Operator's Manual

Radius PCG™

Mainstream Capnograph

Masimo

These operating instructions provide the necessary information for proper operation of all models of the Radius PCG. There may be information provided in this manual that is not relevant for your system. General knowledge of capnography and an understanding of the features and functions of Radius PCG are prerequisites for its proper use. Do not operate Radius PCG without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings and precautions.

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

Wireless Radio:
Contains: FCC ID: VKF-EMMABT | IC: 7362A-EMMABT | Model: EMMA Bluetooth

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About this Manual

This manual explains how to set up and use Radius PCG™. Important safety information relating to general use of Radius PCG appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features and Intended Use

Product Description

The Radius PCG™ (model: EMMA Bluetooth) is a quantitative mainstream carbon dioxide monitor comprised of a Sensor Body that fits on top of a disposable EMMA Airway Adapter.

The Radius PCG™ includes Bluetooth wireless technology so that data can be transferred to a paired device.

Intended Use

Radius PCG™ measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.

Safety Information, Warnings and Cautions

CAUTION: Radius PCG is to be operated by, or under the supervision of, qualified personnel only. Read the manual, accessories directions for use, all precautionary information, and specifications before use.

Safety Warnings and Cautions

WARNING: Radius PCG should only be used for the purpose and in the manner described in this manual.

WARNING: Radius PCG is intended for use by authorized health care professionals only.

WARNING: Radius PCG must not be used with flammable anesthetic agents.

WARNING: If Radius PCG is used with a respirator or with harmful gases such as N_2O, always perform a pre-use tightness check of the patient circuit.

WARNING: EMMA Airway Adapters shall not be reused. Reuse of single use Adapters can cause cross infection.

WARNING: Do not use the EMMA Adult/Pediatric Airway Adapter with infants as the Adapter adds 6 ml dead space to the patient circuit.

WARNING: Do not use the EMMA Infant Airway Adapter with adults/pediatrics as this may cause excessive flow resistance.

WARNING: Do not use the Radius PCG during magnetic resonance imaging (MRI) or in an MRI environment.

Performance Warnings and Cautions

WARNING: Radius PCG is intended only as an adjunct in patient assessment. It shall be used in conjunction with the assessment of clinical signs and symptoms.

WARNING: Use only EMMA Airway Adapters manufactured by Masimo.

WARNING: No modification of the Radius PCG probe or the EMMA Airway Adapters is allowed.

WARNING: Light transmission can be affected by secretions and moisture pooling on the EMMA Airway Adapter XTP™ windows. When using heated humidifiers special care should be paid to position the Airway Adapter in a vertical position and to change Airway Adapter if necessary.

WARNING: Do not use Radius PCG with nebulized medications as this may affect the light transmission of the EMMA Airway Adapter windows.

WARNING: Audible alarm of any monitor may not be heard in some loud environments, such as when sirens are in use and the care provider is more distant from the alarm source. Alarm volume should be tested with the extremes of your noise environment to confirm ability or limitations to hear an alarm in all circumstances of the environment.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.

WARNING: Make sure that Radius PCG is used in the electromagnetic environment specified in this manual.

WARNING: 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 PCG. Otherwise, degradation of the performance of the Radius PCG could result.

WARNING: When used in environments with known sources of RF interference (e.g., diathermy, electrocautery, RFID), avoid close proximity to such devices to minimize the risk of interference that may interrupt the measurement performance.

WARNING: Do not use in aircraft environments during take-off, landing, or while on the ground where rotational radars may be more likely to be present. High levels of electromagnetic interference that can be generated by rotational radars may result in no or inaccurate readings.

WARNING: When used with a Bluetooth connection to Root, the display and alarms on the Radius PCG should be used as the primary monitoring system. Under significant interference, corruption of Bluetooth communication to the Root can occur.

CAUTION: When used in aircraft environments, turn off the Bluetooth radio if not in use to minimize the potential for interference with other surrounding devices.

CAUTION: Turn off the Bluetooth radio if you suspect that the communication has been compromised or if not in use to prevent unauthorized access to data and minimize cybersecurity concerns.

Note: To preserve and maximize battery life, make sure alarm conditions are addressed promptly and the unit is turned off when not in use, especially prior to storage.

Note: Bluetooth functionality is implemented differently by the various connected-device manufacturers and incompatibility between the Radius PCG and your external device may occur.

Note: A trained medical professional must determine the proper EMMA Airway Adapter model for each patient application. No hardware or software configuration changes result from the EMMA Airway Adapter model selected.

Note: The alarm limits will be reset to default values after Radius PCG powers off.

Cleaning and Service Warnings and Cautions

WARNING: Properly use and dispose of batteries or they may leak or explode.

WARNING: Lithium batteries may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate. Dispose of used cells promptly. Keep away from children.

WARNING: Use only Alkaline batteries or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion.

WARNING: Replace batteries immediately when the Battery Status Indicator starts blinking. Remaining battery time depends on battery type and other circumstances and cannot be reliably predicted.

CAUTION: Remove alkaline batteries when the Radius PCG will not be in use for more than 30 days to avoid damage to the device due to batteries that may leak.

CAUTION: Replace both batteries at the same time to avoid mixing fully and partially charged batteries. These actions may cause the batteries to leak; resulting in possible damage to the device.

CAUTION: Do not immerse Radius PCG in any liquid.

CAUTION: Do not apply excessive pressure on the IR-windows.

CAUTION: Never saturate Radius PCG completely with any disinfection solution.

CAUTION: Only perform maintenance procedures specifically described in the manual; otherwise, return Radius PCG for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.

CAUTION: Do not clean Radius PCG with any chemical other than those specified in Maintenance and Cleaning of this manual. These substances may affect the device's materials and damage internal parts.

CAUTION: The Radius PCG device and EMMA Airway Adapters are non-sterile devices. Do not submerge Radius PCG device or EMMA Airway Adapters in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in Maintenance and Cleaning of this manual. Permanent damage to Radius PCG may occur if other unspecified solutions are used.

CAUTION: Never submerge Radius PCG in water or any other liquid solution. This may cause permanent damage to the Radius PCG.

Note: Before cleaning Radius PCG, remove the batteries and make sure the battery cover is re-attached correctly.

Note: The presence of ambient air (0% CO_2) in the EMMA Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the Airway Adapter before or during the Zeroing procedure.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

WARNING: In accordance with international telecommunication requirements, the frequency band of 2.4 GHz and 5.15 to 5.25 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

CAUTION: Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.

CAUTION: EMMA Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.

Note: 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.

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.
- 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.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2: 2015, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: This Class B digital apparatus complies with Canadian ICES-003.

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Note: This device has been evaluated for electro compatibility in an aircraft in accordance with RTCA DO-160G, Section 21, Category M emissions and Section 20, Category R immunity. Avoid using the device in environments with or in close proximity to electrical fields higher than 100 V/m in frequency range of 4 GHz and 8 GHz (i.e., rotational radars) to minimize interruptions in performance.

Chapter 1: Technology Overview

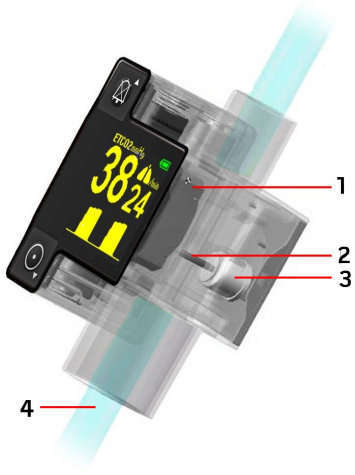
The following chapter contains general descriptions about parameters, measurements, and the technology used in Radius PCG.

Principles of Operation

The measurement of CO_2 in the breathing gas mixture is based on the fact that different gas components absorb infrared light at specific wavelengths. A beam of invisible infrared light is directed through the respiratory gas flow in the EMMA Airway Adapter. As the beam passes through the Airway Adapter, some of the light is absorbed by the gas mixture. The amount of absorbed light is measured by a miniaturized two-channel spectrometer positioned to receive the infrared light beam.

The spectrometer incorporates a filter wheel fitted with two different optical "color" filters. The wavelength ranges of these filters are chosen such that one filters out colors where carbon dioxide has very strong absorption and the other filters out colors where carbon dioxide has no absorption.

The spectrometer also incorporates an infrared detector that converts the light beam to an electrical signal. The electrical signal is converted to a digital value that is fed to a microprocessor. The ratio of the light measured through the two filters is then used by the microprocessor to calculate the carbon dioxide concentration in the breathing gas mixture.



