Owner's Manual

Ear and Forehead Thermometer
Model **BUE1215**

Bubbles

Contents

Introduction

The multi functional thermometer is intended solely for measuring forehead temperature, ear temperature and object temperature. It allows you to quickly and easily measure body temperature and object temperature. It converts the measured heat into a temperature reading displayed on the LCD. The infrared thermometer is intended for the intermittent measurement of human body temperature by people of all ages.
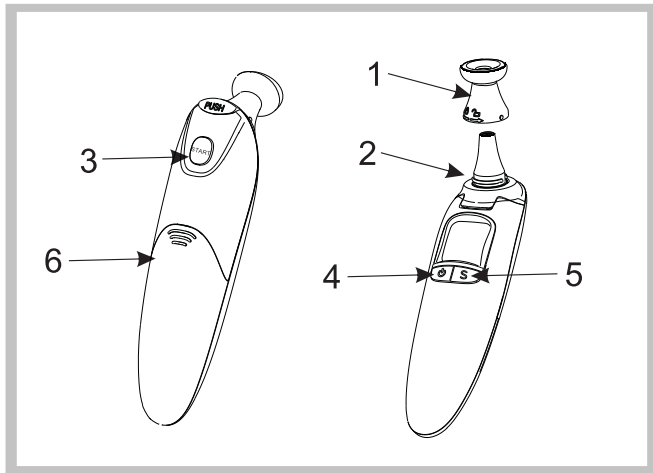
Please read all instructions carefully and thoroughly before using this product.

Warning:
1. This thermometer is intended for home use only. It's not meant to replace a visit to the doctor. Please consult with doctor if you have health concerns.
2. There is no gender or age limitation for using multi functional thermometer.
3. Do not allow children to take their temperatures unsupervised, some parts are small enough to be swallowed.
4. Never immerse this device in water or other liquids(not waterproof).
5. Do not modify this equipment without authorization of manufacturer.
6. Do not expose the thermometer to temperature extremes (below -25℃/-13℉ or over 55℃/131℉) nor excessive humidity (>95%RH).
7. Keep the battery away from children.
8. Remove battery from the device when not in operation for a long time.

Product Description

1. Forehead Cover
2. Probe
3. START Button
4. ⏻ Button
5. S Button
6. Battery Cover

LCD Display Introduction

- AM and PM sign in Time mode
- Time and date
- Low voltage sign
- Object temperature mode
- Ear temperature mode
- Memory mode
- Unit sign: ℃ or ℉
- Temperature Indicator
- Forehead temperature mode
- Temperature result

Basic Functions

|	
Real Time Clock	The real time clock will be recorded with the memory function and help you to recognize each measurement result. → Please see the Real time clock setting section to learn how to setup the time in the first use.
Ear/Forehead Temperature Mode	The thermometer has been designed for practical use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. → Please see the Illustration For Use section to learn how to measure the body temperature.
Object Temperature Mode	The object mode shows the actual, unadjusted surface temperatures, which is different from the body temperature. It can help you to monitor if the object temperature is suitable for the baby or patient, for example the baby's milk. → Please see the Illustration For Use section to learn how to measure the object temperature.
Beep Alarm	If thermometer detects a body temperature ≥ 37.8℃(100.0℉) under ear mode, there will be a long beep sound followed by three short beep sound to warn the user.
Memory Mode	There are each 10 sets memories for ear, forehead and object measurements. Each memory also records the measurement date/time/mode icon.
℃/ ℉ Switch	Please see the Selecting A Temperature Scale section to learn how to change between Celsius and Fahrenheit.

Real Time Clock Setting

When using thermometer for the first time, please set the parameters of the thermometer. With the thermometer off, press and hold *S BUTTON* to enter into setting mode for 3 seconds.
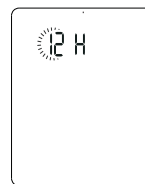
① Set the time format
The device can display the time in either an AM/PM (12-hour) or a 24:00(24-hour) format. Press and release *S BUTTON* to select the format. With the preferred time format on the display, press ⏻ *BUTTON*, the Hour figure is flashing automatically.

