

AVITA

TOUCH FREE Infrared Thermometer

Model: NT16B



INSTRUCTION MANUAL

Please read this instruction manual carefully
before using your ear thermometer

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Introduction

Utilizing infrared technology, this thermometer takes temperatures in seconds by measuring heat generated by measuring heat generated by the surface skin of the forehead or other objects. This product conforms to the provisions of the EC directive MDD(93/42/EEC). Its advantages include:

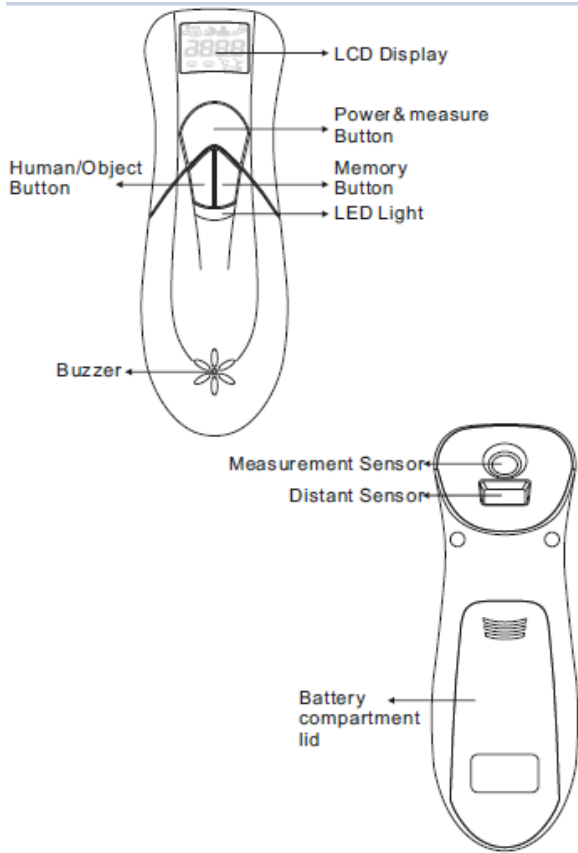
1. 6 in 1 functions
Human Body/Object/Night Mode Option/Fever Alarm/ 30 User Memory/Backlight
2. Night Mode Option
Switch to Night mode to reduce the interference of buzzer during your baby sleeping.
3. Red LED Light for Fever Alarm
This device has the LED light to remind user their readings are over 38°C and plus the beep sound only in Human Body Mode.
4. 30 User 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 “Non-contact” 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.

Important Information Before Use

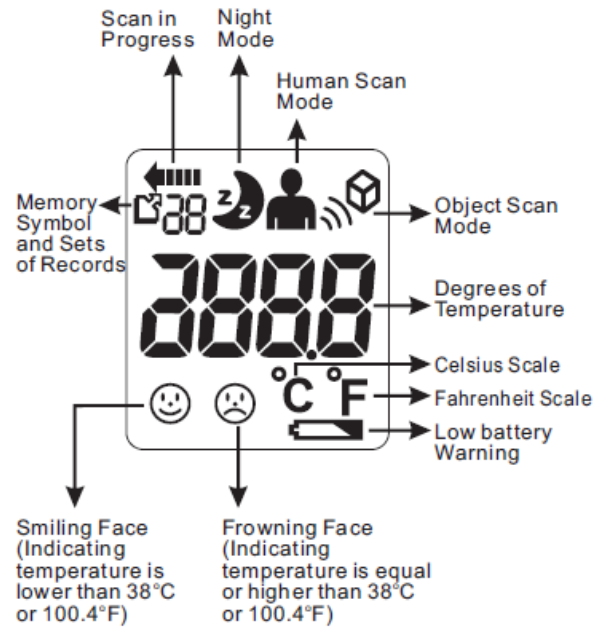
When using this product, please be sure to follow all the notes listed below. Any action against these notices may cause injury or affect the accuracy.

