



Department
of Health

Fridge-Tag®2L Data Logger Training

NYS Vaccines for Children (VFC) Program

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May 2017

Agenda

1. Background (~10 minutes)
2. Training on State-Supplied Fridge-Tag®2L data loggers (~50 minutes)
 - Setup of probe/glycol and device activation
 - How to read current and min/max temperatures
 - How to download data
 - Device maintenance/care

BACKGROUND

NYS Vaccines for Children (VFC) Program Requirement 1: Continuous Temperature Monitoring Devices (Effective January 1, 2018)

1. All VFC providers storing publicly-funded vaccine must use a calibrated, continuous temperature monitoring device or digital data logger (DDL) with an active temperature display and continuous monitoring and recording capabilities where the data can be routinely downloaded.
2. Each VFC Provider is also required to have at least one backup data logger to record temperatures in the event the primary devices malfunction or are being recalibrated.

Refer to updated [Temperature Monitoring Requirements document](#)
for more detailed information

NYS Vaccines for Children (VFC) Program Requirement 2: Min/Max Temperature Reading (Effective January 1, 2018)

- *“...required to assess and record minimum and maximum temperatures at the start of each clinic day.”*
 - *“The minimum and maximum temperatures (min/max) must be recorded.”*
- In 2018, VFC providers will be required to record in NYSIIS:
 - current temperatures inside of storage units twice daily, once when the office first opens and once before closing AND
 - min/max temperatures inside of storage units at least once per day, when the office first opens

What is a Digital Data Logger (DDL)?

- Electronic device with calibrated thermometer that continuously records and stores temperature data at specified time intervals
- Typically small, battery-operated and come with built-in memory for data storage
- Digital display on outside of unit shows current and minimum/maximum temperatures and can indicate an alarm status
- Probe sits on inside of unit monitoring temperatures
 - Some come with probes inserted into thermal buffers
- Detailed temperature data can be reviewed on a computer
 - Either via manual download or wireless transmittal to a cloud server



Source: Centers for Disease Control and Prevention (CDC)

Why are data loggers important?

- Indication of the length of time the unit has been operating outside of recommended range
 - Helps prevent unnecessary disposal of vaccine
 - e.g., unknown temperatures when office is closed may cause manufacturer to recommend discarding vaccine
- Can be a preventative tool
 - Detailed temperature data can show storage unit trends over time and may help to identify gradual storage unit failure

Provider Options for Meeting Requirements

1. Use existing equipment (that **meets requirements**)
 - Refer to [Temperature Monitoring Requirements document](#)
 - Questions to dataloggers@health.ny.gov
2. Use state-supplied Fridge-Tag®2L data loggers (distributed by the NYS VFC program) OR
3. Use a combination of both 1 and 2

OPTION 2: USE STATE-SUPPLIED FRIDGE-TAG®2L DATA LOGGERS

Distribution of Fridge-Tag®2L Data Loggers

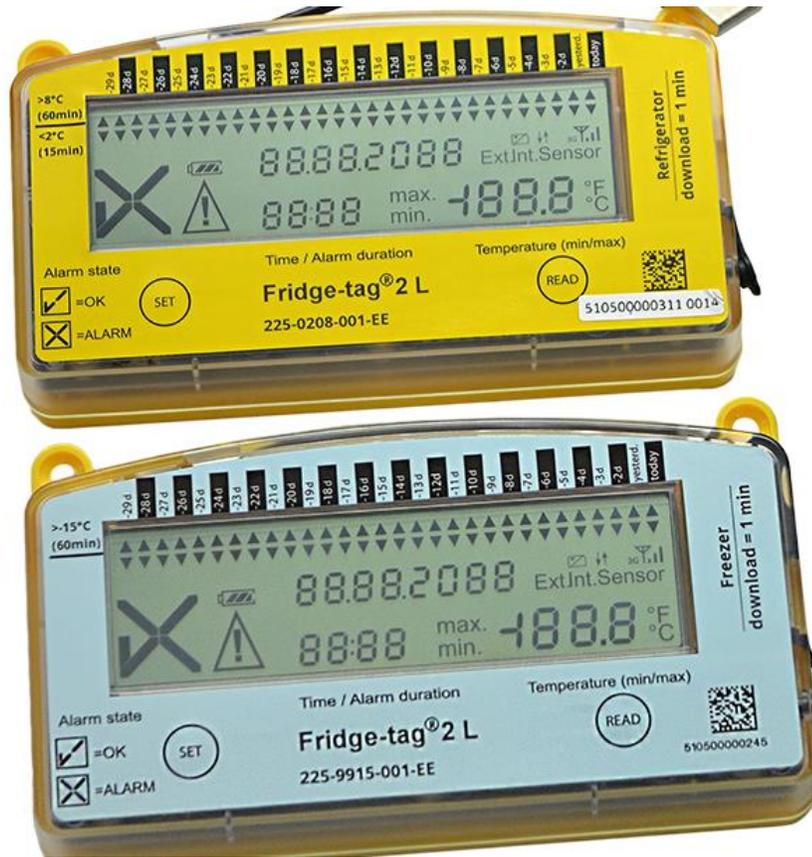
- Each VFC Provider will receive **two** Fridge-Tag®2L data loggers
 - One configured for refrigerator and one configured for freezer
 - Additional devices needed beyond the first two data loggers are provider's responsibility to purchase
- Shipped over the next 5-6 months
- Box is addressed to vaccine coordinator's attention

