A Technology Overview of the Nellcor® OxiMax® Pulse Oximetry System

Nellcor Technical Staff

Why Nellcor Developed the *OxiMax* Pulse Oximetry System

The introduction of the *OxiMax*® Pulse Oximetry System brought Nellcor's fifth-generation pulse oximetry technology to market and marked a fundamental shift in one of the design tenets of pulse oximeters. In the first four generations of Nellcor® pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient.

However, while developing products to meet a broader range of clinical applications and challenges, we recognized that the existing technology platform limited Nellcor, as well as all other pulse oximeter manufacturers. Historically, sensor calibration coefficients have resided within the monitor. A single calibration curve or a limited set of curves is programmed into the monitor, and sensor designs must conform to the preprogrammed data in order to accurately calculate arterial oxygen saturation (SpO_2). This conventional, "in-the-box" calibration scheme has restrained sensor inventions that could address unique patient care needs.

Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named *OxiMax*, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself.

With the *OxiMax* system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The *OxiMax* platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care.

Principles of Pulse Oximetry and Conventional Calibration

To better understand the significance of *OxiMax* technology and what inspired Nellcor to develop it, it may be helpful to review the underlying principles of pulse oximetry.

Light Absorption by Arterial Blood and the Role of LEDs in Pulse Oximetry

Pulse oximeter sensors contain two light emitting diodes (LEDs) used for shining red and infrared (IR) light through blood-perfused tissue. On a heartbeat-by-heartbeat basis, a small amount of arterial blood is pumped into the tissue, which then slowly drains back through the venous system. The amount of the sensor's emitted light that passes through blood-perfused tissue, such as a finger, varies with this cycling blood volume: The more light-absorbing blood present, the less light that travels through the tissue bed to strike the sensor's photodetector. Pulsatile signals allow pulse oximeters to evaluate the signal attenuation caused by arterial blood flow, since light absorption from other tissues is generally unchanging.*

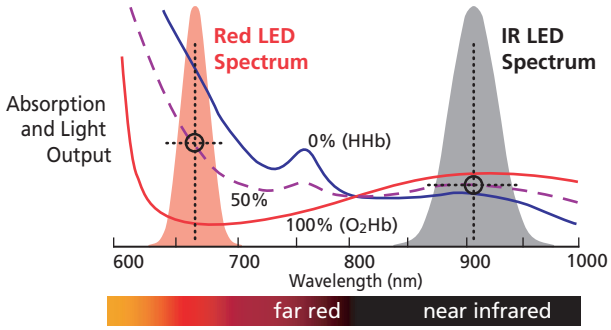

Figure 1
Overlay of typical LED-emitted light spectrum and relative light absorption spectra of oxygenated and deoxygenated hemoglobin. The dashed purple line indicates the spectra of 50%-saturated blood, with the relative absorbance in the red and IR indicated by the black circles.

* The effects of motion and other signal noise do not impact the basic calibration of pulse oximetry.

Figure 1 shows an overlay of the red (660 nm) and infrared (900 nm) light spectra emitted by the LEDs, along with the light absorption of oxygenated and deoxygenated hemoglobin (O_2Hb and HHb, respectively). The dashed purple line corresponds to a blood mixture that is near 50% SaO_2. Absorption of the red and IR light at this saturation is indicated by the black circles at the intersection of the blood absorption curve and the middle of the graphed red and IR spectra.

Because O_2Hb absorbs less red light than infrared light (as indicated by the solid red O_2Hb line in Figure 1), the tissue's cycling blood volume at high saturation has less influence on the detected red signal than on the infrared signal. In other words, the red plethysmograph "wiggle size" (Figure 2) is smaller than the infrared, because this wavelength of light is less influenced by the blood volume changes in the finger. (If, for example, clear saline were pulsing through the vessels, one would not expect the transmitted light levels to change much—regardless of the color of the light used.)

