

<This product is a medical device. >

**[Product name]**

THERMOCARE

**[Model name]**

MT-1000 / MT-3000 / MT-4000

**[Safety Sign]**

Symbols for safety signs are indicated and described on the product exterior, packaging, and in this manual.

Symbols provide users with important cautions, warnings, and prohibitions. You should carefully look at the symbols shown below and use this information for the use and storage of the product.



**Caution**

Caution

This safety sign stands for caution. This relates to problems with possible damage to the product or to patient harm.



**Warning**

Warning

This safety sign stands for a warning. This is related to the problem of possible damage or cause



Prohibition

irreversible damage to the product or the patient.

This safety sign means prohibition. This relates to problems with possible damage to the product or to patient harm.



Obligatory action

This safety sign means "Refer to the user manual."

\* Where deemed necessary, manufacturers are not obligated to make changes to the same specifications as products that have already been sold, with respect to improvements to improve the performance of their products.



**Warning**

1. Use a battery of the specified rating and size (1.5 V, AA size) and replace it correctly according to the + and - directions marked on the battery replacement section. Improper replacement may cause overheating of the battery or a risk of fire or explosion.
2. Other devices may malfunction due to the electromagnetic waves generated by this device, and this device may malfunction due to electromagnetic waves generated by other devices. Do not use adjacent to other devices or load other devices .
3. Do not use this product near equipment that emits RF energy, such as electric cautery or

electric surgery equipment. Body temperature may not be measured by RF energy or may result in inaccurate measurements.

**FCC Information**

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 notification to users**

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 when the equipment is operated in a commercial environment. 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, the user is encouraged to try to correct the interference by consulting with a dealer or an experienced technician for technical assistance.

Any Changes or modifications to the equipment not expressly approved by the party responsible for compliance could void user's authority to

operate the equipment.

**[Applicable standards and references]**

1. EN 60601-1:2013, IEC 60601-1:2012 Medical electrical equipment Part1: General requirements for basic safety and essential performance
2. EN 60601-1-2:2015, IEC 60601-1-2:2014 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
3. EN 60601-1-6:2010, IEC 60601-1-6:2010 Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance-Collateral Standard: Usability
4. IEC 60601-1-11:2015 Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
5. ISO 13485[2016], EN ISO 13485[2016] Medical devices-Quality management system-Requirements for regulatory purposes
6. EN 1041:2008 Information supplied by the manufacturer of medical devices
7. ISO 7010:2019 Graphical symbols–Safety colors and safety signs– Registered safety signs
8. EN ISO 15223-1:2016, ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

## 【Instructions for disposal】



1. When disposing of the device for reasons such as damage to the device, it must be disposed of in accordance with the standard disposal procedure for electrical and electronic products in the country.
2. Do not dispose of used batteries together with general household waste, but dispose of them in a designated place.

## 【Purpose of use】

Infrared skin thermometer is a device that measures body temperature by detecting the surface infrared emission of temporal arteries that is directly connected to the heart.

## 【Product Information】

### ◆ Name of each part

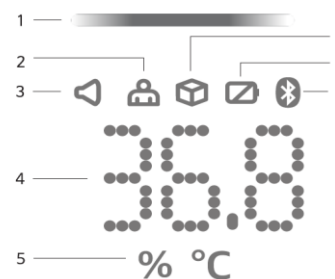


No.	Name	Description
1	Measurement	Displays the measured

	display	temperature, measurement mode and battery status
2	Measurement mode selection	It is used in case of selecting one out of 3 types of mode. 1) People, measurement sound ON 2) People, measurement sound OFF 3) Object, measurement sound ON In case the button is pressed for 3 seconds, it displays the surrounding temperature/humidity information. (After displaying the surrounding humidity for 3 seconds, it displays the surrounding temperature)
3	Power/Measure button	It turns the power ON or measures the temperature.
4	Bluetooth button	Turn the Bluetooth ON/OFF by pressing the button for 2 seconds. (* After Bluetooth connection, button can be pressed for a short period of time in Measurement mode to change the measurement member number.)
5	Temperature and humidity measuring sensor	Detects the temperature and humidity of the measurement environment.
6	Temperature measuring sensor	Detects the infrared rays emitted from the human body or object.
7	Battery	It contains 2 Alkaline AA

	batteries.
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### ◆ Screen description



