

Owner's Manual

Infrared Ear/Forehead Thermometer

Model **DET-2126b**



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Contents

| | |
|---|----|
| Introduction | 02 |
| Product Description | 03 |
| LCD Display Introduction | 04 |
| Basic Functions | 05 |
| Real Time Clock Setting | 06 |
| Body Temperature | 09 |
| Illustration For Use | 10 |
| Temperature Taking Hints | 18 |
| Memory Mode | 20 |
| Care And Cleaning | 21 |
| Battery Replacement | 23 |
| Specifications | 24 |
| Troubleshooting | 25 |
| Calibration | 27 |
| Symbol Explanation | 28 |
| Service | 29 |
| Warranty | 30 |
| FCC Information | 31 |
| Electromagnetic Compatibility Information | 33 |

Introduction

The multi functional thermometer is intended solely for measuring forehead temperature, ear temperature and object temperature. It allows you to quickly and easily measure body temperature and object temperature. It converts the measured heat into a temperature reading displayed on the LCD.

Indications for Use: The infrared ear thermometer is intended for the intermittent measurement of human body temperature. The device can be reused by people of all ages for home use and clinical use.
Intended use: The infrared ear thermometer is used to measure body temperature.



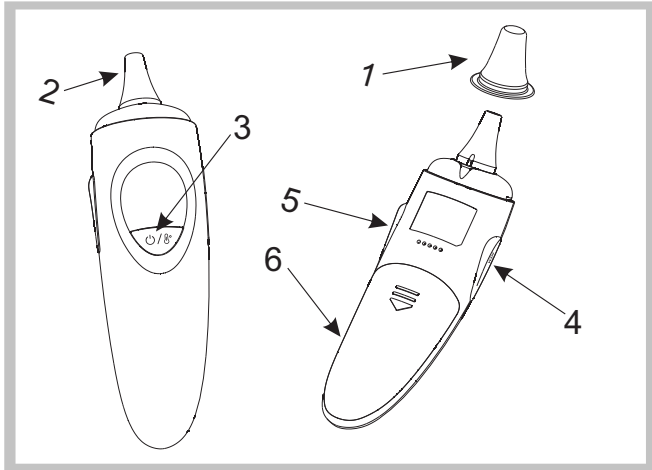
Please read all instructions carefully and thoroughly before using this product.

Warning:

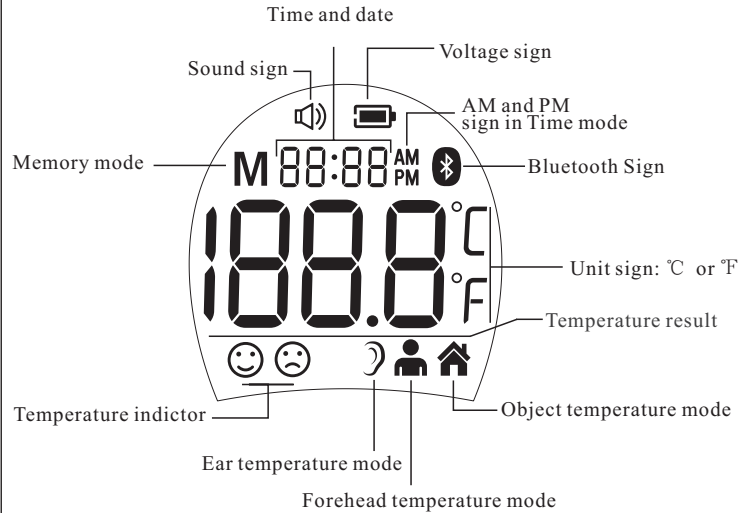
1. It's not meant to replace a visit to the doctor. Please consult with doctor if you have health concerns.
2. There is no gender or age limitation for using infrared ear/forehead thermometer.
3. Do not allow children to take their temperatures unsupervised, some parts are small enough to be swallowed.
4. Never immerse this device in water or other liquids (not waterproof).
5. Do not modify this equipment without authorization of manufacturer.
6. Do not expose the thermometer to temperature extremes (below -25°C/-13°F or over 55°C/131°F) nor excessive humidity (>95%RH).
7. Keep the battery away from children.
8. Remove battery from the device when not in operation for a long time.
9. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
10. ME equipment should not be cleaned while in use.
11. The probe of the ME equipment shall not be serviced or maintained while in use with a patient.