At low saturation this situation is reversed. Low saturation blood (high amount of HHb, indicated by the solid blue line in Figure 1) absorbs red light far more strongly than it absorbs IR light; the resulting red signal pulse amplitude becomes larger than the pulse amplitude of the IR signal.

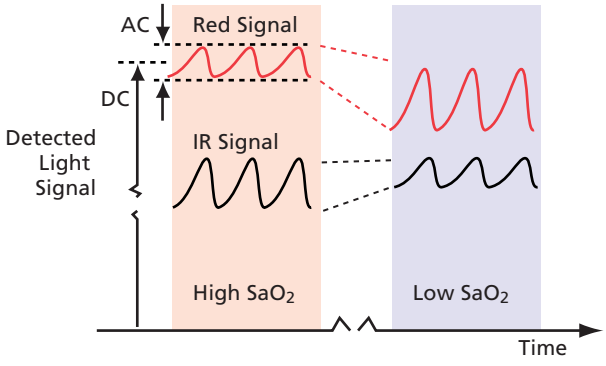

Figure 2
Red and IR light signals at high and low arterial oxygen saturation. At high saturation, the red "pulse amplitude" (AC/DC) is smaller than in the IR. At low saturation, the ratio of relative amplitudes is reversed.

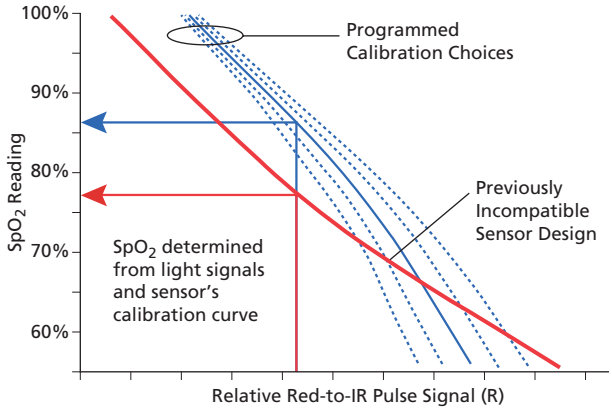

Figure 3
The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals.

Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3).

The Effect of LED Characteristics on Calibration Curves

Because the light absorption of the blood's oxygenated and, more importantly, deoxygenated hemoglobin is significantly wavelength-dependent, the relationship between R and SpO_2 strongly depends on the specific emission characteristics (e.g., color) of the sensor's LEDs.

Suppose the red LED used within a sensor is selected with a slightly different color—for example, one slightly more orange (to the left of the red LED spectrum shown in Figure 1). Light absorption by the blood (black circle) would increase compared with the previously chosen truly red emitter (following along up the dashed purple line), and the resulting apparent pulse size of the detected light signal would increase. Particularly at lower arterial blood saturation, the modulating blood volume in the tissue more greatly influences detected orange light than red light because deoxyhemoglobin absorption in this color region increases significantly as the wavelength becomes shorter.

The impact of this more orange-colored emitter is to shift and rotate the sensor's calibration curve—with more of a change at low saturation than high (see Figure 3, dotted curves to the right of the solid

blue curve). At any given true arterial saturation, the red-to-IR Modulation Ratio will be larger when using red LEDs that are more toward the orange side of the spectrum.

Accurate measurements of saturation require the calibration curve (used to translate the measured Modulation Ratio to its corresponding SpO_2 value) to correspond to the actual LED wavelengths used in the sensor, along with the other optical characteristics of the sensor that affect calibration.

LED manufacturers generally have much less control of batch-to-batch and device-to-device emitter wavelength than is required for accurate pulse oximetry measurements. Wavelength control is less of a concern for the primary uses of red LEDs—automotive tail lights, traffic stoplights, and indicator lamps on stereos, ovens, etc.—simply because the human eye cannot distinguish these subtle color differences. But pulse oximeters can make these distinctions, particularly in the red part of the spectrum. Though semiconductor manufacturers have improved their processes over the years, LED wavelength control has remained problematic for pulse oximeter manufacturers.

