



FOCUS GROUP

Instructions for Use

Trace-Temp1 Device and Trace-TempAI Mobile App

Device P/N: TSTA-0101

**T-SMART Pte Ltd
September 2021**



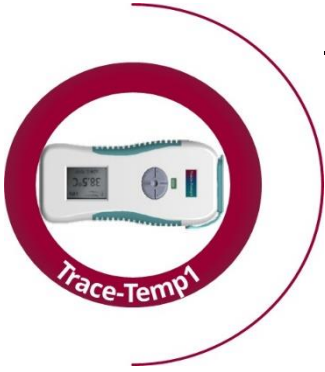


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1. PRODUCT DESCRIPTION

The **Trace-Temp1** is the first temperature monitoring device with Integrated Infrared Technology and Artificial Intelligence. Together with the Trace-TempAI app, they offer a complete set of tools that measure and monitor body temperature. Temperature measurements will now be more accurate, repeatable, and insightful.

2. INTENDED USE

Trace-Temp1 is a Non-Contact Infrared Device (NCID) that measures the body temperature when the device is set in measurement mode and the sensor head surface is pointed to the measured area at distance within 10 cm. It comes with the Trace-TempAI mobile app which is equipped with data analytics function used to analyze an individual user's temperature historical trend pattern.

Disclaimer:

- 1) The Trace-TempAI mobile app only provide a recommendation and are meant purely for informational purposes. This is not a substitute for medical advice, diagnosis, treatment, or professional care. If you have, or suspect to have a health problem, please consult a doctor or if you're facing a medical emergency, please call your local emergency services immediately, or visit the nearest emergency room or urgent care center.
- 2) This IFU (instruction for use) is written in accordance with the current available information and its content are subject to change without prior notice. T-SMART has made every effort to ensure the content of this IFU are accurate and reliable. T-SMART does not assume liability for any loss or damage caused by omissions, inaccuracies, or typographical errors in this IFU. When a software upgrade led to discrepancies in the IFU, the software shall take precedence.

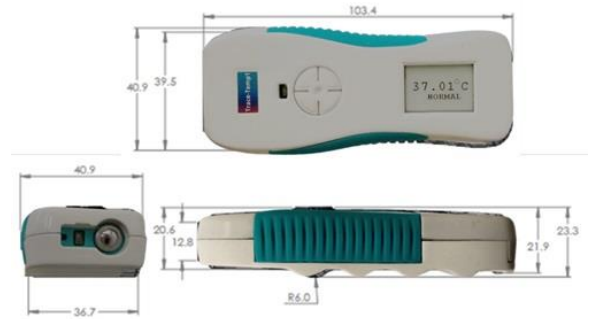


Figure 1: Trace-Temp1 Dimension

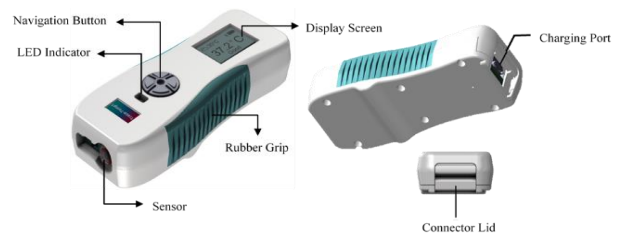


Figure 2: Parts of Trace-Temp1

3. WHY TRACE-TEMP1?

- 1) **Quick response rate of under 2s**
Once Trace-Temp1 device is within the optimal measurement zone and the LED indicator turns green, measurement of forehead temperature will be displayed within 2 seconds.
- 2) **Industry leading temperature accuracy and reliability**
Combining inputs from various sensors and T-SMART's proprietary AI technologies, Trace-Temp1 offer users industry leading accuracy.
- 3) **Smart infrared thermometer and A.I. powered mobile app**
Both Trace-Temp1 and Trace-TempA1 app use Artificial Intelligence to provide user with deeper health insights from daily temperature monitoring.
- 4) **Easy to handle and use**
Slim body with sleek curves. One's fingers and thumb can grip the device more naturally when holding the device, thus providing a firm yet comfortable grip and effective control over the device during each temperature measurement.

