



OPERATION MANUAL

ENGLISH

PAGE 1-34

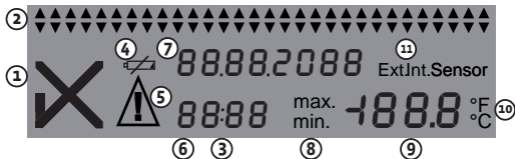
GEBRAUCHSANWEISUNG

DEUTSCH

SEITE 35-68

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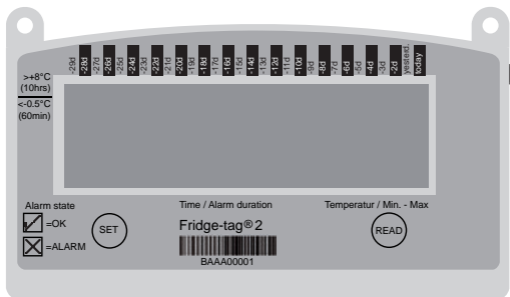
1) Display explanations



- 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)

2) State of delivery / Sleep Mode

Fridge-tag® 2 is shipped in its so-called „Sleep Mode“.

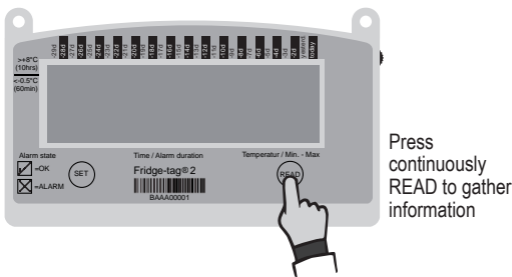


The display (LCD) is blank.

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.

After approx. 30 seconds without any button pressing the Fridge-tag® 2 goes back into Sleep Mode; the display is blank again.



Press continuously READ to gather information

Pressing the READ-button

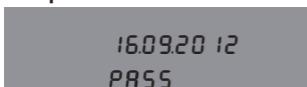
Displayed Information

1st press of READ:



Display test:
all segments activated

2nd press of READ:



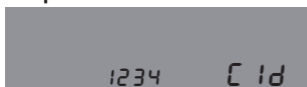
Indication of date and
production test result:
16. September 2012 /
PASS

3rd press of READ:



Indication of the current
temperature and which
sensor is activated

4th press of READ:



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

5th press* of READ:



Indication of upper alarm
settings. Example shows
the following duration and
temperature limits:
> +8.0°C, 10 hours, high

6th press* of READ:



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

7th press of READ:

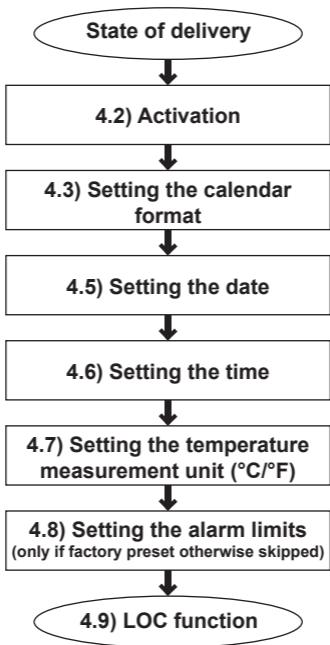


The display is blank again.

*(only indicated if factory preset, otherwise skipped)

4) Activation process

4.1) Overview sequences of activation



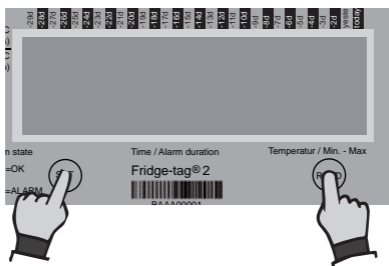
NOTE:

If the activation process has not been completed - after 30 seconds without any button operation - the device will go back into sleep mode. The activation starts from the beginning.

