Idaho Immunization Program
Thermo Recorder Instruction Manual

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INTRODUCTION

The Idaho Immunization Program (IIP) requires Vaccines for Children (VFC) providers to have a certified calibrated, continuously monitoring thermometer in each vaccine storage unit. The IIP supplies T&D TR-52*i* Thermo Recorders to fulfill this requirement. Thermo Recorders are electronic thermometers that continuously record and store temperature readings and indicate through a warning light when out-of-range temperatures have been recorded. Thermo Recorders interface with a computer through a USB-compatible Communication Port so that temperature data can be removed from the device, viewed, and saved.

This document is a step-by-step instruction guide for using the TR-52*i* Thermo Recorders. If you have any additional questions about using the thermometers, please contact the IIP at (208) 334-5931 or IIP@dhw.idaho.gov.

Required Items

- A Thermo Recorder for each vaccine storage unit (refrigerators and freezers), probe and thermal buffer for each vaccine storage unit, an extra battery, and a Communication Port. All items are provided by the IIP.
- Windows-based computer with USB port.
- Vaccine Temperature Log, Vaccine Temperature Incident Information, and Wasted Vaccine Return Form. These forms are available for download on the IIP website at http://www.immunizeidaho.com under the Healthcare Providers website, in the items listed on the right-hand side of the page.

HOW TO DOWNLOAD THE SOFTWARE

Software for the Thermo Recorder and USB Communication Port must be downloaded to your computer before you can access the data stored on the device. Please follow the steps below to download the software to at least one computer in your clinic.

- Do not connect the Communication Port to your computer until the application and USB driver have been installed.
- Visit the T&D website to download the TR-52i application and USB driver. URL: http://tandd.com/support/download/software/tdrec-trxx.html
- The website can also be accessed from the IIP Healthcare Providers website (http://immunizeidaho.com) and under the "Related Links" menu in IRIS. Once you have accessed the T&D website, scroll to the bottom of the webpage and click "I Agree" under the User Agreement.
- Be VERY PATIENT while the download begins (it may take several minutes). Click "Run" to download the installation software. Click "Run" again to begin installation.
- You can also install the program using the provided CD-ROM, "Data Logger System T&D Recorder for Windows".
- The program's installation wizard will guide you through the process.
- Click "Finish" when done.
- This process will download the software for the Thermo Recorder and the driver for the USB Communication Port. At this point, you should be able to download and view data from the device.

GENERAL PROTOCOL FOR USE AND TEMPERATURE RECORDING

At the time of distribution, an IIP staff person will assist your office with the set-up and placement of the Thermo Recorders in all vaccine storage units. Please consult the following guidelines for keeping the device in the proper place and for the IIP's requirements for daily temperature logging and Thermo Recorder maintenance.

Placement of the Thermo Recorder in Vaccine Storage Units

Each clinic is required to have a certified calibrated, continuously monitoring thermometer in each vaccine storage unit. This includes all refrigerators and freezers that contain (or may contain) state-supplied vaccine. If you choose not to use the Thermo Recorders provided by the IIP, your clinic must purchase alternative thermometers with continuous monitoring capabilities and must submit a current certificate of calibration for each unit. The following guidelines pertain to the IIP-supplied Thermo Recorders.

- For each primary vaccine storage unit, you will be supplied with one Thermo Recorder connected to a probe with a thermal buffer at the opposite end.
- Each Thermo Recorder will be labeled for use in either the refrigerator or freezer. The temperature alarm levels are pre-set, so be careful not to mix up the devices.
- In refrigerator units, the thermal buffer should be placed in the center of the fridge. In freezer units, the thermal buffer should be placed next to the vaccine. As with vaccine, the thermal buffer should not be placed near the ceiling, walls, vents, fans, or coils.
- The probe should be taped to the inside wall of the vaccine storage unit and extended through the door. The probe is thin enough that it will not affect the seal of the fridge or freezer door.
- The Thermo Recorder can be attached (via the Velcro on the back of the device) to any stable location **on the outside** of the vaccine storage unit within easy view. The device should not be placed on the door of the storage unit, since opening and closing the door could displace the thermal buffer. Please note, the Thermo Recorder device itself does not go inside of the refrigerator or freezer—**it is intended as an external display only.**
- The Thermo Recorders will be collected by IIP staff approximately annually and sent for recalibration.

