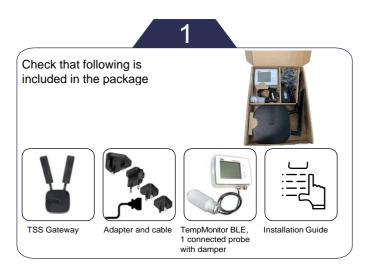
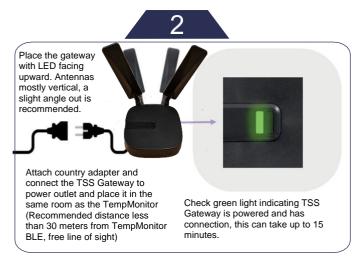
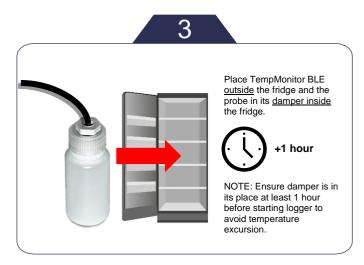


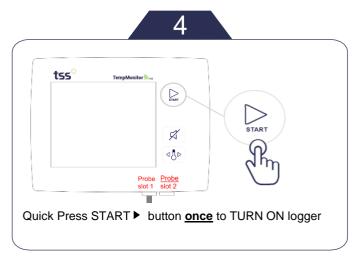
TempMonitor BLE Kit

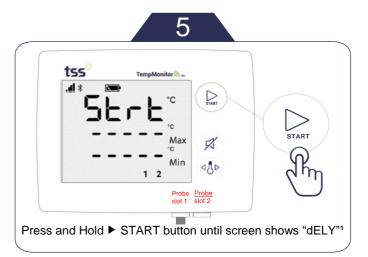
Quick Installation Guide



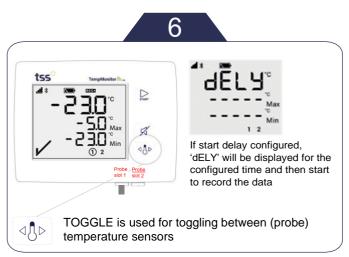








¹ Note, when pressing START button a beep will be heard indicating that the button is activated, ensure that button is <u>continuously pressed</u> for at least 5 seconds until the display changes from "Strt" to "dELY".



Question

What does it mean when the display of the TempMonitor shows "Strt"?	The logger is ready to be started, refer to Quick Installation Guide.
Where is the recommended placement of the TempMonitor?	Recommend placing it outside the refrigerator, using its magnets on the backside. If used in Ambient temperature place logger at appropriate place and put the probe with damper at desired location.
Where is the recommended placement of the probe and the damper?	Placement of damper shall be as close as possible to where the products are stored, if unsure please contact your study manager.
What purpose does the damper serve?	The primary purpose of the damper is to protect against sudden and sharp air temperature changes - such as fluctuations due to the opening or closing of refrigerator doors or normal defrost cycles.
What does Max °C/Min °C mean?	It shows the highest and lowest measured temperature for the last 30 days.
How do I acknowledge a temperature alarm?	By pressing the START button once the Warning symbol will be removed, indicating that the alarm has been acknowledged. If the temperature is within set threshold the cross mark (X) will be changed to check (<). If the temperature is still out of range during the time of acknowledgement the cross mark (X) will remain until the temperature is within range. The buzzer will muted by the acknowledgement. If a new alarm is triggered the buzzer will continue to beep as per configuration.
The logger keeps beeping although it is back within threshold?	The logger has recorded a temperature alarm and has not been acknowledged. Press START button once to acknowledge the temperature alarm.
The display on the logger shows X, indicating temperature alarm, but the logger is within range?	The logger has recorded a temperature alarm and has not been acknowledged. Press START button once to acknowledge the temperature alarm.
Which one is "probe slot 1" and "probe slot 2"?	The Temp Monitor BLE always comes with one mounted (attached) probe, this probe is attached to "probe slot 1" and the other (available) "probe slot" is "probe slot 2". (If a second probe has been ordered, please connect it to the available "probe slot 2")

> I'm pressing the start button, but the logger will not start. What do I need to do?

First of all, verify that the logger is in a state that allow it to be started.

- The display should show "Strt", indicating the logger is ready to be started
- Ensure that the START button is firmly pressed and held down until the screen changes. This can take several seconds.

If the above is unsuccessful, please report back to TSS Customer service.

> I'm being told there is no data in the system, although the logger seems to be working. What do I need to do?

First, verify that the Gateway and the TempMonitor BLE is close to each other, we recommend keeping them in the same room and less than 30 meters apart.

