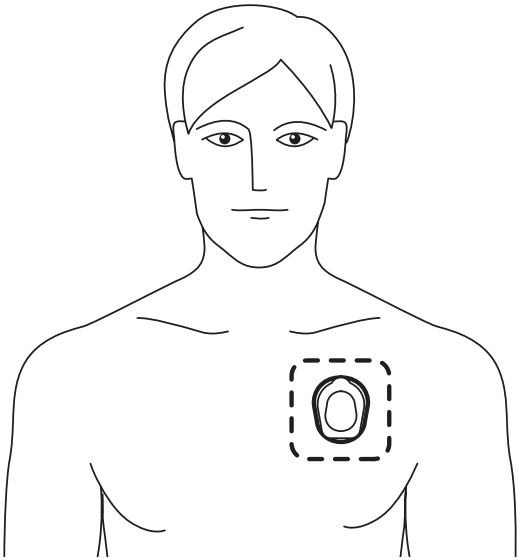
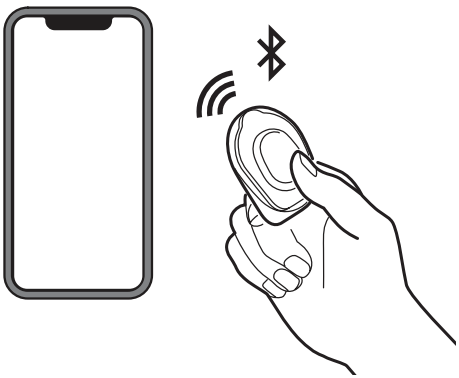
Radius T°™
Patient Temperature Sensor

eIFU indicator





© 2020 Masimo Corporation

Radius T°™
Patient Temperature Sensor

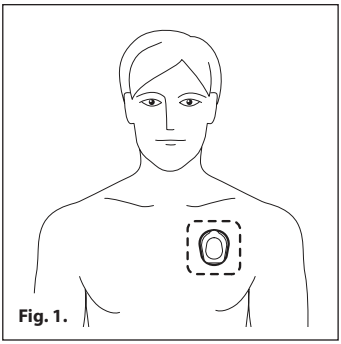


Fig. 1.

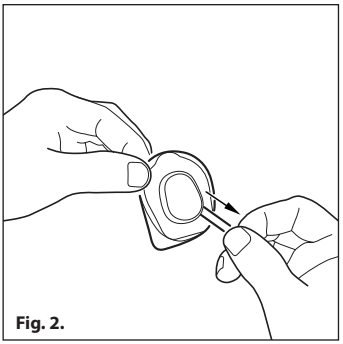


Fig. 2.

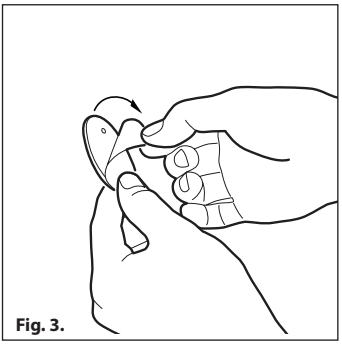


Fig. 3.


Fig. 4.

Radius T°™

en

Patient Temperature Sensor

DIRECTIONS FOR USE

Single patient use only | Not made with natural rubber latex | Non-sterile

Prior to using this sensor, the user should read and understand the Operator's Manual for the Device or Application and this Directions for Use.

INDICATIONS

Radius T°™ disposable sensors are intended for continuous noninvasive monitoring of body temperature for use on Adult and Pediatric patients, 5 years of age or older, in hospitals, hospital-type facilities, and home environments.

Note: *Radius T° is not FDA approved or cleared.*

CONTRAINDICATIONS

Radius T° sensors are contraindicated for patients who exhibit allergic reactions to adhesive tape.

DESCRIPTION

Radius T° sensors are battery powered, disposable sensors that are designed to continuously provide body temperatures that are approximations of oral temperatures. The sensors are adhered to the patient's skin to continuously transmit temperature measurement data via Bluetooth communication to a compatible device or application.

Note: Radius T° sensors are to only be used with compatible devices or applications. Verify compatibility before use to ensure the sensor functions properly.

