Iowa Vaccines for Children Program
Data Logger Implementation Questions and Answers
Updated January 2018

Q1: Why are Vaccines for Children Program providers required to transition to data loggers?

A: Currently, the CDC recommends the use of a continuous monitoring and recording digital data logger (DDL) with a current and valid Certificate of Calibration Testing (also known as a Report of Calibration), set at a minimum recording interval of at least every 30 minutes. Effective January 1, 2018, the CDC requires all Vaccines for Children providers to use a continuous temperature monitoring device. The device must have a current and valid Certificate of Calibration Testing and an active temperature display, with continuous monitoring and recording capabilities where the data can be routinely downloaded.

Q2: Are VFC Program providers required to use the state-supplied data loggers?

A: No. VFC Program providers are NOT required to use the state-supplied data loggers. However, effective January 1, 2018, VFC Program providers must use a data logger to monitor storage unit temperatures which contain VFC vaccine that meet the CDC requirements of having a current and valid Certificate of Calibration Testing, an active temperature display, and continuous monitoring and recording capabilities where the data can be routinely downloaded.

Q3: How are data loggers different than thermometers?

A: Unlike minimum/maximum thermometers, which only shows the warmest and coldest temperatures reached in a unit since the last temperature check, continuous monitoring and recording DDLs provide detailed information on all temperatures recorded at preset intervals. With the data recorded on a DDL providers will know the exact temperatures reached and the exact amount of time vaccine was exposed to out-of-range temperatures during an excursion.

Q4: How accurate are the state-supplied data loggers.

A: The LogTag Tred30-7 data logger is accurate to ±0.3°C at temperatures between -20°C and 40°C (-4°F to 104°F). At temperatures from -40°C to -20°C (-40°F to -4°F) it is accurate to ±0.5°C. The LogTag VFC 400 is accurate to ±0.3°C at temperatures between -40°C to 40°C (-40°F to 104°F). The LogTag Tred30-7 or VFC 400 will not read temperatures colder than -40°C. The digital min/max thermometers previously supplied by the state were accurate to ±1°C. The Immunization Program does not recommend using the previously supplied thermometers once data loggers are installed due to the difference in accuracy of the two temperature monitoring devices.

Q5: Why do providers have to document storage unit temperatures on a temperature log when using a data logger?

A: The VFC Program requires designated staff to check and record refrigerator and freezer temperatures twice daily (at the beginning and end of each day). Each temperature reading must be accompanied by the time of the reading and the name or initials of the person who assessed and recorded the reading. The state-supplied data logger, like most data loggers, does not have the ability to easily document the name or initials of the individual that checked the temperature at the time of each temperature check.

Q6: Do providers have to print data logger temperature reports?

A: Yes. Temperature reports for each storage unit should be downloaded, reviewed, printed and attached to the temperature log at the 15th and final day of each month. Instructions to print data logger temperature reports are available in the LogTag Instructions-Daily Use document (http://idph.iowa.gov/immtb/immunization/storage). Temperature logs, data logger temperature reports and the Vaccine Storage Troubleshooting Record will be reviewed during VFC site visits.

Q7: The data logger displays storage unit temperatures to the decimal point. Do providers need to document the actual temperature on the temperature log or place an X in the corresponding temperature row?

A: Providers should document the actual temperature to the decimal point in the corresponding temperature row. Temperature readings should be placed in the appropriate row of the leading whole number (Example: 46.8° should be placed in the 46° row).

Q8: What are the temperature alarm settings for data loggers?

A: To coincide with the data logger requirements, new temperature alarm settings will be utilized by the Iowa VFC Program. The new temperature alarm settings are as follows. Instructions to reconfigure temperature alarm settings for the state supplied LogTag TRED30 are available on the Immunization Program, Vaccine Storage and Handling webpage.

Refrigerator	**Freezer**
35.9°F and 46.1°F	5.1°F
1.9°C and 8.1°C	-14.9°C

Q9: How does a provider know if the temperatures are out of range?