- Check that the Gateway is online.
 - The Gateway should show a solid green light. If the Gateway is blinking yellow, it means that it can't connect to the Internet. This can be resolved by changing location of the Gateway, typically closer to a window where it has better cellular connectivity. A tip is to check on your mobile phone, if you have cellular coverage with your phone chances are good that the Gateway will work there too.

Tip: check the cellular strength on your mobile phone

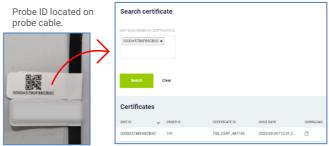


If the above is unsuccessful, please report back to TSS Customer service.

> I need the Calibration Certificate, where can I find it?

The probe is calibrated, and its calibration certificate can be found here* https://certificates.tssgeneral.com/

- Click on SEARCH CERTIFICATE
- Scan or Enter the Probe ID from the label attached to the probe cable and click search.
- Click download to access the certificate.



Scan barcode to start searching for Calibration



*In TSS Clinical Module the calibration certificate is located under TSS > Administration Loggers > Overview > Logger Details

Still having issues or looking for more information? Contact TSS Customer service Please reach out to us at customer.service@tss.se.



User Manual TSS TempMonitor BLE





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1. Introduction

The TSS TempMonitor BLE is a wireless storage logger with an internal temperature sensor and support for up to two probes, that can communicate with TSS Gateway and TSS Mobile App.

1.1 Key Features

The TempMonitor BLE, Bluetooth low energy temperature data logger can be paired with TSS GW, smartphones and transmit data via Bluetooth 5. It records up to 50,000 data points readings and monitors drugs across a range of -50°C to 85°C using it's supported probes.

2. Logger Specifications

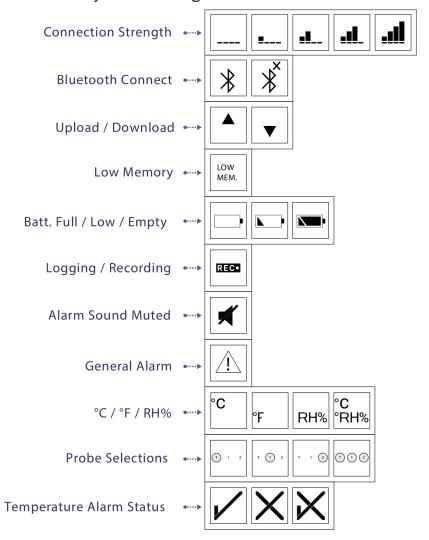
FEATURES

Туре	Temperature Data Logger
Operating Range	-20°C to +50°C, -50°C to +85°C (probe)
Temperature Accuracy	± 0,5°C
Memory Capacity	50 000 Data Points
Temperature Resolution	0,0625°C (1/16th of a Degree)
Compliance	RoHs, CE, FCC, DO-160G
Calibration	Each unit is delivered with calibration certificate from accredited ISO-17025 laboratory
Battery	3 x AAA Alkaline 1.5V (removable)
Alarms/Events	Temperature Alarms, Calibration Expiry, Battery, Probe Disconnect
Audible Alarm/Events	Yes
Buttons	Start, Toggle Temperature, Mute
Sample Rate	1 min to 18 hours
Start Delay	0 min to 30 days
IP Classification	IP54
Security	Highly secure utilizing BLE security features
Weight	Approx. 118 g
Measurement	Approx. 100 mm x 80 mm x 30 mm
Housing	Blistered rugged plastic
Traceability	Unique 16-character ID number that allows for absolute traceability



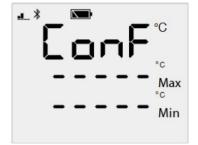
2.1 Display Interface

2.1.1 LCD Symbol meaning



2.1.2 LCD text meaning

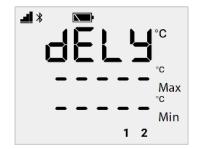
ConF logger is ready for configuration



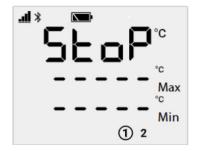
Strt logger is ready to be started



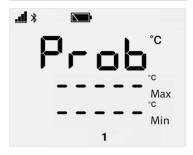
dELy logger started with active start delay



StoP logger is stopped



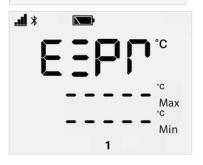
Prob logger can't be started because a probe is missing



UPLd pending upload before logger can be started



EXPR calibration expiry has passed, logger can't be started





2.2 Buttons

Button action are displayed below:



START is used for waking up, starting and acknowledging alarms on logger.



MUTE is used for muting/unmuting the buzzer.



TOGGLE is used for toggling between temperature sensors.