Accommodating LED Variance During Sensor Manufacturing

To accommodate this limited control, every pulse oximeter manufacturer must do some form of emitter wavelength characterization to achieve its accuracy specifications.

Most sensor manufacturers purchase or screen emitters to a narrow range of LED wavelengths and program into the monitor a single calibration curve that corresponds to this range. Some manufacturers use a liberal range of wavelengths with a single curve, resulting in degraded accuracy performance, particularly below 85% saturation. Nellcor has in the past used a resistor-encoding scheme in which several calibration curves are programmed into Nellcor pulse oximeters and pulse oximetry modules to span a broad range of LED wavelengths needed for high-volume sensor manufacturing.

Nellcor's resistor-calibration technique, known as RCAL, communicates to the monitor which of the curves to use. When the sensor is first connected to the oximeter, a resistor housed within the sensor connector plug is read by the oximeter to identify specifically which of the preprogrammed curves should be used to calculate SpO_2 values.

During sensor manufacturing, Nellcor measures the wavelength characteristics of every red and IR LED emitter. Emitters are sorted and placed into bins of similarly colored emitters, with each bin corresponding to an associated proper calibration curve. The RCAL system is used by the monitor to identify from a lookup table which of the preprogrammed curves to use, with specific electrical resistor values assigned to identify each bin (Figure 4). Thus, SpO_2 accuracy is maintained while using the full range of supplied emitter wavelengths. High manufacturing yield can be attained efficiently, since virtually all the emitters can be used.

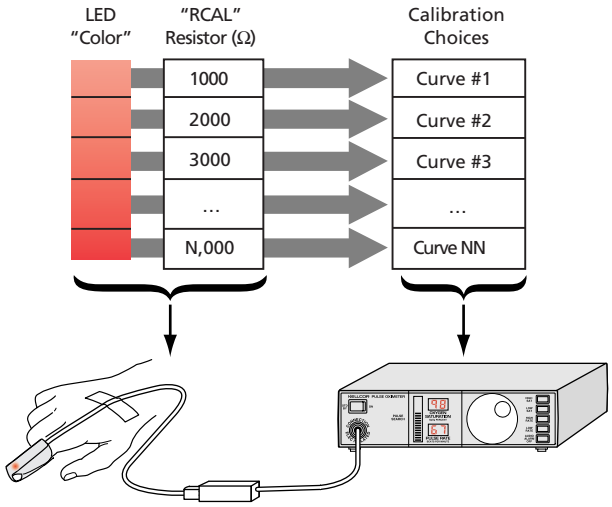

Figure 4
The color (wavelength) of each LED emitter is measured during Nellcor's sensor manufacturing process, and paired in the RCAL scheme with a corresponding electrical resistor. The monitor, in turn, measures the resistor value and uses the associated proper calibration curve for that sensor in determining SpO_2.

Limitations of Monitor-Based Calibration

The need to predefine calibration curves to address LED wavelength variations has hindered pulse oximetry manufacturers from making technological advancements that could enhance clinical care. For instance, manufacturers may not be able to take advantage of newer high-efficiency LEDs, since their spectral properties are sufficiently different from those designed by semiconductor companies years ago. These newer LEDs offer greater versatility in oximeter designs. They can lower the power needs of oximeters, which usually translates to longer battery life, and they can dramatically increase signal strength, which helps improve monitoring performance during challenging conditions. As semiconductor manufacturers continue to improve their own

processes for fabricating state-of-the-art LEDs, Nellcor wants to be able to take advantage of their latest advancements.

Manufacturers are also constrained in creating new types of sensors, because sensor designs that do not precisely conform to the calibration curves preprogrammed in the monitor would result in degraded accuracy. Though in the Nellcor RCAL system many sensors can be developed to fit one or more of the available choices (blue curves in Figure 3), other designs may only moderately fit or miss by an amount that would result in clinically unacceptable accuracy (as depicted by the red curve in Figure 3). This limits possibilities, such as new sensors designed for more convenient placement sites on the patient.

