

PHILIPS

Efficia CM Series
Patient Monitors
with Masimo®

Release 4.0

English



Instructions for Use

Efficia CM Series with Masimo®

Instructions for Use

Release 4.0

English

PHILIPS

Notice

Document Number
453564915841 Revision B

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In this context “member state” refers to European Economic Area (EEA) countries including Switzerland and Turkey.

Printing History

New editions of this document incorporate all material updated since the previous edition. Update packages may be issued between editions and contain replacement and additional pages to be merged by a revision date at the bottom of the page. Pages that are rearranged due to changes on a previous page are not considered revised.

The documentation printing date and part number indicate its current edition. The printing date changes when a new edition is printed. (Minor corrections and updates that are incorporated at reprint do not cause the date to change.) The document part number changes when extensive technical changes are incorporated.

First Edition July 2020
Second Edition June 2021

Conventions

This section describes the conventions used in this guide.

Text Formatting

The following typographical conventions are used in this guide:

Typeface	Usage	Example
Bold	System keys	Press the Main Screen key.
Special bold	User interface text	Open the System Menu.
<i>Italic</i>	Variables, document titles	• <i><product name>-<hardware configuration>-<software version>.cfg</i> • <i>Efficia CM Series Instructions for Use</i>

Decimal Points

Because the Efficia CM Series monitor uses a period (.) to indicate a decimal point in decimal numbers (for example, 10.0), all decimal numbers in this guide use a period as a decimal point. Commas are not used as decimal points.

Notes, Cautions, and Warnings

This guide uses the following conventions for Notes, Cautions, and Warnings.

Note — *A Note calls attention to an important point in the text.*

Caution A Caution calls attention to a condition or possible situation that could damage or destroy the product or the user's work.

Warning A *Warning* calls attention to a condition or possible situation that could cause injury to the user and/or patient.

Explanation of Symbols

This section explains the symbols that appear on the monitor and its packaging.

Product labels have been redesigned to include UDI information, as required by USA regulation. The UDI label contains a device identifier (DI) and a production identifier (PI). The identifiers are machine and human readable.

- The Device Identifier (DI) is a unique GSI GTIN-12 number that has been registered with the US FDA.
- The Production Identifier (PI) is a combination of Lot or Batch Number, Manufacturing Dates, Serial Number and/or Expiration Date, as applicable for the device.

Note: *The symbols that appear on your monitor depend on the monitor model and its configured options.*

Documentation Safety Symbols

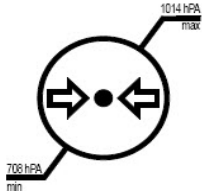
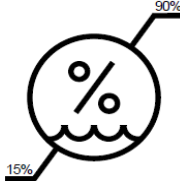
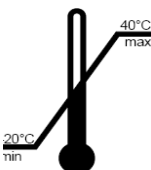
The following safety symbols advise you to read the *Instructions for Use*.

Sign	Description	Standard/Reference
	Refer to the <i>Instructions for Use</i> (Blue safety sign)	ISO 7010* M002
	Consult the <i>Instructions for Use</i>	ISO 15223-1 5.4.3 ISO 7000-1641; IEC 60601-1
	Electronic copy of the <i>Instructions for Use</i> is available at www.philips.com/ifu	ISO 7000 IEC 60601-1

Packaging Symbols

The following symbols appear on the monitor's packaging.

Symbol	Name	Standard/Reference
	This way up	International Air Transport Association, 405B
* ISO 7000 Graphical symbols for use on equipment – Registered symbols ** ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements		

Symbol	Name	Standard/Reference
	Fragile, handle with care	ISO 15223-1** 5.3.1
	Stacking limit by number	ISO 7000** 2403
	Atmospheric pressure range for transport and storage	ISO 15223-1* 5.3.9
	Relative humidity range (non-condensing) for transport and storage	ISO 15223-1* 5.3.8
	Ambient temperature range (non-condensing) for transport and storage	ISO 15223-1* 5.3.5
	Keep dry	ISO 15223-1* 5.3.4
	CE mark: Product meets the requirements of the EU MDR regulation 2017/745	European Union Medical Device Regulation 2017/745
	Recycling	Universal Recycling Symbol
* ISO 7000 Graphical symbols for use on equipment – Registered symbols ** ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements		

Symbol	Name	Standard/Reference
	Medical Device symbol	NA
* ISO 7000 Graphical symbols for use on equipment - Registered symbols ** ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements		

User-Control Symbols

The following symbols appear on and near the user-control buttons on the front of the monitor.

Symbol	Name	Standard/Reference
	On/Standby key	IEC 60417* 5009
	AC power LED	IEC 60417* 5032
	Charging LED	IEC 60417* 5546
	Alarm silence key	IEC 60417* 5576 IEC 60417* 5039
	NBP key	NA
	Freeze Waveform key	NA
	Record key**	NA
	Trend key**	IEC 60417* 5847
	Home Key**	NA
* IEC 60417 Graphical symbols for use on equipment ** CM10 and CM12 monitors only		

Measurement Connector Symbols

The following symbols appear next to measurement connectors on the side of the monitor.

Symbol	Name	Standard/Reference
	Gas input connector	ISO 7000***-0794
	Gas output connector	ISO 7000***-0795
CO₂	CO ₂ connector	NA
	Defibrillation-proof type CF applied part	IEC 60417* 5336
ECG	ECG connector	NA
SpO₂	SpO ₂ connector	NA
	NBP connector	NA
	Caution	ISO 15223-1** 5.4.4
IBP 1 IBP 2	IBP connectors	NA
	Temperature connectors	ISO 7000*** 0034
	Masimo SET® and rainbow (red and black symbol)	NA
	Nellcor OxiMax™ symbol	NA
* IEC 60417 Graphical symbols for use on equipment ** ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements *** ISO 7000 Graphical symbols for use on equipment – Registered symbols		

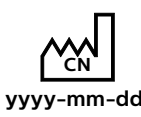
Input/Output Connector Port Symbols

The following symbols appear next to the input/output ports on the rear panel of the monitor.

Symbol	Name	Standard/Reference
	Nurse call connector	IEC 60417* 5336 IEC 60417* 5035
	VGA Output	NA
	ECG Output	NA
	Ethernet port	NA
	USB port	NA
* IEC 60417 Graphical symbols for use on equipment		

Rear Panel Label Symbols

The following symbols appear on the rear panel label of the monitor.

Symbol	Name	Standard/Reference
	Medical Device symbol	NA
	Catalogue number	ISO 15223-1* 5.1.6
	Serial number	ISO 15223-1* 5.1.7
	Monitor key code	NA
	Manufacturer	ISO 15223-1* 5.1.1
	Country and Date of Manufacture	ISO 15223-1* 5.1.3
	RF interference	IEC 60417** 5140
	RCM Mark	Regulatory Compliance Mark for electrical safety, EMC, EME, and telecommunication
	Compliance with WEEE standard	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
Input power and fuse rating 100V-240V ~ 50Hz/60Hz 120VA  2xT 1.6 AL 250V		IEC 60417** 5016
* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements ** IEC 60417 Graphical symbols for use on equipment		

Symbol	Name	Standard/Reference
	Unique Device Identification (UDI) barcode	NA
	Option number	NA
Rx Only	Prescription Use Only (US Federal Law)	21 CFR 801.109(b)(1) Prescription Devices
IPX1	Ingress protection against vertically falling water drops	IEC 60529, Ed. 2.2 Degrees of protection provided by enclosures (IP Code), section 6
	Caution	ISO 15223-1* 5.4.4
	SGS mark	SGS North America Listed Mark
	CE mark CE0123: Product meets the requirements of the EU MDR regulation 2017/745.	European Union Medical Device Regulation 2017/745 The radio device used in the Efficia CM10, CM12, CM100, CM120, and CM150 monitors is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU (Radio Equipment Directive).
	Equipotential grounding post	IEC 60417** 5021
	Part number for label	NA
* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ** IEC 60417 Graphical symbols for use on equipment		

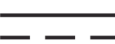
Internal Symbols/Signs

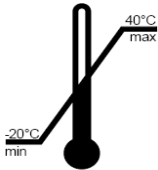
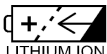
The following symbols are located inside the monitor.

Symbol	Name	Standard/Reference
	Protective earth (ground)	IEC 60417* 5032
	Dangerous Voltage (Yellow safety sign)	ISO 7010**, W012
* IEC 60417 Graphical symbols for use on equipment ** ISO 7010 Graphical symbols – Safety colors and safety signs – Registered safety signs		

Battery Symbols

The following symbols are located on the monitor batteries:

Symbol	Name	Standard/Reference
	CE mark: Product meets the requirements of the EU MDR regulation 2017/745.	European Union Medical Device Regulation 2017/745
	Catalog number	ISO 15223-1* 5.1.6
	Serial number	ISO 15223-1* 5.1.7
	Date of manufacture	ISO 15223-1* 5.1.3
	Batch code	ISO 15223-1* 5.1.5
	Direct current	IEC 60417** 5031
* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ** IEC 60417 Graphical symbols for use on equipment		

Symbol	Name	Standard/Reference
	Temperature limit	ISO 15223-1* 5.3.5
	Lithium-ion Charge Before Use	NA
	Lithium-ion Recycling mark	Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators
	Do not dispose of this product (or any parts of it) in industrial or domestic waste. The system may contain materials or hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information. It is advisable to contact your service personnel before disposing of this product.	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
	Administrative Measure on the Control of Pollution Caused by Electronic Information Products, Chinese Ministry of Information Industry,	2006-02-28, Decree No. 39
	Product is certified to meet all applicable standards requirements.	IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements ** IEC 60417 Graphical symbols for use on equipment		

Symbol	Name	Standard/Reference
	Product is certified to meet all applicable standards requirements.	IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
	Meets safety requirements for portable sealed secondary cells for use in portable applications.	CNS 15364 Bureau of Standards, Metrology and Inspection of China
	Product complies with Japan's Electrical Appliance and Material Safety Law.	Ministry of Economy, Trade and Industry of Japan
	Complies with FCC standards for home or office use.	47 CFR 15.19 (a)(3)
	Product meets requirements for certification by the Bureau of Indian Standards.	IS 16046 Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes -- Safety Requirements for Portable Sealed Secondary Cells, and for Batteries made from them, for use in Portable Applications.
* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ** IEC 60417 Graphical symbols for use on equipment		

Accessory Symbols

The following symbols are located on the accessory packaging or on the accessory itself.

Symbol	Description	Standard/Reference
	CapnoTrak Contains or Presence of Phthalate	n/a

Symbol	Description	Standard/Reference
	Single Use	n/a
IPX4	Ingress protection against splashing water	IEC 60529, Ed. 2.2 Degrees of protection provided by enclosures (IP Code), section 6
IP44	Ingress protection against solid foreign objects of 1.0 mm diameter and against splashing water	IEC 60529, Ed. 2.2 Degrees of protection provided by enclosures (IP Code), section 6

Regulatory and Safety Specifications

Declaration



The Efficia CM10, CM12, CM100, CM120, and CM150 monitors comply with the requirements of the European Union Medical Device Regulation 2017/745, and carry CE-marking accordingly.

The radio device used in the Efficia CM10, CM12, CM100, CM120, and CM150 monitors is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU (Radio Equipment Directive).

Warning

The EU REACH Regulation 1907/2006 requires Philips to provide chemical content information for Substances of Very High Concern (SVHC), if they are present in the relevant article above a concentration of 0.1% weight by weight.

Information on substances, contained in the Philips products, can be found on the Philips REACH website: www.philips.com/REACH.

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Este produto contém a placa MSD45N:
código de homologação ANATEL 05111-21-10188

Rx only

Caution

United States Federal Law restricts this device to sale by or on the order of a physician.

