Temperature Monitoring

1. Temperature ranges

Vaccines must be stored within these ranges:

- Refrigerator: Store between 2.0°C to 8.0°C or 36.0°F to 46.0°F.
- Freezer: Store between -15.0°C to -50.0°C or 5.0°F to -58.0°F.

Any temperature reading outside of the above ranges is a temperature excursion. Exposure to out-of-range temperatures can affect the vaccine and lead to vaccine losses and/or revaccination if administered. **All excursions require follow-up;** requirements are outlined in the temperature excursion section.

2. Temperature review and documentation

Daily temperature review

Daily temperature review of each storage unit is required. The VFC program requires reviewing and documenting the minimum and maximum temperature readings at the beginning of every clinic day. Providers are required to have protocols for reviewing and recording temperature readings in vaccine storage units daily. The process, at a minimum, should include:

- Checking temperatures at the beginning of the clinic day.
- Documenting the minimum and maximum temperatures and then resetting the unit if needed.
- Documenting the current date, time, and name (initials) of the person checking the temperatures.
- Acting if a temperature excursion is identified.

Temperatures should be documented to the tenth decimal place.

5.4°C or 39.3°F

Do not round temperatures to a whole number, especially to determine if an excursion occurred. Due to differences among manufacturer stability reports and rounding, do not apply general rounding rules.

Daily temperature review can be paper-based or electronic. If your system can document the current date, time, and person who checked the temperatures along with the minimum and maximum temperature, electronic documentation is acceptable.

Monitoring the minimum and maximum temperature

This provides the highest and lowest temperature reached since the device was last checked and cleared. Some devices require you to physically reset the minimum and maximum temperatures— this should be done after each reading in the morning. **Not resetting the unit after each reading could cause inaccurate monitoring and leave the vaccine vulnerable to out-of-range temperatures.**

Some devices automatically reset the minimum and maximum temperature at a set time such as at midnight. **It is important that all providers understand the features of your device.**

This image shows an example of acceptable daily temperature monitoring.

For each clinic day, the provider documented the minimum and maximum temperature as well as their initials, date, and time.
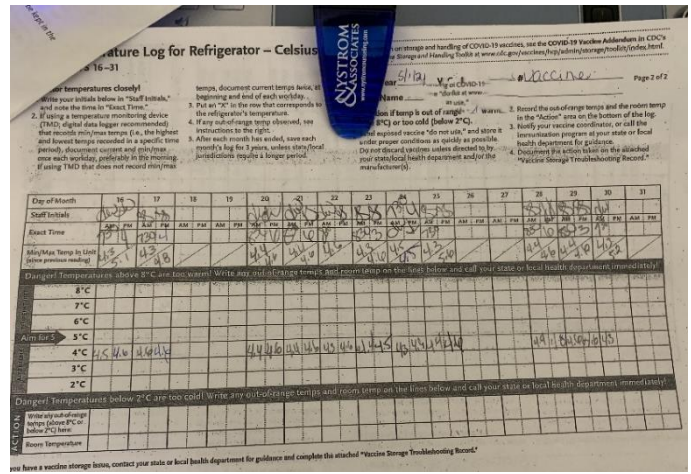
Weekly or monthly temperature review

Temperature data from the DDL must be downloaded and reviewed weekly or monthly and when a temperature excursion is identified. It is recommended and best practice to download and review the data weekly; however, it must be downloaded and reviewed, at a minimum, monthly. The logs should be reviewed for temperature excursions that were missed or temperature trends that could indicate a storage unit performance issue. It is recommended to compare daily temperature checks with data downloads to ensure accurate and complete temperature monitoring. These logs should be kept for a minimum of three years, the same as the paper temperature logs.

Looking for temperature log templates?
- Refrigeration – Fahrenheit
- Refrigeration – Celsius
- Freezer – Fahrenheit
- Freezer – Celsius

Best practice for temperature monitoring is to set up the logging interval at 30 minutes. A longer interval time may increase the likelihood that a temperature excursion could be missed. All investigations regarding a possible excursion must be documented.

Example of data download

In the downloaded data you can see a reading is provided every 30 minutes in one and every 15 minutes in the other. Every system will look different, but for the system to meet VFC requirements it must have the ability to generate a similar report as seen in the examples.

