



# **4100 Bluetooth<sup>®</sup> Enabled Digital Pulse Oximeter, OEM Specification and Technical Information**

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# NONIN<sup>®</sup> Model 4100 containing Bluetooth<sup>®</sup> Technology Specifications

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

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

\*\* ±1 Arms represents approximately 68% of measurements.

**Notes:**

Reusable Sensor Group:

Finger Clip Sensors: 8000AA, 8000AP, 8000AA-WO

Flex Sensors: 8000J, 8008J, 8001J, 8000J-WO

Soft Sensors: 8000SS, 8000SM, 8000SL, 8000SM-WO

Reflectance: 8000R

Ear Clip: 8000Q

Disposable Sensor Group:

7000 Series Sensors: 7000A, 7000P, 7000I, 7000N

6000 Series Sensors: 6000A, 6000P, 6000I, 6000N



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6.	<b>Internal Power</b>	Battery: Two 1.5 volt AA batteries Operating Life: Minimum 120 hours of continuous operation with new batteries Storage Life: 10 months
7.	<b>Weight</b>	4.4 ounces with batteries (125 grams)
8.	<b>Temperature</b>	Operating: -4°F – 122°F (-20°C to +50°C) <ul style="list-style-type: none"><li>Specified operating temperature is for the module.</li><li>Operating temperature of Sensor is not to exceed 104°F (40°C)</li></ul> Storage/Transportation: -22°F - +122°F (-30°C to +50°C)
9.	<b>Operating Altitude</b>	Up to 40,000 feet
10.	<b>Hyperbaric Pressure</b>	Up to 4 atmospheres
11.	<b>Humidity</b>	Operating: 10% to 90% relative humidity, non-condensing Storage/Transportation: 10% to 95% relative humidity, non-condensing Allow to stabilize
12.	<b>Enclosure Degree of Ingress Protection</b>	IPX2
13.	<b>Transmitter</b>	None Bluetooth Compliance: Version 1.1 Operating Frequency: 2.4 to 2.4835 GHz Output Power: <1.1 mW Operating Range: 10-meter radius indoors Network Topology: Point-to-Point Operation: Slave: Model 4100 Patient Module Antenna Type: Internal Modulation Type: Frequency Shift Keying Frequency Hopping Spread Spectrum Band Width: 1 MHz Bluetooth Profiles Supported: Serial Port Profile Antenna Type: Inverted F type antenna Antenna Gain: +2 dB (typ.), +3 dB (max.)
14.	<b>Dimensions</b>	3" x 2.74" x 1.34" (without strap)
15.	<b>Ruggedness</b>	Shock: IEC 60068-2-27 Vibration: Sinusoidal – IEC 60068-2-6 Random – IEC 60068-2-64
16.	<b>Sensors</b>	Designed to use NONIN <sup>®</sup> -branded PureLight <sup>®</sup> sensors only (see Accessories)
17.	<b>Warranty</b>	Three years from the date of delivery.

## Input/Output Formatting Options

### CONFIGURATIONS

The serial-data format and the turn-on mode can be selected via the configuration command. The following table describes the available configurations. The default configuration is #2. The default configuration is used if no configuration command is received during the first 5 seconds after the Bluetooth connection is established. In addition, the turn-on mode is defaulted to sensor turn-on if the batteries are removed. Serial data format #1 is not recommended for new designs; data format #8 should be used instead.

Configuration Command	Serial Data Format	Turn-on Mode
1	1 (3 bytes 1 per/sec)	Sensor
2	2 (5 bytes, 75 per/sec, 8-bit pleth)	Sensor
7	7 (5 bytes, 75 per/sec, 16-bit pleth)	Sensor
8	8 (4 bytes, 1 per/sec)	Sensor
A	1 (3 bytes 1 per/sec)	Spot-check
B	2 (5 bytes, 75 per/sec, 8-bit pleth)	Spot-check
C	7 (5 bytes, 75 per/sec, 16-bit pleth)	Spot-check
D	8 (4 bytes, 1 per/sec)	Spot-check

### TURN ON MODE

In spot-check turn-on mode the model 4100 will turn on when a finger is inserted into the sensor. The 4100 will turn off 10 seconds after the finger is removed, after 3 minutes of out-of-track, or when critical battery is reached in spot-check turn-on mode. This option should only be used with the 8000AA series sensors. Spot-check turn-on mode should not be used with flex-type sensors.