4. HOW THE TRACE-TEMP1 WORK?

- 1) Trace-Temp1 measures the surface temperature of an area in the forehead it is pointed at by sensing infrared emission of the skin. This temperature is then converted to oral equivalent core body temperature.
- 2) The heat radiation is collected from the skin to an infrared detector by a lens. The infrared detector voltage changes with the heat radiation. This change is amplified by a detection circuitry, measured data, and processed together with other additional sensor data be converted into the skin temperature, which then is converted to core body temperature.
- 3) Trace-Temp1 is an A.I. inspired non-contact, infrared temperature monitoring device.
- 4) Trace-Temp1 has a built-in sensor to ensure that the device is of optimal distance from the user (max 10 cm away) before taking the temperature. The temperature will be taken when the LED indicator turns green.
- 5) Together, Trace-Temp1 and Trace-TempAI app offer a complete set of tools that measures and monitors body temperature. Temperature measurements with Trace-Temp1 is accurate, repeatable, and insightful when used in accordance with its operating instruction manual.
- 6) Fever guidance features help you to better understand the meaning of your taken temperature with indications on the display.
- 7) Once the Trace-Temp1 device detected a FEVER, the Trace-TempAI will then notify you via email or push notification on your mobile app.

Reading	Temp. Measurement	Display	Recommendation
Normal	36.1 – 37.5 °C 96.9 – 99.5 °F	37.01 °C NORMAL	Acceptable
Fever	≥ 37.6 °C ≥ 99.7 °F	38.90 °C FEVER	Fever
Low	< 36.1 °C < 96.9 °F	34.45 °C LOW	Below Normal

Table 1: Display Reading

5. HOW TO USE TRACE-TEMP1 DEVICE?

Inside the Box:

- 1- Trace-Temp1 Device
- 1- USB charging Cable
- 1- Pouch
- 1- QR Code for
 - Downloading Trace-TempAI for Android mobile phone
 - Downloading Trace-TempAI for iPhone mobile phone
 - English version of IFU
 - Japanese version of IFU

Remove the Trace-Temp1 from the box and follow these steps.

1) Press center button to turn "ON" the device.

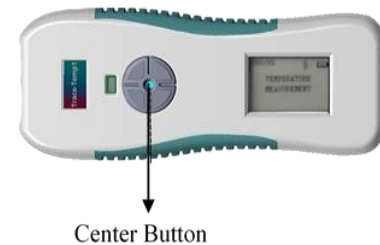


Figure 3: Trace-Temp1 center button

The Trace-Temp1 device is powered by rechargeable battery. Press the center button for at least three (3) seconds to turn ON the device. There will be a "Red" LED light before the display turns **ON**. There will be a greeting message which will fade after a second.

If the battery life has been depleted or shown insufficient amount of energy bar connect the device's charging port with a micro-USB cable and plug it to a power point or power bank for a minimum six (6) hours.

Note that insufficient battery charge may result to a higher temperature measurement reading. Make sure the battery is at least at **30%** when using the Trace-Temp1 device to ensure optimum temperature measurement readings.

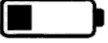
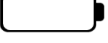
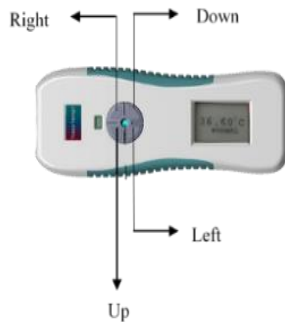
Display	Recommendation
	Plug in USB cable and charge the device for minimum 4 hrs to fully charge.
	Plug in USB cable and charge the device for minimum 6 hrs to fully charge.

Table 2: Battery Life Indication

Note: When charging the device, keep it “ON” to see if the battery indication is fully charge.

2) Changing the temperature scale

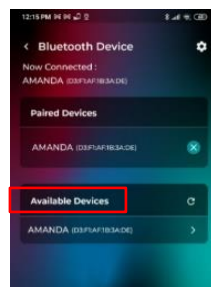
- 1) In the Trace-Temp1 device, press the “center” button for one second to go to “Settings” screen.
- 2) Press the “Down” button to go into temperature screen.
- 3) Press the “Up” or “Down” button to select unit of temperature (°C or °F).
- 4) Press the “Center” to go into temperature scale selection.



