

Infrared Ear/ Forehead Thermometer

TS53B

EN



IP 22 RoHS REACH



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Importer



Distributor

INSTRUCTION MANUAL

Please read this instruction manual carefully
before using your Infrared thermometer

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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/ on the forehead.

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
5. Forehead is scarred or compromised tissues
6. Patient' s skin is on certain medication of measurement site.

Important Information before Use

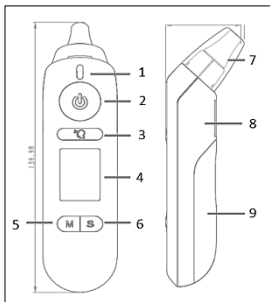
When using this product, please be sure to follow all the notes listed below. Any action against these notices may cause injury or affect the accuracy.

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, local representative 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 LED status indicator (temperature indicator)
- 2 Power/Ear Measure button
- 3 Forehead button
- 4 Lens/ LCD Display
- 5 Memory button
- 6 SET button
- 7 Probe
- 8 Bottom Case
- 9 Battery Compartment Lid

Description of LCD Display

- | | | |
|----|--|--|
| 1 |  | Date |
| 2 |  | Time |
| 3 |  | Measurement in progress |
| 4 |  | Temperatuer unit  |
| 5 |  | Temperatuer unit  |
| 6 |  | Degree of temperature |
| 7 |  | Sound symbol |
| 8 |  | Low battery symbol |
| 9 |  | Memory symbol and sets of records |
| 10 |  | Object measurement |
| 11 |  | Ear measurement |
| 12 |  | Forehead measurement |
| 13 |  | Bluetooth |

Battery Installation

When the battery is low, the battery warning symbol appears . It is still possible to measure temperature. The batteries shall be replaced shortly. When both the battery symbol flashes  and “Lo” appears in the display, the batteries must be replaced immediately. If the batteries are drained, 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.
- It is recommended not to use rechargeable, unqualified or different spec of batteries as it may damage the device or cause circuit shortcut.
- Dispose of used batteries in accordance with the applicable legal regulations. Never dispose of batteries in the normal household waste.

STEPS to change battery

1. Open the battery case by sliding off the cover on the back of the unit.
2. Remove used battery.
3. Replace with 2 x 1.5V LR03(AAA) alkaline batteries in designated area. (check for the right polarity before replace with the new battery)
4. Slide the cover back on. Unit is ready for immediate use

Setting °C/°F and Date/Time

You can configure the following basic settings for the multi-function thermometer: temperature unit (Celsius / Fahrenheit), date, time and Bluetooth®.

- (1) To switch on the device press the ON / OFF / MEASURE button.
- (2) Press the S button for five seconds.
- (3) The current set temperature unit appears on the display.
- (4) Using the S button select the temperature unit (°F or °C). Confirm by pressing the M button.
- (5) The time format will appear on the display. Select the time format (12 hour or 24 hour) using the S button. Confirm by pressing the M button.
- (6) The year display will flash on the display. Using the S button select the current year. Confirm by pressing the M button.
- (7) The month display will flash on the display. Using the S button select the current month. Confirm by pressing the M button.
- (8) The day display will flash on the display. Using the S button select the current day. Confirm by pressing the M button.

Note: *If the 12-hour time format has been configured, the positions for the month and day will be reversed.*

- (9) The hour display will flash on the display. Using the S button select the current hour. Confirm by pressing the M button.
- (10) The minute display will flash on the display. Using the S button select the current minute. Confirm by pressing the M button.
- (11) If no button is pressed within 30 seconds, the basic settings menu will automatically close.
- (12) Bluetooth® will flash on the display. Activate or deactivate Bluetooth® using the S button (ON will appear on the display for activation, OFF will appear on the display for deactivation). Confirm by pressing the M button. The device will save the basic settings and switch off automatically.

Operating the Bluetooth Function

This product is an **Infrared Thermometer with Bluetooth function**. Design without entering personal information. If the device has a transmission function, the transmission measurement data is designed to be encrypted and transmitted, and will not be tampered with or retrieve user-related information during the transmission process. The firmware and software of the product have been programmed in the production process, and the programming interface is different from the data transmission interface. When programming to the microcontroller, use an encrypted programmer, so there is no need to worry about the software being tampered with during transmission.

Bluetooth function requirement:

- An Android device with Android version 4.3 or above and hardware support for Bluetooth 4.2.
- An iOS device with iOS version 5 or above and hardware support for Bluetooth 4.2.

How to activate the Bluetooth function:

Please refer to the instruction manual of your mobile phone or computer for how to activate the Bluetooth function.

Set Up Process

- (1) Please determine your mobile phone or computer has BLE4.2.
- (2) Turn on the **TS53B**, when the Bluetooth icon shows on the device , it means **TS53B** is under broadcast condition.
- (3) Please check the connecting condition from your mobile phone or computer. The device name should be "**TS53B**" .
- (4) Every measure reading will be transfer to your mobile phone or computer automatically.

Measuring Body Temperature in the Ear

1. Remove the front cover.
2. 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. If the icon shows forehead mode, please press Power/Measure button again to change to ear mode. Then wait for 2 beep sounds to let you know the appliance is ready and followed by last temperature reading.
3. 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.
4. Insert the sensor tip carefully and press the Power button for 1 second.
5. The end of the measuring time is signaled with beep sound and the measured value appears on the display.

Measuring Body Temperature on the Forehead

1. The cap should be in position on the probe nozzle.
2. Press the Power/Measure button. All screen data will display on screen. Then the measurement mode flashes on screen. If the icon shows ear mode, please press the Power/Measure button again to change to forehead mode. Then wait for 2 beep sounds to let you know the appliance is ready and followed by last temperature reading.
3. When the beep sounds to let you know the appliance is ready, press the Power/Measure button and maintain pressure.
4. Place the probe on your temple. Slide the probe across your forehead to the other temple, and then release pressure on button to stop temperature taking. You' ll hear a beep and your temperature will come up on the screen.

Note: Forehead temperature may be affected by external climatic conditions. If in doubt, do not hesitate to take your ear temperature.

Memory Function

Memory Recall:

You can recall up to 30 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 press it again to show the last measurement.
2. Press the M button. The last measured value will appear on the display.
3. If you have activated Bluetooth® data transfer, the data will be transferred after the measurement. The thermometer displays the symbol for Bluetooth® during transfer.

Memory Deletion:

Remove batteries, memory will be cleared.

NOTE:

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

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.

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: 2 x 1.5V LR03(AAA) alkaline
- Auto switch-off in 30 seconds without operation
- Memory: 30 sets
- Weight : approx. 62g (without batteries)
- Dimensions : approx. 141.4 x 36 x 42.9 mm (LxWxH)
- Frequency : 2402~2480GHz
- Output power range : <=4dBm
- 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

TS53B is intended for use in the electromagnetic environment specified below. The customer or the user of **TS53B** must make sure that it is used in such an environment.

Guidance and manufacturer' s declaration - Electromagnetic emissions

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	

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.










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.








Guidance and manufacturer' s declaration - Electromagnetic immunity - Enclosure port








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 TS53B 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 minimize 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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