Shenzhen Raycome Health Technology Co., Ltd

Product Name: Handheld Pulsewave Blood Pressure Monitor
Model: RBP-6700

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Handheld Pulsewave Blood Pressure Monitor

Model RBP-6700

INSTRUCTION MANUAL

Shenzhen Raycome Health Technology Co., Ltd

Dear Customer,

Thank you for purchasing the Raycome Health RBP-6700 Handheld Pulsewave Blood Pressure Monitor. In order to use the device correctly and efficiently, please read this Instruction Manual before use；also please take good care of the instruction manual so that you can use it expediently and timely when need.

Version No.: V1.0.

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• SYMBOLS AND ABBREVIATIONS

Identifiers	Indications
CE 0482	This product complies with the European Council Directive 93/42/EEC (Medical Device Directive).
	BF TYPE
LOT	Lot number
SN	Serial number
	Date of manufacturer
	Manufacturer
EC REP	Authorized representative in the European Community
	Consult accompanying documents.
	Dispose of this product and used batteries in accordance with the applicable local regulations for disposal of electrical product
SYS	SYSTOLIC PRESSURE
DIA	DIASTOLIC PRESSURE

• SAFETY INFORMATION

The purpose of the symbols used in the Instruction as safety identifying is to enable you use the product safely and properly, and to prevent harm to you and others or damage to property.

Identifiers	Indications
⚠ CAUTION	It indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
⚠ WARNING	It indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ WARNING

1. Contact your physician for specific information about your blood pressure. Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your physician or licensed healthcare provider.
2. This product is only suitable for measuring blood pressure and pulse rate of adult, its value is for reference.
3. Pregnant women, pre-eclamptic, mental disorder or arrhythmia patients should use this device under practitioner's guidance.
4. Be sure to use and purchase a dedicated lithium battery and power adapter, or it may cause a fire or damage to product.
5. Do not plug in the power adapter plug with wet hands.
6. When common arrhythmias (such as atrial premature ventricular premature and atrial fibrillation) appear, use the product under a doctor's guidance.

⚠ CAUTION

1.Be sure to use and purchase a dedicated double-bladder cuff, or you cannot get accurate results.

2. Do not use a cellular phone near the device, or it may result in an operational failure.
3. Relax yourself and breathe naturally before measuring, please keep quiet and keep correct posture in measuring process. Incorrect posture (for example, incorrect sitting posture, the height of measuring position is inconsistent with the height of the heart) or non-quiet status (for example, limbs shaking, head and body swing, talking and being nervous) may cause measuring results not correct.
4. Do not attempt to maintain or modify the device by yourself. Please contact the manufacturer or authorized distributor if maintenance service needed.
5. Repeat measuring the same person with an interval of at least 5 minutes because too frequent measurements can cause injury to you due to blood flow interference and get incorrect measurements.
6. DualCuff should not be overly persistent, and the pressure should keep below the value of 300mmHg, or it may cause arm blood be unable to timely reflow.
7. Do not use the cuff when arm is wet or sweaty, please use it after wiping up.
8. Do not subject the monitor and the AC adapter to strong shocks, such as dropping on the floor.
9. Do not soak the unit or cuff in water
10. Operate the device only as intended. Do not use the device for any other purpose.
11. Turn off the protection switch before carry.
12. Do not store or use sphygmomanometer outside the specified temperature or humidity range, it may not achieve the claimed performance.
13. If the monitor and battery achieved longevity, do not arbitrarily discard them, they should be processed according to the local environmental protection regulations in order to avoid environmental pollution.
14. The cuff and Li batteries are classified as consumables.
15. The cuff still meets safety and performance requirements after cycle use for 10000 times; Li batteries capacity will decrease after charge-discharge for 300 times.

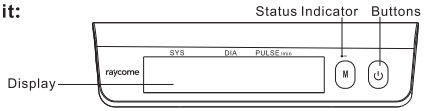
NOTES:

In shutdown status, please ensure the switch in “ON” position, hold the button “M”,then press the button “ ⏻ ” and push the protection switch to “OFF” positin. Finally,loose the buttons “ ⏻ ” and “M” at the same time, the blood pressure monitor will enter the test mode

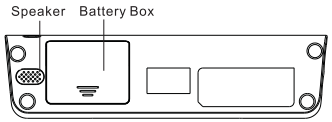
1. Please do not unnecessarily perform the operation, or it may not measure normally.
2. Calibration should be made every three years. Otherwise the device may reach less than the claimed accuracy.

