

TEMPSSEN

USER MANUAL

EN

ITAG[®]4 / ITAG[®]4 Bio/ ITAG[®]4 TH DATA LOGGER

UM-ITAG4-160217 REV.D

www.tempsen-europe.com

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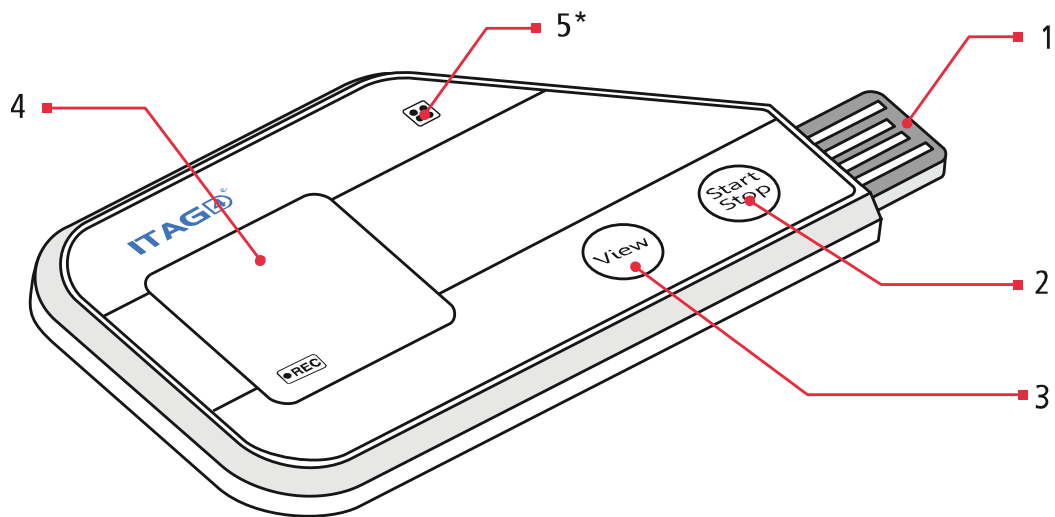
TEMPSSEN EUROPE B.V.

