

**eTE-68B4**

**Infrared Thermometer**



Edition: A0

Thank you for choosing Infrared thermometer. The product combined the newest technology and had passed related certification test. With its unique technology, it can get stable and accurate measurement result every time. This product will self test and display the current room temperature when starting up to ensure the accuracy of the measurement.

This product is suitable for home or hospital to measure and monitor human body temperature, and suitable for people of all ages.












Measurement site of this product :auditory meatus

#### Referent Standards and Documents

No	Standard Name	Reference No.
1	Medical Device Quality System for the regulation	EN ISO13485: 2003
2	Medical device risk management to medical devices	EN ISO14971: 2012
3	Symbol for the label of medical devices	EN 980: 2008
4	Term, symbol and information of medical device— information of medical device manufacturer offering	EN 1041: 2008
5	Medical electrical equipment – Part 1: General requirements for safety	EN60601-1: 2006/AC:2010
6	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests	EN 60601-1-2: 2007
7	Medical electrical equipment -- Part 1-11: General req uirements for basic safety and essential performance - - Collateral standard: Requirements for medical electric al equipment and medical electrical systems used in t he home healthcare environment	IEC60601-1-11:2010
8	Medical device software – Software life-cycle processes	EN 62304: 2006/AC:
9	Medical electrical equipment – Part 1-6: General	EN 60601-1-6: 2010
10	Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8: 2004 /A1:2006
11	Medical devices – Application of usability engineering to medical devices	EN62366: 2008
12	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	MDD 93/42/EEC

13	Medical electrical equipment. Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	ISO80601-2-56:2017
14	EVALUATION OF CLINICAL DATA : A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	MEDDEV2.7.1
15	User Manual	Version:1.0

## Key of symbols

symbol	Description
 <b>WARNING</b>	WARNING indicates a hazardous situation which, if not avoided, could Result in death or serious injury
 <b>CAUTION</b>	CAUTION indicates a hazardous situation which, if not avoided, may result in minor or moderate injury
 <b>NOTICE</b>	NOTICE addresses practices not related to personal injury, such as product and/or property damage
	Type BF
 <b>DISPOSAL</b>	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary
 XXXX	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic community
	<a href="#">Refer to instruction manual / booklet</a>
<b>IP22</b>	Degree of protection against harmful ingress of particulate matter and water.
	Manufacturer
 Company Address	Authorized representative in the European Community
	Date of manufacture
	Serial number

 **WARNING**

**Do not judge your own body state according to if you have fever or not. If you worry about your health, please consult a physician**

**Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.**

**The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.**

**The device requires no calibration.**

**The device is not repairable and contains no user serviceable parts.**

**No modification of this equipment is allowed.**

**Remove batteries if equipment is not likely to be used for some time.**

**The user must check that the equipment functions safely and see that it is in proper working condition before being used.**

**The manufacturer does not require such preventive inspections by other persons.**

**The ear thermometer is used only for testing, it cannot replace a doctor.**

**Please do not use the thermometer in other ways except measure body temperature, if it is used for children please observe the general safety precautions.**

**Please do not dismantle, re-assemble or drop the ear thermometer.**

**The ear thermometer temperature sensing head protective cover or other components should keep away from children.**

**Incorrect usage of battery may cause damage, please do not re-charge, dismantle the battery or throw the battery into fire, please deal with the battery according to local related regulations .**

**Please don't operate the product out of operating conditions or out of the operating temperature range .It may cause measurement value anomaly or malfunction  
Please don't bite, throw, folding ,pull and strong impact the device .Or it may cause a failure  
Please don't measure if have auricle inflammation or otitis media .Or it may aggravate inflammation**



## **CAUTION**

**Please do not dip the device into water or other liquid. Cleaning and disinfecting please follow (cleaning and storage) section in the manual.**

**Keep the device from sunshine, and store in dust free, dry, store temperature of  $-20^{\circ}\text{C}$  -  $+55^{\circ}\text{C}$  ( $-4^{\circ}\text{F}$  -  $+131^{\circ}\text{F}$ ) areas.**

**If the sensor or product is broken, please do not use. If the device is broken, please do not repair it by yourself, contact with your nearest customer service.**

**Left ear wax can cause measurement of low temperature phenomenon, so please make sure the ear is clean to ensure accurate measurement result.**

**Before measurement please make sure the sensor mirror is clean. If there's any dirt, please clean it with alcohol cotton swab before use.**

**The device is made of precision parts. Do not drop it, and protect it from strong impact. Please don't twist the device or sensor.**

**Please clean the thermometer sensor after use, to ensure the measurement accuracy and avoid cross-infection.**

Please don't add any protective sleeve to the sensor, or the measurement result will be incorrect.

please make sure the device appearance is not damaged and the sensing head is not dirty before use. If there is any breakage, please don't use. Damage and smudginess may cause incorrect measurement result.



