Onyx II®
Model 9560 Bluetooth® Fingertip Oximeter
OEM Specification and Technical Information

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NONIN® Onyx II Model 9560 Bluetooth® Fingertip Oximeter Technology Specifications

1.	**Oxygen Saturation Range (SpO_2)**		0 to 100%
2.	**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%
	Oxygen Saturation Accuracy		± 2 digits
	Low Perfusion Oxygen Saturation Accuracy:		± 2 digits
5.	**Pulse Rate Accuracy (A_{rms}**)**		
	Pulse Rate Accuracy (20-250 BPM):		± 3 digits
	Low Perfusion Pulse Rate Accuracy (40-240 BPM):		± 3 digits
6.	**Internal Power**		
		Battery:	Two 1.5 volt AAA batteries
		Operating Life:	600 spot-checks (30 secs/spot-check) in a 6 month period.
		Storage Life:	12 months
7.	**Weight**		63 grams with batteries installed
8.	**Temperature**	Operating:	+5°C to +40°C
		Storage/Transportation:	-40°C to +70°***C
9.	**Operating Altitude**		Up to 40,000 feet / 12,192 meters
10.	**Hyperbaric Pressure**		Up to 4 atmospheres
11.	**Humidity**		
		Operating:	10% to 95% relative humidity, non-condensing
		Storage/Transportation:	10% to 95% relative humidity, non-condensing Allow to stabilize
12.	**Enclosure Degree of Ingress Protection**		IP32

* This information is especially useful for clinicians performing photodynamic therapy.
** ±1 A_{rms} represents approximately 68% of measurements.
*** When the Model 9560 is transferred from a non-operating temperature/humidity condition, allow one hour of stabilization to operating temperature/humidity specifications prior to use.

13.	**Bluetooth Information**		
		Bluetooth Compliance:	Version 2.0
		Operating Frequency:	2.4 to 2.4835 GHz
		Output Power:	<20dBm
		Operating Range:	100-meter radius indoors[1]
		Network Topology:	Point-to-Point
		Operation:	Slave: Model 9560
		Antenna Type:	L-shaped PWB whip-type antenna
		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.	**Dimensions**		3.23cm x 6.40cm x 3.78cm (W x H x D)
15.	**Ruggedness**		
		Shock:	IEC 60068-2-27
		Vibration:	Sinusoidal – IEC 60068-2-6 Random – IEC 60068-2-64, IEC 60068-2-36 Bump – IEC 60068-2-29
17.	**Warranty**		Two years from the date of purchase.

[1] Line of sight when connected to a class 1 device.

Input/Output Formatting Options

Data Format Solutions

The 9560 features four data format solutions. They are:

- Data format 13 – provides easy spot-check measurements with the storage and forwarding of measurements.
- Data format 8 – provides real-time oximetry measurements every second.
- Data format 2 – provides real-time oximetry measurements with compressed waveform (8 bit waveform) every 1/75th of a second.
- Data format 7 – provides real-time oximetry measurements with full resolution waveform (16 bit waveform) every 1/75th of a second.

For greater detail see the appropriate data format section in this document.

Communications Interface

Using **Bluetooth** communications terms, the 9560 oximeter is a slave device. To connect the 9560 oximeter to a master device, the master device must initiate the connection by first pairing with the 9560. The 9560 has a six digit identification number printed on the battery door. To complete the pairing process the six digit number must be provided to the master as the **Bluetooth** PassKey (Bluetooth PIN). Once the pairing is complete the 9560 will automatically reconnect to the master device when possible. The six digit **Bluetooth** PassKey on the 9560 must be entered only during the pairing to a new master.

Note: To connect to a new device (new master) the 9560 must be out of range from the previous master or unpaired from that master.

Specific to Data format 13, after the 9560 turns on and a measurement is available to wirelessly send, the 9560 will send a **Bluetooth** "Page" message to reestablish the connection with the master with which it is paired. If the master is not available the 9560 will become discoverable for pairing to a new master.

