

Tempa Check

4-in-1 Infrared Thermometer



Model: FDIR-V1 Ver. 2.0

User's Manual

1. SUMMARY OF INFRARED THERMOMETER

Thank you very much for choosing our Infrared thermometer. It is a medical quality thermometer for measuring the eardrum and forehead temperature of human body via infrared rays emitted from the eardrum and skin surface. A proper way to measure is very important to obtain precise readings. TO ENSURE PROPER USE, PLEASE BE SURE TO READ THIS USER MANUAL CAREFULLY.

• Please keep these instructions for future reference.

2. SAFETY PRECAUTIONS

WARNING
Conducting self-diagnosis and/ or treatment based on this thermometer's results can be dangerous. Consult your physician for instructions. Do not self-diagnose.
If the infrared sensor becomes dirty, lightly wipe it with a soft dry cloth. If you wipe it with tissue paper or a paper towel, the infrared sensor will be damaged and may measure incorrectly.
Persons who have swimmer's ear (External Otitis) or middle ear infection (Otitis Media or other ear infections or diseases should not use this product to measure ear temperature
Do not touch the infrared sensor with finger or breathe on it. The infrared sensor may become dirty and correct measurement may not be possible.
Store the unit out of children's reach. Children may try to use thermometer by themselves and cause damage to the ear. If a child accidentally swallows a battery or other component, immediately consult the doctor.
If there is a difference in temperature between the place where the unit is stored and the place where you are going to measure, leave the unit in the room where you are going to use for thirty (30) minutes, then measure.
Don't throw the battery into fire this may cause an explosion.

NOTICE
Do not forcibly insert the probe in the ear. If you feel pain during measurement, stop using the unit, It may injure the external auditory canal.
Do not measure when the measured sites are exposed to cold or heat for a long time. If you are under these cases, please leave the room and wait 30 minutes until site temperature has come to room temperature to measure.
Do not use the unit when the external auditory canal is wet such as after swimming or a bath.
When you inform the doctor of your temperature, make sure to tell him/ her where you took the measurement.
Do not measure the sites of scarred tissue or tissue compromised by skin disorders.
Do not measure the site of forehead temperature if that patients has trauma on forehead.
Do not strike, drop, step on, or shake the main unit.
Do not use a portable phone near the unit.
Do not disassemble, repair, or modify the unit.
Do not measure for 30 minutes after exercising, eating or bathing.
Improper maintenance may cause the thermometer to cause harm to the human body.
The main unit is not waterproof. Avoid contact with any liquids (Alcohol, water or cleaning fluid).
Thermometer measurement is not reliable with ambient temperature varies a lot.
When continuously measurements are taken, slight variations to the results are caused by the human body causing the thermometer's baseline to change. This is normal. Use the average of the readings as the true temperature.
Not all humans have the same body temperature. To ensure proper reading, acquire normal temperature of person as a reference for having a fever or not.
Do not measure if that patient is treated with certain drug therapies. In order to ensure the accuracy of measurement data, please don't take measurement of body temperature in strong electromagnetic interference environments.
Do not allow a child or baby to operate thermometer.

Recommendation
Do not use this thermometer for purposes other than those stated in this manual.
Do not leave the product exposed to any chemical solvent, direct sunshine or high temperature.

3. INTENDED USE

This product is intended for the measuring of temperature in the ear canal, forehead temperature ambient temperature and time telling. There is no age restriction on who can use this thermometer.
For safety reasons, children and baby's body temperature must be measured by parent or adults.

4. TEMPERATURE MEASUREMENT MODE AND RANGE DESCRIPTION

The infrared thermometer has the following measurement modes:

- 1) Forehead temperature measurement mode – accurately measures the skin temperature.
- 2) Eardrum temperature measurement mode— accurately measure the skin surface of human eardrum's temperature.

Normal temperature range for different surfaces

Measuring surface	Normal Temperature (°C)	Normal temperature (°F)
Anus	36.6-38.0	97.9-100.4
Oral	35.5-37.5	95.9-99.5
Armpit	34.7-37.3	94.5-99.1
Ear	35.5-37.8	95.9-100
Forehead	35.8-38.0	96.4-100.4

Normal temperature Age Range

Age Range (years old)	Normal Temperature (°C)	Normal temperature (°F)
0-2	36.4-38.0	97.5-100.4
3-10	36.1-37.8	97.0-100.0
11-65	35.9-37.6	96.6-99.7
> 65	35.8-37.5	96.4-99.5

- NOTE: Normal temperature differs depending on surface and individual. To define your normal temperature: measure your temperature at least 2 times in two weeks on the same surface at same time.
- NOTE: When consulting your physician, inform them on what surface the temperature was taken, and note the individual's normal temperature.
- NOTE: Because the forehead temperature is affected by the external environment, be advice that you take the forehead temperature only as reference. When you have a doubt about the measurement result, please use the ear temperature to confirm it.