Reading and Recording Temperatures

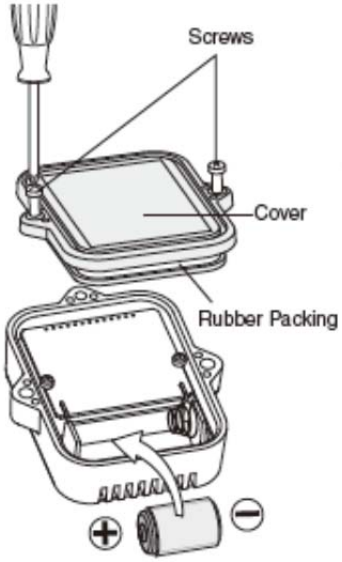
- Even with the continuously recording Thermo Recorder in place, temperatures **must** be logged by clinic immunization staff twice a day, either on a paper log or in the cold storage log on IRIS.
- To determine the current temperature of the vaccine storage unit, view the digital display of the Thermo Recorder. The current Fahrenheit temperature of the unit will be displayed on the device. Because the device is attached to the outside of the unit, you do not need to open the vaccine storage unit to view the temperature.
- Always document the current temperature displayed on the Thermo Recorder rather than documenting temperatures from another thermometer or alarm system.
- Document the temperature displayed on the Thermo Recorder for each vaccine storage unit in the morning upon arrival at the clinic and at the end of the clinic day.
- Record the actual temperature (do not mark an “X”) of the refrigerator and freezer on the temperature log, along with the time the temperature was checked and the initials of the person logging the temperature.
- Temperature documentation is a federal requirement, and the clinic may be liable for any vaccine loss if temperatures are not properly documented.
- This temperature documentation must be kept in a safe, retrievable place for at least **3 years**.

- All office staff should be trained to notify the clinic's immunization coordinator immediately if the alarm light is flashing and the Thermo Recorder is displaying the words "HI" or "LOW".
- Each clinic should have written protocols for responding to a temperature incident posted on or near the vaccine storage units. These protocols must include updated contact information for the immunization coordinator, a back-up emergency contact, and an individual with 24-hour access to the vaccine storage area. The protocol must also include instructions for transporting vaccine to an alternate clinic, hospital, or pharmacy with sufficient storage capacity for all vaccine in the event of a power outage or vaccine storage unit failure.

How to Change the Battery

- When the battery needs to be replaced, the battery replacement mark will appear.

- Remove the screws and open the back cover, using a Philips head #1 screwdriver.



- Remove the battery and wait about three seconds until "bAtt" appears on the screen. If you don't wait for this mark to appear, the battery life warning sign may not disappear from the screen, and saved data may be affected.

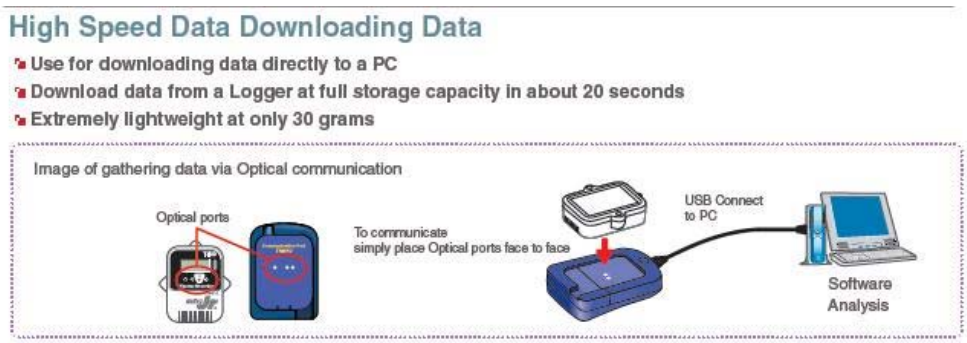
- Replace the battery with a new CR2 lithium battery. You may purchase your own replacement battery or request one from the IIP.
- Replace the back cover, and make sure not to over-tighten the screws.