2.3 Start up Logger



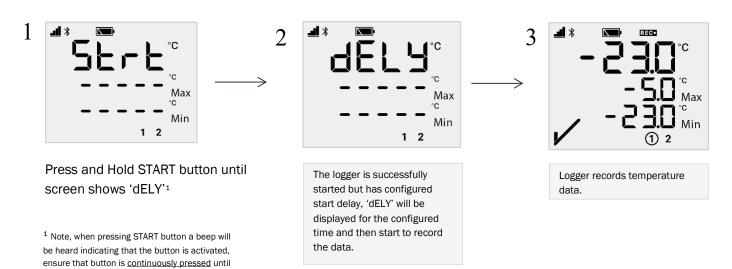
Quick Press **START** button once for to start up the logger.

Screen is lit with symbols.

NOTE: Before starting the logger ensure the probe(s) are placed at the given location.

2.4 Start Logging

the display changes from "Strt" to "dELY".





8 (18)

2.5 Connection and signal strength

To verify that the logger has connection to TSS Gateway the Bluetooth symbol shall be visible on the LCD screen.



Logger has Bluetooth connection to TSS Gateway.

In case the logger cannot establish a Bluetooth connection to the Gateway the symbol will be marked with an X.



Logger does not have Bluetooth connection to TSS Gateway.

The signal strength between the logger and the Gateway is indicated by the signal bar strength on the LCD. The more bars the stronger the signal strength.













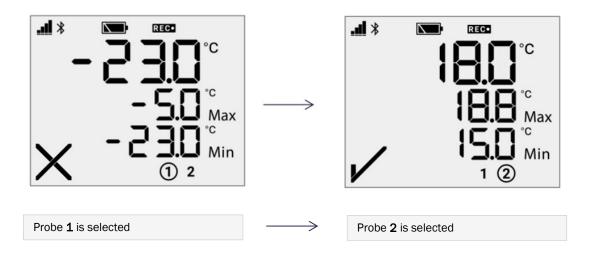
2.6 Toggle Temperature Channels

2.6.1 Probe selection

Press **TOGGLE** to switch between temperature channels if the logger is configured for measuring more than one channel.



TOGGLE is used for toggling between temperature sensors.









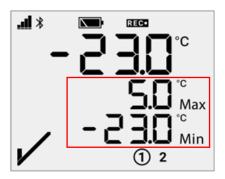
T is the internal temperature sensor. Note that only two channels can be active during recording.



2.7 Max and Min Temperature

The highest (Max) and lowest (Min) recorded temperature values are displayed on the screen. It is based on the values for the Last 30 days.

Max and Min temperature for the Last 30 days





2.8 Alarms and Events

2.8.1 Temperature Alarms

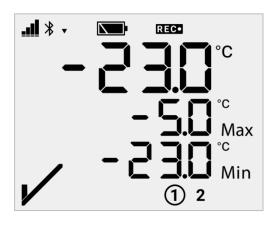


Temperature Alarm symbol is activated

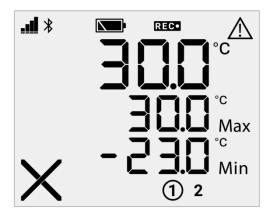


General Warning symbol is activated

No alarm present



Temperature Alarm Triggered



2.8.2 Acknowledge Alarms

Quick Press $\mbox{\bf START}$ button once for acknowledging alarms on the logger.



By pressing the START-button, the General Warning symbol will be removed, indicating that the alarm has been acknowledged. If the temperature is within set threshold the cross mark (X) will be changed to check (\checkmark) .

If the temperature is still out of range during the time of acknowledgement will the cross mark (X) remain until the temperature is within range. The buzzer will be muted by the acknowledgement. If a new alarm is triggered will the buzzer continue to beep as per configuration.



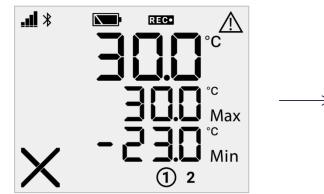
2.9 Mute/Unmute

If an alarm has been triggered the buzzer can be muted by pressing the mute button once. It will be muted for 5 minutes. To unmute the logger, press the mute button once more. The icon will be removed indicating that the logger is no longer muted.

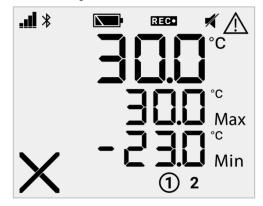


MUTE is used for muting/unmuting the buzzer

Alarm present, Buzzer active



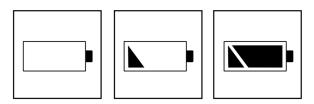
Alarm present, Buzzer muted





2.10 Battery

Battery Level - Always shown to indicate battery level in 1 of 3 states: Full, Low and Critical.



