

WF-4000

Medical digital infrared thermometer



EN Instructions for Use

1. INTRODUCTION

Thank you for choosing the contact-free infrared thermometer WF-4000. The medical digital infrared thermometer WF-4000 is intended for contact-free measurements of the temperature of body, air and objects.

- 3-in-1 thermometer – measurement of the temperature of a human body, ambient air and of the surface temperature of objects.
2. Instant measuring
3. Memory recall of 32 saved readings.
4. Sound signals can be turned off.
5. Elevated temperature warning
6. Switch function °C/°F (Celsius/Fahrenheit scale)
7. Automatic shut-off
8. Large LCD display
9. Compliance with hygiene standards.
10. Comfortable and easy to use.

2. HIGH TEMPERATURE

High temperature is a symptom, not a disease. As a rule, this means that your organism is fighting an infection. In fact, this is a defense reaction of our body, which is characterized by an increase in body temperature above 37°C, heart rate and breathing.

The temperature of a healthy person is influenced by the following factors:

- Metabolic individual characteristics
Age (body temperature is higher in infants and young children, and it decreases with age; more significant temperature fluctuations occur faster and more often in children)
Clothes
Ambient temperature
Time of day (in the morning body temperature is lower, and by the end of the day it becomes higher)
Prior physical activity
Method of measurement
Phase of the menstrual cycle
Skin secretions or sweat on the forehead (when temperature measuring on the forehead)

Remember that the thermometer shall be kept in the room where temperature will be measured for at least half an hour, otherwise a measurement result may be inaccurate.

Table with 2 columns: METHOD OF MEASUREMENT and REFERENCE TEMPERATURE VALUES. Rows include Axillary, Orally, and Intrarectally.

3. PRECAUTIONS

- When using this device, please follow all the specified instructions.
1. Before measurement, patients and the thermometer should be in the environment with a constant room temperature for at least 30 minutes.
2. Take a measurement no earlier than 30 minutes after exercising, bathing or being outdoors.
3. Make sure that the forehead is clean and there are no traces of sweat, cosmetics, cream, etc.
4. When measure somebody continuously, the temperature should be measured every minute.
5. Please collect the record of Individual temperature under the good condition of body in usual days as a reference for checking fever or not.
6. Avoid direct contact of fingers with the measuring sensor.
7. The temperature of a human body is constantly changing and depends on various factors.
8. Use the thermometer only for its intended purpose.
9. Using this thermometer is not intended as a substitute for consultation with your physician.
10. To protect the environment, dispose the used batteries in accordance with national or local regulations.

CONTRAINDICATIONS: none found

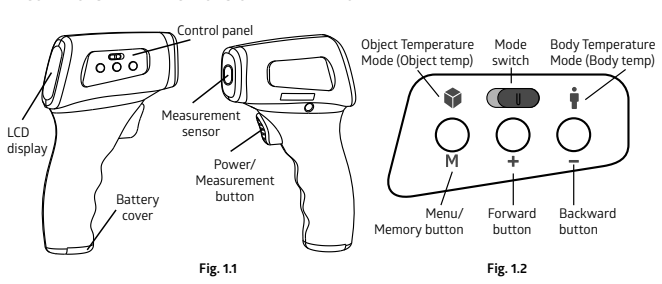
PRECAUTIONS:

- Keep the thermometer out of reach of children, please consult the doctor at once if the children accidental swallow of battery or other component.
The thermometer shall only be used under the supervision of adults.
Do not repair or modify the device, except for the case of battery replacement.
Any modification of the thermometer is not allowed.
Do not use the thermometer in a high humidity environment (above 85%) or in direct sunlight, and to measure very high temperature (above 42°C in the Forehead Temperature Measurement Mode, above 110°C in the Object Temperature Measurement Mode).
Avoid storing the device in damp places, at elevated temperatures, and in direct sunlight.
Avoid strong shaking or dropping of the device.
Don't throw the battery into fire.
Use the thermometer only for its intended purpose.
Do not measure the site of forehead temperature if patient has trauma on forehead.
Do not measure if patient is treated with certain drug therapies because body temperature may increase in the drug within the effort time limit.
Do not use a mobile or cordless phone near the thermometer when measuring.
Please don't measure body temperature in strong electromagnetic interference environment (such as microwave, high frequency equipment operation environment) to ensure the accuracy of measurement data.
This thermometer only a personal device, please do not share with others. Clean the appliance as described in the user manual before using it by other users.
Do not touch the battery output when measuring.
Please store the thermometer according to the technical specifications.
The materials (ABS) of expect contact with patient has passed the ISO 10993-5 and ISO 10993-10 standard test, no toxicity, allergy and irritation reaction. They are compliant with the MDD requirements based on the current science and technology, and other potential allergic reactions are unknown.
The patent is an intended operation. The patient can measure, read data and replace battery under normal circumstances and maintain the device and its accessories according to the user manual.

