CARETALK®

TH1009B

User Manual



Please read this Instruction manual before use

Thermometer

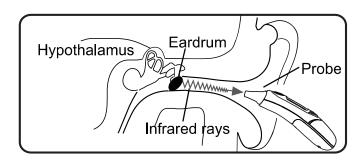
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INTRODUCTION

Thank you for purchasing Ear Thermometer TH1009B from Shenzhen Dongdixin Technology Co., LTD. The thermometer has been carefully developed for accurate, safe and fast human body temperature measurements in the ear temperature measurements.

Research indicates that the ear is an ideal site for taking body temperature, because body temperature is regulated by the hypothalamus, which shares the same blood supply as the tympanic membrane. So please take the ear temperature as much as possible.



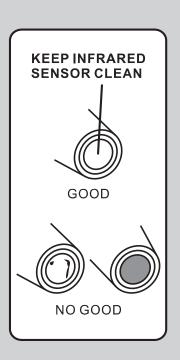
The applied part is the probe tip (type BF). The mode of operation of the thermometer is adjusted mode, and the reference body site is core.

The operator can measure and change battery under normal circumstances and maintain the device and its accessories according to the user manual. The user may be an intended operator.

IMPORTANT SAFETY INFORMATION

However, as with any thermometer, proper technique is critical to obtaining accurate temperatures. Therefore, in order to obtain an accurate measurement, please read this manual carefully before using.

Use of this thermometer is not intended as a substitution for consultation with your physician.



- Measurement results are for reference only. Contact your physician if you have or suspect any health concerns.
- ➤ The Infrared sensor must be kept clean, dry, and undamaged at all times to ensure accurate measurements.
- Earwax in the ear canal may cause an inaccurate measurement, so make sure the ear canal clean.
- ➤ If you clean the ear , please keep waiting for 5~10 minutes before measuring.
- Don't touch or blow the infrared sensor. A polluted infrared sensor may cause inaccuracy.
- Do not use ear measurement mode for measurements other than human body temperature.
- > Avoid measuring the ear temperature if the ear is inflamed or infected.
- ➤ If the temperature of the storage area differs greatly from that of the measuring area, please wait the thermometer temperature to equalize to the room temperature about 30 minutes before use.
- ➤ Keep the device out of the reach of children and pets to avoid inhalation or swallowing of small parts. Children may not be able to use the device according to the instructions Do not allow children to take their temperatures unattended. in this user manual. It is not a toy.
- Do not throw disposable batteries into fire.Batteries may explode.
- ➤ Don't store the thermometer to temperature extremes (below -20°C/-4°F or over 55°C/131°F) or humidity extremes (below 15%RH or over 90%RH). Failing to do so may cause inaccuracy.
- ➤ Don't use the product in a wet ear hole after swimming or bathing. It is possible to damage the ear hole.
- ➤ Don't use the thermometer if the main body is damaged (for example, the infrared sensor is broken). The continuous use of a damaged unit may cause injury, improper results, or serious danger.
- > Don't take apart, repair or change any parts of the unit at any time.
- Don't use a mobile phone nearby when the thermometer is working.
- ➤ If your thermometer will not be used for a long time. It is advised to, remove battery to prevent possible damage due to chemical leakage.
- ➤ If battery does leak, remove carefully. Do not allow bare skin to touch leaking fluid.
- ➤ This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

- If you have allergic reaction to materials, please stop Using the device immediately and consult your physician.
- Store the thermometer in the dry, clean place .Do not leave the product exposed to any chemical solvent, lint, dust, direct sunshine or high temperature.When using, shall not touch battery and the patient simultaneously.
- > Do not maintain or service the device while the device is in use.
- ▶ If you have any problems with this device, such as setting up, maintaining or using, please contact with SERVICE PERSONNEL of manufacturer.
- Please report to manufacturer if any unexpected operation or events occur.



Caution:

this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which is will be used.