Fridge-Tag®2L Data Logger Specifications

- Detachable probe buffered in 7 ml glycol bottle
- Display monitor indicates current and min/max temperature and alarm (also audible alarm)
 - Alarm thresholds are preconfigured by the manufacturer and cannot be modified
 - Min/max temperatures are reset every night at midnight automatically
- Display indicates the last 29 days of temperatures including ability to view dates/times and duration of temperature excursions/alarms
- Requires no additional software installation for data downloads
 - USB flash drive attached to device
 - Produces a detailed PDF report which displays data for last 56 days
- Calibration is valid for 3 years
 - after calibration expires, device should be discarded
(cannot be recalibrated)

FRIDGE-TAG®2L SETUP

Equipment Checklist

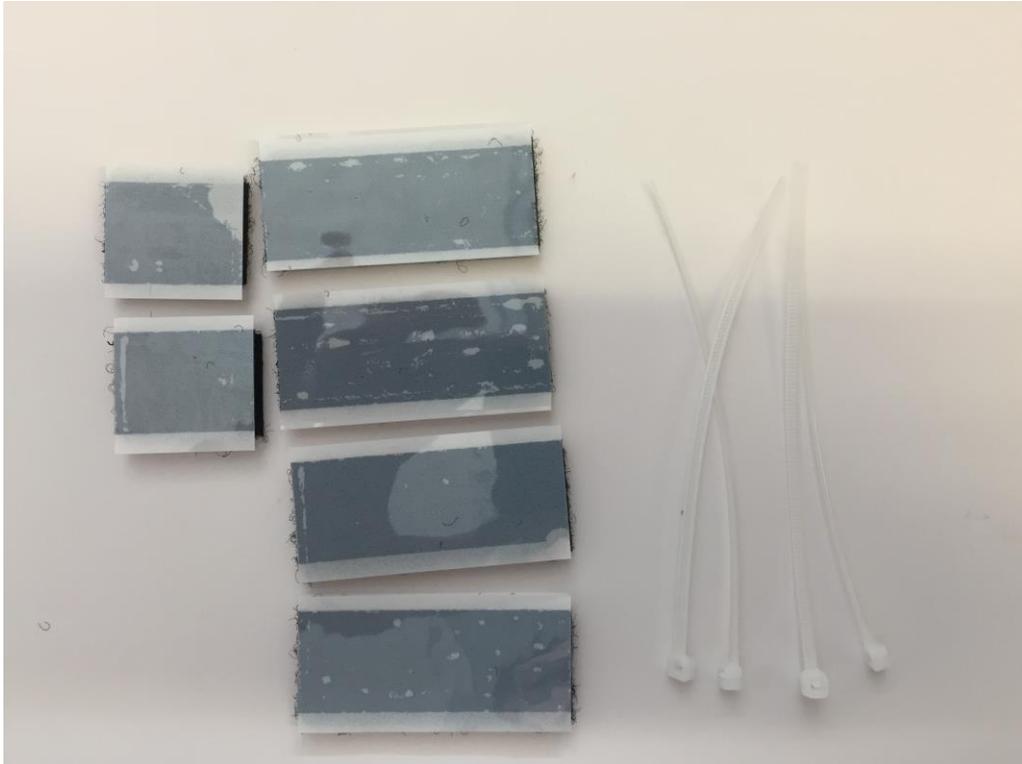


2 Fridge-Tag®2L display monitors
(1 yellow for fridge, 1 blue for freezer)



2 glycol bottles with white probe
cable attached
(1 labeled "fridge",
1 labeled "freezer")

Equipment Checklist (cntd.)

