer data to more permanent storage. Reset device after each data download.);
- Detachable, buffered temperature probe, that can remain in the unit while the temperature is displayed on the outside of the unit (near vaccines); and
- User programmable logging interval (or sampling rate) of 10 minutes or less.\* While the CDC recommends 15 minutes or less, a more frequent sampling rate is allowed and may be preferable to capture more data points and to better estimate the duration of temperature excursions.

## What do I do with the data stored on my data logger?

Even though the data logger is recording, the temperature will need to be checked and manually recorded by office staff twice daily, along with the maximum and minimum temperatures since the last data reset. This recommendation can prevent inadvertent loss of vaccine and the potential need for revaccination by allowing temperature excursions to be identified quickly so that immediate corrective action can be taken. This also provides an opportunity to visually inspect the storage unit, reorganize vaccines by date, and remove any expired vaccines.

<sup>\*</sup>Please note this adds to CDC guidance.



Data logger temperature data should be downloaded, reviewed weekly, and stored for at least 3 years. Documentation of known excursions or thermometer malfunctions should be recorded along with the temperature data and should include corrective actions taken to address the excursions. Software will likely be needed in order to view the stored data. Many data loggers are sold with software included, but some are sold separately. You must be able to review historical data.

### What else do I need to consider?

- Contact your VFC Program to determine their requirements
  - The CDC has published recommendations for the local VFC Awardees who administer the VFC program to pediatricians. Being familiar with the CDC published recommendations will help pediatricians anticipate new requirements but it is the requirements of the pediatrician's individual VFC program that must be followed per VFC contracts.
- Alerts/Alarm phone-dialer (alerts through landline, text, e-mail and/or mobile phone)
  A phone-dialer is able to alert you to a temperature excursion during which no one is in the office to hear
  the local alarm. This allows someone to correct the problem in time to prevent the loss of vaccine. No
  single notification method works best in all situations sometimes you may need a combination of
  methods. Understand the likely outages (eg, local and regional power failure, local and regional internet
  service, local and regional phone/cellular/Voice over Internet Protocol) that you may experience and
  realize the notification system can fail under such adverse conditions. Your office should have a plan in
  place for vaccine storage and transport during emergencies. Please see the AAP Vaccine Storage and
  Handling Disaster Planning resource.
  - Equipment failure, door left open: This is by far the most common occurrence about which to be notified. As mentioned above, your data logger should have an alarm for temperatures exceeding either the high or low threshold. These alarms can notify staff who are physically near and able to respond. You may want to look for a unit that will allow you to program or specify a short/minimal delay before the alarm rings. This will allow you to avoid notification during routine inventory maintenance.
  - Off-site notification: This type of notification can be used after office hours to reach one or more staff responsible for immunizations. Each office should have at least one staff immunization champion a nurse or medical assistant who takes responsibility for and performs regular vaccine management tasks and one physician who oversees immunizations. These staff members can be alerted via phone call, e-mail, or text. The best devices require a response from the person notified a return text or acknowledgement code entered via the phone and will continue to dial staff members until the acknowledgement is received.
  - Power outages: Although the phone-dialer may have its own battery, the phone service going to the dialer may fail.
    - Local power failure (circuit breaker, single building outage) can disable most phone systems unless they have battery backup or a generator. A standard "land line," tied directly to the dialer (does not go through an office phone system) is the most reliable and does not require a power source. Cellular service is also quite reliable and has the advantage of texting and/or voice-calling. E-mail notification, cable phone service, and Voice over Internet Protocol phone systems require internet service which may also be dysfunctional in the building, as modems, routers, switches, and servers all need power to be working. Service



can also be lost in the immediate area, thus rendering these methods less dependable. Some internet devices constantly notify send notifications to an offsite device. If these notifications stop (for example in the case of a power outages), the offsite device will begin calling staff members. This method works even if total power failure occurs.

Regional power failure (natural disasters, foods, hurricane, snow storm, large-scale grid failure) can make notification more difficult since the infrastructure can be compromised. Usually a responsible staff can be aware of such events and should physically go to the site to inspect. Understand the likely outages (local and regional power failure, local and regional internet service, local and regional phone/cellular/VOIP) that you may experience and realize the notification system can fail under such adverse conditions.

### A back-up thermometer

 Have a back-up thermometer to use if/when your primary unit is being tested for calibration. It may be more cost-effective to purchase a new thermometer than to maintain 2 with updated certifications of calibration.

