

# calera<sup>σt</sup> Research

## CALERAresearch Manual



## Continuous Core Body Temperature Monitoring

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## 1. Introduction

**Core Body Temperature** is a vital parameter for monitoring an individual’s health status and refers to the body’s organs’ temperature. It fluctuates following physiological processes, such as physical activity, circadian and ovulation rhythm, or various illnesses and sleeping disorders.

CALERA<sup>®</sup> is a new thermometer technology developed by greenTEG that enables the monitoring of the core temperate with a **wearable device**. CALERA is **accurate, non-invasive, and continuous**. This technology is based on a new thermal energy transfer (heat-flux) sensor developed by greenTEG that enables a solution which works independently of the physical activity level and external environmental conditions. Truly a breakthrough technology in measuring Core Body Temperature!

greenTEG has released its **consumer device CORE** to the market in the middle of 2020. CORE is a compact wireless device that can be worn on the chest with a strap or adhesive patch. CORE has an accompanying phone and watch applications that can be used to display live data and can alert the user with a configurable alarm. CORE communicates wirelessly using Bluetooth Low Energy (BLE) and ANT+ communication profiles.

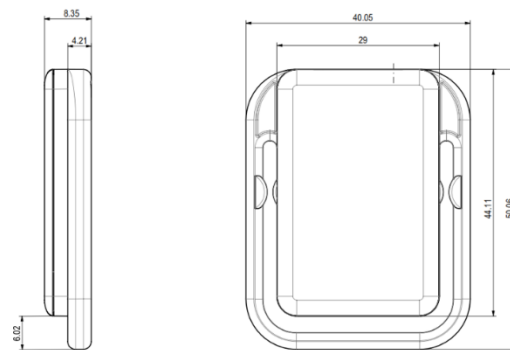


Figure 1: Dimensions of CORE [mm]

**CALERAresearch is our premium version** and is tailored for research studies. The hardware of CORE and CALERAresearch are the same. But CALERAresearch comes with services and functionalities that are designed specifically for researchers. CALERAresearch is also compatible with all apps & tools developed for CORE.

### Features

- ◇ **CALERAresearch Features**
  - High-res. Data (1hz)
  - Local Storage (6.5 days)
  - Individually Calibrated devices
  - Remote Support
  - Research tool (PC/Mac)
- ◇ High accuracy
  - ±0.1°C Skin temp
  - 0.21°C (MAD) core temp
- ◇ Compact Design
  - 50 x 40 x 8.35 mm
  - 17 grams
- ◇ Easy to use
  - Patch or Strap application
  - Long Battery life >6d
  - Waterproof up to 5ft
  - Disinfect with alcohol
- ◇ Connectivity
  - iOS / Android / WatchOS / Garmin ConnectIQ / WearOS
  - BLE & ANT+ Standard profiles
  - API available

### Use Cases

- ◇ Health and Wellness
- ◇ Worker Safety
- ◇ Sleep (circadian cycle) Monitoring
- ◇ Sports Performance
- ◇ Research Applications
- ◇ Elevated body temperature monitoring
- ◇ Early Detection of Thermoregulatory Disease

## 2. CALERAresearch Description

CALERAresearch has the same functionalities as CORE plus some additional benefits tailored for research purposes. The main operating difference is that **CALERAresearch has two modes: standard and logging**. CORE users will only have access to the standard mode.

**Standard Mode:** In standard mode, CALERAresearch needs to be used in combination with the CORE Android or iOS app. After turning on CALERAresearch, it will directly start recording. When you connect the device to the app, all the measured data (T, Ts, HR) will be uploaded to [www.cloud.corebodytemp.com](http://www.cloud.corebodytemp.com). The data can be downloaded with a 1-minute resolution.

**Logging Mode:** In logging mode, all the raw data is saved on the device with a 1Hz resolution.

### CORE vs. CALERAresearch

CALERAresearch has all the same functionalities as CORE plus some additional benefits tailored for research purposes. See Chapter 3 for the instructions to access the logging mode.

