OEM III Pulse Oximetry Module Integration Guide

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Description

Thank you for your interest in Nonin's OEM III Pulse Oximetry Module. The Nonin OEM III module is used for measuring functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate for adult, pediatric, and neonatal patients. It is designed to be used by medical devices manufacturers as a means of incorporating SpO_2 into a host device.

This document has been prepared by Nonin Medical, Inc. to assist manufacturers with the process of integrating Nonin's OEM III module into their device. Nonin seeks to provide all necessary information to ensure an efficient and accurate integration process. Proper integration is, however, the responsibility of the manufacturer of the host device.

About the Technology

Pulse oximeters measure functional oxygen saturation using two components--the oximeter and the sensor--which are validated and calibrated as a system. Pulse oximeter sensors pass red and infrared light through perfused tissue and detect the fluctuating signals caused by arterial blood pressure pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is darker in color. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin from this color difference by calculating the ratio of absorbed red and infrared light as the blood volume at the sensor site fluctuates with each heart beat. Since steady conditions (steady venous blood flow, skin thickness, bone, fingernails, etc.) are not pulsatile, they do not affect the saturation reading.

Pulse oximeters use two different colors of light and thus have the ability to determine one component of blood. Nonin's OEM oximeters are calibrated to closely approximate *functional* oxygen saturation values (SpO_2).

To obtain an accurate SpO_2 and pulse rate measurement, Nonin uses a number of digital filtering and decision algorithms. These algorithms separate the true pulse signal from artifact, motion, and interference. The initial filtering removes most of the interference, after which each potential pulse is examined to determine if it meets the criteria for a true physiological pulse, or if it should be discarded. Because the Nonin algorithms work on a pulse-by-pulse basis, the pulse oximeter can give valid readings even in the presence of arrhythmias and other challenging conditions.

As with all pulse oximeters, it is possible for interference to degrade performance. This may be seen as slower response time, reduced accuracy, or no readings. If too little light passes through the perfused tissue or the pulse is insufficient, the pulse oximeter will not be able to provide a value.

Serial Data Formats

The OEM III features three selectable data format options. Data format 1 is ideal for real time monitoring or data logging and applications where only SpO_2, pulse rate, and signal quality are needed. Data format 2 includes the same parameters as data format 1, six different averaging options for the SpO_2 value, 4 different averaging options for the HR value, plus the pulse waveform using 8 bit compression. Data format 7 is based on data format 2, except it provides a full 16 bit uncompressed resolution for greater pulse waveform analysis.

In addition to the above features, Data formats 2 and 7 feature SpO_2 and Pulse Rate averaging options in two different modes, Standard Mode and Display Mode. These allow the designer to select the option best suited to their particular application.

Standard Mode

SpO_2 and pulse rate values are updated on every pulse beat and when the oximeter goes out of track the values are set to “missing data” immediately. The Standard Mode options (in order from fastest response to slowest) are:

