

INSTRUCTIONS FOR USE

Before first use, pull to remove the tab from the battery cover.

INSTALLING THE HYGIENE COVER

WARNING: Choking from swallowing probe covers and connection ring by children or pets is possible, please keep the probe covers and connection ring at places where children and pets can't reach.

 Gently twist the probe cap to remove. Always use a new and undamaged hygiene cover before each reading. Ensure the ear canal is clean.



- 2. Place a new hygiene cover into the connection ring. See diagram 1.
- Insert the thermometer probe into the centre of the hygiene cover and connection ring.
 See diagram 2.
- 4. Push until it is secure. If the hygiene cover did not connect firmly, this icon will be flashing on the LCD screen. Remove the hygiene cover and re-install.

 Correct installation of the hygiene cover ensures accurate readings.





- Gently pull the baby's ear back, straightening the ear canal. Position the probe snugly into the ear canal, ensuring an accurate reading. See diagram 3 and 4.
- 7. To measure the ear temperature, press the 'Scan' button until there is a long beep.

The LCD screen will light up automatically after pressing the **scan** button, and will automatically turn off after 5 seconds.

- 8. The temperature will show clearly on the LCD display.
- To power off, hold down the 'On/Mem' button for approximately 5 seconds, until the LCD screen shows 'off'. The thermometer will automatically shut down after 1 minute if it is not turned off, prolonging the battery life.

FEVER ALARM

If the thermometer detects a body temperature $\geq 37.5^{\circ}$ C (99.5°F), one long beep will sound followed by three short beeps to warn the user of potential fever.

SWITCHING BETWEEN FAHRENHEIT (°F) AND CELSIUS (°C)

- 1. In 'Power off' mode, press and hold the 'Scan' button.
- Then press the 'On/Mem' button for 3 seconds whilst still holding the scan button. The "°C' will
 change to "°F'. You can use the same process to change from "°F' back to "°C'.

MEMORY FUNCTION

1. Press the 'On/Mem' button again to see the last temperature stored.

The thermometer will automatically save the last reading into the memory, if it is within the temperature range of 34°C to 42.2°C (93.2°F to 108.0°F).

CLEANING AND STORAGE

The probe is the most delicate part of the thermometer. When cleaning the lens handle with care to avoid damage. If device is accidentally used without hygiene cover, clean the probe as follows:

- 1. Use a cotton swab (Alcohol 70% concentration) to clean the lens found inside the probe.
- 2. Allow the probe to fully dry for at least 1 minute.

The thermometer should be stored at temperature between -20°C to +50°C.

Keep the unit dry and away from any liquids and out of direct sunlight.

The probe should not be submerged in any liquids.

If the thermometer is used according to the instructions, periodic re-adjustment is not required.

CHANGING THE BATTERY

Keep the battery away from children.

This device is supplied with one lithium cell battery (CR2032).

- Unscrew battery cover.
- 2. Flip the battery out with a small screw driver.
- 3. Insert the new battery under the metal hook on the left side and press the right side of the battery down firmly. See diagram 5.
- 4. Replace the battery cover.



The positive (+) side up and the negative (-) side pointed down.

SPECIFICATIONS

Temperature measurement range: 34-42.2°C (93.2-108°F)
Operating temperature range: 10-40°C (50-104°F), RH≦85%

Storage temperature range: -20-+50°C, RH≤85% Transportation temperature: < than 70°C, RH≤95%,

Atmospheric pressure: 800~1013 hPa

Enclosure Rating: IP22

Dimensions: 149.1 x 42.5 x 54.9 mm

Weight: 79.7 grams including battery

Battery life: around 3,000 readings. Enable normal use: 1 year

Expected Service Life: 4 years

Complies with ASTM E1965-98, EN12470-5:2003 Clinical thermometers-Part 5: Performance of infra-red ear thermometers (with maximum device), IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards.

Accuracy: +/-0.2 °C (0.4 °F) in a temperature range of 35.5-42°C (95.9-107.6°F). Accuracy of +/-0.3 °C (0.5 °F) for other temperature ranges.

