

印刷要求说明

| | |
|---------------|-----------------------------|
| 物料名称： | 美国Medsorce8813C 英文FDA说明书 |
| 制作时间： | 20220521 |
| 版本版次： | B0 |
| 物料编号： | 7532 8813 00XB |
| 物料尺寸： | 89X115mm |
| 物料材质： | 105G双铜 |
| 表面处理： | |
| 印刷颜色： | 单黑 |
| 备注：此页非印刷页 | |
| 东莞市振海电子科技有限公司 | |



User Manual
Non-Contact Infrared Body Thermometer
MS-131002



Please read this manual before operating this device.
It contains important safety information.
Model HTD8813C

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Foreword

This user manual is intended to provide the necessary information for the proper operation of the MS-131002 non-contact infrared body thermometer.

A general knowledge of infrared thermometers and an understanding of the features and functions of the thermometer are prerequisites for proper use.

The non-contact infrared body thermometer is a medical device designed to last for five years.

Please read this manual before using the thermometer. If you do not fully understand how to use the thermometer, please consult this manual.

Do not operate the thermometer without completely reading and understanding these instructions.

Notice

Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

Safety Information

This device should only be used for the purposes described in these instructions. The manufacturer cannot be held liable for the damage caused by incorrect application.


The non-contact thermometer is designed to minimize the possibility of hazards from errors in the software program by following human factors design, risk analysis, and software validation processes.


Warnings

Warnings are identified by the Warning symbol show above.

- The non-contact infrared body thermometer is to be operated by consumers in the home setting and primary care setting as a screening tool. The manual, includes directions for use, all precautionary information and specifications should be read before use.
- This thermometer is designed to measure human body temperature on the forehead. Do not use it for any other purpose.
- This thermometer is intended to be used as a screening tool in a home setting and a primary care setting.
- Do not use the thermometer if it malfunctions or has been damaged.
- If the ambient temperature changes too much, such as moving the thermometer from a cold room to a warm room, allow the thermometer to adjust to the new temperature. This may take up to 30 minutes. The operating temperature of the thermometer is 59 °F to 104 °F (15 °C to 40 °C).
- Remove the batteries if the thermometer is not likely to be used for a long time.
- The thermometer is not waterproof. Do not immerse it in water or other liquids. For cleaning and disinfection, please follow the instructions contained in the "Cleaning, Care and Storage" section.
- Do not touch the infrared sensor with your fingers.

- If a cold compress has been applied to the patient's forehead, or other physical measures have been used to cool down the patient, avoid using the thermometer, as it may produce a low reading.
- When measuring body temperature using the forehead, select "body" mode. When measuring other objects, liquids or foods, select "surface" mode.
- This product must be operated in a stable environment. If the ambient environment has changed, water may condense on the surface of the infrared sensor. In the event of condensation on the infrared sensor, see the "Cleaning, Care, and Storage" section for guidance.
- Do not use the thermometer near strong electrostatic or magnetic fields. These fields may affect the accuracy of the thermometer.
- When replacing the batteries, do not mix old and new batteries. This may damage the thermometer.
- The accuracy of the measurement may be affected if the forehead is covered by hair, perspiration or clothing.
- This thermometer is intended for screening. If you have any doubt about the result, please measure the temperature using another method.
- The thermometer is calibrated during manufacturing. If used according to the instructions, periodic calibration is not required.

 The thermometer should be kept out of the reach of children and pets. When not in use, store the device in a dry place and protect it against moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the thermometer or thermometer packaging.


 Do not dispose of batteries in a fire.


 Only use recommended batteries. Do not use rechargeable batteries.

 This thermometer is not designed to replace diagnostic thermometers in hospitals.

 Do not drop, disassemble or modify the thermometer.


 Do not use the thermometer if you think it is damaged or notice unusual operation.


 The thermometer is comprised of sensitive components and must be treated with caution.


 Observe the storage and operating conditions described in the "Technical Specifications" section.


 Do not perform service or maintenance while the thermometer is on.

 When using the thermometer, do not touch the battery and patient simultaneously.

 Do not use the device if it is damaged/ degraded/ or if any of the thermometer has become loose. The use of a damaged unit may cause improper results or injury.

 Health Canada Warning: The thermometer is not intended for use on children under the age of two.

 Based on current science and technology, the thermometer is not known to cause any allergic reactions.