	<i>CALERAresearch</i>	<i>CORE</i>
<i>Measurement modes</i>	<ul style="list-style-type: none"> <li>• Standard mode</li> <li>• Logging mode</li> </ul>	<ul style="list-style-type: none"> <li>• Standard mode</li> </ul>
<i>Data Resolution</i>	1x per second	1x per minute
<i>Data Streams</i>	<ul style="list-style-type: none"> <li>• Timestamps</li> <li>• Core temperature</li> <li>• Skin temperature</li> <li>• Accelerometer (x,y,z)</li> <li>• Heart rate (ext. device)</li> <li>• Heat flux (under contract)</li> <li>• Battery level</li> </ul>	<ul style="list-style-type: none"> <li>• Timestamps</li> <li>• Core temperature</li> <li>• Skin temperature</li> <li>• Heart rate (ext. device)</li> </ul>
<i>Calibration</i>	Individually calibrated devices (best accuracy)	Batch calibrated
<i>Other Benefits</i>	<ul style="list-style-type: none"> <li>• Remote support</li> <li>• Research support</li> <li>• Research tool (PC/Mac control)</li> </ul>	

## How to use CORE & CALERAresearch

### How to Wear CORE & CALERAresearch

Our algorithm is optimized for measurements on the chest. It will also give acceptable results on the upper arm, stomach and back, but for research studies, we urge you to measure on the left apical position to get the best possible accuracy.

CORE is initially designed for athletes that can attach CORE to their heart rate belt, but we also offer several other accessories to wear CORE, e.g., chest straps, arm straps, and medical adhesive patches (see Chapter 5 for more details).



## Connect CALERAresearch

CALERAresearch can be connected to all the CALERAresearch and CORE Apps but **only our PC software (Research tool) and the CALERAresearch app gives access to the logging mode.**

### CALERAresearch

- [Android](#)
- [iOS](#)

### CORE

- [Android](#)
- [WearOS](#)
- [iOS & WatchOS](#)
- [Garmin connect IQ](#)

Unique to CALERAresearch is the **Research tool**. With this PC application you can control multiple devices directly and simultaneously from your PC. To use the Research tool you need to use our special Bluetooth dongle.

### Example functions

- Download data
- Update Firmware
- Start / stop measurements

The Research tool (previously called COREtool) can be downloaded from [www.greenteg.com/download-caleraresearch/](http://www.greenteg.com/download-caleraresearch/) (PW = HotHotHot)

## How to get the best out of your measurements?

All the instructions for CORE are also valid for CALERAresearch. For the most up-to-date instructions, have a look at our online CORE manual:

[CORE Manual – An Introductory guide to using and maintaining CORE](#)

### Data Quality:

The app indicates the data quality of the body temperature. Low quality can be caused due to:

- Bad skin contact
- No thermal equilibrium
- Sudden jumps in HR >50

It can take up to 30 minutes to achieve thermal equilibrium. We, therefore, advise you to start the on-body measurement with the device at least 20 minutes before the actual start of your study.

Note: Do not heat or cool the device directly

### Physical Activity:

For high physical activity, the device needs to be [paired to a heart rate monitor](#), and it will switch automatically and use the algorithm optimized for sports to deliver accurate core body temperature. You can use almost any heart rate monitor that supports ANT+ ([compatibility list](#))

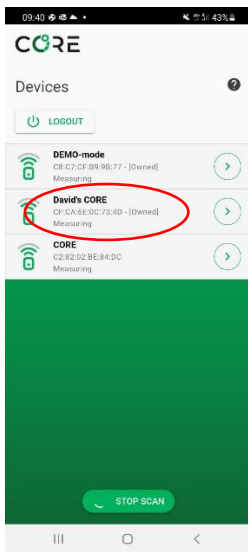
Note: If you are not physically active, do not connect the heart rate monitor, as this will lower the accuracy.

Note: The sports algorithm cannot detect fever

### 3. Research Mode

#### Access Logging Mode

With logging mode, you can save high-resolution data. Please follow these steps to record a measurement. Please make sure you have updated to the newest firmware.



#### STEP 1 Connect device

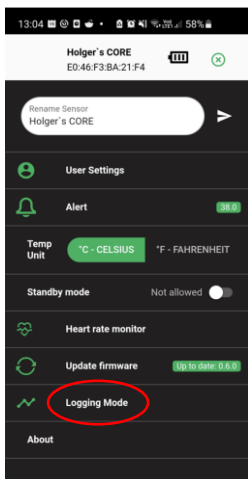
- Charge CORE
- Turn on CORE by shaking
- Start Scan
- Select CORE and connect to app

Since FW 0.4.1 your CORE account must own the device or access must have been shared with you before you can access the research functionalities. You will see this by a [owned] or [shared] behind the CORE name.