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PRODUCT OVERVIEW

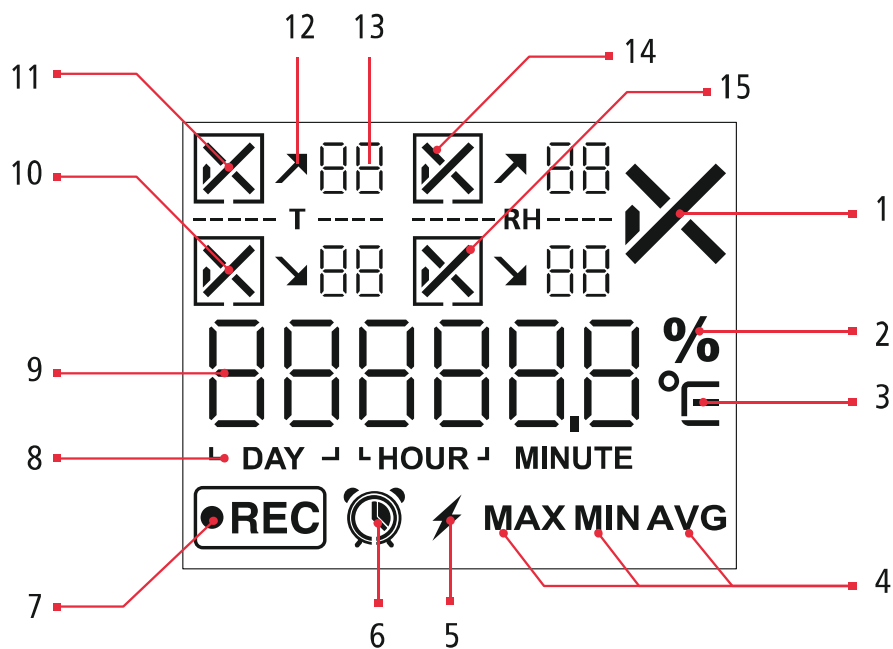
Logger



1. USB Plug
2. Start and Stop Button
3. View Button
4. LCD
5. *Humidity sensor window, only available on ITAG4 TH

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LCD



1. Overall alarm status
2. Relative humidity unit*
3. Temperature unit (Celsius and Fahrenheit)
4. Maximum, minimum, average
5. Power active indicator
6. Start timer and limit violation duration indicators
7. Recording indicator
8. Time units
9. Readings
10. Low alarm zone status (temperature sensor)
11. High alarm zone status (temperature sensor)
12. Limit violation indicator
13. Number of limit violation events
14. High alarm zone status (humidity sensor)*
15. Low alarm zone status (humidity sensor)*

*Applicable on ITAG4 TH

TECHNICAL SPECIFICATIONS

Product		ITAG4	ITAG4 Bio		ITAG4 TH
Type	Single Use				
Sensor	Internal NTC	Internal NTC		Internal temperature and humidity Sensor	
Memory Capacity	7200 readings				
Measurement Range	-30°C...70°C (-22°F...158°F)	-30°C...70°C (-22°F...158°F)		-30°C...70°C, 0% RH...100% RH	
Accuracy	±0.5°C/0.9°F	±0.5°C/0.9°F		± 0.5°C (0°C...60°), ± 1°C (rest range) ±4% RH (20% RH...80% RH) ,±5% RH (rest range)	
Resolution	0.1°C /°F				
Logging Interval	1 minute...2 hours				
Alarm Range	High and low alarm	High and low alarm/5 alarm ranges		High and low alarm	
Battery	CR2032 lithium battery				
Typical Run Time	60 days max				
Shelf Life	2 years (1 year if power activated)				
Automatic Data File	Encrypted PDF report with embedded raw data				
Dimensions	93mm L x 45mm W x 7mm H				
Weight	Approx. 25g				
Protection Class	IP65				

TEMPCENTRE SOFTWARE

Please download and install the latest version of TempCentre software from www.tempsen.com.

How to download TempCentre software?

- If it's your first time to download software from www.tempsen.com, please sign up with the information required prior to downloading, then an email containing download link would be sent to the mail address you left in couple of minutes.
- If you want to download the software from www.tempsen.com again after your successful registration last time, please click "**I already signed up, download now**" button in dialog box, then software would begin to download in couple of minutes.

Installing and using TempCentre software

Please refer to TempCentre User Manual for installation and operation instructions of TempCentre software.

DATA LOGGER CONFIGURATION

Configuring Logger with TempCentre

Connect ITAG4 data logger to USB port of PC, open TempCentre software, select **Configure Device** in tool bar, software would automatically start searching and connecting devices, then user could start programming of this data logger.

Configuring Loggers Online

Connect ITAG4 logger to USB port of PC, open Internet Browser, go to www.itag4.com, input and select configuration parameters you need, then download the configuration profile (.cfg format file), save it into the logger created removable storage device "TempSenDisk".



LCD displays "USB" when logger connected to PC.



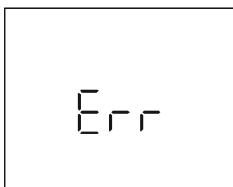
IMPORTANT

- Please only apply configuration profile to the same product model on which configuration file is created based.
- Do not alter the configuration profile downloaded to avoid configuration error.
- Configuration profile contains time zone information, so please do not use this file in areas of different time zones, or it will result in incorrect time base.

Applying Configuration



LCD displays “**ConF**” for configuration success when connection with PC remains. (Only applicable to non-software configuration).



LCD displays “**Err**” for configuration failure, please re-configure device with correct parameters.



IMPORTANT

- Configuration to data logger would erase all data recorded, so please make sure you have save the data before configuration.
- Do not remove data logger from PC before you are prompted of configuration success.

Configuration Options

Trip Number

A unique 10 digits alphanumeric number automatically created for identifying each monitoring task.

Trip Description

A brief note entered by user for describing monitoring task and showing on data report.

