USER MANUAL

Fridge-tag Ultra Low

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User Manual Fridge-tag Ultra Low

1 — Last update: Feb 03, 2021

Berlinger & Co. AG

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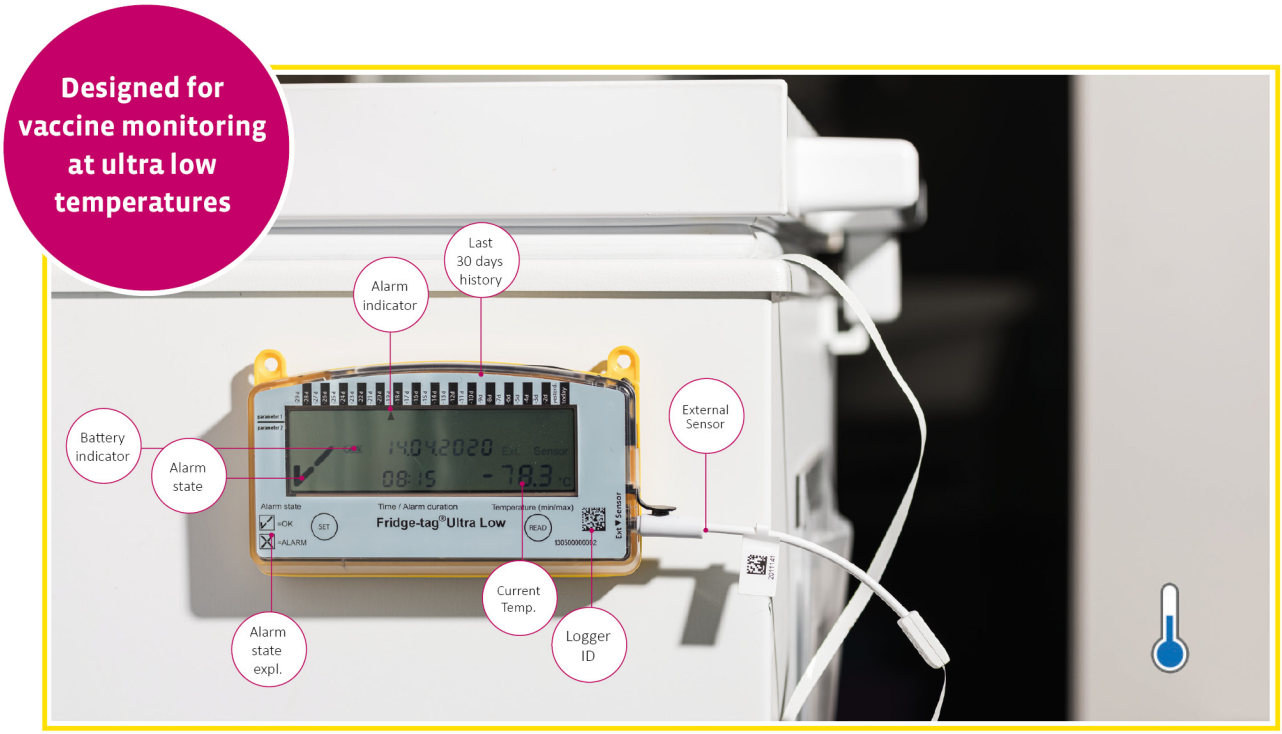
1. Home

Berlinger Fridge-tag Ultra Low



Proven Fridge-tag quality for ultra-low temperatures

The Fridge-tag Ultra Low is the intelligent temperature logger for the continuous monitoring of sensitive vaccines and pharmaceuticals stored at ultra-low temperatures down to -95°C / -139°F.

If an alarm limit is exceeded, an alarm will be triggered on the display and audible notification will be given. A quick decision and immediate action are thus possible.

With the built-in USB connection, a secure PDF/A report, with all relevant temperature data presented in a clear and easy understandable overview including temperature graphs, can be generated.

- Coolest operating temperature with external sensor: –95°C to +0°C / –139°F to +32°F
- Up to 3 years operating time
- User-friendly, reliable and high-precision

Intended purpose of the Fridge-tag Ultra Low

The intended purpose of the Fridge-tag Ultra Low is to measure temperature in a freezer and create a (summary) report upon user request.

Technical Specification
Product Information Overview

2. Important Information

Ensure safety of the products kept in freezer

The Fridge-tag Ultra Low monitors temperature of freezer, not of product itself. The user is at any time responsible for the judgement if the product can safely be used. The Fridge-tag Ultra Low does never make this judgement.

The user must verify that no temperature excursion is noted by the Fridge-tag Ultra Low before a product is taken from freezer. If a temperature excursion is detected, the user may have certain obligations established by (local) regulation. It is the user's responsibility to understand these regulatory obligations and to act accordingly.

Local regulatory requirements / other restrictions

Temperature monitoring of pharmaceutical products, including immunization products, may be subject to (local) regulation that describes how temperature monitoring should be carried out by personnel and what tools must be used. To be in compliance with (local) regulation, the user of the Fridge-tag Ultra Low may be required to carry out additional tasks for example: inspection, verification, signing, and archival. The Fridge-tag Ultra Low may assist the user with these tasks but does not necessarily perform any or all tasks required for the user to be compliant with (local) regulation.
Berlinger does not guarantee that the Fridge-tag Ultra Low and supportive systems comply with any regulation. The Fridge-tag Ultra Low and supportive tools/systems only comply with standards as provided in respective data sheets. Consult with (local) authorities on how to ensure compliance.

Warnings & Precautions

Points to be addressed by the user are, but not limited to:

- The Fridge-tag Ultra Low must be properly mounted. The external temperature sensor must be correctly installed and attached to Fridge-tag Ultra Low as described in this manual. Ensure that the display of the Fridge-tag Ultra Low can be read and the audible warnings can be heard by personnel operating the freezer.
- The Fridge-tag Ultra Low must be activated as described in this manual.
- The user needs to inspect the Fridge-tag Ultra Low, temperature sensor and freezer equipment regularly, typically at least once per working day.
- The user needs to ensure that physical access to the Fridge-tag Ultra Low and the freezer is limited to authorized personnel only. Failing to do so can lead to malicious manipulation of the measurement system e.g. removal of temperature sensor or Fridge-tag Ultra Low, unauthenticated use of the device, such as alarm confirmation, unauthorized access to information, unauthorized configuration change / settings change / date time change.
- The user needs to provide training to personnel.
- When a critical alarm is raised by the device, the user is required to investigate the root cause and confirm the alarm on the device. Without alarm confirmation, the device assumes that the root cause has not been solved and will not raise a new alarm. The device does not document who

confirmed the alarm. If the user needs this information, the documentation is responsibility of customer, including limiting the physical access to the device.

- The Fridge-tag Ultra Low carries a unique identifier. The user needs to document which freezer the Fridge-tag Ultra is monitoring in which time span, if needed for the user to comply with regulation. Additionally, the user needs to document the unique identifier of the temperature sensor used and its calibration certificate.
- In order to have a sound administration (as may be required by regulation), the user needs to ensure that the date and time on the Fridge-tag Ultra Low is correct. It is strongly recommended that the UTC time zone is used, to prevent issues with daylight saving time. However, when another time zone is used, the manufacturer recommends documentation (in SOP) when the date/ time on the Fridge-tag Ultra Low is adjusted and by whom. It is the user's responsibility to ensure that data of Fridge-tag Ultra Low can be correlated with other information, such as inventory kept in freezer.
- Before digital reports of Fridge-tag Ultra Low are used, the user must validate their authenticity using the Verifier. The Verifier can be obtained on Berlinger website. Use of the Verifier is required to achieve compliance with 21 CFR Part 11 requirements.

Other considerations

- The Fridge-tag Ultra Low has no notion of what correct storage conditions are of the products the user stores in freezer. The user is assumed to be aware of what is correct and must be able to assess the impact of measured temperature in a freezer on his products.
- The Fridge-tag Ultra Low has no notion of what the user stores in the freezer, hence the user must document and manage that himself. Additionally, the correlation between measured temperature and the product(s) must be done by the user himself.
- Information generated by Fridge-tag Ultra Low is lost, unavailable or unreliable:
  - When the Fridge-tag Ultra Low is damaged, defective, is used beyond its expiration date or indicates 'empty battery'.
  - When external sensor is not attached or is defective.
  - When the (digital) report is not archived before older data is overwritten. The maximum report length (counted from the current moment) is defined. The Fridge-tag Ultra Low does not warn when older information is overwritten.
  - When the calibration of the temperature sensor has expired.
- The Fridge-tag Ultra Low is compatible with Berlinger SmartView. When the user has a Berlinger SmartView license, the information of Fridge-tag Ultra Low must be uploaded manually to Berlinger SmartView. Berlinger SmartView assumes that the time and date have been set correctly on Fridge-tag Ultra Low. When Berlinger SmartView is used to analyze recorded temperature data of Fridge-tag Ultra Low, it may present different duration values than the Fridge-tag Ultra Low itself. This is due to the fact that the devices measure and analyses temperature on a minute interval, while Berlinger SmartView analyses the data on (given) logging interval. The difference in event duration can be up to two (2) times the logging interval.
- Berlinger gives no guarantees that the Fridge-tag Ultra Low is compatible with third party servers or systems, or that any or all functions of the device work when used with third party systems. Even if at the time of purchase the device is compatible, future compatibility is not guaranteed in any respect.

Battery

The Fridge-tag Ultra Low contains a coin cell Lithium battery. Please, pay strict attention to the following points:

- The housing of the Fridge-tag Ultra Low must never be opened nor destroyed.
- Never expose the Fridge-tag Ultra Low to high temperatures (fire, oven, microwaves, etc.). It may cause injuries.
- Always keep the Fridge-tag Ultra Low out of the reach of children.
- The battery complies with IATA DGR Packaging Instruction 970 Section 2.
- Dispose or recycle the Fridge-tag Ultra Low 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 device can be used up to 3 1/2 years after production date (1/2 year storage / 3 years useful life) on the condition that:

- the buttons are not pressed for very long time.
  Note: Avoid jamming the device between the goods to be monitored in freezer.
- storage and operation of the device remains 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 lifetime of the battery is indicated by the battery indicator on the display (see chapter Display explanations).

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 or use of the device.
- for any problems with the temperature-controlling and/or-cooling unit.
- for the quality of any monitored goods.
- for incorrect readings if the device was used beyond its expiry date.

Additional terms and conditions may apply. Refer to your purchase order agreement for more information.

Warranty: 2 years from date of delivery.
The Seller guarantees that the products supplied are functional and free of material or manufacturing flaws.

This warranty shall only apply provided the products concerned are handled and stored correctly and in accordance with their instructions for use. In particular, the Seller cannot provide any such warranty in connection with normal wear and tear or in the event of improper handling, non-compliance with the

instructions provided, excessive force, excessive use, accident or force majeure.

It is the responsibility of the Buyer to inspect the products immediately upon receipt. Any perceived defects must be communicated to the Seller in detail and in writing without delay, and within seven working days at the latest after such receipt. Any product defects detected at a later stage which were not identified upon receipt (hidden defects) shall be reported to the Seller immediately, in detail and in writing.

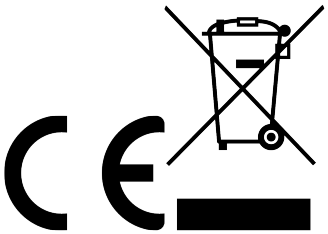
The Seller's warranty on the products supplied shall expire two years after the transfer of the associated benefits and risks (see General Terms and Conditions, para. 4 above). Such warranty shall also expire immediately and in its entirety if the Buyer or any third party makes any changes or repairs to the product(s) concerned without the Seller's written approval.

Should the Seller be required to fulfil a warranty obligation, the Seller shall be free to decide whether to repair or replace the product(s) concerned.

In such an event, the Buyer shall have no further claims on the Seller. In particular, the Buyer shall have no entitlement to any reduction in the purchase price, to the cancellation of the purchase agreement or to compensation for any direct or indirect damages.

In addition, any liability of the Seller arising from or in connection with deliveries shall be excluded, to the extent permitted by law, irrespective of the legal basis.

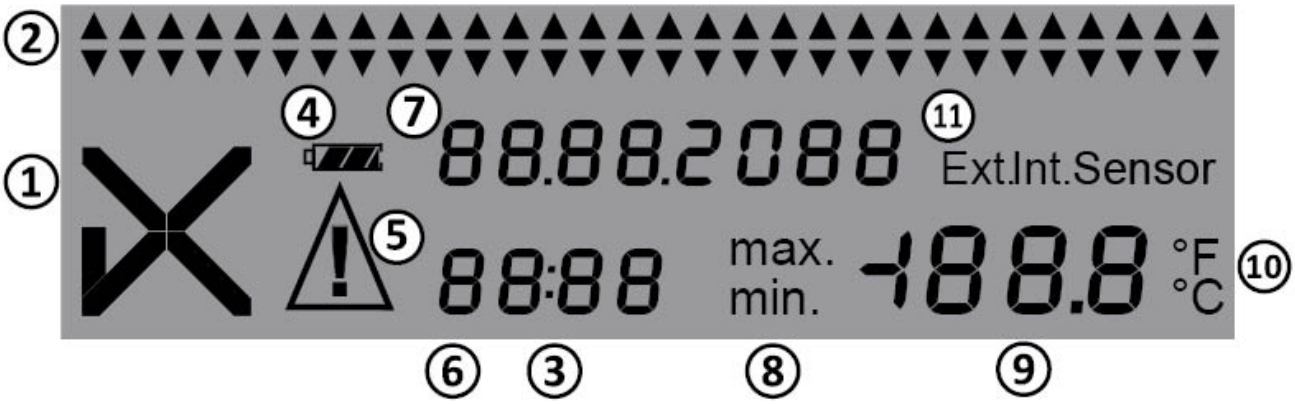
Regulatory certification



Manufactured by:

Berlinger & Co. AG
Mitteldorfstrasse 2
9608 Ganterschwil
SWITZERLAND

3. Display explanations

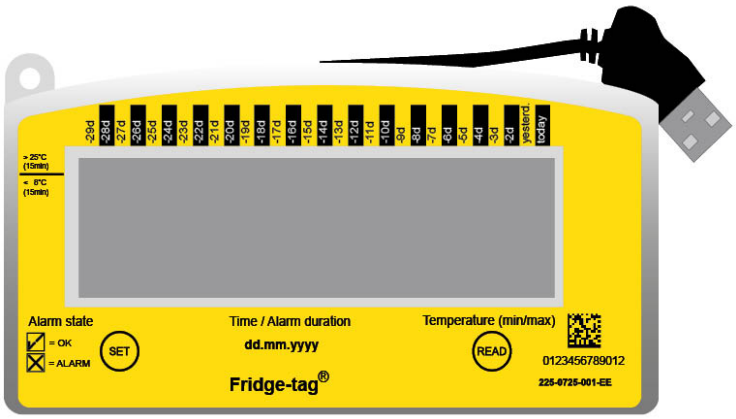


1. ✓ (OK symbol) or ✕ (alarm symbol)
2. Daily HIGH/LOW alarm indicators ▲▼ (showing the history of the last 30 days)
3. Power indicator (colon is flashing)
4. Battery indicator (indicates the remaining capacity of the battery)
5. Additional warning symbol ⚠
6. Time, duration and text display
7. Date and text display
8. Display of measured minimum/maximum temperature
9. Temperature display
10. Display of the temperature measurement unit (°F/°C)
11. Display of the activated sensor:
    Int. = internal sensor
    Ext. = external sensor (cable with temperature sensor)

Note: All illustrations in the User Manual refer to the Fridge-tag with internal sensor. Differences between internal and external sensors are additionally described.

