

### Update Regarding Refrigerated Vaccine Temperature Ranges

All vaccines supplied by the Philadelphia Vaccine for Children (VFC) and the Vaccines for Adults at Risk Program (VFAAR) must be stored in accordance with the CDC's new Fahrenheit temperature range. The new required Fahrenheit temperature range is between **36°F and 46°F** (previously between 35°F and 46°F). The Celsius temperature range (between 2°C and 8°C) remains unchanged.

By February 27<sup>th</sup>, 2017 Philadelphia VFC/VFAAR facilities using Fahrenheit temperature monitoring should begin documenting refrigerated temperatures by using the revised temperature log that is attached to this announcement and available at <https://vax.phila.gov>.

By March 2017, all VFC/VFAAR providers will be required to follow the new Fahrenheit temperature range of 36°F to 46°F.

Philadelphia has created a new manual temperature log to comply with these changes. Along with the change in temperature range, we have also added the following:

1. A new section to document the daily minimum and maximum temperature.
  - Minimum and maximum temperatures should be documented at the start of each clinic day.
  - If you would like assistance with finding your minimum and maximum temperatures using your thermometer, please contact Adam Howsare or Alexis Bridges at 215-685-6777 or [tempcheck@phila.gov](mailto:tempcheck@phila.gov)
2. The monitoring for the refrigerator and freezer are now on separate pages. The previous temperature log allowed sites to record refrigerator and freezer temperatures on the same page.
3. All out of range temperatures should be recorded at the bottom of the temperature log. You should note the temperature and take action by contacting the Philadelphia Immunization Program's Storage and Handling team at [tempcheck@phila.gov](mailto:tempcheck@phila.gov).

The frequently asked questions (FAQ) document can be found at [Q&A - Adjustment to CDC's Recommended Fahrenheit Temperature Range for Refrigerated Vaccine Storage](#).

The updated Vaccine Storage and Handling Toolkit, released in June 2016 reflects the adjusted Fahrenheit temperature range and can be accessed at <http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>.

If you have questions, please contact Storage and Handling at [tempcheck@phila.gov](mailto:tempcheck@phila.gov).

# VFC & VFAAR

## Storage and Handling Guide



### Storage and Handling FAQ

**1. What are the new temperature ranges for the refrigerator?**

The CDC recently updated the acceptable Fahrenheit temperature range for all refrigerated vaccines to 36-46°F. Celsius remains unchanged at 2-8°C. A member of the Storage and Handling team will be visiting your site to program your digital data loggers with the updated temperature ranges.

**2. Is there a revised temperature log for manually recording temperatures?**

Yes. Revised temperature logs can be found at <https://vax.phila.gov>. The temperature logs are updated with the revised ranges and min/max fields. The revised logs require that the refrigerator and freezer temperatures are recorded on separate pages, in accordance to our January 2016 guidance requiring standalone freezers.

**3. Why are Digital Data Loggers (DDLs) required? What makes them different than other thermometers?**

Digital Data Loggers provide 24/7 temperature monitoring. They are taking a temperature every 6 minutes, which gives a more accurate picture of what is happening in the storage unit. In the event of a temperature excursion, sites will be able to give vaccine manufacturers precise information regarding the temperature and length of excursion. The Immunization Program supplies a limited amount of DDLs to providers. These DDLs cost the health department about \$110 each and about \$40 for maintenance. The DDLs that are used by the health department are in line with strict CDC requirements and standards for DDLs.

**4. What happens if I do not send in my temperature readings?**

Monitoring reports/logs should be submitted to PDPH on a monthly basis and/or every time a provider orders – whichever is more frequent. Failure to routinely submit temperature readings can delay future orders, and potentially lead to removal of any VFC/VFAAR vaccines currently held by your clinic.

**5. How do I know if my refrigerator/freezer went out of range?**

Digital Data Loggers have a visual alarm that is shown above and below the temperature reading (some DDLs will have audible alarms as well). If you see the word **“ALARM”** above the temperature reading or in a black box below the temperature, or an **X** symbol, then the storage unit has experienced an excursion. It is your responsibility to download and e-mail the data to VFC at [tempcheck@phila.gov](mailto:tempcheck@phila.gov) as soon as you see it. The alarm will remain on the data logger until you download and reset it. When you see an alarm, whether during your twice daily checks or any other time, download the data and send it to TempCheck. VFC will reply with an action plan. For providers that use calibrated thermometers, the reading display will give you a temperature reading and the MIN/MAX will also alert you to the highest and lowest reading within a 24hr period. If you have an excursion, contact TempCheck and submit your temperature logs.

