

Protocol for Continuous Temperature Monitoring



Fridge-tag®2/Data Logger

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I. **Background:**

The Centers for Disease Control and Prevention (CDC) has developed interim guidance for the proper storage and handling of vaccine. These recommendations include the use of continuous temperature monitoring devices, or digital data loggers, for all vaccine storage units (refrigerators and freezers).

The data logger should provide a digital display of the internal storage unit temperature including min/max temperatures and current temperature. Data loggers are preferred over other types of thermometers as they can provide an indication of the length of time a storage unit has been operating outside the recommended vaccine storage temperature range, whenever a temperature excursion occurs.

Continuous monitoring refers to the thermometer's ability to track and record temperatures over time. Unlike a simple min/max thermometer, which provides only information about the warmest and coldest temperature that was reached; the continuous monitoring device provides detailed information on temperatures recorded at pre-set intervals. Digital data loggers work by storing continuous temperature data in the devices memory. This stored data then can be downloaded to a PC or Mac for review and archive.

In addition, the digital data logger should have the following:

- Hi/Lo alarm for out-of-range temperatures
- Display of current temperature, as well as minimum and maximum temperature;
- Reset button ;
- Low battery indicator;
- Accuracy of +/- 1°F (0.5°C);
- Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full
- User programmable logging interval (or reading rate) of 10 minutes or less;
- Detachable temperature buffered probe

II. Purpose:

In an effort to meet CDC requirements, the Alabama Vaccines for Children (VFC) Program is now using the Fridge-Tag® 2 manufactured by Berlinger & Co. AG.. Berlinger developed a product in this device that specifically meets the needs of public and private healthcare providers who are managing vaccine supplies, making the transition to continuous temperature monitoring simple and reliable.

The intention of this manual is to provide guidelines for implementing the use of the Fridge-tag® 2 in accordance with VFC Program specifications, as well as to provide detailed instruction for operating the device, originated by Berlinger & Co. AG.

III. Equipment:

The Fridge-tag® 2 digital data logger produces a 60 day report that can be printed, emailed and stored. It comes with an NIST traceable certificate of accuracy. Simply detach it from the external probe, connect it to any computer via USB, and download the report like a removable memory stick. Software is not needed. Fridge-tag® 2 reports are 21 CFR Part 11 compliant to meet FDA and CDC requirements.

The Fridge-tag® 2 tracks temperatures minute per minute. This allows for continuous temperature monitoring of the vaccine storage unit. The Fridge-tag® 2 has been calibrated and ISO 17025 certified for a period of 2 years.

The Fridge-tag® 2



Advantages to Using the Fridge-tag® 2

- Uninterrupted temperature monitoring
- Data retention for the last 60 days (PDF file)
- 30 days available for read out on monitor
- Easy handling, no software needed to analyze the data
- Pre-set alarms to alert personnel of temperature excursions
- Detailed information on temperature excursions (minimum and maximum temperatures reached and duration of excursion(s) in hours and minutes)

IV. Placement of the Fridge-tag® 2:

The Fridge-tag® 2 is equipped with a display monitor and a bio-safe glycol filled vial (buffered probe) and connecting cable.

- The Fridge-tag® 2 display monitor should be positioned outside the vaccine storage unit. The bio-safe glycol filled bottle/probe should be centrally place inside the storage unit along with the vaccine supply away from ceilings, walls, vents, fans and coils.
- 1. Place the glycol filled vial inside the storage unit (It is recommended to do this 30 minutes prior to device activation to allow it to acclimate and prevent erroneous temperature readings upon initiation of the device).
 2. Pass the connecting cable through the back hinge of the storage unit door (gap between the door and unit when opened). *** (Important tip: Secure the cable against the interior wall with duct tape prior to the wire’s exit to the outside monitor. This will keep it secure inside the storage unit and prevent the vial from moving when disconnecting the device for report downloading.)*
 3. Affix the Fridge-tag®2 display monitor to the outside door or side of storage unit with the magnet provided. *(**Again using duct tape to tape the cable in place on the storage unit door.)*
- The display monitor shows the temperature measured by the bio-safe glycol filled vial/probe with an External sensor.
 - *Note: After disconnecting the display monitor when downloading temperature data, be sure to re-connect the appropriate device with pre-set alarm parameters to the correct unit, either refrigerator or freezer.*



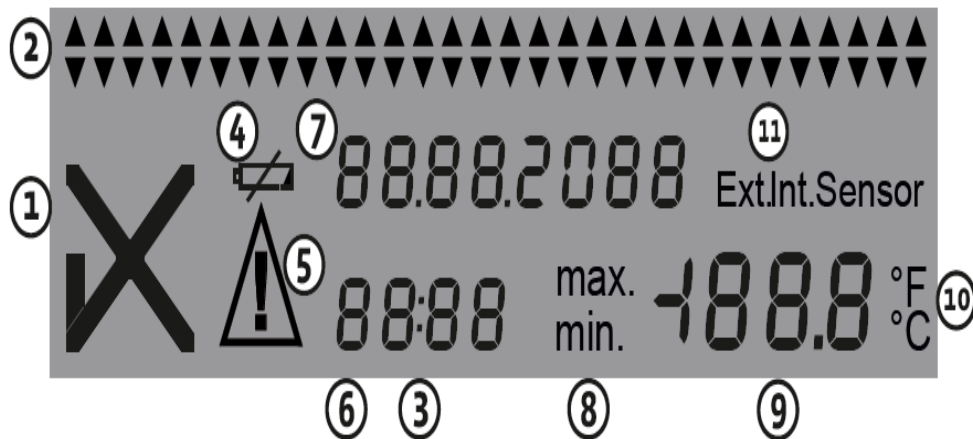
V. Preset Alarm Parameters

Your Fridge-tag® 2 device(s) are pre-set to monitor either your refrigerated vaccine storage unit (refrigerator) temperatures or your frozen vaccine storage unit (freezer) temperatures in degrees centigrade:

Fridge-tag 2® pre-set alarm parameters:

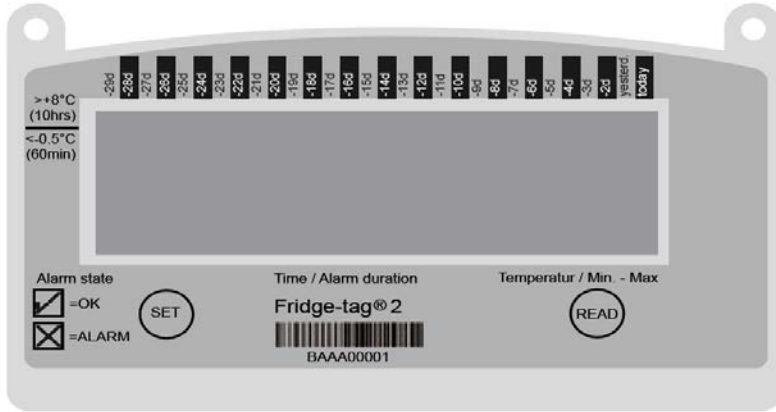
Refrigerated Vaccine (Refrigerator)		Frozen Vaccine (Freezer)	
upper limit: >8°C	ALARM will occur following a 60 minute interval of temperature >8°C	upper limit: >-15°C	ALARM will occur following a 60 minute interval of temperature > -15°C.
lower limit: <2°C	ALARM will occur following a 15 minute interval of temperature <2°C	lower limit: <-30°C	

