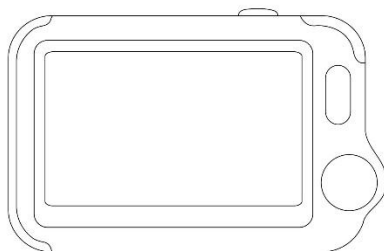




Checkme Lite Health Monitor

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Checkme Lite Health Monitor User's Manual

Warnings and Cautionary Advices

- We recommend not to use this device if you have a pacemaker or other implanted devices. Follow the advice given by your doctor, if applicable.
- Do not use this device with a defibrillator.
- Do not use this device during MRI examination.
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device.
- This device displays changes in the heart rhythm and blood oxygenation etc. which may have various different causes. These may be harmless, but may also be triggered by illnesses or diseases of differing degree of severity. Please consult a medical specialist if you believe you may have an illness or disease.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- The device has no alarms and will not sound if the measurement reading is too low or too high.

1. About Checkme

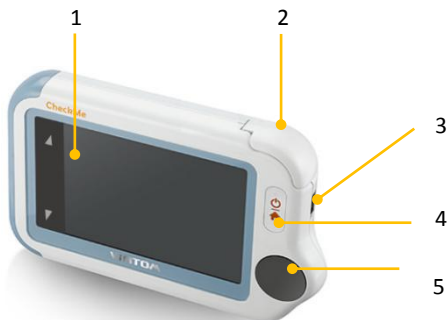
1.1 Intended Use

The Checkme Lite health monitor is intended to be used for measuring, displaying, storing and reviewing of multiple physiological parameters including ECG, pulse oxygen saturation (SpO₂) and systolic blood pressure (SBP) in home or healthcare facilities environment.

ECG and SBP are intended for use with adult.

The data and results provided by this device are for pre-check screening purpose only and cannot be directly used for diagnostic or treatment.

1.2 Outline



1. Touch Screen
2. Internal SpO₂ sensor
3. Micro-USB connector
It connects with USB cable for charging.
4. Home button
 - When the monitor is off, press this button to power it on.
 - When the monitor is on, press and hold it for 2 seconds to turn it off.
 - During operation, press this button will switch to Main Screen or return to upper menu.
5. ECG right electrode
(Put right thumb on it.)

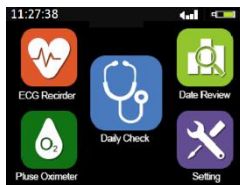


6. Speaker
7. ECG left electrode
(Put it to your left palm, left abdomen or left knee.)
8. Neck stripe hole
9. ECG back electrode

(Put right forefinger or middle finger on it.)

1.3 Main Screen

The Main Screen is shown as below.



Press an icon in the Main Screen will start a measurement, activate a function, or open corresponding menu.

The device will enter Main Screen when:

- No operation is detected for 60 seconds in result screen, the device will automatically switch to Main Screen.
- Pressing the Home button in other screen interface.

You can change the sound volume by tapping the ▼ button on the left of the screen, then tap the <Volume> area. Or you can also go to the Setting menu to change it.

1.4 Symbols

Symbol	Meaning
	Application part type BF
	Manufacturer
CE0197	In conformity with Directive 93/42/EEC
	European Representative
	Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”.
IP22	Against ingress of solid foreign objects $\geq 12.5\text{mm}$ diameter; Against dripping (15° tilted)
	Follow operating instructions



No alarm system.

2. Getting Started

2.1 Power On/Off

Press the Home button to power on the device. Press and hold Home button for 2 seconds to power off the device.

2.2 Initial Settings

The first time when the Checkme is powered on, you can set up your Checkme step by step. You can also change the settings in the <Settings> menu.

3. Using Checkme

3.1 Prior to Use

Before using ECG

Before using Daily Check or ECG Recorder function, pay attention to the following points in order to obtain precise measurements.

- If your skin or hands are dry, moisten them before taking the measurement.
- During the measurement, do not touch your body with the hand with which you are taking the measurement.
- Please note that there must be no skin contact between your right and left hand. Otherwise, the measurement cannot be taken correctly.
- Stay still during the measurement, do not speak and move.
- If possible, take the measurement when sitting instead of standing.

Before using Oximeter

Before using Daily Check and Oximeter function, pay attention to the following points in order to obtain precise measurements.

- The finger inserted in SpO₂ sensor must be clean.
- Any of the following conditions may cause inaccurate measurements, including but not limited to:
 - Flickering or very bright light;
 - Poor blood circulation;
 - Low hemoglobin;
 - Hypotension, severe vasoconstriction, severe anemia or hypothermia;
 - Nail polish, artificial nails;

- Any tests recently performed on you that required an injection of intravascular dyes.
- The Oximeter may not work if you have poor circulation. Rub your finger to increase circulation, or place the SpO₂ sensor on another finger.
- The Oximeter measures oxygen saturation of functional hemoglobin. High levels of dysfunctional hemoglobin (caused by sickle cell anemia, carbon monoxide, etc.) could affect the accuracy of the measurements.
- The pleth waveform displayed on the device is normalized.

