

 **berlinger**
feel safe

Fridge-tag® 2 – Storage temperature monitor with USB port

Precision monitoring in fridges, cold rooms and displays:



- in hospitals and clinics
- in pharmacies and chemists
- in health centers
- in medical and veterinary practices
- in the doctor's or sales rep's bag
- in transport cooler bags
- as long-term monitoring in clinical studies
- at home: for representatives, patients etc.
- in old people's and care homes
- in regional immunization centers
- etc.

Precision monitoring of foodstuffs and other perishable products in refrigerated displays, racks and storage rooms:



- in food shops
- butchers
- delicatessens, cake shops, confectioners
- shopping centers and supermarkets
- displays of fresh fish, cheese and meat
- kiosks
- restaurants and hotels
- canteens and large-scale catering facilities
- pet food shops
- etc.

The advantages of using the Fridge-tag® 2

- USB interface and PDF report generation for easy data read-out without installing of software
- As soon as the device is connected to a PC or Mac, the Fridge-tag® 2 automatically generates a PDF report
- It is easy to send the PDF report by e-mail
- No need for a time-consuming handwritten report any more - therefore no transcription errors
- Individual alarm programming tailored to customers' needs
- Exact date and time display
- Displays the lowest and highest temperatures each day
- Accumulated time periods each time an alarm limit is exceeded
- Alarm display per day: 30-day overview as a display / up to 60 days' overview in a report
- Immediate and simple decision-making thanks to the easy-to-read OK / ALARM display (for 30 days)
- Temperature measurement interval: each minute
- User-friendly, reliable and high-precision, as exact as Swiss clockwork
- Exact measurement of temperature and time - NIST / ILAC traceable with calibration certificate
- Complies with FDA regulations 21 CFR Part 11
- Long operating time
- Available with a removable external temperature sensor (optional)



>+8.0°C
(60min)
≤+2.0°C
(60min)



16.09.20 12
13:47

Int.Sensor
05.6 °C

Temperatur / Min. - Max

READ

Alarm state
☒ =OK
☐ =ALARM

SET

Time / Alarm duration
Fridge-tag® 2
BAAA00001

-29d -28d -27d -26d -25d -24d -23d -22d -21d -20d -19d -18d -17d -16d -15d -14d -13d -12d -11d -10d -9d -8d -7d -6d -5d -4d -3d -2d yesterd. today

Display explanation



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)

Functions of the Fridge-tag® 2

Data read-out without software via USB

As soon as the Fridge-tag® 2 is connected via USB to a PC or Mac, it creates a PDF or an ASCII file. Thanks to the electronic signature the raw data can be verified to be in compliance with the FDA regulations 21 CFR Part 11. Any changes are immediately recognized and the document rejected. This means that each month you obtain a report and the assurance that your temperature-sensitive goods are stored and recorded in accordance with regulations.

Individual alarm programming

2 alarm limits (1 upper and one lower Alarm limit) can be programmed individually at a temperature range of -20 °C up to +50 °C. The alarm limits can be ordered either as default factory settings or set personally on site.

Exact measurement of temperature and time

The Fridge-tag® 2 is a high-precision, electronic temperature monitor. It is 100% calibrated and has a measurement precision of +/- 0.5 °C. Temperature measurement occurs every minute throughout the entire monitoring time. This guarantees faultless and extremely accurate measurement results. Even if an alarm limit has been exceeded and the Fridge-tag® 2 alarm is displayed, it accumulates each additional temperature threshold violation. The precision time measurement is generated by a built-in quartz. NIST/ILAC traceable.