VI. Display Explanations



- ① OK (✓) or Alarm (X) indicator
- ② HIGH / LOW alarm indicators showing history of the last 30 days
- ③ Power on indicator (double point is flashing)
- ④ Battery low indicator (approx. up to 1 month remaining)
- ⑤ Additional warning symbol (indicates when a new alarm was observed, will disappear after checking details)
- ⑥ Time, duration and text indicator
- ⑦ Date and text indicator
- ⑧ Indicator of measured minimum/maximum temperature
- ⑨ Temperature display
- ⑩ Indicator of the temperature measurement unit (°F/°C)
- ⑪ Indicator of activated sensor:
 Int. = internal sensor (inside the Fridge-tag® 2)
 Ext. = external sensor (cable with temperature sensor)

VII. Initiating the Fridge-tag® 2



Upon arrival, the Fridge-tag 2 LCD screen will be blank

A. Display test

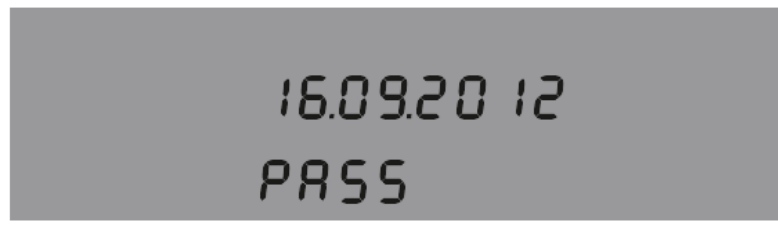
1. Press the READ button: All segments are activated.

1st press of READ:



2. Press READ a second time: Indication of date and production test result will appear
Example: (16. September 2012/PASS)

2nd press of READ:



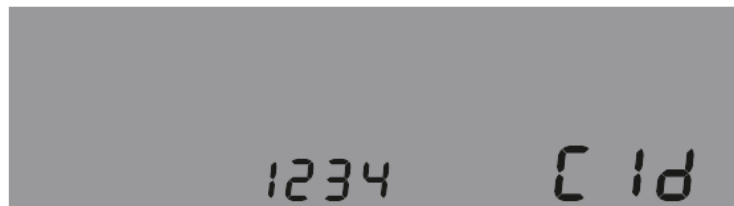
3. Press read a third time: Indication of the current temperature and activation of sensor

3rd press of READ:



4. Press read a 4th time: Indication of configuration ID number (example: 1234)

4th press of READ:



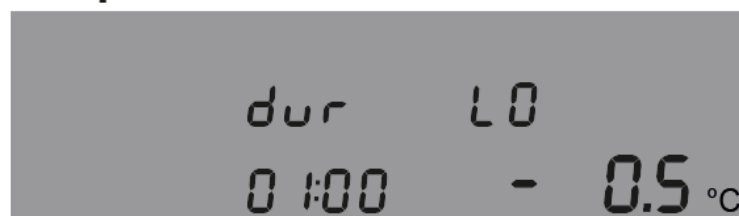
5. Press read a 5th time: Indication of 1st alarm settings and Alarm type: Time and temperature limits (example shows: >+8.0°C, 10 hours, High)

5th press* of READ:



6. Press read a 6th time: Indication of the 2nd alarm settings and Alarm type: Time and temperature limits (example shows: <-0.5°C, 60 minutes., Low)

6th press* of READ:



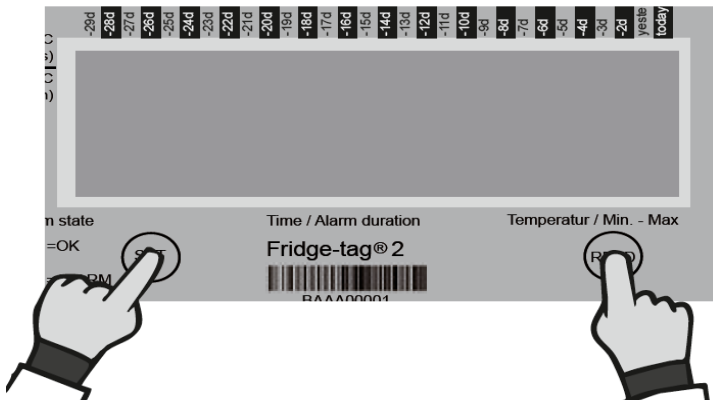
7. Press read a 7th time: The display is blank again.

7th press of READ:

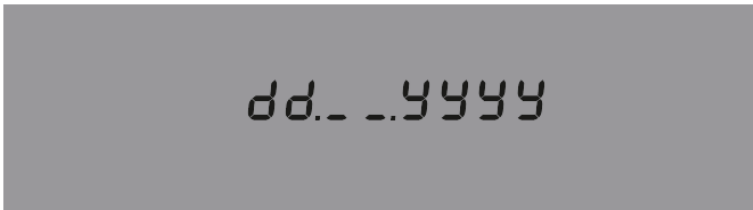


B. Device Activation

1. Press the SET and READ buttons simultaneously for more than 3 seconds.

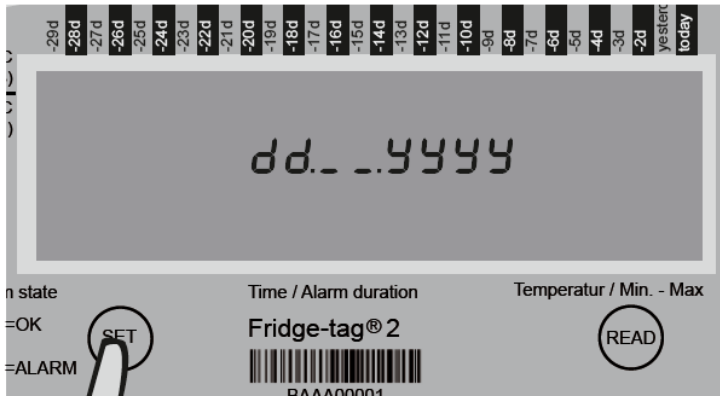


2. Successful activation is indicated when the following is visible:



C. Setting the calendar Format

Option 1: Setting the date format to dd.mm.yyyy

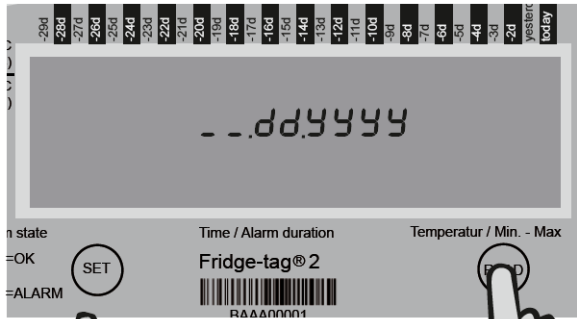


Press SET to save the calendar format

Option 2: Setting the date format to mm.dd.yyyy

1. Press READ to change the calendar format
2. Press SET to save the calendar format

*After setting the calendar format, the first digit of the date will start flashing.



