



# Tennessee Immunization Program

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## Vaccine Storage Unit and Temperature Monitoring and Excursion Guidance For Non-Health Department Facilities

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## Section 1. Vaccine Storage Units and Monitoring Equipment

Proper use of good quality vaccine storage and temperature monitoring equipment is the best way to assure you do not waste vaccine or administer vaccine that has been compromised due to inappropriate storage conditions.

### A. Vaccine Storage Units

- The Tennessee Immunization Program (TIP) *strongly recommends* the use of purpose-built or pharmaceutical/medical grade units or stand-alone refrigerator and freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, storage unit purpose-built for vaccine storage.
- At this time, a permissible, but *not* recommended, alternative to stand-alone units is using **only** the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines. A separate stand-alone freezer is required to be used to store frozen vaccines: studies have demonstrated that the freezer section of combination units is not capable of reliably maintaining appropriate frozen vaccine storage temperatures.
- The use of dormitory or bar-style refrigerator/freezers is prohibited at any time for storing VFC vaccine.
- Storage units should follow the maintenance schedules provided in the owner manual.
- Please contact TIP if you are in the process of purchasing a new vaccine storage unit. We can ensure that you have the most current VFC program requirements and recommendations for vaccine storage units prior to your purchase.

### B. Additional Requirements for a Storage Unit Include:

- Enough room to store the largest inventory a provider might have at the busiest point in the year without crowding. [Think flu season!]
- Protection for the power source of all vaccine storage equipment by means of warning labels such as “Do Not Disconnect” posted at the electrical outlet and the circuit breaker, back-up generators and/or developing appropriate policies/protocols.
- We recommend that the unit has sufficient room to store water bottles in the refrigerator and *frozen* water bottles in the freezer. This is called “thermal ballast” and they help stabilize the temperature during routine use and during brief power outages.

### C. Continuous Temperature Monitoring Devices

1. Requirement: Each storage unit is required to have either a certified min/max digital thermometer *or* a certified, calibrated digital data logger with continuous monitoring and recording capabilities. This document references the “Fridge Tag 2” brand of data logger used in many practices; however, there are several other brands of loggers available that also meet VFC needs. Data loggers should have data that can be routinely downloaded and have the following capabilities:
  - An active display that is placed on the outside of the unit door to allow for reading temperatures without opening the unit door
  - A detachable, buffered probe. Any type of buffer is acceptable, including glass beads or glycol; buffering smooths out the temperatures recorded and helps approximate the temperature of the vaccine rather than the more quickly changing air temperature of the unit. For liquid buffers, volumes between 5 and 60ml are acceptable to the CDC.
  - Alarm for out-of-range temperatures
  - Low battery indicator
  - Accuracy of +/- 1°F (0.5°C)
  - Memory Storage of at least 4000 readings
  - User programmable logging interval (or reading rate)

Each digital data logger or thermometer must have a current and valid Certificate of Calibration Testing (or Reports of Calibration Testing). Calibration testing must be performed by a laboratory accredited by an ILAC MRA signatory body or an entity that provides documentation demonstrating the calibration testing performed meets **ISO/IEC 17025 International standards** for calibration testing and traceability.

*Note: In 2018, the CDC will require all VFC providers to use a certified, calibrated continuous data logger with the above capabilities.*

2. Data Logger Purpose: Provides detailed information on all temperatures recorded at preset intervals between fifteen minutes and one hour. Temperatures are considered accurate, barring failure of the device. Unless the device has apparently failed, we use the data logger recordings to define the duration and extent of a temperature excursion and to determine whether the vaccine is still usable. For the common Fridge Tag 2 device, a PDF record of the logged temperatures is produced by plugging the device into any USB port on any computer.
3. Settings: The Fridge Tag 2 digital data loggers currently in use record temperatures every 15 minutes. Alarm triggers have already been preset by the manufacturer. The alarm settings (see below) are designed to indicate a too cold

refrigerator excursion of 15 consecutive minutes, and a too warm refrigerator excursion of 60 consecutive minutes. The freezer alarms are set to show a too warm excursion of 60 consecutive minutes. These settings cannot be changed in this model. Refer to procedure guidance for definitions of when an excursion is reportable. Clinics using other brands of data loggers should refer to their settings.