Nellcor's RCAL calibration curves were created in the middle 1980s, based on LEDs and sensor designs of the time. New sensors developed since then have had to conform to these preprogrammed curves to ensure compatibility across the installed base of Nellcor pulse oximeters and OEM multiparameter monitors. Though not overly restrictive through the 1980s and 1990s, this "in-the-box" calibration scheme limits the ability to create new types of sensors. For pulse oximetry in the 2000s, the *OxiMax* platform allows more innovative and versatile designs.

Digital Memory Chip Is the Key to *OxiMax* Versatility

In developing the *OxiMax* Pulse Oximetry System, Nellcor focused on achieving these goals:

- Provide customers with superior levels of monitor and sensor performance.
- Create latitude for accommodating future sensor designs as patient care evolves.

The *OxiMax* system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor *OxiMax* sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every *OxiMax* sensor provides precisely the versatility Nellcor sought. The *OxiMax* platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints.

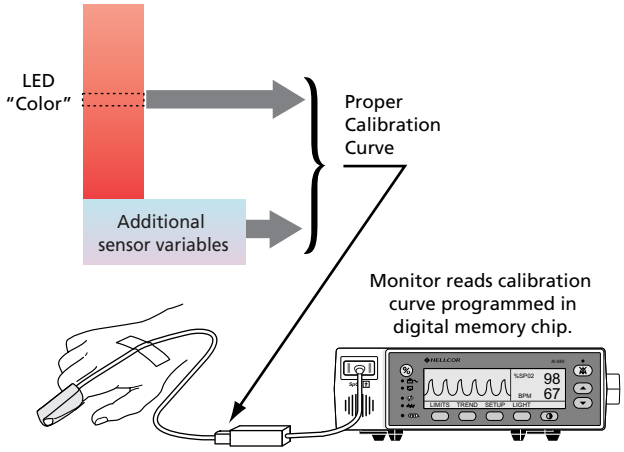

Figure 5
A small digital memory chip resides in every *OxiMax* sensor. The chip is programmed with the full calibration information for that sensor, along with any other sensor-specific data the oximeter can use for enhanced performance.

Sensor Calibration and the New Versatility

Sensor calibration requirements still exist with the *OxiMax* platform; however, instead of relying on a limited number of preprogrammed curves within the monitor, the *OxiMax* system relocates the sensor's individual calibration curve into the sensor itself. In this new design, every *OxiMax* sensor is digitally programmed with the specific coefficients that define its proper calibration curve.

As before, Nellcor fully characterizes the optical properties of each sensor's emitter assembly, though now additional factors are considered to better account for the spectral properties that affect accuracy. The appropriate calibration coefficients for each sensor are determined using a proprietary method and are then stored directly within the digital memory chip.

The past limitations of monitor-based calibration simply vanish. Nellcor can now store within the chip virtually any calibration curve needed, whether for today's sensor designs or for those to be created in the future. Because new curves can be developed as needed, Nellcor can design new sensors with improved performance. Nellcor can also utilize optical components previously incompatible with its earlier oximeters.

Though pulse oximeter monitors could conceivably be reprogrammed with additional curves, the process is unwieldy and cumbersome, particularly with large numbers of installed standalone and multiparameter monitors in hospitals around the nation and throughout the world. With the

OxiMax platform, accommodating updated or entirely new sensor calibration becomes a seamless process for the hospital staff: It occurs automatically when the sensor is plugged in. Implementing upgrades through sensors, rather than monitors, is more cost effective for the customer.

The memory chip also provides room for additional sensor-specific operating parameters to be stored within the sensor. For example, the model name of the sensor being used is stored, and model-specific troubleshooting tips are provided to the bedside caregiver for optimal sensor application, as described in the Sensor Messages section.

