4 in 1 Ear & Forehead Infrared thermometer

Please read the guide carefully before use and keep it in a safe place.
For American please refer to "°F", for European please refer to "°C".

User's Manual

1. Summary of Non-Contact Infrared Thermometer

The FDIR-V16 is a high technology medical thermometer for measuring eardrum and forehead temperature of human body via in frared rays emitted from the eardrum and skin surface.
Following the correct way to measure is very important to obtain a precise temperature.
To ensure proper use, please be sure to read this user manual carefully.

- In order to properly use this product, please carefully read the full text of this manual before using, in particular the "safety precautions" section.
- Please keep these instructions handy in a safe place for reference.

2. Safety precautions

All the materials used in the FDIR-V16 have passed the non toxicity testing of the international regulations.

Warning

- Use of this thermometer is not intended as a substitute for consultation with your physician. It is dangerous for users to perform a self-evaluation and self-treatment based on the measuring result. Be sure to follow doctor's instruction.
- Keep the thermometer out of reach of children. If the battery or other component is swallowed nent, please consult a doctor immediately.
- Don't throw the battery into fire.

Notice

- The device is a precision instrument, don't drop, tramp or impose any vibration or impact on the ther mometer.
- Do not touch the lens of the probe with your fingers, and do not dissemble the device by yourself.
- Before measuring the temperature, make sure there is no hair or sweat in the way.
- After you do some exercise, eating and bathing, you should stay still indoors about 30 minutes before measurement.
- To make the measurement data reliable and stable, when ambient temperature varies a lot, the ther mometer should be placed indoors for about 30 minutes before using.
- When we measure somebody continuously, the temperature should be measured every minute, if you need to measure yourself continuously for a short time, there are some slight errors when you read the temperature ,which is a normal phenomenon. At this time, we should choose the average.
- There is no absolute standard about the temperature of the human, so please try to collect the re cording of individual temperature in normal conditions, as a reference for having a fever or not.
- Do not measure the sites of scarred tissue or tissue compromised by skin disorders, because sensing body temperature from sites of scarred tissue or tissue compromised by skin disorders.
- Do not measure the forehead temperature if the patient has trauma on forehead.
- Do not measure when the measuring site (forehead) is exposed to direct sunlight, fireplace heat, cold compress therapies, direct air conditioner flow. If you are in these environments please leave and wait for 30 minutes to measure.
- Do not immerse the device into water or any other liquid, and don't expose directly to sunlight.
- In order to ensure the accuracy of measurement data, please don't take measurement of body tem perature in strong electromagnetic interference environment (such as microwave, high frequency equipment operation environment).

3. Intended use

Only use this product for the temperature measurement of ear and forehead. It can be used for anybody, e.g. for new-born, for children and adults.
For safety reasons, measurement of children or baby's temperature must be measured by adults. Children and babies should not operate the thermometer.

4. Temperature Measurement Modes and Range Description:

The infrared thermometer has the following measurement modes:
1) Forehead temperature measurement mode -- measures the skin surface of human forehead's temperature accurately.
2) Eardrum temperature measurement mode—measures the skin surface of a humans eardrum temperature accurately.

Normal temperature range for different measuring position:

Measuring position	Normal temperature (℃)	Normal temperature (℉)
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
Forehead	35.8-38.0	96.4-100.4
ear	35.5-37.8	95.9-100

Normal Forehead Temperature Range Based on Different Ages:

Ages	Normal temperature (℃)	Normal temperature (℉)
0-2 years old	36.4-38.0	97.5-100.4
3-10 years old	36.1-37.8	97.0-100.0
11-65 years old	35.9-37.6	96.6-99.7
＞ 65 years old	35.8-37.5	96.4-99.5

NOTE: The normal temperature and difference between the different body parts can vary between individuals. To define your average temperature, measure your temperature for a least 2 weeks in the same ear canal and forehead position.

NOTE: When consulting your physician, communicate the temperature that the thermometer recorded and in what position and room environment as well as your normal body temperature range as additional reference.

NOTE: Because the forehead temperature is affected by the external environment (eg: environment, air conditoning and color, etc),we advise 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. Features

Two user design
The product has a two user mode, each user's test data is stored separately

High reliability
This product has passed the life and reliability test of the manufacturer, the time to failure is≥1000h of use.

High accuracy
This product has passed the European Union infrared thermometer performance standards for measuring clinical requirements, measuring clinical repeatability is no more than ±0.5℉ (0.3℃).

LED display
When the temperature exceeds the range, LCD will display the Lo or Hi prompt.
When the operating environment exceeds the design specifications, the LCD will display the Err prompt. When the thermometer battery power is insufficient, it has low voltage icon.
Has the hardware self-test function, when hardware malfunction is detected, the Err will display prompts.