#### STEP 2 Settings menu

- Open settings menu



#### STEP 3 Logging mode

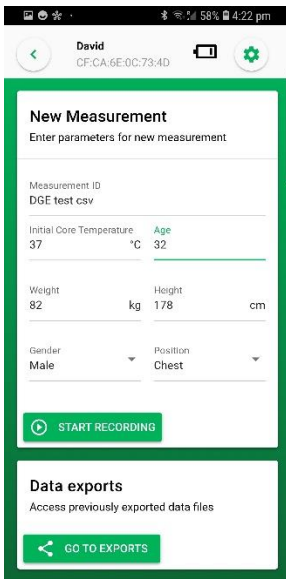
- Press "Logging Mode"

This button will only be available when you have bought CALERAresearch or research functionality.

Your CORE account must own the device or the device must have been shared with your account.

Note: Internet connection is required for logging mode

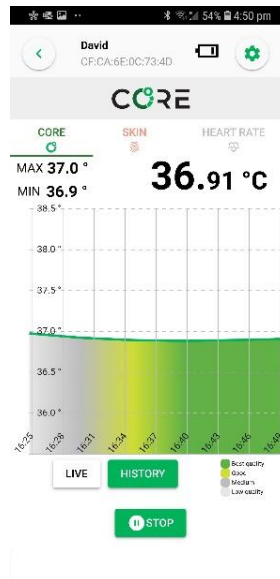




**STEP 4 Start Measurement**

- ➔ Fill in measurement fields
- ➔ Next measurement will take the same values
- ➔ Press Start Recording

Note: You can also share your downloaded data from here



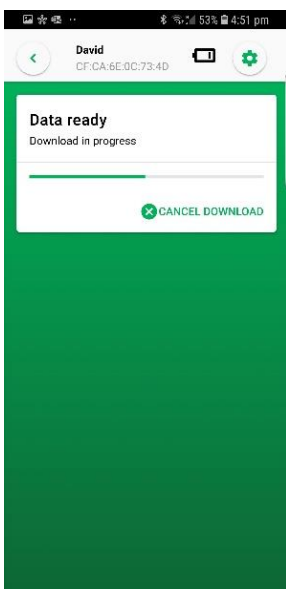
**STEP 5 Show Temperature**

- ➔ The measurement will start.
- ➔ You can now close the APP.

**STEP 6 End Measurement**

- ➔ Press stop

Note: CORE has a maximum local storage for 6,5 days of data. There will be no warning if this is exceeded and data will not be overwritten.

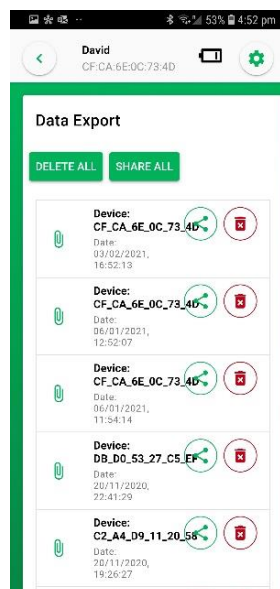


**STEP 7 Data Download**

- ➔ Tips & tricks for stable download
  - Install latest firmware
  - Use Android
  - Leave app on foreground
  - Close other apps
  - CORE & phone always need to be close, recommended to lay them down.

- ➔ **Warning:** Data download takes approximately 4 minutes per hour of data

Note: If you have multiple COREs, inquire us for our download dongle.



**STEP 8 Data export**

- ➔ Share your downloaded data

## Encryption levels

There are three encryption levels that give access to different raw-data streams. Encryption C is our standard encryption level for CALERAresearch. The device can also be used as a heat-flux sensor using encryption level B. Encryption level A gives full access, but this is rarely shared. Please contact us if you need A or B access.

	Time	Timestamps	Core Temperature	Skin Temperature	Heat-Flux	Heart rate	Accelerometer	Battery level
<i>Encryption A</i>	X	X	X	X	X	X	X	X
<i>Encryption B</i>	X	X		X	X	X	X	X
<i>Encryption C</i>	X	X	X	X		X	X	X

## Data export file

The generated CSV file is separated by a semicolon (;). The file contains a header section with 11 to 13 rows of metadata (can vary depending on firmware version) followed by the measurement data (see figure below).