Logging Interval

The recording and sampling interval for data logger, optional from 1 minute to 2 hours.

Startup Mode

↻ Manual Start

Device needs to be started by pressing **Start/Stop** button for **3** seconds

Start Delay

The time device needs to wait before recording starts after manually activated, optional from 1 minute to 10 days.

➡ Auto Start

Device automatically starts recording on the specific date/time preset, no need to press **Start/Stop** button after configuration.

Button Settings

➡ Disable Stop Button

This option is used to avoid mistaken Stop Button action, once enabled, device could not be stopped by pressing **Start/Stop** button, recording stops when logging cycle completes, however, you are still allowed to stop recording through TempCentre.

Alarm Settings

➡ Alarm Mode

- No alarm setting
- High & Low alarm, 2 alarm ranges determined by 2 alarm limits.
- Multiple Alarm ranges, 5 alarm ranges determined by 5 alarm limits.
 - High alarm zones: A1, A2, A3
 - Ideal range: A4 (No alarm will be triggered when data falls within this range)
 - Low alarm zone: A5, A6

■ Only ITAG4 Bio supports multiple alarm ranges.

➡ Alarm Type

- **Single Event**
Alarm could only be triggered when data over high limit (or under low limit) not less than an alarm delay continuously.
- **Cumulative Alarm**
Alarm could be triggered once the cumulative total time data over high limit (or under low limit) is not less than an alarm delay.

PDF Report Settings

➡ PDF Report Title

This report title would be used for PDF report created automatically by data logger.

➡ Time Base

Select Time Zone and enable/disable Day Light Saving time (DST) for PDF report.

➡ Language

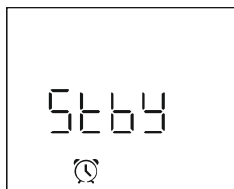
Select language for PDF report.

LCD Screens after Configuration



Manual Start

*LCD displays "**Stby**" after configuration.*



Auto Start

*LCD displays "**Stby**" and a **Clock** after configuration indicating logger is waiting for **Auto Start** on pre-set time.*

RECORDING

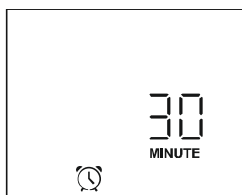
Start Recording

Manual Start

Press and hold **Start/Stop** button for **3** seconds to manually active data logger, if logger was set to Start Delay, then recording would only start after **Start Delay** time passes.

LCD displays “HoLd” while pressing button to activate device, to remind user current button action is effective and please keep unit recording starts.

➡ Start Delay



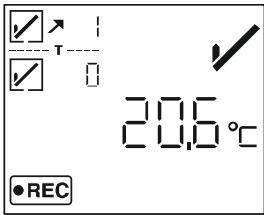
*Start delay time and a **Clock** appear on LCD and logger begins countdown after logger started manually, refresh frequency of countdown time changes as per remaining delay time, for example, when there is 2 hours left, delay time refreshes each one hour, 59 minutes left, LCD refreshes each 1 minute. (In this case, start delay time is 30 minutes)*

Auto Start

Device starts recording on pre-set time automatically, no need to press **Start/Stop** button after configuration.

-
- ITAG4 data logger could not be configured again after recording begins.
-

In Recording



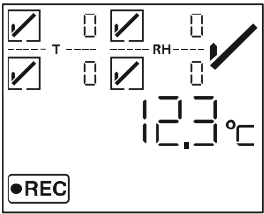
“REC” appears in left bottom screen indicates logger is currently recording.