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1

Overview

This guide describes how to operate the Masimo SET[®] and Masimo rainbow[®] SET options on the Efficia CM10, CM12, CM100, CM120, and CM150 patient monitors. It also includes safety information, specifications, alarm messages, and a list of compatible accessories.

For detailed information on operating the Efficia CM Series monitors and troubleshooting problems, see the *Efficia CM Series Patient Monitors Instructions for Use*.

For proper placement of your Masimo[®] sensor or reusable sensor, and cleaning instructions, see the *Instructions for Use* included in the sensor box.

Notes

- The Masimo SET[®] option is available on the Efficia CM10, CM12, CM100, CM120, and CM150 patient monitors. The Masimo rainbow[®] SET option is only available on the Efficia CM100, CM120, and CM150 patient monitors. These options are not available in all countries.
 - This document includes information on functions and features which may not be available on all Efficia CM Series patient monitors or may be available only in selected regions. For information specific to your region, please contact your local Philips representative.
-

Intended Purpose

The device is intended to be used for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates.

Intended Use

The device is intended for monitoring, analysis, recording and alarming of multiple physiological parameters for adult, pediatric and neonatal.

Indications for Use

The Efficia CM10, CM12, CM100, CM120 and CM150 patient monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring, analysis, recording and alarming of multiple physiological parameters in healthcare environments for the patient types listed below.

Standard and optional parameters include:

Parameter	Patient Types		
	Adult	Pediatric	Neonatal
ECG	✓	✓	✓
Respiration - Impedance	✓	✓	✓
Respiration - awRR	✓	✓	✓
Respiration - RRa	✓		
NBP	✓	✓	✓
SpO ₂	✓	✓	✓
SpHb	✓	✓	
SpCO	✓	✓	
Temperature	✓	✓	✓
CO ₂ - mainstream	✓	✓	✓
CO ₂ - Sidestream	✓	✓	✓
IBP	✓	✓	✓
Cardiac Output	✓	✓	
Arrhythmia - Cardiotach	✓	✓	✓
Arrhythmia (Basic)	✓	✓	
Arrhythmia (Enhanced)	✓	✓	
ST Segment analysis	✓		
QT/QTc	✓	✓	✓
GAS	✓	✓	✓
BISx/BISx4 Parameters	✓	✓	

Use Environment

- Intended for monitoring, analysis, recording and alarming of multiple physiological parameters in healthcare environments.
- Additionally, the monitor may be used in transport situations within a healthcare facility.
- Transport outside the healthcare facility is considered misuse.

User Profile

The Efficia CM Series patient monitors are intended for use by healthcare professionals.

Patient Population

The Efficia CM Series patient monitors are intended for adult, pediatric and neonatal patients.

Essential Performance

Under normal operating conditions, the Efficia CM patient monitors can acquire and display information for each measurement, provide detection and notification of life-threatening physiological alarm conditions in the form of audible and visual alarm signals, and indicate when the described functionality is inoperative.

Normal operating conditions include electromagnetic interference, which is deemed a typical characteristic of the clinical environment.

The useful life of the Efficia CM patient monitors is expected to be 10 years.

Monitor Configurations

The Efficia CM patient monitors include standard and optional features, based on the model.

The following table lists the five models, the standard features in each model, as well as optional features. In the table, a solid circle indicates a standard feature, a hollow circle indicates an optional feature, and NA indicates the feature is not available for that model.

	CM100 863300	CM10 863301	CM120 863302	CM12 863303	CM150 863304
Philips NBP	•	•	•	•	•
NBP Venous Puncture	○	○	○	○	○
Philips SpO ₂	•	•	•	•	•
Masimo SET SpO ₂ ¹	○	○	○	○	○
Masimo Rainbow ¹	○	NA	○	NA	○
Nellcor OxiMax™	○	○	○	○	○
3/5-Lead ECG sets	•	•	•	•	•
10-Lead ECG sets	NA	NA	○	○	○
Basic Arrhythmia Analysis	•	•	•	•	•
Enhanced Arrhythmia Analysis	○	○	○	○	○
ST Analysis	•	•	•	•	•
ST Map	NA	NA	•	○	•
Impedance Respiration	•	•	•	•	•
IBP (2 channels)	○	○	○	○	○
Continuous Temperature (2 channels)	•	•	•	•	•

	CM100 863300	CM10 863301	CM120 863302	CM12 863303	CM150 863304
Full disclosure	o	o	o	o	o
Medtronic Microstream CO ₂	o	o	o	o	o
Respironics CapnoStat Mainstream CO ₂	o	o	o	o	o
Respironics Mainstream LoFlo CO ₂	o	o	o	o	o
Respironics CapnoTrak Sidestream CO ₂	o	o	o	o	o
Cardiac Output	NA	NA	o	o	o
QT/QTc	•	•	•	•	•
Pulse Pressure Variation	•	•	•	•	•
Early Warning Scores	o	o	o	o	o
Calculators: Drug, Hemodynamic, Oxygen and Renal (Standard for Rel 4.0 and higher)	o	o	o	o	o
Pulmonary Artery Wedge invasive pressure (PAWP) (bundled with Cardiac Output)	NA	NA	o	o	o
OxyCRG	•	•	•	•	•
OxyCRG Trend (saves up to 48 hours of OxyCRG waveforms) (bundled with Full Disclosure option)	o	o	o	o	o
Bed to Bed	•	•	•	•	•
Touch screen	•	o	•	o	•
Default number of waveforms displayed. Requires touch screen.	8	8	8	12	12
Barcode scanner for patient ID entry	o	o	o	o	o
Recorder	o	o	o	o	o
Video output	•	•	•	•	•
ECG output	•	o	•	•	•
Wireless connectivity to EMR	o	o	o	o	o
HL7 Data Export	•	o	•	o	•
Night Mode	•	•	•	•	•
Efficia Central Station connectivity ²	•	•	•	•	•

	CM100 863300	CM10 863301	CM120 863302	CM12 863303	CM150 863304
Dual battery capability	NA	NA	•	•	•
Efficia Rack and Modules Connectivity ³	NA	NA	•	•	•
Monitor ADT Interface with IBE	o	NA	o	NA	o

¹. Masimo SET and Masimo Rainbow may not be available in all countries.

². The Efficia Central Station may not be available in all countries. Efficia CM series monitors only connect to the Efficia Central Station. For detailed information, see the Efficia Central Station Instructions for Use.

³. The Efficia Rack and Modules may not be available in all countries.

Masimo options

	Efficia Patient Monitors				
Parameter	CM10	CM12	CM100	CM120	CM150
Masimo SET SpO ₂	✓	✓	✓	✓	✓
Masimo Rainbow SpHb/SpOC*			✓	✓	✓
Masimo Rainbow SpCO*			✓	✓	✓
Masimo Rainbow RRa*			✓	✓	✓

**Optional feature*

Caution

Rx Use Only

Efficia CM Series Patient Monitors Documentation

Efficia CM Series documentation includes:

- *Efficia CM Series Patient Monitors Instructions for Use*: Provides information for day-to-day operation of the Efficia CM Series monitors. Also includes safety information, monitor specifications, and a list of compatible accessories.

Note — *For information about purchasing additional copies of the Efficia CM Series Patient Monitors Instructions for Use, contact the Philips Customer Care Center.*

- *Efficia CM Series Patient Monitors Installation and Configuration Guide*: Provides instructions for unpacking, installing, and connecting all hardware. Includes initial testing and configuration procedures. Also includes instructions for returning the monitor.
- *Efficia CM Series Patient Monitors Quick Cards*: Provides brief descriptions of commonly used Efficia CM Series functions.
- *Efficia CM Series Patient Monitors Service Guide*: Provides instructions for testing the monitor. Includes assembly diagrams, spare parts lists and troubleshooting information.
- *Efficia CM Series Patient Monitors Repair Guide*: Provides instructions for repairing the monitor. Includes assembly diagrams, spare parts lists and troubleshooting information.
- *Efficia CM Series Patient Monitors Data Export Guide*: Provides detailed information about the syntax and structure of the HL7 messages that are exported from the CM Series monitors.
- *Efficia CM Series Patient Monitors Network Configuration Guide*: Provides instructions for configuring your CM Series monitor to connect to a network using a wired LAN connection, a wireless LAN connection, or an RS-232 serial adapter.

Monitoring SpO₂ and Respiration

This chapter describes how to use the optional Masimo module to measure oxygen saturation (SpO₂) and pulse rate, along with optional measurements of Acoustic Respiration Rate (RRa™), total hemoglobin (SpHb®), total oxygen (SpOC), and Carboxyhemoglobin (SpCO). The Masimo measurements available on your monitor depend on the options selected at the time of purchase.

Masimo SET® provides the following information:

- SpO₂ value — The percentage of oxygen saturation within the blood
- SpO₂ (pleth) waveform
- Pulse rate value — The arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm)
- Perfusion Index — Indicates the arterial pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal

In addition to the options listed above, Masimo rainbow® options also include:

- SpHb — The total hemoglobin concentration in arterial blood
- RRa — An acoustic respiration rate
- RRa waveform
- SpOC — The total oxygen content present in the blood
- SpCO — The percentage of Carboxyhemoglobin in the blood

Caution

Use caution when selecting which respiration measurement options to observe, since each measurement may have different values.

Notes

- *Masimo rainbow® comes in the following three option packages. The options you get depend on the packages you order:*
 - *SET plus SpHb and SpOC*
 - *SET plus SpCO*
 - *SET plus RRa*
 - *Masimo rainbow® options require that you must also have Masimo SET®.*
 - *Masimo RRa is not available for pediatric patients. Other Masimo measurement options might not apply to all patient types; adult, pediatric, and neonatal. For more information, refer to the Intended Use and Indications for Use section of the Efficia CM Series Patient Monitors Instructions for Use.*
 - *SpHb and SpCO are not supported for neonatal patients.*
 - *Pulse oximeter equipment is calibrated to display functional oxygen saturation.*
-

Selecting a Sensor

The sensors you require depend on the Masimo measurements available on your monitor. When selecting a sensor, consider the patient's weight and activity level, adequacy of perfusion, availability of sensor sites, need for sterility, and anticipated duration of monitoring.

For complete information on applying a sensor, see the directions for use provided with your sensor.

For a list of compatible Masimo sensors, see Chapter 3, "Accessories List."

Note — *All sensors must be obtained from Masimo.*

Connecting SpO₂ Cables

If the sensor uses an adapter cable, plug the sensor into the adapter cable, and then plug the adapter cable into the SpO₂ input connector on the side panel. For detailed instructions, see the directions for use provided with the sensor.

SpO₂ input
connector

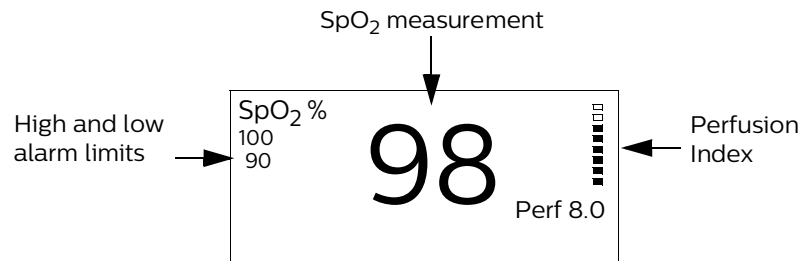


Warnings

- Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.
 - Do not attempt to reprocess, recondition or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to harm.
-

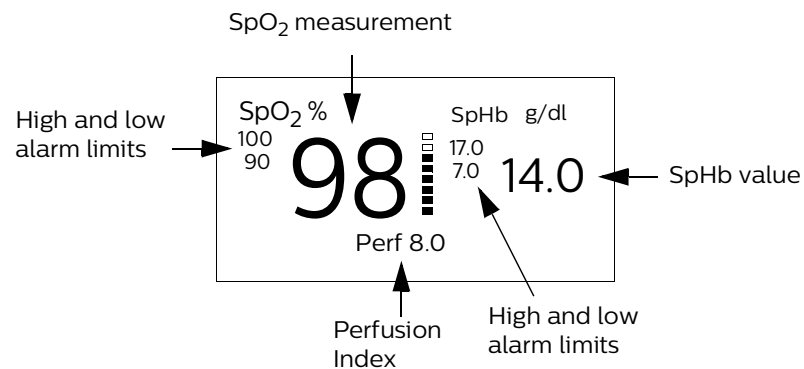
The SpO₂ Numeric Pane

The following illustration shows the components of the SpO₂ numeric pane in a monitor with the Masimo SET option.



