



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

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Table of Contents

Model 9560 Bluetooth® Profiles	3
<i>Health Device Profile (HDP).....</i>	<i>3</i>
<i>Communications Interface (HDP).....</i>	<i>3</i>
<i>Serial Port Profile (SPP)</i>	<i>3</i>
<i>Communications Interface (SPP)</i>	<i>3</i>
<i>Connection Details.....</i>	<i>4</i>
<i>SmartPoint™ Technology.....</i>	<i>5</i>
<i>Command Protocols.....</i>	<i>5</i>
<i>Data Formats</i>	
<i>Serial Data Format #13.....</i>	<i>8</i>
<i>Serial Data Format #2:.....</i>	<i>11</i>
<i>Serial Data Format #7:.....</i>	<i>15</i>
<i>Serial Data Format #8.....</i>	<i>19</i>
Indications for Use.....	21
Regulatory Information.....	23
<i>Declaration of Conformity with FCC and Canadian Ministry of Health Rules for</i>	
<i>Electromagnetic Compatibility.....</i>	<i>23</i>
<i>Federal Communications Commission (FCC) Notice</i>	<i>23</i>
Using the Model 9560	24
<i>Guide to Symbols on the Module</i>	<i>24</i>
<i>Installing Batteries</i>	<i>24</i>
<i>Using Model 9560 and Verifying Operation.....</i>	<i>25</i>
<i>Using the Lanyard and Carrying Case</i>	<i>26</i>
<i>Model 9560 Care, Maintenance, and Cleaning</i>	<i>26</i>
<i>Cleaning the Inner Surfaces of the Model 9560</i>	<i>26</i>
Manufacturer’s Declaration.....	27
Testing Summary	30
<i>SpO₂ Accuracy Testing.....</i>	<i>30</i>
<i>Low Perfusion Testing</i>	<i>30</i>

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

1.	Oxygen Saturation Range (SpO₂)	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: 910 nanometers @ 1.2 mW maximum average
	(using NONIN PureLight [®] Sensor):	
4.	SpO₂ Accuracy (Arms**)	70-100%
	Oxygen Saturation Accuracy:	± 2 digits
	Low Perfusion Oxygen Saturation Accuracy:	± 2 digits
5.	Pulse Rate Accuracy (Arms**)	
	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:	Star
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:	Health Device Profile (HDP), Serial Port Profile (SPP)

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.

Model 9560 Bluetooth® Profiles

The Health Device Profile (HDP) and the Serial Port Profile (SPP) are the two profiles available for a Bluetooth connection. If a successful HDP connection cannot be made, an SPP connection will be attempted.

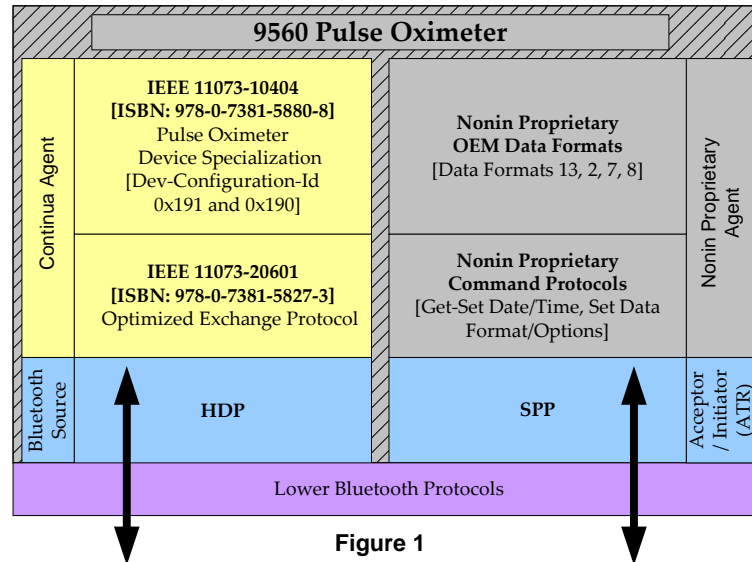


Figure 1

Health Device Profile (HDP)

This Bluetooth profile defines a connection for qualified Healthcare and Fitness devices. These devices are called Source and Sink devices. Source devices include pulse oximeters (9560), weight scales, glucose meters, thermometers and blood pressure monitors. Sink devices include mobile phones, desktop and laptop computers, and health appliances.

For more information on HDP specification, please refer to www.bluetooth.com for publically available HDP and MCAP specifications. Further information regarding testing can be obtained by joining the Bluetooth SIG at www.bluetooth.org.