Warnings and Cautionary Advices

- Limit finger movement as much as possible when using the Daily Check or Oximeter, which might result in incorrect reading or analysis.

3.2 Daily Check

About Daily Check

Warnings and Cautionary Advices

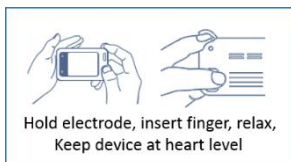
- When using Daily Check, please ensure you select the right user. It must be same as the user when doing calibration. Wrong user will result in incorrect blood pressure readings.
- To ensure better tracking of your health status, it is strongly suggested that every Daily Check measurement is made at the same time period when your body is in the relative same situation. E.g., every morning when get up, or every night before go to bed.

Daily Check measurement is a function that combines the measuring of ECG (Electrocardiograph) waveform, HR (heart rate), SpO₂ (blood oxygenation), PI (Pulse Index), systolic Blood Pressure. It takes only 20 seconds to collect your vital signs before giving results.

Using Daily Check

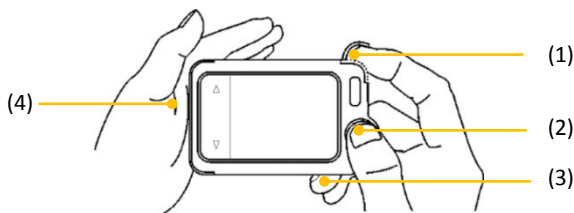
To start a Daily Check, follow the steps as below.

1. Tap the **<Daily Check>** icon in the middle of the Main screen.
2. Choose a user from user A, user B, user C, user D.
3. Hold the device according to the instruction, keep the device at the same level as your heart, and keep stable posture and stay calm.



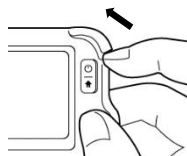
Don't exert too much pressure on the ECG electrode, which may result in EMG (electromyograph) interference. Just hold gently and ensure good contact with the ECG electrode. Do not exert pressure on the finger that put in the SpO₂ sensor. Just fit it inside but gently to ensure good blood perfusion.

- (1) Put the right forefinger into the built-in SpO₂ sensor. Use the finger nail to squeeze the edge of the SpO₂ sensor cover, then

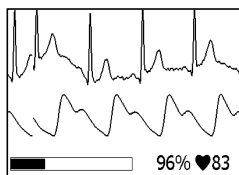


move in upward to the left to raise it up as shown below.

- (2) Press the right thumb on the right electrode.
- (3) Press the right middle finger on the back electrode.
- (4) Press the left electrode to the left palm.



4. Once the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
5. When the bar is fully filled, the device will analysis your data, and then show the measurement result.



BP Calibration

To get blood pressure readings, this device should be calibrated by a doctor with a traditional cuff blood pressure (BP) meter. Because of individual differences, each user must make his/her own calibration before using Daily Check to measure or track the blood pressure. The calibration should be performed when the user is under calm status.

To calibrate with a cuff BP meter, follow the steps as below.

1. Find a qualified traditional cuff BP meter.
2. Sit down and stay calm.
3. Place the cuff on you left arm according to instructions.
4. Select the **<Settings>** icon.
5. Select **<BP Calibration>**, and then choose the right user.
6. Ensure that the cuff is at the same level as your heart. Then start the blood pressure measurement from the cuff BP meter. When the measurement is finished, remember the systolic BP number.
7. Press the ► button on the Checkme screen, and follow the steps as described in **Using Daily check**.
8. When measurement is finished, manually input the number of systolic pressure.
9. Repeat the calibration once again by following the 6-8 steps.

If the readings of two blood pressure measurements are very close to each other, then the calibration is valid and finished. If the readings are not close to each other, please wait for a few minutes, and then start the calibration again.

For a given user, it is suggested to make BP calibration every three months.

3.3 ECG Recorder

Different methods of taking the ECG measurement are available on Checkme. The ECG recorder offers two different methods to measuring ECG:

- Lead I: right hand to left hand
- Lead II: right hand to left abdomen or left knee

Please keep stable posture and stay calm during the measurement. Movements may result in interference and incorrect readings or analysis result.