4. State of delivery / sleep mode

The Fridge-tag is shipped in sleep mode.

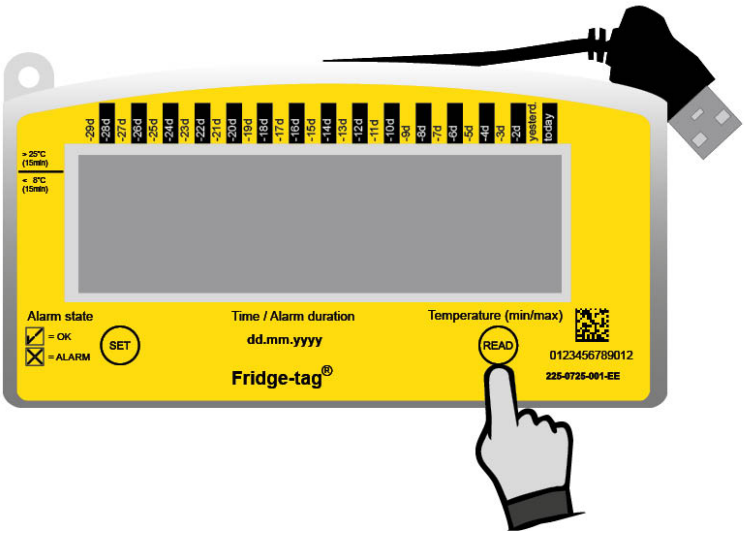


The display (LCD) is blank.

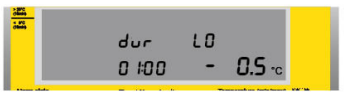
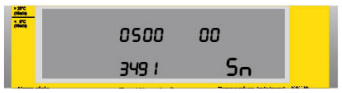
5. Read out information prior to activation (in sleep mode)

The following page shows which information will be indicated on the screen upon successive READ button pressings while in sleep mode.

Note: After approx. 60 seconds without to press any button of the Fridge-tag the devices goes back into sleep mode; the display is blank again. Start from the beginning.



Press repeatedly READ to gather information.

After 1st pressing of READ		Display test: all segments activated
After 2nd pressing of READ		Indication of date and production test result: 16 February 2018/PASS (quality check passed)
After 3rd pressing of READ		Indication of the current temperature and which sensor is activated (internal/external). Display shows —.-°C if external sensor is not connected.
After 4th pressing of READ		Indication of configuration ID (e.g. 1234)
After 5th pressing of READ *		Indication of upper alarm settings. Example shows duration and temperature limits: 10 hours, >+8°C, high
After 6th pressing of READ *		Indication of lower alarm settings. Example shows duration and temperature limits: 1 hour, <–0.5°C, low
After 7th pressing of READ		Serial number of the device

After 8th pressing of READ		PCb number (manufacturer information)
After 9th pressing of READ		Battery power: 3 bars = full (>70%) 2 bars = half-full (>30–70%) 1 bar = low (0–30%)** **Device should be replaced.
After 10th pressing of READ		The display is blank again.

*Only indicated if preset by factory, otherwise skipped.

6. Placing the Fridge-tag

Placing the Fridge-tag with an external sensor

Warning: Pay attention to your safety and protection when installing the external sensor in your freezer and follow your organization's instructions for proper handling at ultra-low temperatures.

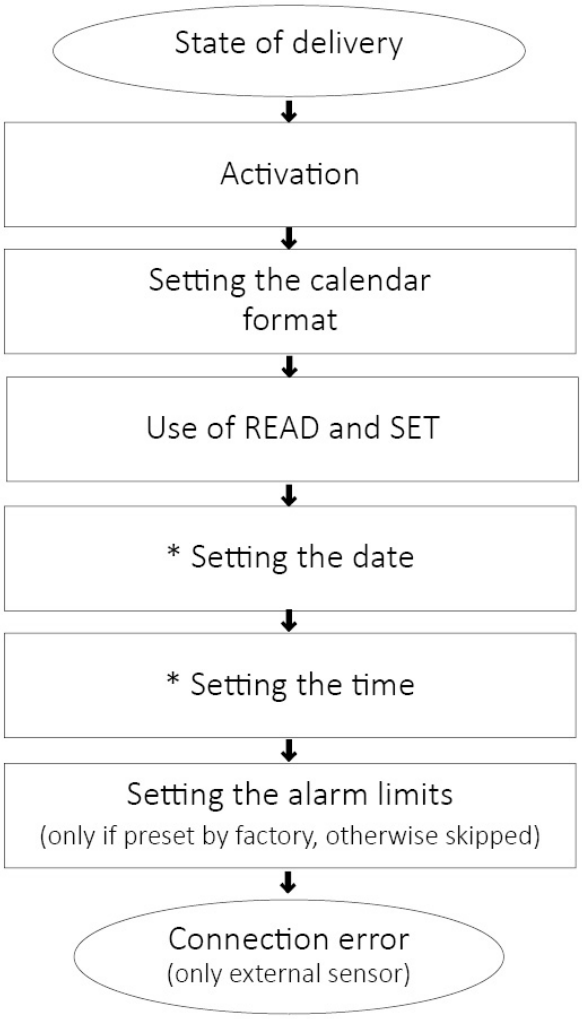
Two hours before activating the Fridge-tag the external sensor must be placed in its predetermined location. It is recommended and important to place the external sensor in the center of the freezer for an optimal temperature observation and to avoid any incorrect measurements when starting the device.
For the right positioning of the external sensor within the freezer, please follow the instructions of WHO, CDC or any other governmental requirements of your country.

1. External Sensor
2. Flat cable
3. Fridge-tag

Note: Do not bend or fold the cable of the external sensor to prevent it from getting damaged. The bending radius should not be smaller than 1 cm / 0.4 inch.

7. Activation process

Overview: sequences of activation



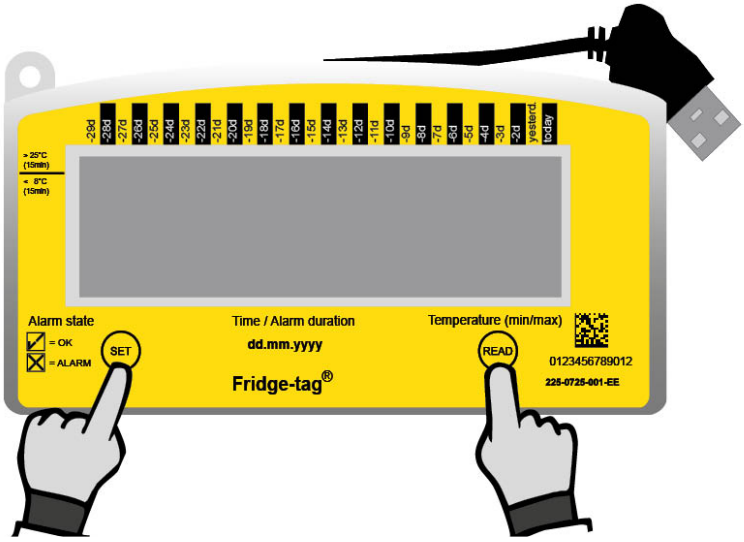
*If “Disable User Clock Adjust” in the configuration is enabled points “Setting the date” and “Setting the time” are skipped upon activation

Note: As long as 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 has to be started 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.

7.1. Activation of the device

To activate the device press, the SET and the READ button simultaneously during at least 3 seconds.

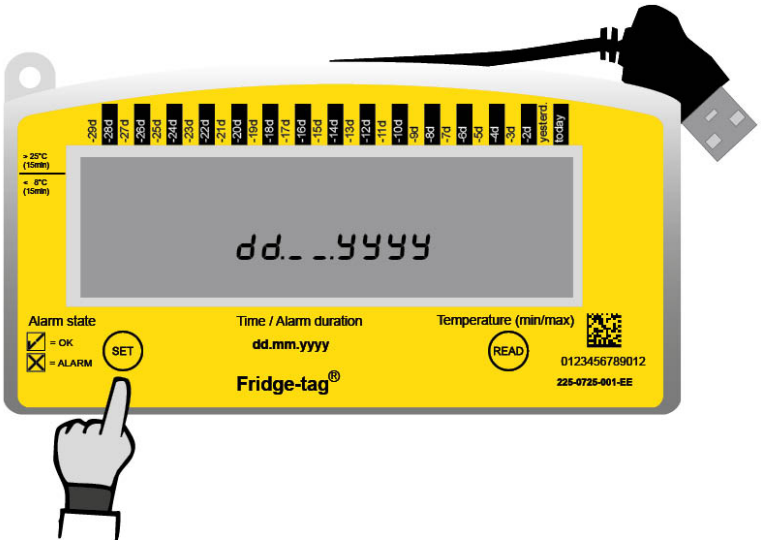


Note: Once the device is activated, it cannot be stopped anymore.

Activation has been successful when the following indication appears on the screen:

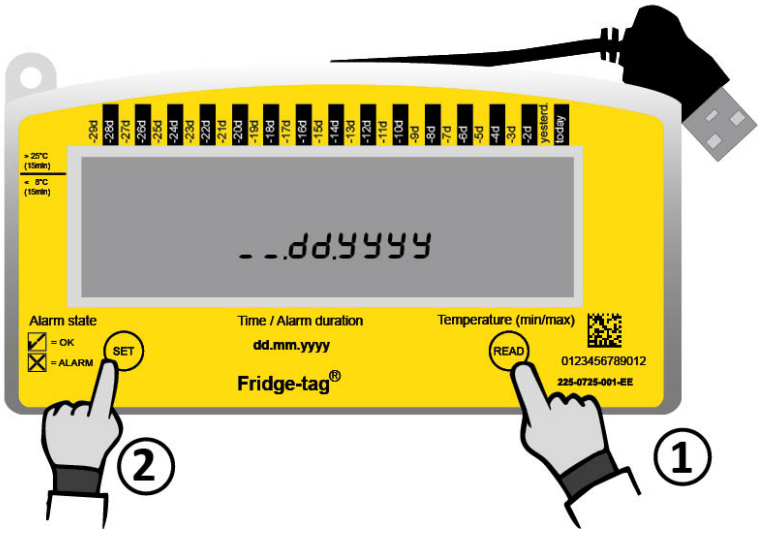
7.2. Setting the calendar format

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



Press SET to save the calendar format.

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



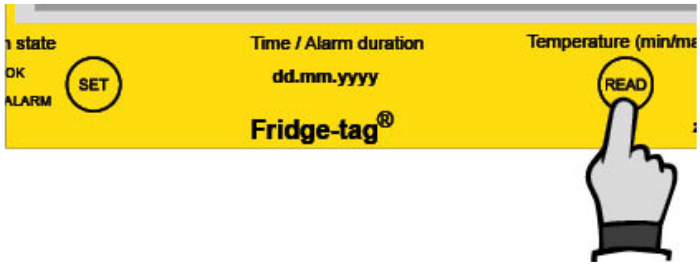
1. Press READ to change the calendar format.
2. Then press SET to save the calendar format.

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

7.3. Using the READ and the SET buttons

READ button

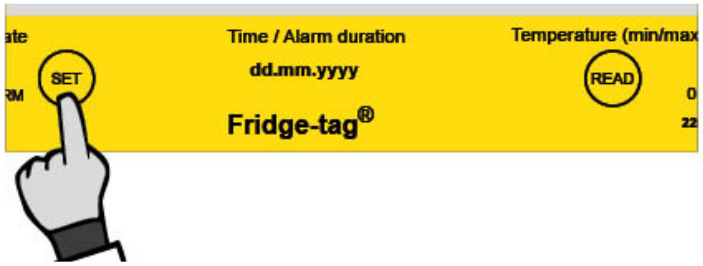
The READ button is used to adjust the numbers. Each time you press the READ button, the number in the flashing digit will increase by 1. If you press READ more than necessary, continue pressing the READ button until you obtain the desired number.



