

Addendum

# Radical-7<sup>®</sup> Pulse CO-Oximeter<sup>®</sup> with ORi<sup>™</sup>





## Not for Sale in the USA - For Export Only

These operating instructions provide the necessary information for proper operation of all models of the Radical-7 with ORi. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Radical-7 with ORi are prerequisites for its proper use. Do not operate Radical-7 with ORi without completely reading and understanding these instructions.

**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.

**Note:** Cleared Use Only: The device and related accessories 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.

**CAUTION:** Use of this device must follow the order of a physician.

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

Wireless Radio

FCF ID: VKF-RAD7CA or VKF-RAD7A, IC: 7362A-RAD7CA or 7362A-RAD7A

Masimo Corporation  
52 Discovery  
Irvine, CA 92618, USA  
Tel.: 949-297-7000  
Fax.: 949-297-7001  
www.masimo.com

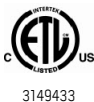


EU authorized representative for Masimo Corporation:




MDSS GmbH  
Schiffgraben 41  
D-30175 Hannover, Germany

Authorized Brazil Company Representative:  
MASIMO IMPORTAÇÃO E DISTRIBUIÇÃO DE PRODUTOS MÉDICOS LTDA  
Alameda Tangará, 80  
Salas 402 e 404 Bloco A  
Cotia – SP  
Brazil  
06711-020



MEDICAL ELECTRICAL EQUIPMENT  
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY  
IN ACCORDANCE WITH  
ANSI/AAMI ES 60601-1:2005/A1, CAN/CSA C22.2 No. 60601-1:2014, and  
applicable Particular (EN/ISO 80601-2-61:2011) and related Collateral (IEC  
60601-1-8:2006/AMD1:2012) Standards for which the product has been  
found to comply by Intertek.

Patents: [www.masimo.com/patents.htm](http://www.masimo.com/patents.htm)

®, Masimo®, Pulse CO-Oximeter®, Radical-7®, and Root® are federally registered trademarks of Masimo Corporation.

ORi™ is a trademark of Masimo Corporation. All other trademarks and registered trademarks are property of their respective owners.

© 2022 Masimo Corporation

# Addendum, Radical-7 Operator's Manual: ORi

---

This addendum provides updates to the following:

## **Operator's Manual, Radical-7**

- 35196/LAB-5476 and equivalent translations

This addendum covers the ORi feature of the Radical-7 device. For all other information, refer to the ***Operator's Manual, Radical-7***.



# Contents

---

<b>Addendum, Radical-7 Operator's Manual: ORi</b> -----	<b>3</b>
<b>Key Feature Update</b> -----	<b>3</b>
<b>Safety Information, Warnings, and Cautions</b> -----	<b>7</b>
Performance Warnings and Cautions-----	7
<b>Technology Overview</b> -----	<b>9</b>
Masimo rainbow SET® Parallel Engines -----	9
General Description for Oxygen Reserve Index (ORi) -----	9
<b>Operation</b> -----	<b>11</b>
Configuring Parameters-----	11
Parameter Settings -----	11
Visualization -----	14
<b>Messages</b> -----	<b>15</b>
ORi Messages -----	15
<b>Specifications</b> -----	<b>17</b>
Measurement Range-----	17





# Key Feature Update

---

The following added feature is available for the Radical-7:

- Oxygen Reserve Index (ORI) provides a trended index that extends oxygen monitoring in the moderate hyperoxic range.



# Safety Information, Warnings, and Cautions

---

## Performance Warnings and Cautions

**WARNING:** Optical, pleth-based measurements (e.g. SpO<sub>2</sub>, SpHb, SpOC, SpMet, SpCO, RRp, and ORi) can be affected by the following:

- Improper sensor application or use of use of incorrect sensor.
- Blood pressure cuff applied to the same arm as the sensor site.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.
- Abnormal venous pulsations (e.g. tricuspid valve regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- A physiological condition that may effect vasomotor tone or changes in vasomotor tone.

