

# Radical-7® Pulse CO-Oximeter® with RPi™





## 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 RPVi. 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 RPVi are prerequisites for its proper use. Do not operate Radical-7 with RPVi 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

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

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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)

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

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This addendum provides updates to the following:

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

- 35196/LAB-5476 and equivalent translations

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



# Contents

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<b>Addendum, Radical-7 Operator's Manual: RPVi</b>	<b>1</b>
<b>Key Feature Update</b>	<b>5</b>
<b>Technology Overview</b>	<b>7</b>
General Description for RPVi	7
Citations for PVi	7
<b>Operation</b>	<b>9</b>
Configuring Parameters	9
Parameter Settings	9
Visualization	11
<b>Messages</b>	<b>13</b>
RPVi Messages	13
<b>Specifications</b>	<b>13</b>
Measurement Range	13





# Key Feature Update

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

- RPVi is a continuous and noninvasive measurement of the dynamic changes in perfusion index that occur during one or more complete respiratory cycles, expressed as a percentage. RPVi is a multi-wavelength version of PVi provided with rainbow® technology.



# Technology Overview

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

## General Description for RPVi

RPVi is a continuous and noninvasive measurement of the dynamic changes in perfusion index that occur during one or more complete respiratory cycles, expressed as a percentage. RPVi is a multi-wavelength version of PVi provided with rainbow technology.

PVi may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

The utility of PVi has been evaluated in clinical studies [1-11]. Technical and clinical factors that may affect PVi include probe malposition, probe site, patient motion, skin incision, spontaneous breathing activity, lung compliance, open pericardium, use of vasopressors or vasodilators, low perfusion index, subject age, arrhythmias, left or right heart failure, and tidal volume [12-14].

## Citations for PVi

1. Cannesson M., Desebbe O., Rosamel P., Delannoy B., Robin J., Bastien O., Lehot J.J. *Pleth Variability Index to Monitor the Respiratory Variations in the Pulse Oximeter Plethysmographic Waveform Amplitude and Predict Fluid Responsiveness in the Operating Theatre.* *Br J Anaesth.* 2008 Aug;101(2):200-6.
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3. Zimmermann M., Feibicke T., Keyl C., Prasser C., Moritz S., Graf B.M., Wiesenack C. *Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery.* *Eur J Anaesthesiol.* 2010 Jun;27(6):555-61.
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10. *Feissel M., Kalakhy R., Banwarth P., Badie J., Pavon A., Faller J.P., Quenot JP. Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study. J Crit Care. 2013 Oct;28(5):634-9.*
11. *Yu Y., Dong J., Xu Z., Shen H., Zheng J. Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*
12. *Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J., Bastien O., Lehot J.J., Cannesson M. Br. J. Anaesth 2011 Sep;107(3):329-35.*
13. *Cannesson M. Arterial pressure variation and goal-directed fluid therapy. J Cardiothorac Vasc Anesth. 2010 Jun;24(3):487-97.*
14. *Takeyama M, Matsunaga A, Kakihana Y, Masuda M, Kuniyoshi T, Kanmura Y. Impact of Skin Incision on the Pleth Variability Index. J Clin Monit Comput 2011 Aug;25(4):215-21.*

# Operation

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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 9.

## rainbow Parameter Settings

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



### Parameter Settings

See **Parameter Settings** on page 9.

## 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 RPVi Setting. See **RPVi Settings** on page 9.

## RPVi Settings

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

**RPVi Alarms** on page 10.

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

**RPVi Trends** on page 10.

**RPVi Histogram** on page 10.

## RPVi Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	The High Limit is upper threshold that triggers an alarm.	Medium	Off	2 to 99, in steps of 1, or Off When set to Off, alarms are disabled.
Low Limit	The Low Limit is lower threshold that triggers an alarm.	Medium	Off	Off, or 1 to 98 in steps of 1 When set to Off, alarms are disabled.
High Caution Range*	Upper area of the display range that provides a caution indicator.	NA	Off	Off, or 1 to 10, in steps of 1
Low Caution Range*	Lower area of the display range that provides a caution indicator.	NA	Off	Off, or 1 to 10 in steps of 1
Silence Duration*	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 sec, 1, 2, 5, or 10 minutes

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

## RPVi Trends

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

Options	Description	Factory Default Settings	User Configurable Settings
View Trends	Allows RPVi history trends to be viewed.	NA	NA
Y-Axis Max	The RPVi Trend Max, indicating the highest value that will be shown.	30	1 to 100 in steps of 1
Y-Axis Min	The RPVi Trend Min, indicating the lowest value that will be shown.	0	0 to 99 in steps of 1

## RPVi Histogram

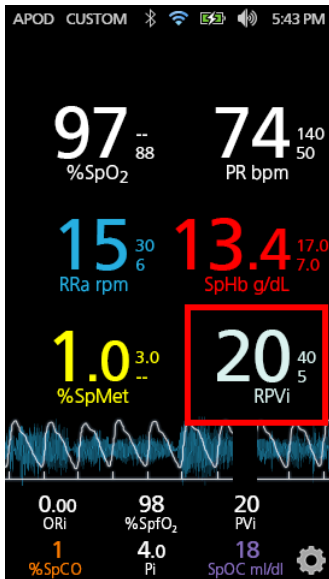
From the *Histogram* screen, change any of the following options:

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.	0-20	0 to 96 in steps of 1
Bin 2		21-40	1 to 97 in steps of 1
Bin 3		41-60	2 to 98 in steps of 1
Bin 4		61-80	3 to 99 in steps of 1
Bin 5		81-100	4 to 100 in steps of 1

\* 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 4 to 62, Bin 1 changes to a span of 0 to 3, Bin 3 changes to a span of 63 to 63, Bin 4 changes to a span of 64 to 80, and Bin 5 remains 81 to 100.

## Visualization

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



When Radical-7 is connected to Root:

**Note:** RPVi will not display on Root unless appropriate software is installed on Root. Otherwise, RPVi displays on Radical-7 when docked into Root.

- RPVi 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
RPVi	Vascular



# Messages

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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*.

## RPVi Messages

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

Message	Potential Causes	Next Steps
Low RPi SIQ	<ul style="list-style-type: none"><li>Indicates low signal quality of RPi 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.</li></ul>

# Specifications

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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
RPVi	0 to 100%







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