In sensor turn-on mode the 4100 will turn on when the sensor is connected. The 4100 will turn off when the sensor is disconnected, after 10 minutes of out-of-track condition, or when critical battery is reached in sensor turn-on mode.

### SERIAL INPUT SPECIFICATIONS

One of four serial-data formats and one of two turn-on modes can be selected by sending a configuration command to the model 4100 after Bluetooth connection is established. If no configuration command is received within 5 seconds after Bluetooth connection is established, the 4100 will automatically use the default configuration: serial data format #2 and sensor turn-on mode. Therefore, if a configuration different from the default is desired, the configuration command should be sent to the 4100 each time Bluetooth connection is established. The following commands will be recognized:

1. Set Configuration

Protocol:

Command: "Dn" where n is configuration # in ASCII (1-2,7-8,A-D)

Response \*: <ACK>

Denied Response \*: <NAK> if out of range data

Note: 1 character expected following the "D" so length is inherent, no need for termination

2. Unrecognized Command (until 1<sup>st</sup> character of command is recognized)

Response \*: <NAK>

\* The response or the denied response will only occur during the first 5 seconds after Bluetooth connection is established. Only the first valid command will be acknowledged <ACK> during that time.

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 - SpO <sub>2</sub>							
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 <sub>2</sub>	Standard 4-beat average values not including display holds.

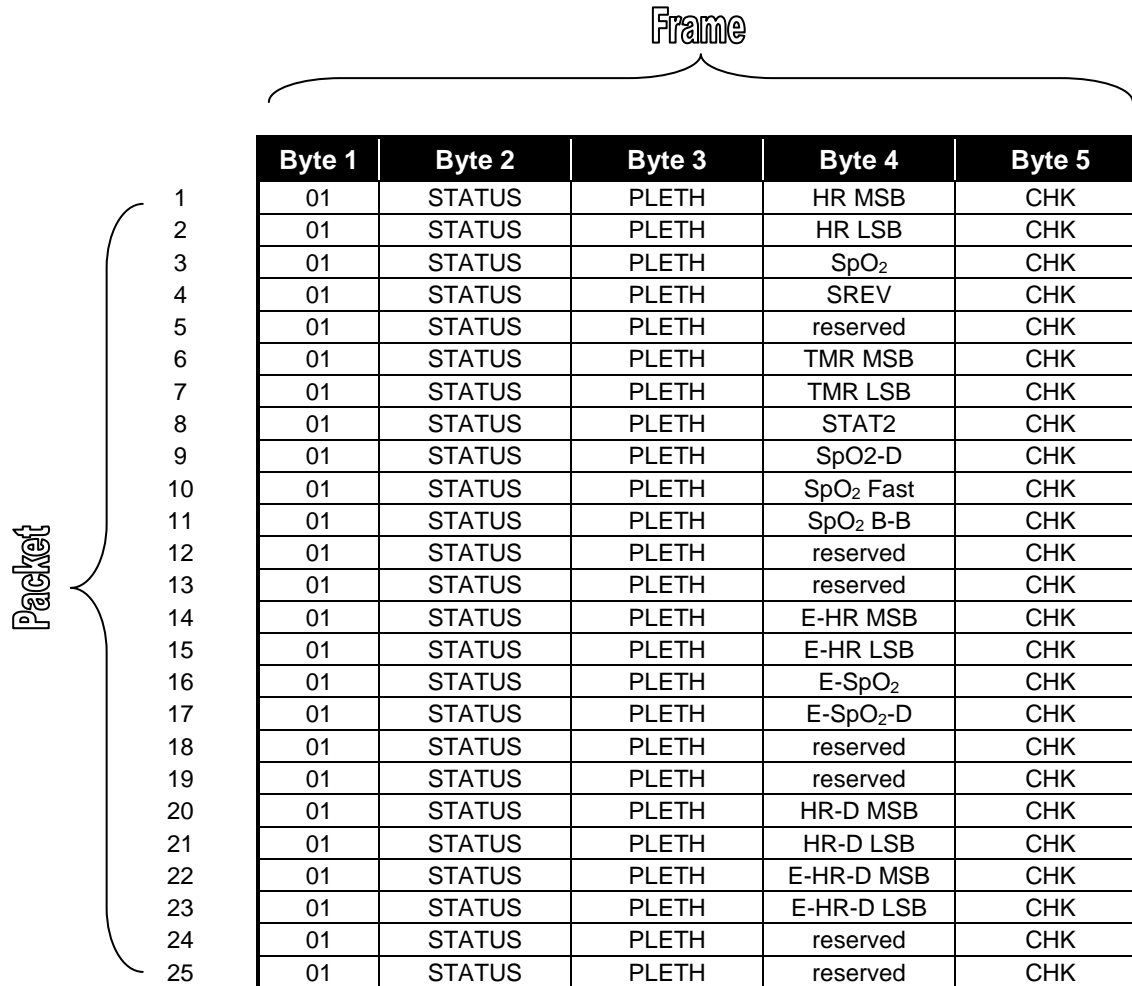
**Note:** When SpO<sub>2</sub> and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO<sub>2</sub> equals 127.