Product Description

1. Probe Cover
2. Probe
3. Test Button/Power Button
4. Memory Button
5. Setting Button/Voice Button
6. Battery Cover



LCD Display Introduction

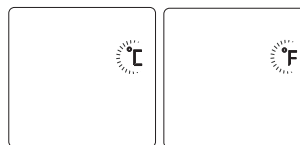


Basic Functions

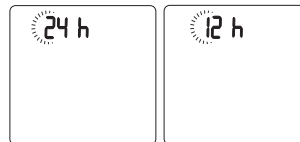
| | |
|-------------------------------|--|
| Real Time Clock | The real time clock will be recorded with the memory function and help you to recognize each measurement result. → Please see the Real time clock setting section to learn how to setup the time in the first use. |
| Ear/Forehead Temperature Mode | The thermometer has been designed for practical use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. → Please see the Illustration For Use section to learn how to measure the body temperature. |
| Object Temperature Mode | The object mode shows the actual, unadjusted surface temperatures, which is different from the body temperature. It can help you to monitor if the object temperature is suitable for the baby or patient, for example the baby's milk. Measure time of object mode: Approx. one second. Measuring range of object mode: 0°C~100°C(32°F~212°F). Laboratory accuracy of object mode: ±4% or ±2°C(4°F) whichever is greater. → Please see the Illustration For Use section to learn how to measure the object temperature. |
| Memory Mode | There are 30 sets memories for ear, forehead and object measurements. Each memory also records the measurement date/time/mode icon. |
| °C/°F Switch | Please see the Real Time Clock Setting section to learn how to change between Celsius and Fahrenheit. |
| Voice | The thermometer will broadcast the result after finishing measurement. |
| Vibration | After the voice is turned off, the vibration will be automatically turned on. The thermometer will vibrate at the end of the measurement. |

Real Time Clock Setting

When using thermometer for the first time, please set the parameters of the thermometer. With the thermometer off, press and hold **Setting Button** to enter into setting mode.



① Set the unit
Press **Test Button** to select the unit you want.
After the unit is set, press **Setting Button**, the time format figure will appear.



② Set the time format
The device can display the time in either an AM/PM (12-hour) or a 24:00 (24-hour) format. Press and release **Test Button** to select the format.
With the preferred time format on the display, press **Setting Button**, the Hour figure is flashing automatically.



③ Set the hour
Press and release the **Test Button** to advance one hour until the correct hour appears.
After the hour is set, press **Setting Button**, the Minute figure is flashing automatically.

Real Time Clock Setting

16:00

④ Set the minute
Press and release the *Test Button* to advance one minute until the correct minute appears. After the minute is set, press *Setting Button*, the Year figure is flashing automatically.

20 20

⑤ Set the year
Press and release the *Test Button* to advance one year until the correct year appears. After the year is set, press *Setting Button*, the Month figure will appear.

12-22

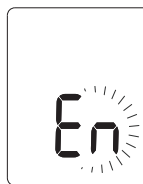
⑥ Set the month
Press and release the *Test Button* to advance one month until the correct month appears. After the month is set, press *Setting Button*, the Date figure is flashing automatically.

12-22

⑦ Set the date
Press and release the *Test Button* to advance one day until the correct month appears. After the day is set, press *Setting Button*, language selection interface will appear.

7

Real Time Clock Setting



⑧ Set the language of voice
The device can set the language of voice in either Chinese or English format. Press and release *Test Button* to select the format. With the preferred language format on the display, press *Setting Button* to exit the setting mode.

8

Body Temperature

The temperature of a healthy person is affected by various factors: the person's individual metabolism, their age(body temperature is higher in babies and toddlers and decreases with age. Greater temperature fluctuations occur faster and more often in children, e.g. due to growth spurts), their clothing, the ambient temperature, the time of day(body temperature is lower in the morning and increases throughout the day towards evening), the preceding physical and, to a lesser extent, mental activity.

It is suggested that users develop the habit of daily measurement, and use this product to establish a private normal temperature range for themselves and their families as a reference for measurement.