For backwards compatibility, when using data formats 2, 7, or 8, the 9560 will not initiate the **Bluetooth** "Page". The master must initiate the **Bluetooth** "Page Scan" to automatically reestablish the connection to the 9560. Once the **Bluetooth** connection is made the 9560 will automatically send continuous data to the master as defined in the data format sections.

For greater detail on establishing a **Bluetooth** wireless connection refer to Nonin's Bluetooth Connection Brief.

Note: A Bluetooth connection indicator is not available on the 9560 product.

Once the **Bluetooth** connection is established, the 9560 receives and transmits data using the SPP protocol using the following settings:

Bits per second	Data bits	Parity	Stop bits	Flow Control
9600	8	None	1	None

Note: Throughout this document all values are in decimal unless otherwise noted. The decimal number must be converted to 8 bit hex for data transmission. A hex value will be described with this format: 0xZZ, where ZZ is the hex value with a range of 0 to FF.

Selecting the Data Format

To select the data format the host must send the 9560 the following 6 byte command string:

Byte 1	Byte2	Byte3	Byte4	Byte5	Byte6
Start(STX)	Op Code	Data Size	Data Type	Data Format	ETX
0x02	0x70	0x02	0x02	0xZZ where ZZ is (0D, 08, 07, or 02)	0x03

Response: During the first five seconds from connection after the 9560 receives a command it will respond with an ACK (0x06) for a supported command or NAK (0x15) for an unsupported command.

Once the data format is changed, the 9560 will retain the new data format until changed to a different data format. Because the data format is retained in non-volatile memory, the data format will be retained after a battery change. If the data format is not changed the 9560 will default to data format 13.

Setting / Retrieving Time in the 9560

The host can set and retrieve the time from the 9560. The date and time must conform to the ranges defined below. The date and time will be lost when replacing the batteries.

Name	Dec Range	Comments
YY (year)	00-99	
MM (month)	1-12	
DD (day)	1-31*	Depends on leap-year, and month for accurate range
hh (hour)	0-23	
mm (minute)	0-59	
ss (second)	0-59	

Setting the Time:

To set the time in the 9560 the host must send the 9560 a 10 byte command.

Byte 1	Byte2	Byte3	Byte4	Byte5	Byte6	Byte7	Byte8	Byte9	Byte10
Start(STX)	Op Code	Data Size	Year	Month	Day	Hour	Minute	Second	ETX
0x02	0x72	0x06	YY	MM	DD	hh	mm	ss	0x03

Example:

Date: 12-31-2050 & Time: 14:30:15 (Hours:Minutes:Seconds)

Byte 1	Byte2	Byte3	Byte4	Byte5	Byte6	Byte7	Byte8	Byte9	Byte10
Start(STX)	Op Code	Data Size	Year	Month	Day	Hour	Minute	Second	ETX
0x02	0x72	0x06	0x32	0x0C	0x1F	0x0E	0x1E	0x0F	0x03

Response: None.

Retrieving Time from the 9560

To retrieve the time from the 9560, the host must send a 4 byte command string.

Byte 1 Start (STX)	Byte 2 Op Code	Byte 3 Data size	Byte 4 End(ETX)
02 hex	72 hex	00	03 hex

Response: The 9560 sends the date and time as part of the following 10 byte string.

Byte 1	Byte2	Byte3	Byte4	Byte5	Byte6	Byte7	Byte8	Byte9	Byte10
Start(STX)	Op Code	Data Size	Year	Month	Day	Hour	Minute	Second	ETX
02 hex	F2 hex	06 hex	YY	MM	DD	hh	mm	ss	03 hex

Data Format 13 - SmartPoint™ Algorithm

Data format 13 uses a SmartPoint Algorithm to determine a reliable single point measurement. The 9560 will acquire a SmartPoint measurement within 40 seconds from power-on. An indicator on the 9560 display flashes while acquiring the measurement and stops flashing after the SmartPoint value is transmitted or stored into memory when a wireless transmission is not possible. If after 40 seconds a high quality measurement is not possible the SmartPoint Algorithm will send the current measurement and mark the measurement as not completing the algorithm. Low perfusion (weak pulse signal conditions) or artifact pulse conditions may affect the ability to obtain the high quality measurement indication.

