### TOUCH FRFF Infrared Thermometer

NT16



FN











P 22 ROHS REACH



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Importer



Distributor

### INSTRUCTION MANUAL

Please read this instruction manual carefully before using your forehead thermometer

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### Introduction

#### Intended use

This Touch Free Infrared Thermometers is intended for home use and the intermittent measurement of human body forehead temperature in people of all ages.

### 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.

#### 1. 6 in 1 functions

Human Body/ Object/ Night Mode Option/ Fever Alarm/ Memory/ Backlight

- 2. Night Mode Option
  - Switch to Night mode to reduce the interference of buzzer during your baby sleeping.
- 3. Red LED Light for Fever Alarm

This device has the LED light to remind user their readings are over 38°C and plus the beep sound only in Human Body Mode.

- 4. 30 Users Memory
- 5. Illuminated Backlight Display
- 6. °C/°F Switch-able Function
- 7. One-second Reading
- 8. Auto power off for power saving

- Low-battery Indicator
   Indications for battery condition and measuring range.
- 10.Large LCD Display
- 11. Economic design and convenience:

This is a "TOUCH FREE" medical thermometer that enables temperature readings, designed for sanitary conditions, cleanliness, and convenience. Simply move the thermometer close to the subject's forehead or object at the distance indicated by the device.

- 12.Instant Measurement
  - By using our unique technology, users can get their precise body temperature instantly and accurate.
- Handicapped persons and children need assistance by another person to use the device.

### Contraindications:

- 1. Scarred or compromised tissues on measurement site.
- 2. Patient' s skin' s on certain medication of measurement site.

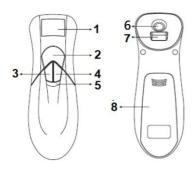
### Important Information before Use

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. No modification of this equipment is allowed.
- 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.
- 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.
- 12. 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. ACAUTION: Please keep this device away from pets, pests, and children.
- CAUTION: Please keep away from children and pets, because small parts may be inhaled or swallowed.
- 17. 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.
- 18. If you would require any assistance during setting up, using or maintaining, please contact the manufacturer.
- Avoid using the device near an operating cell phone or microwave oven.

## **Product Identification**



- 1 Display LCD
- 2 Measure Button
- 3 Human/Object Button
- 4 Memory Button
- 5 LED Light
- 6 Measurement Sensor
- 7 Distance Detection Sensor
- 8 Battery Cover

# **Description of LCD Display**

Measuring sequence in process

Night Mode (Mute Mode)

Human Mode

Object Mode

Degree of measurement

°C Celsius Scale

Fahrenheit Scale

Low battery indicator

Frowning Face (temperature is equal or higher than 38°C)

Smiling Face

(temperature is lower than 38°C)

Memory Symbol and sets of records

# **Battery Installation**

#### Low battery warning:

When the battery power becomes low, the low battery symbol "" will appear on the display. The thermometer can still be used during this time, but the batteries should be replaced as soon as possible. If the batteries run out completely, "Lo" will be displayed along with the low battery symbol "". In this case, the batteries will need to be replaced before using the thermometer again.

# **∴** CAUTION:

- 1. Risk of explosion if battery is replaced by an incorrect type.
- It is recommended not to use rechargeable, unqualified or different spec of batteries as it may damage the device or cause circuit shortcut.

### Replacing the Battery:

- 1. Gently slide the battery cover back.
- 2. Carefully remove the old batteries and properly discard.
- Insert new batteries (Two 1.5V alkaline AAA(LR03) Size) according to the proper polarity.
- 4. Slide the battery cover back on.

### **NOTE:** Battery-operated

- Please properly dispose of the batteries away from small children and heat
- It is recommended to remove the batteries if the unit will not be used for an extended period of time.
- 3. Batteries must be disposed of in accordance with local environmental and institutional policies.
- Dispose of used batteries in accordance with the applicable legal regulations. Never dispose of batteries in the normal household waste.