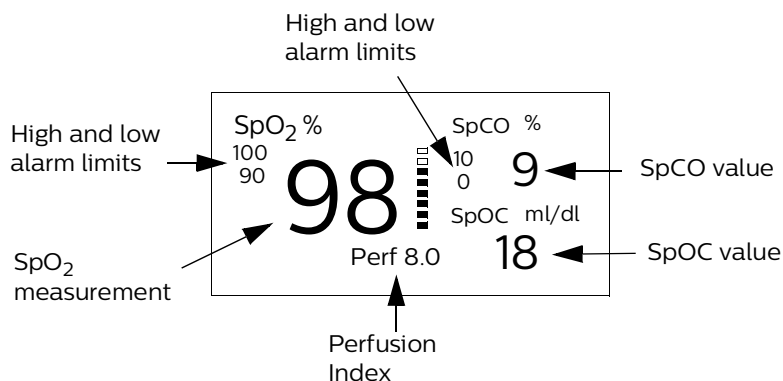
The next illustrations show the components of the SpO₂ numeric pane in a monitor with the Masimo rainbow SET option enabled for SpHb, SpOC, and SpCO. Although they are on the same pane, the illustrations show that the right side of the pane changes, alternating the SpHb and SpOC/SpCO displays.

The following illustration shows the right side of the SpO₂ numeric pane when SpHb is displayed.



If there is not enough space to display all available SpO₂ values, the SpO₂ values will rotate every 3 seconds.

The following illustration shows the right side of the SpO₂ numeric pane when SpOC and SpCO are displayed.



Perfusion Index

The Perfusion Index (PI) gives an indication of perfusion at the monitoring site. PI is a relative number and varies between monitoring sites and from patient to patient, as physiological conditions vary. When placing a sensor, you can use PI to quickly evaluate the application site that has the best perfusion.

In the SpO₂ numeric pane, an eight-segment bar represents the PI. The color of the bar indicates the strength of perfusion at the monitoring site. If the perfusion is strong, the bar turns blue. If the perfusion is weak, the bar turns red and a **PulseOx Low Perfusion Index** message appears in the message pane.

The following table describes the number and color of solid segments in the bar and the corresponding PI.

Perfusion Index	Segments
0%	No solid segments, the entire bar is red.
≤ 0.5%	1 solid red segment, the entire bar is red.
≤ 1.0%	1 blue
≤ 2.0%	2 blue
≤ 3.0%	3 blue
≤ 4.0%	4 blue
≤ 6.0%	5 blue
≤ 8.0%	6 blue
< 10.0%	7 blue
≥ 10.0%	8 blue

Changing SpO2 Settings

Use the **SpO₂ Menu** to:

- Change the SpO₂, SpHb, and SpCO alarm limits
- Configure additional SpO₂ settings
- Configure SpHb settings (if available on the monitor)
- Add perfusion indication
- View delay settings set by your administrator

To open the **SpO₂ Menu**:

- Select the SpO₂ numeric pane.

The **SpO₂ Menu** appears and current settings are displayed.

Changing the SpO2, SpHb and SpCO Alarm Limits

For information on changing the SpO₂, SpHb, and SpCO alarm limits, see the *Efficia CM Series Patient Monitors Instructions for Use*.

The SpO₂, SpHb, and SpCO default alarm limits are:

Alarm Limits	Adult	Pediatric	Neonatal
SpO ₂ high limit	100%	100%	95%
SpO ₂ low limit	90%	90%	85%
SpHb high limit	17.0 g/dl (10.6 mmol/l)	17.0 g/dl (10.6 mmol/l)	NA
SpHb low limit	7.0 g/dl (4.3 mmol/l)	7.0 g/dl (4.3 mmol/l)	NA
SpCO high limit	10%	10%	NA
SpCO low limit	0%	0%	NA

Caution

SpHb and SpCO monitoring is for Adult and Pediatric patients only. Neonatal patients are not supported.

Changing the SpO2 Averaging Time

Note — *SpOC is calculated and displayed and does not have limits.*

Use the **SpO₂ Averaging** option to select the length of time over which subtle variations in the SpO₂ value are measured and averaged.

Fast averaging is useful for situations where an extremely fast measurement is required or few artifacts are expected. Use slow averaging if you expect the number of artifacts to be relatively high.

Select **8 seconds** for most monitoring situations.

To change the **SpO₂ Averaging** time:

Step	
1	Open the SpO₂ Menu and select the SpO₂ Settings Menu . The SpO₂ Settings Menu appears.
2	Select the SpO₂ Averaging menu item.
3	Select one of the following options: • 2–4 seconds • 4–6 seconds • 8 seconds • 10 seconds • 12 seconds • 14 seconds • 16 seconds
4	To return to the previous menu, select the Return button (left arrow). To close the menu, select Home or Close .

Changing the Sensitivity Mode

Use the **Sensitivity Mode** setting to adapt the SpO₂ measurement sensitivity to the patient's level of SpO₂ signal strength and quality at the measurement site.

Warning

When using the **Maximum Sensitivity** setting, performance of the **Sensor Off** alarms may be compromised. If you select the **Maximum Sensitivity** setting and the sensor becomes dislodged from the patient, the potential for false readings may increase due to environmental “noise” such as light, vibration, and excessive air movement.

To change the **Sensitivity Mode** setting:

Step	
1	Open the SpO₂ Menu and select the SpO₂ Settings Menu button. The SpO₂ Settings Menu appears.
2	Select the Sensitivity Mode menu item.
3	Select one of the following options: • Normal — Use this setting for most monitoring situations. • Maximum — Use this setting on patients with weak signals (caused by high ambient noise or low perfusion) or on patients in higher acuity settings. • APOD (Adaptive Probe Off Detection) — Use this setting to protect against erroneous pulse rate and SpO₂ readings that can occur when a sensor becomes detached from the patient. Note — <i>The APOD setting is the least effective for patients with low perfusion, but may be optimal for unattended patients.</i>
4	To return to the previous menu, select the Return button (left arrow). To close the menu, select Home or Close .

Enabling FastSat

When enabled, the **FastSat** option detects and displays fast changes in SpO₂ by giving priority to the most recent data.

FastSat is useful in clinical settings that require a fast SpO₂ response time. It is not recommended for routine use.

Step	
1	Open the SpO₂ Menu and select the SpO₂ Settings Menu button. The SpO₂ Settings Menu appears.
2	Select the FastSat menu item.
3	Select one of the following options: • On • Off
4	To return to the previous menu, select the Return button (left arrow). To close the menu, select Home or Close .

FastSat is not available when the **SpO₂ Averaging** time is **2–4 seconds** or **4–6 seconds**.

Monitoring SpHb and SpOC

SpHb represents the total hemoglobin concentration in arterial blood.

SpOC is the derived measurement of the amount of oxygen in arterial blood, which may provide useful information about oxygen both dissolved in plasma and combined with hemoglobin. SpOC calculation is based on SpHb and SpO₂ values.

This section describes how to configure SpHb settings in the **SpHb Settings Menu**.

Caution

SpHb and SpCO monitoring is supported on Adult and Pediatric patients only. Neonatal patients are not supported.

Changing the SpHb Averaging Time

Use the **SpHb Averaging** option to select the length of time over which rapid variations in SpHb values are measured and averaged.

The default setting is **Medium**.

To change the **SpHb Averaging** time:

Step	
1	Open the SpO₂ Menu and select the SpHb Settings Menu button. The SpHb Settings Menu appears.
2	Select the SpHb Averaging menu item.
3	Select one of the following options: • Short • Medium • Long
4	To return to the previous menu, select the Return button (left arrow). To close the menu, select Home or Close .

Changing the SpHb Mode

You can obtain hemoglobin readings from either arterial or venous blood sample sources. Use the **SpHb Mode** setting to change the source.

Note — *Arterial Hb measurements are normally slightly lower than Hb measurements derived from venous blood.*

To change the SpHb mode:

Step	
1	Open the SpO₂ Menu and select the SpHb Settings Menu button. The SpHb Settings Menu appears.
2	Select the SpHb Mode menu item.
3	Select one of the following options: • Arterial • Venous
4	To return to the previous menu, select the Return button (left arrow). To close the menu, select Home or Close .

Changing the SpHb Precision

Use the **SpHb Precision** option to select the desired level of granularity for the SpHb value. The value is rounded up or down, based on the selected option.

To change the **SpHb Precision**:

Step	
1	Open the SpO₂ Menu and select the SpHb Settings Menu button. The SpHb Settings Menu appears.
2	Select the SpHb Precision menu item.
3	Select one of the following options: • Nearest 0.1 • Nearest 0.5 • Whole number
4	To return to the previous menu, select the Return button (left arrow). To close the menu, select Home or Close .

Changing the SpHb Unit of Measurement

The SpHb can be displayed in g/dl (grams per deciliter) or mmol/l (millimoles per liter).

To change the **SpHb** unit of measurement:

Step	
1	Open the SpO₂ Menu and select the SpHb Settings Menu button. The SpHb Settings Menu appears.
2	Select the SpHb Units menu item.
3	Select one of the following options: • g/dl • mmol/l
4	To return to the previous menu, select the Return button (left arrow). To close the menu, select Home or Close .

Monitoring RRa

The Acoustic Respiration Rate (RRa) measurement uses acoustic technology to continuously measure a patient's respiration rate based on airflow sounds generated during the breathing cycle of inspiration and expiration.

To measure RRa, an acoustic sensor must be connected and SpO₂ must be monitored.

This section describes how to configure RRa settings in the **RRa Menu**. For information on using RRa waveform to determine correct placement of the RRa sensor, see "RRa Waveform Overview" on page 2-19.

Warning	Because of different methods of measuring respiration, there may be different values obtained. For the most accurate measurements, follow the Instructions for Use provided with your sensor. Keep in mind that measuring respiration with Masimo RRa can be affected by the placement of the sensor or from noises in the room.
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Caution	RRa monitoring is supported on Adult patients only. Pediatric and Neonatal patients are not supported.
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Note — *If your monitor includes Impedance respiration, Masimo rainbow RRa and CO₂ options, you may see three respiration rates with different values. You can choose to disable the audible alarm for the respiration rates, as described in the Efficia CM Series Patient Monitors Patient Monitors Instructions for Use.*

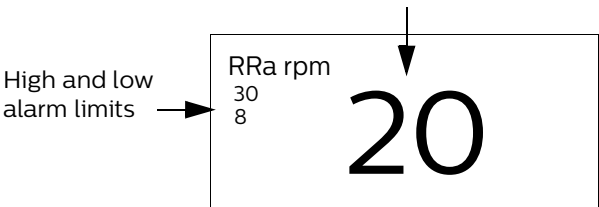
RRa Freshness Timeout

RRa Freshness Timeout is the maximum amount of time the monitor will display the last known RRa value before the RRa value is invalidated by either disruptive movement or sensor displacement. When the Freshness Timeout expires, the monitor will sound any RRa interference or no sensor alarms, if present.