If the 9560 is unable to establish a wireless connection the SmartPoint measurement will be stored into memory. The 9560 has memory capacity to store a minimum of 20 SmartPoint measurements. When a wireless connection is made the 9560 oximeter will forward the oldest stored measurements prior to sending the new measurement. After stored measurements are sent they are removed from memory.

Notes:

If the finger is removed before 40 seconds and a high quality measurement is not available no data will be sent or stored in memory.

Stored measurements will be lost after battery replacement.

Data Packet Description

The 9560 includes 6 bytes of header information, a minimum of 14 bytes of spot-check data, and 2 bytes of footer information. To determine the total length for the expandable Spot-check data, the host must capture the data length from bytes 5 and 6 of the header. With the minimum data length of 14, the data length defined in bytes 5 and 6 will be (0x00) (0x0E) (14 bytes decimal).

The Spot-check data consists of – time of spot-check, SpO_2, Pulse Rate, and status.

Header	Byte #	Data	Information	Format
	1	00	NULL start sync	Hex
	2	02	STX – start of packet	Hex
	3	00	Packet type MSB	Hex
	4	0D	Packet type LSB	Hex
	5	00	* Data Length MSB (variable)	Hex
	6	0E	* Data Length LSB (variable)	Hex
*expandable Spot-check data	7	20	Hundredths place of Year (default to 20)	BCD
	8	Year of Measurement	Year of Measurement (00-99)	BCD
	9	Month of Measurement	Month of Measurement (01-12)	BCD
	10	Day of Measurement	Day of Measurement (01-31 depending on the month)	BCD
	11	Hour of Measurement	Hour of Measurement (00-23)	BCD
	12	Minute of Measurement	Minute of Measurement (00-59)	BCD
	13	Second of Measurement	Second of Measurement (00-59)	BCD
	14	00	Fraction of second	BCD
	15	STATUS MSB	See STATUS specification below	Hex
	16	STATUS LSB	See STATUS specification below	Hex
	17	Pulse Rate MSB	See HR format below	Hex
	18	Pulse Rate LSB	See HR format below	Hex
	19	00 to FF	Reserved for future use	Hex
	20	SpO_2	See SpO_2 format below	Hex
Footer	21	Checksum LSB	LSB of sum of Spot-check Data	Hex
	22	03	ETX – end of transmission	Hex

* This data section is expandable. As new parameters are available the data length will increase. The minimum length of the Spot-check Data is 14 bytes (0x0E).

Data Format #13

Data Packet Description (continued)

Status (MSB)							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
R	R	R	R	R	R	SPA	NOMS

Status (LSB)							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
R	R	R	MEM	R	R	R	LOW BAT

The following are all active high:

SPA:	SmartPoint Algorithm	High Quality SmartPoint Measurement.
NOMS:	No Measurement	No measurement for SpO_2 or Pulse Rate.
MEM:	From Memory	Stored measurement from memory
LOW BAT:	Low Battery condition	Low Batteries. Replace batteries as soon as possible.
R:	Reserved	Reserved for future use

16-Bit HR Format:

	7	6	5	4	3	2	1	0
HR MSB	R	R	R	R	R	R	R	HR8

	7	6	5	4	3	2	1	0
HR LSB	HR7	HR6	HR5	HR4	HR3	HR2	HR1	HR0

8-Bit SpO_2 Format:

	7	6	5	4	3	2	1	0
SpO_2	R	SP6	SP5	SP4	SP3	SP2	SP1	SP0

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. The missing data could be result of these conditions:

1. Device is positioned improperly on finger.
2. Device was removed from the finger prior to a reading.
3. Signal at the finger is not discernable - warm the hand.

Serial Date Format #2:

This data format provides continuous data transmission of a 5 byte data packet sent 75 times per second. The data packet includes real-time data of: 8-bit waveform value, beat-to-beat SpO_2 value, SpO_2 and Pulse Rates values formatted for both recording and display purposes, status of the measurement and battery.

