### Infrared Ear/ Forehead Thermometer

**TS37** 



FN











# P 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

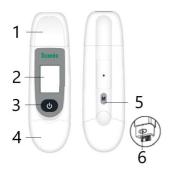
When using this product, please be sure to follow all the notes listed below. Any action against these notices may cause injury or affect the accuracy.

- 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.
- It is recommended that user may take 3 temperatures. If they are different, use the highest reading.
- 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.
- Avoid measuring temperature in 30 minutes after exercise, bathing, or returning from outdoor.
- 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.
- 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.
- 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.
- If you would require any assistance during setting up, using or maintaining, please contact the manufacturer.
- Avoid usin9g 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 Forehead/ Cover Cap
- 2 Display
- 3 Power/Ear Measure button
- 4 Battery Cover
- 5 Memory Button
- 6 Time Setting Button

# Description of LCD Display

| 1  | ଜ              | Ear measurement mode             |
|----|----------------|----------------------------------|
| 2  | $\bigcirc$     | Forehead measurement mode        |
| 3  | $\bigcirc$     | Clock                            |
| 4  | (3)            | Smiling Face                     |
| 5  | 8              | Frowning Face                    |
| 6  | 00:00<br>00:00 | Degrees of Temperature           |
| 7  | <b>4</b>       | Scan in Process                  |
| 8  | <u> </u>       | Memory Symbol and Sets of Record |
| 9  | Û              | Low Battery Warning              |
| 10 | င              | Temperatuer unit Celcius         |
| 11 | ۴              | Temperatuer unit Fahrenheit      |

### **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 batteries 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.

## Changing the Measurement Unit (°C/°F)

- 1. Press the "Power/ Measure" button to turn on the unit.
- If you wish to change the temperature scale of your thermometer, turn your thermometer on and then press the "Power/ Measure" button two more times in rapid succession.

### **Memory Function**

- 1. The device can recall up to 10 measurements
- Press the "Memory" button. The first reading displayed is the latest measurement stored in memory.
- Continue to press the "Memory" button to view the next previously stored measurement.

### Measuring Body Temperature in the Ear

- 1. Remove the Cover cap..
- 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 beep sound 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.
- Insert the sensor tip carefully and press the Power button for 1 second.
- 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.
- 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 beep sound 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.

### **Clock Time and Ambient Temperature**

When the thermometer is used for the first time or after a battery change, the time must first be set. Then the ambient temperature measuring mode is automatically activated.

If you do not need the room temperature or time to be displayed, or if you wish to preserve the battery, do not program in the time after changing the battery. This way you can turn on the thermometer for ear/ forehead measurement as described. However, it then switches off completely.

### Setting the time

- Open the battery compartment by pressing the knob for opening the battery compartment with a pointed object and removing the battery compartment cover.
- 2. Press the "Time Setting" button for setting the time until the hour display flashes. The hours are set by pressing the Power button several times until the required hour setting is reached.
- 3. You can now switch from the hour setting to the minute setting by pressing the time setting button again. The minute display flashes. Adjust the minute setting in the same way that you adjusted the hour setting. When you have set the time, press "Time Setting" button again for confirmation.
- 3. The display of the device now alternates between the time and the ambient temperature.

Note: Using the device as a room thermometer and clock constitutes a continual measuring process, which significantly reduces the battery service life.

### 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  $% \left( 1\right) =\left( 1\right) \left( 1\right)$ 

error message will appear as described below.

| LCD Display | Cause  | Solution  |
|-------------|--|---|
| н,          | is higher than 43°C (109.4°F)                              | Operate the<br>thermometer only<br>between the specified<br>temperature ranges. If  |
| Lo          | The temperature<br>measured is lower than<br>34°C (93.2°F) | necessary, clean the<br>sensor tip. In the event<br>of a repeated error<br>message, contact your<br>retailer or Customer<br>Services. |
| -           | is not in the range  | Operate the<br>thermometer only<br>between the specified<br>temperature ranges.   |