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



	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 <sub>2</sub>	CHK
4	01	STATUS	PLETH	SREV	CHK
5	01	STATUS	PLETH	reserved	CHK
6	01	STATUS	PLETH	TMR MSB	CHK
7	01	STATUS	PLETH	TMR LSB	CHK
8	01	STATUS	PLETH	STAT2	CHK
9	01	STATUS	PLETH	SpO <sub>2</sub> -D	CHK
10	01	STATUS	PLETH	SpO <sub>2</sub> Fast	CHK
11	01	STATUS	PLETH	SpO <sub>2</sub> 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 <sub>2</sub>	CHK
17	01	STATUS	PLETH	E-SpO <sub>2</sub> -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	SNSF	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.
SNSF:	Sensor Fault	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	Bit = 1 to signal frame 1 (occurs 1 of 25).

Generic HR Format:

	7	6	5	4	3	2	1	0
<b>HR MSB</b>	X	X	X	X	X	X	HR8	HR7
	7	6	5	4	3	2	1	0
<b>HR LSB</b>	X	HR6	HR5	HR4	HR3	HR2	HR1	HR0

Generic SpO<sub>2</sub> Format:

	7	6	5	4	3	2	1	0
<b>SPO<sub>2</sub></b>	X	SP6	SP5	SP4	SP3	SP2	SP1	SP0

HR:	4-beat average values in standard mode.
SpO <sub>2</sub> :	4-beat average values in standard mode.
HR-D:	4-beat average displayed values in display mode.
SpO <sub>2</sub> -D:	4-beat average displayed values in display mode.
SpO <sub>2</sub> Fast:	Non-slew limited saturation with 4-beat averaging in standard mode.
SpO <sub>2</sub> : 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 <sub>2</sub> :	8-beat average values in standard mode.
E-HR-D:	8-beat average displayed values in display mode.
E-SpO <sub>2</sub> -D:	8-beat average displayed values in display mode.
PLETH:	8-Bit Plethysmographic Pulse Amplitude.
SREV:	Oximeter Firmware Revision Level.
TMR:	1/3 Second Timer, LSB=least significant 7 bits, MSB + most significant 7 bits
STAT2:	Status Byte 2 (occurs 1 of 25) – description given below.
CHK:	Checksum = (Byte 1) + (Byte 2) + (Byte 3) + (Byte 4) modulo 256

**Note: When SpO<sub>2</sub> and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO<sub>2</sub> equals 127.**

Mode	In Track	Out of Track
Standard	SpO <sub>2</sub> and pulse rate updated on every pulse beat	SpO <sub>2</sub> and Heart Rate values are set to missing data values and out of track indicated.
Display	SpO <sub>2</sub> 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.