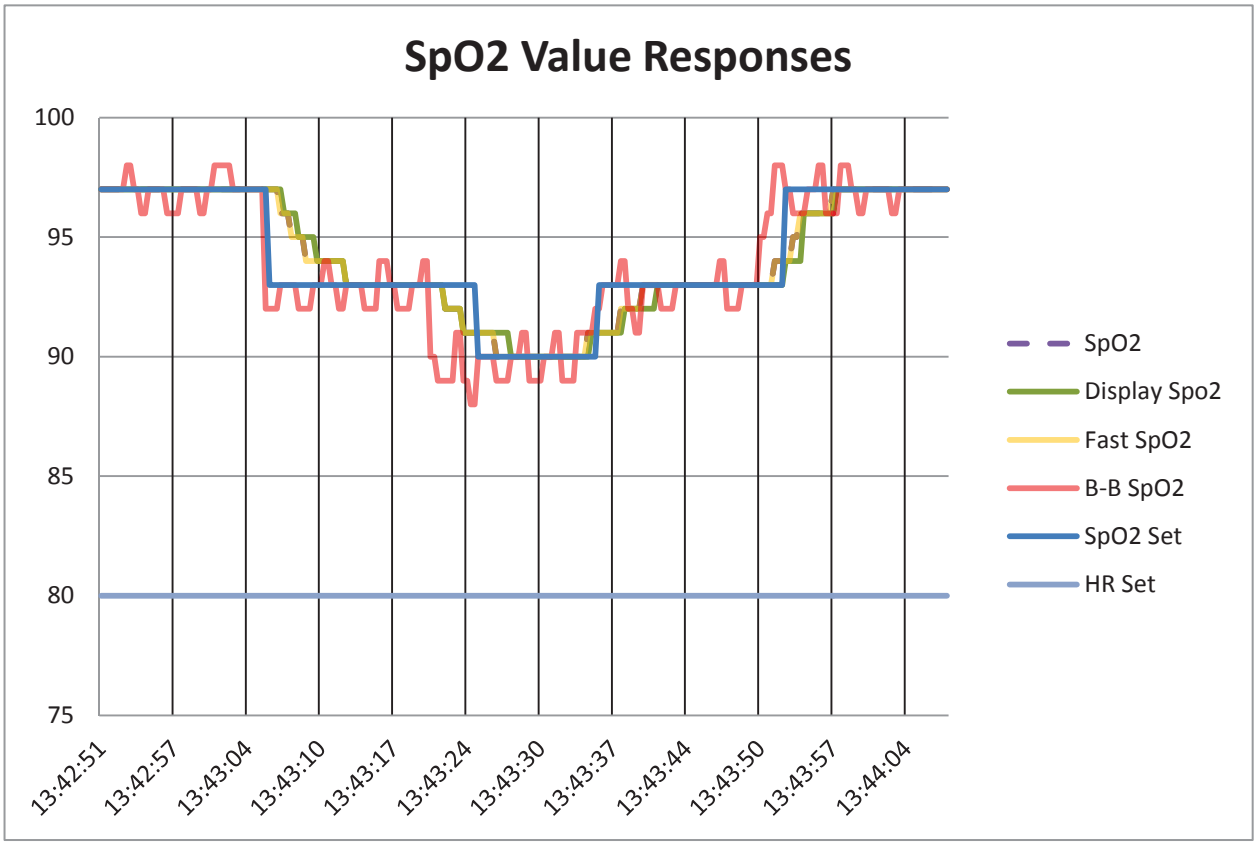
- SpO_2 B-B: Un-averaged, non-slew limited, beat to beat value in Standard Mode – this mode will be the fastest to respond to changes in desaturation, but is also the most sensitive. This option might be used in conjunction with another mode for applications where capturing depth and duration of the desaturation event is of paramount importance, such as sleep diagnostics.
- SpO_2 Fast: Non-slew limited saturation with a 4-beat average in Standard Mode.
- SpO_2: 4-beat slew limited average values in Standard Mode.
- E-SpO_2: 8-beat average values in Standard Mode – this option is the slowest to respond to changes in desaturation, and will be the least sensitive to artifact. This option might be used in applications where alarm management is a higher priority.
- HR: 4-beat average values in Standard Mode.
- E-HR: 8-beat average values in Standard Mode.

Display Mode

SpO_2 and pulse rate values are updated every 1.5 seconds, and when the oximeter goes out of track, the last in-track values will be transmitted for ten seconds. After ten seconds values are set to “missing data.” The Display Mode is recommended for vital signs monitoring applications, and the averaging options (in order from fastest response to slowest) are:

- SpO_2-D: 4-beat average displayed values in Display Mode (this is the default mode used in most of Nonin’s branded products, and mimics the way most bedside oximeters operate in a hospital environment).
- E-SpO_2-D: 8-beat average displayed values in Display Mode
- HR-D: 4-beat average displayed values in Display Mode
- E-HR-D: 8-beat average displayed values in Display Mode

The following table provides an example of the difference between the various SpO_2 averaging options offered in data formats 2 and 7 during a simulated desaturation event:



Data Format #1 - Synchronization Suggestions for Host Device

Use the following guide to develop your synchronization routine for data format #1.