No.	Name	Description
1	LED status display light	Different color is displayed depending on temperature measurement range.
2	Temperature measurement mode	Displays the temperature measurement mode.
3	Measurement sound display light	Indicates whether the sound has been turned ON/OFF.
4	Measured temperature	Displays the measured temperature. (* In the temperature measurement body after Bluetooth connection, the measurement member number that has been selected is displayed).
5	Unit display	In case the surrounding humidity is indicated, % is displayed and as for body temperature, object temperature and surrounding temperature, °C

		is displayed.
6	Object measurement mode	Displays the object measurement mode.
7	Battery warning light	In case there is less than 10% battery left, the warning light is displayed in red.
8	Bluetooth connection	It turns blue when Bluetooth is ON.

## 【Features】

Name	Description
Rated Voltage	DC 3V (1.5V AA-type * 2EA, 0.15A)
Display method	LED display (measurement sound)
Measurement Range	A. Body temperature : 22.0°C ~ 42.2°C B. Object temperature : 10.0°C ~ 70.0°C C. Humidity : 0%~100%
Accuracy	A. Body temperature: ±0.3°C (However, ±0.2°C in the range 36.0°C ~ 39.0°C) B. Object temperature : ± 2.0°C
Minimum scale unit	0.1 for temperature / 0.1 for humidity
Measurement time	Within 1 second
Memory capacity	1,000

## 【Power】

1. Insert 2 1.5V AA-type batteries into the

product.

2. Press the Power/Measure button to turn on the power.

### **[Measuring body temperature]**

1. Press the Mode setting button to select out of "People, measurement sound ON" / "People, measuring sound OFF" / "Object, measurement sound ON" for setting.
2. Place it at the measurement area (temporal artery) then press the Measure button.
3. The measured temperature can be checked in the measurement display and the high temperature/low temperature status is indicated in the LED display light.
4. When the body temperature is measured, the surrounding temperature and humidity are measured together and they can be checked in the Mobile App.
  - 1) Measurement range below 36.0°C: Orange light
  - 2) Measurement range of 36.0°C ~ 37.6°C: Green
  - 3) Measurement range of 37.6°C ~ 38.5°C: Orange
  - 4) Measurement range exceeding 38.5°C: Red

### **[Measuring object temperature]**

1. Press the Mode setting button to set as "Object, measurement sound ON".
2. After placing it at the object subject to measurement, press the Measure button then release.
3. The measured temperature can be checked in the measurement display.

4. The temperature measurement range of object is 10°C ~70°C.

### **[Measuring surrounding temperature / humidity]**

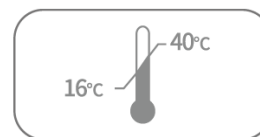
1. Press the Mode setting button for more than 3 seconds to measure the surrounding temperature/humidity.
  2. After the surrounding humidity is displayed for 3 seconds, the surrounding temperature is displayed.
- (※ Information on the surrounding temperature and humidity that have been measured must only be checked for reference.)

### **[Precautions before use]**

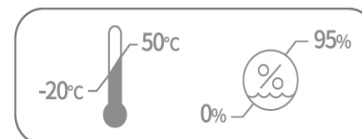
1. Learn how to use the product by reading the User Manual thoroughly.
2. Use in surrounding temperature of 16°C ~ 40°C. (Use after it has been indoors for 30 minutes).
3. Maintain an appropriate distance from direct fire that could interfere with the measurement.
4. Check the connection status of the battery.
5. Check if there is damage or abnormality in the device.
6. Be aware of damage caused by impact.
7. The body temperature may differ slightly (0.1~0.4°C) depending on the measurement area (mouth, ear, forehead).
8. To save the battery, it is better to connect to THERMOCARE mobile App through Bluetooth after several measurements.

### **[Operating condition and storage environment]**

- ◆ Operating temperature: 16°C ~ 40°C



- ◆ Storage temperature and humidity: -20°C ~ 50°C /95% below



### **[How to store and manage after use]**

1. Store away from water.
  2. In case it is not used for a long period of time, remove the batteries.
  3. Keep it safety, away from vibration, impact and the like.
  4. Store away from children under the age of 12.
  5. Avoid direct fire and sunlight. Store in places without dust or pollutant.
  6. This product does not require inspection, calibration or maintenance during use. However, if an error in body temperature measurement occurs or is expected to occur, request the manufacturer for correction or inspection.
  7. Discretionary disassembly of the device and replacement of internal parts are not permitted. All information on repair and replacement of the device (part replacement method and circuit diagram, etc.) is provided to our A/S team and must be performed by the personnel designated by our company.
- In case damage has been discovered, do not

attempt to repair. Contact the Customer Center.