COMPONENTS OF THE PRODUCT

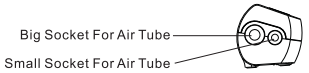
Main Unit:



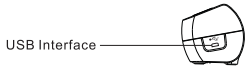
Front



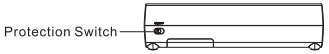
Back



Left Side

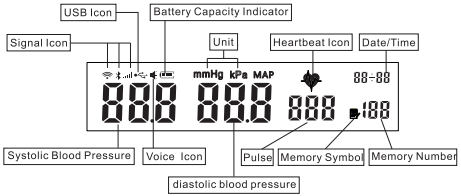


Right Side

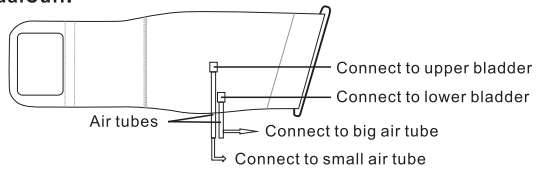


Rear Side

Display:



DualCuff:

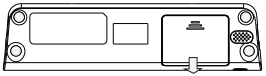


Cuffs specification (Applicable Arm Circumference):
Size S: 15cm ~ 22cm (5.9” ~ 8.7”)
Size M: 23cm ~ 32cm (9.1” ~ 12.6”)
Size L: 33cm ~ 42cm (13.0” ~ 16.5”)
Different sizes of cuff are optional. Please refer to packing list which indicates which size packed.

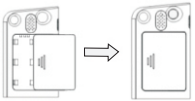
* Cuff is consumable. Please replace the cuff in time in order to have correct blood pressure measurement.
* Please purchase a new cuff for replacement if there is air leak.

BATTERY INSTALLATION

1.Slip off the battery cover as the arrow direction.



2.The lithium battery electrode is loaded in the direction of the copper foil electrode interface of the battery bin, then put the battery cover on. As shown below.

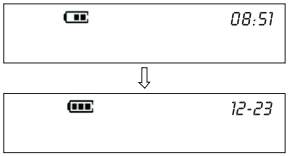


NOTES:

- "▭"icon lights indicates low battery, please charge the battery.
- Please turn off the device before remove the battery.
- After the battery removed, stored memory will be still saved.
- Used batteries are classified as hazardous waste. Do not arbitrarily discard them in household rubbish bins. They should be processed according to the local environmental protection regulations.

RECHARGE THE BATTERY

- When the upper left corner of the screen displays symbol"▭"or "EE 7" error indicator, it means low power, please charge the battery in time.
- Device can be recharged no matter it is on or off. In charging process, the display will loop the symbols"▭→▭→▭→▭". The symbol"▭" indicates battery full charged. The screen when charging is as shown below.



display of switch in "ON" position

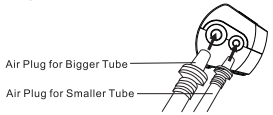
display of switch in "OFF" position

NOTES:

- Do not plug in the power adapter with wet hands. It's not advised to measure blood pressure when it is charging.
- It is suggested to be full charged before storage if it's not used more than 3 months.

APPLYING THE CUFF

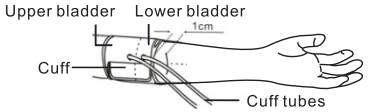
1.Make sure the air plugs are separately inserted into the corresponding sockets in the main unit.



NOTE: The DualCuff must be fully exhausted before plugging into the unit.

2.Take off the thick garments and cuff has to be applied on the bare skin. Thin clothing does not affect the measurement if it does not take pressure to the arm.

3.Apply the DualCuff as shown below. Put your arm through the cuff loop. The bottom of the cuff should be approximately 1 cm above the elbow. The tubes should run down centre of arm approximately even with middle finger.

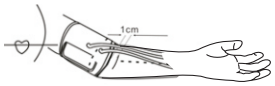


NOTE: Do not put your thick clothes into cuffs.

