

Infrared Ear Thermometer

TS21

EN



CE
2797



IP 22 RoHS REACH



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Importer



Distributor

INSTRUCTION MANUAL

Please read this instruction manual carefully
before using your Infrared thermometer

Contents

Introduction	1
Important Information before Use	2
Product Identification	4
Description of LCD Display	5
Battery Installation	6
Setting °C/°F.....	7
Memory Function	7
Measuring Body Temperature in the Ear.....	8
Cleaning and Disinfecting.....	9
Error Codes	10
Trouble Shootings	11
Technical Specification	13
EMC Tables.....	14
Explanation of Symbols.....	16

Introduction

Intended Use

This thermometer is intended for home use and the measurement of human body temperature in people of all ages. This thermometer takes temperatures in seconds by measuring the heat generated by the ear canal.

Type of Use/ Reuse

Multiple patient multiple use

Intended User

The Patient is an intended operator.

Patient selection criteria: Handicapped persons and children are the exception of handicapped persons and children need assistance by another person to use the device.

Contraindication:



1. The ear is infected with otitis or suppuration.
2. The ear canal treated with ear drops or other medications.
3. Blood or drainage in ear canal.
4. Face and/or ear deformities

Important Information before Use

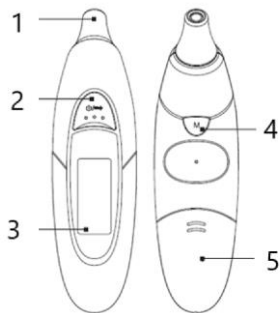
When using this product, please be sure to follow all the notes listed below. Any action against these notices may cause injury or affect the accuracy.

1. Do not disassemble, repair, or remodel the thermometer.
2. Be sure to clean the thermometer lens each time after usage.
3. Avoid direct finger contact with the lens.
4. **WARNING:** No modification of this equipment is allowed.
5. It is recommended that user may take 3 temperatures. If they are different, use the highest reading.
6. Do not expose the thermometer to extreme temperature, very high humidity, or direct sunlight.
7. Avoid extreme shock or dropping the device.
8. Before the measurement, patients and thermometer should stay in steady state room condition for at least 30 minutes.
9. Avoid measuring temperature in 30 minutes after exercise, bathing, or returning from outdoor.
10. To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations.
11. Please use the thermometer solely for its intended purpose.
12. There are no absolute body temperature standards. Keep reliable records of your personal temperature to serve as a reference for judging a fever.
13. Under any circumstances, the temperature taking result is **ONLY** for reference. Before taking any medical action, please consult your physician.
14. The thermometer is calibrated at the time of manufacture. If at any

time you question the accuracy of temperature measurements, please contact an authorized distributor for sending calibration services, additional cost may apply for return shipping fee.

15.  CAUTION - Avoid potential allergic reactions, please avoid the front of scanner in direct contact to patient's wound.
16.  CAUTION - Please keep this device away from pets, pests, and children.
17.  CAUTION: Please keep away from children and pets, because small parts may be inhaled or swallowed.
18. If you would require any assistance during setting up, using or maintaining, please contact the manufacturer.
19. Avoid using the device near an operating cell phone or microwave oven.
20. If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.
21. Neonatal under 6 months, the ear canal is still under development, very narrow so the temperature of the eardrum often cannot be recorded and the result displayed is often too low.
22. Make sure the ear canal is clean not blocked by earwax.

Product Identification



- 1 Probe
- 2 Power/ Measurement Button
- 3 LCD Display
- 4 Memory Button
- 5 Battery door

Description of LCD Display



Measurement in progress



Temperatuer unit Celcius



Temperatuer unit Fahrenheit



Degree of temperature



Low battery symbol



Memory symbol and sets of records





Smiling Face



Frowning Face

Battery Installation

When the batteries get weak, the battery warning symbol appears . It is still possible to measure temperature. The batteries must be replaced. When the battery symbol flashes  and "Lo" appears in the display, the batteries must be replaced. If the batteries are too flat, then the thermometer will switch off automatically.

NOTE:

- It is recommended to remove the batteries if the unit will not be used for an extended period of time.
- Please properly dispose of the batteries away from small children and heat.
- Batteries must be disposed of in accordance with local environmental and institutional policies.
- Do not use rechargeable batteries.

