PHILIPS

Masimo rainbow SET™

IntelliVue Module Pulse CO-Oximeter

Distributed by Philips for IntelliVue Patient Monitors

Philips 867191 technical data sheet

The Masimo rainbow SET™ IntelliVue Module Pulse CO-Oximeter is a noninvasive monitor that measures arterial oxygen saturation (SpO_2), pulse rate (PR), and Perfusion Index (Perf), along with optional measurements of hemoglobin (SpHb®), total oxygen content (SpOC), carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), Pleth Variability Index (PVI®), and Acoustic Respiration Rate (RRa®).

Features

· Displays realtime waveform plethysmogram
· Interfaces with Masimo SpO_2 and rainbow sensors
· Displays notification of poor signal quality and low perfusion conditions to aid in alternate sensor site selection
· Perfusion Index (Perf) with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion
· Numerical display of Perfusion Index (Perf), 0.02–20%
· Signal Quality Index Indicator (SQI)
· Masimo rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (SpCO), methemoglobin (SpMet), and total hemoglobin (SpHb), as well as providing a more reliable probe-off detection
· Total arterial oxygen content (SpOC) provides a calculated measurement of the amount of oxygen in arterial blood, which may provide useful information about oxygen both dissolved in plasma and combined with hemoglobin

· Pleth Variability Index (PVI) may show changes that reflect physiological factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions
· Respiration rate can be determined by the acoustic (RRa) waveform
· FastSat tracks rapid changes in arterial O_2

The Masimo rainbow SET IntelliVue Module Pulse CO-Oximeter features Masimo rainbow® technology in a single-width IntelliVue-compatible module. The Masimo rainbow SET IntelliVue Module Pulse CO-Oximeter is compatible with the following Philips IntelliVue Patient Monitoring Systems with software revision L.0 or later:
· IntelliVue MP40 in internal slots
· IntelliVue MP50 in internal slots
· IntelliVue MP60 via FMS-4 or FMS-8
· IntelliVue MP70 via FMS-4 or FMS-8
· IntelliVue MP80 via FMS-4 or FMS-8
· IntelliVue MP90 via FMS-4 or FMS-8
· IntelliVue MX500 in internal slots
· IntelliVue MX550 in internal slots
· IntelliVue MX600 via FMS-4 or FMS-8
· IntelliVue MX700 via FMS-4 or FMS-8
· IntelliVue MX800 via FMS-4 or FMS-8

Intended Use

The Masimo rainbow SET IntelliVue Module Pulse CO-Oximeter is intended to be used with compatible Philips IntelliVue Patient Monitors.

The Masimo rainbow SET IntelliVue Module Pulse CO-Oximeter is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo rainbow SET IntelliVue Module Pulse CO-Oximeter is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

The device is intended for use by trained healthcare professionals.

Rx only: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Specifications

Safety Specifications

The device complies with the Medical Device Directive 93/42/EEC and, among other standards, with:
- ANSI/AAMI ES60601-1: 2005
- UL 60601-1: 2003
- CAN/CSA C22.2 No. 60601-1:2008
- CAN/CSA C22.2 No. 601.1-M90
- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
- IEC 60601-1: 1988 + A1: 1991 + A2: 1995
- EN 60601-1: 1990 +A2:1995 + A11: 1993 + A12: 1998 + A13: 1996

Physical Specifications

Product	Max. Weight	WxHxD
IntelliVue Pulse CO-Oximeter module Masimo rainbow SET	0.3 kg (0.7 lb)	36 x 102 x 111 mm (1.4 x 4.0 x 4.4 in)

Environmental Specifications

Item	Condition	Range
Temperature Range	Operating	0–55° C, ambient humidity (32–131° F)
	Storage	–40–70° C, ambient humidity (–40°–158° F)
	Transport	–40–70° C, ambient humidity (–40°–158° F)
Humidity Range	Operating	95% RH max. at 40° C
	Storage	95%, RH max. at 65° C
	Transport	95%, RH max. at 65° C

Item	Condition	Range
Altitude Range	Operating	up to 4600 m (15000 ft)
	Storage	–380–5,560 m (–1250–18250 ft)
	Transport	–380–5,560 m (–1250–18250 ft)
Vibration	Per IEC 60068-2-6, IEC 60068-2-64	
Shock	Per IEC 60068-2-27	