 This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS.

1 - Overview

Indication for use

The electronic thermometer HTD8813C is infrared thermometers which use Infrared sensor to detect human body temperature of patients of all ages, It is intended to be used on one's forehead to detect body temperature. The HTD8813C is intended for use in home and clinical environment.

Description of Non-Contact Infrared Body Thermometer

Introduction and Operating Principle

This non-contact thermometer is a hand-held, reusable, battery-operated device which measures human body temperature via the patient's forehead.

The operating principle is based on infrared sensor technology. The infrared sensor can output different signals when measuring different object temperatures or in different ambient temperatures. An application-specific integrated circuit then turns the signal from the infrared sensor into a digital value for display on the LCD screen.

Description of Controls, Indicators and Symbols

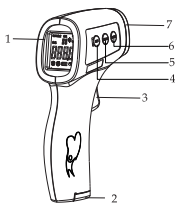


Figure 1: Overview

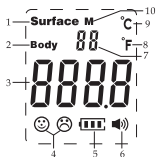














Figure 2: Display

1. Liquid Crystal Display (LCD)
2. Battery Cover
3. On/Scan Button
4. Set Button
5. Memo Button
6. Mode Button
7. Infrared Sensor
1. Surface Mode
2. Body Mode
3. Digital Display
4. Fever Indicator
5. Battery Indicator
6. Buzzer On/Off
7. Memory Index
8. Fahrenheit
9. Celsius
10. Memory Mode

Thermometer Applications

| Thermometer Model Number | Thermometer | Adult | | Pediatric | |
|--------------------------|---------------------------------------|-------|----------|-----------|----------|
| | | Ear | Forehead | Ear | Forehead |
| HTD8813C/REF:MS-131002 | Non-Contact Infrared Body Thermometer | | √ | | √ |

Equipment Symbols

| | | | |
|--|--|---|---|
|  | Warning |  | Compliance with WEEE Standard |
|  | Non-Sterile Package |  | DO NOT THROW AWAY Intended for multiple uses |
|  | Consult instructions for use |  | Operating atmospheric pressure |
|  | Operating Temperature |  | Serial number |
|  | Operating Humidity |  | Recyclable |
|  | Manufacturer |  | This device complies with Part 15 of FCC (Federal Communications Commission) rules. |
| IP22 | Ingress Protection: The first 2 indicates protection from the ingress of solid foreign objects 12.5 mm in diameter and greater. The second 2 indicates protection from the ingress of vertically falling water drops when the enclosure is tilted not greater than 15 degrees from vertical. | | |

Technical Specifications

| Specification | Value(s) |
|---------------------|--|
| Measurement Units | Fahrenheit (°F) / Celsius (°C) |
| Operating Mode | Adjusted mode (Body mode) Direct mode (Surface mode) |
| Measuring Site | Forehead |
| Reference Body Site | Axillary |
| Rated Output Range | Body mode: 93.2 °F – 109.4°F (34.0 °C – 43.0 °C) Surface mode: 32.0 °F – 212.0 °F (0.0 °C – 100.0 °C) |

| | |
|-------------------------------------|---|
| Output Range | Body mode: 93.2 °F - 109.4 °F (34.0 °C - 43°C) Surface mode: 32.0 °F - 212.0 °F (0.0 °C - 100.0 °C) |
| Laboratory Accuracy | Body mode: 93.2 °F - 94.8 °F ±0.5 °F (34.0 °C - 34.9 °C ±0.3 °C) 95.0 °F - 107.6 °F ±0.4 °F (35.0 °C - 42.0 °C ±0.2 °C) 107.8 °F - 109.4 °F ±0.5 °F (42.1 °C - 43 °C ±0.3 °C) Surface mode: ±3.6 °F (±2.0 °C) |
| Temperature Resolution | Fahrenheit: 0.1 Celsius: 0.1 |
| Three Color Backlight (Color Alarm) | Green - Normal Temperature: 95.9°F - 99.1 °F (35.5 °C - 37.3 °C) Yellow - Slight Fever: 99.3 °F - 100.4 °F (37.4 °C - 38.0 °C) Red - High Fever: 100.6°F - 109.4 °F (38.1 °C - 43 °C) Notes: 1.Surface Mode always displays a green backlight. 2. In Body Mode, a reading of 93.2 °F - 95.8 °F (34.0 °C - 35.4 °C) displays a green backlight. |
| Auto Power Off | ≤ 18 s |
| Measuring Time | ≤ 2 s |
| Measuring Distance | 0.4 - 2.0 in (1 - 5 cm) |
| Memory | 50 measurements |