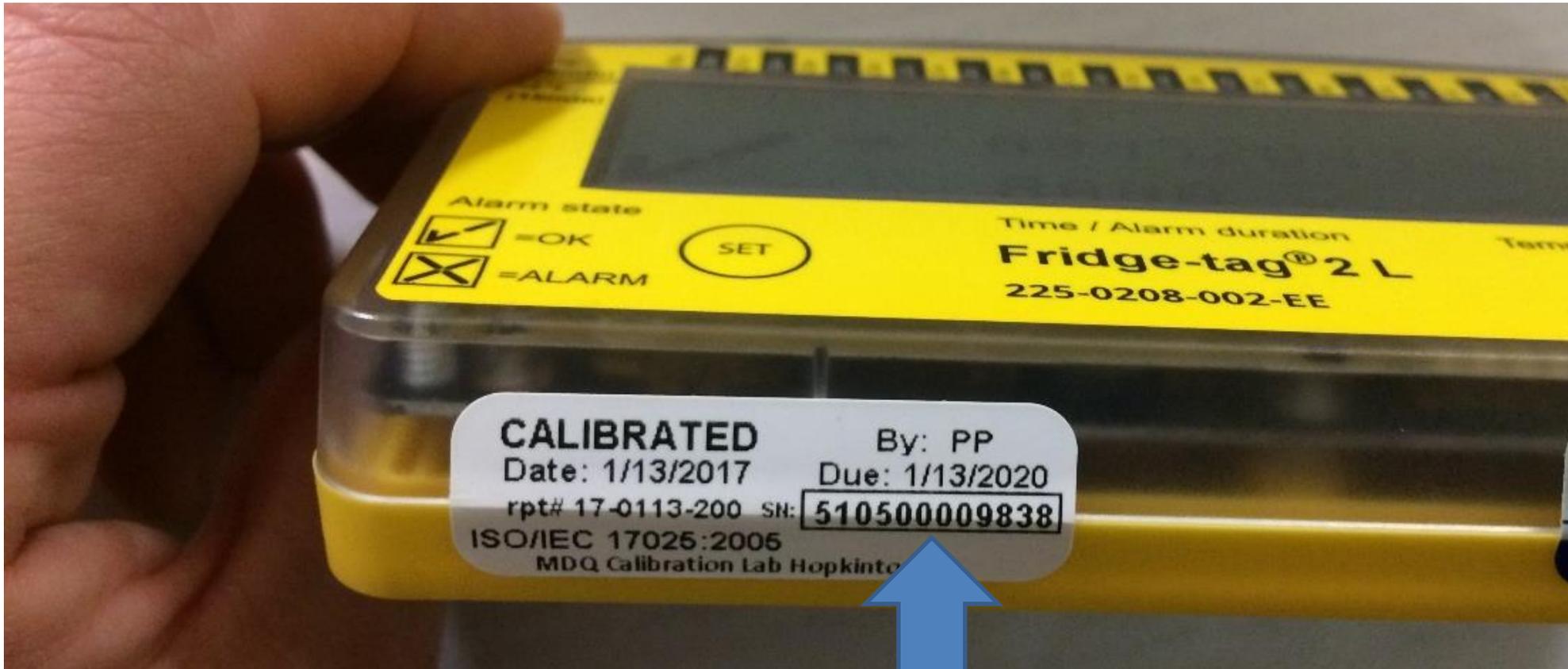


6 Velcro strips and 4 zip ties



2 calibration certificates
(1 for Refrigerator, 1 for Freezer)

Location of Serial Number on Fridge-Tag®2L Display Monitor



Review the Calibration Certificate

Confirm that the serial number on each calibration certificate matches the serial number on each display monitor



879 Maple St. Hopkinton, New Hampshire 03229



Accreditation # 76289

Certificate of Calibration

Report Number: 1
Calibration Date: F
Calibration Due Da

- Model reads FRIDGE-TAG2L for fridge version and FRIDGE-TAG2L-FZR for freezer version
- Unique serial number corresponds to serial number on each device.
- If discrepancies are identified, contact the VFC Program at 1-800-543-7468 or dataloggers@health.ny.gov

Manufacturer: Berlinger
 Model: FRIDGE-TAG2L
 Serial Number: 510500009838

is calibration testing was performed
I Institute of Standards and Technology



Setting up the Glycol/Probe Cable

1. Place the glycol-filled bottle inside the storage unit where publicly-funded vaccine is stored at least 2 hours prior to device activation.
 - If the unit has wire shelves, the glycol can be hung between the shelves using zip ties.
 - **Do not tie the zip ties too tightly around the probe cable as this can damage the cable.**
 - If the unit has plastic or glass shelves, the glycol can be secured directly to the shelf using the smaller Velcro strips.