**First save file as .XLSX if you want to work directly in this file, otherwise you will lose data.**

	A	B	C	D	E	F	G	H	I	J	K	L
1	ble_address=EA:7A:6B:6B:65:63											
2	device_id=2A:7A:6B:6B:65:63											
3	measurement_id=031											
4	core_temp=37000											
5	age=22											
6	weight=68											
7	height=179											
8	gender=0											
9	position=1											
10	permission_level=C											
11	firmware_version=0.8.0											
12	firmware_channel=A684C8A1											
13	S0=946	S1=946	T0off=-88	T1off=-88	nw=3600	nc=3600	IIR=3600	dTdt=10	IIRdT=100	acc=50	CBTOff=0	h=2350
14												
15	timestamp [us]	time [UTC-OFS=+0800]	hf_a0 [counts]	temp_a0 [mC]	status	hr	ax	ay	az	battery_voltage [mV]	cbt [mC]	
16	1680670000000000	05.04.2023 13:53	-1	24966	0	0	63	0	10	4180	0	
17	1680670000000000	05.04.2023 13:53	-1	24966	0	0	63	0	10	4180	0	
18	1680670000000000	05.04.2023 13:53	-1	24966	0	0	63	0	10	4170	0	
19	1680670000000000	05.04.2023 13:53	-1	24974	0	0	17	12	62	4170	0	
20	1680670000000000	05.04.2023 13:53	54	25114	0	0	-2	5	64	4170	0	
21	1680670000000000	05.04.2023 13:53	123	25288	0	0	7	14	65	4170	0	
22	1680670000000000	05.04.2023 13:53	115	25382	0	0	15	21	60	4170	0	
23	1680670000000000	05.04.2023 13:53	139	25546	0	0	49	11	37	4170	0	
24	1680670000000000	05.04.2023 13:53	172	25728	17	0	35	23	49	4170	37000	

### Measurement columns:

<b>timestamp [us]</b>	Timestamp in UNIX time in us (microseconds elapsed since January 1th 1970).
<b>time [UTC-OFS=+0100]</b>	Timestamp of the data point in the format 'DD:MM:YYYY hh:mm:ss'
<b>hf_a0</b>	Raw heat flux sensor signal in ADC counts (unitless).
<b>temp_a0 [mC]</b>	Uncorrected skin temperature signal in millidegree Celsius.
<b>status</b>	Debugging Information
<b>hr</b>	beats per minute (bpm) of the heart
<b>ax, ay, az</b>	X, Y and Z component of acceleration in counts. <i>Divide by 64 to get acceleration in G.</i>
<b>battery_voltage [mV]</b>	Coin cell voltage in millivolts. Can be used to estimate battery health.
<b>cbt [mC]</b>	Core body temperature estimation output in millidegrees.

### How to obtain heat flux and skin temperature:

**Heat Flux:** Multiply the raw heat flux sensor signal by 1.953125 uV to get raw sensor voltage. To obtain a heat flux value in W/m<sup>2</sup>, you additionally need to divide the sensor signal by its corresponding sensitivity. The sensitivity of each sensor is given in row 13 of the header section (S0 and S1) in the unit of nV/(W/m<sup>2</sup>)

$$\text{Heat flux sensor A voltage [in uV]} = \text{hf\_a0 [in counts]} * 1.953125 \text{ uV}$$

$$\text{Heat flux A [in W/m}^2\text{]} = \text{hf\_a0 [in counts]} * 1.953125 / (\text{S0}/1000)$$

**Skin temperature:** Remove sensor offset (T0off in row 13 of the header) and divide by 1000.




$$\text{Skin Temperature A [in }^\circ\text{C]} = (\text{temp\_a0 [in mC]} - \text{T0off}) / 1000$$

## 4. Products

Article Number	Description
A-166255	<p><b>COREresearch / CALERAresearch</b></p> <ul style="list-style-type: none"> <li>-Individually calibrated devices (highest accuracy)</li> <li>-Indefinite access to logging mode</li> </ul>
A-166251	<p><b>CORE</b></p> <ul style="list-style-type: none"> <li>-Consumer version w/o logging mode or individually calibration</li> <li>-upgrade available for logging mode</li> </ul>

## 5. Accessories

The latest updates can be found on our [webshop](#). The most important accessories are summed below.