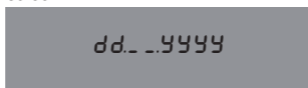
If you want to read or change settings (e.g. change °F to °C) after the activation has been completed, proceed as described in chapter „Read and Change settings / How to correct setting mistakes“

4.2) Activation

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



Successful activation is visible when the following indication will appear on the screen:



4.3) 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

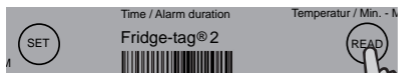
Then press SET to save the calendar format



After setting the calendar 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.

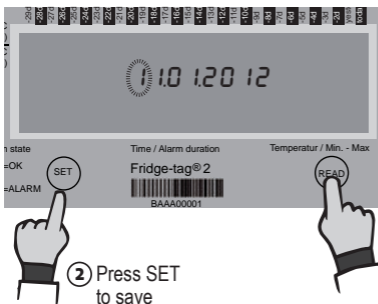


Press SET to confirm

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

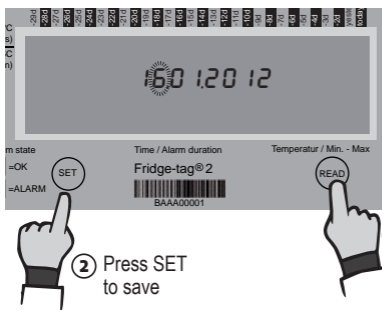
The following example shows how to set the date to: 16th of Sep. 2012 (16.09.2012) in Europe format



The first digit is flashing:

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:



② Press SET to save



①

Press READ until „0“ appears as the third digit



The fourth digit is flashing:



② Press SET to save



①

Press READ until „9“ appears as the fourth digit



The seventh digit is flashing:



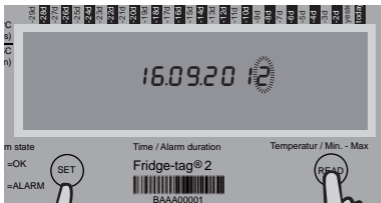
② Press SET to save



①

Press READ until „1“ appears as the seventh digit

The eighth digit
is flashing:



② Press SET
to save



① Press READ
until „2“
appears as the
eighth digit

The date is set now 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).

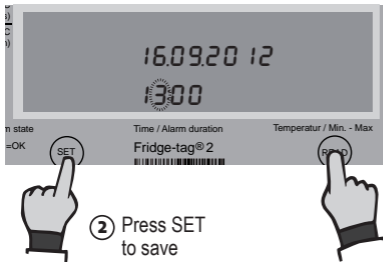


② Press SET
to save



The first digit is
flashing:

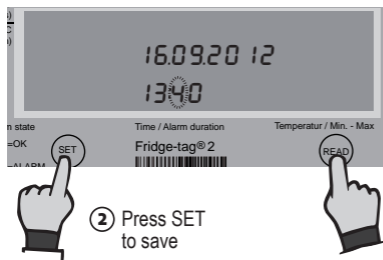
① Press READ
once until „1“
appears as the
first digit



The second digit is flashing:

- 1 Press READ three times until „3“ appears as the second digit

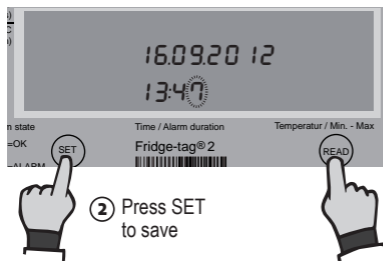
- 2 Press SET to save



The third digit is flashing:

- 1 Press READ four times until „4“ appears as the third digit

- 2 Press SET to save



The fourth digit is flashing:

- 1 Press READ seven times until „7“ appears as the fourth digit

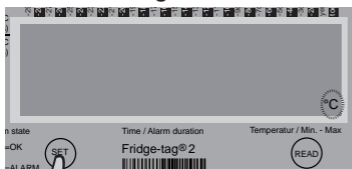
- 2 Press SET to save

The time is now set to: 13:47

After finishing the time setting, the „°C“ sign will appear at the right bottom corner.