1. Open the battery case by sliding off the cover on the back of the unit.
2. Remove used battery.
3. Replace with 1 x 3V CR2032 battery in designated area. The larger part of the battery should be facing up. You should still be able to see the "+" sign when battery is installed.
4. Slide the cover back on. Unit is ready for immediate use

Dispose of used batteries in accordance with the applicable legal regulations. Never dispose of batteries in the normal household waste.

Setting °C/°F

Changing the Measurement Unit (°C/°F)

1. Press the “Power & Measure Button” to turn on the unit.
2. If you wish to change the temperature scale of your thermometer, turn your thermometer on and then press the “Power & Measure Button” and “Memory Button” to switch the unit..

Memory Function

Memory Recall:

You can recall up to 9 measurements currently stored in memory to share with your physician or trained healthcare professional.

1. When the device is on, press once briefly on the “Memory” Button, then pass it again to show the last measurement.
2. Press the “Memory” button. The last measured value will appear on the display.

Memory Deletion:

Remove batteries, memory will be cleared.

NOTE:

All the readings will be cleared no matter record in Human Mode or Object Mode.

Measuring Body Temperature in the Ear

1. Press the Power/Measure button for 1 second to switch the thermometer on. All screen data will display on screen. Then the measurement mode flashes on screen. Then wait for beep sound to let you know the appliance is ready and followed by last temperature reading.
2. Make sure that the sensor tip and also the ear canal are clean. As the ear canal is slightly curved, you have to pull the ear slightly up and backwards before inserting the sensor tip. This is important so that the sensor tip can be pointed directly at the eardrum.
3. Insert the sensor tip carefully and press the Power button for 1 second.
4. The end of the measuring time is signaled with beep sound and the measured value appears on the display.

Cleaning and Disinfecting

For home use device disinfection, 75% alcohol (available in the pharmacy) can be used.

- Probe and Tip
Clean the probe and tip before and after each measurement.
- Thermometer:
Use a soft, dry cloth to clean thermometer body. Never use abrasive cleaning agents, thinners or benzene for cleaning. Do not scratch the surface of the probe lens or the display. Do not expose the thermometer to extreme temperatures, humidity, direct sunlight, or shock.

Error Codes

When a malfunction or incorrect temperature measurement occurs, an error message will appear as described below.


LCD Display	Cause	Solution
H _i	The temperature measured is higher than 43°C (109.4°F)	Operate the thermometer only between the specified temperature ranges. If necessary, clean the sensor tip. In the event of a repeated error message, contact your retailer or Customer Services.
Lo	The temperature measured is lower than 34°C (93.2°F)	
Err	The operating temperature is not in the range 15°C~40°C (59°F~104°F)	Operate the thermometer only between the specified temperature ranges.

Trouble Shootings

Trouble	Probable Case	Recommended Action
Failed to power on.	Batteries are drained.	Replace with a new battery
	Batteries are not correctly aligned with terminals.	Reinsert batteries correctly.
	The thermometer is damaged.	Contact your retailer or Customer Services.
Low battery symbol appears.	Low battery.	Replace with a new battery as soon as practical
	In colder temperature batteries have weaker electrical charges.	Warm up the batteries or use the device in a warmer setting.
The measurement is abnormal or if there is any doubt on the measured result	Incorrect measure position.	Reposition the probe point the eardrum.
	The measuring is hampered by earwax	Remove obstructions from ear.
	The lens of probe is dirty.	Clean the lens according to <i>cleaning and disinfecting</i> .
	You have just come from extreme temperatures environment.	Stay in steady state room at least for 30 minutes.
	The thermometer has been stored in a cold room or exposed to direct sunlight.	Put the thermometer in steady state room at least for 30 minutes.
Power switches off automatically.	System design.	Push the power button again.

Trouble	Probable Case	Recommended Action
	Batteries are drained.	Replace with a new battery
	The thermometer is damaged.	Contact your retailer or Customer Services.