| Power Supply Requirements | |
|---------------------------|---|
| Batteries | 1.5V AAA Alkaline Battery x 2 (IEC Type LR03) |
| Adaptable Range | 2.6V - 3.6V |

| Environmental Conditions | |
|----------------------------------|--|
| Operating Conditions | Temperature: 59.0 °F - 104.0 °F (15.0 °C - 40.0 °C) Relative Humidity: ≤ 85% Atmospheric Pressure: 70 - 106 KPa |
| Transport and Storage Conditions | Temperature: -4.0 °F - 131.0 °F (-20.0 °C - 55.0 °C) Relative Humidity: ≤ 93% Atmospheric Pressure: 70 - 106 KPa |

| Physical Properties | |
|----------------------------|---|
| Weight (without batteries) | 3.0 ounces (84 grams) |
| Size | Length: 5.9" (138mm) Width: 3.7" (95mm) Height: 1.7" (40mm) |

| Compliance | |
|--|---|
| Basic Safety and Essential Performance | EN 60601-1: 2006+A1:2013, EN 60601-1-2:2015 |
| Type of Protection | Internally Powered Equipment (on battery power) |
| Degree of Protection | Non-Applied Part |

| | |
|-------------------------------|------------------------|
| Front Panel and Case Labeling | EN/ISO 15223-1:2016 |
| Temperature | EN/ISO 80601-2-56:2017 |
| Home Healthcare Environment | EN 60601-1-11:2015 |

Calculated Values of the Indicators According to ASTM E1965-98

| Age group | Group I (Infants) | Group II (Children) | Group III (Adults) |
|---------------------------------|----------------------|------------------------|-----------------------|
| Bias (\bar{x}_d) | 0,05 | 0,07 | -0,04 |
| Uncertainty | ±0.20 | ±0.19 | ±0.18 |
| Clinical Repeatability | 0.13 | | |
| Compared with equivalent device | -0.06 | | |

Note: the above value is calculated from clinical data of HTD8816C.

Safety Classification of ME Equipment

| | |
|---|---------------------------------|
| Protection against electric shock | Internally Powered ME Equipment |
| Applied Part | No Applied Parts |
| Protection against harmful ingress of water or particulate matter | IP22 |
| Mode of Operation | Continuous Operation |

2 - Operation

2.1 Battery Installation

- 1) Pull the battery cover forward as indicated by the arrow.
- 2) Insert two AAA-size batteries. Ensure correct polarity as indicated inside the battery cover.
- 3) Slide the battery cover back in until it snaps in place.

2.2 Before Using the Thermometer

Be sure to read and understand all warnings listed in the instructions before use.

- If the ambient temperature changes too much, such as moving the thermometer from a cold room to a warm room, allow the thermometer to adjust to the new temperature. This may take up to 30 minutes.
- The ambient temperature around the patient should be stable. Keep away from large air flows such as fans or air-conditioning vents.
- Do not use the thermometer in bright sunlight.
- If a patient moves from a colder environment into a warmer test environment, they should remain in the test environment for at least 5 minutes prior to taking a measurement. This will ensure the patient is consistent with the ambient temperature.

2.3 Thermometer Self-Test

When the thermometer is off, press the On/Scan button to initiate a self-test. The thermometer will briefly illuminate all segments of the display with green backlighting and then complete a measurement.

2.4 Temperature Modes

The thermometer is capable of measuring body temperature and surface temperature. By default, the thermometer will enter Body Mode when turned on. To toggle between body temperature and surface temperature, press the Mode Button when the device is on.

2.5 Body Temperature

Taking a Body Measurement

- Align the thermometer with the middle of the forehead to measure body temperature (between and above the eyebrows).
- Ensure the distance between the thermometer and the patient's forehead is between 0.4" and 2.0" (1cm – 5 cm). See Figure 3.

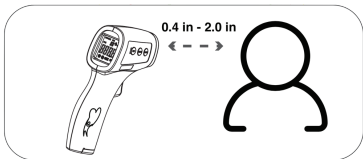


Figure 3

- Press and release the On/Scan button.
- The measurement will be displayed within two seconds.
- The thermometer will produce an audible indication when the measurement is complete if audio is enabled.
- Wait at least one second before taking the next measurement.
- If a continuous series of measurements is being performed, wait at least 30 seconds after every 5th measurement.

