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MEMO

TO: Prevention Partnership Providers and
Local Public Health Units

FROM: Molly Howell, MPH
Immunization Program Manager

RE: Important Reminder for Fridge-tag®2 Users

DATE: June 23, 2014

The North Dakota Department of Health (NDDoH) Immunization Program distributed the Fridge-tag®2 data loggers in May 2014. Only providers who requested the data loggers received them. Fridge-tag®2 is the most reliable thermometer for monitoring vaccine temperatures, as it measures and records temperatures every minute. All providers who received data loggers from the immunization program must start using the data loggers as soon as possible, if they have not already done so.

The Fridge-tag®2 generates a 60 day temperature data report in PDF file. Providers must download the temperature data from the data logger and email it to dohtemplogs@nd.gov once a month. If the temperature data is not downloaded monthly, the data logger will overwrite the temperature data. Providers must save the PDF file using their provider number, month and year (Example: 9999May2014). Please do not fax the PDF files. In addition to the PDF file providers send to the immunization program, providers must continue to check and document refrigerator and freezer temperatures twice a day on a paper temperature log. Paper temperature logs do not need to be submitted to the NDDoH, but providers will be asked for the paper temperature logs during Vaccine for Children (VFC) Program visits.

Providers must check the minimum and maximum temperatures on the Fridge-tag®2 twice daily by pressing the “Read” button. When providers check the minimum and maximum temperatures, the data logger prints “am” and “pm” signatures. The immunization program will check for the signatures and contact providers who are not checking the minimum and maximum temperatures twice daily and do not have the “am” and “pm” signatures on their PDF report.

Providers must check for alarm signs every time they check temperature. Fridge-tag®2 displays three types of alarms; a big “X” sign, which shows history of alarm in the past 30 days including the current date. The second type of alarm is an exclamation mark in a triangle that shows occurrence of alarm that was not checked by pressing the read button. The other important alarm is a downward arrow under a day that shows a lower temperature on the day shown. Upward arrow shows a higher alarm on the day shown. When any of these alarm signs are shown on the data logger, the provider must download the information and look at the cause of alarm and email the information to the immunization program. Please note that connection errors can also cause alarm signs and can be identified from the PDF report. Providers must not disconnect the data logger from their unit to avoid frequent alarms. Short training videos on how to use Fridge-tag®2 is available at: nhipconference.com/Training_Opportunities.html.

All alarms must be reported to the immunization program immediately. Detecting and responding to alarm temperatures immediately may save providers from having to revaccinate kids. Revaccination due to vaccine storage and handling failure will result in loss of patient confidence in the provider. Providers who do not detect and report out-of-range temperatures immediately will need to revaccinate kids who receive vaccines that are exposed to out-of-range temperatures.

Since implementing data loggers, some providers have found that their vaccine storage units are not maintaining appropriate temperatures. The Centers for Disease Control and Prevention (CDC) requires all VFC providers to use a vaccine storage unit that can maintain the required vaccine storage temperatures. CDC recommends the use of stand-alone refrigerator and freezer units and does not recommend the use of the freezer portion of combination unit, as they do not maintain the required vaccine temperatures. Providers who use units that do not maintain the required temperatures, especially combination freezer and fridge units will need to replace their storage units.

If you have any questions or concerns, please contact the NDDoH Immunization Program at 701.328.3386 or toll-free at 800.472.2180.

NORTH DAKOTA DEPARTMENT of HEALTH

Fridge-tag®2 Data logger

1. How do I send the PDF file (temperature data) from the data logger?

The new data logger generates a 60 day temperature data report in a PDF file. Providers must download the temperature data from the data logger, save it to their computer and then email it as an attachment to the immunization program once a month. Providers should email the PDF file to dohtemplogs@nd.gov. Please do not fax the PDF files.

2. Do I need to clear the memory after downloading the data?

You do not need to clear the memory of the data logger. The data logger will automatically clear the memory after 60 days.

3. Do I need to use paper temperature logs after implementing data loggers?

Yes. In addition to the PDF file providers send to the immunization program, providers must continue to check and document refrigerator and freezer temperatures twice a day (morning and afternoon) on a paper temperature log. Providers will be asked for the paper temperature logs during Vaccine For Children (VFC) site visits. The temperature logs must be kept for at least three years for compliance with VFC requirements. Please do not fax or email the paper temperature logs to the NDDoH immunization program.

4. How do I start the data logger?

Please watch the video that is available at: nhipconference.com/Training_Opportunities.html or www.ndhealth.gov/Immunize/Providers/Education.htm

5. I started the device but I don't think I entered the right information (e.g. date or time) into it. Can you help me reset the device?

