OEM III Module Specification
and
Technical Information

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Table of Contents

Nonin® OEM III Specifications

1.	**Displayed Oxygen Saturation Range (SpO_2)**		0 to 100%	
2.	**Displayed Pulse Rate Range**		18 to 321 beats per minute (BPM)	
3.	**Measurement Wavelengths and Output Power****			
		Red:	660 nanometers @ 0.8 mW maximum average	
		Infrared (using NONIN PureLight® Sensor):	910 nanometers @ 1.2 mW maximum average	
4.	**SpO_2 Accuracy (A_{rms}*)**		70-100%	
			Adults/Pediatrics	**Neonates**
	No Motion			
	REUSABLE:	Finger Clip:	± 2 digits	± 3 digits
		Flex:	± 3 digits	± 3 digits
		Soft Sensor:	± 2 digits	N/A
		8000R:	± 3 digits	N/A
		8000Q:	± 4 digits	N/A
	DISPOSABLE:	6000 Series:	± 2 digits	± 3 digits
		7000 Series	± 3 digits	± 4 digits
	Motion			
	REUSABLE:	Finger Clip:	± 2 digits	± 3 digits
		Flex:	± 3 digits	± 4 digits
		Soft Sensor:	± 3 digits	± 4 digits
	Low Perfusion	All Sensors:	± 2 digits	± 3 digits
5.	**Pulse Rate Accuracy**			
			Adults/Pediatrics	**Neonates**
	No Motion (18-300 BPM)			
	RESUABLE:	Finger Clip:	± 3 digits	± 3 digits
		Flex:	± 3 digits	± 3 digits
		Soft Sensor:	± 3 digits	± 3 digits
		8000R:	± 3 digits	± 3 digits
		8000Q:	± 3 digits	± 3 digits
	DISPOSABLE:	6000 Series:	± 3 digits	± 3 digits
		7000 Series:	± 3 digits	± 3 digits
	Motion (40-240 BPM)			
	REUSABLE:	Finger Clip:	± 5 digits	± 5 digits
		Flex:	± 5 digits	± 5 digits
		Soft Sensor:	± 5 digits	± 5 digits
	Low Perfusion (40-240 BPM)	All Sensors:	± 3 digits	± 3 digits

Notes:

Reusable Group:

Finger Clip Sensors: 8000AA-1, 8000AA-3, 8000AP-1, 8000AP-3
Flex Sensors: 8000J-1, 8000J-3, 8008J, 8001J
Soft Sensors: 8000SS, 8000SM, 8000SL

Disposable Group:

Flexi-Form® II (7000 Series) Sensors: 7000A, 7000P, 7000I, 7000N
6000 Series Sensors: 6000A, 6000P, 6000I, 6000N

* ±1 A_{rms} represents approximately 68% of measurements.

** This information is especially useful for clinicians performing photodynamic therapy.

Nonin® OEM III Specifications

5.	**Temperature (Operating)**	0°C to +50°C (32°F – 122°F) • Specified operating temperature is for the module. • Operating temperature of Sensor is not to exceed 40°C (104°F)
	Temperature (Storage/Transportation)	-20°C to +70°C (-4°F - +158°F)
6.	**Humidity (Operating)**	10 to 90% non-condensing
	Humidity (Storage/Transportation)	10 to 95% non-condensing
7.	**Power Draw**	29 mW typical operation @ 3.3VDC input voltage 45 mW typical operation @ 5.0VDC input voltage
8.	**Voltage Input**	+3.3VDC (3.2V to 3.5V), w/50mV max. ripple +5.0VDC ±0.25VDC, w/50mV max. ripple
9.	**I/O Signals**	0 to +3.3VDC (nominal) @ +3.3VDC input voltage 0 to +5.0VDC (nominal) @ +5.0VDC input voltage
10.	**Dimensions**	1.35" x 0.95" x 0.235" (34.3 x 24.1 x 6.2 mm)
11.	**Weight**	5.3g (0.19 oz.) (with shield)
12.	**Ruggedness (Shock)**	IEC 60068-2-27
	Ruggedness (Vibration)	Sinusoidal – IEC 60068-2-6 Random – IEC 60068-2-64
13.	**Sensors**	Designed to use NONIN®-branded PureLight® sensors only (see Accessories)
14.	**Shielding**	An RF shield is included (placed over the analog components)

Serial Output Formatting Options

The format for serial output data is determined by the amount of resistance present between the serial data format switch (J1, pin 9) and ground (J1, pin 15). If J1, pin 9 is left unconnected, then the default format is serial data format #2 (see "Serial Output Formatting Options").