Technical Specification

- Range of Measurement :
Human Body: 34°C – 43°C (93.2°F – 109.4°F)
- Measuring accuracy :
Human Body: 34°C – 43°C (93.2°F – 109.4°F) ±0.2°C (0.4°F)
- Operating environment :
15°C – 40°C (59°F – 104°F)
with relative humidity 15% to 95% (non-condensing)
Atmospheric Pressure: 700~1060 hPa
- Storage/ Transportation environment :
-25°C – 55°C (-13°F ~+131°F)
with relative humidity 15% to 95% (non-condensing)
Atmospheric Pressure: 700~1060 hPa
- Display resolution : 0.1°C
- Power supply: 1 x 3V CR2032
- Auto switch-off in 60 seconds without operation 
- Memory: 10 sets
- Weight : approx. 45g (without batteries)
- Dimensions : approx. 108.6 x 30.2 x 42.1 mm (L×W×H)
- Shelf Life : 3 years
- Battery Operation Time: About 90 minutes (Depends on different brand of batteries.)
- For Customer Service










To obtain further service please contact AViTA Corp. for the address of the repair location. Enclose the Proof of Purchase. Include \$10.00 USD for the return shipping and handling. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.








EMC Tables








<p>TS21 is intended for use in the electromagnetic environment specified below. The customer or the user of TS21 must make sure that it is used in such an environment.</p>			
<p>Guidance and manufacturer' s declaration - Electromagnetic emissions</p>			
Phenomenon	Professional healthcare facility environment a)	HOME HEALTHCARE ENVIRONMENT a)	
Conducted and radiated RF MISSIONS	CISPR 11 Group 1 Class A (Not BLE Function) Group 2 Class A (With BLE Function)	CISPR 11 Group 1 Class B (Not BLE Function) Group 2 Class B (With BLE Function)	
Harmonic distortion	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested		
Voltage fluctuations and flickering	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested		
<p>a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive acceptance limits of Group 1 Class B (CISPR 11) have been considered and applied. The equipment is suitable for use in the mentioned environments when directly connected to the Public Mains Network.</p> <p>b) The test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEM used will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.</p>			
<p>Guidance and manufacturer' s declaration - Electromagnetic immunity - Enclosure port</p>			
Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8kV contact ± 2 kV, ±4kV ±, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	a)	10 V/m b) 80MHz - 2.7 GHz 80% AM at 1kHz

Proximity fields from RF wireless communications equipment	IEC 61000-4-3	<p>COMPLIANT</p> <p>NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the TS21 can be requested from supplier using the contact information provided in this manual. However, it is advisable to keep the electromechanical aerosol equipment at an adequate distance of, at least, 0.5 m from mobile phones or other RF communications transmitters to minimise possible interference.</p>
RATED power frequency magnetic fields.	IEC 61000-4-8	<p>30 A/m c) 50 Hz or 60 Hz</p>
<p>a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive IMMUNITY acceptance limits have been considered and applied.</p> <p>b) Before modulation is applied.</p> <p>c) This test level assumes a minimum distance of at least 15 cm between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic fields.</p>		

Explanation of Symbols

	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745
	Medical Device
	Manufacturer
	Authorized representative in the European Community
	Date of manufacture (YYYY-MM-DD or YYYY-MM)
	Batch code (YYMMWWWW)
	Serial number (YYMWWWWXXXXX)
	Keep dry
	Temperature limit

	Humidity limitation
	Atmospheric pressure limitation
	Caution
	Consult the instruction for use
	Disposal information: Should you wish to dispose of the article, do so in accordance with current regulations. Details are available from your local authority. WEEE 2012/19/EU Directives
RoHS	This product fulfilling the requirements of the RoHS Directive 2011/65/EU.
REACH	This product fulfilling the requirements of the REACH Directive EC 1907/2006 and its amendments, do not contain Substances of Very High Concern in concentration above the limit of 0.1 %. No substance(s) is/are present in the parts of the product above the concentration of 0.1 % weight by weight.
	Stand-by
	Device classification type BF

<p>IP 22</p>	<p>This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm \varnothing and greater and against vertically falling water drops when enclosure tilted up to 15°)</p>
	<p>The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.</p>
	<p>Importer</p>
	<p>Distributor</p>
	<p>Model Number</p>
	<p>Country of Manufacturer</p>
	<p>Unique Device Identifier</p>
	<p>Keep away from sunlight</p>

Electronic IFU available at <http://www.avita.com.tw>

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