The Efficia CM Series monitor is configured with a 5-minute default **Freshness Timeout**. Only the system administrator may change this default.

The RRa Numeric Pane

The following illustration shows the components of the RRa numeric pane in a monitor with the Masimo rainbow SET option, enabled for RRa measurement.



To open the **RRa Menu**:

- Select the RRa numeric pane.
The **RRa Menu** appears and current RRa settings are displayed.

Changing the RRa Alarm Limits

For information on changing the RRa alarm limits, see the *Efficia CM Series Patient Monitors Instructions for Use*.

The RRa default alarm limits are:

Alarm Limits	Adult	Pediatric	Neonatal
RRa high limit	30 rpm	NA	NA
RRa low limit	8 rpm	NA	NA

Note — RRa monitoring is for Adult patients only. Pediatric and Neonatal patients are not supported.

Changing the RRa Averaging Time

Use the **RRa Averaging** option to select the length of time over which variations in respiration rate are measured and averaged.

The default setting is **Slow**.

To change the **RRa Averaging** time:

Step	
1	Open the RRa Menu and select the RRa Averaging menu.
2	Select one of the following options: • None • Fast — 10 seconds • Medium — 20 seconds • Slow — 30 seconds • Trending — 1 minute
3	To close the menu, select Home or Close .

Changing the RRa Pause Time

The **RRa Pause Time** is the time the monitor will wait between breaths for the patient to resume breathing before generating an **RRa Pause** alarm. For example, a setting of **20 seconds** means that an alarm will be activated when no breaths are detected for a period of at least 20 seconds.

The default value is **30 seconds**.

To change the **RRa Pause** time:

Step	
1	Open the RRa Menu and select the RRa Pause Time menu.
2	Select one of the following options: • 15 seconds • 20 seconds • 25 seconds • 30 seconds • 35 seconds • 40 seconds
3	To close the menu, select Home or Close .

SpCO Measurements

If enabled in a monitor with the Masimo rainbow SET option, the SpCO measurements will display in the SpO₂ numeric pane.

SpCO represents the percentage of Carboxyhemoglobin within the blood as measured by rainbow multi-LED, allowing clinicians to noninvasively and immediately diagnose, monitor and treat patients poisoned by carbon monoxide.

Note — *For information on changing the SpCO alarm limits, see the Efficia CM Series Patient Monitors Instructions for Use.*

Desaturation Alarm (Desat) Delay

The Desaturation (Desat) alarm is a high-priority alarm that alerts you to a potentially life-threatening drop in oxygen saturation. The Desat alarm limit is fixed at 10 less than the current low limit for adults and pediatric patients and 5 less for neonates.

The Desat alarm is not configurable; it is based on the current SpO₂ low alarm limit.

Your system administrator can set an alarm delay for the Desat alarm, which does not sound until the alarm criteria are met.

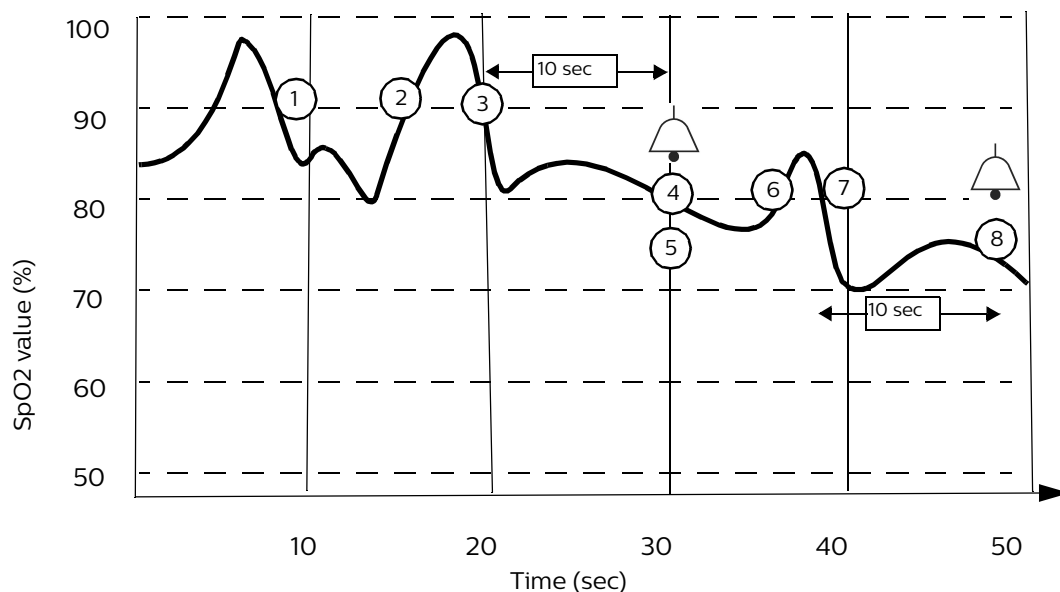
SpO₂ Alarm Delay

If your system administrator configures an SpO₂ alarm delay time, and the SpO₂ value exceeds the current high or low alarm limits, the monitor does not issue an SpO₂ alarm until the specified alarm delay time elapses. For example, if your system administrator sets the SpO₂ alarm delay time to 10 seconds, the monitor will generate an alarm when the SpO₂ value exceeds the high or low alarm limits for more than 10 seconds.

The **SpO₂ Alarm Delay** can be up to 30 seconds for the **High/Low** setting and for the **Desat** setting. If your system administrator has enabled the **SpO₂ Alarm Delay** option on your monitor, the current settings are displayed in the **SpO₂ Menu**.

In the following example, the SpO₂ settings are configured on the monitor as follows:

- The SpO₂ low alarm limit is 90%.
- The Desat alarm limit is 80% (10 less than the current SpO₂ low alarm limit).
- The SpO₂ high/low alarm delay is 10 seconds.
- The SpO₂ Desat alarm delay is 10 seconds.



In the example above:

1. The SpO₂ value falls below 90%. The High/Low alarm delay timer starts.
2. The SpO₂ value goes above 90% before 10 seconds has lapsed. The High/Low alarm delay timer resets.
3. The SpO₂ value falls below 90%. The High/Low alarm delay timer starts.
4. The SpO₂ value remains below 90% for 10 seconds. The **SpO₂ Low** alarm sounds.
5. The SpO₂ value falls below 80%. The Desat alarm delay timer starts.
6. The SpO₂ value goes above 80%. The Desat alarm delay timer resets.
7. The SpO₂ value falls below 80%. The Desat alarm delay timer starts.
8. The SpO₂ value remains below 80% for 10 seconds. The **SpO₂ Desat** alarm sounds.

RRa Alarm Delay

If your system administrator configures an RRa alarm delay time, and the RRa value exceeds the current high or low alarm limits, the monitor does not issue an RRa alarm until the specified alarm delay time elapses. For example, if your system administrator sets the RRa alarm delay time to 10 seconds, the monitor will generate an alarm when the RRa value exceeds the high or low alarm limits for more than 10 seconds.

The **RRa Alarm Delay** can be up to 60 seconds for the **Masimo RRa Alarm Delay** setting. If your system administrator has enabled the **RRa Alarm Delay** option on your monitor, the current settings are displayed in the **RRa Menu**.

Configuring the SpO2 Waveform

In each display setting for the monitor, (e.g., 5 Waveform Layout, 8 Waveform Layout, etc.), the ECG waveform is always displayed at the top of the screen. Any one of the remaining waves can display the SpO₂ waveform.

Displaying the SpO2 Waveform

To display the SpO₂ waveform:

Step	
1	Select a waveform pane. The Waveform Menu for the currently displayed waveform appears.
2	Select the Select Waveform menu item.
3	Select SpO₂ from the menu options.
4	To close the menu, select Home or Close .

Changing the SpO2 Waveform Speed

The **Sweep Speed** determines the speed at which the SpO₂ waveform is drawn across the screen.

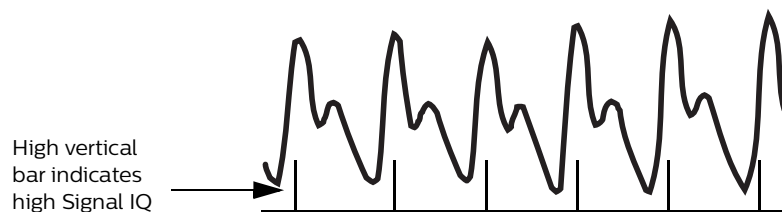
To change the SpO₂ waveform sweep speed:

Step	
1	Open the SpO₂ Waveform Menu .
2	Select the Sweep Speed menu item.
3	Select one of the following options: • 12.5 mm/s • 25.0 mm/s • 50.0 mm/s
4	To close the menu, select Home or Close .

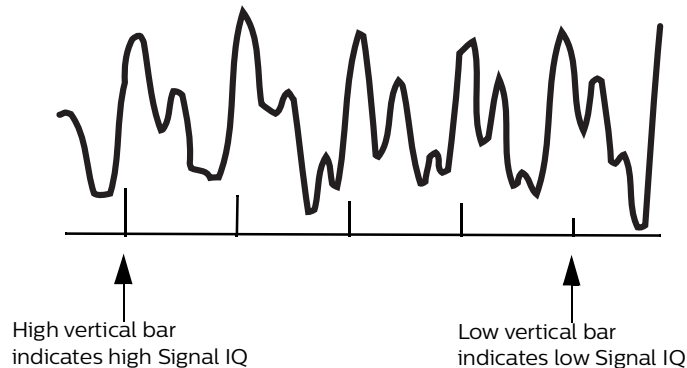
Enabling SpO2 Signal IQ

The **SpO₂ Signal IQ** option is useful in determining measurement quality and can also be used to determine the occurrence of a patient's pulse. When enabled, the Signal IQ displays as a vertical bar in the waveform and coincides with the peak of an arterial pulsation. The height of the vertical bar indicates the confidence in the measurement. A high vertical bar indicates higher confidence in the measurement. A small vertical bar indicates lower confidence in the displayed measurement.

The following illustration shows a typical SpO₂ waveform with no motion. The vertical bars in the Signal IQ indicate high confidence in the measurement.



In the following illustration, increased motion has completely obscured the waveform. The decreasing height of the vertical bars indicates lower confidence in the measurement.



By default, the SpO₂ Signal IQ is **Off**.

To enable or disable SpO₂ Signal IQ:

Step	
1	Open the SpO₂ Waveform Menu .
2	Select the SpO₂ Signal IQ menu item.
3	Select one of the following options: • On • Off
4	To close the menu, select Home or Close .

Masimo Pulse Smart Tone

Smart Tone effects the pulse beep and allows a pulse beep to continue even when the Pleth waveform is corrupted due to motion. When the Smart Tone is off, the pulse beep is suppressed during signs of motion.

Your biomedical engineer can enable the Masimo Pulse Smart Tone from the Admin menu.

Configuring the RRa Waveform

In each display setting for the monitor, (e.g., 5 Waveform Layout, 8 Waveform Layout, etc.), the ECG waveform is always displayed at the top of the screen. Any one of the remaining waves can display the RRa waveform.

RRa Waveform Overview

The rainbow acoustic respiration sensor detects upper airway acoustical signals produced by turbulent airflow that occurs during both inhalation and exhalation. The amplitude of the acoustic signal is related to the strength of the breath, sensor placement, and conduction of sound from the trachea through the muscle and skin in the patient's neck to the sensor.

