DeRoyal®

TEMPLE TOUCH PRO™ (TTP™)

Non-Invasive Core Temperature Monitoring System

USER MANUAL

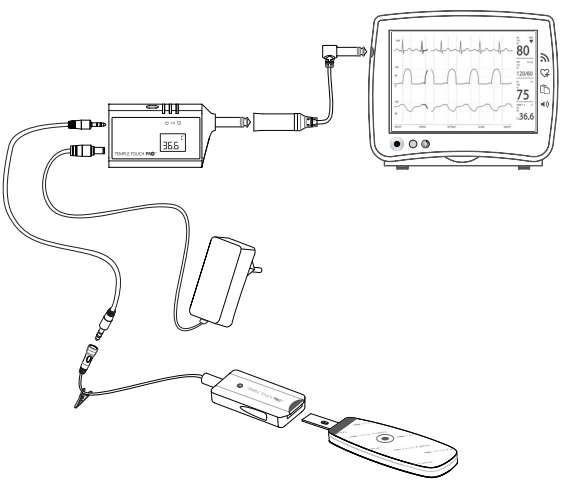


Table of Contents

Abbreviations Dictionary

Abbreviation	Full Term
TTP™	Temple Touch Pro™
MCU	Monitor Connecting Unit
SCU	Sensor Connecting Unit
SU	Sensor Unit
VSM	Vital Signs Monitor

1 .Temple Touch Pro™ (TTP™) Introduction

The purpose of this document is to describe the proper way to setup, use and maintain the Temple Touch Pro™ (TTP™) system.

The TTP™ system and the manual are intended to be used by healthcare professionals in medical care environments only. Prior to installing or using the TTP™ system, read and follow all instructions, labeling and accompanying documents supplied with the TTP™ system. Failure to follow instructions could lead to misuse of the device, device malfunction or patient injury.

2. Intended Use of the TTP™

The TTP™ is intended to measure and monitor core body temperature of patients of all ages, by applying an SU on the temple.

3. Warning and Safety Notices

WARNINGS:

1. The TTP™ system shall be attached to other equipment only by authorized personnel.
2. Do not use the TTP™ system if one or more of its components appear to be damaged, broken, cracked, burned, torn, etc.
3. Do not attempt to repair or modify any of the TTP™ system components.
4. For safe use, use ONLY original TTP™ system components and accessories. Use only the original TTP™ MCU and power supply specified and supplied for this product and certified for the country of use.

5. The TTP™ MCU must be connected to the applied part connector of a safety approved medical grade vital signs monitor (VSM). The connection shall be made to the VSM input for applied part which is marked as CF applied part.

6. Keep power supply visible and accessible at all times. The power outlet shall be easily accessible. To disconnect the TTP™ system from mains (power line): Disconnect the power supply from the wall outlet.

7. Use only a properly grounded power outlet; do not use extension cables or multiple portable socket outlets.

8. Do not allow the power supply to get wet.

9. Do not use the TTP™ system in the presence of a flammable anesthetic mixture or nitrous oxide.

10. Do not use any of the TTP™ system components in an MRI environment.

11. Do not allow the patient to lie on the TTP™ SCU.

12. Always position cables and wires away from the patient's body.

13. Do not use an exterior device to secure the TTP™ SU to the patient.

14. Limit use of the TTP™ SU to 24 hours in order to reduce the risk of skin irritations.

15. In cases of intentional hyperthermia or hypothermia therapy use a different thermometer to measure body temperature.

16. Whenever you doubt the temperature reading provided by TTP™ system, confirm temperature reading with a separate thermometer.
17. When disposing the TTP SU, follow facilities policies and procedures for disposal of contaminated materials.
18. Perform decontamination procedures prior to reusing the TTP™ system's reusable parts (MCU, SCU, extension cable, monitor extension cable and power supply) and prior to disposal.
19. Do not leave pediatric patients unattended while using the TTP™ system.
20. 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.