5. FEATURE

Functional diversity
4-in-1 unique design can take ear/ forehead/ ambient temperature and display time on a clock display

High efficiency
This thermometer provides instant readings in one second.
This product has passed the European Union and Chinese infrared thermometer performances standards for measuring clinical requirements; measuring clinical repeatability varying no more than ±0.3°C.

Simple to use
Cover free probe is easy to use. Automatically converts from forehead temperature into ear temperature thermometer with the removal of the front cover.

High body temperature indicator
When the temperature exceeds 38.0°C (100.4°F), the thermometer will send out "Beep-Beep-Beep" a long one followed by two short ones, and the icon will show.

A wide range of temperature
Body temperature measurement mode is ±32°C -42.9°C.

Automatic display of memory
Every time you turn it on, the previous reading will be shown.

6. OVERALL DESCRIPTION

Main component including



LCD display description

	Temperature value
	Measuring in progress
	Object temperature mode
	Ear Scan Mode
	Forehead Scan Mode
	High body temperatures symbol
	Temperature unit: °C or °F
	Clock mode symbol
	Low battery indication icon
	Last Memorized Temperature Display

7. OPERATION INSTRUCTION

【Preparation】

- 1) If there is low voltage icon for the thermometer, replace the batteries to ensure power supply.
- 2) When you press the " " button, the system will self check software and hardware. If there are problems, LCD will display "Err" symbol.
- 3) In order to have accurate measuring results, put the thermometer in the measurement environment for 30 minutes.
- 4) If you want measure forehead temperature, clean forehead and arrange hair, make sure the forehead is naked and clean, in order to ensure the accuracy of measurement;
- 5) If you want measure ear temperature, clean subject ear canal, make sure the ear is clean.

【Time and Ambient Temperature】

Set the time when you use the device for the first time or when you reinstall the battery. Then, the function of displaying the environmental temperature and time will automatically start up.

1. Method of setting
Open the battery cap on the back, press the [Time Setting] button to start hour (hour number flashes) and minute(minute number flashes) setting, and Press the button of scan to adjust the numbers.
2. Mode of display
When time has been set, the thermometer will display the time and environmental temperature in turns while not being used to measure body temperature.



【Instruction for use】

Taking Temperature in Ear Temperature Mode

1. When the system is in the state of time/environmental temperature display, press the button of scan, and the last temperature measurement will be displayed, then after "Beep-Beep", the system enters into the mode of measurement.
2. Remove the forehead cap, and the thermometer enters into the ear measuring mode.
3. When measuring ear temperature, insert the probe into the ear first, then press the [Scan] button. One second later you will hear "Beep", and you can remove the thermometer. The measurement is completed.
4. When the measured temperature exceeds 38.0°C(100.4°F) , the thermometer will send sound "Beep-Beep-Beep-" a long one and two short ones, and the display will show the icon of fever.

NOTE:

1. Keep the probe surface clean, otherwise the measurement can't be accurate.
2. Clean the probe with clean cloth or paper moistened with water or alcohol, and conduct measurement after the water on the surface of the probe all evaporates.



TEMPERATURE TAKING HINTS

- The right ear temperature may differ from the left ear. Therefore, always take the temperature in the same ear.
- The ear must be free from obstruction or excess earwax build-up to take an accurate reading.
- External factors may influence ear temperatures, including when an individual has:
 - been lying on one ear or the other
 - had their ears covered
 - been exposed to very hot or very cold temperatures, or
 - been recently swimming or bathing.
- In these cases, remove the individual from the situation and wait 30 minutes prior to taking a temperature.
- Use the untreated ear if prescription ear drops or other ear medications have been placed in the ear canal.
- Don't use the thermometer outdoors.

【Taking Temperature in Forehead Temperature Mode】

1. When the system is in the state of time environmental temperature display, press the [Scan] button and the last temperature reading will be displayed. Then, the system will go "Beep-Beep" and enter into the mode of measurement.
2. Make sure the forehead cap is on, and press the button of scan directly to measure the forehead temperature.
3. When measuring the forehead temperature, keep the button of scan pressed, put the tip of the probe on your forehead, be sure the correct temperature has been taken, then release the button of scan, you can get the result.
4. When the measured temperature exceeds 38.0°C(100.4°F), the thermometer will send out "Beep—Beep-Beep", a long one and two short ones, and the display will show the icon of fever.



