

TEMP TRAQ®

User Manual

Model Number	TT-100	TT-200
Operating Time (hrs.)	24	48

⚠ Important: Read instructions carefully before use. High, prolonged fever requires medical attention. If symptoms persist, contact your healthcare provider.

Introduction to TempTraq

Welcome to TempTraq®, continuous temperature monitoring.

Intended Use

TempTraq® is a Bluetooth® continuous temperature monitor in the form of a one-time use, disposable patch. The patch senses, records and transmits body temperature via Bluetooth® Version 4.0. Temperature information from the patch is monitored using a smart device (Apple® or Android™ with Bluetooth® Version 4.0 capability running the TempTraq app). TempTraq measures under-the-arm "axillary" temperature which is displayed in the TempTraq app.

Indications for Use

The wireless thermometers are battery-operated electronic devices with intended use of measuring human body temperature precisely. These devices are single-use and intended for armpit temperature measurement for persons of all ages.

Warnings and Precautions

When using this product always follow these basic safety precautions to ensure that the patch accurately reads temperature and to avoid skin irritation. Failure to follow these precautions could result in inaccurate temperature readings resulting in delay in treatment, or could result in skin irritation and mild discomfort.

- ⚠ DO NOT** use the patch for any other purpose besides measuring human body temperature.
- ⚠ DO NOT** place the patch over wounds, sores or abrasions.
- ⚠ DO NOT** excessively bend or twist the TempTraq patch.
- ⚠ DO NOT** immerse the patch in water. Patch may be removed for a bath or shower and then re-applied afterwards.
- ⚠ DO NOT** use the patch if it has been damaged or immersed in water.
- ⚠ DO NOT** attempt to take apart the patch; there are no user serviceable parts.
- ⚠ DO NOT** wear TempTraq during an MRI scan. TempTraq has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of TempTraq in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- ⚠ DO NOT** wear TempTraq during an X-ray or CT scan. Wearing a TempTraq patch during an X-ray or CT scan may block visualization in the application area.

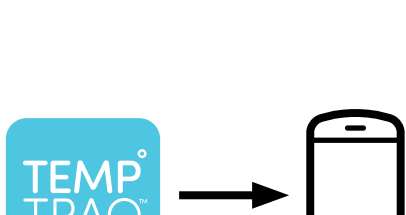
Patch adhesive may irritate sensitive skin or cause allergic reactions. Contact your doctor if irritation or allergic reactions persist.

For Best Results

- Clean and dry skin to remove deodorants or lotions, which can reduce adhesion of the patch.
- The sensor - marked "underarm" - must be positioned high and in the center of the armpit. Hold the arm at a 45° angle when applying the patch so that the center of the armpit is easy to identify.
- Wait 8 minutes for the patch to warm up to body temperature.
- Maintain the placement of your arm along the side of your body to ensure an accurate temperature reading. Temperature measurements can be affected by cold or hot ambient temperatures if the arm is not at the side.
- Communication from the patch to the smart device is possible up to a distance of 40 feet (12 meters) but may be affected by objects between the patch and smart device.
- Individuals with high BMI may inadvertently cover the patch antenna with their arm reducing the read range of the patch.
- For improved reception of temperature data from the patch, keep the phone awake, and try moving it closer to the patch.

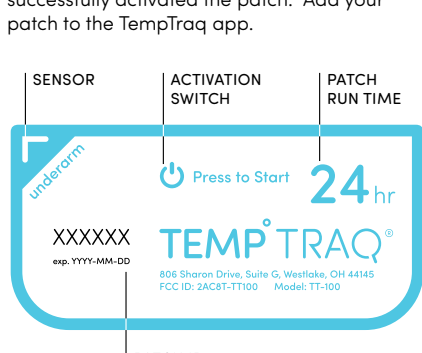
1. Download and Install App

The TempTraq app can be downloaded from the App Store™ or Google Play™ store.



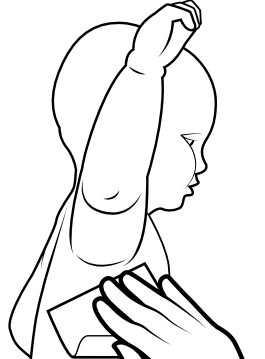
2. Activate Patch

Squeeze the (⏻) symbol between the thumb and forefingers to activate the patch. You will feel the switch "click" when you have successfully activated the patch. Add your patch to the TempTraq app.