9

Illustration For Use

► Before measurement:

- Check before each use that the lens is intact. If it is damaged, contact your retailer or the service address.
- Bear in mind that the thermometer needs to have been in the room in which the measurement is taken for at least 30 minutes before use.
- Users and the thermometer should be in the same ambient temperature.
- Before each measurement, make sure that the device is in the appropriate mode for the measurement that you wish to take.

► How to switch between ear/forehead and object mode:

- When the device is on, press and hold the *Setting Button* to switch between ear mode/forehead mode and object mode. When the forehead cap is installed, the thermometer will automatically switch to forehead mode and when not installed, the thermometer will automatically switch to ear mode.

► To measure forehead temperature:

Note:

- Oils or cosmetics on the forehead may give a lower temperature reading than the actual one. Remove dirt from the forehead before taking a measurement. Wait at least 10 minutes after washing the forehead area before taking a reading.

10

Illustration For Use

- Do not use the thermometer on a perspiring or sweating forehead, as this may affect the reading.
- Remove hat and hair and wait 10 minutes before taking a reading.

1. Install the forehead cap.
2. Press the *Test Button* to switch on the thermometer and the display is activated to show all segments.
3. After self-checking, Figure 1 appears on the display screen with voice, so you can start a new measurement.
4. Place the probe with the forehead cap fitted on the temple.
5. Press the *Test Button* to start measurement.
6. Move the thermometer smoothly over the forehead to the other temple and back.
7. The measured value appears on the display and the end of the measuring is signalled by voice. If the voice is turned off, the end of the measurement is signalled by vibration.
8. The thermometer will shut off automatically after 30 seconds of inactivity. To prolong battery life, press and hold the *Test Button* to turn the unit off.

11

Figure 1

Illustration For Use

▶ To measure ear temperature:

- Some people produce different readings in their left and right ear. In order to record temperature changes, always measure a person's temperature in the same ear.
- As ear wax can affect the measurement, you should clean the ear before measuring if necessary.

1. Remove the forehead cap.
2. Press the *Test Button* to switch on the thermometer and the display is activated to show all segments.
3. After self-checking Figure 2 appears on the display screen with beep, so you can start a new measurement.
4. Make sure that the sensor tip and the ear canal are clean. As the ear canal is slightly curved, you have to pull the ear slightly up and backwards before inserting the sensor tip.(See Figure 3)

- When using the thermometer on infants under age 1, pull the ear up making sure the sensor faces the eardrum(See Figure 4).
- When using the thermometer on individuals over the age of 1, pull the ear back making sure the sensor faces the eardrum. (See Figure 5).

5. Press the *Test Button* to start the measurement.

12

Illustration For Use

6. The measured value appears on the display and the end of the measuring is signalled by voice.

Note: A waiting period of 20 seconds between testing is recommended to avoid excessive cooling of the skin.
7. The thermometer will shut off automatically after 30 seconds of inactivity. To prolong battery life, press and hold the *Test Button* to turn the unit off.

Figure 2

Figure 4

Figure 5

Figure 3

13

Illustration For Use

▶ To measure object temperature:

1. Press the *Test Button* to switch on the thermometer.
2. Press and hold *Setting button* to switch to object temperature mode. Figure 6 appears on the display screen with voice, so you can start a new measurement.
3. Aim the thermometer at the center of the object you want to measure with a distance of 1 to 2 cm.
4. Press the *Test Button* to start measurement.
5. The measured value appears on the display and the end of the measuring is signalled by voice. If the voice is turned off, the end of the measurement is signalled by vibration.
6. To exit object temperature mode, press and hold *Setting Button* to switch back to forehead/ear mode.
7. The thermometer will shut off automatically after 30 seconds of inactivity. To prolong battery life, press and hold the *Test Button* to turn the unit off.

Remarks:

This mode shows the actual, unadjusted surface temperatures, which is different from the body temperature.

Figure 6

14

Illustration For Use

► After measurement:

1. Power off: Device will automatically shut off if left idle for more than 30 seconds to extend battery life.
2. Clean the probe after each use to ensure an accurate reading and avoid cross contamination.

(See the section of Care and Cleaning for details.)