- It may take about 10 seconds for the display to reappear after changing the battery.
- If you replace the battery in a timely manner, soon after the battery life warning sign appears, all data on the device will be saved. If the battery is changed after the display has completely shut off, the previously recorded data will be lost. Refer to Appendix A for instructions for devise set-up (recording conditions and alarm levels).
- The previously set recording conditions and alarm levels will remain set after changing the battery. There is no need to re-set the device or put it to sleep before reconnecting to the probe. The alarm levels will be automatically reactivated once the device begins to record in-range fridge or freezer temperatures.

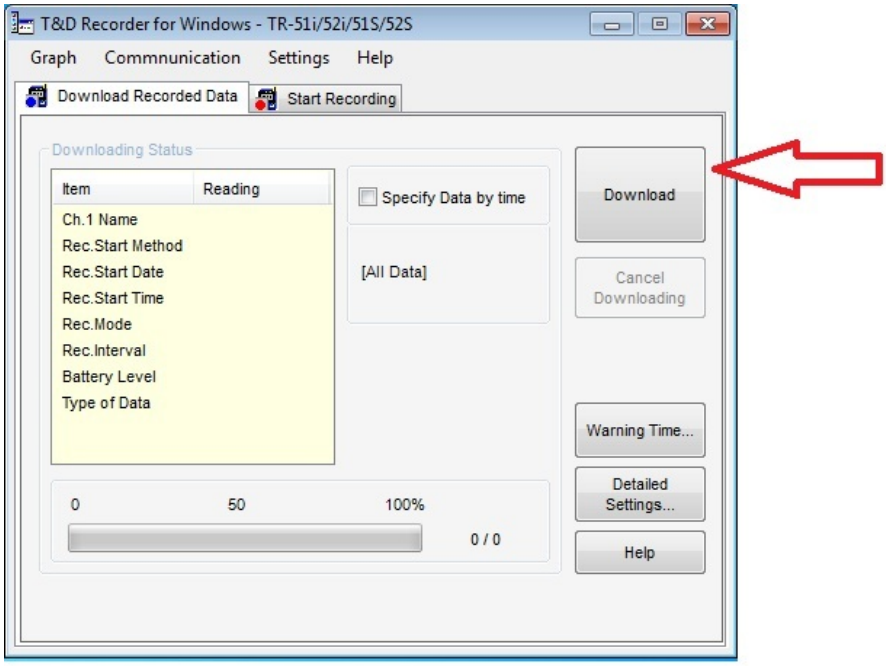
HOW TO DOWNLOAD DATA

The Thermo Recorder data should be downloaded **any time** the alarm light is flashing and the temperature reading is blinking and alternating with the words “HI” or “LOW”.

- Remove the Thermo Recorder from the side of the fridge/freezer by removing the probe from the bottom of the device (do not remove the probe and thermal buffer from inside the vaccine storage unit).
- Plug the Communication Port into a USB port on your computer.
- Place the Thermo Recorder face down on the Communication Port. Make sure the fit is secure.