BODY TEMPERATURE

Normal body temperature is a range. A person's normal temperature range tends to decrease with age. The following table shows normal temperature ranges by age:

Normal temperature ranges by age:

| 0 – 2 years | 36.4 – 38.0 °C | 97.5 – 100.4 °F |
|---------------|----------------|-----------------|
| 3 – 10 years | 36.1 – 37.8 °C | 97.0 – 100.0 °F |
| 11 – 65 years | 35.9 – 37.6 °C | 96.6 – 99.7 °F |
| > 65 years | 35.8 – 37.5 °C | 96.4 – 99.5 °F |

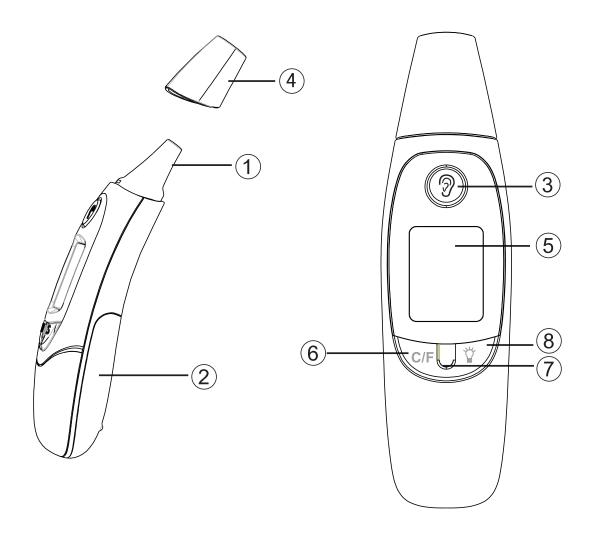
The range of normal temperature varies from person to person and can be influenced by many factors such as time of day, measure from different sites, level of activity, medications, emotion and so on. So we recommend that you practice with the Thermometer on yourself and family members when you are healthy. This way you know how the thermometer works and can feel more confident of the measurements you take when a family member is ill.

PACKAGE COMPONENTS

| NO. | DESCRIPTION | QUANTITY |
|-----|------------------|----------|
| 1 | Ear Thermometer | 1 piece |
| 2 | 1.5V battery AAA | 2 pieces |
| 3 | User manual | 1 piece |

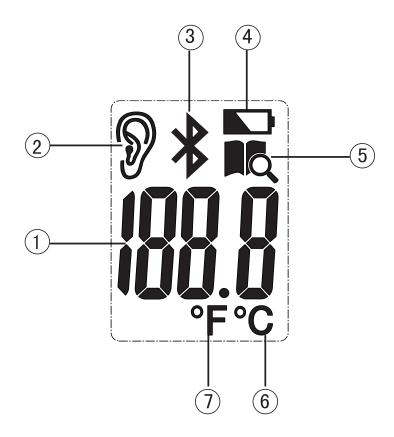
PRESENTATION

Operation panel



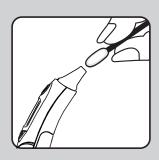
- 1) Infrared sensor
- 2) Battery cover
- 3) Ear measuring button
- 4) Cap
- 5) LCD display
- 6) C/F button
- 7) LED display
- 8) Backlight

LCD display

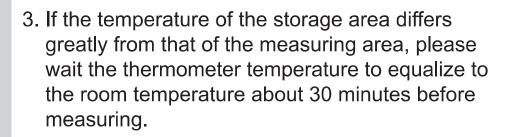


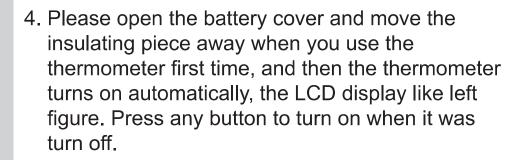
- 1) Temperature display
- 2) Ear temperature symbol
- 3) Bluetooth symbol
- 4) Low battery symbol
- 5) Memory mode symbol
- 6) Centigrade degree symbol
- 7) Fahrenheit degree symbol

BEFORE USE

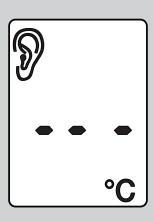


- 1. To achieve accurate measurement, it is very important to check the infrared sensor and sure it is clean before using.
 - To clean the sensor, gently wipe its surface with a cotton swab slightly moistened with alcohol and immediately wipe dry with a clean cotton swab. After cleaning, allow at least 20 minutes drying time before taking temperatures.
- 2. Earwax in the ear canal may cause an inaccurate measurement, so make sure the ear canal is clean. If you clean the ear, please keep waiting for 5~10 minutes before measuring.





