

Nellcor™ Pulse Oximetry

Medtronic



%SpO₂ 13:48:46

PR BPM

98 = 65

SpO₂ (%)



HISTORY

From One Product to Complete Solutions

1981: Nellcor™ was founded over three decades ago to market the first Pulse Oximeter and has grown to become the world's foremost supplier of pulse oximetry. Nellcor™ began as a small company in Hayward, California, across the bay from Stanford Medical Centre. Merging medical science and technology, Nellcor™ pioneered pulse oximetry as we know it today and rapidly gained prominence as the worldwide leader in pulse oximetry products.

With every Nellcor™ product, clinicians can expect an exceptional level of customer service and technical support. They can also take advantage of a comprehensive array of Clinical Education Resources. We have an expert team of Product Specialists and Clinical Educators ready to assist our customers wherever they deliver patient care.

Dedicated to Innovation

Nellcor™ remains committed to producing leading-edge products that help clinicians provide better patient care. Nellcor™ continues to pioneer innovative non-invasive solutions with new and vital parameters and predictive and interpretive information. Technology, such as the OxiMax™ Pulse Oximetry System, illustrate Nellcor's™ technological expertise and dedication to continually improving patient care. We offer the most comprehensive selection of pulse oximetry monitors and sensors, with a proven record for performance. We are an established leader in the industry and have an extensive portfolio of products and programs designed to meet our customer's most stringent clinical needs and to provide financial value.

In late 2014 we released our new Nellcor™ Respiration Rate software to be used with the new PM1000N-RR Monitor and new Adult Respiration Rate Sensor (Code 10068119) for patients >30kgs. This single sensor will provide SpO₂, heart rate and now respiration rate continuously and non-invasively.





NELLCOR™ OXIMAX™ PULSE OXIMETRY

Our latest pulse oximetry platform, the OxiMax™ Pulse Oximetry System, includes a broad selection of monitors and sensors. The OxiMax™ platform provides exceptional monitoring performance and enables Nellcor™ to offer innovative sensors that address specific clinical challenges.

In addition, the OxiMax™ platform has enabled Nellcor™ to expand the accuracy specifications of certain OxiMax™ sensors to an industry-leading $\pm 3\%$ in the 60% - 80% SpO₂ range. This LoSat expanded accuracy feature helps clinicians better manage patients in the challenging lower saturation ranges.

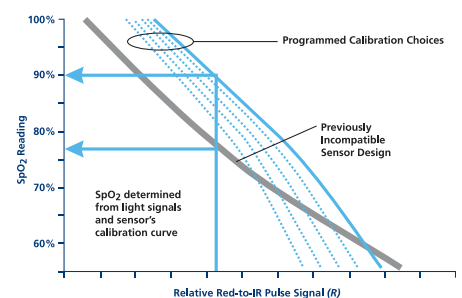
PERFORMANCE THAT SPEAKS TO YOU

With the OxiMax™ Pulse Oximetry System, Nellcor™ embarks on a technology platform that enables us to break free from the past and bring you pulse oximetry like you've never experienced before. Previously, sensor calibration resided within the monitor, and sensor designs had to conform to the pre-programmed data in order to calculate oxygen saturation (SpO₂). Now a digital memory chip is embedded in the sensor itself that contains all the calibration and operating characteristics for that specific sensor design. This gives the monitor the flexibility to operate accurately with a diverse range of sensor designs, while opening up a whole new world of pulse oximetry innovation that will help you provide better patient care.

LIMITATIONS OF MONITOR BASED CALIBRATION

Traditional pulse oximetry requires one calibration curve or a limited set of curves to be programmed within the monitor. Sensor designs must conform to the pre-programmed data to accurately calculate oxygen saturation (SpO₂). OxiMax™ technology moves the sensor's specific calibration information into the sensor, providing infinite latitude in sensor design.

Note: When OxiMax™ sensors are used with previous-generation Nellcor™ and Nellcor™ compatible monitors, many OxiMax™ system features are not accessible. Because of their unique performance characteristics, the Max-Fast™ Forehead Sensor and SoftCare™ Non-adhesive Sensors do not operate with previous-generation Nellcor™ monitors.