## **CAUTION**

**Please read the manual carefully before use, and keep it in safe place.**

**To make sure the measurement result is accurate, please wait at least 30 seconds after measuring every time, then you can measure again.**

**After cleaning the inductive head with alcohol, the device should be kept for a few minutes till the alcohol volatilize, and the inductive head back to natural temperature. Usually the suggested time is 5 minutes, otherwise the result may be incorrect.**

**Because baby's temperature adjustment ability has not been perfect, if the environment temperature changed sharply, do not use the device test baby's temperature, the result may be incorrect. Wait a few minutes in the same environment till the baby's temperature become stable.**

**When testing ,suggest test in the same ear, because the temperature of left and right ear is different.**

**The following situations should test three times, and use the highest one:**

- 1) baby who born in 100 days.**
- 2) Baby under 3 years, the baby whose immune system has defects,**

**User who use the device in the first time, before he is familiar with the device and get the stable temperature reading.**

**FCC Caution:**

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**FCC RF Radiation Exposure Statement:**

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

**SPECIFICATIONS**

Item NO.	eTE-68B4
Test site	ear
test range	32.0℃-43℃ (89.6°F -109.4°F)
measurement accuracy	±0.2℃ (36℃≤t<39) ; ±0.3℃ other range
Use environment	10℃ ~ 40℃ <85%RH
temperature division	0.1℃/0.1°F
indicator or fever alarm	buzzer“bi-bi”
information storage	store the latest 32 group test data before turn off
unit shift	℃/°F
Automatic off	approx. 20±5's after use

storage and transport condition	-20℃ - +55℃ (-4°F -+131°F)
storage environment humidity	15%RH-93%RH
power supply	2 x AAA
battery life time	5000 times
low battery indicator	Below DC2.65V±0.15V
clinical allow maximum error margin	This product pass clinical verification, the clinical maximum allowable error is 0.3℃

### Body temperature

A person's normal temperature range tends to decrease with age. The following table shows normal ThermoScan ranges by age.

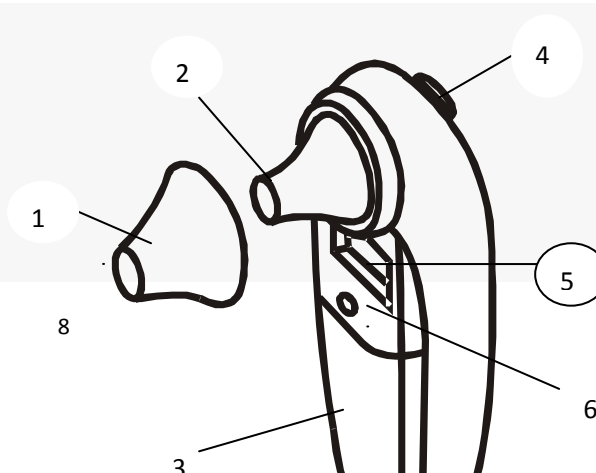
Normal ThermoScan ranges by age :

0 – 2 years	97.5 – 100.4 °F	36.4 – 38.0 °C
3 – 10 years	97.0 – 100.0 °F	36.1 – 37.8 °C
11 – 65 years	96.6 – 99.7 °F	35.9 – 37.6 °C
> 65 years	96.4 – 99.5 °F	35.8 – 37.5 °C

The normal temperature range will change between different people and different time in a day. So make sure you and your family member's normal temperature is very important. You can use this product to observe you and your family normal temperature range easily.

### Operating Information:

1. Protect a set
2. Probe membrane
3. battery cover





4. Scan/M button
5. LCD
6. ON/OFF button

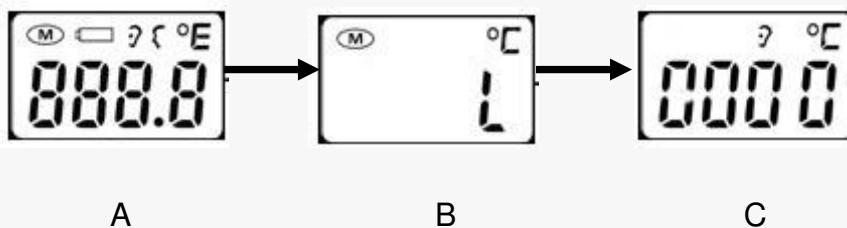
- Operating instructions:

Open the battery cover, place two AAA batteries according to the indication sign in the battery case, and take off the protection cover on the head.