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### 6. What is the protocol for responding to excursions?

- **Label exposed vaccine “do not use,”** and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed by the Philadelphia Immunization Program.
- **Record the out-of-range temperatures and the room temperature** in the “Action” area on the bottom of your updated temperature log sheet.
- **Notify your vaccine coordinator** or call the Philadelphia Immunization Program for guidance.
- **Document all action taken.**
- **Contact TempCheck immediately** at [TempCheck@phila.gov](mailto:TempCheck@phila.gov).

For some storage unit excursions, the VFC program will require that you contact the vaccine manufacturers and complete an [Emergency Response Form](#). **This step is crucial**, the form documents if the vaccines are viable. This information must come directly from the manufacturers and sites are required to provide a case number for each manufacturer. VFC staff will audit these forms. A new form is required every time you report an excursion event. The viability of the vaccine depends on a number of factors such as time, temperature, lot number, and vaccine type. In addition, the vaccine manufacturers are constantly testing their vaccines for viability. Recommendations may change depending on any new data they receive. **DO NOT** assume viability of vaccines, always contact the manufacturer.

### 7. Oh No! My vaccines aren't viable, what do I do now?

In the event that the manufacturer determines that vaccines are no longer viable, the VFC coordinator will follow-up with you regarding next steps and possible reimbursement of vaccines. The following steps need to be completed:

1. Complete your Emergency Response Form and fax it to Philadelphia Immunization Program at 215-238-6948.
2. Contact [dphproviderhelp@phila.gov](mailto:dphproviderhelp@phila.gov) for assistance with utilizing the returns module on PhilaVax to return any spoiled vaccine.

### 8. Can I use water bottles in my refrigerator?

We always recommend utilizing water bottles in your refrigerator to maintain a constant temperature. The only exception is if you are using a pharmacy grade refrigerator that specifically says otherwise.

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### 9. I need to defrost my freezer, what is the process?

Storage units, particularly freezers, can build up an excess of ice. Always inform VFC when you are planning to defrost a storage unit. When defrosting units storing VFC/VFAAR vaccines, please do the following:

1. Contact [tempcheck@phila.gov](mailto:tempcheck@phila.gov) and notify them that you will be defrosting your unit. Leave the data logger in the unit during the defrost process.
2. Place your back-up thermometer in the secondary unit where you plan to move the vaccines for one hour. Ensure that the temperature is within range before you move vaccines to this temporary storage location. This could be your back-up unit or another unit in the practice.
3. Transfer the vaccines to the secondary storage unit.
4. Make a note of when you start the defrost process. The data logger probe will warm up with the defrosting storage unit, which will trigger an alarm.
5. Follow the defrosting instructions for your specific freezer. Once the defrost process is complete, wait until the data logger shows that the temperature is back into normal range.
6. Transfer the vaccines back into the freezer.
7. Download the data from the data logger and e-mail it to us. Include when you started and stopped the defrost process.
8. Reconnect and restart the data logger and monitor for any future alarms.

### 10. What is a back-up thermometer?

Every VFC/VFAAR provider is supplied a digital Hi/Lo thermometer. These thermometers were mailed in June 2015 or delivered by your VFC Nurse. You should use this thermometer only if your primary thermometer breaks or fails in some way. You will use the backup thermometer for your paper logs until we can come out and fix the issue. If you do not have a backup thermometer, please contact TempCheck and we will provide one for you.

### 11. What about dial/built-in thermometers? Can they be used?

Many refrigerators come with a dial or built in thermometer. Some providers like to place this thermometer in the storage unit as a sort of “backup” to the Digital Data Loggers or the digital Hi/Low thermometers. Dial and Built-In thermometers are inaccurate and cannot be used to monitor temperatures. They do not meet the CDC’s temperature monitoring requirements. These thermometers cannot be used to record temperatures on your paper logs, or to confirm the accuracy of VFC thermometers as they have not been calibrated, most do not contain glycol probes, and do not give you a digital reading of the temperature. While some built-in thermometers might meet the CDC’s stringent requirements you must first contact TempCheck to verify their approval. In the event of an excursion, the VFC program will only accept readings from a digital Hi/Low thermometer or a Digital Data Logger.