The rainbow Acoustic Monitoring algorithms distinguish breath patterns from other biological signals such as carotid pulses, vocalization, coughs, and ambient background noise, as well as respiratory synchronous signals such as snoring or wheezing to produce a reliable measurement.

Displaying the RRa Waveform

To display the RRa waveform:

Step	
1	Select a waveform pane. The Waveform Menu for the currently displayed waveform appears.
2	Select the Select Waveform menu item.
3	Select RRa from the menu options.
4	To close the menu, select Home or Close .

Changing the RRa Waveform Speed

The **Sweep Speed** determines the speed at which the RRa waveform is drawn across the screen.

To change the RRa waveform sweep speed:

Step	
1	Open the RRa Waveform Menu .
2	Select the Sweep Speed menu item.
3	Select one of the following options: • 12.5 mm/s • 25.0 mm/s • 50.0 mm/s
4	To close the menu, select Home or Close .

Identifying the SpO₂ Hardware Module

To identify the Masimo SpO₂ module in your monitor:

Step	
1	Select the System button. The System Menu appears.
2	On the General tab, select Configuration . The text SpO₂-M indicates that the monitor has a Masimo SpO ₂ module.
3	To close the menu, select Home or Close .

Status Messages

Masimo status messages appear on the bottom of the pane below the SpO₂ and RRA waveforms when the condition is detected. These messages are displayed only if a low-, medium-, or high-priority alarm does not occur at the same time. These are only visual messages; no sound occurs.

The Masimo status messages are displayed in white text on a black background. If multiple status messages occur at the same time, the messages rotate every 1.5 seconds.

SpO₂ Status Messages

The following table contains a list of SpO₂ status messages and their possible causes.

Status Message	Cause
PulseOx Sensor Initializing	The monitor is checking the sensor for proper functioning and performance. If values are not displayed within 30 seconds, disconnect and reconnect the sensor. If values are still not displayed, replace the sensor.
PulseOx Searching	The monitor is searching for a pulse. If it fails to detect a pulse within 30 seconds, disconnect and reconnect the sensor. If the pulse search continues, move the sensor to a better perfused site.
PulseOx Demo Mode	A demo sensor is connected to the monitor. A demo sensor does not monitor patient parameters.
Low SpO₂ SIQ	Low SpO ₂ signal. May be due to improper sensor placement.

Status Message	Cause
Low Pulse SIQ	Low pulse rate signal. May be due to improper sensor placement.
Low PI Confidence	The signal is too small. Move the sensor to a better perfused site.
Low SpHb SIQ	Low SpHb signal. May be due to improper sensor placement.
Low SpHb PI	Low perfusion for SpHb. May be due to improper sensor placement.
Low SpCO SIQ	Low SpCO signal. May be due to improper sensor placement.
Low SpCO PI	Low perfusion for SpCO. May be due to improper sensor placement.
Low SpOC SIQ	Low SpOC signal. May be due to improper sensor placement.
Low SpOC PI	Low perfusion for SpOC. May be due to improper sensor placement.

RRa Status Messages

The following table contains a list of RRa status messages and their possible causes.

Status Message	Cause
Low RRa SIQ	Low RRa signal. May be due to improper sensor placement.
RRa Interference Detected	May be due to either of the following: • High intensity light or excessive ambient light • Incorrect line frequency setting

SpO2 Safety Information

Warnings

- Do not use the TC-I sensor for patients with pierced ears at the measuring site.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- A Pulse CO-Oximeter should be considered an early warning device. Blood samples should be analyzed by laboratory instruments prior to clinical decision-making to completely understand the patient's condition.
- When HR/Pulse tone is enabled and the tone is from the ECG, there is no tone modulation for changes in SpO₂. If notification of subtle changes in SpO₂ are needed, adjust the SpO₂ alarm limits to ensure alarm notifications.
- Do not rely exclusively on the audible alarm system for patient monitoring. The most reliable method of patient monitoring requires correct operation of the monitor and close observation of the patient.
- For measurements of high or low SpHb readings, blood samples should be analyzed by laboratory instruments prior to clinical decision-making to completely understand the patient's condition.
- SpO₂ is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO₂ measurement.
- For increased COHb: COHb levels above normal tend to increase the level of SpO₂. The level of increase is approximately equal to the amount of COHb that is present.

Note — High levels of COHb may occur with a seemingly normal SpO₂. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.

- For increased MetHb: The SpO₂ may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO₂ may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Very low arterial Oxygen Saturation (SpO₂) levels may cause inaccurate SpCO measurements.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Hemoglobin synthesis disorders may cause erroneous SpHb readings.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO₂, SPCO, SpHb, and SPOC measurements.
- Motion artifact may lead to inaccurate SPCO, SpHb, and SPOC measurements.
- Severe anemia may cause erroneous SpO₂ readings.

- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.
- Do not use tape to secure the sensor to the site. This can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.
- If the sensor is wrapped too tightly or supplemental tape is used, venous congestion/pulsations may occur, causing erroneous readings.
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (that is, sensor on hand of a patient in a bed with arm dangling to the floor).
- Venous pulsations may cause erroneous low readings (that is, tricuspid value regurgitation).
- Loss of pulse signal can occur when:
 - The sensor is too tight.
 - The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
 - There is arterial occlusion proximal to the sensor.
 - The patient is in cardiac arrest or is in shock.
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.
- Misapplied sensors or sensors that become partially dislodged may cause either over or under readings of actual arterial oxygen saturation.
- If both the SpO₂ and RRa sensors are removed, the SpO₂ and RRa measurements display a question mark (-?-) in their numerical panes.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- Unintended overheating of SpO₂ sensors can cause localized skin reddening to the patient.
- High intensity extreme lights (including pulsating strobe lights) directed on the sensor may not allow the Pulse CO-Oximeter to obtain readings.
- High ambient light sources can interfere with the sensor performance. To prevent interference, cover the sensor site with opaque material.
- The Pulse CO-Oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.
- Defibrillator protection requires the use of Philips specified accessories.
- Before use, carefully read the sensor's *Directions for Use*.
- Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor's *Directions for Use* to ensure skin integrity and correct positioning and adhesion of the sensor.
- The Pulse CO-Oximeter is NOT intended for use as an apnea monitor.

- To avoid cross contamination only use Masimo single use sensors on the same patient.
- Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide. See the cleaning instructions in the *Directions for Use* for the Masimo re-usable sensors.
- SpO₂ monitoring is required when monitoring RRA (Acoustic Respiration)
- Excessive ambient noise may affect the accuracy of the respiration rate reading from the Acoustic Respiration Sensor.
- After an RRA sensor is removed from a patient, it is possible that the sensor can detect ambient noise in the patient environment and present it as a measurement.
- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2:2014, Medical Electrical Equipment—Part 1-2 General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic compatibility Requirements and tests, and by the European Union as the European Norm, EN 60601-1-2:2015. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving device.
 - Increase the separation between the equipment.
 - Consult the manufacturer for help.
- Do not place the monitor on electrical equipment that may affect the Pulse CO-Oximeter, preventing it from working properly.
- Electric shock hazard. Only a qualified operator may perform maintenance procedures.

To protect against injury from electric shock, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Always turn off and disconnect the power cord from the AC power supply before cleaning the device.
- Use cleaning solutions sparingly.
- To ensure patient electrical isolation, connect only to other equipment with electrically isolated circuits.
- Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.
- Do not attempt to reprocess, recondition or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to harm.
- Explosion hazard. Do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

- The monitor is to be operated by qualified personnel only. The Operators manual, directions for use, all precautionary information, and specifications should be read before use.
- To ensure the integrity of patient electronic protected health information, establish and enforce precautions that allow only authorized personnel to operate the monitor.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not lift the monitor by the patient cable.
- Always remove the sensor from the patient and completely disconnect the patient from the monitor before bathing the patient.
- Do not expose the monitor to excessive moisture such as direct exposure to rain. Excessive moisture can cause the monitor to perform inaccurately or fail.
- Do not immerse the sensor or patient cable in water, or solvents, or cleaning solutions. (The sensors and connectors are not waterproof.)
- Ensure the Dual rainbow Cable is physically intact, with no broken or frayed wires or damaged parts. Visually inspect the cable and discard if cracks or discolorations are found. Never use damaged cables or one with exposed electrical contacts.
- To avoid damage to the Dual rainbow Cable, always hold the cable by the connector rather than the cable when connecting or disconnecting either end.

Cautions

- Do not use the Pulse CO-Oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pulse CO-Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- If using pulse CO-oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.
- Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.
- Nail polish or nail fungus on the application site may cause inaccurate results.
- Circulation distal to the sensor site should be checked routinely.
- A functional tester cannot be utilized to assess the accuracy of the Pulse CO-Oximeter or any sensors.
- Do not modify or alter the sensor in any way. Alterations or modifications may affect performance and/or accuracy.
- The Dual rainbow cable is designed to directly interface with validated rainbow Acoustic Monitoring enabled devices.
- Failure to properly connect the Dual rainbow Cable to the rainbow Acoustic Monitoring enabled device may result in intermittent readings, inaccurate results, or no reading.

3

Accessories List

This chapter lists accessories that are compatible with the Efficia CM Series patient monitors with the Masimo SET® or Masimo rainbow® SET options. Not all accessories are available in all countries.

Warning Use only approved accessories with the Efficia CM patient monitor. The use of unapproved accessories can diminish performance or safety. For a list of accessories compatible with the Efficia CM patient monitors see, *Efficia CM Series Instructions for Use*.

Note — The sensors described in this chapter are those compatible with the Efficia CM Series monitors. Contact your local Masimo representative to obtain any of these accessories.

Masimo Patient Cables

Description	Cable Length	Part Number
rainbow 25 Patient Cable, Dual RC25-10 (adapts Masimo SET, SpHb, SpCO, and RRa sensors to Masimo SpO ₂ input connector)	10 ft	989803182431
rainbow 25 Patient Cable, RC25-4, Straight (adapts Masimo SET and SpHb sensors to Masimo SpO ₂ input connector)	4 ft	989803182421
LNCS Patient Cable, Red 25 LNC-4, Straight (adapts Masimo SET sensors to Masimo SpO ₂ input connector)	4 ft	989803186531
LNCS Adapter Cable. LNCS sensors to Philips monitor	9.84 ft	989803148221
LNOP Adapter Cable, LNOP sensors to Philips monitor	11.8 ft	M1020-61100

Note — For information on the sensor specifications, including accuracy, see Chapter 4, “Specifications.”