LCD Examples - Home Screen



No Alarm Setting

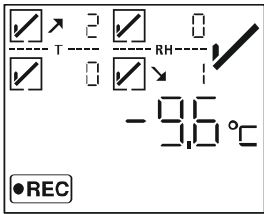
Current Reading: 25.7°C



No Alarm, No Limit Violation Event

Current Reading: 12.3°C

*RH channel only available on ITAG TH



No Alarm

High alarm zone (Temp)

Violation event: 2

Low alarm zone (Temp)

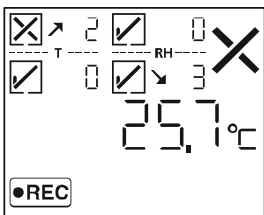
Violation event: 0

High alarm zone (RH)

Violation event: 0

Low alarm zone (RH)

Violation event: 1



Alarm

High alarm zone (Temp): Alarm

Violation event: 2

Low alarm zone (Temp)

Violation event: 0

High alarm zone (RH)

Violation event: 0

Low alarm zone (RH)

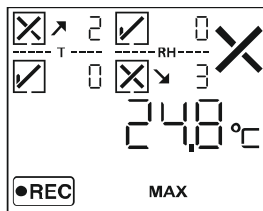
Violation event: 3

For multiple alarm ranges model, Alarm zone A1, A2, A3 are deemed as high alarm zones, A5, A6 are deemed as low alarm zones, all numbers of violation events in each high alarm zone will be added up and total number shows in high alarm zone area of home screen, the same applies to low alarm zones.

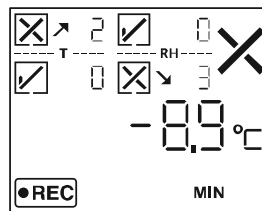
Due to LCD only has 2 digits displaying number of violation events for each alarm zone, so 99 is the biggest number on LCD indicating the violation events, please refer to data report for the real number of violation events when LCD shows 99 for violation events.

LCD Examples – View Logging Statistics

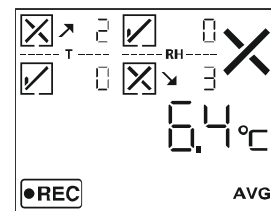
Click on **View** button to view monitoring statistics and alarm information screen by screen.



Maximum Value

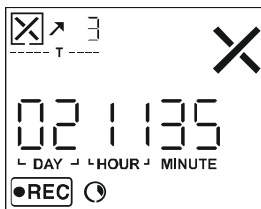


Minimum Value



Average Value

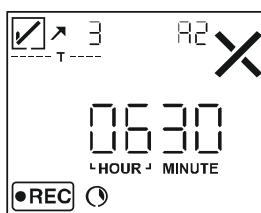
Statistics for each alarm zone



High Alarm Zone (Temp): Alarm

Violation Event: 3

Total violation time: 2 days 11 hours 35 minutes

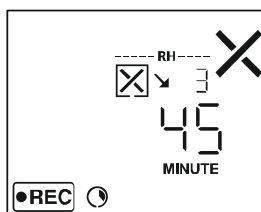


High Alarm Zone (Temp) - A2: OK

Multiple Alarm Ranges

Violation Event: 3

Total violation time: 6 hours 30 minutes



Low Alarm Zone (RH): Alarm

Violation Event: 3

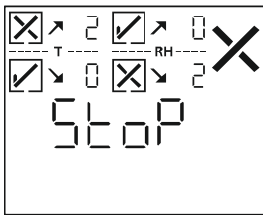
Total violation time: 45 minutes

Stopping recording

Press **Start/Stop** button and hold for at least **3** seconds to stop recording.

Logger would stop recording too after logging cycle completes (memory full).

LCD displays “HoLd” while pressing button to stop device, to remind user current button action is effective and please keep unit recording stops.



Recording Stops

“StoP” displays after recording stopped.

-
- Logger could not be stopped by pressing **Start/Stop** button within 30 minutes after recording started.
-

DOWNLOADING DATA

Downloading Data by Obtaining PDF Report

Connect logger to USB port of PC, data logger will start generating PDF report and it may take couple of seconds for the process to complete.



LCD displays “PdF” indicating logger is currently generating PDF report, then changes to “USb” after PDF report is successfully created.

After PDF report is created, open removable storage device named “TempSenDisk” in computer, copy the PDF report to your computer, then open and view it with Adobe PDF reader software.