Note: Selection of HDP is required to meet Continua Guidelines.

Further information regarding Continua Health Alliance and related specifications can be obtained by applying for membership at www.continuahealthalliance.org.

Communications Interface (HDP)

The Health Device Profile (HDP) operates with the ISO/IEEE 11073-20601 Personal Health Data Exchange Protocol. The device specialization for a Pulse Oximeter, ISO/IEEE 11073-10404, provides interoperability for the Model 9560 as a Pulse Oximeter when HDP is selected. Dev-Configuration-Id 0x191 (default) and 0x190 are supported.

For more information on the IEEE specifications, please consult www.ieee.org.

Note: The remainder of this document describes Nonin’s proprietary protocols over the Serial Port Profile (SPP).

Serial Port Profile (SPP)

This Bluetooth profile defines an emulated serial port / RS-232 cable replacement between two Bluetooth devices. These devices are called acceptors and initiators. The 9560 using a Nonin feature called Attempt to Reconnect (ATR) enables the 9560 to act as an initiator. When this feature is disabled, the 9560 acts as an acceptor.

Communications Interface (SPP)

The 9560 features a command protocol interface that enables the configuration of internal settings and the selection of predefined data format solutions.

Data Format Solutions:

- Data format 13 (default) – provides easy spot-check measurements with the capability to store and forward measurements. ATR is available solely for this data format and is enabled by default.
- Data format 2 – provides real-time oximetry measurements with compressed waveform (8 bit waveform) every 1/3rd of a second.
- Data format 7 – provides real-time oximetry measurements with full resolution waveform (16 bit waveform) every 1/3rd of a second.
- Data format 8 – provides real-time oximetry measurements every second.

Connection Details

Data Format 13, with ATR (attempt-to-reconnect) enabled, is the default data format for the 9560 device. See the section on “Selecting the Data Format” for instructions to change the data format. ATR assists the 9560 in being a true spot check device, where the system to which the 9560 is transferring information is an automatic connection, such that the system does not need to actively search for the 9560.

Pairing:

In **Bluetooth** communications terms, the 9560 is a slave device as shown in Figure 2 below. To connect the 9560 to a master device, the master device must first associate with the 9560 and initiate the connection by inquiring for the 9560.

To be discoverable, the 9560 must be powered on with a finger inserted. The 9560 will be discoverable for a minimum of 2 minutes with the finger inserted. During the master device’s inquiry of the slave, the 9560 (as the slave) will provide a friendly name starting with “Nonin_Medical_Inc.” and followed by a six digit number, referred to as the PIN, to the master. The PIN is etched on the battery door. The master device must follow the inquiry process by pairing.

To complete the pairing process the PIN must be provided by the master device as the **Bluetooth** PassKey (Bluetooth PIN). It is at this point that the master device can connect to the 9560.

Connection details specific to Data Format 13 (default, with Attempt to Reconnect (ATR) enabled):

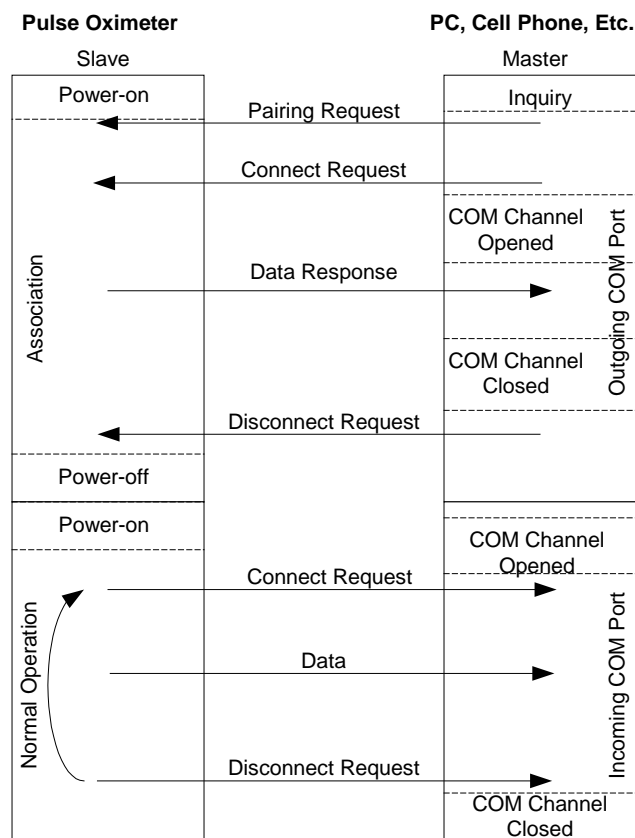


Figure 2 (default)

Refer to Figure 2. The master device must have two com ports available if DF#13 w/ ATR enabled is used. Once the 9560 is powered on, the master device will search for it and pair with it. *Note that the 9560 remembers the previous master device it was connected to and will not be discoverable unless that master device is turned off or not in range.* During this process COM ports will be assigned. The master will then disconnect.