A: The data logger will display ALARM above the current temperature when the temperatures have gone out-of-range in the storage unit. The blue Log Tag TRED 30-7R data logger does not have an audible alarm; the red Log Tag VFC 400 does have an audible alarm. The tables below include the temperatures at which the data logger will alarm when the respective duration is reached.

Celsius Alarm	Alarm Type	Temperature	Duration
Refrigerator	Low	1.9°C	30 min
	High	8.1 °C	30 min
Freezer	Low	-40.0 °C	30 min
	High	-14.9 °C	1 hour

Fahrenheit Alarm	Alarm Type	Temperature	Duration
Refrigerator	Low	35.9°F	30 min
	High	46.1 °F	30 min
Freezer	Low	-40.0 °F	30 min
	High	5.1 °F	1 hour

Q10: How will providers know when the alarm has been triggered?

A: VFC Program providers are required to document temperatures on the temperature logs twice a day (AM/PM). During these readings, health care providers should carefully review the data logger display to determine if the alarm has been triggered.

If an alarm has been triggered on the Log Tag TRED 30-7R, the word ALARM will display on the screen above the current temperature. The TRED 30-7R data logger does not have an audible alarm. At the bottom of the screen a blue rectangle will appear that will read TODAY on the first day an ALARM is triggered. When midnight is reached the blue rectangle will say -1d to indicate the alarm was triggered 1 day ago. If the alarm condition is still being met (e.g., the current temperature is still out-of-range) two blue rectangles will be displayed; one will read TODAY, the other will read "-1d" to indicate the alarm was triggered yesterday, and is still being triggered today.

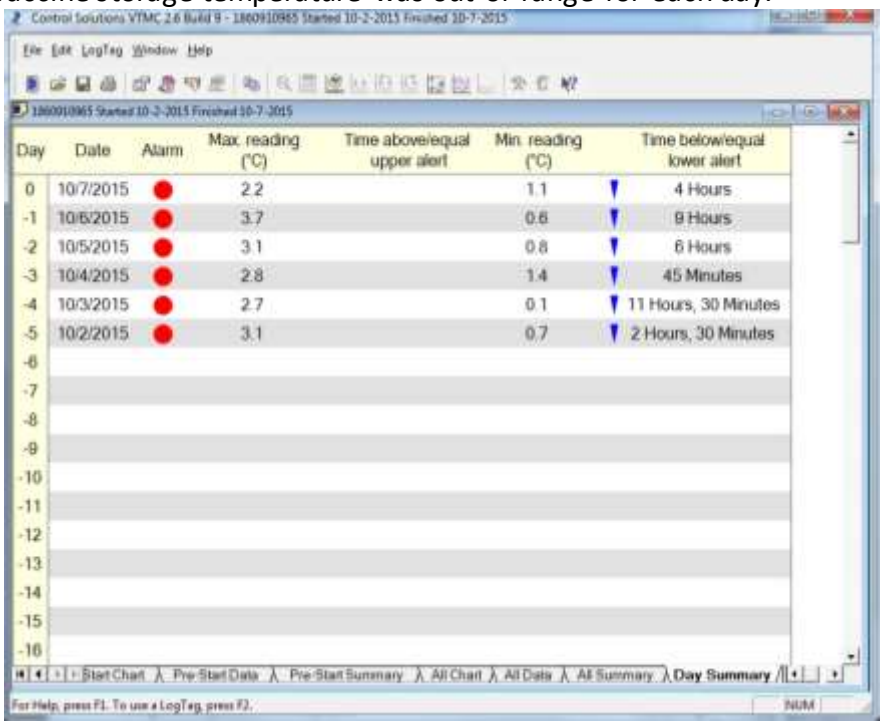
If an alarm has been triggered on the Log Tag VFC 400, an "X" will be displayed, an audible alarm will be heard and a black square will appear at the bottom of the screen indicating when the alarm was triggered.

Q11: What action needs to be taken when an Alarm is triggered?