WARNINGS, CAUTIONS, AND NOTES

- Only use Masimo authorized applications with Radius T°. Using unauthorized applications or devices with Radius T° may result in no or incorrect readings.
- The Radius T° Sensor should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- The sensor should be free of visible defects, discoloration, and damage. If the sensor is discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.
- Do not use the sensor during MRI scanning or in a MRI environment as it may result in physical harm.
- Do not use Radius T° sensors in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments or nitrous oxide to avoid risk of exposure.
- Avoid contact with the sensor during defibrillation. Defibrillation may result in temporary loss of temperature readings.
- Using during electrocautery may cause no or incorrect temperature readings.
- Avoid placing the sensor over compromised skin, excessive hair, implants, ports, subcutaneous or dermal fillers or scar tissue, as this may result in incorrect readings.
- Do not apply over or near pacemakers to avoid any potential interference from the Bluetooth communication.
- Radius T° should not be used near electrical equipment that may affect the sensor's ability from working properly.
- Check the sensor site to ensure skin integrity and to avoid damage or irritation to the skin.
- Incorrect readings may be caused by sensors that are not placed on an appropriate application site.
- Radius T° may not reflect the actual body temperature when used on patients undergoing treatments that may alter their normal temperature regulation (e.g. therapeutic hypothermia, antipyretics).
- Avoid direct heating or cooling of the Radius T° sensor. Localized temperature exposure of the sensor may result in no or incorrect readings.
- Sensors that become partially dislodged may cause no or incorrect readings.
- Rapid or large changes in ambient temperature may cause no or incorrect readings.
- Periodically check the sensor site for proper adhesion to minimize the risk of incorrect or no readings.
- Change or modifications that are not expressly approved by the manufacturer could void the user's authority to operate the equipment.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave or ethylene oxide as it will damage the sensor.
- Do not attempt to reuse on multiple patients, reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Radius T°, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

- Keep the Radius T° away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.
- The frequency bands of this device (2.4 GHz) are only for indoor use, in accordance with international telecommunication requirements.

INSTRUCTIONS

A) Site Selection

- Select a site on the left side of the chest where the skin is clean of debris and dry prior to sensor placement. Refer to **Fig. 1.**
- The site should be hair-free, cleaned of debris and dry prior to sensor placement.

B) Applying the sensor

1. Open the package and remove the sensor.
2. Pull and remove the plastic battery tab. Refer to **Fig. 2.**
3. Peel off the release liner from the sensor. Refer to **Fig. 3.**

   Note: Avoid contact with the exposed sensor adhesive.
4. Place the sensor to the selected application site.

   Note: Ensure that the skin of the patient is relaxed and not stretched in any way and that there are no skin folds under the sensor pad.
5. Press around the perimeter of the sensor to ensure the adhesive is secure to the patient's skin.

C) Pairing the Sensor

1. Once battery tab is removed, sensor is available for Bluetooth pairing. Refer to **Fig. 4.**
2. A solid blue light indicates the sensor is connected.
3. Check the application display to ensure the sensor is communicating correctly.

   Note: Readings may take up to 15 minutes to appear on the application.
4. Periodically check the sensor or application for a solid blue light to confirm that is it connected.

D) Sensor Reapplication

Note: Radius T° sensors are designed for removal and reapplication no more than one (1) time over the life of the product.

1. Clean and dry the sensor application site.
2. Gently wipe the exposed sensor adhesive with an alcohol wipe and allow to dry to restore the adhesive properties.
3. Follow steps 1 through 5 from above to re-apply the sensor.

D) Removing the Sensor

1. Peel gently to remove the sensor from the patient.

   Note: Disposal of Product: Comply with local laws in the disposal of the sensor, battery and its accessories.

LIGHT INDICATOR GUIDE/TROUBLESHOOTING

Color	Sensor	Description	Next steps
No light	---	• Sensor power is off.	• Confirm battery pull tab has been removed to activate the battery. • Replace the sensor.
Green	flashing	• Sensor is on and waiting to pair with host device.	• Follow instructions to pair with the host device.
Blue	flashing	• Sensor is waiting for user confirmation that desired sensor was paired to the host device.	• Verify sensor attachment so that host device can receive data.
	solid	• Successful pairing of sensor and host device. • Host device successfully receiving data.	
Orange	flashing	• Low sensor battery	• Consider replacing the sensor..
Red	flashing	• Depleted sensor battery • Hardware or sensor failure, sensor blinking board failure code	• Replace the sensor..

For additional help, contact Masimo Technical Services at (949) 297-7498. Local contact information can be found at: http://service.masimo.com.

SPECIFICATIONS

The Radius T° sensors have the following specifications:

Temperature measurement accuracy	±0.1°C in the range of 25°C to 43°C
Application Site	Upper Chest, below the left collarbone
Product Use/Battery Life	Minimum of 8 days, (192 hours) of continuous run time

The laboratory accuracy of Radius T^{0} is ±0.1^{0}C (0.18^{0}F) for an input surface temperature range of 25^{0}C to 43^{0}C (77^{0}F to 109.4^{0}F).

Radius T^{0} has been validated on 112 subjects, 5 years of age or older, against a reference clinical thermometer. Results have shown a clinical bias of -0.17^{0}C (-0.30^{0}F) with limits of agreement ≤ 0.96^{0}C (1.73^{0}F).

