Addendum

Root®
with EWS

MASIMO

Addendum, Root Operator's Manual: Early Warning Score (EWS)

This addendum provides updates to the following:

Operator's Manual, Root®

- 37365/LAB-8425 and equivalent translations
- 37503/LAB-8542 and equivalent translations

Operator's Manual, Root® with noninvasive blood pressure and temperature

- 37705/LAB-8747 and equivalent translations
- 38280/LAB-9274 and equivalent translations

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 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.

WARNING: Confirm the Early Warning Score (EWS) being used is suitable for the patient type and conditions. Certain EWS systems may exclude certain patient types and patient conditions.

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

EWS is an optional feature of Root that can be enabled through the *Access Control* settings.

Refer to the Operator's Manual for Root or Root with noninvasive blood pressure and temperature.

Access Control

Option	Description	Factory Default Setting	Configurable Settings
EWS Enabled	Enables / disables the EWS feature. See ***Early Warning Score (EWS)*** on page 6.	Off	On or Off

Early Warning Score (EWS)

Root 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), Children's Early Warning Tool (CEWT), or can be customized to match a facility's protocol.

As a default, EWS on Root 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 is an optional feature of Root that can be enabled through the *Access Control* setting. See ***Access Control*** on page 5.

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)

Root 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:

- **Stand-Alone EWS Calculation:** When NOT connected to Patient SafetyNet*** and an EMR system, through the EWS Action Menu. See ***Stand-Alone EWS Calculation*** on page 7.
- **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 10.

For information on how EWS is calculated, see ***How the EWS is Calculated*** on page 11.

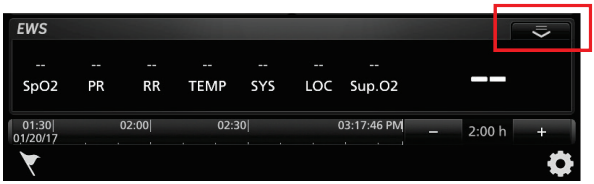
* *Royal College of Physicians. National Early Warning Score (NEWS): Standardising the assessment of acute illness severity in the NHS.* Report of a working party. London: RCP, 2012.

***Configured by authorized personnel only.*

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

Stand-Alone EWS Calculation

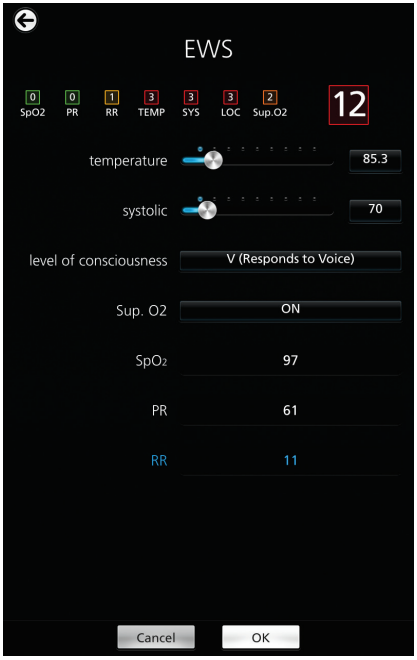
Stand-Alone EWS calculation is performed through the EWS window Action Menu.



1. To perform a Stand-Alone EWS Calculation, select the icon from the Action Menu. The Root EWS Screen will then be displayed.

2. Manually input EWS contributors not automatically captured. See ***EWS Manually Entered Contributor Settings*** on page 8 for information about settings.

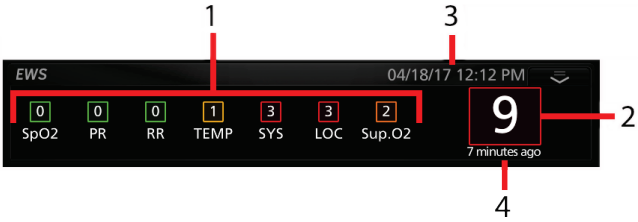
   Note: Automatically captured data cannot be manually adjusted. Manual-entry contributors will be provided with a drop-down or slider to allow data entry.