Serial Output Formatting Options

Serial Format #	J1, Pin 9 Status
#1	0Ω to 626Ω
#2	297KΩ to ∞Ω
#7	4.3KΩ, ± 5%

The serial transmission rate for all data formats shall be as follows:

Bits per Second	Data Bits	Parity	Stop Bits	Flow Control
9600	8	None	1	None

Serial Data Format #1:

Packet Description

Three bytes of data are transmitted 1 once per second.

Byte 1 - Status							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
1	SNSD	OOT	LPRF	MPRF	ARTF	HR8	HR7
*__Note__: Bit 7 is always set							

Byte 2 - Heart Rate							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
0	HR6	HR5	HR4	HR3	HR2	HR1	HR0
*__Note__: Bit 7 is always clear							

Byte 3 - SpO2							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
0	SP6	SP5	SP4	SP3	SP2	SP1	SP0
*__Note:__ Bit 7 is always clear							

The following are all active high:

SNSD:	Sensor Disconnect	– Sensor is not connected to oximeter or sensor is inoperable.
OOT:	Out Of Track	– An absence of consecutive good pulse signals.
LPRF:	Low Perfusion	– Amplitude representation of low signal quality (holds for entire duration).
MPRF:	Marginal Perfusion	– Amplitude representation of medium signal quality (holds for entire duration).
ARTF:	Artifact	– A detected pulse beat didn't match the current pulse interval.
HR8 – HR0:	Heart Rate	– Standard 4-beat average values not including display holds.
SP6 – SP0:	SpO_2	– Standard 4-beat average values not including display holds.

When SpO_2 and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO_2 equals 127.

Serial Data Format #2:

Packet Description

A frame consists of 5 bytes; a packet consists of 25 frames. Three packets (75 frames) are transmitted each second.

Frame

Packet

	Byte 1	Byte 2	Byte 3	Byte 4	Byte 5
1	01	STATUS	PLETH	HR MSB	CHK
2	01	STATUS	PLETH	HR LSB	CHK
3	01	STATUS	PLETH	SpO_2	CHK
4	01	STATUS	PLETH	REV	CHK
5	01	STATUS	PLETH	reserved	CHK
6	01	STATUS	PLETH	reserved	CHK
7	01	STATUS	PLETH	reserved	CHK
8	01	STATUS	PLETH	reserved	CHK
9	01	STATUS	PLETH	SpO2-D	CHK
10	01	STATUS	PLETH	SpO_2 Fast	CHK
11	01	STATUS	PLETH	SpO_2 B-B	CHK
12	01	STATUS	PLETH	reserved	CHK
13	01	STATUS	PLETH	reserved	CHK
14	01	STATUS	PLETH	E-HR MSB	CHK
15	01	STATUS	PLETH	E-HR LSB	CHK
16	01	STATUS	PLETH	E-SpO_2	CHK
17	01	STATUS	PLETH	E-SpO_2-D	CHK
18	01	STATUS	PLETH	reserved	CHK
19	01	STATUS	PLETH	reserved	CHK
20	01	STATUS	PLETH	HR-D MSB	CHK
21	01	STATUS	PLETH	HR-D LSB	CHK
22	01	STATUS	PLETH	E-HR-D MSB	CHK
23	01	STATUS	PLETH	E-HR-D LSB	CHK
24	01	STATUS	PLETH	reserved	CHK
25	01	STATUS	PLETH	reserved	CHK

Notes:

- Byte number 1 in each frame is set to a value of 1.
- Reserved bytes are undefined.

