Addendum

Radical-7® Pulse CO-Oximeter®

with Oxygen Reserve index (ORi™)

Masimo

These operating instructions provide the necessary information for proper operation of all models of the Radical-7. 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 are prerequisites for its proper use. Do not operate Radical-7 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: VFK-RAD7A or VFK-RAD7B | FCC Model: Radical-7 | IC ID: 7362A-RAD7A or 7362A-RAD7B | IC Model: VFK-RAD7A or VFK-RAD7B

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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***

Addendum, Radical-7 Operator's Manual: ORi

This addendum provides updates to the following:

Operator's Manual, Radical-7

- 301261/LAB-5475 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

Product Description, Features and Indications for Use

The Radical-7 is a noninvasive monitor that measures arterial oxygen saturation (SpO_2), pulse rate (PR), perfusion index (Pi), and Pleth Variability Index (PVi) along with optional non-invasive measurements of total hemoglobin (SpHb), carboxyhemoglobin (SpCO), total oxygen content (SpOC), methemoglobin (SpMet), Acoustic Respiration Rate (RRa), Oxygen Reserve Index (ORi), and Pleth Respiration Rate (RRp).

The Radical-7 can be used as either a Handheld or a Standalone monitor. The Radical-7 features a touchscreen that continuously displays numeric values for all parameters.

The Radical-7 provides graphical displays for plethysmographic waveform, respiratory waveform, Signal Identification and Quality Indicator (Signal IQ).

The Radical-7 can also be used to interface with a multi-parameter patient monitor to send Masimo SET pulse oximetry information to that monitor for display.

The Radical-7 has an embedded 802.11 wireless radio that can be used for connectivity.

Key Feature Update

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

- Oxygen Reserve Index (ORi), an index to be used to monitor oxygen saturation of patients on supplemental oxygen as an adjunct to SpO_2.

Indications for Use

The ORi feature is intended to be used in patients undergoing surgery as an adjunct to SpO_2 for increased monitoring resolution of elevated hemoglobin oxygen saturation levels (e.g., due to administration of supplemental oxygen).

The ORi feature is indicated for the monitoring of hemoglobin oxygen saturation levels in patients 18 years and older (adults and transitional adolescents), on supplemental oxygen during no-motion conditions perioperatively in hospital environments.

Safety Information, Warnings, and Cautions

The following information is an addendum to be used with the content in ***Safety information, Warnings and Cautions*** of the ***Operator's Manual, Radical-7® Pulse CO-Oximeter®.***

Performance Warnings and Cautions

WARNING: ORi is intended to be used with SpO_2 to provide increased specificity to elevated oxygen levels (e.g., Supplemental Oxygen). For clinical conditions where exposure to excessive oxygen can be particularly harmful, a lower targeted SpO_2 value should be used in conjunction with ORi.

WARNING: Optical, pleth-based measurements (e.g. SpO_2, PVi, SpHb, SpOC, SpMet, SpCO, RRp, and ORi) can be affected by the following:

- Improper sensor application or 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 value 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:

- Low arterial perfusion (<0.2).
- Motion induced artifact.
- Elevated COHb and/or MetHb levels.
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (Quantitative defects such as Thalassemias).
- Hypotension, severe vasoconstriction, severe anemia, or hypothermia.

WARNING: ORi is not intended as a replacement for SpO_2 monitoring, PaO_2 monitoring, or as a sole indicator of the patient's condition. ORi is to be used only when patients are receiving supplemental oxygen.

WARNING: ORi trend should be used as an adjunct to SpO_2 for patients under supplemental oxygen. A specific ORi value does not represent a specific oxygenation level. It provides a reference value in the assessment of the direction of the oxygenation of hemoglobin.

WARNING: The responsiveness of ORi may vary for each patient and even within patients depending on the clinical scenario. Therefore, the ORi trend should not be used as a replacement for other monitoring (e.g., pulse oximetry/SaO_2, ABG/PaO_2). It should be used as an adjunct.

WARNING: In the event of a rapid drop in ORi, it is important to check the oxygen delivery to the patient and other clinical signs of impaired oxygenation, including changes in patient's cardiovascular function or clinical condition.