Example of glycol “hanging” underneath wire shelf

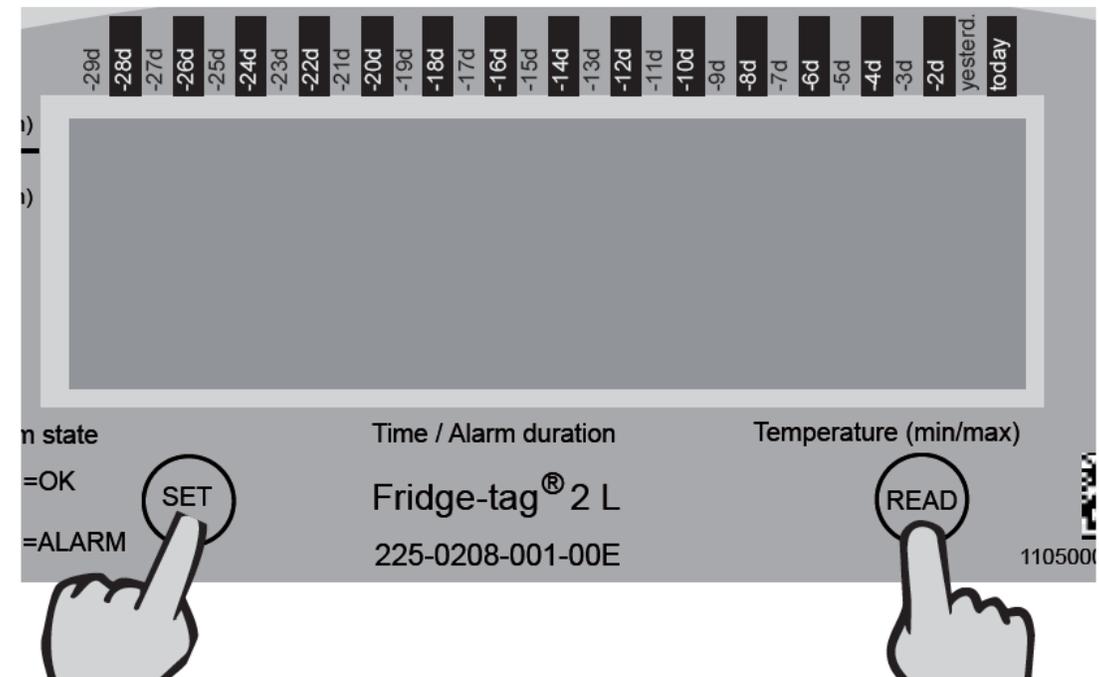


Setting up the Probe Cable

2. Pass the white connecting probe cable through the gap in the storage unit door
 - can be passed through a probe access port, if available
 - small hole for probe available on some purpose-built units
 - check product manual or with manufacturer
3. Secure the cable against the interior wall and shelf with duct, packing tape or zip ties.
 - prevents glycol from moving/tipping over

Fridge-Tag®2L Display Monitor Activation

- **Activate display monitors after glycol has adjusted to storage unit temperatures (≥ 2 hours)**
- Devices are shipped in “Sleep Mode”
 - LCD display is blank prior to activation



Berlinger USA Fridge-Tag®2L Training Videos

- *“How to Start the Fridge-Tag®2L”*
 - <https://www.youtube.com/watch?v=Yf5prLtl37g>
- How to Change date/time and/or C° to F°
 - <https://www.youtube.com/watch?v=GRzUv2oISuA>

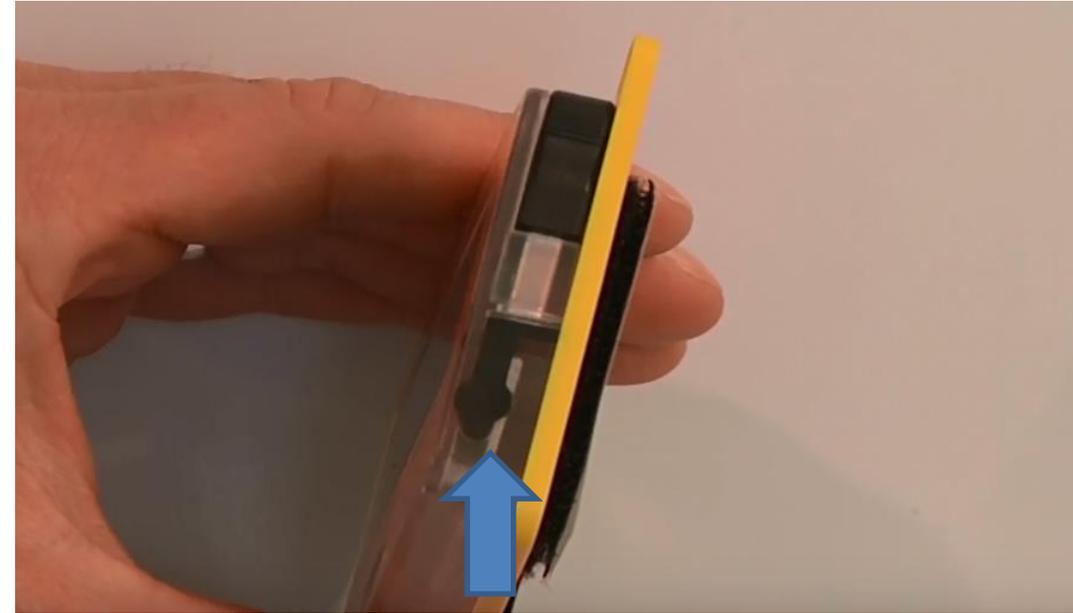
Display Monitor Setup - Preparation

- Display monitor should be adhered to side of the unit
 - Can use storage unit door
 - Make sure that door doesn't open into wall or other objects that could damage the device
- **Before adhering the display monitor using Velcro, make sure that the white probe cable can reach the location**
- Yellow-label display monitor goes in refrigerator, blue-label display monitor goes in freezer
- Connect display monitor to probe in storage unit within 15 minutes to avoid a connection error alarm



Display Monitor Setup

1. Insert the white probe wire into the right side of the display monitor.
 - You may need to remove the black stopper from the probe hole.
 - You should hear a “click” confirming the probe is fully inserted.