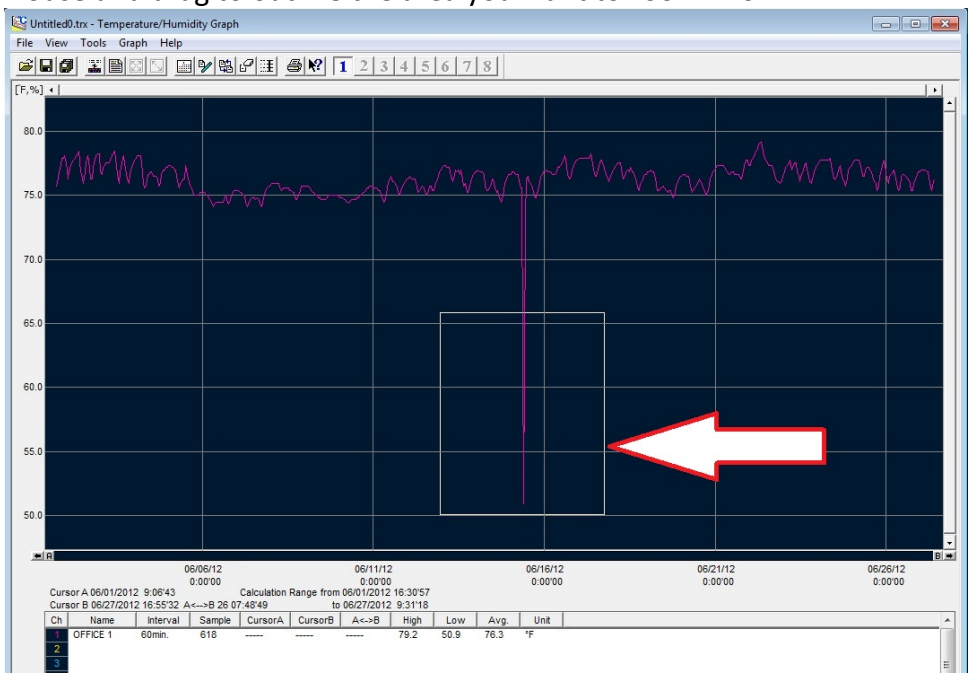


- After the Thermo Recorder is placed on the Communication Port that is connected to your computer, the application will automatically open. If the software doesn’t reopen, re-check that the Thermo Recorder is placed securely in the Communication Port.
- The application can also be opened manually. Click Start > All Programs > T&D Recorder for Windows (TR-5,7xU) > T&D Recorder for Windows > TR-51*i*/52*i*.
- When the T&D Recorder window appears, click the “Download” button on the right side of the window.