Byte 1 Always 128 or greater
Byte 2 Always 127 or less
Byte 3 Always 127 or less

To identify byte 1, look for bit 7. A source code example to identify byte 1 is as follows: if bit 7 of byte x is set, then byte 1 = byte x.

Code Sample in C:

```
buf_pointer = %RCV_BUFFER;     // Set a pointer to the starting address of
                               // the receive buffer
RCV.Flag.pkt_sync = FALSE;     // Clear Sync Flag

// increment buf_pointer until it finds the sync byte of the packet
// RCV.Flag.pkt_sync will not be set if pointer does not find a sync byte

for ( ;buf_pointer < RCV_BUFFER_MAX; ++buf_pointer)
{
      if (*buf_pointer > 127)
      {
// buf_pointer points to the starting address of the packet in
// the receive buffer
      RCV.Flag.pkt_sync = True;    // Set an flag to indicate sync
      break;                       // exit "for" loop
      }
}
```

Data Format #2 – Synchronization Suggestions for Host Device

Use the following guide to develop your synchronization routine for data format #2.

Byte 1 - Always 01
Byte 2 - Always 128 or greater
Byte 3 - Can be any number between 0 and 255
Byte 4 - Always 127 or less (exception: with firmware REV 50, frames 24 and 25 may exceed this value)
Byte 5 - Can be any number between 0 and 255; is the sum of bytes 1-4

A recommended formula is as follows (except for OEM modules using firmware REV 50 - see above):
In sync if byte1=01 and byte2>127and byte4<128 and
byte5=(byte1+byte2+byte3+byte4)

The floating byte position (byte4) can be tracked as follows:

1. Query byte2, bit0 until set. This indicates you are on frame 1 and byte4=HR MSB.
2. Keep a running counter of which frame you are on.
3. Check the status of byte2, bit0 of each frame, and confirm it is clear.
4. Cross-reference frame number to corresponding data format chart for description of byte4 data.

If frame count equals 25, then go to Step 1. Otherwise, skip to Step 2.

NOTE: To ensure the highest level of confidence in data, verify all 25 frames before displaying data. Discard if all 25 frames cannot be confirmed. Each second represents a total of 75 frames.

Code Sample in C:

```
buf_pointer = %RCV_BUFFER;    // Set a pointer to the starting address of the
receive
// buffer
RCV.Flag.pkt_sync = FALSE;          // Clear Sync Flag
frm_chksum = 0;                     // 8-bit variable

// increment buf_pointer until it finds the sync byte of the packet
// RCV.Flag.pkt_sync will not be set if pointer does not find a sync byte

for ( ;buf_pointer < RCV_BUFFER_MAX; ++buf_pointer)
{
      if (*buf_pointer == 1)
      {
frm_chksum = *buf_pointer + *(buf_pointer+1) + *(buf_pointer+2) +
*(buf_pointer+3);
if (*(buf_pointer+1) > 127 && *(buf_pointer+1) & 0x01 && *(buf_pointer+4) ==
frm_chksum)
      {
// buf_pointer points to the starting address of the packet in the receive //
buffer
      RCV.Flag.pkt_sync = True;   // Set an flag to indicate sync
      break;                      // exit "for" loop
      }
      }
}
```

Data Format #7 - Synchronization Suggestions for Host Device

Use the following guide to develop your synchronization routine for data format #7.

Byte 1 - Always 128 or greater
Byte 2 - Can be any number between 0 and 255
Byte 3 - Can be any number between 0 and 255
Byte 4 - Always 127 or less (exception: with firmware REV 50, frames 24 and 25 may exceed this value)
Byte 5 - Can be any number between 0 and 255; is the sum of bytes 1-4

The floating byte position (byte4) can be tracked as follows:

1. Query byte1, bit0 until set. This indicates you are on frame 1 and byte4=HR MSB.
2. Keep a running counter of which frame you are on.
3. Check the status of byte1, bit0 of each frame, and confirm it is clear.
4. Cross-reference frame number to corresponding data format chart for description of byte4 data.

If frame count equals 25, then go to Step 1. Otherwise, skip to Step 2.