3. Clean the Area

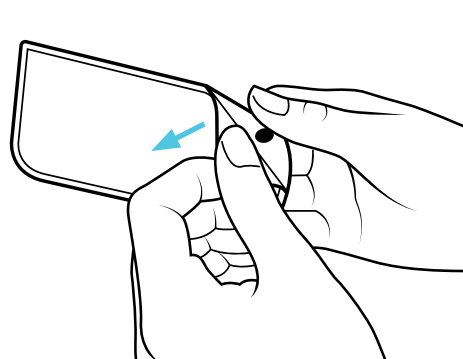
Clean and dry skin to remove deodorants or lotions.



Key for obtaining accurate temperature measurements

4. Remove Backing

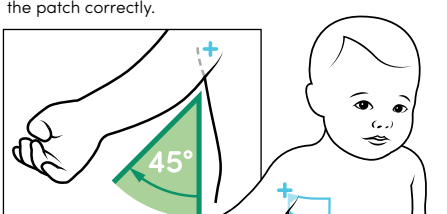
Remove the backing from the patch just prior to application.



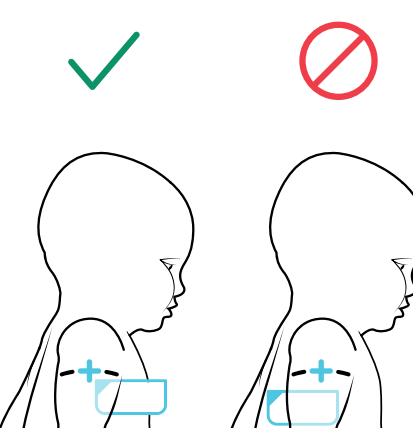
Key for obtaining accurate temperature measurements

5. Apply Patch

Apply the patch directly under the arm on either side of the body with the sensor - the corner marked "underarm" - high and in the center of the armpit (+). Hold the arm at a 45 degree angle away from the side when applying the patch so that the center of the armpit is easy to identify. If applied correctly the TempTraq logo will be in an upright position. Patch may be removed and re-applied if needed to position the patch correctly.



Key for obtaining accurate temperature measurements



TempTraq Temperature Measurement

TempTraq measures under-the-arm "axillary" temperature which is displayed in the TempTraq app.

Temperature Indications

The TempTraq app uses color coding to aid the user:

GREEN

indicates a temperature is in the normal range.

ORANGE

indicates a temperature of 100.4°F (38.0°C) or higher.

RED

indicates a temperature equal to or higher than the alert temperature that you selected.

A Guide to Understanding the Patch Detail Screen

Bluetooth Signal
Pulses blue when data is received from the patch.

Temperature Indications
The orange temperature is pre-set at 100.4°F as an indicator of high temperature. The red temperature indicates the user-selected temperature alert setting.

Temperature Scale
Shows graphically how close current temperature is to the orange and red temperature settings.

Temperature History
Displays a graph of the historical temperature data received from the patch.

Notes Button
Navigates to the Notes function to add or edit notes.

Last Updated
Last time that data was received from the patch.

Time Remaining
Shows how much runtime is remaining for the current active patch and continuously counts down as the patch runs.

Current Temperature
Displays the current temperature measured by the patch. Background color of the circle changes from green to orange at 100.4°F and from orange to red at the user selected temperature alert setting.

History Button
Navigates to the History screen to view historical temperature data received from the patch.

Troubleshooting Guide

Problem	Troubleshooting Hints
Patch ID is not visible in the Select Patch list when adding the patch	<ul style="list-style-type: none">Patch may not be activated. Press button on patch to activate.TempTraq only requires a single press of the "ON" switch to start operation. Avoid repeated pressing of the "ON" switch which may damage the circuit and cause TempTraq to fail.
App is showing "No temperature data received in last 60 minutes..."	<ul style="list-style-type: none">Move the smart device running the TempTraq app closer to the patch. The patch can send temperature data up to 40 feet (12 meters). This distance is reduced by walls and objects between the patch and the smart device.For improved reception of temperature data from the patch, keep the phone awake, and try moving it closer to the patch.
Temperatures from the patch are lower than expected	<ul style="list-style-type: none">Check to make sure that the patch is properly positioned with the sensor - marked "underarm" - correctly positioned in the armpit as shown in the instructions for use.Lower than expected temperature readings can also be caused by exposure to cold ambient temperatures, for example, when the arm is raised.Confirm the patch is correctly reading temperature by measuring axillary temperature with a digital thermometer.
Temperatures from the patch are higher than expected.	<ul style="list-style-type: none">Confirm the patch is correctly reading temperature by measuring axillary temperature with a digital thermometer.
No audible alert is received from the smart device when there is an alert.	<ul style="list-style-type: none">Check to ensure that the phone volume is set to an audible level and is not set to mute.Check settings for the app to ensure that notifications are enabled and sound is enabled for notifications.Note that the audible alert only sounds for a short period. The visual notification remains active in the app until canceled by the user.
No alert is received when temperature measured by the patch exceeds the user set alert level	<ul style="list-style-type: none">Check to make sure that the smart device running the app is in range of the patch. A temperature alert will not be generated if the smart device is not receiving data from the patch.Check to ensure that the app is running. No alerts will be generated if the app is not running.
App displays "Patch Error"	<ul style="list-style-type: none">Patch is not functioning correctly and needs to be replaced. Contact Customer Care at 1 (440) 249-5440 for return instructions.
App displays "Rapid temperature drop detected..."	<ul style="list-style-type: none">Can be caused by the arm being raised, exposing the patch to ambient temperatures. For best results the arm should be down and relaxed at the side. Dismiss this alert, or Disable to permanently silence this alert for this patch.