4.7) Setting the temperature measurement unit

Option 1: Setting the measurement unit in Centigrade

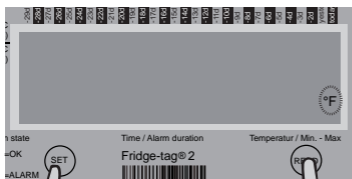


The „°C“ is flashing:



Press SET to confirm the temperature measurement unit in °C

Option 2: Setting the measurement unit in Fahrenheit:



The „°C“ is flashing:



Press SET to confirm the temperature measurement unit in °F



①

Press READ to change the temperature measurement unit to °F

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. Proceed now with chapter 4.9, LOC function.

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

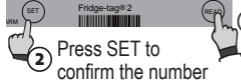
This adjustment is done in 4 steps:

- 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 first digit of the duration of the alarm limit is flashing:

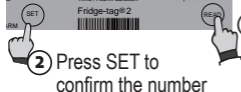


2 Press SET to confirm the number

1 Press READ to adjust the number.



The second digit of the duration of the alarm limit is flashing:

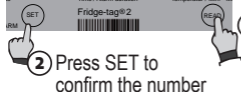


2 Press SET to confirm the number

1 Press READ to adjust the number.



The third digit of the duration of the alarm limit is flashing:



2 Press SET to confirm the number

1 Press READ to adjust the number.



The fourth digit of the duration of the alarm limit is flashing:

Press SET to confirm the number

Press READ to adjust the number.

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 -30°C (-22°F) and no higher than $+55^{\circ}\text{C}$ ($+131^{\circ}\text{F}$).

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 above $+100^{\circ}\text{F}$. This choice is done by repetitively pressing READ until the desired range is indicated.

Instruction for setting a positive temperature limit between $0^{\circ}\text{C}/0^{\circ}\text{F}$ and $+55.0^{\circ}\text{C}/99.9^{\circ}\text{F}$



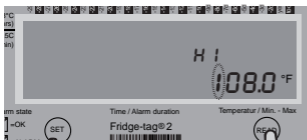
Press READ until the display shows **no flashing sign:**

Press SET to adjust the limit between $0^{\circ}\text{C}/0^{\circ}\text{F}$ and $+55.0^{\circ}\text{C}/99.9^{\circ}\text{F}$

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.

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

(Important: the maximum Celsius temperature is +55.0°C. This Option B is only for temperatures in Fahrenheit)



Press READ until a flashing leading „1“ is indicated on the display:

2 Press SET to adjust the limit equal or above 100°F

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 0.0°C/0°F



Press READ until the flashing „-“ sign is indicated on the screen:

2 Press SET to set the limit below 0°C/0°F

The next digit can now be set. Press READ until the 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:

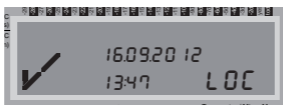
In case the desired temperature limit cannot be confirmed, check if the temperature is set within the allowed operating temperature range.

4.9) LOC function

The Fridge-tag® 2 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 is connected to a PC / Mac

After these actions have been completed, the Fridge-tag® 2 will not record temperatures for a period of 10 minutes (other setting upon request). In the display the symbol „LOC“ appears. This function prevents recordings of false data which could be caused by heat while holding the device in the hands and 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

Fridge-tag® 2 with an internal sensor

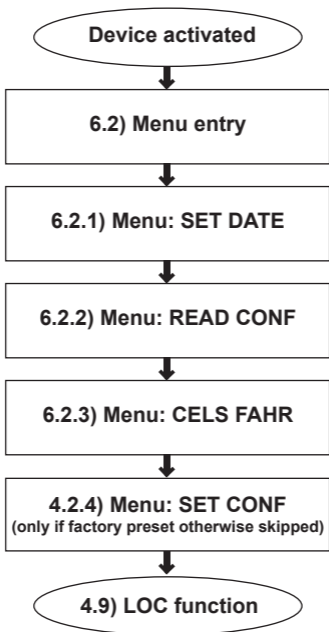
The activated Fridge-tag® 2 must be placed immediately in its predetermined location. It is recommended and important to place the device as close to the supervised goods as possible to ensure a perfect temperature observation.