The next power-on of the 9560 will result in a connection request to the master device with which it is paired on the first SPP server channel. The 9560 will connect as a preferred slave acting as a master. The receiving device must accept the connection after receiving the request. It is at this point that a role switch within the Bluetooth lower protocol layers can occur to switch the 9560 back to being a slave and promote the receiving device to be the master.

If the original master which initiated the inquiry is not available, the 9560 will store the oximetry measurement into memory for transmission after the next power-on.

The 9560 will be discoverable during this process for approximately 2 minutes. The Bluetooth service name will be whatever is associated with the first SPP server channel.

Depending on the Bluetooth stack or hardware used, the PIN may need to be re-entered. If PIN entry is required at each subsequent connection you may need to change your stack settings so the stack will retain the previous device’s key.

This “connection-back” option can be disabled if the data format selection option is used. See ATR (Attempt to Reconnect) in the “Selecting the Data Format” section that follows.

Connection details for data formats 2, 7, and 8:

For data formats 2, 7 and 8 the 9560 will not initiate the connection. If your system has only one COM port available, use of these alternate data formats is recommended. (The default data format 13 can be used, but ATR must be disabled using the Selecting the Data Format process below.) The master device must initiate the connection by occasionally polling for the 9560. **Refer to Figure 3.** This is because the 9560 may pass in and out of range.

The 9560 will be available for connection to a new master once it has been disconnected from its current master. This disconnection may be due to a connection drop of any kind (i.e. out of range, master radio is shut off, or the connection is closed by the master).

After the connection is made, the 9560 will automatically send continuous data to the master as defined in the Data Format Solutions section.

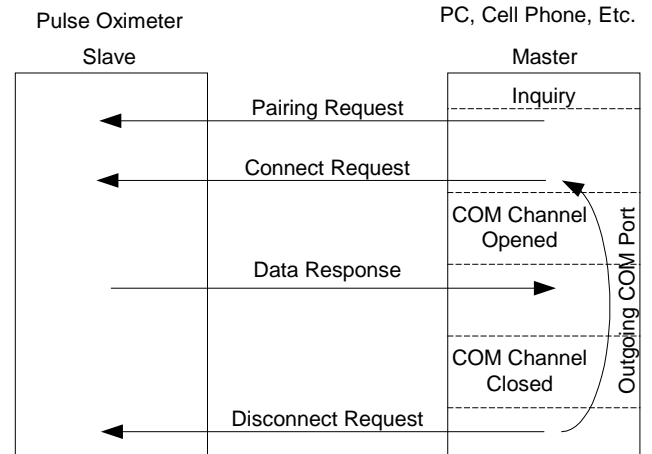


Figure 3

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

SmartPoint™ Technology

SmartPoint Technology provides a fast and accurate snapshot of the patient’s SpO₂ and pulse rate and eliminates the guesswork in determining which oximetry values to use for analysis. The SmartPoint algorithm automatically determines when a high quality measurement is ready to be wirelessly transmitted. Each measurement includes an indicator of quality.

The 9560 will typically acquire a SmartPoint measurement within 40 seconds from power-on. If the algorithm no longer detects a high quality measurement due to such pulse conditions like low perfusion (weak pulse signal conditions) or artifact, the SmartPoint Algorithm will send the current measurement and indicate in the packet that the measurement did not meet the criteria for SmartPoint quality criteria.

Command Protocols

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

Bits per second	Data bits	Parity	Stop bits	Flow Control
9600 minimum	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.

During an active connection, there are several commands which may be sent from the connected device to the 9560.

These commands include:

- Selecting the Data Format
- Setting/Receiving the Date and Time in the 9560
- Retrieving the Serial Number in the 9560

Note: After a successful connection there is a 5 second window where communication can take place uninterrupted. After the initial 5 seconds, the use of these commands will interrupt continuous data formats 2, 7 and 8.