PDF/A-Report

All relevant information about temperature measurement and recordings from the last 60 days is shown as a table in the report. You also receive the following data:

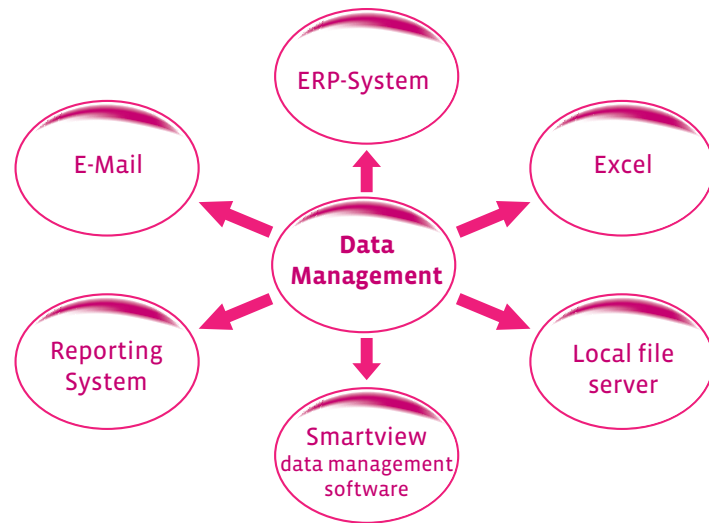
- Time statement as to when each respective Fridge-tag® 2 was started
- Unique identification number
- Programmed alarm parameters
- Average temperature for each day
- Highest and lowest temperature measured each day
- Details of the triggered alarms

Detailed evaluation of temperature threshold of the overrun

The Fridge-tag® 2 shows irrevocably the exact point in time and the date of all limit violations. Additional information such as how long limits were exceeded and the highest and lowest temperatures help in making binding decisions. The details can be easily read on the device and in the easy-to-read PDF report.

Archiving and document management

The device generates an ASCII and PDF file. The ASCII file is compatible with most data management and data analysis software systems. It can be easily imported into an existing ERP or data management system for storage and access.



The internal sensor explained

The device is placed immediately next to the goods to be monitored and the temperature values are monitored and recorded by the Fridge-tag® 2 sensor.

The external sensor explained (optional)

The Fridge-tag® 2 can be positioned outside the refrigerator or cold room. The external cable sensor is placed next to the goods to be monitored. The display shows the temperature measured by the external sensor. The PDF report shows additionally the temperature which the internal sensor of the Fridge-tag® 2 has measured on the time of the alarm. This means that you receive information on temperature conditions outside the refrigerator when the alarm is triggered. (External sensor can be equipped optionally with a bottle filled with bio-safe glycol).

Reading the history of Fridge-tag® 2

View the past 30 days directly on the device or 60 days on the generated files (PDF / ASCII). Any up or down arrows will indicate the day, temperatures were too high or too low compared to the alarm settings. You have 3 options to read out data of the temperature excursions, or of the highest and lowest measured daily temperatures, etc.

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

Press READ button briefly = the display jumps from one day to the next

Displays the extreme temperatures and if present the precise information about temperature threshold violations. During this read out the Fridge-tag® 2 does not record any temperatures so that no false values are measured, which can occur for instance from hand warming.

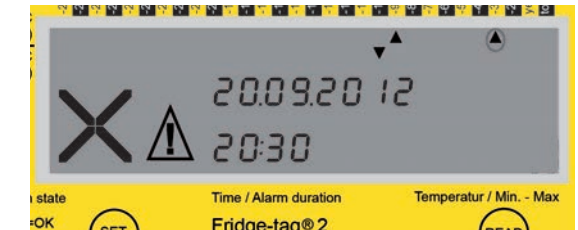


Example of an OK display:
Displays the lowest temperature currently being measured

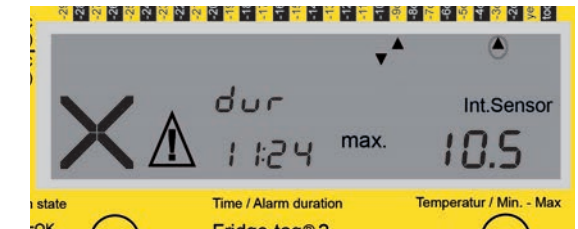
Option 2: Read out alarms only directly on the device with the ALARM-SUPER-JUMP function (30 day overview)

Keep READ button pressed down for 3 seconds = the display jumps from alarm event to alarm event

With the help of the innovative ALARM-SUPER-JUMP function, the alarm display jumps directly to the respective day when an alarm has been triggered. This saves time during read-out and helps to evaluate relevant data as quickly as possible.



