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Radius PPG™

Chip and Receiver

DIRECTIONS FOR USE

 Recycle

 Not made with natural rubber latex

 Non-sterile

Prior to using this product the user should read and understand the Operator's Manual for the device/monitor. The Directions for Use for the sensor, and this Directions for Use.

INDICATIONS

Masimo Radius PPG™ is intended for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR).

Masimo Radius PPG is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric and neonatal patients during both in motion and motion conditions and for patients who are well or poorly perfused in hospital, hospital-type facilities and home environments. Devices with Masimo technology are only to be used with Masimo sensors and cables.

CONTRAINDICATIONS

The Radius PPG is contraindicated for patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

DESCRIPTION

Radius PPG consists of three parts:

- Radius PPG wireless receiver
- Radius PPG reusable chip
- Radius PPG adhesive sensor (shipped separately; see Directions for Use for the Radius PPG Adhesive Sensor)

Radius PPG is a wireless sensor for use with devices containing Masimo technology MX Version 7.1 & x or higher. Consult individual device manufacturers for compatibility of particular device and sensor models. Each device manufacturer is responsible for determining whether their device is compatible with each sensor model.

WARNINGS, CAUTIONS, AND NOTES

- 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 host (see Wireless Technology Information for details); moving outside of this range may cause a loss in connection with the host device.
- 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, Wi-Fi, and electromagnetic security systems.

INSTRUCTIONS

a) Initial setup

1. Verify you have all components. Refer to **Fig. 1**.
2. Turn on the patient monitor.
3. Plug the cable into the patient monitor. Refer to **Fig. 2**. The light on wireless receiver will be white.
4. Attach the wireless receiver to the side of the patient monitor using the adhesive provided. Refer to **Fig. 3**.
5. Avoid covering speakers or holes used for mounting when attaching the module. Refer to **Fig. 4**.
6. Attach the chip holder near the receiver on the patient monitor. Refer to **Fig. 5**.
7. Verify that the wireless receiver is attached and plugged in to patient monitor. Verify that the chip holder is attached to patient monitor. Refer to **Fig. 6**.

b) Pairing the reusable transmitter chip with the wireless receiver

1. Ensure the device is powered on. Refer to **Fig. 7**.
2. Hold the reusable chip to the indent on the wireless receiver until the Bluetooth symbol on the wireless receiver turns green. Refer to **Fig. 8**.
3. Insert the reusable chip into the sensor attachment strap until there is a tactile or audible click of connection. Refer to **Fig. 9**.
4. Verify the light on the wireless receiver turns blue. (See **LIGHT INDICATOR GUIDE** section.)

c) Disconnecting

1. Push-down on the tab to release the reusable chip from the sensor. Refer to **Fig. 10**.
2. After cleaning, store the reusable chip in the chip holder attached to the patient monitor. Refer back to **Fig. 6**.
3. Discard the adhesive sensor and strap.

CLEANING

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

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

To surface clean the reusable chip and wireless receiver:

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

CAUTIONS:

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

LIGHT INDICATOR GUIDE			
Color	Wireless receiver	Transmitter chip	Description
No light	—	—	• Wireless receiver cable is not connected to host device with power • Chip not connected to sensor with battery
White	solid	—	• Wireless receiver is connected to host device with power ready to initiate pairing with transmitter chip • Pairing search period has expired
Green	solid (2 seconds) flashing (30 seconds)	—	• Chip and receiver are linked • Pairing search period
Blue	solid	flashing	• Successful pairing of receiver and chip
Purple	flashing	flashing	• Battery seal tab has not been removed to activate battery • Battery is obstructed
Orange	flashing	flashing	• Low sensor battery
Red	flashing	flashing	• Depleted sensor battery • Hardware or sensor failure, chip blinking based failure code

ACCURACY SPECIFICATIONS (Amax*)				
Oxygen Saturation (SpO2)			Pulse Rate* (PR) 25–240 bpm	
SpO2 Accuracy, No Motion† (70–100%)	Adults, Pediatrics, Infants	2%	All patient populations	
	Neonates‡	3%	No Motion	3 bpm
SpO2 Accuracy, Motion†	All patient populations	3%	Motion	5 bpm
SpO2 Accuracy, Low Perfusion†	All patient populations	2%	Low Perfusion	3 bpm

NOTE: Amax accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fall within ±1σ (one σ) of the reference measurements in a controlled study.

The Masimo SET Technology has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 75%–100% SpO2 against a laboratory co-oximeter.

The Masimo SET Technology has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies while performing walking and stepping motions at 2 to 4 ft/s at an amplitude of 1 to 2 cm and a non-pigmented motion between 1 to 5 ft/s at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 75%–100% SpO2 against a laboratory co-oximeter.

The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Baskin Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 75% to 100%.

The Masimo SET Technology has been validated for pulse rate accuracy for the range of 25–240 bpm in bench top testing against a Baskin Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 75% to 100%.

The saturation accuracy of the Neonate and Preterm sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.