### Switching Between Fahrenheit or Celsius

Your thermometer can display results in either degrees Celsius (°C) or degrees Fahrenheit (°F). With combination of Memory and Mode button are able to change the mode to either °C or °F with a beep sound.

# Switching between 4 Kinds of Measuring Mode

- 1 Under power on status, you can press the Mode Button to switch different measuring mode. There are 4 kinds of mode which including Human, Object, Human/Night, and Object/Night Mode (in order).
- The beep sounds will be off (mute) when your choice in Human/Night Mode, and Object/Night Mode, and the Moon symbol "">" will appears on the LCD in both Night Modes.



#### NOTE:

Each press will comes with a beep sound to ensure the setting is activated. (Except both Night Modes)

# **Tips for Measuring Human Temperature**

Bear in mind that the thermometer needs to have been in the room in which the measurement is taken for at least 30 minutes before use.

#### NOTE:

- Attempting to take temperature readings from sites on the body other than the forehead may produce inaccurate results.
- The patient should remain still while the reading is being taken.
- Readings taken while asleep should not be compared directly to readings taken while awake, as body temperature while asleep is typically lower.
- Do not take body temperature readings within 30 minutes of being outdoors, exercising or bathing.

# Measuring Human Temperature

#### Taking a Measurement

- Press the Power Button to power on the thermometer. The unit will
  run a self-test and the LCD will briefly display all of its symbols during
  this time. When the device is ready, "00 "appear on the screen, and
  the thermometer is ready to take a measurement.
- Select the desired mode by pressing and releasing the Human/Object Button.

#### Note:

- When taking a patient's temperature, ensure that the thermometer is in Human Mode; the Human symbol " in will appear on the display.
- If the patient' s skin is covered with hair, sweat, or dirt, clean the area and wait 10 minutes before taking a measurement.
- Ensure that the thermometer is held firmly during measurement and that the patient does not move until the measurement is complete.

- Movement can impact the measurement.
- 3. Position the thermometer under 3cm (around 1 inch) from the center of the patient's forehead with the sensor aimed between the eyebrows.
- 4. Press and release the Measure Button.
- 5. Slowly move the device toward or farther from the forehead until you have reached the correct distance. (If the distance is beyond the correct distance, the dash-icon on the display flashes with beep sound in this sequence until the correct distance is achieved.)

#### Note:

When the user presses the Measure Button, this workflow begins and they require time for device to capture the temperature. After capture the temperature, the display turns to stand-by mode.

- As you hear a short beep means this temperature reading has been completed and accompany with a back-light.
- 7. If the temperature measurement is below 38°C, a "Smiling Face" will appear next to the reading. If the reading is 38°C or above, a "Frowning Face" will display and the LED light up to alert.
- 8. After about 30 seconds after use, the thermometer will automatically beep and shut off.

#### Fever Alarm:

Only in Human Mode and Human/Night Mode.

# Measuring Object/Liquid Temperature

- Press the "Measure Button" to turn the thermometer on. All symbols on the display will momentarily appear.
- Ensure that the thermometer is in Object Mode; the Object symbol
   " will be on the display. To alternate between modes press and
  release the Human/Object Mode Button until you see the desired
  measurement symbol on the display.
- 3. Position the thermometer under 3cm (around 1 inch) from the object.
- Release the "Measure Button" and the temperature reading will be displayed.
- After use, the thermometer will automatically beep and shut off after idling.

# **Memory Function**

### Memory Recall:

You can recall up to 30 measurements currently stored in memory to share with your physician or trained healthcare professional.

- When the device is on, press once briefly on the Memory Button, then pass it again to show the last measurement accompanied by "\sqrt{" symbol.
- 2. The " symbol or " " symbol will appear with each measurement stored in memory to indicate whether a person or object temperature was taken.
- 3. Each press of the same button recalls a previous measurement.

#### Memory Deletion:

- Under power on status, you may hold press the "Memory button" to delete all the readings. The LCD shows "--" with one beep sound to indicate that all memories are cleared.
- 2. Remove batteries, memory will be cleared.