Body Measurement Results

- If the measurement is below 93.2 °F (34.0 °C), the display will show "Lo", a green backlight and beep three times if audio is enabled.

- **If the measurement is between 95.9 °F and 99.1 °F (35.5 °C and 37.3 °C) the display will show the temperature, a green backlight, a happy face icon and beep once if audio is enabled. This indicates normal body temperature.**
- **If the measurement is between 99.3 °F and 100.4 °F (37.4 °C and 38.0 °C), the display will show the temperature, a yellow backlight, a sad face icon and emit a series of beeps if audio is enabled. This indicates a slight fever**
- **If the measurement is between 100.6 °F and 109.4 °F (38.1 °C and 43°C), the display will show the temperature, a red backlight, a sad face icon and emit a series of beeps if audio is enabled. This indicates a high fever.**
- **If the measurement is greater than 109.4 °F (43 °C), the display will show “Hi”, a green backlight and beep three times if audio is enabled.**

2.6 Surface Temperature

Taking a Surface Measurement

- Ensure the distance between the thermometer and the surface to be measured is between 0.4” and 2.0” (1 cm and 5 cm).
- Press and release the On/Scan button.
- The measurement will be displayed within one second.
- The thermometer will produce a tone when the measurement is complete if audio is enabled.

Surface Measurement Results

- **If the temperature is less than 32.0 °F (0.0 °C), the display will show “Lo”, a green backlight and beep three times if audio is enabled.**
- **If the temperature is between 32.0 °F and 212.0 °F (0.0 °C and 100.0 °C), the display will show the temperature, a green backlight and beep once if audio is enabled.**
- **If the temperature is greater than 212.0 °F (100.0 °C), the display will show “Hi”, a green backlight and beep three times if audio is enabled.**

2.7 Memory Mode

The thermometer will automatically store the previous 50 temperature measurements. Temperatures that registered High or Low are out of range and are not stored.

- To enter Memory Mode, press the Memo Button while the unit is off or after the completion of a temperature reading.
- Upon entering Memory Mode, the most recent temperature measurement will be displayed.
- Press the Memo Button to display the next temperature measurement.
- Each stored measurement will display the following information:
 - o The memory index value (1-50, newest to oldest).
 - o The temperature.

- o The units (°F or °C).
 - o Whether body or surface temperature.
 - o For body temperature, a happy or sad face icon
- Every stored measurement **will** be displayed with a green backlight.
 - To **clear** the stored values, press and **hold** the Memory Button until “**Clr**” is displayed.
 - Empty memory cells **will** be displayed with “ - - - ” as the temperature value.

2.8 Parameter Mode

The thermometer has four parameters that can be tailored to certain populations or environmental conditions.

Entering Parameter Mode

- Ensure the thermometer is on.
- Press and **hold** the Set Button until “F1” and then “Unit” is displayed.

Temperature Units (F1)

The thermometer can be set to display the temperature in Fahrenheit or Celsius.

- Press either the Memo Button or the Mode Button to toggle between Fahrenheit and Celsius.
- When the desired units have been selected, press the Set Button to move to the next parameter.

Fever Threshold (F2)

The thermometer allows the fever threshold to be modified. This is the value at which the thermometer will indicate a slight fever. The default value is 100.5 °F.

- The threshold value **will** be displayed as it is modified.
- Press the Memo Button to increase the threshold by approximately 0.2 °F (0.1 °C).
- Press the Mode Button to decrease the threshold by approximately 0.2 °F (0.1 °C).
- When the desired threshold has been selected, press the Set Button to move to the next parameter.

Audio (F3)

The thermometer can be used with audio enabled or disabled.

- Press either the Memo Button or the Mode Button to toggle between audio enabled and audio disabled.
- When the desired audio setting has been selected, press the Set Button to move to the final parameter.

Note: The audio can also be enabled and disabled via Set Button when not in Parameter Mode.









Exit setting mode

In the F3 mode, press the SET button will automatically turn off the screen, exit setting.

