# Infrared Ear/ Forehead Thermometer

# TS42B

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| EC | REP | MDSS GmbH |

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Importer

Distributor

## INSTRUCTION MANUAL

Please read this instruction manual carefully
before using your Infrared thermometer

## Contents

# 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
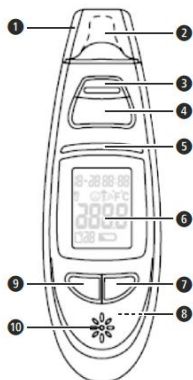


| 1 | Probe Cover |
|---|---|
| 2 | Probe |
| 3 | Forehead Scan Mode |
| 4 | Ear Scan Mode |
| 5 | LED Light |
| 6 | LCD Display |
| 7 | Setting Button |
| 8 | Battery Cover(On the back side) |
| 9 | Memory Button |
| 10 | Speaker |

**Description of LCD Display**

| | | |
|---|---|---|
| 1 | 18-28 | Date |
| 2 | ☺ | Forehead Scan Mode |
| 3 | 👂 | Ear Scan Mode |
| 4 | ⌇ | Object Mode |
| 5 | 📄28 | Memory symbol and sets of records |
| 6 | 🔋 | Low Battery Indicator |
| 7 | 8888 | Degree of Measurement |
| 8 | °C | Celsius Scale |
| 8 | °F | Fahrenheit Scale |
| 9 | ⬆ | Measurement in Progress |
| 10 | 88:88 | Time |

**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.

## Measuring Object/ Liquid Temperature

1. Press the "Forehead Measure" button or "Power/Ear Measure" button for 1 second to switch the thermometer on. Following a successful self-test, the device emits two short beeps.
2. Then press the "Memory" and "SET" buttons simultaneously for 3 seconds to switch to the "Object Scan Mode ".

   The 🔊 symbol appears in the display.

3. Point the sensor tip towards the object or liquid (maintaining a distance of 3 cm), then take one press on "Forehead Measure" button or "Power/Ear Measure" button to take a measurement (never immerse in liquids).
4. After the measurement process is complete, there comes a short beep and the measured value appears on the display.
5. Please note that the displayed temperature is the measured and not the adapted surface temperature. It is not the same as the temperature.
6. To switch back to the thermometer mode, press the "Memory" and "SET" buttons simultaneously for 3 seconds until the "🔊" symbol disappears and there is a short beep.

## Setting °C/°F and Date/Time

When the thermometer is used for the first time and each time the batteries are changed, the date and time are displayed in the format 1-1 00:00 during the basic set-up (after the self-test). Set each of the following settings in turn: unit in which the temperature will be displayed, date and time. To set the device, proceed in stages:

Unit – year – month – day – hours – minutes

After install batteries (first time use), the device performs a brief self-test: all elements of the display are shown for approx. 1 second. Following a successful self-test, the device emits two short beeps. In Standby mode, the date and time are shown and "--" is displayed.

### 1. Changing from Fahrenheit to Celsius

(1) Press the "SET" button for 3 seconds to set the °C/°F.

(2) Press the "Memory" button to confirm entry.

### 2. Date/Time Function

(1) Press the "SET" button to change.

(2) Press the "Memory" button to confirm entry.

(3) The blinking Date, followed by Year, Hour and Minute will display. Repeat steps (1) and (2) to adjust the date/time setting.

(4) Your unit is now ready to take a reading, or press the "Memory" button to turn the unit off.

(5) After this process, the thermometer shows the word "OFF" in the display and switches off automatically.

**Memory Function**

1. The device can recall up to 30 measurements
2. Press the "Memory Recall" button. The first reading displayed is the latest measurement stored in memory.
3. Continue to press the "Memory Button" to view the next previously stored measurement.

**Operating the Bluetooth Function**

When the user connects with the mobile phone for the first time, user will need to enter the pairing password on the mobile phone, and the password will be displayed on the device's LCD ensure the security of the data transmission.

Note: When connecting to the mobile phone for the first time, make sure that the pairing password is not leaked.

Note:

Please refer to the instruction manual of your smart phone for how to activate the Bluetooth function.

Set Up Process

1. Download an app which supports Bluetooth 4.0 from the iTune App Store or Google Play.
2. Enable Bluetooth on your mobile device.
3. Open the app and activate the scan function.

4. Turn on the TS42B.
5. The app should automatically detect your TS42B. Tap the TS42B that is showed in the device list.
6. Your TS42B is now successfully connected to your mobile device. Every temperature reading will be transfer to your mobile device automatically.
7. When the user connects with the mobile phone for the first time, user will need to enter the pairing password on the mobile phone, and the password will be displayed on the device's LCD ensure the security of the data transmission.

Note:

   When connecting to the mobile phone for the first time, make sure that the pairing password is not leaked.

**Cleaning and Disinfecting**

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

• Probe and Tip

Clean the probe and tip with an75% Ethanol or Isopropyl alcohol 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.

## 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.

## Error Codes

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

| LCD Display | Cause | Solution |
|---|---|---|
| **Hi** | 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 or rescan the forehead. |
| | The measuring is hampered by earwax , hair, oil, sweat, etc. | Remove obstructions from ear or forehead. |
| | The lens of probe is dirty. | Clean the lens according to *cleaning and disinfecting*. |
| | 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. |

| Trouble | Probable Case | Recommended Action |
|---|---|---|
| | Measurement was taken in incorrect mode. | Switch to proper mode. |
| Power switches off automatically. | System design. | Push the power button again. |
| | 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 up to 95% (non-condensing)
  Atmospheric Pressure: 700~1060 hPa
- Storage/ Transportation environment :
  -25°C – 55°C  (-13°F ~+131°F)
  with relative humidity up 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 60 seconds without operation ⏻
- Memory: 30 sets
- Weight : approx. 65g (without batteries)
- Dimensions :
  approx. 134.3 x 42.4 x 47.6 mm (L×W×H)
- Service 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

TS42B is intended for use in the electromagnetic environment specified below. The customer or the user of TS42B 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 | |

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| 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 | COMPLIANT NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the **TS42B** 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. | |
| RATED power frequency magnetic fields. | IEC 61000-4-8 | 30 A/m c) 50 Hz or 60 Hz | |

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.
b) Before modulation is applied.
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.

## Explanation of Symbols

| | |
|---|---|
| $C \epsilon$ 2797 | The CE marking with the Registration Number of the Notified Body. This denotes the compliance of **Regulation (EU) 2017/745** |
| MD | Medical Device |
| ▲▲ | Manufacturer |
| EC REP | Authorized representative in the European Community |
| � | Date of manufacture (YYYY-MM-DD or YYYY-MM) |
| LOT | Batch code (YYMMWWWW) |
| SN | Serial number (YYMWWWXXXXX) |
| ☂ | Keep dry |
| ⌡ | Temperature limit |

| | |
|---|---|
| (symbol) | Humidity limitation |
| (symbol) | Atmospheric pressure limitation |
| (symbol) | Caution |
| (symbol) | Consult the instruction for use |
| (symbol) | 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. |
| (symbol) | Stand-by |
| (symbol) | Device classification type BF |

| | |
|---|---|
| **IP 22** | This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm ∅ and greater and against vertically falling water drops when enclosure tiled up to 15°) |
|  | 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. |
|  | Importer |
|  | Distributor |
| # | Model Number |
|  | Country of Manufacturer |
| UDI | Unique Device Identifier |
|  | Keep away from sunlight |

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

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