For the right positioning of the Fridge-tag® 2 within the Fridge, please follow the instructions of WHO, CDC or any other governmental requirements of your country.

(For more information visit www.berlinger.ch/Fridge-tag2)

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

6.1) Overview menu



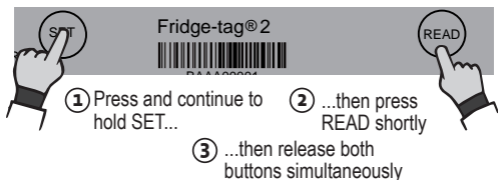
NOTE:

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

In order to change more than one setting (e.g. time & Celsius to Fahrenheit) you must complete each task, exit menu mode 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 now 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 will be locked for 24 hours from the following midnight (e.g. changes on the 15th Sep., 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 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.

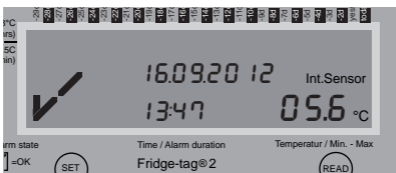
7) Display indication during measurement mode

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



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

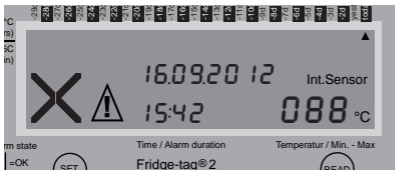
Example of OK Display - during measurement




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 internal sensor.

A (✓) (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 (✓) (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). 

Note:

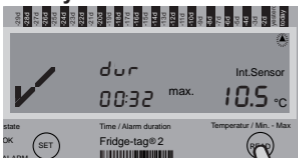
 The warning symbol will remain visible until the user reads the details of the triggered alarm/s. After that it will disappear. ALARM indications cannot be cancelled nor reset.

8) 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).

8.1) 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



Press READ once

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).

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 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“



Press READ



The following information is indicated on the screen:

- The **ALARM** symbol
- 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“:



Press READ a second time



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**

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**

Information:

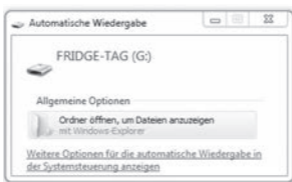
Press and hold the READ button again for at least **3 seconds** and the next Alarm event will appear on the screen.

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

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



The following window will appear:



Now open the files generated by the Fridge-tag® 2



Information:

For this process no additional software is necessary.

Information: File names on the Fridge-tag® 2 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: b	Battery changed
Event: a	Alarm configuration changed
Average temp.	Average temperature
Status: in progress	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	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

ASCII-file generated by a Fridge-tag® 2

For details about the ASCII file please visit our website:
www.berlinger.ch

8.4) Verification process

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

1st step:

Download the software „Verifier“ from our website:

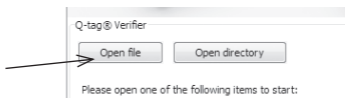
www.berlinger.ch/Fridge-tag2

2nd step:

Open the software. The following window will appear:

3rd step:

Click on „Open file“



4th step:

Select the file you would like to verify.

Option 1:

Select the files directly from the Fridge-tag[®] 2 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:



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

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

9) Explanations 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-out mode (e.g. changing time, date and during reading of 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.

10) Expire code explanation

Sample: exp 2016-07

The sample shows the expiry date of the Fridge-tag® 2 as July 2016 (2016-07).

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

11) 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 4 years - expiry date printed on label
Protection class	IP64

12) 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 contains a CR Lithium battery. Please pay strict attention to the following points:

- 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, micro waves, etc.). It may cause injuries.
- 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 as dangerous good.
- 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.

Useful life

The devices can be used up to 4 years after production date (1 year storage / 3 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 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.

Attention

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

Q-tag®

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