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. It is ill-advised to disassemble the thermometer.
12. Please use the thermometer solely for its intended purpose.
13. Carefully hold the device when in use to avoid dropping the device.
14. Allow one minute between successive measurements as slight variations may occur if measurements are taken over a short period of time. Use average temperatures instead.
15. There are no absolute body temperature standards. Keep reliable records of your personal temperature to serve as a reference for judging a fever.
16. Under any circumstances, the temperature taking result is ONLY for reference. Before taking any medical action, please consult your physician.
17. It is recommended calibrate the device every 1 year.
18. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Product Identification



Description of LCD Display



Battery Installation

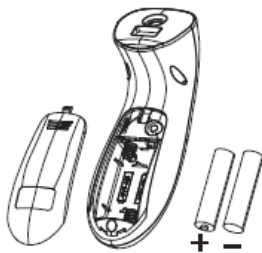
Low battery warning:

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.



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 Size) according to the proper polarity.
4. Slide the battery cover back on.



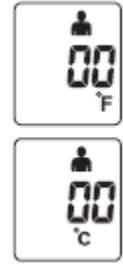
NOTE: Battery-operated

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. For long durations of non-operation, please remove all batteries from the device.
4. Batteries must be disposed of in accordance with local environmental and institutional policies.
5. 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

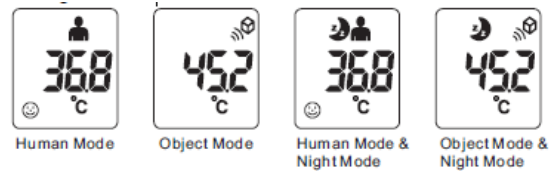
Your thermometer can display results in either degrees Celsius ($^{\circ}\text{C}$) or degrees Fahrenheit ($^{\circ}\text{F}$).

To switch between Celsius and Fahrenheit, while the unit is on press and hold both the Human/Object button and the Memory button for approximately 3 seconds. This will change the mode to either $^{\circ}\text{C}$ or $^{\circ}\text{F}$. Once the thermometer beeps, at which time the mode has been changed and you may release the buttons.



Switching between 4 Kinds of Scan Mode

1. Under power on status, you can press the Human/Object button to switch different scan 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 closed when your choice in Human/Night mode, and Object/Night mode, and the Moon symbol will appears on the LCD in both Night mode.



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.
- Infrared forehead temperature readings are equivalent to oral temperature readings. In all of these cases, please consult your doctor.
- 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

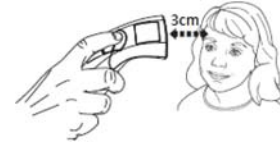
1. Press the Measure button to power on the thermometer.
The unit will run a self-test and the LCD will briefly display all of its symbols during this time. When the device is ready, '00' will appear on the screen, and the thermometer will beep twice.
2. Select the desired mode by pressing and releasing the Human/Object button.

Note:

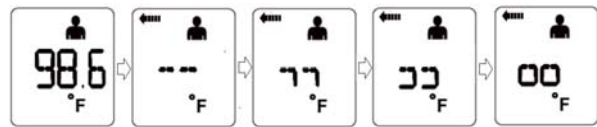
- When taking a patient's temperature, ensure that the thermometer is in Human mode; the Human symbol "👤" will appear on the display.
- If the patient's skin is covered with hair, sweat, or dirt, clean the area and wait 10 minutes before taking a measurement.
- Ensure that the thermometer is held firmly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

Measuring Human Temperature

3. Position the thermometer under 3cm (around 1 inches) from the center of the patient's forehead with the sensor aimed between the eyebrows.



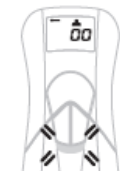
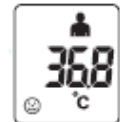
4. Press and release the Measure button.
5. Slowly move the device toward or farther from the forehead until you have reached the correct distance. (If the distance is beyond the correct distance, the dash-icon on the display flashes with beep sound in this sequence until the correct distance is achieved.)



Note:

When the user presses the measure button, this workflow begins and they have 20 seconds to capture the temperature. After 20 seconds, the display turn 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 be appear next to the reading. If the reading is 38°C or above, a "Frowning Face" will be displayed and the RED LED light up.
8. After about 30 seconds after use, the thermometer will automatically beep and shut off.