② Set the hour
Press and release the *S BUTTON* to advance one hour until the correct hour appears. After the hour is set, press ⏻ *BUTTON*, the Minute figure is flashing automatically.

③ Set the minute
Press and release the *S BUTTON* to advance one minute until the correct minute appears. After the minute is set, press ⏻ *BUTTON*, the Year figure is flashing automatically.

Real Time Clock Setting

④ Set the year
Press and release the *S BUTTON* to advance one year until the correct year appears.
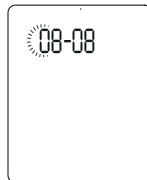After the year is set, press ⏻ *BUTTON*, the Month figure will appear.

⑤ Set the month
Press and release the *S BUTTON* to advance one month until the correct month appears.
After the month is set, press ⏻ *BUTTON*, the Date figure is flashing automatically.

⑥ Set the date
Press and release the *S BUTTON* to advance one day until the correct month appears.
After the day is set, press ⏻ *BUTTON* to exit the setting mode.

Body Temperature

The temperature of a healthy person is affected by various factors: the person's individual metabolism, their age(body temperature is higher in babies and toddlers and decreases with age. Greater temperature fluctuations occur faster and more often in children, e.g. due to growth spurts), their clothing, the ambient temperature, the time of day(body temperature is lower in the morning and increases throughout the day towards evening), the preceding physical and, to a lesser extent, mental activity.

It is suggested that users develop the habit of daily measurement, and use this product to establish a private normal temperature range for themselves and their families as a reference for measurement.

Illustration For Use

▶ **Before measurement:**
● Check before each use that the lens is intact. If it is damaged, contact your retailer or the service address.
● 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.
● Users and the thermometer should be in the same ambient temperature.
● Before each measurement, make sure that the device is in the appropriate mode for the measurement that you wish to take.

▶ **How to switch between ear and forehead mode:**
● When the device is on, Press and hold the *S BUTTON* to switch between ear mode and forehead mode.

▶ **To measure forehead temperature:**
Note:
● Oils or cosmetics on the forehead may give a lower temperature reading than the actual one. Remove dirt from the forehead before taking a measurement. Wait at least 10 minutes after washing the forehead area before taking a reading.

Illustration For Use

● Do not use the thermometer on a perspiring or sweating forehead, as this may affect the reading.
● Remove hat and hair and wait 10 minutes before taking a reading.
1. Install the forehead cap.
2. Press the ⏻ *BUTTON* to switch on the thermometer and the display is activated to show all segments.
3. After self-checking, Figure 1 appears on the display screen with beeps, so you can start a new measurement.
4. Place the probe with the forehead cap fitted on the temple.
5. Press the *START BUTTON* to start measurement.
6. Move the thermometer smoothly over the forehead to the other temple and back.
7. The measured value appears on the display and the end of the measuring is signalled by a short beep.
8. The thermometer will shut off automatically after 60 seconds of inactivity. To prolong battery life, press the ⏻ *BUTTON* to turn the unit off.

Figure 1

Illustration For Use

▶ **To measure ear temperature:**

● Some people produce different readings in their left and right ear. In order to record temperature changes, always measure a person's temperature in the same ear.

● As ear wax can affect the measurement, you should clean the ear before measuring if necessary.

1. Remove the forehead cap.

2. Press the ⏻ *BUTTON* to switch on the thermometer and the display is activated to show all segments.

3. After self-checking Figure 2 appears on the display screen with beeps, so you can start a new measurement.

4. Make sure that the sensor tip and the ear canal are clean. As the ear canal is slightly curved, you have to pull the ear slightly up and backwards before inserting the sensor tip.(See Figure 3)

   ● When using the thermometer on infants under age 1, pull the ear up making sure the sensor faces the eardrum.(See Figure 4)

   ● When using the thermometer on individuals over the age of 1, pull the ear back making sure the sensor faces the eardrum. (See Figure 5).