HOW DO OTHER BRANDS OF PULSE OXIMETRY WORK?

Other brands use a form of Resistor Calibration or RCAL Technology (analogue technology). This technology was originally developed and patented by Nellcor™ but now other pulse oximetry companies can utilise this technology. Unfortunately RCAL Technology does not guarantee the saturation accuracies in the low ranges of 60-80% SpO₂ due to the limitation of the pre-programmed calibration choices (as discussed on the previous page). Nellcor™ uses the pulse rate prior to determining the SpO₂ value.

Other companies are also known to focus on their signal processing but are still using analogue technology.

In summary, both forms of technology, analogue and digital are very good with reading through movement but the digital technology allows tighter accuracies in the low saturation ranges of 60-80% SpO₂ versus the standard 70-100% SpO₂.

This is why the Nellcor™ OxiMax™ platform has enabled the development of specialist sensors such as the Max-Fast™ Forehead Sensor to deal with patients that are poorly perfused and also have low SpO₂ levels.

NELLCOR™ OXIMAX™ TECHNOLOGY IS AVAILABLE IN MOST BRANDS OF MULTI PARAMETER MONITORING.

The Nellcor™ OxiMax™ platform is also available with the listed monitoring companies in various forms, either in the multi measurement server, a separate module or in a pod form. Customers have the option to request Nellcor™ OxiMax™ technology as their preferred oximetry technology when ordering the Multi Parameter Monitoring System. If Nellcor™ OxiMax™ technology is not requested, the standard analogue oximetry technology (RCAL) will be provided.

Most patient monitor manufacturers in the past also offered Nellcor™ technology in their products, making them compatible with Nellcor™ sensors. This is why with some of your older monitoring systems you can still use Nellcor™ sensors but these monitors do not have our Nellcor™ OxiMax™ technology due to their age.

Nellcor™ OxiMax™ Works Here/ Covidien Nellcor™ SpO₂

- In the past our customers may have sighted the “Nellcor Works Here™” icon which means that you can use all our Nellcor™ sensors EXCLUDING the MaxFast™ Forehead Sensor and SoftCare™ non-adhesive Sensors. This is our RCAL Technology (our previous Resistor Calibration Technology - RCAL).
- When you now see the “Nellcor OxiMax™ Works Here™/Covidien Nellcor™ SpO₂” icon, this indicates that you have our latest level of technology (digital technology) to use all of our sensor range, including the MaxFast™ Forehead Sensor and SoftCare™ non-adhesive sensors.



Compatibility:

- Dräger Medical
- GE Healthcare
- Mindray [Datascope Patient Monitoring]
- Philips
- Spacelabs Healthcare
- Welch Allyn
- Plus Others...

OXIMAX™ MAXFAST™ FOREHEAD SENSOR

Why a Forehead Sensor Makes Sense

Offering a significant advancement in patient safety monitoring, the MaxFast™ Forehead Sensor is part of the OxiMax™ Pulse Oximetry System. The MaxFast™ Forehead Sensor provides an effective monitoring option when digit sensors fail to obtain a SpO₂ signal during poor perfusion conditions, detecting changes in SpO₂ notably earlier than digit sensors.

Faster Hypoxaemia Detection

Designed for use on the patient's forehead, placed over the supraorbital arterial bed, a site closer to the heart and with no vasoconstrictive properties. The MaxFast™ Forehead Sensor responds to changes in oxygen saturation typically one to two minutes sooner than digit sensors. This sensor is specifically designed for patients with weak pulses and peripheral shutdown.