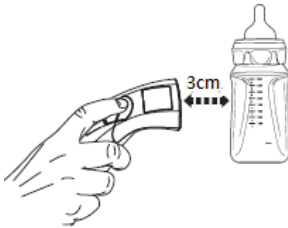


Fever Alarm:

Only in Human Mode and Human/Night Mode

Measuring Object/Liquid Temperature

1. Press the Power 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 inches) from the object.



4. Press and release the "Power & Measure button" and the temperature reading will be displayed.



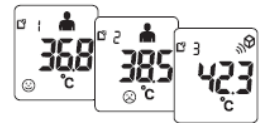
5. After about 30 seconds after use, the thermometer will automatically beep and shut off.

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 "MEM button", then pass it again to show the last measurement accompanied by "MEM" symbol.
2. The "MEM" symbol or "MEM" 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, so "MEM" then all the way to "MEM".



Memory Deletion:

1. Under power on status, you may keep press MEM Button for more than 3 seconds to delete all the readings.
2. You will see "00" on display and "sound a beep", that mean all the memories are cleared.
3. Automatically on the 31th measurement: when the 30 memories have been used up, any new measurement will be recorded with "MEM" and the oldest memory deleted without you having to do anything.

Note:

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

Clinical accuracy validation method

NT16B is an adjusted mode clinical thermometer the validated information for clinical accuracy in each adjusted mode are:

- GroupA1: $\Delta_{cb}=-0.01^{\circ}\text{C}$, $L_A=0.18$, $\sigma_r=\pm 0.08^{\circ}\text{C}$
- GroupA2: $\Delta_{cb}= 0.06^{\circ}\text{C}$, $L_A=0.22$, $\sigma_r=\pm 0.08^{\circ}\text{C}$
- GroupB : $\Delta_{cb}=-0.01^{\circ}\text{C}$, $L_A=0.20$, $\sigma_r=\pm 0.07^{\circ}\text{C}$
- GroupC : $\Delta_{cb}=-0.01^{\circ}\text{C}$, $L_A=0.18$, $\sigma_r=\pm 0.07^{\circ}\text{C}$

cb: CLINICAL BIAS

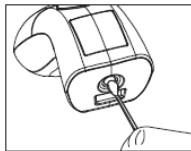
L_A : LIMITS OF AGREEMENT

σ_r : CLINICAL REPEATABILITY

Cleaning and Disinfecting

For home use device disinfection, 70% Ethanol or Isopropyl alcohol(available in the pharmacy) can be used.

- Clean the measuring sensor after each use. Use a clean cloth or cotton bud that can be moistened with 70 % alcohol.
- To clean the entire device, please use a soft cloth slightly moistened with a mild soapy solution. Under no circumstances may liquid enter the device. Do not use the device again until it is completely dry.



Applied Standards

This product conforms to the provisions of the EC directive MDD(93/ 42/ EEC). The following standards apply to design and/or manufacture of the products:



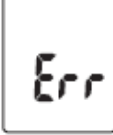
- **ISO 80601-2-56**
Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- **IEC/EN 60601-1**
Medical electrical equipment- Part 1: General requirement for safety
- **IEC/EN 60601-1-2**
Medical electrical equipment- Part 2: Collateral standard: Electromagnetic compatibility - Requirements and tests

FCC Important Information

- a. **FCC Caution: To assure continued compliance, (example – use only shielded interface cables when connecting to computer or peripheral devices). Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.**
- b. **This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.**
- c. **This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be colocated or operating in conjunction with any other antenna or transmitter.**

Error Codes

When a malfunction or incorrect temperature measurement occurs, an error message will appear as described below.

LCD Display	Cause	Solution
	The temperature measured is higher than 1. Human thermometer mode: 43°C (109.4°F) 2. Object temperature 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.
	The temperature measured is lower than 1. Human thermometer mode: 34°C (93.2°F) 2. Object temperature mode: 0°C (32°F)	Operate the thermometer only between the specified temperature ranges.
	The operating temperature is not in the range 15°C~35°C (59°F~95°F)	Operate the thermometer only between the specified temperature ranges.

Operating the Bluetooth function

What You Need

NT16BB Bluetooth IR Ear Thermometer

An Android device with Android version 4.3 or above and hardware support for Bluetooth 4.0.

An iOS device with iOS version 5 or above and hardware support for Bluetooth 4.0. All devices Apple released since the iPhone 4S (including the 4S) do, the older ones don't.