5. Press the *START BUTTON* to start the measurement.

Illustration For Use

6. The measured value appears on the display and the end of the measuring is signalled by a short beep.
   Note: A waiting period of 20 seconds between testing is recommended to avoid excessive cooling of the skin.

7. The thermometer will shut off automatically after 60 seconds of inactivity. To prolong battery life, press the ⏻ *BUTTON* to turn the unit off.
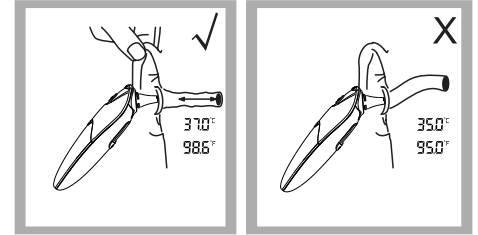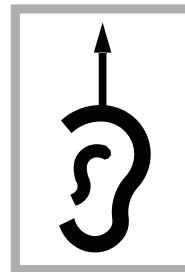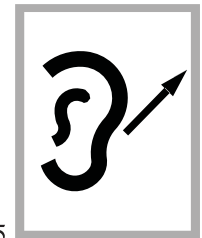
Figure 2

Figure 3

Figure 4   Figure 5

Illustration For Use

▶ **To measure object temperature:**

1. Press the ⏻ button to switch on the thermometer.

2. Hold down the ⏻ *BUTTON* and the *S BUTTON* simultaneously for 2 seconds to switch to object temperature mode(📶 appears on the LCD display.

3. Aim the thermometer at the center of the object you want to measure with a distance of 1 to 2 cm.

4. Press the *START BUTTON* to start measurement.

5. The measured value appears on the display and the end of the measuring is signalled by a short beep.

6. To exit object temperature mode, hold down the ⏻ *BUTTON* and the *S BUTTON* simultaneously again for 3 seconds.

7. The thermometer will shut off automatically after 60 seconds of inactivity. To prolong battery life, press the ⏻ *BUTTON* to turn the unit off.
   Remarks:
   This mode shows the actual, unadjusted surface temperatures, which is different from the body temperature.

Illustration For Use

▶ **After measurement:**

1. Power off: Device will automatically shut off if left idle for more than 1 minute to extend battery life.

2. Clean the probe after each use to ensure an accurate reading and avoid cross contamination.
   (See the section of Care and Cleaning for details.)

▶ **Temperature indicator:**

In Ear/Forehead mode:

1. If the temperature reading is below 37.8℃（100.0℉）, a happy face ☺ will be displayed next to the reading.

2. If the temperature reading is 37.8℃（100.0℉）or above, a bad face ☹ will be displayed next to the reading.

▶ **BackLight:**

The display will only be lighted GREEN for 3 seconds when the unit is ready for measurement and a measurement is completed. The backlight design is to the benefit of reading in the night .

Temperature Taking Hints

To ensure that the reading always reflects the body temperature accurately, you need to take account of the following factors which may affect an accurate reading.

1. It is important to know each individual's normal temperature when they are well. This is the only way to accurately diagnose a fever. To determine normal temperature, take multiple readings when healthy. Re-measure with a standard digital thermometer for confirmation.

2. The probe window of the thermometer is the most delicate part of the device. Do not touch the probe window. The accuracy of the reading may be affected if the probe window is damaged or dirty.

3. Users should not drink, eat, or be physically active such as bathing, showering, shampooing and hair drying before/while taking the measurement. In these cases, wait 20 minutes prior to taking a temperature.

4. Holding a hand on the forehead for any length of time will affect the temperature reading.

Temperature Taking Hints

5. Do not take temperature over scar tissue, open sores or abrasions.

6. Don't take a measurement while or immediately after nursing a baby.

7. Do not use this thermometer outdoors.

8. Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.