CAUTIONS:

1. Do not use the TTP™ SU on damaged / irritated skin.
2. Clean the TTP™ SCU before connecting to a new TTP™ SU.
3. Do not reattach the TTP™ SU as it might weaken the adhesive, damage the TTP™ SU, or compromise the TTP™ system performance.
4. Follow applicable regulations when disposing of this device and any of its electronic components.

NOTICES:

1. The TTP™ system meets medical electronic interference requirements. If radio frequency interference occurs, connect the TTP™ system to a different power source.
2. Do not store any of the TTP™ system components in a wet or damp place.
3. Do not spray, immerse or use abrasive cleaners or solvents to clean the TTP™ system. Do not subject the TTP™ system components to any sterilization process.
4. The TTP™ SU is not made with natural latex material.
5. The manufacturer declines any form of responsibility and liability as an outcome of improper setup, operation or storage or unqualified modifications or repairs.


Follow instructions for use


Defibrillation-proof type CF


Single use only


Keep dry


Class II equipment if powered with Mean Well's AC/DC adaptor GSMO6E12-1PJ or equivalent

4. Temple Touch Pro™ - System Description

The TTP™ system continuously monitors the patient's core body temperature. The TTP™ system contains the following components: a Sensor Unit (SU), which is connected to a Sensor Connecting Unit (SCU) which is connected to the Monitor Connecting Unit (MCU). The Monitor Connecting Unit (MCU) is connected to a power supply and to the Vital Signs Monitor (VSM).

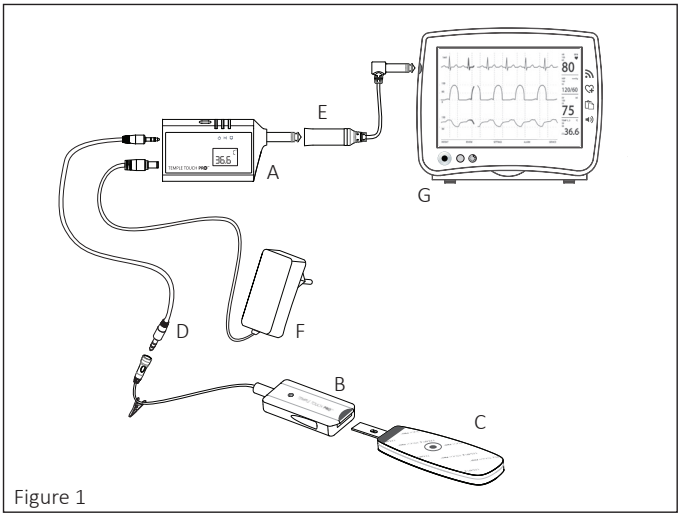


Figure 1

A. MCU
B. SCU
C. SU
D. Extension cable
E. Monitor extension cable
F. Power supply
G. VSM

The TTP™ Sensor Unit (SU)

The SU is a non-sterile, disposable sensing unit which is placed on the patient's temple from the initial stages of medical care (such as surgery preparation), and may be affixed to the patient's temple until it is no longer required to monitor the patient's core temperature (such as - upon discharge from PACU).

The SU is comprised of a temperature sensor module, a bio compatible adhesive layer, with two isolation layers in between.

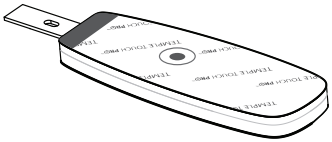


Figure 2

The TTP™ Sensor Connecting Unit (SCU)

The SCU is a cable with connector suitable to connect the SU to the SCU.
The SU is connected to the SCU as shown below:

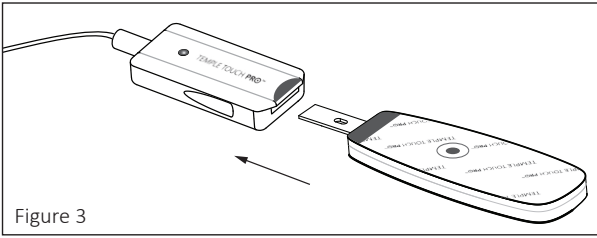


Figure 3

The TTP™ Monitor Connecting Unit (MCU)

The MCU receives data from the SU through the SCU and transmits the information related to the patient's core temperature to the VSM. The MCU is connected to the power supply via Inlet B.