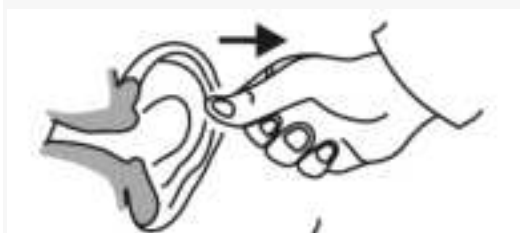
### CAUTION

Protective cover is used only when storing ,you must take down protective cover when measuring.

2、 Press the "ON/OFF" button and the device start self calibration,all symbols (picture A) will display on the LCD with buzzing about one second.Picture B is detecting the measuring head temperature,when it displays "0000"(picture C), the device is ready for testing.



3、 pull the ear, and keep the ear straight.

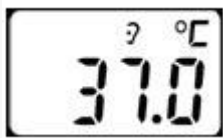


A, Baby under 1 year should pull the ear back-forward. B, baby older than 1 year and adult should pull

up-back forward.

5、 Insert the temperature sensing head into the ear canal,and combine closely to make sure to measure accurate ear temperature.

6、 Move out the device, and the temperature will display on LCD.



7、 Wait 30 second, and then start next test.

8、 If no operation in  $60 \pm 5$  second, the device will shut off automatically.

 CAUTION

Please don't touch the heat detection , also don't let's impact .otherwise it will cause measurement value anomaly or malfunction

. The left ear canal and the right ear readings may be different , so please measure in the same ear canal.

.Accurate temperature can be measured only if there is no obstruction and no excessive accumulation of ear wax in the ear

.The ear temperature may be high if you lie on the side and one ear is compressed,so after going to bed please do not measure in the ear which is compressed on the side

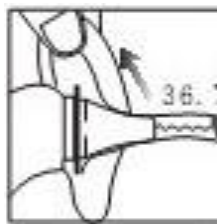
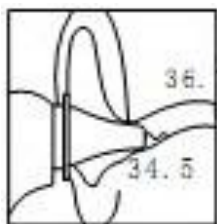
.If you want to measure after eating ,doing sports and going out ,please have a rest for thirty minutes to avoid inaccurate measurement result

.Repeated measure:If want to measure again you should wait for a minute.

.The ear thermometer is appropriate in measuring the temperature of human body ear canal, compared with the common clinical thermometer, it measures principle and diagraph part all different, as a result is not likely to acquire same measured value.

.The ear thermometer is a kind of high –tech and high sensitive thermometer. So it's very high request for operating environment and measuring a method when using. And easy to cause the measurement not correct due to human operate not the ear thermometer problem , please read the instructions carefully before use

The correct method to insert in the ear canal



Inaccuracy

## Exactitude

Before measuring ,please confirm the direction of the ear canal.

Human ear canal is not straight will bend with increased age

Opposite the ear tympanic membrane, gently pull back, it is easy to tympanic membrane direction

The correct measurement method to measuring others

When measuring the ear temperature for adults or children, please clearly see the ear canal, then deep into as much as possible

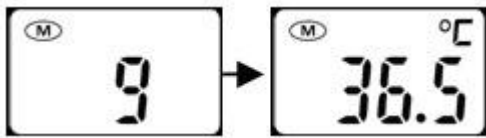
When measuring the ear temperature for active child, please put one hand on the other side to make sure the head is not rotation,after you clearly see the ear canal, then deep into as much as possible

When measuring the ear temperature for sleeping baby.Please make sure the ear up (let face in a horizontal position), with one hand holds the head to avoid head rotation

When the ear is small can't insert , the tympanic direction just plug into the ear canal

### Check the memory and delete the memory data.

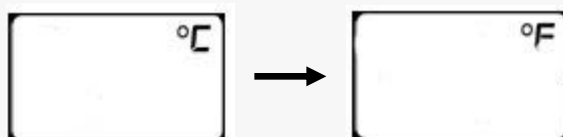
- 1、 The latest test data will be saved before shut off, and 12 memories can be kept mostly.
- 2、 Press "Scan/M" button when the device is off, the latest test data will display.



- 3、 Press"Scan/M" button continuously can check all the saved data.
- 4、 If the saved data more than 12 groups, the first one will be deleted.

### Unit shift

- 1、 Press "Scan/M" and "ON/OFF" buttons the same time when the device is off to enter Unit shift mode.
- 2、 Press "Scan/M" button can change the unit.



- 3、 press "ON/OFF" to finish unit shift.