Highly Accurate

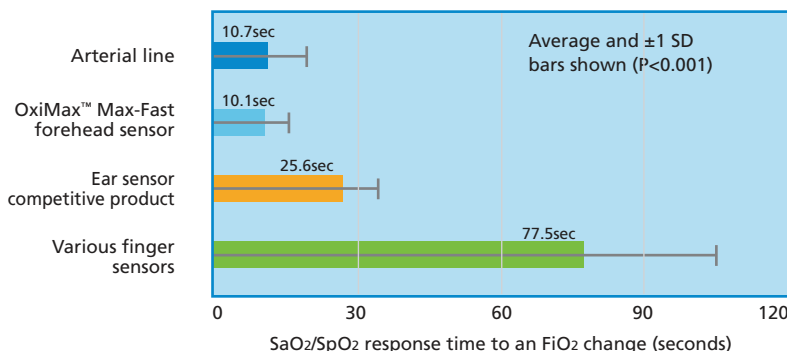
The MaxFast™ Forehead Sensor is more accurate than all other ear, nose and forehead sensors.¹ It also has our industry leading LoSat expanded accuracy range (+/-3% in the 60% – 80% SpO₂ range) and can be used with Nellcor™ OxiMax™ pulse oximetry, for better patient management.¹



OxiMax™
MAXFASTI



Response to a hypoxic event with peripheral vasoconstriction
not all sensor sites are the same



OXIMAX™ SOFTCARE™ NON-ADHESIVE SENSORS

A Gentle Alternative for Poor Skin Integrity

Designed for the OxiMax™ Pulse Oximetry System, SoftCare™ non-adhesive sensors give clinicians an alternative to adhesive sensors for patients with fragile skin. SoftCare™ non-adhesive sensors are ideal for monitoring neonates and preterm infants, geriatric and burn patients.

The SoftCare™ Non-Adhesive Solution

Nellcor™ was the first company to offer a non-adhesive pulse oximetry sensor with a comfortable, secure “second-skin” fit. SoftCare™ non-adhesive sensors coupled with OxiMax™ technology deliver

exceptional monitoring performance, even for your most challenging patients.

- Sensors fasten with Velcro® instead of adhesive tape.
- Sensor bandage is made of a soft, pliable, low-profile foam material that gives it “stickiness” to help keep the sensor in place without adhesives.
- Sensors are designed for single-patient use and are packaged sterile to help alleviate infection control concerns.
- Design eliminates the need to remove and apply additional adhesive when checking or changing sensor sites.
- Improved optics maximises signal acquisition to overcome challenges of weak pulses and thick or darkly pigmented skin.

Three SoftCare™ Choices

SoftCare™ non-adhesive sensors come in three models designed for neonatal and adult patients:

- SC-PR-I for preterm infants weighing < 1.5 kg.
- SC-NEO-I for neonatal patients weighing 1.5 to 5 kg.
- SC-A-I for adult patients weighing > 40 kg.

SoftCare™

SC-PR-I (<1,5KG)

SC-NEO-I (1,5 to 5KG)

SC-A-I (>40KG)



OXIMAX™ ADHESIVE SENSOR RANGE

Nellcor™ OxiMax™ adhesive sensors are designed for continuous monitoring. They help pulse oximetry technology deal with patient movement due to the adhesion preventing actual movement of the sensor on the patient's skin.

They are highly accurate and feature tear-resistant bandages that provide a comfortable, secure "second-skin" fit. The sensor bandage is also designed to prevent ambient light from interfering with SpO₂ readings.

Product Features

- Sterile, single-patient-use sensors for neonates through to adults.
- LoSat expanded accuracy range helps clinicians better manage patients in the challenging lower saturation ranges of 60% to 80% SpO₂.
- Tear-resistant bandages for durability.
- Extra electronic shielding in the bandage prevents light interference.
- Compatible with OxiMax™ and earlier-generation Nellcor™ pulse oximetry.
- OxiMax™ digital memory chip enables special communication features when sensors are used with full-featured OxiMax™ Pulse Oximeters.
- Sensor Messaging relays trouble shooting tips for optimal sensor placement.
- Sensor Event Reporting allows alarm event history to travel with the patient for quick assessment at various points of care.

Note: LoSat feature is not available in the MAX-R nasal sensor.