Selecting the Data Format

To select the data format the host on the master side must send the 9560 the following 8 byte command:

Byte 1	Byte2	Byte3	Byte4	Byte5	Byte 6	Byte 7	Byte 8
Start(STX)	Op Code	Data Size	Data Type	Data Format	Options	Checksum	ETX
0x02	0x70	0x04	0x02	0xZZ where ZZ is (0D, 08, 07, or 02)	Format Specific	0x76 + Data Format + Options	0x03

The Options field (byte 6) is only valid when the Data Format field (byte 5) is set to 0x0D (Data Format 13), for all other data formats, please set this byte to 0x00.

For Data Format 13, Options are set as follows:

Byte 6 (DF13) Options	Bit 7 (ATR)	Bit 6 Reserved	Bit 0 through Bit 5 Expansion Options
	0 = Enabled (Default) 1 = Disabled	Set to 0	0 = Disabled (Default) 1 = Enabled 2 through 63 = reserved, do not use

Response: After receiving a data format command, the 9560 will respond with an ACK (0x06) for a supported format or NAK (0x15) for an unsupported format.

Alternatively for legacy devices, this can be a 6 byte selection if the Options are not required. Simply ignore columns containing Options byte (byte 6) and Checksum byte (byte 7) and adjust the Data Size byte to 0x02. In this case for Data Format 13, to set the ATR (Attempt to Reconnect) option to FALSE, set Byte 4 to 0x00 and byte 5 to 0x02.

Once the data format is changed, the 9560 will retain the new data format until it is 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 initially from the factory to data format 13 with the ATR option set to TRUE.

Example: To change the data format from the default of DF13 with no serial expansion option and ATR enabled to DF13 with the serial expansion option enabled and ATR enabled, send the following command:

02 70 04 02 0D 01 84 03

To change the device back to the default without the option, send the following command:

02 70 04 02 0D 00 83 03

Setting / Retrieving Date and Time in the 9560

The host on the master side can set and retrieve the date and 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	Decimal Range
YY (year)	00-99
MM (month)	1-12
DD (day)	1-31*
hh (hour)	0-23
mm (minute)	0-59
ss (second)	0-59

*Depends on leap-year, and month for accurate range

Setting the Date and Time:

To set the date and time in the 9560 the host on the master side 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 Date and Time from the 9560:

To retrieve the date and time from the 9560, the host on the master side must send a 4 byte command:

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

Response: The 9560 sends the date and time as part of the following 10 bytes:

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

Retrieving Serial Number from the 9560

To retrieve the serial number from the 9560 (Rev 147 and later), the host on the master side must send a 6 byte command:

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5	Byte 6
Start (STX)	Op Code	Data size	ID Code	Checksum	End(ETX)
02 hex	74 hex	02 hex	02 hex	02 hex	03 hex

Response: The 9560 sends the serial number as part of the following 15 bytes:

Byte 1	Byte2	Byte3	Byte4	Byte5 through Byte13	Byte 14	Byte15
Start (STX)	Op Code	Data Size	ID Code	Serial Number, MSB first	Checksum	ETX
02 hex	F4 hex	0Bhex	02 hex	9 digit Serial Number	Sum of Byte 4 through Byte 13	03 hex

Serial Data Format #13

Data format 13 attempts to send only one measurement when a SmartPoint measurement is available or after 40 seconds from power-on. An indicator on the 9560 display flashes while acquiring the measurement. The indicator will stop flashing after a measurement is transmitted, or in the event that a wireless transmission is not possible, will stop flashing when the measurement is stored into memory.

Packet Description

The data format #13 packet 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 the time of spot-check, SpO₂, Pulse Rate, and status.

Header	Byte #	Data	Information	Format
Header	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 [see notes]	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
Optional Data	XX*	See Optional Data	See Optional Data	NA
Footer	21	Checksum LSB	LSB of sum of Spot-check Data	Hex
	22	03	ETX – end of transmission	Hex

Notes:

* This data section is expandable and the length is defined during the data format selection process in Byte 5 and 6. The minimum length of the Spot-check Data section of the packet is 14 bytes (0x0E).

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 SpO₂ Format:

	7	6	5	4	3	2	1	0
SpO₂	R	SP6	SP5	SP4	SP3	SP2	SP1	SP0

When SpO₂ and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO₂ 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 or choose a different finger.

Memory Storage of Spot-Check Measurements

The 9560 has memory capacity to store a minimum of 20 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 SmartPoint measurement is not available, no data will be sent or stored in memory.

Stored measurements will be lost after battery replacement.