1 Spectrometer with optical filter wheel and infrared detector
2 Infrared light beam
3 Infrared light source
4 Respiratory gas

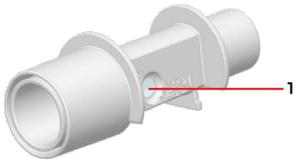
EMMA Airway Adapter

Respiratory gas measurements are, as described in the previous section, obtained by continuously measuring the infrared light absorption through the EMMA Airway Adapter. The Airway Adapter is fitted with optical XTP™ windows that are transparent to light in the wavelength ranges of interest. The Airway Adapter may, for example, be inserted between the endotracheal tube and the resuscitation bag or between the resuscitation bag and the patient mask.

The Airway Adapter is available in two models: Adult/Pediatric and Infant. Radius PCG operates to specification with either Airway Adapter model when used with its appropriate patient population.

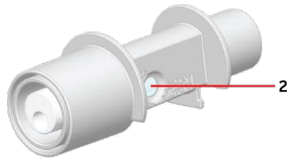
- The Airway Adapters are intended for single patient use. They are disposable and shall not be re-used. Reuse of single patient use Adapters can cause cross infection.
- Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.

EMMA Airway Adapter Adult/Pediatric (REF 100620)



1. XTP window (Adult/Pediatric)

EMMA Airway Adapter Infant (REF 100660)



2. XTP window (Infant)

Note: A trained medical professional must determine the proper EMMA Airway Adapter model for each patient application. No hardware or software configuration changes result from the Airway Adapter model selected.

Chapter 2: Description

This chapter contains the description of the Radius PCG physical features.

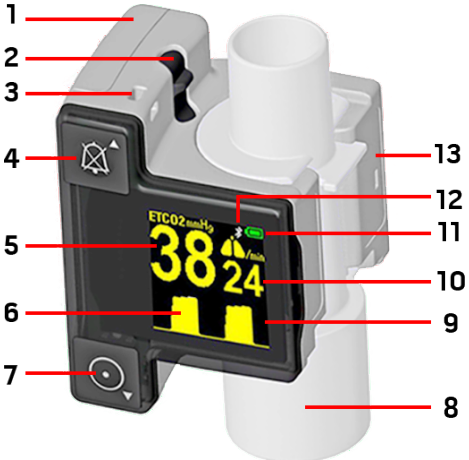
General System Description

The Radius PCG system includes the following:

- Radius PCG Device
- Two (2) AAA Batteries

For a complete list of compatible EMMA Airway Adapters, visit www.masimo.com.

Features



1 Battery Cover
2 Battery Cover release button
3 Lanyard attachment
4 Alarm Silence button
5 $EtCO_2$ Value
6 Capnogram
7 Power On button
8 EMMA Airway Adapter
9 Alarm Status
10 Respiratory Rate Value
11 Battery Status Indicator
12 Bluetooth Indicator
13 Radius PCG Sensor Body

Chapter 3: Basic Setup and Use

This chapter contains information about setting up Radius PCG before use.

Installing Batteries

Unpack and inspect the Radius PCG for external damage. Please contact your local distributor in case of damage.

1. Press the **Battery Cover** release button into the Radius PCG Sensor Body until the Battery Cover pops off.

2. Open the battery compartment and insert two (2) AAA batteries. Make sure the batteries are fitted according to the indicated polarity. After battery installation, snap the **Battery Cover** back into place.

Attaching Airway Adapter

Snap the EMMA Airway Adapter into the Radius PCG Capnograph.

It will click into place when properly inserted.

Connecting to a Tube or Mask

The Radius PCG can be connected to a patient using an endotracheal tube or mask. The following pictures illustrate these two methods of connection.

Endotracheal tube

Mask

Power On

1. To power on Radius PCG, press the Power On button.

2. When the Radius PCG is ready the $EtCO_2$ Value displays "0" and the Respiratory Rate Value displays dashes "- -".

The audible alarm sound may be checked by detaching the Airway Adapter to generate a *No Adapter* alarm.

If the $EtCO_2$ Value is non-zero, ensure that there has not been an accumulation of CO_2 between the Radius PCG Sensor Body and the Airway Adapter by removing and reattaching the Airway Adapter. If the $EtCO_2$ Value still displays a non-zero value after this procedure, perform a Zeroing procedure. See ***Zeroing Procedure*** on page 60.

Power Off

The Radius PCG switches off automatically during following conditions:

- If no breath is detected within 2 minutes from power up.
- If no breath is detected for 2 minutes and the alarm has been silenced.
- 15 seconds after the Airway Adapter is removed.

Note: The device will not automatically power off if there is an alarm condition other than a *No Adapter* alarm detected (e.g. *Clogged Adapter*).

Bluetooth Setup

For Radius PCG Bluetooth Setup instructions for connection with Root, see ***Pairing Radius PCG to Root*** on page 67.

Chapter 4: Operation

The information in this chapter assumes that Radius PCG is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate Radius PCG without completely reading and understanding these instructions.

Radius PCG Display

The Radius PCG is fitted with a graphic OLED-display that displays End-Tidal Carbon Dioxide ($EtCO_2$) and Respiratory Rate (RR) parameters as well as the CO_2 waveform (Capnogram).

1 $EtCO_2$ Parameter Value
2 Capnogram
3 RR Parameter Value

$EtCO_2$

The Radius PCG is available in versions displaying End-Tidal Carbon Dioxide ($EtCO_2$) either in mmHg (0 - 99 mmHg) or kPa (0.0 - 9.9 kPa). $EtCO_2$ values are displayed after one breath and the averaged value is updated every breath.

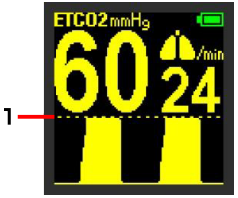
Respiratory Rate

Respiratory Rate (RR) is displayed as breaths per minute (3 - 150 bpm). RR is displayed after two breaths and the value is updated every breath.

Capnogram

The Capnogram is displayed as a filled graph with a 14.4 sec horizontal sweep and a fixed 0-53 mmHg/0-7 kPa scale.

If the CO_2 level reaches or exceeds 53 mmHg/7 kPa, a horizontal dashed line (1) will be displayed to indicate that the Capnogram is saturated.



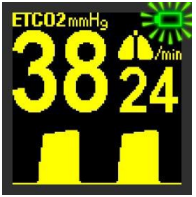
Auto Brightness

To extend battery life time the Radius PCG display has an automatic brightness control which will be activated during stable conditions. Any change in displayed vital parameters, alarm or pressing any button will return the Radius PCG display to normal brightness.

Battery Status Indicator

The *Battery Status Indicator* is  normally lit with a steady green light in the upper right corner of the display (Battery OK or Weak). When batteries are low, the Battery Status Indicator starts blinking.

Battery Status	Battery Voltage*	Battery Status Indicator
OK	>2.4V	
Weak	2.2V to 2.4V	

Battery Status	Battery Voltage*	Battery Status Indicator
Low	<2.2V	

* Typical values.

There will be an audible tone beep repeated every 80 seconds when batteries are low.

The terminal voltage of alkaline batteries recovers when the batteries are not in use. The remaining time prediction is thus unreliable during the first period after power on. Nearly depleted batteries may still be able to provide a voltage above the threshold for battery low indication, even if the internal battery resistance is too high to provide sufficient current to start up the device next time the power on button is activated.

To extend battery life time the Radius PCG display has an automatic brightness control, which will be activated during stable conditions. Any change in displayed vital parameters, alarm or pressing any button will return the Radius PCG display to normal brightness.

Controls

The Radius PCG has one Power On and one Alarm Silence button. These buttons are also be used for adjusting the high and low $EtCO_2$ alarm limits up and down.

1 Power On/Adjust Down button
2 Alarm Silence/Adjust Up button

Parameter Settings

The following information contains default alarm limits and information for adjusting $EtCO_2$ alarm limits.

Default Alarm Limits

The default factory settings for the RR and the $EtCO_2$ alarms are as follows:

	Lower Limit	Upper Limit
RR (No Breath)	3 bpm (20 seconds)	NA
$EtCO_2$	OFF	50 mmHg (7.0 kPa)

EtCO2 Settings

The adjustment ranges for the $EtCO_2$ alarm limits are as follows:

	Lower range	Upper range
$EtCO_2$ (mmHg)	OFF; 1 – 89 mmHg	11 – 99 mmHg; OFF
$EtCO_2$ (kPa)	OFF; 0.1 – 8.9 kPa	1.1 – 9.9 kPa; OFF

Note: The alarm limits will be reset to default values after Radius PCG powers off.

