CONTEC™

TP500 CE 0123

Infrared Thermometer

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Thanks for purchasing our device.

Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly.

Responsibility of the company

Our company is only responsible for the safety, reliability and performance of the device in the following conditions: the installation and maintenance are performed by personnel approved by our company, and the device is used in accordance with the operating instructions.

Warranty

The device cannot be repaired by the user. All repairs should be performed by a technician authorized by our company. As requested by user, we will provide circuit diagrams, calibration methods and other information after paid by user, to help to repair the parts of the device classified as serviceable by qualified technicians. The warranty of this device covers all device failures caused by the failure of materials or production procedures. During the warranty period, all faulty parts can be repaired and replaced free of charge. Man-made damage is not covered by the warranty.

Explanation of notes in the user manual:

⚠**Warning**⚠

It indicates the information that you should know to avoid possible damage of patient and medical personnel.

⚠**Caution**⚠

It indicates the information that you should know to avoid possible damage of device.

⚠**Note**⚠

It indicates the important information that you should know.

⚠**Warning**⚠

The device is not intended for use for treatment purpose.

⚠**Warning**⚠

Do not refit the device.

⚠**Note**⚠

If the hospital or institution using this device fails to implement a satisfactory maintenance plan, it will cause abnormal device failure and may endanger human health.

Chapter 1 Overview

1.1 Product composition and intended use

Name: Infrared Thermometer

Model: TP500

Composition: shell, circuit board, temp. measuring part, display screen and power supply.

Application: to measure patient's temperature on forehead.

The device adopts infrared temperature measurement technology, which can quickly measure the target temperature and perform intelligent analysis and processing. The measurement process is: the infrared sensor in the measurement part receives the infrared radiation energy of the human body or an object, and the measurement circuit magnifies the signal, after compensation conversion and correction by the processor, the measured temperature value will be displayed on the screen. The data measured under Body-mode is estimated from the data measured under Obj-mode (calibration mode). The method is to convert and compensate the data measured under Obj-mode and the compensated value under different environments obtained by statistic rule, to get a value which is equivalent to the oral temperature value.

This device is suitable for body temperature measurement of adults, children and neonates. It is recommended that the device be operated by an adult.

The device is intended to be used in hospitals, community clinics and other similar places.

Note: According to the difference of human skin and the parts of the body to be measured, the measured temperature will be different, which is normal. It is because that the more exposed body part is more affected by the ambient temperature.

1.2 Performance parameters

- Degree of protection against ingress of liquid: IPX0
- Safety class: The device can not be used in the presence of a mixture of flammable anesthetic gas with air or oxygen or nitrous oxide.
- Operating mode: continuous running
- Unit: ℃/℉
- Resolution: 0.1 ℃
- Range of displayed temperature: 32.0℃ ~ 43.0 ℃
- Max. allowable error: ± 0.2 ℃
- Max. allowable clinical repeatability: ± 0.3 ℃
- Measurement time: < 1 s
- Display: LCD display screen
- Memory: 30 groups of data
- Power management: Automatic shutdown when there is no operation; battery level indication; low battery prompt
- Power supply: DC 3V (2 AAA batteries)
- Date of manufacture: see the label
- Weight: about 130 g
- Normal working and storage condition:

  Temperature:

  Working: 16 ℃ ~ 35 ℃

  Transport and storage: -20℃ ~ +55℃

  Humidity:

  Working: ≤ 85 % (no condensation)

  Transport and storage: ≤ 95 % (no condensation)

  Atmospheric pressure:

  Working: 700 hPa ~ 1060 hPa

  Transport and storage: 500 hPa ~ 1060 hPa

1.3 Precautions

⚠**Caution**⚠

The service life of the device is 5 years. When the products described in this manual are about to expire, they must be disposed of in accordance with relevant treatment specifications. If you would like further information, please contact our company or its representative.

⚠**Note**⚠

- Contraindications: None.
- Do not place the device near charged object to avoid electric shock.
- Do not use this device in an environment with relative humidity greater than 85%.
- The device should away from electromagnetic area (such as radio, mobile phone, etc.).
- Please do not expose the device to the sun or near the stove, or contact with water.
- Avoid impact or accidently falling, and do not use it if it is damaged.

1.4 Accessories

- User manual(1)

1.5 Symbols

Your device may not have all symbols below.

Symbol	Description	Symbol	Description
	Attention! Please refer to the accompanying document (the user manual)		Please refer to the manual booklet
	Battery		Manufacturer
	Type BF applied part (probe)		This way up
	Temperature limit		Fragile, handle with care
	Humidity limit		Atmospheric pressure limit
	Service life		Keep away from rain
	Stacking limit by number	P/N	Material code by manufacturer
	Date of manufacture		Batch code
	European Representative.	SN	Serial number
	Waste disposal symbol. This symbol indicates that electrical and electronic equipment waste cannot be disposed of as unsorted municipal waste and must be recycled separately.		
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.		