The TTP™ system is designed to display operation feedback through the MCU LEDs and the SCU LED located on the SCU.

Figure 4

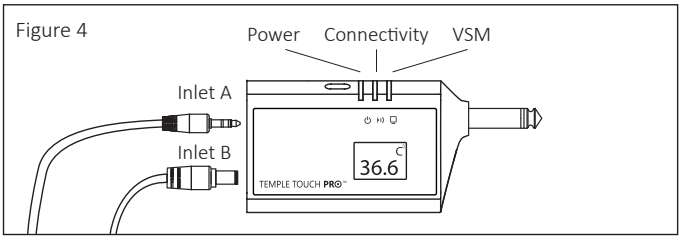


Table A.1 - LED Indication Description:

LED name	Symbol	Color	Functionality	Location
POWER		Yellow	Turns ON when the MCU is properly connected to a power supply.	MCU
CONNECTIVITY		Green	Blinks when the MCU is properly connected to the SCU.	MCU
VSM		Green	Turns ON when the MCU is properly connected to the VSM and fully functioning.	MCU
SCU		Green	Turns ON when the SU is properly connected to the SCU.	SCU

5. How does Temple Touch Pro™ work

Core temperature is defined as the temperature of the blood flow in the pulmonary artery. Under known parameters one can utilize Temporal Artery blood flow characteristics to derive the core temperature.

The SU is attached to the skin above the Temporal Artery and measures heat flux and the skin temperature above the Temporal Artery. The MCU acquires the data from the SU and accurately calculates the patient's core temperature.

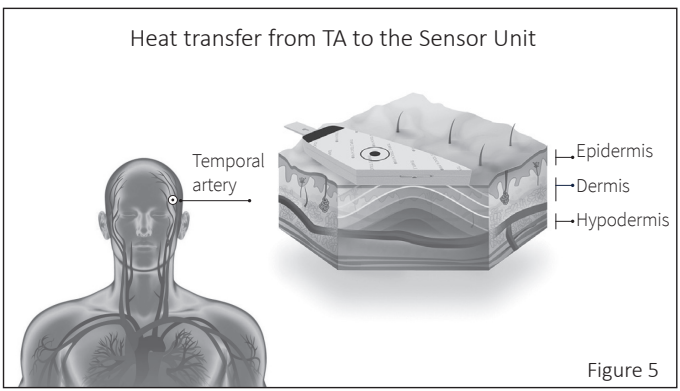


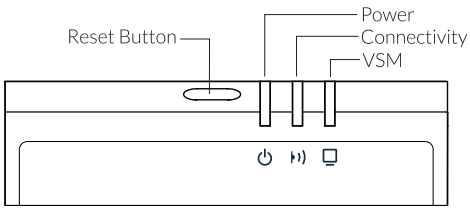
Figure 5

6. Setting up Temple Touch Pro™

Note!
Setup of the TTP system shall follow the sequence below:

1. Make sure the VSM is turned on and fully operative according to the instructions provided by the VSM manufacturer.
2. Connect the power supply to the MCU's power supply inlet. (Display MCU all segments will appear for 2 seconds).
3. Connect the MCU to the VSM.
4. Restart the MCU by pressing and holding the RESET button for 3 seconds in the following cases:

- After placing the SU on the patient for the first time (Refer to section 7: "Instruction for Use").
- If the SU was separated from the patient's skin at any point after the initial placement.
- After any component of the TTP System (MCU/SCU/SU) was disconnected from a running TTP setup.
- If any abnormal outcome is displayed on the Vital Signs Monitor.



7. Instructions for Use

1. Ensure the MCU is connected to the VSM and to the Power Supply (see section 6 above).
2. Ensure the patient's temple is intact and use an alcohol wipe to clean and disinfect the patient's temple. Allow the temple to completely dry (at least 2 minutes).

Note: The temple is located between the end of the hairline and the eyebrow.