At this point, you can opt to use the Trace-Temp1 without the app as a standalone device.

3) Device Bluetooth Setting and Pairing

Go to Trace-TempAI “Setting” under “Bluetooth Device” search for the available device a.k.a. AMANDA to pair with the Trace-TempAI mobile app. Once connected the screen will automatically goes to “Live Data” page.

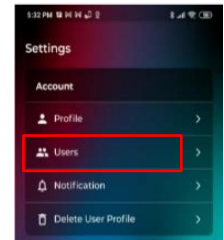


4) Setting Admin (Name) Profile in Trace-Temp1 device welcome screen

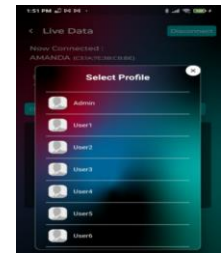


Figure 4: Trace-Temp1 welcome screen

Go the Trace-TempAI mobile app “Setting” create an Admin user profile in “User Page”.



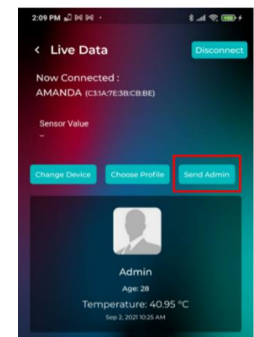
In “Live Data” page choose a profile (select the Admin User Profile), stay on this page while setting the admin profile in Trace-Temp1 device



Turn “ON” the Trace-Temp1 device by pressing the center button once, wait for the light to turn “Blue” then short press the center button again. Wait for the light to turn “Red” and the screen display will show “Setting”.



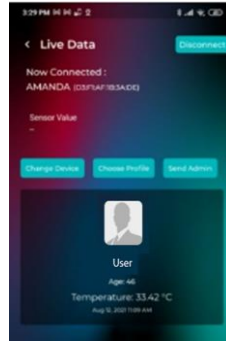
In the Trace-TempAI app “Live Data” page, press the “Send Admin” tab. And once the screen show “Completed” short press the center button on the Trace-Temp1 device.



Reset the Trace-Temp1 device and you’re ready to make the temperature measurement

5) Sending Temperature Measurement Data to Trace-TempAI app

In Trace-TempAI **“Setting”** go to the **“Live Data”** page and choose a profile name.



It is important that you stay in the **“Live Data”** page for the App to capture and push the temperature measurement data from the Trace-Temp1 to the Trace-TempAI mobile app.

See the Trace-Temp1, If the LED light turns **“Blue”** start the measurement by pointing the sensor to the head temperature measurement location within 10 cm in distance. Then press either **“Right”** or **“Up”** button to push the data to the Trace-TempAI app.



Note:

- a) If the temperature measure value is not successfully push to the Trace-Temp1 app, change the by pressing the **“Change Device”** button on the **“Live Data”** page and connect again with the same AMANDA MAC-ID.
- b) Once you take the temperature, the **“Right”** or **“Up”** button must be pressed within six (6) seconds to push the temperature measured value in the Trace-TempAI app.
- c) You cannot view the **“Live Data”** page unless the Trace-Temp1 device and the Trace-TempAI mobile app is paired and connected.
- d) The Trace-Temp1 LED will turn **“Blue”** if there is no object within range and the LED will turn **“Green”** if it's taking the measurements.

6) Measuring the Body Temperature

If there is no object in front of the sensor within 10 cm, the display screen will show **“Distance Out of Range”** and the LED indicator will turn **“Blue”**. Point the sensor to the head temperature measurement location and wait until the LED turns **“Green”**. The display will show the measured temperature for six (6) seconds.

After the measured temperature is displayed for six seconds, the device will check again if any object is within 10 cm from the sensor. If yes, the device will repeat the temperature measurement cycle again.

Note if **“down”** button is pressed before the six seconds display time is up, the device will immediately repeat the temperature measurement cycle gain. If no object is found for three (3) minutes, the Trace-Temp1 device will automatically turn off.

