

Health Monitoring +

User Manual



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Thank you for using this Health Monitor. Please read this User Manual carefully in order to use the medical device safely and correctly.

Intended Use

Health Monitor is intended to be used for measuring, displaying, and storing body temperature, blood pressure and pulse rate in the home or in healthcare facilities.

- The device cannot be used for self-diagnosis.
- The device obtains the body temperature by measuring the forehead area.
- The device obtains the blood pressure by measuring the upper arm site.
- This product should not encourage self-medication or adaptation of the treatment.
- Always consult the doctor if the patient has any questions, or he/she believes he has abnormal measurements.
- Blood pressure measurement isn't used for neonatal or children under 12 years old.
- Body temperature measurement isn't used for neonatal or children under 5 years old.
- The operator must be able to read English.

Functions

The Health Monitor is a wireless device that uses Bluetooth for signal transmission and needs to be connected to a mobile phone application. Through infrared sensors, pressure sensors measurements of body temperature, blood pressure and pulse rate information are taken, and via Bluetooth the information is transferred to the application on the phone. The user can view the temperature, blood pressure and pulse rate in the mobile phone application.

Contraindications

- Children or anybody that can't read the instructions should not use the device.
- Do not use the device on a body part with injury and skin infection.
- Users with blood circulation issues or blood diseases please only use under the guidance of a doctor for those who have disturbance of blood circulation or blood disease.
- Self-measurement for blood pressure is not suggested for those with high psychological anxiety.
- Blood pressure measurement is not to be used for neonatal or children under 12 years old.
- Body temperature measurement is not to be used for neonatal or children under 5 years old.
- This device is not to be used in an ICU.

Product Composition

The Health Monitor consists of the device, cuff and mobile-phone application program. The device is mainly composed of PCB, Plastics, Rechargeable Lithium-Ion Battery, Pump, etc.

Product specification and performance characteristics

The Health Monitor consists of the device, cuff and mobile-phone application program. The device is mainly composed of PCB, Plastics, Rechargeable Lithium-Ion Battery, Pump, etc.

Product Name	Health Monitor	Product Model	HC-03
Software	Health Monitor	SW Version	V0.0.10
Battery Nominal Voltage	3.N	Input Voltage	5V/0.25V
Battery Rated Capacity	400mAh	Size	70mm x 7Q mm x 18.4mm

Working Frequency	2.4000-2.4835GHz	Net Weight	about 70g
Communication Protocol	Bluetooth 4.0	Resting pressure rated range	0-300mmHg
Validity period of product	3 years	Validity period of cuff	2 years
Lifetime of battery	Charge-discharge cycles 300 times		
Pressure measurement		Body temperature measurement	
Measurement body part	Upper arm	Measurement body part	Forehead
Circumference	22-35cm	Measurement scope	28-42°C
Measurement scope of systolic pressure	60-230mmHg	Measuring error	±0.2°C, for 35-42°C ±0.4°C, for <35°C
Measurement scope of diastolic pressure	40-130mmHg	/	/
Pressure error	±3mmHg	/	/
Measurement scope of pulse rate	40-180bPm	/	/
Pulse rate error	±5%	/	/
Temperature	5°C-40°C	Temperature	-25°C - +70°C
Humidity	15%-93%	Humidity	593%
Atmospheric Pressure	70-106 kPa	Atmospheric Pressure	50-106kPa

Product Structure

ECG /
Temperature
Sensor



Blood Oxygen Sensor

USB Charging Port

Product Safety Class

Protection against electric shock	Class II
Applied parts	BF
Protection against harmful ingress of water or particulate matter	IP22
Mode of operation	Not continuous operation
Used in an Oxygen rich environment	Not intended for using in Oxygen rich environment

Applied mobile phones (Network, Data Couplings)

Health Monitor shall be used together with application program in mobile phones. The mobile phone shall satisfy the following 2 requirements.

Bluetooth 4.0

Android 4.3 or higher version, iOS 7.0 or higher version.

Package List Accessories

Health Monitor x1, Cuff x1 & User Manual x1

List Battery Charging

Cuff (XD-01) x1 & USB line x1

The color of battery icon on APP means electric quantity status.