Byte 4 – Stat2							
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0
0	R	R	R	R	TURN ON	CRIT BAT	LOW BAT
TURN ON: 1 = Spot Check, 0 = Sensor CRIT BAT: 1 = Critical Battery condition – device will turn off after sending this status. LOW BAT: 1 = Low Battery condition – less than ½ hour run-time remains. R = Reserved							

## 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				
		Byte 1	Byte 2	Byte 3	Byte 4	Byte 5
Packet	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 <sub>2</sub>	CHK
	4	STATUS	PLETH MSB	PLETH LSB	SREV	CHK
	5	STATUS	PLETH MSB	PLETH LSB	reserved	CHK
	6	STATUS	PLETH MSB	PLETH LSB	TMR MSB	CHK
	7	STATUS	PLETH MSB	PLETH LSB	TMR LSB	CHK
	8	STATUS	PLETH MSB	PLETH LSB	STAT2	CHK
	9	STATUS	PLETH MSB	PLETH LSB	SpO <sub>2</sub> -D	CHK
	10	STATUS	PLETH MSB	PLETH LSB	SpO <sub>2</sub> Fast	CHK
	11	STATUS	PLETH MSB	PLETH LSB	SpO <sub>2</sub> 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 <sub>2</sub>	CHK
	17	STATUS	PLETH MSB	PLETH LSB	E-SpO <sub>2</sub> -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:

- Byte number 1 in each frame is greater than 127.
- Reserved bytes are undefined.

Byte 1 - Status							
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0
1	SNSD	ARTF	OOT	SNSF	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.
SNSF:	Sensor Fault	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	Bit = 1 to signal frame 1 (occurs 1 of 25).

Generic HR Format:

	7	6	5	4	3	2	1	0
<b>HR MSB</b>	X	X	X	X	X	X	HR8	HR7
	7	6	5	4	3	2	1	0
<b>HR LSB</b>	X	HR6	HR5	HR4	HR3	HR2	HR1	HR0

Generic SpO<sub>2</sub> Format:

	7	6	5	4	3	2	1	0
<b>SPO<sub>2</sub></b>	X	SP6	SP5	SP4	SP3	SP2	SP1	SP0

HR:	4-beat average values in standard mode.
SpO <sub>2</sub> :	4-beat average values in standard mode.
HR-D:	4-beat average displayed values in display mode.
SpO <sub>2</sub> -D:	4-beat average displayed values in display mode.
SpO <sub>2</sub> Fast:	Non-slew limited saturation with 4-beat averaging in standard mode.
SpO <sub>2</sub> : 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 <sub>2</sub> :	8-beat average values in standard mode.
E-HR-D:	8-beat average displayed values in display mode.
E-SpO <sub>2</sub> -D:	8-beat average displayed values in display mode.
PLETH:	8-Bit Plethysmographic Pulse Amplitude.
SREV:	Oximeter Firmware Revision Level.
TMR:	1/3 Second Timer, LSB=least significant 7 bits, MSB + most significant 7 bits
STAT2:	Status Byte 2 (occurs 1 of 25) – description given below.
CHK:	Checksum = (Byte 1) + (Byte 2) + (Byte 3) + (Byte 4) modulo 256.

**Note: When SpO<sub>2</sub> and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO<sub>2</sub> equals 127.**

Mode	In Track	Out of Track
Standard	SpO <sub>2</sub> and pulse rate updated on every pulse beat	Values are set to “out of range”, sensor fault indicated.
Display	SpO <sub>2</sub> and pulse rate updated every 1.5 seconds	Last in track values transmitted for ten seconds and sensor fault indicated. After ten seconds, values are set to “out of range”.

