

RootiRx
ECG Event Recorder

Instruction Manual

User Manual V1.0

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EC REP

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CE

0598

€0560

Authorised Representative in the European community

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BEFORE USE

Introduction

Thank you for purchasing the Rooti Rx.

Fill in for future reference

DATE PURCHASED: _____

SERIAL NUMBER: _____

(• Staple your purchase receipt here _____)

Product Description

The Rooti Rx is a compact physiological monitoring module. The intended use of Rooti Rx is to provide a facility in the home, workplace and for recording and transmitting single lead EGG data to a qualified receiving station for interpretation by medical professionals. The Rooti Rx stores one lead electrocardiography(ECG) signals and recording data transmission via WiFi.

To interpret recording data should be skilled at the level of a technician, doctor, nurse, or medical specialist.

The Rooti Rx comes with the following components:

- Rooti Rx
- Charging Dock
- Electrode Sticker x3
- Instruction Manual



Please read this instruction manual thoroughly before using the unit.
Please keep for future reference.

Safety Information

To assure the correct use of the product basic safety measures should always be followed including the warnings and cautions listed in this instruction manual.

Icon Explanation			
	Do not reuse		Manufacturer
	Temperature limitation		Date of Manufacture
	Read this instruction manual thoroughly before using the unit.		CE Certificate
	Type BF applied part		RF CE Certificate
	Authorised representative in the European Community		Use By
	Battery must be recycled		Direct Current
	Batch Code		Serial Number
	IP58 Ingress Protection 5: Dust Protected 8: Protected against the effects of temporary immersion in water		Caution: 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.

Operating The Rooti Rx

Read all of the information in the instruction manual and any other literature in the box before operating the unit.

Subjects fitted with a heart pacemaker should not use the Rooti Rx.

The Rooti Rx should not be used in conjunction with any defibrillator, including implanted or AED devices.

Please use standard USB power outlet. The USB power outlet must be certified to IEC/EN 60601-1 for 2 MOPP and examined regularly. When wearing the Rooti Rx to shower, RED LED flashes temporarily. Wipe dry the Rooti Rx after shower, RED LED stops flashing. If RED LED still flashes, please change new Electrode Pads. If LED continues flashing after all these steps or user has any other problem, please CONSULT DOCTOR.

- If user feels itchy and allergic after the electrode sticker long-time attached to skin, please remove the sticker and ask users to CONSULT DOCTOR.
- We advise pregnant women and children to use this product under the supervision of a doctor.
- No modification of this equipment is allowed.
- Be aware of choking resulting from a child swallowing a small part that has become detached from Rooti Rx.

Care And Maintenance

- Operate the Rooti Rx only as intended. Do not use the Rooti Rx for any other purpose.
- Do not submerge the Rooti Rx or any of the components in water. Do not wear Rooti Rx to swimming or taking a bath.
- Store the Rooti Rx and the components in a clean, safe location. (-10~60 C / 10~95% R.H. (noncondensing))
- Ingress Protection
- 5:Dust Protected
- 8:Protected against the effects of temporary immersion in water
- The conductive parts of electrodes and associated connectors for type BF or CF applied parts, including neutral electrode, should not contact other conductive parts including earth.
- The disposal of Rooti Rx and accessories follows normal electronic waste recycling method.

Side Effect

- If long time wearing Rooti Rx, users may feel itchy and a little bit allergic on skin.

Contraindication

following patient must be follow the doctor's instructions to use:

1. Chronic Disease patients
2. Allergic to Polyester patient
3. Pregnant woman
4. Children
5. Breastfeeding women

Before Taking a Measurement

To ensure a reliable measurement, follow these recommendations:

- We suggest using alcohol pad to clean the back of Rooti Rx (Sensor Pad) before and after use.
- During recording, please do not take off the Rooti Rx.
- Electrode Sticker is only for ONE time use. Please change a new sticker every time before use.
- When wearing the Rooti Rx to shower, RED LED flashes temporarily. Wipe dry the Rooti Rx after shower, RED LED stops flashing. If RED LED still flashes, please change new monitoring electrodes. If LED continues flashing after all these steps or user has any other problem, please CONSULT DOCTOR.
- Please make sure to put the Rooti Rx onto the Charging Dock before data downloading.

To have a better using experience, read the following items.