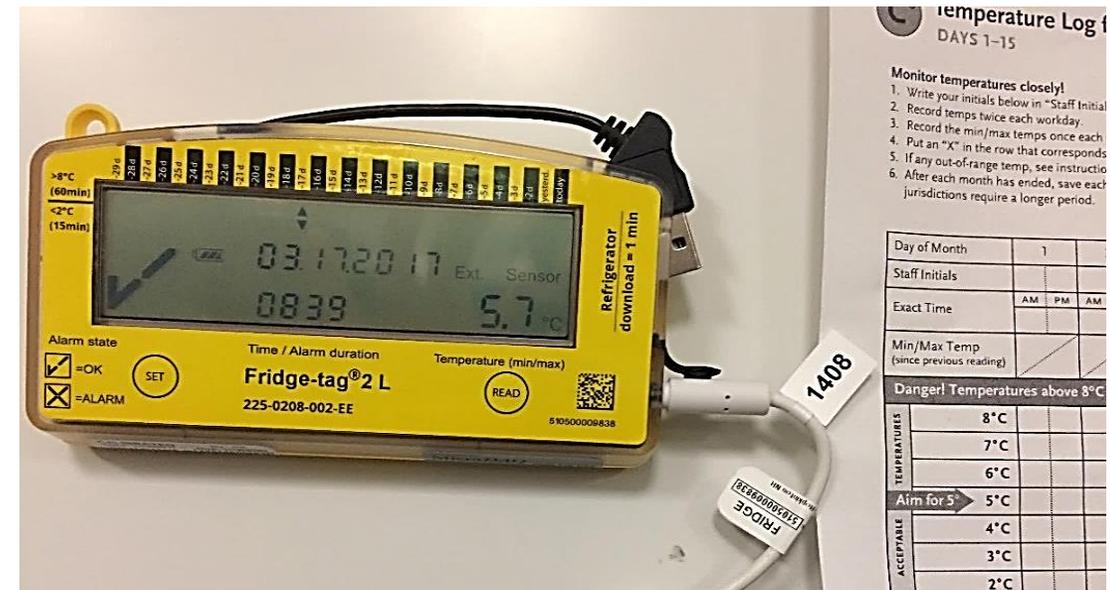
Display Monitor Setup

2. Affix the Fridge-tag®2L display monitor to the side of the storage unit with the Velcro strips provided.



Finish Display Monitor Setup

3. After one minute, the current temperature reading will display on the screen.
4. Make a note of the device serial number and which storage unit the device will be used for
 - needed later when setting up folders for downloading data
5. Keep current temperature monitoring devices in place until comfortable with using new data loggers



PERFORMING TWICE DAILY TEMPERATURE CHECKS USING THE FRIDGE-TAG®2L

NYS VFC Program

Requirements for Monitoring Temperatures

Use of Fridge-Tag®2L (or any other continuous temperature monitoring device) does not replace your twice daily temperature checks or entry of temperatures into the NYSIIS temperature log.

1. Check temperatures twice daily in every storage unit that stores publicly-funded vaccine.
2. Enter all temperatures into the NYSIIS Temperature log.
 - Can transfer from paper log into NYSIIS on a weekly basis
 - Link to paper temperature log: <http://www.immunize.org/handouts/temperature-logs.asp>
3. Minimum of four (4) temperature readings documented in NYSIIS for each day that your office is open:
 - Current temperature reading when office opens
 - Minimum temperature reading when office opens
 - Maximum temperature reading when office opens
 - Current temperature reading before office closes for the day

NYS VFC Program

Requirements for Monitoring Temperatures

3. Report all out of range temperatures to NYS VFC program at 1-800-543-7468
 - Alarms
 - Current and min/max readings that were out of range but did not trigger an alarm

Understanding Minimum and Maximum (Min/Max) Temperatures

- The coldest (min) and the warmest (max) temperatures inside of the storage unit that were recorded by the temperature monitoring device since it was last checked and/or cleared.
 - **Fridge-Tag®2L min/max readings automatically reset every night at midnight**
 - **Morning min/max temperature check will show warmest/coldest temperatures your storage unit has had since midnight**
 - **Good practice to go back and review min/max temperatures from the day before**
- Min/max readings help to detect fluctuations caused by usage or defrost cycles
 - Ideally should be little variation between min/max and current
- Min/max temperature readings should be between acceptable temperature ranges*
 - **Any min/max reading outside of acceptable range is considered a temperature excursion and must be reported to the NYS VFC Program at 1-800-543-7468.**

*Acceptable temperature range for refrigerated vaccine = between 36°F and 46°F or between 2°C and 8°C. Acceptable temperature range for frozen vaccine = between -58°F and +5°F or between -50°C and -15°C.

