

AViTA

TOUCH FREE Infrared Thermometer

NT16B



EN



CE
2797



IP 22 RoHS REACH

EC REP

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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

9. 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 accurately.

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.
5. 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.
8. Before the measurement, patients and thermometer should stay in steady state room condition for at least 30 minutes.
9. 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.
12. 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. It is recommended calibrate the device every 1 year.
15.  CAUTION: Please keep this device away from pets, pests, and children.
16.  CAUTION: Please keep away from children and pets, because

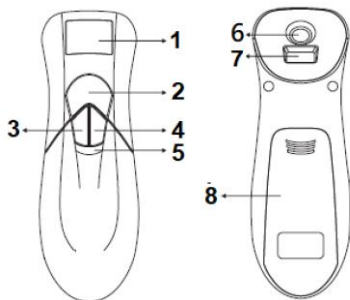
small parts may be inhaled or swallowed.

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.
19. Avoid using the device near an operating cell phone or microwave oven.

Contraindications:

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

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



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:

Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

Replacing the Battery:

1. Gently slide the battery cover back.
2. Carefully remove the old batteries and properly discard.
3. 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

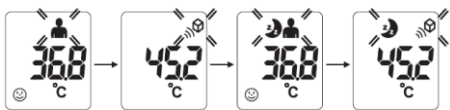
1. Please properly dispose of the batteries away from small children and heat.
2. It is recommended to remove the batteries if the unit will not be used for an extended period of time.
3. Batteries must be disposed of in accordance with local environmental and institutional policies.
4. Dispose of used 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 ($^{\circ}\text{C}$) or degrees Fahrenheit ($^{\circ}\text{F}$). With combination of Memory and Mode button are able to change the mode to either $^{\circ}\text{C}$ or $^{\circ}\text{F}$ 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).
2. 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 come 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

1. 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.
2. 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 "  " 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.

6. 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

1. Press the "Measure Button" to turn the thermometer on. All symbols on the display will momentarily appear.
2. 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.
4. Release the "Measure Button" and the temperature reading will be displayed.
5. 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.

1. When the device is on, press once briefly on the Memory Button, then pass it again to show the last measurement accompanied by “” 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:

1. 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 |
|----------------|--|--|
| H _i | The temperature measured is higher than measurement range. Human mode: 43°C (109.4°F) Object mode: 100°C (212.0°F) | Operate the thermometer only between the specified temperature ranges. If necessary, clean the sensor tip. In the event of a repeated error message, contact your retailer or Customer Services. |
| Lo | The temperature measured is lower than measurement range. Human mode: 34°C (93.2°F) Object mode: 0°C (32.0°F) | |
| Err | The operating temperature is not in the range: 15°C~40°C (59°F~104°F) | Operate the thermometer only between the specified temperature ranges. |

Operating the Bluetooth function

Note:

Please refer to the instruction manual of your smart phone for how to activate the Bluetooth function.






Set Up Process

1. Download an app which supports Bluetooth 4.0 from the iTunes App Store or Google Play.
2. Enable Bluetooth on your mobile device.
3. Open the app and activate the measure function.
4. Turn on the device.
5. The app should automatically detect your device. Tap the device that is showed in the device list.
6. Your device is now successfully connected to your mobile device. Every temperature reading will be transfer to your mobile device automatically.
7. When the user connects with the mobile phone for the first time, user will need to enter the pairing password on the mobile phone, and the password will be displayed on the device's LCD ensure the security of the data transmission.

Note:

When connecting to the mobile phone for the first time, make sure that the pairing password is not leaked.

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 : $\pm 0.2^{\circ}\text{C}(\pm 0.4^{\circ}\text{F})$: from 34°C~43°C (93.2°F~109.4°F)
Object : $< 40^{\circ}\text{C} \pm 2^{\circ}\text{C}$; $\geq 40^{\circ}\text{C} \pm 5\%$
- 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 
- Storage/ Transportation environment :
-25 to 55 °C(-13 to 131 °F) 
with relative humidity 15% to 95% (non condensing) 
- Atmospheric pressure: 700~1060 hPa 
- Power supply : 2 x 1.5V AAA size alkaline batteries
- Weight : approx. 80g (with batteries)
- Memory: 30 sets
- Dimensions : approx. 129.9X44.5X52.4mm (L×W×H)
- Operation Distance : 3 cm
- Frequency : 2402~2480GHz
- Output power range : $\leq 4\text{dBm}$
- Battery Operation Time: about 90 minutes (Depends on different brand of batteries.)
- Reference body site: Ear temperature
- For Customer Service