3. Select OK to display the EWS.

   The individual contributor scores (1) and EWS aggregate score (2) will appear in the EWS window of the Main Screen along with the time and date (3) the score was provided.

   Additionally, the time since the last EWS Calculation (4) was performed will appear directly below the EWS aggregate score.



Reset EWS

To reset EWS contributors, select the icon from the EWS Action Menu on the Main Screen. This will reset all EWS contributors until a new EWS calculation is performed.

EWS Manually Entered Contributor Settings

Options	Description	Factory Default Settings	User Configurable Settings
RR*	Respiration Rate	--	-- and 1 to 70 in increments of 1
Temperature**	Patient temperature measurement	--	-- and from 80.1°F to 110.0°F in increments of 0.1 -- and from 26.8°C to 43.3°C in increments of 0.1
Systolic**	Patient systolic measurement	--	-- and 41 to 260 in increments of 1
Level of Consciousness	Patient level of Consciousness	--	--, A (Alert), V (Responds to Voice), P (Responds to Pain), or U (Unresponsive)

Options	Description	Factory Default Settings	User Configurable Settings
Sup. O_2	Supplemental oxygen	--	Supplemental Oxygen settings: --, On, or Off
	Flow rate provided to patient	--	Flow Rate settings: --, Off, 1/4 L/min to 15 L/min in increments of 1/4 L/min.
Respiratory Distress (RD)	Assessment of the severity of difficulty breathing	--	--, Nil, Mild, Moderate, and Severe
Capillary Refill Time (CRT)	Time taken for color to return to an external capillary bed after the application of pressure to the point of blanching	--	--, 1 to 4 sec in increments of 1 sec

* Displays when device or sensor is not connected to Root.

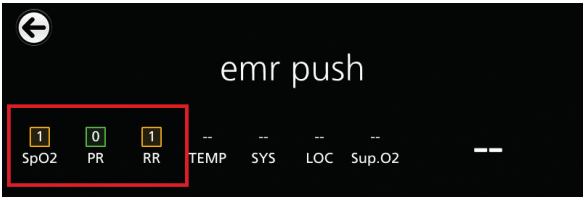
** Not displayed if a temperature/blood pressure measurement is taken using Root with noninvasive blood pressure and temperature.

EWS Calculation Using EMR Push

EWS Calculation Using EMR Push is performed through the EMR Push icon when the Root is connected to Patient SafetyNet and an EMR system.

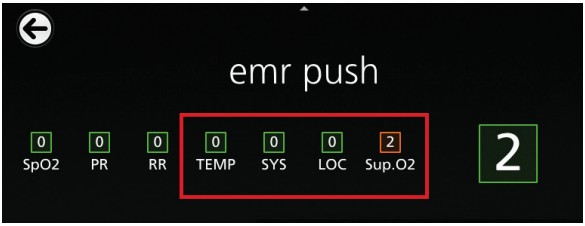
For more information about EMR push, see ***Sending Data to the EMR*** in the ***Operator's Manual, Root® with noninvasive blood pressure and temperature*** or in the ***Operator's Manual, Root®***.

1. To perform an EWS Calculation Using EMR Push, select the EMR Push icon from the Action Bar. The Root EMR Push Screen will then be displayed with automatically captured contributor settings.



2. Manually input EWS contributors not automatically captured.

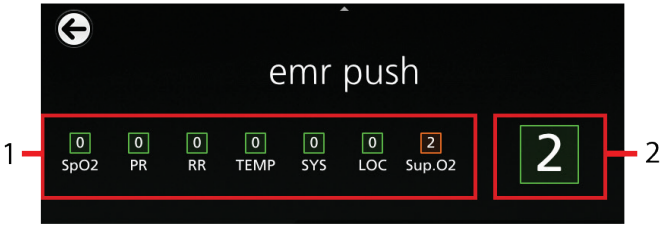
   See ***EWS Manually Entered Contributor Settings*** on page 8 for information about settings.