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	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_2-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 (range of 0 to 255).

Byte 1 – START BYTE:

Always set to a 01 value.

Byte 2 – STATUS BYTE

This byte provides status information at a rate of 1/75th of second.

Range: 128 to 255

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

The following are all active high:

R:	Reserved	Reserved for future use
ARTF:	Artifact – short term	Indicates artifact condition of each pulse (occurs only during pulse)
OOT:	Out Of Track	An absence of consecutive good pulse signals. Indicates sustained periods of Artifact.
SNSA:	Sensor Alarm	Device is providing unusable data for analysis (set when the finger is removed)
RPRF:	*Red Perfusion	Amplitude representation of low/poor signal quality (occurs only during pulse).
YPRF:	*Yellow Perfusion	Amplitude representation of low/marginal signal quality (occurs only during pulse).
GPRF:	*Green Perfusion	Amplitude representation of high signal quality (occurs only during pulse).
SYNC:	Frame Sync	1 on Frame 1 (0 on frames 2 through 25).

* The oximeter reports each pulse by setting/clearing the RPRF and GPRF bits for a period of 12 frames (160mS). The table below describes the condition and state of the pulse perfusion bits.

Condition	RPRF Bit 2 of Status Byte	GPRF Bit 1 of Status Byte
Green – high pulse signal	0	1
Yellow – low/marginal pulse signal	1	1
Red – low/no pulse signal	1	0

Byte 3 – PLETH BYTE

This byte consists of an 8 bit plethsmographic waveform (pulse waveform). The pulse oximeter infra-red signal is filtered and then compressed into an 8 bit value. The compression provides good detail for low to large pulse signals. For uncompressed waveform refer to Data Format 7.

Range: 00 to 255

Byte 4 – FLOAT BYTE

This byte is used for SpO_2, Pulse Rate, and information that can be processed at a rate of 1/3 of second.

Range: 00 to 127

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

Byte 4: STAT2

BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0
0	R	SPA	R	R	R	R	LOW BAT

LOW BAT:	1= Low Batteries. Replace batteries as soon as possible.
SPA:	1 = High Quality SmartPoint Measurement
R:	Reserved (range- 0 or 1)

Formatted for Recording Purposes:

These values are formatted for recording purposes every 1/3 of second. When the finger is removed from the device these values will be formatted with the missing data value. These values are retained for legacy purposes and are formatted with the missing data values during periods of sustained artifact.

HR:	4-beat Pulse Rate Average
E-HR:	8-beat Pulse Rate Extended Average
SpO_2:	4-beat SpO_2 Average
E-SpO_2:	8-beat SpO_2 Extended Average
SpO_2 Fast:	4-beat Average optimized for fast responding
SpO_2 B-B:	Beat to Beat value – No Average

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.

Formatted for Display Purposes:

These values are formatted for display purposes every 1.5 seconds. They provide the most reliable readings possible during periods of artifact. When the device is removed from the finger the last SpO_2 and Pulse Rate reading will be reported for 10 seconds before changing to the missing data value. During this 10 second period the sensor alarm bit (SNSA) is set, indicating that the finger has been removed. This feature is useful for spot-check measurements.

HR-D:	4-beat Pulse Rate Average
E-HR-D:	8-beat Pulse Rate Extended Average
SpO_2-D:	4-beat SpO_2 Average
E-SpO_2-D:	8-beat SpO_2 Extended Average

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.

HR Format:

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

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

SpO_2 Format:

	7	6	5	4	3	2	1	0
SpO_2	0	SP6	SP5	SP4	SP3	SP2	SP1	SP0

R = Reserved (range 0 or 1)

Byte 5 – CHK

This byte is used for the checksum of bytes 1 through 4.

Range: 00 to 255

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

Serial Data Format #7:

This data format provides the same information as Data Format 2, except that the waveform value provides the full resolution of 16-bits instead of 8-bits.

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	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_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:

Byte number 1 in each frame is greater than 127.

Reserved bytes are undefined (range of 0 to 255).

