Nellcor™ Bedside Respiratory Patient Monitoring System PM1000N

Nellcor™ Bedside Respiratory Patient Monitoring System Features

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

**Speed**
Quickly react to changing patient status with technology that has been shown to respond and display changes in patient oxygenation and pulse rate more quickly than other technologies.

**Motion Tolerance**
Accurately assess patients’ status during periods of movement or noise, avoiding dropouts or delays. Covidien is the first and only company to receive FDA clearance for a motion-tolerant pulse oximetry and compliance with ISO 80601-2-61.

**Alarm Management**
Distinguish between clinically significant desaturations and transient events with SatSeconds alarm management, and identify indications of repetitive reductions in airflow (RRIA) through an adult patient’s upper airway and into the lungs with OxiMax™ Saturation Pattern Detection alert (SPD).

The Nellcor™ bedside respiratory patient monitoring system incorporates the latest Nellcor™ digital signal processing technology for accurate, reliable readings even during low perfusion and motion. Its intuitive, easy-to-read, graphical user interface and color touchscreen provide you with easy access to the critical information you need.

The system provides continuous SpO2, pulse rate and respiration rate monitoring, Nellcor™ SatSeconds alarm management, and OxiMax™ SPD alert, so you can confidently detect respiratory complications early and intervene quickly. The system’s highly modular software and hardware can be upgraded on-site with new features and parameters, offering long-term functionality and flexibility.

The system memory stores up to 48 hours worth of trend data at one second intervals, for review of real time and historical trend data. With this information, clinicians get a complete picture of patient status and are better informed to make treatment decisions.

Examples of PM1000N screen layouts
Features and Specifications

**Performance**

**Measurement Range**
- \( \text{SpO}_2 \): 1% to 100%
- Pulse rate: 20 to 250 beats per minute (bpm)
- Pulse amplitude: 0.03% to 20%

**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% ±3 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: 80-263 VAC, 47/63 Hz, 30 VA power
- Fuse rating: Slow blow 1.5A 250V

**Battery**
- Type: Li-Ion
- Battery capacity: 6 hours under nominal load conditions

**Environmental**

**Operating Temperature**
- Instrument: 5°C to 40°C (41°F to 104°F)
- Transport/Storage Temperature (in shipping carton): -40°C to 70°C (-40°F to 160°F)

**Operating Humidity**
- 15% to 95% noncondensing

**Operating Altitude**
- -304.8 m to 4572 m (-1000 ft to 15,000 ft)

**Physical Characteristics**

**Weight**
- 3.4kg (7.5 lbs)

**Size**
- 254 x 165 x 127 (mm)
- 10 x 6.5 x 5 (in)

**Equipment Compliance**

**Standards Compliance**
- EN ISO 80601-2-61:2011
- EN IEC 60601-1:2005
- EN IEC 60601-1-2: 2007.03.01 3rd edition
- EN IEC 60601-1-2: 2nd edition
- EN IEC 60601-1-9: 2007
- ISO 10993-1:2003
- CAN/CSA C22.2 No. 60601-1-08
- WEEE 2002/96/EC
- RoHS directive 2011/65/EU

**Equipment Classifications**

**Type of protection against electric shock:**
- Class 1 (internally powered)

**Degree of protection against electric shock:**
- Type BF - Applied part

**Mode of operation:**
- Continuous

**Electromagnetic compatibility:**
- Liquid ingress: IPX1

**Degree of safety:**
- Not suitable for use in the presence of flammable anesthetics

**Output**

- Stores up to 48 hours of trend data readings that can be downloaded for analysis and archive
- Capability to connect to both wired and wireless LAN networks
- Capability to connect to Philips Vuelink Module and Nurse Call via wireless serial port
- Capability to download trend data to PC

**Display/Indicators**

**Pulse Amplitude Indicator**
- 16 segments

**Plethysmographic waveform**
- Real time numbers
- Real time trend data

**Multiple alarm conditions**
- Up to 3 alarm conditions simultaneously

**SatSeconds Alarm Management**
- OxiMax SPD Alert
- Battery Charging
- Clock
- Event Marker
- Histogram Display
- Clinical Log
- Neonatal Default Mode

**Alarms**

- Audible and visual alarms for high/low saturation and pulse rate
- SatSeconds Alarm Management settings: 10, 25, 50 and 100, or OFF
- Saturation Pattern Detection sensitivity setting: 1, 2, 3 or OFF
- Pulse Rate Delay settings: 5, 10 or OFF
- Audible and visual warning indicators for low battery and sensor off
- Audible and visual sensor disconnect alarms
- Communication failure visual alarm
- Backup audible alarm
- Variable pitch beep tone for point-by-point changes in \( \text{SpO}_2 \)
- User configurable sensor alarm prioritization

**Optional Accessories**

- GCX mounting adapter
- Interface cable

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4. 510(k): # K123581 510(k) Submission Date 11/19/2012
5. For accurate and reliable in low perfusion: 510(k): # K012891 510(k) Submission Date 3/07/2002 clinical publications at NCT01720355 at Clinical Trials.gov
6. For accurate and reliable in motion: 510(k): # K123581 510(k) Submission Date 11/19/2012 clinical publications at NCT01720355 at Clinical Trials.gov

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