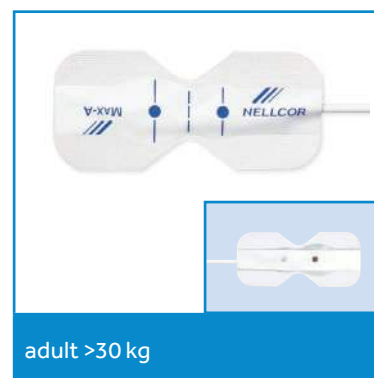
OxiMax™ Nasal Sensor

MAXRI



OxiMax™ Adult/Adult Long Sensor

MAXAI / MAX-AL-I



OxiMax™ Infant Sensor

MAX-I-I



OxiMax™ Neonatal Sensor

MAX-N-I



OxiMax™ Respiration Rate Sensor

10068119



OxiMax™ Paediatric Sensor

MAX-P-I





OXIMAX™ REUSABLE SENSOR RANGE

Reusable sensor options designed for spot checks or short-term monitoring. All of our reusable sensors work with OxiMax™ Pulse Oximeters as well as earlier generation Nellcor™ Pulse Oximetry.

Product Features

- All models shipped non-sterile.
- Easy-to-use design.
- Built-in shielding protects signal from electronic noise.
- High quality LEDs maximise tracking capabilities.

Indications For Usage

- Neonatal through to adult patients (see weight ranges under ordering information).
- Almost any clinical setting requiring SpO₂ spot checks or short term monitoring.

OxiMax™ OXIBAND™

OXI-A/N



adult/neonatal <3 kg or >40 kg

OxiMax™ OXIBAND™

OXI-P/I



paediatric/infant 3-40 kg

OxiMax™ DURASENSOR™

DS100A



adult >40 kg

FlexMax™ and FlexMax-P Sensors

- The new flexible reusable rubber pulse oximetry sensor – for a broad range of sizes. It comes in two sizes — large and small — with a >20 kilogram weight range, one of the broadest available.
- Designed for dippable cleaning.
- Use it for transport, in the hospital, at home or even rotary and fixed-wing aircraft.

OxiMax™

FLEXMAX/FLEXMAX-P



adult/paed >20kg



OXIMAX™ REUSABLE SENSOR ACCESSORIES

D-YS

- Dura-Y™ ear clip accessory (D-YSE) available for alternative application site.
- PediCheck™ paediatric spot-check clip (D-YSPD) accessory available for spot-check monitoring not exceeding 20 minutes.

OxiMax™ DURA-Y™

D-YS



multisite >1kg

OxiMax™ D-YSE

D-YSE (for use with D-YS)

D-YS has to be ordered seperately.



ear clip >30 kg

OxiMax™ PEDICHECK™ Replacement Sleeve

PDSLIV (for use with D-YS)

D-YS has to be ordered seperately.



paediatric spot check 3-40kg

OxiMax™ PEDICHECK™

D-YSPD (for use with D-YS)

D-YS has to be ordered seperately.



paediatric spot check 3-40kg

POSEY



Posey™ wrap for OXI-P/I, OXI-A/N and D-YS sensors
(code: POSEY)

FOAMA/N



Foam wrap for OXI-A/N and D-YS sensors
(code: FOAMA/N)

ADH-A/N



Adhesive wrap for OXI-A/N and D-YS sensors
(code: ADH-A/N)

FOAMP/I



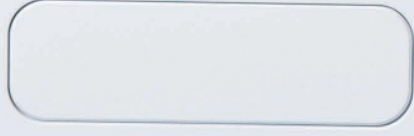
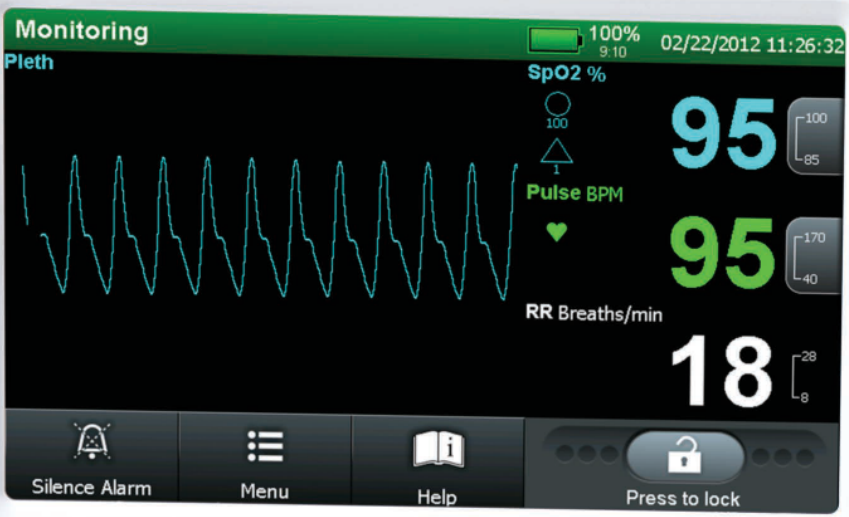
Foam wrap for OXI-P/I and D-YS sensors
(code: FOAMP/I)