**WARNING:** Inaccurate ORi readings may be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Low arterial perfusion
- Motion artifact
- Patient attached to blood pressure cuff
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Vasospastic disease such as Raynaud's
- Peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc

- Elevated levels of Dyshemoglobin
- Patient is under Hypocapnic and Hypercapnic Conditions
- EMI radiation interference
- Birthmark(s) or skin discolorations in sensor path
- Moisture on the skin
- Deformed Fingers
- Foreign objects in the light path
- Excessive ambient light or direct sunlight
- Use of incorrect sensor type(size)
- Extreme anemia or extremely low total hemoglobin concentrations
- Severe vasoconstriction, or hypothermia
- Low ORi SIQ episodes

**WARNING:** ORi is not intended as a replacement for SpO<sub>2</sub> monitoring, PaO<sub>2</sub> monitoring, or as a sole indicator of the patient condition.

**CAUTION:** ORi may not indicate additional changes in oxygen states above 200 mmHg of PaO<sub>2</sub>.

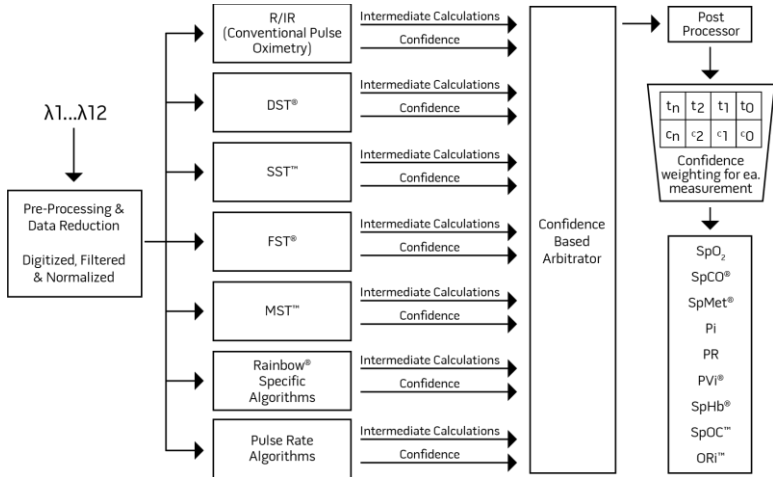
**Note:** Physiological conditions that result in loss of pulsatile signal may result in no SpO<sub>2</sub>, SpHb, SpOC, SpCO, SpMet, RRP, and ORi readings.

# Technology Overview

The following information is an addendum to be used with the content in **Chapter 1: Technology** of the *Operator's Manual, Radical-7*.

## Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



## General Description for Oxygen Reserve Index (ORi)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring changes in oxygen states in hyperoxic conditions. It relies on the same principles of pulse oximetry to make its ORi measurement.

The measurement is taken by a sensor capable of measuring ORi, usually on the fingertip for adult or pediatric patients. The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the device. The device displays the processed data as an indicator of changes in oxygen states in hyperoxic conditions.

## Successful Monitoring for ORi

A stable ORi reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See **Safety Information, Warnings, and Cautions** on page 7 and **Troubleshooting Measurements** in the *Operator's Manual, Radical-7*.



# Operation

---

The following information is an addendum to be used with the content in **Chapter 4: Operation** of the *Operator's Manual, Radical-7*.



## Configuring Parameters

Each parameter displayed on Root and Radical-7 can be configured in its respective menu on Root. Configurable options include Alarm Settings and Averaging Time.

**There are two ways to access any parameter's settings menu on Root:**

1. From the Main Screen on Root, press on any of the parameters displayed in the rainbow window to access its respective settings menu.

*Or*

2. Press the gear icon  on the bottom right-hand corner of the Main Screen on Root to access the Main Menu. Then press the rainbow tile  to access the rainbow menu. See *rainbow Parameter Settings* on page 11.

## rainbow Parameter Settings

The *rainbow* menu allows the user to view and customize settings for rainbow parameters:



### Parameter Settings

See *ORi Settings* on page 12.

## Parameter Settings



### To access any of the available parameter setting screens

1. From the *Parameter Settings* screen, to access the desired parameter, flick the on-screen icons left or right.
2. Touch the icon for ORi Settings. See *ORi Settings* on page 12.