# VFC & VFAAR

## Storage and Handling Guide



### 12. BACK UP LOCATION

Every VFC/VFAAR provider is required to have an off-site backup location in the event of power outages and equipment malfunctions. This information should be submitted when completing your enrollment form for the VFC program. Here is a list of approved and non-approved locations.

- | <b>1. <u>Approved</u></b>  | <b><u>Non-approved</u></b>      |
|--|---------------------------------|
| 2. Pharmacies  | At Home                         |
| 3. Doctor's offices  | Combination units               |
| 4. Partnering Sites  | Personal deep freezers          |
| 5. Other clinics   | Storage containers with dry ice |
| 6. <b><i>Contact VFC to see if your back-up location is approved</i></b> |                                 |

#### **IMPORTANT THINGS TO REMEMBER:**

Do not use extension cords or surge protectors to plug up your unit. All units should be plugged directly into a wall outlet.

Ensure that the unit, plug, and circuit breaker are clearly labeled to prevent loss of power.

Units should not be moved inside the office without contacting VFC.

Always turn off your Digital Data Logger before disconnecting and reconnecting it.

#### **Contact Information**

[TempCheck@phila.gov](mailto:TempCheck@phila.gov)

Alexis Bridges and Adam Howsare

215-685-6777

# VFC & VFAAR

## Storage and Handling Guide



DEPARTMENT OF  
PUBLIC HEALTH



### Temperature Log for Freezer – Fahrenheit

DAYS 1-15

Month/Year \_\_\_\_\_ VFC or VFAAR PIN \_\_\_\_\_ Page 1 of 2

Facility Name \_\_\_\_\_ Room \_\_\_\_\_

#### Monitor temperatures closely!

1. Monitor storage temperatures with a certified, calibrated digital data logger.
2. Write your initials below in "Staff Initials," and note the time in "Exact Time."
3. Record temps twice each workday.
4. Record the min/max temps once each workday – in the morning.
5. Put an "X" in the row that corresponds to the freezer's temperature.
6. If any out-of-range temp, see instructions to the right.
7. After each month has ended, save each month's log for 3 years.

#### Take action if temp is out of range – too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed by the Philadelphia Immunization Program.
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the Philadelphia Immunization Program for guidance.
4. Document all action taken.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials	MN MN														
Exact Time	AM PM														
Min/Max Temp (since previous reading)	-3° 4°														
<b>Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call the Immunization Program immediately!</b>															
ACCEPTABLE TEMPERATURES	5°F														
	4°F														
	3°F														
	2°F														
	1°F														
	0°F														
	-1°F	X													
	-2°F														
	-3°F														
	-4°F														
-58°F to -5°F															
ACTION	Write any out-of-range temps (above 5°F or below -58°F) here.	10°													
	Room Temperature	70°													

If you have a vaccine storage issue contact the Philadelphia Immunization Program immediately. For VFC: 215-685-6424. For VFAAR: 215-685-6837.

September 2016 FAX: 215-238-6939 OR MAIL: Immunization Program 500 S. Broad St., Basement Philadelphia, PA 19146 <http://kids.phila.gov/>

### How to Use the Temperature Log: Temperature Logs must be utilized along with certified, calibrated digital data loggers to monitor storage temperature. Please go to the Storage and Handling Kit at [CDC.gov](http://CDC.gov) for more information.

1. Record the min/max temperatures at the start of each clinic day.
  - a. Initial and write in the exact time the DDL was checked. Place an X next to the temperature reading at the time of each recording.
  - b. If using a **Digital Thermometer** remember to **reset** your minimum and maximum after documenting your temperatures at the start of each clinic day by either pressing '**memory clear**' on certain thermometers or '**min reset**' and '**max reset**' on more current models. If using a **Digital Data Logger** press the review button **twice** to obtain both your minimum and maximum temperatures.
  - c. If you have any questions please contact TempCheck at [tempcheck@phila.gov](mailto:tempcheck@phila.gov)

**Out of Range Temperatures:** Take action if your temperature readings are out of range. Label exposed vaccines "do not use", and store them under proper conditions as quickly as possible. DO NOT discard vaccines unless directed by the Philadelphia Immunization Program.

2. Record the **out-of-range temperatures** and the **room temperature** in the **Action** section on the bottom of the log.
3. Notify your vaccine coordinator and call the Philadelphia Immunization Program for guidance at **215-685-6424**.
4. Document all action taken.