ADH-P/I



Adhesive wrap for OXI-P/I and D-YS sensors
(code: ADH-P/I)

COVIDIEN
Nellcor



OXIMAX™ MONITORS

Nellcor Bedside Respiratory Patient Monitoring System

The Nellcor™ Bedside Respiratory Patient Monitoring System incorporates the latest Nellcor digital signal processing technology for accurate, readings even during low perfusion and other forms of signal interference. Its intuitive, easy-to-read, graphical user interface and state-of-the-art colour touchscreen provide you with easy-access to the critical information you need.

The system memory stores up to 48 hours worth of trend data at one second intervals. You can view the data in real time, as historical trend data in graphical and tabular views, or download the data to a USB flash drive.

Single Sensor Technology. Efficient, Early Warning to Evolving Respiratory Compromise

Nellcor™ Respiration Rate technology provides an assessment of your patients' oxygenation and respiration rate trend through a single finger sensor. This new technology delivers non-invasive, continuous monitoring of respiratory status

and an early warning of impending respiratory distress.

The Respiration Rate software uses pulse oximetry technology, sensors and workflows to derive respiration rate based on the changes in the photoplethysmogram (pleth) waveform that occur as a result of breathing. Breathing causes changes in the cardiovascular, respiratory and autonomic nervous systems and results in changes in the pleth waveform. These modulations can be used to calculate respiration rate.

Nellcor™ Respiration Rate complements SpO₂, pulse rate and Saturation Pattern Detection (SPD) Alert to provide a more complete picture of a patient's respiratory status. Using this information, clinicians may identify evolving respiratory compromise sooner and intervene more quickly to minimise the risk of dangerous respiratory events.

Alarm Management System

Saturation Pattern Detection (SPD™) alert which detects desaturation patterns indicative of repetitive reductions in airflow

in adults, even if the patient hasn't crossed the SpO₂ threshold. AMS also includes SatSeconds™ Alarm Management System, which provides a practical way to reduce less clinically significant alarms.

Nellcor™ Respiration Rate Software Features

- Provides a continuous, non-invasive measurement of respiration rate in adults in hospitals and hospital-type facilities.
- Accuracy of ±1 breath per minute when compared to respiration rate derived from a capnography based reference.



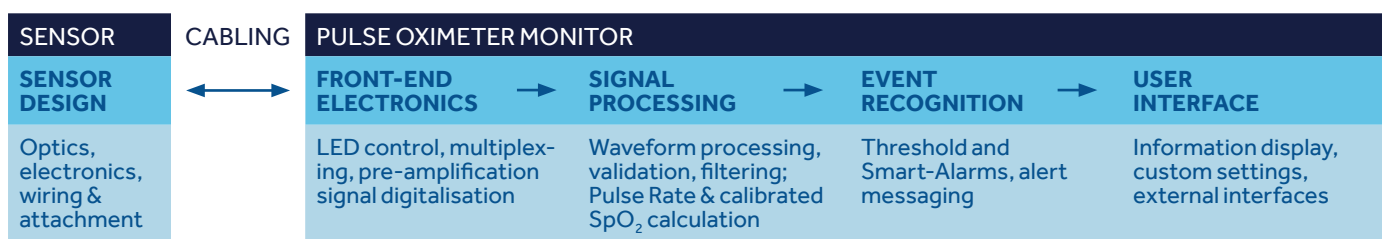
Code: PM1000N-RR-MAX
(including one case of adhesive sensors of customer choice)