Accessory	Description
	<p><b>CORE heart rate monitor</b></p> <p>For high physical activity, a heart rate monitor needs to be paired with CORE to ensure the best accuracy. The heart rate signal delivers crucial metrics that help CORE recognize fast changes in intensity (for example, a cyclist who reaches the summit and then descends).</p> <p>CORE can be paired to most existing (current generation) heart rate monitors.</p> <p>This is the CardioSport TP5 Heart Rate Monitor, which has proven to be a reliable and robust solution compatible with CORE.</p>
	<p><b>CORE chest strap</b></p> <p>For the most accurate core body temperature measurements, CORE is worn on the chest. The chest strap is a convenient and reusable solution for wearing the CORE discretely for an extended duration</p>
	<p><b>CORE arm strap</b></p> <p>Many people find the convenience of wearing CORE on the arm strap (compared to a chest strap) an acceptable trade-off.</p> <p>Please note, when CORE is worn on the arm, the accuracy of the core body temperature measurements is lower as the thermoregulation of the arm can differ from the torso/chest.</p>



### CORE adhesive patches (24 Pack)

Our specially designed medical-grade patches are a convenient way to wear your CORE.

These custom patches are explicitly produced for CORE using high-grade, medically certified materials. The patches are designed to minimize skin irritation.

The medical patches are suited for every-day use and can be used while sleeping. For active sports-use and excess movement, sweat, or water immersion, we recommend instead switching to a chest strap to ensure your CORE remains securely fitted.



### Six bay CORE charging station charging station

The CORE six-bay charging station is a convenient way to store and charge up to six CORE devices. Specifically designed for CORE, the charging station is simple and helps organise and charge multiple CORE devices.



### CORE charging cable

Replacement magnetic charging cable for CORE.

Charging a fully drained CORE takes about 2 hours and CORE will operate for 5 - 6 days on a single charge.

**Note**, it is recommended to use a powered USB port. As CORE draws a small current, portable power packs / battery packs may not activate when trying to charge CORE.



### WASP router for BLE & ANT+ devices

We offer a router solution able to monitor multiple CORE and other devices simultaneously inside your organization.

The WASP-N bridges Bluetooth® and/or ANT+ sensor data directly onto wireless networks using its integrated 802.11b/g/n radio.

- Monitor 50 ANT+ and BLE devices
- WIFI connection to your network
- Rechargeable battery and USB powered
- Range:10+ m

**Note**, we offer several router solutions, please contact us for more information

## 6. Clinically Validated Solution

The accuracy of the core body temperature solution from greenTEG has been validated through numerous independent clinical and case studies.

The algorithm has been tested on many candidates over the past several years with varying ages, weights, BMI, and under different activities including sports, sleeping and daily life. For the reference temperatures to validate accuracy, ingestible thermometer pills have been used with a duration of 24h to 72h.

The accuracy based on the conditions mentioned above is shown in Figure 2. It leads to a mean absolute deviation of 0.21 °C, a 95% limit of agreement of  $\pm 0.55$  °C and a correlation coefficient of 0.92. A comparative study between various thermometers over 200 patients concluded that the best non-invasive medical grade thermometer had a limit of agreement between  $-0.7$  and  $0.5$  °C. However, only when measured by a professional, at low activity and room temperature<sup>1</sup>. Figure 3 shows the measured temperature profile of a subject with an elevated body temperature. One can see that the predicted core body temperature follows the reference temperature closely.

### greenTEG AG @ A GLANCE

greenTEG is focused on delivering the highest quality thermal sensing solutions. Founded as a spin-off from ETH Zürich, greenTEG's expertise in thermal sensing solutions has been developed for more than 10 years through partnerships with our international customer base. greenTEG develops, manufactures and markets thermal sensor solutions for a growing customer base active in photonics, building physics, MedTech, automotive, processing industry, and R&D. CORE ventures is affiliated with greenTEG AG.