Power saving function
When the thermometer is not in use after approximately 30 seconds it will automatically enter standby mode and the screen will display the time and environmental temperature alternately.

Memory storage function
The thermometer is able to record the previous 32 temperature recordings for your reference.

Backlight indication function
With the backlight indication function, it is easy for people to identify the temperature in a dark environment.

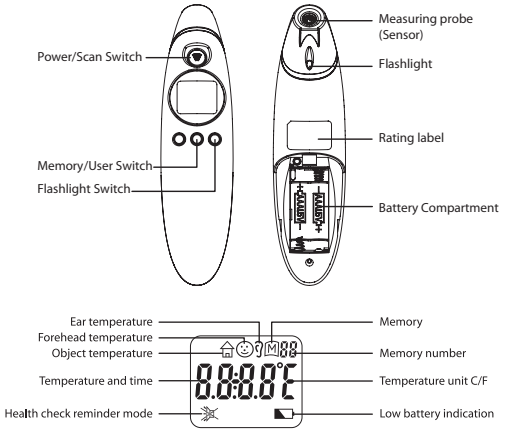
Two-color LED indication function
In the forehead temperature measure mode:
If the body temperature is within 89.6℉ -99.5℉ (32℃ -37.5℃), the Green LED will light up indicating a safe body temperature.
If the body temperature is within 99.6℉ -109.2℉ (37.6℃ -42.9℃), the Red LED will light up indicating potential fever symptoms.

Flashlight function
The product is equipped with a flashlight, so you can take babies temperature at night time whilst baby is sleeping.

6. Care and Cleaning

The measuring probe tip is the mode delicate component of the thermometer and it must be clean and undamaged to ensure accurate readings. To clean the probe tip please follow these instructions:
1. Very gently wipe the surface of the probe tip with a cotton swap or soft cloth moistended with alcohol or an alcohol wipe.
2. After cleaning, inspect the probe tip to ensure that is it clean and undamaged.
3. If you find the probe tip is damaged do not use the thermometer and contact customer service.
4. Use a soft dry cloth to clean the thermometer LCD screen and surface of the body. Do not use abrasive cleaners and never immerse the product in water.

7. Overall description



8. Operation Instruction

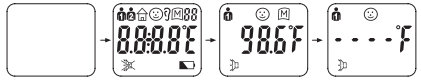
1) Replace the batteries to ensure efficient power supply if there is a low battery icon showing.
2) Ensure the sensor is clean. Refer to the section above, Care and Cleaning for details. If the sensor's lens is damaged, please stop using it and contact Customer Care.
3) When you press the [Power/Scan] button, the system self tests the software and hardware. If there are problems, the LCD will display "Err" symbol. Check if the sensor laser is dirty or damaged.
4) To ensure an accurate measuring result, put the thermometer in the measurement environment for 30 minutes so the thermometer is acclimatized.
5) Accuracy of unexpected fluctuations in ambient temperature may decrease the measurement results. When the thermometer displays different ambient temperatures in the same position it may not be able to provide an accurate result. Be sure to take the temperature in an environment where the room termpature is stable (ie not in front of an air conditioner).
6) Clean forehead and move hair aside. The forehead should be unobstructed and clean, in order to ensure the accuracy of the measurement.
7) The probe tip is required to be cleaned after each use so it can be re-used. See chapter 6 above "Care and Cleaning". After ensuring the thermometer is clean you should always store the thermomter in accordance with Chapter 9 "Storage".

【Instruction for use】

1) Before measurement begins.

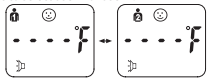
Power on

For the first use, put the battery inside the battery compartment. The product into the off state, press the [Power /Scan] button to turn on. It will then boot as follows:
- Red backlight on, then Green backlight on, then boot LCD 2 seconds.
- Green LCD light turns on at the same time and the LCD shows last temperature recording
- The thermometer then enters the measurement state.



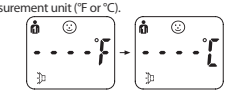
(2) User selection

Press memory key for 3 seconds to select user 1 or user 2.



(3) Measurement unit selection

Press unit key to set measurement unit (℉ or ℃).



(4) Measure selected site

Put on the probe cover to switch to forehead mode or leave it off and and the thermometer enters into the ear measuring mode.

When measuring the ear temperature, insert the probe into the ear first, then press the power key. One second later you will hear "Beep", and you can remove the thermometer.
The measurement is completed.

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*
  - *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.*

(2) Forhead temperature measure

Install the forehead cap, and press the scan button directly to measure the forehead temperature. When measuring the forehead temperature, put the tip of the probe on your forehead and press the scan button. The display will then show the tempreature reading in one second.