Masimo rainbow Reusable Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Finger sensor for SpHb and SpO ₂ , for patient size > 30 kg (66 lb)	rainbow DCI SC-200	rainbow 25 Patient Cable, RC25-4
Pediatric	Finger sensor for SpHb and SpO ₂ , for patient size 10 kg – 50 kg (22 lb – 110 lb)	rainbow DCIP SC-200	
Adult	Finger sensor for SpHb and SpO ₂ , for patient size > 30 kg (66 lb)	rainbow DCI SC-400	
Pediatric	Finger sensor for SpHb and SpO ₂ , for patient size 10 kg – 50 kg (22 lb – 110 lb)	rainbow DCIP SC-400	
Adult	Finger sensor for SpHb and SpO ₂ , for patient size > 30 kg (66 lb)	rainbow DCI SC-1000	
Pediatric	Finger sensor for SpHb and SpO ₂ , for patient size 10 kg – 50 kg (22 lb – 110 lb)	rainbow DCIP SC-1000	
Adult	Finger sensor for SpO ₂ and SpCO, for patient size > 30 kg (66 lb)	rainbow DCI	
Pediatric	Slender digit sensor for SpO ₂ and SpCO, for patient size 10 kg – 50 kg (22 lb – 110 lb)	rainbow DCIP	

Masimo rainbow ReSposable Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Finger sensor for SpHb and SpO ₂ , for patient size > 30 kg (66 lb)	rainbow R2-25 Two-Piece Adhesive Sensor	rainbow 25 Patient Cable, RC25-4
Pediatric	Finger sensor for SpHb and SpO ₂ , for patient size 10 kg – 50 kg (22 lb – 110 lb)	rainbow R2-20 Two-Piece Adhesive Sensor	

Masimo rainbow Adhesive Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Finger sensor for SpO ₂ and SpCO, for patient size > 30 kg (66 lb)	rainbow R25	rainbow 25 Patient Cable, RC25-4
Adult	Finger sensor for SpHb and SpO ₂ , for patient size > 30 kg (66 lb)	rainbow R1 25L	
Adult	Finger sensor for SpO ₂ and SpCO, for patient size > 30 kg (66 lb)	rainbow R25-L	
Neonatal	Hand/foot sensor for SpO ₂ , for patient size < 3 kg (6.6 lb)		
Pediatric	Finger sensor for SpO ₂ and SpCO, for patient size 10 kg – 50 kg (22 lb – 110 lb)	rainbow R20	
Infant	Thumb/great toe sensor for SpHb and SpO ₂ , for patient size 3 kg – 10 kg (7 lb – 22 lb)	rainbow R1 20L	rainbow 25 Patient Cable, RC25-4
	Finger sensor for SpHb and SpO ₂ , for patient size 10 kg – 30 kg (22 lb – 66 lb)		
Infant	Thumb/great toe sensor for SpO ₂ and SpCO, for patient size 3 kg – 10 kg (7 lb – 22 lb)	rainbow R20-L	
	Finger sensor for SpO ₂ , for patient size 10 kg – 30 kg (22 lb – 66 lb)		

Masimo LNCS Reusable Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Finger sensor for patient size > 30 kg (66 lb)	LNCS DCI	LNCS Patient Cable, Red 25, LNC-4
Pediatric	Finger sensor for patient size 10 kg – 50 kg (22 lb – 110 lb)	LNCS DCIP	
Adult	Ear lobe sensor for patient size > 30 kg (66 lb)	LNCS TC-I	
Neonatal/ Infant/ Adult	Foot sensor for patient size 1 kg – 3 kg (2.2 lb – 6.6 lb) Finger/great toe sensor for patient size 3 kg – 10 kg (6.6 lb – 22 lb) Finger/great toe sensor for patient size > 10 kg (22 lb)	LNCS YI	
Adult	Forehead sensor for patient size > 30 kg (66 lb)	LNCS TF-I	
Adult	Finger sensor for patient size > 30 kg (66 lb)	LNCS DBI	

Masimo LNCS Adhesive Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Finger sensor for patient size > 30 kg (66 lb), 18 in.	LNCS Adtx	LNCS Patient Cable, Red 25 LNC-4
Adult	Finger sensor for patient size > 30 kg (66 lb), 3 ft	LNCS Adtx-3	
Pediatric	Finger sensor for patient size 10 kg – 50 kg (22 lb – 110 lb), 18 in.	LNCS Pdtx	
Pediatric	Finger sensor for patient size 10 kg – 50 kg (22 lb – 110 lb), 3 ft	LNCS Pdtx-3	
Infant	Great toe sensor for patient size 3 kg – 20 kg (6.6 lb – 44 lb), 18 in.	LNCS Inf	
Infant	Great toe sensor for patient size 3 kg – 20 kg (6.6 lb – 44 lb), 3 ft	LNCS Inf-3	
Neonatal	Foot sensor for patient size < 3 kg (6.6 lb), 18 in. Finger sensor for patient size > 40 kg (88 lb), 18 in.	LNCS Neo	
Neonatal	Foot sensor for patient size < 3 kg (6.6 lb), 3 ft Finger sensor for patient size > 40 kg (88 lb), 3 ft	LNCS Neo-3	
Neonatal	Sensitive skin foot sensor for patient size < 1 kg (2.2 lb), 18 in.	LNCS NeoPt	
Neonatal	Sensitive skin foot sensor for patient size < 1 kg (2.2 lb), 3 ft	LNCS NeoPt-3	
Neonatal	Non-adhesive foot sensor for patient size < 1 kg (2.2 lb), 18 in.	LNCS NeoPt-500	LNCS Patient Cable, Red 25 LNC-4
Adult	Finger sensor for patient size > 30 kg (66 lb)	LNCS Trauma	
Newborn Neonatal	Foot sensor for patient size < 3 kg (6.6 lb), 18 in.	LNCS Newborn Neonatal	
Newborn Infant	Great toe sensor for patient size 3 kg – 10 kg (6.6 lb – 22 lb) Finger sensor for patient size 10 kg – 30 kg (22 lb – 66 lb)	LNCS Newborn Infant/ Pediatrics	
Adult/ Pediatric	Disposable ear sensor for patient size > 30 kg (66 lb)	LNCS E-1	

Masimo M-LNCS Reusable Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Finger sensor for patient size > 30 kg (66 lb)	M-LNCS DCI	LNCS Patient Cable, Red 25 LNC-4
Pediatric	Finger sensor for patient size 10 kg – 50 kg (22 lb – 110 lb)	M-LNCS DCIP	
Adult	Ear lobe sensor for patient size > 30 kg (66 lb)	M-LNCS TC-I	
Neonatal/ Infant/ Adult	Foot sensor for patient size 1 kg – 3 kg (2.2 lb – 6.6 lb) Finger/great toe sensor for patient size 3 kg – 10 kg (6.6 lb – 22 lb) Finger/great toe sensor for patient size > 10 kg (22 lb)	M-LNCS YI	
Adult	Forehead sensor for patient size > 30 kg (66 lb)	M-LNCS TF-I	
Adult	Finger sensor for patient size > 30 kg (66 lb)	M-LNCS DBI	

Masimo M-LNCS Adhesive Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Finger sensor for patient size > 30 kg (66 lb), 18 in.	M-LNCS Amtx	LNCS Patient Cable, Red 25 LNC-4
Adult	Finger sensor for patient size > 30 kg (66 lb), 3 ft	M-LNCS Amtx-3	
Pediatric	Finger sensor for patient size 10 kg – 50 kg (22 lb – 110 lb), 18 in.	M-LNCS Pmtx	
Pediatric	Finger sensor for patient size 10 kg – 50 kg (22 lb – 110 lb), 3 ft	M-LNCS Pmtx-3	
Infant	Great toe sensor for patient size 3 kg – 20 kg (6.6 lb – 44 lb), 18 in.	M-LNCS Inf	
Infant	Great toe sensor for patient size 3 kg – 20 kg (6.6 lb – 44 lb), 3 ft	M-LNCS Inf-3	
Neonatal	Foot sensor for patient size < 3 kg (6.6 lb), 18 in. Finger sensor for patient size > 40 kg (88 lb), 18 in.	M-LNCS Neo	
Neonatal	Foot sensor for patient size < 3 kg (6.6 lb), 3 ft Finger sensor for patient size > 40 kg (88 lb), 3 ft	M-LNCS Neo-3	
Neonatal	Sensitive skin foot sensor for patient size < 1kg (2.2 lb), 18 in.	M-LNCS NeoPt	
Neonatal	Sensitive skin foot sensor for patient size < 1 kg (2.2 lb), 3 ft	M-LNCS NeoPt-3	
Neonatal	Non-adhesive foot sensor for patient size < 1 kg (2.2 lb), 18 in.	M-LNCS NeoPt-500	LNCS Patient Cable, Red 25 LNC-4
Adult	Finger sensor for patient size > 30 kg (66 lb)	M-LNCS Trauma	
Newborn Neonatal	Foot sensor for patient size < 3 kg (6.6 lb), 18 in.	M-LNCS Newborn Neonatal	
Newborn Infant	Great toe sensor for patient size 3 kg – 10 kg (6.6 lb – 22 lb) Finger sensor for patient size 10 kg – 30 kg (22 lb – 66 lb)	M-LNCS Newborn Infant/Pediatrics	
Adult/ Pediatric	Disposable ear sensor for patient size > 30 kg (66 lb)	M-LNCS E-1	

Masimo Acoustic Respiration Sensors

Patient Category	Description	Sensor	Use With This Cable
Adult	Neck sensor for patient size > 30 kg (66 lb)	RAS-125 Acoustic Respiration	rainbow 25 Patient Cable, Dual RC25-10
Adult/ Pediatric	Neck sensor for patient size > 10 kg (22 lb)	RAS-125c Acoustic Respiration	

4

Specifications

Masimo SpO₂ Specifications

Parameter	Specification
SpO ₂ Input Connector	Masimo 25 pin connector Type CF (3M 10220-6212VC)
Accuracy (See “Accuracy Notes” on page 4-4.)	
SpO ₂ Accuracy, No Motion	60%–80% ± 3%, Adults/Pediatrics/Infants 70%–100% ± 2%, Adults/Pediatrics/Infants; ± 3% Neonates
SpO ₂ Accuracy, Motion	70%–100% ± 3%, Adults/Pediatrics/Infants/Neonates
SpO ₂ Accuracy, Low Perfusion	70%–100% ± 2%, Adults/Pediatrics/Infants/Neonates
Pulse Rate Accuracy, No Motion	± 3 bpm in the range 25 bpm–240 bpm, Adults/Pediatrics/Infants/Neonates
Pulse Rate Accuracy, Motion	± 5 bpm in the range 25 bpm–240 bpm, Adults/Pediatrics/Infants/Neonates
Pulse Rate, Low Perfusion	± 5 bpm in the range 25 bpm–240 bpm, Adults/Pediatrics/Infants/Neonates
SpHb Accuracy	±1 g/dl (1.0 mmol/l) in the range 8 g/dl–17 g/dl (4.5 mmol/l–10.6 mmol/l) arterial or venous, Adults/Pediatrics <i>Note — Total Hemoglobin (SpHb), enabled with Masimo rainbow, is only supported on Adult and Pediatric patients.</i>
SpCO Accuracy	1%–40% ± 3%, Adults/Pediatrics/Infants

Parameter	Specification
RRa™ Accuracy	± 1 breath per minute in the range 4–70 breaths per minute (rpm), Adults (> 30 kg) and Adults/Pediatrics (> 10 kg) Note — Acoustic Respiration (RRa), enabled with Masimo rainbow, is only supported on Adult patients.
Resolution	
SpO ₂ Measurement Resolution	1%
Pulse Rate Resolution	1 bpm
SpHb Measurement Resolution	0.1 g/dl (0.1 mmol/l)
SpCO Measurement Resolution	1%
RRa Measurement Resolution	1 breath per minute (rpm)
SpO ₂ and PR current measurement delay	≤ 10 s (this delay represents the time between signal acquisition and the parameter becoming available).
SpO ₂ and PR initial measurement delay	≤ 20 s (this additional delay is required when applying the sensor / measurement to the patient for the first time).
Range	
SpO ₂ Measurement Range	0%–100%
Pulse Rate Measurement Range	25 bpm–240 bpm
SpHb Measurement Range	0 g/dl–25 g/dl (0 mmol–15.5 mmol/l)
SpCO Carboxyhemoglobin Saturation Range	0%–99%
SpOC Total Oxygen Concentration Range	0–35 ml/dl
RRa Measurement Range	0–70 breaths per minute
Wavelength Range	500 nm–1400 nm for all specified sensors
Update rate PR, SpO ₂	≤ 1 sec
Maximum Optical Output Power	≤ 25 mW for all specified sensors

Parameter	Specification
Surface temperature of the sensor	Does not exceed 41°C
Operating Atmospheric Pressure ¹	Masimo SpO ₂ board 100-1060 mbar, -1000 to 18000 ft
Operating Temperature ²	0°C to 50°C
Storage Temperature ³	-40°C to 70°C
Relative Humidity ⁴	10-90%
Patents: www.masimo.com/patents.htm	
Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.	