-
- Logger would be ready for communication with TempCentre software only after PDF report is completely created.
-

PDF Report

The PDF report automatically created by ITAG4 data loggers are protected and encrypted from tamper, with all raw data embedded, you are allowed to open this PDF file with TempCentre for further analysis and archiving, and upload it to TempSen’s **Cold Chain Cloud™** online data management, analysis and sharing center, www.coldchaincloud.com, to enable shipment build and worldwide data sharing, alarm notification between shipper, receiver and QA management personnel.

Authenticity and integrity of PDF reports downloaded from ITAG4 could be verified using TempCentre (version 2.0 or higher) or Cold Chain Cloud™ service.



IMPORTANT

Please **DO NOT** save the PDF report that you copied from logger as a new file. Please do not perform any “Save” action through PDF reader software. Otherwise, content inside PDF file will be reorganized by Adobe PDF reader and cause raw data embedded unrecognizable.

Please **DO NOT** remove data logger from USB port while it’s still in the process of creating PDF report (“PDF” on LCD indicates that logger is creating PDF report). Otherwise logger would be seriously damaged.

Downloading Data via TempCentre

Connect logger to PC, open TempCentre software, and click **Download** in toolbar, then TempCentre would search, connect logger and download data automatically.

Please remember to save data to data base of TempCentre by clicking “**Apply**” button in software

DATA RESULTS EXPLANATION

Device Information

Current Status

Running status of logger when downloading data.

Logging Summary

Start Time

The time the first data point is recorded at.

Stop Time

The time the last data point is recorded at.

Trip Length

Total recording duration time, which is calculated from the first point to the last point.

Alarms

Total Violation Time (Total Time)

The total time measurement values violate each alarm limit.

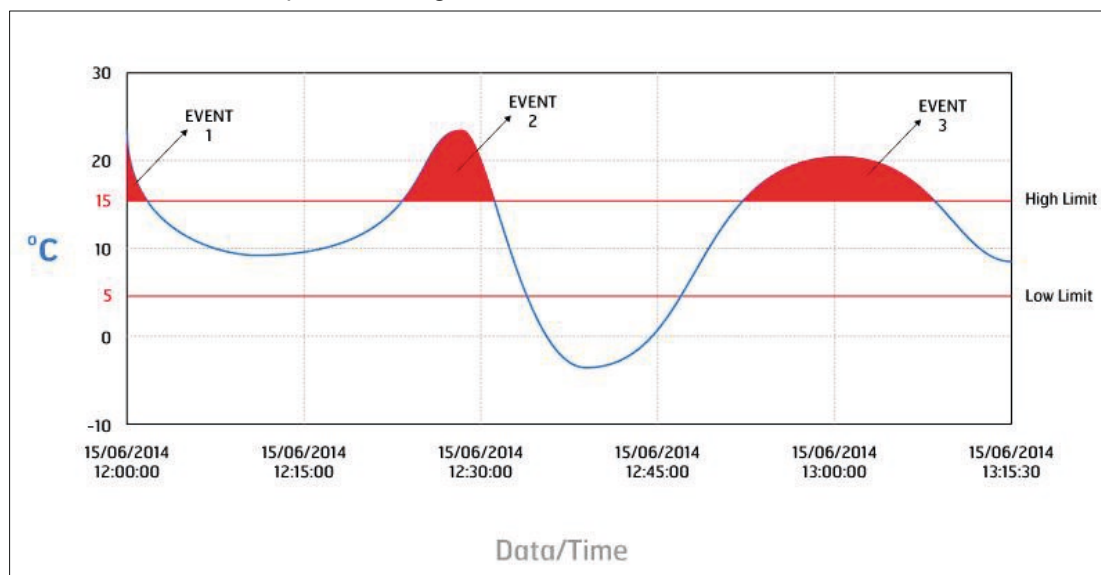


IMPORTANT

Violation time calculation method changes from ITAG4 Bio (X1.3) and ITAG4/ITAG4 TH (X2.0). Now violation time of each event = number of violation points x logging interval.

Limit Violation Event (Events)

A consecutive series of data points over preset high alarm limit or under low limit would be deemed as one violation event. In example below, high alarm zone has three limit violation events.