It is recommended that the accuracy should be checked by manufacture every 1 years. To obtain the 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








| | | |
|--|---|--|
| <p>NT16B is intended for use in the electromagnetic environment specified below. The customer or the user of NT16B must make sure that it is used in such an environment.</p> | | |
| <p>Guidance and manufacturer' s declaration - Electromagnetic emissions</p> | | |
| Phenomenon | Professional healthcare facility environment a) | HOME HEALTHCARE ENVIRONMENT a) |
| Conducted and radiated RF MISSIONS | a) | CISPR 11 Group 1 Class B |
| Harmonic distortion | Not applicable | |
| Voltage fluctuations and flickering | Not applicable | |
| <p>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.</p> | | |
| <p>Guidance and manufacturer' s declaration - Electromagnetic immunity - Enclosure port</p> | | |
| Phenomenon | Basic EMC standard or test method | Immunity test levels |
| | | Professional healthcare facility environment |
| | | HOME HEALTHCARE ENVIRONMENT |
| ELECTROSTATIC DISCHARGE | IEC 61000-4-2 | ± 8kV contact ± 2 kV, ±4kV ±, ±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 NT16B 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 |
| <p>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.</p> <p>b) Before modulation is applied.</p> <p>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.</p> | | |

Explanation of Symbols

| | |
|---|---|
|  | The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745 |
|  | Medical Device |
|  | Manufacturer |
|  | Authorized representative in the European Community |
|  | Date of manufacture (YYYY-MM-DD or YYYY-MM) |
|  | Batch code (YYMMWWWW) |
|  | Serial number (YYMWWWWXXXXX) |
|  | Keep dry |
|  | Temperature limit |

| | |
|---|--|
|  | Humidity limitation |
|  | Atmospheric pressure limitation |
|  | Caution |
|  | Consult the instruction for use |
|  | 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. |
|  | Stand-by |
|  | Device classification type BF |

| <p>IP 22</p> | <p>This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm \varnothing and greater and against vertically falling water drops when enclosure tilted up to 15°)</p> | | | | | | | | | | | | | | | | | |
|--|--|------------------|--|----|--------------|------------------|------|-------------------------|---------|------|--------------------|-----------------|------|------------|--------------|------|---------------|--------------|
|  | <p>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.</p> | | | | | | | | | | | | | | | | | |
|  | <p>Importer</p> | | | | | | | | | | | | | | | | | |
|  | <p>Distributor</p> | | | | | | | | | | | | | | | | | |
|  | <p>Model Number</p> | | | | | | | | | | | | | | | | | |
|  | <p>Country of Manufacturer</p> | | | | | | | | | | | | | | | | | |
|  | <p>Unique Device Identifier</p> <table border="1" data-bbox="263 872 967 1088"> <thead> <tr> <th data-bbox="263 872 335 919">AI</th> <th data-bbox="335 872 672 919">Data Element</th> <th data-bbox="672 872 967 919">Data Type/Format</th> </tr> </thead> <tbody> <tr> <td data-bbox="263 919 335 966">(01)</td> <td data-bbox="335 919 672 966">Device Identifier(GTIN)</td> <td data-bbox="672 919 967 966">Numeric</td> </tr> <tr> <td data-bbox="263 966 335 1013">(11)</td> <td data-bbox="335 966 672 1013">Manufacturing Date</td> <td data-bbox="672 966 967 1013">Numeric: YYMMDD</td> </tr> <tr> <td data-bbox="263 1013 335 1061">(10)</td> <td data-bbox="335 1013 672 1061">Lot Number</td> <td data-bbox="672 1013 967 1061">Alphanumeric</td> </tr> <tr> <td data-bbox="263 1061 335 1088">(21)</td> <td data-bbox="335 1061 672 1088">Serial Number</td> <td data-bbox="672 1061 967 1088">Alphanumeric</td> </tr> </tbody> </table> | | | AI | Data Element | Data Type/Format | (01) | Device Identifier(GTIN) | Numeric | (11) | Manufacturing Date | Numeric: YYMMDD | (10) | Lot Number | Alphanumeric | (21) | Serial Number | Alphanumeric |
| AI | Data Element | Data Type/Format | | | | | | | | | | | | | | | | |
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| (10) | Lot Number | Alphanumeric | | | | | | | | | | | | | | | | |
| (21) | Serial Number | Alphanumeric | | | | | | | | | | | | | | | | |
|  | <p>Keep away from sunlight</p> | | | | | | | | | | | | | | | | | |

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

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