4. After completing the measurement, please pack the protective cover and store it in required environment.

#### **Cleaning instructions:**

- 1、 Sensitive head is the most important part of the device, and the front mirror is fragile. The sensitive head can be cleaned with cotton swab or soft cloth with alcohol / warm water
- 2、 Clean LCD and cover with clean soft cloth, do not use solvent, do not dip into water or other liquid.

3、 Please cover protective cover if don't use, avoid dust pollution and direct sunlight. Storage of the thermometer environmental conditions should maintain relative stability, had better be in 10–40, humidity is not more than 85% RH environment, so it is easy to use at any time

- Description of maintenance and who should do it: Please hand it over to a professional personnel to carry on maintaining
- Storage instructions:

Please pack good protective sleeve in the collection bag if don't use the thermometer. If it is not installed protective sleeve state custody, it may cause a malfunction

Please make sure the thermometer, collection bag and protective sleeve out of the reach of the baby, otherwise may cause failure

Please don't put the thermometer into the collection bag storage when it's wet. Or it may cause a failure


. please do not place the device in too high/low temperature and humidity environment, to avoid sunshine, keep away from electric shock and dusty environment.

Please keep the device in dry environment, and the temperature should be -20℃–

+ 55℃. Please do not put this product in condition which exceeds above required storage and transportation conditions.

. Take out the batteries if the device will not be used for long time, in case the battery may destroy the device.

#### **Replacing the batteries**

1. When voltage of the batteries is low, the LCD will display “” symbol, please place two new batteries in unit. The Infrared Thermometer can not work accurately under the

condition of low voltage.

2.The Infrared Thermometer is supplied with “AAA”DC1.5V×2PCS

3.remove the battery cover and take out old batteries

4.place two new batteries according to the “+”or”-“

5.please take out the batteries to avoid battery leaking if the unit is not used for over six months

- Instructions on how to safely dispose of the device:
- Batteries should be disposed of separately from household waste. Always dispose of batteries as per your local regulations. Again, do not dispose of batteries with normal household waste.

Observe the local regulations for material disposal. Dispose of the device in accordance with local regulations. If you have any questions, please contact the local authorities responsible for waste disposal.


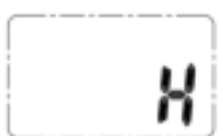

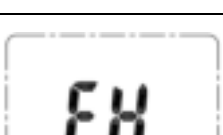
- Instructions on accessories:


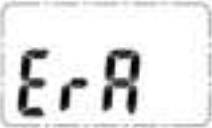

. battery : AAA×2PCS

Instruction manual 1 PCS

. Infrared thermometer 1PCS

- **Troubleshooting Information:**

Err message	Situation	Solution
	Low power.	replace battery.
	measured temperature is high.	Make sure the thermometer is properly inserted ,then take a new temperature
	Measured temperature was low.	Make sure the thermometer is properly inserted ,then take a new temperature
	Ambient temperature is too high.	Allow the thermometer to remain for 30 minutes in a room where the temperature is between 10 and 40℃ or 50 and 104°F

	Ambient temperature is too low.	Allow the thermometer to remain for 30 minutes in a room where the temperature is between 10 and 40°C or 50 and 104°F
	Unstable ambient temperature	When the ambient temperature changes, please put the product in the current environment for half an hour before use.
	Sensor Error.	Please try again after placing the product. If it is still abnormal, please contact your local dealer
No display	Dead battery or no battery	Insert new battery

## CLASSIFICATION

1. Internally powered equipment;
2. Type BF applied part: Probe;
3. IP22;
4. Not category AP / APG equipment;
5. Mode of operation: continuous operation.

## Additional Information:

non-toxic, No Stimulation, No sensitization adverse reaction for user during test.

### ● Disease and self-care information:

The device has been calibrated before delivery, if you use it according to manual instruction, there is no need to calibrate .If there's any question regarding to test, please contact with professional person (our company)

Be subjected to vibration of the strong row such as the product, outside the dint function is damaged or the measurement result have problem, please do not use, please contact with my company.

If the product suffer strong vibration, damage or have query about the measurement results.Please do not use, please contact with our company.

### ● Warranty:

if you use the device according to the manual, replace it within 3 months and guarantee for free a year.

The following situations are not included in warranty time:

- 1) problem caused by self dismounting
- 2) problem caused by shocking during use or delivery.
- 3) problem caused by incorrect maintenance
- 4) problem caused by incorrect operating, problems caused by unprofessional repair.

. supply the purchase prove when require warranty.

the repair will be charged if not in warranty period or range

. we keep the final explanation right for above warranty.

#### **User Assistance Information:**



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