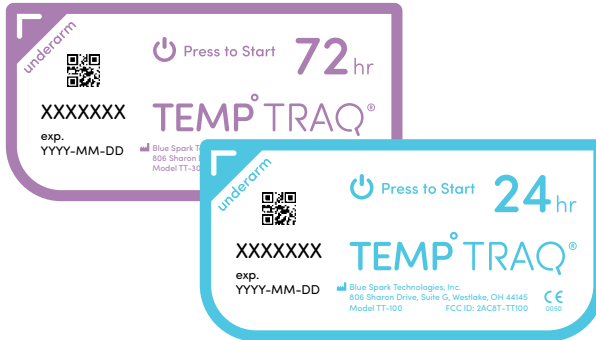


TEMP° TRAQ®

US Clinical User Manual



Model Number	TT-100	TT-300
Operating Time (hrs.)	24	72



Important: Read instructions carefully before use.

Introduction to TempTraq

Welcome to TempTraq®, continuous temperature monitoring.

Device Description

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 – US





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.

TempTraq Temperature Measurement

TempTraq measures under-the-arm “axillary” temperature.

Temperature Indications

The TempTraq app uses color coding to aid the user:

	Indicates a temperature at or below the low temperature limit.
	Indicates a temperature below 38.0 °C (100.4 °F) (Default).
	Indicates a temperature of 38.0 °C (100.4 °F) (Default) or higher.
	Indicates a temperature equal to or higher than the alert temperature selected for that patient.

TempTraq Clinician Web Application

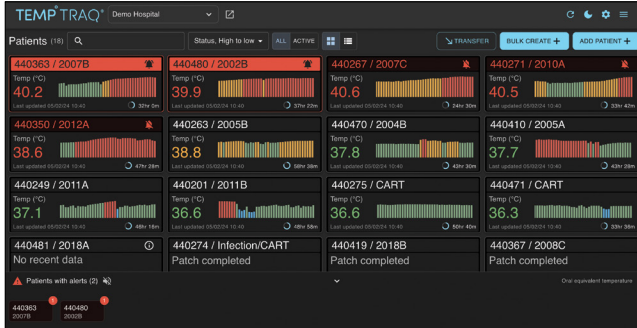
The application enables you to view all patients currently in your account. Each patient file shown below in the Patients screen provides the status of a patient. Select the file for that patient to navigate to the Patients screen (shown below) for additional information, including all of the patches currently assigned to that patient.

Application link: <https://clinician.temptraq.com> using Chrome, Firefox or Safari.

Login using your email address and password provided by Blue Spark.

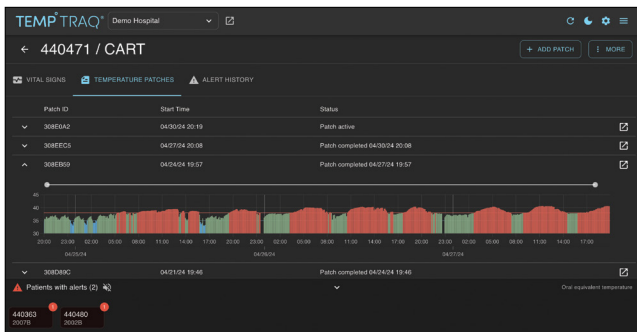
Adding a New Patient – Select “+ Add Patient” in the Patients Screen.

Patients Screen



Adding a New Patch – Select “+ Add Patch” in the Patient Detail Screen shown below. Patch ID may be added using a bar code.

Patient Detail Screen



Additional information available at <https://temptraq.healthcare/resources>.

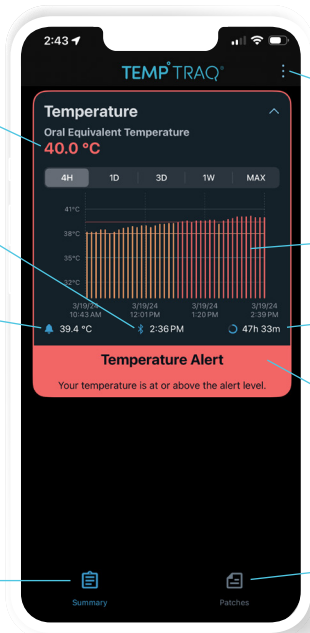
TempTraq Patient Application

Current Temperature: last temperature reported from the TempTraq patch

Bluetooth: time of the last Bluetooth transmission from the patch

Alert Temperature: alert temperature set by the clinician

Summary: main page of application showing most recent temperature information



Menu: access to Account, Demographics, Settings, For Best Results, Instructions and Website

Temperature History: graph of the last 4 hours of temperature data

Time Remaining: time remaining on the current TempTraq patch

Alerts and Status Messages: alerts and status information for the user related to temperature

Patches: listing of all TempTraq patches assigned to the user with access to historical data

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 should 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. 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 wearing 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.



CAUTION: The patch does not alert for hypothermia (commonly, a temperature of $< 36^{\circ}\text{C}/96.8^{\circ}\text{F}$).