► BackLight:

In Ear/Forehead mode:

1. The display will be lighted GREEN for 3 seconds with a happy face 😊 when the unit is ready for measurement and a measurement is completed with a reading less than 37.3°C(99.1°F).
2. The display will be lighted YELLOW for 3 seconds with a happy face 😊 when a measurement is completed with a reading less than 37.8°C(100.0°F).
3. The display will be lighted RED for 3 seconds with a bad face ☹ when a measurement is completed with a reading equal to or higher than 37.8°C(100.0°F).

In Object mode:

The display will only be lighted Green for 3 seconds when the unit is ready for measurement and a measurement is completed.

15

Illustration For Use

► Bluetooth requirements

The thermometer requires a bluetooth device with:

- . Bluetooth 5.0 or later
- . Android 6.0 or later
- . IOS 10.0 or later

And works with:

- . iphone , iPod, iPad
- . Android Phones and Tablets

► Using for the first time

1. Download the "JoyHealth" App from Website or APP Store (Such as Apple Store).
2. Open the App on your phone or tablet. If requested, you should enable Bluetooth on your device. You can enable Bluetooth under the Settings menu on your smart phone or tablet.
3. Create a new user login, or login with your existing user name and password.
4. Selection device "Thermometer".

16

Illustration For Use

► Match your thermometer with a Smart Device

1. If this is your first time using it, bind first. Open "SETTING" menu, choose "Bind and unbind device" and select the appropriate model.
The date and time on your thermometer will automatically be updated when it's connected with your phone.
2. Confirm that your thermometer is connected successfully.
When your thermometer is connected successfully to your smart phone, the "📶" symbol stop flashing and keep showing.

► Transfer your readings

1. As soon as your measurement is finished, open the app on your smart phone to transfer the readings.
Note: On the matched smart phone, Bluetooth must be enabled.
2. You can view your temperature readings in the app.

17

Temperature Taking Hints

To ensure that the reading always reflects the body temperature accurately, you need to take account of the following factors which may affect an accurate reading.

1. It is important to know each individual's normal temperature when they are well. This is the only way to accurately diagnose a fever. To determine normal temperature, take multiple readings when healthy. Re-measure with a standard digital thermometer for confirmation.
2. The probe window of the thermometer is the most delicate part of the device. Do not touch the probe window. The accuracy of the reading may be affected if the probe window is damaged or dirty.
3. Users should not drink, eat, or be physically active such as bathing, showering, shampooing and hair drying before/while taking the measurement. In these cases, wait 20 minutes prior to taking a temperature.
4. Holding a hand on the forehead for any length of time will affect the temperature reading.

18

Temperature Taking Hints

5. Do not take temperature over scar tissue, open sores or abrasions.
6. Don't take a measurement while or immediately after nursing a baby.
7. Do not use this thermometer outdoors.
8. Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.
9. If the thermometer is stored in a significantly different environment than testing location, place it in the testing location for approximately 30 minutes prior to use.
10. The patient is an intended operator.

19

Memory Mode

1. The Memory Mode can be accessed either in ear mode, forehead mode or object mode:
When the thermometer has been turned on and followed by Figure 1/2/6 or finished testing, press the *Memory Button*. The letter M will appear in the upper left corner of the display. (See Figure 7)
2. The thermometer will automatically memorize the last 30 temperature readings. Each memory also records the measurement date/time/mode icon. Each time the *Memory Button* is pressed, the screen displays past readings that correspond with a number 1-30. The number 1 reflects the most recent reading, while the number 30 reveals the oldest reading stored in memory. (See Figure 8)
3. In the memory mode, the mode icon always exists. The user can press the *Test Button* to take new measurements.

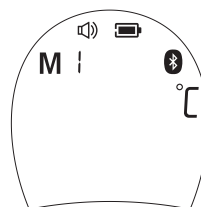


Figure 7

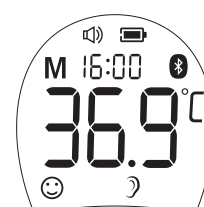


Figure 8

20

Care And Cleaning

1. The probe window must be kept clean, dry, and undamaged at all times to ensure accurate readings. The accuracy of temperature readings can be affected by damage to the probe window, or the presence of dirt and ear wax on the probe window.
2. Fingerprints, earwax, dust and other soiling compounds reduce transparency of the window and result in lower temperature readings.
3. The probe window is the most delicate part of the thermometer. To safely clean the window, gently wipe its surface with a cotton swab slightly moistened with isopropyl alcohol and immediately wipe dry with a clean cotton swab. After cleaning, allow at least 5 minutes drying time before taking temperatures.
Note: Do not use any chemical other than isopropyl alcohol to clean the probe window.
4. Use a soft, dry cloth to clean the thermometer display and exterior.
5. The thermometer is not waterproof. Do not submerge the unit in water when cleaning.
6. Store the thermometer in a dry location, free from dust and contamination and away from direct sunlight.