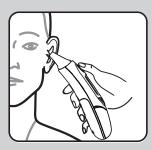




HOW TO MEASURE EAR TEMPERATURE

- 1. Remove the cap before using. Place the thermometer in your hand as shown with your thumb or forefinger on the **[EAR]** button.
- Do not press the button yet.
- Make sure the probe is clean before measuring.
- 2. Insert the probe very gently and slowly into the ear canal.
- ➤ Hold the thermometer so that the probe faces straight in the direction of the eardrum.
- ➤ It is important to point the probe window of thermometer toward the eardrum and its periphery inside the ear.
- ➤ Hold the outer ear and gently pull it toward the rear of the head to straighten the ear canal.
- ➤ Always insert the thermometer into the same ear with the same direction and depth.
- 3. Press the **[EAR]** button to start the measurement until you hear two 'DIDI' beep. (approx. 1 second). The measurement is complete.
- 4. Remove the thermometer from the ear canal. The LCD displays the measured temperature. A new measurement only can be taken 6 seconds after the Last time temperature measurement.









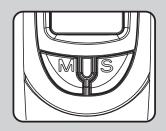




TEMPERATURE TAKING HINTS

- 1. A temperature measurement taken from right ear may differ from a measurement taken from left ear. Therefore, always take the temperature in the same ear.
- 2. External factors may influence ear temperature. particularly when an individual has:
- been lying on one ear or the other
- had their ears covered
- been exposed to very hot or very cold temperatures
- been recently swimming or bathing In these cases, let the individual stay away from the above scenario and station in a room for 30 minutes prior to talking a temperature
- 3. For people wearing hearing aid device or ear plugs, remove the device and wait 30 minutes prior to taking a temperature.
- 4. Use the untreated ear if ear drops or other ear medications have been placed in the ear canal.
- 5. With object measurement, the current surface temperature of the object is displayed. It can be different from its internal temperature, especially if the surface is exposed to direct sunlight or a draught.

TEMPERATURE LED INDICATION



There are red colors LED temperature indicator in this Unit, The relevant LED red light after the measurement The detail range refer to following:

Red LED: 38.0°C(100.4°F)~42.9°C(109.3°F)

CHECK THE MEMORY

When sleep mode by **[EAR]** button into standby mode if there are test data shows the temperature of the last test, if there is no temperature is not displayed

CELSIUS/FAHRENHEIT OPTION

In standby mode or measuring mode, you can switch between Celsius (°C) and Fahrenheit (°F) by press [C/F] button until you hear one or two "beep" sounds.

REPLACING THE BATTERY

When the low battery indicator " appears on the LCD, or the thermometer does not function at all, you should replace new battery as soon as possible. The thermometer is supplied with two batteries (2×AAA).

Remove the battery cover, pull up the batteries, then insert new AAA batteries into the battery compartment.

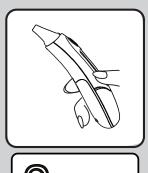
Make sure you are installing batteries properly, ensure to match the positive and negative polarity marked in the battery compartment.

Slide battery cover back until it snaps in place.

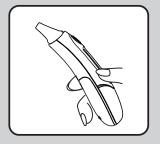


Caution:

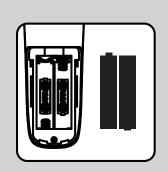
To protect the environment, dispose of exhausted battery according to national or local regulations. Keep the battery out of the reach of children.











PAIRING THE THERMOMETER TO YOUR MOBILE DEVICE

- 1. Download the App from App Store. The App is available for iOS® 7.0+.
- 2. Install the app on your mobile device, start the setup wizard and follow the steps to create a user profile and add the thermometer.
- 3. Make sure the app is active and Bluetooth on your mobile device is on when pairing is in progress.
- 4. Press the power button to turn on the thermometer. The app identifies the thermometer and requests to pair.
 - ➤ The app identifies the thermometer and requests to pair.
 - ➤ The Bluetooth icon lights up when the thermometer is connected to your mobile device.
 - ➤ When the thermometer has paired successfully with your mobile device, your personal measurement results are automatically transmitted to your mobile device via Bluetooth.
- 5. The thermometer switches off automatically after 60 seconds of no operation.

Note: Only when the health app is active, your personal health data can be transmitted.

