Addendum to Pulse Oximetry Monitor OEM Modules

Introduction

This addendum provides supplemental information to the individual pulse oximetry monitor’s Engineering Product Specifications, Original Equipment Manufacturer (OEM) modules, and systems manuals.

The information provided is divided into the following major topics:

• Applicability
• Safety
• Range of Peak Wavelengths and Maximum Output Power
• Data Update Period, Effect of Data Averaging, and Other Signal Processing
• Test Considerations and Oximeter Accuracy
• Compliance

Applicability

This addendum applies to all NELL (NELL-1, NELL-2, and NELL-3) and specific MP (MP100, MP506, and MP507) series OEM modules contained in applicable Nellcor-manufactured or distributed pulse oximetry monitors, unless noted otherwise.
Safety

**Warning**

The operator is responsible for checking the compatibility of the pulse oximetry monitor, sensor, and patient cable prior to use. Incompatible components can result in degraded performance and/or device malfunction.

When Nellcor pulse oximetry sensors are connected to a Nellcor pulse oximetry monitor or patient monitor licensed to use Nellcor sensors, sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001. No special safety precautions are required.

Range of Peak Wavelengths and Maximum Output Power

**Electrical/Optical Specifications**

Nellcor pulse oximetry sensors contain light emitting diodes (LEDs) that emit red light at a wavelength of approximately 660 nm, and infrared light at a wavelength of approximately 900 nm. The total optical output power of the sensor LEDs is less than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy.

Data Update Period, Effect of Data Averaging, and Other Signal Processing

There are various matrices within the saturation pulse rate detection algorithm of each OEM board. Some of these are used to assess the severity of conditions presented to the board measuring SpO₂ and pulse rate on a patient. These individual matrices or combinations of these matrices are used to drive the LED indicators on the monitor display(s).

The advanced signal processing in the algorithms automatically extends the amount of data required for measuring SpO₂ and pulse rate depending on the measuring conditions. During normal measurement conditions, the averaging time is six to seven
seconds (approximately three seconds in Fast Mode). The OEM board automatically adjusts the signal processing during degraded conditions such as those caused by low perfusion, interference, (e.g. external interference such as ambient light, electromagnetic interference, and patient motion), or a combination of these, which results in an increase in the dynamic averaging beyond the minimum as set by the Response Mode. If the result of the dynamic averaging time exceeds 20 seconds for SpO\textsubscript{2}, the PULSE SEARCH indicator is illuminated solid, and the SpO\textsubscript{2} and pulse rate will continue to be updated every second. As these conditions extend, the amount of data required continues to increase. If the dynamic averaging time for SpO\textsubscript{2} reaches 40 seconds, and/or 50 seconds for Pulse Rate, a low priority alarm state results: The pulse search indicator begins flashing, the SpO\textsubscript{2} and pulse rate displays flash zeros indicating a loss of pulse condition and an audible alarm state is activated.

**Plethysmographic Waveform Output**

For systems that feature a waveform, or blip bar display, the Plethysmographic Waveform output is a non-normalized waveform that may be used to display the real-time sensor signal. The relative pulsatile strength and quality of the incoming signals can be observed.

**OxiMax® Algorithm**

The *OxiMax*\textsuperscript{®} algorithm automatically extends the amount of data required for measuring SpO\textsubscript{2} and pulse rate depending on the measurement conditions. During normal measurement conditions in the Normal response mode, the averaging time is 6 to 7 seconds. During difficult measurement conditions, which can be caused by low perfusion, motion, ambient light, electrocautery, or other interference, or a combination of these factors, the *OxiMax* algorithm automatically extends the dynamic averaging time required beyond 7 seconds.
If the resulting dynamic averaging time exceeds 20 seconds, the pulse search bit will be set while SpO₂ and Pulse Rate values continue to be updated every second.

As measurement conditions become even more difficult, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the Pulse Timeout bit will be set and the module will report a zero saturation indicating a loss-of-pulse condition.

**Fast Response Mode**

For systems featuring the *Fast* response mode (NELL 1, NELL 2), this setting dictates the response time (2 to 4 seconds in *Fast* mode and 6 to 7 seconds in *Normal* mode) applied by the OxiMAX algorithm in its calculation of SpO₂. The OxiMAX algorithm’s calculation of pulse rate is unaffected by the response mode setting. The data storage interval in the monitor’s trend memory is decreased automatically to 2 seconds when the monitor is set to operate in the *Fast* mode (the storage interval is 4 seconds in the *Normal* mode).

