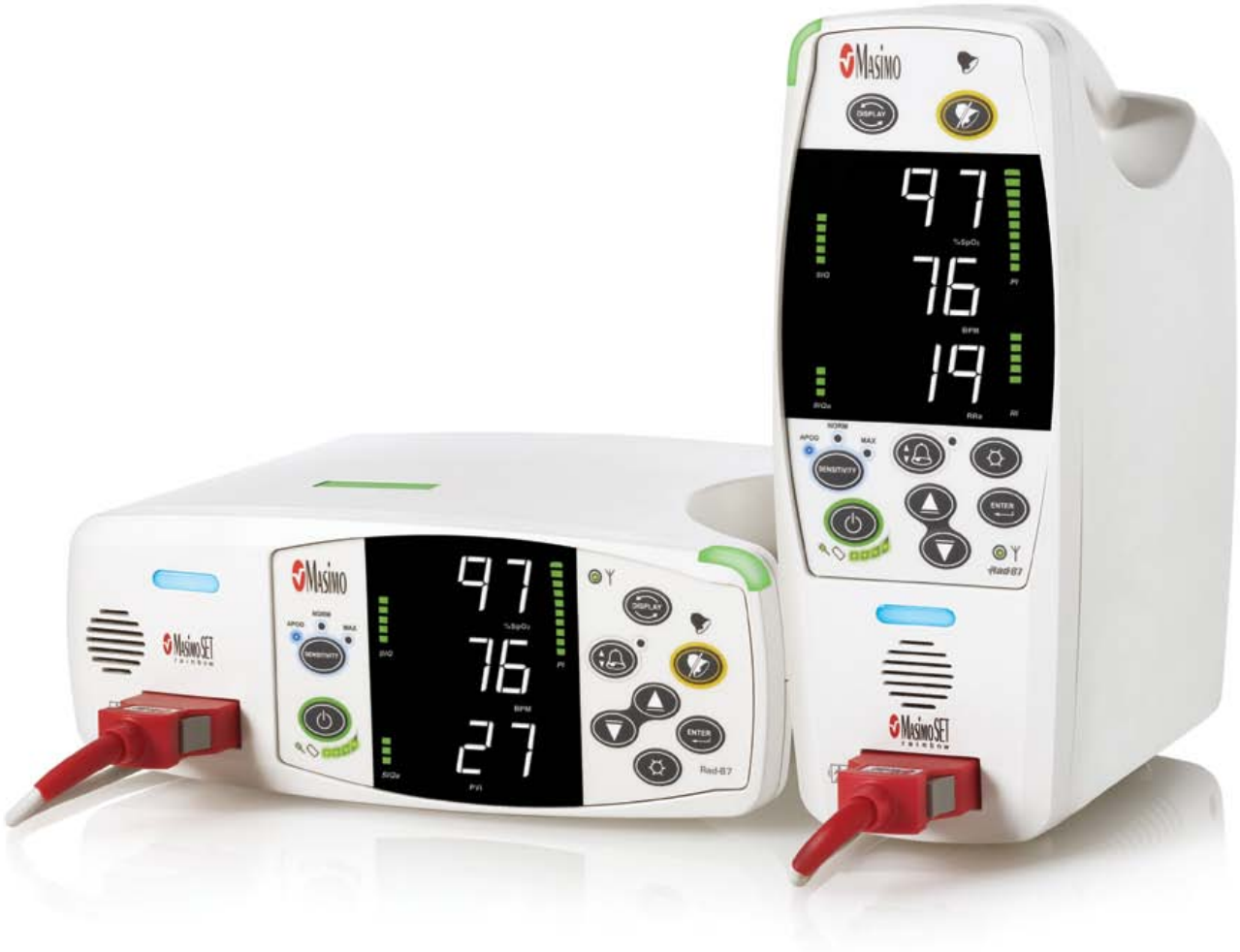
PULSE CO-OXIMETRY™

Rad-87™

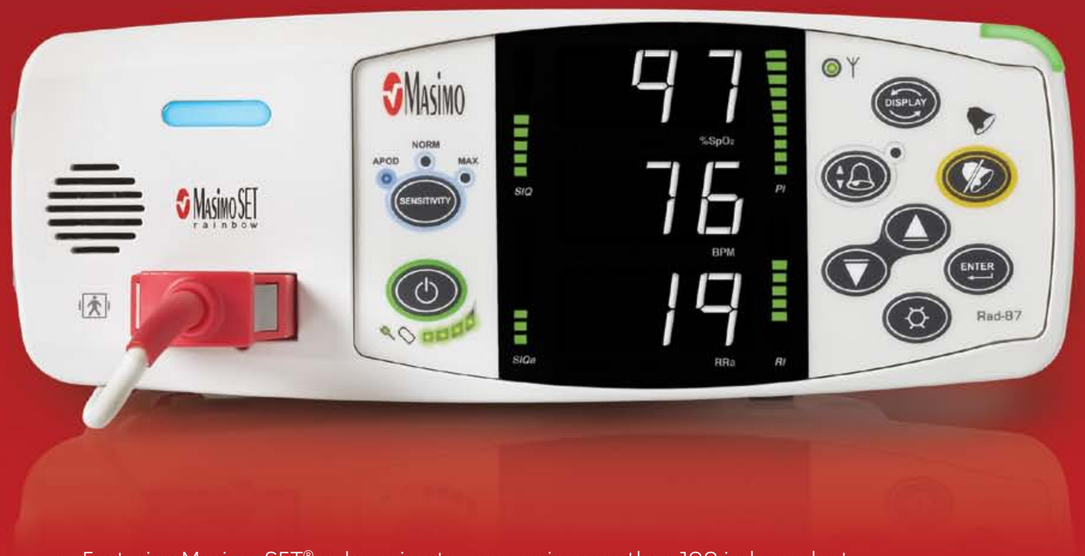
Upgradable rainbow® technology in a versatile, easy-to-use bedside monitor



Choose the noninvasive measurements that are right for your clinical setting—
oxygen saturation, pulse rate, and perfusion index in addition to total haemoglobin, total arterial oxygen content, pleth variablity index, carboxyhaemoglobin, methaemoglobin, and respiration rate

MASIMO

Masimo Rad-87

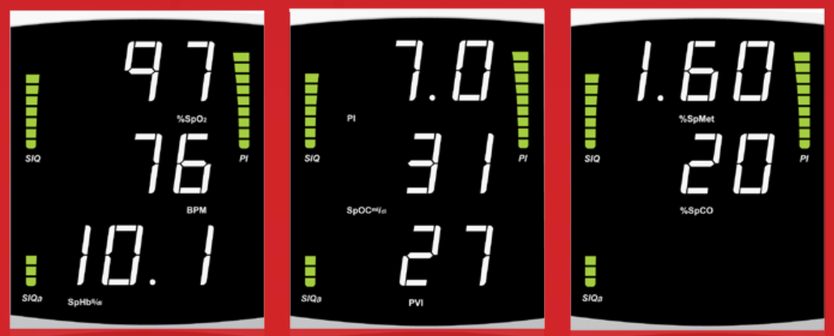


> Featuring Masimo SET® pulse oximetry, proven in more than 100 independent and objective studies.[1]

> Upgradable Masimo rainbow® SET technology platform lets you add total haemoglobin (SpHb®) and total arterial oxygen content (SpOC™) through simple field-installed software upgrades.

> Additional upgrades allow you to continuously and noninvasively measure carboxyhaemoglobin (SpCO®), methaemoglobin (SpMet®), pleth variability index (PVI®), and acoustic respiration rate (RRa™).

CUSTOM CONFIGURATION OPTIONS:



Instantly access, view, or modify alarm settings at the bedside.

Choose APOD®, Normal, or Max sensitivity with the touch of a button and verify settings at a glance.

In addition to SpO_2 and pulse rate, the Rad-87 allows you to select and display either SpHb, PVI, or RRa on the main screen, with additional measurements displayed on subsequent screens accessed with the press of a button.

> The Rad-87 features a built-in 802.11 radio, allowing for bidirectional wireless communication with Masimo Patient SafetyNet*, the remote monitoring and clinician notification system that helps you keep patients safe on general care floors.

FEATURES:

> A simple, user-centered design allows activation of many features with a single touch.

> Easy-to-read, high-contrast display eliminates confusion common with many bedside monitors.

> One platform, multiple measurements—fully upgradable to all rainbow measurements.

