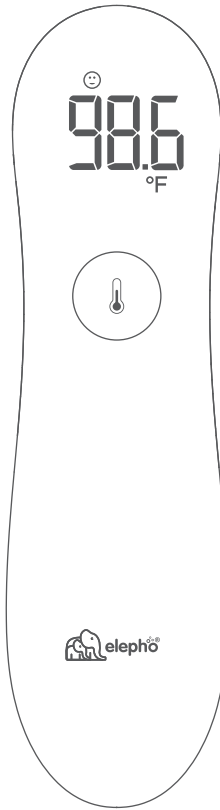


## User Manual



### Product introduction:

Thank you for selecting and purchasing an eTherm thermometer. This high-tech infrared thermometer is used to measure human body temperature by absorbing infrared (IR) energy from a person's forehead or from within the ear. Product/model name: eTherm Infrared Thermometer. Item/Device #: FDIR-V4 User manual version: V1.0

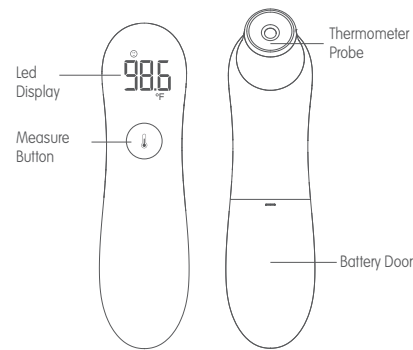
### Package Contents:

Open the package to make sure that everything is there.

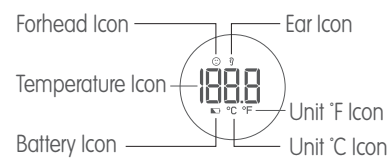
Quantity	Part
1	eTherm Thermometer Device
1	User Manual
1	Quick User Guide
2	AAA Battery

### Product Components:

The eTherm thermometer consists of a plastic outer shell, an infrared temperature sensor module and probe, audio module, LED display and battery. Product front and back views are shown below:



### LCD Display Description



### Intended Use and Application:

The eTherm uses infrared temperature measurement methodology to measure the temperature of the forehead or the ear canal and can be used for babies, children and adults.

This product MUST be operated, and its use supervised, by an adult when taking temperature measurements of babies and children.

### Contraindications: Where This Product Should NOT Be Used

Do not use the eTherm to measure the temperature of an inflammation, trauma or postoperative lesions, such as a region in an organ or tissue which has suffered damage

through injury or disease, including wounds, ulcers, abscesses, or tumors.

### Regarding eTherm Measurements:

Please note the following when you take measurements with your eTherm.

1. This product is intended for personal use only.
2. In order to avoid cross contamination, always clean the thermometer probe with an alcohol cleaning pad, or equivalent, and use a commercially available protective sleeve when measuring temperature via the ear canal.
3. Measurement results are for reference only. They are not intended for self diagnosis or treatment. Consult your doctor or a medical professional before taking action.
4. There is no one standard temperature of a human body. It is important to know your normal average body temperature so you can assess whether or not you have a fever.
5. Before measuring forehead temperature, make sure you have cleaned perspiration, cosmetics and any oil deposits from the skin.
6. Before measuring ear temperature, make sure there is no wax in the ear canal which can affect the accuracy of the temperature reading.
7. When taking repeated measurements, it is a normal phenomenon to see small deviations. We therefore recommended that you measure body temperature three times and then take the average of the readings for the most accurate result.

8. For accurate readings DO NOT take body temperature measurements within 30 minutes of showering, exercising, or eating, since these activities can affect your core body temperature. Body temperature measurements are more accurate during a state of rest.

9. DO NOT measure body temperature near an inflammation or scar tissue, since this may affect the accuracy of the reading.

10. DO NOT measure the body temperature immediately after taking medicine, since this may affect the accuracy of the reading.

11. DO NOT measure body temperature in an environment where the ambient (air) temperature changes rapidly, such as near an air conditioner or heater, since this may affect the accuracy of the reading.

12. DO NOT measure body temperature in an environment with strong electromagnetic interference, such as near a working microwave oven, induction cooker, or active mobile phone, since this may affect the accuracy of the reading.

### While Using your eTherm:

1. This product is a precision measurement device. Replace and store in a secure and dry environment after use to avoid contact with liquids or pieces of small foreign materials, such

as dust, dirt etc.

2. Avoid dropping the device since this will cause damage to the measurement probe and will affect the accuracy of the reading.

3. Avoid any impact by any external force on the product.

4. Avoid direct contact of the temperature probe with your fingers or excessive blowing from your mouth.

5. If the internal infrared probe is covered, damaged, or is not clean, this could affect the accuracy of the reading.

6. Keep this product out of the reach of babies and children to prevent loss of parts or any risk of swallowing parts or batteries.