## ORi Settings

From the *ORi Settings* screen, access any of the following options:

**ORi Alarms** on page 12.

See **About Parameter Information** in **Chapter 4: Operation** of the **Operator's Manual, Radical-7**.

**ORi Trends** on page 13.

**ORi Histogram** on page 13.

## ORi Alarms

From the *Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	0.02 to 0.99 or Off in steps of 0.01 When set to Off, alarm is disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	Off, or 0.01 to 0.98 in steps of 0.01 When set to Off, alarm is disabled.
Trending Down Alarm	Trending Down Alarm is displayed when a rapid decrease in ORI is measured.	N/A	Off	On or Off
High Caution Range*	Upper area of the display range that provides a caution indicator.	N/A	Off	Off, or 0.01 to 0.10 in steps of 0.01
Low Caution Range*	Lower area of the display range that provides a caution indicator.	N/A	Off	Off, or 0.01 to 0.10 in steps of 0.01
Silence Duration*	Temporarily suspend audible alarms for a period of time.	N/A	2 minutes	30 seconds, or 1, 2, or 5 minutes

\*Appears when docked to a Root with compatible software.



## ORi Trends

From the *Trends* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
View Trends	Allows ORi history trends to be viewed.	NA	NA
Y-Axis Max	The ORi Trend Max, indicating the highest value that will be shown.	1.00	0.01 to 1.00 in steps of 0.01
Y-Axis Min	The ORi Trend Min, indicating the lowest value that will be shown.	0.00	0.00 to 0.99 in steps of 0.01

## ORi Histogram

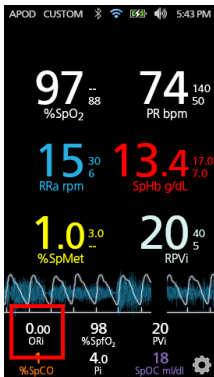
From the *Histogram* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0.00-0.20	0.00 to 0.96 in steps of 0.01
Bin 2		0.21-0.40	0.01 to 0.97 in steps of 0.01
Bin 3		0.41-0.60	0.02 to 0.98 in steps of 0.01
Bin 4		0.61-0.80	0.03 to 0.99 in steps of 0.01
Bin 5		0.81-1.00	0.04 to 1.00 in steps of 0.01

\* If one of the Bin settings is changed, all other Bin settings are effected. For example, if Bin 2 is changed to a span of 0.04 to 0.32, Bin 1 changes to a span of 0.00 to 0.03, and Bin 3 changes to a span of 0.33 to 0.60.

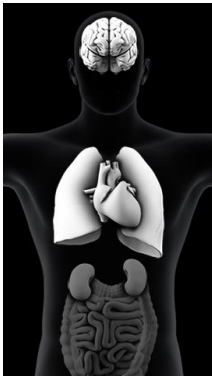
## Visualization

When stand alone or docked to RDS, ORi displays on Radical-7.



When Radical-7 is connected to Root:

- ORi parameter displays on the Root screen.
- Radical-7 provides a supplemental visualization of the alarm status for the connected Masimo medical technologies.



## Parameter Visualization Table

Alarms for various parameters and/or measurements are displayed as follows:

Parameter or Measurement	Area Displayed on Visualization Screen
ORi	Lungs

# Messages

---

The following information is an addendum to be used with the content in **Chapter 6: Alarms and Messages** of the *Operator's Manual, Radical-7*.

## ORi Messages

The following section lists ORi specific messages, their potential causes, and next steps.

Message	Potential Causes	Next Steps
<i>Low ORi SIQ</i>	<ul style="list-style-type: none"><li>Indicates low signal quality of ORi measurement.</li></ul>	<ul style="list-style-type: none"><li>Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See <b>Successful Monitoring for ORi</b> on page 9.</li></ul>



# Specifications

---

The following information is an addendum to be used with the content in **Chapter 8: Specifications** of the *Operator's Manual, Radical-7*.

## Measurement Range

Measurement	Display Range
ORi	0.00 to 1.0







[www.masimo.com](http://www.masimo.com)

38990/LAB-9665D-0422