Press READ to adjust the number

SET button

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

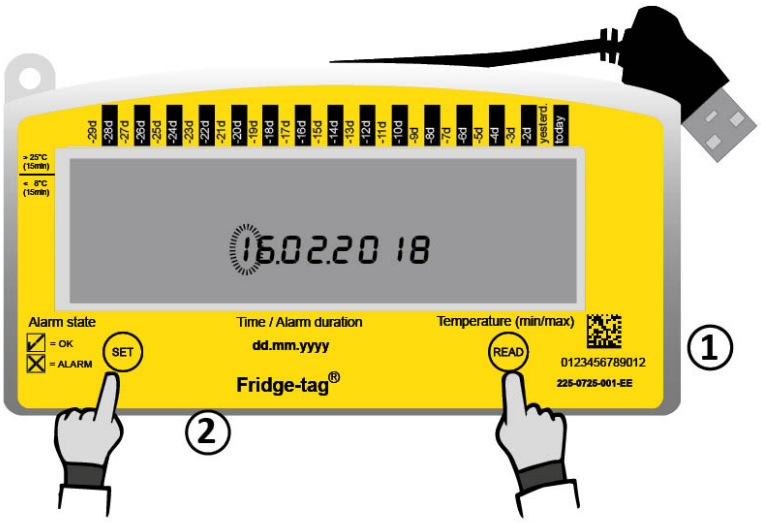
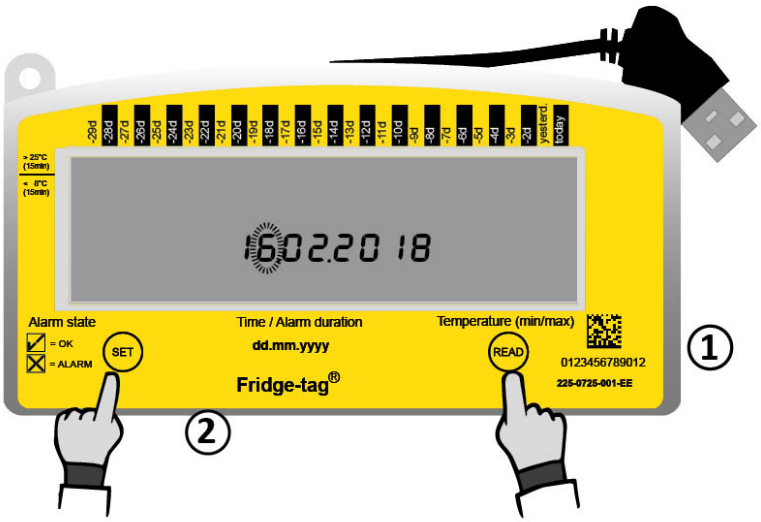
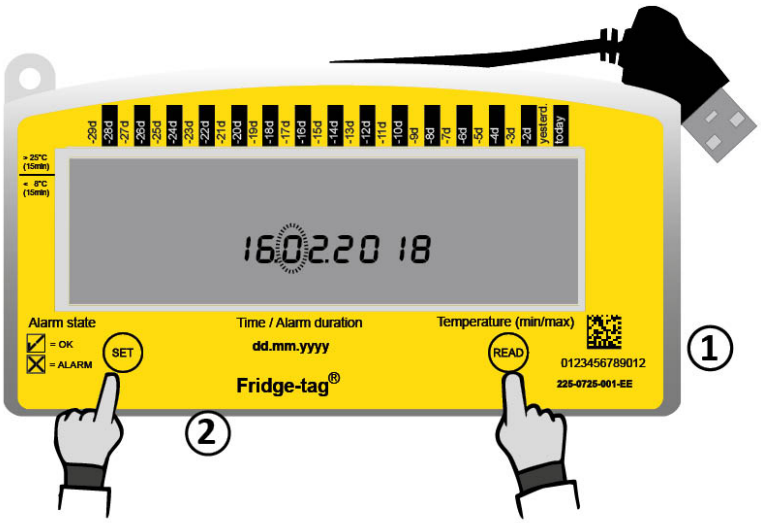


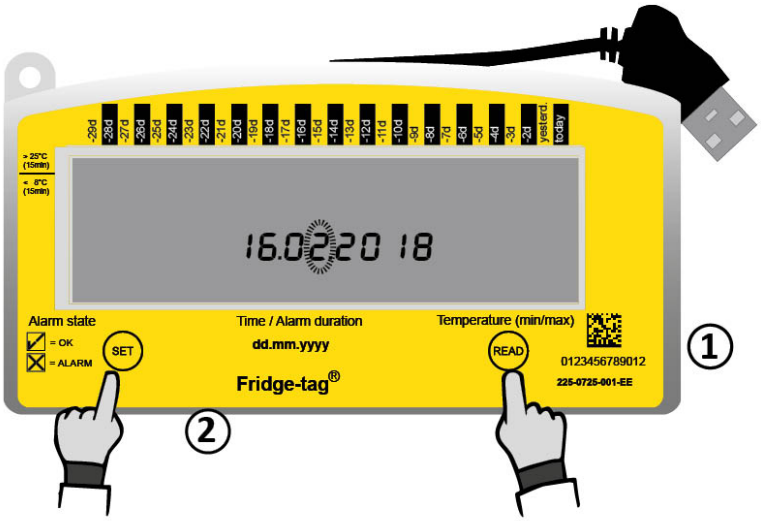
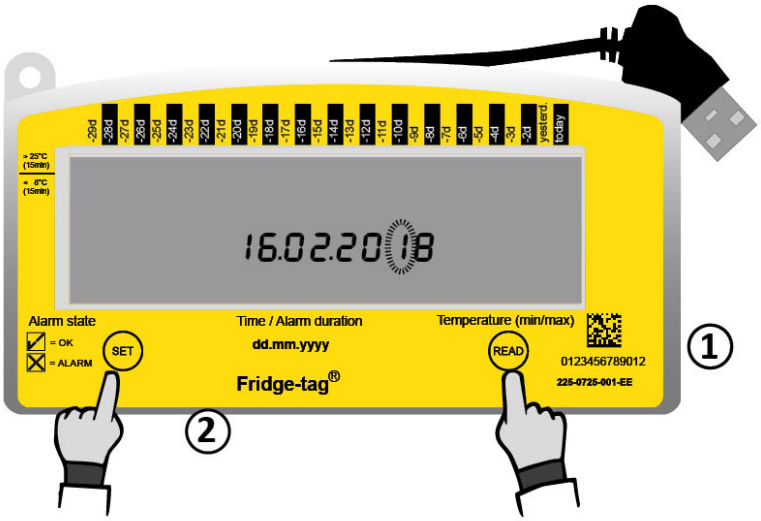
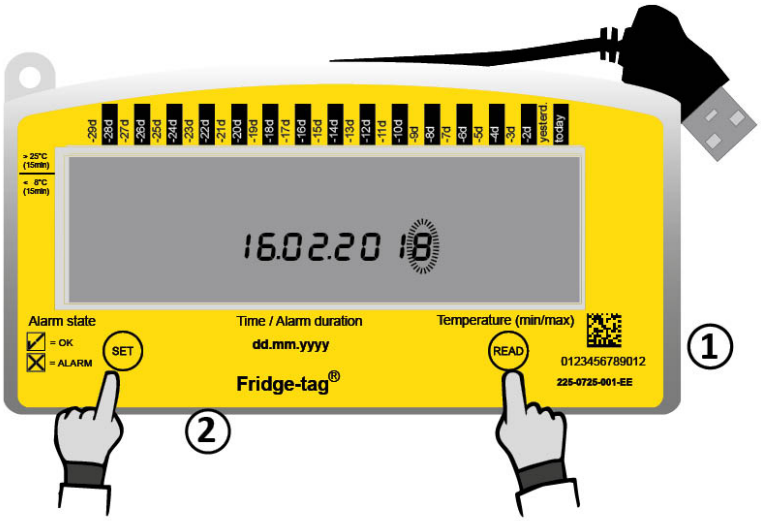
Press SET to confirm.

Note: If SET is pressed mistakenly, continue with the setup instructions. This chapter describes how to rectify the error.

7.4. Setting the date

The following example shows how to set the date to:
16 February 2018 (16.02.2018) in European format.

The 1st digit is flashing.		1. Press READ until “1” appears as the first digit. 2. Press SET to save.
The 2nd digit is flashing.		1. Press READ until “6” appears as the second digit. 2. Press SET to save
The 3rd digit is flashing.		1. Press READ until “0” appears as the third digit. 2. Press SET to save.

The 4th digit is flashing.		1. Press READ until “2” appears as the fourth digit. 2. Press SET to save. **Note:** The fifth and the sixth digit are set automatically.
The 7th digit is flashing.		1. Press READ until “1” appears as the seventh digit. 2. Press SET to save.
The 8th digit is flashing.		1. Press READ until “8” appears as the eighth digit. 2. Press SET to save.

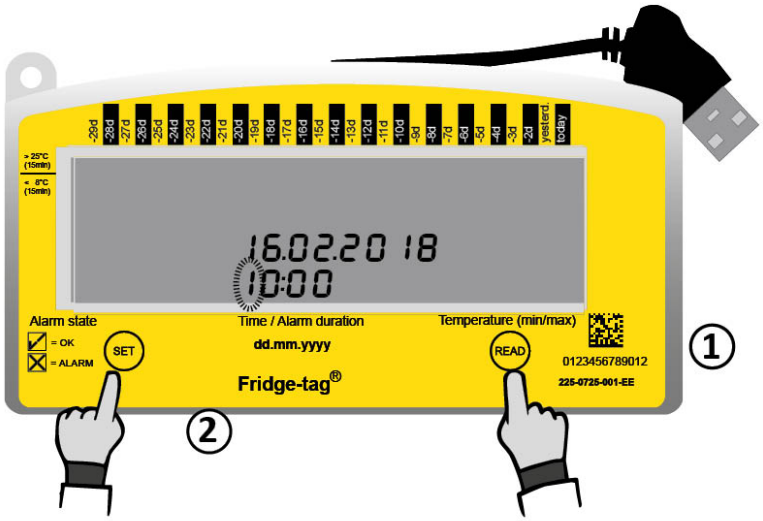
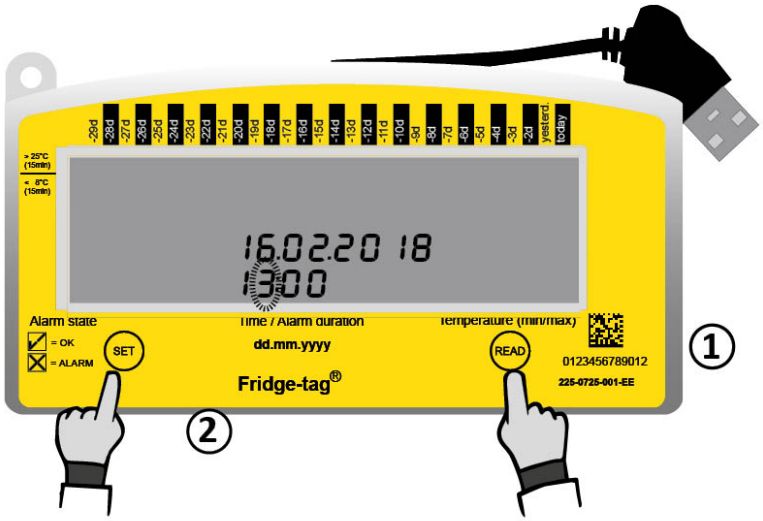
The date is now set to: 16.02.2018.

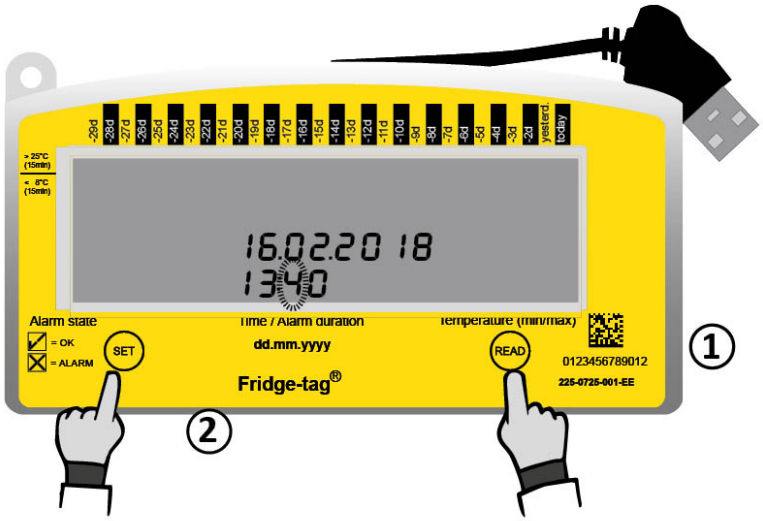
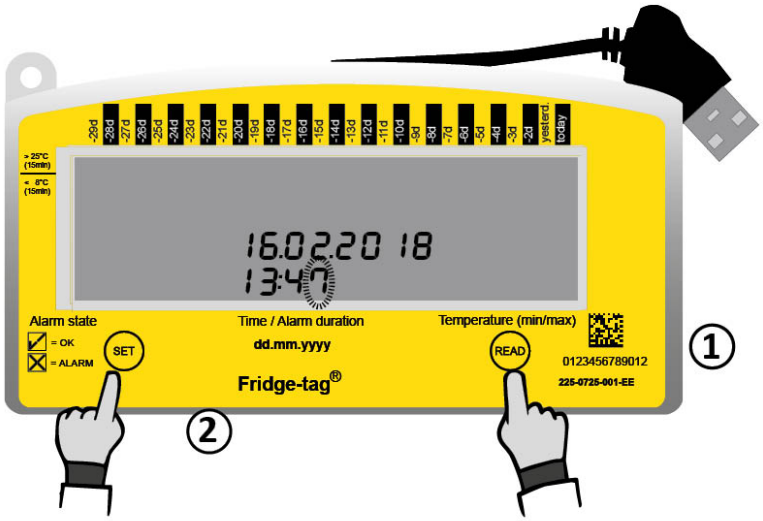
Note: After setting the date, the first digit of the time will start flashing.

7.5. Setting the time

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

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

The 1st digit is flashing:		1. Press READ until “1” appears as the first digit. 2. Press SET to save.
The 2nd digit is flashing.		1. Press READ until “3” appears as the second digit. 2. Press SET to save.

The 3rd digit is flashing.		1. Press READ until “4” appears as the third digit. 2. Press SET to save.
The 4th digit is flashing.		1. Press READ until “7” appears as the fourth digit. 2. Press SET to save.