- RED: The battery is near power off
- YELLOW: Low power
- GREEN: Sufficient power
- BLUE: Full power

Cautions for battery charging

- Please charge timely when low power caution appears on APP.
- Power light is blue and flickering during charging.
- Do not use the device during charging.

Power ON & OFF

Power ON: press power key 2 seconds. The device shakes slightly. Power on is successful with blue power light. **Power OFF:** press power key 2 seconds. The device shakes slightly. Power off is successful with power light off.

APP Download

Go to the respective App stores and search for Qlupod.

Device Connection

Press the power key and hold 2 seconds to power on. Open the APP. The device will connect to the APP automatically with the electrical quantity icon appearing on the APP. If the electrical quantity icon is not shown on APP, click the Bluetooth icon to set up the connection manually.

Cautions for using the APP

1. Confirm the system specification in the mobile phone complies with the requirements before downloading the APP.
2. To set up the automatic connection between mobile phone and device, the device should be powered on before logging into the APP.
3. Most malfunctions can be solved after rebooting the device and the APP.

Troubleshooting

Malfunctions	Reason	Solution
Failure of downloading APP	Mobile phone does not satisfy the requirements	Check the version of Bluetooth and system of mobile phone
Failure of automatic connection	Wrong operation sequence	Power on the device first, then log into the APP or connect manually

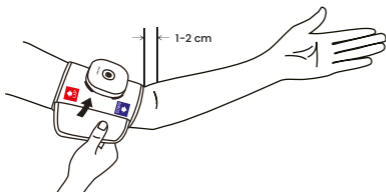
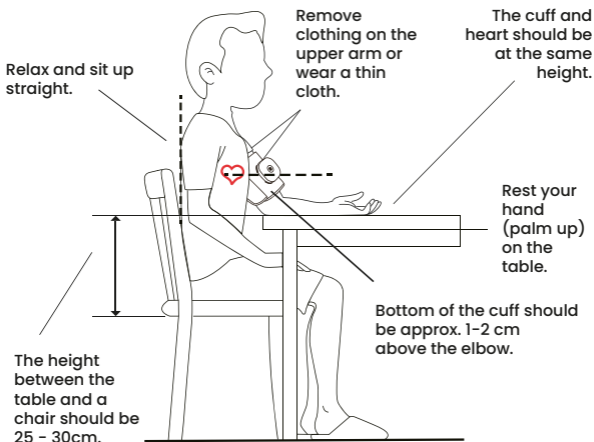
Failure of connection or finding the device	Weak sensitivity of Bluetooth of mobile phone	Power on the device first, then log into the APP or connect manually
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Instruction for blood pressure measurement

Blood pressure measurement will be influenced by body posture, wearing method of cuff, physical condition, and surrounding environment. The position of the cuff and heart should be kept at the same horizontal level during measurement.

1. Keep calm for 5 minutes before measurement. Do not speak or talk during measurement to avoid influence on accuracy. Arm should be kept naked or dressed in thin cloth.
2. Power on the device and buckle in the cuff correctly. Tie up the cuff 1-2 cm above the upper elbow joint. Degree of tightness should be comfortable.
3. Sit up straight. Keep the limb positioned on a stable table or platform with proper height. Keep the palm up and relaxed. The position of the cuff and heart should be kept at the same horizontal level during measurement.
4. Open the APP. The device can connect to the APP automatically or manually with the appearance of an electrical quantity icon on the APP. After the device connects to the APP successfully, select blood pressure in the APP interface and click "Start". The cuff will be inflated, and measurement will be started. Keep calm during measurement.
5. System will stop automatically after measurement. The measured value will be shown.
6. Take off the cuff, and clear up.

Do not evaluate the result only by your own experience. Please consult the doctor.



Troubleshooting

Malfunctions	Reason	Solution
Low reading	Wrong wrapping of cuff Moving, speaking, or wrong sitting posture during measurement.	Wrap the cuff correctly. Adjust the sitting position keep calm during measurement. Please refer to user manual for operation details.
Failure of inflating	Leakage of cuff or wrong position of device.	Re-position the device. Contact the manufacturer for replacing the cuff if the cuff is broken.
Failure of measurement	Wrong position of device, or inadequate battery charge.	Check the position of the device by referring to the user manual. Check the power quantity. Ensure the battery is sufficiently charged. Please refer to the user manual for operation details.