RECOMMENDATIONS

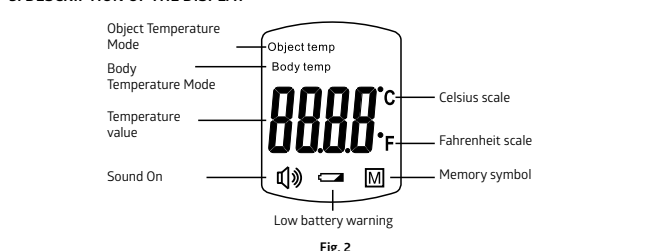
- 1) Don't use this thermometer for other purposes.
2) It is forbidden to leave the product exposed to any chemical solvent, direct sunshine or high temperature in case of damaging the product or the battery
3) Do not measure while talking on the phone.
4) Please report to MANUFACTURER if any unexpected operation or events occurs.

4. CONTROLS AND INDICATORS OF THE THERMOMETER



Buttons table with 2 columns: Buttons and Description. Rows include Mode switch, Menu/Memory button, Forward button, Backward button.

5. DESCRIPTION OF THE DISPLAY



6. INSTALLATION AND REPLACEMENT OF BATTERIES

- Low battery warning: When the battery symbol appears on the screen...
Battery replacement: 1. Slide the battery cover carefully (Fig. 3). 2. Carefully remove old batteries and dispose them properly. 3. Insert new batteries (two 1.5 V AA batteries) observing polarity. 4. Slide the battery cover back.

NOTE: Keep batteries out of reach of children and away from heat sources. It is recommended to remove batteries if the device will not be used for a long time.

7. TEMPERATURE MEASUREMENT

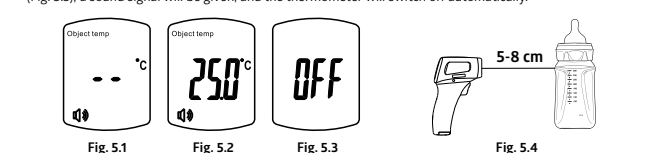
7.1 Body temperature measurement:

- 1. Press the Power/Measurement button to switch on the thermometer.
2. After switching on, the device immediately starts automatic testing with all screen elements displayed, and then operational readiness is displayed (Fig. 4.1).
3. Make sure the device is in the Body Temperature Mode (Body temp) as shown in the figure. If necessary, switch the mode.
4. Point the front end of the thermometer at the forehead. Keep the thermometer about 5-8 cm away from the forehead (Fig. 4.4).
5. After measurement, if the thermometer is not used for 10 seconds, OFF (i. e. switched off) will be displayed (Fig. 4.3), a sound signal will be given, and the thermometer will switch off automatically.



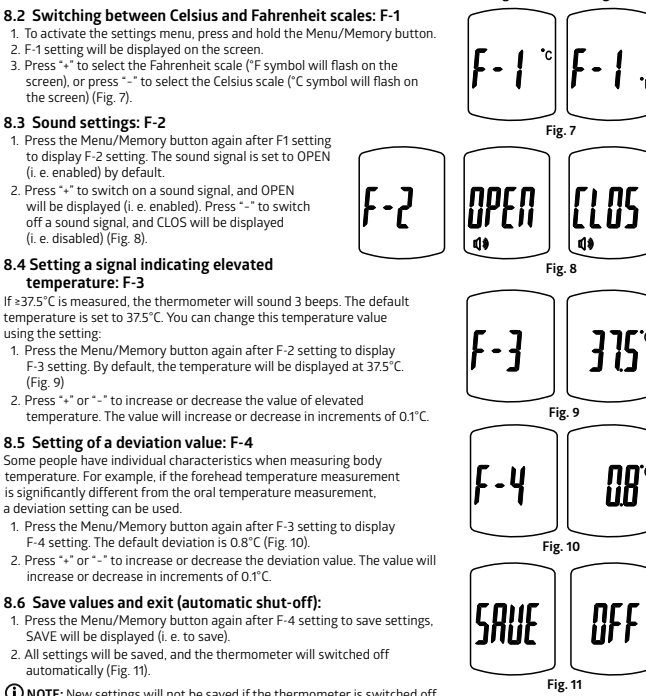
7.2 Measuring the temperature of water, air and surface of objects:

- 1. Press the Power/Measurement button to switch on the thermometer.
2. After switching on, the device immediately starts automatic testing with all screen elements displayed, and then operational readiness is displayed (Fig. 5.1).
3. Make sure the device is in the Object Temperature Mode (Object temp) as shown in the figure. If necessary, switch the mode.
4. Point the front end of the thermometer at a point in space, surface of water or at an object. Bring the thermometer to an object at a distance about 5 to 8 cm (Fig. 5.4).
5. After measurement, if the thermometer is not used for 10 seconds, OFF (i. e. switched off) will be displayed (Fig. 5.3), a sound signal will be given, and the thermometer will switch off automatically.



8. USE OF SETUP FUNCTIONS:

- By activating the settings menu, users can select certain functions (F1/F2/F3/F4) and configure them as required.
8.1 Switching between Body and Object Temperature Measurement Modes:
8.2 Switching between Celsius and Fahrenheit scales: F-1
8.3 Sound settings: F-2
8.4 Setting a signal indicating elevated temperature: F-3
8.5 Setting of a deviation value: F-4
8.6 Save values and exit (automatic shut-off):



NOTE: New settings will not be saved if the thermometer is switched off during the setup procedure.