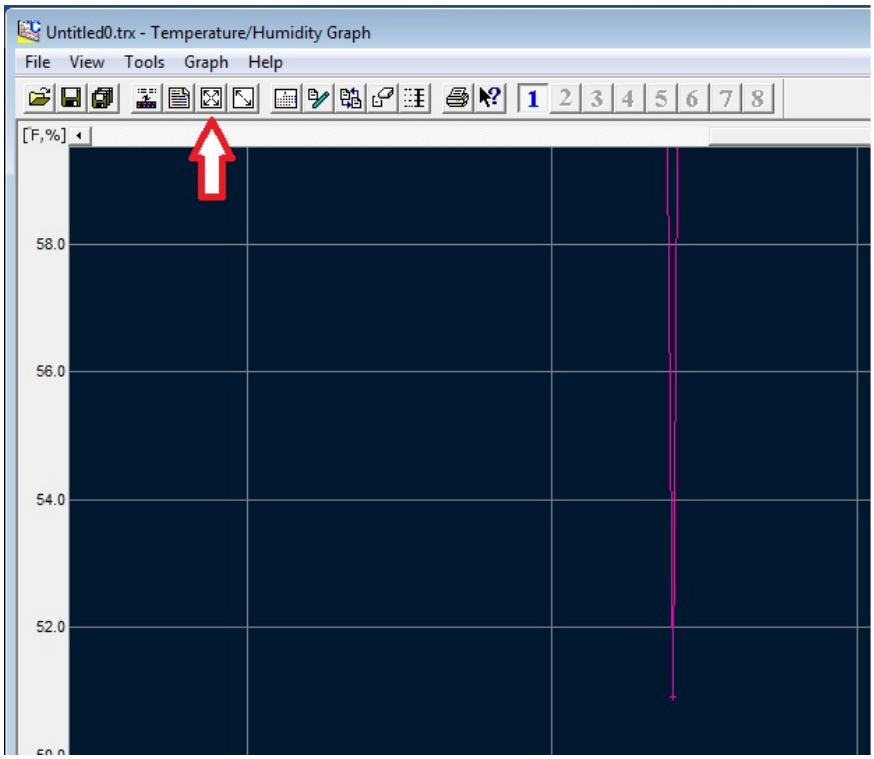


- After downloading has been completed, a graph will be displayed. Click OK on download has been completed.
- If temperatures on the graph are displayed in Celsius, and you prefer to view in Fahrenheit, select “Tools” from the menu options at the top of the screen, and select “Shift Unit [C/F]”.

- To zoom in to view a sub-set of recorded temperatures, press the left button of the mouse and drag to outline the area you want to zoom in on.

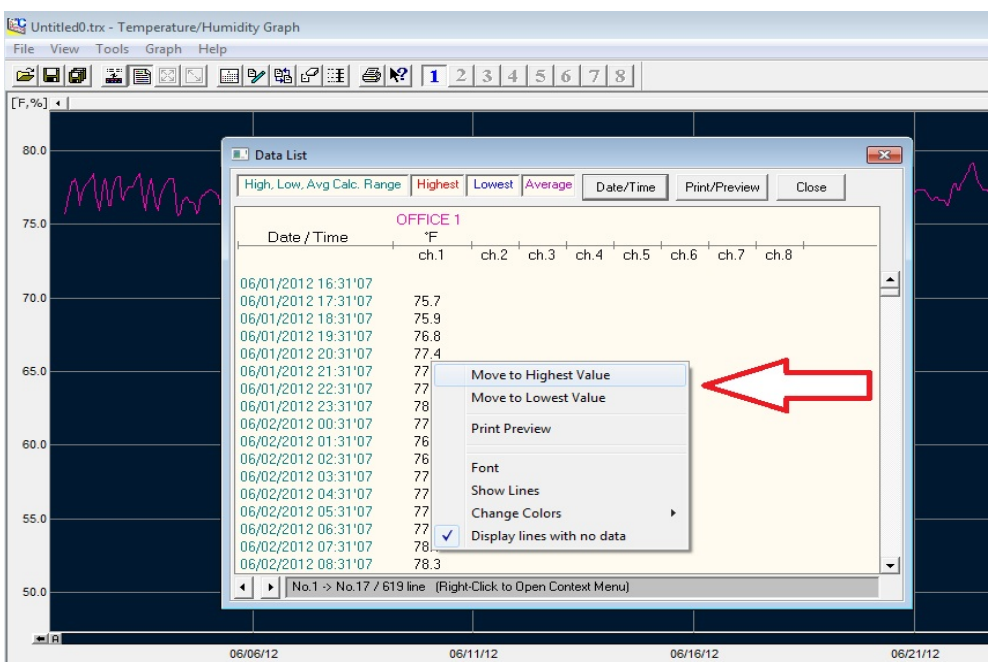


- Click the “Return to Original Size” icon to return to viewing the entire graph (using the right button of the mouse will also give you the option to return to original graph).