Figure 6

3. Connect the SU to the SCU.

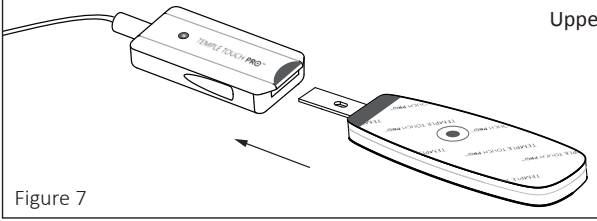


Figure 7

4. Peel the liner off the SU to expose the adhesive (The figure shows the bottom part of the SU).

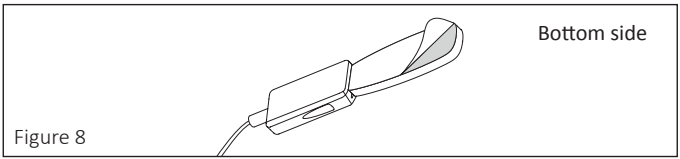


Figure 8

5. Place the center of the SU on the patient's temple. Gently press the surrounding edge of the SU to ensure good adhesion to the skin.


Figure 9

Limit use of the SU to 24 hours in order to reduce the risk of skin irritations.

6. Connect the SCU to the MCU. The CONNECTIVITY LED will start blinking, indicating the MCU communication activity. At the same time, the SCU LED will turn on and stay on constantly. The VSM will display temperature within less than 3 minutes.

7. Support the SCU cable with the provided clip. Make sure the SCU cable is placed loosely next to the patient to ensure the SU is kept in place properly during the medical procedures.

8. In normal system activity, the LEDs operation will occur as described in table A.1 (LED Indication description): Should you notice a different LED feedback, please refer to section 8: Troubleshooting.

How to transfer a patient connected to the TTP™ system?

In order to transfer a patient from one location to another:

1. Disconnect the SCU from the extension cable. Make sure the SCU is secured on the patient's gown and that the SU remains in place, on the patient's temple properly connected to the SCU.
2. When the patient arrives at the next point of care, ensure the MCU at the new location is already connected to the VSM and to a power supply. Reconnect the SCU to the new MCU. Then restart the MCU.
3. The VSM will display the patient's temperature. Make sure to follow steps 1-6 in this chapter (instruction for use) to ensure good temperature monitoring after patient transfer.

How to remove the SU from the patient?

When core body temperature monitoring is no longer required, take the following steps:

1. Disconnect the SCU from the SU. Then remove the SU from the patient by carefully pulling the tab on the edge of the SU. Use an alcohol swab if needed.
2. Dispose the SU safely. Follow applicable disposal regulations.

Shutting down the MCU

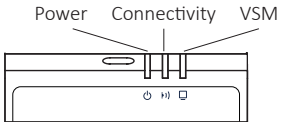
In general, there is no need to power off the TTP™ System as it can stay connected to the VSM at all times. To shut down the TTP™ system, disconnect the AC Power supply from Inlet B of the MCU.

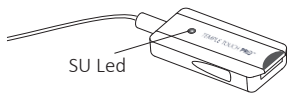
Switch temperature scale on MCU

MCU can display temperature measurements in either Celsius or Fahrenheit. To switch scales (Celsius to Fahrenheit and vice versa) press and release the RESET button.

8. Troubleshooting - Errors

The TTP™ system is designed to display system related feedback warnings through its LEDs array, please refer to table A.1. For LED indications at normal functionality.





When an error occurs, the following indication warnings will appear:

Error Indication	Possible Cause	Instructions
POWER LED ⏻ is OFF	The MCU is not powered properly.	1. Ensure the power supply is properly connected to a wall outlet, and that the power supply is properly connected to the MCU. 2. If POWER LED is still OFF, replace power supply. Refer to IFU section 3.3 - warning and safety notices. 3. If POWER LED is still OFF, replace MCU. 4. If POWER LED is still OFF, contact service.
Connectivity LED is OFF VSM LED ▭ is OFF ERR4 message on LCD	The connection between the SCU and the MCU is lost.	1. Ensure the SCU is properly connected to the MCU. 2. If CONNECTIVITY LED is still OFF, replace SCU. 3. If CONNECTIVITY LED is still OFF, replace MCU. 4. If CONNECTIVITY LED is still OFF, contact service.