Byte 2 - Status							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
1	SNSD	ARTF	OOT	SNSA	YPRF		SYNC
					RPRF	GPRF	
*__Note__: Bit 7 is always set.							

The following are all active high:

SNSD:	Sensor Disconnect	– Sensor is not connected to oximeter or sensor is inoperable.
ARTF:	Artifact	– A detected pulse beat didn't match the current pulse interval
OOT:	Out Of Track	– An absence of consecutive good pulse signals
SNSA:	Sensor Alarm	– Sensor is providing unusable data for analysis
RPRF:	Red Perfusion	– Amplitude representation of low signal quality (occurs only during pulse)
YPRF:	Yellow Perfusion	– Amplitude representation of medium signal quality (occurs only during pulse)
GPRF:	Green Perfusion	– Amplitude representation of high signal quality (occurs only during pulse)
SYNC:	Frame Sync	(occurs 1 of 25)

Generic HR Format:

	7	6	5	4	3	2	1	0
HR MSB	X	X	X	X	X	X	HR8	HR7

	7	6	5	4	3	2	1	0
HR LSB	X	HR6	HR5	HR4	HR3	HR2	HR1	HR0

Generic SpO_2 Format:

	7	6	5	4	3	2	1	0
SPO_2	X	SP6	SP5	SP4	SP3	SP2	SP1	SP0

HR: 4-beat average values in standard mode.

SpO_2: 4-beat average values in standard mode.

HR-D: 4-beat average displayed values in display mode

SpO_2-D: 4-beat average displayed values in display mode

SpO_2 Fast: Non-slew limited saturation with 4-beat averaging in standard mode.

SpO_2: B-B: Un-averaged, non-slew limited, beat to beat value in standard mode.

E-HR: 8-beat average values in standard mode.

E-SpO_2: 8-beat average values in standard mode.

E-HR-D: 8-beat average displayed values in display mode

E-SpO_2-D: 8-beat average displayed values in display mode

PLETH: 8-Bit Plethysmographic Pulse Amplitude

SREV: Oximeter Firmware Revision Level

CHK: Checksum = (Byte 1) + (Byte 2) + (Byte 3) + (Byte 4) modulo 256

When SpO_2 and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO_2 equals 127.

Mode	In Track	Out of Track
Standard	SpO_2 and pulse rate updated on every pulse beat	SpO_2 and Heart Rate values are set to missing data values and out of track indicated.
Display	SpO_2 and pulse rate updated every 1.5 seconds	Last in track values transmitted for ten seconds and out of track indicated. After ten seconds, values are set to missing data values.

Serial Data Format #7:

Packet Description

A frame consists of 5 bytes; a packet consists of 25 frames. Three packets (75 frames) are transmitted each second.