Specifications

Model Numbers (Patch Operating Life)	TT-100 (24 hrs.), TT-200 (48 hrs.)
Patch Dimensions	Length: 100.0 mm (3.94 in), Height: 50.0 mm (1.97 in), Thickness: 2.0 mm (0.08 in)
Patch Weight	5.1 grams (0.18 ounces)
Patch Environmental Conditions	
• Transport and Storage	-4 to 122 °F (-20 to 50 °C) / 15 - 95% RH (non-condensing)
• Use	61 to 104 °F (16 to 40 °C) / 15 - 95% RH (non-condensing)
Temperature Measurement Location	Axillary (under the arm) - TempTraq measures under-the-arm "axillary" temperature which is displayed in the TempTraq app.
Temperature Range	86.0 °F - 108.3 °F (30.0 °C - 42.4 °C). Axillary body temperature is typically 1 °F lower than oral temperature measurements. Temperatures below this range will be displayed in the app as "Lo". Temperatures above this range will be displayed in the app as "Hi".
Temperature Indications	Less than 100.4 °F (38.0 °C) - GREEN Equal to or greater than 100.4 °F (38.0 °C) - ORANGE Equal to or greater than the user defined alert temperature - RED
Accuracy	Conforms with ASTM E1112-00 (2011); +/- 0.1 °C or +/- 0.2 °F over the temperature range of the device
Display Resolution	0.1 °F (0.1 °C)
Response Time	Once applied to the underarm, the patch requires up to 8 minutes to reach a stable reading
Transmission Distance	Patch will transmit up to 40 feet (12 meters) when applied to the underarm
Compatible Smart Devices	Smartphones and tablets with Bluetooth® 4.0 running Apple® operating system iOS 8.0 or later or Android™ operating system 4.3 or later. Visit temptraq.com for a list of compatible devices.
Standards	ASTM E1112-00 (2011) standard for electronic thermometers IEC 60601-1 Medical Design Standards, 3rd Edition IEC 60601-1-2 Electromagnetic Compatibility Bluetooth® Version 4.0
Radio Regulations	FCC Part 15 Industry Canada License exempt RSS standard(s) ISO/IEC 60601-1-2 Electromagnetic Compatibility CISPR 11 Group 1, Class B Radiated Emissions within 30 - 1,000 MHz
Water Ingress Protection	IP24 - Protected from damage due to water splashing on the product.

This thermometer conforms to all requirements established in ASTM standard E1112-00. Full responsibility for conformance of this product to the specification is assumed by Blue Spark Technologies, Inc., 806 Sharon Drive, Suite G, Westlake, Ohio 44145

1. (Geneva II, Cuzzo B, Fazili T, Javaid W. Normal Body Temperature: A Systematic Review. Open Forum Infect Dis. 2019 Apr 9;6(4):ofz032. doi: 10.1093/ofid/ofz032. PMID: 30976605; PMCID: PMC6456186.)

TempTraq Connect

TempTraq Connect enables you to invite anyone anywhere in the world to view temperature data from a patch that you are monitoring on your smart device.

- Sign into TempTraq Connect within the TempTraq app.
- Select the patch that you wish to share.
- From the Patch Detail screen select the TempTraq Connect cloud icon.
- Enter the e-mail address for the user that you wish to share the patch with.

- The TempTraq Connect screen for that patch will show who you have shared the patch with. You can share the patch with multiple Connect users, and you can add and delete users from this list.

When someone invites you to view a patch using TempTraq Connect you may view the data available for that patch.

