1. SUMMARY OF INFRARED THERMOMETER

Thank you very much for choosing our infrared thermometer. It is a high-technology medical thermal imager for measuring ear and forehead temperature of human body. As infrared rays emitted from the eardrum and forehead, it will allow you to learn and judge your family's health status quickly and easily. A correct way to use is very important to obtain the precise temperature. To protect the product, be sure to use the product carefully.

• To ensure proper use, please be sure to read this manual carefully, paying attention to the instructions. Please keep the instructions handy for reference.

2. SAFETY PRECAUTIONS

3. INTENDED USE

Except for measurement of ear and forehead temperature, don't use the product for other purposes. It can be useful as an original instrument for well-being check in children and adults.

For the safety reasons, children or the baby's body temperature must be measured by a patient or adult. Child or baby cannot operate the thermometer.

4. TEMPERATURE MEASUREMENT MODE AND RANGE DESCRIPTION

The infrared thermometer has the following measurement modes.

1) Object temperature mode

Object temperature mode allows measuring the skin surface of human body, accurately temperature, as long as the surface temperature can be affected by the environment. The thermometer can be used to use the ear temperature diagnostic tool, and the forehead temperature diagnostic tool.

2) Ear temperature mode

Ear temperature mode uses the measurement of ear temperature. It can be used to measure the ear temperature, in the same ear.

3) Forehead scan mode

The forehead scan mode is used to measure the forehead temperature. The forehead temperature is used as an alternative reference.

NOTE:

The normal temperature and difference of the forehead between different skin types are different. Therefore, it is recommended to use forehead temperature as an alternative reference.

5. FEATURE

5.1 Functional diversity

There is a unique design to take ear/head/object temperature. The ambient temperature and clock display.

5.2 High efficiency

High efficiency means that the product provides the readings in one second.

6. OVERALL DESCRIPTION

Main components:

- LCD display
- Power/Scan button
- Time setting button
- Back cover
- Forehead cap
- Probe
- Base stand

7. OPERATION INSTRUCTION

[Preparation]

Replace the batteries to ensure power supply. If there is low voltage in the thermometer, follow the instructions below.

1. Open the battery cover. It is marked with BATTERY SYMBOL.

2. Replace the battery and be sure to close the battery cover tightly.

3. mode button, the system has self-testing of software and hardware. If there is problem, LCD will display “Error” symbol.

4. In order to make the accurate reading, put the thermometer in the environment for about 1 minute, then press the scan button.

5. If you need to measure ear or forehead temperature, take the forehead probe and put it on the forehead. If necessary, the screen will display “Beep-Beep” and the temperature will be displayed.

6. If you want to measure ear temperature, take the ear temperature probe and put it on the ear. If necessary, the screen will display “Beep-Beep” and the temperature will be displayed.

7. Mode button, the system has self-testing of software and hardware. If there is problem, LCD will display “Error” symbol.

8. In order to make the accurate reading, put the thermometer in the environment for about 1 minute, then press the scan button.

9. If you need to measure ear or forehead temperature, take the forehead probe and put it on the forehead. If necessary, the screen will display “Beep-Beep” and the temperature will be displayed.

10. If you want to measure ear temperature, take the ear temperature probe and put it on the ear. If necessary, the screen will display “Beep-Beep” and the temperature will be displayed.

8. MEASUREMENT RANGE

9. TEMPERATURE TAKING HINTS

【Temperature taking in Ear/ forehead temperature】

When the measured temperature exceeds 38°C (100.4°F), the thermometer will send out “Beep-Beep” sound and display “Fever” icon. If the patient is treated with certain drug therapies, do not use the ear temperature diagnostic tool.

【Temperature taking in Ear temperature】

• The ear temperature must be free from obstruction or excess tear wax build-up to take an accurate reading.

【Temperature taking in Object temperature】

• The probe tip must be clean before use.

【Temperature taking in Ambient temperature】

The ambient temperature is taken as an additional reference.

NOTE:

The screen will display “Beep-Beep” when the temperature exceeds 38°C (100.4°F), and the temperature will be displayed.

【Temperature taking in Clock display】

The clock display is used to display the time and temperature.

NOTE:

The screen will display “Beep-Beep” when the temperature exceeds 38°C (100.4°F), and the temperature will be displayed.

【Temperature taking in Battery level】

The screen will display “Beep-Beep” when the temperature exceeds 38°C (100.4°F), and the temperature will be displayed.

【Temperature taking in Measuring unit】

If the measured temperature exceeds 38°C (100.4°F), the thermometer will send out “Beep-Beep” sound and display “Fever” icon.

【Temperature taking in Ambient temperature】

The ambient temperature is taken as an additional reference.

NOTE:

The screen will display “Beep-Beep” when the temperature exceeds 38°C (100.4°F), and the temperature will be displayed.

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【Temperature taking in Ambient temperature】

The ambient temperature is taken as an additional reference.

NOTE:

The screen will display “Beep-Beep” when the temperature exceeds 38°C (100.4°F), and the temperature will be displayed.
3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to measurement, please contact distributor or manufacturer, the contact information see last page.

1) We do not authorize any institution or individual to maintain and repair of the product. If you have any questions, you may refer to the local authorities responsible for warranty.

 very gently wipe the surface with a cotton swab or soft cloth moistened with alcohol. After the water or the other liquid.

The sensor or hardware is damaged

The probability is higher in the places with a cotton swab or soft cloth moistened with alcohol. After the alcohol has completely dried out.

The lens is damaged, contact the distributor.