Frame

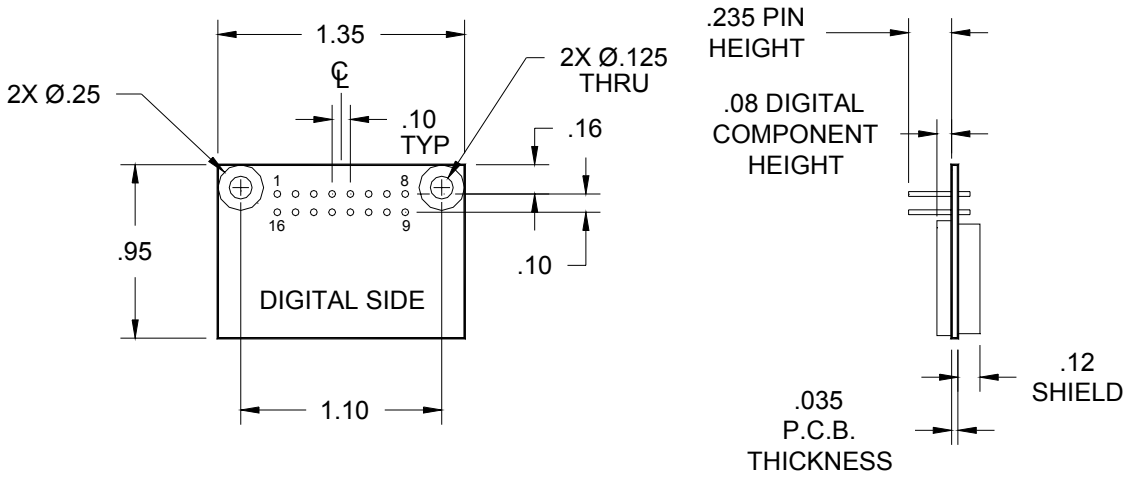
Packet

	Byte 1	Byte 2	Byte 3	Byte 4	Byte 5
1	STATUS	PLETH (MSB)	PLETH (LSB)	HR MSB	CHK
2	STATUS	PLETH (MSB)	PLETH (LSB)	HR LSB	CHK
3	STATUS	PLETH (MSB)	PLETH (LSB)	SpO_2	CHK
4	STATUS	PLETH (MSB)	PLETH (LSB)	REV	CHK
5	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
6	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
7	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
8	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
9	STATUS	PLETH (MSB)	PLETH (LSB)	SpO_2-D	CHK
10	STATUS	PLETH (MSB)	PLETH (LSB)	SpO_2 Fast	CHK
11	STATUS	PLETH (MSB)	PLETH (LSB)	SpO_2 B-B	CHK
12	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
13	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
14	STATUS	PLETH (MSB)	PLETH (LSB)	E-HR MSB	CHK
15	STATUS	PLETH (MSB)	PLETH (LSB)	E-HR LSB	CHK
16	STATUS	PLETH (MSB)	PLETH (LSB)	E-SpO_2	CHK
17	STATUS	PLETH (MSB)	PLETH (LSB)	E-SpO_2-D	CHK
18	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
19	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
20	STATUS	PLETH (MSB)	PLETH (LSB)	HR-D MSB	CHK
21	STATUS	PLETH (MSB)	PLETH (LSB)	HR-D LSB	CHK
22	STATUS	PLETH (MSB)	PLETH (LSB)	E-HR-D MSB	CHK
23	STATUS	PLETH (MSB)	PLETH (LSB)	E-HR-D LSB	CHK
24	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK
25	STATUS	PLETH (MSB)	PLETH (LSB)	reserved	CHK

Notes:

- Refer to DF#2 for definitions on Status Byte, Byte 4 and Checksum
- PLETH(MSB) and PLETH(LSB) make up a 16-bit pleth (ex. PLETH(MSB)*256 + PLETH(LSB))

(DIMENSIONS IN INCHES)



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) [1]
J1-09 = Serial Data Format Switch [2]
J1-10 = Serial Input (future use)[1]

SENSOR CONNECTION:

	9 Pin	UNI EXT Patient Extension	
J1	D-Sub	Cable Color	Description
J1-01	7	Cable Shield	Cable shield
J1-02	5	Coax Signal	Photo diode signal
J1-04	9	Coax Shield	Photo diode bias
J1-05	6	Green	Sensor type #1 line
J1-06	2	Red	LED drive line
J1-07	3	Black	LED drive line
J1-12	1	Yellow	Sensor type #2/1 wire

PIN ASSIGNMENTS:

J1-01 = Cable shield
J1-02 = Photo diode signal
J1-03 = Signal shield
J1-04 = Photo diode bias
J1-05 = Sensor type #1 line
J1-06 = LED drive line
J1-07 = LED drive line
J1-08 = Reserved [3]
J1-09 = Serial Data Format Switch
J1-10 = Serial Input (future use)[1]
J1-11 = Serial Output
J1-12 = Sensor type #2/1 wire
J1-13 = Reset (Optional) [1]
J1-14 = Photo Plethysmogram Digital Output [1,4]
J1-15 = Ground
J1-16 = +3.3VDC (3.2V to 3.5V), 50mV max. ripple
+5.0VDC ±0.25VDC, 50mV max ripple

Notes:

1. Pins may be left un-terminated
2. Pin 9 may be left un-terminated for Data Format #2
3. Pins marked “Reserved” should be left un-terminated
4. Additional details can be found in technical note T-0604.