- Sign into Connect within the TempTraq app to view a patch that has been shared with you.
- Patch Name, Current Temperature, Temperature History, Temperature Alert Setting, and Notes will be available to view, but cannot be changed.
- When viewing a shared patch, no alerts are generated on your device for that patch. Alerts only occur on the device that is within 40 ft. of the patch and that is receiving data from the patch via Bluetooth 4.0.
- You may delete the patch from the Patch List screen.
- If you log out of Connect, shared patches will no longer be visible on your phone.

TempTraq Connect Troubleshooting Guide

Problem	Troubleshooting Hints
Unable to access Connect within the app	<ul style="list-style-type: none">• User must be logged into Connect to access features of Connect. Select "Log In" in the Hamburger menu to log into Connect.
Unable to view a shared patch	<ul style="list-style-type: none">• Check to ensure that the latest version of the app is installed on the device• Check to ensure that you are logged into Connect on your phone
Unable to change the "Temperature Alert" setting or "Name" when viewing a shared patch	<ul style="list-style-type: none">• Only the user monitoring the patch locally and sharing the patch can change the "Alert Temperature" or "Name"
Not receiving alerts when viewing a shared patch	<ul style="list-style-type: none">• Only the user monitoring the patch locally and sharing the patch will receive alerts on their phone
A shared patch is no longer visible in the app	<ul style="list-style-type: none">• Check with the person who shared the patch to ensure that they are still sharing the patch with you• Check to ensure that you are still logged into Connect
No longer receiving temperature data updates for a shared patch. App displays "No temperature data received in last 60 minutes..."	<ul style="list-style-type: none">• The person that shared the patch may no longer be receiving updates from the patch. This could occur if they are too far from the patch or have closed the TempTraq app.• Check to ensure that your phone is connected to the internet via cellular or WiFi

Additional User Information



IMPORTANT: Read instructions carefully before use.



Type BF Applied Part

User should contact Blue Spark Technologies, Inc. for assistance in using TempTraq when needed, or to report unexpected operation or events.

⚠ WARNING: No modification of this equipment is allowed.

⚠ WARNING: Do not modify this equipment without authorization of the manufacturer.

⚠ WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

Performance of this device may be degraded should one or more of the following occur:

- Operation outside of the manufacturer's stated temperature and humidity range
- Storage outside of the manufacturer's stated temperature and humidity range
- Mechanical shock

The device or its components are not intended to be serviced, replaced, or repaired. Device is powered by a 3V non-rechargeable battery. Not intended to be recharged, serviced, replaced, or repaired.

The device is single use only. Do not reuse.

May be safely applied to self or used on others.

May be discarded in common household waste.

Warranty

TempTraq warrants each new TempTraq patch against defects in materials or workmanship until the expiration date of the product, and agrees to replace any defective product without charge.

IMPORTANT:

This warranty does not cover damage resulting from accident, misuse or abuse, or lack of reasonable care. No responsibility is assumed for any special, incidental or consequential damages. To obtain warranty replacement, simply call TempTraq Customer Care at 1 (440) 249-5440 for return instructions, or email info@temptraq.com.

NOTE:

No other warranty, written or verbal is authorized by TempTraq. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.

Cyber Security Recommendations

TempTraq applications provide security by design. Released TempTraq applications on the iOS App Store or Google Play Store are not able to be modified.

Follow these tips to safeguard your TempTraq device and prevent unauthorized access and usage:

- TempTraq Connect users should register their accounts with a trusted email and complex password. Long and complex passcodes are always recommended, as they are harder to guess or attack.
- TempTraq Connect users should only share their temperature data with trusted subscribers. When inviting subscribers to your Share List, confirm you enter the valid email belonging to the intended subscriber.
- Logging out of TempTraq Connect will delete your data from the TempTraq Connect Consumer cloud server and any subscriber's devices.
- Do not leave your connected smart device unattended when idle.
- Use passcodes for locking your connected smart device to prevent unauthorized access.
- Use the most recent versions of iOS and Android to ensure use of the most up to date security controls.

If you detect a cybersecurity incident affecting a TempTraq device or suspect one may have occurred, please immediately notify Blue Spark. Common examples of cybersecurity incidents include, but are not limited to, lost, stolen, or tampered with TempTraq devices.

FCC Statement and Legal Notices

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions (1) this device may not cause harmful interference, and (2) this device must accept any interference received including interference that may cause undesired operation.

FCC WARNING: any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment under FCC regulations.

NOTE: this equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

P/N: TT-100-201 Rev 5

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Protected by U.S. Patent Nos. 8,029,927; 8,268,475; 8,722,235. Other foreign patents pending.

Need More?

VISIT TEMPTRAQ.COM

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EMAIL info@temptraq.com

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