WARNING: TempTraq (Models TT-100, TT-300) should not be used adjacent to, or stacked with, other equipment.



WARNING: TempTraq (Models TT-100, TT-300) may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.



CAUTION: Measurement error may occur if the device is not used in appropriate operating conditions.

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

Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information contained within this manual.

Specifications

Model Numbers (Patch Operating Life)	TT-100 (24 hrs.), TT-300 (72 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 <ul style="list-style-type: none"> • Transport and Storage • Use 	-20 to 50 °C (-4 to 122 °F) / 15 - 95% RH (non-condensing) 16 to 40 °C (61 to 104 °F) / 15 - 95% RH (non-condensing)
Temperature Measurement Location	Axillary (under the arm) - TempTraq measures under-the-arm "axillary" temperature. Axillary body temperature is typically 0.6 °C (1 °F) lower than oral temperature measurements. ¹
Temperature Range	30.6 °C - 42.9 °C (87.0 °F - 109.3 °F). 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 or equal to low temperature threshold - BLUE Less than 38.0 °C (100.4 °F) (Default) - GREEN Equal to or greater than 38.0 °C (100.4 °F) (Default) - 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 °C (0.1 °F)
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 12 meters (40 feet) when applied to the underarm.
Compatible Smart Devices	Smartphones or tablets with Bluetooth® 4.0 running Apple® or Android™ operating systems released in the last three years.
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 ISO 80601-2-56 Medical electrical equipment Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
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.

Patch Application

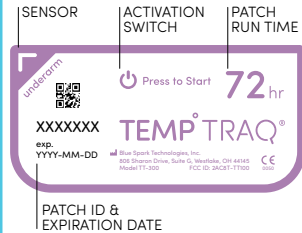
1. Clean the Area



Key for obtaining accurate temperature measurements

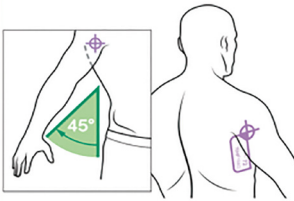
Clean and dry the underarm skin to remove deodorants, lotions, or any skin application which can make the patch less sticky.

2. Activate Patch

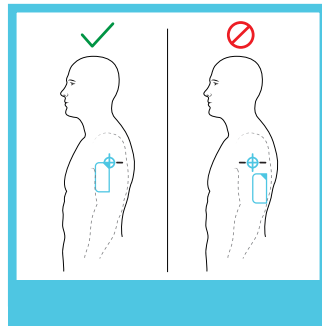


Squeeze the “Press to Start” symbol between the thumb and forefinger to activate the patch. You will feel the switch “click” when you have successfully activated the patch. Remove the backing from the patch just prior to application.

3. Apply Patch



Key for obtaining accurate temperature measurements



The sensor - marked “underarm” - must be placed high and in the center of the armpit. Hold the arm out from the body at a 45° angle to find the center of the armpit. The patch will be more comfortable and stay in place better if placed vertically, as shown.










For Best Results









- Clean and dry the underarm skin to remove deodorants, lotions, or any skin application which can make the patch less sticky.
- The sensor - marked "underarm" - must be placed high and in the center of the armpit. Hold the arm out from the body at a 45° angle to find the center of the armpit. The patch will be more comfortable and stay in place better if placed vertically, as shown.
- Wait 8 minutes for the patch to warm up to body temperature. While your arm is comfortably at your side the TempTraq patch will deliver correct temperatures. Temperature measurements can change in cold or hot room temperatures if the arm is not at your side.
- The device collecting temperature data from the TempTraq patch (Bluetooth gateway or mobile phone running the Patient Application) needs to be within 40 feet (12 meters) of the TempTraq patch to receive temperatures. The smart device may need to be kept at a closer distance if there are objects between the patch and the smart device.
- Individuals with large arms may accidentally cover the patch antenna requiring the smart device to be kept at a closer distance.
- If you are not receiving temperatures from the patch on the smart device, move the smart device running the TempTraq app closer to the patch and keep the TempTraq app visible on the smart device screen.
- **Please remove** TempTraq before bathing or showering and replace afterwards.
- **Please remove** the TempTraq patch before CT Scan, MRI, X-Ray or Radiation Therapy. Replace the TempTraq patch after the procedure.