2.9 Notes

- If you experience problems with this thermometer, such as configuration, maintenance or use, please contact the SERVICE PERSONNEL. Do not attempt to open or repair the device yourself.
- Please report to us any unexpected operation or events.
- The patient is an intended operator. They can determine the state of the batteries and change the batteries. The patient can maintain the device and its accessories according to the user manual under normal circumstances.

3 - Troubleshooting

| Message | | Solution |
|---|---|--|
|  Body $^{\circ}\text{C}$ | Body: The temperature measured is not within the typical human body temperature range of 93.2 $^{\circ}\text{F}$ to 109.4 $^{\circ}\text{F}$ (34.0 $^{\circ}\text{C}$ to 43 $^{\circ}\text{C}$). | Ensure the correct distance and location is being used to measure the temperature. |
|  Body $^{\circ}\text{C}$ | Surface: The temperature measure is not within the measurable range of 32.0 $^{\circ}\text{F}$ – 212.0 $^{\circ}\text{F}$ (0.0 $^{\circ}\text{C}$ – 100.0 $^{\circ}\text{C}$). | Do not attempt to measure temperatures outside the allowable range. |
|  Body $^{\circ}\text{C}$ | Improper Distance | Ensure the proper distance is used: 0,4" – 2,0" (1 cm – 5 cm). |
| | Incorrect test position. | Ensure the correct position is used. |
| | The subject's hair, antipyretic stickers or perspiration is affecting the measurement. | Remove any items that may interfere with the measurement. |
|  Body $^{\circ}\text{C}$ | The device temperature exceeds the allowable operating temperature range. | Move to a location within the operating temperature range and allow the thermometer to adjust to the new temperature. |
|  | The screen flickers and then turns off. | Replace the batteries. If the error persists, the device may be damaged. |
|  | Battery capacity is too low. Temperature measurement is not allowed. | Replace batteries. |
|  | The ambient temperature has changed too quickly. | Allow the thermometer to adjust to the new temperature. |
|  | Blank Screen a) The power is off b) Improper battery installation c) The batteries are depleted. d) Device is damaged | a) Press the On/Scan button. b) Check battery polarity. c) Replace the batteries d) Contact retailer or service center. |

4 – Replacing the Batteries

Caution: The thermometer does not operate with dead or low batteries and does not allow connection to an external power supply.

- 1) Before replacing the batteries, ensure the device is off.
- 2) Pull the battery cover forward as indicated by the arrow.
- 3) Remove the old batteries.
- 4) Insert two AAA-size batteries. Ensure correct polarity as indicated inside the battery cover.
- 5) Slide the battery cover back in until it snaps in place.
- 6) Dispose of the batteries in accordance with local regulations.

If the device does not function after replacing the batteries:

- Check for proper battery polarity.
- Try a fresh set of batteries.
- The unit may have locked up if the batteries were removed while the unit was powered. In this case, remove the batteries, wait 30 seconds, and then reinsert the batteries.



Warning

Do not recharge, disassemble, or dispose of in a fire.

- The typical service life for a set of new batteries is 2000 measurements with an operation time of 18 seconds per measurement.
- Only use the recommended batteries.
- Do not attempt to recharge non-rechargeable batteries.
- Do not dispose of batteries in a fire.
- Remove the batteries if the thermometer is not to be used for a long period of time.

5 – Cleaning, Care and Storage

1). Cleaning:

Purpose: This thermometer is for single patient reuse to measure body temperature, you may clean the surface of thermometer since which can be contaminated during use with organic soil and microorganisms carried by human hands immediately after each use.

Cleaning Agent: 70% isopropyl alcohol wipe.

Method of Cleaning: To thoroughly clean the device, immediately after each use, rubbing device (including markings) such as the probe, shell, button and LCD screen by hands without undue pressure with 70% isopropyl alcohol wipes for 15s and sensor of thermometer for 3s immediately after each measurement.

Note: Ensure that no liquid enters the interior of the thermometer, never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the instrument in water or other cleaning liquids. Wait 10 minutes after cleaning, allowing the thermometer to air-dry before taking a temperature measurement.

Visual Inspection: After cleaning, there should be no visible blotches and oil stains on the device under natural light, if there are still blotches and/or oil stains, repeat the cleaning steps mentioned above until there are no visible blotches and oil stains.

Disposing of the device if there is corrosion, discoloration, pitting or cracked seals after cleaning, enquire about the options for environment-friendly and appropriate disposal. Take local regulations into account. Reuse Life: 5 years.