Error Indication	Possible Cause	Instructions
SCU LED is blinking VSM LED is OFF ERR3 message on LCD	The SU is not properly connected or damaged or the SCU is damaged.	1. Ensure the SU is properly connected to the SCU. 2. If SCU LED is still blinking, replace SU. 3. If SCU LED is still blinking, replace SCU. 4. If SCU LED is still blinking, contact service.
VSM LED is constantly OFF ERR5 message on LCD	The MCU's ambient temperature reading exceeds the specified range (15°C - 40°C).	1. Ensure that the ambient temperature is within the specified range. 2. Assure that the MCU is not located near extreme temperature heat source. 3. Press and hold the RESET button for 3 seconds. Then wait 10 seconds. 4. If VSM LED is still off, replace MCU. 5. If VSM LED is still off, contact service.
VSM LED is constantly OFF ERR1 message on LCD	There is a problem with the MCU's ambient sensor.	1. Replace MCU. 2. If VSM LED is still off, contact service.
The VSM reads 25°C or 45°C ERR6 message on LCD	The measured temperature is outside of the specified measuring range. POSSIBILITY OF EXTREME AND DANGEROUS PATIENT TEMPERATURE	1. Ensure that the SU is properly attached to the temple. 2. Check ambient conditions around the patient, as well as patients warming or cooling system. 3. Wait 3 minutes and check again the LEDs on MCU and the VSM reading.

9. Care and Maintenance

CAUTION:

- Do not expose the TTP™ system to extreme temperatures, humidity, direct sunlight or shock.
- Keep the TTP™ system away from hot or boiling water and chemicals.
- Do not spray cleaning solutions onto any of the TTP™ components. The system is NOT water resistant.
- Do not immerse or use wet fabric on any of the system's components as moisture might damage the electrical components and lead to incorrect temperature measurements.

Cleaning the MCU and SCU

Clean the MCU on an as-needed basis or per facility policies and procedures for cleaning electronic equipment.

1. Disconnect MCU from power outlet and from the SCU. Disconnect the MCU from the VSM.
2. Use a slightly damp soft fabric moistened with a mild, nonabrasive cleaning solution to clean the device surface and cables. Avoid spillover of fluids into the system's parts.
3. Dry with a soft fabric.

Disinfecting the SCU

1. Clean the SCU between each use.
2. Wipe down the SCU using a damp soft fabric and 70% isopropyl alcohol. Avoid spillover of fluids into the system's parts.
3. Dry with a soft fabric.

Storage

Notice: Do not store the TTP™ system components in a wet or damp place as it might damage the electrical components.

Store all TTP™ components at room temperature and in a dry place when not in use.

Functionality Check

Once Every 2 years, use the TTP Functionality Check kit.

Functionality check instructions will be provided in the kit.

If the check fails contact service.

10. Specifications

	Sensor Unit
Type\model number	Temple Touch Pro™ (TTP™)
Major components	Sensor Unit, Sensor Connecting unit, Monitor Connecting Unit
Dimensions: WXLXH	(1.8X6.4X0.42)cm
Weight	1.08g
Shelf Life	2 years
Adhesive layer	Biocompatible Adhesive tape (medical graded)
Measurement location	Temple area of the forehead
Monitor extension cable length	N/A
SCU cable length	N/A
MCU extension cable length	N/A
MCU to VSM connection	N/A
MCU Power Supply	N/A
Accuracy	Complies with ASTM E 1112-00 & EN 12470-4 requirements: 25°C to 45°C ± 0.2°C (77°F to 113°F ± 0.4°F)
Recommended functionality check for system	Every 2 years

