

**scala**  
**Infrared-Ear-  
Thermometer**  
**SC 8178**



**CE** 0197

**GB** Instruction manual

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## **SAFETY INSTRUCTIONS**



### Warnings

1. Read the entire instruction manual before trying to operate the device.
2. The device is delivered non-sterile; please clean the device before measuring.
3. Stop using the device if malfunctions appear or if it operates abnormally.
4. Children should not use the device without the supervision of an adult. Keep out of reach of unsupervised children.
5. Do not use the device when flammable materials are around.
6. Do not place the device on scarred tissue, open wounds or abrasions.
7. If the device has been kept or stored in extreme temperatures, wait at least one hour for the device to return to room temperature before measuring.
8. Do not touch the probe, unless the device is on the measuring.
9. The device is not water resistance, please keep dry.
10. Do not drop the thermometer or expose it to heavy shock.
11. Do not bite or swallow the probe and the battery cover.
12. Do not let thermometer come into contact with any thinner or chemical solvents.
13. Components may be harmful if swallowed. Contact a physician immediately should this occur.
14. Do not use if the display malfunctions or it operates irregularly.
15. Do not put this unit in dishwasher.
16. Performance of the thermometer may be degraded if: Operated or stored outside stated temperature and humidity ranges or if the patient's temperature is below the ambient (room) temperature.

17. Only use the thermometer indoors and do not use it near mobile phones or microwave ovens. In the case of thermometer whose maximum power exceeds 2 W, the minimum distance from thermometer should be 3,3 meters.

18. ORAL TEMPERATURES READINGS ARE OFTEN 0,5°C LOWER THAN ACTUAL BODY TEMPERATURE READINGS.

19. The reading is for reference, if feel sick or uncomfortable, please contact the physician.

20. The thermometer is a direct mode thermometer. Reference site is ear and the measuring side is ear.



### Cautions

1. Do not scrape or scratch the probe as it will hamper the effectiveness of the device.
2. Do not dismantle the device except when replacing the battery.
3. Wait at least thirty minutes after exercising, bathing or eating before taking a measurement.
4. If the subject's body temperature is lower than the room temperature, a false reading may occur.
5. To ensure the best performance of the device, please follow the **Product Specification** "Storage condition" regarding temperature and humidity ranges for storing the device.
6. Dispose of the device and battery according to your local regulatory or environmental protection agency.
7. The device is not intended for use in the emergency medical services environment.

For maximal performance of the device, we recommend a regular check up and device calibration every two years.

### **DEVICE DESCRIPTION AND INTENDED USE**

The thermometer is an electronic device intended to measure the body (human) temperature. It is designed to absorb the infrared from human body to detect your temperature. It can be used with adult or pediatric patients and it can be used in household.

### **ABOUT BODY TEMPERATURE**

A person's normal body temperature can range from 35,5°C to 37,8°C throughout the day. We recommend taking your temperature at different times during the day when you are NOT sick. This will give you a preliminary reference to know what your normal temperature is and how it fluctuated during a normal day. Then, when you feel sick or discomfort, knowing this will provide an index for a reliable diagnosis of a fever.

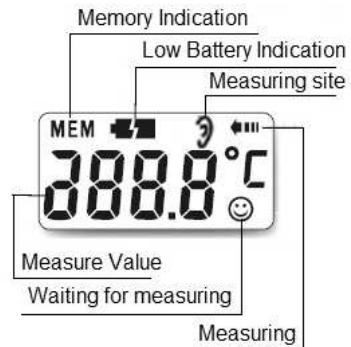
### **CONTRAINDICATIONS**

1. Place the probe in scarred tissue or tissue compromised by any disorders of measuring site.
2. Patients in trauma or treat with certain drug therapies of measuring site.

### **DEVICE OVERVIEW**



### **DISPLAY OVERVIEW**
















### QUICK START



1. Install battery into the device. Make sure the polarity (+ and -) of the battery matches as shown in the battery compartment
2. Press and release the ON/OFF button, you will hear a short beep. The device will be ready for measuring when two short beeps are heard.
3. Place the Probe on the measuring site.
4. Press the ON/OFF Button then read the temperature on the LC Display.