**Test Considerations and Oximeter Accuracy**

**Functional Testers and Patient Simulators**

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Nellcor pulse oximeter sensors, cables and monitors. See the individual testing device’s operator's manual for the procedures specific to the model of tester being used.

While such devices may be useful for verifying that the pulse oximeter sensor, cable, and monitor are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system’s SpO₂ measurements.

Fully evaluating the accuracy of the SpO₂ measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient’s tissue. These capabilities are beyond the
scope of known bench top testers, including known devices which claim to measure sensor LED wavelength.

SpO₂ measurement accuracy can only be evaluated in vivo by comparing pulse oximeter readings with values traceable to SaO₂ measurements obtained from simultaneously sampled arterial blood using a laboratory CO-oximeter.

Many functional testers and patient simulators have been designed to interface with the pulse oximeter's expected calibration curves and may be suitable for use with Nellcor monitors and/or sensors. Not all such devices, however, are adapted for use with the Nellcor OxiMAX digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO₂ measurement values may differ from the setting of the test device.

For a properly functioning monitor, this difference will be reproducible over time and from monitor to monitor within the performance specifications of the test device.

**Accuracy and Motion Tolerance**

For products with accuracy claims in the presence of motion, reading accuracy was validated, in part, in studies conducted on healthy adult volunteers under controlled laboratory conditions over the saturation range of 70% to 100%. Pulse oximeter SpO₂ was compared to SaO₂ measured to blood CO-oximetry, and PR was compared to EKG heart rate.

Sensors were fitted on the digits and optically shielded from one another, with subjects instructed to move their fingers with tapping, rubbing and non-repetitive movements, in response to a random noise in the range of 1 Hz to 4 Hz, and with an amplitude of 1 cm to 2 cm.

**Accuracy with Low Perfusion**

Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude between 0.03% and 1.5 %) was validated using signals supplied by a patient simulator. SpO₂ and pulse rate values were varied across the monitoring range over a
range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

**Accuracy of SpO₂**

Validating SpO₂ accuracy is the sole responsibility of the patient monitor manufacturer, and can only be assured when the equipment is used according to the manufacturer’s directions.

**Compliance**

When the patient monitor system using Nellcor oximetry in the form of an OEM module, or patient monitors licensed to use Nellcor oximetry, are used in conjunction with Nellcor sensors and cables, the system is compliant with ISO 9919:2005, provided other patient monitor system requirements of the standard are met. It is the responsibility of the OEM or Licensee to conform to the standard in the areas that are beyond the scope of the Nellcor componentry, sensors or cables.

When used with Nellcor sensors and the appropriate Nellcor pulse oximetry cable, the Nellcor OEM board is compliant with ISO 9919:2005 with the following exceptions:

**Clause 201.5.4.1**


**Clause 50.101**

Manufacturer Responsibility and ISO 9919:2005

The information in this document is supplied to assist companies in successfully integrating Nellcor Pulse Oximetry modules in compliance with ISO 9919:2005. It is recommended that all companies implementing Nellcor OEM modules into their devices obtain a copy of ISO 9919:2005 and carefully review this standard for applicability to their intended device. Because many clauses of ISO 9919:2005 are system-related, these will have to be addressed at a system level, and cannot be addressed solely by the OEM module.

It is the responsibility of the monitor manufacturer to test the finished device in accordance with the following clauses, and any other system-related clauses which may apply to the finished monitor.

These “system” clauses include, but are not limited to:

Clause 6.1

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Information will need to be supplied to show that the pulse oximetry equipment is calibrated to display functional oxygen saturation. The saturation display should be labeled % SpO₂. Display of the Pulse Rate should be marked as beats/min, or in equivalent symbols. (Nellcor OEM boards communicate values of SpO₂ and Pulse Rate determined in compliance with this section.)

Clause 6.8.2

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8) A description of the signal inadequacy indicator and its function needs to be provided. If there is a waveform displayed, a statement as to whether or not it is normalized shall be provided. Nellcor OEM modules communicate a non-normalized depiction of the plethysmographic waveform, as well as non-normalized pulse-size “blip-bar” information that can be used for this function.
Clause 6.8.2

9) It is the responsibility of the monitor manufacturer to set the range of adjustable alarm limits.

11-12) It is the responsibility of the monitor manufacturer to make available the list pulse oximetry sensors and cables that have been validated for use on the monitor.

Clauses 21.5, 21.101, 21.102, 36, 44.6, 49.101, 49.102, 50.101, 50.102, 50.103, 50.104, 201.1.2, 201.5.4.1