If the high $EtCO_2$ limit is decreased close to the low $EtCO_2$ limit, the low limit will be automatically adjusted in order to maintain a minimum difference of 10 mmHg (1.0 kPa) between the high and low alarm limit. Similarly, if the low $EtCO_2$ limit is increased close to the high $EtCO_2$ limit, the high limit will be automatically adjusted to maintain a minimum difference of 10 mmHg (1.0 kPa) between the high and low alarm limit.

If no buttons have been activated for a short period during alarm limit adjustment, the Radius PCG will automatically resume normal operation.

Low EtCO2 Alarm

1. Press and hold the Power On button until the display shows the "Lo ETCO2 Screen" and the $EtCO_2$ display shows the current low $EtCO_2$ alarm limit. See ***Controls*** on page 31.
2. Release the Power On button.
3. To adjust the alarm limit: press the Alarm Silence button (▲) to increase, or the Power On button (▼) to decrease the value. It is possible to switch off the low $EtCO_2$ alarm by adjusting the limit down to 0. The Radius PCG will indicate this setting by showing "- -" on the $EtCO_2$ display during the adjustment routine.

   If no button has been activated for a short period, the Radius PCG will automatically resume normal operation.

High EtCO2 Alarm

1. Press and hold the Alarm Silence button until the display shows the **Hi ETCO2 Screen** and the $EtCO_2$ display shows the current high $EtCO_2$ alarm limit. See ***Controls*** on page 31.
2. Release the Alarm Silence button.
3. To adjust the alarm limit: press the **Alarm Silence** button (▲) to increase, or the **Power On** button (▼) to decrease the value. It is possible to switch off the high $EtCO_2$ alarm by adjusting the limit above 99 mmHg (9.9 kPa). The Radius PCG will indicate this setting by showing "- -" on the $EtCO_2$ display during the adjustment routine.

   If no button has been activated for a short period, the Radius PCG will automatically resume normal operation.

Bluetooth Operation

The Radius PCG Bluetooth provides a Bluetooth Low Energy (LE) wireless option to allow the transfer of data to a paired device. The paired connection only allows the Radius PCG to communicate to a single device at a time to minimize the risk of unauthorized data access.

To prevent unauthorized data communication, the Bluetooth is disabled by default and must be enabled each time by the user. The unique Bluetooth address contains the product name plus the serial number of the device. Confirm the correct connection by verifying the appropriate serial number is displayed on the paired device.

When the Bluetooth is enabled, the Bluetooth indicator will appear on the screen to allow confirmation that the Bluetooth is active. Disable the Bluetooth to stop or prevent authorized communication of data.

Once Bluetooth is enabled on Radius PCG, refer to the User Manual for the device for pairing instructions. To pair Radius PCG to Root, follow the procedure in ***Pairing Radius PCG to Root*** on page 67.

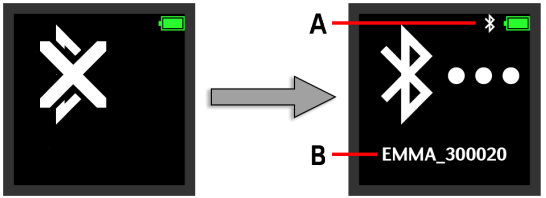
If you experience interruption or reduction in the Quality of Service (QoS) of the Bluetooth communication, latency's in data communication greater than 30s, verify that both paired devices are in line of sight of one another and decrease the separation distance, if possible.

Note: Radius PCG uses a proprietary Bluetooth protocol. This helps to ensure that data is only communicated with Masimo authorized device (e.g., Root).

To enable Bluetooth operation:

1. Press the On button two (2) times to enter Bluetooth mode. See ***Features*** on page 20.
2. Press the On button once (1) again to enable Bluetooth. When Bluetooth is enabled, the Bluetooth symbol (A) and the serial number (B) for the Radius PCG display on the screen as shown.

   Note: If Radius PCG is off, it must be turned on before Bluetooth can be enabled.



To disable Bluetooth operation:

1. Press the On button two (2) times to enter Bluetooth mode.
2. Press the On button once (1) again to disable Bluetooth.

Chapter 5: Alarms and Messages

Alarms and Messages

The Radius PCG is equipped with an Alarm Status Indicator and an audible alarm. The audible alarm can be silenced for 2 minutes by pressing the **Alarm Silence** button. See ***Controls*** on page 31.

- When the audible alarm is silenced, the yellow silence alarm indicator in the bottom right corner of the display, i.e. the *Alarm Status Silence Indicator*, will be lit.
- Pressing the Alarm Silence button again during the 2 minutes mute period will reactivate the audible alarm.
- If a No Breath alarm is muted by pressing the Alarm Silence button, the Radius PCG will automatically switch off after 2 minutes provided that no new breaths are detected.

- If the alarm situation passes while the audible alarm is silenced, the alarm icon turns green.
- Pressing the Alarm Silence button during no alarm will also show a green silence alarm indicator in the bottom right corner of the display.

Alarm Signals

Alarm	at t = 0 Alarm Priority: Low	at t = 20 Alarm Priority: Low	t = 40, 60, 80, ... Alarm Priority: Medium
No Breath	 (((•)))	 (((•))) (((•)))	 (((•))) (((•))) (((•)))
Low $EtCO_2$		n/a	
High $EtCO_2$		n/a	
Clogged Adapter [1]	 (((•)))	n/a	n/a

Alarm	at t = 0 Alarm Priority: Low	at t = 20 Alarm Priority: Low	t = 40, 60, 80, ... Alarm Priority: Medium
No Adapter [1]	 (((•)))	n/a	n/a
Zero point adjustment [1]	 (((•)))	n/a	n/a

[1] See ***Chapter 6: Troubleshooting*** on page 41.

Note: t = 0 is defined as the time when the alarm condition first is indicated. t = 40, 60, 80, ... shall be interpreted as "40 sec later than t = 0", "60 sec later than t = 0", "80 sec later than t = 0" etc. For Low $EtCO_2$ and Hi $EtCO_2$, there is a 20 sec delay before t = 0 when the alarm condition is indicated (i.e. the Alarm Signal Generation Delay is 20 sec).

Alarms and Messages

Active alarms are further displayed according to the following table:

Alarm	Screen	ETCO2 Value	RR Value
No Breath	NORMAL	value steady [1]	"- -" flashing [2]
Low $EtCO_2$	NORMAL	value flashing	value steady
High $EtCO_2$	NORMAL	value flashing	value steady
Clogged Adapter	ADAPTER	n/a	n/a
No Adapter	ADAPTER	n/a	n/a
Zero point adjustment [3]	NORMAL	value steady	value steady

Note 1: $EtCO_2$ value displays momentary CO_2 during No Breath.

Note 2: RR value displays "- -" steady if no breath at all detected from power on.

Note 3: Perform Zeroing procedure. See ***Zeroing Procedure*** on page 60.

Chapter 6: Troubleshooting

Troubleshooting Radius PCG

Error	Possible Causes	Recommended Solutions
No Adapter alarm is displayed	Indicates that an EMMA Airway Adapter needs to be installed.	Connect an EMMA Airway Adapter. See ***Attaching Airway Adapter*** on page 23.
Clogged Adapter alarm is displayed	Indicates that the EMMA Airway Adapter needs to be replaced with a new one.	Replace the EMMA Airway Adapter with a new one.
Zero point adjustment alarm is displayed	A zero point adjustment is required.	Perform a Zeroing procedure. See ***Zeroing Procedure*** on page 60.
The unit does not complete the turn on sequence	Low battery	Replace the batteries.
The unit does not turn on	• No battery • Low battery	Replace the batteries.
The measured values of $EtCO_2$ are out of specified accuracy	Incorrect zero reference	Perform a Zeroing procedure and verify the measurement with reference gas. See ***Chapter 8: Service and Maintenance*** on page 57.

Error	Possible Causes	Recommended Solutions
Numbers appear dim	• Automatic brightness control is activated. • Exposed to bright lights or sunlight.	Pressing any button will return the Radius PCG display to normal brightness. See ***Controls*** on page 31.
Measurement does not display on the connected device using optional Bluetooth	• Bluetooth is not connected. • Connected device or Radius PCG out of range. • Connected device damaged. • Radius PCG damaged.	• Confirm Bluetooth is on for the Radius PCG and the connected device. See ***Bluetooth Operation*** on page 35. • Move the Radius PCG and connected device closer to each other. • Check that Radius PCG is paired to the correct connected device. • Contact Masimo Technical Services. See ***Contacting Masimo*** on page 63.