POSTURES INSTRUCTIONS

1.Sit in a chair with your feet flat on the floor .

2.Bending the arm slightly breezily and naturally place your arm on a table so that the cuff center is at the same level as your heart.



3.Be relaxed and breathe normally before measurement.

NOTES:

- Do not put your arm on the airway tubes. Or this will restrict the flow of air to the DualCuff.
- Your arm cuff and heart should be on the same level. Otherwise, measurement accuracy will be affected.

SETTING THE DATE\TIME \UNIT

After batteries are installed, ensure the protection switch in “ON” position. Please press and hold the button “M”, then press the button “ ⏻ ” and then loosen the buttons synchronously to enter Date/Time/Unit setting status.

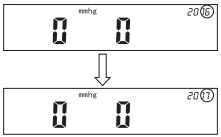
NOTES:

- Set the monitor to the current date and time before taking a measurement for the first time.
- If the date and time are not set correctly, the time of measurement stored in the memory may not be correct.
- When the batteries are removed for a long time, you may need to reset the date and time.

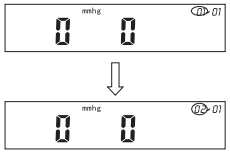
SET THE TIME

Set the date and time with year, month, day, hour, minute sequentially as the following steps.

1. When entering the setting status, the year will flash on the display.
2. The year can be set between 2016 and 2030. Press the button “M” to advance by increments of one year. Press and hold the “M” button to increase year value faster.



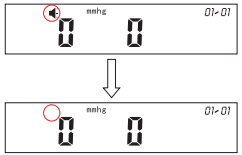
3. Press the button " ⏻ " to confirm the current year. The month flashes on the display.
4. Press the button "M" to advance by increments of one month. Press and hold the "M" button to increase month number faster.



5. Press the button " ⏻ " to confirm the current month. The day flashes on the display.
6. Set the day, hour and minute with the same method as setting year and month.
7. Press the button " ⏻ " to confirm the current minute and then enter voice setting.

SETTING THE VOICE

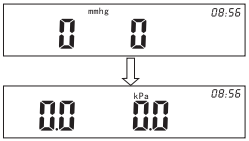
Under voice setting status, voice icon flashes on the display, you can turn on or turn off the voice function by press the " M " button.



Press the button " ⏻ " to confirm and enter unit setting.

SETTING THE UNIT

The 'mmHg' symbol or 'kPa' symbol flashes on the display under unit setting status . Press the button "M" to change the unit status.



Press the button " ⏻ " to save the setting value and quit the setting

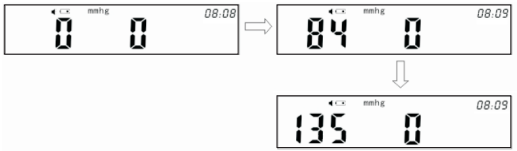
TAKING A MEASUREMENT

This device has two units optional: millimeters of mercury (mmHg) and kilopascals (kPa), the initial state is displayed in mmHg.

The following values are displayed mmHg as an example.

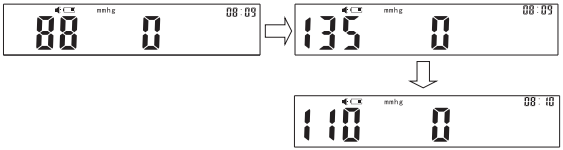
Users should try to relax the body before the test, and sit for 2-3 minutes. Users are advised to be measured at the same time each day.

1. Apply the DualCuff correctly (Refer to the section 'APPLYING THE DUALCUFF') and set right measuring postures (Refer to the section 'POSTURES INSTRUCTIONS'). Please keep quiet when measuring.
2. When protection switch in "ON" position, press the button " ⏻ " to enter the standby mode.
3. In standby mode, press the button " ⏻ " to start measurement, the device starts inflation.



4. If the display shows the error code, such as'EE5', during inflation process, it means a failure of inflation . You need to restart the measurement.

5. The state indicator light keeps on if the device is normal working during measurement.
6. Inflation stops automatically and the measurement starts. The device deflates uniformly, decreasing numbers appear on the display.