1st display of an ALARM indication:
Date and time of alarm



2nd display of an ALARM indication:
Extreme temperature and period of time the limit was exceeded

Option 3:
Read out the data from the PDF/A and ASCII document, generated via USB interface (60 day overview)

As soon as the Fridge-tag® 2 is connected via USB to a PC or Mac, it creates a PDF/A and an ASCII document.

The clearly laid out PDF document shows all the results such as date and time when the alarm limit was exceeded. This provides you at a glance with all the relevant data for the last 60 days which can be sent easily by e-mail or electronically filed in a folder.

In addition, the raw data (PDF or ASCII file) can be read into an existing ERP or other data management system directly and the process of archiving and tracking can be automated.

The digital signature for both files (PDF and ASCII) can be verified with the assistance of free software, which confirms the data has been unaltered (to comply with the FDA regulation 21 CFR Part 11).

Explanation of PDF report:

DateDate of measurement

Event: tTime / date changed

Event: aAlarm configuration changed

Average temp. Average temperature

Status: in progressThe data collection of „Today“ is not yet complete

Status: OKNo 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 on device yet)

Status: ALARMAlarm/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 RangeTime outside of the alarm limits

DurationDuration of an external sensor connection error

Alarm trigger timeTime at which the alarm was triggered

PDF document of the Fridge-tag® 2

Identification number: 1234
Date and time of report creation: 3.12.2012 10:05h
Upper alarm limit: Above +8.0°C for 60min
Lower alarm limit: Below +2.0°C for 60min
Low battery since: 25.11.2012

No.	Date (dd.MM.yyyy)	Events*	Average temp.	Lower alarm limit					Upper alarm limit					Ext. sensor connection error			Signature / notes
				Status	Min. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.	Status	Max. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.	Status	Duration	Alarm trigger time	
1	Today		+4.6°C	In progress	+4.1°C	0min			In progress	+5.3°C	0min						
2	02.12.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.3°C	0min						
3	01.12.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.2°C	0min						
4	30.11.2012		+4.3°C	ok	+3.9°C	0min			ok	+5.4°C	0min						
5	29.11.2012		+2.2°C	ALARM!	-1.5°C	2h 30min	06:05h		ok	+3.3°C	0min						
6	28.11.2012		+3.4°C	ok	+2.8°C	0min			ok	+3.8°C	0min						
7	27.11.2012		+3.4°C	ok	+2.8°C	0min			ok	+3.9°C	0min						
8	26.11.2012		+3.5°C	ok	+2.9°C	0min			ok	+4.1°C	0min						
9	25.11.2012		+4.6°C	ok	+4.1°C	0min			ok	+5.3°C	0min						
10	24.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.2°C	0min						
11	23.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.1°C	0min						
12	22.11.2012		+4.3°C	ok	+3.9°C	0min			ok	+5.1°C	0min						
13	21.11.2012		+4.6°C	ok	+4.1°C	0min			ok	+5.2°C	0min						
14	20.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.3°C	0min						
15	19.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.2°C	0min						
16	18.11.2012		+4.3°C	ok	+3.9°C	0min			ok	+5.1°C	0min						
17	17.11.2012		+4.6°C	ok	+4.1°C	0min			ok	+5.1°C	0min						
18	16.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.2°C	0min						
19	15.11.2012		+10.5°C	ok	+4.5°C	0min			ALARM	+20.5°C	3h 0min	22:00h					
20	14.11.2012		+12.5°C	ok	+4.5°C	0min			ALARM	+20.5°C	7h 15min	01:00h					
21	13.11.2012		+4.6°C	ok	+4.1°C	0min			ok	+5.2°C	0min						
22	12.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.1°C	0min						
23	11.11.2012		+2.5°C	ok	+ -1.0°C	3Cmin			ok	+5.1°C	0min						
24	10.11.2012		+4.3°C	ok	+3.9°C	0min			ok	+5.2°C	0min						
25	09.11.2012		+4.6°C	ok	+4.1°C	0min			ok	+5.3°C	0min						
26	08.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.2°C	0min						
27	07.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.1°C	0min						
28	06.11.2012		+4.3°C	ok	+3.9°C	0min			ok	+5.1°C	0min						
29	05.11.2012		+4.6°C	ok	+4.1°C	0min			ok	+5.2°C	0min						
30	04.11.2012		+4.5°C	ok	+4.0°C	0min			ok	+5.3°C	0min						