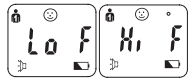
TEMPERATURE TAKING HINTS

- *Before take the temperature, please brush back any hair to prevent measurement deviation.*
- *The sweat on head or cosmetic can affect the accuracy of measurement. Please maintain the cleanness of the forehead when measuring.*
- *It is normal that there may be temperature difference depending on various skin types and color, since different skin type will reflect different voltage of infrared ray.*
- *Don't use the thermometer outdoors.*

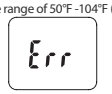
(3) Temperature test information

If the temperature range is 89.6℉ -99.5℉ (32℃ -37.5℃), the green backlight will display.
If the temperature is above 99.6℉ -109.2℉ (37.6℃~42.9℃), the red backlight will display.
If the measured temperature is higher than 109.2℉ (42.9℃) , it will display " HI".

If the measured temperature is below 89.6℉ (32℃) , it will display "Lo".

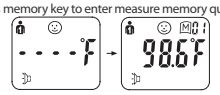


If the ambient temperature outside the range of 50℉ -104℉ (10-40℃), the thermometer shows "Err";

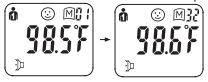


4) Memory query mode

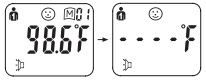
At the measure mode, Press memory key to enter measure memory query mode of the user



In the memory query mode, Press Memory/User key to move through previous measurements, number will start from 1, 2,.. 32 and the screen will show the corresponding number records.



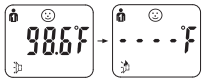
In the memory query mode, without any action in 3s, it will turn off the current mode and return to measure mode



5) Flashlight

Pressing the flashlight key will turn on or off the flashlight function.

(5) Following use of the flashlight, 10±2 seconds, the unit will enter into measurement mode.



(6) If no further operation after voice broadcast and work out the set up mode 30±10seconds, LCD will show "off", the unit will enter into shutdown mode accompany with "beep" voice.

9. Storage & Handling

Store the thermometer in a clean and dry location that's free from dust and contamination.
Ensure the therometer is stored out of direct sunlight.

Do not expose the thermometer to temperature extremes (below -4°F/ -20°C or over 122°F / 50°C) or excessive humidity (>95% RH)
The operating ambient temperature range for this thermometer is 50°- 104°F (10°-40°C).

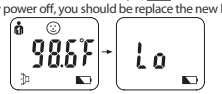
Attention

- Before taking the temperature, please take off the hat or move forehead hair asied to prevent incorrect measurement.
- The sweat on head or cosmetics can affect the accuracy of measurement, please maintain the cleanliness of the forehead when measuring.
- It is normal that there may be temperature differences depending on various skin types and color, since different skin type will reflect different voltage of infrared ray.

10. Battery installment and replacement

Every time you turn on the thermometer, it will detect the battery voltage. When the battery is lower than d.c. 2.7V it displays "", indicating that the voltage is on the low side, and please keep attention and replace battery in time. Figure as

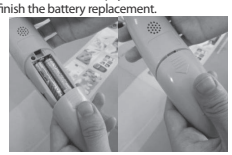
When the battery voltage is lower than d.c. 2.5V it displa "" and "Lo" sign, "" icon flash, after 3 times it will be automatically power off, you should be replace the new batteries.



Battery replacement

(1) Open the battery cover and take out the old batteries.

(2) Follow the polarity marking in the battery compartment, put the new batteries to the battery compartment and keep it fixed well. Please pay attention to the electrode and don't make a mistake, then cover the case to finish the battery replacement.



Notice:

- Please observe the related national laws of disposing the abandoned battery and don't litter to the garbage can.
- Please take out the battery if the device is not used for long periods of time.
- Please don't put the battery in the fire.

11. Maintenance

1. We do not authorize any institution or individual to maintain and repair of the product. If you suspect that the products have any questions, please contact the manufacturer or distributor to handle the case.
2. The user must not attempt any repairs to the device or any of its accessories. Please contact the retailer for repair.
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!

12. Calibration

The thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to the use instruction, periodic re-adjustment is not required. If any time your question the accuracy of measurement, please contact distributor or manufacturer, the contact information see last page.

13. Storage

1. Don't put the thermometer under the sunshine, high temperature and moist environments or someplace which maybe get in touch with fire or is vulnerable to vibration.
2. Take out the battery if you don't use the device for a long time.