Byte 1 – STATUS BYTE

This byte provides status information at a rate of 1/75th of a second.

Range: 128 to 255

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

The following are all active high:

R:	Reserved	Reserved for future use.
ARTF:	Artifact	Indicates artifact condition of each pulse (occurs only during pulse).
OOT:	Out Of Track	An absence of consecutive good pulse signals. Indicates sustained period of Artifact.
SNSA:	Sensor Alarm	Device is providing unusable data for analysis (set when the finger is removed).
RPRF:	*Red Perfusion	Amplitude representation of low/no pulse signal (occurs only during pulse).
YPRF:	*Yellow Perfusion	Amplitude representation of low/marginal signal quality (occurs only during pulse).
GPRF:	*Green Perfusion	Amplitude representation of high signal quality (occurs only during pulse).
SYNC:	Frame Sync	= 1 to Frame 1 (=0 on frames 2 through 25).

* The oximeter reports each pulse by setting/clearing the RPRF and GPRF bits for a period of 12 frames (160mS). The table below describes the condition and state of the pulse perfusion bits.

Condition	RPRF Bit 2 of Status Byte	GPRF Bit 1 of Status Byte
Green – high pulse signal	0	1
Yellow – low/marginal pulse signal	1	1
Red – low/no pulse signal	1	0

Byte 2 & 3 – PLETH BYTE

These two bytes consist of a 16 bit plethsmographic waveform (pulse waveform).

Range: 0 to 65535 (MSB:LSB)

Byte 2 = MSB Pulse Waveform

Byte 3 = LSB Pulse Waveform

Pulse waveform value = (Byte 2 decimal value * 256) + Byte 3 decimal value

Byte 4 – FLOAT BYTE

This byte is used for SpO_2, Pulse Rate, and information that can be processed at a rate of 1/3 of second.

Range: 00 to 127

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

Byte 4: STAT2							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
0	R	SPA	R	R	R	R	LOW BAT

LOW BAT:	1 = Low Batteries. Replace batteries as soon as possible.
SPA:	1 = High quality SmartPoint Measurement
R:	= Reserved (range - 0 or 1)

Formatted for Recording Purposes:

These values are formatted for recording purposes every 1/3 of second. When the finger is removed from the device these values will immediately be formatted with the missing data value. These values are retained for legacy purposes and are formatted with the missing data values during periods of sustained artifact.

HR:	4-beat Pulse Rate Average
E-HR:	8-beat Pulse Rate Extended Average
SpO_2:	4-beat SpO_2 Average
E- SpO_2:	8-beat SpO_2 Extended Average
SpO_2 Fast:	4-beat Average optimized for fast responding
SpO_2 B-B:	Beat to Beat value – No Average

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.

Formatted for Display Purposes:

These values are formatted for display purposes every 1.5 seconds. They provide the most reliable reading possible during periods of artifact. When the device is removed from the finger the last SpO_2 and Pulse Rate reading will be reported for 10 seconds before changing to the missing data value. During this 10 second period the sensor alarm bit (SNSA) is set, indicating that the finger has been removed. This feature is useful for spot-check measurements.

HR-D:	4-beat Pulse Rate Average
E-HR-D:	8-beat Pulse Rate Extended Average
SpO_2-D:	4-beat SpO_2 Average
E- SpO_2-D:	8-beat SpO_2 Extended Average

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.

HR Format:

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

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

SpO_2 Format:

	7	6	5	4	3	2	1	0
SpO_2	0	SP6	SP5	SP4	SP3	SP2	SP1	SP0

R = Reserved (range- 0 or 1)

Byte 5 – CHK

This byte is used for the checksum of bytes 1 through 4.

Range: 00 to 255

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

Serial Data Format #8

This data format provides continuous data transmission of a 4 byte data packet sent once per second. The data packet includes real-time data of: SpO_2 and Pulse Rate formatted for display, status information of the measurement, and status of the battery.

Packet Description

Three bytes of data are transmitted 1 once per second.