Chapter 7: Specifications

Radius PCG Specifications

Display Range

Measurement	Display Range
$EtCO_2$ (End-Tidal CO_2) [1], [2] *	0 mmHg to 99 mmHg 0 kPa to 9.9 kPa
RR (Respiration Rate)	3 BPM to 150 BPM

* ETCO2 will be within specification for respiration rates up to 150 bpm [3]

Accuracy (ARMS)

Carbon Dioxide (CO_2) [4]	
Range 0 mmHg to 99 mmHg	0-40 mmHg ± 2 mmHg, 41-99 mmHg 6% of reading during standard conditions
Range 0 kPa to 9.9 kPa	0-5.3 kPa ± 0.3 kPa, 5.4-9.9 kPa 6% of reading during standard conditions
Respiration Rate (RR)	
Range 3 to 150 bpm	±1 bpm

Electrical

Battery	
Type	Two (2) AAA Cell Batteries, Alkaline or Lithium
Capacity - Alkaline [5]	Approx. 4 hours
Capacity - Lithium L92 [5]	Approx. 8 hours

Environmental

Environmental Conditions	
Operating Temperature	-5 to 50°C (23 to 122°F)
Transient Operating Temperature (at least 20 minutes)	-20 to -5°C (-4 to 23°F) [6]
Storage/Transport Temperature	-40 to 70°C (-40 to 158°F)
Operating Humidity	< 50 hPa H2O (non-condensing) (41% RH at 50 °C)
Storage Humidity	10 to 95% RH (condensing) at a water vapor partial pressure not exceeding 50 hPa (95 % RH at 32 °C)
Operating Atmospheric Pressure	60 to 120kPa [1] (i.e. Altitude up to 4000 m)
Storage Atmospheric Pressure	50 to 120 kPa

Physical Characteristics

Physical Characteristics	
Dimensions	52 mm x 44 mm x 39 mm (2.1" x 1.8" x 1.6")
Weight	Approx. 65 g (2.1 oz.) with batteries
Display Type	96 x 96 pixel RGB OLED-display
Expected Service Life	5 Years

Alarms

Audio Alarm Description
No Breath, Low ETCO2, High ETCO2, Clogged Adapter, No Adapter, Zero point adjustment, Low Battery

Alarm Characteristic	Description
Alarm Volume	v≥ 57 dB(A); ≤ 67 dB(A)

Compliance

Safety Standards Compliance	
EN 60601-1:2006/AMD1:2013	EN ISO 80601-2-55:2018
EN 60601-1-2:2015	EN ISO 5356-1:2015
EN 60601-1-8:2007, C1:2010, A1:2013	EN ISO 14971:2012
EN 60601-1-12:2015	EN ISO 15223-1:2016

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (Battery power)
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from solid and liquid ingress	IP44, Protection from tools and small wires greater than 1mm in diameter and from water spray from any direction.
Mode of Operation	Continuous operation
Sterility	No part of Radius PCG is sterile

Wireless Specifications

Communication (Bluetooth)	
Type	Bluetooth GFSK
Frequency	2402-2480 MHz
Max Peak Output Power	-1 dBm
Antenna Peak Gain	-7 dBi
Recommended Range	~10 feet (~3 meters) line-of-sight

Radio Compliance	
Radio Modes	Bluetooth LE (v4.0)
USA	FCC ID: VKF-EMMABT FCC parts 15.207 and 15.247
Canada	IC: 7362A-EMMABT RSS-247
Europe	RED 2014/53/EU ETSI EN 300 328 ETSI EN 301 489-1 ETSI EN 301 489-17
Japan	Japanese Radio Law, Item 19 of Article 2-1

Additional Specifications

General	Specifications
Description	Compact, battery powered, quantitative capnograph for mainstream CO_2 monitoring of adult, pediatric and infant patients.
Measurements [1]	The CO_2 partial pressure is measured based on a 2 channel NDIR type gas analyzer at 4–5 μm with data acquisition rate at 10 kHz (sample rate 20 Hz / channel).
Models	CO_2 displayed in kPa or mmHg
Drift of measurement Accuracy	No drift
Recovery Time After Defibrillator Test	Unaffected
Highest Surface Temperature	
At Ambient Temperature	Surface Temperature
23°C / 73°F	30°C / 86°F
50°C / 122°F	57°C / 135°F

Data Output	Specifications
Breath Detection	Adaptive threshold, minimum 1kPa CO_2 change.

Data Output	Specifications
Adult/Pediatric	Dead space 6 ml, Flow resistance < 0,3 cm H2O (@ 30 LPM)
Infant	Dead space 1 ml, Flow resistance < 1,3 cm H2O (@ 10 LPM)

Gas Analyzer	Specifications
Warm-up	In operation and full accuracy within 15 seconds.
Warm-up time after storage at -40°C	A warm-up period of 15 minutes is required before Radius PCG is ready for use after being stored with batteries mounted at –40°C when the ambient temperature is 20°C.
Cool-down time after storage at 70°C	In operation and full accuracy within 15 seconds.
Calibration	No routine calibration is required.
Total System Response Time	< 0.7 seconds

Guidance and Manufacturer's Declaration-Electromagnetic Compatibility

Radius PCG is intended for use in professional environments (e.g., intensive care unit, patient room and operating suite) and transport environments (e.g., emergency services, road ambulances, and aircrafts). Radius PCG has not been evaluated for special environments (e.g., near Magnetic resonance imaging (MRI) systems).

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	Radius PCG 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	Radius PCG is suitable for use in all establishments.
RF Emissions RTCA DO-160G, Section 21	Category M	Suitable for use in passenger cabin or in the cockpit of a transport aircraft.

During immunity testing the essential performance of Radius PCG was assessed based upon the gas measurement accuracy (see Citation [4]) including gas reading alarm conditions, or generation of technical alarm conditions. For higher immunity conditions above 100 V/m at frequencies between 4 GHz to 8 GHz (i.e., exposure to rotational radar), the essential performance was determined based upon the return of the device to normal operation without permanent damage.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**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	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Radiated RF IEC 61000-4-3	10 V/m (80 MHz to 2.7 GHz)	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Radius PCG than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Otherwise, degradation of the performance of this equipment could result. d = 0.6*SQRT(P) 80 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter and d is the recommended separation distance in meters (m).

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Radiated RF RTCA DO-160G, Section 20, Category R	20 V/m (100 MHz to 400 MHz) 150 V/m (400 MHz to 8 GHz)	20 V/m 100 MHz to 400 MHz 150 V/m 400 MHz to 8 GHz 102 V/m 4 GHz to 8 GHz	RF communication equipment should be used no closer to any part of the Radius PCG than the recommended separation distances calculated from the equation. Otherwise, degradation of the performance of this equipment could results. $d = 0.3\sqrt{P}$ 100 MHz to 400 MHz $d = 0.04\sqrt{P}$ 400 MHz to 4 GHz[a] $d = 0.06\sqrt{P}$ 4 GHz to 8 GHz where P is the maximum output power rating of the transmitter and d is the recommended separation distance in meters (m).
[a] In the presence of higher electromagnetic fields above 100V/m at 4 GHz to 8 GHz (i.e., exposure to rotational radars), temporary saturation of the measurement signal may be observed. If this occurs, attempt to increase the separation distance from the RF source.			

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Radius PCG

The Radius PCG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Radius PCG gas analyzer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Radius PCG gas analyzer 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]**			
	80 MHz to 2.7 GHz $d = 0.6\sqrt{P}$	100 MHz to 400 MHz $d = 0.3\sqrt{P}$	400 MHz to 4 GHz $d = 0.04\sqrt{P}$	4 GHz to 8 GHz $d = 0.06\sqrt{P}$
0,01	0.06	0.03	0.004	0.006
0,1	0.19	0.095	0.013	0.019
1	0.6	0.3	0.04	0.06
10	1.9	0.95	0.13	0.19
100	6	3	0.4	0.6

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

Symbols

The following symbols are found on the Radius PCG, or packaging and are defined below.