¹. See the Efficia CM Series, *Instructions for Use*, for Environmental Specifications for the monitors.
Composite tested 1013 - 701 mbar, 0 - 3000 meters, 0 - 9842 feet above sea level.

². Composite test range: 10° C to 40° C

³. Composite test range: -10° C to 50° C without paper

⁴. Composite test range: 15% to 90% without paper non-condensing

Accuracy Notes

- SpO₂ and SpCO accuracy was determined by testing on healthy adult volunteers in the range of 60–100% SpO₂, and 0–40% SpCO against a laboratory CO-Oximeter. SpO₂ accuracy was determined on 16 neonatal NICU patients ranging in age from 7–135 days old and weighing between 0.5–4.25 kg. Seventy-nine (79) data samples were collected over a range of 70–100% SaO₂ and 0.5–2.5% MetHb with a resultant accuracy of 2.9% SpO₂.
- The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- The Masimo sensors have been validated for pulse rate accuracy for the range of 25–240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8–17 g/dl SpHb against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
- The following substances may interfere with pulse CO-Oximetry measurements:
 - Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO₂ and SpCO measurements.
 - Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO₂ measurements
 - Very low Arterial Oxygen Saturation (SpO₂) levels may cause inaccurate SpCO measurements
 - Severe anemia may cause erroneous SpO₂ readings.
 - Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
 - Elevated levels of total bilirubin may lead to inaccurate SpO₂, SpCO, and SpHb readings.

Parameter Accuracy for Masimo Sensors

The following tables contain the parameter accuracy of each Masimo sensor type. For information on sensor accuracy, see “Sensor Accuracy Notes” on page 4-10.

Masimo rainbow Sensors

Sensors	SpO ₂ Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpHb/SpCO Accuracy
	No Motion	Motion	No Motion	Motion	SpO ₂	Pulse Rate	No Motion
rainbow Reusable Sensors							
rainbow DCI SC-200	60% – 80% ± 3%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl (SpHb)
rainbow DCIP SC-200	70% – 100% ± 2%						
rainbow DCI SC-400							
rainbow DCIP SC-400							
rainbow DCI SC-1000							
rainbow DCIP SC-1000							
rainbow DCI rainbow DCIP	60% – 80% ± 3% 70% – 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3% (SpCO)

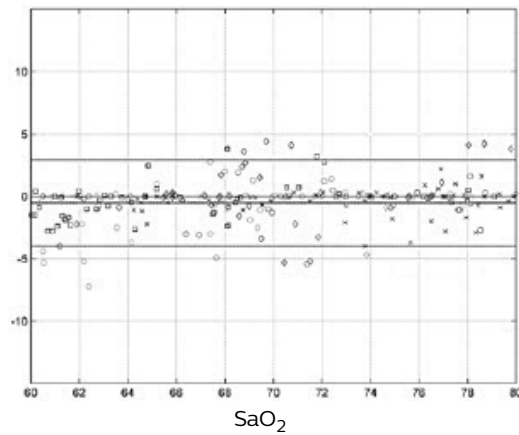
Sensors	SpO ₂ Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpHb/ SpCO Accuracy
	No Motion	Motion	No Motion	Motion	SpO ₂	Pulse Rate	No Motion
rainbow ReSposable Sensors							
rainbow R2-25 rainbow R2-20	60% – 80% ± 3% 70% – 100% ± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm	± 1 g/dl (SpHb)
rainbow Sensors							
rainbow R25 rainbow R20 rainbow R20-L rainbow R25-L*	60% – 80% ± 3% 70% – 100% ± 2% < 3 kg*: 70% – 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3% (SpCO)
rainbow R1 25L rainbow R1 20L	60% – 80% ± 3% 70% – 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl (SpHb)
*See sensor directions for use for neonatal test results.							

rainbow DCI and R2-25 Sensors Performance Specifications

The tables below show A_{rms} values measured using the rainbow DCI and R2-25 sensors with Masimo SET Oximetry Technology in a clinical study.

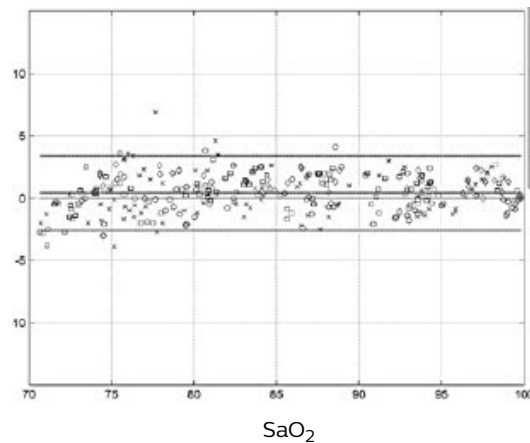
SaO_2 versus error ($SpO_2 - SaO_2$) with linear regression fit and upper 95% and lower 95% limits of agreement.

rainbow DCI



Range	A_{rms}
75-80%	1.56%
70-75%	1.67%
65-70%	1.86%
60-65%	2.13%

rainbow R2-25



Range	A_{rms}
90-100%	1.25%
80-90%	1.45%
70-80%	1.94%

Masimo LNCS Sensors

Sensors	SpO ₂ Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
	No Motion	Motion	No Motion	Motion	SpO ₂	Pulse Rate
LNCS Reusable Sensors						
LNCS DCI LNCS DCIP LNCS Trauma LNCS Newborn Infant/Pediatrics	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS TC-I *	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
LNCS YI	1-3kg: ± 3% 3-10 kg: ± 2% > 10 kg: ± 2%	± 3%	± 3 bpm	± 5 bpm	N/A	N/A
LNCS TF-I * LNCS DBI	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm
LNCS Sensors						
LNCS Aidx LNCS Aidx-3 LNCS Pidx LNCS Pidx-3 LNCS Inf LNCS Inf-3	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Neo LNCS Neo-3	< 3kg: ± 3% > 40 kg: ± 2%	± 3%	± 3 bpm	± 5 bpm	< 3kg: ± 3% > 40 kg: ± 2%	± 3 bpm
LNCS NeoPt LNCS NeoPt-3 LNCS NeoPt-500 LNCS Newborn Neonatal	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNCS E-1	± 2.5%	N/A	± 3 bpm	N/A	± 2.5%	± 3 bpm
* The LNCS TF-I and TC-I sensors were not validated under motion conditions.						

Masimo M-LNCS Sensors

Sensors	SpO ₂ Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
	No Motion	Motion	No Motion	Motion	SpO ₂	Pulse Rate
M-LNCS Reusable Sensors						
M-LNCS DCI M-LNCS DCIP M-LNCS Trauma M-LNCS Newborn Infant/Pediatrics	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS TC-I *	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
M-LNCS YI	1-3 kg: ± 3% 3-10 kg: ± 2% > 10 kg: ± 2%	± 3%	± 3 bpm	± 5 bpm	1-3 kg: ± 3% 3-10 kg: ± 2% > 10 kg: ± 2%	± 3 bpm
M-LNCS TF-I *	± 2%	N/A	± 3 bpm	N/A	N/A	N/A
M-LNCS Sensors						
M-LNCS Aidx M-LNCS Aidx-3 M-LNCS Pidx M-LNCS Pidx-3 M-LNCS Inf M-LNCS Inf-3 M-LNCS Trauma M-LNCS Newborn Infant/Pediatrics	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS Neo M-LNCS Neo-3	< 3 kg: ± 3% > 40 kg: ± 2%	± 3%	± 3 bpm	± 5 bpm	< 3 kg: ± 3% > 40 kg: ± 2%	± 3 bpm
M-LNCS NeoPt M-LNCS NeoPt-3 M-LNCS NeoPt-500 M-LNCS Newborn Neonatal	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
M-LNCS DBI *	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm
* The M-LNCS TF-I, TC-I and DBI sensors were not validated under motion conditions.						

Masimo Acoustic Respiration Sensors

Sensor	RPM Accuracy No Motion
Adult Disposable Acoustic Respiration Sensor	± 1 rpm
Adult/Pediatric Disposable Acoustic Respiration, Cloth Sensor	± 1 rpm

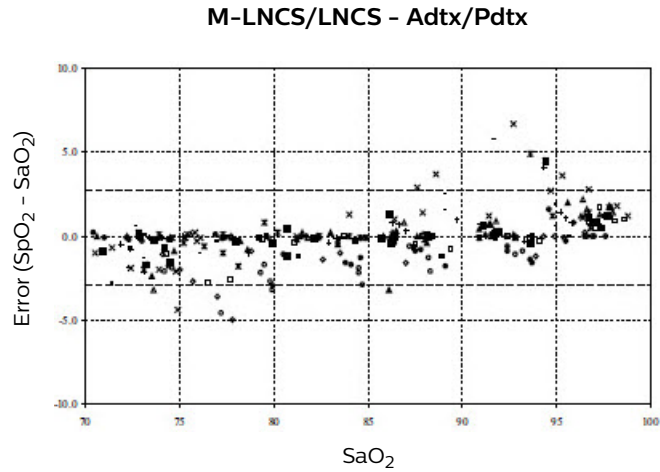
Sensor Accuracy Notes

- Masimo SET technology with LNOP, LNCS, and M-LNCS sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor. 1% has been added to the saturation accuracy for neonatal sensors to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- Masimo SET technology with LNOP, LNCS, and M-LNCS sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviations, which encompasses 68% of the population.
- Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- The Masimo SET technology with LNOP Neo, LNCS Neo, and M-LNCS Neo sensors has also been validated for neonatal motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor.
- Masimo SET technology with LNOP, LNCS, and M-LNCS sensors has been validated for pulse rate accuracy for the range of 25–240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and sensors at least every 8 hours.
- The TF-I sensor must be removed and repositioned to a different monitoring site at least every 2 hours. If extended monitoring is required, use of a single patient digit sensor is recommended.

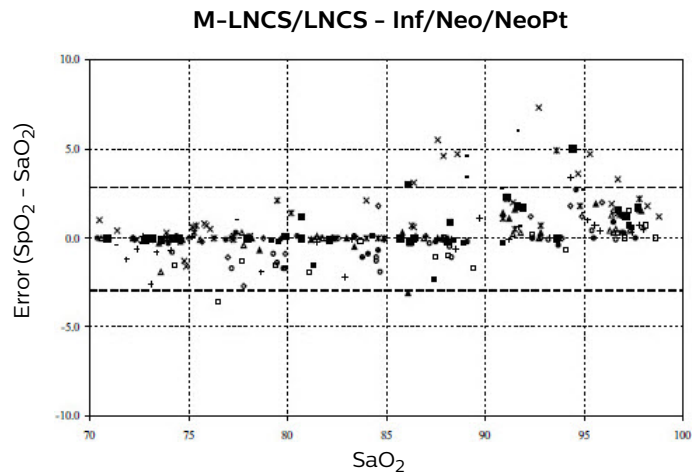
Masimo M-LNCS and LNCS Sensors Performance Specifications

The tables below show A_{rms} values measured using the M-LNCS Series and LNCS Series sensors with Masimo SET Oximetry Technology in a clinical study.

SaO_2 versus error ($SpO_2 - SaO_2$) with linear regression fit and upper 95% and lower 95% limits of agreement.