The time is now set to 13:47.

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

As soon as the last digit of the time setting is confirmed, the activation is completed.

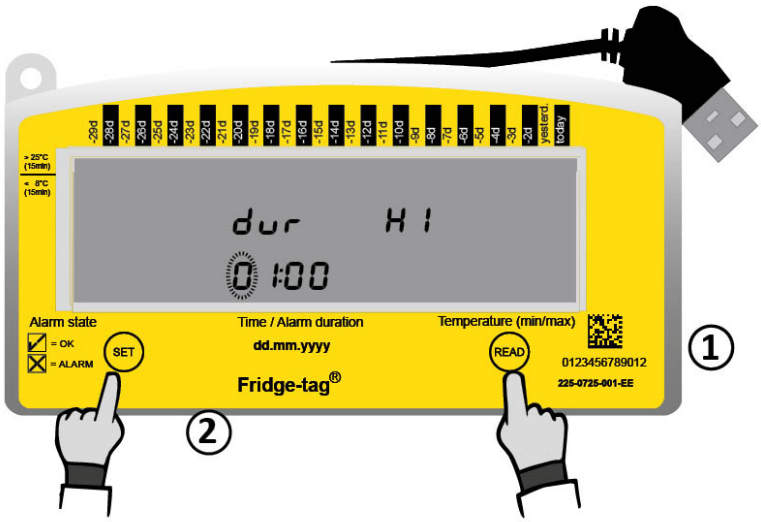
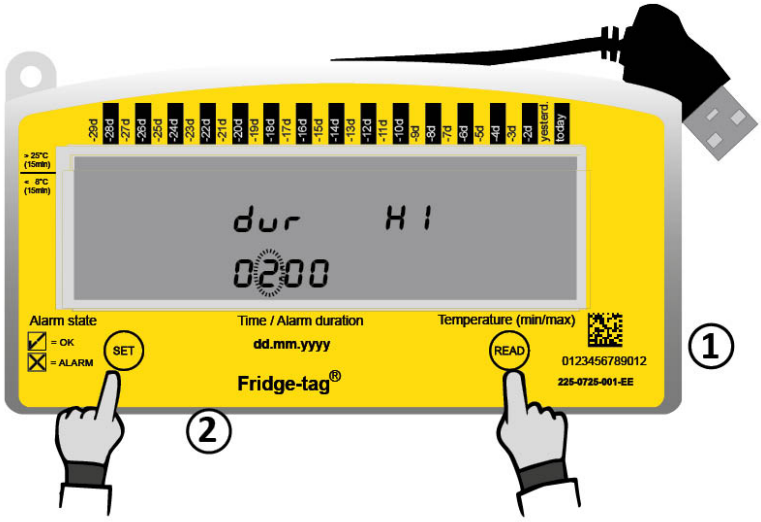
Connect the device with the external sensor. During max. 1 minute after activation no temperature is displayed on the screen.

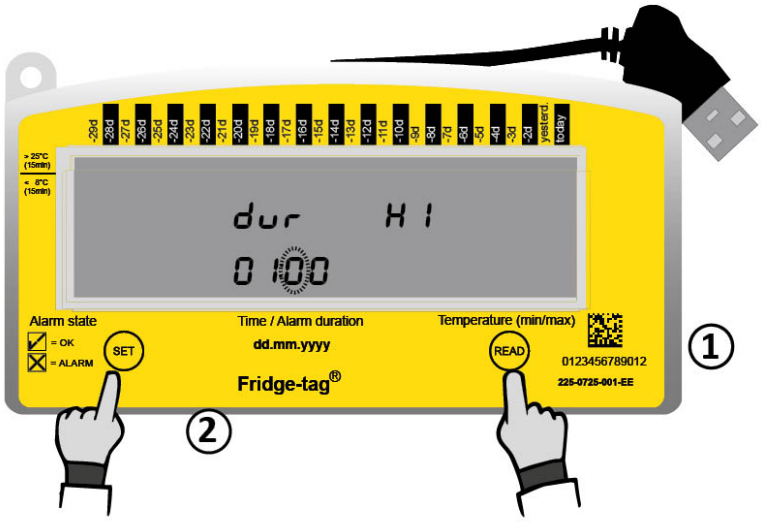
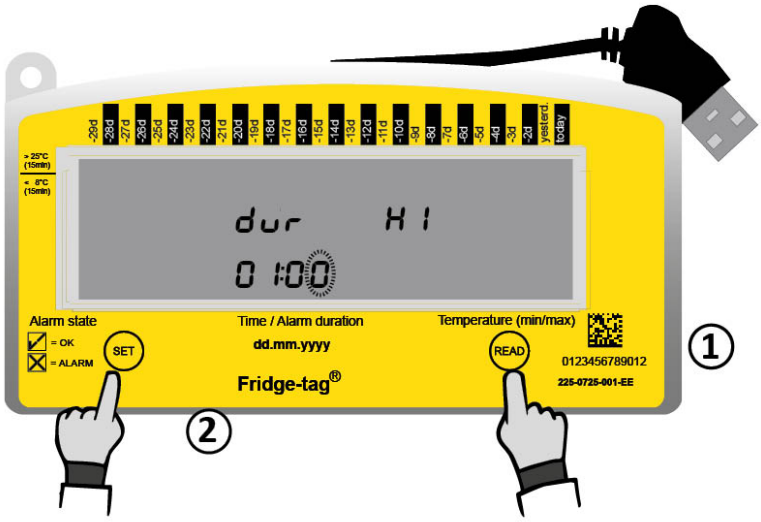
7.6. Setting the alarm limits (not standard, only if preset by factory)

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 and LO alarm durations, they are completed in the same manner

The 1st digit of the duration of the alarm limit is flashing.		1. Press READ to adjust the number. 2. Press SET to confirm the number.
The 2nd digit of the duration of the alarm limit is flashing.		1. Press READ to adjust the number. 2. Press SET to confirm the number.

The 3rd digit of the duration of the alarm limit is flashing.		1. Press READ to adjust the number. 2. Press SET to confirm the number.
The 4th digit of the duration of the alarm limit is flashing.		1. Press READ to adjust the number. 2. Press SET to confirm the number.

The duration of the alarm limit is now set.

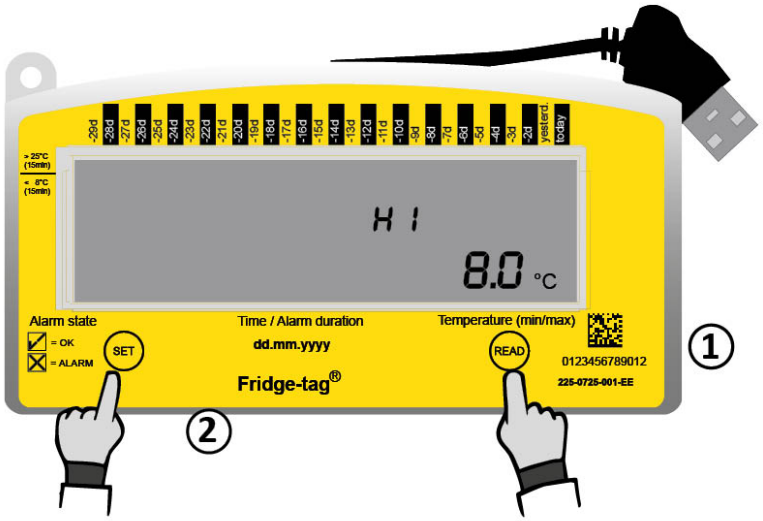
2. and 4. Setting the HI and LO alarm temperatures, they are completed in the same manner

> ! Alarm temperature limits must be not lower than –90°C (–130°F) and no higher than -5°C (+23°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 you may further choose if the limit shall be equal or above +100°F. This choice is done by repeatedly 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. Learn more.

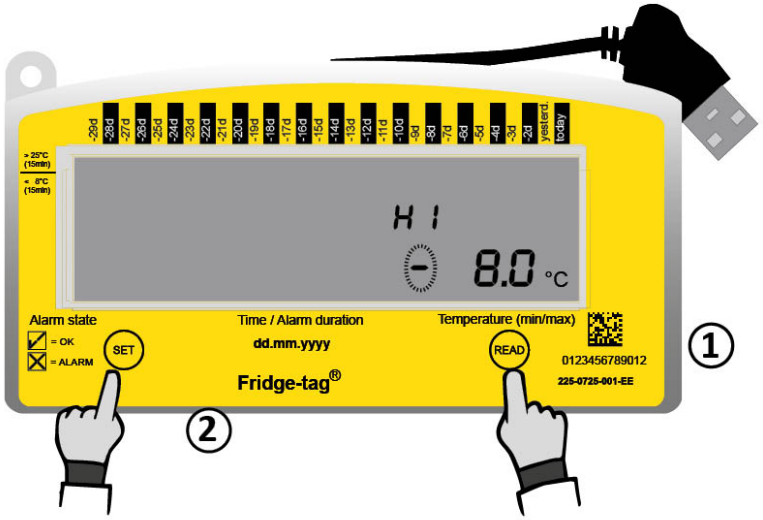
Instruction for setting a positive temperature limit between 0°C/0°F and +55°C/+131°F (external sensor)



1. Press READ until the display shows no flashing sign.
2. Press SET to adjust the limit between 0°C/0°F and +50°C/+122°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.

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



1. Press READ until the "-" sign is flashing.
2. Press SET to set the 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 limits 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.
Connect the device with the external sensor.

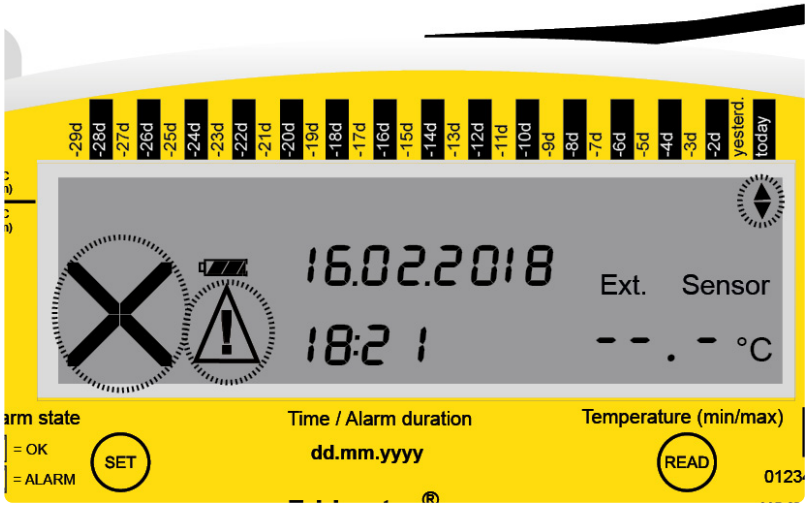
Note: In case the desired temperature limit cannot be confirmed, check if the temperature is set within the allowed operating temperature range.

7.7. Connection error (external sensor only)

After 10 minutes (factory standard) without a connection between the device and the external sensor the following display appears and:

- The buzzer will beep twice at intervals of three minutes for a maximum of 168 hours (7 days).
- The whole display starts blinking.
- Any button pressed will stop the display from blinking.
- The buzzer only stops if the connection error is corrected. If the error still exists, the buzzer continuously beeps at a three-minute interval for 168 hours (7 days).

Display status: external sensor error



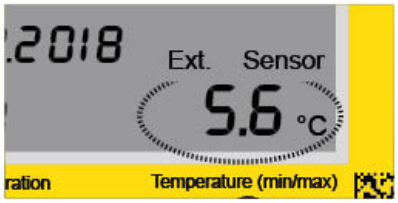
How to fix the connection error

Please check the following two points:

1. If the external sensors properly connected with the device?
2. Does the external sensor cable have any defects?

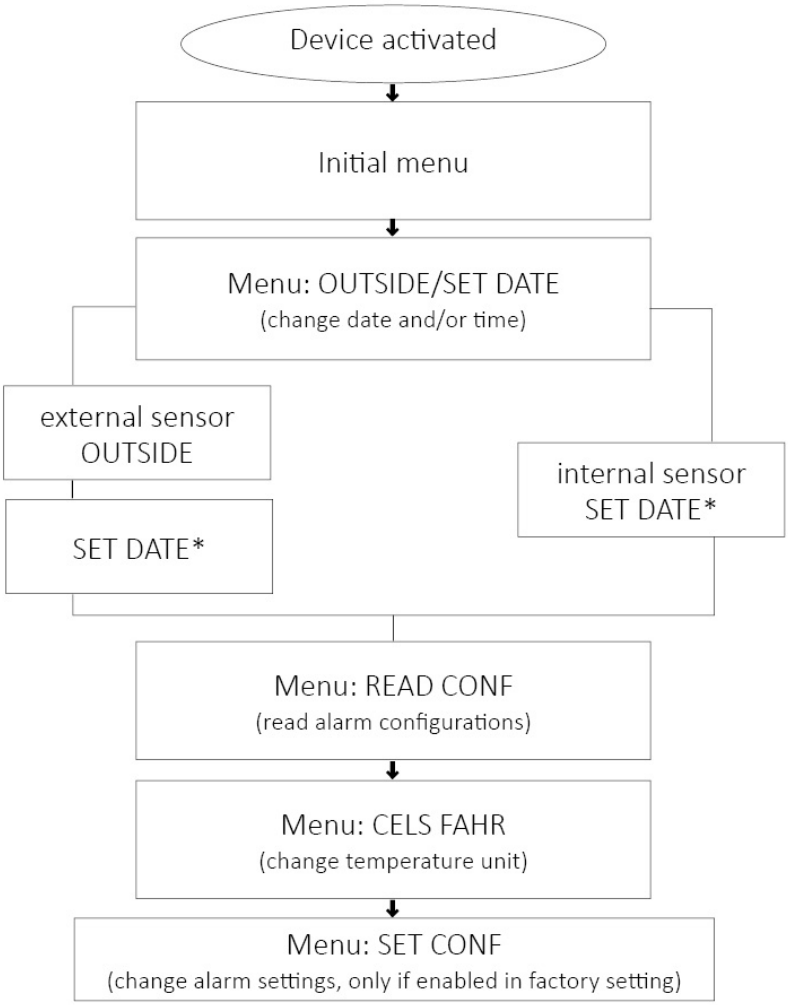
Note: As soon as the error(s) have been cleared, the measuring will continue and the connection error buzzer stops to beep automatically. During max. 1 minute after the connection no temperature is displayed on the screen.