② Then press SET to save the calendar format

① Press READ to change the calendar format

D. Instructions for using the READ and SET button

The **READ** button is used to adjust the number. Each time you press the **READ** button, the number in the flashing digit will increase by 1. If you press **READ** more than necessary, continue pressing the **READ** button until you obtain the desired number.



Press READ to adjust the number

The **SET** button is used to save the number. After pressing the **SET** button the next digit will start flashing.

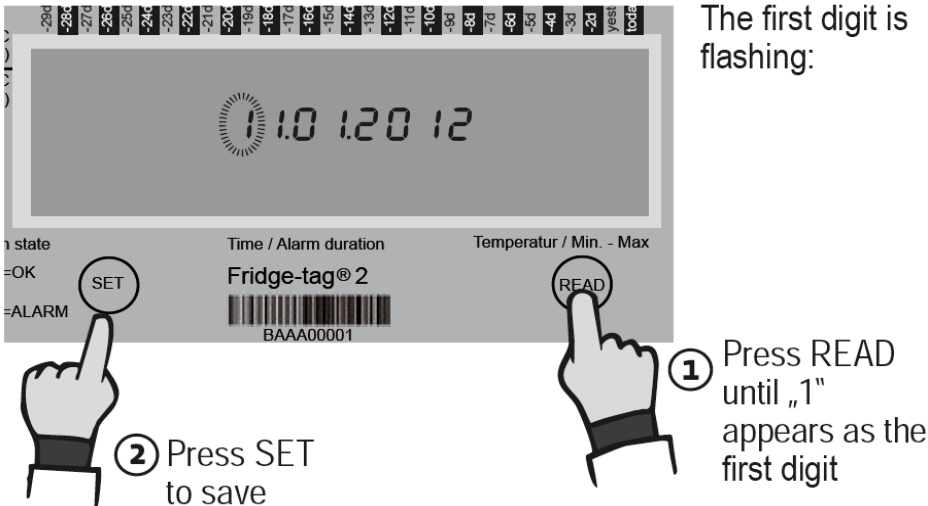


Press SET to confirm

E. Setting the Date

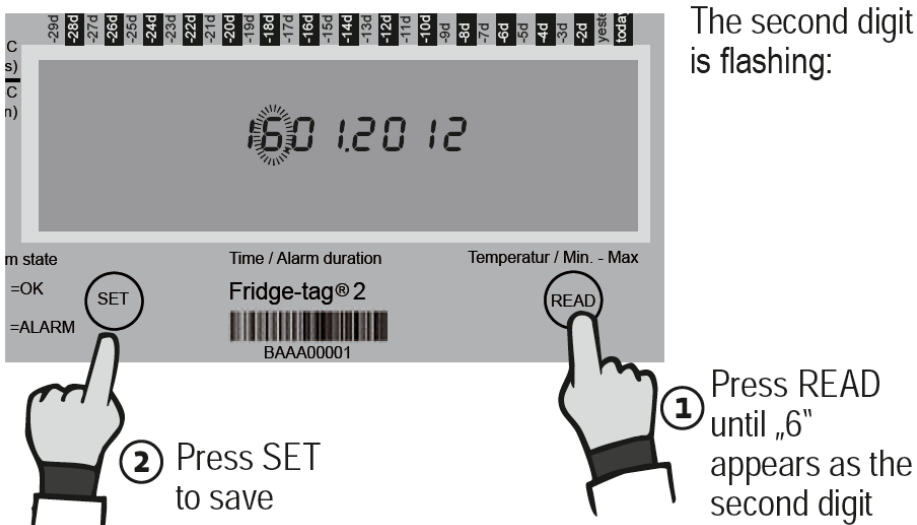
The following example shows how to set the date to: 16th of Sept. 2012 (16.09.2012)

1. Press **READ** until "1" appears as the first digit
2. Press **SET** to save



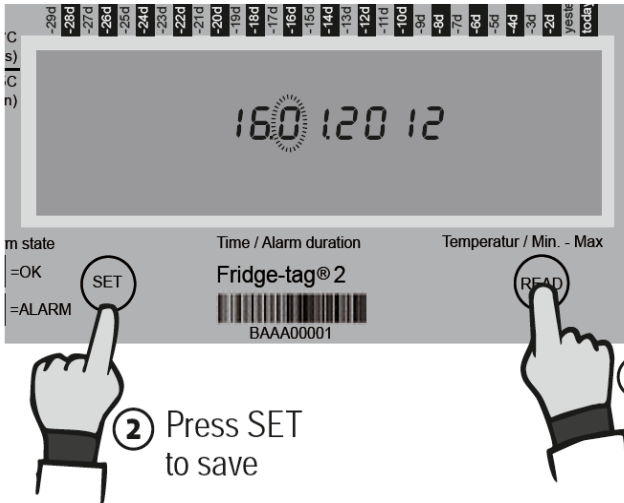
The second digit is flashing:

1. Press **READ** until "6" appears as the second digit
2. Press **SET** to save



The third digit is flashing:

1. Press **READ** until "0" appears as the third digit
2. Press **SET** to save



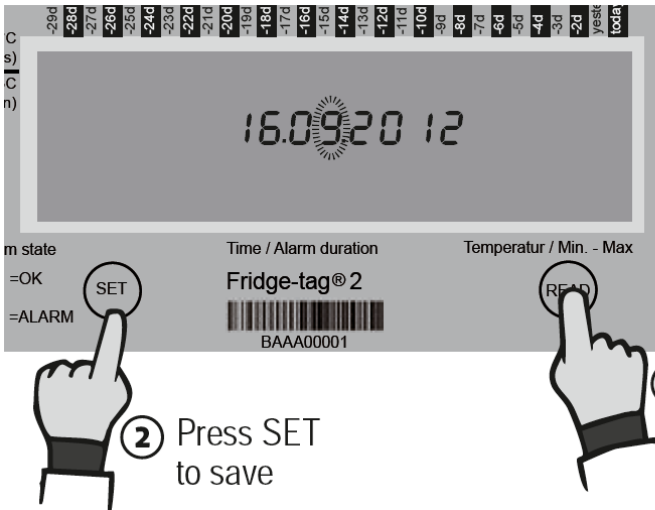
The third digit is flashing:

1 Press READ until „0" appears as the third digit

2 Press SET to save

The fourth digit is flashing:

1. Press **READ** until "9" appears as the fourth digit
2. Press **SET** to save



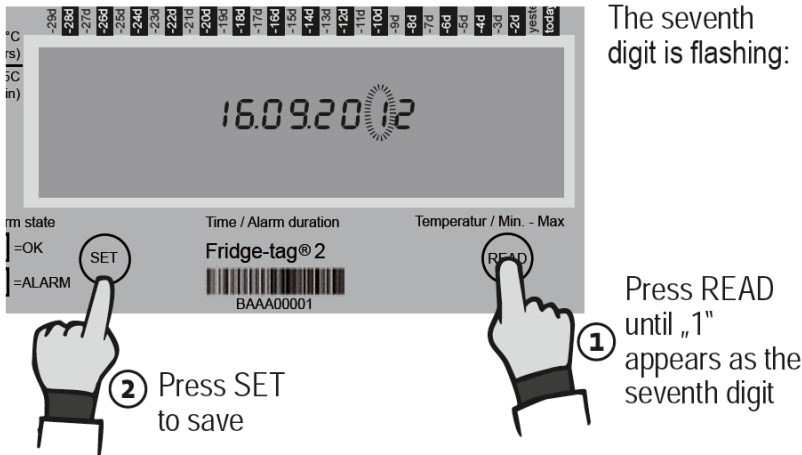
The fourth digit is flashing:

1 Press READ until „9" appears as the fourth digit

2 Press SET to save

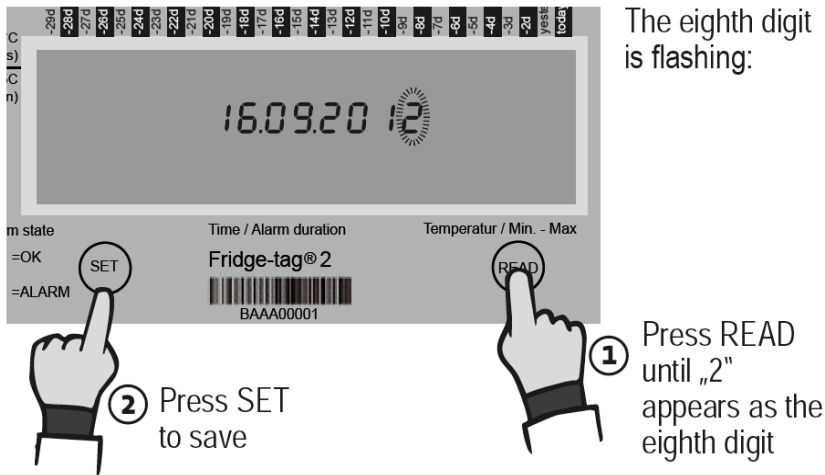
The seventh digit is flashing:

1. Press READ until "1" appears as the seventh digit
2. Press SET to save



The eighth digit is flashing:

1. Press READ until "2" appears as the eighth digit
2. Press SET to save



The date is now set to: 16.09.2012

After setting the date, the first digit of the time will start flashing.

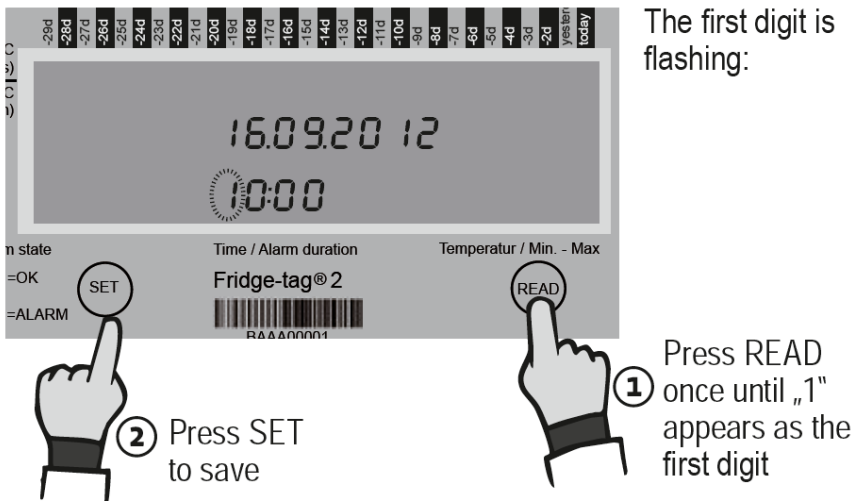
F. Setting the time

This example shows how to set the time to 13:47

The clock function operates as a 24 hour clock (e.g. 13:47= 1:47pm)

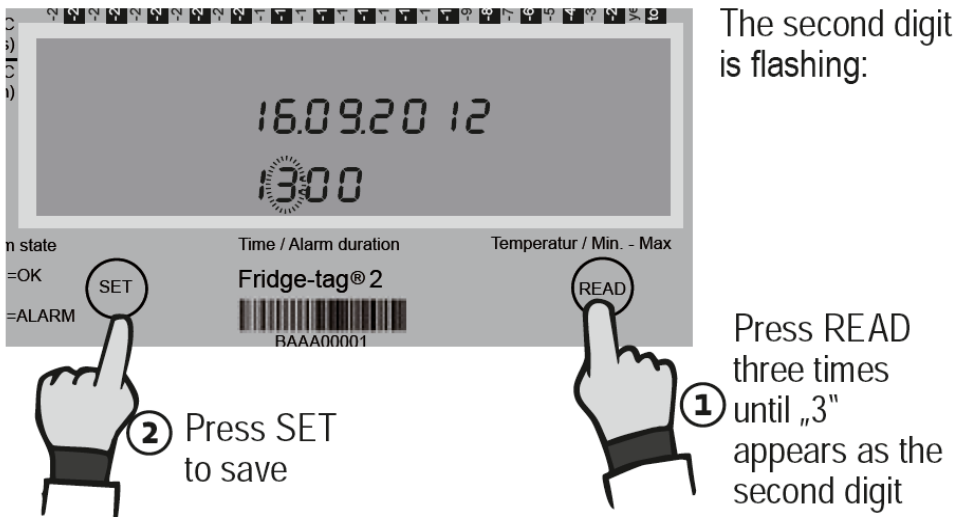
The first digit is flashing:

1. Press READ once until "1" appears as the first digit
2. Press SET to save



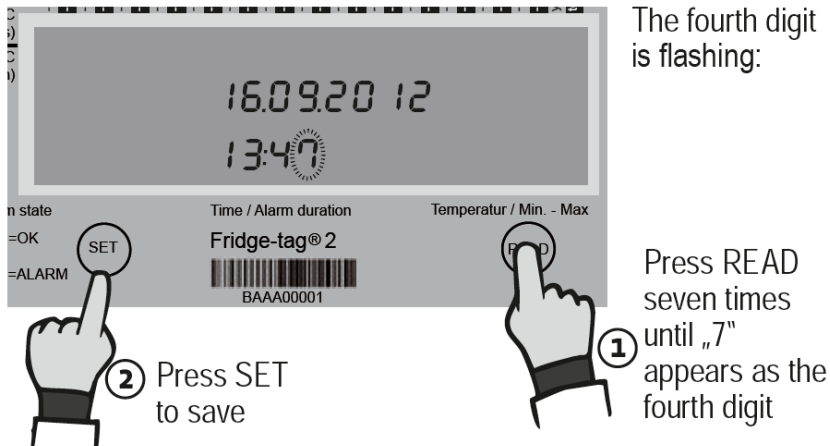
The second digit is flashing:

1. Press READ until "3" appears as the second digit
2. Press SET to save



The fourth digit is flashing:

1. Press **READ** seven times until “7” appears as the fourth digit
2. Press **SET** to save



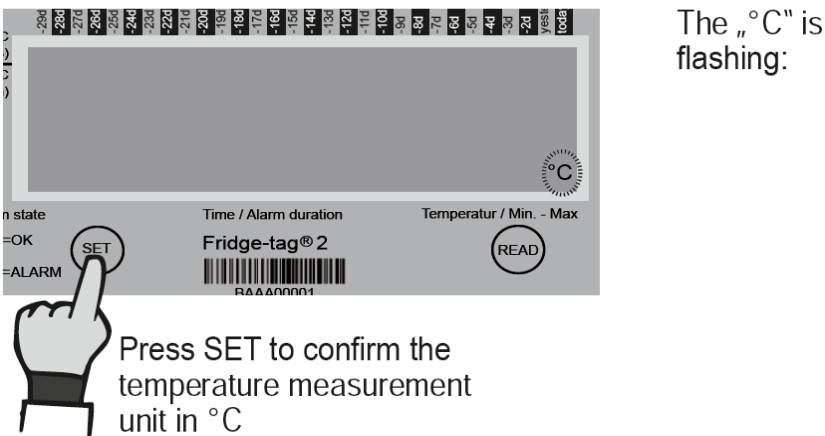
The time is now set to: **13:47**

After finishing the time setting the “°C” symbol will appear at the right bottom corner.

