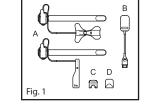
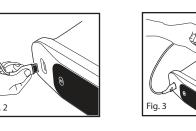
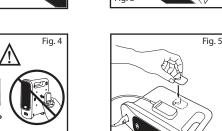
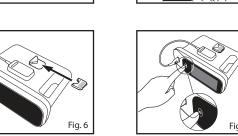
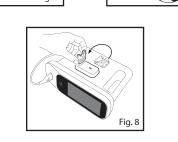
F Radius PPG™ Radius PPG™ Radius PPG™ Radius PPG™ Radius PPG™ **Chip and Receiver Chip and Receiver Chip and Receiver Chip and Receiver Chip and Receiver** ISTRUZIONI PER L'USO INSTRUCCIONES DE USO DIRECTIONS FOR USE GEBRAUCHSANWEISUNG Mode D'EMPLOI Enthält keinen Latex aus Naturkautschuk Non contiene lattice di gomma naturale Non sterile Fabricado sin látex de caucho natural Ne contient pas de latex naturel Non stérile Not made with natural rubber latex



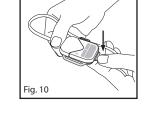


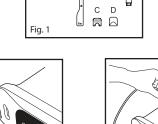


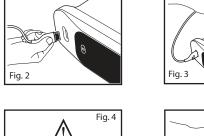


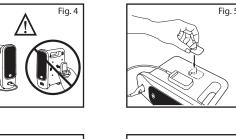


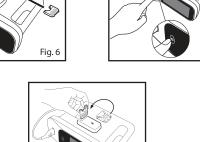




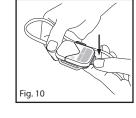












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When using Radius PPG, relocate the devices away from sources that may interfere with the Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service (see Specifications 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. INSTRUCTIONS

INDICATIONS

a) Initial setup1. Verify you have all components. Refer to Fig. 1. 2. Turn on the patient monitor.

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.

A. Radius PPG adhesive sensor B. Radius PPG wireless bluetooth receiver C. Radius PPG reusable chip D. Radius PPG reusable chip holder for device 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.**

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 no motion and motion conditions and for patients who are well or poorly perfused in hospital, hospital-type facilities and home environments.

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 reusable chip
Radius PPG adhesive sensor (shipped seperately, 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 7.14.8.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.

· 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.

Devices with Masimo technology are only to be used with Masimo sensors and cables.

 $\bullet \ \ \, \text{To ensure continued monitoring, routinely verify the wireless connection}.$

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

c) Disconnecting1. 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.

4. Verify the light on the wireless receiver turns blue. (See LIGHT INDICATOR GUIDE section.)

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:

c. Quaternary ammonium chloride solution

3. Allow the reusable chip and wireless receiver to dry thoroughly before using again.

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.

Color	Wireless receiver	Transmitter chip	Description	Next steps	
No light			Wireless receiver cable is not connected to host device with power Chip not connected to sensor with battery	Turn on patient monitor and pluginto patient monitor See <i>Instructions</i> , section <i>a</i>) for set	
White	solid		Wireless receiver is connected to host device with power ready to initiate pairing with transmitter chip Paring search period has expired	Hold reusable chip to the indent wireless receiver to initiate pairing See <i>Instructions</i> , section <i>b</i>) for pairing	
Green	solid (2 seconds)		Chip and receiver are linked	Insert reusable chip into sensor attachment strap to complete page. See Instructions, section b) for page.	
	flashing (30 seconds)	flashing (30 seconds)	Pairing search period		
Blue	solid	flashing	Successful pairing of receiver and chip	Verify sensor attachment so host can receive data	
Purple	flashing	flashing	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 se wait 30 seconds, insert chip into s (Refer to Figs. 9 and 10.)	
Orange	flashing	flashing	Low sensor battery	Consider replacing sensor, do not discard reusable chip See <i>Instructions</i> , section <i>c</i>) for disconnecting	
Red	flashing	flashing	Depleted sensor battery Hardware or sensor failure, chip blinking board failure code	Replace sensor, do not discard ret chip. If issue persists, replace reus chip See Instructions, section c) for disconnecting Contact Masimo Technical Supporeplace sensor and chip	

Oxygen Saturation (SpO ₂)			Pulse Rate4(PR) 25-	240 bpm
SpO ₂ Accuracy, No Motion ¹	Adults, Pediatrics, Infants	2%	All patient po	pulations
(70–100%)	Neonates ⁵	3%	No Motion	3 bpm
SpO2 Accuracy, Motion ²	All patient populations	3%	Motion	5 bpm
SpO ₂ Accuracy, Low Perfusion ³	All patient populations	2%	Low Perfusion	3 bpm

volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70%-100% SpO2 against c

ranging from 70% to 100%.