Measuring

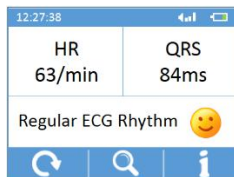
To start an ECG Recorder measurement,

1. In the Main Screen, tap the **<ECG Recorder>** icon.
 2. Choose the method A or B.
 3. Follow the instruction according to the mode you selected.
- Press the right thumb on the right electrode;
 - Press the right forefinger on the back



electrode;

- For Lead I, press the left electrode to the left palm;
 - For Lead II, press the left electrode to the left lower abdomen;
- Do not press the device too firmly against your skin, which may result in EMG (electromyography) interference. After you finish the above steps, hold the device stably and stay calm.
4. Once the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
 5. When the bar is fully filled, the device will analysis your data, and then show the measurement result.



3.4 Oximeter

The Checkme Health Monitor measures the amount of oxygen in your blood (SpO₂), your pulse rate (PR) and pulse index (PI).

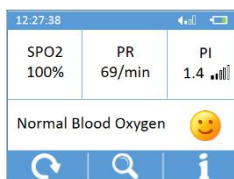
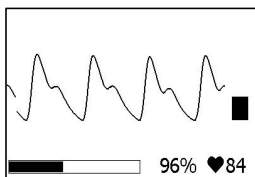
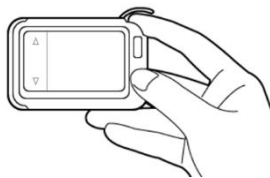
Measuring

To start a Oximeter measurement,

1. In the Main Screen, tap the “Pulse Oximeter” icon.
2. Insert the forefinger into the built-in SpO₂ sensor as shown below.

Relax your forefinger and do exert pressure.

3. When the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
4. When the bar is fully filled, the device will analysis your data, and then show the measurement result.



4. Settings

4.1 Opening Settings Menu

To open the Settings menu, tap the <Settings> icon to open the menu as below.



4.2 Changing Sound Volume

In the Settings menu, tap the <Volume> area to change the volume directly.

Or use the quick setting by tapping the ▼ area on the left side of the screen.

4.3 Changing Brightness

In the Settings menu, tap the <Brightness> area to change the Brightness directly

Or use the quick setting by tapping the ▼ area on the left side of the screen.

4.4 Setting Date & Time

1. Choose <Date & Time>.
2. Tap "+" or "-" button to change the date and time.

4.5 Turning on/off Voice Guide

In the Settings menu, tap the <Voice Guide> area to turn on/off voice guide directly. Or use the quick setting by tapping the ▼ area on the left side of the screen.

4.6 Choosing Language

1. In the Settings menu, choose <Language>.
2. Choose the language from the list.
3. Press the Home Button to return to the Settings menu.

4.7 Erasing Data

In the Setting menu, tap <Erase All Data>, and then <Yes>. Please be noted that all measurements saved in the device will be deleted.

4.8 Factory Reset

1. In the Setting menu, choose <Factory Reset>, then tap <Yes>.
- All measurements, user information and other settings saved in the

device will be deleted, and the device will be restored to the factory default settings.

4.9 Identify Software Version

Choose **<About>** in the **<Settings>** menu to identify the software version of your device. Telling the version information when reporting a problem may help to identify and solve your problem.

5. Review

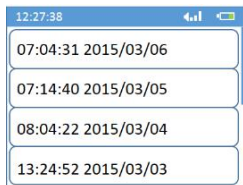
To open the **<Data Review>** menu, tap the **<Data Review>** icon in Main screen.



5.1 Reviewing Daily Check

To review Daily Check records,

1. In the **<Data Review>** menu, select **<DailyCheck>**.
2. Select one record to review more information as below.



In this menu, you can:

- Select  to delete this measurement
- Select  to replay the ECG waveform as shown below.
- Select  to return to the Daily Check list.



5.2 Reviewing ECG Recorder

To review ECG Recorder records, in the **<Data Review>** menu, select **<ECG Recorder>**. The operations you can perform is almost the same with Daily Check.

5.3 Reviewing Oximeter

To review Oximeter records, in the **<Data Review>** menu, select **<Oximeter>**. The operations you can perform is almost the same with Daily Check.

6. Maintenance

6.1 Battery

This monitor is designed to operate on rechargeable Lithium-ion battery. The battery is charged automatically when the monitor is connected to a powered USB port.

On-screen battery symbols indicate the battery status as follow:

 The battery is fully charged.

 The solid portion represents the remained battery energy. If the solid portion moves from left to right, then it means that the battery is being charged.

 Indicates that the battery is almost depleted and need to be charged immediately. Otherwise the device will shut down automatically.

To charge the battery, connect the USB charging cable as shown.

The device cannot be used for any measurement during charging.

Use USB charging devices comply with electrical safety standard, for example IEC 60950.



6.2 Care and Cleaning

Clean the device by carefully swabbing the device surface with a soft cloth swab with water or alcohol.