Byte 4 – Stat2							
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0
R	R	R	R	R	TURN ON	CRIT BAT	LOW BAT
TURN ON: 1 = Spot Check, 0 = Sensor CRIT BAT: 1 = Critical Battery condition – device will turn off after sending this status. LOW BAT: 1 = Low Battery condition – less than ½ hour run-time remains. R = Reserved							

## SERIAL DATA FORMAT #8

### 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
<b>*Note:</b> Bit 7 is always set							

Byte 2 - Heart Rate (HR-D)							
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0
0	HR6	HR5	HR4	HR3	HR2	HR1	HR0
<b>*Note:</b> Bit 7 is always clear							

Byte 3 - SpO2-D							
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0
0	SP6	SP5	SP4	SP3	SP2	SP1	SP0
<b>*Note:</b> Bit 7 is always clear							

Byte 4 – Status2							
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0
0	R	R	R	SNSF	TURN ON	CRIT BAT	LOW BAT
<b>*Note:</b> 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.
SNSF:	Sensor Fault	Sensor is providing unusable data for analysis.
TURN ON:	Turn On Mode	1 = Spot Check, 0 = Sensor.
CRIT BAT:	Critical Battery	Critical Battery condition – device will turn off after sending this status.
LOW BAT:	Low Battery	Low Battery condition – less than ½ hour run-time remains.
R:	Reserved	
HR8 – HR0:	Heart Rate (HR-D)	Standard 4-beat average values including display holds.
SP6 – SP0:	SpO <sub>2</sub>	Standard 4-beat average values including display holds.

**Note:** When SpO<sub>2</sub> and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO<sub>2</sub> equals 127.

## Accessories

The following NONIN® accessories may be used with the 4100 Oximeter. See the respective sensor instructions for detailed information regarding specified sensor use (patient population, body/tissue, and application).

### Nonin PureLight® Reusable Pulse Oximetry Sensors and Accessories for 4100 Bluetooth® Enabled OEM Digital Pulse Oximeter:

Model Number	Description
8000AA-WO	Adult Finger Clip Sensor – WristOx, 12 inch/0.3 meters cable, 8 pin D Style Connector
8000J-WO	Adult Flex Sensor - WristOx, 12 inch/0.3 meters cable, 8 pin D Style Connector, w/25 FlexiWraps
8000SM-WO	Soft Sensor Medium, 12 inch/0.3 meters cable, 8 pin D Style Connector
4100WB	4100 Disposable Wrist Strap
3100I	Sensor Adapter Cable for compatibility with NONIN PureLight® Sensor – WristOx, 7 inch/0.18 meters cable, 8 pin to 9 pin Connector

### Use the 4100 Oximeter with the 3100I Adapter Cable for compatibility with these NONIN PureLight Sensors and Accessories:

#### PureLight® Reusable Pulse Oximetry Sensors

Model Number	Description
8000AA	8000AA Adult Articulated Internal Spring Finger Clip, 3 feet/1 meter cable
8000AP	8000AP Pediatric External Spring Finger Clip, 3 feet/1 meter cable
8000Q	8000Q Ear Clip Sensor, 3 feet/1 meter cable
8000R	8000R Reflectance sensor w/8000H, 3 feet/1 meter cable
8000H	8000H Reflectance Sensor Holder, 10 caps and 20 adhesive stickers
8000J	8000J Adult Flex sensor, w/25 FlexiWrap®-Adult 8000JFW, 3 feet/1 meter cable
8001J	80001J Neonatal Flex sensor, w/25 FlexiWrap®-Neonatal 8001JFW, 3 feet/1 meter cable
8008J	8008J Infant Flex sensor, w/25 FlexiWrap®-Infant 8008JFW, 3 feet / 1 meter cable

#### PureLight® Reusable Pulse Oximetry Sensor Accessories

Model Number	Description
8000JFW	FlexiWrap – Adult 8000JFW, Package of 25
8001JFW	FlexiWrap – Neonatal 8001JFW, Package of 25
8008JFW	FlexiWrap – Infant 8008JFW, Package of 25

### PureLight® Reusable Pulse Oximetry Soft Sensors

<b>Model Number</b>	<b>Description</b>
8000SS	Sensor, Reusable, Soft, Small, 1 meter cable
8000SM	Sensor, Reusable, Soft, Medium, 1 meter cable
8000SL	Sensor, Reusable, Soft, Large, 1 meter cable