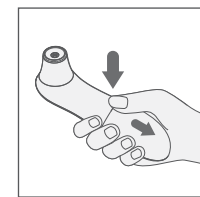
7. Remove the batteries from the battery compartment if the thermometer is not to be used for more than three months.

8. The product should NOT be used for self-diagnosis and/or self-treatment based on readings obtained. Always consult your medical professional for recommended treatment.

9. DO NOT try to disassemble and reassemble the product: this will void the warranty and may affect the accuracy of the reading.

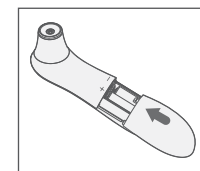
10. DO NOT place the thermometer or batteries into a fire to prevent a potential explosion.

### Getting Started:



1. Remove the eTherm thermometer from the packaging.

2. Gently **press** the battery door and slide it downwards to open it.



3. Position the two batteries provided in the packaging in the battery housing; taking care to insert them according to the polarity symbols engraved in the plastic casing to ensure correct placement.

4. Replace the battery door.

The eTherm automatically begins a self-test, after which it is ready for use. If the battery power indicates a low reading during start-up, replace the battery to ensure adequate power supply for continued use.

### Measurement Process: Switching Measurement Modes

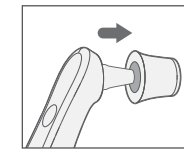


This device detects the measurement mode (forehead or ear) automatically. If the temperature cap is on the device the forehead measurement mode is active.

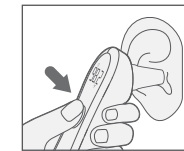


When the temperature cap is removed from the device the measuring mode is automatically set to ear mode.

### For Ear Temperature Measurement

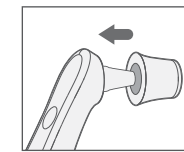


Remove the thermometer cap. The display indicates that the thermometer is in ear measurement mode.

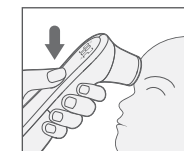


Place the thermometer probe gently into the ear canal with minimum pressure to ensure that it sits firmly and feels comfortable

### For Forehead Temperature Measurement



Place the thermometer cap on the device. The display indicates that the thermometer is in forehead measurement mode.



Position the thermometer probe at the center of the forehead with light skin contact.

### To take a temperature measurement (in either modes)

When the device is in position lightly **press** and **release** the Measure Button. The eTherm beeps when the measurement is completed. Remove the device and read the measurement result.

### Beeper (audio) Sounds

If the measurement result is between 89.6°F - 99.3°F (32.0°C - 37.4°C) the thermometer beeps once. If the measurement result is 99.5°F (37.5°C) or above, the infrared thermometer beeps twice, indicating an above-normal temperature. If the measurement result is 101.5°F (38.6°C) or above, the infrared thermometer beeps four times, indicating an elevated temperature. Please refer to table below as reference.

Temperature Range	Temperature Range
89.6°F - 99.3°F (32.0°C - 37.4°C)	Single beep
99.5°F - 101.3°F (37.5°C - 38.5°C)	Double beep (x2)
101.5°F - 109.2°F (38.6°C - 42.9°C)	Quadruple beep (x4)

### Power Off: Auto-off Battery Saving Mode

If the device is not in use for eight seconds the device automatically powers off to save battery life. There is no need to manually turn the

device off after use.

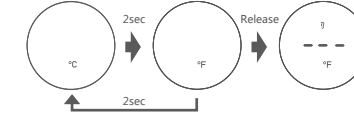
### Temperature Unit Selection:

The eTherm can be set to display temperature readings in either Celsius or Fahrenheit units. To change the temperature unit system:

1. Turn off the device.
2. **Press** and hold the Measure Button for eight seconds. The measurement system (C or F) automatically appears on the display.



3. Keep pressing the measuring button; the measuring units will automatically switch from C to F or from F to C. The desired measuring units are now set on the device.



### What You Should Know about Body Temperature

The temperature of the human body varies between individuals and depending on environment and physical activity levels the temperature of individuals may also vary from time to time. The following table indicates a general normative temperature range which should be read for reference only.

Armpit	94.5°F - 99.1°F	34.7°C - 37.3°C
Oral	95.9°F - 99.5°F	35.5°C - 37.5°C
Anus	97.9°F - 100.4°F	36.6°C - 38.0°C
Ear	95.9°F - 100°F	35.5°C - 37.8°C

Note: The temperature ranges above are for reference only and are NOT definitive for all individuals. Always consult your medical professional regarding your temperature measurements rather than rely on self diagnosis and self administrated treatment.

### Calibration:

The thermometer is calibrated in the factory at the time of manufacture. The product service life is typically two years from first use, after which product accuracy is not guaranteed. Please refer to the warranty policy.