- Quick RED LED flashing indicates LOW POWER while slow RED LED flashing indicates LEAD OFF.
- When connecting to Rooti Rx, users cannot use the internet at the same time.
- If user feels itchy and allergic after the electrode sticker long-time attached to skin, please remove the sticker and ask users to CONSULT DOCTOR.

OPERATION INSTRUCTIONS

Rooti Rx

Front

Function Button

LED

rooti

Back

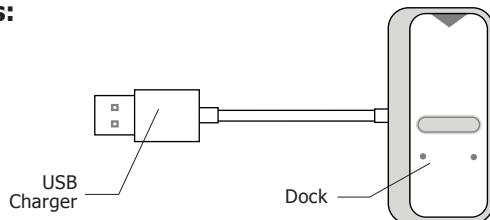
Sensor Pad

...

Notice: We suggest using ALCOHOL PAD to clean the back of Rooti Rx (Sensor Pad) before and after use.

Components:

Charging Dock

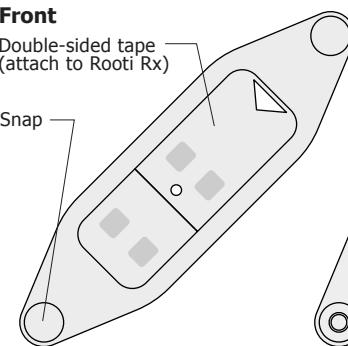


Electrode Sticker

Front

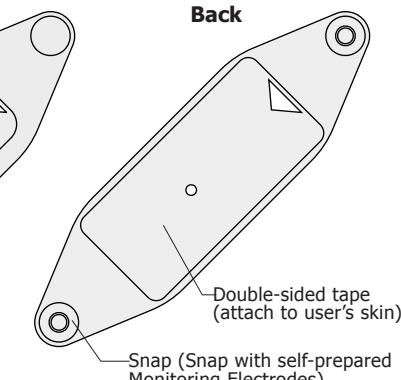
Double-sided tape (attach to Rooti Rx)

Snap



Back

Double-sided tape (attach to user's skin)

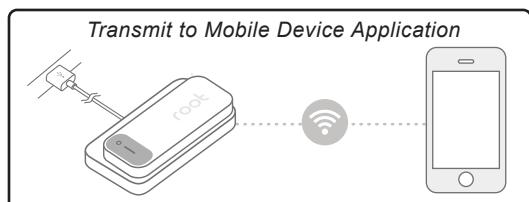


Rooti Link

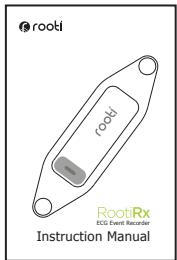
Rooti Rx has to be worked along with App "Rooti Link". Download "Rooti Link" in Apple Store and follow the on-screen instruction to set up the Rooti Rx.

Compatibility

- iOS 8+
- iPhone 5+
- iPad Mini
- iPad 3+



Instruction Manual



Features

- ECG (EC38 Type 3)
- Skin Temperature
- Uses Standard ECG Electrodes
- Wi-Fi data download
- Rechargeable
- USB charging
- Red/ Green/ Blue LED
- Function button
- IP58

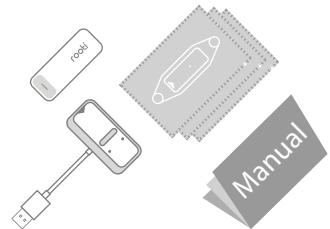
Applications

- Hospital General Care
- Skilled Nursing Facilities
- Home based Remote Patient Monitoring
- Physiological status monitoring in real world situations

Getting Started

1. Inside the box

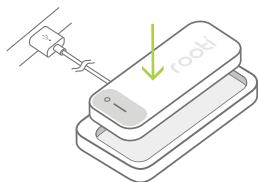
Rooti Rx x1
Electrode Sticker pack x3
Charging Dock x1
Instruction Manual x1



2. Charge Rooti Rx

Put the Rooti Rx into Charging Dock and plug it into power outlet, meanwhile, Green LED flashes. When full-charged the Rooti Rx, LED lights out.

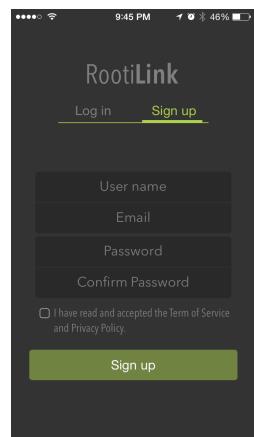
*ATTENTION: To achieve maximum product utility, please make sure to fully charge the Rooti Rx before use.