A: If an alarm has been triggered, the health care provider should immediately store the vaccine appropriately and download the data logger to a computer. Reports can be downloaded by following the steps under Downloading Data in the second page of the Instructions for Daily Use document. Contact the vaccine manufacturers and the Immunization Program. Each date/time an alarm is triggered it is important to document vaccine manufacturers' recommendations about the vaccines' stability on the Emergency Vaccine Response Worksheet and what actions were taken on the Vaccine Storage Troubleshooting Record. Temperature logs, data logger temperature reports and the Vaccine Storage Troubleshooting Record will be reviewed during VFC site visits.

Q12: What information do providers need to have available when contacting vaccine manufacturers about out-of-range temperatures?

A: Health care providers should have available the maximum or minimum temperature the storage unit(s) reached and the cumulative amount of time the vaccines were exposed to out-of-range temperatures. After downloading the data (see Downloading Data in the second page of the Instructions for Daily Use document) select the Day Summary tab at the bottom of the report to obtain this information. The tab includes the amount of time the vaccine storage temperature was out-of-range for each day.



Day	Date	Alarm	Max. reading (°C)	Time above/equal upper alert	Min. reading (°C)	Time below/equal lower alert
0	10/7/2015	●	2.2		1.1	4 Hours
-1	10/6/2015	●	3.7		0.6	9 Hours
-2	10/5/2015	●	3.1		0.8	6 Hours
-3	10/4/2015	●	2.8		1.4	45 Minutes
-4	10/3/2015	●	2.7		0.1	11 Hours, 30 Minutes
-5	10/2/2015	●	3.1		0.7	2 Hours, 30 Minutes
-6						
-7						
-8						
-9						
-10						
-11						
-12						
-13						
-14						
-15						
-16						

Start Chart | Pre-Start Data | Pre-Start Summary | All Chart | All Data | All Summary | Day Summary

For each day the following is displayed:

- Date,
- Whether an alarm was triggered for the day (indicated by a red ●),
- Maximum temperature reached for the day, (a ▲ if the alarm was triggered because of a temperature above the warm threshold or a ▼ if the alarm was triggered because of a temperature below the cold threshold),
- Cumulative time the temperature was at or above the upper limit for the day,
- Minimum temperature reached for the day, (a ▲ if the alarm was triggered because of a temperature above the warm threshold or a ▼ if the alarm was triggered because of a temperature below the cold threshold), and
- Cumulative time the temperature was at or below the upper limit for the day.

If vaccines were previously exposed to out-of-range temperatures, provide this information to the vaccine manufacturers including the previous excursions' total time out-of-range and temperature reached.

Q13: What actions should a VFC Program provider take if the temperature reading of a storage unit is different between the data logger and the previously supplied thermometer?

A: Previous temperature readings when using a *certified calibrated thermometer* should be considered accurate for the time period in which the thermometer was used. When the data logger is implemented, the temperatures readings from the *certified calibrated data logger* should be used. The temperature readings may be different between the temperature monitoring devices. The state-supplied data logger provides a more accurate reading (± 0.3°C). Health care providers may need to adjust storage unit temperatures or purchase a new storage unit to meet vaccine storage and handling requirements. If a new vaccine storage unit is required, health care providers should purchase a purpose built/pharmaceutical grade unit or a stand-alone refrigerator or freezer only unit. Standard household combination refrigerator/freezer units are not the best option to appropriately store vaccine.

Q14: Should I maintain the previously used thermometer and the new data logger to monitor storage unit temperatures?

A: No. Effective January 1, 2018, VFC Program providers must use a data logger to monitor storage unit temperatures which contain VFC vaccine. The state-supplied data logger provides a more accurate reading (± 0.3°C) than the previously supplied thermometer.

Q15: Does recalibration of a data logger using a "master" certified calibrated temperature monitoring device to validate temperatures comply with VFC Certificate of Calibration requirements?

A: No. Recalibration of a temperature monitoring device must be performed by an ILAC MRA accredited laboratory or a laboratory in compliance with ISO 17025 standards. Comparison of a master temperature monitoring device that has a certificate of calibration complaint with ISO 17025 standards to a clinic's data logger cannot be used to recertify the calibration of the data logger. Valid and current certificates of calibration testing must be maintained for each temperature monitoring device.