ENVIRONMENTAL

Storage/Transport Temperature	-20°C to 50°C @ ambient humidity
Operating Temperature	10°C to 40°C @ ambient humidity
Storage/Transport Humidity	10% RH to 95% RH (non-condensing) @ ambient temperature
Operating Humidity	10% RH to 95% RH (non-condensing) @ ambient temperature
Atmospheric Pressure	700 to 1060 hPa @ ambient temperature and humidity

WIRELESS TECHNOLOGY INFORMATION

Type	Bluetooth Low Energy
Data Transmission Rate	Minimum packet rate of 0.0167 Hz (1/60 Hz)
Max. Output Power	(EIRP): 9.9 dBm
Modulation Type	GFSK
Frequency Range	2402–2480 MHz
Antenna Peak Gain	+5.67dBi

FCC ID are as follows: FCC ID: VKF-RADIUST, IC ID: 7362A- RADIUS T

CAUTION: In order to maintain Bluetooth connectivity with the host device ensure that Radius T° is within specified distance and line of sight of the host device.

RF Radiation Exposure Statement: This equipment has been exempted from FCC RF radiation exposure testing and IC RSS 102 RF radiation exposure limits set forth for an uncontrolled environment.

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: 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.

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

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)	
	80 MHz to 800 MHz $d = 1.17*\sqrt{P}$	800 MHz a 2.5 GHz $d = 2.33*\sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.7	7.37
100	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.

GUIDANCE AND MANUFACTURER'S DECLARATION- ELECTROMAGNETIC EMISSIONS

The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF Emissions CISPR 11	Group 1	The ME Equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment 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	+/- 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%.
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Guidance - Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.

Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	RECOMMENDED SEPARATION DISTANCE
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz 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, 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: 

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.

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 ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATION EQUIPMENT						
TEST FREQUENCY	**BAND (A) (MHZ)**	**SERVICE (A)**	**MODULATION (B)**	**MAXIMUM POWER (W)**	**DISTANCE (M)**	**IMMUNITY TEST LEVEL (V/M)**
385	380-395	TETRA 400	Pulse modulation (b) 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM (c) +/- 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation (b) 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation (b) 18 Hz	2	0,3	28
1 720 1 845 1 970	1 700-1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3. 4. 35: UMTS	Pulse modulation (b) 217 Hz	2	0,3	28
2 450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation (b) 217 Hz	2	0,3	28
5 240 5 500 5 785	5 100-5 800	WLAN 802.11 a/n	Pulse modulation (b) 217 Hz	0,2	0,3	9

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

(a) For some services, only the uplink frequencies are included.
(b) The carrier shall be modulated use a 50% duty cycle square wave signal.
(c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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 instrument or system, has been modified, or has been disassembled or reassembled. This warranty does not extend to sensors or patient cables 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 SHALL NOT BE DEEMED TO PRECLUDE ANY LIABILITY THAT, UNDER APPLICABLE PRODUCTS LIABILITY LAW, CANNOT LEGALLY BE PRECLUDED BY CONTRACT.

NO IMPLIED LICENSE

This single-patient sensor is licensed to you under the patents owned by Masimo for single-patient use only. By acceptance or use of this product, you acknowledge and agree that no license is granted for use of this product with more than a single patient.

After single-patient use, discard sensor.

Purchase or possession of this sensor confers no express or implied license to use the sensor with any device which is not separately authorized to use Masimo sensors.

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	Federal law (USA) restricts this device to sale by or on the order of a physician
	Consult instructions for use	LOT	Lot code	CE 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	NON STERILE	Non-sterile
	Use By YYYY-MM-DD	%	Storage humidity Limitation		Not made with natural rubber latex
2	Do not re-use/Single patient use only		Atmospheric pressure limitation		Body weight
	Caution		Do not use if package is damaged and consult instructions for use		Storage temperature range
FC	Federal Communications Commission (FCC) Licensing		Bluetooth		Keep dry
1	Single patient - multiple use	FCC ID:	Identifies unit has been registered as a radio device	IP24	Protection from ingress of particulates and water spray from any direction
MD	Medical device	UDI	Unique device identifier	eIFU indicator	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available in all countries.**

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

Masimo, , and Root are federally registered trademarks of Masimo Corporation.

Radius T° is a trademark of Masimo Corporation.

All other products, logos, or company names mentioned herein may be trademarks and/or registered trademarks of their respective companies.

© 2020 Masimo Corporation

Manufacturer:
Masimo Corporation
52 Discovery
Irvine, CA 92618
USA

www.masimo.com

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

CE 0123

10714A-eIFU-0720