SPECIFICATIONS

| | T |
|----------------------------------|--|
| Power supply: | DC 3V (2 x AAA battery) |
| Body measuring range: | 32.4°C ~ 42.9°C (90.3°F ~ 109.3°F) |
| Ear measuring accuracy: | ±0.2°C(±0.4°F) |
| Dimension: | 131.8(L)x37.7(W)x37.3(D)mm |
| Weight: | About 53.5g (without battery) |
| Ear operating condition: | 10.0°C~40.0°C (50.0°F~104.0°F) with a relative humidity of 15%~85% Atmosphere pressure: 700hPa-1060hPa |
| Storage and transport condition: | -20°C~55°C (-4°F~131°F) with a relative humidity of 15%~90% Atmosphere pressure: 700hPa-1060hPa |
| Maximum separation distance: | 10m (In the open environment) |
| Service life: | 2 years |
| Service life of the battery: | With a new battery(Carbon)approx. 6 months based on the use frequency at 5 times/day |



Caution:

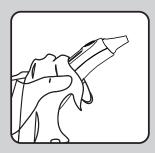
This thermometer has been thoroughly tested and inspected to assure proper performance and operation!

DESCRIPTION OF THE WIRELESS FUNCTIONS AND TECHNOLOGY

| RF Frequency | 2.4GHZ-2.48GHZ |
|-------------------|-----------------|
| Channel Bandwidth | 2 M H z (-20db) |
| Operation Voltage | DC3.0V |
| | |
| Modulation type | GFSK |
| Number of channel | 40 |
| Chanel spacing | 2 MHz |
| Channel frequency | 40 Channels |
| Antenna gain | 0dBi |
| | |

The TH1009B device use the one-on-one connection of the BLE4.0, and our device as a peripheral, response to the APP's connection request passively, establish a one-on-one connection with the APP. After the TH1009B device connects to the APP, the device will not be connected to other wireless device or controlled. After the APP connect to the peripheral device, the APP will send the command, and when the TH1009B device ensure this command is right, your personal health data can be transmitted.





CARE AND CLEANING

To ensure accurate measurements, keeping the infrared sensor and distance sensor tip clean and free of scratches is very important. Finger prints, dirt will affect the accuracy of the thermometer. In order to get an accurate measurement, please clean the infrared sensor and distance sensor tip. Gently wipe its surface with a cotton swab slightly moistened with alcohol and immediately wipe dry with a clean cotton swab.

Use a soft dry cloth to clean the body of the thermometer. Never clean the thermometer with an abrasive cleanser, thinner and benzene or submerge the thermometer into water or other liquids.

After cleaning, place the thermometer in the protective case. Store it in a clean, dry place at room temperature. Never expose the thermometer to extreme temperatures, humidity, direct sunlight or shock.

CALIBRATION

The thermometer is initially calibrated during manufacturing, before ex-factory. If the thermometer is used according to the instruction, periodic recalibration is not required. If at any time you question the accuracy of the measurement, please contact the retailer immediately.

Don't attempt to modify or reassemble the thermometer.

TROUBLESHOOTING

| Troubles Checklists | | Counter measures |
|---|--|---|
| No response / Automatic reset when pull out insulator | Battery used up? Battery in wrong polarity? Poor battery contact | Change new battery or take out battery and reinsert correctly |
| | The measured temperature is lower than 34.0°C/93.2°F or higher than 42.9°C/109.3°F Please check the operation method | Follow user manual for proper measurement. |
| | Hardware problem | Contact your distributor |
| | Operating temperature is out of the range | Use the thermometer in the range of operating conditions |
| [t-t] | The sensor temperature has not been stabilised. | Wait about 10 seconds and take a measurement again. |

| Troubles | Checklists | Counter measures |
|--|--|---|
| The measurement is not accurate or if there is any | Please check if the infrared sensor is clean or not | Clean the infrared sensor with cotton swab according to user manual |
| doubt on the measured result | Please check the measuring way is correct or not | Ensure you have read the manual and know how to use the thermometer properly. |
| The measurement is not accurate or if there | Please check if you have let the thermometer and patient gets stabilized in the room for 30 minutes at least | Please keep the thermometer and patient in the measuring room at least 30 minutes before using |
| is any doubt of the measure result | Are you using the thermometer indoor | Please take the measurement indoor |
| | Please check if you held the thermometer in your hand too long and affect the accuracy | Put the thermometer on the table in the room where the measurement is taking place and let it cool down first |
| 36.6 | Please check if there is low battery symbol on LCD | Change new battery |

NORMALIZED SYMBOLS



Applied part of type BF (The applied part is the probe tip)



Disposal in accordance with Directive 2012/19/EU (WEEE)



Complies with the European Medical Device Directive (93/42/EEC) and amended by directive 2007/47/EC requirements. Notified body TÜV Rheinland (CE0197)



The name and the address of the manufacturer



The name and the address of the Authorized EC-representative in Europe



Caution



Refer to Instruction Manual.