P2	Time	Date
4.7 --.--	8:30	4/12/2024
4.72 --.--	8:15	4/12/2024
4.72 --.--	8:00	4/12/2024
4.71 --.--	7:45	4/12/2024
4.72 --.--	7:30	4/12/2024
4.71 --.--	7:15	4/12/2024
4.71 --.--	7:00	4/12/2024
4.75 --.--	6:45	4/12/2024
4.71 --.--	6:30	4/12/2024
4.72 --.--	6:15	4/12/2024
4.73 --.--	6:00	4/12/2024
4.71 --.--	5:45	4/12/2024
4.72 --.--	5:30	4/12/2024
4.73 --.--	5:15	4/12/2024
4.71 --.--	5:00	4/12/2024
4.74 --.--	4:45	4/12/2024
4.73 --.--	4:30	4/12/2024
4.73 --.--	4:15	4/12/2024
4.74 --.--	4:00	4/12/2024

	A	B	C	D
1	Log Time	Temperature (℃)	Temperature2 (℃)	
2	2024-03-18 00:06:04	3.9	3.8	
3	2024-03-18 00:36:04	4.1	4.0	
4	2024-03-18 01:06:04	4.2	4.1	
5	2024-03-18 01:36:04	3.7	3.6	
6	2024-03-18 02:06:04	3.5	3.4	
7	2024-03-18 02:36:04	3.7	3.7	
8	2024-03-18 03:06:04	3.8	3.7	
9	2024-03-18 03:36:04	3.8	3.7	
10	2024-03-18 04:06:04	4.2	4.1	
11	2024-03-18 04:36:04	4.3	4.2	
12	2024-03-18 05:06:04	3.9	3.8	
13	2024-03-18 05:36:04	3.7	3.6	
14	2024-03-18 06:06:04	3.8	3.6	
15	2024-03-18 06:36:04	3.5	3.4	
16	2024-03-18 07:06:04	4.0	3.9	
17	2024-03-18 07:36:04	4.2	4.1	

3. Temperature excursions

What is a temperature excursion?

A temperature excursion refers to any storage temperature outside the recommended range for a vaccine.

	Low temperature	High temperature
Refrigerator	1.9°C or colder (35.9°F)	8.1°C or warmer (46.1°F)
Freezer	-50.1°C or colder (-58.1°F)	-14.9°C or warmer (5.1°F)

How to identify and respond to a temperature excursion?

Situations	Examples	Steps to Take
Situation 1: **The unit is currently out of range and the DDL alarm is on.**	*It is a busy clinic day and staff have been in and out of the refrigerator all morning. During the afternoon you start to complete your weekly physical vaccine inventory. Within 10 minutes of starting, the DDL alarm goes off and you record the temperature at 8.2°C.*	Begin to stabilize temperatures in the storage unit. Examples of actions to stabilize temperatures include closing the unit door and checking to ensure a tight seal, checking power supply to the unit, and checking DDL probe placement. Monitor for 30 minutes. If the unit does not return to recommended temperatures, move the vaccines to your back-up storage unit location and begin to follow the instructions to respond to and report a temperature excursion below. If the unit returns to recommended ranges within 30 minutes, document the incident and, if applicable, implement procedures to prevent an excursion in the future.
Situation 2: **The unit is currently in range but the minimum or maximum indicate an out-of-range temperature.**	*During the Monday morning temperature check, the unit's current temperature was 5.4°C but the maximum temperature reading was 10.2°C.*	Begin to follow the instructions to respond to and report a temperature excursion below.

Instructions to respond to and report a temperature excursion

1. Label the vaccine "do not use." This ensures vaccines are not administered while investigating a temperature excursion.
2. Notify the appropriate contacts about the temperature excursion.
3. Obtain and document the details of the excursion.
   a. Download and review the temperature data. Determine the highest and/or lowest temperature and the duration of the excursion.
   b. Collect the vaccine information of all vaccines in the unit (lot number, expiration dates).
   c. Obtain historical data about previous excursions, if appliable.
4. Contact the manufacturer and obtain determination reports. These reports state if the vaccine is still viable.
5. Next steps:
   a. **If the vaccine is still viable**, remove the "do not use" sign and attempt to correct the issue to prevent future excursions. Label the vaccine noting the excursion, as this information will be needed if another excursion occurs. Complete the Wisconsin VFC program's temperature excursion report and send the report, with the determination reports, to the VFC program at vfc@wisconsin.gov.
   b. **If the vaccine is not viable**, remove the non-viable vaccine from the unit to prevent accidental use. Complete the Wisconsin VFC program's temperature excursion report and send the report, with the determination reports, to the VFC program at vfc@wisconsin.gov.

Temperature excursion forms and resources

Temperature Excursion Incident Report, F-02257 (Word)
Vaccine Return - Request for Authorization to Return (wisconsin.gov)
Temperature Excursion Flow Chart
Vaccine Storage Troubleshooting Record
Emergency Response Worksheet