Chapter 2 Preparations before Measurement

2.1 Appearance

1) Infrared sensor

2) LCD screen

3) Button

4) Battery cover

2.2 Installation of battery

Following the direction in below figures, press down and slide the battery cover at the bottom of device to open it, install 2 AAA batteries, and close the battery cover. Pay attention to the polarity symbols inside the battery compartment. The positive and negative terminals of the battery cannot be reversed.

Figure 1 Figure 2 Figure 3

⚠**Note**⚠

- Please refer to the maintenance instructions for product inspection before preparing for measurement.
- When the battery icon becomes ▭, it indicates that the battery is about to run out, you can still continue the test, but please replace 2 new batteries of the same model as soon as possible to avoid affecting normal use.
- If the device is not used for a long time, please remove the batteries to prevent battery leakage causing device damage.
- Please pay attention to the polarity of the battery. Wrong installation may cause device damage.
- Rechargeable battery is not allowed to use on the device. Only single-purpose battery can be used. Do not throw used batteries into fire.
- The disposal of waste batteries should follow local environmental protection regulations.

2.3 Button and parameter setting

Button symbol: "⏻"

1) In device off state, pressing the button could turn on the device, and the device performs self-test, after self-test is completed, it enters startup interface and makes a beep sound, if self-test fails, it prompts for failure on the screen.

2) In device on state, short press the button to start measuring.

3) In device on state, long press the button to enter review interface.

4) In review interface, long press the button to enter parameter setting interface. In the setting interface, short press button to switch items, when the cursor moves to the item to be set, long press the button to make it under selected state, then short press button to adjust its parameter. After setting the parameters, long press the button to save and exit.

Parameters in the following can be set:

① Sound prompt

② Unit: ℃ and ℉

③ Mode: User can switch the mode to "Obj" (calibration mode). This setting will not be saved, the device automatically enters "Body" mode after restart.

Note: The body temperature is different from the skin temperature. In "Body" mode, the device measures the human body temperature, and in "Object" mode, it measures the skin temperature. Please be sure to select the "Body" mode when measuring body temperature.

Chapter 3 Measurement

3.1 Measurement steps

1) After turning on the device, align the detection hole to the center of the forehead (above the place between eyebrows) and keep vertical, the distance from the device to the forehead should be less than 3 cm (do not directly touch the user's skin).
2) Press the button to start measuring.
3) After measuring, the temperature value will display on the screen. If measuring unsuccessfully, "---" and corresponding error reason will display on the screen.

⚠**Note**⚠

The relevant prompts display on the screen when the temperature measured exceeds the normal temperature of human body.

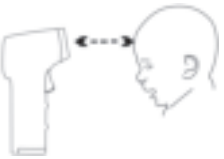
When the temperature measured is less than 32.0℃, it displays "Body Temp Lo" and the screen backlight is yellow;

When the temperature measured is greater than or equal to 32.0℃ and less than 37.6℃, the screen backlight is blue;

When the temperature measured is greater than or equal to 37.6℃ and less than 38.4℃, it displays "Body Temp Hi" and the screen backlight is yellow;

When the temperature measured is greater than 38.4℃, it displays "Body Temp Hi" and the screen backlight is red.

⚠**Note**⚠



- Before measuring, make sure that the measurement position is not covered by hair, sweat, cosmetics or hat, and do not measure on forehead with trauma, sweat, bangs, cooling patch, cosmetics or scar. As it may cause an inaccurate measurement.
- When the forehead temperature is influenced by environment temperature or the forehead has sweat, please measure aiming at earlobe.

- The ambient temperature around the tester should be stable, do not measure in places with large air flow, such as fan, air-conditioning outlet, etc.
- When the device is taken out from the place where has a large difference with the use environment, it should be left in the use environment for 30 minutes before measuring.
- Avoid using it when some cooling measures (such as cold compresses, sweating, etc.) are being taken on the feverish forehead, as it may result in a lower result.
- It is recommended to take three measurements per time, if the three values are different, please take the highest value. The measured results are only for reference, please do not diagnose and treat by yourself based on the results, please go to hospital for treatment if necessary.
- When the ambient temperature has a great change, please do not start measuring immediately.
- When measuring continuously for a long time, the measured results may have a little deviation, which is normal. As when holding the device, the temperature of hand affects the measurement for the device to the ambient temperature. So it is recommended to leave the device away from your hand after measuring several times or not measure.

3.2 Shutdown

The device will shut down automatically when there is no operation.