During a connection error no data will be recorded.



8. Read and change settings / How to correct setting mistakes

Overview: menu

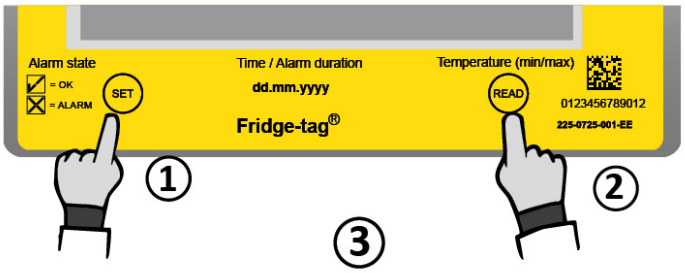


*If “Disable User Clock Adjust” in the configuration is enabled point “SET DATE” are skipped upon activation

Note: If you scroll through the menu and you reach the display of the measuring mode, you need to restart from the beginning by accessing the menu.
In order to adjust more than one setting (e.g. time and Celsius to Fahrenheit) you must complete each change and return to menu mode for the 2nd change.

8.1. Initial menu (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 preset alarm limits please proceed as follows:



1. Press and hold SET …
2. … then press READ shortly …
3. … then release both buttons simultaneously.

SET DATE (internal sensor) is now displayed on the screen.
OUTSIDE (external sensor) is now displayed on the screen.

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

You can access the following 4 menus:

OUTSIDE (external sensor): first screen, shows the temperature measured with the internal sensor of the Fridge-tag (normal ambient temperature).
Press READ once to get to SET DATE.

SET DATE (internal sensor): Configuration with internal sensor,
SET DATE is directly shown.

1. SET DATE: change date and/or time settings
2. READ CONF: read the alarm settings
3. CELS FAHR: change the temperature unit
4. SET CONF: change the alarm settings (only if enabled in factory setting)

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

Access the menu “SET DATE”

External sensor: The display shows OUTSIDE. Press READ until the display shows SET DATE.
Internal sensor: 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 here.

Note: Time and date adjustments have no effect on the alarm records. 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 adjustments during the same day is unlimited. After an adjustment has been made, the Fridge-tag will be locked for 24 hours from the following midnight (e.g. changes on 15 September., device locked from 00:01 am on the 16 September until 00:01 am on the 17 September). This is for security reasons.

Access the menu “READ CONF”

The display shows SET DATE (internal sensor), OUTSIDE (external sensor). 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 press READ repeatedly to scroll through the preset alarm parameters.

Access the menu “CELS FAHR”

The display shows 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 measurement unit.

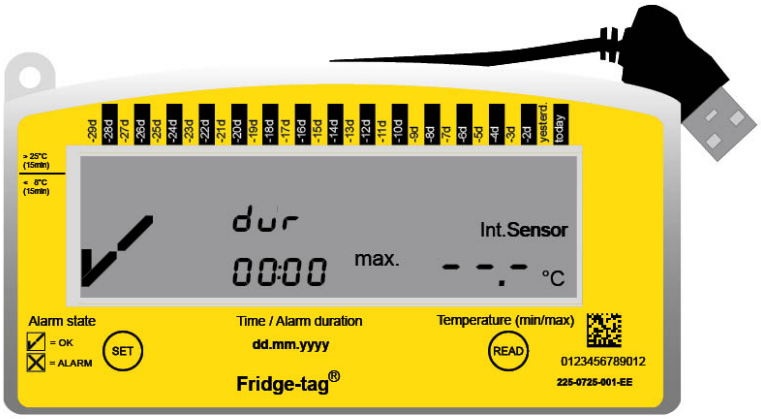
Access the menu “SET CONF”*

The display shows 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 this chapter.

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

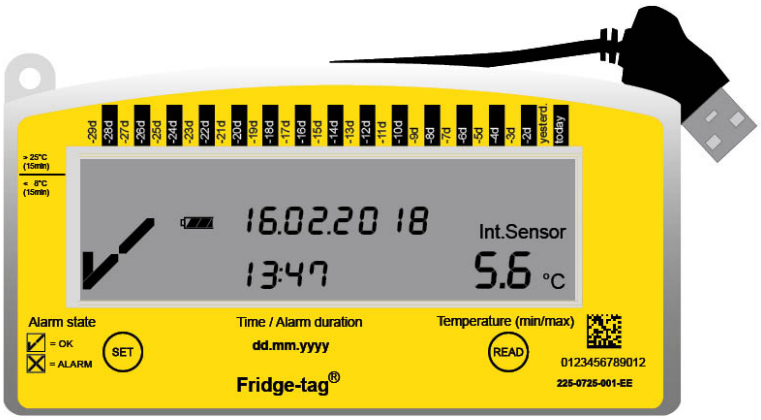
9. Screen displays during measurement mode

Indication for max. 1 minute after completing the activation or after connecting the device with the external sensor. For a maximum of 1 minute no temperature is displayed on the screen, indicated by —.-.



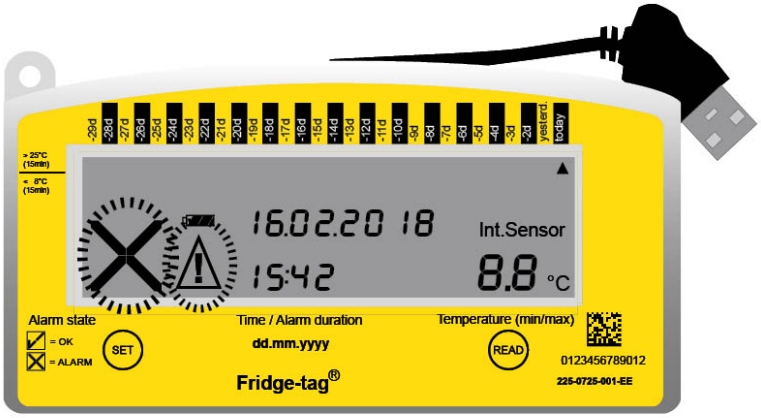
Example OK display – during measurement

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 will also indicate whether the measuring is made with an internal sensor or an external sensor. The OK symbol ✔ is shown during normal operation as long as no alarms have been recorded. The temperature and time conditions were within the preset alarm limits.



Example alarm display – during measurement

If the preset alarm limits are exceeded, the following information will be displayed on the screen:



- ✓ (OK symbol) will be replaced by ✕ (alarm symbol)
- An additional alarm indicator ▲ will be indicated in the upper display area to show which alarm limit has been exceed and on which day.
- In addition to the alarm symbol ✕ the warning symbol ⚠ will appear next to it.

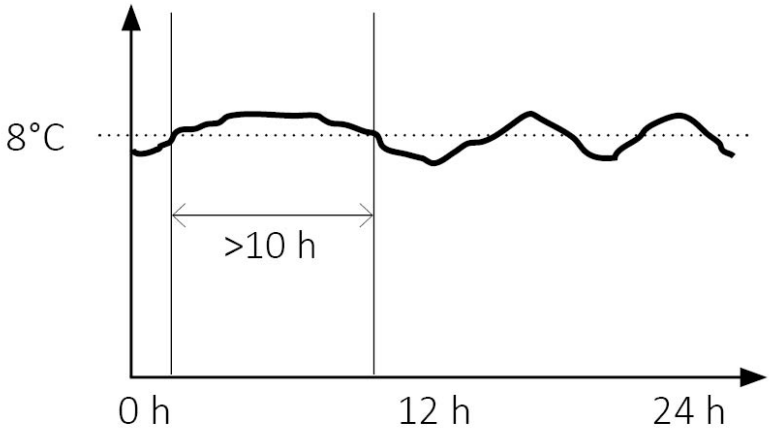
10. Alarm trigger function

Single-event alarm triggering

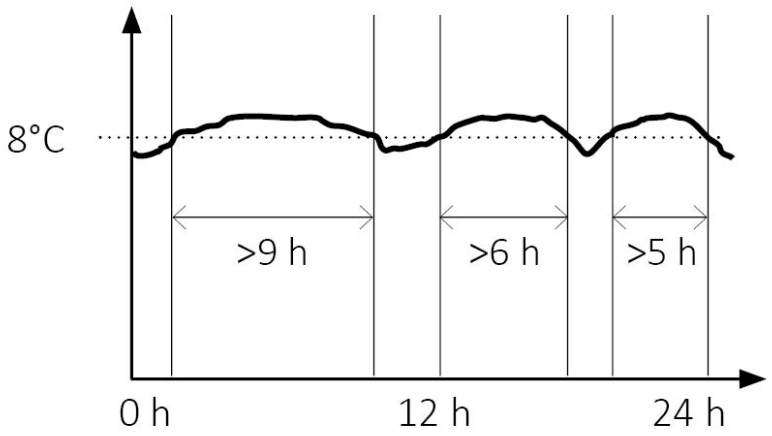
The upper or lower alarm triggering is done with a single-event alarm algorithm. Any kind of alarm is triggered if the temperature is continuously out of the preset alarm limits for longer than the preset alarm trigger time.

Upper alarm triggering

Setting upper limit: Temperature >8.0°C, duration >10 hours
For the upper alarm to be triggered the temperature needs to be continuously above 8°C for more than 10 hours.
Alarm triggered: alarm symbol ✕ and warning symbol ⚠ displayed.



In the example below the sum* of the daily upper temperature deviation is about 20 hours. No alarm will be triggered! The temperature was not continuously out of the preset alarm limits for more than 10 hours in one row.
No Alarm triggered: OK symbol ✓ on the display.

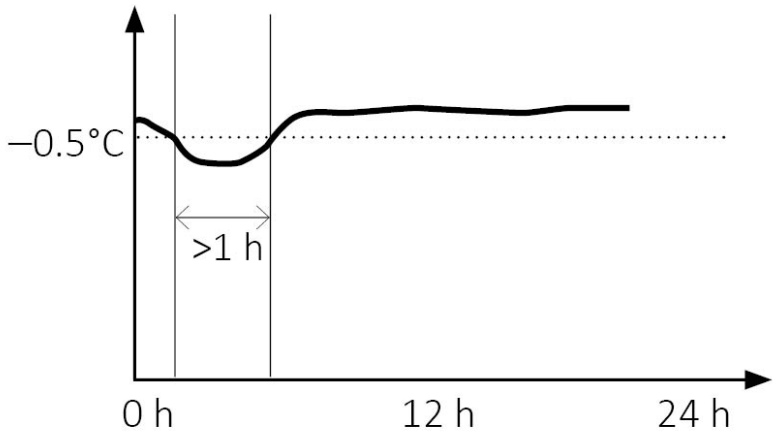


*The sum of the deviations is visible in the daily statistics in the column “Cumulative daily time above the

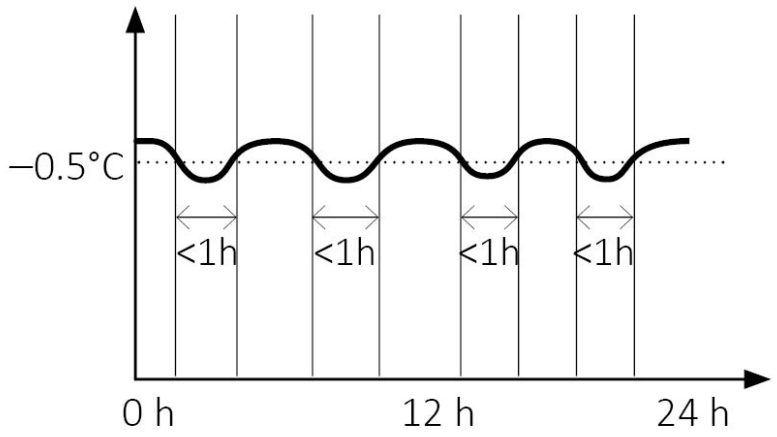
limit.”

Lower alarm triggering

Setting lower limit: Temperature <–0.5°C, duration >1 hour
For a lower alarm to be triggered the temperature needs to be continuously below –0.5°C for more than 1 hour.
Alarm triggered: alarm symbol ✕ and warning symbol ⚠ displayed.



In the example below multiple low temperature deviations* are occurring. No alarm will be triggered. Each temperature deviation was less than 1 hour out of the preset alarm limits.
No Alarm triggered: OK symbol ✓ on the display.



*The sum of the deviations is visible in the daily statistics in the column “Cumulative daily time below the limit.”

10.1. Alarm display and confirmation options

Option 1: Alarm indication “all alarms”

With this option the alarms will be visible on the display with an alarm symbol ✕ for 30 days.

By pressing the READ button, the warning symbol ⚠ will be disabled for the corresponding alarms. The alarm symbol ✕ cannot be canceled nor reset.

