

Fridge-tag[®] 2 E

with internal sensor



OPERATION MANUAL

ENGLISH

PAGE 1-36

MODE D'EMPLOI

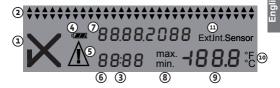
FRANCAIS

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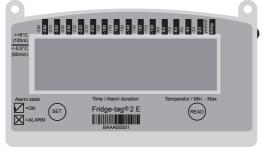
1) Display explanations



- OK (√) or ALARM (X) indicator
- HIGH / LOW alarm indicators (showing history of the last 30 days)
- (3) Power on indicator (double point is flashing)
- Battery power This icon indicates the remaining capacity of the battery
- 5 Additional warning symbol
- (6) Time, duration and text indicator
- (7) Date and text indicator
- (8) Indicator of measured minimum/maximum temperature
- Temperature display
- (10) Indicator of the temperature measurement unit (°F or °C)
- Indicator of activated sensor: Int. = internal sensor (inside the Fridge-tag® 2 E) Ext. = external sensor (cable with temperature sensor)

2) State of delivery / Sleep Mode

Fridge-tag® 2 E is shipped in its so-called "Sleep Mode".

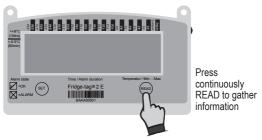


The display (LCD) is blank.

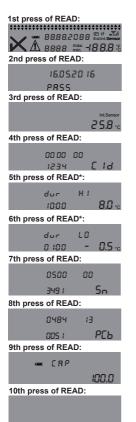
3) Gathering information prior to device activation (in Sleep Mode)

The following chart shows which information will be indicated on the LCD screen upon successive READ button pressings while in Sleep Mode.

Note: After approx. 60 seconds without any button pressing the Fridge-tag[®] 2 E goes back into Sleep Mode; the display is blank again.



Pressing the READ-button



Displayed Information

Display test: all segments activated

Indication of date and production test result: 16. September 2015 / PASS

Indication of the current temperature and which sensor is activated (--.-°C if is not connected)

Indication of configuration ID number (e.g. 1234)

Indication of upper alarm settings. Example shows duration and temperature limits: 10 hours, >+8°C, high

Indication lower alarm settings: example shows duration and temperture limits: 60 min., <-0.5°C, low

Serial number of the device

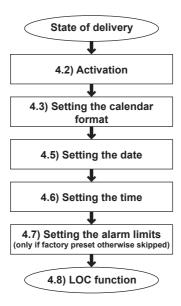
PCB number (manufacturer information only)

Battery power: 3 bar = full (>70%) 2 bar = half-full (30-70%) 1 bar* = low (0-30%) *Device should be replaced.

The display is blank again.

*(only indicated if factory preset, otherwise skipped)

4) Activation process 4.1) Overview sequences of activation



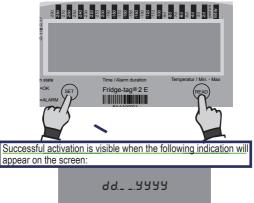
NOTE:

If the activation process has not been completed - after approx. 60 seconds without any button operation - the device will go back into Sleep Mode. The activation starts from the beginning.

If you want to read or change settings (e.g. change °F to °C) after the activation has been completed, proceed as described in chapter "Read and change settings / How to correct setting mistakes"

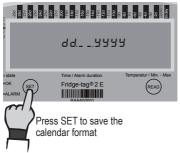
4.2) Activation

To activate the device press the SET and the READ button simultaneously for more than 3 seconds.



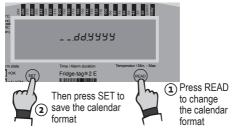
4.3) Setting the calendar format

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



English

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



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

4.4) Instruction for the use of the READ and the 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

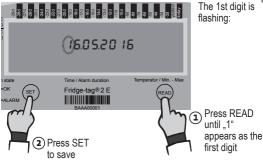
The **SET button** is used to save the number. After pressing the SET button the next digit will start flashing.