The strength of the *OxiMax* platform resides in the flexibility provided by the sensor's digital memory chip. Not only have new features been introduced with the first *OxiMax* products, but also future enhancements can be accommodated because Nellcor designed the *OxiMax* platform to be extensible. The system architecture gives design engineers complete flexibility for expanding the clinical utility of the system.

Summary of *OxiMax* digital memory chip benefits:

- Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor.
- Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages.
- Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report.

The *OxiMax* Pulse Oximetry System

The *OxiMax* system includes a new line of pulse oximetry monitors and *OxiMax*-enabled OEM modules. These products contain Nellcor's advanced digital signal processing technology. This technology enables the monitor to deliver accurate SpO_2 and pulse rate readings even when confronted with challenging conditions, such as patient motion combined with low pulse perfusion. The system also includes a complete line of single-patient-use and reusable *OxiMax* sensors.

The new *OxiMax* sensors, with the exception of the *MAX-FAST*™ Forehead Sensor and *SoftCare*™ Nonadhesive Sensors, can be used with earlier Nellcor technology. However, some of the *OxiMax*-specific features will not be accessible. Such backward-compatible *OxiMax* sensor models are identified by their purple connector plugs.

The *MAX-FAST* and *SoftCare* sensors were the first sensors to be engineered as part of the *OxiMax* system. Because of unique operating characteristics and calibration curves outside those established in legacy Nellcor systems, these sensors operate only with *OxiMax* monitors. A white connector plug identifies these sensors as exclusively for use with *OxiMax* technology.

MAX-FAST Forehead Sensor Delivers a Low Perfusion Solution

When patients have poor pulse perfusion, arterial blood traveling from the heart reaches the head sooner than it reaches distal sites such as the fingers. This concept inspired the creation of the Nellcor *MAX-FAST* Forehead Sensor. Designed for use on the patient's forehead, the *MAX-FAST* sensor responds to changes in arterial oxygen saturation typically one to two minutes sooner than digit sensors for patients with weak pulses.[1]

In addition to alerting clinicians earlier to hypoxemic events, the *MAX-FAST* sensor is often able to provide SpO_2 readings when conventional monitors with digit sensors fail. Because forehead circulation is fed by the supraorbital artery, this area is not prone to vasoconstriction during low perfusion. Thus, when digit sensors fail to detect adequate pulsatile signals, the *MAX-FAST* sensor provides an effective monitoring option.

The new versatility of the *OxiMax* platform enabled Nellcor to design a forehead sensor that is more accurate than other sensors designed for head sites (forehead, ear or nose). The *MAX-FAST* sensor has an accuracy level of ±2%, which is comparable to many digit sensors. No other "head" sensor provides this level of accuracy.

The *MAX-FAST* sensor replaces the Nellcor RS-10 Reflectance Sensor—a forehead sensor based on earlier technology. The bandaging material and adhesive attachment of the *MAX-FAST* sensor have been updated, and it has a more efficient and spectrally different LED compared with other Nellcor sensors. Because the *MAX-FAST* sensor is calibrated specifically for use on the forehead, its calibration differs from the existing RCAL curve set.

Following is a summary of *MAX-FAST* Forehead Sensor advantages:

- During poor peripheral perfusion, *OxiMax* systems using *MAX-FAST* sensors reflect changes in SpO_2 typically one to two minutes earlier than sensors placed on digits.[1]
- The *MAX-FAST* sensor can often obtain SpO_2 readings when digit sensors fail to detect pulsatile signals.
- The forehead site is less vulnerable to peripheral vasoconstriction and hence maintains signals longer than digit sensors during conditions of poor peripheral circulation. Ear sensors also show degraded signal strength during similar monitoring conditions.[2]
- The forehead sensor site is readily accessible, particularly in the operating room when patients' hands are covered and beyond the reach of the anesthesiologist.
- SpO_2 accuracy is improved over prior head sensor options; *MAX-FAST* accuracy is comparable to adult finger sensors (±2 saturation points, 1 SD).
- The head is typically a lower motion site than the hands, and thus often offers more reliable readings on moving patients.[3]
- Opaque sensor optics allow the sensor to tolerate high ambient lighting environments.
- A single *MAX-FAST* sensor can be used for up to two days, with appropriate site inspections and changes.