Troubleshooting Guide

Problem	Troubleshooting Hints
Temperatures from the patch are lower than expected	<p>Check to make sure that the patch is properly positioned with the sensor – marked “underarm” – correctly positioned in the axilla as shown in the Patch Application section.</p> <p>Lower than expected temperature readings can also be caused by exposure to cold ambient temperatures, for example, when the arm is raised.</p>
Patient or Clinician Application displays a “Replace Patch” alert	<p>Patch is not functioning correctly and needs to be replaced. Contact Customer Care for replacement. The Customer Care phone number is provided on the back of this User Manual.</p>
Patient or Clinician Application displays a “No Recent Data” alert	<p>No current temperature data has been received from the patch for the last 15 minutes. Patient needs to try moving the smart device running the Patient Application closer to the patch.</p>
Patient or Clinician Application displays “Check Network Connectivity”	<p>Indicates loss of network connectivity. Check network connectivity for the smart device.</p>
Patient Application displays “Rapid Temperature Drop” alert	<p>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.</p>
Patch moves after being applied to the patient	<p>If the patch moves after being applied consider using an approved adhesive to secure the patch. (Tegaderm or medical tape)</p>

Symbol Definition


	Manufacturer
	Lot
	CE MARKING OF CONFORMITY
	REF
	Do Not Re-Use
	Do Not Use if Package is Damaged
	Caution
	Read Instructions Carefully Before Use
	Type BF Applied Part

	Consult Instructions for Use
	Authorized Representative in the European Community
	Temperature Limits
	Humidity Limits
	Use By Date
	Unique Device Identifier
	Medical Device
	EESS: Electrical Equipment Safety System

Additional User Information

IMPORTANT: Read instructions carefully before use.

 Type BF Applied Part

 Consult Instructions for Use

The TempTraq device is not sterile

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.

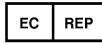
Not intended to be recharged, serviced, replaced, or repaired.

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.

 Blue Spark Technologies, Inc.
806 Sharon Drive, Suite G
Westlake, OH 44145, USA



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



Declarations

This TempTraq product has been tested to comply with the requirements of IEC 60601-1- 2 for electromagnetic compatibility (EMC).

The material that contacts the skin has been tested to meet bio compatibility requirements per ISO 10993.

Declaration Tables

Guidance and manufacturer's declaration – electromagnetic emissions

TempTraq (Models: TT-100, TT-300) are intended for use in the electromagnetic environment specified below. The customer or the user of TempTraq (Models: TT-100, TT-300) should assure that they are used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions (CISPR 11)	Group 1	TempTraq (Models: TT-100, TT-300) use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class B	TempTraq (Models: TT-100, TT-300) are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000- 3-2)	Not applicable	
Voltage fluctuations/ flicker emissions (IEC 61000-3-3)	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity


TempTraq (Models: TT-100, TT-300) are intended for use in the electromagnetic environment specified below. The customer or the user of TempTraq (Models: TT-100, TT-300) should assure that they are used in such an environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst (IEC 61000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of TempTraq (Models: TT-100, TT-300) requires continued operation during power mains interruptions, it is recommended that TempTraq (Models: TT-100, TT-300) be powered from an uninterruptible power supply or a battery. NOTE: UT is the a.c. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Notes: TempTraq (Models: TT-100, TT-300) are battery powered

Guidance and manufacturer's declaration – electromagnetic immunity

TempTraq (Models: TT-100, TT-300) are intended for use in the electromagnetic environment specified below. The customer or the user of TempTraq (Models: TT-100, TT-300) should assure that they are used in such an environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment – Guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of TempTraq (Models: TT-100, TT-300) including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p>
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz	Not Applicable	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \text{ 800 MHz to 2.5 GHz}$
			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range. (b)</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which TempTraq (Model TT-100) is used exceeds the applicable RF compliance level above, TempTraq (Model TT-100) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating TempTraq (Model TT-100).

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and TempTraq

TempTraq (Models: TT-100, TT-300) are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of TempTraq (Models: TT-100, TT-300) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and TempTraq (Models: TT-100, TT-300) as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz outside ISM bands $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.1167	0.1167	0.2333
0.1	0.3689	0.3689	0.7379
1	1.1667	1.1667	2.3333
10	3.6893	3.6893	7.3786
100	11.6667	11.6667	23.3333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Mobile RF communications equipment can effect medical electrical equipment; please ensure adequate separation distance from RF equipment.

FCC Statement and Legal Notices

Compliance limited to USA. 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.

Cyber Security Recommendations

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

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

- When creating login credentials for a patient, clinicians should consider creating accounts using de-identified Patient IDs and complex passwords.
- Clinicians should only utilize the optional second patient ID to facilitate better patient recognition. Misuse of the second patient ID may introduce unnecessary cybersecurity risks.
- Do not leave your connected smart device or computer unattended when idle.
- Use complex passcodes and/or passwords to lock your connected smart device or computer to prevent unauthorized access.
- Avoid connection of unauthorized external devices to computers that run the TempTraq Clinician Web Application.
- Follow hospital security policies related to computing devices session timeouts.
- 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.

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 which replacement is the exclusive remedy for any breach of warranty.

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 the number listed on the back of this User Manual for return instructions, or email info@temptraq.com.

NOTE:

NO OTHER WARRANTY, WRITTEN OR VERBAL IS AUTHORIZED BY TEMPTRAQ AND ALL OTHER WARRANTIES ARE EXPRESSLY DISCLAIMED. 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.

Need More?

Visit temptraq.com
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P/N: TT-100-296-ENG Rev 4

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Patent: www.temptraq.com/patents