MONITOR WITH CONFIDENCE



Nellcor™ Bedside SpO₂ Patient Monitoring System, PM100N

ACCURACY

Accurately assesses patients' status with pulse oximetry measurements of \pm 2 for 70% to 100% saturation, and low saturation accuracy of \pm 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. Medtronic 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 SpO₂ 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 SpO₂
- 96-hour trend memory

THE NELLCOR™ BEDSIDE SpO₂ 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 SpO₂ 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
- 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 SpO₂ Patient Monitoring System clinicians can feel confident in their ability to detect respiratory complications early and intervene promptly.





Features and specifications

Performance

MEASUREMENT RANGE		
SpO₂	1% to 100%	
Pulse rate	20 to 250 beats per minute (bpm)	
Pulse amplitude	0.03% to 20%	

Measurement Accuracy

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SATURATION			
Adult	70% to 100% ± 2 digits		
Neonate	70% to 100% ± 2 digits		
Adult and neonate low sat	60% to 80% ± 3 digits		
Lowperfusion	70% to 100% ± 2 digits		
Adult and neonate with motion	70% to 100% ± 3 digits		
PULSE RATE			
Adult and neonate	20 to 250 bpm ± 3 digits		
Lowperfusion	20 to 250 bpm ± 3 digits		
Adult and neonate with motion	20 to 250 bpm ± 5 digits		

Electrical

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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		
Туре	Lithiumion	
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 95% 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 × 255 W × 155 D (mm), (3.23 H × 10.04 W × 6.10 D (in)	

Equipment Compliance

Standards Compliance

- EC 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
- GCX roll stand
- Adapter plate
- Carrying case
- GCX wall mount arm and channel

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 $^{\infty}$ 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.

References

- 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
- 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.
- 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.
- $6.\quad \mathsf{Declaration}\,\mathsf{of}\,\mathsf{Conformity}\,\mathsf{n}^{\circ}\mathsf{10138709}\,\mathsf{rev}\,\mathsf{A}\,\mathsf{-}\,\mathsf{Sept}\,\mathsf{24th},\mathsf{2014}$

