Infrared Ear/ Forehead Thermometer

TS27



FN















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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, 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 Memory button
- 3 Setting button
- 4 LED status indicator (temperature indicator)
- 5 Power/Ear Measure button
- 6 Forehead Measure button
- 7 LCD Display

Description of LCD Display

AM 88 + 88 Date/ Time

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III Measurement in progress

* Temperature Unit (Celcius/ Fahrenheit)

Degree of temperature

Sound symbol

JULI Degree of temperature

.,

Low battery symbol

Memory symbol

Object measurement

Ear measurement

Forehead measurement

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 $2 \times 1.5 \text{V LR03}(AAA)$ 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 "Power/Ear Measure" button.
- (2) Press the "Setting" button (left side of the unit) for 5 seconds.
- (3) The current set temperature unit appears on the display.
- (4) Using the "Setting" button select the temperature unit (°F or °C). Confirm by pressing the "Memory" button.
- (5) The time format will appear on the display. Select the time format (12 hour or 24 hour) using the "Setting" button. Confirm by pressing the "Memory" button.
- (6) The year display will flash on the display. Using the "Setting" button select the current year. Confirm by pressing the "Memory" button.
- (7) The month display will flash on the display. Using the "Setting" button select the current month. Confirm by pressing the "Memory" button.
- (8) The day display will flash on the display. Using the "Setting" button select the current day. Confirm by pressing the "Memory" 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 "Setting" button select the current hour. Confirm by pressing the "Memory" button.
- (10) The minute display will flash on the display. Using the "Setting" button select the current minute. Confirm by pressing the "Memory" button.
- (11) If no button is pressed within 30 seconds, the basic settings menu will automatically close.

Measuring Body Temperature in the Ear

- Remove the front cover.
- Press the Power/Measure button to switch the thermometer on.
 Follows with 2 beep sound, the display will fully flash and a blue
 backlight will recall the last measurement when turned on. If the
 icon shows forehead mode, please press Power/Measure button
 again to change to ear mode. Then wait for a beep sounds to know
 the device is ready and followed by last temperature reading.
- 3. Make sure that the sensor tip and the ear canal are both 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.
- Wait for a beep sound and the measured value appears on the display.
- For switch off the thermometer or automatically shut down comes with a beep sound.

Note: When measurement indicates a fever situation, a red flash light with one long beep two short beep sound will alert the user. Please seek for medical attention immediately.

Measuring Body Temperature on the Forehead

- 1. The cap should be in position on the probe nozzle.
- Press the Power/Measure button to switch the thermometer on.
 The display will fully flash and a blue backlight will recall the last measurement when turned on. If the icon shows ear mode, please press the Power/Measure button again to change to forehead mode. Then wait for a 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.
- For switch off the thermometer or automatically shut down comes with a beep sound.

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

When measurement indicates a fever situation, a red flash light with one long beep two short beep sound will alert the user. Please seek for medical attention immediately.

Measuring Object/Liquid Temperature

- While the thermometer is turned on, long press on both the "Memory" and "Setting" button to switch to the Object/Liquid mode. When switch mode successfully, follows with a short beep sound.
- Point the sensor tip towards the object or liquid (maintaining a distance of 3 cm), then take one press on "Forehead Measure" button to take a measurement (never immerse into liquids).
- 4. After the measurement process is complete, there comes a short beep and the measured value appears on the display.
- 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 to the other thermometer mode, long press the "Memory" and "Setting" buttons.

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 pass it again to show the last measurement.
- Press the "Memory" 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.

Sound Function

- 1. Turn on the sound. Simply press "Setting" button.
- 2. Press again to turn off the Sound.

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 thermometer only between the specified temperature ranges. If
Lo	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.
-	is not in the range	Operate the thermometer only between the specified temperature ranges.

Trouble Shootings

irouble Shootin	gs	
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	least for 30 minutes.
	direct sunlight.	
	Measurement was	Switch to proper mode.
	taken in incorrect	
	mode.	
Power switches	System design.	Push the power button
off automatically.		again.
	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 30 seconds without operation
- · Memory: 30 sets
- · Weight: approx. 62g (without batteries)
- Dimensions: approx. 141.4 x 36.3 x 43.2 mm(LxWxH)
- · 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

TS27 is intended for use in the electromagnetic environment specified below. The customer or the user of TS27 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
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	Immunity test levels	
	standard or test method		HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2		t ±, ±8 kV, ±15 kV air
		± 2 KV, ±4KV	I, IOKV, IIJKV ali
Radiated RF EM fields	IEC 61000-4-3	a)	10 V/m b) 80MHz - 2.7 GHz 80% AM at 1kHz

D	IEC C1000 4 3	COLUBLIANIT
Proximity fields	IEC 61000-4-3	COMPLIANT
from RF wireless		NOTE: Further information about
communications		distances to be maintained between
equipment		portable and mobile RF
		communications equipment
		(transmitters) and the TS27 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	IEC 61000-4-8	30 A/m c)
frequency		50 Hz or 60 Hz
magnetic fields.		

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
<u>~</u>	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°)
X	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