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Nellcor™ Bedside SpO_2 Patient Monitoring System, PM100N

Accuracy
Accurately assesses patients' status with pulse oximetry measurements of ± 2 for 70% to 100% saturation, and low saturation accuracy of ± 3 for 60% to 80%.

Speed
Reacts to patient status with technology that displays patient oxygenation and pulse rate more quickly than other technologies.[4,5]

Motion Tolerance
Accurately assesses patients' status during periods of movement or noise, avoiding dropouts or delays. Covidien is the first company to receive FDA clearance for a motion--tolerant pulse oximeter that is also compliant with ISO 80601-2-61.[3,6]

Flexible. Affordable. Intuitive
- Displays real-time SpO_2 and pulse rate measurements, plethysmographic waveforms and pulse amplitude
- SatSeconds alarm management
- Sleep Study mode
- Homecare mode
- Adult, Pediatric, Neonate modes
- Intuitive, easy-to-read, color, multiple-language user interface with on-screen help messages
- Easy-to-use jog dial interface
- Compact, portable, durable design with built-in handle
- Variable pitch beep tone for point-by-point differentiation in SpO_2
- 96-hour trend memory

Monitor with confidence

The Nellcor™ Bedside SpO_2 Patient Monitoring System

- Incorporates the latest Nellcor™ digital signal processing technology for accurate, reliable readings even during low perfusion, motion and other forms of signal interference[1,2]
- Provides clinicians with real-time information regarding their patients' respiratory status, including continuous SpO_2 and pulse rate monitoring and trending data
- Includes SatSeconds alarm management, a clinician-controlled feature that can distinguish between real, clinically significant events and transient events by taking into account both the severity and the duration of any desaturation event
- Meets IEC 60601-1-11 standards for home health equipment compliant Homecare and Sleep Study modes for safe and effective use of the monitor by lay users and in non-hospital settings[3,6]

With the Nellcor™ Bedside SpO_2 Patient Monitoring System clinicians can feel confident in their ability to detect respiratory complications early and intervene promptly.

Features and specifications

Performance

Measurement Range	SpO_2: 1% to 100%
Pulse rate	20 to 250 beats per minute (bpm)
Pulse amplitude	0.03% to 20%

Measurement Accuracy

Saturation

Adult	70% to 100% ± 2 digits
Adult and neonate low sat	60% to 80% ± 3 digits
Neonate	70% to 100% ± 2 digits
Low perfusion	70% to 100% ± 2 digits
Adult and neonate with motion	70% to 100% ± 4 digits

Pulse rate

Adult and neonate	20 to 250 bpm ± 3 digits
Low perfusion	20 to 250 bpm ± 3 digits
Adult and neonate with motion	20 to 250 bpm ± 5 digits

Electrical

Instrument

Power requirements	100 to 240 VAC, 50/60 Hz, 45 VA
Fuse rating	Fast-acting 2 A 32VAC/DC, Fast-acting 500 mA 32VAC/50DC

Battery

Type	Lithium ion
Battery capacity	Minimum of five hours using new, fully charged battery with no alarms; optional 10-hour battery

Environmental

Operating Temperature

Instrument	5 °C to 40 °C (41 °F to 104 °F)
Transport/Storage Temperature (in shipping carton)	-20 °C to 60 °C (-4 °F to 140 °F)
Operating Humidity	15% to 93% noncondensing
Operating Altitude	-170 m to 4877 m (-557 ft to 16,000 ft)

Physical Characteristics

Weight	1.5 kg (3 lbs)
Size	82 H x 255 W x 155 D (mm), (3.23 H x 10.04 W x 6.10 D (in)

Equipment Compliance

Standards Compliance

- IEC 60601-1:2005+A1:2012, EN 60601-1:2006/AC:2010
- IEC 60601-1:1998 + A1:1991 +A2:1995, EN 60601-1:1990 +A11:1993 +A12:1993 +A13:1996
- IEC 60601-1-2:2007, EN60601-1-2:2007
- IEC 60601-1-6:2010, EN 60601-1-6:2010 +A1:2013
- IEC 60601-1-8:2006, EN 60601-1-8:2006 +A1:2012
- IEC 60601-1-11:2010, EN 60601-1-11:2010
- ISO 9919:2005, EN ISO 9919:2009
- ISO 80601-2-61:2011, EN ISO 80601-2-61:2011
- CAN/CSA C22.2 No. 601.1 M90
- UL 60601-1: 1st edition
- 802.11 B/G/N WLAN connectivity

Equipment Classifications

- Type of protection against electric shock: Class 2 (internally powered)
- Degree of protection against electric shock: Type BF – Applied part
- Mode of operation: Continuous
- Electromagnetic compatibility: IEC 60601-1-2:2007
- Liquid ingress: IP 22
- Degree of safety: Not suitable for use in the presence of flammable anesthetics

Output

- Trend data download via wired or USB for archiving or data analysis

Display/Indicators

- Pulse amplitude indicator (eight segments)
- Visual indicators: Pulse search, audible alarms silenced or off, interference indicator, battery charging, and SatSeconds alarm management clock, pleth wave form

Alarms

- SatSeconds alarm management
- Audible and Visual alarms for high/low saturation and pulse rate, low battery, sensor off, and sensor disconnect
- Categories: Patient status and system status
- Priorities: Low, medium and high
- Notification: Audible and visual
- Setting: Default, institutional and last setting
- Alarm system delay: <10 s

Optional Accessories

- 10 and 15 hour battery
- Adapter plate
- GCX wall mount arm and channel
- GCX roll stand
- Carrying case

Available Modes

- Standard – Hospital, hospital-type facilities, and intra-hospital transport.
- Homecare – Simplified monitoring for use in the home by caregivers
- Sleep Study – Muted audible and visual queues to aid sleep studies

Connectivity

- Supports wired and USB trend data export to an external personal computer for archiving or data analysis
- Nurse call capability

Simple set up and maintenance

The Nellcor™ Bedside SpO_2 Patient Monitoring System meets medical electrical equipment standards,[3] is RoHs compliant,[6] and enables hospital staff to set institutional defaults, replace the battery, perform diagnostics to troubleshoot performance issues, and perform on-site maintenance on the monitor.

1. Clinical Report, COVMOPR0384, Motion, LAMP-C (p/n 10099560)
2. Clinical Report, COVMOPR0250, LowSat Accuracy, LAMP-C (p/n 10099561)
3. 510(k) K123581 and certificate US-23250-M1-UL
4. Saraswat A, Simionato L, Dawson J, et al. Determining the best method of Nellcor pulse oximeter sensor application in neonates. *Acta Paediatr.* 2012;10195):484-487.
5. O'Donnell CPF, Kamlin COF, Davis PG, Morley CJ. Obtaining pulse oximetry data in neonates: a randomized crossover study of sensor application techniques. *Arch Dis Child Fetal Neonatal Ed.* 2005;90:F84-F85.
6. Declaration of Conformity n°10138709 rev A - Sept 24th, 2014

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