G. Setting the temperature measurement unit in Centigrade:

The “°C” is flashing

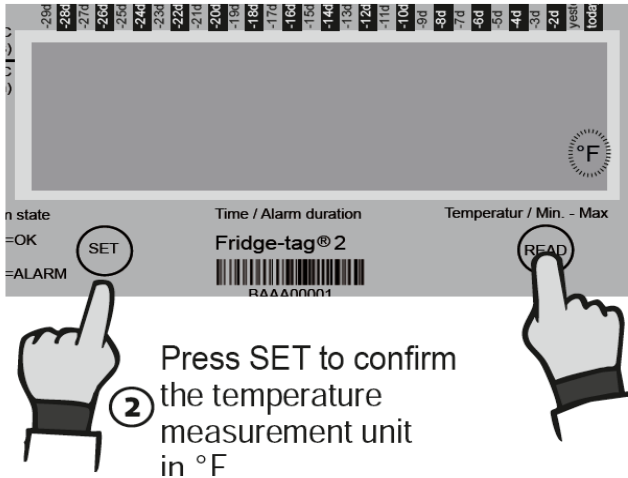
1. Press SET to confirm the temperature measurement unit in °C.



Setting the measurement unit in Fahrenheit

The “°C” is flashing:

1. Press READ to change the temperature measurement unit to °F.
2. Press SET to confirm the temperature measurement unit in °F.



The „°C” is flashing:

Press READ to change the temperature measurement unit to °F

The activation is now completed and on the display the word “LOC” appears.

H. LOC function

For a period of 10 minutes the Fridge-tag 2 does not measure the temperature when the following actions take place:

- When activation is completed
- After the last button operation
- The Fridge-tag 2 is connected to a PC/Mac

After the actions have been completed the sign “LOC” appears on the screen. This function prevents recordings of false data which could be caused by heat while holding the device in the hand and it allows an adaption to the environmental temperature before normal recording continues.



Note: Temperature history can still be retrieved in **LOC** mode by pressing the **READ** button.

I. Change Mode in Fridge-tag®2

Overview

The Fridge-tag®2 data logger has 3 possible screen modes:
 CURRENT STATUS (the device is logging/working)
 HISTORY (reading through the logged data)
 CHANGE (editing or displaying set-up options)

If you are reading the HISTORY you cannot enter CHANGE mode. You must be in CURRENT STATUS mode to enter into CHANGE mode. Pressing SET will change from HISTORY to CURRENT STATUS mode.

Decide which function you want to change. If you want to change more than one functional area you must do that separately by accessing the change mode twice. The functions work much like setting a digital watch where one button scrolls through the options and the other selects the desired display.

BUTTON FUNCTIONS

READ=CHANGE

SET= ACCEPT WHAT I SEE ON SCREEN AND GO ON TO THE NEXT STEP

Making the Change

Once in CHANGE mode you must choose the function you wish to change:

As you press READ the list of functional change options will appear in this order:

Out SlDE (confirms the unit has an external sensor)

Units without the external sensor will not see Out SlDE and will only see Set dAtE first

Set dAtE (for changing the Date and/or the Time)

rEAd COnF (for only SEEING the current alarm settings)

CELS FAHr (for changing between Celsius and Fahrenheit)

Even when the device displays LOC you can enter it to make changes.

If the device is left untouched in CHANGE mode, it will revert back to CURRENT STATUS mode.

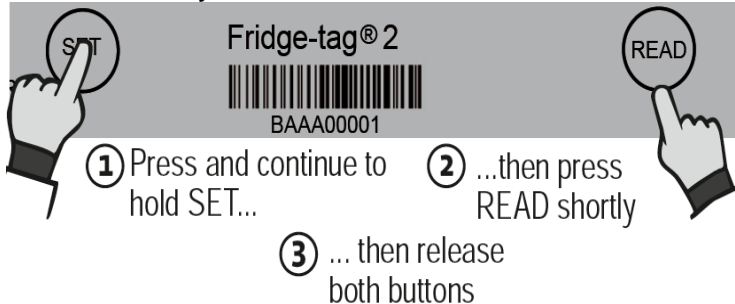
Note:

- Time and date adjustments have no effect on the alarm recording.
- The time does not change automatically with daylight savings time (please see steps for entering change mode above)
- Adjustments can only be made for date and time settings and for changing the temperature measurement unit.
- Once the device is activated, it cannot be stopped anymore.
- The number of time adjustments during the same day is unlimited. After the adjustment has been done, the Fridge-tag 2 will be locked for 24 hours from the following midnight (e.g. changes on the 15th of Sept., device locked from 00:01 am on the 16th until 00:01 am on the 17th). This is for security reasons.

i. TO CHANGE FROM °C TO °F:

Access CHANGE mode by pressing SET button quickly (this assures you are in CURRENT STATUS (you do not want to be in HISTORY or CHANGE mode).

1. While holding the SET button press the READ button and release both buttons quickly and simultaneously.



2. You should see OUT SlDE on the display.
3. Press READ and see Set dAtE on the display.
4. Press READ see rEAd COnF on the display
5. Press READ see CELS FAHr
6. Press SET: °C will begin flashing in lower right corner of screen
7. Press READ: °F will begin flashing in lower right corner of screen
8. Press SET
9. The device will return to CURRENT STATUS

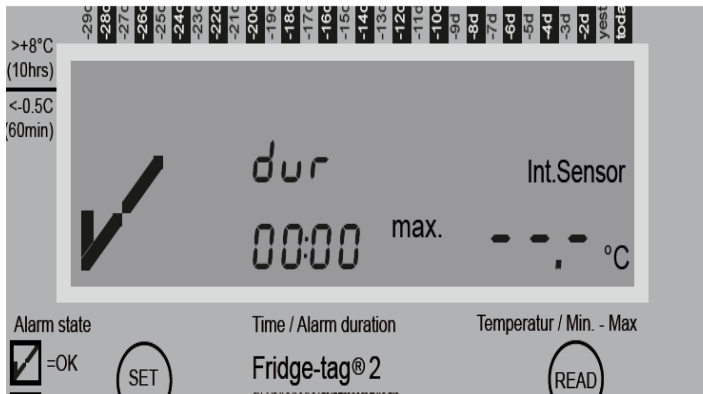
ii. TO CHANGE THE TIME:

Access CHANGE mode by pressing SET button quickly (this assures you are in CURRENT STATUS (you do not want to be in HISTORY mode or CHANGE mode).

