# Infrared Far Thermometer





FN





CE 🕱 🕅 🕅 IP 22 RoHS REACH



MDSS GmbH Schiffgraben 41 30175 Hannover Germany



AVITA Corporation 9F., No. 78, Sec. 1, Kwang Fu Rd., San Chung Dist., New Taipei City 24158, Taiwan, China



China, AViTA(WUJIANG)



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                         |    |
| Memory Function                       |    |
| Measuring Body Temperature in the Ear | 8  |
| Cleaning and Disinfecting             | 9  |
| Error Codes                           |    |
| Trouble Shootings                     |    |
| Technical Specification               |    |
| 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.
- Do not expose the thermometer to extreme temperature, very high humidity, or direct sunlight.
- 7. Avoid extreme shock or dropping the device.
- 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.
- 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.
- There are no absolute body temperature standards. Keep reliable records of your personal temperature to serve as a reference for judging a fever.
- 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. ACAUTION: 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.
- 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 Memory Button
- 3 Power/ Measurement Button
- 4 LCD Display

# Description of LCD Display

| <b>III</b> | Measurement in progress           |
|------------|-----------------------------------|
| Ĉ          | Temperatuer unit Celcius          |
| ۴          | Temperatuer unit Fahrenheit       |
| 8888       | Degree of temperature             |
|            | Low battery symbol                |
| M8         | Memory symbol and sets of records |
| ٢          | Smiling Face                      |
| ٢          | Frowning Face                     |
|            |                                   |

# **Battery Installation**

When the battery is low, the battery warning symbol appears  $\square$  . It is still possible to measure temperature. The batteries shall be replaced shortly. When both the battery symbol flashes  $\square$  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

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" 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

- 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  |
|-------------|---|---|
| Х,          | The temperature measured  | Operate the<br>thermometer only<br>between the specified  |
| Lo          | The temperature<br>measured is lower than<br>34°C (93.2°F)  | temperature ranges. If<br>necessary, clean the<br>sensor tip. In the event<br>of a repeated error<br>message, contact your<br>retailer or Customer<br>Services. |
| Err         | The operating temperature<br>is not in the range<br>$15^{\circ}C \sim 40^{\circ}C$ (59°E ~ 104°E) | Operate the<br>thermometer only<br>between the specified<br>temperature ranges.   |

# **Trouble Shootings**

| 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.           |
| abnormal or if     | The measuring is       | Remove obstructions          |
| there is any       | hampered by earwax     | from ear.                    |
| doubt on the       | The lens of probe is   | Clean the lens               |
| measured result    | 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         |
|                    | room or exposed to     | least for 30 minutes.        |
|                    | direct sunlight.       |                              |
| Power switches     | System design.         | Push the power button        |
| off automatically. |                        | again.                       |

| Trouble | Probable Case          | Recommended Action       |
|---------|------------------------|--------------------------|
|         | Batteries are drained. | Replace with a new       |
|         |                        | battery                  |
|         | The thermometer is     | Contact your retailer or |
|         | damaged.               | 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: 2 x 1.5V LR03(AAA) alkaline
- Auto switch-off in 60 seconds without operation  $\bigcirc$
- Memory: 10 sets
- Weight : approx. 60g (without batteries)
- Dimensions : approx. 139.7 x 36.3 x 44.4 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

| TS15 is intended f   | or use in the ele  | octromagnotic   | environment specified                         |
|--|--|---|---|
| below The custon   | ner or the user of   | of TS15 must m  | ake sure that it is used                      |
| in such an enviror   |  |   |   |
|  |  | eclaration - Ele  | ctromagnetic emissions                        |
| Phenomenor   | Profossi   | onal healthcare   |   |
|  | facility e   | environment a)  | ENVIRONMENT a)                                |
| Conducted and  | CISPR 11   |   | CISPR 11                                      |
| radiated RF MISSI  |  | Class A (Not BL   |   |
|  | Function   |   | BLE Function)                                 |
|  |  | Class A (With   | Group 2 Class B (With                         |
| Harmonic distorti  | BLE Func   |   | BLE Function)                                 |
| Harmonic distorti  |  |   |   |
|  |  | wer by Battery  |   |
| Voltage fluctuatio   | ns Not appl  | AC input needs  | s to be tested                                |
| and flickering   | INOL appl  | wer by Battery  | or DC Input)                                  |
| and mekening   |  | AC input needs  |   |
| 2) The equinment   |  |   | alth Environments and                         |
|  |  |   | o patient rooms and                           |
| respiratory treatm   | ent facilities in  | hospital or clini   | ics The more restrictive                      |
| 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 a   |  |   |   |
|  |  |   | ected 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  | in in in in it is the test is |   |
|  | standard or  |   | HOME HEALTHCARE                               |
|  | test method  | healthcare  | ENVIRONMENT                                   |
|  |  | facility  |   |
|  | 150 01000 4 2  | environment   | 1   |
| ELECTROSTATIC<br>DISCHARGE   | IEC 61000-4-2  | ± 8kV contact   |   |
| Radiated RF EM   | IEC 61000-4-3  |   | ±, ±8 kV, ±15 kV air<br>10 V/m b) 80MHz - 2.7 |
| fields   | IEC 01000-4-3  | a)  | GHz 80% AM at 1kHz                            |
| 110103   |  | 1   |   |

| Proximity fields<br>from RF wireless<br>communications<br>equipment             | IEC 61000-4-3   | COMPLIANT<br>NOTE: Further information about<br>distances to be maintained between<br>portable and mobile RF<br>communications equipment<br>(transmitters) and the <b>TS15</b> can be<br>requested from supplier using the<br>contact information provided in this<br>manual. However, it is advisable to<br>keep the electromechanical aerosol<br>equipment at an adequate distance<br>of, at least, 0.5 m from mobile phones<br>or other RF communications<br>transmitters to minimise possible<br>interference. |
|---|---|--|
| RATED power<br>frequency<br>magnetic fields.                                    | IEC 61000-4-8   | 30 A/m c)<br>50 Hz or 60 Hz  |
| Professional Healt<br>respiratory treatm<br>IMMUNITY accep<br>b) Before modulat | th Care Environr<br>nent facilities in l<br>tance limits have<br>tion is applied. | se in Home Health Environments and<br>nents limited to patient rooms and<br>hospital or clinics. The more restrictive<br>e been considered and applied.<br>um distance of at least 15 cm between   |

the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic fields.

# **Explanation of Symbols**

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

| <u></u>     | Humidity limitation   |
|-------------|---|
|             | Atmospheric pressure limitation   |
| $\triangle$ | Caution   |
| <b>6</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<br>Directive EC 1907/2006 and its amendments, do not<br>contain Substances of Very High Concern in concentration<br>above the limit of 0.1 %. No substance(s) is/are present in<br>the parts of the product above the concentration of 0.1 %<br>weight by weight. |
| U           | Stand-by  |
| Ŕ           | 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 $\emptyset$ and greater and against vertically falling water drops when enclosure tiled up to 15°) |
|----------|---|
| <b>X</b> | The empty, completely flat batteries must be disposed of<br>through specially designated collection boxes, recycling<br>points or electronics retailers. You are legally required to<br>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

TS15P-22672AV 2022.12.22