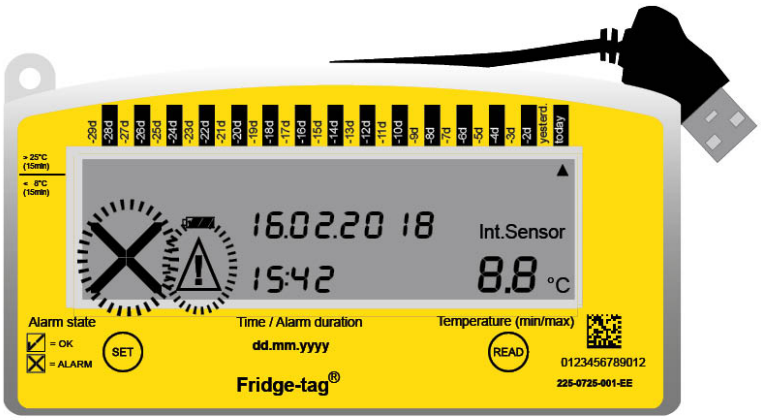
Note:

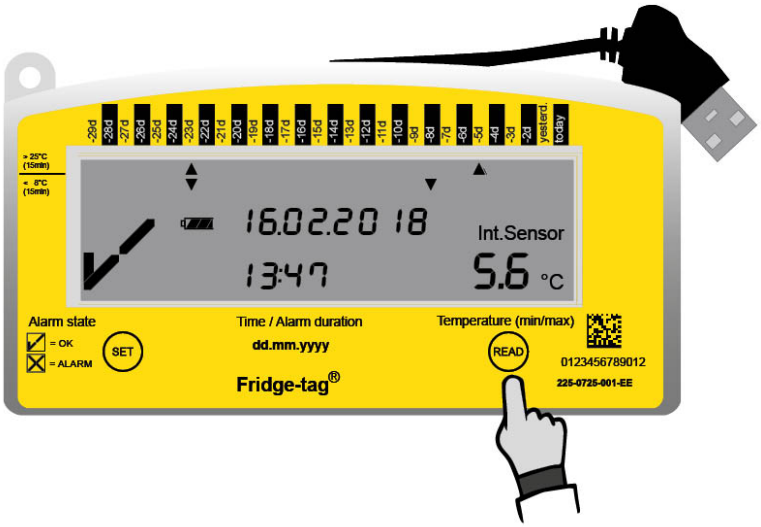
- In this mode only one upper and one lower alarm will be triggered per day.
- The alarm symbol ✕ will be present on the display for 30 days.
- The warning symbol ⚠ can be deactivated by confirming all existing alarms in the readout mode.
- The alarm buzzer stops when the alarm is confirmed within the set alarm limits. Otherwise the buzzer pauses for approx. 1 hour and starts again for up to 168 hours (7 days).

Option 2: Alarm indication “unconfirmed alarms”

The alarms are shown with the alarm symbol ✕ until all alarms (in the 30-day history) have been

confirmed as solved by pressing the READ button. Afterwards the display will show the OK symbol ✓ until a new alarm is triggered.





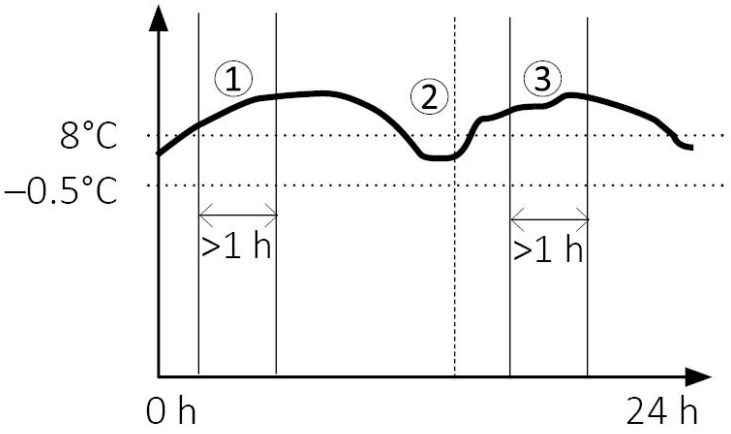
By pressing the READ button the warning symbol ⚠ will be disabled for the corresponding alarms. The alarm symbol ✕ disappears and the OK symbol ✓ will be shown again.

Confirmation options of currently triggered alarms of the day

1. Device is within the set alarm limits

Press the READ button and the alarm symbol ✕ and the warning symbol ⚠ will immediately disappear and the optional buzzer stops. A new alarm will be triggered as soon as the set alarm limits are exceeded again.

Settings: upper temperature limit >8.0°C and duration >1 hour, lower temperature limit <–0.5°C and duration 1 hour

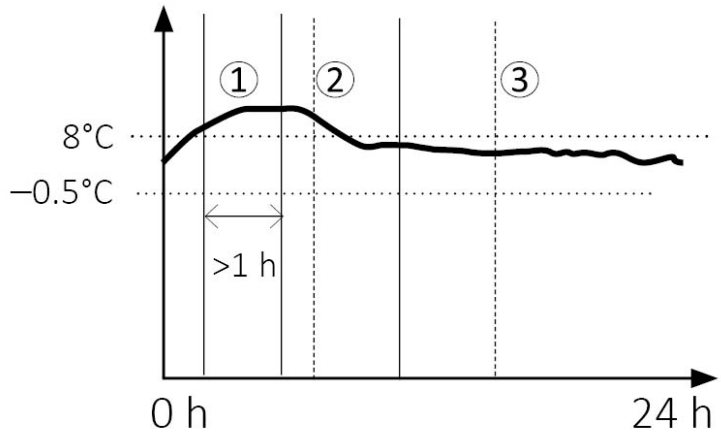


1. Alarm triggered: alarm symbol ✕ and warning symbol ⚠ on display
2. Alarm confirmed within the set temperature limits: ✓ (OK symbol) on display
3. Alarm triggered: alarm symbol ✕ and warning symbol ⚠ on display.

2. Device is outside the set alarm limits

If the READ button is pressed still during a temperature violation the buzzer will be muted for approx. 1 hour. The alarm symbol ✕ and the warning symbol ⚠ will stay on the display for the corresponding alarm. If the temperature still exceeds the limit after 1 hour, the buzzer will restart beeping.

Settings: upper temperature limit Temperature >8.0°C and duration >1 hour, lower temperature limit <–0.5°C and duration 1 hour



1. Alarm triggered: alarm symbol ✕ and warning symbol ⚠ on display.
2. Alarm confirmed when the temperature exceeds the set temperature limits: alarm symbol ✕ and warning symbol ⚠ remain on display.
3. Temperature is back within the alarm limits. Now the alarm can be successfully confirmed. OK symbol ✓ on display.

Note: How the alarm symbol ✕ and the warning symbol ⚠ react is specified during configuration of the

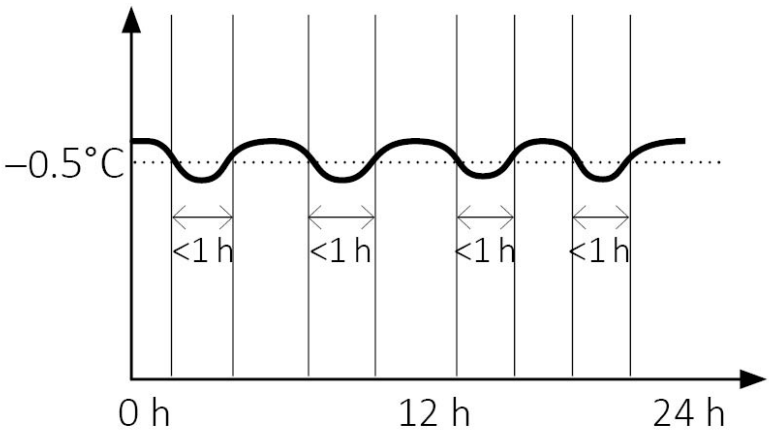
device in the factory settings.

10.2. Cumulative daily time above/below the limit

The alarm trigger algorithm is based on a single event, although the Fridge-tag is measuring on a daily basis the individual total time above or below the temperature limits. This measurement is not used for any alarm condition. These recordings are only available in the generated PDF/ASCII files.

Note: It could be that the total cumulative time above/below the temperature limits is longer than the configured single-event alarm time without any alarm triggering.

Example setup: lower temperature limit <–0.5°C, duration >1 hour



In the above example multiple low temperature deviations with exposure times of less than 1 hour occurred. The cumulative daily time below the limits adds up to about 3.5 hours but no alarm will be triggered. The same behavior also applies to the upper alarm.

11. Audio alarm (optional factory setting)

In case an upper or lower alarm is triggered, 3 audible alarm signals are emitted immediately. Thereafter:

- Every minute 1 alarm signal for maximally 168 hours (7 days).
- After 168 hours (7 days) the buzzer will stop.
- If an alarm event is confirmed (READ is pressed) while the limits are still exceeded the buzzer pauses for approx. 1 hour and then restarts beeping every 3 minutes.
- Confirmation within the alarm limits will stop the buzzer.

In case of a connection error see here.

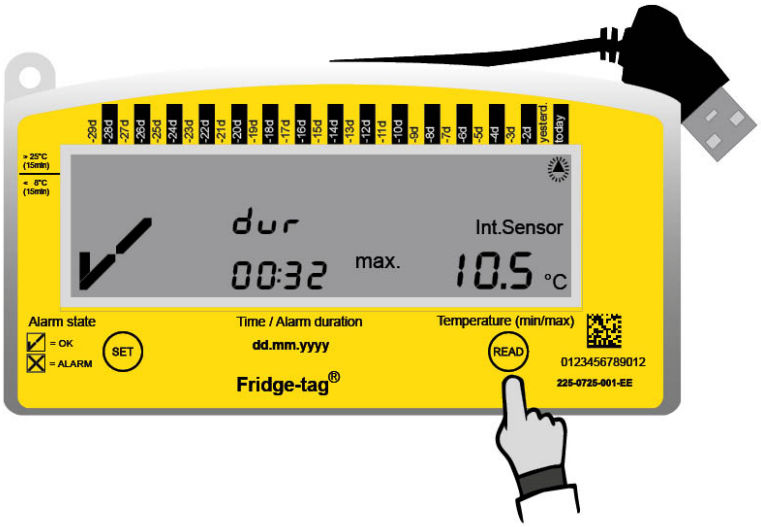
12. Reading the history / Readout mode

The information of the temperature deviations can either be viewed for the past 30 days directly on the device or for 28/56/84/112 days in the generated files (PDF/ASCII).

Note: The external sensor of the Fridge-tag can remain at its location for the readout process. Please consider that there may occur a connection error after more than 10 minutes without connection between the device and the sensor.

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

Example of an OK display during readout of the history



Press READ once

The following information is indicated on the screen:

- The OK symbol ✔
- The corresponding flashing arrow ▲ (example: high arrow “today”)
- Highest recorded temperature (example: +10.5˚C)
- Duration of the exceedance of the preset high limit temperature (example 00:32; hh:min)

Press READ a second time

The following information is indicated on the screen:

- The OK symbol ✔
- The corresponding flashing arrow ▼ (example: low arrow of “today”)

- Lowest recorded temperature (example: +2.9˚C)
- Duration of the exceedance of the preset low temperature limit (example 00:00; hh:min)

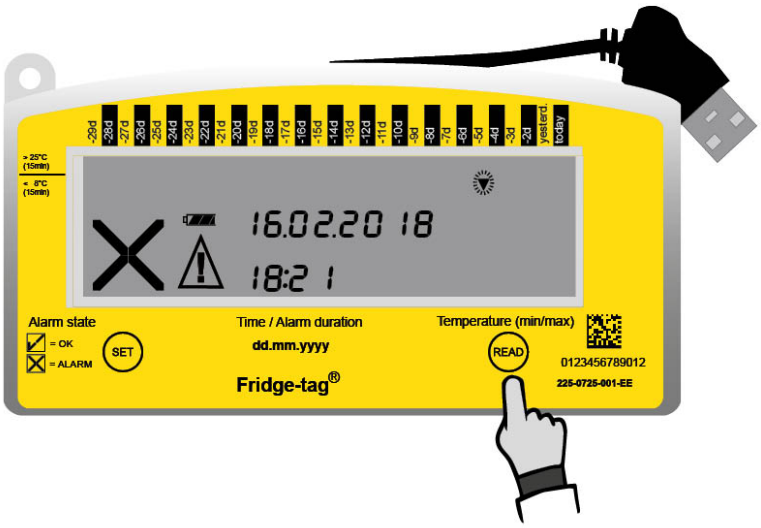
Note: in the Readout mode the flashing arrows display the day where your are (30-day history) and show the highest ▲ and lowest ▼ measured temperature of the corresponding day. If a limit has been exceeded also the duration is shown.

Note: Press repeatedly the READ button to read out day per day the details of the past 30 days.

When you reach an alarm event, the indication on the screen of the Fridge-tag will be different than the OK display.

Example of an alarm display during readout of the history

1st display of a “lower alarm event”

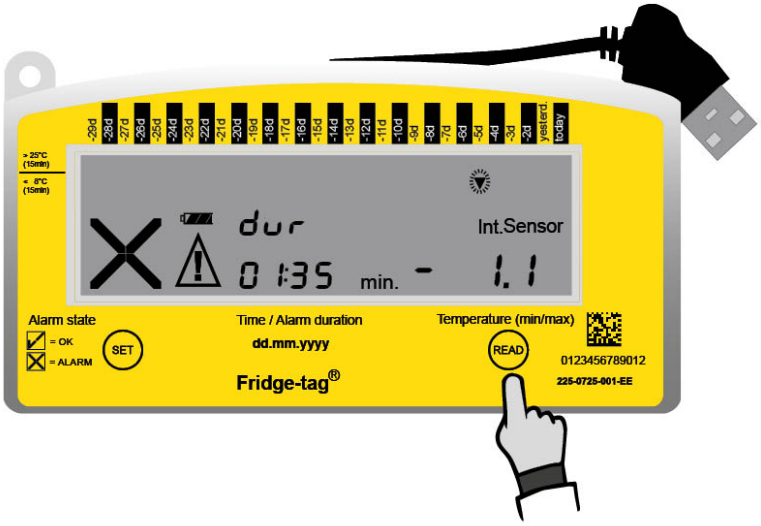


Press READ once

The following information is indicated on the screen:

- The alarm- ✕ and the warning symbol ⚠
- The corresponding alarm indicator ▼ (lower alarm limit)
- Day of alarm (example: 5 days ago: –5d)
- The date of the alarm (example: 16.02.2018)
- The time of the alarm (example: 18:21)

2nd display of a “lower alarm event”



Press READ a second time

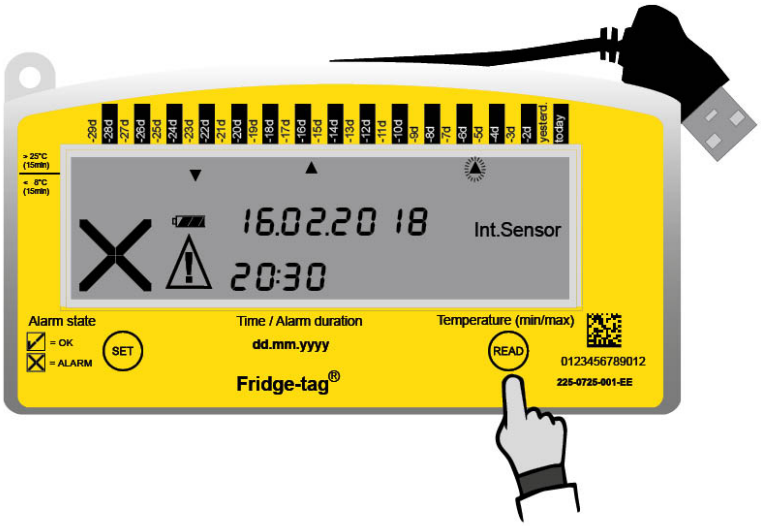
The following additional information is indicated on the screen:

- Lowest recorded temperature (example: –1.1˚C)
- The duration ot the exceedance of the preset low temperature limit (example: 01:35; hh:mm)
- Temperature recording in this example with internal sensor

12.2. Option 2: Read out alarms directly on the device – use the Alarm Super Jump function (30-day history)

If you like to read out the alarms directly on the Fridge-tag, press the READ button for at least 3 seconds.