### EXPLANATION OF SYMBOLS

<b>0/I</b> bzw. 	ON/OFF Button
	Wait for measuring
	Measuring site is ear canal
	Measuring
	Low battery indication
<b>MEMORY</b>	Memory indication
 <b>0197</b>	conform with EC directive 93/42/EEC and subsequent changes.
	Please read thoroughly before using.
	Keep dry
	Warning and Caution

<b>IP 20</b>	2: Protected against solid foreign objects of 12,5 mm diameter and greater. 0: Liquid ingress protection; none. Non-protected Enclosures classified according to degree of protection against ingress water and particulate matter (IPN1N2) as detail in IEC 60529. ME equipment or its parts marked with IP environment code per IEC 60529 according to classification in 6.3 (Table D.3, code2).
<b>OFF</b>	Power off
 	Disposal notes
<b>RoHS</b> conform 2011/65/EU	This is denotes the compliance of Restriction of Hazardous Substances Directive.
 Registration, Evaluation and Authorisation of Chemicals	REACH symbol Registration, Evaluation, Authorization and Restriction of Chemicals is a European Union regulation.
	Type BF Applied Part
<b>LOT</b> <b>MMYY</b>	Production period (month / year)

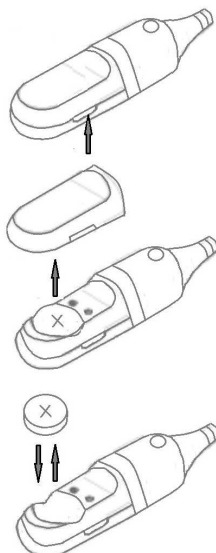
	Manufacturer
EC REP	Authorized Representative in the EU
	No PHT

### BATTERY INSTALLATION

1. Replace with a new CE2032 battery when the low battery indication appears.
2. Remove battery if the device is not likely to be used for a long period of time.
3. Do not dispose the battery in a fire, the battery will explode.

#### Replacing / Installing Battery

1. Remove the battery cover to insert a battery.



2. Confirm the polarity (+ and -) of a battery is correct as indicated inside the compartment and insert a battery accordingly.
3. Replace the battery cover.

### MEMORY FUNCTIONS

#### Recall memories

1. When the unit is off, press and hold the ON/OFF Button around 3 seconds until the last memory shows.
2. You may continue to press and release the ON/OFF Button to recall up to 9 previous records.
3. Discontinue pressing the ON/OFF Button to stop recalling memories.
4. The memory will flash for times then the device is ready to do a new measurement.



#### Delete memories

When the device is in memory mode, press and hold the ON/OFF Button to delete all memories, then the device will be off automatically.

1. To stop deleting memories, do not press the ON/OFF Button when you see "dEL".
- 2 Then the device will return to memory mode after 2 seconds then it is ready for measurement.



## MEASUREMENT CONSIDERATION



### Caution

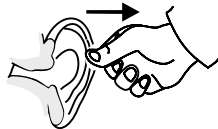
1. Make sure the measuring site is dry, and clean prior to measurement taking.
2. Clean the Probe before and after each measurement to prevent cross-contamination, see **CLEANING AND DISINFECTION**.
3. After cleaning and disinfection the Probe, please wait for 2 minutes to do a measurement at least.

## PREPARING FOR A MEASUREMENT

1. Straighten the ear canal.

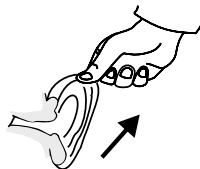
For children under 12 months:

Make the ear canal straight by gently pulling the ear backward.



For children over 12 months and adults:

Make the ear canal straight by gently pulling the ear backward and upward.



2. Place the Probe inside the ear canal
3. Press and release ON/OFF Button to do a measurement.

## DOING A MEASUREMENT

1. Press the ON/OFF Button to turn on the device, it will do auto self-diagnosis.
2. After completing self-diagnosis, the device will be ready for measurement.
3. Press and release the ON/OFF Button then read the temperature.