The following data is available as expandable options (See Selecting Data Format section on page 6):

Optional Data

Note: This is optional data, the decision whether or not to include it needs to be selected by the configuring application.

Optional Data	Byte #	Data	Information	Format
Serial Number Expansion Option	21	S9	Serial Number	ASCII
	22	S8	Serial Number	ASCII
	23	S7	Serial Number	ASCII
	24	S6	Serial Number	ASCII
	25	S5	Serial Number	ASCII
	26	S4	Serial Number	ASCII
	27	S3	Serial Number	ASCII
	28	S2	Serial Number	ASCII
	29	S1	Serial Number	ASCII

Serial Number is represented as (S9)(S8)(S7)(S6)(S5)(S4)(S3)(S2)(S1).

Serial Data 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 including: 8-bit waveform value, six different output options for the SpO₂ value, four different averaging options for the Pulse Rate values, and options formatted for both recording and display purposes, as well as status information for the measurement and status of the battery.

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	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	<i>reserved</i>	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	<i>reserved</i>	CHK
	13	01	STATUS	PLETH	<i>reserved</i>	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	<i>reserved</i>	CHK
	19	01	STATUS	PLETH	<i>reserved</i>	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	<i>reserved</i>	CHK
	25	01	STATUS	PLETH	<i>reserved</i>	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.
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 (160 ms). 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: 0 to 255

Byte 4 – FLOAT BYTE

This byte is used for SpO₂, 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

The following are all active high:

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

Standard Mode - Formatted for Recording Purposes:

These values are formatted for recording purposes and are updated every 1/3 of second. When the finger is removed from the device these values will be formatted with the missing data value. The following output options are available in standard mode:

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 SpO₂ and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO₂ equals 127.

Display Mode - Formatted for Display Purposes:

These values are formatted for display purposes and are updated every 1.5 seconds. When the device is removed from the finger, the last SpO₂ 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. The following output options are available in Display Mode:

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 SpO₂ and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO₂ 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

SpO₂ Format:

	7	6	5	4	3	2	1	0
SpO₂	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.

		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 ₂	CHK
		4	STATUS	PLETH MSB	PLETH LSB	SREV	CHK
		5	STATUS	PLETH MSB	PLETH LSB	<i>reserved</i>	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	<i>reserved</i>	CHK
		13	STATUS	PLETH MSB	PLETH LSB	<i>reserved</i>	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	<i>reserved</i>	CHK
		19	STATUS	PLETH MSB	PLETH LSB	<i>reserved</i>	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	<i>reserved</i>	CHK
		25	STATUS	PLETH MSB	PLETH LSB	<i>reserved</i>	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.
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 (160 ms). 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 SpO₂, Pulse Rate, and information that can be processed at a rate of 1/3 of a 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

The following are all active high:

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

Standard Mode - Formatted for Recording Purposes:

These values are formatted for recording purposes and are updated every 1/3 of second. When the finger is removed from the device these values will be formatted with the missing data value. The following output options are available in standard mode:

HR: 4-beat Pulse Rate Average
 E-HR: 8-beat Pulse Rate Extended Average
 SpO₂: 4-beat SpO₂ Average
 E- SpO₂: 8-beat SpO₂ Extended Average
 SpO₂ Fast: 4-beat Average optimized for fast responding
 SpO₂ B-B: Beat to Beat value – No Average

When SpO₂ and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO₂ equals 127.



Display Mode - Formatted for Display Purposes:

These values are formatted for display purposes and are updated every 1.5 seconds. When the device is removed from the finger the last SpO₂ 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. The following output options are available in Display Mode:

- HR-D: 4-beat Pulse Rate Average
- E-HR-D: 8-beat Pulse Rate Extended Average
- SpO₂-D: 4-beat SpO₂ Average
- E- SpO₂-D: 8-beat SpO₂ Extended Average

When SpO₂ and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO₂ 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

SpO₂ Format:

	7	6	5	4	3	2	1	0
SpO₂	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 including: SpO₂ and Pulse Rate formatted for display, status of the measurement, and status of the battery.

Packet Description

Three bytes of data are transmitted 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 - SpO ₂ -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	SNSA	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.
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 SpO₂ and Pulse Rate values are formatted for display purposes and are updated every 1.5 seconds. When the device is removed from the finger the last SpO₂ 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. The following output options are available in Display Mode:

HR-D:	4-beat Pulse Rate Average
SpO ₂ -D:	4-beat SpO ₂ Average

When SpO₂ and HR cannot be computed, the system will send a missing data indicator. For missing data, the HR equals 511 and the SpO₂ 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 (%SpO₂) 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.
Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.