Symbols	Definition	Symbols	Definition
	Follow Instructions for use		Defibrillation Proof Type BF
REF	Catalog number (model number)	SN	Serial number
LOT	Lot Code		Manufacturer
	Use by Date YYYY-MM-DD		Date of Manufacture YYYY-MM-DD
	Storage humidity limitation		Storage temperature range
	Atmospheric pressure limitation		Do not Reuse

Symbols	Definition	Symbols	Definition
CE 0413	Mark of Conformity to European medical device directive 93/42/EEC		Separate collection for electrical and electronic equipment (WEEE)
	Bluetooth	 3JSV	UL LLC certification
IP44	Protection from tools and small wires greater than 1mm in diameter and from water spray from any direction.	**Rx ONLY**	**Caution:** Federal law restricts this device to sale by or on the order of a licensed physician.
FCC ID:	Identifies unit has been registered as a radio device		Non-ionizing electromagnetic radiation
	Federal Communications Commission (FCC) licensing	-	--
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] The Radius PCG displays CO_2 in partial pressure units (kPa or mmHg) and compensates the displayed value for the actual barometric pressure. The $EtCO_2$ value is the max partial CO_2 pressure measured within a breath and the displayed value is:

– the latest $EtCO_2$ values i.e. if $\Delta EtCO_2 \geq 25\%$ or

– the average of up to four $EtCO_2$ values measured within 30s given $\Delta EtCO_2 < 25\%$.

[2] Gas reading showing actual partial pressure at current humidity level. Partial pressure of CO_2 in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), is typically 6% lower than the corresponding CO_2 partial pressure after removal of all water vapor (ATPD).

[3] $EtCO_2$ was measured at I/E ratio 1:1 using breath simulator according to the test setup in EN ISO 80601-2-55 fig. 201.101. The measured $EtCO_2$ was within the accuracy range for all respiration rates up to 150 bpm.

[4] To include quantitative effect on gas reading from variations in environment conditions (outside STP, electromagnetic disturbances) and presence of Halothane, Ethanol, Isopropyl alcohol, He, Acetone and Methane, the CO_2 accuracy range should be increased to ±4 mmHg/ ±0.5 kPa or ±10% of reading whichever is the greater. In addition, the following interference effects on CO_2 readings exists:

- *60 vol% of N_2O typically increases CO_2-readings by 10%*
- *60 vol% of O_2 typically decreases CO_2-readings by 4% (Radius PCG compensates CO_2-values for influence from 21% O_2 as default)*
- *5 vol% of ENF, ISO, SEV typically increases CO_2-readings by 8%*
- *15 vol% of DES typically increases CO_2-readings by 12%*
- *80% Xe typically decreases CO_2-readings by 10%*
- *50% He typically decreases CO_2-readings by 6%.*

[5] Battery life test was performed using Energizer brand batteries. www.energizer.com.

[6] Based upon the chemistry, Alkaline batteries may not last more 20 minute of transient use. For longer transient use times, use Lithium batteries which have been tested to operate > 2 hours under normal use.

Chapter 8: Service and Maintenance

The following chapter contains information about cleaning, battery operation, performance verification, service, repair, and warranty.

Cleaning

Radius PCG Cleaning

CAUTION: Do not immerse Radius PCG in any liquid.

CAUTION: Do not apply excessive pressure on the IR-windows.

Note: Before cleaning Radius PCG, remove the batteries and make sure the battery cover is re-attached correctly.

To clean Radius PCG, follow the instructions below:

1. Remove the Airway Adapter.
2. Wipe each of the outer surfaces twice or until the surfaces are free of any visible residue, using one of the following solutions:

   - A cloth moistened with 70% Isopropyl Alcohol
   - A quaternary ammonium chloride solution wipe (for example CaviWipes™)

   Note: Pay particular attention to crevices and hard to reach areas of the device. Use a soft bristled brush to gently remove any visible residue from crevices as necessary.

3. Repeat the above cleaning step using a fresh cloth or wipe.
4. Allow the Radius PCG device to dry thoroughly before using again.

The surfaces of Radius PCG have been tested to be chemically resistant to the following disinfectants/solutions:

- 70% Isopropyl alcohol
- 70% Ethyl alcohol
- Quaternary ammonium chloride solution wipe
- Cidex Plus (3.4% glutaraldehyde)
- 0.5% Sodium hypochlorite (1:10 Bleach to water solution)
- Accelerated hydrogen peroxide

Always wipe off residues of disinfection solutions with a wet cloth after exposure.

CAUTION: Never saturate Radius PCG completely with any disinfection solution.

Airway Adapter Cleaning

- The EMMA Airway Adapters are not intended to be cleaned.
- The Airway Adapters are intended for single patient use. They are disposable and shall not be re-used. Reuse of single patient use Adapters can cause cross infection.
- Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.

Maintenance

Battery Replacement

WARNING: Lithium batteries may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate. Dispose of used cell promptly. Keep away from children.

WARNING: Use only Alkaline batteries or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion.

To replace the batteries:

1. Open the battery compartment by pressing the release button. See ***Installing Batteries*** on page 21.
2. Gently remove the depleted batteries.
3. Insert two new AAA type batteries into the battery compartment. Make sure that the batteries are fitted according to the polarity marking.
4. When the batteries are properly fitted, gently snap the battery cover back into place.

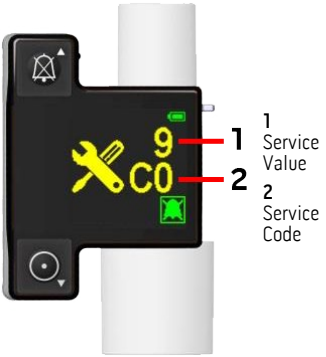
Note: Always carry spare batteries in the Radius PCG pouch.

Zeroing Procedure

Zeroing is recommended after 500 hours of operation or whenever an offset in gas readings is discovered. Zeroing of the Radius PCG is performed by the following procedure:

Note: The presence of ambient air (0% CO2) in the EMMA Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the Airway Adapter before or during the Zeroing procedure.

1. Start the Radius PCG by pressing the Power On button. See ***Controls*** on page 31.
2. Make sure that a new Airway Adapter is properly fitted. See ***Attaching Airway Adapter*** on page 23.
3. Press and hold down simultaneously the Power On and Alarm Silence button until the Service Screen display the Service code “C0” and the Service value “10”. Keep both buttons depressed while the Service value starts "counting down" i.e. displaying "9" - "8" - "7" etc. until "0" is displayed.
4. When the Service value “0” is shown, zeroing of the Radius PCG is complete.*



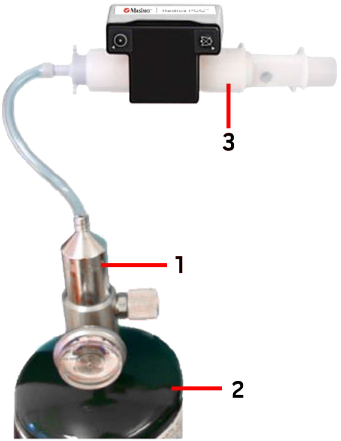
* The Radius PCG will return to normal measuring mode when the Service value has reached "0" or if any of the buttons are released.

Gas Span Check

The Radius PCG does not require any routine calibration. A gas span check is recommended at regular intervals to make sure the measurement is within accuracy levels. The suggested interval for gas span check is once every year. The following items are required to perform a gas span check of Radius PCG:

Attach the flow regulator to the calibration gas cylinder. Ensure that the valve is shut off completely.

1. Attach a new Airway Adapter to the Radius PCG.
2. Turn on the Radius PCG and ensure that the $EtCO_2$ reading is zero. Otherwise, conduct a Zeroing procedure according to chapter 7.4 above before proceeding.
3. Insert the 15M connector into one end of the Airway Adapter, and connect a second Airway Adapter to the other end (see picture).
4. Turn on the regulator flow.
5. After 30 seconds, record the $EtCO_2$ reading.
6. Turn off the flow.
7. Determine and record an estimated ambient atmospheric pressure in mmHg.
8. Use the following table to determine if the unit is reading within specified limits.



1 A gas flow regulator with a plastic tube and a 15M connector

2 Calibration gas (5% CO2, 21% O2, Balance N2)

3 Two (2) Airway Adapters

Barometric pressure [mmHg]	Radius PCG $EtCO_2$ readings should be between	
	5% CO_2 [mmHg]	5% CO_2 [kPa]
660-679	31-36	4,1-4,8
680-699	32-37	4,3-4,9
700-719	33-38	4,4-5,1
720-739	34-39	4,5-5,2
740-759	35-40	4,6-5,4
760-779	36-41	4,8-5,5
780-799	37-42	4,9-5,6

If the unit is reading within the above range then your Radius PCG has been successfully verified.

If the unit is not reading within the above range, disconnect the Airway Adapter from the gas cylinder, and perform a Zeroing procedure and then repeat the Gas span check procedure. See ***Zeroing Procedure*** on page 60. If verification still fails, contact your local distributor for further instructions.

Service and Return Procedure

Contact Masimo for product support. If needed, an RMA will be provided for repair or replacement. Masimo can be reached at 800-326-4890. For customers outside the United States, local contact information can be found at http://service.masimo.com.