NVIRONMENTA	L 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	ntinuous usage			
VIKELESS TECHT	NOLOGY INFORMATI	tooth LE Wireless Technology Information		
	Diue			
Modulation Type		GFSK		
Max. Output Power		+8 dBm		
Frequency Range		2402 MHz - 2480 MHz		

Delay <30 seconds
Proprietary binary protoc Quality of Service (QoS) FCC ID are as follows: Chip: VKF-AIRTB01 Receiver: VKF-AIRDG01 IC IDs are as follows: Chip: 7362A-AIRTB01 Receiver: 7362A-AIRDG01

Radius PPG Receiver: 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 300 328 V2.2.1 WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the

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

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 corcur 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.

For Both and experience and experienced radio/17 rectificant for nelp.

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

WARKAN I Y
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.

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 PRODUCT(S) 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 A THOUGHT I THAT DEEN 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 DEVICETHAT IS NOT AN AUTHORIZED DEVICE OR SEPARATELY AUTHORIZED TO USE MASIMO PRODUCTS. RECOMMENDED SEPARATION DISTANCES

The ME Equipment is intended for use customer or the user of the ME Equip between portable and mobile RF cor according to the maximum output pow	in an electromagnetic envi ment can help prevent elec nmunications equipment (t	tromagnetic interference by m ransmitters) and the ME Equip	disturbances are controlled. The aintaining a minimum distance
RATED MAXIMUM OUTPUT	SEPARATION DISTA	NCE ACCORDING TO FREQUEN	CY OF TRANSMITTER (m)
POWER OF TRANSMITTER (W)	150 K Hz 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 of be estimated using the equation applies the transmitter in watts (W) according	cable to the frequency of th	ne transmitter, where P is the ma	

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

	autions and adverse		t or product labeling:	,	
SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
(blue background)	Follow instructions for use	Ø	Separate collection for electrical and electronic equipment (WEEE).	Rx ONLY	Caution: Federal law (USA) restrict this device to sale by or on the orde of a physician
[]i	Consult instructions for use	LOT	Lot code	C € 0123	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	ੈ∄凸	Body weight
SN	Serial Number	[‡] x	Light Emitting Diode (LED) LED emits light when current flows through	1	Storage temperature range
	Do not discard	>	Greater than		Keep dry
NON	Non-Sterile	<	Less than	®	Do not use if package is damaged
	Not made with natural rubber latex	(E)	Storage humidity limitation	€	Atmospheric pressure limitation
<u>^</u>	Caution	*	Bluetooth	(yellow background)	Warning
Ī	Fragile, handle with care	F©	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
IP47	Protected against solid foreign objects of 1.0 mm diameter and greater and protected against the effects of temporary	IP22	Protected against solid foreign objects of 12.5 mm diameter and greater and protection against vertically falling water	W India	Instructions/Directions for Use/ Manuals are available in electronic format @ http://www.Masimo.com TechDocs

Masimo, SET, X-Cal, and 🐧 are federally registered trademarks of Masimo Corporation

Radius PPG™ **Chip and Receiver**

EU Authorized Representative for Masimo Corporation: EC REP MDSS GmbH Schiffgraben 41 D-30175 Hannover, Germany



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www.masimo.com



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300633/10353BC-101219

Radius PPGTM
Chip and Receiver Radius PPGTM
Chip and Receiver Radius PPG™
Chip and Receiver 使用说明

使用方法 BRUKSANVISNING BRUGSANVISNING INSTRUÇÕES DE UTILIZAÇÃO 天然ゴムは不使用 🌊 非殺菌 Rikke fremstillet med naturlig gummilatex 🛕 lkke-steril Não fabricado com látex de borracha natural Não esterilizado ₩ 非天然乳胶制造 0

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Radius PPGTM
Chip and Receiver
INSTRUKCJA UŻYTKOWANIA

Produkt został wykonany bez zastosowania lateksu naturalnego

A Niejalowe Radius PPG™
Chip and Receiver Radius PPG™
Chip and Receiver Radius PPG™
Chip and Receiver Radius PPG™ Chip and Receiver Radius PPG™
Chip and Receiver

Neobsahuje přírodní latex

INSTRUCȚIUNI DE UTILIZARE

Produs care nu conține latex din cauciuc natural Nesteril KÄYTTÖOHJEET BRUKSANVISNING POKYNY K POUŽITÍ HASZNÁLATI ÚTMUTATÓ ₩ Ei sisällä luonnonkumilateksia ♣ Ei-steriili Er ikke fremstilt med naturgummilateks 🔝 lkke-steril Nem tartalmaz természetes latexgumit 🔑 Nem steril Nesterilní

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Radius PPGTM
Chip and Receiver

УКАЗАНИЯ ПО ИСПОЛЬЗОВАНИЮ

Маготовлено без использования
натурального латекса

В Без стерилизации Radius PPG™
Chip and Receiver Radius PPG™ Chip and Receiver Radius PPG™
Chip and Receiver Radius PPGTM
Chip and Receiver ko ar Radius PPGTM
Chip and Receiver إرشادات الاستخدام D

KULLANIM KILAVUZU ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ 🐰 لا يحتري هذا المنتج على مطاط اللاتكس الطبيعي Δεν έχει κατασκευαστεί με φυσικό 🚉 Μη αποστειρωμένοι \boxtimes Reusable Doğal kauçuk lateks ile üretilmemiştir 🚖 Steril değildir NON