Number of violation event for each alarm zone shows on LCD and in “Events” column of alarm statistics in data report.

Alarm First Triggered Time (First Triggered@)

The time an alarm is first triggered at.

For example, logger is set to logging interval of 1 minute, alarm delay is 5 minutes, logger is started at 09:00, and readings are all over high limit after recording begins, so first alarm will be triggered at 09:05, and this is the Alarm First Triggered Time.

BATTERY

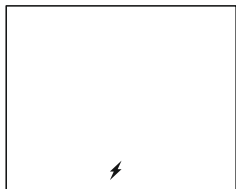
ITAG®4 series data loggers are equipped with one CR2032 lithium metal battery, which passed the Part III, Sub Section 38.3 of the UN Manual of Tests and Criteria. ITAG®4 data logger is also certified to meet requirements in General Requirements and Section II of Packaging Instruction 970, IATA Dangerous Goods Regulations 56th Edition. ITAG®4 complies with DO160G Environmental Conditions and Test Procedures for Airborne Equipment.

Shelf Life / Expiry Date

ITAG4 series data loggers are supplied power system disabled, shelf life (validity of device) is two years from manufacturing date.

Expiry date is printed on the back of each logger, please make sure you will use the logger before expiry date.

Once logger is connected to computer, power system of logger will be activated, then the guaranteed shelf life will be reduced to one year, you need to use the logger ASAP. So please **DO NOT** connect logger to computer if you do not plan to use the logger immediately.



A lightening icon appears at bottom of LCD means power is already active.

Please note two years shelf life is only applicable to ITAG4 loggers not connected to computer yet. Factory programmed ITAG4 loggers come with one year shelf life.

ERROR CODES

Error codes usually could be found on the upper left corner of a PDF report created by data logger, if you find an error code in a data report, it means data logger detected an exception related to recording.

Code 0004 (*0004), logger used to be reset during recording, which may cause missing of data point.

Code 0005 (*0005), an internal time error is detected when activating a logger, to avoid creating incorrect data record, logger would not be activated in this case until new configuration is carried out.

MKT

MKT (Mean Kinetic Temperature) is a simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods. Calculation,

$$T_{mkt} = \frac{\Delta E/R}{-\ln\left(\frac{e^{-\frac{\Delta E}{RT_1}} + e^{-\frac{\Delta E}{RT_2}} + \dots + e^{-\frac{\Delta E}{RT_n}}}{n}\right)}$$

ΔE = activation energy (standard value: 83.144 kJ/mol)

R = 8.314472 J/mol (universal gas constant)

T = temperature in degrees K

n = the number of sample periods over which data is collected

Note: $\ln$ is the natural log and e is the natural log base.

Why is MKT important in the life of pharmaceuticals and perishable goods?

The pharmaceutical and food industries are two closely regulated markets. The FDA provides regulations that require warehouse and shipment temperatures to be closely controlled and monitored. In addition, the FDA requires well-documented verification of these storage environments and any corrective actions taken if temperatures exceed specified storage conditions.

ADDITIONAL INFORMATION

- LCD may function abnormally after taken out from environment down to -20°C to room temperature, please wait for few minutes for it to restore to normal status.
- To avoid damaging your data logger, please do not disconnect it from USB port while it is communicating with the computer.
- Do not use any aggressive cleaning agents or solvents to clean device.
- Data stored in data logger is retrievable even battery runs out.
- Please do not heat, microwave or recharge battery.
- Please follow local regulations when recycling or disposing of data data logger.

GLOSSARY

Terms	Explanation
Logging Interval	Unit time required to record one data point.
Start Delay	The time device needs to wait before starting recording after manually activated.
Alarm Delay	Time threshold required for triggering an alarm
Limit Violation	Measurement value goes above high limit or drops below low limit.
Violation Event	A consecutive series of data points over a high limit (or under a low limit) is deemed as a violation event.
Alarm Zone	Measurement ranges defined by alarm limits.
Trip Number	A unique 10 digits alphanumeric number automatically created for identifying each monitoring task.
Trip Description	A brief note entered by user for describing a monitoring task and shows on data report.
Temperature Start	After logger is manually activated, device starts recording when temperature meets the preset temperature conditions.
Repeat Start	Repeat Start is an independent option of Startup, if enabled, you could restart Alpha data logger for next round of monitoring with the same recording parameters of previous recording by pressing Start/Stop button, no need to program the logger again.
Auto Start	Device automatically starts recording on the specific date/time preset, no need to press Start/Stop button after configuration.