9. If the thermometer is stored in a significantly different environment than testing location, place it in the testing location for approximately 30 minutes prior to use.

Memory Mode

1. The Memory Mode can be accessed ether in ear mode, forehead mode or object mode:
   When the thermometer has been turned on and followed by Figure 2 or finished testing, press and hold the ⏻ *BUTTON* for three seconds. The letter MEM will appear in the center left corner of the display. (See Figure 6)

2. The thermometer will automatically memorize the last 10 temperature readings. Each memory also records the measurement date/time/mode icon. Each time the ⏻ *BUTTON* is pressed, the screen displays past readings that correspond with a number 1-10. The number 1 reflects the most recent reading, while the number 10 reveals the oldest reading stored in memory.(See Figure 7)

3. In the memory mode, the mode icon always exist. The user can press the *START BUTTON* to take new measurements.

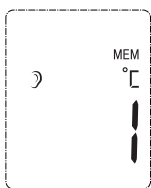Figure 6   Figure 7

Selecting A Temperature Scale

1. Temperature readings are available in the Celsius (℃) or Fahrenheit (℉) scale.

2. With the unit off, press and hold the *START BUTTON* for 3 seconds to enter into unit changing mode.

3. Press and release *S BUTTON* to select the unit.

4. When the preferred unit on the display, press ⏻ *BUTTON* to exit the unit changing mode.
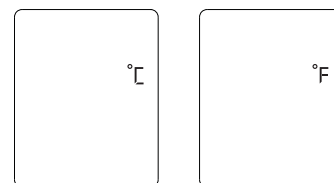
Figure 8

Care And Cleaning

1. The probe window must be kept clean, dry, and undamaged at all times to ensure accurate readings. The accuracy of temperature readings can be affected by damage to the probe window, or the presence of dirt and ear wax on the probe window.
2. Fingerprints, earwax, dust and other soiling compounds reduce transparency of the window and result in lower temperature readings.
3. The probe window is the most delicate part of the thermometer. To safely clean the window, gently wipe its surface with a cotton swab slightly moistened with isopropyl alcohol and immediately wipe dry with a clean cotton swab. After cleaning, allow at least 5 minutes drying time before taking temperatures.
   Note: Do not use any chemical other than isopropyl alcohol to clean the probe window.
4. Use a soft, dry cloth to clean the thermometer display and exterior.
5. The thermometer is not waterproof. Do not submerge the unit in water when cleaning.
6. Store the thermometer in a dry location, free from dust and contamination and away from direct sunlight.

Care And Cleaning

7. Periodic cleaning and disinfection of the device following use to prevent patient cross infection.
   -Use a soft cloth slightly moistened with a 75% isopropyl alcohol solution to disinfect the thermometer and probe. Do not use abrasive cleaners.
8. Ensure that children do not use the instrument unsupervised; some parts are small enough to be swallowed.
9. Do not remove or modify the equipment without permission.
10. Strong electromagnetic fields may interfere with the proper operation of the thermometer. The device needs special pre-cautions regarding EMC according to the EMC information.
11. It is not intended for use in the oxygen rich environment and presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
12. Put the thermometer back to the original packaging after using.

Battery Replacement

1. Replace battery when " " appears in the upper right corner of LCD display. (See Figure 9)
2. Slide battery cover down as shown in Figure 10.
3. Remove battery and install 2 new AAA alkaline batteries as shown in Figure 11.
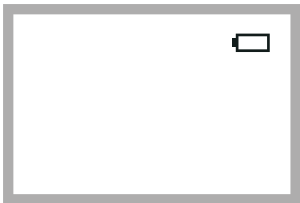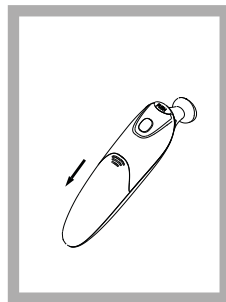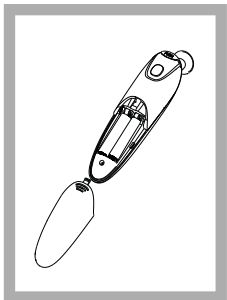4. Slide battery cover back on.