WARNING: Oxygenation should not be titrated to a maximum ORi value. Not all patients will reach the same maximum ORi value. PaO_2 reference measurements should be used to verify hyperoxygenation status.

WARNING: An ORi value of 0.7 to 1 does not necessarily correlate with a PaO_2 value of >250 mmHg within the same subject or between subjects. This could lead directly to patient harm of desaturation when the clinician inappropriately decreases oxygen supply in the intraoperative period in the cohort of patients where PaO_2 is 250 mmHg or lower at ORi of 0.7 to 1. Concomitant use of SpO_2 by pulse oximetry with ORi is critical. Suspected hypoxemia must include check of the patient cardiopulmonary status and be verified by arterial blood analysis.

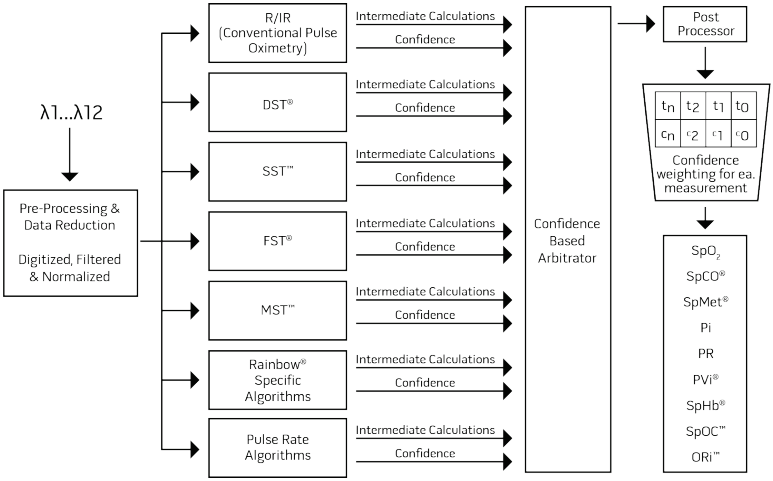
Note: Physiological conditions that result in loss of pulsatile signal may result in no SpO_2, SpHb, SpOC, SpCO, SpMet, RRp, and ORi readings.

Technology Overview

The following information is an addendum to be used with the content in ***Technology Overview*** of the ***Operator's Manual, Radical-7® Pulse CO-Oximeter®.***

Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



General Description for Oxygen Reserve Index (ORi)

ORi is a feature intended to extend monitoring resolution of hemoglobin oxygen saturation under supplemental oxygen. The feature is intended to be used in conjunction with SpO_2 monitoring provided by a pulse oximeter. The ORi feature utilizes the same principles of operation as pulse oximetry, utilizing hemoglobin wavelength absorption characteristics to determine relative blood oxygen saturation. Whereas SpO_2 monitoring provides visibility to blood oxygen saturation in the transition from normoxia to hypoxia on the hemoglobin oxygen disassociation curve, ORi provides visibility to the transition from normoxia to hyperoxia and within the moderate hyperoxic range (100-250 mmHg PaO_2). The following is the intended benefits of the ORi feature:

- Increased monitoring resolution to help increase visibility to oxygenation under supplemental oxygen.

The measurement is taken by a sensor capable of measuring ORi, on the fingertip of adult 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.

Successful Monitoring for ORi

Successful clinical use of ORi requires the use of SpO_2 and a clinician's assessment of the ORi trend. A specific ORi value is not intended to be reflective of a specific oxygenation state and will not be characteristically the same for a patient. It is to be used only when patients are provided with

supplemental oxygen. If the SpO_2 value is below 95%, the ORi value will be set to "0". When an ORi value is not able to be determined, the ORi will appear as "---" on the display. Check the sensor application to see that the emitter and detector are aligned.

In the event of a rapid drop in ORi, it is important to check the oxygen delivery to the patient and other clinical signs of impaired oxygenation, including changes in patient's cardiovascular function or clinical condition.

A stable ORi reading is associated with correct sensor placement, absence of motion, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Absence of motion does not mean that muscles need to be fully relaxed. 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 and Troubleshooting Measurements.