### PureLight® Flexi-Form® II Disposable Pulse Oximetry Sensors

<b>Model Number</b>	<b>Description</b>
7000A	Flexi-Form® II Adult 7000A Package of 10, 3 feet/1 meter cable
7000P	Flexi-Form® II Pediatric 7000P Package of 10, 3 feet/1 meter cable
7000I	Flexi-Form® II Infant 7000I Package of 10, 3 feet/1 meter cable
7000N	Flexi-Form® II Adult 7000N Package of 10, 3 feet/1 meter cable
7000D	Flexi-Form® II Assortment (4-A, 2-I, 2-N, 2-P), 3 feet/1 meter cable

### PureLight® Value Line Disposable Pulse Oximetry Sensors

<b>Model Number</b>	<b>Description</b>
6000A	Value Line Sensor, Disposable, Adult, Package of 24, 45cm cable
6000P	Value Line Sensor, Disposable, Pediatric, Package of 24, 45cm cable
6000I	Value Line Sensor, Disposable, Infant, Package of 24, 90cm cable
6000N	Value Line Sensor, Disposable, Neonate, Package of 24, 90cm cable

### Pulse Oximeter Accessories

<b>Model Number</b>	<b>Description</b>
UNI-RA-0	Right Angle Connector – 6 inches/0.15 meter cable
8000S	Pulse Oximeter Patient Simulator

## Indications for Use

Nonin's Bluetooth®-enabled Avant® 4100 Wrist-Worn Patient Module allows SpO<sub>2</sub>, pulse rate, and plethysmographic data to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device, such as Nonin's Avant 4000. The patient module includes a class II Bluetooth radio with a range of approximately 30 feet (spherical radius).

### Contraindications

- Do not use this module in a Magnetic Resonance (MR) environment.
- Do not use this device in an explosive atmosphere or in the presence of flammable anesthetics or gases
- Do not use this module during defibrillation.

### Warnings

- Use the Avant 4100 module within its designated range (approximately 30 feet, spherical radius, from patient module to the display). Moving outside this range may cause missing, lost, and / or inaccurate data.
- This module is only intended as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- This module must be able to measure the pulse properly to obtain an accurate SpO<sub>2</sub> measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO<sub>2</sub> measurement.
- Oximeter readings may be affected by the use of an electrosurgical unit (ESU).
- 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.
- Use only NONIN®-branded PureLight® pulse oximeter sensors. Using other manufacturers' sensors can result in improper pulse oximeter performance.
- Do not use a damaged sensor.
- Carefully route cables and connections to reduce the possibility of entanglement or strangulation.

### Cautions

- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors may vary due to medical status or skin condition.
- To avoid the risk of confusing or misinterpreting patient data, verify that the patient module is paired with the correct display unit.
- The pulse oximeter sensor may not work when circulation is reduced. Warm or rub the finger, or reposition the sensor.
- In some circumstances, the module may interpret motion as good pulse quality. Minimize patient motion as much as possible.
- Do not autoclave or immerse this module in liquid or use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.
- A functional tester cannot be used to assess the accuracy of the module or sensor.
- 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 can affect medical electrical equipment.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Remove batteries if the module is not used for at least 30 days.

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. If you are unsure how to reach your distributor, please call Nonin for your distributor's contract information.

If the module fails to respond as described, discontinue use until the situation is corrected by qualified personnel.

This module is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. 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, infusion lines)
- 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

This module might misinterpret motion as good pulse quality. Minimize finger motion or change the type of sensor being used.

Do not fasten the patient module too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.

## Regulatory Information

### Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declares under its sole responsibility that Models 4000 and 4100, to which this declaration relates, comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.









### Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for assistance.
- RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components and provide a separation distance of 15mm (0.6 inches) to the body. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
- The module 4100 is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the United States FCC. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and has been tested in accordance with the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. 1528-200X (Draft 6.5, January 2002).
- The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

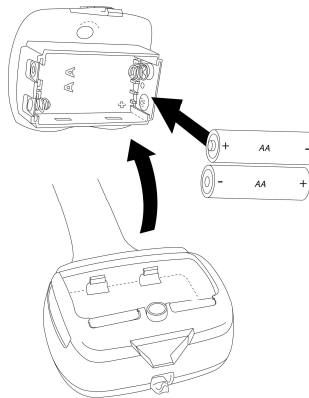
# Using the 4100

## Guide to Symbols on the Module

	<b>Consult Instructions for Use.</b>
	<b>Type BF Applied Part</b> (Patient isolation from electrical shock).
	<b>UL Mark for Canada and the United States</b> with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 30EM and CAN/CSA C22.2 No. 601.1.
	<b>CE Marking</b> indicating conformance to EC directive No. 93/42/EEC concerning medical products.
<b>SN</b>	<b>Serial Number</b>
	<b>Non-ionizing electromagnetic radiation.</b> Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.
	<b>Remote Alarms; Not for Continuous Monitoring.</b>
	Indicates separate collection for electrical and electronic equipment (WEEE).
	<b>Bluetooth®</b>

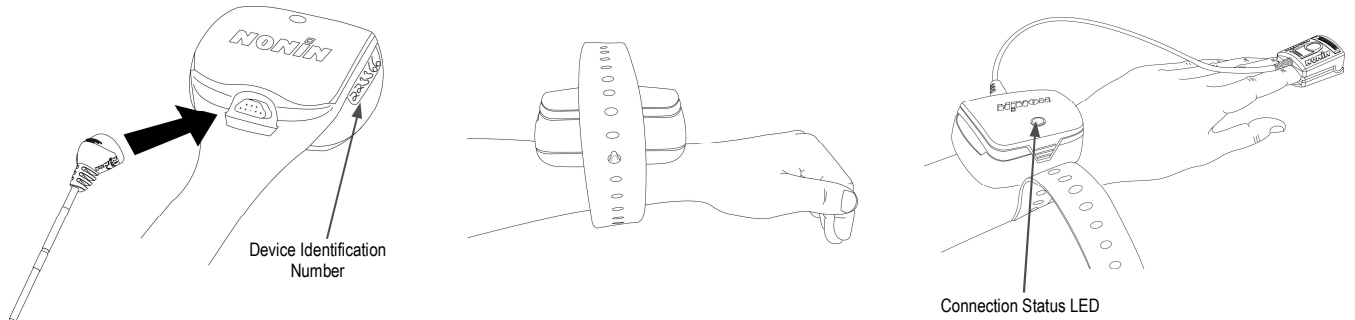
## Installing Batteries

The patient module requires two AA-size alkaline batteries, providing 120 hours (minimum) continuous use.



## Securing the Wristband and Attaching the Sensor

Attach the sensor to the patient module before securing the wristband to the patient's wrist. Before attaching the wristband on the patient, plug the sensor into the connector at the top of the module. When properly connected, the red triangle on the sensor connector is not visible (see illustration below). The wristband may be cut to length for patient comfort. The patient module activates when the sensor is connected. The Connection Status LED flashes green to indicate connection. When it flashes amber, no connection is established.



### NOTES:

- Each patient module contains a unique 6-digit device identification number. This number is used when pairing the patient module to the host unit. Refer to the host system operator's manual for additional information.
- The patient module must communicate from the display unit (host) device. The 4100 *does not* initiate communication.



**Caution:** Before using any sensor, inspect the connector pins; if damaged or bent, do not use sensor. Carefully read the Sensor Instructions for Use.

## Cleaning Instructions

Clean the patient module and wristband, if reused, with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the module, and do not allow any liquids to enter any openings in the module. Allow the unit to dry thoroughly before use.



**Caution:** Do not immerse the module in liquid, and do not use caustic or abrasive cleaning agents on the module.

Clean the module separately from its associated sensors. For instructions regarding cleaning pulse oximeter sensors, refer to the appropriate pulse oximeter sensor package Instructions for Use (IFU).