Figure 9

Figure 10

Figure 11

Specifications

Measuring range	Ear/Forehead mode: 34.0℃~43.0℃(93.2℉~109.4℉) Object mode: 0℃~100℃(32℉~212℉)
Measuring site	Ear canal(Ear Mode)、Forehead(Forehead Mode)
Reference body site	Oral (This thermometer converts the ear temperature to display its "oral equivalent.")
Operation mode	Ear/Forehead mode(Adjust mode)
Laboratory accuracy	Ear/Forehead mode: ±0.2℃ (0.4℉) during 35.5℃~42.0℃ (95.9℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉) operating temperature range ±0.3℃ (0.5℉) for other measuring and operating temperature range Object mode: ±4% or ±2℃(4℉) whichever is greater
Display resolution	0.1℃ or 0.1℉
Measure time	Ear mode/Object mode: Approx. one second Forehead: Approx. three seconds
Operating temperature range:	10℃~40℃(50℉~104℉), 15%~85%RH, non-condensing Atmospheric Pressure : 700hPa ~ 1060hPa
Storage and transport temperature range	-25℃~ 55℃ (-13℉~131℉), 15%~95%RH, non-condensing Atmospheric Pressure : 700hPa ~ 1060hPa
Clinical accuracy	Clinical bias：0.05℃ (0.09℉) Clinical repeatability：0.11℃ (0.20℉) Limits of agreement:1.04℃ (1.88℉)
Shock	withstands drop of 3 feet
Dimension	155 * 39* 50mm
Weight	Approx.85grams(with batteries)
Battery	DC3V(2×AAA battery)
Battery life	Approx. 1 year/6000 readings
Expected service life	Three years
Ingress protecting rating	IP22

Troubleshooting

Error message	Problem	Solution
Er 1	Measurement before thermometer is ready	Take a measurement until thermometer is ready(with 2 beeps).
Er2	The ambient temperature is not within the range between 10℃ and 40℃ (50℉～104℉).	Place the thermometer in a room for at least 30 minutes at room temperature between 10℃ and 40℃ (50℉～104℉)
Er3	The thermometer is placed incorrectly or unsteady.	Read Illustration For Use thoroughly and take a new temperature measurement.
Er4	The thermometer showing a rapid ambient temperature change.	Allow the thermometer to rest in a room for at least 30 minutes at room temperature: between 10℃ and 40℃ (50℉～104℉)
Er5	The thermometer is not functioning properly.	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service.

Troubleshooting

Error message	Problem	Solution
Hi	In Ear/Forehead mode: Temperature taken is higher than 43.0 ℃ (109.4℉). In Object mode: Temperature taken is higher than 100 ℃ (212℉).	Read Temperature Taking Hints Thoroughly, then take a new temperature measurement.
Lo	In Ear/Forehead mode: Temperature taken is lower than 34.0 ℃ (93.2℉). In Object mode: Temperature taken is lower than 0℃(32℉).	Read Temperature Taking Hints thoroughly , then make sure the lens filter are clean, then take a new temperature measurement.
▭	The thermometer could not work due to low battery.	Replace two new alkaline batteries size AAA.

Calibration

The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the use instruction, periodic readjustment is not required. However, We recommends checking calibration every two years or whenever clinical accuracy of the thermometer is in question. Please send the complete device to the dealers or manufacturer.

The above recommendations do not supersede the legal requirements. The user must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device which are required by the scope of relevant laws, directives or ordinances where the device is used.

A clinical summary and procedures for checking calibration are available upon request.(Turn on the thermometer and press the power button long time until entering into calibrate mode, software version will be displayed.)