1. While holding SET button press the READ button, then release both buttons quickly and simultaneously. You should see OUT SlDE on the display
2. Press READ see Set dAtE on the display
3. Press SET see date format flashing
4. Press SET 7 times to set date and access the time format
5. Press SET if the 10+hours is correct or READ to change through options (0-9) and press SET when the desired number is displayed
6. Press SET if the minutes are correct or READ to change through the options (0-9) and press SET when the desired number is displayed.
7. The device will return to CURRENT STATUS.

J. Display Indication-OK/ALARM

Indication of the 1st minute after completing the settings and the LOC function



For a maximum of 1 minute no current temperature is displayed on the screen.

i. Example of OK Display-during measurement




- Once the device is fully activated the (✓) OK symbol, the current temperature reading, the time and the date will be displayed on the screen. The Fridge-tag® 2 will also indicate that the measuring is made with an External sensor.
- A (✓) OK symbol is indicated during normal operation as long as not alarms have been recorded. The temperature and time conditions were within the pre-set alarm parameters.

ii. Example of ALARM Display-during measurement



If the temperature and time conditions are outside the pre-set alarm parameters the following will be displayed on the screen:

1. The (✓) (OK symbol) will be replaced by (X) ALARM symbol
2. An additional arrow will be indicated in the upper display area to show which ALARM limit has been violated and on which day.
3. In addition to the (X) (ALARM symbol) the warning symbol (!) will appear beside the (X) 

Note: the warning symbol will remain visible until the user reads the details of the triggered alarm(s). After that it will disappear.
4. Alarm indications cannot be cancelled or reset. The (X) will remain on the device for 30 days following the occurrence of the last alarm.

VIII. Reading the Temperature History

- **Option 1: Read out day to day directly on the device (30 day overview)**
- **Option 2: Read out Alarms only, directly on the device with the ALARM SUPER JUMP function (30 day overview)**
- **Option 3: Read out the data from the PDF/A* and ASCII document generated via USB interface (60 day overview) (Downloading Data: Generating a Report)**

➤ **Option 1: Read out day to day directly on the device (30 day overview)**

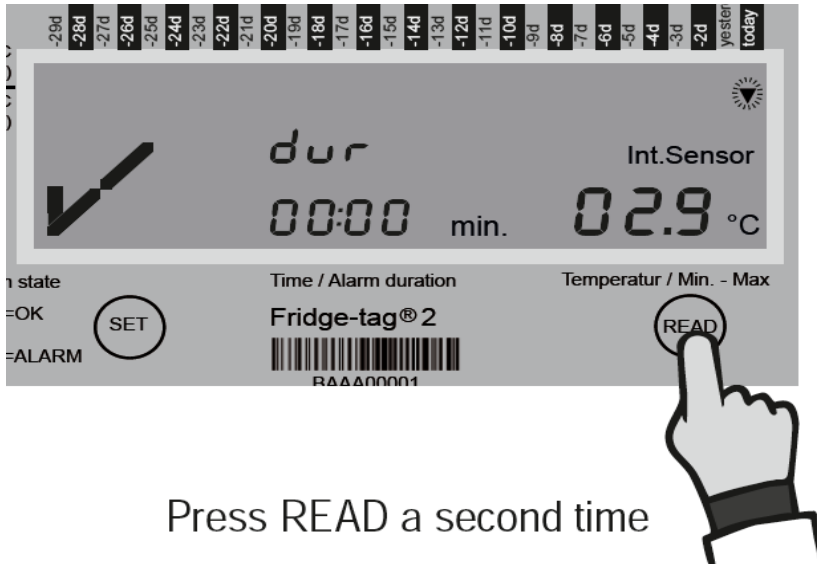
Example of an **OK** display- during read out of the history



Press READ 1x

The Following information is indicated on the screen:

- The **OK** symbol
- The corresponding arrow (example **high** (▲)arrow of today)
- Highest Recorded temperature (example: **+10.5°C**)
- The time duration out of the preset temperature high limit (example: **00:32**; hrs:min)



Press READ a second time

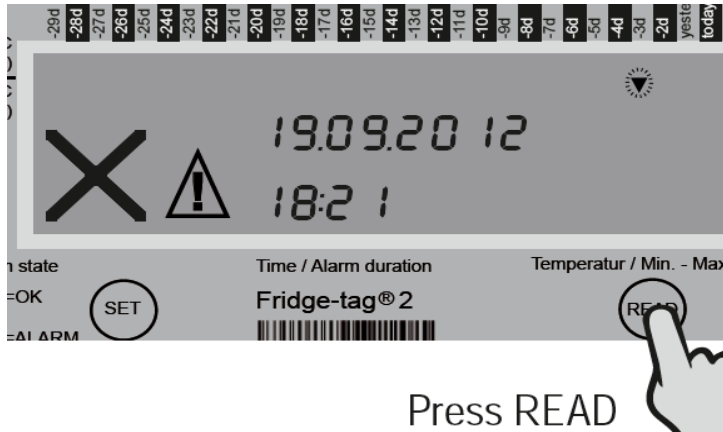
The following information is indicated on the screen:

- The OK symbol
- The corresponding arrow (example: **low** arrow (▼) of today).
- Lowest recorded temperature (example: **+2.9°C**)
- The time duration out of the preset temperature low limit (example **00:00**;hrs:min).

*Continue to repetitively press the READ button to read out the details of the past 30 days.

*When you reach an ALARM event, the indication on the screen of the Fridge-tag® 2 will be different to the indication of an OK display.

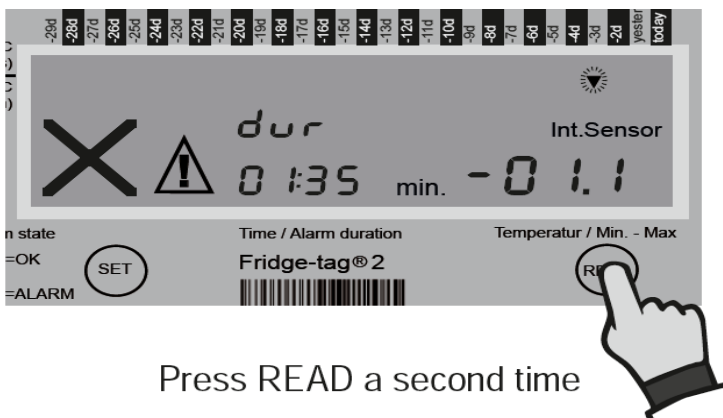
Example of an ALARM display-during read out of the history 1st displayed screen of a “lower ALARM event”



The following information is indicated on the screen:

- The ALARM symbol **X**.
- The corresponding arrow: **Lower ALARM limit (▼)**
- Day of Alarm: 3 days ago (-3d)
- The date of excursion: **19:09.2012**
- The time of excursion: **18:21**

2nd displayed screen of a “lower ALARM event”:



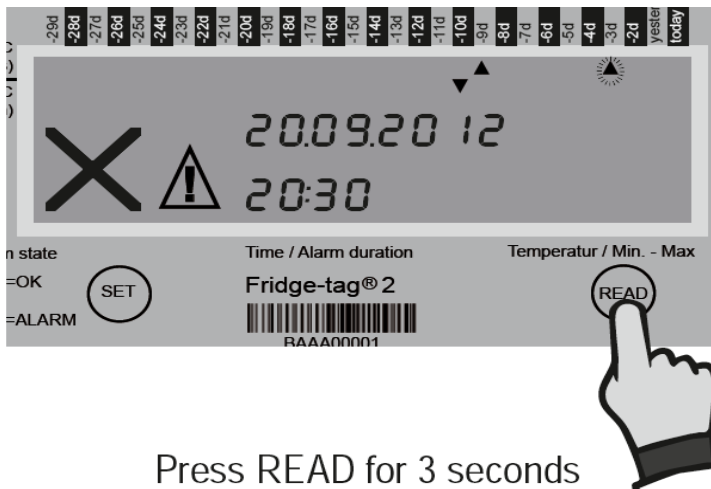
The following additional information is indicated on the screen:

- Lowest recorded temperature: **-1.1°C**
- The time duration out of the preset temperature low limit: **01:35**; hrs: min
- Temperature recording with: Internal sensor

➤ **Option 2: Read out Alarms only, directly on the device with the ALARM-SUPER-JUMP function (30 day history)**

If you like to read out only the ALARMS directly on the device, press and hold the READ button for at least **3 seconds**.

1st displayed screen of the latest ALARM event:

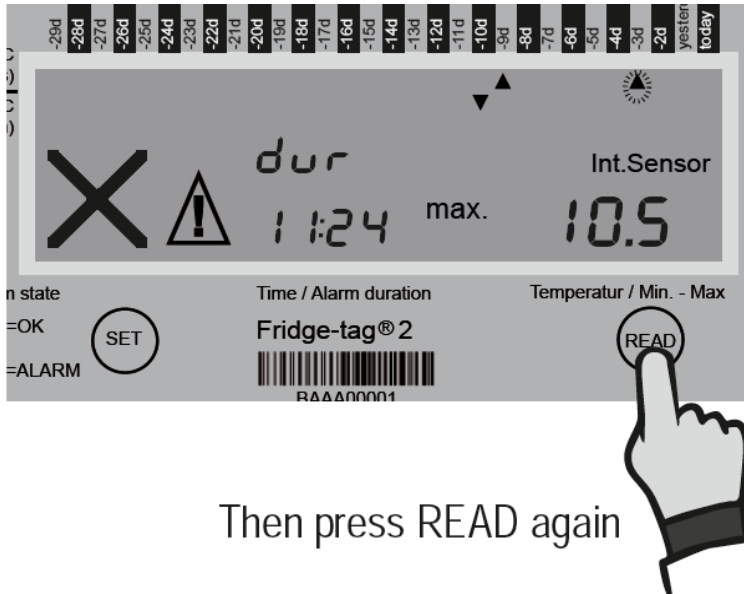


Press READ for 3 seconds

The following information is indicated on the screen:

- The ALARM (X) symbol
- The corresponding arrow: **Upper ALARM limit (▲)**
- Day of Alarm: 3 days ago (-3d)
- The date of excursion: **20.09.2012**
- The time of excursion: **20:30**

2nd displayed screen of the latest ALARM event



Then press READ again

The following additional information is indicated on the screen:

- Highest recorded temperature (example: **+10.5°C**)
- The time duration out of the preset temperature high limit (example **11:24**; hrs: min).
- Temperature recording with: Internal Sensor *Note: your Fridge-tag®2 device is equipped with an External sensor/Bio-safe glycol filled vial and probe).

Information:

Press and hold the READ button again for at least 3 seconds and the next Alarm event will appear on the screen.

➤ Option 3: Downloading Data: Generating a report

Plug the Fridge-tag® 2 into any computer via USB Interface.

1. Detach the wire from the port on the side of the Fridge-tag 2 external monitor
2. Gently pull out the USB wire on top of the device and plug it in to the USB port on your desk top or lap top computer.
3. Open "My Computer" from the Start Menu to access the Fridge-tag 2 drive and double click on the icon to view the files (PDF and ASCII/text).
4. Click on the PDF file to open the report.
5. **Save** downloaded data to your computer for archive, print, and/or email to the VVFC Program Manager for review.
6. Rename each file with the date of download for easy reference.
7. Maintain a file of all downloaded temperature reports for a period of 3 years.

Sample of a PDF-file generated by a Fridge-tag® 2

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PDF document of the Fridge-tag® 2

Identification number: 1234
 Date and time of report creation: 03.12.2012 10:05h
 Upper alarm limit: Above +8.0°C for 10hrs
 Lower alarm limit: Below -0.5°C for 60min
 Low battery since: 25.11.2012

No.	Date (dd.MM.yyyy)	Events*	Average temp.	Lower alarm limit			Upper alarm limit			Ext. sensor connection error			Signature / notes						
				Status	Min. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.	Status	Max. temp.	Duration out of range	Alarm trigger time		Alarm ambient temp.	Status	Duration	Alarm trigger time		
1	Today		+4.6°C	In progress	+4.1°C	0min													
2	02.12.2012		+4.5°C	ok	+4.0°C	0min													
3	01.12.2012		+4.5°C	ok	+4.0°C	0min													
4	30.11.2012		+4.3°C	ok	+3.9°C	0min													
5	29.11.2012		+2.2°C	ALARM!	-1.5°C	2h 30min	10:07h												
6	28.11.2012		+3.4°C	ok	+2.8°C	0min													
7	27.11.2012		+3.4°C	ok	+2.8°C	0min													
8	26.11.2012		+3.5°C	ok	+2.9°C	0min													
9	25.11.2012		+4.6°C	ok	+4.1°C	0min													
10	24.11.2012		+4.5°C	ok	+4.0°C	0min													
11	23.11.2012		+4.5°C	ok	+4.0°C	0min													
12	22.11.2012		+4.3°C	ok	+3.9°C	0min													
13	21.11.2012		+4.6°C	ok	+4.1°C	0min													
14	20.11.2012		+2.0°C	ALARM	-2.0°C	3h 10min	10:20h												
15	19.11.2012		+4.5°C	ok	+4.0°C	0min													
16	18.11.2012		+4.3°C	ok	+3.9°C	0min													
17	17.11.2012		+4.6°C	ok	+4.1°C	0min													
18	16.11.2012		+4.5°C	ok	+4.0°C	0min													
19	15.11.2012		+8.5°C	ok	+7.5°C	0min													
20	14.11.2012		+4.3°C	ok	+3.9°C	0min													
21	13.11.2012		+4.6°C	ok	+4.1°C	0min													
22	12.11.2012		+4.5°C	ok	+4.0°C	0min													
23	11.11.2012		+2.5°C	ok	+1.0°C	30min													
24	10.11.2012		+4.3°C	ok	+3.9°C	0min													
25	09.11.2012		+4.6°C	ok	+4.1°C	0min													
26	08.11.2012		+4.5°C	ok	+4.0°C	0min													
27	07.11.2012		+4.5°C	ok	+4.0°C	0min													
28	06.11.2012		+4.3°C	ok	+3.9°C	0min													
29	05.11.2012		+4.6°C	ok	+4.1°C	0min													
30	04.11.2012		+4.5°C	ok	+4.0°C	0min													