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 NT16BB.
5. The app should automatically detect your NT16BB. Tap the NT16BB that is showed in the device list.
6. Your NT16BB is now successfully connected to your mobile device. Every temperature reading will be transfer to your mobile device automatically.

Operating the Bluetooth function

- 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 to 43 °C (93.2 to 109.4 °F)
Object : < 40°C ± 2°C; >= 40°C ± 5%
- Display resolution : 0.1°C
- Measuring site: Forehead
- Reference body site: Ear
- Operating environment :
15°C~35°C (59°F ~ 95°F)
with relative humidity up to 95% (non condensing)
- Storage/ Transportation environment :
-25 to 55 °C(-13 to 131 °F)
with relative humidity up to 95% (non condensing)
- Power supply : 2 x 1.5V AAA size alkaline batteries
- Weight : approx. 80g (with batteries)
- Dimensions :
approx. 52.4mmX44.5mmX129.9mm (L×W×H)
- Operation Distance : 3 cm
- 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

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information.

1. Electromagnetic/Radio Frequency Interference (EMC/RFI):
Readings may be affected if the unit is operated within a radio frequency electromagnetic field strength of approximately 3 volts per meter, but the performance of the instrument will not be permanently affected. Care should be taken to keep the NT16B at least 6 inches away from R/C transmitters to avoid radio frequency interference.
2. Avoid keeping the NT16B too close to objects that continuously generate high heat (like a hot plate) for long periods of time, which can cause overheating of the NT16B.

Table 1 For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration-electromagnetic emissions		
The NT16B TOUCH FREE Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the NT16B TOUCH FREE Infrared Thermometer should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The NT16B TOUCH FREE Infrared Thermometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NT16B TOUCH FREE Infrared Thermometer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Not applicable	


EMC Tables

Table 2 For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
The NT16B TOUCH FREE Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the NT16B TOUCH FREE Infrared Thermometer should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV air for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT for 0.5 cycle) 40% UT (60% dip in UT for 5 cycles) 70% UT (30% dip in UT for 25 cycles) 5% UT (>95% dip in UT for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the use of the TS41 Ear/Forehead/Object Thermometer requires continued operation during power mains interruptions, it is recommended that the TS41 Ear/Forehead/Object Thermometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE <u>Ut</u> is the a.c. mains voltage prior to application of the test level.			

EMC Tables

Table 3 For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING









Guidance and manufacturer's declaration-electromagnetic immunity			
The NT16B TOUCH FREE Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the NT16B TOUCH FREE Infrared Thermometer should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the NT16B TOUCH FREE Infrared Thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d=1.2√P d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey," should be less than the compliance level in each frequency range." Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations from radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretic call with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NT16B TOUCH FREE Infrared Thermometer is used exceeds the applicable RF compliance level above, the NT16B TOUCH FREE Infrared Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NT16B TOUCH FREE Infrared Thermometer. Over the frequency range 150kHz to 80MHz, field strengths should be less than [V1] V/m.			

EMC Tables


Table 4 For EQUIPMETN and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the NT16B TOUCH FREE Infrared Thermometer			
<p>The NT16B TOUCH FREE Infrared Thermometer is intended for use in an electromagnetic environment in which radiated RF distances are controlled. The customer or the user of the NT16B TOUCH FREE Infrared Thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NT16B TOUCH FREE Infrared Thermometer as recommended below according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz d=1.2√P	80kHz to 800MHz d=1.2√P	800kHz to 2.5GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Explanation of Symbols

	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of European Medical Device Directive 93/42/EEC
	Follow instructions 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
	Type of protection of applied part against electric shock, body floating
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 tilted up to 15°)
	Temperature limits
	European Authorized Representative
	Manufacturer's name and address
	SN YYMWWWXXXXX SN: Product Serial Number YY: year, M:month, WWW: working sheet, XXXXX: serial no.

EC	REP	Wellkong Ltd 29 Harley St. W1G 9QR LONDON, U.K.
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 Manufacturer:
AVITA Corporation
9F., No. 78, Sec. 1, Guangfu Rd.,
Sanchong Dist., New Taipei City,
Taiwan (R.O.C.)

No.858, Jiao Tong Road,
Wujiang Economic Development Zone
Jiangsu Province, P.R.C.
Postcode: 215200
Made in China

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