21

Care And Cleaning

7. Periodic cleaning of the device following use to prevent patient cross infection.
-Use a soft cloth slightly moistened with a 75% isopropyl alcohol solution to wipe the thermometer and probe. Do not use abrasive cleaners.
8. Ensure that children do not use the instrument unsupervised; some parts are small enough to be swallowed.
9. Do not remove or modify the equipment without permission.
10. Strong electromagnetic fields may interfere with the proper operation of the thermometer. The device needs special pre-cautions regarding EMC according to the EMC information.
11. It is not intended for use in the oxygen rich environment and presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
12. Put the thermometer back to the original packaging after using.

22

Battery Replacement


1. Replace battery when "  " appears in the upper right corner of LCD display. (See Figure 9)
2. Slide battery cover down as shown in Figure 10.
3. Remove battery and install 2 new AAA alkaline batteries as shown in Figure 11.
4. Slide battery cover back on.



Figure 9

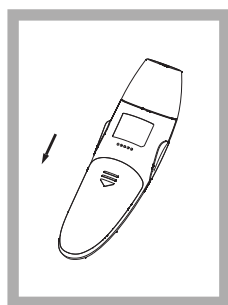


Figure 10

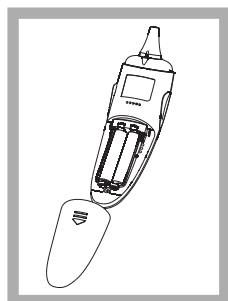


Figure 11

23

Specifications

| | |
|---|--|
| Measuring range | Ear/Forehead mode: 34.0°C~43.0°C(93.2°F~109.4°F) |
| Measuring site | Ear canal(Ear Mode)、Forehead(Forehead Mode) |
| Reference body site | Oral (This thermometer converts the ear temperature to display its "oral equivalent.") |
| Operation mode | Ear/Forehead mode(Adjust mode) |
| Laboratory accuracy | Ear/Forehead mode: ±0.2°C (0.4°F) during 35.5°C~42.0°C (95.9°F~107.6°F) at 15°C~35°C (59.0°F~95.0°F) operating temperature range ±0.3°C (0.5°F) for other measuring and operating temperature range |
| Display resolution | 0.1°C or 0.1°F |
| Measure time | Ear/Forehead mode: Approx. one second |
| Operating temperature range: | 10°C~40°C(50°F~104°F), 15%~85%RH, non-condensing Atmospheric Pressure : 70kPa ~ 106kPa |
| Storage and transport temperature range | -25°C~ 55°C (-13°F~131°F), 15%~95%RH, non-condensing Atmospheric Pressure : 70kPa ~ 106kPa |
| Clinical accuracy | 0-1 year: Ear temperature: Clinical bias: 0.05°C (0.09°F) ; Clinical repeatability: 0.21°C (0.38°F) ; Limits of agreement: 0.76°C (1.37°F) Forehead temperature: Clinical bias: 0.08°C (0.14°F) ; Clinical repeatability: 0.33°C (0.59°F) ; Limits of agreement: 0.73°C (1.31°F) 1-5 years: Ear temperature: Clinical bias: 0.11°C (0.20°F) ; Clinical repeatability: 0.34°C (0.61°F) ; Limits of agreement: 1.36°C (2.45°F) Forehead temperature: Clinical bias: 0.24°C (0.43°F) ; Clinical repeatability: 0.40°C (0.72°F) ; Limits of agreement: 1.49°C (2.68°F) over 5 years: Ear temperature: Clinical bias: 0.21°C (0.38°F) ; Clinical repeatability: 0.21°C (0.38°F) ; Limits of agreement: 0.99°C (1.78°F) Forehead temperature: Clinical bias: 0.22°C (0.40°F) ; Clinical repeatability: 0.26°C (0.47°F) ; Limits of agreement: 1.10°C (1.98°F) |
| Shock | withstands drop of 3 feet |
| Dimension | 155*43*30.5mm |
| Weight | Approx. 93 grams(with batteries) |
| Battery | DC3V(2×AAA battery) |
| Battery life | Approx. 3000 readings |
| Expected service life/ Shelf life | Three years |
| Ingress protecting rating | IP22 |
| Accessories | Battery |
| Contraindications | None |
| Applied part | Probe |
| Bluetooth technical parameters | Modulation mode: GFSK Frequency range: 2400-2483.5MHz Bandwidth occupied: ≤2MHz Transmit power: ≤20db |