Celsius Alarm	Duration	Temperature	Alarm Type
<b>Ref.</b>	00:60	8.0	HI
	00:15	2.0	LO
<b>Freezer</b>	00:60	-15.0	HI

Fahrenheit Alarm	Duration	Temperature	Alarm Type
<b>Ref.</b>	00:60	46.0	HI
	00:15	35.6	LO
<b>Freezer</b>	00:60	5.0	HI

Note: The Fridge Tag2 has a removable wire probe leading to the digital data logger. The wire should enter the unit on the hinge side, high in the corner. Tape the wire in the doorframe with thin clear packing tape to ensure a good seal. Secure the glycol **probe in the center of the unit** using Velcro to secure to shelving or by placing it in a paper cup.

#### D. Back-up Thermometer

1. Requirement: Effective January 2015, the CDC requires all VFC providers to have at least one backup thermometer with a valid and current certificate of calibration **readily available** to ensure that temperature assessment and recordings can be performed twice a day.
2. Purpose: Backup thermometers must be readily available in case a thermometer in use is no longer working appropriately, if emergency transport is required or if the current data logger must be disconnected for calibration testing.
3. Note: CDC recommends that the backup thermometer be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.

## Section 2. Temperature Monitoring Procedures

Temperature monitoring is the primary responsibility of the vaccine coordinator and back-up coordinator. Designated staff must **review temperatures** within each vaccine storage unit **two times each day** (beginning and end). This review must be documented, as should any actions that are taken if the temperatures readings are out of acceptable range.

The refrigerator should maintain temperatures between 36°F and 46°F (2°C and 8°C). Set the temperature mid-range to **achieve an average of 40°F (5°C)**. The freezer should maintain temperatures between -58°F and +5°F (-50°C and -15°C).

#### A. Daily Temperature Monitoring Procedures for Fridge Tag2

If you are using a type of digital data logger other than the Fridge Tag2, review your device manual for instructions on reviewing temperatures and downloading temperature logs. Regardless of the system, the basics of the process below should still be followed to meet requirements of the VFC program. Always contact TIP for guidance prior to using vaccine after any reportable temperature excursion.

**Morning and Afternoon (twice each day):**

1. When the clinic opens, **record the temperature check** in each storage unit by pushing the “read” button on the refrigerator and the freezer units *three times*. Write the time and date of each reading, the initials of person who recorded the reading and whether any new alarms were present on each unit’s Digital Data Logger Sign-off Sheet.
  - a. Look for alarm issues by quickly scanning the lower left hand corner of the device for the **X** and triangle **Δ** symbols indicating an alarm has occurred: If an alarm has occurred, **Press the “Read” button four times to get the information you need about the excursion and to clear the alarm**. Each time you press “Read”, you will get new information (see below) Note: The X symbol can come back in the same day if the problem persists.
    1. The *first* press of the “Read” button the display will show the temperature at the time of the excursion.
    2. The *second* press of the “Read” button will display the date and time of temperature excursion.
    3. The *third* press of the “Read” button will display the duration of the temperature excursion.
    4. The *fourth* press of the “Read” button will clear the alarm.
    5. For *any* new alarm, then refer to the **Temperature Excursion** section (page 8) of this document.
  - b. If no alarm is present (all is normal), make a brief visual inspection of the unit (and correct problems if found):
    - Food and drinks NOT stored in any refrigerator or freezer used for vaccine storage.
    - Vaccine NOT stored in the doors, drawers, or floor of refrigerator or freezer.
    - Vaccines are stacked with at least one inch of air space between the stacks and two inches between stacks and walls of the unit so air can circulate around the vaccines
    - Store bottles of water in the lowest compartment of the refrigerator and in the doors. If space permits, add extra ice packs (a good choice is frozen water bottles, easily usable in case of emergency transport) in the freezer to help maintain temperatures in case of a power outage.

- VFC vaccines are clearly labeled and separated from privately purchased vaccine for easy identification.

**Afternoon: Repeat the above steps about an hour before closing.** We recommend that you not wait until the very end of clinic in case a problem is found and you need consultation. TIP staff is unavailable after 4:30PM Central Time on weekdays, except in case of emergency.