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

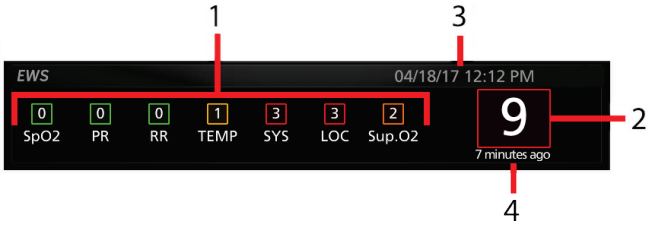
   See EMR Push Manual-Entry Item Settings in the ***Operator's Manual, Root® with noninvasive blood pressure and temperature*** or in the ***Operator's Manual, Root®***. for information about settings.

The EWS individual contributor scores (1) and EWS aggregate score (2) will be displayed at the top of the EMR Push screen.



The individual contributor scores (1) and EWS aggregate score (2) will also appear in the EWS window of the Main Screen along with the time and date (3) the score was provided.

Additionally, the time since the last EWS Calculation (4) was performed will appear directly below the EWS aggregate score.



How the EWS is Calculated

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 Root 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	--

Score/Physiological Parameters	3*	2	1	0	1	2	3*
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 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 Root provides the following color indicators for different clinical risk levels:

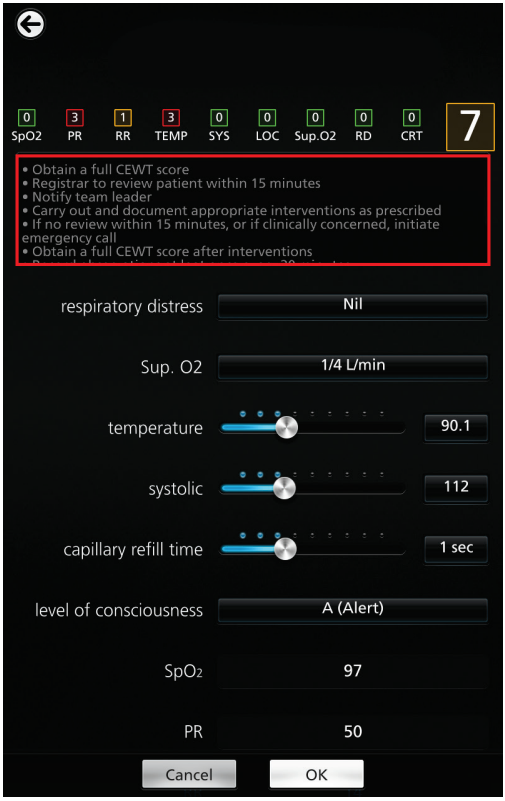
EWS Score	NEWS Clinical Risk	Aggregated Score Color
0 *or* an aggregate EWS of 1 to 4	Low	Green
Individual parameter score of 3 or Aggregate EWS score of 5 to 6	Medium	Yellow
Aggregate EWS of 7 or higher	High	Red

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*.

EWS Prompt Window

The EWS prompt window displays customized messages based on a calculated score to prompt clinician for next steps. Messages can be customized according to hospital protocol using MICT by authorized personnel.



Troubleshooting

Troubleshooting EWS

Symptom	Possible Cause	Correction
EWS Action Menu does not display on Root	Root has become disconnected from Patient SafetyNet.	Power cycle Root to display the EWS Action Menu.
	EWS not enabled on Root.	Confirm EWS feature is enabled in the Access Control Menu.
Selecting EMR push icon does not perform EWS calculation	EWS not enabled on Root.	Confirm EWS feature is enabled in the Access Control Menu.

THIS PAGE INTENTIONALLY BLANK

www.masimo.com

38747/LAB-9529C-0717