Parameter Specifications

Display Range		SpO₂ (oxygen saturation) 0–100%
Accuracy		
	No motion [1]	60–80%: Adults, Pediatrics, Infants ±3% A_{RMS}
	No motion [2]	70–100%: Adults, Pediatrics, Infants ±2% A_{RMS}
	No motion [2]	70–100%: Neonates ±3% A_{RMS}
	Motion [3]	70–100%: All patient populations ±3% A_{RMS}
	Low perfusion [4]	70–100%: All patient populations ±2% A_{RMS}
Resolution		1%

Note: Display Range row — SpO_2 (oxygen saturation) 0–100%.

Pulse Rate Specifications

Display Range	PR (Pulse Rate) 25–240 bpm	
Accuracy		
	No motion [5]	25–240 bpm: All patient populations ±3 bpm A_{RMS}
	Motion [5]	25–240 bpm: All patient populations ±5 bpm A_{RMS}
	Low perfusion [5]	25–240 bpm: All patient populations ±3 bpm A_{RMS}
	Resolution	1 bpm

Perfusion Indicator Specifications

Measurement Range	Perf (Perfusion Index) 0.02–20%

Carboxyhemoglobin Specifications

Display Range	SpCO (Carboxyhemoglobin) 0–99%
Accuracy	1–40%: All patient populations ±3% A_{RMS}
Resolution	1%

Methemoglobin Specifications

Display Range	SpMet (Methemoglobin) 0–99%
Accuracy	1–15%: All patient populations ±1% A_{RMS}
Resolution	0.1%

Hemoglobin Specifications

Display Range	SpHb (Hemoglobin) 0–25.0 g/dl
Accuracy	8–17 g/dl: All patient populations ±1 g/dl A_{RMS}
Resolution	0.1 g/dl

Oxygen Content Specifications

Display Range	SpOC (Oxygen Content) 0–35 ml of O_2/dl of blood

Acoustic Respiration Rate Specifications

Display Range	RRa (Acoustic Respiration Rate) 0–70 respirations per minute
Measurement Range	4–70 respirations/min
Accuracy	Adults, Pediatrics, ±1 respirations/min A_{RMS}
Resolution	1 rpm

Pleth Variability Index Specifications

Measurement range	PVI (Pleth Variability Index) 0–100%

[1] SpO$_2$, SpCO, and SpMet accuracy was determined by testing on healthy adult volunteers in the range 60–100% SpO$_2$, 0–40% SpCO, and 0–15% SpMet against a laboratory CO-Oximeter. SpO$_2$ and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7–135 days old and weighing between 0.5 kg and 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70–100% SaO$_2$ and 0.5–2.5% HbMet with a resultant accuracy of 2.9% SpO$_2$ and 0.9% SpMet. Contact Masimo for testing specifications.

[2] The Masimo rainbow SET technology with Masimo sensors has 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% SpO$_2$ against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population weight.

[3] Unless otherwise stated in the sensor Directions for Use, Masimo SET® technology and sensors have been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2–4 Hz at an amplitude of 1–2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[4] The Masimo SET technology has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2TM* simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70–100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[5] Masimo rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25–240 bpm in bench top testing against a Biotek Index 2TM* simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[6] 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 Coulter Counter. The 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.

[7] Respiration rate accuracy for the Masimo Acoustic Respiration Sensor and Instrument has been validated for the range of 4–70 respirations per minute in bench top testing. Clinical validation for up to 30 respirations per minute was also performed with the Masimo Acoustic Respiration Sensor and Instrument.

*Registered trademark of Fluke Biomedical Corporation, Everett, Washington.

Ordering Information

Product Structure for Masimo rainbow SET IVM

867191 #SP5	Masimo rainbow SET SpO$_2$
867191 #SP5, #R11	Masimo rainbow SET Parameter Bundle: SpO$_2$ +SpHb/SpOC+PVI
867191 #SP5, #R12, #R21	Masimo rainbow SET Parameter Bundle: SpO$_2$ +SpHb/SpOC+PVI +SpMet+SpCO +RRa

Documentation

The English printed manual is shipped with the module and is available in electronic format at:

http://www.Masimo.com/TechDocs

Note: eIFU is not available for CE mark countries.

Trademark Acknowledgments

Patents: www.masimo.com/patents.htm

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