Operation

The following information is an addendum to be used with the content in ***Operation*** of the ***Operator's Manual, Radical-7® Pulse CO-Oximeter®.***

Accessing Main Menu Options

To access Main Menu options, press the Main Menu icon in the bottom Right corner of the touchscreen:

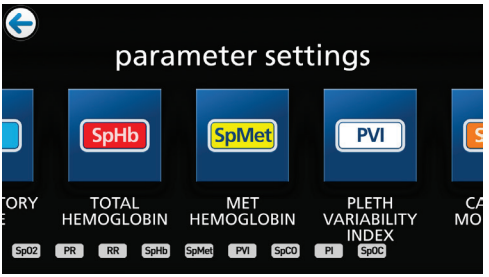
The Main Menu options are:

Parameter Settings

See Parameter Settings.

Parameter Settings

The following is an example of the *Parameter Settings* screen. Only parameters that have been loaded onto the system will be visible.



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 of the desired parameter. For details, see any of the following sections:

- See ***ORi Settings*** on page 13.

ORi Settings

From the *ORi Settings* screen, access the following screens:

ORi Alarms on page 14

ORi Histogram on page 14

Trends on page 15

See ***About Parameter Information*** in ***Operation*** of the ***Operator's Manual, Radical-7® Pulse CO-Oximeter®.***

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 0.70 or Off in increments 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.

Trends

Trend settings allow the user to configure the Y-axis maximum and Y-axis minimum for each parameter. The maximum and minimum possible values differ depending on the selected parameter. See ***Customizing Trend View*** in ***Operation*** of the ***Operator's Manual, Radical-7® Pulse CO-Oximeter®.*** for additional information.

ORi Trends

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

Options	Description	Factory Default Settings	User Configurable Settings
Y-Axis Min	The ORi Trend Min, indicating the lowest value that will be shown.	0.00	0.00 to 0.99 in increments of 0.01
Y-Axis Max	The ORi Trend Max, indicating the highest value that will be shown.	1.00	0.01 to 1.00 in increments of 0.01

Visualization

When the Radical-7 is docked to Root, the Radical-7 provides a supplemental visualization of the alarm status for the connected Masimo medical technologies.

Note: The visualization may not be visible on Radical-7 depending on the layout settings in Root. Refer to the Operator's Manual for Root for layout setting information.

Parameter Visualization Table

Monitoring and alarm status for various parameters and/or measurements are visualized using the following areas/organs on the screen:

Parameter or Measurement	Area Displayed on Visualization Screen
ORi	Lung

Messages

The following information is an addendum to be used with the content in ***Alarms and Messages*** of the ***Operator's Manual, Radical-7® Pulse CO-Oximeter®.***

ORi Messages

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

Message	Potential Causes	Next Steps
Low ORi SIQ	• Indicates low signal quality of ORi measurement.	• Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See Successful Monitoring for ORi.

Specifications

The following information is an addendum to be used with the content in ***Specifications*** of the ***Operator's Manual, Radical-7® Pulse CO-Oximeter®.***

Display Range and Display Resolution

Measurement	Display Range	Resolution
ORi (Oxygen Reserve index)	0.00 to 1.00 (Graphical)	0.01
	0.00 to 1.00 (Numeric)	0.01

ORi Specifications

Oxygen Reserve Index (ORi)		
Application Site	18 years and older	Fingertip
Response Range	18 years and older	100-250 mmHg PaO2
Predictability of Hyperoxia (AUC of ROC)	18 years and older	≥ 0.8

ORi Performance Summary

The performance of the ORi was evaluated using clinical data collected from a combination of 206 healthy volunteers and patients undergoing surgery from three datasets. One dataset included prospectively collected data from 52 healthy volunteers that underwent controlled hyperoxygenation using different supplemental oxygen levels (FiO_2). One dataset included prospectively collected data from 31 surgery patients that underwent a pre-intubation hyperoxygenation protocol. The third dataset included retrospectively analyzed convenience data collected from 133 surgical patients under supplemental oxygenation. Each dataset included PaO_2 values determined by a blood draw as a reference for the classification of hyperoxia. ORi, SpO_2, and PaO_2 data pairing was done time synchronized and PaO_2 data was captured independently. The combined dataset was analyzed for the performance of the ORi in its ability to add resolution to changes in oxygenation in the moderate hyperoxia range of 100-250 mmHg PaO_2 as compared to SpO_2.