Please watch the Change Mode Screen video that is available at: nhipconference.com/Training_Opportunities.html or www.ndhealth.gov/Immunize/Providers/Education.htm

6. I do not know how to set the alarms. What alarm setting should I put into the device?

You **do not** need to set the alarm. It is set by the manufacturer. Below are the alarm levels set by the manufacturer.
Refrigerator:
- High alarm: 60 minutes above 8ºC
- Low alarm: 15 minutes below 2ºC

Freezers:
- High alarm: 60 minutes above –15ºC
- Low alarm: 23 hours and 59 minutes below -30°C (set for accuracy reasons as the device is not measuring temperatures below -30°C accurately).

7. My freezer is within the appropriate range for vaccine storage, but the data logger is showing an alarm?

The temperature range for freezers is -15°C to -50°C. However, the lowest temperature Fridge-tag®2 can measure is -30°C. If your freezer is colder than -30°C for 23 hours and 59 minutes in a day, the data logger will display an alarm. If possible, set your freezer to a warmer temperature of around -25°C, if not you might have to ignore the low alarms.

8. I do not know how to reset the minimum and maximum temperature?

You do not need to reset the minimum and maximum temperatures. The data logger will reset it automatically.

9. What is the signature function in Fridge-tag®2?

The Fridge-tag®2 data logger has a signature function that tracks if providers check the minimum and maximum temperatures by pressing the read button twice a day. When providers check the min/max in the morning the thermometer types "am" in the report and when they check the temperatures in the afternoon, it types "pm". All providers are required to check the current, minimum and maximum temperatures twice a day. The immunization program will contact providers

who do not check them twice daily.

10. My Fridge-tag®2 data logger shows the right temperature but the X in the corner of the device will not go away. What is wrong?

This is normal, especially when someone is using the Fridge-tag®2 for the first time. The X will only go away after 30 consecutive days without an alarm.
However, the "!" sign goes away. The X is meant to keep the users attention on a storage area that may need extra attention until it is operating within the desired range.

11. Why is there an exclamation mark (!) next to the X?

This means that the device detected alarm temperatures and that no one has pressed the READ button to see what was wrong (either today or during any of the previous alarms). Because this mark goes away when someone reads the information, the supervisor will know if someone is not checking temperatures if this mark is displayed. To know which days were not read, print a PDF report and look for the exclamation point (!) next to the word alarm. This indicates the days when the device was in an alarm state and a person did not read it.

12. I know I set up the device correctly, yet it is not reading temperatures. Is it defective? Why doesn't it show temperatures?

Try to twist and press the sensor in place. Wait one full minute (the device needs one minute to observe temperatures). Did this work? If not, see below for further advice.
NO - When you press the READ button does the information on the LCD screen change?

- If YES, check question number 4 for proper initiation of a new device. When pressing the READ button you will see seven different screens if it is not set up correctly.
- If NO, the screens do not change when pressing READ then contact the immunization program.

13. Why does it sometimes say LOC on the screen?

LOC means the device is not reading temperatures. This mode will last for only 10 minutes. The reason a device goes into LOC mode is to ensure that it does not measure temperatures other than in the space it is intended to monitor (refrigerator or freezer). LOC appears on the display whenever the external sensor is unplugged from the unit.

14. There are black arrows on the unit and there is an X in the left corner, but the temperature displayed on the unit is within the appropriate range set in the device. What is wrong?

The unit has recorded an alarm and the temperature in your refrigerator or freezer has come back within range. You can know when the temperature excursion occurred and if it was a high temperature or low temperature reading by looking at the device. By connecting to a computer you can download the PDF report and see exactly what happened and when.

15. What day did the alarm occur?

The easiest way to know what day the alarm occurred is by downloading the temperature.

- What does it say above the black arrow (or first black arrow when scanning from the right side to the left side of the device)?
- Example: It says -4d. That means it was 4 days ago.
- The negative symbol in front of a number means X days ago (in the example it is 4 days ago).
- The device can display an alarm up to 29 days ago (-29d, found at the far left of the device).

16. Was it a high temperature or low temperature alarm?

If the arrow is pointing up it was a high temperature alarm.
If the arrow is pointing down it was a low temperature alarm.
We can see exactly how long it was in alarm mode and what was the highest or lowest temperature recorded by accessing the history mode: Press the READ button to see the max/min temperature by day:

- FIRST PRESS = high temperature TODAY

Contact the Immunization program at 701.328.3386 or 800.472.2180.