Code: PM1000N-RR-1A
(including one reusable sensor of customer choice (DS100A or D-YS or OXI-A/N or OXI-P/I))



Code: PM1000N-MAX
(including one case of adhesive sensors of customer choice)

Code: PM1000N-1A
(including one reusable sensor of customer choice (DS100A or D-YS or OXI-A/N or OXI-P/I))



OXIMAX™ MONITORS

Nellcor Bedside SpO₂ Patient Monitoring System

The Nellcor™ Bedside SpO₂ Patient Monitoring System incorporates the latest Nellcor digital signal processing technology for accurate readings even during low perfusion and other forms of signal interference.

The Nellcor™ Bedside SpO₂ Patient Monitoring System with OxiMax™ technology offers a compact, bedside design with improved functionality such as an intuitive, easy-to-use and easy-to-read, colour user interface, which makes it simpler for clinicians to review and download critical patient data. With continuous SpO₂ and pulse rate monitoring, trending data and SatSeconds™ alarm management, clinicians can feel confident in the ability to detect respiratory complications earlier and intervene sooner.

- 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

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.

Features & Benefits

- Flexible. Affordable. Intuitive
- Displays real-time SpO₂ and pulse rate measurements, plethysmographic waveforms and pulse amplitude
- SatSeconds alarm management
- Sleep Study Mode, which enables the clinician to dim the LCD display and silence alarms to prevent disruption of patients' sleep
- Homecare mode
- Adult, Paediatric, Neonate modes with on-screen help messages
- Easy-to-use jog dial interface
- Compact, portable, durable design with built-in handle
- 96-hour trend memory

Code: PM100N-MAX

(including one case of adhesive sensors of customer choice)

Code: PM100N-1A

(including one reusable sensor of customer choice (DS100A or D-YS or OXI-A/N or OXI-P/I))



NELLCOR™ SpO₂ MODULE FOR PHILLIPS INTELLIVUE™* MONITOR

Why Nellcor™ Pulse Oximetry With Oximax™ Technology?

Founded on three basic principles:

- **Track the truth**
- **Give no false assurance**
- **Do no harm.**

These principles guide the design of our Nellcor™ pulse oximetry with OxiMax™ technology, which provides clinical performance that helps ensure appropriate oxygenation throughout the cardiorespiratory cycle - even in such difficult monitoring conditions as low perfusion and signal interference.¹

Philips Multi-Measurement Modules (MMS and X2) Option A04, Nellcor™ SpO₂ Module, and configured patient monitors (MP2 and MP5) Option SP4 incorporate Nellcor™ pulse oximetry with OxiMax™ technology, and achieve accurate readings - even during low perfusion or signal interference.

Nellcor™ SpO₂ Module Features

- Designed to be used in a range of critical care environments
- Compatible with the full line of Nellcor™ sensors with OxiMax™ technology, including the Nellcor™ SpO₂ forehead sensor
- Produces the numerics for the arterial oxygen saturation value, a real-time wave for the plethysmogram, and the pulse rate numeric for display on Philips IntelliVue™ patient monitors
- Rugged design to withstand the stresses of the clinical environment
- Light indicator for identifying affected parameter module during a monitor task
- Colour-coded patient cable connectors for quick and easy identification
- Compatible with the following monitor families: IntelliVue™ MP40/50/60/70/80/90/MX600/700/800 with software revision C.0 or higher

Nellcor™ SpO₂ Forehead Sensors

The Nellcor™ SpO₂ forehead sensor offers industry-leading LoSat expanded accuracy, 60% to 80% SpO₂ +/-3 when used with OxiMax™ technology,² for better management of difficult-to-monitor patients.