> Alarms and alerts can be modified at the bedside or via the Masimo Patient SafetyNet Remote Monitoring and Clinician Notification System.

> Perfusion Index (PI) with trending capability indicates arterial pulse signal strength and may identify patient compromise.

> Compatible with Phillips Vuelink™ device interface module.

> Adaptive Threshold Alarm™ option is designed to reduce nuisance alarms by dynamic adjustment of the audible alarms based on the patient's baseline value and the fixed alarm threshold.[2]

> Signal IQ® provides signal identification and quality indication during excessive motion and low signal-to-noise situations.

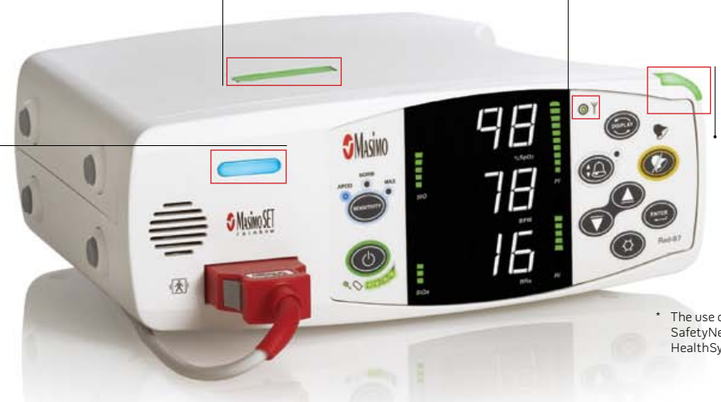
> Compatible with 802.11a/b/g.

AT-A-GLANCE DISPLAYS:

Top-side LCD Display: confirms changes to settings of the device and, when used as part of Patient SafetyNet, displays patient information.

Wireless Connectivity Indicator: provides easy verification of network connection when used as part of Patient SafetyNet.

Device Profile Indicator: verifies through color-coding that the device is in the correct care area and is configured properly.



System Status Indicator: notifies users of alarm and data-collection alerts, even when parameter display screen is not visible to clinician.

* The use of the trademark Patient SafetyNet is under license from University HealthSystem Consortium.

PERFORMANCE

Measurement Range
- SpO_2 ..... 0 – 100%
- SpMet ..... 0 – 99.9%
- SpCO ..... 0 – 99%
- SpHb ..... 0 – 25 g/dL
- SpOC ..... 0 – 35 ml of O_2/dL of blood
- Pulse Rate ..... 25 – 240 bpm
- Perfusion Index ..... 0.02 – 20%
- PVI ..... 0 – 100%
- RRa ..... 0 – 70 breaths per minute

Oxygen Saturation Accuracy SpO_2[2]
- Saturation ..... 60 – 80%
- No Motion
  - Adults/Infants/Paediatrics ..... ± 3%
- Saturation ..... 70 – 100%
- No Motion
  - Adults/Infants/Paediatrics ..... ± 2%
  - Neonates ..... ± 3%
- Motion
  - Adults/Infants/Paediatrics/Neonates ..... ± 3%
- Low Perfusion
  - Adults/Infants/Paediatrics/Neonates ..... ± 2%

Pulse Rate Accuracy[2]
- Pulse Rate ..... 25 – 240 bpm
- No Motion
  - Adults/Infants/Paediatrics/Neonates ..... ± 3 bpm
- Motion
  - Adults/Infants/Paediatrics/Neonates ..... ± 5 bpm
- Low Perfusion
  - Adults/Infants/Paediatrics/Neonates ..... ± 3 bpm

Carboxyhaemoglobin Saturation Accuracy (%SpCO)[2]
- Adults/Infants/Paediatrics ..... 1 – 40% ± 3%

Methaemoglobin Saturation Accuracy (%SpMet)[2]
- Adults/Infants/Paediatrics/Neonates ..... 1 – 15% ± 1%

Total Haemoglobin Accuracy (SpHb g/dL)[2]
- Adults/Paediatrics ..... 8 – 17 g/dL ± 1 g/dL