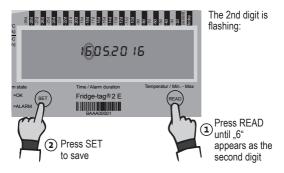


Note: If SET is pressed mistakenly, continue with the set up. Instructions for changing the mistake are described in chapter "Read and change settings / How to correct setting mistakes".

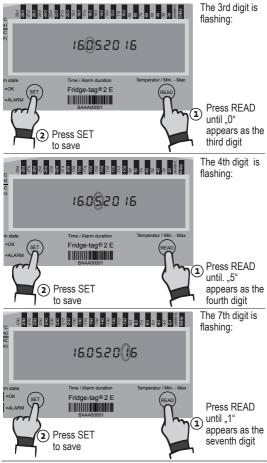
4.5) Setting the date

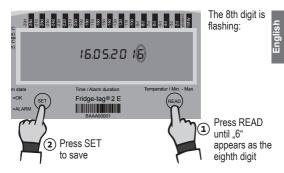
The following example shows how to set the date to: 16th of Sep. 2012 (16.09.2012) in Europe format





English





The date is now set to: 16.09.2012

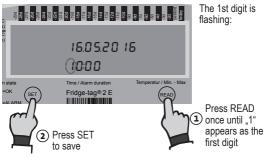
After setting the date, the first digit of the time will start flashing.

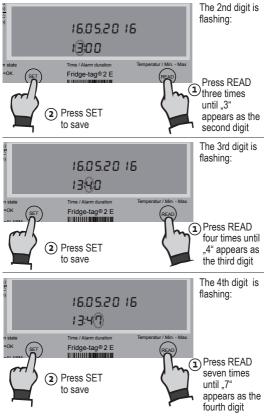
4.6) Setting the time

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

Note:

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





The time is now set to: 13:47

English

IMPORTANT: If the device is configured with self-programmable alarm limits proceed with the following chapter.

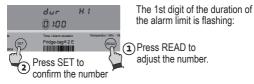
If not, the activation is now completed and on the display the word "LOC" appears. Please proceed now with chapter 4.8, LOC function.

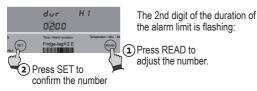
4.7) Setting the alarm limits (Not standard, only by special order)

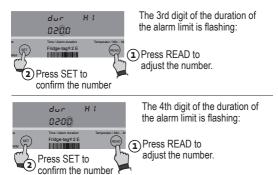
This adjustment is done in 4 steps:

- 1) Setting the duration of the upper alarm limit
- 2) Setting the temperature of the upper alarm limit
- 3) Setting the duration to the lower alarm limit
- 4) Setting the temperature of the lower alarm limit

1) and 3) Setting the HI & LO alarm duration, they are completed in the same manner







The duration of the alarm limit is now set.

2) and 4) Setting the HI and LO alarm temperature, they are completed in the same manner

Note: Alarm temperature limits must be no lower than -20 $^{\circ}$ C (-4 $^{\circ}$ F) and no higher than +50 $^{\circ}$ C (+122 $^{\circ}$ F).

First you have to choose the range of the desired temperature limit. You have the choice between negative and positive temperatures. In case of a positive limit in Fahrenheit scale you may further choose if the limit shall be equal or above +100 °F. This choice is done by repetitively pressing READ until the desired range is indicated.

Note: The temperature measurement unit (°C / °F) can only be changed after the device is activated in the menu. Go to chapter "Read and change settings / How to correct setting mistakes". Instruction for setting a positive temperature limit between 0 °C / 0 °F and +50 °C / +122 °F



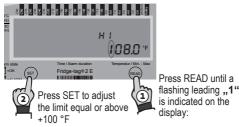
1=OH

Press READ until the display shows **no flashing sign**:

The next digit can now be set. Press READ until you reach the desired number. Then press SET to confirm it. Then the next digit will start flashing. Continue until all digits of the alarm temperature are set.