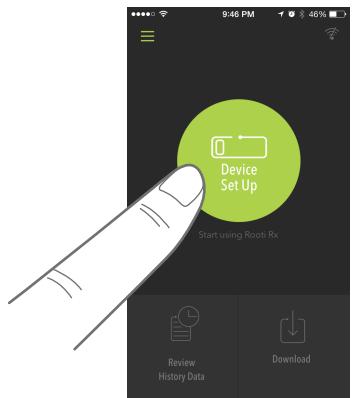
3. Download RootiLink App for your patient

First, help your patient to set up RootiLink, the app for Rooti Rx. Ensure smart device is connected to Internet and search for "RootiLink" in App Store, download and set up a RootiLink account for your patient.

- (1) After downloaded, start RootiLink.
- (2) Sign up a new account for RootiLink, set up your personal profile.

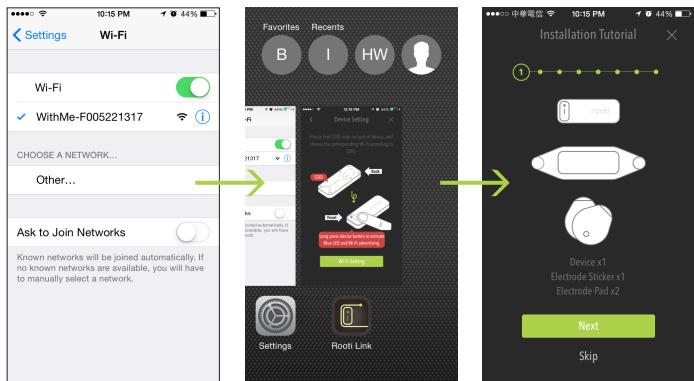


(3) Tap "Device Set Up" in main page.



(4) Follow the instructions in the app and connect RootiLink with Rooti Rx.

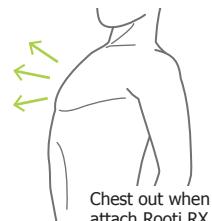
Notice: After connecting Wi-fi in Apple system, quickly press Home key twice to go back RootiLink.



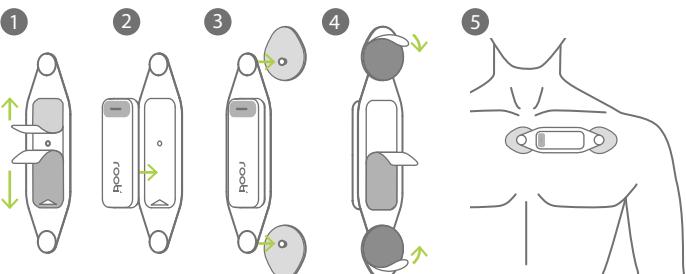
4. Offer Rooti Rx as a Tool for Your Patients

Follow the instructions in the app, set up Rooti Rx for your patients and start recording.

- (1) Step 1: Remove double-sided tape in the front side of Electrode Sticker.
- (2) Step 2: Stick the Rooti Rx onto the FRONT of Electrode Sticker. Aim the circle steel dot to the hole of sticker.
- (3) Step 3: Snap in Monitoring Electrodes^{*a} to Electrode Sticker.
- (4) Step 4: Remove adhesive tapes on the BACK of Electrode Sticker.
- (5) Step 5: Ask patients to stand still, chin up and chest out. Attach Rooti Rx on top of patients' left chest. Make sure the sticker can cover on skin properly without abnormal stretching or twisting. (Approximately 3cm upper from left nipple.)

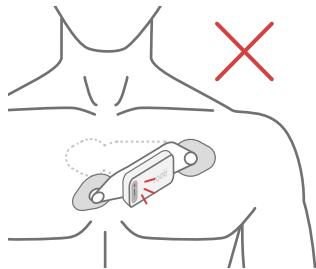
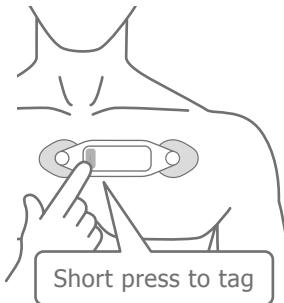


Chest out when attach Rooti RX



*ATTENTION:

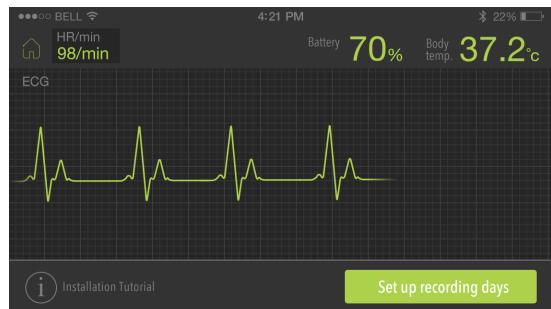
- a. Please use certificated self-prepared standard Monitoring Electrodes sold in general pharmacy.
- b. During the recording, teach patients to short press the button when they feel uncomfortable, and Rooti Rx will record ECG tags.



c. If Rooti Rx leads off or not attaches well to your body, Red LED will keep lighting up. Please go back to hospital for medical support.

5. Preview mode

After set up Rooti Rx, check the patients' ECG signal/ skin temperature through Preview mode of RootiLink. Make sure the ECG signal is stable and well-performed.



6. Set up recording days and countdown timer starts counting.

At this time, Rooti Rx will work as a standalone recorder.

7. Review Record for Your Patients

After recording, help your patients to download their record in the app. Review history ECG data as your further diagnose references.

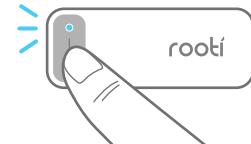
(1) Reopen RootiLink.



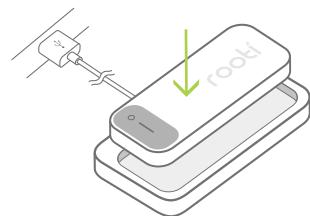
(2) Remove electrode sticker from the Rooti Rx.



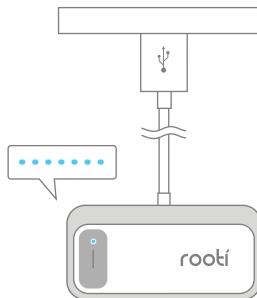
(3) Follow the on-screen instruction in the app. Long press the Rooti Rx function button and activate Wi-Fi advertising (BLUE LED) to reconnect Rooti Rx with RootiLink.



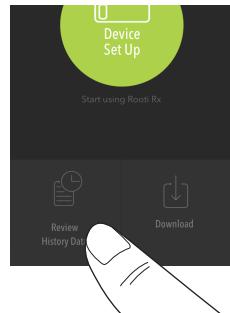
(4) Tap "Download" and put the Rooti Rx into Charging Dock. Plug into power through USB charger.



(5) During the download, Rooti Rx flashes Blue LEDs quickly.



(6) When download completed, you can review ECG Tag or ECG Date in History Data.



LED Indications



- Short Press
- Long Press

On Body	Battery Low	•••••	
	Lead Off	— — — —	
	Record ECG tags	N/A	○
Off Body	Pairing:	•••••	●
	Uploading:	— — — —	
On Base	Battery Check: full	•	○
	Battery Check: Low	•	○
	Charging:	— — — —	
	Finish Charging:	N/A	

Troubleshooting

When short press the Rooti Rx, it indicates Red LED.

Please charge the Rooti Rx by plugging into the Charging Dock.

When connecting my phone with the Rooti Rx, why it stuck in the Wi-Fi searching list?

iOS: Press "Home Key" twice to go back RootiLink

Why is Rooti Rx keeps flashing RED?

••••• Rooti Rx is LOW BATTERY, please CONSULT DOCTOR/ MEDICAL PROFESSIONALS.

— — — — Rooti Rx is in LEAD OFF status

1. Please adjust Monitoring Electrodes and Electrode Sticker, see if they are finely attached.

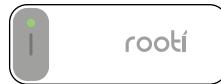
2. If 1. cannot solve the problem, change new Monitoring Electrodes.

3. If 1. & 2. are not available to solve this problem, please CONSULT DOCTOR/ MEDICAL PROFESSIONALS.

I am charging the Rooti Rx, it's originally lightening GREEN, but it's now no LED signal.

Rooti Rx is now fully battery charged.