### Cleaning the Device:

The thermometer probe is the most delicate part of the device. It must be kept clean and intact to ensure accurate readings. In order to clean the probe, please follow the below recommendations:

· Wipe the surface of the probe gently with 75% isopropyl alcohol using cotton bud or an equivalent soft cloth.

· Use a dry soft cloth to clean the screen (display) and thermometer casing. If the thermometer casing needs cleaning wipe it with 75% isopropyl alcohol on a soft cloth.

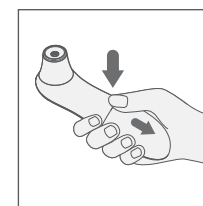
· The device is NOT water-proof. DO NOT immerse it in water or use detergents or cleansing liquids. Any water damage will void the product warranty.

· If the thermometer probe is damaged during cleaning the unit will not function correctly. Only the manufacturer is authorized to dismantle or repair the thermometer probe and any unauthorized dismantling of the thermometer probe, product modules or part of it will automatically void the warranty.

### Battery Replacement:

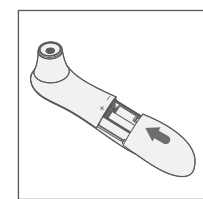
When the eTherm is powered on it automatically detects the battery power level. If the battery power is low but still sufficient to obtain a reading, the low power symbol (Lo) appears on the screen along with the measurement result. However, when the battery power is critically low, the low power symbol (Lo) flashes continuously on the screen, and measurements cannot be taken. After eight seconds the device automatically shuts down to maintain minimum battery power.

To continue using the device replace the batteries as follows.



1. Gently **press** the battery door and slide it downwards to open it.

2. Remove the old batteries and dispose of them according to local regulations.



3. Insert two new AAA batteries in the battery housing, taking care to insert them according to the polarity symbols engraved in the plastic casing to ensure correct placement.

4. Replace the battery door.

Note: Please follow local regulations regarding the disposing of the batteries. DO NOT discard old batteries in an open fire.

Remove the batteries from the battery compartment if the thermometer is not to be used for more than three months.









Please read the guide carefully before use and keep it well.

For American please refer to "°F"

For European please refer to "°C"

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## Troubleshooting:

Problem or error message	Checklists	Solution
No response	The batteries are dead?	Replace batteries with new ones.
	The batteries type are wrong or reversed polarity?	Remove the batteries and adjust them correctly.
 	Poor battery connection?	Refer to the user manual and measure the temperature again.
	Temperature is measured beyond temperature range from 89.6°F - 109.2°F (32.0°C - 42.9°C).	Refer to the user manual and measure the temperature again.
	Lo: means that the temperature measured is too low Hi: means that the temperature measured is too high	Keep the thermometer in the environment where the temperature is between 50°F - 104°F (10°C - 40°C) for 30 minutes.
	The ambient temperature is beyond the operating range of 50°F - 104°F (10°C - 40°C)	Please replace the battery in time not to disturb usage.
	Battery is running low	Must replace new battery to continue usage.
	The battery is almost dead and can not be used anymore.	Please contact distributor for support
	Battery is almost dead and can not be used anymore.	
	Hardware damage	

If you are concerned that the device might not be functioning correctly, do not attempt to repair the thermometer yourself.

The thermometer is a very precise product. Any improper or unauthorized repair or disassembly will cause inaccuracy of the measurements and will VOID the product warranty.









Please contact point of purchase support for any product issues within the warranty period.

## Product Specifications:


<b>Item/Device #:</b> FDIR-V4	<b>Product/model name:</b> eTherm
<b>Power Supply:</b> DC 3V, 2*1.5V AAA batteries	
<b>Measurement Range:</b> 89.6°F - 109.0°F (32.0°C - 42.9°C)	
<b>Measurement Accuracy:</b> Within measurement range: 95.0°F - 107.6°F : +/- 0.4°F (35.0°C - 42.0°C : +/- 0.2°C) Outside this range: +/- 0.5°F (+/-0.3°C)	
<b>Display Resolution:</b> 0.1°C /0.1°F	

<b>Clinical Repeatability:</b> Within +/- 0.5°F/0.3°C
<b>Measurement Position:</b> Ear canal or forehead
<b>Reference Position:</b> Oral cavity
<b>Operating Conditions:</b> Temperature: 50.0°F -104.0°F (10.0°C - 40.0°C) Humidity: 30-85% RH Atmospheric pressure: 70 kPa - 106 kPa
<b>Transport/Storage Condition:</b> Temperature: -13.0°F to 131.0°F (-25.0°C to 55.0°C) Humidity: <95% Atmospheric pressure: 70 kPa - 106 kPa
<b>Battery Life:</b> Approximately two years or 1000 measurements
<b>Product Size:</b> 138 mm*38 mm*44 mm
<b>Product Weight:</b> 90 g
<b>Product Service Life:</b> Two years
<b>Warranty:</b> One year
<b>Software Version:</b> V1.0 (firmware)