Type BF applied part   Direct Current

Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products

Consult Accompanying Documents

LOT   Batch Code

Storage and Transportation Temperature Limit: -13℉～131℉(-25℃~55℃)

Service

The thermometer has a limited one year warranty. Do not attempt to disassemble or repair the thermometer by yourself. Should service be required during or after the warranty period you must contact the manufacturer. Repackage the thermometer carefully in its original packaging or securely pack to avoid damage during shipping. Include the original sales slip indicating the date of purchase, a note describing the problem, and your return address. Send the thermometer prepaid and insured.
The lay operator or lay responsible organization should contact the manufacturer or the manufacturer's representative:
 – for assistance, if needed, in setting up, using or maintaining the thermometer; or
 – to report unexpected operation or events.

CE 0197   The product is in compliance with the requirements of MDD 93/42/EEC, "0197" is the identification number of notify body;

Warranty

This appliance conforms to the following standards:
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 60601-1-11 Medical electrical equipment —Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment and complies with the requirements of IEC 60601-1-2(EMC) , IEC 60601-1(Safety) standards. And the manufacturer is ISO 13485 certified.

Thermometer is warranted by manufacture to be free from defects in material and workmanship under normal use and service for a period of one year from the date of delivery to the first user who purchases the instrument. This warranty does not cover batteries, damage to the probe window, or damage to the instrument caused by misuse, negligence or accident, and extends to only to the first purchaser of the product.

Electromagnetic Compatibility Information

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Electromagnetic Compatibility Information

Table 1

Guidance and declaration of manufacturer-electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Warning:
1. The Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.)
2. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Compatibility Information

Table 2

Guidance and declaration of manufacturer-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environm entguidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm$ 8 kV contact $\pm$ 2 kV ,$\pm$ 4 kV $\pm$ 8 kV, $\pm$ 15 kV air	$\pm$ 8kV contact $\pm$ 2 kV , $\pm$ 4 kV $\pm$ 8 kV, $\pm$ 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient/burst IEC 61000-4-4	$\pm$ 2 kV for power supply lines $\pm$ 1 kV for input/output lines	N/A	
Surge IEC 61000-4-5	$\pm$ 1 kV differential mode $\pm$ 2 kV common mode	N/A	
Voltage dips, short interruptions and voltage variations on p-ower supply in-put lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 5 sec	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m;50Hz or 60Hz	30A/m;50Hz or 60Hz	Power frequency magnetic fields should be at levels charactertic of a typical location in a typical comme-rcial or hospital environment.

Table 3

Guidance and declaration of manufacturer-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environmentguidance
Conducted RF IEC 61000-4-6	**3 V 0.15MHz to 80 MHz 6V in ISM and amateur radio bands between 0.15MHz and 80 MHZ 80% AM at 1kHz**	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended seperation distance $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	**10 V/m 80 MHz to 2.7 GHz**	10 V/m	$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 Ghz where P is the maximum output power rating of the transmitter in watts (W) according to the trans-mitter manufacturer and d is the recommended separation distance in metres (m).
RF Wireless Communication Equipment IEC 61000-4-3	**380MHz, 27V /m**	**380MHz, 27V /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.
	450MHz, 28V /m	**450MHz, 28V /m**	Interference may occur in the vicinity of equipment marked with the following symbol:
	710MHz,745 MHZ,780MHz 9V/m	**710MHz,745 MHZ,780MHz 9V/m**	
	810MHz,870 MHZ,930MHz 28V/m	**810MHz,870 MHZ,930MHz 28V/m**	$(((\cdot)))$
	1720MHz,1845 MHZ,1970MHz 28V/m	**1720MHz,1845 MHZ,1970MHz 28V/m**	
	2450MHz, 28V /m	**2450MHz, 28V /m**	
	5240MHz,5500 MHZ,5785MHz 9V/m	**5240MHz,5500 MHZ,5785MHz 9V/m**	

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device		
The device is intended for use in an electromagnetic environment in which radiated therefore disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.		

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higer 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.