Clean contaminated/dirty equipment before returning per Maintenance and Cleaning instructions. Make sure the equipment is fully dry before packing. Package the device securely, in the original shipping box if possible, and enclose the following information and items:

- Include the RMA form provided, or a letter describing in detail any difficulties experienced with Radius PCG. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included. Purchase Order number to cover repair if the device is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information. Person (name, telephone/Telex/fax number and country) to contact for any questions about the repairs.
- A certificate stating that the device has been decontaminated for bloodborne pathogens.
- Return the device to Masimo at the address listed in ***Contacting Masimo*** on page 63 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product Radius PCG and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any

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Appendix A: Operation with Root

Overview

Radius PCG computes and analyzes End-tidal Carbon Dioxide ($EtCO_2$), Fractional concentration of inspired Carbon Dioxide ($FiCO_2$)* and Respiration Rate (RR) based on the samples gathered from Radius PCG's breathing circuit, via the airway adapter. The Bluetooth connection allows the Radius PCG parameters to display on Root in the *Capnography* window.

* $FiCO_2$ does not display on the Radius PCG device, $FiCO_2$ only displays on Root.

Setting Up

Pairing Radius PCG to Root

Upon successful pairing of Radius PCG to Root, capnography measurements collected using the Radius PCG Capnograph display on both devices. On Root, the data is displayed in the Capnography window on the Main Screen of Root. See ***Capnography Window*** on page 71.

Note: Bluetooth functionality is implemented differently by the various connected-device manufacturers and incompatibility between the Radius PCG and your external device may occur.

Note: Radius PCG can be paired to Root while an ISA Sidestream Gas Analyzer is connected to Root through the MOC-9 connection, however, the *Unable to handle Capnography channel on Bluetooth* message displays, and the *Capnography* window is populated from the ISA Sidestream Gas Analyzer. See ***Troubleshooting Radius PCG*** on page 41.

To pair Radius PCG with Root:

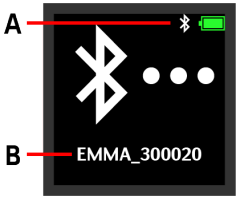
1. Press the On Button to turn on Radius PCG. See ***Features*** on page 20.
2. On Root, at the bottom right corner of the Main Screen, press the **Main Menu** icon  .

3. Select the **Device Settings** menu icon.
4. Select the **Bluetooth** menu icon.

   Note: If Bluetooth is Off, turn it On, select OK and wait for the Masimo device MAC address to appear before proceeding to the next step.
5. On the **Bluetooth** screen, select the EMMA *Pair* button. The *Pair EMMA* screen displays.
6. On Radius PCG, press the On button two (2) times to enter Bluetooth mode.

   Note: For complete information about the Bluetooth connection on Radius PCG including enabling and disabling the Bluetooth, see ***Bluetooth Operation*** on page 35.
7. Press the On button once (1) again to enable Bluetooth. When Bluetooth is enabled, the Bluetooth symbol **(A)** and the serial number **(B)** for the Radius PCG display on the screen.

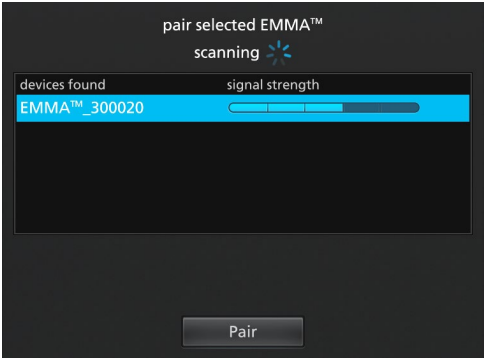
   Note: If Radius PCG is off, it must be turned on before Bluetooth can be enabled.



8. Place Radius PCG close to Root. Radius PCG should appear under the *Devices Found* list on the Root screen.

   Note: The number displayed is the serial number of the Radius PCG device. See ***About*** on page 84 for additional information. This can provide assistance if multiple Radius PCG devices are within range of the Masimo device when pairing and displayed under the *Devices Found* list.

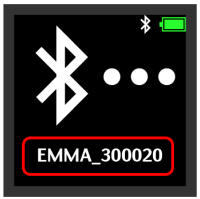
9. Press/select the desired Radius PCG under the *Devices Found* list, and then press/select the *Pair* button.

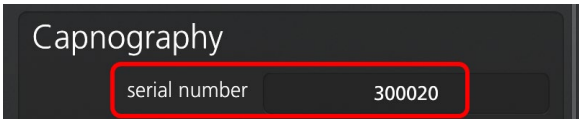


10. After pressing/selecting the *Pair* button, Root returns to the *Bluetooth* screen.
    - The MAC address for Radius PCG displays on the screen.
    - The Info screen icon displays next to the MAC address. See ***Accessing the Radius PCG Info Screen*** on page 84.

Confirm Correct Radius PCG Connection

To confirm the correct Radius PCG is paired to Root, verify that the Radius PCG serial number displayed on the *About* screen matches the serial number displayed on the Radius PCG screen when Bluetooth is enabled. See ***About*** on page 84.





Reestablishing Radius PCG Connection with Root

Radius PCG may become disconnected from the Masimo device for a number of reasons, which may include:

- Moving out of Bluetooth range
- Powering off from non-use
- Bluetooth connection is turned off on the Masimo device

To reestablish communication with the Masimo device, cycle the Radius PCG Bluetooth Off and back On.

1. Press the Radius PCG On button two (2) times to enter Bluetooth mode.
2. Press the Radius PCG On button once (1) again to disable Bluetooth.
3. Press the Radius PCG On button once (1) again to enable Bluetooth.

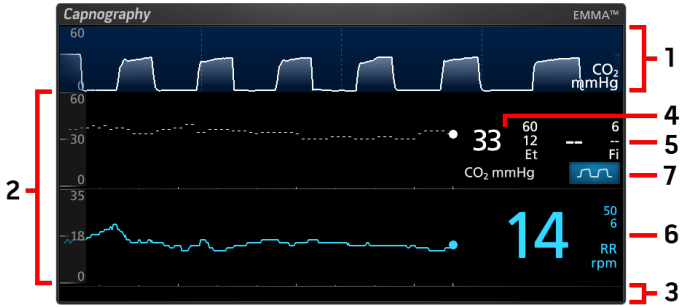
The Masimo device and Radius PCG communication should resume. If a communication issue continues, forget Radius PCG on the Masimo device (disconnect) and pair again. See ***Disconnecting Radius PCG from the Masimo Device*** on page 85.

Operation

Capnography Window

Parameters and measurements display in the *Capnography* window. Capnography parameters display by default as numeric values and as a graphical representation.

When multiple technologies are connected to the Masimo device, each technology's parameters are displayed in an individual window. On Root, the relative size of each window can be configured using the Layout feature, which is accessible though the Layout icon in the Main Menu. For additional information, see the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature***. The image below is an example of the Root Radius PCG *Capnography* window.



Ref.	Feature
1	**Capnograph Display** See ***Capnograph Display*** on page 73.
2	**Trend** See ***Chapter 3: Operation*** in the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature.***
3	**Well** See ***Chapter 3: Operation*** in the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature.***
4	**$EtCO_2$ Display** See ***Parameter Settings*** on page 74.
5	**$FiCO_2$ Display*** See ***Parameter Settings*** on page 74.
6	**RR Display** See ***Parameter Settings*** on page 74.
7	**Toggle Waveform On/Off** See ***Capnograph Display*** on page 73.

* $FiCO_2$ does not display on the Radius PCG device. $FiCO_2$ only displays on Root as a placeholder and parameter values are not displayed.

Capnograph Display

The capnograph display is a waveform representation of a patient's CO_2 levels throughout inhalation and exhalation.

Waveforms

Values are represented by a waveform that ranges from 0 to 60 mmHg (additional units of measure available: kPa, vol%). When a CO_2 waveform is not available, a straight line is displayed.

View/Hide Waveform

To toggle the waveform on or off, touch the capnograph icon  at the right end of the individual parameter display.

Accessing Main Menu Options

To access the Main Menu options:

At the bottom right corner of the touchscreen, press/select the **Main Menu** icon.

With Radius PCG connected to the Masimo device, the *Main Menu* options change and are reflected below.

Layout
See ***Chapter 3: Operation*** of the ***Operator's Manual, Root®.***

Capnography
See ***Capnography Settings*** on page 74.

Device Settings
See ***Device Settings*** on page 83.

About
See ***About*** on page 84.

Capnography Settings

The *Capnography* menu allows the user to view and customize settings for Capnography on Root ***ONLY***.