1st display of the latest alarm event

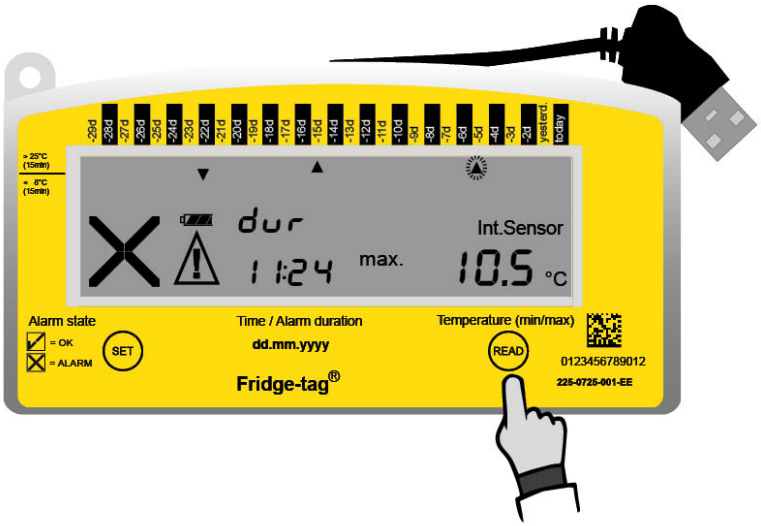


Press READ for 3 seconds

The following information is indicated on the screen:

- The alarm symbol ✕ and the warning symbol ⚠
- The corresponding alarm indicator ▲ (higher alarm limit)
- Day of alarm (example: 5 days ago: –5d)
- The date of the alarm (example: 16.02.2018)
- The time of excursion (example: 20:30)

2nd display of the latest alarm event



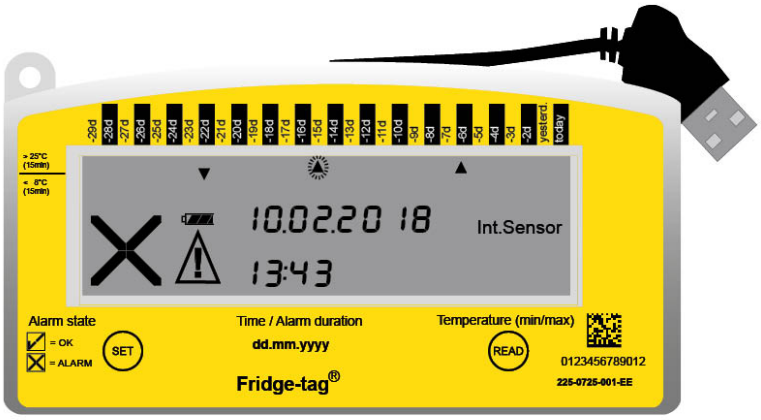
Press READ again

The following additional information is indicated on the screen:

- Highest recorded temperature (example: +10.5˚C)
- The duration of the exceedance of the preset high temperature limit (example: 11:24; hh:mm.)
- Temperature recording in this example with internal sensor

Note: Press the READ button again for at least 3 seconds and the next alarm event will appear on the screen.

Display of the next alarm event

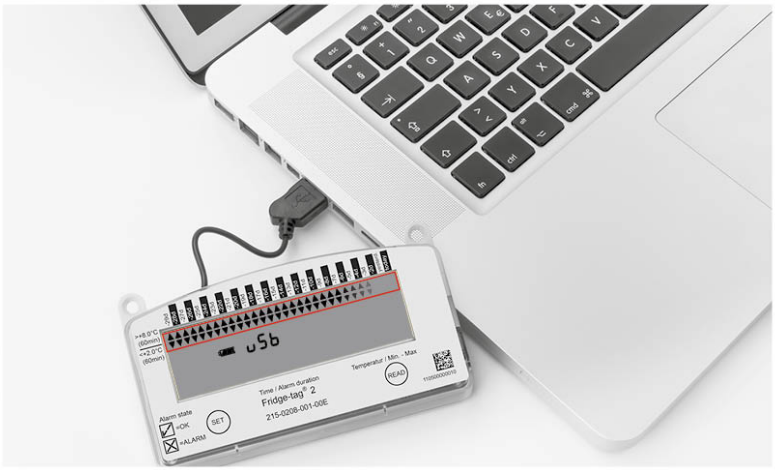


Note: Press the READ button again for 3 seconds to jump to the next alarm event. And so on.

Note: Pressing SET in the „Read out Mode“ brings you back to the „Measurement Mode“.

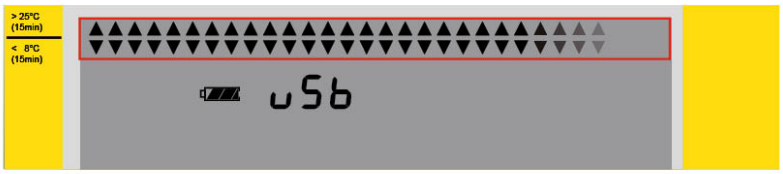
12.3. Option 3: Read out data from the files generated by the Fridge-tag by connecting it with a computer

Plug the Fridge-tag into any computer via USB interface. Make sure the device is plugged in properly.
Note: Disconnect the external sensor from the device first.



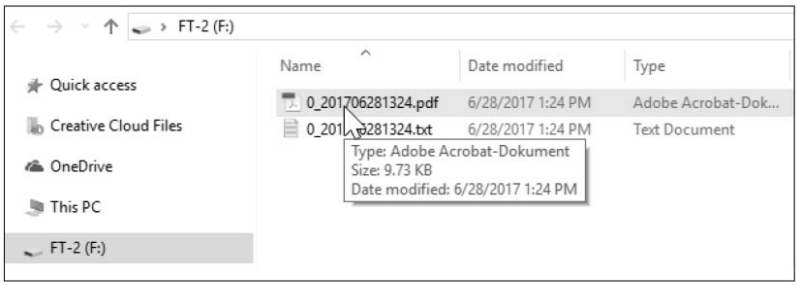
The Fridge-tag will now generate a PDF and ASCII report of the last 28, 56, 84 or 112 days (factory setting). Depending on the configuration, this process may take up to 2 minutes. Now choose the appropriate file generated by the Fridge-tag.

USB connection of the Fridge-tag
The continuously appearing arrows in the upper display area indicate that the device is operating.

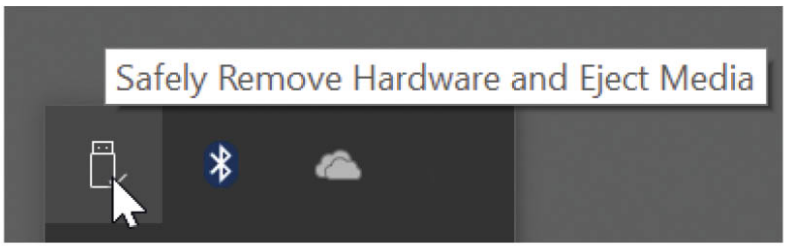


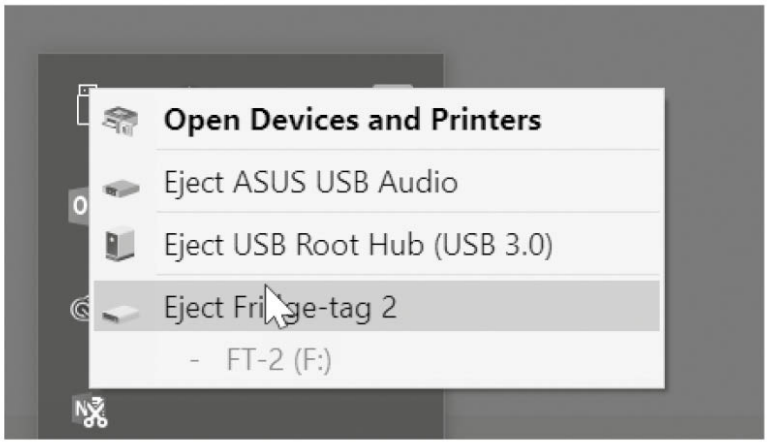
Note: This process must not be interrupted until the OK symbol appears on the display. This indicates that the creation of the ASCII and PDF files has been successfully completed.

The hard drive of the Fridge-tag is shown in your explorer. Open the desired file generated by the device.



Note: To disconnect the device properly, please always use the function “Safely Remove Hardware” on your PC/Mac.

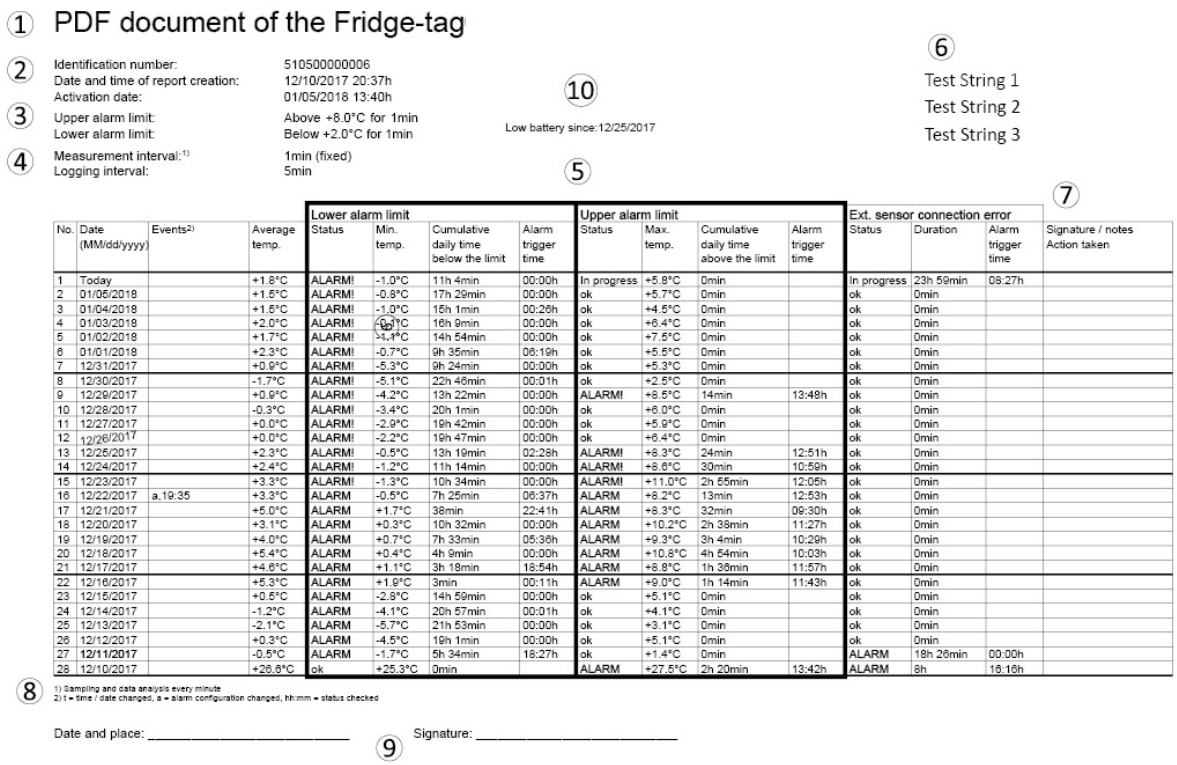


	Right-click the icon “Safely Remove Hardware and Eject Media” in the Windows taskbar (lower right corner). Choose the corresponding device to remove.
	Do not disconnect the device before you receive the depitcted message, otherwise the device can be damaged.

Note: For this process no additional software is necessary.