IP22

The first number 2: Protected against solid foreign objects of 12,5 mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15°, on either side of the vertical.



Represent the manufacture date and serial number.



Transportation and storage temperature from -20 °C to 55 °C



Transportation and storage humidity limits from 15% to 90%



Transportation and storage atmospheric pressure limits from 700 hPa to 1060 hPa

DISPOSAL

Exhausted battery does not belong to household waste. Dispose the battery according to the current federal, state and local regulation. As a consumer, you are obligated by law to return the used batteries.

NOTES:

- 1) Under the environment with electrostatic discharge, the unit may malfunction and may require user to reset the unit.
- 2) Dispose the used batteries with care; please consult the retailer for details.





WARRANTY

One year warranty is available from purchasing date, excluding caused failures listed below:

- 1. Failure resulted in unauthorized disassembly and modification.
- 2. Failure resulted in unexpected drop during application or transportation.
- 3. Failure resulted in operation away from proper instruction in User's Manual.

Present the warranty card Card with seal of distribution center (include. name and address) for free repairing .

IMPORANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY(EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices. Medical devices manufactured by Shenzhen Dongdixin Technology Co.,ltd. conform to this IEC 60601-1-2 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed: The use of accessories and cables other than those specified by manufacturer, with the exception of cables sold by manufacturer as replacement parts for internal components, may result in increased emission or decreased immunity of the device.

- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

(Table 1)

Guidance and manufacturer's declaration – electromagnetic emissions

The thermometer are intended for use in the electromagnetic environment specified below. The customer or the user of these thermometer should assure that it is used in such environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|---|----------------|---|
| RF emissions CISPR 11 | Group 1 | The thermometer use 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 thermometer are suitable for use |
| Harmonic emissions IEC 61000-3-2 | Not applicable | directly connected to the public |
| Voltage fluctuations/ flicker emissions IEC61000-3-3 | Not applicable | low-voltage power supply network that supplies buildings used for domestic purposes. |

(Table 2)

Guidance and manufacturer's declaration – electromagnetic immunity

The thermometer are intended for use in the electromagnetic environment specified below. The customer or the user of these thermometer should assure that it is used in such environment.

| Immunity test | IEC 60601 Test level | Compliance level | Electromagnetic environment – guidance |
|---|-------------------------------|-------------------------------|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV 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 | Not applicable | Not applicable | Not applicable |
| Surge IEC 61000-4-5 | Not applicable | Not applicable | Not applicable |
| Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11 | Not applicable | Not applicable | Not applicable |
| Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

(Table 4)

Guidance and manufacturer's declaration – electromagnetic immunity

The thermometer are intended for use in the electromagnetic environment specified below. The customers or the users of these thermometer should assure that it is used in such environment.

| Immunity | IEC 60601 | Compliance | Electromagnetic environment – guidance |
|---|--|------------|---|
| test | Test level | level | |
| Conducted RF IEC 61000 -4-6 Radiated RF IEC 61000-4-3 | Not applicable 3 V/m 80 MHz to 2.5 GHz | | Portable and mobile RF communications equipment should be used no closer to any part of the thermometer including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend 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 he 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, |

| a. should be less than the |
|----------------------------|
| compliance level in each |
| frequency range. |

b. Interference may occur in the vicinity of equipment marked with he following symbol:



Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- ^a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically 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 thermometer are used exceeds the applicable RF compliance level above, the thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the thermometer.
- Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

(Table 6)

Recommended separation distance between portable and mobile RF communications equipment and the thermometer

The thermometer are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of these thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the thermometer as recommended below, according to the maximum output power of the communications equipment.

| Output Power of | Separation distance according to frequency of transmitter in meter | | |
|---------------------|--|------------------------------------|------------------------------------|
| Transmitter in Watt | 150 kHz to 80 MHZ d = 1.2 √P | 80 MHz to 800 MHZ d = 1.2 √P | 800 MHz 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 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

FCC COMPLIANCE INFORMATION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- > Reorient or relocate the receiving antenna.
- ➤ Increase the separation between the equipment and receiver.
- ➤ Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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.

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EC REP

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