- SECOND PRESS = low temperature TODAY
- THIRD PRESS = high temperature YESTERDAY
- FOURTH PRESS = low temperature YESTERDAY
- FIFTH PRESS = high temperature -2days (2 days ago)
- SIXTH PRESS = low temperature -2days (2 days ago)
- Keep pressing if the ALARM ARROW you want to read has not yet been reached.

17. What kind of sound does the alarm make? I do not hear a beep or bell?

The Fridge-tag® 2 does not make a sound. It provides a VISUAL ALARM only. The VISUAL ALARMS are:

- Up or Down arrows at the top – indicates that temperatures were above (UP arrow) or below (DOWN arrow) the alarm settings on a particular day within the past 30 days (Note: above the arrow it indicates if it was today, yesterday, -2d (this means 2 days ago) all the way to -29d (this means 29 days ago).
- A GIANT X on the left indicates that the thermometer recorded out-of-range temperatures in the past 30 days.
- The exclamation (!) in a triangle (universal alert symbol) - means a technician has not pressed the READ button to see the temperatures since the alarm was triggered. This symbol will disappear after the technician views the temperatures of the problem date.

18. My Fridge-tag®2 is not displaying or reading temperatures?

Please be certain that the external sensor (probe) is fully inserted into the port by firmly pressing and twisting the connector into place. You have to hear a “click” sound when you connect it.

19. How do I know if the battery is expired and without power?

There is a universal low battery indicator symbol to the left of the date. If this symbol is present on the screen you have approximately 30 days to replace the device before it will stop working. If you see this symbol we recommend downloading the report every day until a new device is in place. The battery of the Fridge-tag®2 will last at least for 2 years.

20. Why can’t I change the battery on the Fridge-tag® 2?

The Fridge-tag® 2 temperature sensor is calibrated to a precise standard. If the battery is changed it will VOID the certificate of accuracy supplied by the manufacturer. Also, having a constant source of power ensures that the information contained in the device has not been erased or reset in any way.

21. How do I get report from the data logger?

Please watch the reports section of the video available at: nhipconference.com/Training_Opportunities.html
or www.ndhealth.gov/Immunize/Providers/Education.htm

22. What do I do with my old thermometers?

Please disconnect your old thermometer within two months after implementing the Fridge-tag®2 data logger. The Centers for Disease Control and Prevention (CDC) will require all VFC providers to have a back-up thermometer for the 2015 VFC enrollment. Please keep your old thermometer as a back-up thermometer. Please keep the certificates of calibration up-to-date.

23. My old thermometer does not show any out-of-range temperatures, but Fridge-tag®2 is showing me a lot of out-of-range temperatures. What is the problem? Is it the Fridge-tag® 2?

No, the Fridge-tag® 2 data logger is the most accurate data logger so; the problem is with your storage unit. Your old thermometer was not recording temperatures continuously but the Fridge-tag® 2 does. Fridge-tag® 2 tells you a complete history of your temperature data 24 hours a day. If your unit is poor at maintaining appropriate temperatures for vaccine storage and handling, you might need to replace your refrigerator or freezer unit.
If you are using a combination refrigerator/freezer unit and Fridge-tag® 2 data logger is detecting freezing temperatures in the refrigerator part of the unit, you may need to purchase a stand-alone freezer to store frozen vaccines and discontinue the use of the freezer portion of the combination unit.

24. What should I do if the Fridge-tag® 2 data logger has detected out-of-range temperatures and there is an alarm?

a. Please do not use the vaccines in the refrigerator until you have contacted all of the vaccine manufacturers. The manufacturer will determine if the vaccine is viable.
b. If the vaccine is determined to be nonviable, please complete the vaccine wastage form available on our website at www.ndhealth.gov/Immunize/Providers/Wastage.aspx. All nonviable vaccine will need to be sent back to McKesson.
c. Make small adjustments to your storage unit to see if the temperatures will stabilize:
    i. **Thermostat** - Please try to adjust the thermostat to a warmer position and see if the alarm situation changes. Check the temperature for two days, download and email the temperature data to the immunization program. The immunization program will look at the data and decide future actions from there. It is possible that a slight adjustment in the thermostat will solve the out-of-range temperatures. When you adjust the thermostat, please check both the freezer and refrigerator temperatures.
    ii. **Water bottles** - Adding water bottles to the unit might help stabilize the temperatures. It is important that you add water bottles to the top shelf of the refrigerator to absorb cold air blown in from the freezer to reduce the risk of vaccines becoming too cold.
    iii. **Glycol probe** - Another option is to check where your glycol probe (liquid bottle for your thermometer) is located. The probe should be in the center of the unit, close to where you store vaccines. If it is not at the center please move it to the center of the unit. Also if it is under the vent coming from the freezer, it might affect the temperature reading.