Measured A_{rms} Values	
Range	A_{rms}
90-100%	1.64%
80-90%	1.07%
70-80%	1.55%
Overall Claimed Accuracy Value	
70-100%	$\pm 2\%$



Measured A_{rms} Values	
Range	A_{rms}
90-100%	1.85%
80-90%	1.44%
70-80%	0.89%

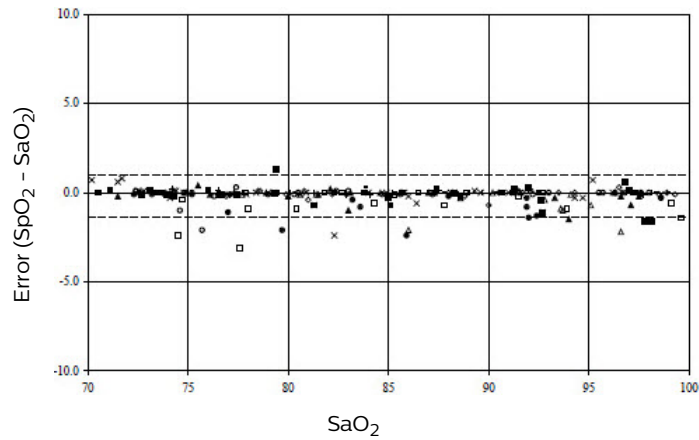
Range	A_{rms}		
	Inf	Neo ¹	NeoPt
70-100%	± 2%	± 2% Adult ± 3% Neonatal	± 3%
Overall Claimed Accuracy Value			

¹. The saturation accuracy of the Neonate and Preterm sensors was validated on Adult volunteers and 1% was added to account for the properties of fetal hemoglobin.

Masimo M-LNCS/LNCS DCI and DCIP Sensors Performance Specifications

The tables below show A_{rms} values measured using the M-LNCS/LNCS DCI and DCIP sensors with Masimo SET Oximetry Technology in a clinical study.

SaO_2 versus error ($SpO_2 - SaO_2$) with linear regression fit and upper 95% and lower 95% limits of agreement.



Range	A_{rms}
90-100%	0.6%
80-90%	0.5%
70-80%	0.7%
Overall Claimed Accuracy Value	
70-100%	$\pm 2\%$

A

Profile Settings

Profiles are predefined monitor configurations that can be used for different monitoring situations. The monitor ships with the following three default profiles:

- Operating Room (OR)
- General Ward (GW)
- Intensive Care Unit (ICU)

The default profile settings cannot be changed; however, your system administrator can create up to three customized profiles for different care settings.

Profile settings are password protected. Only your system administrator can load a profile on the system and create custom profile settings. For more information on all CM10, CM12, CM100, CM120, and CM150 profile settings, see the *Efficia CM Series Patient Monitors Instructions for Use*.

Viewing the Current Profile

To determine which profile is currently loaded on the system:

Step	
1	Select the System button.
2	Select the General tab.
3	View the Current Profile setting.

Profile Configurations

The following table lists the default configurations of the default profiles, GW, ICU, and OR. The default configuration for the customizable profiles are the same as the GW default configuration.

Parameter		GW	ICU	OR
SpO ₂	Sweep speed	25.0 mm/s	25.0 mm/s	25.0 mm/s
	SpO ₂ Audible alarm	Yes	Yes	Yes
	SpHb Audible alarm	Yes	Yes	Yes
	SpCO Audible alarm	Yes	Yes	Yes
	SpO ₂ high/low alarm delay	0 second	0 second	0 second
	SpO ₂ desat alarm delay	0 second	0 second	0 second
	SpO ₂ response	Normal	Normal	Normal
	Perfusion indicator	On	On	On
Acoustic	Sweep speed	25.0 mm/s	25.0 mm/s	25.0 mm/s
Respiration	Audible alarm	Yes	Yes	Yes
	RRa averaging	Slow	Slow	Slow
	RRa pause time	30 seconds	30 seconds	30 seconds
	RRa freshness time out	5 minutes	5 minutes	5 minutes
	RRa alarm delay	30 seconds	30 seconds	30 seconds

Profile Alarm Limit Settings

The following table lists the default alarm limit settings in the three default profiles. The alarm limit settings are the same for the three default profiles. You can change alarm limit settings, but the settings will return to the default profile values when you admit a patient, discharge a patient or select the **Restore Default Alarm Settings** button in the **Alarm Menu**

If your monitor is using a custom profile, see your system administrator for a list of the default alarm settings used in the custom profile.

Default Alarm Limits

The following table lists the default alarm LIMITS for physiological alarms in each of the three default profiles: OR, GW, and ICU.

Table 1

	Adult	Pediatric	Neonatal
Alarm	OR / GW / ICU	OR / GW / ICU	OR / GW / ICU
Pulse Rate High (SpO₂)	120 bpm	160 bpm	200 bpm
Pulse Rate Low (SpO₂)	50 bpm	75 bpm	100 bpm
SpHb High	17.0 g/dl 10.6 mmol/l	17.0 g/dl 10.6 mmol/l	NA
SpHb Low	7.0 g/dl 4.3 mmol/l	7.0 g/dl 4.3 mmol/l	NA
SpO₂ High	100%	100%	95%
SpO₂ Low	90%	90%	85%
SpCO High	10%	10%	NA
SpCO Low	0%	0%	NA
RRa High	30 rpm	NA	NA
RRa Low	8 rpm	NA	NA

B

Alarm Specifications

This appendix contains a listing of physiological and technical alarm messages. It also contains a table of factory default alarm limits and the calculations used for the **Auto Set Alarm Limits** option.

Physiological Alarms

The following table contains a listing of physiological alarm messages.

Alarm Message	Priority	Cause
Respiratory Pause	High	Respiration paused.
RRa High	Medium	The RRa value has exceeded the high alarm limit.
RRa Low	Medium	The RRa value has dropped below the low alarm limit.
SpHb High	Medium	The SpHb value has exceeded the high alarm limit.
SpHb Low	Medium	The SpHb value has dropped below the low alarm limit.
SpCO High	Medium	The SpCO value has exceeded the high alarm limit.
SpCO Low	Medium	The SpCO value has dropped below the low alarm limit.
SpO ₂ Desat	High	The oxygen saturation value has dropped dangerously low. The SpO ₂ Desat alarm sounds when the SpO ₂ value is 10 less than the current low limit for adult and pediatric patients and 5 less for neonatal patients.
SpO ₂ High	Medium	The SpO ₂ value has exceeded the high alarm limit.
SpO ₂ Low	Medium	The SpO ₂ value has dropped below the low alarm limit.

Technical Alarms

The following table contains a list of technical alarm messages.

Alarm Message	Priority	Cause
Check PulseOx Sensor Connection	Low	Sensor may not be fully connected or damaged.
Incompatible PulseOx Sensor	Low	Incompatible sensor. Replace with a compatible Masimo sensor.
Incompatible PulseOx Cable	Low	Incompatible cable. Replace with a compatible Masimo cable.
Incompatible PulseOx Adhesive Sensor	Low	Incompatible sensor. Replace with a compatible Masimo sensor.
PulseOx - Cable Life Near Expiration	Low	Cable life is near expiration.
PulseOx - Adhesive Life Near Expiration	Low	Adhesive life is near expiration.
PulseOx - Check cable PulseOx - Sensor Fault	Low	Check cable and sensor fault.
PulseOx - Sensor Life Near Expiration	Low	Sensor life is near expiration.
PulseOx Sensor Not Connected	Low	The sensor is disconnected from the cable.
PulseOx Cable Not Connected	Low	The cable is disconnected from the monitor.
PulseOx Interference Detected	Low	This visual-only message may be due to the following: • High intensity light or excessive ambient light • Incorrect line frequency setting
PulseOx Low Perfusion Index	Low	Low perfusion. May be due to improper sensor placement. This is only a visual message.
PulseOx Adhesive Sensor Not Connected	Low	The sensor is disconnected from the cable.
PulseOx Sensor Off Patient	High	The monitor has been placed in Continuous mode and the sensor is not longer connected to the patient.

Alarm Message	Priority	Cause
PulseOx SpO ₂ Only Mode	Low	Occurs during an unsuccessful sensor initialization/pulse search. This is only a visual message. See the sensor <i>Instructions for Use</i> .
Replace PulseOx Sensor	Low	The sensor is not working or has expired.
Replace PulseOx Cable	Low	The cable is not working or has expired.
Replace PulseOx Adhesive Sensor	Low	The sensor is not working or has expired.
SpCO Equip Malfunc	Low	SpCO equipment malfunction. Contact your technical support team to check the error log for details.
SpHb Equipment Malfunc	Low	SpHb equipment malfunction. See your system administrator to check the error log for details.
SpHb Sensor Expired	Low	The SpHb sensor has expired.
SpHb Sensor Expires Soon	Low	The SpHb sensor will expire soon.
SpO ₂ Equip Malfunc	Low	SpO ₂ equipment malfunction. Contact your technical support team to check the error log for details.
SpOC Equip Malfunc	Low	SpOC equipment malfunction. Contact your technical support team to check the error log for details.
Incompatible RRa Cable	Low	Incompatible cable. Replace with a compatible Masimo cable.
Incompatible RRa Sensor	Low	Incompatible sensor. Replace with a compatible Masimo sensor.
RRa Sensor Not Connected	Low	The sensor is disconnected from the cable.
RRa Cable Not Connected	Low	The cable is disconnected from the monitor.
Replace RRa Sensor	Low	The sensor is not working or has expired.
Replace RRa Cable	Low	The cable is not working or has expired.
RRa Equip Malfunc	Low	RRa equipment malfunction. See your system administrator to check the error log for details.
RRa Sensor Off Patient	High	The monitor has been placed in Continuous mode and the sensor is no longer connected to the patient.

Auto Set Alarms

The following tables list the formulas used for calculating automatic alarm limits. For information on setting automatic alarm limits, see the *Efficia CM100, CM120 and CM150 Patient Monitors Instructions For Use*.

Parameter	Adult		Pediatric		Neonatal	
	Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Pulse Rate (SpO ₂)	Pulse x 0.8 or 26 bpm (whichever is greater)	Pulse x 1.25 or 239 bpm (whichever is smaller)	Pulse x 0.8 or 26 bpm (whichever is greater)	Pulse x 1.25 or 239 bpm (whichever is smaller)	Pulse – 30 (within 80 – 100 bpm)	Pulse + 40 (within 180 – 210 bpm)
Respiration (Acoustic)	RRa x 0.5 or 4 rpm (whichever is greater)	RRa x 1.5 or 30 rpm (whichever is smaller)	NA	NA	NA	NA
SpCO	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit	NA	NA
SpHb	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit	NA	NA
SpO ₂	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit	Same as default alarm limit



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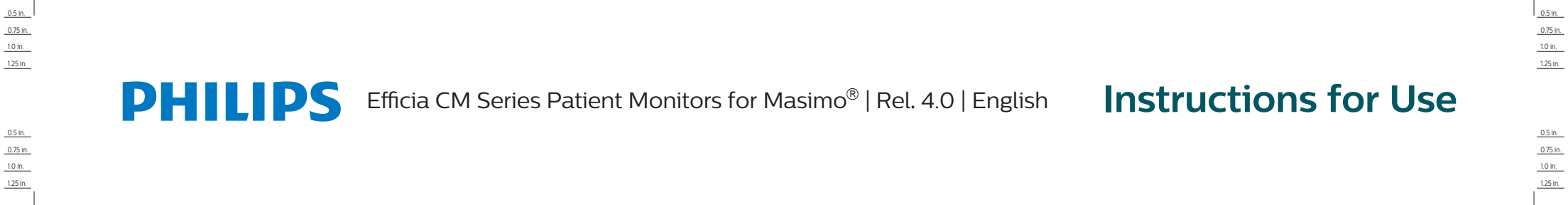
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Printed in China

453564915841, Revision B



CE 0123



Efficia CM Series Patient Monitors for Masimo[®] | Rel. 4.0 | English

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