Infrared Ear/ Forehead Thermometer

TS9

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 Power/ Measure Button
- 3 LCD Display
- 4 Infrared Sensor
- 5 Battery Cover

Description of LCD Display

Memory symbol (for the last stored record)

Degrees of Temperature

Celsius Scale

Measuring in Progress

Ear measurement mode

Forehead measurement mode

Low battery Warning

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 $1 \times 3V$ 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.

Measuring Body Temperature in the Ear

- 1. Remove the Forehead/ Cover cap.
- 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 into ear canal carefully and then press the Power/Measure button for 1 second and release.
- 5. The end of the measuring time is signaled with a short beep and the measured value appears on the display.

Measuring Body Temperature on the Forehead

Please note that the forehead/temples must be free from sweat and cosmetics and that taking medication and skin irritations can distort the result when measuring temperature on the forehead.

- 1. The cap should be in position on the probe nozzle.
- Make sure that the Forehead/Cover cap is put on. Press the Power/Measure button for 1 second to switch the thermometer on.
- Place the measuring head with the Forehead/Cover cap fitted on the temples, hold on the Power/ Measure button and move the thermometer smoothly over the forehead to the other temple.
- Release the button. The end of the measuring time
 is signaled with a short beep and the measured value appears on
 the display.

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

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
	is higher than 43°C (109.4°F)	Operate the thermometer only between the specified temperature ranges. If
	The temperature measured is lower than 34°C (93.2°F)	necessary, clean the sensor tip. In the event of a repeated error message, contact your retailer or Customer Services.
Ecc	is not in the range	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	Incorrect measure position.	Reposition the probe point the eardrum or rescan the forehead.
there is any doubt on the measured result	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 <i>cleaning</i> 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 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 30 seconds without operation
- Weight: approx. 51g (without batteries)
- · Dimensions:

approx. 108.7x 49.3 x 34 mm (L x W x 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

TS9 is intended for use in the electromagnetic environment specified below. The customer or the user of TS9 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 o Only the AC input needs t	
Voltage fluctuations and flickering	Not applicable (Note: Power by Battery o Only the AC input needs t	

- 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

Basic EMC Immunity test levels Phenomenon standard or Professional HOME HEALTHCARE test method healthcare ENVIRONMENT facility environment **ELECTROSTATIC** IEC 61000-4-2 ± 8kV contact DISCHARGE ± 2 kV, ±4kV ±, ±8 kV, ±15 kV air Radiated RF EM IEC 61000-4-3 10 V/m b) 80MHz - 2.7 a) fields GHz 80% AM at 1kHz

Proximity fields	IEC 61000-4-3	COMPLIANT
From RF wireless communications equipment	IEC 61000-4-5	NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the TS9 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) 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 E 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
سا	Date of manufacture (YYYY-MM-DD or YYYY-MM)
LOT	Batch code (YYMMWWWW)
SN	Serial number (YYMWWWXXXXX)
*	Keep dry
1	Temperature limit

<u></u>	Humidity limitation
(-)	Atmospheric pressure limitation
\triangle	Caution
(2)	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.
U	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

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