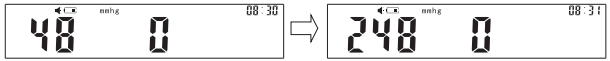
7. After the measurement finished, the DualCuff deflates quickly. Your blood pressure and pulse rate are displayed, and the monitor will save the result automatically.
8. Press the button " ⏻ " to turn off the monitor. Directly press the button " ⏻ " if you want to stop measurement.

NOTES:

- The monitor will automatically turn off after 60 seconds without operation.
- Do not repeat the measurements in a short time, or it may cause arm blood can't timely return which may result in incorrect results. A new measurement can be started after at least five minutes once the previous measurement finished.
- If the body movement occurs in the measurement process, an error message will appear (refer to "Error Indicator"). Please re-measure and keep quiet until the measurement finished.
- If a system error occurs in the measurement process for some reasons which results in measurement failure, or the cuff is excessively inflated, please press the button " ⏻ " to turn off the device and restart it.

INFLATING MANUALLY

Use manual inflating to get higher pressure if you find pressure value is not enough. Press and hold the button " ⏻ " when arm cuff is inflating until the pressure value reaches your expectation. Then arm cuff starts to deflate as normal measurement status.



NOTES:

- Do not inflate manually when not necessary.
- The monitor could not inflate above 270 mmHg, it will begin to deflate and enter into measurement state when the pressure reaches up to 270 mmHg.

USING MEMORY FUNCTION

The monitor automatically stores up to 100 sets of measurement values. When 100 sets of measurement values have been stored, the earliest record will be deleted to save the most recent values.

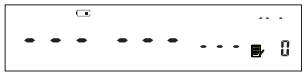
TO DISPLAY THE MEASUREMENT VALUES

1. When protection switch in “ON” position ,without entering the setting or measuring status, press the button “M”, the memory symbol flashes on the display, and then you can check the memory value.
2. By pressing the button “M”, the memory number decreases by one, the values are displayed from the most recent to the earliest. Until the earliest memory value displays, press the button “M”, it will display the most recent memory value,loop as mentioned above. As the following pictures.

3. Press “ ⏻ ” to exit.

TO DELETE ALL VALUES STORED IN THE MEMORY

Press and hold the button “M” for more than three seconds to delete all the stored data. The display screen after deleting is as shown below.



NOTES:

- You cannot partially delete values stored in the memory. but only delete all the values.

DATA TRANSFER

The monitor can use bluetooth and USB interface to transfer data.
(refer to the “Bluetooth Blood Pressure Monitor Instruction Manual”)

CARE AND MAINTENANCE

1. If the monitor gets dirty, use soft cloth dipped little water or a mild detergent to slightly wipe it. Do not use gasoline, thinners and other solvents.
2. Do not wet the DualCuff or let the liquid enter the device during cleaning.
3. Do not crash or fall down the monitor .
4. Keep the monitor and accessories in packing case when not in use.
5. Do not subject the monitor to extreme high or low temperatures, humidity or direct sunlight.
6. Do not forcefully bend the DualCuff or airway tubes.
7. Do not start measurement when the DualCuff is not applied, or else, the DualCuff may be damaged.
8. Do not disassemble or attempt to repair the unit or components.
9. Remove the batteries if the unit will not be used for three months or longer.

ERROR INDICATORS

Error Code	Reasons	Measures
EE1	Upper bladder pressure reaches 280mmHg by accident	Turn off the monitor or pull up the big cuff tubes
EE2	Air tube not connected correctly	Connect the tube correctly
	Air is leaking from the upper bladder	Replace the cuff with the new one
EE5	Downstream air tube not connected correctly	Connect the tube correctly
	Air is leaking from the lower bladder	Replace the cuff with the new one
EE6	Cuff not applied correctly or no pulsewave signal	Apply the cuff correctly or measure repeatedly. If the error appears again, please contact Raycome Health
EE7	Low battery	Please charge in time
EE11	Air tube connected correctly but wear the cuff in wrong direction	Apply the cuff correctly
Others	Unknown errors	Contact Raycome Health

TROUBLESHOOTING TIPS

The following chart lists common faults you may come across when you use blood pressure monitor. Please contact our after-sales service department for help in case problems still cannot be solved.