Head Temperature Measurement Locations

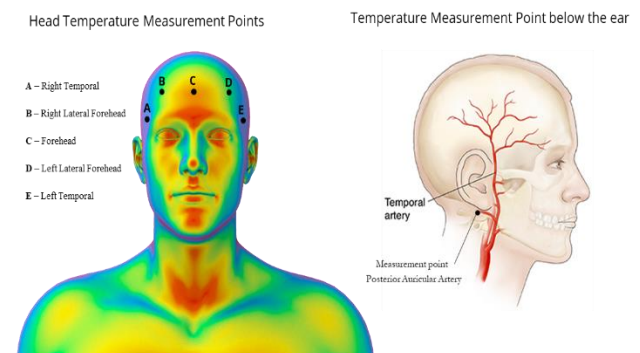


Figure 5: Head Temperature points

Note: Ideal temperature measuring points is at the temporal or the Posterior Auricular Artery since it presents an isothermic surface, as various small arteries passing close to the surface create 'hot-spots'.

6. WARNINGS AND PRECAUTIONS

- a) Ensure to observe proper hygiene and cleanliness when using the device. If you are sharing the device, ensure to wash your hands before and after you use it.
- b) Regularly clean the device.
- c) Never use the thermometer for purposes other than that it is intended for. Please follow the general safety precautions when using with children.
- d) Never immerse the thermometer into water or other liquids (not waterproof). For cleaning and disinfecting please follow the instructions "Care and Cleaning" section.
- e) Do not store this thermometer in extreme temperatures below -20 °C or over 60 °C (below -4

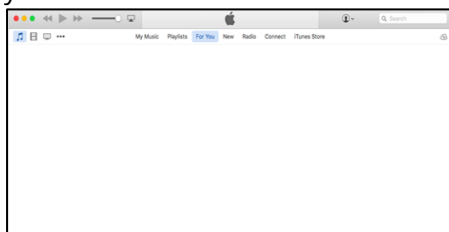
- °F or over 140 °F) or in excessive humidity (above 75% non-condensing relative humidity).
- f) Avoid direct sunlight on the display screen for a long time.
- g) If thermometer is stored in a location that is cooler or warmer than where it is being used, let it sit in the user's room for 10 minutes before taking the measurement.
- h) This thermometer is not intended for pre-term babies or small-for-gestational age babies.
- i) This thermometer is not intended to interpret hypothermic temperatures.
- j) Do not allow children to take their temperatures unattended.
- k) Even in the absence of fever, those who exhibit a normal temperature may still need to receive medical attention. People who are on antibiotics, analgesics, or antipyretics should not be assessed solely on temperature readings to determine the severity of their illness.
- l) Do not modify the device without the authorization of the manufacturer.

7. THE TRACE-TEMPAI MOBILE APP

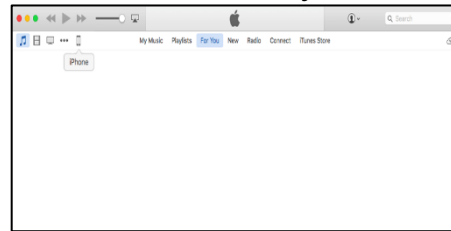
For Focus Group:

- 1) The Trace-TempAI is best suited for use in Android 8, 9, 10 and 11 version. Other than these android versions the Trace-TempAI app might not work to its full features.
- 2) iOS user, need to submit the UDID of their device.
 - A) How to find the Unique Device Identifier (UDID) on the iPhone

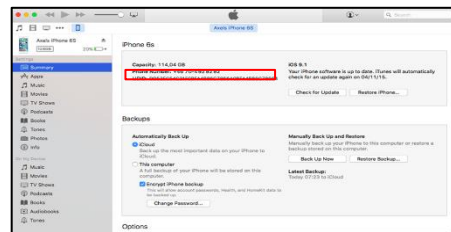
- 1. Launch iTunes on your PC or Mac & connect your iPhone.



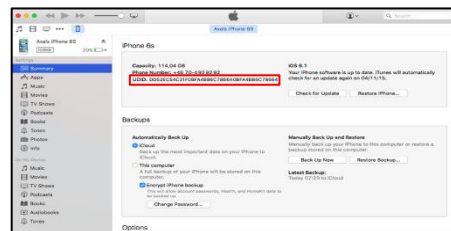
- 2. Under Devices, click on your device.