6.3 Trouble Shooting

Problem	Possible Cause	Solution
The device does not turn on.	1. The battery may be low. 2. The device might be damaged	1. Charge the battery and try again. 2. Please contact with your local distributor.
The ECG waveform amplitude is small	The lead you choose is not suitable for you.	Change another lead and try again.
ECG waveform	1. The pressure exerted	1. Hold the device

drifts	on the electrode is not stable or too much. 2. Hand or body may be moving.	stably and gently. 2. Try to keep perfectly still and test again.
SpO ₂ or pulse rate shows no value, or the number fluctuates	1. Finger may not be inserted correctly. 2. Finger or hand may be moving.	1. Remove finger and reinsert, as directed. 2. Try to keep perfectly still and test again.
“Error XX” occurred.	Software or hardware failure.	Restart the device. If the error persists, contact with authorized service center.
SpO ₂ value is too low when measured using integrated sensor.	1. Finger pressed too hard. 2. Finger may not be inserted correctly.	1. Reinsert your finger gently and stably. 2. Make sure your finger is in right position.
BP calibration failed.	1. The difference between two calibrations is too large. 2. Input a wrong systolic reading.	1. Try to keep perfectly still and calibrate again. 2. Make sure input the right number.

Have the device repaired by authorized service centers only, otherwise its warranty is invalid.

7. Specifications

Environmental		
Item	Operating	Storage
Temperature	5 to 45°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	
Physical		
Size	88×56×13 mm	
Weight	64 g (main unit)	

Display	2.4" touch screen, color, backlit
Connector	Micro-USB connector
Power Supply	
Battery type	Rechargeable lithium-polymer battery
Battery run time	Daily check: > 200 times
Charge time	Less than 2 hours to 90%
ECG	
Lead type	Integrated ECG electrodes
Lead set	Lead I, lead II
Record length	30s
Sampling	500 Hz / 16 bit
Display Gain	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV 10 mm/mV, 20 mm/mV
Sweep speed	25 mm/s
Bandwidth	0.67 to 40Hz
Electrode offset potential tolerance	± 300 mV
HR measurement range	30 to 250 bpm
Accuracy	± 2 bpm or $\pm 2\%$, whichever is greater Heart rate is calculated based on average of every 5 to 30 QRS complex.
Measurement summary	Heart rate, QRS duration, Rhythm analysis (Regular ECG Rhythm, High Heart Rate, Low Heart Rate, High QRS Value, Irregular ECG Rhythm, Unable to analyze)
Standards	Meet standards of ISO 80601-2-61
Measurement accuracy verification: The SpO ₂ accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurement are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.	
SpO ₂ range	70% to 100%
SpO ₂ Accuracy (Arms)	80-100%: $\pm 2\%$, 70-79%: $\pm 3\%$
PR range	30 to 250 bpm
PR accuracy	± 2 bpm or $\pm 2\%$, whichever is greater
PI range	0.5-15

Measurement summary	SpO ₂ , PR, PI, Summary (Normal Blood Oxygen, Low Blood Oxygen, Unable to analyze)
Blood Pressure Variation	
Measurement method	Cuff-free non-invasive technology
Measurement summary	systolic pressure based on individual calibration coefficient
Review	
Waveform review	Full disclosure waveform
Storage	100 pcs of records

8. Electromagnetic Compatibility

The device meets the requirements of EN 60601-1-2. All the accessories also meet the requirements of EN 60601-1-2 when in use with this device.

Warnings and Cautionary Advices

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

Guidance and Declaration - Electromagnetic Emissions

The Health Monitor 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.

Emission tests	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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 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
Harmonic emissions IEC61000-3-2	Class A	
Voltage	Complies	

Fluctuations / Flicker Emissions IEC 61000-3-3		domestic purposes.
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Guidance and Declaration - Electromagnetic Immunity			
The Health Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Health Monitor should assure that it is used in such an environment.			
Immunity test	IEC60601 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	Floors 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 for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	
Voltage dips, short Interruptions and Voltage variations on power supply input lines	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT)	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT)	Mains power quality should be that of a typical commercial or hospital environment. If the user of our

IEC 61000-4-11	for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 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_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity

The Health Monitor is intended for use in the specified electromagnetic environment. The customer or the user of the Health Monitor should assure that it is used in such an environment as described below.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms 150 kHz to 80 MHz outside ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$
Radiated	3 V/m 80	3 V/m 80	Recommended separation

RF IEC61000- 4-3	MHz to 2.5 GHz	MHz to 2.5 GHz	distances: 80 MHz~800 MHz: $d = 1.2\sqrt{P}$ 800MHz-2.5GHz: $d = 2.3\sqrt{P}$ 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 ^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: 
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Note 1: At 80 MHz to 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.

^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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

^b Over frequency range 150kHz to 80MHz. For Resp field strength should be less than 1V/m.

Recommended separation distances between portable and mobile

RF communications equipment and the device

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

Rated max. output power of transmitter (W)	Separation distance according to frequency of the transmitter (m)		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

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.



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