12.4. PDF report explanation

Sample of a PDF file generated by a Fridge-tag Ultra Low (page 1/2)



① PDF document of the Fridge-tag

② Identification number: 510500000006
Date and time of report creation: 12/10/2017 20:37h
Activation date: 01/05/2018 13:40h

③ Upper alarm limit: Above +8.0°C for 1min
Lower alarm limit: Below +2.0°C for 1min

④ Measurement interval:[1] 1min (fixed)
Logging interval: 5min

⑤

⑥ Test String 1
Test String 2
Test String 3

⑦

⑩ Low battery since:12/25/2017

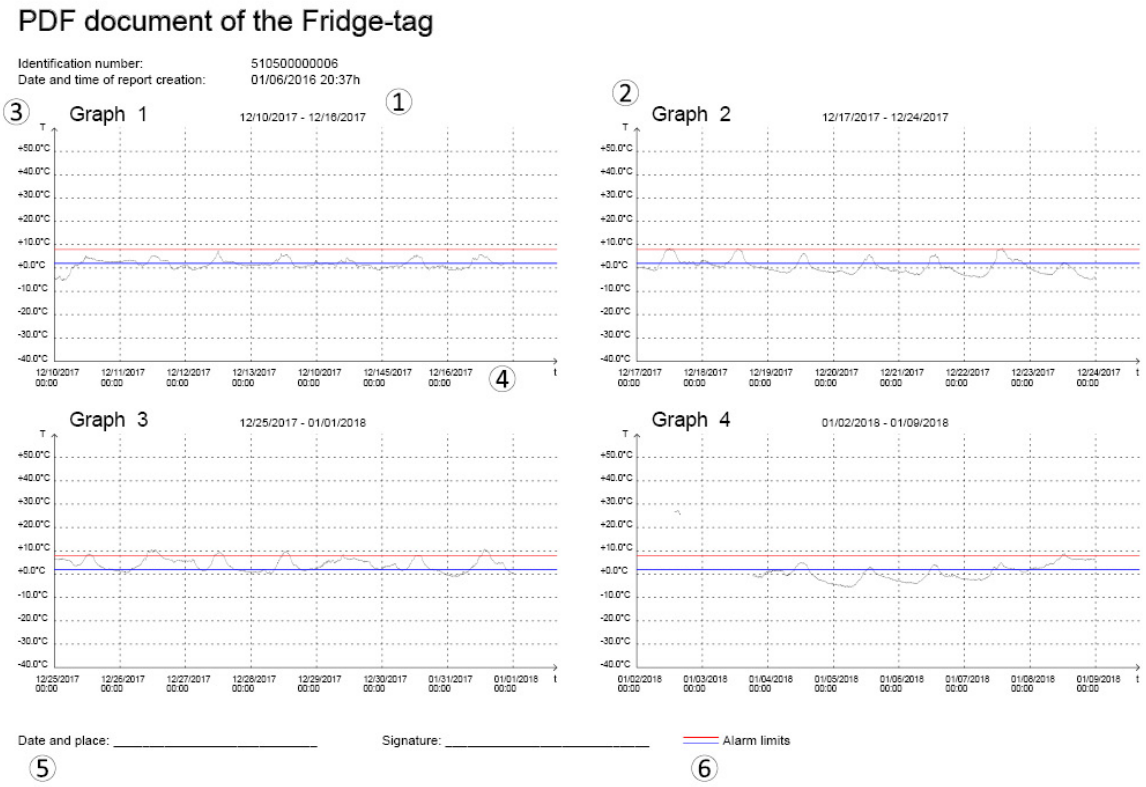
				Lower alarm limit				Upper alarm limit				Ext. sensor connection error			
No.	Date (MM/dd/yyyy)	Events[2]	Average temp.	Status	Min. temp.	Cumulative daily time below the limit	Alarm trigger time	Status	Max. temp.	Cumulative daily time above the limit	Alarm trigger time	Status	Duration	Alarm trigger time	Signature / notes Action taken
1	Today		+1.8°C	ALARM!	-1.0°C	11h 4min	00:00h	In progress	+5.9°C	0min		In progress	23h 59min	08:27h	
2	01/05/2018		+1.5°C	ALARM!	-0.8°C	17h 29min	00:00h	ok	+5.7°C	0min		ok	0min		
3	01/04/2018		+1.5°C	ALARM!	-1.0°C	15h 1min	00:26h	ok	+4.5°C	0min		ok	0min		
4	01/03/2018		+2.0°C	ALARM!	-0.7°C	16h 9min	00:00h	ok	+6.4°C	0min		ok	0min		
5	01/02/2018		+1.7°C	ALARM!	-1.1°C	14h 54min	00:00h	ok	+7.5°C	0min		ok	0min		
6	01/01/2018		+2.3°C	ALARM!	-0.7°C	9h 35min	06:19h	ok	+5.5°C	0min		ok	0min		
7	12/31/2017		+0.9°C	ALARM!	-5.3°C	9h 24min	00:00h	ok	+5.3°C	0min		ok	0min		
8	12/30/2017		-1.7°C	ALARM!	-5.1°C	22h 46min	00:01h	ok	+2.5°C	0min		ok	0min		
9	12/29/2017		+0.9°C	ALARM!	-4.2°C	13h 22min	00:00h	ALARM!	+8.5°C	14min	13:48h	ok	0min		
10	12/28/2017		-0.3°C	ALARM!	-3.4°C	20h 1min	00:00h	ok	+6.0°C	0min		ok	0min		
11	12/27/2017		+0.0°C	ALARM!	-2.9°C	19h 42min	00:00h	ok	+5.9°C	0min		ok	0min		
12	12/26/2017		+0.0°C	ALARM!	-2.2°C	19h 47min	00:00h	ok	+6.4°C	0min		ok	0min		
13	12/25/2017		+2.3°C	ALARM!	-0.5°C	13h 19min	02:28h	ALARM!	+8.3°C	24min	12:51h	ok	0min		
14	12/24/2017		+2.4°C	ALARM!	-1.2°C	11h 14min	00:00h	ALARM!	+8.6°C	30min	10:59h	ok	0min		
15	12/23/2017		+3.3°C	ALARM!	-1.3°C	10h 34min	00:00h	ALARM!	+11.0°C	2h 55min	12:05h	ok	0min		
16	12/22/2017	a,19:35	+3.3°C	ALARM	-0.5°C	7h 25min	06:37h	ALARM	+8.2°C	13min	12:53h	ok	0min		
17	12/21/2017		+5.0°C	ALARM	+1.7°C	38min	22:41h	ALARM	+8.3°C	32min	09:30h	ok	0min		
18	12/20/2017		+3.1°C	ALARM	+0.3°C	10h 32min	00:00h	ALARM	+10.2°C	2h 38min	11:27h	ok	0min		
19	12/19/2017		+4.0°C	ALARM	+0.7°C	7h 33min	05:36h	ALARM	+9.3°C	3h 4min	10:29h	ok	0min		
20	12/18/2017		+5.4°C	ALARM	+0.4°C	4h 9min	00:00h	ALARM	+10.8°C	4h 54min	10:03h	ok	0min		
21	12/17/2017		+4.6°C	ALARM	+1.1°C	3h 18min	18:54h	ALARM	+8.8°C	1h 36min	11:57h	ok	0min		
22	12/16/2017		+5.3°C	ALARM	+1.9°C	3min	00:11h	ALARM	+9.0°C	1h 14min	11:43h	ok	0min		
23	12/15/2017		+0.5°C	ALARM	-2.8°C	14h 59min	00:00h	ok	+5.1°C	0min		ok	0min		
24	12/14/2017		-1.2°C	ALARM	-4.1°C	20h 57min	00:01h	ok	+4.1°C	0min		ok	0min		
25	12/13/2017		-2.1°C	ALARM	-5.7°C	21h 53min	00:00h	ok	+3.1°C	0min		ok	0min		
26	12/12/2017		+0.3°C	ALARM	-4.5°C	19h 1min	00:00h	ok	+5.1°C	0min		ok	0min		
27	12/11/2017		-0.5°C	ALARM	-1.7°C	5h 34min	18:27h	ok	+1.4°C	0min		ALARM	19h 26min	00:00h	
28	12/10/2017		+26.6°C	ok	+25.3°C	0min		ALARM	+27.5°C	2h 20min	13:42h	ALARM	8h	16:16h	

⑧ 1) Sampling and data analysis every minute
2) t = time / date changed, a = alarm configuration changed, hh:mm = status checked

Date and place: _____ ⑨ Signature: _____

1. Document title and device type
2. Device ID and further information
3. Alarm settings
4. Measuring and logging interval
5. Event and alarm table (latest info in line 1, top line)
6. Up to 3 user-defineable strings (max. 30 characters each). Factory preset.
7. Placeholder for notes
8. Note 1: Reference for measurement interval, Note 2: Legend for events column (hh:mm —> 1 time stamp/half day)
9. Placeholder for date/place and signature
10. Battery warning with timestamp

Sample of a PDF file generated by a Fridge-tag Ultra Low (page 2/2)



1. Each graph shows data from a period of 7 days
2. Incrementally numbered graphs
3. Temperature scale
4. Time scale
5. Placeholder for date/place and signature
6. Alarm limits

Graph behavior when date / time is changed manually

1. Date change positive
2. Date change negative
3. Time change positive (e.g. summer/winter time)
4. Time change negative (e.g. summer/winter time)

12.5. Autoscaling of graphs in PDF

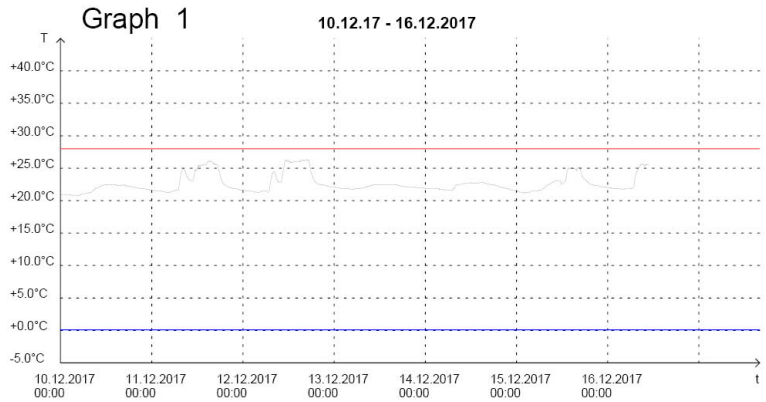
The graph of the report is created dynamically depending on the following settings:

- the alarm limits of the device
- the highest and lowest measured value

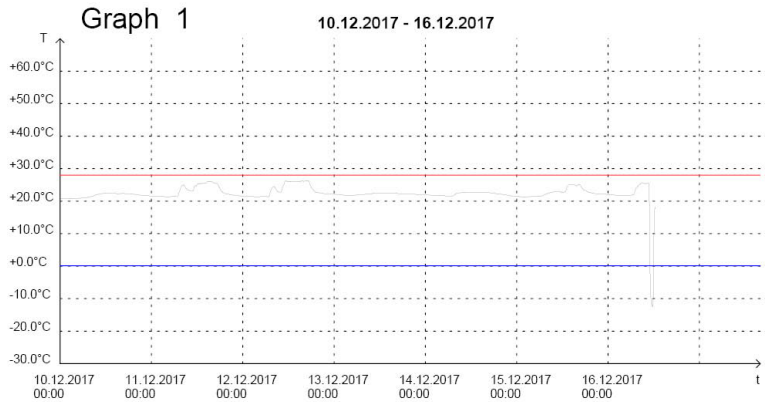
This is valid for all graphs in the PDF file until:

- the highest and lowest measured values drop out of the history
- the temperature settings are changed (self-configurable device only)

Example below: The scale of the graph depends on the alarm limits set. The temperature scale ranges from +40°C to –5°C for the limits of +0.5°C and +28°C.



Example below: The scale of the graph depends on the highest and lowest measured temperature values. The temperature scale ranges from –30°C to +60°C. Lowest measured temperature: –12°C, highest measured temperature: +25°C.



12.6. Temperature record duration (optional factory setting)

Selectable record duration: 28, 56, 84, 112 days.

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

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 “Today” is not yet complete
Status: OK	No alarm has been triggered in the past 30 days. (No alarm has yet been triggered since the data was read out on the device.*)
Status: Alarm ⚠	Alarm(s) have been triggered (With alarm symbol ⚠ means that the details of the corresponding alarm have not been read out yet.*)
Status: Alarm	Alarm(s) have been triggered (Without alarm symbol ⚠ means that the details of the corresponding alarm have already been read out on the device.*)
Min. temp.	Lowest recorded temperature
Cum. duration	Cumulative daily time below/above the limit
Alarm trigger time	Time at which the alarm was triggered
Max. temp.	Highest recorded temperature
Duration	Duration of an external sensor connection error

*For more information go to chapter Alarm trigger function

12.7. Verification process

This process verifies if the files (PDF and ASCII) created by the Fridge-tag are authentic and have not been manipulated or accidentally changed (meets the strict FDA 21 CFR Part 11 requirements).
Note: Please ensure that the latest version of “JAVA Runtime” is previously installed on your computer.

Step 1
Download the software Berlinger Verifier from our website: www.berlinger.com/verifier

Step 2
Open the software. The following window will appear:

Step 3
Click on “Open file”

Step 4
Select the file you would like to verify.

Option 1
Select the files directly from the Fridge-tag 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 PDF and ASCII files. The same OK or error messages will appear.

13. Explanations of terms

Readout mode:
In order to avoid incorrect data, the Fridge-tag does not measure the temperature while settings are changed or during or Readout mode (e.g. changing time, date and during reading of history). The Fridge-tag will fall back into normal operation after approx. 60 seconds without pressing any buttons.

External sensor:
After 10 minutes (factory setting) without connection between external sensor and device, two audio signals sound every three minutes for a maximum of 168 hours (7 days) and the entire display starts flashing.

HI or LO indicator (external sensor):
If the Fridge-tag measures temperatures above +0°C (+32°F) or below –95°C (-139°F), it shows HI or LO on the screen. The temperature will not be logged and not be shown in the PDF/ASCII file. The regular measurements and monitoring of alarm limits will continue as usual. As soon as the temperature is between +0°C (+32°F) and –95°C (-139°F) numbers will be displayed again.

14. Expire code explanation

Sample: exp 2020-07

The sample shows the expiry date of the Fridge-tag as July 2020 (yyyy-mm).

15. Firmware

Firmware: 4.0p0

16. Glossary

Glossary of Terms

Abbreviation	Title	Description
SOP	Standard Operating Procedure	Standard Operating Procedure (short SOP) is a binding textual description of the processes of procedures including the examination of results and their documentation.

Glossary of Symbols

Symbol	Description
✓	OK symbol
✕	alarm symbol
▼	LOW alarm indicator
▲	HIGH alarm indicator
⚠	warning symbol

! The warning box includes important informations or warnings.