#### **A. Weekly Vaccine Monitoring Activity:**

1. The VFC Contact or their Back-up *reviews the Digital Data Logger Sign-off Sheet for each unit* to ensure that the unit was checked twice each clinic day and any new alarms were documented.
2. *Download the data logger report* from the Fridge Tag2 onto a computer (by connecting it to the USB port in any computer) on the same day each week.
  - a. An alarm will occur if the Fridge Tag2 is disconnected from the probe for more than 10 minutes. If this happens, note it and clear the alarm.
3. **Print** the PDF version of the digital data logger report and **sign** the comments section to show that the weekly report was reviewed. Signatures on each day are *not* necessary. This is only to confirm that the report was reviewed for the week.
  - a. Note any alarms on the logger report and whether staff responded appropriately. All information about a TE, including the data logger report and any follow up, should be filed with the temperature logs for the unit and retained for three years.
4. At this time, **review your vaccine inventory and ensure vaccines with the shortest expiration dates in the front to be used first.**

#### **B. Monthly Vaccine Monitoring Activities:**

1. Visually check storage units for correct vaccine and probe placement.
2. Inspect the storage units for cleanliness. Follow the manufacturer's maintenance schedule for the storage unit. Replace the Digital Data Logger Sign-off Sheet for each storage unit. File the completed sheet with the PDF temperature logs for each unit. These documents are required to be maintained for three years.
3. Review vaccine inventory and *notify TIP* if there is any VFC vaccine with short expiration dates (expiring within 90 days from the current date) that you will not be able to use before expiration. **Vaccine Inventory Reconciliation is done every month even if vaccine is not ordered.**

#### **C. Monitoring Temperatures with a Min/Max Digital Thermometer**

1. Manual record daily temperature readings on temperature log. Temperature documentation must contain: (1) at least two temperature readings per day, (2) the minimum and maximum temperature should be recorded in the

- morning reading (3) the time and date of each reading and (4) the name (or initials) of the person who assessed and recorded the reading. Temperature logs are available in the Documents section on the TennIIS website.
2. The temperature log must be posted on each vaccine storage unit or nearby in a readily accessible and visible location.
  3. **If temperature is out-of-range**, follow proper steps for responding to a temperature excursion and **contact TIP immediately (or immediately on the next business day)** for evaluation. **Do not use vaccine** until TIP staff have evaluated the excursion and determined usability.
  4. Temperature logs are required to be maintained for three years.
  5. **Once every week:** review your vaccine inventory and ensure vaccines with the shortest expiration dates in the front to be used first.
  6. **Once every month:** review vaccine inventory and notify TIP if there is any VFC vaccine with short expiration dates (expiring within 90 days from the current date) that you will not be able to use before expiration. Vaccine Inventory Reconciliation is done every month *even if vaccine is not ordered*.

Note: The temperature logs are being updated to include the minimum and maximum temperature readings and will be available in March 2016.

## Section 3. Temperature Excursions

### A. Definitions: Three Levels of Temperature Excursions (“TEs”)

Temperature Excursion: Any time the temperature in a refrigerator unit is outside 2.0°C through 8.0°C (36° through 46°F) or the temperature in a freezer unit is above -15°C (5°F).

1. **Level 1: Non-Reportable Temperature Excursion:** An unavoidable brief time outside the routine recommended ranges that does not necessitate further inquiry. These are often readily explainable (loading or counting inventory, brief defrost cycle, short power outage or door left ajar). Further description is located in the Temperature Excursions Procedures section.
2. **Level 2: Reportable Temperature Excursion:** A TE that could possibly compromise vaccine and should be reported to the Tennessee Immunization Program (TIP) Quality Assurance (QA) Team for further evaluation before any affected vaccine is used. Vaccine should be quarantined immediately with a “Do Not Use Until Notified by TIP” sign. **A reportable TE will not necessarily require calls to manufacturers or action or result in waste of vaccine. However, they do require evaluation by TIP.** Further description is located in the Temperature Excursions Procedures section.
3. **Level 3: Actionable Temperature Excursion:** TEs that require actions, including waste of certain affected vaccines, transfer of vaccines,

replacement or repair of storage unit. Not all reportable TEs end up requiring action.