8. Keep in room temperature and if it has not been stored in room temperature, store the product in room temperature for 30 minutes before using the product.
9. The probe (temperature measuring part) of the thermometer is an extremely sensitive part so it must be clean and free from damage at all times for accurate measurement. Maintain a clean status and store in dry places.

### **[Precautions during use]**

1. The temperature measured at the right side of the forehead and at the left side of the forehead may differ.
2. Do not use this device for unintended purpose.
3. Measurement may be inaccurate in case there is insufficient battery. In such a case, change the battery before use.
4. Ensure that babies and infants do not suck the probe (temperature measuring part) of the thermometer or the battery or touch with wet hands.
5. In case the baby or infant has come indoors from outside or in case the thermometer has been placed in a place with different temperature environment, use it after 30 minutes.
6. In case there is sweat on the forehead, measure the area behind the earlobe instead of the forehead. Lift the hair around the ears completely and measure the area behind the earlobe.
7. Measure repeatedly for more than 3 times in

the following circumstances.

- 1) Infant under 90 days old
- 2) In case measurement out of the average body temperature has been displayed in a child under the age of 3.
- 3) In case the product has been used for the first time or in case similar products have not been used before.

### 【Bluetooth connection】

#### 1. Mobile app installation

\* Android : Google Play Store

\* iOS: Apple App Store

Download and install the Thermocare app.

#### 2. Device registration

Click the device registration button on the mobile app and follow the instructions to register the device.

#### 3. Bluetooth connection

Press the Bluetooth button to connect the device and the app.



### 【Power off】

If not reused after measurement, the power is

automatically turned off after 15 seconds. However, in case of Bluetooth operation, the power is automatically turned off after 1 minute and 15 seconds.

### 【Replacing batteries】

Uses two 1.5v AA batteries. When the low battery icon appears on the LED Display, replace it with a new battery. Gently press the battery cover down and remove it. Insert the battery according to the electrode as indicated on the product. However, be sure to install it carefully with the polarity of the battery. Push up the battery cover until it clicks into place.

### 【Trouble Shooting】

LED Display	Cause and Countermeasure
Err	<p><b>Cause</b></p> <ul style="list-style-type: none"> <li>• When the outside temperature is outside the proper temperature (16°C~40°C)</li> <li>• Out of measurement range</li> </ul> <p><b>Countermeasure</b></p> <ul style="list-style-type: none"> <li>• Measure after storing for about 30 minutes in a place where the temperature is between 16°C and 40°C.</li> <li>• Check that the temperature sensing unit is clean and remove any foreign substances.</li> <li>• Remove the battery, reinsert it after 1 minute, and measure the temperature again. If the same error message persists after that, contact the Customer Service</li> </ul>

	Center.
HI	<p><b>Cause</b></p> <p>When measuring temperature range is exceeded</p> <ul style="list-style-type: none"> <li>- Human Body Mode: Measurement temperature exceeds 42.2°C</li> <li>- Object mode: Measurement temperature exceeds 70.0°C</li> </ul>
LO	<p><b>Cause</b></p> <ul style="list-style-type: none"> <li>• If it is below the measurement temperature range</li> <li>- Human Body Mode: Measurement temperature is less than 22.0°C</li> <li>- Object mode: Measurement temperature is less than 10°C</li> </ul> <p><b>Countermeasure</b></p> <ul style="list-style-type: none"> <li>• Use the product within the measurement range. (HI / LO common)</li> </ul> <p>If the error message persists, contact the customer service center.</p>
	<p><b>Cause</b></p> <ul style="list-style-type: none"> <li>• When the battery life is almost exhausted</li> <li>• When the battery life is over and accurate body temperature measurement is impossible</li> </ul> <p><b>Countermeasure</b></p> <ul style="list-style-type: none"> <li>• Replace with new batteries.</li> </ul>

### 【Manufacture no.】

Indicated on the product

### 【Year of manufacture】

Indicated on the product

### 【Packaging unit】

1 EA

### 【Manufacture license no.】

4627

### 【Manufacture certification no.】

No. 16- 4397

### 【Manufacturer】

#### T&R BIOFAB CO.,LTD

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