## CLEANING AND DISINFECTION

1. To clean and disinfect the device, use a cotton swab or pad moistened with 70% alcohol to wipe the Probe.
2. Use a cloth dampened with water or neutral detergent to clean and dry the device.
3. Do not use thinner, benzene and other harsh cleaners for cleaning the device.
4. Do not immerse the unit in water or liquid of any kind. The unit is not waterproof.



Do not submerge or expose the device to water



Do not use corrosive detergent to clean the device. Clean and disinfect the thermometer before and after use.

### Cleaning process

1. Pre-cleaning with cold water wash several times.
2. Clean the Probe with solution of 5-10% mild detergent about 10 - 15 minutes.
3. The continuously cleaning operation with cold water to avoid the chemical residues remaining on the device.
4. Rinse the device with reverse osmosis water (R.O. water) or distilled water to ensure the removal of all remnants of the cleansing agent.

5. If necessary, repeat step 2 to step 4 in order to make sure the device was clean.
6. A final wipe down by a clean wiper is necessary to avoid water stains.

Disinfection process

1. To disinfect the device when completed the cleaning process.
2. Wiping the Probe with a cloth dipped in a disinfectant solution such as rubbing 70-75% alcohol solution: contact time  $\geq$  10 min for disinfection.
3. The disinfectant free rinse without residues.

*Drying process*

1. After cleaning and disinfection process.
2. Put the device to air-dry in the room temperature (20-30°C), exposure time around 30-60 min.
3. And store the device in a dry, clean and dust-free environment at moderate temperatures of 5°C to 40°C.

**CARE AND STORAGE**

1. Do not drop or crush the device. It is not shock proof.
2. Do not dismantle or modify the device other than changing the battery.
3. Do not store the device in an extreme environment with direct sunlight, high/low temperatures or in a location with high humidity or severe dust.

Please contact your local agents or distributors if the device does not function properly as specified under **PRODUCT SPECIFICATION**

**PRODUCT SPECIFICATION**

Measuring site	Ear canal
Measuring time	1 second
Measuring range	32,2°C - 43,3°C
Accuracy	34,0°C - 43,0°C: +/-0,2°C other range +/-0,4°C
Measuring unit	°C
Resolution	0,1°C
Memory	9 sets
Operation condition	+16°C - +35°C, a relative humidity range of 15% to 90%, non-condensing, an atmospheric pressure range of 700hPa to 1060 hPa
Storage condition	-25°C to +5°C, and +5-35°C at a relative humidity up to 90% (non-condensing), >35°C to 55°C at a water vapour pressure up to 50 hPa, relative humidity is variable within 30-90% range
Clinical repeatability	less than + 0,3°C
Battery	1 x CR2032
Battery life	More than 3.000 measurements
Auto shut off	after 10 seconds of inactivity
Dimension	102,5 x 26 x 26 mm
Weight	45 g including battery
Certification	ISO 13485 und ISO 80601-2-56

Specifications may change as technical improvements take place

### TROUBLESHOOTING

H	The reading is higher than measuring range. Please wait a few minutes and measure again.
L	The reading is lower than measuring range. Please wait a few minutes and measure again.
Er1	The ambient temperature is out of the operating condition.
Err	The device self-diagnostic is failed. Please contact the distributor.

### WARRANTY

We grant a warranty of two years for the thermometer. The cash voucher is your warranty certificate. The product will be repaired free during the warranty period. The warranty does not cover damage due to improper handling, accident, non-compliance with the instructions for use or unauthorized modifications of the product.

### DISPOSAL NOTES



Defective blood pressure monitors or monitors at the end of their life may contain material that might be a hazard to the environment.

Dispose of the blood pressure monitor as prescribed, i.e., at a collection point for electrical scrap.

The disposal of batteries is regulated. Spent batteries are collected at collection points provided by battery dealers and the communities.



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