Calibration of blood pressure by using static pressure

HC-03 is based on oscillometer, which means the blood pressure calculated is accurate only if the static pressure is accurate. Therefore, to calibrate the blood pressure, static pressure should be calibrated. FLUCK BP Pump 2 Blood Pressure Simulator is used to calibrate the static blood pressure.

Calibration process:

1. Use airway tube to connect HC-03 and FLUCK BP Pump 2.
2. Press CUFF and select Internal.
3. Press Option and select static pressure of 0-300mmHg.
4. Run the APP to connect HC-03. Enter engineering test mode by inputting engineering code.
5. Select static pressure test item HC-03 closed pressure on APP.
6. Press Start button on FLUCK BP Pump 2 to start the inflation. The inflation will be stopped automatically when the pressure reaches the setting.
7. Compare the static pressure value on FLUCK BP Pump 2 and APP. The gap shall be smaller than $\pm 3\text{mmHg}$.

Instruction for body temperature measurement

Power on the device and open the APP. The device can connect to the APP automatically or manually with the appearance of an electrical quantity icon on the APP.

Keep forehead dry and clean. Take the device and align the infrared detection head to the center of forehead. Keep the device 1-2 cm away from skin.

Select "Temperature" in the App. Click "Start" for measurement. System will stop automatically after measurement. The measured value will be shown.

Temperature sensor: aim for the forehead.



Troubleshooting

Malfunctions	Reason	Solution
Big measurement error	Sweat, water, oil and etc. on forehead.	Clean the forehead before measurement.
	Leakage of cuff or wrong position of device.	Keep 2-1 cm distance between detector head and forehead.

⚠ General Warning

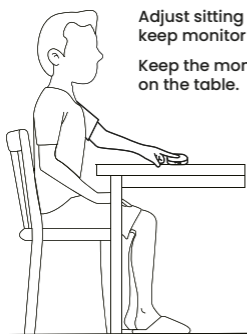
- Please read this User Manual carefully in order to use the medical device safely and correctly.
- Please use the device in the specified environment. Do not use the device in an environment with strong electromagnetic interference or high frequency surgical equipment.
- Contact the manufacturer when facing damage or malfunction. Do not disassemble or repair the device by yourself.
- Do not disassemble or modify the device by yourself.
- Do not use it when the device requires maintenance.
- Do not place the device in an environment with strong acid or alkali. Otherwise, the lifetime and measurement accuracy of the device may be affected.
- The APP of the device is designed for smartphones with Bluetooth 4.0, Android 4.3 or higher version, iOS 7.0 or higher version. Please confirm your smartphone is compliant with the requirements before hand

to avoid damaging the smartphone.

- Keep the device away from fire or heat sources since it contains battery and electronic components.
- Children can use the device under a guardians' supervision. Keep the device in a place where children can not touch it since the device contains small components.
- Do not calibrate it by yourselves. The calibration is done before delivery. Please contact the manufacturer when calibration is needed.
- Do not operate the device out of the scope of specified temperatures for measurement. e. Otherwise the performance could be affected.
- Do not store and transport the device out of the scope of specified environmental temperature and humidity. Otherwise, the performance could be affected.
- The device's performance could be affected when the optical component is damaged or polluted.
- The device's performance could be affected when the device is vibrating or is dropped.
- Charger, mobile displayer with Bluetooth and health monitor contribute a ME (medical electrical) system.
- An ME SYSTEM shall provide:
 - within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and
 - outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards.
- Please use the charger complying with IEC60601-1 or other relative electrical standards (e.g., IEC60950). Otherwise, there could be the risk of electrical shock.
- The mobile devices such as mobile phone connected to Health Monitor shall have a protection level of IP22 at least.
- Please use the accessories such as cuff and cable specified by the manufacturer. Otherwise, it could lead to inaccurate measurement or damage to the device.
- Stop using the device and contact after-sales service if you find the performance has changed.