Indications for Use

The OEM III module is intended to provide medical device manufacturers with a small, low-power device that can be easily integrated into a host device. The module measures functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate (BPM) for adult, pediatric, infant and neonatal patients. When integrated with a medical device manufacturer's host system, the OEM III module may be used in any environment where pulse oximetry measurements are made.

Contraindications

- Do not use this device in an MR environment.
- Explosive Hazard: Do not use this device in an explosive atmosphere or in the presence of flammable anesthetics or gases
- This module does not meet defibrillation-proof requirement per IEC 60601-1: 1990, clause 17.h.

Warnings

- Use only with NONIN®-branded PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN® pulse oximeters. Using other manufacturers' sensors can result in inaccurate pulse oximeter performance.
- Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g., blood pressure cuff) hinder pulse measurements.
- As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- Operation of this module below the minimum amplitude of 0.3% modulation may cause inaccurate results.
- The use of accessories, sensors, and cables other than those specified by NONIN® (may result in increased emission and/or decreased immunity of this device.
- Do not use a damaged sensor.

⚠ Cautions

- The accuracy of the SpO_2 measurement may be affected if the total sensor cable length (including extension cables) is greater than 3 meters.
- Follow local, state, or national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device.
- This pulse oximeter module is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following: excessive ambient light, excessive motion, electrosurgical interference, blood flow restrictors (arterial catheters, blood pressure cuffs, infusing lines, etc.), moisture in the sensor, improperly applied sensor, incorrect sensor type, poor pulse quality, venous pulsations, anemia or low hemoglobin concentrations, cardiogreen or other intravascular dyes, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin, artificial nails or fingernail polish, or a sensor not at heart level.
- This device has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, this device may still interpret motion as good pulse quality. This covers all available outputs (i.e. SpO_2, HR, PLETH, PPG).
- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity may vary due to medical status or skin condition. Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.

⚠ Cautions

- This equipment complies with IEC EN 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Portable and mobile RF communications equipment may affect medical electrical equipment.
- Oximeter readings may be affected by the use of an electrosurgical unit (ESU)
- The oximeter sensor may not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

For more information about required safety and regulatory requirements for pulse oximeters, refer to ISO 9919: 2005 and IEC 60601-1:1990. Additional safety information can be found in the labeling provided with each NONIN® sensor.

Equipment Response Time

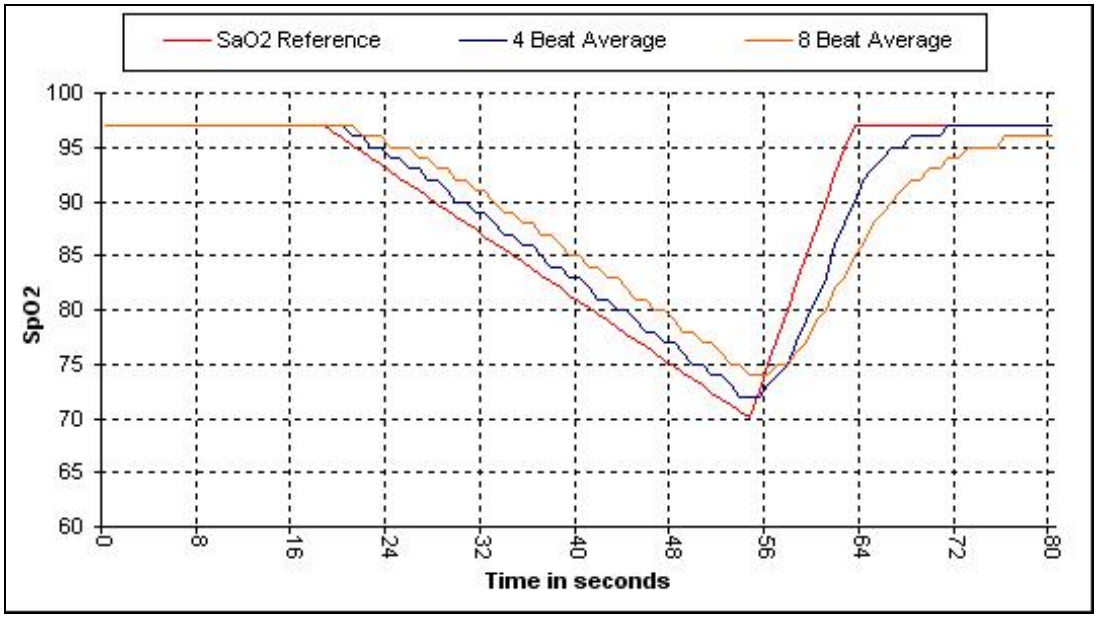
SpO_2 Values	Average	Latency
Standard/Fast Averaged SpO_2	4 beat exponential	2 beats
Extended Averaged SpO_2	8 beat exponential	2 beats