ENVIRONMENTAL SPECIFICATIONS	
Storage/Transport Temperature	-40°C – +70°C @ ambient humidity
Operating Temperature	0°C – 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	96 hours in typical continuous usage
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WIRELESS TECHNOLOGY INFORMATION	
Bluetooth LE Wireless Technology Information	
Modulation Type	LE 1M
Max. Output Power	+4 dBm
Frequency Range	2402 MHz – 2480 MHz
Antenna Peak Gain	1 dBi
Recommended Range	100 ft (1–30 meters) line-of-sight
Quality of Service (QoS)	Delay <30 seconds
Security	Proprietary binary protocol

ECC ID are as follows: Chip: WFE-ABTB1 Receiver: WFE-ABDG1

K: CN are as follows: Chip: 7362A-ABTB1 Receiver: 7362A-ABDG1

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 301 489-17 V3.1.1	
EN 301 489-3 V2.1.1	EN 300 330 V2.1.0	EN 300 328 V2.2.1	

WARNING: Changes or modification 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 telecommunications 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 RSSI. 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.

RF Radiation Exposure Statement: Radius PPG Receiver has been exempted from IC RSS 102 RF radiation exposure limits set forth for an uncontrolled environment.

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, WRITTEN 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.

IN NO EVENT SHALL MASIMO BE LIABLE TO BUYER OR ANY OTHER PERSON FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST PROFITS, EVEN IF ADVISED OF THE POSSIBILITY THEREOF. IN NO EVENT SHALL MASIMO'S LIABILITY ARISING FROM ANY PRODUCTS SOLD TO BUYER UNDER A CONTRACT, WARRANTY, TORT OR OTHER CLAIM EXCEED THE AMOUNT PAID BY BUYER FOR THE LOT OF PRODUCTS INVOLVED IN SUCH CLAIM. IN NO EVENT SHALL MASIMO BE LIABLE FOR ANY DAMAGES ASSOCIATED A PRODUCT THAT HAS BEEN REPROCESSED, RECONDITIONED OR RECYCLED. THE LIMITATIONS IN THIS SECTION SHALL NOT BE DEEMED TO PRECLUDE ANY LIABILITY THAT, UNDER APPLICABLE PRODUCTS LIABILITY LAW, CANNOT LEGALLY BE PRECLUDED BY CONTRACT.

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 ELECTRONIC EQUIPMENT AND THE ME EQUIPMENT			
MAXIMUM OUTPUT POWER OF TRANSMITTER (W)		SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)	
150 KHz to 80 MHz 4–1.77 W [†]		80 MHz to 800 MHz 4–1.77 W [†]	800 MHz to 2.5 GHz 4–2.33 W [†]
0.01	0.12	0.12	0.23
0.1	0.3	0.3	0.4
1	1.17	1.17	2.33
10	3.7	3.7	7.4
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's label.

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.

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.

The following symbols may appear on the product or product labeling:			
SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Follow instructions for use		Separate collection for electrical and electronic equipment (WEEE)
	Lot code		Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	Manufacturer		Mark of conformity to European Medical Device Directive 93/42/EEC
	Catalogue number (model number)		Authorized representative in the European community
	Date of manufacture (YYMMDD)		Body weight
	Serial Number		Light Emitting Diode (LED) LED emits light when current flows through
	Do not discard		Keep dry
	Non-Sterile		Do not use if package is damaged
	Not made with natural rubber latex		Atmospheric pressure limitation
	Caution		Warning
	Fragile, handle with care		Identifies unit has been registered as a radio device
	Protected against solid foreign objects of 1.5 mm diameter and greater and protected against the effects of temporary immersion in water		Protected against solid objects of 12.5 mm diameter and greater and protection against water drops when enclosure is tilted at 15 degrees

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

Radius PPG is a trademark of Masimo Corporation.

Masimo, SET, X, and  are federally registered trademarks of Masimo Corporation.