Warning

Please check whether the device and its accessories can work normally before use.

Caution

Please do not knock or drop the device during measuring.

Note

Please use the device in required working and storage environments, otherwise the result may not be measured or the measured result may be inaccurate.

3.3 General knowledge of body temperature

The human body is a complex biological integrated system, and the body temperature is an important data on judging whether the life activities are normal, we usually check health condition by measuring the temperature on forehead, cochlea, anus, mouth and armpit, etc. The temperatures measured on different parts are different. Compared with the mercury thermometer, the clinical repeatability for the device is less than ± 0.3 ℃.

The body temperature changes with the different time of the day, and it is also affected by other external conditions, such as age, gender, skin color and thickness, etc. We recommend to measure regularly under the following conditions:

- Measure with the same thermometer
- Measure at the same place.
- Measure at the same time every day.

Chapter 4 Maintenance

4.1 Maintenance and inspection

Please take the following inspections before using the device:

- Check whether there is any mechanical damage.
- Check whether the infrared detector has any damage.
- Check all functions of the device and make sure that the device is in good working condition.

If any damage sign is found, please contact the qualified service personnel.

The infrared thermometer is an adjusted mode device,the measurement accuracy has been calibrated before leaving factory.After every 6 ~ 12 months or maintenance, a comprehensive inspection (including functions, safety and accuracy) to the device must be carried out by the qualified personnel.

All inspections required to open the device must be performed by the qualified service personnel. Safety and maintenance inspections can also be performed by company personnel. Your local company office will be happy to provide the information related to signing a maintenance contract.

4.2 Cleaning

- When using the device, please pay attention to its cleaning to avoid cross infection.
- When the surface of the device or the detector is contaminated, wipe it with 75% medical alcohol cotton ball, then wipe with a dry or soft cloth.

Warning

The device should not be maintained and cleaned while in use.The battery must be removed before cleaning the device.

Caution

- High-pressure sterilization cannot be used on the device.
- Do not immerse the device in liquid.
- Do not use the device if any damage sign on temperature probe or cable is found.
- If the device is dirty, wipe it with a soft and dry cloth.
- If the device is extremely dirty, wipe it with 75% medical alcohol cotton ball, then dry thoroughly.

Warning

Do not allow water to enter the device.

Warning

Do not wipe the device with volatile oil, diluent or gasoline, etc.

4.3 Storage method

Warning

Do not place the device in following places:

- Where is easy to be splashed by water.
- Direct sunlight, high temperature, humidity and dusty places.
- Where is inclined or subject to vibration or knock.
- Where chemicals or corrosive gases are stored.

Chapter 5 Troubleshooting

During using, the following problems may appear, please find a solution following the instructions below. If the problem exists still, please contact our customer service.

Problem and reason	Solution
Surface temperature is too low: it is affected by hair or sweat, etc.	Make sure there is no obstruction when measuring.
Surface temperature is too high.	Make sure the device is used within a measurable temperature range.
Surface temperature is too low: the measurement distance is too far.	Make sure to operate the device in accordance with requirements, then measure again.
Low power / the device can not be turned on.	Check the battery polarities to make sure they are installed properly; Low voltage, replace two new “AAA” batteries.

Appendix I EMC declaration

Table 1:

Guidance and manufacturer’s declaration –electromagnetic emission	
The Infrared Thermometer is intended for use in the electromagnetic environment specified below. The purchaser or the user of the device should assure that it is used in such environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable

Table 2:

Guidance and manufacturer’s declaration-electromagnetic immunity		
The Infrared Thermometer is intended for use in the electromagnetic environment specified below. The purchaser or the user of the Infrared Thermometer should assure that it is used in such environment.		
Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	±8kV contact ±15 kV air
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m

Table 3:

Guidance and manufacturer’s declaration – electromagnetic immunity		
The Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer the user of the Infrared Thermometer should assure that it is used in such environment.		
Immunity test	IEC 60601 test level	Compliance level
Radiated RF IEC61000-4-3	3 V/m 80 MHz- 2.7 GHz	3 V/m80 MHz- 2.7 GHz
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.		
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 the Infrared Thermometer is used exceeds the applicable RF compliance level above, the Infrared Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Infrared Thermometer.		

Table 4

Guidance and manufacturer’s declaration - electromagnetic Immunity							
The Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infrared Thermometer should assure that it is used in such an environment							
	Test Frequency (MHz)	**Band a)** (MHz)	**Service a)**	**Modulation b)**	**Modulation b)** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 –390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5500						
	5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does notrepresent actual modulation, it would be worst case.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

Warning

- Don’t near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TP500, including cables specified by the manufacturer.Otherwise, degradation of the performance of this equipment could result.

Note:

- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.