SoftCare Nonadhesive Sensors Help Protect Fragile Skin

Another *OxiMax* sensor developed to address a specific clinical need is the *SoftCare* Nonadhesive Sensor. The *SoftCare* sensor was designed in response to concerns that applying and removing adhesives can cause skin trauma for neonatal patients with fragile skin. Adhesives can also be a concern for geriatric and burn patients. While most single-patient-use sensors use adhesive tape, the *SoftCare* Nonadhesive Sensor fastens with Velcro® instead. The sensor bandage is made of a soft, pliable foam material that gives it "stiction" to help keep the sensor securely in place.

As with the *MAX-FAST* Forehead Sensor, Nellcor was able to design the *SoftCare* sensor with a high accuracy specification (±2% on adults, ±3% on neonates) due to the flexibility in selecting calibration curves. *SoftCare* sensors are also designed with high-efficiency LEDs that enhance the sensor's ability to acquire a pulsatile signal, even when challenged with thicker or darkly pigmented skin, or weak pulses.

OxiMax Communication Features

Taking advantage of the digital memory housed within each *OxiMax* sensor, Nellcor was able to develop new pulse oximeter functions that communicate with the caregiver to enhance monitoring effectiveness and patient management. Two of these functions, Sensor Messages and Sensor Event Report, are available in full-featured *OxiMax* monitors, such as the *OxiMax* N-595 Pulse Oximeter.

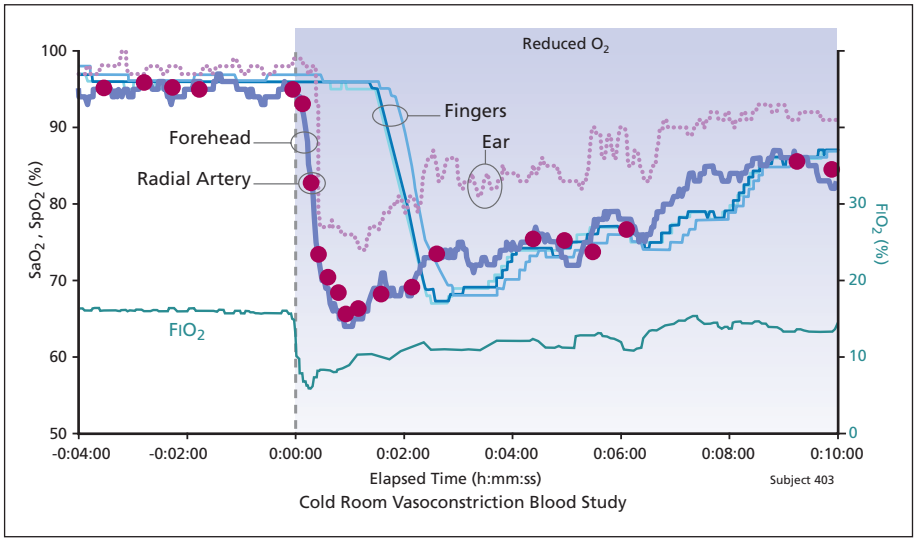

Figure 6
The *MAX-FAST* Forehead Sensor detects changes in SpO_2 faster than finger sensors, and with accuracy that more closely tracks to arterial blood data.

Sensor Messages Function Helps Caregivers With Sensor Application

The Sensor Messages function is a new clinical utility that provides troubleshooting tips to aid clinicians in optimizing sensor application.

