Addendum

Rad-97™ Pulse CO-Oximeter®
with EWS

Masimo

These operating instructions provide the necessary information for proper operation of all models of the Rad-97. 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 Rad-97 are prerequisites for its proper use. Do not operate Rad-97 without completely reading and understanding these instructions.

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.

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

CE 0123

EU authorized representative for Masimo Corporation:

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

3149433

MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005, CAN/CSA C22.2 No. 60601-1:2008, and applicable Particular (EN/ISO 80601-2-61:2011) and related Collateral (IEC 60601-1-8:2006) Standards for which the product has been found to comply by Intertek.

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

Contents

Addendum, Rad-97 Operator's Manual: Early Warning Score (EWS)

This addendum provides updates to the following:

Operator's Manual, Rad-97™ Pulse CO-Oximeter®

- 38053/LAB-9103 and equivalent translations
- 38281/LAB-9275 and equivalent translations

This addendum covers the Early Warning Score (EWS) operation of the Rad-97 device. For all other information, refer to the above listed manuals.

Safety Information, Warnings, and Cautions

Performance Warnings and Cautions

WARNING: The Early Warning Score (EWS) feature is intended to help clinicians calculate Early Warning Scores based upon established methods.

WARNING: The Early Warning Score (EWS) feature is not intended as a definitive clinical assessment of the patient condition. The result should be evaluated in conjunction with the patient's clinical status and confirmed with additional diagnostic tests consistent with each hospital's policy. Any concern about a patient's clinical condition should prompt an urgent clinical review, irrespective of EWS.

WARNING: Confirm the Early Warning Score (EWS) being used is suitable for the patient type. Certain EWS systems may exclude certain patient types (e.g. Children <16 years, pregnant women) because the physiological response to acute illness can be modified.

WARNING: Confirm the Early Warning Score (EWS) being used is suitable for the patient condition. Certain EWS systems may be unreliable on patient with certain conditions (e.g. spinal cord injury, tetraplegia, high level paraplegia) owing to functional disturbances of the autonomic nervous system.

Note: The Early Warning Score (EWS) is a static calculation based upon the captured and manually inputted parameter data at the time of the calculation request.

Operation

Early Warning Score (EWS)

The EWS is an optional feature of Rad-97 and must be configured by qualified Masimo personnel only.

Rad-97 has the ability to automate Early Warning Score (EWS) calculations based upon published standards such as National Early Warning Score (NEWS)*, Pediatric Early Warning Score (PEWS), or can be customized to match a facility's protocol.

The following information is an example of when Rad-97 is configured with National Early Warning Score (NEWS) calculations.

EWS on Rad-97 is aligned with the NEWS system established by the Royal College of Physicians* using seven (7) physiological contributors as the basis of the scoring system. Based on NEWS, each physiological contributor is scored from 0 to 3 according to the mapping from its range to a score (for example, pulse rate from 51 to 90 equates to a 0 score). All of the scores are aggregated to provide the NEWS.

The EWS feature works by automating established EWS calculations based upon all of the following contributors:

- Oxygen Saturation (SpO_2)
- Pulse Rate (PR)
- Respiration Rate (RR)
- Body Temperature (TEMP)
- Systolic Blood Pressure (SYS)
- Level of Consciousness (LOC)
- Supplemental O_2 (Sup. O_2)

Rad-97 can also be configured** to include the following additional contributors:

- Respiratory Distress (RD)
- Capillary Refill Time (CRT)

The EWS calculation can be performed one of two (2) ways:

- **EWS Calculation Using Vital Signs Check:** When in Vital Signs Check (VSC) Mode, through VSC operation. See ***EWS Calculation Using Vital Signs Check (VSC)*** on page 12.
- **EWS Calculation Using EMR Push:** When connected to Patient SafetyNet and an EMR system, through EMR Push operation. See ***EWS Calculation Using EMR Push*** on page 11.

For information on how EWS is calculated, see ***How the EWS is Calculated*** on page 10.

**Royal College of Physicians. National Early Warning Score (NEWS): Standardising the assessment of acute illness severity in the NHS.* Report of a working party. London: RCP, 2012.

***Configured by authorized personnel only.*

****The use of the trademark PATIENT SAFETYNET is under license from University Health System Consortium.*

How the EWS is Calculated

The following information is an example of when Rad-97 is configured with National Early Warning Score (NEWS) calculations. Individual EWS contributors are scored in accordance with the guidance provided from NEWS.

Note: These scores are a reflection of NEWS standards; they may not be reflective of NEWS if Rad-97 is customized.

Score/Physiological Parameters	**3***	**2**	**1**	**0**	**1**	**2**	**3***
Oxygen Saturation (SpO_2)	≤91	92-93	94-95	≥96	--	--	--
Pulse Rate (PR)	≤40	--	41-50	51-90	91-110	111-130	≥131
Respiration Rate (RR)	≤8	--	9-11	12-20	--	21-24	≥25
Body Temperature (TEMP) °C	≤35.0	--	35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	--
Body Temperature (TEMP) °F	≤95.0	--	95.1 - 96.8	96.9 - 100.4	100.5 - 102.2	≥102.3	--
Systolic Blood Pressure (SYS)	≤90	91-100	101-110	111-219	--	--	≥220
Level of Consciousness (LOC)	--	--	--	A	--	--	V, P, or U
Supplemental O_2 (Sup. O_2)	--	Yes	--	No	--	--	--

** A score of 3 is representative of an extreme variation in a single physiological parameter.*

EWS Calculation Using EMR Push

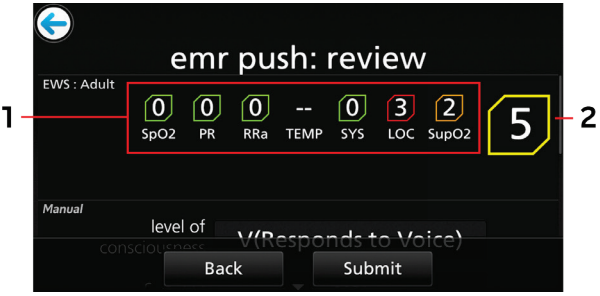
EWS Calculation when in Continuous Mode is performed through EMR Push when Rad-97 is connected to Patient SafetyNet and an EMR system and a patient is admitted.