WARRANTY

TempSen warrants this TempSen-branded hardware product against defects in materials and workmanship under normal use for a period of ONE (1) YEAR from the date of retail purchase by the original end-user purchaser ("Warranty Period"). If a hardware defect arises and a valid claim within the Warranty Period, as its option and to the extent permitted by law, TempSen will either (1) repair the hardware defect at no charge, using new parts or parts equivalent to new in performance and reliability, (2) exchange the new product with a product is new or equivalent to new in performance and reliability and is at least functionally equivalent to the original product, or (3) refund the purchase price of this product. TempSen may request that you replace defective parts with new or refurbished user-installable parts that TempSen provides in fulfillment of its warranty obligation. A replacement product or parts, including a user-installable part that has been installed in accordance with instructions provided by TempSen, assumes the remaining warranty of the original product or ninety (90) days from the date of replacement or repair, whichever provides longer coverage for you. When a product or part is exchanged, any replacement item becomes your property and the replaced item becomes TempSen's property. Parts provided by TempSen in fulfillment it's warranty obligation must be used in products for which warranty service is claimed. When a refund is given, the product for which the refund is provided must be returned to TempSen and becomes TempSen's property.

EXCLUSIONS AND LIMITATIONS

This Limited Warranty applies only to the hardware product manufactured by or for TempSen that can be identified by the "TempSen" trademark, trade name, or logo affixed to it. The Limited Warranty does not apply to any non-TempSen hardware product or any software, even if packaged or sold with the TempSen hardware. Manufacturers, suppliers, publishers, other than TempSen, may provide their own warranties to the end user purchaser, but TempSen, in so far as permitted by law, provides their products "as is". Software distributed by TempSen with or without the TempSen brand name (including, but not limited to system software) is not covered under this Limited Warranty. Refer to the licensing agreement accompanying the software for details of your rights with respect to its use.

TempSen does not warrant that the operation of product will be uninterrupted or error-free. TempSen is not responsible for the damage arising from failure to follow instructions relating to the product's use.

This warranty does not apply: (a) to consumable parts, such as batteries, unless damage has occurred due to a defect in materials or workmanship; (b) to cosmetic damage, including but not limited to scratches, dents, and broken plastic on ports; (c) to damage caused with non-TempSen products; (d) to damage caused by accident, abuse, misuse, flood, fire, earthquake, or other external causes; (e) to damage caused by operating the product outside the permitted or intended uses described by TempSen; (f) to damage caused by service (including upgrades and expansions) performed by anyone who is not a representative of TempSen or TempSen Authorized Service Provider; (g) to a product or part that has been modified to alter functionality or capability without the written permission of TempSen; or (h) if any TempSen serial number has been removed or defaced.

IMPORTANT: DO NOT OPEN THE HARDWARE PRODUCT. OPENING THE HARDWARE PRODUCT MAY CAUSE DAMAGE THAT IS NOT COVERED BY THIS WARRANTY. ONLY TEMPSSEN OR AN AUTHORIZED SERVICE PROVIDER SHOULD PERFORM SERVICE ON THIS HARDWARE PRODUCT.

REVISION HISTORY

Revision	Date	Details
A	02/17/2016	First version
B	03/02/2016	Added recording results explanation
C	06/07/2016	Corrected few mistakes
D	05/18/2017	Violation time calculation method changed

log  cold chain

TEMPSEN EUROPE B.V.

Tempsen Europe B.V.
Gantellaan 26, 2681 LG Monster

Mobile: +31 (0)6 54 60 70 69 • Office: +31 (0)174 785565
info@tempsen-europe.com • www.tempsen-europe.com