The below Receiver Operator Curves (ROC) from the clinical study data shows the comparative oxygen responsiveness of ORi in predicting hyperoxia based upon a hyperoxia threshold of 150 mmHg PaO2 on a mix of healthy and hospitalized subjects.

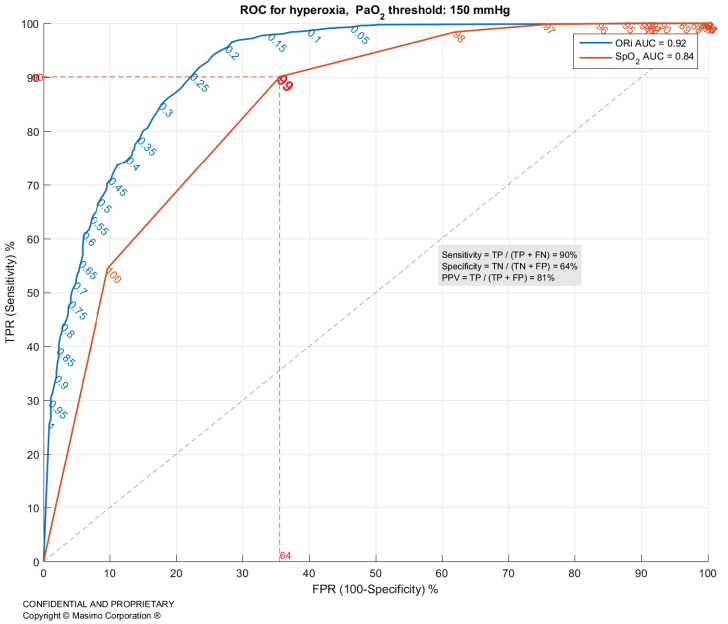


Figure 4: ROC Curve for ORi and SpO_2 for PaO_2 threshold of 150 mmHg

The study found ORi had a higher positive predictive value (PPV), greater area-under-the-curve (AUC) and enhanced incremental resolution than SpO_2 for the detection of hyperoxia. See the comparison of ORi and SpO_2 at 4 levels of PaO_2.

Hyperoxia PaO2 threshold (mm Hg)	ORI PPV (%)	SpO2 PPV (%)	ORi AUC	SpO2 AUC	ORi Threshold	SpO2 Threshold
105	98	95	0.95	0.93	0.1	98
120	97	94	0.96	0.90	0.2	99
150	88	81	0.92	0.84	0.3	99
200	62	49	0.88	0.78	0.45	99
250	38	36	0.84	0.75	0.55	100

The table below shows the comparison of the sensitivity/specificity of a 0.01 ORi threshold to that of a 96% SpO_2 threshold for hyperoxia from the validation study. The ORi and SpO_2 levels represent the minimum level used to predict hyperoxia.

Hyperoxia PaO_2 Threshold (mmHg)	ORi (≥0.01)		SpO_2 (≥96%)	
	Sensitivity	Specificity	Sensitivity	Specificity
105	95 +/- 1	86 +/- 4	100 +/- 0	37 +/- 5
120	98 +/- 1	73 +/- 4	100 +/- 0	26 +/- 4
150	100 +/- 0	48 +/- 3	100 +/- 0	16 +/- 2
200	100 +/- 0	29 +/- 2	100 +/- 0	10 +/- 2
250	100 +/- 0	24 +/- 2	100 +/- 0	8 +/- 1

The study data supported the primary endpoints of a AUC ≥ 0.8 and the improved detection as compared to SpO_2 based upon AUC and PPV.

The data also supported the secondary endpoint of ORi providing additional incremental resolution from SpO_2. See table below that shows the increased ORi range.

Hyperoxia PaO2 Threshold (mm Hg)	ORi Threshold	SpO2 Threshold
105	0.1	98
120	0.2	99
150	0.3	99
200	0.45	99
250	0.55	100
% of Range	64.3%	2%

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