Cautions

This device has no audible alarms and is intended only for spot-checking.

Inspect the device application site at least every 6 to 8 hours to ensure correct device alignment and skin integrity. Patient sensitivity to the device may vary due to the medical status or skin condition.

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
- 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 60601-1-2:2004 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 if 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. C95.1-2005 and has been tested in accordance with the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. 1528-2003.
- 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

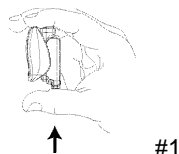
	Consult Instructions for Use.
	Caution!
	Type BF Applied Part (Patient isolation from electrical shock).
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 30EM and CAN/CSA C22.2 No. 601.1.
	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
	Radio Equipment Class Identifier
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.
	Remote Alarms; Not for Continuous Monitoring.
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Bluetooth®
	Indoor use (France only)
	Continua Certified™ signifies that this product has been tested and proven to be interoperable with other products that carry the "Continua Certified™" symbol.
pin	Personal Identification Number
BDA	Bluetooth Device Address
Ver	Version

NOTE: Where applicable, an additional label bearing your country radio communications license information will appear on the side of your device. This is not a serial number or device identifier.

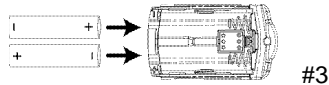
Installing Batteries

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.

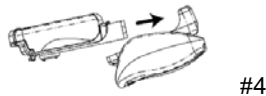
Note: Rechargeable batteries may be used; however, they require more frequent replacement.



1. 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.*



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.*



5. Visually inspect to ensure that the battery cover is properly placed.
6. After installing batteries, for proper initialization and detection of the battery status, wait a minimum of 5 seconds before activating the device. Should the device be activated within 5 seconds after battery installation, low battery indication may result. Simply allow the device to turn off for proper initialization.

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 the user 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.

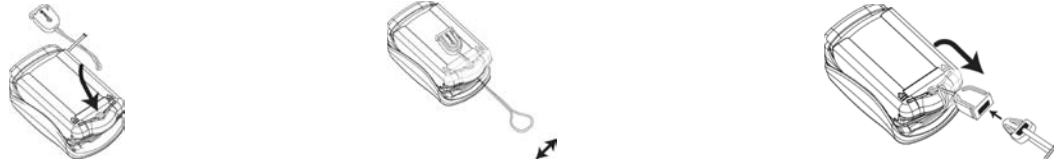
A minus sign (-) appears in the left-most digit of the %SpO₂ display when the Model 9560 senses that the finger has been removed. The last measured SpO₂ and pulse rate values freeze for 10 seconds, and then "OFF" will appear in the display while the device turns off. The device will automatically shut off (to conserve battery life) approximately 20 seconds after the finger is removed, or after a 2-minute period of inadequate pulse signal.

When the Model 9560 is placed on the finger and powered on, and not in a connection with an electronic medical record (EMR) system, it will be available for a wireless connection (Bluetooth®) for a minimum of 90 seconds. It will remain in this mode until:

- a successful wireless connection occurs with your EMR system,
- two minutes have passed without a successful wireless connection with your EMR system, or
- the Model 9560 is powered off.

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 than 90° angle, 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 a mild detergent; see **CAUTION** below. Do not use any 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
<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 2	This device 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	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	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	±5% U_T (>95% dip in U_T) for 0.5 cycles ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	N/A	Mains power quality should be that of a typical commercial or hospital environment.
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
<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>N/A</p> <p>3 V/m</p>	<p>Recommended Separation Distance</p> <p>$d = 1.17 \sqrt{P}$</p> <p>$d = 1.17 \sqrt{P}$ 80 MHz to 800MHz</p> <p>$d = 2.33 \sqrt{P}$ 800MHz to 2.5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>Notes:</p> <ul style="list-style-type: none"> • 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.

<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>			
	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:			
<ul style="list-style-type: none"> • 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

SpO₂ accuracy, motion and low perfusion testing was conducted by NONIN[®] Medical, Incorporated as described below.

SpO₂ Accuracy Testing

SpO₂ 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 (SpO₂) of the sensors is compared to arterial hemoglobin oxygen (SaO₂) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors is in comparison to the co-oximeter samples measured over the SpO₂ 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 SpO₂ Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO₂ levels. The module must maintain accuracy in accordance with ISO 9919:2005 for pulse rate and SpO₂ at the lowest obtainable pulse amplitude (0.3% modulation).