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

Byte 4 – Status2							
BIT7	**BIT6**	**BIT5**	**BIT4**	**BIT3**	**BIT2**	**BIT1**	**BIT0**
0	R	SPA	R	SNSF	R	R	LOW BAT
*__Note__: Bit 7 is always clear							

The following are all active high:

ARTF:	Artifact	Indicated artifact condition on each pulse
OOT:	Out Of Track	An absence of consecutive good pulse signals. Indicates sustained period of Artifact
LPRF:	Low Perfusion	Amplitude representation of low/no signal quality (holds for entire duration).
MPRF:	Marginal Perfusion	Amplitude representation of low/marginal signal quality (holds for entire duration).
SNSA:	Sensor Alarm	Device is providing unusable data for analysis (set when the finger is removed)
SPA:	SmartPoint Algorithm	High quality SmartPoint measurement
LOW BAT:	Low Battery condition	Low Batteries. Replace batteries as soon as possible.
HR8 – HR0:	Heart Rate (HR-D)	4-beat Pulse Rate average formatted for display
SP6 – SP0:	SpO_2 (SpO_2-D)	4-beat SpO_2 average formatted for display
R	Reserved (range – 0 or 1)	Reserved for future use.

The SpO_2 and Pulse Rate values are formatted for display purposes every 1.5 seconds. They provide the most reliable reading possible during periods of artifact. When the device is removed from the finger the last SpO_2 and Pulse Rate reading will be reported for 10 seconds before changing to the missing data value. During this 10 second period the sensor alarm bit (SNSA) is set, indicating that the finger has been removed. This feature is useful for spot-check measurements.

HR-D:	4-beat Pulse Rate Average
SpO_2-D:	4-beat SpO_2 Average

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.

Indications for Use

The NONIN® Model 9560 Finger Pulse Oximeter is a small, lightweight, portable, wireless device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

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
This device is not defibrillation proof per IEC 60601-1:1990 clause 17h.

Warnings

Use the Model 9560 within its designated range (approximately 328 feet/100 meters, spherical radius, line of sight when connected to a class I device, from patient module to the display). Moving outside this range may cause missing, lost, and / or inaccurate data.
This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
The device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
General operation of the device may be affected by the use of an electrosurgical unit (ESU).
The use of batteries other than those specified in these instructions may result in increased electromagnetic emission and/or decreased immunity of this device.
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.

⚠ Cautions

This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin may affect measurement accuracy.
This device has no audible alarms and is intended only for spot-checking.
This device 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: • Do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s) (IVs) • excessive light, such as sunlight or direct home lighting • excessive motion • moisture in the device • improperly applied device • finger is outside recommended size range • poor pulse quality • venous pulsations • anemia or low hemoglobin concentrations • cardiogreen or other intravascular dyes • carboxyhemoglobin • methemoglobin • dysfunctional hemoglobin

⚠ Cautions
• artificial nails or fingernail polish
The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
This device's display will go blank after 30 seconds of no readings or poor readings.
Do not sterilize, autoclave or immerse this device in liquid.
Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.
A flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring.
Do not hang the lanyard from the device's flexible circuit/strain relief.
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor 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.
Batteries may leak or explode is used or disposed of improperly. Remove batteries if the device will be stored for more than 30 days. Do not use different types of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.
Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
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 contact information.

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 Model 9560, 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 Model 9560 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 Model 9560

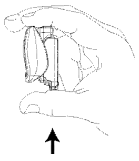
Guide to Symbols on the Module

	Consult Instructions for Use.
	Caution!
	Type BF Applied Part (Patient isolation from electrical shock).
	UL Mark for Canada and the United States 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.
	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
SN	**Serial Number**
	Battery Orientation
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.
SpO_2	**Remote Alarms; Not for Continuous Monitoring.**
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Bluetooth®

Installing Batteries

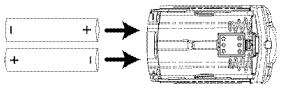
Two 1.5 volt AAA-size batteries power the Model 9560 for approximately 600 spot checks. NONIN® recommends using alkaline batteries (included with each new Model 9560). When batteries are low, the numeric displays flash once per second. Remove batteries if the device will be stored for more than 30 days. Replace low batteries as soon as possible, using the instructions below.