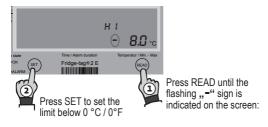
Instruction for setting a positive Fahrenheit temperature limit equal or above +100 °F

(Important: the maximum Celsius temperature is +50 °C. This Option is only for temperatures in Fahrenheit)



The next digit of the temperature starts flashing. Set the number and continue until all digits of the alarm temperature are set.

Setting a negative temperature limit below 0 °C / 0 °F



The next digit can now be set. Press READ until you reach the desired number. Then press SET to confirm it. Then the next digit will start flashing. Continue until all digits of the alarm temperature are set.

As soon as the parameters of the upper alarm limit are set, the first digit of the duration of the lower alarm limit will start flashing. Proceed the same way as you did with the upper alarm limit.

As soon as the last digit of the lower alarm limit is confirmed, the activation is completed. The display will now indicate the word "LOC".

Note:

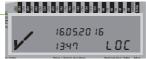
In case the desired temperature limit cannot be confirmed, check if the temperature is set within the allowed operating temperature range.

4.8) LOC function

The Fridge-tag® 2 E does not measure temperatures under the following circumstances:

- · During the activation process of the device
- · While pressing buttons (READ or SET)
- While the Fridge-tag[®] 2 E is connected to a PC / Mac

After these actions have been completed, the Fridge-tag® 2 E will not record temperatures for a period of 10 minutes (other setting upon request). In the display the symbol "LOC" appears. This function prevents false recordings of data which could be caused by heat while holding the device in the hands. Additionally it allows an adaption to the environmental temperature before normal recording continues.



NOTE:

- Even in LOC mode the user can press the READ button to retrieve history information, change any setting or download a report to a computer. The whole LOC period will start again after the last button operation.
- If an action is interrupted, the device will start the LOC function approximately 30 seconds after last button operation.

5) Placing the Fridge-tag[®] 2 E

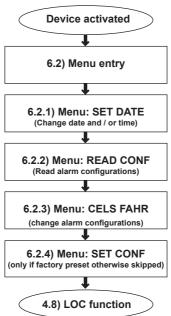
Fridge-tag® 2 E with an internal sensor

The activated Fridge-tag® 2 E must be placed immediately in its predetermined location. It is recommended and important to place the device as close to the supervised goods as possible to ensure a perfect temperature observation.

Note: For the right positioning of the Fridge-tag[®] 2 E within the fridge, please follow the instructions of WHO, CDC or any other governmental requirements of your country. (For more information visit www.berlinger.com)

6) Read and change settings / How to correct setting mistakes

6.1) Overview menu



NOTE:

If you scroll through the menu and you reach the LOC function you need to restart from the begining by accessing the menu. Even in LOC mode you can access the menu to read and change

settings. In order to adjust more than one setting (e.g. time & Celsius to

In order to adjust more than one setting (e.g. time & Celsius to Fahrenheit) you must complete each change and return to menu mode for the 2nd change.

6.2) Menu entry to read and change settings

To change the date format, the date, the time, the temperature measurement unit or the alarm settings or to read the pre-set alarm limits please proceed as follows:



"SET DATE" is now displayed on the screen.

You entered the menu mode and may choose which item to see or change.

You can access the following 4 menus:

- 1) SET DATE change date and/or time settings
- 2) READ CONF read the alarm settings
- 3) CELS FAHR change to Celsius or Fahrenheit
- 4) SET CONF change the alarm settings (only if factory pre-set)

Use the **READ button** to scroll through the menu. Use the **SET button** to access the corresponding menu.

6.2.1) Access the menu "SET DATE"

The display shows the menu "SET DATE". **Press SET** to access the menu to adjust the date format, date or time settings. Then follow the steps as described in chapter "Setting the date and time".