NOTE: To ensure the highest level of confidence in data, verify all 25 frames before displaying data. Discard if all 25 frames cannot be confirmed. Each second represents a total of 75 frames.

Code Sample in C:

```
buf_pointer = %RCV_BUFFER; // Set a pointer to the starting address of the
receive buffer
RCV.Flag.pkt_sync = FALSE; // Clear Sync Flag
frm_chksum = 0;            // 8-bit variable

// increment buf_pointer until it finds the sync byte of the packet
// RCV.Flag.pkt_sync will not be set if pointer does not find a sync byte

for ( ;buf_pointer < RCV_BUFFER_MAX; ++buf_pointer)
{
      if (*buf_pointer > 127 && *buf_pointer & 0x01)
      {
frm_chksum = *buf_pointer + *(buf_pointer+1) + *(buf_pointer+2) +
*(buf_pointer+3);
      if (frm_chksum == *(buf_pointer+4)
      {
// buf_pointer points to the starting address of the packet in the receive //
buffer
      RCV.Flag.pkt_sync = True;   // Set an flag to indicate sync
      break;                      // exit "for" loop
      }
      }
}
```

Calibration

Because the pulse oximeter does all critical computations in the software and there are no critical parts to drift, no re-calibration is required during the life of the device.

Use of Nonin Sensors

Because accuracy begins with the sensor it is important to use only Nonin PureLight Sensors. Nonin's unique approach in using the PureLight Process is much different than the other manufacturers. Only Nonin sensors are designed to match the sensor calibration curve programmed into each Nonin oximeter.

Nonin Pulse oximeters are designed with calibration curves that specifically match the emitters in the sensor. Nonin's approach is to tightly sort emitters for highly specified PureLight Emitters. Because of the PureLight process, original Nonin's sensors must be used to guarantee the highest accuracy.

Sensor Selection and Positioning

Nonin offers a wide variety of sensors to meet the needs of any monitoring application and correct positioning of the sensor is critical for accurate measurements.

When using fingertip sensors, all emitted light must pass through the fingertip. The sensor should not be pressed against any surface such as a tabletop while on the finger, and should not be squeezed or taped tightly. For best results, keep the sensor at the patient's heart or chest level. When using clip-type sensors, the sensor springs provide the correct pressure and any additional pressure may cause inaccurate readings. Please refer to the specific Instructions for Use for each sensor.

Response Time

When using an oximeter as a spot-check device where only a single value is recorded, it is important to ensure sufficient time for the device to go into track to obtain representative readings. The module should send at least 10 seconds of continuous good perfusion data before relying on the readings.

Power Supply Specifications

The OEM III can operate at input voltages of either 3.3 +/- 5% or 5.0 +/- 5% volts with a maximum of 50 mV ripple.

Since the performance of the OEM III is dependent upon the supply ripple, the use of a linear regulator to condition input power is recommended. If a switching/boost type regulator is required, please contact Nonin for assistance on recommended verification tests to ensure that the regulator noise does not impact accuracy during low perfusion conditions.

OEM III Module/Sensor Connector Placement

In order to ensure optimum signals, the OEM III module should be placed as close to the Sensor Connector as possible (see Figure 1).

The Sensor Connector should have a metal shell which can be electrically bonded to the motherboard ground.

The OEM III Module should be placed as far away as possible from noisy circuitry such as switching power supplies, high speed digital, etc.