Capnography setting changes made on the Masimo device are NOT transferred to the Radius PCG device. Changes to Capnography settings for the Radius PCG device are made on the device itself (and are NOT transfered to the Masimo device). See ***Chapter 4: Operation*** on page 27 for information about settings for the Radius PCG device.

The following *Capnography* settings options are available:

Parameter Settings

See ***Capnography Settings*** on page 74.

Additional Settings

See ***Additional Settings*** on page 82.

Parameter Settings

From the *Capnography* screen, touch *Parameter Settings*, and then change individual parameter settings/alarms by selecting one of the following parameters:

End-tidal Carbon Dioxide

See ***End-tidal Carbon Dioxide (EtCO2)*** on page 75.

Respiratory Rate

See ***RR Settings*** on page 79.

Inspired Carbon Dioxide*

See ***Inspired Carbon Dioxide (FiCO2)*** on page 77.

* $FiCO_2$ does not display on the Radius PCG device, $FiCO_2$ only displays on the Masimo device.

End-tidal Carbon Dioxide (EtCO2)

From the *End-Tidal Carbon Dioxide Settings* screen, access the following screens:

EtCO2 Alarms on page 75

About Parameter Information on page 80

Trends on page 81

From the *End-Tidal Carbon Dioxide* screen, touch *Alarms*, and then change any of the following options:

WARNING: Alarm limits on the Radius PCG device and the Masimo device are set independently of each other. If alarm limits are not set the same, the Masimo device may not alarm at the same time as the Radius PCG device. See ***Chapter 4: Operation*** on page 27 for information on adjusting alarm limits on the Radius PCG device.

Options*	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	7.9 vol% 7.9 kPa 60 mmHg	0.2 to 24.9 vol% in steps of 0.1, or Off 0.2 to 29.9 kPa in steps of 0.1, or Off 2 to 224 mmHg in steps of 1, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	1.6 vol% 1.6 kPa 12 mmHg	Off, or 0.1 to 24.8 vol% in steps of 0.1 Off, or 0.1 to 29.8 kPa in steps of 0.1 Off, or 1 to 223 mmHg in steps of 1 When set to Off, alarm is disabled

Options*	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Caution Range	Upper area of the display range that provides a caution indicator.	NA	Off	Off, or 0.1 to 2.5 vol% in steps of 0.1 Off, or 0.1 to 3.2 kPa in steps of 0.1 Off, or 1 to 24 mmHg in steps of 1
Low Caution range	Lower area of the display range that provides a caution indicator.	NA	Off	Off, or 0.1 to 2.5 vol% in steps of 0.1 Off, or 0.1 to 3.2 kPa in steps of 0.1 Off, or 1 to 24 mmHg in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2, or 5 minutes
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	NA	30 seconds	0, 5, 10, 15, 20, 30, or 60 seconds

* Capnography setting changes made on the Masimo device are not transferred to the Radius PCG device. Changes to Capnography settings for the Radius PCG device are made on the device itself. See ***Chapter 4: Operation*** on page 27 for information about settings for the Radius PCG device.

Inspired Carbon Dioxide (FiCO2)

From the *Inspired Carbon Dioxide Settings* screen, access the following screens:

FiCO2 Alarms on page 77

About Parameter Information on page 80

Trends on page 81

From the *Inspired Carbon Dioxide* screen, touch *Alarms*, and then change any of the following options:

WARNING: Alarm limits on the Radius PCG device and the Masimo device are set independently of each other. If alarm limits are not set the same, the Masimo device may not alarm at the same time as the Radius PCG device. See ***Chapter 4: Operation*** on page 27 for information on adjusting alarm limits on the Radius PCG device.

Note: At this time, $FiCO_2$ is not displayed on Radius PCG or the Masimo device. The following information only discusses the settings on the Masimo device, however, $FiCO_2$ parameters DO NOT display.

Options*	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	0.8 vol% 0.8 kPa 6 mmHg	0.2 to 24.9 vol% in steps of 0.1, or Off 0.2 to 29.9 kPa in steps of 0.1, or Off 2-224 mmHg in steps of 1, or Off When set to Off, alarm is disabled

Options*	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Low	Off	Off, or 0.1 to 24.8 vol% in steps of 0.1 Off, or 0.1 to 29.8 kPa in steps of 0.1 Off, or 1-223 mmHg in steps of 1 When set to Off, alarm is disabled
High Caution Range	Upper area of the display range that provides a caution indicator.	NA	Off	Off, or 0.1 to 2.5 vol% in steps of 0.1 Off, or 0.1 to 3.2 kPa in steps of 0.1 Off, or 1 to 24 mmHg in steps of 1
Low Caution Range	Lower area of the display range that provides a caution indicator.	NA	Off	Off, or 0.1 to 2.5 vol% in steps of 0.1 Off, or 0.1 to 3.2 kPa in steps of 0.1 Off, or 1 to 24 mmHg in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2, or 5 minutes
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	NA	30 seconds	0, 5, 10, 15, 20, 30, or 60 seconds

* Capnography setting changes made on the Masimo device are not transferred to the Radius PCG device. Changes to Capnography settings for the Radius PCG device are made on the device itself. See ***Chapter 4: Operation*** on page 27 for information about settings for the Radius PCG device.

RR Settings

From the *Respiratory Rate Settings* screen, access the following screens:

RR Alarms on page 79

About Parameter Information on page 80

Trends on page 81

From the *Respiratory Rate* screen, touch *Alarms*, and then change any of the following options:

WARNING: Alarm limits on the Radius PCG device and the Masimo device are set independently of each other. If alarm limits are not set the same, the Masimo device may not alarm at the same time as the Radius PCG device. See ***Chapter 4: Operation*** on page 27 for information on adjusting alarm limits on the Radius PCG device.

Options*	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	50	2-149 in steps of 1, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	6	Off, or 1-148 in steps of 1 When set to Off, alarm is disabled
High Caution Range	Area of the display range that provides a caution indicator.	NA	Off	Off, or 1 to 15 in steps of 1 When set to Off, alarm is disabled

Options*	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Low Caution Range	Area of the display range that provides a caution indicator.	NA	Off	Off, or 1 to 15 in steps of 1 When set to Off, alarm is disabled
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2, or 5 minutes
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	NA	30 seconds	0, 5, 10, 15, 20, 30, or 60 seconds

* Capnography setting changes made on the Masimo device are not transferred to the Radius PCG device. Changes to Capnography settings for the Radius PCG device are made on the device itself. See ***Chapter 4: Operation*** on page 27 for information about settings for the Radius PCG device.

About Parameter Information

Additional information about each parameter is available.

To access additional information about parameters:

1. From the *Parameter Settings* screen, touch the **About** icon. The following is an example for $EtCO_2$.

2. An *About* screen appears for the selected parameter and displays information about the parameter.

Trends

From any of the capnography parameter setting screens, touch *Trends*, and then change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Y-Axis Max			
$EtCO_2$, $FiCO_2$	The Trend Max is the highest value displayed.	8.0 vol% 8.0 kPa 60 mmHg	0.1 to 25.0 vol% in steps of 0.1 0.1 to 30.0 kPa in steps of 0.1 1 to 225 mmHg in steps of 1
RR		35	1 to 150 in steps of 1
Y-Axis Min			
$EtCO_2$, $FiCO_2$	The Trend Max is the highest value displayed.	0.0 vol% 0.0 kPa 0 mmHg	0.0 to 24.9 vol% in steps of 0.1 0.0 to 29.9 kPa in steps of 0.1 0 to 224 mmHg in steps of 1
RR		0	0 to 149 in steps of 1

Additional Settings

Use the *Additional Settings* screen to configure the following:

Options*	Description	Factory Default Settings	User Configurable Settings
Apnea Timeout**	Displays the set no-breath timeout	20 seconds	NA
Set O_2 Range**	Displays the set O_2 range	0-30 vol%	NA
Set N_2O Range**	Displays the set N_2O Range	0-30 vol%	NA
CO_2 Unit of Measure	Sets the CO_2 display unit	mmHg	mmHg, kPa***, or vol%

* Capnography setting changes made on the Masimo device are not transferred to the Radius PCG device. Changes to Capnography settings for the Radius PCG device are made on the device itself. See ***Chapter 4: Operation*** on page 27 for information about settings for the Radius PCG device.

** These fields are read-only and cannot be configured by the user.

*** Selecting kPa will cause all stored Trend data to be erased.

Device Settings

The **Device Settings** menu allows the user to view and customize settings for the Masimo device.

The **Device Settings** options are:

Bluetooth

See ***Bluetooth*** on page 83.