This thermometer converts the ear temperature to display its "oral equivalent." (according to the result of the clinical evaluation)

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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 Digital Ear Thermometer is used exceeds the applicable RF compliance level above, the Digital Ear Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Digital Ear 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 - ELECTROMAGNETIC IMMUNITY

The Digital Ear Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Ear Thermometer. 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 | 6 kV contact 8 kV air | 6 kV contact 8 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 %. |
| Electrical fast transient/burst IEC 61000-4-4 | 2 kV for power supply lines 1 kV for input/output lines | applicable that of a typical com | |
| Surge IEC 61000-4-5 | 5 2 kV line(s) to earth applicable that of a typic | | Mains power quality should be that of a typical commercial or hospital environment. |
| interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec | Not applicable | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Digital Ear Thermometer requires continued operation during power mains interruptions, it is recommended that the Digital Ear Thermometer be powered from an uninterruptible power supply or a battery. |
| lower requency 50/60 Hz) nagnetic field EC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

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

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF (RADIO FREQUENCY) COMMUNICATIONS EQUIPMENT AND THE ME EQUIPMENT OR ME SYSTEM

The Digital Ear Thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Digital Ear Thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Digital Ear Thermometer as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|--|--|-------------------|--------------------|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz |
| | $d = 1,2 \sqrt{P}$ | d = 1,2 √P | d = 2,3 √P |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

TROUBLESHOOTING

| ERROR MESSAGE | PROBLEM | SOLUTION |
|------------------|--|---|
| ESS NCC | Device stabilization in process. | Wait until 📝 stops flashing. |
| <u> </u> | Battery is low and no more measurements are possible. | Replace the battery. |
| Er 1 | Measurement before device stabilization. | Wait until 📝 stops flashing. |
| | The device showing a rapid ambient temperature change. | Allow the thermometer to rest in a room for at least 30 minutes at room temperature: 10 °C and 40 °C (50 °F \sim 104 °F). |
| | The ambient temperature is not within the range between 10 °C and 40 °C (50 °F \sim 104 °F). | Allow the thermometer to rest in a room at least 30 minutes at room temperature: 10°C and 40°C ($50^{\circ}\text{F} \sim 104^{\circ}\text{F}$). |
| Er | Error 5~9 , the system is not functioning properly. | Unload the battery, wait for 1 minute and repower it. |
| H | Temperature taken is higher than 42.2 °C (108.0 °F). | Check the integrity of the hygiene cover and take a new temperature measurement. |
| Lo | Temperature taken is lower than 34 °C (93.2 °F). | Make sure the hygiene cover is clean and take a new temperature measurement. |
| [88.8] | Device can not be powered on to the ready stage. | Insert a new battery. |

It is recommended that you measure 3 times in the same ear. If the 3 measurements are different, select the highest temperature.

There is no gender and age limitation for using infrared thermometers.

Clinical repeatability 0.18°C newborn to 1 year old, 0.17°C 1-5years old, 0.15°C 5years+ Holding the thermometer too long may cause a higher ambient temperature reading. This could make the body temperature measurement lower than usual.

This product comes with a 12 month warranty. Manufacture Date: as the serial number (please open the battery cover, it is shown on the inside of the device.) Ex.SN:E912A000001, the first "E" is External, the second number "9" is the manufacture year 2009, the third and the fourth number "12" is the manufacture month, the remaining figures are the serial number.



SYMBOL DESCRIPTIONS

| ((| The CE mark and Notified Body Registration Numbers, the | | Indicates this device is subject to the Waste Electrical and Electronic Equipment Directive in the European | $\overline{\mathbb{A}}$ | Caution | |
|---------|---|---|---|-------------------------|--|--|
| 0120 | requirement of Annex II from Medical Device Directive 93/42/EEC are met. | | Union. To protect the environment, dispose of useless device at appropriate collection sites according to national or local regulations. | 2 | Do not reuse | |
| []i | Please read the instructions for use | | Paper Recycling | *** | Manufacturer | |
| <u></u> | BF type applied part | Z | Battery Recycling | EC REP | Authorized representative in the European community | |
| IP22 | Classification for water ingress and particulate matter. | | | | | |

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

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

| Emissions test | Compliance | Electromagnetic environment – guidance | |
|---|----------------|--|--|
| RF emissions CISPR 11 | Group 1 | The Digital Ear Thermometer uses RF (Radio Frequency) 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. | |
| RF emissions CISPR 11 | Class B | The Digital Ear Thermometer is suitable for use in | |
| Harmonic emissions IEC 61000-3-2 | Not applicable | all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not applicable | supplies buildings used for domestic purposes. | |

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

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

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|---------------|-------------------------|---------------------|--|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Digital Ear Thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Conducted RF | 3 Vrms | Not applicable | Recommended separation distance |
| IEC 61000-4-6 | 150 kHz to 80 MHz | | $d = 1,2 \ \sqrt{P}$ $d = 1,2 \ \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \ \sqrt{P}$ 800 MHz to 2,5 GHz |
| | | | where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). |
| Radiated RF | 3 V/m | 3 V/m | Field strengths from fixed RF transmitters, as |
| IEC 61000-4-3 | 80 MHz to 2,5 GHz | | determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b. |
| | | | Interference may occur in the vicinity of equipment marked with the following symbol: (((•))) |