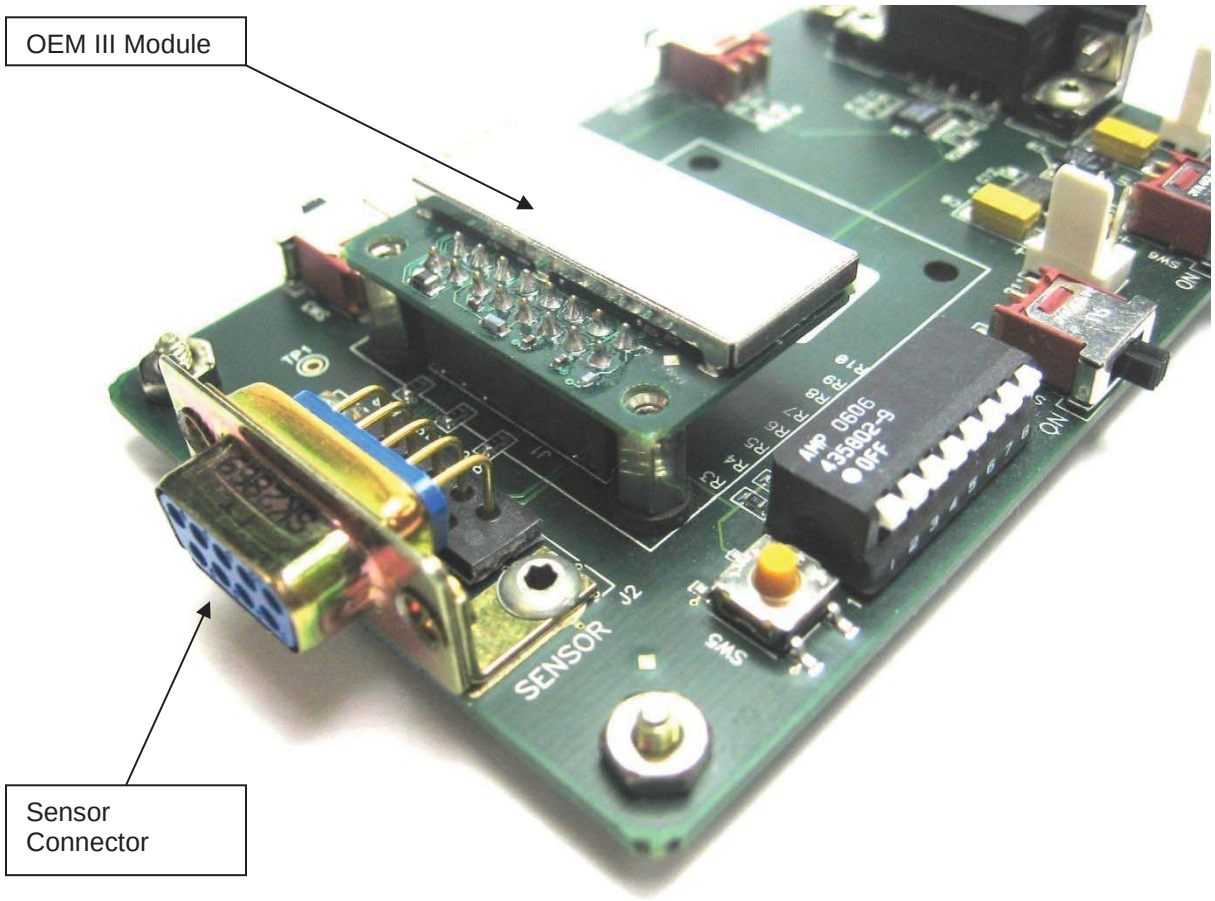


Figure 1.

Additional Components

Nonin's OEM Modules have been designed to accommodate and protect against surges and ESD strikes and provide optimal performance on challenging patients with weak signals. To prevent degraded performance with patients that have low perfusion, DO NOT add protection-type components to the sensor connections or any unnecessary circuit components in series or parallel to traces which connect the module to the sensor connector. **The most common integration error is the addition of surge suppressors, ferrite beads and similar components between the oximeter and the sensor.** This may result in inaccurate readings in low perfusion situations, and may not be easily detected when tested on a healthy human finger. 1 nF decoupling capacitors may be placed at sensor connector pins 1 and 6 for additional EMC Immunity (see Figure 2).

Routing of Traces between OEM III Module and Sensor Connector

The Photo Diode Signal and Photo Diode Bias (J1-02 and J1-04) should be routed side by side and above a noise-free ground plane (see *Figure #2*). The recommended trace width for the photo diode signal and bias is 0.005" (0.127 mm). Do not allow other traces to be routed between photo diode signal and bias traces.

The LED drive circuit traces (J1-6 and J1-7) should be routed side by side with recommended minimum trace width of 0.010" (0.254 mm).