# 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
<i>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.</i>		
RF Emissions CISPR 11	Group 1	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.
RF Emissions CISPR 11	Class B	
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
<i>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.</i>			
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.
<b>Note:</b> $U_T$ 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
<p><i>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.</i></p>			
<p>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.</p>			
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p><b>Recommended Separation Distance</b></p> <p><math>d = 1.17 \sqrt{P}</math></p> <p><math>d = 1.17 \sqrt{P}</math> 80 MHz to 800MHz</p> <p><math>d = 2.33 \sqrt{P}</math> 800MHz to 2.5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.</li> <li>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</li> </ul> <p>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.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.</p>			

**Table 4: Recommended Separation Distances**

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

<p><i>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.</i></p>			
	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
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p>			
<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.</li> <li>• These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</li> </ul>			

## Equipment Response Time

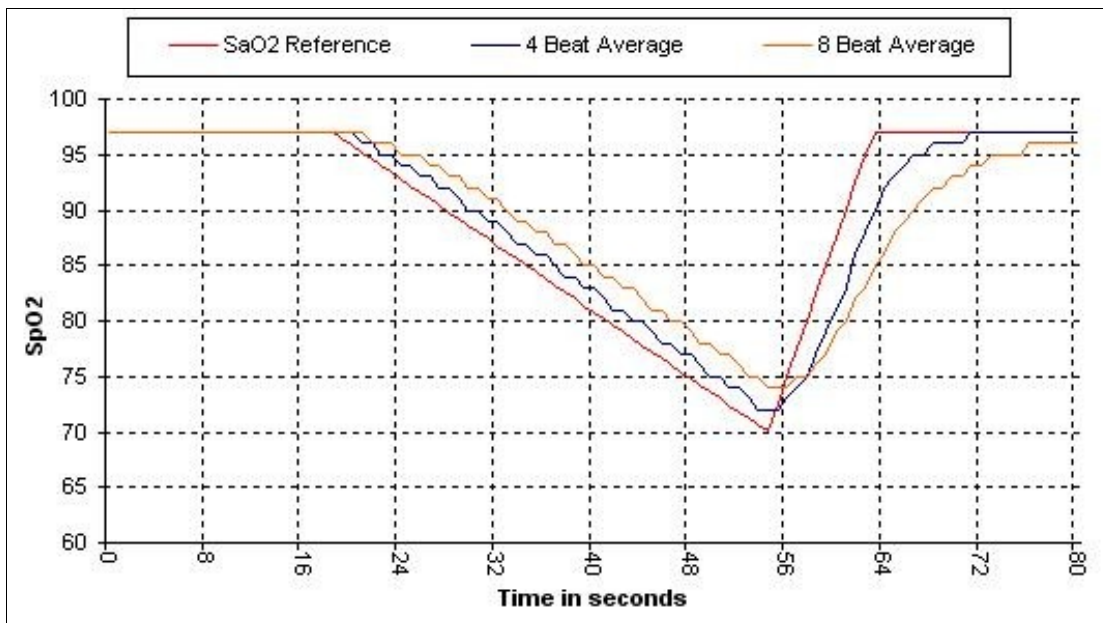
SpO <sub>2</sub> Values	Average	Latency
Standard/Fast Averaged SpO <sub>2</sub>	4 beat exponential	2 beats
Extended Averaged SpO <sub>2</sub>	8 beat exponential	2 beats

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<sub>2</sub> Exponential Averaging*

SpO<sub>2</sub> 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.

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## Testing Summary

SpO<sub>2</sub> accuracy, motion and low perfusion testing was conducted by NONIN<sup>®</sup> Medical, Incorporated as described below.

### SpO<sub>2</sub> Accuracy Testing

SpO<sub>2</sub> 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<sub>2</sub>) of the sensors is compared to arterial hemoglobin oxygen (SaO<sub>2</sub>) 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<sub>2</sub> 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<sub>2</sub> Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO<sub>2</sub> levels. The module must maintain accuracy in accordance with ISO 9919:2005 for pulse rate and SpO<sub>2</sub> at the lowest obtainable pulse amplitude (0.3% modulation).