Information:

- Time and date adjustments have no effect on the alarm records.
- Once the device is activated, it cannot be stopped anymore.
- The number of time adjustments during the same day is unlimited. **Note:** After the adjustment has been done, the Fridge-tag[®] 2 E will be locked for 24 hours from the following midnight (e.g. changes on the 15th May, device locked from 00:01 am on the 16th until 00.01 am on the 17th). This is for security reasons.

6.2.2) Access the menu "READ CONF"

The display shows the menu "SET DATE". **Press READ** until the display shows "READ CONF". Then **Press SET** to access the menu to read the current alarm configurations. First the display check appears. Then continuously press **READ** to scroll through the pre-set alarm parameters.

6.2.3) Access the menu "CELS FAHR"

The display shows the menu "SET DATE". **Press READ** until the display shows "CELS FAHR". Then **Press SET** to access the menu to change the temperature measurement unit. To change the measurement unit (Celsius / Fahrenheit) **press READ** until the display shows the desired sign (°C / °F). **Press SET** to confirm the mesurement unit.

6.2.4)* Access the menu "SET CONF"

The display shows the menu "SET DATE". **Press READ** until the display shows "SET CONF". **Press SET** to access the menu to change the alarm configurations. To change the alarm limits (duration or temperature) please proceed as described in chapter "Setting the alarm limits".

*Changes of the alarm limits are only possible for devices which are programmed with this feature.

7) Display indication during measurement mode

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



During max. 1 minute after the LOC-period no current temperature is displayed on the screen.

Example of OK Display - during measurement



Once the device is fully activated the (\checkmark) OK symbol, the current temperature reading, the time and the date will be displayed on the screen. The Fridge-tag[®] 2 E will also indicate that the measuring is made with an internal sensor.

A ($\sqrt{}$) OK symbol is indicated during normal operation as long as no alarms have been recorded. The temperature and time conditions were within the preset alarm parameters.

Example of ALARM Display - during measurement



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

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

8) Warning symbol <u>/</u>

Option 1: The warning symbol will remain visible until the user reads the details of the triggered alarm/s from the display. After that it will disappear. ALARM indications cannot be cancelled nor reset.

Option 2: The warning and ALARM symbol (X) will remain visible until the user reads the details of the triggered alarm/s from the display. After that both symbols will disappear and the display will go back to the OK Symbol ($\sqrt{$).

Note: How the ALARM symbol (X) and the warning symbol react is specified in the configuration of the device.

9) Reading the History

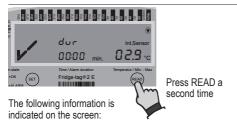
The information of the temperature excursions can either be viewed for the past 30 days directly on the device or for 60 days on the generated files (PDF/ASCII).

9.1) Option 1: Read out day-per-day directly on the device (30 day history)

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



- 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).



- 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).

5

Note: Continue repetitively pressing the READ button to read out day per day the details of the past 30 days.

Information:

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

Example of an ALARM display - during reading out of the history

1st displayed screen of a "lower ALARM event"



The following information is indicated on the screen:

- The ALARM symbol
- · The corresponding arrow (example: Lower ALARM limit)
- Day of Alarm (example: 3 days ago -3d)
- The date of excursion (example: 19.05.2016)
- The time of excursion (example: 18:21)

2nd displayed screen of a "lower ALARM event":



The following additional information is indicated on the screen:

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

9.2) Option 2: Read out only alarms directly on the device - use 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:



The following information is indicated on the screen:

- · The ALARM symbol
- The corresponding arrow (example: Upper ALARM limit)
- Day of Alarm (example: 3 days ago -3d)
- The date of excursion (example: 19.05.2016)
- The time of excursion (example: 20:30)

2nd displayed screen of the latest ALARM event



The following additional information is indicated on the screen:

- Highest recorded temperature (example: +10.5 °C)
- The time duration out of the preset high temperature limit (example 11:24; hrs:min).
- Temperature recording with (example: Internal sensor)

Information:

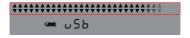
Press and hold the READ button again for at least **3 seconds** and the next Alarm event will appear on the screen.