If the sensor connector is not directly mounted to the board containing the OEM III Module and an additional connection is required, this connection should not be made with a ribbon cable, as this cable does not provide adequate shielding to protect the sensitive photodiode signal. Every effort should be made to avoid the use of additional cable between the oximeter and the sensor connectors. However, if additional cable is require please contact Nonin for recommendations and additional testing requirements.

Grounding

The module grounds (J1- 1, 3, and 15) and DB9 ground (DB9-7) should be connected to the motherboard ground plane in the partitioned region where the module is placed in host unit.

Do not place module above, between, or in close proximity to any potentially significant or noisy ground currents passing between the circuit sections on the motherboard as this may subject the signals to interference.

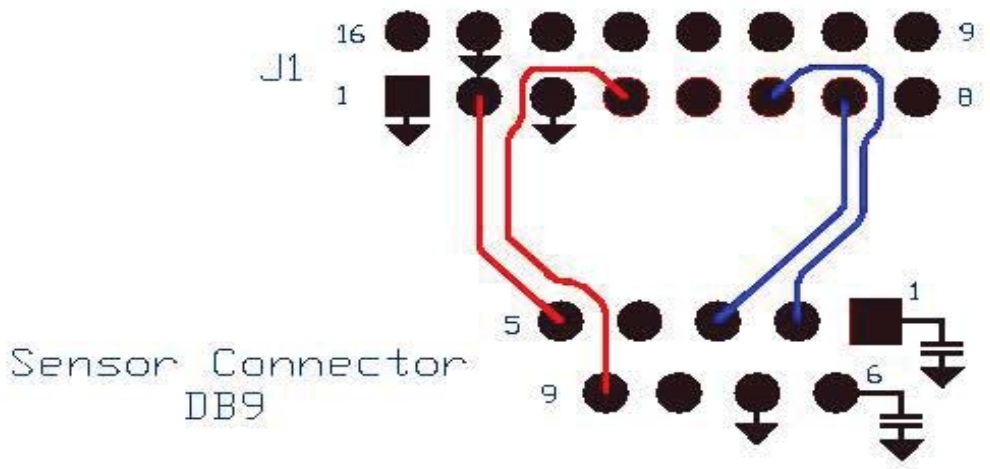


Figure 2 – Critical Tracing Recommendations: J1 = OEM Module Connector

OEM III Pin Assignments

PIN ASSIGNMENTS

J1-01 = Ground
J1-02 = Photo diode signal
J1-03 = Ground
J1-04 = Photo diode bias
J1-05 = Sensor type #1 line
J1-06 = LED drive line
J1-07 = LED drive line
J1-08 = Reserved 1
J1-09 = Serial Data Format Switch
J1-10 = Serial Input (future use) 2
J1-11 = Serial Output
J1-12 = Sensor type #2/1 wire
J1-13 = Reset (Optional) 2
J1-14 = Photo Plethysmogram Digital Output 2
J1-15 = Ground
J1-16 = +3.3VDC (3.2V to 3.5V), 50mV max. ripple
+5.0VDC ±0.25VDC, 50mV max ripple

OUTPUTS

J1-11 = Serial Output

INPUTS

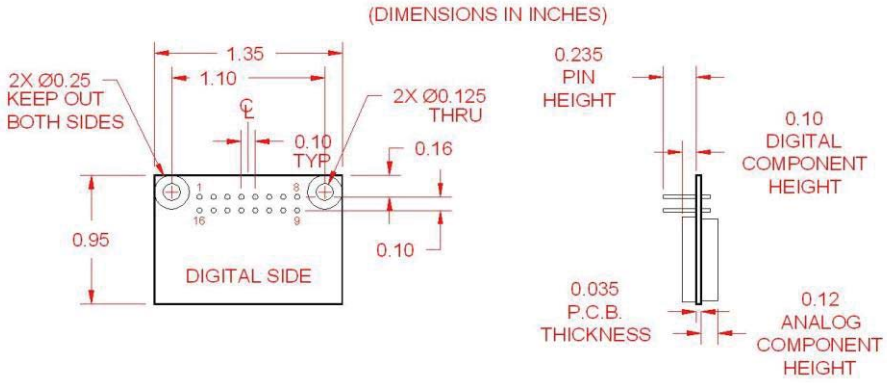
J1-16 = +3.3VDC (3.2V to 3.5V), 50mV max. ripple
+5.0VDC ±0.25VDC, 50mV max ripple
J1-15 = Ground
J1-13 = Reset (optional) 2
J1-09 = Serial Data Format Switch 3
J1-10 = Serial Input (future use) 2

Notes:
[1]Pins marked “Reserved” should be left un-terminated.
[2]Pins may be left un-terminated.
[3]Pin 9 may be left un-terminated for data format #2.