TEMPERATURE TAKING HINTS

- Before taking the temperature, clear the forehead of hair to prevent measured deviation.
- The sweat on head or cosmetics will affect the accuracy of measurement, please maintain the forehead clean when measuring.
- It is normal that there may be temperature variations depending on various skin types and color.
- Don't use the thermometer outdoors.

【Taking Temperature in Object Temperature Mode】

In the mode of shutdown, keep the [Power/Scan] button pressed until the " " shows on the LCD, at this time you have entered the object temperature mode.
It can't be changed between the forehead and ear temperature in this mode.

TEMPERATURE TAKING HINTS

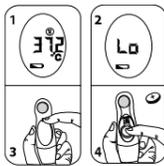
- Please don't measure the surface of heat-insulated objects.
- Please do not directly measure the surface of hot liquids, because the hot steam fog can condense in the sensor lens and cause the measurement deviation.

【Changing the Measurement Unit】

The infrared thermometer can display temperature measurements in either °C or °F. To change the measurement unit between °C and °F : After all icons displaying and when the picture “- °C” or “- °F” displaying, please press the scan button, turn the °C or °F to °F or °C. Wait for 3 seconds and the thermometer will automatically enter the measurement mode.

【Battery installment and replacement】

- When the quantity of electric charge is not sufficient, the icon of low battery will appear on the lower part of the screen. This means that it will soon be time to replace it.(Refer to the Picture 9.1)
- When the quantity of electric charge of the battery is lower than the minimal value, “Lo” symbols will be displayed on the screen, and battery icon flashes and the sound of “Beep” is sent out (Refer to the Picture 9.2).Unless you change a new battery, you cannot use the thermometer to conduct measurement.
- Operation of changing battery:
 - Take out the old battery: open the battery cap (Refer to the Picture 9.3).
 - Put a new battery on: put on a CR2032 lithium battery with cathode downward into the battery seat. (Refer to the Picture 9.4)



Notice:

- Please observe local laws on disposing of used batteries.
- Do not throw in the garbage can.
- Please take out the battery if the device is not used for long periods of time.
- Don't put the battery in the fire.

To protect the environment, dispose of used battery at your retail store or at appropriate collection sites according to local regulations.

8. CARE AND CLEANING

Probe tip (lens) is the most precise part in the thermometer. Please keep clean in order to assure the accuracy of the reading.

The probe tip and lens are the most delicate part of the thermometer. It has to be clean and dried to ensure accurate readings.

Please use the following ways to clean the probe:

- Gently wipe the surface with a cotton swab or soft cloth moistened with alcohol.
- After the alcohol has completely dried out: If the lens is damaged, contact the distributor.

Cleaning the unit's body:

- Use a soft, dry cloth to clean the thermometer display and unit body.
- If very dirty, use a soft with alcohol for cleaning.

NOTES:

- Don not use abrasive cleaners.
- Don't use other non-recommended methods to disinfect.
- Non-waterproof. Don't use the abrasive cleaner to clean the product, don't drop the thermometer in the water or any other liquid.

9. MAINTENANCE

- We do not authorize any institution or individual to maintain and/or repair this product. If you suspect that the product is damaged or if you have any questions, please contact the manufacturer or distributor to handle the case.
- The user must not attempt any repairs of the device or any of its accessories. Please contact the retailer for repair.
- Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

WARNING: No modifications of this equipment are allowed!

10. CALIBRATION

The thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to these instruction, periodic calibration is not required. If any time your question the accuracy of the measurements, please contact distributor or manufacturer. For contact information see last page.

11. STORAGE

- Do not store the thermometer in places were there thermometer can come into contact with sunshine, high temperature or moist environment.
- Do not put someplace where it may come in contact with fire or is vulnerable to vibration.
- Take out the battery before storing.

12. ACCESSORIES

Only use original accessories. Check that the contents are in the box at the time of delivery.