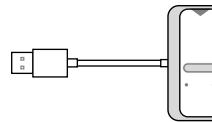
Specification



Rooti Rx

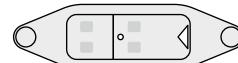
Brand	Rooti	
Model	Rooti Rx	
Item	Rooti Rx	
Measurement Method	One Lead Electrocardiogram, EKG/ECG	
Rating	Direct Current 3.7v 250 mAh	
Power Source	Lithium-ion Polymer Battery Pack 250 mAh AHB521630	
Battery Life	2 year or 500 times Expected Service Life: 1 year	
Operating Environment	Record mode Environment	0~40°C 20~93 %R.H. 80,0 kPa to 101,3 kPa (noncondensing)
	Charging mode and others	0~50°C 20~93 %R.H. 80,0 kPa to 101,3 kPa (noncondensing)
Storage and transportation Environment	-10~60°C / 10~95 %R.H.(noncondensing)	
Main Unit Weight	14 g ± 1 g	
Dimensions for Main Unit	62 * 22.5 * 8.45 mm	
Accessory	Charging dock, Electrode sticker	

Charging Dock



Brand	Rooti
Model	Rooti Rx
Item	Charging Dock
Operating Environment	0~50°C / 20~93 %R.H. Atmospheric pressure 80,0 kPa to 101,3 kPa (noncondensing)
Service Life	Expected Service Life: 1 year
Storage and transportation Environment	-10~60°C / 10~95 %R.H.(noncondensing)
Main Unit Weight	18 g
Dimensions for Main Unit	64 * 30 * 7 mm

Electrode Sticker



Brand	Rooti
Model	Rooti Rx
Item	Electrode Sticker
Operating Environment	0~50°C / 20~93 %R.H. Atmospheric pressure 80,0 kPa to 101,3 kPa (noncondensing)
Storage and transportation Environment	-10~60°C / 10~95 %R.H.(noncondensing)
Main Unit Weight	3.2 g
Dimensions for Main Unit	32.7 * 115 * 5.2 mm

Federal Communications Commission (FCC) Statement

(1) This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1) this device may not cause harmful interference and

2) this device must accept any interference received, including interference that may cause undesired operation of the device.

(2) You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

(3) This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

FCC RF Exposure:

"For body worn operation, this Rooti RX has been tested and meets FCC RF exposure guidelines when used with an accessory that contains no metal and that positions the Rooti RX a minimum of **5mm** from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines."

To comply with the FCC RF exposure compliance requirements, this device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

European Union Regulatory Notice

This device bearing the CE marking is in compliance with the essential requirements and other relevant provisions of Directive : 1999/5/EC. This device complies with the following harmonized European standards.

Radio: ETSI EN 300 328 V1.9.1 : 2015 / BS EN 62479 : 2010

EMC: EN 301 489 -1 v1.9.2: 2011 / EN 301 489 -17 v2.2.1: 2012

EN 55022: 2010+AC: 2011

EN61000-3-2 : 2006+A1:2009+A2:2009 / EN61000-3-3 : 2008

EN 61000-4-2 : 2009 / EN 61000-4-5 : 2006

EN 61000-4-3 : 2006+A1:2008+A2:2010 / EN 61000-4-6 : 2014

EN 61000-4-4 : 2012 / EN 61000-4-11 : 2004

Safety : EN 60950-1: 2006+A11: 2009+A1: 2010+A12: 2011+A2: 2013



Guidance and manufacturer's declaration -electromagnetic emissions

The Rooti RX is intended for use in the electromagnetic environment specified below.

The customer or the user of the Rooti RX should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Rooti RX 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 Rooti RX 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	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration-electromagnetic immunity

The Rooti RX is intended for use in the electromagnetic environment specified below.

The customer or the user of the Rooti RX should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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	± 2kV for power supply lines ± 1kV for input/ output lines	± 22kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV differential 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 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 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Rooti RX requires continued operation during power mains interruptions, it is recommended that the Rooti RX 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	The Rooti RX 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

The Rooti RX is intended for use in the electromagnetic environment specified below.

The customer or the user of the Rooti RX 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	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Rooti RX including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \text{ 80MHz to 800 MHz}$ $d = 2,3 \sqrt{P} \text{ 800MHz to 2,5 GHz}$ 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). 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: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 Rooti RX is used exceeds the applicable RF compliance level above, the Rooti RX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Rooti RX.

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

Recommended separation distance between portable and mobile RF communications equipment and the Rooti RX

The Rooti RX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Rooti RX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Rooti RX 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		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 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	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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 higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.