SENSOR CONNECTION

9 Pin D-Sub	J1 OEM Module	Patient Extension Cable Color	Description
7	N/A	Cable shield	Ground
5	J1-02	Coax signal	Photo diode signal
9	J1-04	Coax shield	Photo diode bias
6	J1-05	Green	Sensor type #1 line
2	J1-06	Red	LED drive line
3	J1-07	Black	LED drive line
1	J1-12	Yellow	Sensor type #2/1 wire (optional)

OEM III Dimensions



Note: For your reference: the connector on the OEM module (J1) is manufactured by Samtec, part number MTLW-108-05-G-D-170.

Testing

Once the integration process is complete, Nonin recommends testing the integrated module with a pulse oximetry simulator. Nonin offers several simulators for sale. There are also a number of commercially available simulators manufactured by third parties. Nonin has tested these simulators extensively, and recommends the following models:

Manufacturer	Simulator Name	Type	Settings	Simulates	User Programmable
Datrend	Oxitest Plus 7	Optical	Nonin Xpod, OEM	5 preset SpO2 levels from 70-97% 20-250 BPM 0-100% pulse amplitude in 1% increments 4 preset artifact conditions 9 preset patient conditions	Yes
Fluke	ProSim 8	Optical	Nonin	30 - 100% SpO2 saturation in 1% increments Pulse amplitude from 0 - 20% modulation 4 preset transmission values 30 – 300 BPM 0 – 5% respiration artifact 6 ambient light artifact settings	Yes
Clinical Dynamics	SmartSat	Non-Optical	PureSat	1-100% SpO2 saturation in 1% increments 20-300 BPM Pulse amplitude from 0.10 - 20.0% modulation Motion artifact at frequency of 4 Hz 5 Preset arrhythmia conditions	Yes
Nonin	OEM Bench Test Simulator	Non-Optical	N/A	6 preset SpO2 Levels from 63% to 98% 9 preset HR Levels from 38 to 288 BPM 5 pulse amplitude Levels	No
Nonin	8000S	Non-Optical	N/A	1 preset SpO2 Level, 1 HR Level	No

Additionally, it is highly recommended that OEM partners send their devices to Nonin for testing and evaluation prior to launching the device on the market. This service is provided to Nonin OEM customers free of charge, and will help ensure that the OEM III Module has been properly integrated. To make arrangements for your device to be tested, please contact your OEM account manager.

Manuals and Reference Materials

Because the OEM III Module is a component rather than a finished device, no end user instruction manual is provided. The instructions will vary greatly depending on the host device in which the module is incorporated. Nonin will, however, gladly provide example manuals from our finished oximeters as reference tools to our OEM customers. The ultimate responsibility for the manual of the finished medical device into which the OEM III Module is incorporated lies with the manufacturer of that device.

All Nonin sensors are sold with an “Instructions for Use” insert that can also be used for guidance.

Assistance with Regulatory Approval

The OEM III Module is considered a component, and therefore does not carry its own regulatory clearance as a finished medical device. Regulatory approval for the host device is the responsibility of the manufacturer, but Nonin will gladly assist by providing copies of test documentation and verification procedures used during the process of validating the module. Please note that this test information is considered confidential and should be used for regulatory approval purposes only.

Service, Support, and Warranty

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of three years from the date of purchase, each OEM III Pulse Oximeter module.

Nonin shall repair or replace the OEM Pulse Oximeter module found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period.