Battery alarm levels can be configured and in case a battery alarm is triggered the general warning sign will be activated on the LCD.



General Warning symbol is activated

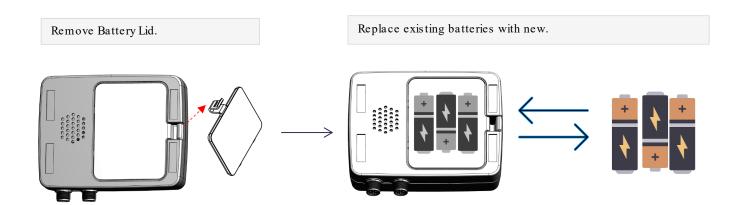
2.11 Battery replacement

The logger is equipped with user replaceable batteries, see section 3.2 Battery for details. When a low battery warning appears, it is time to change batteries. The logger requires three user-replaceable **AAA 1.5V alkaline** or optional lithium batteries.

Before starting the procedure:

• make it sure that there is up-to-date data in your system from the logger.

To replace the batteries simply remove the battery lid and replace the existing batteries with new. Close the lid.



The logger will automatically continue logging temperature after the new batteries have been inserted¹. If there was any unread temperature measurement, event, probe event or alarm the logger display will show



Upload. This indicates that the logger is waiting for the Gateway to read out the unread events before it can start logging temperature again. Ensure the Gateway is online.

 $^{
m 1}$ Note, if the probe is removed before battery replacement and connected again after batteries have been inserted the logger must be manually started on start button.

2.12 Calibration Expiry

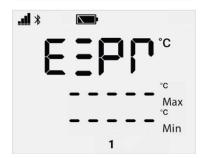
When the sensor(s) have less than 60 days until they expire a General Warning symbol will be lit. Additional notifications related to the Calibration Expiry are handled by TSS Cloud.



General Warning symbol is activated

Note, if a sensor has expired it is not possible to start the logger.

EXPR calibration expiry has passed, logger can't be started





2.13 Memory

In case the logger has not been connected to the Gateway for a long period of time a low memory symbol can appear. This is to indicate that the logger's memory is starting to get full. During normal operations with the logger connected to a Gateway this will not happen. In case this this message appears ensure that the Gateway is connected to power and is online.





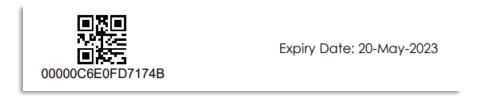
3. General Logger Information

3.1 Logger and Probe Identification

Each TempMonitor BLE is identified with a unique 16-character id, located on its back.



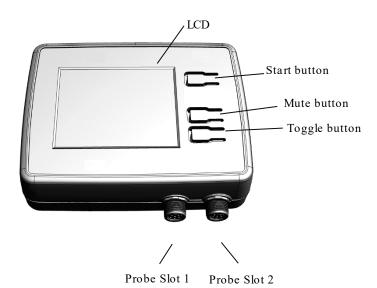
Each Probe TMBLE100, is identified with a unique 16-chracter id. The Expiry Date of the probe is stated too.

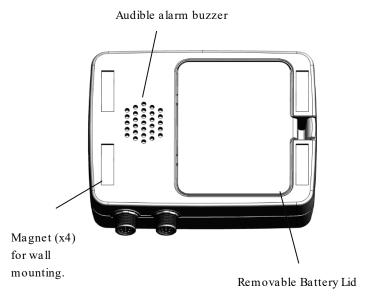




3.2 Logger Components

Front





Back

3.3 Battery

The logger requires three user-replaceable **AAA 1.5 V alkaline** or optional lithium batteries for operation at the extreme ends of the logger operating range. Expected battery life varies based on the ambient temperature where the logger is deployed, the frequency of connecting to the phone or tablet and downloading reports, the duration of audible alarms, and battery performance. New batteries typically last at least 1 year with logging intervals of 5 minutes. Deployments in cold or hot temperatures or a logging interval faster than 5 minutes can impact battery life. Estimates are not guaranteed due to uncertainties in initial battery conditions and operating environment.

WARNING: Do not cut open, incinerate, heat above 85°C (185°F), or recharge the lithium batteries. The batteries may explode if the logger is exposed to extreme heat or conditions that could damage or destroy the battery case. Do not dispose of the logger or batteries in fire. Do not expose the contents of the batteries to water. Dispose of the batteries according to local regulations for lithium batteries.



4. Troubleshooting

Should you experience issues with any of the above steps, or with the TSS TempMonitor BLE in general, please reach out to us at customer.service@tss.se.