9.3) Option 3: Read out data from the files generated by the Fridge-tag[®] 2 E by connecting it with a computer (60 day history)

Plug the Fridge-tag[®] 2 E into any computer via USB Interface. Make sure the device is plugged in properly.



Wait sufficient time for the device to generate the ASCII and PDF files (depending on the programming, this process may take up to 30 seconds). You can see that the device is working from the continuously appearing arrows in the upper display area.



Note: This process must not be interrupted, until the tick appears on the display, indicating that the report creation is complete.



When the report creation is complete, one of the following windows will appear on your computer: Open the appropriate file generated by the Fridge-tag[®] 2 E.



Information:

For this process no additional software is necessary.

Note:

For a proper USB-port disconnection of the device, please always use the "safely remove hardware" function any our PC/Mac.



Right mouse click on the icon to Eject ... (choose the right device to remove).

Do not disconnect the device before you receive the following message:



English

PDF document of the Fridge-tag® 2

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4 04.11.2016 11:17h 24.10.2016 11:21h	Above +8.0°C for 1h Below +2.0°C for 1h	1min (fixed)
Identification number: Date and time of report creation: Activation date:	Upper alarm limit: Lower alarm limit:	Measurement interval: ¹⁾

				Lower alarm limit	n limit			Upper alarm limit	m limit				
ž	No. Date	Events ²⁾	Average	Status	Min.	Cumulative	Alarm	Status	Max.	Cumulative	Aarm	Signature / notes	
	(dd.MM.ywy)	2	temp.		temp.	daily time below the limit	trigger time		temp.	daily time above the limit	trizger time	Action taken	
-	Today		+21.8°C	In progress +21.0*C	+21.0°C	Omin		ALARMI	+26.7*C	11h 17min	00:00h		-
C 1			+22.8°C	ok	+19.1*C	Omin		ALARMI	+24.1°C		400:00		
0	02.11.2016		+21.9°C	×	+20.6°C	Omin		ALARMI	+23.3°C		400:00		
4			+20.4*C		+20.0°C	Omin		ALARMI	+21.0°C		00:00H		-
6			+20.7*C		+20.3*C	Omin		ALARMI	+21.9°C		00:00H		
0			+20.6°C		+20.3°C	Omin		ALARMI	+21.1°C		00:00		-
~	29.10.2016		+20.6°C		+20.4°C	Omin		ALARMI	+21.1°C		400:00		-
0			+21.4°C		+20.8°C	Omin		ALARMI	+22.5°C		00:00		-
0	27.10.2016		+13.1°C	×	+1.1°C	4h 41min		ALARMI	+23.3*C		12:05h		-
9	26.10.2016	08:41,12:19	+3.0°C	ALARM	+0.8°C	7h 12min	12:16h	ALARM	+8.6°C		15:04h		-
5	25.10.2016	09:49	+3.0°C	ALARM	-6.1°C	6h 21min	11:21h	ALARM	+10.0°C	1h 30min	12-52h		-
12	24.10.2016		+2.8°C	k k	+1.5°C	2h 35min		ok	+9.6°C	Smin			-
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Signature

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

Information: File names on the Fridge-tag® 2 E are write protected. The names may only be changed after downloading onto a computer. Changing is either possible directly on unopened files or via open and save commands with the Adobe Reader. Using other programs may cause loss of the digital signature.

Explanation of PDF report:

Date	Date of measurement		
Event: t	Time / date changed		
Event: a	Alarm configuration changed		
Event: hh:mm	Time stamp: status checked		
Average temp.	Average temperature		
Status: in progress	The data collection of "Today" is not yet complete		
Status: OK	No alarm has been triggered the past 30 days (No alarm has yet been triggered since the last data read out on the device.*)		
Status: ALARM!	Alarm/s have been triggered (With "!" means that the details of the corresponding alarm have not been read out yet*)		
Status: ALARM	Alarm/s have been triggered (Without "!" means that the 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		
* For more information go to chapter 8 "Warning symbol"			

ıglish

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9.4) Veryfication process

This process is to verify if the files (PDF and ASCII-file) created by the Fridge-tag[®] 2 E are authentic and have not been manipulated or accidentally changed (meets the strict FDA 21 CFR Part 11 requirements).