Instruction for blood oxygen measurement

1. Power on the device and open the APP. The device can connect to APP automatically or manually with the appearance of an electrical quantity icon on APP.
2. Keep still and calm. Put the middle finger above the blood oxygen probe and make the finger pulp touch the probe.
3. Select "Oximetric in the App. Click "Start" for measurement.
4. System will stop automatically after measurement. The measured value will be shown.



Adjust sitting position
keep monitor on the table.

Keep the monitor flat
on the table.



Put fingertip
of index finger
the oxygen
detector.

Troubleshooting

Malfunctions	Reason	Solution
Data changed a lot in a short period	Measured way or body gesture was wrong.	Re-measure according to the instruction.
Unable to get measured results	Finger overexerted.	Lightly press the middle finger on the device, do not overexert.
	Finger is too thin.	Use another finger to measure, ensure the finger covering the blood-oxygen light during the process.

Cautions

Please relax for at least 5 minutes before

measurement. Do not eat, drink alcohol or coffee, exercise, or bath for 30 minutes before measurement.

Please relax as much as possible and not talk during the measurement procedure.

The health monitor should be horizontally placed during the measurement.

It's recommendable to measure by middle finger, nails hold up. Clean the fingers before the measurement.

DO NOT move the finger during the measurement.

There are some differences on the blood pressure on different fingers, blood circulation, physiological features, hence try to use the same finger to take measurements.

The paralysis state caused by the continuous blood-pressure measurements can influence the blood circulation, which may affect the oximetry values, so do not measure the blood oxygen after finishing the blood pressure measurement.

DO NOT paint the nail polish on the measuring finger.

DO NOT take measurement under strong light.

DO NOT measure after sporting.

The measured blood-oxygen value may be incorrect if the tester's finger skin is too thick or has pigment deposition.

If there are foreign matters between the probe and the measured parts, it may influence measured result.

Cold fingertip skin or poor peripheral circulation caused by low temperature treatment or prolonged exposure to low temperature environment can result in insufficient pulse signal, too low measured value or unable to measure.

Instruction for ECG measurement

1. Power on the device and open the APP. The device can connect to APP automatically or manually with appearing of electrical quantity icon on APP.
2. Keep still and calm. Hold the device by left hand, and the thumb touches the metal part on the top of blood oxygen sensor, other fingers touch the metal label at the back of device. The power button aims to palm.
3. Right hand touches the body temperature sensor. Two hands don't touch each other.
4. Select "ECG" in App. Click "Start" for measurement.
5. System will stop automatically after measurement. The measured value will be shown.



Troubleshooting

Malfunctions	Reason	Solution
ECG Diagram Reverse	The position of 2 hands is reverse.	Please place the monitor correctly in both hands, according to the instructions.

Cautions

Please relax at least 5 minutes before measurement. Do not eat, drink alcohol or coffee, exercise, bath, etc. 30 minutes before measurement.

Please relax as much as possible and not talk during the measurement procedure.

To avoid the external disturbance, please do the measurement in a quiet environment.

DO NOT do the measurement under the charging.

Please place two hands in correct position.

DO NOT do the measurement with wet hands.

During the measurement, two hands DO NOT touch each other.

Maintenance

Do not do servicing and maintenance while the device is in use. Please do maintenance using the following methods.

- Do not wash the cuff with water. Clean with soft and clean fabric.
- Do not scrub the device with wet fabric since the device is not waterproof.
- Fabric stained with neutral detergent or water could be used for cleaning. The fabric shall be twisted before cleaning. If necessary, degreasing cotton stained with ethanol could be used for disinfection.

- Keep the device away from fire or heat sources since it contains battery and electronic components.

- Calibration is suggested to be conducted every 2 years, although a strict test is finished for each function before delivery. Please contact the manufacturer when calibration is needed.

- Do not disassemble or repair by yourself. Please dial customer service hotline for consultation due to product quality issues or any doubts for measurement results.

Please store the device using the following methods.

Keep the device away from high temperature, moist, direct sunshine, dust, salty air.

Keep the device away from places which could cause the working position to be at a slant, or for the device to be shaking or impacted. and impacting.

Keep the device away from places with chemicals or corrosive gas.

Do not drop the device from any height.

Do not fold the cuff tightly.