The Sensor Messages feature of the *OxiMax* system examines the information available from the sensor, and uses a proprietary algorithm to evaluate parameters programmed into the memory chip of the particular sensor being used and current signal characteristics coming from the patient. If the monitor is unable to post saturation or pulse rate values after the clinician applies and connects the sensor, the Sensor Messages feature displays specific suggestions to improve signal acquisition. (When the sensor is not placed properly, the monitor will display zeroes rather than show inaccurate SpO_2 readings.) Any combination of three conditions may be displayed, along with up to five Action Messages (see Table 1). The Action Messages are tailored to the type of sensor connected to the monitor.

Conditions	Action Messages
•Sensor Off	•Adhesive/*OxiMax* Sensor
•Weak Pulse	•Reposition Sensor
•Weak Signal	•Warm Site
•Motion Interference	•Alternate Site
•Excess Infrared Light	•Nasal/Ear Sensor
•Electrical/Light Interference	•Clean Sensor Site (R-15)
•High Pulse Amplitude	•Ear/Forehead Sensor
	•Secure Cable
	•Headband (*MAX-FAST*)
	•Bandage Assembly
	•Nail Polish
	•Sensor Too Tight
	•Isolate Interference
	•Cover Sensor Site

Table 1
This table shows all the possible conditions and action messages that can be displayed with the Sensor Messages function. Depending on the particular situation and sensor type being used, the monitor will display up to three conditions and up to five action messages. These messages help the clinician address sensor application problems that may be preventing the monitor from posting SpO_2 readings.

For example, the *OxiMax* system can warn clinicians that the sensor may be positioned on an inappropriate site for that type of sensor. Improper sensor placement, such as a digit sensor placed on the forehead, is a common problem with less experienced caregivers. In this situation the caregiver may be inclined to throw away the sensor and try a new one, thinking the sensor was faulty. The Sensor Messages function helps eliminate this problem by alerting the clinician to move the sensor to a proper site. In short, Sensor Messages helps take the guesswork out of sensor application, which saves clinician time and prevents sensor waste.

Sensor Event Report Aids in Patient Assessment

Full-featured *OxiMax* monitors can record data to, and display previously recorded information from, an *OxiMax* sensor's digital memory chip. Using a feature called Sensor Event Report, alarm events stored in the sensor can easily be accessed and displayed on the monitor. This allows caregivers to quickly assess whether patients have had hypoxic events during transport or in the prior areas of care.**

Consider the following scenario in which an *OxiMax* sensor is applied to a patient. After undergoing major surgery, the patient leaves the operating room and is transferred directly to the ICU. Upon arrival in the ICU the critical care clinicians connect the patient to a monitor containing *OxiMax* pulse oximetry, and they notice the patient's SpO_2 is low. The anesthesiologist reported SpO_2 above 90% when the patient left the OR, so the clinicians wonder what has happened. Using the Sensor Event Report function they can view alarm events stored in the *OxiMax* sensor. The monitor displays the severity and timing of alarm violations that occurred during the transport period. This information helps the clinicians to better plan and manage care for this particular patient.

Conclusion

The *OxiMax* Pulse Oximetry System was designed with the future in mind. As clinicians continually seek better ways to care for and treat their patients, Nellcor wants to keep pace with technology that supports their goals. Nellcor engineers, with their years of experience in designing pulse oximetry systems, developed *OxiMax* technology to gain the versatility needed to make pulse oximetry monitoring as effective as possible. The *OxiMax* platform, with the digital memory chip in the sensor, frees us from the constraints of the past monitor-based sensor calibration scheme, and gives Nellcor the latitude to provide clinicians with new types of sensors and monitoring features.

**Non-*OxiMax* monitors do not have the necessary hardware to write-to or read-from the digital memory chip and therefore cannot create or access Sensor Event Reports. The Sensor Event Report feature can only be accessed with *OxiMax*-enabled monitors that have the necessary display capability.

References

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