Note: Rechargeable batteries may be used; however, they require more frequent replacement.



#1

1. Hold the Model 9560 as shown above, pressing upward and then pulling outward slightly with the thumb to release the device's battery tray.
2. Remove the battery cover and the depleted batteries, disposing of the batteries properly.
3. Insert two new 1.5 volt AAA-size batteries. Follow the polarity markings (+ and -) as illustrated. *Proper positioning of the batteries is essential for operation.*



#3

4. Carefully guide the battery cover back onto the Model 9560, pressing downward and pushing inward slightly to re-secure the battery cover. *Do not force it into place; it fits only when properly positioned*.

#4

5. Visually inspect to ensure that the battery cover is properly placed.
6. Insert your finger into the device to verify operation.

Using Model 9560 and Verifying Operation

The Model 9560 contains numeric LEDs that display oxygen saturation and pulse rate. A tricolor LED display provides a visual indication of the pulse signal quality, while blinking at the corresponding pulse rate. This display changes colors to alert you to changes in pulse quality that may affect the readings: *green* indicates a good pulse signal, *yellow* indicates a marginal pulse signal and *red* indicates an inadequate pulse signal.

Activate the Model 9560 by inserting the patient's finger into the unit. The Model 9560 detects the inserted finger and automatically illuminates the displays. Correct positioning of the light emitter and photodetector on the finger is critical for accurate measurements. All emitted light must pass through the fingertip.

⚠	**Caution:** Do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s) (IVs).

While on the finger, do not press the Model 9560 against any surface and do not squeeze or hold it together. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.

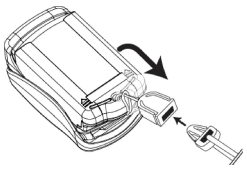
1. Insert the patient's finger, nail side up, into the Model 9560 until the fingertip touches the built-in stop guide.
2. Make sure the finger is lying flat (not on its side) and is centered within the device. For best results, keep the Model 9560 at the patient's heart or chest level.
3. If the device does not turn on, remove the finger and wait a few seconds before reinserting it.

When a finger is inserted, the Model 9560 performs a brief startup sequence. Verify that all LEDs illuminate during the startup sequence. If any LED is not lit, do not use the Model 9560; contact NONIN® Technical Service for repair or replacement. In the factory default mode after the startup sequence, the two flashing red bars will appear on the left hand side of the Model 9560 display. Wait until these bars disappear before removing the finger.

A minus sign (-) appears in the left-most digit of the %SpO_2 display when the Model 9560 senses that the finger has been removed. The last measured SpO_2 and pulse rate values freeze for 10 seconds, and then the displays go blank. The device will automatically shut off (to conserve battery life) approximately 20 seconds after the finger is removed, or after a 2-minute period of inadequate pulse signal

Using the Lanyard and Carrying Case

A lanyard and carrying case are provided for convenience. The Model 9560 will function with or without the lanyard. If lanyard use is desired, thread the lanyard as shown below.



Model 9560 Care, Maintenance, and Cleaning

The advanced digital circuitry within the Model 9560 requires no calibration or periodic maintenance other than battery replacement. Field repair of the Model 9560 circuitry is not possible. Do not attempt to open the Model 9560 case or repair the electronics. Opening the case will damage the Model 9560 and void the warranty. Do not open the Model 9560 more the 90°, and do not twist or pull on the device when cleaning.

Cleaning the Inner Surfaces of the Model 9560

1. Wipe the surfaces with a soft cloth dampened with isopropyl alcohol or a mild detergent; see **CAUTION** below. If low-level disinfection is required, a cloth dampened with 10% bleach / 90% water solution may also be used. Do not use undiluted bleach or andy cleaning solution other than those recommended here, as permanent damage could result.
2. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry.

Caution: Do not sterilize, autoclave or immerse this device in liquid. Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.

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.

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.

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).