Quantity	Parts
1pc	Device
1pc	CR2032 battery
1pc	User Manual
1pc	Base stand

13. TROUBLE-SHOOTING

Troubles or error message	Checklists or situation	Countermeasures or solution
No response/ Automatically reset	The batteries are used up?	Replace new batteries
	Battery in wrong polarity or type?	Take out batteries and reinsert it in the correct polarity.
	Poor battery contact correct	Take out the batteries and replace new one.
The thermometer show the symbol "Hi" or "Lo"	Temperature hampered by an air flux. In the forehead measurement mode: --Temperature readings too close together. -- Measured the other object, such as the sunlight, the air from the fireplace. Hi: Higher than 42.9°C;	Please leave the status and wait for 30 minutes to measure. Re-measure according to the manual.
	In the object measurement mode: --Temperature readings too close together. -- The object temperature is higher than 100°C. Hi: Higher than 100.0°C;	
	The hair and sweat prevent the temperature achievement.	
The thermometer show the symbol "Lo"	Temperature hampered by an air flux. In the forehead measurement mode: -- The measuring distance is too far. -- Measured the other object, such as the air from the air conditioner. Lo: Less than 32.0°C	
	In the object measurement mode: -- The measuring distance is too far. -- Have water vapor condenses on the lens. Lo: Less than 0°C	
	The ambient temperature is beyond of range of measurement (10°C-40°C or 50°F-104°F)	
Err	The sensor or hardware are damaged	Eliminate the possibility of temperature changes first ,then send the device to your dealer for repair
	Low batter, but you can still use it.	Keep an eye on power and continue to use.
Lo	Low battery, you can't use it.	Replace the battery.

14. SPECIFICATIONS

Device name	Tempa Check Infrared Thermometer
Model	FDIR-V1
Measurement mode	Forehead, ear and object temperature
Power supply	d.c.3V, CR2032 batteries
Measuring range:	32.0-42.9°C (89.6-109.2°F)
Measuring range:	For human body temperature: 32.0°C-42.9°C (89.6°F-109.2°F) For object temperature: 0°C-100°C (32°F-212°F)
Measuring accuracy: (At laboratory conditions)	For human body temperature: ± 0.2°C/0.4°F 35. 5°C -42.0°C(95.9°F-107.6°F) ± 0.3°C/0.5°F for other ranges For object temperature: ±1.0°C/ 1.8°F within 15-60°C(59.0°F-140.0°F); for other range , ±2.0°C/ 3.6°F
Clinical repeatability:	Within ±0.3°C
Resolution of display	0.1°C/0.1°F
Operation condition	15.0°C-40.0°C(59.0°F-104°F) Relative humidity: 20% to 95% RH
Transportation and storage condition	-25-55°C(-13°F-131.0°F), Relative humidity ≤95%RH,
Size	133.8×32.7×23mm
Weight	39g
High body temperature	≥38.0°C(100.4°F)
Grade of waterproof	IP22
Electric shock	Internally powered ME equipment
Applied part	Type BF applied part, including the whole unit
Mode of operation	Continuous operation
Note: Not intended to be sterilized.	
Not for use in an OXYGEN RICH ENVIRONMENT	

*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) for this thermometer is ±0.2°C(0.4°F), whereas for mercury-in-glass thermometer, the requirement per ASTM standards E 667-86 is ±0.1°C(0.2°F).

15. STANDARD LIST

The FDIR-V1 complies with following applicable standards:

EN 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 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 12470-5	Clinical thermometers – Part 5: Performance of infra-red ear thermometers (with maximum device)
EN 62304	Medical device software - Software life-cycle processes
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ASTM E 1965	Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature

16. DISPOSAL



Dispose of the device in accordance with the regulation applicable at the place of operation. Dispose of at public collection point in the EU countries – 2002/96/EC WEEE Directive.
If you have any queries, please refer to the local authorities responsible for waste disposal.

NOTES:

- Handing of battery and wastes method, please act according to the native law to proceed to handle.
- Take out the battery if you are not going to use the unit for a long time.

To protect the environment, dispose of empty battery at your retail store or at appropriate collection sites according to national or local regulations.
Dispose of at public collection point in the EU countries – 2006/66/EC Directive.



17. NORMALIZED SYMBOLS

	Attention: see Instructions for use!
	Applied part of type BF
	The batteries and electronic instruments must be disposed of in accordance with the locally applicable regulation, not with domestic waste.
	Complies with the European Medical Device Directive (93/42/EEC), Notified Body is SGS United Kingdom Ltd.
	Manufacturer information: Home Aide Diagnostics, Inc.
	Authorized representative in the European Community.
	IP code of the device: this device's grade of against ingress of solid foreign objects -- ≥12.5mm diameter (and the against access to hazardous parts with finger); the grade of waterproof is dripping (15° tilted)
	Batch code

18. 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 the warranty period.
- The following cases are excluded under the warranty
 - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
 - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
 - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
 - Accessories which are subject to normal wear and tear.
- 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.



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