1.  When the quantity of electric charge is not sufficient, the icon of low battery will appear on the

2.  When the quantity of electric charge of the battery is lower than

3.  Take out the old battery: open the battery cap (Refer to the Picture 9.3).

4.  Take out the new battery on by cut CR2032. Return the cap of operation (Refer to the Picture 34).

5.  The probe tip and lens are the most delicate part of the thermometer. It has to be clean and intact to assure the accuracy of figure.

Notice:

Please observe the related national laws of disposing the abandoned battery and don’t allow the garbage can.

Please take out the battery of the device is not used for long periods of time.

Please don’t put the battery in the fire.

To prevent the environment, dispose of empty battery at your retail or at appropriate collection sites according to national or local regulations.

9. MAINTENANCE

1) We do not acknowledge any instruction on maintenance and repair of the product. If you suspect that the products have any questions, please contact the manufacturer or distributor.

2) The user must not attempt any repairs to the device or any of its accessories. Please contact the manufacturer or distributor.

3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

WARNING: No modification of this equipment is allowed.

10. CALIBRATION

The thermometer is initially sealed at the time of manufacture. If this thermometer used according to the use instruction, periodic calibration is recommended. If any time you question the accuracy of measurement, please contact distributor or manufacturer, the contact information see last page.

11. STORAGE

1) Don’t put the thermometer under the sunshine, high temperature and moist environment or someplace which may get into the touch by water or vulnerable to vibration.

2) Take out the battery if the device is not used for a long time.

12. ACCESSORIES

Only use original accessories. Check if the contents of the delivery are complete.

13. TROUBLE-SHOOTING

Symptom

Cause

Solution

No response

Automatic reset

Battery depletion

Deplete the battery.

Accumulator contact

Deplete the battery.

Battery in reincorporation

Deplete the battery.

Battery contact

Deplete the battery.

0.00°C or 0.00°F readings

Deplete the battery.

15. STANDARD LIST

Pediatric Technologist Co, Ltd declares that the FDIR-V1 device is compliant with following applicable standards:

1) CE-0001-1.2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Conformity Assessment - Requirements and tests

2) CE-0001-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Conformity Assessment - Requirements and tests

3) ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes

4) AS/NZS 1705:1999 Standard Spurgeon for Infrared Thermometer for Determination of Patient Temperature

16. DISPOSAL

Disposal of the device and warranty method please see the instruction to dispose to proceed.

- Take out the battery if you are not going to use the unit for a long time.

- Return the battery to the distributor according to national or local regulations.

- Dispose of the device and battery in accordance with the regulation applicable at the place of operation.

- Dispose of the device and battery in accordance with the locally applicable regulation, not with domestic waste.

- The FDIR-V1 device is intended for use in the electromagnetic environment specified below.

- The FDIR-V1 device is intended for use in the electromagnetic environment specified below.

The above specifications are subject to change without prior notice.

EN 1041 Information supplied by the manufacturer with medical devices

EN 1638-1 Medical electrical equipment – Part 1-1: General requirements for basic safety and essential performance

EN 50470 Magnetic field strength disturbances due to mobile radio telephone equipment and systems – Part 1: Limits

EN 1705:1999 ISO 1705:1999

17. NORMALIZED SYMBOLS

18. Electromagnetic Compatibility (EMC) Tables

Guidance and manufacturer's declaration — electromagnetic emission

The FDIR-V1 device is intended for use in the electromagnetic environment specified below.

The FDIR-V1 device is intended for use in the electromagnetic environment specified below.

The device designed for EMR energy only for its intended function, without RF energy being applied to any other equipment nearby or within the same unit.

The FDIR-V1 device is intended for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that applies buildings used for domestic purposes.

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Guidance and manufacturer's declaration — electromagnetic immunity

The FDIR-V1 device is intended for use in the electromagnetic environment specified below.

The FDIR-V1 device is intended for use in the electromagnetic environment specified below.

The above specifications are subject to change without prior notice.

Note: ASTM laboratory accuracy requirements in the display range of 36 to 39°C (96.8 to 102.2°F)

*The above specifications are subject to change without prior notice.

ISO 15223-1 Medical device – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

EN 1041 Information supplied by the manufacturer with medical devices

EN 1638-1 Medical electrical equipment – Part 1-1: General requirements for basic safety and essential performance

EN 50470 Magnetic field strength disturbances due to mobile radio telephone equipment and systems – Part 1: Limits

EN 1705:1999 ISO 1705:1999

19. Software Version

The thermometer's software version is v1.0.

20. WARRANTY

1. The warranty period for device is one year from date of delivery. In case of a warranty claim, the device shall be returned, accompanied by the proof of the sales receipt or invoice.

2. Repairs under warranty do not extend the warranty period.

3. The following are excluded under the warranty:

- All damage which has arisen due to improper treatment, e.g. noncompliance of the user instructions.

- All damage which is due to repairs or tampering by the customer or an unauthorized third party.

- All damage which is due to transportation or mishandling by the manufacturer or the consumer during or to transport to the service center.

- Accessories which are not part of the equipment delivered.

- Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

For object temperature: ±1.0°C/ 1.8°F  within 15-60°C(59.0°F-140.0°F);

± 0.3°C/0.5°F  for other ranges

For human body temperature:

±8kV air

±8kV air

±8kV air

±8kV air

±8kV air

±1.0°C/ 1.8°F  within 15-60°C(59.0°F-140.0°F);

± 0.3°C/0.5°F  for other ranges

Confirmed separation distances between portable and mobile RF communications equipment and antennas as shown in the following symbol:

Information: Famidoc Technology Co., Ltd.

www.SimpleDiagnostics.com

PO Box 128
Williston Park, NY 11596 USA

Tel: 631-924-2490

Outside USA: Tel 1-954-663-0372

www.SimpleDiagnostics.com

www.SimpleDiagnostics.com

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