Ideal average temperature for refrigerator = 41°F or 5°C
Ideal temperature for freezer = 0°F or -18°C



Min/Max Temperatures are a Preventative Tool

- When min/max temperature readings are borderline or just within the acceptable range, take action to help prevent temperature excursions **before they occur**
- For example, consistently seeing a maximum temperature of 46°F and a minimum temperature of 44°F
 - Storage unit thermostat may be set too warm
 - Make small adjustment to thermostat and monitor very closely
 - Thermostat changes can take up to 24 hours to effect temperatures
 - Do not make a change before closing for the day or for the weekend
 - Storage unit may be overcrowded
 - Consider moving some vaccine to another unit (that meets VFC Program requirements)

Berlinger USA Fridge-Tag®2L Training Video

Check Daily Temperatures using the Fridge-Tag®2L

- *“How to read the Fridge-Tag®2L Screen”*
- https://youtu.be/iT_TjZmSZps

Warning Symbol

- Displays when there is an alarm that has not been read or a min/max temperature has not been viewed
 - Once the temperatures are viewed for those days, the warning symbol will disappear.
- Includes weekend temps and days when the office is closed
 - **Always press READ button to cycle back to view min/max temperatures from over the weekend or days when the office is closed**



Warning symbol appears because there are previously unchecked min/max temperatures

Today's max temperature is in range

ALARMS

Fridge-Tag®2L Pre-Set Alarm Thresholds

Refrigerator: ALARM will occur following a 60-minute interval of temperature $>8^{\circ}\text{C}$ (46°F) and ALARM will occur following an observed temperature value $<2^{\circ}\text{C}$ (36°F) for 15 minutes or more.

Freezer: ALARM will occur following a 60-minute interval of temperature $>-15^{\circ}\text{C}$ (5°F).

Fridge-Tag®2L Alarm Indicators

- Audible alarm
 - if the temperature in the unit is currently out of range and has exceeded the pre-configured alarm thresholds
- Alarm info in downloaded reports
- Symbol of X on display monitor

X Marks the Spot!

- If an X is indicated on the display this can indicate any of the following :
 1. An alarm is currently active
 - X and **current** out of range temperature
 - device may also be beeping
 - » audible alarm only sounds for first 11 hours of event
 2. No alarms are currently active but there are previous alarms that have not been reviewed
 - X and current temperature is in range
 3. A connection error alarm is active – display monitor is not connected to the probe
 - X and no temperature value (dashes)

Example of a current low alarm

Beep!!



Today's date

Down arrow under TODAY indicates a low temperature alarm observed today

Device is in alarm status

Warning symbol remains visible until details of the alarm is read*

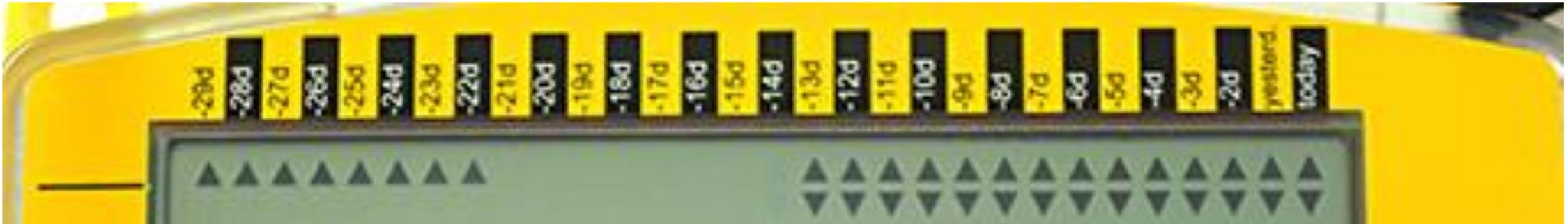
Current time (2:50 pm)

Current temperature is out of range

*Alarms cannot be cancelled or reset/cleared. Alarm events continue to show along the top of the display for 30 days.

Reading the Alarm History on the Fridge-Tag®2L Display

- Previous alarms are indicated along top of device (piano keys) for the last 29 days
- # of days in the past (-2d = 2 days, etc.) and a high and/or low alarm is indicated
- Duration of the alarm is also available on the display



Example of a Fridge-Tag®2L that is currently in range but has previous unaddressed alarms



Previous high alarms were also recorded yesterday, 2 days ago and 5 days ago

Today's date

Both a high ▲ and low ▼ alarm were observed today

Device has previous unaddressed alarms

Warning symbol remains visible until details of all alarms are read.