## **B. Reportable Temperature Excursion Procedures**

1. Is this a **reportable** temperature excursion? Yes, if it meets **any one** of the five criteria below:
  - a. Refrigerator temperature dipped below 2.0°C (36°F) for 15 consecutive minutes (or longer).
    - Freezing temperatures below 0°C (32°F) quickly damage vaccine. Quick intervention may be necessary to save vaccine if temperature begins to get too cold.
  - b. Refrigerator was above 8.0°C (46°F) for at least 60 consecutive minutes.
  - c. Freezer temperature above -15°C (5°F) for more than 60 consecutive minutes.
    - Routine defrost cycles may go above -15°C (5°F) for less than 60 minutes. There is vaccine stability data to support these types of excursions.
  - d. TE is part of a pattern of frequent excursions, regardless of duration.
  - e. You are concerned about TE even though it doesn't meet above criteria.
  
2. Reporting Temperature Excursions **During Business Hours**: Monday – Friday (8:00AM – 4:30PM Central Time):
  - a. If TE is still occurring (temperatures are currently out of range) take the following steps to restore proper storage conditions.
    - Quarantine vaccine; label "Do Not Use until Notified by TIP".
    - Immediately call TIP QA team at 800-404-3006. If the call is not answered, call the CEDEP main desk at 615-741-7247 and ask the receptionist to locate someone in TIP.
    - Check to see if the storage unit is unplugged
    - Check to see if the storage unit door is open and is sealed adequately
    - Check the thermostat setting
    - Check location of the probe; should be in the middle of the unit with the vaccine
    - Check the coils and vents for dust
    - If instructed by TIP, follow your Emergency Storage and Handling Plan posted on or beside the storage unit. If storage unit cannot be used, transfer vaccine to the designated back up location.

- Download temperature log from digital data logger or document current temperature reading on temperature log
  - Note how long the temperature was out of range
  - Note the minimum and maximum temperatures
  - Fax data logger report or temperature log to 615-401-6829
- b. If temperature is currently *in range* complete the following steps:
- Quarantine vaccine; label “Do Not Use until Notified by TIP”.
  - Immediately call TIP QA team at 800-404-3006. If the call is not answered promptly, call the CEDEP main desk at 615-741-7247 and ask the receptionist to locate someone in TIP.
  - Download temperature log from digital data logger or document current temperature reading on temperature log
  - Note how long the temperature was out of range
  - Note the maximum and minimum temperatures
  - Fax data logger report or temperature log to 615-401-6829
- c. **If experiencing a power outage**, contact utility company. **If restoration is expected within four hours, do not move vaccine.** Keep the door closed and monitor temperature. This brief TE may be less harmful than transporting vaccine. If power outage is going to last more than four hours, follow your Emergency Storage and Handling Plan.
- d. TIP QA team will take necessary information and if needed, follow up with vaccine manufacturers.
- TIP QA team will follow up on each reportable TE by phone with the clinic staff person and possibly with a brief email summary of the event and guidance on standard template that can be filed with the unit temperature logs.
  - If the TE results in transferring vaccine to another location, the clinic staff will follow the steps for packing and monitoring that are detailed in the current Emergency Storage and Handling Plan posted on or near the storage unit.
  - **Do not use any vaccine until approved by TIP.**
3. Reporting Temperature Excursion **After Business Hours:**
- a. Quarantine vaccine; label “Do Not Use until Notified by TIP”.
  - b. Download data logger report and review.
  - c. Check to see if the storage unit is unplugged
  - d. Check to see if the storage unit door is open and is sealed adequately
  - e. Check the thermostat setting
  - f. Check location of the probe; should be in the middle of the unit with the vaccine

- g. Check the coils and vents for dust
- h. Follow the Emergency Storage and Handling Plan posted on or near the unit.
  - a. If storage unit is not currently in range and the problem is such that it cannot be reliably and promptly returned to proper temperatures, consider transferring vaccine to the designated back up location listed in your Emergency Storage and Handling Plan.
- e. Remember: **If experiencing a power outage**, contact utility company. **If restoration is expected within four hours, do not move vaccine.** Keep the door closed and monitor temperature. This brief TE may be less harmful than transporting vaccine. If power outage is going to last more than four hours, follow your Emergency Storage and Handling Plan.
- e. **As soon as TIP offices open** (8AM Central Time), the next business day contact the TIP QA staff to report TE.
- i. If guidance is needed about vaccine use *before* the next business day contact TIP at 615-741-7247 or 800-404-3006.
  - The on-call senior epidemiologist for CEDEP will provide a basic consultation but will *not* provide advice on the viability of the vaccine. In emergencies where vaccine must be used before business hours (e.g., newborn nursery in a hospital), Dr. Kelly Moore will be contacted for further consultation.