Number	Phenomenon of fault	Possible reason	Solution
1	No display appears on the screen after starting up.	No power	Please charge in time.
		Incorrect batteries installation	Check the battery installation for proper placement of the battery polarities.
2	Display "Hold" when starting up	The protection switch not in "ON" position	Pull the protection switch in "ON" position
3	Unable to measure or measurement value is too high	The cuff center may not be at the same level with the heart	Please apply the arm cuff correctly
4	Measurement values always vary and appear too high or too low	Blood pressure measurement varies under stress	Take a deep breath to relax before measurement

PRODUCT SPECIFICATION

Name: Handheld Pulsewave Blood Pressure Monitor

Model: RBP-6700

Measurement Range: Pressure: 0 to 270mmHg(0 to 36kPa)
Pulse rate: 40 to 180/min

Accuracy: Pressure: ± 3mmHg (±0. 4kPa)
Pulse rate: ±5%

Storage Capacity: 100 sets

Power Supply: DC3.7V (Li batteries)

Operating Temperature/Relative Humidity/Air Pressure: 5℃ to 40℃ (41℉ to 104℉)/15% to 80% RH/80kPa to 106kPa

Storage and Transportation Temperature/ Relative Humidity/Air Pressure: -20℃ to +55℃ (-4℉ to 131℉)/≤93% RH/50kPa to 106kPa

Main Unit Dimension:7.94'' (L) × 2.05'' (W) × 1.97'' (H)
(201.8mm×52mm×50mm)

Shock Protection: Internal power, Type BF applied part

Main Unit Weight: Approximately 261g (9.2 OZ) not including batteries

Cuff for Applicable Arm Circumference: 15cm~42cm

APPENDIX A: PACKING LIST

When the user opens Blood pressure monitors packaging, please check the following packing list . If objects are not complete or have other questions, please contact Raycome Health or authorized distributors.

No.	Name	Quantity
1	Main unit	1
2	DualCuff □ S ☑M □ L	1
3	Lithium Battery	1
4	USB cable	1
5	Instruction manual	1

APPENDIX B:EMC

⚠ Please install and use this instrument according to the EMC information provided in this Instruction Manual.

⚠ The portable and mobile RF communications equipment can affect this instrument's normal operation.

⚠ Please use the accessories sold by our company, the inappropriate one may result in increased emission or decreased immunity of this instrument.

⚠ The instrument should not be used adjacent or stacked with other equipment and if adjacent or stacked use is necessary, please verify its normal operation in the configuration in
which it will be used.

Table 1:

1	**Guidance and manufacturer's declaration-electromagnetic emission**		
2	The Handheld Pulsewave Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Handheld Pulsewave Blood Pressure Monitor should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment-guidance**
4	RF emissions EN 55011	Group 1	The Handheld Pulsewave Blood Pressure Monitor 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.
5	RF emissions EN 55011	Class B	The Handheld Pulsewave Blood Pressure monitor 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.
6	Harmonic emissions EN 61000-3-2	Not applicable	
7	Voltage fluctuations/ flicker emissions EN 61000-3-3	Not applicable	

Table 2:

Guidance and manufacturer's declaration – electromagnetic immunity			
The Handheld Pulsewave Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulsewave Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge EN 61000-4-5	±1 kV differential mode ± 2 kV 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 EN 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Handheld Pulsewave Blood Pressure Monitor requires continued operation during power mains interruptions, it is recommended that the Pulsewave Blood Pressure Monitor be powered from an uninterruptible power supply or a battery.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment -guidance
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U.is the a. c. mains voltage prior to application of the test level			

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity

The Handheld Pulsewave Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulsewave Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test	EN 60601 test level	Compli -ance level	Electromagnetic environment-guidance
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHZ	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Handheld Pulsewave Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF EN 61000-4-3	3 V/m 80 MHZ to 2.5 GHz	3 V/m	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 metres (m).[b] 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 the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 radios, amateur 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 Child Pulsewave Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Child Pulsewave Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Child Pulsewave Blood Pressure Monitor.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m

Table 4:

Recommended separation distances between portable and mobile RF communications equipment and the Pulsewave Blood Pressure Monitor

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

Rated maximum output of transmitter W	Separation distance according to frequency of transmitterm		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.