## Standard Symbols:

	Attention: See instructions for use!
	Caution! Consult accompanying documents
	Type BF applied parts
	Batch code
	Serial number
	Complies with the European Medical Device Directive (93/42/EEC), Notified Body is SGS United Kingdom Ltd.
	IP code of the device: this device's grade of against ingress of solid foreign objects
	Disposal in accordance with Directive 2002/96/ EC (WEEE)

## Regulatory Information:

Conducted RF IEC61000-4-6 Radiated RF IEC 61000-4-3
3V rms 150 kHz to 80 MHz 3V rms 3V/m 3V/m 80 MHz to 2.5 GHz ±
6kV contact ±8k Vair
Portable and mobile RF communications equipment should be used no closer to any part of the FDIR-V4 device than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  d=1.2 √P d=1.2 √P 80 MHz to 800 MHz d=2.4 √P 800MHz to 2,5MHz
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).  Field strengths from fixed RF transmitters, as 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: 

## Electromagnetic Compatibility Information

### Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The FDIR-V4 device is intended for use in the electromagnetic environment specified below. The customer or the user of the FDIR-V4 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF emissions CISPR11	Group 1	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.

RF emissions CISPR11	Class B	The FDIR-V4 device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings Used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC61000-3-3	Not applicable	

### Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The FDIR-V4 device is intended for use in the electromagnetic environment specified below. The customer or the user of the FDIR-V4 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air

Note 1: At 80 MHz end 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 FDIR-V4 device is used exceeds the applicable RF compliance level above, the should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FDIR-V4.

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

## Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the FDIR-V4 Device

FDIR-V4 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FDIR-V4 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FDIR-V4 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of separation distance according to frequency of transmitter m transmitter W

Electrostatic Discharge (ESD) IEC61000-4-2	150 kHz to 80 MHz	80MHz to 800 MHz	800M Hz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	7.8	7.8	3.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, 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) accordable 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.

## FDIR-V4 Standards

FDIR-V4 complies with the following standards.

<b>IEC 60601-1-2</b> Collateral standard: Electromagnetic compatibility requirements and tests and essential performance
<b>EN 12470-5</b> Clinical thermometers – Part 5: Performance of infra-red ear thermometers (with maximum device)
<b>ASTM E 1965</b> Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature
<b>IEC 62304</b> Medical device software - Software life- cycle processes
<b>IEC 62366</b> Medical devices — Application of usability engineering to medical devices IEC 62366:2007
<b>ISO 80601-2-562-56</b> Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
<b>ISO 10993-1</b> Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process
<b>EN ISO 15223-1</b> Medical device –symbols to be used with medical device labels, labeling and information to be supplied – Part 1; General requirements
<b>EN 1041</b> Information supplied by the manufacturer with medical devices
<b>IEC 60601-1</b> Medical electrical equipment Part 1: General requirements for basic safety and essential performance Medical electrical equipment – Part 1-11
<b>IEC 60601-1-11</b> General requirements for basicw safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
<b>IP22</b> Medical electrical equipment -- Part 1-2: General requirements for basic safety services. IP code of the device: this device's grade of against ingress of solid foreign objects

## Warranty

The warranty period for device is one year from date of delivery. In case of a warranty claim, the date of delivery has to be proven by means of the sales receipt or invoice.

Repairs under warranty do not extend after the warranty period.

The following cases are excluded under the warranty:

- All damage due to improper treatment, e.g. failure to follow the user guide.
- All damage due to repair or tampering by the customer or unauthorized third parties.
- Damage incurred during transport from the manufacturer to the consumer or during transport to the service center.
- Accessories that are subject to normal wear and tear.
- Battery replacement is not covered under the warranty.

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.

**Contact your point of sales representatives and include your product purchase receipt as evidence for service support during the warranty period.**

On-line product support at:  
[www.elepho.com/help-support/](http://www.elepho.com/help-support/)

E-mail support via:  
[customercare@elepho.com](mailto:customercare@elepho.com)

Telephone support via Elepho Consumer Relations at: **1-833-435-3746 (1-833-4-ELEPHO)**

General information regarding Elepho full product line via: [www.elepho.com](http://www.elepho.com)



**Manufactured for: Elepho Inc, 466 Central Ave (2nd floor), Cedarhurst, New York 1 516. USA**

**Website: [www.elepho.com](http://www.elepho.com)**

**Item/Device #: FDIR-V4;**  
**Product/model name: eTherm**

This product design is protected and registered under the EUIPO patent and trademark office