### **C. Non-Reportable Temperature Excursion Procedure**

- a. Clear the alarm on the digital data logger (Press "Read" 4 times, if using a Fridge Tag 2 data logger, see daily vaccine monitoring instructions for details).
- b. Initial and record time on the Digital Data Logger Sign-off Sheet and indicate "yes" new alarm was noted.
- c. Write "non-reportable" on PDF of data logger report that was reviewed to evaluate alarm
- d. File the data logger report with the other temperature logs for that unit and maintain for three years
- e. No further action necessary

## Resources and References

1. CDC's Vaccine Storage and Handling Toolkit  
<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>
2. Routine Vaccine Management Tool: Non-Health Department  
[http://www.tn.gov/assets/entities/health/attachments/2016\\_RoutineVaccineManagementToolPrivateProvider.pdf](http://www.tn.gov/assets/entities/health/attachments/2016_RoutineVaccineManagementToolPrivateProvider.pdf)
3. Fahrenheit (°F) Temperature Log  
[http://www.tn.gov/assets/entities/health/attachments/Fahrenheit\\_Refrigerator\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Fahrenheit_Refrigerator_Temperature_Logs.pdf)  
  
[http://www.tn.gov/assets/entities/health/attachments/Fahrenheit\\_Freezer\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Fahrenheit_Freezer_Temperature_Logs.pdf)
4. Celsius (°C) Temperature Log  
[http://www.tn.gov/assets/entities/health/attachments/Celsius\\_Refrigerator\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Celsius_Refrigerator_Temperature_Logs.pdf)  
  
[http://www.tn.gov/assets/entities/health/attachments/Celsius\\_Freezer\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Celsius_Freezer_Temperature_Logs.pdf)
5. Packing Vaccines for Transport during Emergencies  
<http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>

## Vaccine Storage Unit Digital Data Logger Sign-off Sheet

Vaccine storage temperatures must be checked twice each day when the clinic is open. After checking, note the time and your name/initials below, and check if a new alarm signal was present. Follow appropriate procedures to evaluate whether a new alarm signal was present. Follow appropriate procedures to evaluate a new alarm and document follow-up on the data logger print out.

**Clear the alarm on the data logger.**

**UNIT (circle): R or F    VFC PIN #: \_\_\_\_\_    UNIT LOCATION: \_\_\_\_\_    MONTH/YR: \_\_\_\_\_**

Day of Month	MORNING (AM)				AFTERNOON (PM)			
	Time	Name or initials	New Alarm?  (Circle)		Time	Name or Initials	New Alarm?  (Circle)	
1			Y	N			Y	N
2			Y	N			Y	N
3			Y	N			Y	N
4			Y	N			Y	N
5			Y	N			Y	N
6			Y	N			Y	N
7			Y	N			Y	N
8			Y	N			Y	N
9			Y	N			Y	N
10			Y	N			Y	N
11			Y	N			Y	N
12			Y	N			Y	N
13			Y	N			Y	N
14			Y	N			Y	N
15			Y	N			Y	N
16			Y	N			Y	N
17			Y	N			Y	N
18			Y	N			Y	N
19			Y	N			Y	N
20			Y	N			Y	N
21			Y	N			Y	N
22			Y	N			Y	N
23			Y	N			Y	N
24			Y	N			Y	N
25			Y	N			Y	N
26			Y	N			Y	N
27			Y	N			Y	N
28			Y	N			Y	N
29			Y	N			Y	N
30			Y	N			Y	N
31			Y	N			Y	N

Documentation is required by the federal Vaccines for Children Program. File in paper form or scan and save electronically along with the corresponding month's data logger reports for the unit. Retain for three years.

TN Immunization Program Phone: 800-404-3006 or 615-741-7247

