Medtronic

Connect with every touch.

Introducing the Nellcor™ OxySoft™ neonatal-adult SpO$_2$ sensor

Discover the first pulse oximetry sensor to use a silicone adhesive – that's designed with your everyday realities in mind. Built to perform in the most challenging conditions, the Nellcor™ OxySoft™ SpO$_2$ sensor repositions with ease while helping to protect fragile skin.[1]

Its innovative silicone adhesive combines with brighter LEDs and a lower profile on a flexible circuit – giving you a more reliable way to remain connected to patient readings.[2,3] And more time to connect with each patient.

50%
better signal acquisition in simulated low perfusion and thicker tissue[4]

Critical decisions need reliable readings

Getting stable pulse oximetry readings can often be a challenge. With brighter LEDs and thoughtful cord placement, the Nellcor™ OxySoft™ SpO$_2$ sensor can overcome the limitations that impact those readings for a difference you'll know, with insights you can trust.[4]

- **50% better signal acquisition** and **50% reduction in time to post** in simulated low perfusion and thicker tissue[4,†]
- Manages motion interference[5]
- 10 out of 10 clinicians recommend using OxySoft™ during challenging conditions based on blinded, hands-on evaluation[6]

18
repositions[5]

Busy days demand efficiency

When sensors lose adhesiveness and stick together, you lose valuable time in your day. The Nellcor™ OxySoft™ SpO^2 sensor can simplify your workflow and reduce waste.[1,6,7]

- Easy to peel apart and reposition[1,6,‡]
- Withstands up to 18 repositions[7]
- Helps you use less[1,6,7]

87%
less protein removal from fragile skin[1,‡]

Fragile skin deserves protection

The delicate skin of your littlest patients require the lightest touch. The Nellcor™ OxySoft™ SpO$_2$ sensor's silicone adhesive helps enable removal without pulling on or damaging fragile skin.[1] And its lower profile and thin and flexible design provides the staying power[6] to withstand the wiggles of your tiniest patients.

- **Removes 87% less skin cells** from fragile skin[1,‡]
- **Stays in place longer**, even through motion[6]

Nellcor™ OxySoft™ SpO$_2$ sensors

Order Number	Description
OxySoftN	SPO2 SENSOR NEO/ADULT - for professional use
OxySoftNJ	SPO2 SENSOR NEO/ADULT SOFT25 - for users in Japan
OxySoftNCov	SPO2 SENSOR NEO/ADULT COVDN
OxySoftNHC	SPO2 SENSOR NEO/ADULT HOME - for home use

Features and specifications

Range and accuracy

Measurement Accuracy	
Sensor Saturation Accuracy	
Low perfusion	70% to 100% ± 2 digits
Adult and neonate	70 to 100% ± 2 digits
Adult and neonate with motion	70 to 100% ± 3 digits
Low saturation	60 to 80% ± 3 digits
Pulse Rate Accuracy	
Normal conditions	20 to 250 bpm ±3 BPM
Low perfusion	20 to 250 bpm ±3 BPM
Motion	20 to 250 bpm ±3 digits*

*≤3 digits was the actual study finding, however, study was designed to test ≤5 digits

Environmental

	Transport and Storage	Operating Conditions
Temperature	-40°C to 70°C (-40°F to 158°F)	0°C to 40°C (32°F to 104°F)
Atmospheric pressure range	500 hPa to 1060 hPa	620 hPa to 1060 hPa
Relative humidity	15% to 95% non-condensing	15% to 95% non-condensing

Standards compliance

IEC 60601-1: Medical electrical equipment –Part 1: General requirements for basic safety and essential performance

ISO80601-2-61: Medical electrical equipment –Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

IEC 60601-1-2 2nd, 3rd and 4th editions Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-1-1-11: Medical electrical equipment –Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC60601-1-12: Medical electrical equipment –Part 1-12: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

ISO 10993: Biological Evaluation of Medical Devices

IEC62471: Photobiological safety of lamps and lamp system

Equipment classifications

This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices may result in bio-incompatibility, infection, or product failure risks to the patient.

The Nellcor™ pulse oximetry monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.
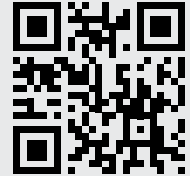
† Compared to MaxN during internal head-to-head bench testing.

‡ Based on validation data in head-to-head clinical testing compared to MaxN

1. Internal test report CSR 2021 03 12 v.1.0 - CyberDERM S20-12.
2. MDT20028OXYLOV, Rev 2 - SpO2 Accuracy Validation of OxySoft.
3. RE00301248, RevA - System compatibility verification report.
4. RE00368468, RevB - Expanded Claims Bench Test Report.
5. MDT20006OXYVMT, Rev 4 - SpO2 Accuracy Validation of OxySoft during motion and non-motion.
6. RE00357465, RevA - Marketing Validation Report.
7. Internal test report CSR 2021 03 12 v.1.0 - CyberDERM S20-14.

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