- 3. Next click on the 'Serial Number'.



- 4. This should change the Serial Number into the UDID



- 5. Right click to 'Edit' and then 'Copy'
- 6. Paste into your Email, and you should see the UDID in your email message.
- 7. Send your email to tracetemp@tsmartsystems.com
- 8. Wait for the confirmation email and the download link of the iOS version.

Alternatively, you can see the link for the instruction on How to find the Unique Device Identifier (UDID) on the iPhone: <https://www.itexico.com/blog/find-unique-device-identifier-udid-on-the-iphone>

- 3) Scan the QR Code to download the Trace-TempAI Mobile App and other useful information



Landing Page



After the installation of the Trace-TempAI app the screen will be directed to the landing page

Create your account.

You will be asked for an **"OTP"** to verify your account via email.

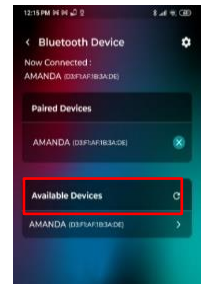


Sign Up Page



Create an account using your email address or Google account

Go to Trace-TempAI **"Setting"** under "Bluetooth Device" search for the available device a.k.a. AMANDA to pair with the Trace-TempAI mobile app. Once connected the screen will automatically goes to **"Live Data"** page.

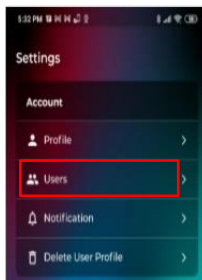


Sign In Page



Sign in using your email address or Google account

In the Trace-TempAI mobile app **"Setting"** under the **"Users"** page create a user profile(s).



Up to 50 user profiles can be created.

Home Page



The home screen will show the Insight of your body temperature measurements and the latest news and updates

2) Historical Measurement Data

Go to Historical Measurement page



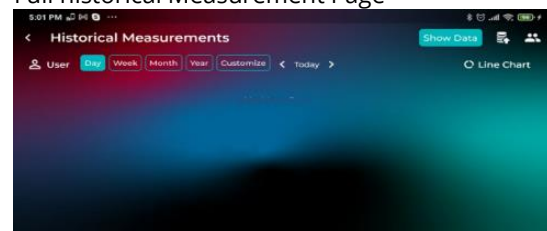
8. HOW TO USE TRACE-TEMPAI APP?

1) Set-up the Trace-Temp1 device and Trace-TempAI App

Tap the Trace-TempAI app icon on your mobile phone screen to launch the application



Full historical Measurement Page



Select a user



To select multiple users, press the **“Group”** tab then select the “Users” you want to include.



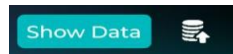
Choose the period to show the historical data or customized by choosing the start date and end date of the data to be displayed



Choose the type of chart to display the graph of the data selected.



To see the historical data in table format, press the **“Show Data”** tab

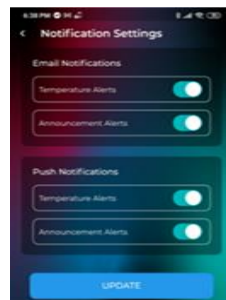


To export your temperature measurement data, press the “Export Data” tab.



3) Set Notification Alert

Go to “Setting” and press **“Notification”** page to set your notification preference via email notification or push notification or both.



Whenever there is a “Fever” reading in the Trace-Temp1 there will be a “Fever Alert” notification in your mobile app and your email depend on your notification preference.

9. GUIDELINES FOR TEMPERATURE MEASUREMENTS

- The thermometer and the user should be in the same ambient temperature for at least 10 minutes.
- Aim the NCID sensor head to the target forehead. Always hold the thermometer steadily at the forehead when taking a reading. A stabilized green

color shows the temperature is taken. Don't take a measurement while or immediately after nursing a baby.

- Do not immediately use the device to measure when you just moved from one environment temperature to another. Allow 10 to 30 minutes to let the device temperature be adjusted to the ambient.
- Users should not drink, eat, or be physically active before or while taking the measurement.
- Before taking a measurement, remove any head covering, dirt or hair from the forehead area. Wait 10 minutes after cleaning before taking measurement.
- Always take the temperature exactly as directed. Temperature results may vary if positioned in the wrong location.
- In the following situations, it is recommended that three temperatures in the same location be taken and the highest one taken as the reading:
 - Children under three years of age with a compromised immune system and for whom the presence or absence of fever is critical.
 - When the user is learning how to use the thermometer for the first time until he/she has familiarized himself/herself with the instrument and obtains consistent readings.