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Radius PPG™

Chip and Receiver

Mode D'EMPLOI

 Ne contient pas de latex naturel

 Non stérile

de

Radius PPG™

Chip and Receiver

GEBRAUCHSANWEISUNG

 Enthält keinen Latex aus Naturkautschuk

 Nicht steril

es

Radius PPG™

Chip and Receiver

ISTRUZIONI PER L'USO

 Non contiene lattice di gomma naturale

 Non sterile

es

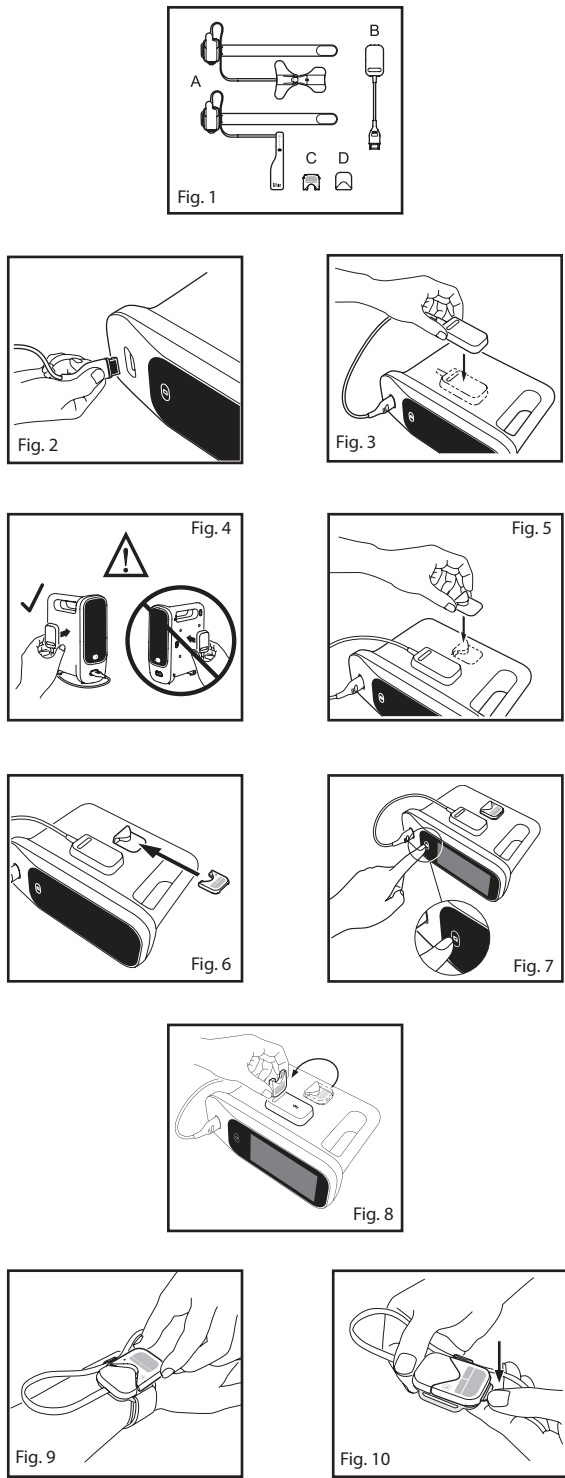
Radius PPG™

Chip and Receiver

INSTRUCCIONES DE USO

 Fabricado sin látex de caucho natural

 No esteril



Radius PPG™

Chip and Receiver

EU Authorized Representative for Masimo Corporation:

[CE REP]

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

Manufacturer:



Masimo Corporation
52 Discovery
Irvine, CA 92618
USA
www.masimo.com

Radius PPG™

Chip and Receiver

sv

BRUKSANVISNING

 Inte tillverkat med naturgummlatex

 Steril

Radius PPG™

Chip and Receiver

nl

GEbruIKSAANWIJZING

 Bij de productie is geen latex van natuurrubber gebruikt

 Niet steril

Radius PPG™

Chip and Receiver

da

BRUGSANVISNING

 Ikke fremstillet med naturligt gummlatex

 Ikke steril

Radius PPG™

Chip and Receiver

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INSTRUÇÕES DE UTILIZAÇÃO

 Não fabricado com látex de borracha natural

 Não esterilizado

Radius PPG™

Chip and Receiver

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使用说明

 非天然乳胶制造

 未消毒



Radius PPG™

Chip and Receiver

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使用方法

 天然ゴムは不使用

 非殺菌

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Radius PPG™
Chip and Receiver

KÄYTTÖOHJEET

 Ei sovelletä luonnontumallesiä

 Ei-steriili

fi

Radius PPG™
Chip and Receiver

BRUKSANVISNING

 Ei läike hennöblit med naturgummlätsleks

 läike-steril

no

Radius PPG™
Chip and Receiver

POKYNY K POUŽITÍ

 Neodshuje přirodní latex

 Nesterilní

cs

Radius PPG™
Chip and Receiver

HASZNÁLATI ÚTMUTATÓ

 Nem tartalmaz természetes látsgumit

 Nem steril

hu

Radius PPG™
Chip and Receiver

INSTRUKCJA UŻYTKOWANIA

 Produkt został wykonany bez zastosowania lateksu naturalnego

 Niejakości

pl

Radius PPG™
Chip and Receiver

INSTRUCȚIUNI DE UTILIZARE

 Produsul care nu conține latex din cauciuc natural

 Nesteril

Radius PPG™
Chip and Receiver

NÁVOD NA POUŽITIE
 Pri výrobe sa nepoužíva prírodný gumový latex  Nestlé

sk

Radius PPG™
Chip and Receiver

KULLANIM KILAVUZU
 Reusable  Doğal kauçuk latex ile üretilmiştir  Steril değildir

tr

Radius PPG™
Chip and Receiver

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
 Δεν έχει κατασκευαστεί με φυσικό ελαστικό latex  Μη απορριμώμενο

el

Radius PPG™
Chip and Receiver

УКАЗАНИЯ ПО ИСПОЛЬЗОВАНИЮ
 Изготовлено без использования натурального латекса  без стерилизации

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Radius PPG™
Chip and Receiver

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إرشادات الاستخدام
 لا يحتوي هذا المنتج على مطاط لاتكس طبيعي  

Radius PPG™
Chip and Receiver