1st step:

Download the software "Verifier" from our website: <u>www.berlinger.com</u>

2nd step:

Open the software. The following window will appear:

3rd step:

Click on "Open file"

Q-tag® Verifier		
Open file	Open directory	
Please open one of	f the following items to start:	

4th step:

Select the file you would like to verify.

Option 1:

Select the files directly from the Fridge-tag[®] 2 E which is connected to your computer.

Option 2:

Select the files from the place where you saved them on your computer.

When the file is correct and in its original condition, the following window will appear:

Open directory	
	Open directory

In case the file has been changed, an "error message" will appear.

Proceed the same way with the PDF or the ASCII-file. The same OK or ERROR messages will appear.

10) Explanations of terms Read out mode

In order to avoid incorrect data, the Fridge-tag® 2 E does not collect any readings while in the Adjustment or Read-out mode (e.g. changing time, date and during reading of history). The Fridge-tag® 2 E will fall back into normal operation after approx. 60 seconds without pressing any buttons. The LOC function will be activated.

11) Expire code explanation Sample: exp 2021-07

The sample shows the expiry date of the Fridge-tag[®] 2 E as July 2021 (2021-07).

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

12) Technical specifications

Storage condition (inactive)	0 °C to +30 °C	
Operating temperature	-25 °C to +55 °C*	
Display visible	-10 °C to +55 °C	
Accuracy of temperature	+/- 0.8 °C (-25 °C to -10 °C)	
measurement	+/- 0.5 °C (-10 °C to +40 °C)	
	+/- 0.8 °C (+40 °C to +55 °C)	
Accuracy of time measurement	+/- 30 minutes/year	
Temperature measurement interval every minute		
Operating lifetime	up to 5 years - (check	
	battery indicator)	
Protection class	IP64	

* for temperatures below 0 °C (+32 °F) we highly recommend to use an external sensor in order to avoid a shorter battery life.

13) Important Information

Liability

The manufacturer shall not be held liable:

- · if the device was used beyond the manufacturer's given limitations.
- · for any claims due to the improper storage and use of the device.
- · for any problems with the temperature controlling and / or cooling unit.
- · for the bad quality of any monitored goods.
- for incorrect readings if the device was used beyond its expiry date.
 Warranty: 2 years from date of delivery.

Battery

The Fridge-tag® 2 E contains a CR Lithium battery. Please pay strict attention to the following points:

- The housing of the Fridge-tag[®] 2 E must never be opened nor destroyed
- Never expose the Fridge-tag[®] 2 E to temperatures above the allowed range (fire, oven, micro waves, etc.).It may cause injuries.
- · Always keep the Fridge-tag® 2 E out of the reach of Children
- The battery complies with IATA DGR Packaging Instruction 970 Section 2 and is therefore not considered as dangerous good.
- Dispose or recycle the Fridge-tag® 2 E in accordance with the WEEE 2012/19/EU guidelines or your local regulations. The device may also be returned to the manufacturer for proper recycling.

Useful life

The devices can be used up to 5 years after production date

- (1 year storage / 4 years useful life) on the condition that:
- the buttons are not pressed for very long time, e.g. if jammed between the goods in a shipment.
- storage and operation of the device should remain inside the recommendations of the manufacturer, especially temperatures below 0 °C or +32 °F could have a negative influence for the operating lifetime of the battery.

The end of the useful life is indicated by the battery indicator on the display (see chapter "Display information" on page 5) .

Attention

 The Fridge-tag[®] 2 E monitors temperature exposure and not the product quality. Its purpose is to signal if product quality evaluation or testing is required.



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20161104_Release_1.0

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