Current time (6:37 PM)

Current temperature inside the unit is in range

Example of ALARM event from history – low alarm event - 1st screen

1. Press and hold the READ button for 3 seconds to be brought to the first alarm.

An alarm was indicated

Date the alarm occurred

▼ or ▲ will flash under the day the alarm was observed. In this example, the alarm occurred earlier the same day.

The details of the alarm have not been read

Time (beginning) of the alarm (3:26 pm)

NEW YORK STATE OF OPPORTUNITY. Department of Health

Example of ALARM event from history – low alarm event 2nd screen

2. Press the READ Button a second time to read the details of the first alarm.

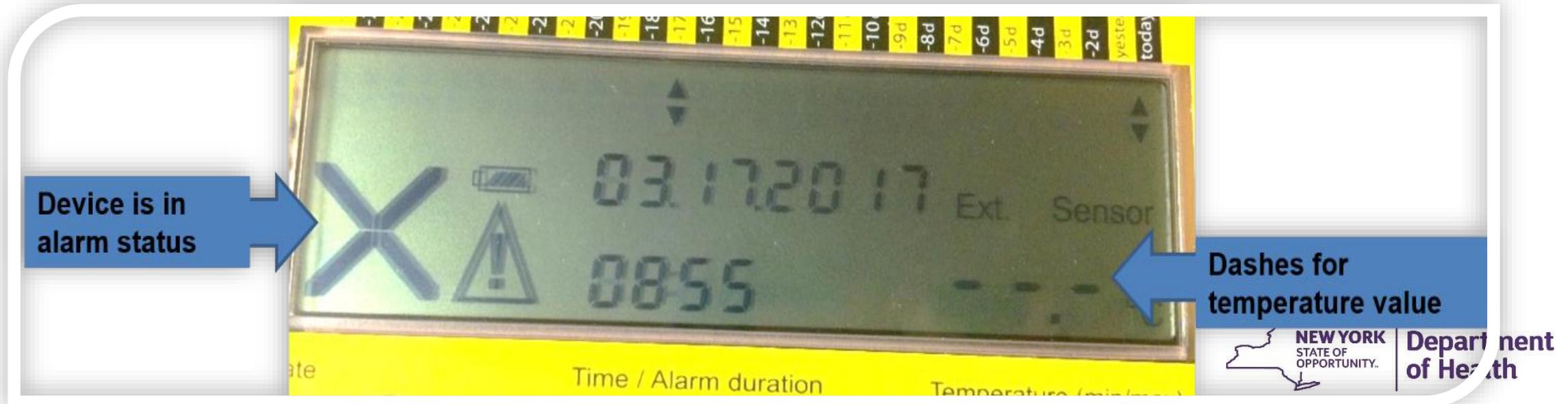


Lowest temperature value observed

Total time out of range (dur = duration) 1 hour 28 minutes

Connection Error Alarm

- A connection error alarm displays on screen after 15 minutes if probe is not connected or is defective.
- Ensure that the probe is firmly secure. Press and twist until you hear a click.
- As soon as issue is fixed, display will show current temperature again and logging will continue
- Will also display in downloaded reports
- **Connection error alarms do not require follow up with VFC program**



Responding to Fridge-Tag®2L Alarms

1. **Follow steps in your practice's emergency plan, when needed.**
2. Label the vaccine "Do Not Use".
3. Contact the NYS VFC Program. The VFC Program may direct you to:
 - Download data and send PDF file to dataloggers@health.ny.gov
 - Contact the vaccine manufacturers to determine viability and complete a [Manufacturer Follow Up form](#)
 - Complete a NYSIIS Returns/Wastage Request for any vaccine that was determined to be unusable
4. Document the excursion in the NYSIIS temperature log.
5. Clear the "X" from the Fridge-Tag®2L display monitor.



Source: Centers for Disease Control and Prevention

“Clearing the X”

1. Clear the X on the Fridge-Tag®2L display monitor after temperatures have returned to normal range and the alarm has been reported to the VFC Program
 - Can only be cleared from the display monitor
2. While viewing the alarm event, be sure to press the READ button to navigate back to the day before the alarm was observed.
 - commits temperature check to memory and clears the X from the main screen

DOWNLOADING DATA

Downloading Fridge-Tag®2L Data

- The VFC Vaccine Coordinator and/or Backup Vaccine Coordinator are responsible for downloading and reviewing the data on a weekly basis.
- The VFC Program may request that you download and send the data if you have an alarm.
 - Only send data to the VFC Program if alarms are indicated.
 - NYS VFC does not have mechanism to collect routine data logger data.
- Downloaded data logger data should be kept for a minimum of three years.
 - Save data files to pre-determined folders in a shared drive so that they can be easily accessed and/or recovered.
- The Fridge-Tag®2L allows 15 minutes for display monitor to be disconnected from probe in storage unit
 - After 15 minutes it will go into a “connection error alarm”

Fridge-Tag®2L Downloaded Reports

- Reports are generated in PDF and text format
- The reports always contain up to 56 days of data.
 - On Day 57 of readings, the report drops the oldest day of data and will continue to do so, always keeping the most recent 56 days available.
 - Reports cannot be deleted off of the Fridge-Tag2L drive.
- The PDF report has a total of 4 pages. Pages 1 and 2 display the first 28 days of temperature data. Pages 3 and 4 display days 29-56 of data.