General rules in Temperature Measurement

- Wipe any sweat with a dry cloth before temperature measurement.
- Avoid any cooling or warming cloths on the forehead for at least 30 minutes prior to measurement.
- Do not take temperature measurements over skin with scar tissue, open sores, or abrasions.
- Keep the measurement sensor and lens clean. Avoid touching the sensor or lens directly.

Care and Cleaning of the Trace-Temp1 Device

- Use an alcohol or cotton swab moistened with alcohol (70% isopropyl) to clean the thermometer casing.
- Ensure that no liquid enters the interior of the thermometer. Never use abrasive cleaning agents,

or thinners for cleaning and never immerse the instrument in water or other cleaning liquids. Wait for 10 minutes after cleaning before taking a temperature measurement.

- c) Never insert a sharp object into the scanner area or any open surface on the thermometer.

10. UNDERSTANDING HEALTH AND WELLNESS

In most adults, an oral or axillary temperature above 37.6°C (99.7°F) or a rectal or ear temperature above 38.1°C (100.6°F) is considered a fever. A child has a fever when his or her rectal temperature is higher than 38°C (100.4°F) or armpit (axillary) temperature is higher than 37.5°C (99.5°F). Infants less than 3 months old with a rectal temperature of 38°C (100.4°F) or higher or an armpit (axillary) temperature of 37.5°C (99.5°F) or higher should be seen by a doctor.

A fever may occur as a reaction to:

- **Infection.** This is the most common cause of a fever. Infections may affect the whole body or one body part.
- **Medicines.** These include antibiotics, opioids, antihistamines, and many others. This is called a "drug fever." Medicines like antibiotics raise the body temperature directly. Other medicines keep the body from resetting its temperature when other things cause the temperature to rise.
- **Severe trauma or injury.** This may include heart attack, stroke, heatstroke, or burns.
- **Other medical conditions.** These include arthritis, hyperthyroidism, and even some cancers, such as leukemia and lung cancer.

Reference: <https://www.healthlinkbc.ca/medical-tests/hw198785>

Understanding the Body Temperature Baseline:

The normal body temperature for an adult is around 37°C (98.6°F), but every person's baseline body temperature is slightly different, and may consistently be a little higher or lower.

It is important to know an individual's baseline temperature when they are well. This is the only way to accurately diagnose a fever.

Essentially, a baseline calculates as an average taken when conditions are normal and not influenced by unusual events. Measure your body temperature 3x a day (Morning, Afternoon, Evening – same time every day) for one week (if you are well and not stressed).

11. PRODUCT SPECIFICATION

Operational Specifications	
Measuring Range	34.4 °C to 42.2 °C (94.0 to 108.0 °F)
Resolution	0.1 °C / °F
Accuracy	±0.2 °C (0.4 °F)
LED Indicator	Red Power On
	Blue Distance out of range
	Green Taking measurement
Measuring Distance	0 to 100 mm (0 to 3.94 inches)
Operating Temp.	15 °C to 40 °C (59 °F to 104 °F)
Measurement Time	Less than 2 seconds
Automatic Switch-off	After 3 minutes of inactivity

Features	
Type	Infrared Temperature Monitoring Device (Trace-Temp1)
Microprocessor	ARM® 32-bit Cortex® -M4-CPU
Connectivity	Bluetooth 5.2M LE for smartphones and tablets
Sensors	Thermopile detector with very low temperature coefficient of responsivity of 0.04% / °C
Display	2.6 cm (1.02-inches) display
Battery	200mAh Lithium-ion Polymer battery, USB-rechargeable
Weight	55 grams (0.12 lbs.)
Application Software	Temperature charting and data analysis for clinical fever monitoring. Normal and
Long Term Storage Specifications	
Storage temperature	-20 °C to 60 °C (-13 °F to 140 °F)
Humidity	≤ 75% RH

12. CONTACT US

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