Nonin Xpod Patient Cable Oximeter, Rev. 29+ **Specifications**

1. Oxygen Saturation Range 0 to 100% 2. Pulse Rate Range 18 to 300 pulses per minute 3. Measurement Wavelengths Red - 660 Nanometers @ 3 mW nominal

Infrared - 910 Nanometers @ 3 mW nominal

4. Accuracy*

SpO₂ (70-100%) (±1 SD) ◆ No Motion

> - Adults, Pediatrics ±2 digits ±3 digits - Neonates

Motion

- Adults, Pediatrics ±2 digits ±3 digits - Neonates

Low Perfusion

- Adults, Pediatrics ±2 digits ±3 digits - Neonates

Heart Rate No Motion (18 - 300 BPM)

> - Adults, Pediatrics ±3 digits

- Neonates Motion (40 - 240 BPM)

> - Adults, Pediatrics ±5 digits

- Neonates

Low Perfusion (40 - 240 BPM)

- Adults, Pediatrics ±3 digits

- Neonates

5. Temperature

a) Operating 0°C to $+50^{\circ}\text{C}$ b) Non Operating -20° C to $+50^{\circ}$ C

6. Humidity

> a) Operating 10 to 90% Noncondensing b) Non Operating 10 to 95% Noncondensing

Power Draw 60 mW - typical operating 7. 2 to 6 volts dc operating Voltage Input 8.

Note: Sensor is not isolated from input voltage

9. Output Digital Signals 0 - 5 volts (nominally)

Patient Isolation Meets IEC 60601-1 Dielectric withstand 10.

11. Leakage Current Not applicable

12. Dimensions 2.1" x 0.8" x 0.6" (53 x 20 x 15mm) Weight 75g (including 6' cable and connector) 13.

Ruggedness immersion

a) Shock Per IEC 68-2-27

b) Vibration Mil-standard 810C, method 514-2

15. Sensors Designed to use Nonin sensors only

• Standard Deviation (SD) is a statistical measure: up to 32% of the readings may fall outside these limits.

^{*} All accuracy specifications are results determined by induced Hypoxia studies on healthy adult volunteers using the 8000AA Finger Clip Sensor.

INPUTS:

Red Wire = V+ (2-6VDC, 60mw typical)

Black Wire = Ground Cable Shield = Ground

(Both Black wire and cable shield must be attached to ground on the host device)

Yellow Wire = ECG Sync (Optional)

Note: Sensor is not isolated from input voltage.

OUTPUTS:

Green Wire = Serial Output

FORMATTING OPTIONS:

ORDER#	MODEL#	SERIAL FORMAT #	WITH CONNECTOR
3873-001	3011	#1	No
3873-002	3012	#2	No
3873-101	3011	#1	Yes
3873-202	3012	#2	Yes

SERIAL DATA FORMAT #1:

1) Serial format

9600, n, 8, 1

2) Rate

Send 3 bytes of data once a second.

3) Data

1st byte = **Status**

BIT 7 = ALWAYS SET TO "1"

BIT 6 = SENSOR DISCONNECTED, SET IF TRUE

BIT 5 = OUT OF TRACK, SET IF TRUE

BIT 4 = LOW PERFUSION, SET IF TRUE

BIT 3 = MARGINAL PERFUSION, SET IF TRUE

BIT 2 = BAD PULSE, SET IF TRUE

BIT 1 = HEART RATE BIT 8

BIT 0 = HEART RATE BIT 7

2nd byte = **Heart Rate** (511 = bad data) BIT "7" IS ALWAYS SET TO "0".

HEART RATE DATA = BITS 0 - 6

PLUS BITS 0 & 1 OF THE STATUS BYTE TO PROVIDE 9 BITS OF

RESOLUTION.

3rd byte = SpO2 (127 = bad data)

SERIAL DATA FORMAT #2:

1) Serial format	9600, n, 8, 1					
2) Rate	Send 5 bytes of data 75 times a second.					
3) Data	•					
a. HR value bits 7&8 (128-511), 511 =	bad data 1 byte 3 times a second					
b. HR value bits 0-6 (0-127)	1 byte 3 times a second					
c. SpO2 value 0 - 100	1 byte 3 times a second					
d. Firmware revision level	1 byte 3 times a second					
e. Status byte 128 - 255	1 byte 75 times a second					
Bit 0 frame Sync, set for 1 of 2	25, clear for 2-25 of 25					
Bit 1 green perfusion, set if tru	e only during pulse					
Bit 2 red perfusion, set if true	only during pulse					
Bit 3 sensor alarm, set if true						
Bit 4 out of track, set if true						
Bit 5 bad pulse, set if true						
Bit 6 sensor disconnected, set	if true					
Bit 7 always set						
Note: bits 1 & 2 are set for ye	ellow perfusion.					
f. Plethysmographic pulse value 0 - 25-	1 byte 75 times a second					
g. Sync character (01)	1 byte 75 times a second					
h. Checksum = byte $1 + byte 2 + byte$	3 + byte 4 1 byte 75 times a second					
E . 114 D .						
Extended Averaging Data	-1 11. 41. 2. 1					
i. E-HR value bits 7&8 (128-511), 511 =	· · · · · · · · · · · · · · · · · · ·					
j. E-HR value bits 0-6 (0-127)	1 byte 3 times a second					
k. E-SpO2 value 0 - 100	1 byte 3 times a second					
Non-Slew Limited with Standard Averaging						
l. SpO2 Slew value 0 - 100, 127 = bad d	ata 1 byte 3 times a second					
Beat to Beat Value (No Averaging or Slew Limitin	· · · · · · · · · · · · · · · · · · ·					
m. SpO2 B-B value 0 - 100, 127 = bad d						
Display Data						
SpO2-D Display Value with Standard Averaging						
n. 0-11, 127 = bad data	1 byte 3 times a second					
E-SpO2-D Display Value with Extended Averagin	•					
o. 0-100, 127 = bad data	1 byte 3 times a second					
HR-D-MSB Display Value with Standard Averagi	•					
p. HR Value bits 7&8, 511 = bad data	1 byte 3 times a second					
HR-D-LSB Display Value with Standard Averagin	, g					
q. HR Value bits 0-6 (0-127)	1 byte 3 times a second					
E-HR-D-MSB Display Value with Extended Aver	raging					
r. HR Value bits $7\&8$, $511 = bad data$	1 byte 3 times a second					
E-HR-D-LSB Display Value with Extended Averaging						
s. HR Value bits 0-6 (0-127)	1 byte 3 times a second					

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Data would be sent in the following format