Pulse Rate Values	Average	Latency
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats
Extended Averaged Pulse Rate	8 beat exponential	2 beats

Example – SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second (7.5% over 10 seconds)

Pulse Rate – 75 BPM



Specific to this example:

- The response of the 4-beat average is 1.5 seconds.
- The response of the 8-beat average is 3 seconds.

Accessories

The following NONIN® accessories may be used with the OEM III module. See the respective sensor instructions for detailed information regarding specified sensor use (patient population, body/tissue, and application).

Model Number	Description
8000AA	Adult Articulated Internal Spring Finger Clip, 3 feet / 1 meter cable
8000AP	Pediatric External Spring Finger Clip, 3 feet / 1 meter cable
8000J	Adult Flex, 3 feet / 1 meter cable
8001J	Neonatal Flex, 3 feet / 1 meter cable
8008J	Infant Flex, 3 feet / 1 meter cable
8000Q	Ear Clip, 3 feet / 1 meter cable
8000R	Reflectance, 3 feet / 1 meter cable
8000SS	Sensor, Reusable, Soft, Small, 1 Meter
8000SM	Sensor, Reusable, Soft, Medium, 1 Meter
8000SL	Sensor, Reusable, Soft, Large, 1 Meter
7000A	Flexi-Form® II Adult, 3 feet / 11 meter, 10-pack
7000P	Flexi-Form® II Pediatric, 3 feet / 1 meter cable, 10-pack
7000I	Flexi-Form® II Infant, 3 feet / 11 meter, 10-pack
7000N	Flexi-Form® II Adult, 3 feet / 11 meter, 10-pack
6000A	Sensor, Disposable, Adult, 45cm Cable
6000P	Sensor, Disposable, Pediatric, 45cm Cable
6000I	Sensor, Disposable, Infant, 90cm Cable
6000N	Sensor, Disposable, Neonate, 90cm Cable
UNI-RA-0	7.5” 90-degree Patient Cable
UNI EXT-X	Patient Extension Cable (1 or 3 meter with 3.3V input, 1,3,6 or 9 meter with +5V input)

Testing Summary

SpO_2 accuracy, motion and low perfusion testing was conducted by NONIN® Medical, Incorporated as described below.

SpO_2 Accuracy Testing

SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 9919:2005, Standard Specification for Pulse Oximeters for Accuracy.

Pulse Rate Motion Testing

This test measures pulse rate accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 9919:2005 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels.. The module must maintain accuracy in accordance with ISO 9919:2005 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Manufacturer's Declaration

See the following tables for specific information regarding this module's compliance to IEC 60601-1-2:2001.

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment— Guidance
This module is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	This module uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This module is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 2: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This module is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	N/A	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	N/A	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the module requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery pack.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage before application of the test level.			

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This module is intended for use in the electromagnetic environment specified below. The customer and/or user of this module should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the module, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17 $\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.17 $\sqrt{P}$ 80 MHz to 800MHz d = 2.33 $\sqrt{P}$ 800MHz to 2.5 GHz
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Notes: • At 80 MHz and 800MHz, the separation distance for the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the module.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Table 4: Recommended Separation Distances

The following table describes the recommended separation distances between portable and mobile RF communications equipment and this module.

This module is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Customers or users of this module can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the module as recommended below, according to maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter *W*	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Notes: • At 80 MHz and 800MHz, the separation distance for the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			