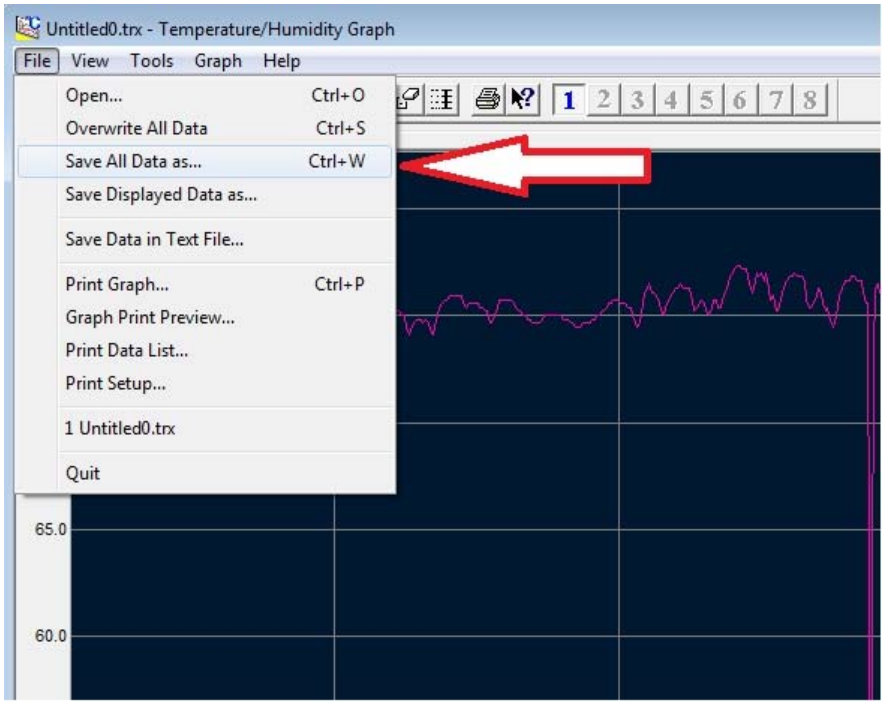


- To view a list of all temperatures recorded, select “View” from the menu options at the top of the screen, and select “View Data List…”

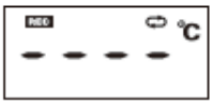
- The highest temperature recorded is displayed in red, lowest in blue. By right-clicking on the list of temperatures, you can select options to move to the highest or lowest temperature recorded.



- When finished viewing data, save it. To save the Thermo Recorder file, select “Save All Data As…” from the File menu, and select a location on your computer to save this data.



- To save the data as a text file that can be imported into Excel, select “Save Data in Text File…” from the File menu, and choose to save the file with Tab delimiters. Select a location on your computer to save the file.
- To view the data in an Excel spreadsheet, open the .txt file just saved in Excel (Excel will automatically lead you through the steps to open a tab delimited file).
- You do not have to re-set the upper and lower alarm limits after downloading the data.
- Once you have completed the download, the alarm warning light will be turned off.
- Remove the Thermo Recorder from the Communication Port and return it to the side of the fridge/freezer, plugging in the probe at the bottom of the device. In a few seconds, the Recorder will display the temperature again.
- If the probe is not properly connected, or is damaged, the display will not show a temperature reading.



HOW TO RESPOND TO A TEMPERATURE INCIDENT

- Never ignore a flashing alarm! The alarm will flash any time the temperature exceeds the pre-set maximum and minimum temperatures for vaccines. If the alarm is flashing, the temperature has gone out-of-range. Please note: there is no sound when the alarm is alerting you to an out-of-range temperature. You will see a red flashing light and the temperature reading will blink, alternating with the words “HI” or “LOW”, depending on whether the out-of-range temperature was above or below the pre-set alarm levels.

- Quarantine the vaccine to ensure it is not used while the temperature incident is being investigated. If the fridge or freezer temperatures are currently out-of-range, move the vaccine to another storage unit able to maintain in-range temperatures.
- Follow the steps in the previous section to download the temperatures and identify the cause of the alarm. Once you identify the duration and range of the temperature incident, contact the IIP at (208) 334-5931 to report the incident.
- If the vaccine was stored at out-of-range temperatures for more than one hour, or if the temperature variation was extreme, you must contact the IIP to determine whether the vaccine was compromised. The IIP may instruct you to contact the vaccine manufacturers. After speaking with the manufacturers, please report back to the IIP to develop a plan of action for resolving the incident.
- If the temperature incident is deemed to be the result of a fridge or freezer malfunction, you will be required to document steps taken to fix the problem and submit 5 days of stable (in-range) temperatures before vaccine may be moved back into the fridge or freezer. You will also be asked to submit the Vaccine Temperature Incident Form and Wasted Vaccine Return Form for any temperature incident. All temperature incidents require an action plan and five days of stable temps before vaccine should be put in a fridge or freezer.
- Any time the alarm on the Thermo Recorder is flashing, the device is malfunctioning, or if the probe needs to be removed from the fridge or freezer, you must document actions taken on your temperature log sheet and contact the IIP for guidance.
- A temperature incident that is not reported to the IIP will result in a one-year probation, and the clinic may be liable for any vaccine loss.