#### NOTE:

All the readings will be cleared no matter record in Human Mode or Object Mode.

# Cleaning and Disinfecting

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

- Measurement Sensor
   Clean the measurement sensor with an alcohol swab 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.

Display	Cause	Solution
		Operate the thermometer
<b>3</b>	, ,	only between the specified
,,,,		temperature ranges. If
	` '	necessary, clean the sensor
	The temperature measured is	tip. In the event of a repeated
1 _	,	error message, contact your
LO	Human mode: 34°C (93.2°F)	retailer or Customer Services.
	Object mode: 0°C (32.0°F)	
_	The operating temperature is not	Operate the thermometer
500	in the range:	only between the specified
£,,		temperature ranges.

Troubleshooting

Troubleshooting		
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 center of the
abnormal or if		forehead.
there is any	The measuring	Maintain a distance of 3
doubt on the	distance is too far.	cm.
measured result		 
	The measuring is	Remove obstructions
	hampered by hair,	from forehead.
	perspiration, oil, sweat,	
	makeup, etc.	Class that laws
	The lens of probe is	Clean the lens
	dirty.	according to <i>cleaning</i>
	Var. have ivet some	and disinfecting.
	You have just come	Stay in steady state

	from extreme temperatures environment.	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.
	Measurement was taken in surface temperature mode.	Switch mode to human 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**

· Measuring range:

Human Body: 34°C~43°C (93.2°F~109.4°F) Object: 0°C~100°C (32.0°F~212.0°F)

· Calibration Accuracy:

Human Body: ±0.2°C(±0.4°F): from 34°C~43°C (93.2°F~109.4°F)

Object :  $< 40^{\circ}C \pm 2^{\circ}C; > = 40^{\circ}C \pm 5\%$ 

• Display resolution: 0.1°C

• Operating environment: 15°C~40°C (59°F ~ 104°F) with relative humidity 15% to 95% (non condensing)

Atmospheric pressure: 700~1060 hPa 700 Pa

• Storage/ Transportation environment:

with relative humidity 15% to 95% (non condensing)

• Atmospheric pressure: 700~1060 hPa 700 - 1060 hPa

• Power supply : 2 x 1.5V AAA size alkaline batteries

• Weight: approx. 80g (with batteries)

· Memory: 30 sets

Dimensions: approx. 129.93X44.48X52.43mm (L×W×H)

• Operation Distance: 3 cm

 Battery Operation Time: about 90 minutes (Depends on different brand of batteries.)

· Reference body site: Ear temperature

· Shelf Life: 3 years

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**

NT16 is intended for use in the electromagnetic environment specified below. The customer or the user of NT16 must make sure that it is used in such an environment

Guidance and manufacturer's declaration - Electromagnetic emissions			
Phenomenon	Professional healthcare	HOME HEALTHCARE	
	facility environment a)	ENVIRONMENT a)	
Conducted and	CISPR 11	CISPR 11	
radiated RF MISSIONS	Group 1 Class A (Not BLE		
	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 or DC Input)		
	Only the AC input needs to be tested		
Voltage fluctuations	Not applicable		
and flickering	d flickering (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
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 NT16 can be requested from supplier using the contact information provided in this manual. However, it is advisable to keep the 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**

<b>C E</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
سا	Date of manufacture (YYMMDD or YYYY-MM)
LOT	Batch code (YYMMWWWW)
SN	Serial number (YYMWWWXXXXX)
<del>*</del>	Keep dry
1	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.
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°)	
<b>X</b>	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	
Unique Device Identifier		Data Tuna/Farmat
	Al Data Element (01) Device Identifier(GTIN)	Data Type/Format Numeric
UDI	(11) Manufacturing Date	Numeric: YYMMDD
	(10) Lot Number	Alphanumeric
	(21) Serial Number	Alphanumeric
*	Keep away from sunlight	

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

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