24

Troubleshooting

| Error message | Problem | Solution |
|---------------|---|---|
| --- | Measurement before thermometer is ready | Take a measurement until thermometer is ready(with voice). |
| Er-2 | The ambient temperature is not within the range between 10°C and 40°C (50°F~104°F). | Place the thermometer in a room for at least 30 minutes at room temperature between 10°C and 40°C (50°F~104°F) |
| Er-3 | The thermometer is placed incorrectly or unsteady. | Read Illustration For Use thoroughly and take a new temperature measurement. |
| Er-4 | The thermometer showing a rapid ambient temperature change. | Allow the thermometer to rest in a room for at least 30 minutes at room temperature: between 10°C and 40°C (50°F~104°F) |
| Er-5 | The thermometer is not functioning properly. | Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service. |

25

Troubleshooting

| Error message | Problem | Solution |
|---|---|---|
| H ₁ | In Ear/Forehead mode: Temperature taken is higher than 43.0 °C (109.4°F). In Object mode: Temperature taken is higher than 100 °C (212°F). | Read Temperature Taking Hints Thoroughly, then take a new temperature measurement. |
| Lo | In Ear/Forehead mode: Temperature taken is lower than 34.0 °C (93.2°F). In Object mode: Temperature taken is lower than 0°C(32°F). | Read Temperature Taking Hints thoroughly , then make sure the lens filter are clean, then take a new temperature measurement. |
|  | The thermometer works properly. | Use the thermometer normally |
|  | When battery outline flashes, it indicates that the power is low, but you can continue to measure. | The thermometer will take a proper measurement but batteries must be replaced soon. |
|  | The thermometer could not work due to low battery. | Replace two new alkaline batteries size AAA. |

26

Calibration













The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the use instruction, periodic readjustment is not required. However, We recommends checking calibration every two years or whenever clinical accuracy of the thermometer is in question. Please send the complete device to the dealers or manufacturer.

The above recommendations do not supersede the legal requirements. The user must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device which are required by the scope of relevant laws, directives or ordinances where the device is used.

A clinical summary and procedures for checking calibration are available upon request.(Turn on the thermometer and press the test button long time until entering into calibrate mode, software version will be displayed.)

27

Symbol Explanation

| | |
|---|--|
|  | Caution |
|  | Direct Current |
|  | Batch Code |
|  | Storage and Transportation Temperature Limit: -13°F ~131°F (-25°C ~55°C) |
|  | TYPE BF APPLIED PART |
|  | Refer to instruction manual/booklet |
|  | General symbol for recovery/recyclable |
|  | Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products. |
|  | Atmospheric pressure limitation |
|  | Storage and Transportation Humidity limitation: 15%~95%RH |
|  | Manufacturing Date |
|  | Manufacturer |
| IP22 | The first num.2:Protected against solid foreign objects of 12,5 mm Ø and greater. The second num.2:Protection against vertically falling water drops when ENCLOSURE tilted up to 15°. |

28

Service

The thermometer has a limited one year warranty. Do not attempt to disassemble or repair the thermometer by yourself. Should service be required during or after the warranty period you must contact the manufacturer. Repackage the thermometer carefully in its original packaging or securely pack to avoid damage during shipping. Include the original sales slip indicating the date of purchase, a note describing the problem, and your return address. Send the thermometer prepaid and insured.

The lay operator or lay responsible organization should contact the manufacturer or the manufacturer's representative:

- for assistance, if needed, in setting up, using or maintaining the thermometer; or
- to report unexpected operation or events.