Date and place: _____ Signature: _____Page 1

* t = time / date changed, a = alarm configuration changed

Technical specification of the Fridge-tag® 2

Hardware		
External dimensions (L x W x H)	128 x 75 x 16 mm	
Size of the LCD display	95 x 27 mm	
Weight	96 g	
Storage condition (inactive)	0 °C to +30 °C	+32 ° F to +86 °F
Operating temperature	-25 °C to +55 °C *	-13 ° F to +131 °F *
(Display visible)	-10 °C to +55 °C	+14 ° F to +131 °F
Alarm temperature range	-20 °C to +50 °C, in 0.1 °C increments	-4 ° F to +122 °F
Alarm limits	2 individually programmable alarm limits (1 upper and 1 lower alarm limit)	
Alarm time	1 minute to 23 h 59 min	
Temperature measurement interval	Every minute	
Accuracy of temperature measurement	+/- 0.8 °C (-25 °C to -10 °C) +/- 0.5 °C (-10 °C to +40 °C) +/- 0.8 °C (+40 °C to +55 °C)	+/- 1.44 °F (-13 °F to +14 °F) +/- 0.9 °F (+14 °F to + 104 °F) +/- 1.44 °F (+104 °F to +131 °F)
Measurement accuracy of the time	+/- 30 minutes / year	

Calibration	Every device is calibrated / NIST / ILAC traceable
Date / time programming	Date and time will be set when device is activated (see operation manual)
Protection class	IP64
Operating lifetime	up to 3 1/2 years (1/2 year storage / 3 years useful life) - Estimated operating lifetime of the battery is printed on the back.
Manipulation	Fridge-tag® 2 cannot be manipulated or reset without destroying it.

Software	
Format of the original document	ASCII (it can also be imported by many ERP systems) / PDF
Free software for verifying PDF and ASCII file	JAVA™ / The software verifies the digital signature of the ASCII and PDF files. FDA regulation 21 CFR Part 11 compliant. Software is compliant with the requirements of GAMP 5.

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

Subjet to change. Please note that all information in this document is correct at the time of publication. Due to our policy of continuous product develop- ment, we reserve the right to change this information without prior notice.



Freeze-tag®

Monitoring of the freezing point



Q-tag® Quad

Multi-alarm shipping and storage temperature monitor



Q-tag® CLm

Multi-alarm shipping and storage temperature monitor



Q-tag® CLm doc family

USB multi-alarm shipping temperature logger



Q-tag® 2/2R plus

Shipping temperature monitor (single use / reusable)



Fridge-tag® family

Storage temperature monitor with USB port



Central Monitoring System (CMS)

Environmental monitoring based on wireless network



Data Management System

Web based reporting, analyzing and statistics software

feel safe – with temperature monitoring systems from Berlinger

SWISS
Quality



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Berlinger & Co. AG

Mitteldorfstrasse 2
9608 Ganterschwil
Switzerland

Tel. +41 71 982 88 11
Fax +41 71 982 88 39
info@berlinger.com
www.berlinger.com

Berlinger USA LLC

222 Turnpike Road
Suite 3
Westborough, MA 01581
USA

Tel. +1 508 366 0084
Fax +1 508 366 0087
info.us@berlinger.com
www.berlinger.com