14. Accessories

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

Quantity	Parts
1pc	Thermometer
1pc	Quickstart Guide
1pc	User Manual

15. 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 the batteries and replace new ones.
	Poor battery contact	Take out batteries and reinsert it correct.
The thermometer show the symbol "Hi"	Temperature hampered by an air flux.	Please leave the status and wait for 30 minutes to measure. Re-measure
	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 109.2°F (42.9°C);	Please leave the status and wait for 30 minutes to measure. Re-measure according to the manual.
The thermometer show the symbol "Lo"	The hair and sweat prevent correct temperature.	
	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 89.6°F (32.0°C)	
Err	The ambient temperature is beyond of range of measurement (50°F-104°F or 10°C-40°C)	Keep the thermometer in the room Whose Temperature is (50°F-104°F or 10°C-40°C) for 30 minutes
	The sensor or hardware is damaged	Excluding the possibility of temperature allowance first ,then send the device to your dealer for repair
98.6°F	Low batter, but you can still use it	Keep an eye on power and continue to use.
Lo	Lower battery, however you can't use it	Replace the new battery.

16. Specifications

Device name	Infrared Thermometer
Model	Cherub Baby Code: CHTH001/A Factory Code: FDIR-V16
Measurement site	Forehead and ear temperature
Measure time	About 1 second
Power supply	d.c.3V, 2×1.5V AAA batteries
Measuring range:	89.6°F -109.2°F (32.0-42.9°C)
Measuring accuracy: (At laboratory conditions)	± 0.4°F/0.2°C during 95.0°F-107.6°F (35. 0°C -42.0°C); ± 0.5°F/0.3°C during 89.6°F-94.8°F(32.0°C -34.9°C) and 107.7°F-109.2°F(42.1°C -42.9°C)
Clinical repeatability:	Within ±0.5°F/0.3°C
Resolution of display	0.1°C/0.1°F
Operation condition	50°F-104°F(10.0°C - 40.0°C), 15%-95%RH
Storage condition	163.0 x 40.5 x 28.5 mm
Weight	69g
Storage condition	-13 to +131°F(-25-55°C), ≤95%RH
Size	163*40.5*28.5mm
Weight	80g(With batteries)
High body temperature hint	≥99.6°F (≥37.6°C)
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

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

Note: ASTM laboratory accuracy requirements in the display range of 95.9°F to 107.6°F/35.5°C to 42.0°C for this thermometer is ±0.4°F/0.2°C, whereas for mercury-in-glass thermometer, the requirement per ASTM standards E 667-86 is ±0.2°F/0.1°C.

17. Standard list

Cherub Baby declares that the thermometer complies with following applicable standards:

EN 1041	Information supplied by the manufacturer with medical devices
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/IEC 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN/IEC 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 the home healthcare environment
EN/IEC 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)
ASTME 1965	Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature
EN/IEC 62304	Medical device software - Software life-cycle processes
EN/IEC 62366	Medical devices — Application of usability engineering to medical devices IEC 62366:2007
EN/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/ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

18. DISPOSAL

Spent batteries should not go in the household waste. Dispose of the battery according to the current regulations. As a consumer, you have obligation to dispose of batteries correctly.
Dispose of at public collection point in the EU countries – 2002/96/EC WEEE Directive.
Consult your municipal authority or your dealer for information about disposal.
At the end of the product lifecycle, do not throw this product into the normal household
garbage, but bring it to a collection point for the recycling of electronic equipment.
Waste Electrical and Electronic Equipment can have potentially harmful effects on the environment.
Incorrect disposal can cause harmful toxins to build up in the air, water and soil and can be harmful to human health.

19. 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.
	Disposal in accordance with Directive 2002/96/EC (WEEE)
CE 0120	Complies with the European Medical Device Directive (93/42/EEC), Notified Body is SGS United Kingdom Ltd.
	Manufacturer information: The manufacturer Famidoc Technology Co., Ltd.
IP22	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).
LOT	Batch code

20. Electromagnetic Compatibility (EMC) Tables

1) The Infrared Thermometer needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS
2) Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.

Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3.3 m at an IMMUNITY LEVEL of 3 V/m

21. WARRANTY

1. The warranty period for device is one year from the date of purchase. For further details on the warranty and to make a warranty claim please visit www.cherubbaby.com.au

Customer Care
Cherub Baby
Phone: +61(03)90051734 or mail@cherubbaby.com.au

This product conforms to the provisions of the EC directive 93/42/EEC (Medical Device Directive).
MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC.
Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
Please do not dispose of the product in the household waste at the end of its useful lifecycle.
Sponsor: Cherub Baby, 9/6a Railway ave, Oakleigh VIC 3166, mail@cherubbaby.com.au, +61390051734
Manufacturer: Famidoc Technology Co., Ltd. Add.: No. 212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town, Donguang 523853, Guangdong Province, P.R. China.
Edition: V1.0