Page 1

Signature: _____

Date and place: _____

*1 = time / date changed, b = battery changed, a = alarm configuration changed

Explanation of PDF report:

DATE	Date of measurement
Event: t	Time/ date changed
Event: b	Battery changed
Event: a	Alarm configuration changed
Average temp.	The data collection of “Today” is not yet complete
Status: OK	No alarm has been triggered
Status: ALARM!	Alarm(s) have been triggered (With “!” means that the details of the corresponding alarm have not been read out yet
Status: ALARM	Alarms have been triggered (Without “!” means that details of the corresponding alarm have already been read out on the device
Min. temp.	Lowest recorded temperature
Max. temp.	Highest recorded temperature
Duration out of Range	Time outside of the alarm limits
Duration	Duration of an external sensor connection error
Alarm trigger time	Time at which the alarm was triggered

IX. Protocol for Reading, Downloading and Reporting Temperature Data:

1. Become familiar with how to operate your Fridge-tag®2 device.
2. READ your temperature data on the data logger as often as possible but at a very minimum of twice daily during operating business hours. It is important that you check and record the temperatures of both the refrigerator and freezer units at the beginning and end of each workday. **If there is an alarm on your device, READ out the temperature history immediately to determine the duration and extent of the temperature excursion. Immediate corrective action can then be taken as necessary. It is vital that appropriate action is taken to rectify the cause of the temperature excursion and preserve vaccine viability.**
 - a. Refer to Appendix 1: *Emergency Response Worksheet*
3. The logger will have 30 days of data for review from the display; the PDF report contains 60 day's data. You'll want to keep a printed monthly log with your twice daily temp logs. (Saving the PDF files monthly as an electronic back-up would serve as a 'best-practice'). Be sure to use the "save as" option and give each file a unique name. (e.g., JulyRefrigeratorTemps.pdf).

***Important:** It is highly recommended if you have more than one data logger, that each device be labeled (with a sharpie or other permanent method) which device is dedicated to each storage unit.

X. Explanation of Terms:

- **Read out mode**

In order to avoid incorrect data, the Fridge-tag 2 does not collect any readings while in the Adjustment or READ mode(e.g. changing time, date and during reading history). The Fridge-tag 2 will fall back into normal operation after 30 seconds without pressing any buttons. The LOC function will be activated.

- **HI or LO indicator (with an internal sensor)**

If the Fridge-tag 2 measures temperatures above +55°C or below -30°C, it shows “HI and “LO” on the screen and also in its extreme temperature memory. The regular measurements and monitoring of alarm limits will continue as usual. As soon as the temperature is between +55°C and -30°C numbers will be displayed again.

- **Expire code explanation: Sample exp 2016-07**

The sample shows the expiry date of the Fridge-tag 2 as July, 2016.m

More information about the Fridge-tag® 2 can be found in the sales brochure and the website www.berlinger.com

Technical specifications

Storage condition (inactive)	-30°C to +60°C
Operating Temperature	-30°C to +55°C
Display visible	-10°C to +55°C
Accuracy of temperature measurement	+/- 0.5°C (-5°C to +30°C) +/- 0.6°C (beyond this range)
Accuracy of time measurement	+/- 30 minutes/year
Temperature measurement interval	Every minute
Operating lifetime	Up to 3 ½ years following manufacture date
Protection class	IP67

XI. Battery Specifications and Care

- The Fridge-tag®2 contains a CR Lithium battery. Please pay strict attention to the following:
- The housing of the Fridge-tag®2 must never be opened nor destroyed
- Never expose the Fridge-tag®2 to temperatures above the allowed range (fire, oven, microwaves,etc.)
- Always keep the Fridge-tag 2 out of the reach of children
- The battery complies with IATA DGR Packaging Instruction 970 Section 2 and is therefore not considered dangerous.
- Dispose or recycle the battery in accordance with your local regulations. The Fridge-tag®2 may also be returned to the manufacturer for proper recycling.

XII. Life of Device

The devices can be used up to 3 ½ years after production date with respect to the following conditions:

- The buttons are not pressed for a very long time, e.g. if jammed between the items in storage
- Storage and operation of the device remains inside the recommendations of the manufacturer, especially very low temperatures should be avoided.
- The end of the battery life is indicated by the low battery indicator on the display. Please make sure to replace devices with activated low battery indicator within 20 days. Accuracy and proper function of the device cannot be assured beyond this period.

For additional online Resources, Downloads and Instructional Video, visit:

<http://www.berlinger.ch/en/berlinger/main/ambient-tag/downloads/fridge-tagr-2.html>

Appendix 1

Emergency Response Worksheet

What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Notify the local or state health department or call the manufacturer (see manufacturers' phone numbers below).
4. Record action taken.

Record this information*:

1. Temperature of refrigerator: current _____ max. _____ min. _____
2. Temperature of freezer: current _____ max. _____ min. _____
3. Air temperature of room where refrigerator is located: _____
4. Estimated amount of time the unit's temperature was outside normal range:
refrigerator _____ freezer _____
5. Vaccines in the refrigerator/freezer during the event (use the table below)

*Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Vaccines Stored in Freezer

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Other Conditions

1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Y N
3. Other: _____

Manufacturers

- Crucell Vaccines Inc. (800) 533-5899
- CSL Biotherapies, Inc. (888) 435-8633
- GlaxoSmithKline (888) 825-5249
- MedImmune, Inc. (877) 633-4411
- Merck & Co., Inc. (800) 672-6372
- Novartis Vaccines (800) 244-7668
- Pfizer Inc. (800) 438-1985
- sanofi pasteur (800) 822-2463

Other Resources

Local health department phone number _____ State health department phone number _____

Adapted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010.

www.immunize.org/catg.d/p3051.pdf • Item #P3051 (10/10)

Additional Resources:

<http://www.berlinger.ch/en/berlinger/main/ambient-tag/downloads/fridge-tagr-2.html>

<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>

- CDC Vaccine Storage and Handling Guide

<http://www.cdc.gov/vaccines/recs/storage/guide/default.htm>

- Immunization Action Coalition Emergency Response Worksheet

<http://www.immunize.org/catg.d/p3051.pdf>

- IAC has created temperature recording logs and a troubleshooting record: “Vaccine Storage Troubleshooting Record” to document unacceptable vaccine storage events. These materials provide guidance on the appropriate steps to take in the event of a storage problem (see www.immunize.org/handouts/vaccine-storage-handling.asp)

Internet Link to Instructional Videos:

- <http://www.berlingerusa.com/fridgetag2/supportvideos/>

The above link provides step-by-step instructions to perform the following tasks on your Fridge-tag®2 data loggers:

- Video 1: How to Start the Fridge-tag® 2
- Video 2: How to install the Fridge-tag® 2 sensor in a refrigerator
- Video 3: How to read reports for Fridge-tag® 2
- Video 4: How to read Fridge-tag® 2 screen, daily min/max temperatures and track reading activity
- Video 5: How to change Fridge-tag® 2 time, date, celsius