# **Trouble Shootings**

| Trouble Shootin | ys                     |                              |
|-----------------|------------------------|------------------------------|
| Trouble         | Probable Case          | Recommended Action           |
| Failed to power | Batteries are drained. | Replace with a new           |
| on.             |                        | battery                      |
|                 | Batteries are not      | Reinsert batteries           |
|                 | correctly aligned with | correctly.                   |
|                 | terminals.             |                              |
|                 | The thermometer is     | Contact your retailer or     |
|                 | damaged.               | Customer Services.           |
| Low battery     | Low battery.           | Replace with a new           |
| symbol appears. |                        | battery as soon as           |
|                 |                        | practical                    |
|                 | In colder temperature  | Warm up the batteries        |
|                 | batteries have weaker  | or use the device in a       |
|                 | electrical charges.    | warmer setting.              |
| The             | Incorrect measure      | Reposition the probe         |
| measurement is  | position.              | point the eardrum or         |
| abnormal or if  |                        | rescan the forehead.         |
| there is any    | The measuring          | Move the probe closer        |
| doubt on the    | distance is too far.   | to the measuring site.       |
| measured result | The measuring is       | Remove obstructions          |
|                 | hampered by earwax,    | from ear or forehead.        |
|                 | hair, oil, sweat, etc. |                              |
|                 | The lens of probe is   | Clean the lens               |
|                 | dirty.                 | according to <i>cleaning</i> |
|                 |                        | and disinfecting.            |
|                 | You have just come     | Stay in steady state         |
|                 | from extreme           | room at least for 30         |
|                 | temperatures           | minutes.                     |
|                 | environment.           |                              |
|                 | The thermometer has    | Put the thermometer in       |
|                 | been stored in a cold  | steady state room at         |

| Trouble                           | Probable Case                            | Recommended Action                          |
|-----------------------------------|--|---|
|                                   | room or exposed to direct sunlight.      | least for 30 minutes.                       |
|                                   | 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 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 (1)
- · Memory: 10 sets
- · Weight: approx. 45g (without batteries)
- Dimensions: approx. 112.4 x 34 x 25.5 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**

TS37 is intended for use in the electromagnetic environment specified below. The customer or the user of TS37 must make sure that it is used in such an environment.

| Guidance and manufacturer's declaration - Electromagnetic emissions |                           |                       |
|---|---------------------------|-----------------------|
| Phenomenon  | Professional healthcare   | HOME HEALTHCARE       |
| THEHOMETON  | facility environment a)   | ENVIRONMENT a)        |
| Conducted and   | CISPR 11                  | CISPR 11              |
| radiated RF MISSIONS  | Group 1 Class A (Not BLE  | Group 1 Class B (Not  |
|   | Function)                 | BLE Function)         |
|   | Group 2 Class A (With     | Group 2 Class B (With |
|   | BLE Function)             | BLE Function)         |
| Harmonic distortion   | Not applicable            |                       |
|   | (Note: Power by Battery o | r DC Input)           |
|   | Only the AC input needs t | o be tested           |
| Voltage fluctuations  | Not applicable            |                       |
| and flickering  | (Note: Power by Battery o | r DC Input)           |
|   | Only the AC input needs t | o 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                 |               | Immunity test levels |   |
|                            | test method   |                      | HOME HEALTHCARE<br>ENVIRONMENT              |
| ELECTROSTATIC<br>DISCHARGE | IEC 61000-4-2 |                      | t<br>±, ±8 kV, ±15 kV air                   |
| Radiated RF EM fields      | IEC 61000-4-3 | a)                   | 10 V/m b) 80MHz - 2.7<br>GHz 80% AM at 1kHz |

| Proximity fields                                | IEC 61000-4-3 | COMPLIANT   |
|---|---------------|---|
| From RF wireless<br>communications<br>equipment | IEC 01000-4-5 | NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the TS37 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. |
| RATED power frequency magnetic fields.          | IEC 61000-4-8 | 30 A/m c)<br>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**

| <b>€</b> 2797 | The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745 |
|---------------|---|
| MD            | Medical Device  |
| <u>س</u>      | Manufacturer  |
| EC REP        | Authorized representative in the European Community   |
| <u>~</u>      | Date of manufacture<br>(YYYY-MM-DD or YYYY-MM)  |
| LOT           | Batch code<br>(YYMMWWWW)  |
| SN            | Serial number<br>(YYMWWWXXXXX)  |
| <del>*</del>  | Keep dry  |
| *             | Temperature limit   |

| <u></u>       | Humidity limitation  |
|---------------|--|
| ( <del></del> | Atmospheric pressure limitation  |
| $\triangle$   | Caution  |
| <b>(2)</b>    | Consult the instruction for use  |
| X             | 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. |
| Ů             | Stand-by   |
| ☀             | 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 Ø 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  |
| CN    | Country of Manufacturer   |
| UDI   | Unique Device Identifier  |
| *     | Keep away from sunlight   |

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