

Radius PPG™ and Masimo SafetyNet™

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Supplement

DIRECTIONS FOR USE

Reusable Not made with natural rubber latex Non-sterile

Prior to using this product the user should read and understand the Directions for Use for the sensor, and this Directions for Use.

WARNINGS, CAUTIONS AND NOTES

- Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.
- Do not leave the sensor components unattended around children. Small items may become choking hazards.
- To ensure continued monitoring, routinely verify the wireless connection.
- When using multiple Radius PPG sensors, repeat pairing before monitoring to ensure proper wireless connection.
- When using Radius PPG, keep it within the recommended range from the connected device (see Wireless Technology Information for details); moving outside of this range may cause a loss in connection with the smart device/mobile application.
- When using Radius PPG, relocate the devices away from sources that may interfere with the Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service (see Specifications for details) of the Bluetooth connection. Devices that may cause RFI include but are not limited to the following: electrocautery equipment, diathermy equipment, other cellular telephones, wireless PC and tablets, pagers, RFID devices, MRI, and electromagnetic security systems.

LIGHT INDICATOR GUIDE

The reusable chip includes a light to indicate battery and pairing status. Refer to the table for a description of the color of the flashing light, and next steps.

Color	Description	Next steps
Green	• Successful insertion of chip into sensor	• Follow app instructions for pairing
Blue	• Successful pairing of chip to mobile device and app	• Verify data is displayed on app
Purple	• Battery seal tab has not been removed to activate battery • Battery is obstructed	• Remove tab to activate battery • Refer to Directions for Use for the Radius PPG Adhesive Sensor • Disconnect reusable chip from sensor, wait 30 seconds, insert chip into sensor
Orange	• Low sensor battery	• Consider replacing sensor, do not discard reusable chip
Red	• Depleted sensor battery • Hardware or sensor failure, chip blinking board failure code	• Replace sensor, do not discard reusable chip. If issue persists, replace reusable chip • Contact Masimo Technical Support, or replace sensor and chip

CLEANING

WARNING: Before cleaning, make sure the device is off and is not applied to a patient.

Thoroughly clean the Radius PPG reusable chip before applying to a new patient.

To surface clean the reusable chip:

- Remove the sensor from the patient and disconnect the reusable chip.
- Wipe all surfaces of the reusable chip with one of the following:
 - 70% Isopropyl alcohol
 - 10% (1:10) chlorine bleach to water solution
 - Quaternary ammonium chloride solution
- Allow the reusable chip and receiver to dry thoroughly before using again.

CAUTIONS:

- To avoid permanent damage to the reusable chip, do not use undiluted bleach (5–5.25% sodium hypochlorite) or any other cleaning solution not recommended.
- Do not immerse the reusable chip in any liquid solution.
- Do not sterilize by irradiation, steam, autoclave or ethylene oxide.

ENVIRONMENTAL SPECIFICATIONS

Storage/Transport Temperature	-40 – +70°C @ ambient humidity
Operating Temperature	0–40°C @ ambient humidity
Storage/Transport Humidity	5–95% non-condensing
Operating Humidity	5–95% non-condensing
Atmospheric Pressure	540 to 1060 mBar @ ambient temperature and humidity

BATTERY LIFE

Battery Life	96 hours in typical continuous usage
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WIRELESS TECHNOLOGY INFORMATION

Bluetooth LE Wireless Technology Information	
Modulation Type	GFSK
Max. Output Power	+8 dBm
Frequency Range	2402–2480 MHz
Antenna Peak Gain	1 dBi
Recommended Range	100 ft (~30 meters) line-of-sight
Quality of Service (QoS)	Delay < 30 seconds
Security	Proprietary binary protocol

FCC ID are as follows: Chip: VKF-AIRTB01

IC IDs are as follows: Chip: 7362A-AIRTB01

EU Radio Equipment Directive (RED 2014/53/EU)	
Radius PPG Receiver:	Radius PPG Chip:
EN 301 489-17 V3.1.1	EN 300 328 V2.2.1
EN 301 489-3 V2.1.1	EN 300 330 V2.1.0
	EN 301 489-17 V3.1.1
	EN 300 328 V2.2.1

WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

WARNING: The frequency bands of this device (2.4 GHz) are only for indoor use, in accordance with international telecommunication requirements.

CAUTION: Keep the Radius PPG away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.

Note: This device complies with part 15 of FCC Rules and Industry Canada's license-exempt RSSs'. 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.

Note: When using Radius PPG consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

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

RF Radiation Exposure Statement: This equipment has been exempted from FCC RF radiation exposure testing set forth for an uncontrolled environment.

Note: Users are advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250–5350 MHz and 5650–5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices

WARRANTY

Masimo warrants to the initial buyer only that these products, when used in accordance with the directions provided with the Products by Masimo, will be free of defects in materials and workmanship for a period of six (6) months. Single use products are warranted for single patient use only.

THE FOREGOING IS THE SOLE AND EXCLUSIVE WARRANTY APPLICABLE TO THE PRODUCTS SOLD BY MASIMO TO BUYER. MASIMO EXPRESSLY DISCLAIMS ALL OTHER ORAL, EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. MASIMO'S SOLE OBLIGATION AND BUYER'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT MASIMO'S OPTION, TO REPAIR OR REPLACE THE PRODUCT.

WARRANTY EXCLUSIONS

This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product, or has been subject to misuse, neglect, accident or externally created damage. This warranty does not extend to any product that has been connected to any unintended device or system, has been modified, or has been disassembled or reassembled. This warranty does not extend to products that have been reprocessed, reconditioned or recycled.

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NO IMPLIED LICENSE

PURCHASE OR POSSESSION OF THIS PRODUCT DOES NOT CARRY ANY EXPRESS OR IMPLIED LICENSE TO USE WITH ANY DEVICE THAT IS NOT AN AUTHORIZED DEVICE OR SEPARATELY AUTHORIZED TO USE MASIMO PRODUCTS.

RECOMMENDED SEPARATION DISTANCES

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND THE ME EQUIPMENT			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.			
RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (M)		
	150 kHz to 80 MHz d = 1.17*√P	80 MHz to 800 MHz d = 1.17*√P	800 MHz a 2.5 GHz d = 2.33*√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) 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 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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CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

The following symbols may appear on the product or product labeling:

SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
 (blue background)	Follow instructions for use		Separate collection for electrical and electronic equipment (WEEE).	Rx ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	Consult instructions for use	LOT	Lot code		Mark of conformity to European Medical Device Directive 93/42/EEC
	Manufacturer	REF	Catalogue number (model number)	EC REP	Authorized representative in the European community
	Date of manufacture YYYY-MM-DD	####	Masimo reference number		Body weight
SN	Serial Number		Light Emitting Diode (LED) LED emits light when current flows through		Storage temperature range
	Do not discard	>	Greater than		Keep dry
	Non-Sterile	<	Less than		Do not use if package is damaged and consult instructions for use
	Not made with natural rubber latex		Storage humidity limitation		Atmospheric pressure limitation
	Caution		Bluetooth	 (yellow background)	Warning
	Fragile, handle with care	FC	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
		MD	Medical device	UDI	Unique device identifier
IP47	Protected against solid foreign objects of 1.0 mm diameter and greater and protected against the effects of temporary immersion in water	IP22	Protected against solid foreign objects of 12.5 mm diameter and greater and protection against vertically falling water drops when enclosure is tilted at 15 degrees		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eFU is not available in all countries.

Patents: <http://www.masimo.com/patents.htm>

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