Figure 2: Bland-Altman plot showing the confidence interval for different core body temperature measurements of CORE compared to the ePill (Gold Standard)

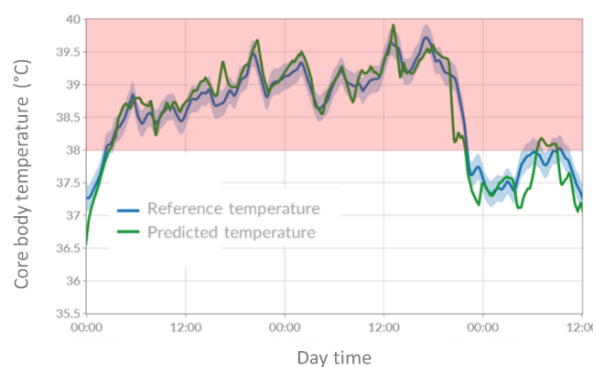


Figure 3: Core body temperature of a subject before and during a time of elevated body temperature. The blue curve representing the reference temperature measured with an ingestible temperature pill and the green curve is core body temperature measured with the CORE device.

## 7. Datasheet

<b>Product Name</b>	<b>CALERAresearch</b>
Article Number	A-166255
CALERAresearch	A rechargeable wearable device for continuous monitoring of Core Body Temperature
In the box	<b>CALERAresearch</b> Body Temperature Patch Set of medical-grade adhesive tapes USB charging cable Quick Start guide, warranty and manual
Connectivity	Smartphone Apps: Android & iOS Smartwatch Apps: Garmin ConnectIO, Apple WatchOS, soon Android WearOS Compatible with many existing third-party apps and devices
Automatically updateable to the latest technology	Over the air firmware updates enable CORE to automatically update to the latest and most accurate solutions available without having to upgrade hardware
<b>Technical Data</b>	
Outer casing	Made of durable skin-compatible polymer. Fully sealed with no moving parts
Compact Size	50mm x 40mm x 8.5mm Lightweight at only 17 grams
Power supply	Rechargeable lithium-polymer battery via magnetic USB cable
Battery life	Constant transmit time > 6 day Standby mode > 5 weeks
Internal memory	Record up to 6.5 days of high-resolution data
Data streams	Core & skin temperature, acceleration, timestamps, battery level , heat flux (under NDA), heart rate (from external device)
Communication Protocol	Standard BLE Health Thermometer profile Standard ANT+ Thermometer profile
Sampling rate	1 HZ
Skin temperature accuracy	±0.1°C
Core Body Temperature accuracy measured at chest	± 0.55°C (2σ); 0.21°C Mean Absolute Deviation
Calibration	Individually calibrated to ensure the highest performance
Water Rating	Waterproof up to 5ft
Product features	- Smartphone application (Android/iOS/WatchOS/Wear OS/Garmin) - Live display of current core body and skin temperature (via app) - Download of high-resolution data

## 8. Disclaimer

**Warning: CALERAresearch is not a medical device.**

It is not intended to diagnose, treat, cure, or prevent any disease or health condition. It does not have FDA or Medical CE approval. CALERAresearch should be used by healthy adults in a safe environment and is only meant to inform you about your overall wellbeing. No medical advice can be concluded from the measured temperature data, and it cannot replace the services of health care professionals. Deviations from the normal body temperature range should be investigated by a certified medical professional and no conclusion regarding your health can be drawn from a core temperature that is within the healthy range. Never disregard professional medical advice or delay in seeking it because of the temperature measurements by CALERAresearch. The use-case scenarios that are shown on any printed or digital material from CALERAresearch or greenTEG are only used to inform the public about our research topics. It does not prove the current application of CALERAresearch in these fields. If the CALERAresearch causes any redness or skin irritation, remove the product immediately. greenTEG is not responsible for any decisions, and potential subsequent incidents, you or someone that takes care of you might make, based on the measured core body temperature by CALERAresearch.

CALERAresearch received emergency use case authorisation (EUA) in October of 2020 to use the device as a clinical thermometer in the US during the Covid-19 crisis.

### **Battery Safety Instructions**

The following precautions are necessary to ensure safety when using and storing the CORE sensor:

- replacement of a battery with an incorrect type that can defeat a safeguard (for example, in the case of some lithium battery types);
- disposal of a battery into fire or a hot oven, or mechanically crushing or cutting of a battery, that can result in an explosion;
- leaving a battery in an extremely high temperature surrounding environment that can result in an explosion or the leakage of flammable liquid or gas; and
- a battery subjected to extremely low air pressure that may result in an explosion or the leakage of flammable liquid or gas.