Sensor Connecting Unit	Monitor Connecting Unit
Temple Touch Pro™ (TTP™)	Temple Touch Pro™ (TTP™)
Sensor Unit, Sensor Connecting unit, Monitor Connecting Unit	Sensor Unit, Sensor Connecting unit, Monitor Connecting Unit
(1.8X3.85X0.72)cm	(10.93X4.24X2.14)cm
7.5g	44.4g
3 years	3 years
N/A	N/A
N/A	N/A
N/A	40cm
14.96 inch / 38cm	N/A
N/A	2.4m
N/A	YSI 400 compatible.
N/A	Power rating 5VDC, 170mA
Complies with ASTM E 1112-00 & EN 12470-4 requirements: 25°C to 45°C ± 0.2°C (77°F to 113°F ± 0.4°F)	Complies with ASTM E 1112-00 & EN 12470-4 requirements: 25°C to 45°C ± 0.2°C (77°F to 113°F ± 0.4°F)
Every 2 years	Every 2 years

	Sensor Unit
External power supply	90-260 VAC, 47~63Hz. Output 5V DC 36W. The unit shall be used with dedicated medical grade AC/DC adapter. The system shall be classified as Class II when used with Mean Well's GSM36U05-1PJ.
Time response	180 seconds
Measuring range	25°C to 45°C (77°F to 113°F)
Unit of measurement	Celsius, Fahrenheit
Immunity to Defibrillation	The SU considered as type CF defibrillation proof applied part
Ambient temperature range	15°C to 40°C (59°F to 104°F)
Operating humidity	30% to 75% RH, non-condensing
Storage and transport temperature range	-25°C to 55°C (-13°F to 131°F) Store all TTP™ components at room temperature and in a dry place when not in use.

Sensor Connecting Unit	Monitor Connecting Unit
90-260 VAC, 47~63Hz. Output 5V DC 36W. The unit shall be used with dedicated medical grade AC/DC adapter. The system shall be classified as Class II when used with Mean Well's GSM36U05-1PJ.	90-260 VAC, 47~63Hz. Output 5V DC 36W. The unit shall be used with dedicated medical grade AC/DC adapter. The system shall be classified as Class II when used with Mean Well's GSM36U05-1PJ.
180 seconds	180 seconds
25°C to 45°C (77°F to 113°F)	25°C to 45°C (77°F to 113°F)
Celsius, Fahrenheit	Celsius, Fahrenheit
The SU considered as type CF defibrillation proof applied part	The SU considered as type CF defibrillation proof applied part
15°C to 40°C (59°F to 104°F)	15°C to 40°C (59°F to 104°F)
30% to 75% RH, non-condensing	30% to 75% RH, non-condensing
-25°C to 55°C (-13°F to 131°F) Store all TTP™ components at room temperature and in a dry place when not in use.	-25°C to 55°C (-13°F to 131°F) Store all TTP™ components at room temperature and in a dry place when not in use.

Classification

Medical - general medical equipment as to electrical shock, fire and mechanical hazards in accordance with IEC 60601-1; CAN / CSA-C22.2.

Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class II, Type CF, Defibrillation-Proof, Ordinary Equipment. Conforms to EN12470. Not suitable for use in the presence of flammable anesthetic mixtures with air or nitrous oxide.

Classified with respect to electric shock, fire, and mechanical hazards only, in accordance with IEC 60601-1, and Canadian/ CSA C22.2. No. 601.1. ANSI/AAMI ES 60601-1; 2005.

Classified under the Medical Device Directive as a Class II device.

11. Service and Warranty

Distributed by:
DeRoyal Industries, Inc.
200 DeBusk Ln.
Powell, TN 37849
888.938.7828
www.deroyal.com

Made in Israel

Warranty: 2 years from production date.

The FCC wants you to Know

This equipment has been tested and found to comply with the limits for a Class B digital device, according 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.

FCC ID: 2AK7V Product code: TTP-RFU-001
Distributed by: DeRoyal Industries, Inc.

- This device complies with Part 15 of the FCC Rules.
- Operation is subject to the following two conditions:
- This device may not cause harmful interference, and this device must accept any interference received, including interference that may cause undesired operation.
- Changes or modifications to this equipment not expressly approved by the party responsible for compliance (Medisim Ltd.) could void the user's authority to operate the equipment.
- This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.