### A unit with a continuous-tracking feature

Older thermometers may directly record the unit's temperature onto a circular piece of graph paper.
 These have been totally replaced by electronic versions and should not be used. (Please note: use of continuous tracking with a data logger does not preclude you from manually recording the temperature twice daily!).

#### • Vaccine Insurance

- When private-purchase vaccine expires or is destroyed by temperature excursions, the manufacturer may take back non-influenza vaccine and exchange all for new vaccine. Replacement is not an option if the vaccine is physically destroyed (fire) or in case of theft. Returning vaccine is not currently an option for doses purchased through the CDC VFC contract and given to practices. Practice owners may be financially responsible for all VFC vaccine spoilage. Follow state VFC program guidance on returning vaccine. The degree of VFC financial risk is determined by the local VFC program, not the CDC. Contact your local VFC program to determine your financial risk when storing VFC vaccine. Practices with excellent storage programs may be excused from financial responsibility for events beyond their reasonable control.
- Insurance is an option for both private-purchase and VFC vaccine. As with any insurance policy, be very sure you understand exactly what is and is not covered write the insurance agent asking:
   "Please give me a list in writing as to what losses you will not cover."

#### Spare refrigerator and transport containers

- Consider placing a spare thermometer (with a buffered probe) in your employee or break-room refrigerator and maintain/monitor that refrigerator between 2°C and 8°C
   (36° F and 46°F) just like you would a vaccine refrigerator. That way if you have an unexpected equipment failure, you can remove all food and have a readily available refrigerator that you know is capable of storing the vaccine at the appropriate temperature.
- Have coolers capable of safely transporting your vaccine to an alternate refrigerator in case of power failure stored in your building. Conditioned frozen water bottles make excellent coolant for transport of refrigerated vaccine and should be on hand at all times. (See <u>CDC Packing Vaccines</u> <u>for Transport during Emergencies</u>).



### • Electrical backup for refrigerators

- Although battery backups are appropriate for computers to help deal with minor power outages, battery backups are NEVER appropriate for refrigerators. Refrigerator compressors draw too much current for battery backup devices and will likely fail. If the power returns in a few moments, the device will remain "off" and so will the refrigerator.
- o In areas at risk for power outages, propane or natural gas emergency generators are appropriate. They must have automatic start and be professionally installed by an electrician.
- Gasoline and diesel fuel are not appropriate fuels for emergency refrigerators because they age quickly.
- Be aware that refrigerators can exceed 8°C (46°F) in about 3 hours of no power at room temperature.

### How do you determine if the refrigerator is failing or the data logger is wrong?

- To check the accuracy of a data logger, you can do an Ice Melting Point Test. <u>Watch this</u> <u>demonstration</u>.
- O An easy method is to purchase a soup thermos, fill with more ice than water, and place the certified probe into the water + ice while in the refrigerator. If, after 10 minutes, the thermometer reads within +/- 0.5° of 0°C (+/-1° of 32°F) and holds that range for another 10 minutes, then the thermometer passed and demonstrated that it is accurate. If it fails, it should be replaced.
- Refrigerators can slowly decline in function. If you find that you are turning the thermostat colder and colder to maintain
  - 5°C (41°F)you should replace the refrigerator immediately.
- View the <u>Immunization Action Coalition Resources</u> for documenting and correcting any unacceptable vaccine storage event.
- If testing shows the device is reporting inaccurate temperature do not try to adjust it, replace the temperature monitoring device.

#### How do you place a data logger in a refrigerator?

- The data loggers with a removable temperature probe usually have a wire leading to the probe. There are some that function wirelessly, but most use a wire. Purpose-built (vaccine/medical) refrigerators often have a plug that covers a hole through the side or rear wall of the unit designed to feed the probe wire into the unit without gapping the door.
- o If the storage unit has no port, the probe should enter through the door opening on the hinge side high in the top corner. The seals are sensitive to gaps caused by the monitor wire and frost will build up in freezers due to the gap allowing moist air to enter. This can be reduced by tightly taping the wire in the door frame with thin clear packing tape for a good seal.
- Place the probe in glycol in the center of the refrigerator with several loops of extra wire. That will
  allow you to move it throughout the vaccine storage area to verify that the entire refrigerator is kept
  at the temperature appropriate for vaccines.





Special thanks to the Oregon Immunization Program for sharing material from their 2012 Thermometer Guide!