Hz			BYTE		ŀ	Ηz			BYTE		H	łz			BY	TE	
1/75	1	2	3	4	5	1/7 5	1	2	3	4	5	1/ 75	1	2	3	4	5
1	01	STATUS	PLETH	HR MSB	CHK	26	01	STATUS	PLETH	HR MSB	CHK	51	01	STATUS	PLETH	HR MSB	CHK
2	01	STATUS	PLETH	HR LSB	CHK	27	01	STATUS	PLETH	HR LSB	CHK	52	01	STATUS	PLETH	HR LSB	CHK
3	01	STATUS	PLETH	SpO2	CHK	28	01	STATUS	PLETH	SpO2	CHK	53	01	STATUS	PLETH	SPO2	CHK
4	01	STATUS	PLETH	REV	CHK	29	01	STATUS	PLETH	REV	CHK	54	01	STATUS	PLETH	REV	CHK
5	01	STATUS	PLETH	*	CHK	30	01	STATUS	PLETH	*	CHK	55	01	STATUS	PLETH	*	CHK
6	01	STATUS	PLETH	*	CHK	31	01	STATUS	PLETH	*	CHK	56	01	STATUS	PLETH	*	CHK
7	01	STATUS	PLETH	*	CHK	32	01	STATUS	PLETH	*	CHK	57	01	STATUS	PLETH	*	CHK
8	01	STATUS	PLETH	*	CHK	33	01	STATUS	PLETH	*	CHK	58	01	STATUS	PLETH	*	CHK
9	01	STATUS	PLETH	SpO2-D	CHK	34	01	STATUS	PLETH	SpO2-D	CHK	59	01	STATUS	PLETH	SpO2-D	CHK
10	01	STATUS	PLETH	SpO2 Slew	CHK	35	01	STATUS	PLETH	SpO2 Slew	CHK	60	01	STATUS	PLETH	SpO2 Slew	CHK
11	01	STATUS	PLETH	SpO2 B-B	CHK	36	01	STATUS	PLETH	SpO2 B-B	CHK	61	01	STATUS	PLETH	SpO2 B-B	CHK
12	01	STATUS	PLETH	*	CHK	37	01	STATUS	PLETH	*	CHK	62	01	STATUS	PLETH	*	CHK
13	01	STATUS	PLETH	*	CHK	38	01	STATUS	PLETH	*	CHK	63	01	STATUS	PLETH	*	CHK
14	01	STATUS	PLETH	E-HR MSB	CHK	39	01	STATUS	PLETH	E-HR MSB	CHK	64	01	STATUS	PLETH	E-HR MLSB	CHK
15	01	STATUS	PLETH	E-HR LSB	CHK	40	01	STATUS	PLETH	E-HR LSB	CHK	65	01	STATUS	PLETH	E-HR LSB	CHK
16	01	STATUS	PLETH	E-SpO2	CHK	41	01	STATUS	PLETH	E-SpO2	CHK	66	01	STATUS	PLETH	E-SpO2	CHK
17	01	STATUS	PLETH	E-SpO2-D	CHK	42	01	STATUS	PLETH	E-SpO2-D	CHK	67	01	STATUS	PLETH	E-SpO2-D	CHK
18	01	STATUS	PLETH	*	CHK	43	01	STATUS	PLETH	*	CHK	68	01	STATUS	PLETH	*	CHK
19	01	STATUS	PLETH	*	CHK	44	01	STATUS	PLETH	*	CHK	69	01	STATUS	PLETH	*	CHK
20	01	STATUS	PLETH	HR-D-MSB	CHK	45	01	STATUS	PLETH	HR-D-MSB	CHK	70	01	STATUS	PLETH	HR-D-MSB	CHK
21	01	STATUS	PLETH	HR-D-LSB	CHK	46	01	STATUS	PLETH	HR-D-LSB	CHK	71	01	STATUS	PLETH	HR-D-LSB	CHK
22	01	STATUS	PLETH	E-HR-D-MSB	CHK	47	01	STATUS	PLETH	E-HR-D-MSB	CHK	72	01	STATUS	PLETH	E-HR-D-MSB	CHK
23	01	STATUS	PLETH	E-HR-D-LSB	CHK	48	01	STATUS	PLETH	E-HR-D-LSB	CHK	73	01	STATUS	PLETH	E-HR-D-LSB	CHK
24	01	STATUS	PLETH	*	CHK	49	01	STATUS	PLETH	*	CHK	74	01	STATUS	PLETH	*	CHK
25	01	STATUS	PLETH	*	CHK	50	01	STATUS	PLETH	*	CHK	75	01	STATUS	PLETH	*	CHK

^{*} Undefined

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Xpod Precautions for Use

Contraindications

• Do not use the Xpod in an MRI environment.

Warnings

- Use only NONIN-manufactured PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
- Explosion Hazard: Do not use the Xpod in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- Operation of this device below the amplitude of 0.5% modulation may cause inaccurate results.
- 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.
- This device does not meet defibrillation-proof requirement per IEC 60601-1: 1990, clause 17.h.
- This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.
- The use of accessories, sensors, and cables other than those specified by NONIN (except transducers and cables sold by NONIN as replacement parts for internal components) may result in increased emission and/or decreased immunity of this device.

Cautions

- Use of the pulse quality indicator (provided with all output formats) is recommended to aid in detecting a patient's perfusion level.
- The accuracy of the SpO2 measurement may be affected if the total cable length (including extension cables) is greater than 3 meters.
- This pulse oximetry system 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.
- The Xpod has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the Xpod may still interpret motion as good pulse quality. This covers all available outputs.
- 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.
- This equipment complies with International Standard 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 interference due to close proximity or strength of a source might disrupt the device's performance. 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 document.
- This device has not been tested for immunity to electromagnetic disturbances.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

For more information about required safety and regulatory requirements for medical devices, refer to EN865 and IEC 60601-1. Additional safety information can be found in the labeling provided with each Nonin sensor.

Intended Use

The Xpod 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 (%SpO2) and pulse rate (BPM) for adult, pediatric, and neonatal patients. The module also has the ability to measure SpO2 and higher pulse rates for veterinary use. When mated with a medical device manufacturer's host system, the Xpod may be used in any environment where pulse oximetry measurements are made.

Manufacturer's Declaration

Refer to the following table for specific information regarding this device's compliance to IEC Standard 60601-1-2.

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment— Guidance					
This device is intended for use in the electromagnetic environment specified helow. 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 device 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	his device is suitable for use in all establishments, including domestic and those directly connected to the					
Harmonic Emissions IEC 61000-3-2	N/A	public low-voltage power supply network that supplies buildings used for domestic purposes.					
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A						

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