2). Care

The lens is very delicate. It is very important to protect the lens from dirt and damage. The Infrared probe is very delicate. Do not touch or use tools press it. Must be carefully protected otherwise it will affect the accuracy of the measure.

3). Storage

Always keep the thermometer within the storage temperature and humidity range as specified. It is recommended to store the thermometer in a dry location free from dust.

Always keep the thermometer within the storage temperature range (-20 °C to 55 °C or -4 °F to 131 °F) and humidity range (≤93% non condensing). At least 30 min required of equipment to warm from the minimum storage temperature between uses until it is ready for intended use.

At least 30 min required for the equipment to cool from the maximum storage temperature between uses until it is ready for intended use.

It is recommended to store the thermometer in a dry location free from dust. Do not expose the thermometer to direct sunlight, high temperature/ humidity or any extreme environment, otherwise the function will be reduced.

When the ambient temperature of the thermometer changes too much, such as moving the thermometer from one place of lower temperature to another place of higher temperature, allow the thermometer to remain in a room for 30 minutes where the temperature is between 15 °C to 40 °C.

6 – Disposal

- Batteries should be disposed of in accordance with local regulations.
- Do not dispose of the thermometer in the unsorted municipal waste stream. Enquire about options for environmentally friendly and appropriate disposal. Take local regulations into account.

7 – Calibration

The thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to the instructions, periodic re-adjustment is not required. If at any time you question the accuracy of the temperature measurements, please contact service personnel.

8-EMC Declaration

1) This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2)* Caution: Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

3) *Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4) * Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

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

Guidance and manufacture's declaration – electromagnetic immunity


The Infrared Body Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of Infrared Body Thermometer should assure that it is used in such an environment.

| Anti-interference detection | IEC 60601 test level | Compliance level |
|--|--|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | Contact: ± 8 KV Air: $\pm 2, \pm 4, \pm 8, \pm 15$ KV | Contact: ± 8 KV Air: $\pm 2, \pm 4, \pm 8, \pm 15$ KV |
| Electrical fast transient/burst IEC 61000-4-4 | The input a.c. power ports: ± 2 KV The input d.c. power ports: ± 2 KV Signal input/output ports: ± 1 KV | Not applicable |
| Surge IEC 61000-4-5 | Input power ports: $+0.5, +1.0$ KV Signal input/output: $+2.0$ KV | Not applicable |
| Voltage dips IEC 61000-4-11 | 0.5 cycles for $> 95\%$ (sync angle (degrees): 0, 45, 90, 135, 180, 225, 270, 315) 1 cycles for $> 95\%$ UT (sync angle (degrees): 0) 25 (50Hz)/30 (60Hz) cycles for 30% U T (sync angle (degrees): 0) | Not applicable |
| Voltage interruption IEC 61000-4-11 | 250 (50Hz)/300 (60Hz) cycles for $> 95\%$ UT (sync angle (degrees): 0) | |
| Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8 | 30A/m | 30A/m |

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

The Infrared Body Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infrared Body Thermometer should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level |
|---------------------------------|---|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | Not applicable |
| Radiated RF IEC 61000-4-3 | Professional healthcare environment: 3 V/m Home healthcare environment: 10 Vm 80 MHz to 2700 MHz | Professional healthcare environment: 3 V/m Home healthcare environment: 10 Vm 80 MHz to 2700 MHz  |

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 the Non Contact Infrared Body Thermometer is used exceeds the applicable RF compliance level above, the Non Contact Infrared Body Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Non Contact Infrared Body Thermometer.

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

Guidance and manufacturer's declaration - RF wireless communication equipment immunity

| Test frequency (MHz) | Band ^{a)} (MHz) | Service ^{a)} | Modulation ^{b)} | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|-------------------------|-----------------------------|--|---|----------------------|-----------------|------------------------------|
| 385 | 380 - 390 | TETRA 400 | Pulse modulation ^{b)} 18 Hz | 1,8 | 0,3 | 27 |
| 450 | 430 - 470 | 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 | 1700 - 1990 | 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 | 2400 - 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation ^{b)} 217 Hz | 2 | 0,3 | 28 |
| 5240 | 5100 - 5800 | WLAN 802.11 a/n | Pulse modulation ^{b)} 217 Hz | 0,2 | 0,3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

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 not represent actual modulation, it would be worst case.

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