For more information about admitting a patient and using EMR push, see ***Patient Admit/Discharge*** and ***EMR Push*** in the ***Operator's Manual, Rad-97™ Pulse CO-Oximeter®***.

1. To perform an EWS Calculation Using EMR Push, select the EMR Push icon  .
2. Manually input any EWS contributors not automatically captured.

   Note: Automatically captured data cannot be manually adjusted. Manual-entry contributors will be provided with a drop-down or slider to allow data entry.

3. Select the **Review** button. The EWS individual contributor scores (1) and EWS aggregate score (2) are displayed at the top of the *EMR Push: Review* screen.



4. Select the **Submit** button to send the data to the EMR system. The individual contributor scores and EWS aggregate score and are sent to the EMR system. Select the **Back** button to return to the *EMR Push* screen.

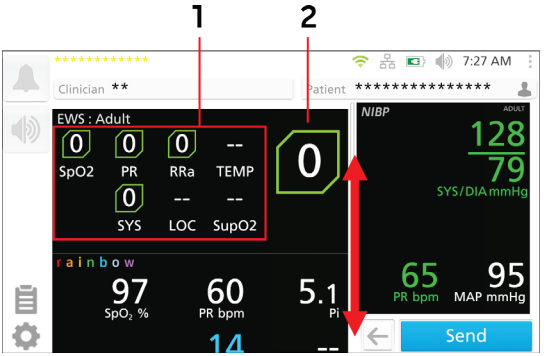
EWS Calculation Using Vital Signs Check (VSC)

When Rad-97 is in Vital Signs Check Mode, the EWS Calculation is performed when a Vital Signs Check session is saved or sent. When the Rad-97 is connected to Patient SafetyNet and an EMR system, the VSC session and EWS calculations are sent to the EMR.

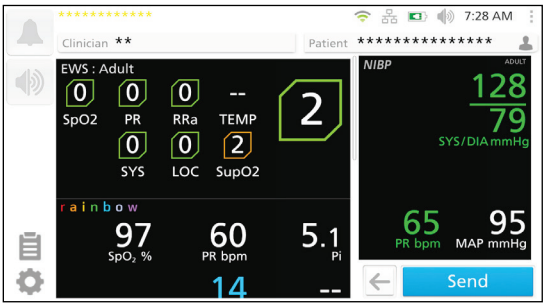
For more information about Vital Signs Check (VSC) mode and operation, see the ***Addendum, Rad-97™ Pulse CO-Oximeter® with Vital Signs Check***.

1. To perform an EWS Calculation, perform a Vital Signs Check. When complete, select the **Next** button. The EWS individual contributor scores (1) and EWS aggregate score (2) are displayed at the top of the VSC session screen. Scroll to the bottom of the VSC screen and manually input any EWS contributors not automatically captured.

   Note: Automatically captured data cannot be manually adjusted. Manual-entry contributors will be provided with a drop-down or slider to allow data entry.



   After selecting date for additional contributors, they are reflected in the EWS information.



2. Select the **Save** or **Send** button.
   - When NOT connected to Patient SafetyNet the **Save** button is displayed. The individual contributor scores and EWS aggregate score are saved in a session

on Rad-97 along with the VSC results. See ***Sessions*** in the ***Addendum, Rad-97™ Pulse CO-Oximeter® with Vital Signs Check***.

- When connected to Patient SafetyNet the **Send** button is displayed. The individual contributor scores and EWS aggregate score are sent to the EMR system along with the VSC results. A session is also saved on Rad-97.

EWS Clinical Risk Level Indicators

WARNING: The Early Warning Score (EWS) feature is intended to help clinicians calculate Early Warning Scores based upon established methods.

WARNING: The Early Warning Score (EWS) feature is not intended as a definitive assessment of the patient condition. The result should be evaluated in conjunction with the patient's clinical status and confirmed with additional diagnostic tests consistent with each hospital's policy.

Clinical risk levels are defaulted to those established by the Royal College of Physicians for NEWS.

The aggregate EWS score on Rad-97 provides the following color indicators for different clinical risk levels:

EWS Score	Clinical Risk	Aggregated Score Color
0 *or* an aggregate EWS of 1 to 4	Low	Green
Individual parameter score of 3 **or** Aggregate EWS score of 5 to 6	Medium	Yellow
Aggregate EWS of 7 or higher	High	Red

E Indicator

The *E Indicator* appears when a contributor exceeds a user defined threshold. Thresholds are customized using the Masimo Instrument Configuration Tool (MICT) by authorized personnel. When the contributor threshold is exceeded, the overall EWS score is replaced with an "E" in a red box (see screen shot below). Each contributor can be configured to have an *E Indicator*.

Troubleshooting

Troubleshooting EWS

Symptom	Possible Cause	Correction
Selecting EMR push icon does not perform EWS calculation	EWS not enabled on Rad-97.	Confirm EWS feature is enabled.
Selecting Save or Send after VSC session does not perform EWS calculation		

www.masimo.com

300596/LAB-10342B-0919