Bluetooth

Use the *Bluetooth* screen to enable or disable Bluetooth connectivity, connect devices to the Masimo device using a Bluetooth connection or view connected device information. For complete information on the Masimo device Bluetooth menu, see the Operator's Manual for the Masimo device.

Option	Description	Factory Default Setting	Configurable Settings
Bluetooth	Enables or disables Bluetooth connectivity.	Off	On or Off
EMMA	Pairs Radius PCG to Root.	NA	Pair, Info*

* After paring, the Radius PCG Info screen can be accessed through the *Bluetooth* screen. See the ***Accessing the Radius PCG Info Screen*** on page 84.

About

Listed under *Capnography*, use the *About* screen to view information for the Radius PCG device. These details may be helpful during troubleshooting.

Item*	Description
Serial number	Displays the Radius PCG serial number.**
HW Version	Displays the Radius PCG hardware version number.**
SW Version	Displays the Radius PCG software version number.**
MAC address	Displays the Radius PCG Bluetooth MAC address.
Signal Strength	Displays the Radius PCG Bluetooth received signal strength indicator (RSSI).**

* These fields are read-only and cannot be configured by the user.

** Displays when Radius PCG is turned on and connected to the Masimo device.

Accessing the Radius PCG Info Screen

The following information is for viewing the Radius PCG Info screen. Radius PCG information as well as disconnecting (un-pairing) from the Masimo device are available on this screen.

To access the Radius PCG Info screen:

1. On the Masimo device, touch the Bluetooth icon on the main screen, or navigate to the *Bluetooth* screen. See ***Device Settings*** on page 83.
2. Next to *Radius PCG*, touch the information icon  . The Radius PCG Info screen displays.

Radius PCG Info

The Radius PCG Info screen displays the following information for Radius PCG:

Item*	Description
HW Version	Displays the Radius PCG hardware version number.**
SW Version	Displays the Radius PCG software version number.**
MAC address	Displays the Radius PCG Bluetooth MAC address.
Signal Strength	Displays the Radius PCG Bluetooth received signal strength indicator (RSSI).**
Forget	Press/select to disconnect the Bluetooth connection between Radius PCG and the Masimo device. See ***Disconnecting Radius PCG from the Masimo Device*** on page 85.

* These fields are read-only and cannot be configured by the user.

** Displays when Radius PCG is turned on and connected to the Masimo device.

Disconnecting Radius PCG from the Masimo Device

To disconnect Radius PCG from the Masimo device, perform the following:

1. Access the Radius PCG Info Screen. See ***Accessing the Radius PCG Info Screen*** on page 84.
2. Press/select the **Forget** button.
3. On the *Forget Device* pop-up window, press/select the **Forget** button to confirm.
   Note: Press/select the **Cancel** button to leave Radius PCG paired to the Masimo device.

Root Messages

The following section lists common Radius PCG related messages that may appear on the Masimo device, their potential causes, and next steps.

Alarm/Exception Messages	Activation	Alarm Priority	Next Steps
No Breath Detected	Indicates no breath is detected within selected apnea timeout setting.	High	• Confirm patient is properly connected to Radius PCG. • Replace the adapter or sampling line.
Replace Adapter	• Indicates that an adapter is clogged or blocked, not allowing flow. • Indicates that the adapter should be replaced.	High	Check for a blockage and replace the adapter if necessary.
No Adapter	Adapter disconnected/not detected	High	Connect an adapter to Radius PCG
Low $EtCO_2$ SIQ *Low $FiCO_2$ SIQ*	Indicates low signal confidence in the measurement displayed.	NA	Ensure patient is properly connected to Radius PCG.
Zeroing Required	A zero point adjustment is required.	High	Perform the zeroing procedure. See ***Zeroing Procedure*** on page 60.

Alarm/Exception Messages	Activation	Alarm Priority	Next Steps
Capnography Disconnected	• Radius PCG is out of Bluetooth range. • Radius PCG has turned off.	High	• Ensure Radius PCG is within Bluetooth range during operation. • Turn Radius PCG on.
Unable to handle Capnography channel on Bluetooth	Radius PCG is paired to Root and a capnography device is connected to Root through the MOC-9 connection. The *Capnography* window is populated from the MOC-9 capnography device.*	High	Only one (1) capnography device can be connected to Root at one time. Disconnect one of the capnography devices.
Unable to handle Capnography channel on MOC-9 port X (1-3)	A capnography device is connected to Root through the MOC-9 connection and Radius PCG is paired to Root. The *Capnography* window is populated from the Radius PCG.	High	Only one (1) capnography device can be connected to Root at one time. Disconnect one of the capnography devices.

* Radius PCG does not reconnect automatically after disconnecting the capnography device from the MOC-9 connection. Radius PCG must be disconnected and paired again to communicate with Root and display its data on the *Main Screen*.

Troubleshooting Radius PCG with Root

Symptom	Possible Cause	Correction
Root Bluetooth settings do not display the ability to pair Radius PCG.	Root software requires updating.	Upgrade software to V2.0.9.6 or higher.

Symptom	Possible Cause	Correction
Cannot pair Radius PCG to Masimo device.	• Masimo device Bluetooth may be off. • Radius PCG may be out of Bluetooth range with the Masimo device. • Internal failure.	• Ensure Bluetooth on the Masimo device is turned on. • Ensure Radius PCG is within range of the Masimo device when pairing. • Radius PCG requires service. See ***Service and Return Procedure*** on page 63.

Root Specifications

Display Range

Measurement	Display Range*
$EtCO_2$ (End-Tidal CO_2)	0% to 25%
	0 kPa to 32.5 kPa
	0 mmHg to 244 mmHg
$FiCO_2$ (Fractional Concentration of Inspired CO_2)**	0% to 25%
	0 kPa to 32.5 kPa
	0 mmHg to 244 mmHg
RR (Respiration Rate)	0 BPM to 150 BPM

* The display ranges in this table represent the display ranges on Root and do not represent the display ranges for Radius PCG. For Radius PCG specifications, see ***Radius PCG Specifications*** on page 43.

** $FiCO_2$ does not display on the Radius PCG device, $FiCO_2$ only displays on Root. Parameter values are not displayed.

Resolution

Parameter	Resolution
$EtCO_2$	0.1%
	0.1 kPa
	1 mmHg
$FiCO_2$*	0.1%
	0.1 kPa
	1 mmHg
RR	1 BPM

* This parameter does not display on Radius PCG.

Waveform Scale

The following table contains Capnogram waveform display ranges.

Measurement	Waveform Scale
$EtCO_2$	0 to 8 vol%
	0 to 8 kPa
	0 to 60 mmHg

Bluetooth Operational Range

Bluetooth Operational Range	
Maximum distance from Masimo Device	Approx. 32 feet (10 meters)

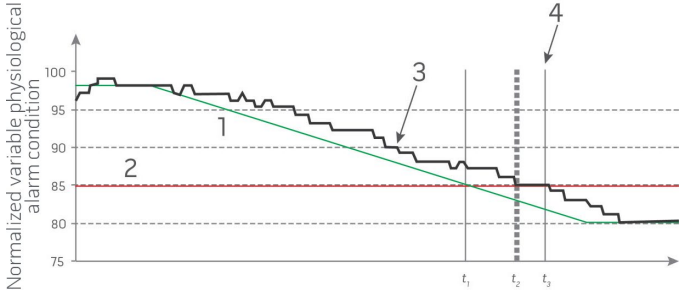
Minimum Root Software Version

Device	Specifications
Root	Software greater than v2.0.9.6

Appendix B: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

As with any monitoring equipment, the audible and visual alarms are subject to alarm response delay, which is composed of Alarm Condition Delay and Alarm Signal Generation Delay. Alarm Condition Delay is the time from the occurrence of the triggering event to when the alarm system determines the alarm condition exists. While Alarm Signal Generation Delay is the time from the onset of an alarm condition to the generation of its alarm signal. The graphic below is a simplified illustration of the concept of alarm response delay and does not reflect actual lengths of delays.



Ref	Definition	Ref	Definition	Ref	Definition
1	Instantaneous signal from the patient	3	Displayed Value	*t*	Time
2	Alarm Limit	4	Alarm Signal Generation	--	--

- The Alarm Condition Delay is graphically represented as $t_2 - t_1$ in the figure above to show the delay due to processing and averaging.
- The Alarm Signal Generation Delay is graphically represented as $t_3 - t_2$ in the figure above to show the delay due to alarm system strategy and communication time.
- The overall alarm system delay time is graphically represented as $t_3 - t_1$.

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