Respiration Rate Accuracy[2]
- Adults ..... 4 – 70 ± 1 breaths per minute

Resolution
- Oxyhaemoglobin Saturation (%SpO_2) 1%
- Carboxyhaemoglobin Saturation (%SpCO), Digital Display 1%
- Methaemoglobin Saturation (%SpMet), Digital Display 0.1%
- Total Haemoglobin (SpHb g/dL) ..... 0.1 g/dL
- Pulse Rate (bpm) ..... 1 bpm

Electrical
- AC Power Requirements ..... 100-240 VAC, 47-83 Hz
- Power Consumption ..... 15 VA Max

Batteries
- Type ..... Sealed lead acid
- Capacity (battery life) ..... up to 4 hours[3]
- Charging Time ..... 8 hours

Environmental
- Operating Temperature ..... 5°C to 40°C (41°F to 104°F)
- Storage Temperature ..... -40°C to + 70°C (-40°F to 158°F)
- Operating Humidity ..... 5% to 95%, noncondensing
- Operating Altitude ..... 500 mbar to 1060 mbar pressure
  -304 m to 5,486 m (-1000 ft to 18,000 ft)

Physical Characteristics
- Dimensions ..... 20.8 cm x 15.2 cm x 7.6 cm
  (8.2" x 6.0" x 3.0")
- Weight ..... 2.1 lbs = .908 kg = 32 oz
- Trending ..... 72 hours of trending at 2-second resolution

Modes
- Averaging Mode ..... 2, 4, 8, 10, 12, 14, or 16 seconds
- Sensitivity ..... APOD, Normal, and Max

Alarms
- High/low audible and visual alarms for parameters (SpO_2 range 1 – 99% then "---", SpHb range 0.1 – 24.5 g/dL then "---" SpCO, range 1 – 99% then "---", SpMet range 1 – 99% then "---", pulse rate range 25 – 240 bpm), sensor condition, system failure and low battery alarms
- Alarm Volume Range ..... 45 – 85 db

Display/Indicators
- Data Display: %SpO_2, %SpMet, %SpCO, SpHb g/dL, SpOC ml/dl, PVI, wireless, sensitivity, system status light, device profile light, pulse rate, alarm status, alarm silenced status, AC power, Signal IQ / pleth bar, perfusion index bar, battery status, no sensor, sensor off
- Display Language ..... English (default)
- APOD, Normal, and Max ..... LED

Output Interface
1) Serial RS-232
2) Nurse Call
3) Wireless Radio (if installed) ..... 802.11 a/b/g
4) Patient SafetyNet, RadNet, Philips Vuelink

Compliance
- Safety Standard for Medical Equipment ..... IEC 60601-1 2nd Edition
  UL 60601-1
  CAN/CSA C22.2 No. 601-1
  JIS T 6061-1
- Type of Protection ..... Class 1 (AC Power)
  Internally Powered (Battery Power)
- Degree of Protection (Pulse CO-Oximeter Cable) ..... Type BF,
  Defib Proof (Applied-Part)
- Mode of Operation ..... Continuous
- EMC Standard 60601-1-2

Radio
- USA ..... FCC ID VKF-Rad87
  FCC Parts 15.247 and 15.407
- Canada ..... IC ID 7362A-Rad87
  RSS-210
- Europe ..... EN 300328
  EN 301893
  EN 301489-17

[1] Shah N et al. *Journal of Clinical Anesthesia*. 2012. In press.

[2] SpO_2, SpCO, and SpMet accuracy has been validated on healthy adult male and female volunteers with light to dark skin pigmentations in the range of 60% - 100% SpO_2, 0% - 40% SpCO, and 0% - 15% SpMet against a laboratory CO-Oximeter. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentations in the range of 8 g/dL to 17 g/dL SpHb against a laboratory CO-Oximeter. The SpCO, SpMet and SpHb have not been validated with motion or low perfusion. Pulse Rate accuracy has been validated in the range of 25-240 bpm in bench top testing against a Biotek Index2 simulator. Respiration rate accuracy has been validated for the range of 4 to 70 breaths per minute in bench top testing. Clinical validation for up to 30 breaths per minute was also performed with the Masimo Acoustic Respiration sensor and instrument. The variation in accuracy specifications equals plus or minus 1 standard deviation which encompasses 68% of the population. Contact Masimo for testing specifications.

[3] This represents approximate runtime at the lowest indicator brightness and pulse tone turned off using a fully charged battery without radio power.

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