After the settings menu activation, the thermometer cannot measure temperature. When the Power/Measurement button is pressed, the thermometer will not switch to measurement mode.

9. MEMORY FEATURE

Recall memory: You can recall 32 previously recorded measurements to show them to your doctor or a qualified health care professional.

- 1. When the device is on, press the Menu/Memory button. The Memory button will display the previously recorded measurement, which will be accompanied by displaying the "M" symbol.
2. Press "*" or "-" to scroll 32 previously recorded measurement results.
3. Press the Power/Measurement button to exit the Memory Function and change to the Temperature Measurement Mode.

10. TROUBLESHOOTING

Troubleshooting table with 3 columns: Cause, Solution to the problem. Rows include 'Body temp Lo', 'Body temp Hi', and 'Err'.

11. CARE AND MAINTENANCE

- Measurement sensor: Carefully clean with an alcohol-soaked swab. Do not use water for cleaning the lens.
Thermometer housing: Clean with a soft dry cloth. Do not use water for cleaning the device.

12. SPECIFICATIONS AND PACKAGE CONTENTS

Specifications table with 2 columns: Item and Value. Rows include Dimensions, Weight, Temperature range, Measurement accuracy, Resolution, Operation conditions, Storage temperature, Memory capacity, and Battery.

PACKAGE CONTENTS

- Medical digital infrared thermometer;
Batteries: 1.5 V AA batteries (2 pcs.);
Case bag;
Instructions for Use.

13. STANDARD COMPLIANCE

- ISO 15223-1: Symbols for use in the labeling of medical devices.
EN 1041: Information supplied by the manufacturer with medical devices.
EN 60601-1: Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility-Requirements and tests.
EN 60601-1-6: Medical electrical equipment - Part 6: General requirements for basic safety and essential performance - Collateral standard: Usability.
EN 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 home healthcare environment.
ISO 12470-5: Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device).
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.
EN 62304: Medical device software - Software life-cycle processes.
EN 62366: Medical devices - Application of usability engineering to medical devices.
EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

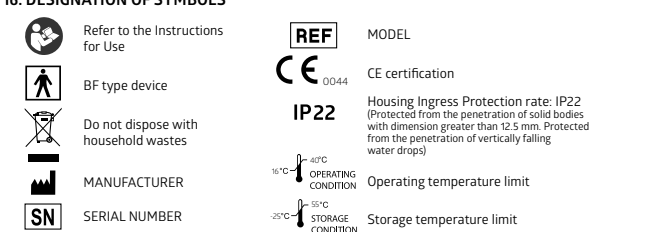
14. STORAGE

- Storage temperature: -25°C to 55°C (-13°F to 131°F).
Relative humidity should not exceed 85%.
Protect the thermometer against falls and bumps.
Protect the thermometer against direct sunlight.

15. DISPOSAL

The device shall be disposed in accordance with the accepted regulations and shall not be disposed with household wastes.

16. DESIGNATION OF SYMBOLS



17. WARRANTY

Warranty period is 2 years from the date of purchase. This warranty doesn't cover any damages caused by improper using, and also battery, protective cover and packaging. When a manufacturing defect is revealed during the warranty period a faulty unit would be repaired or, if repairing is impossible, replaced with another one. The manufacturer may change units partially or completely if necessary, without prior notice.

The date of manufacture of the device is specified in the serial number indicated on the device. The first two digits indicate the year, and the following two digits indicate the month of production.

18. EMC DECLARATION

- 1. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the Infrared Thermometer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
3. 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 Infrared Thermometer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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ELECTROMAGNETIC COMPATIBILITY INFORMATION

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

EMC emission table with 3 columns: Immunity test, IEC 60601 test level, Compliance level. Rows include Emissions test, RF emissions, RF emissions CISPR 11, Harmonic emissions, Voltage fluctuations, flicker emissions.

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT AND SYSTEMS

EMC immunity table with 4 columns: Immunity test, IEC 60601 test level, Compliance level, Electromagnetic environment – guidance. Rows include Electrostatic discharge (ESD), Electrostatic transient / burst, Surge, Voltage dips, short interruptions and voltage variations on power supply input lines, Power frequency (50/60 Hz), Magnetic field.

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT AND SYSTEM

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

EMC immunity table with 4 columns: Immunity test, IEC 60601 test level, Compliance level, Electromagnetic environment – guidance. Rows include Conducted RF, Radiated RF.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

- a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.795 MHz to 6.795 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, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
b. Field strengths from fixed transmitters, such as base stations (for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Infrared thermometer is used exceeds the applicable RF compliance level above, the Infrared thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Infrared thermometer.
c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3kV/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT AND SYSTEMS

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

Table with 4 columns: Rated maximum output of transmitter, Separation distance according to frequency of transmitter, 150 kHz to 80 MHz outside ISM and amateur radio bands, 150 kHz to 80 MHz in ISM and amateur radio bands, 80 MHz to 800 MHz, 800 MHz to 2.7 GHz.

For transmitters rated at a maximum output power not listed above the recommended separation distance in metres (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.