This warranty excludes cost of delivery to and from Nonin. Nonin reserves the right to charge a fee for a warranty repair request on any OEM Pulse Oximeter module found to be within specifications (no trouble found). This OEM Pulse Oximeter module is a precision electronic instrument and must be repaired by knowledgeable and specially trained Nonin Medical Inc. personnel only. All non-warranty work shall be done according to Nonin standard rates and charges in effect at the time of delivery to Nonin.

This warranty is subject to change without notice.

Return Authorization

If a product needs to be returned to Nonin for service, please contact us to obtain a Return Authorization Number (RAN). This number is required before returning product to Nonin to ensure that is tracked properly and ensures rapid service. To obtain a RAN, please provide the OEM module serial number to Nonin Customer Support:

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OEM III Evaluation Kits

Nonin offers an evaluation kit for the OEM III modules. These kits come with everything needed to connect the OEM module to a computer as well as a set of demonstration software. Please note that the computer software and interface board that are included with the kit are intended for evaluation purposes only, and are not intended for use as part of a finished medical device.

Troubleshooting

Problem	Possible Cause	Possible Solution
The sensor disconnect bit is set.	A sensor fault exists. The sensor may have become dislodged from the module or from the patient.	Verify that the sensor is correctly connected to the module and the patient; try a new sensor if the condition persists.
The out-of-track bit is set.	No signal is detected because the sensor is not plugged in.	Verify the sensor connections.
	A sensor failure.	Replace the sensor.
The pulse rate from the module does not correlate to the pulse rate displayed on the ECG monitor.	Excessive motion at the sensor site may be prohibiting the module from acquiring a consistent pulse signal.	Eliminate or reduce the cause of the motion artifact or reposition the sensor to a new sensor site where motion is not present.
	The patient may have an arrhythmia resulting in some heartbeats that do not yield a pulse quality signal at the sensor site.	Examine the patient. The condition may persist even though both monitors are functioning properly if the patient's arrhythmia persists.
	A non-Nonin sensor is being used.	Replace the sensor with a Nonin sensor.
	The ECG monitor may not be functioning properly.	Examine the patient: replace the ECG monitor or refer to the operator's manual for the ECG monitor.
An erratic pulse rate and/or marginal perfusion bit is set during the concurrent use of electrosurgical equipment (ESU).	The ESU may be interfering with the pulse oximeter performance.	Examine the patient. Move the module, cables, and sensors as far away from the ESU as possible or refer to the ESU operator's manual.

Problem	Possible Cause	Possible Solution
The marginal perfusion bit is set with each pulse.	The quality of the pulse signal at the sensor site is marginal.	Examine the patient: reposition the sensor or select an alternate sensor site.
You are unable to receive data without one of the low perfusion, marginal perfusion, or artifact bits set.	Low patient pulse strength; or the sensor site is poorly perfused; or the sensor is not correctly positioned.	Reposition the sensor on the patient. Ensure that sensor site is warm. Lower body temperature at sensor site will give poor readings.
	The sensor is attached too tightly, or tape or other items are restricting the pulse quality at the sensor site.	Reapply the sensor, select an alternate sensor site, or remove the restrictive material from the sensor site.
	Circulation is reduced due to excess pressure between the sensor and a hard surface.	Allow the sensor and finger, foot, etc., to rest comfortably on the surface.
	Excessive ambient light.	Reduce the ambient light.
	Excessive patient motion.	Reduce the patient motion.
	The sensor is applied to a polished finger or toe nail.	Remove the nail polish.
	Interference from: • Arterial catheter • Blood pressure cuff • Electrosurgical procedure • Infusion line	Reduce or eliminate the interference.

Problem	Possible Cause	Possible Solution
The low perfusion bit is set and the SpO_2 and/or pulse rate are set to Out of Track.	An inadequate signal at the sensor site.	Examine the patient. Reposition the sensor or select an alternate sensor site.
	Excessive motion at the sensor site may be prohibiting the module from acquiring a consistent pulse signal.	Eliminate or reduce the cause of the motion artifact or reposition the sensor to a sensor site where motion is not present.
	A sensor failure.	Replace the sensor.

Please contact Nonin with any questions about this guide or if any additional assistance is required.

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