Repairs

Do not disassemble or repair by yourself. Please dial

customer service hotline +41 (0) 71 510 05 45 for consultation due to product quality issues or any doubts for measurement results.

The cuff is specified for the device. Please contact the manufacturer for repair or purchase. Do not change it by yourself.

Any repairs can only be done by authorized persons.

Cleaning and disinfection

Please clean by using soft dry cloth.

When the device is very dirty, water or neutral agent could be used but test before cleaning.

If necessary, degreasing cotton with ethanol could be used for disinfection.

Environmental protection

When disposing of the device, cuff or waste battery please refer to local regulations. Please do not discard it casually.

After-sales Guarantee

1. If device malfunctions happen within 7 days after purchase selling, consumers could select refund, exchange goods, or repair. Free repair is provided for non-accidental artificial damage within 1 year after purchase selling. For the reasonable requests outside the free exchange or repair time window, technical service may be provided with including changing of materials that form the device, repair, and service.




















2. Purchase date is determined by the invoice issued by the manufacturer or authorized dealer.

The guarantee does not apply for the below conditions

- Any non-accidental damage or malfunction caused by using the device in an abnormal working environment, by not following the instructions for use, or by not using the device under the specified conditions.
- Disassembly, repair, or changes to the device by yourself without agreement by the manufacturer.

- Damage caused by improper transportation after purchase.
- Damage caused by force majeure (e.g., flood, thunder strike, earthquake, abnormal voltage, etc.).
- Normal wear and other conditions affecting normal operation.
- Purchase from an unauthorized channel not connected to QluPod. The guarantee is only applicable for the device itself.

Symbol Definition

	PRODUCT CODE		LOT NUMBER
	MANUFACTURER		TEMPERATURE LIMIT
	KEEP IN A DRY, COOL PLACE		KEEP AWAY FROM SUNLIGHT
	MEDICAL DEVICE COMPLIES WITH DIRECTIVE 93/24/EEC		HUMIDITY LIMIT
	CONSULT INSTRUCTIONS FOR USE		SMALTIMENTO RAE
	CAUTION: READ INSTRUCTIONS (WARNINGS) CAREFULLY		EXPIRATION DATE
	AUTHORIZED REPRESENTATIVE IN A EUROPEAN COMMUNITY		COVERING PROTECTION RATE
	DON'T USE IF PACKAGE IS DAMAGED		ATMOSPHERIC PRESSURE LIMIT
	CLASS II APPLIED		TYPE BF APPLIED PART
	FOLLOW INSTRUCTIONS FOR USE		

EMC Declaration

Guidance and manufacturer's declaration - electromagnetic emission - for all EQUIPMENT AND SYSTEMS.

1	Guidance and manufacturer's declaration - electromagnetic emission.		
2	The HC-03 is intended for use in the electromagnetic environment specified below. The customer or the user of HC-03 should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	CLASS 1	The HC-03 uses RF energy only for internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.


5	Harmonic emissions IEC 61000-3-2	CLASS B	The HC-03 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 IEC 61000-3-2	CLASS A	
7	Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS.

Guidance and manufacturer's declaration - electromagnetic immunity			
The HC-03 is intended for use in the electromagnetic environment specified below. The customer or the user of the HC--03 should assure that it is used in such an environment.			
Immunity test	EN 60601 test	Compliance	Electromagnetic Environment
Electrostatic discharge (ESD) IEC61010-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 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	± 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 differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HC-03 requires continued operation during power mains interruptions, it is recommended that the HC-03 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-6	400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity	
The HC-03 is intended for use in the electromagnetic environment specified below. The customer or the user of the HC--03 should assure that it is used in such an environment.	

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V (V)	<p>Portable and mobile communication equipment should be used no closer to any part of the HC-03, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = \left[\frac{3.5}{\sqrt{1}} \right] \sqrt{P}$</p> <p>$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz; $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2.5 GHz</p> <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, are determined by an electromagnetic site survey, and should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10V/m (E)	

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 HC-03 is used exceeds the applicable RF compliance level above, the HC-03 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HC-03.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distances between portable and mobile RF communications EQUIPMENT or SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF Communications equipment and the HC-03

The HC-03 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HC-03 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HC-03 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 transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.01	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 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 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.