Prior to First Download: Create Folders for Data Storage

- **Before downloading for the first time, create folders on your computer for the storage of temperature data.**
 - Create folders on a “shared drive” or other centralized location
 - If your practice does not have a shared drive
 - use a shared computer for downloading data
 - limit the # of staff downloading
 - Name folders according to location, storage unit type and last four digits of device serial number
 - Ex. 1st Floor Fridge - 9838

Berlinger USA Fridge-Tag®2L Training Video

How to Download Fridge-Tag®2L Data to PC

- *“How to Download and Understand the Fridge-Tag®2L Report”*
 - <https://www.youtube.com/watch?v=0ooNYcvPako>
- Page 15 of Implementation and User Guide
- Quick reference sheets on downloading data and attaching files to an email

Ideal Average Temperatures for Refrigerated and Frozen Vaccine

- Refrigerated Vaccine: Ideal temperature is 41°F or 5°C
- Frozen Vaccine: Ideal temperature is 0°F or -18°C

DEVICE MAINTENANCE

Fridge-Tag®2L Calibration

- Performed by an ILAC-accredited laboratory
- Meets NYS VFC Program requirements
- Valid for three (3) years
- **Device cannot be recalibrated and is intended to be discarded after calibration has expired**
 - Dispose or recycle of the device in accordance with your local regulations or return the device to the manufacturer contact to ensure proper recycling.
 - Instructions for returning to manufacturer are listed in policy document and user guide

Device Care

- Don't crush/twist the white Fridge-Tag®2L probe wires.
- Don't allow glycol to tip or fall over inside of storage unit. Glycol bottle should sit upright in the center of the unit.
- When disconnecting the Fridge-Tag®2L display monitor from your computer, always use "Safely Remove Hardware" feature in Windows.
- Don't place Fridge-Tag®2L display monitors inside of storage units.
- Take care when inserting the probe wire into the side of the Fridge-Tag®2L display. Don't force or jam the probe into the hole.

Warranty for State-Supplied Fridge-Tag®2L Data Loggers

- Two-year product replacement warranty for devices that malfunction
 - Includes units that experience battery failure within two years
- Providers are responsible for protecting each Fridge-Tag®2L device from damage.
- **Units that are damaged or broken due to operator error/ misuse or fail outside of the warranty period will not be replaced by the NYS VFC program.**
- Contact the NYS VFC Program for device trouble shooting and/or information on warranty replacement at 1-800-543-7468 or dataloggers@health.ny.gov
- Additional information can be found in Fridge-Tag®2L Policy document



Additional and Backup Continuous Temperature Monitoring Devices

- Continuous temperature monitoring devices required in each storage unit containing publicly–funded vaccine by January 1, 2018
 - **Devices for any storage units beyond first 2 units, you will need to purchase**
 - Contact product vendor <https://www.microdaq.com/contact-microdaq>
 - Approximate price is \$149
- Back-up continuous temperature monitoring devices– one required at each site
 - **You are responsible for purchasing a back up data logger**
 - Programmable version of Fridge-Tag®2L is available (can be set for either a fridge or a freezer)
 - Contact product manufacturer Berlinger USA at 1-508-366-0084 or info.us@berlinger.com for more information and where to purchase
 - Approximate price is \$159 for programmable version

Contact the VFC program via phone (1-800-543-7468) when any of the following apply:

- The Fridge-Tag®2L has an active or unaddressed alarm indicated on the display monitor (X)
- Unaddressed alarms are discovered during the weekly data download
- Min/max or current temperature readings are out of range

Questions about the device, program requirements, or if you require technical support contact dataloggers@health.ny.gov

Resources

New York State Vaccines for Children (VFC) Program

Phone: 1-800-543-7468 Email: nyvfc@health.ny.gov Web: www.health.ny.gov/vfc

Data Logger Support and Temperature Excursion Data: dataloggers@health.ny.gov

2018 Temperature Monitoring Requirements:

http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/temp_monitor_device_guidance.pdf

MicroDAQ.com, LTD (NYS Fridge-Tag®2L Vendor)

NYS VFC Fridge-Tag®2L Training and Informational Materials <http://www.microdaq.com/nys>

Technical Support: <https://www.microdaq.com/contact-microdaq> or (603) 746-5524 option "1"

Support Hours are Monday through Friday: 9 am to 4:30 pm EST

Berlinger USA

Device Technical Support/Programmable Fridge-Tag®2L data loggers

1-508-366-0084 or info.us@berlinger.com