QUICK REFERENCE

This page is a quick overview of the steps to take if the Thermo Recorder indicates that fridge or freezer temperatures have gone out-of-range. These instructions should be accessible to all clinic staff.

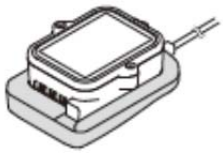
- Store refrigerated vaccines between 35°F and 46°F (2°C and 8°C).
- Store frozen vaccines between -58°F and +5°F (-50°C and -15°C).

Never ignore a flashing alarm! The red alarm light will flash any time the temperature exceeds the pre-set maximum and minimum temperatures for vaccines. The temperature reading will also blink, alternating with the words "HI" or "LOW", depending on whether the out-of-range temperature was above or below the pre-set alarm levels.

Step One: Immediately notify the immunization coordinator, back-up person, or another supervisor that the vaccine alarm is flashing.

Step Two: Quarantine the vaccine by marking it with a "Do Not Use" sign. If the fridge or freezer temperatures are currently out-of-range, move the vaccine to another storage unit able to maintain in-range temperatures.

Step Three: Remove the Thermo Recorder from the side of the fridge or freezer by removing the probe from the bottom of the device (do not remove the probe from inside the vaccine storage unit). Take the device to the computer in your office that has the Thermo Recorder software installed. Plug the Communication Port into a USB port on the computer, and place the Thermo Recorder face down on the Communication Port. The application will automatically open.



Step Four: When the T&D Recorder window appears, click the "Download" button on the right side of the window. A graph will appear with all the recorded data displayed. To view a list of all temperatures recorded, select "View" from the menu options at the top of the screen, and select "View Data List…" Out-of-range temperatures will appear in red (high) or blue (low).

Step Five: Once you identify the duration and range of the temperature incident, contact the IIP at (208) 334-5931 to report the incident.

APPENDIX A

Thermo Recorder instructions for device set-up (recording conditions and alarm levels)

In the event that a provider or the IIP staff need to set up the alarm levels and recording conditions, please follow the following steps:

- Before the Thermo Recorder can be set up, the software must be installed and the device must be connected to a computer via the Communication Port (see instruction manual for details).
- Once the software window opens, click on the "Start Recording" tab and from there, select the following options:
    - immediate start
    - recording interval of 15 minutes
    - endless recording
    - Fahrenheit
    - permit infrared communication
- To set the alarm levels, determine whether the Thermo Recorder will be placed in a refrigerator or freezer. Click on "Settings"> "Software Settings". Select Fahrenheit for "Temp. Unit to be displayed in Software Program" and click OK. Click on the box labeled "Warning settings". Click on check box next to "Set Limits". Set the temperature range (upper of 46, lower of 35 for fridge temps; upper of 5, lower of -58, for freezer temps) and set "judgment time" to 30 minutes.
- Click the box to start recording and recording will begin. Wait for the "Communication has been completed" box to appear before removing the Thermo Recorder from the Communication Port.
- If the upper and lower temperature limits are set in an environment where the upper limits is exceeded (for example, if the limits are set while the probe is in a room-temperature environment), once recording is started, the monitoring function will automatically enter a "wait" mode. Once the device measures a temperature within the set limits, the monitoring function will begin to operate.