29

Warranty

This appliance conforms to the following standards:

ISO 80601-2-56 Medical electrical equipment —Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement, IEC 60601-1-11 Medical electrical equipment —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 and complies with the requirements of IEC 60601-1-2(EMC) , IEC 60601-1(Safety) standards. And the manufacturer is ISO 13485 certified.

Thermometer is warranted by manufacture to be free from defects in material and workmanship under normal use and service for a period of one year from the date of delivery to the first user who purchases the instrument. This warranty does not cover batteries, damage to the probe window, or damage to the instrument caused by misuse, negligence or accident, and extends to only to the first purchaser of the product.

30

FCC Information

Caution: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user authority to operate the equipment.

*Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. 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 and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to 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.

31

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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

32

Electromagnetic Compatibility Information

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

33

Electromagnetic Compatibility Information

Table 1

| Guidance and manufacturer's declaration – electromagnetic emission | | |
|---|--------------------|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| Conducted emission CISPR 11 | Not applicable | The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| Radiated emission CISPR 11 | Group 1 Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Not applicable | |

34

Electromagnetic Compatibility Information

Table 2

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|--|---|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air | ± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrostatic transient / burst IEC 61000-4-4 | ± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines | N/A | N/A |
| Surge IEC 61000-4-5 | ± 0.5 kV, ± 1 kV differential mode line-line | N/A | N/A |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0° | N/A | N/A |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m, 50/60Hz | 30 A/m, 50/60Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Proximity magnetic fields | IEC 61000-4-39 | See Table 3 | See Table 3 |

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

Electromagnetic Compatibility Information

Table 3

| Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields | | |
|--|-----------------------------|---------------------------|
| Test frequency | Modulation | IMMUNITY TEST LEVEL (A/m) |
| 30 kHz a) | CW | 8 |
| 134.2 kHz | Pulse modulation 2.1 kHz b) | 65 c) |
| 13.56 MHz | Pulse modulation 50 kHz b) | 7.5 c) |

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) r.m.s., before modulation is applied.

Table 4

| Guidance and manufacturer's declaration – electromagnetic immunity | | |
|---|--|------------------|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 6 Vrms 150 kHz to 80 MHz outside ISM bandsa | N/A |
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2.7 GHz | 10 V/m |

Electromagnetic Compatibility Information

Table 4 continued

| |
|--|
| <p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>a The ISM(industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHzto6,795 MHz;13,553 MHz to 13,567 MHz;26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz,3,5 MHz to 4,0 MHz,5,3 MHz to 5,4 MHz,7 MHz to 7,3 MHz,10,1 MHz to 10,15 MHz,14 MHz to 14,2 MHz,18,07 MHz to 18,17 MHz,21,0MHz to 21,4MHz,24,89 MHz to 24,99 MHz,28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.</p> <p>b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.</p> <p>c 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> |
|--|

Electromagnetic Compatibility Information

Table 5

| Recommended separation distances between RF wireless communications equipment | | | | |
|--|-----------------|----------|----------------------|------------------|
| The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment. | | | | |
| Frequency MHz | Maximum Power W | Distance | IEC 60601 Test Level | Compliance Level |
| 385 | 1.8 | 0.3 | 27 | 27 |
| 450 | 2 | 0.3 | 28 | 28 |
| 710 | 0.2 | 0.3 | 9 | 9 |
| 745 | | | | |
| 780 | | | | |
| 810 | 2 | 0.3 | 28 | 28 |
| 870 | | | | |
| 930 | | | | |
| 1720 | 2 | 0.3 | 28 | 28 |
| 1845 | | | | |
| 1970 | | | | |
| 2450 | 2 | 0.3 | 28 | 28 |
| 5240 | 0.2 | 0.3 | 9 | 9 |
| 5500 | | | | |
| 5785 | | | | |

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic Compatibility Information

WARNINGS!

- This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.
- The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Portable and mobile RF communications can affect the device. The device needs special pre-cautions regarding EMC according to the EMC information provided in the accompany documents.
- Do not use the devices in the MR environment.
- The Operator should not use the system and should inform the customer service, if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES.
- PRECAUTION: The performance of the device may be degraded should one or more of the following occur:
 - Operation outside the manufacturer's stated temperature and humidity range.
 - Storage outside the manufacturer's stated temperature and humidity range.
 - Mechanical shock (for example, drop test) or degraded sensor.
 - Patient temperature is below ambient temperature.