Please note that the American Academy of Pediatrics cannot endorse or recommend specific products or brands. This guide is only meant to aid you in your selection of vaccine storage equipment. The terms and conditions related to your purchase are between you and the vendor.

While we attempt to keep this document updated, model numbers, styles, and features change often. Before making your final decision, contact the manufacturer/vendor for up-to-date pricing and specifications, and check with your VFC coordinator to verify a product meets their requirements.

## **Data logger manufacturers and distributors:**

Accsense	http://www.accsense.com/p_p_a102.html
Berlinger	http://www.berlinger.com/en/temperature-monitoring/products- hardware/data-loggers/
Control Solutions Inc.	www.vfcdataloggers.com
Dickson	http://www.dicksondata.com/products/find/data-logger
DeltaTrak	http://www.deltatrak.com/product/381-flashlink-certified-vaccine-usb-pdf-data-logger-model-40527
Lascar Electronics	http://www.lascarelectronics.com/data-logger/
Onset (Hobo)	http://www.onsetcomp.com/
SensoScientific	http://www.sensoscientific.com/vaccine-vfc/
T&D Corporation	http://www.tandd.com/#fragment-1
Temperature Guard	http://temperatureguard.com/
Temperature@lert	http://www.temperaturealert.com/Temperature-Alarm.aspx
Tip Temperature Products	www.tiptemp.com

## Alarm phone-dialer manufacturers:

Dickson	http://www.dicksondata.com/
DeltaTrak	http://www.deltatrak.com/flashtrak-wrm#specifications
Sensaphone	http://www.sensaphone.com
Temperature Guard	http://temperatureguard.com/
United Security Products	http://www.unitedsecurity.com/
Temperature@lert	http://www.temperaturealert.com/Temperature-Alarm.aspx



In order to be assured your data logger meets all desired specifications, you may want to discuss them with your vendor. Below is a list of questions to ask your vendor to help you understand all the functions of a data logger. You may use the chart on the next page to fill-in information and compare models.

### Questions to ask about desired specifications:

- Does this data logger display the current, minimum, and maximum temperature? Is the display outside of the vaccine storage unit (refrigerator or freezer) where it can be easily accessed?
- Does the unit have an alarm that will alert the user if temperature exceeds the high/low thresholds?
- Does the unit have a reset button that clears the minimum and maximum temperatures since the last clearing?
- Does the unit have a low battery indicator?
- Does the unit have one or more detachable temperature probe(s) in glycol or suitable temperature buffer?
- Does the temperature probe and unit measure accurately, within +/- 0.5°C (+/-1°F) and come with a Certificate of Traceability and Calibration?
- Can it record at least a month worth of readings at a 10 minute sample rate?
- Does this unit loop data (record over the oldest data) when memory is full?
- Is the logging interval customizable? At what intervals can this device record?

#### Questions to ask about additional features:

- Can this unit connect more than one probe?
- Can this unit transmit data wirelessly?
- Is a power cord available?
  - o If not, does the battery last at least 1 year?
  - o How long does the battery last?
  - o Is the battery replaceable?
- Is software included or available for separate purchase? (If separate, considering purchasing to access your stored data).
- What are the system requirements for the software?
- Can this unit place phone calls (landline and mobile), send text messages, and/or send e-mail messages to several numbers and addresses if it detects a temperature excursion?
  - If so, can a user query the monitor for additional readings while traveling to the office?
     (If it "recovers" as in a power outage, you want to be able to return home).



You may use this chart to fill-in information and compare models. Please note that the American Academy of Pediatrics cannot endorse specific products. This guide is only meant to aid you in your selection of vaccine temperature monitoring equipment. The terms and conditions related to your purchase are between you and the vendor.

Data logg make/mo	( OCT	Hi/Lo alarm	Current min & max temp display	Maximum and Minimum Temperature Reset button	Low battery indicator	Accuracy	Memory storage	Programmable logging interval of 10minutes or less? Y/N Rate?	Does data loop when memory is full?	Data displayed outside of unit and downloaded without disruption of probe?	Frequency & Cost of Re- Calibration  Can an Ice Melting Point (IMP) Verification be done by user?	Other features
Monitor A	Example	Yes	Yes	Yes, logger can be cleared	Yes (indicate s when A/C power is removed)	±0.45°C	60,000	Y Various intervals available	Yes	Yes, remote probe	Annually \$99-\$269 Check with VFC Coordinator	Relay (function for external alarm hook-up); UBS/flash card