- Detects changes in SpO₂ one to two minutes earlier than digit sensors during poor perfusion²
- Less affected by signal interference³
- Forehead can be more accessible to clinicians than hands

Nellcor™ SpO₂ Sensors (non-adhesive)

These sensors give clinicians a gentle alternative to adhesive sensors for patients with fragile skin. Ideal for monitoring neonates and preterm infants, geriatric and burn patients, or other patients with sensitive skin.

- Sensors fasten with Velcro® fasteners instead of adhesive tape
- Sensor bandage is made of a soft, pliable, low profile foam material that gives it "stiction" to help keep the sensor in place without adhesives
- Sensors are designed for single-patient use and are packaged sterile to help alleviate infection-control concerns



Code: 10076644
(includes 1 x 3m Interface Cable)

1. Covidien FDA 510(k) K012891.

2. MAX-R ± 3.5 digits determined between saturations of 80%–100%.

3. MAX-N: Clinical functionality has been demonstrated on a population of hospitalised neonate patient. The observed SpO₂ accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weighing from 750 to 4100 grams, and 63 observations made spanning a range of 85 to 99% SaO₂ while monitored with Nellcor™ OxiMax™ N-595 pulse oximeters. The accuracy specification has been determined between saturations of 80%–100%.

NEW NELLCOR™ OXIMAX™ HAND-HELD PULSE OXIMETER

The Nellcor™ PM10N Portable SpO₂ Patient Monitoring System effectively monitors a broad range of patients across care areas and provides analytics for robust data analysis.

The Nellcor™ Portable SpO₂ Patient Monitoring System is a convenient, handheld monitor that is capable of spot-checks and continuous monitoring in hospital, mobile, sleep study and home use settings. The monitor incorporates Nellcor™ OxiMax™ digital signal processing technology to deliver accurate SpO₂ and pulse rate values even during low perfusion and signal interference, including patient motion. The monitoring system includes a vivid 3-inch colour LCD screen, connectivity to analytic tools, compatibility with the entire line of Nellcor™ sensors with OxiMax™ technology, and a robust monitoring feature set including SpO₂, pulse rate, SatSeconds alarm management and pleth waveform information. The monitor has the added functionality of home-care and sleep study modes for simplified monitoring in the hospital and home settings.

- Small, lightweight, ergonomic handheld monitor for continuous and spot-check pulse oximetry monitoring
- Supports a robust data set, including real-time SpO₂ /PR values, SatSeconds, pleth waveform, blip bar and tabular trend data
- Sleep Study Mode, which enables the clinician to dim the LCD display and silence alarms to prevent disruption of patients' sleep
- LoSat expanded accuracy range (60% to 100% SpO₂) when used with Nellcor™ adhesive sensors with OxiMax™ technology
- Supports wired data export to an external PC for data analysis and printing functions. 80 hours of data storage capability
- Compatible with Nellcor™ Analytics Tool (NAT) software that may be downloaded from our website*: covidien.com/NellcorAnalyticsTool

Code: PM10N-1A
(including one reusable sensor of customer choice)

Code: PM10N-BOOT-1A
(including boot & one reusable sensor of customer choice)

Code: PM10N-MAX
(including one case of adhesive sensors of customer choice)

Code: PM10N+BOOT-MAX
(including boot & one case of adhesive sensors of customer choice)

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MICROSTREAM™ CAPNOGRAPH

Capnostream™ 35 Portable Respiratory Monitor

With a combination of Microstream™ capnography and Nellcor™ pulse oximetry technologies, you can count on the Capnostream™ 35 portable respiratory monitor to deliver. Continuous monitoring of etCO₂, respiration rate, and SpO₂. In virtually any clinical setting. It brings certainty where it matters most.

- Portable, rugged, lightweight, ergonomic design - helps you facilitate moving a patient between areas of care
- Smart algorithms - engineered to give you an early indication of changes in respiratory status that may need intervention
- Advanced data management - connectivity to web-enabled devices for remote patient monitoring via Vital Sync™



Code: PM35MN01







REFERENCE

1. Nellcor™ OxiMax Pulse Oximeter Accuracy, Paul D. Mannheimer, PhD; Nooshin A. Asbaugh; and the Nellcor Technical Staff

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PM 380-02-18 ANZ. #5100-072018