

WristOx₂[™] Model 3150 Bluetooth[®] Wrist-Worn Pulse Oximeter OEM Specification and Technical Information

Nonin[®] Medical, Inc. 13700 1st Avenue North Plymouth, Minnesota 55441-5443 USA

+1 763-553-9968 800-356-8874 (USA and Canada) Fax +1 763-553-7807 E-mail: info@nonin.com <u>www.nonin.com</u>

© 2010 Nonin Medical, Inc.

7970-000-01



Contents

Specifications	1
Model 3150 Bluetooth [®] Profiles	4
Serial Port Profile (SPP)	4
Health Device Profile (HDP)	5
Establishing a Blustooth Connection	5
Initial Bluetooth Connection Process	5
Connection using One Bluetooth Channel	
Connection Using Two Bluetooth Channels – DF13 with ATR Enabled	
	•
Operation Modes	8
	۵ 8 م
Stanuby On - Activation Modes	o o و
Snot Check Mode	8
Sensor Activation Mode	9
Programmed Mode	9
Command Protocolo	40
Command Protocols	10
Level T Commands – Real-lime Operation	10
Set Data Format and Activation	10
Set Multiple Parameters	
Date and Time Settings	
Get Serial Number from 3150	14
Set Bluetooth Timeout Period	14
Level 2 Commands – Computer Mode	15
Communication Rate	15
Set Configuration Sector	
Get Configuration Sector	
Set Date and Time Command	
Set Bluetooth Time-out Period	
Memory Playback Command	
Cancel Memory Playback Command	
Clear Stored Patient Data Records from Memory	20
Sorial Data Format Definition (SPP Profile)	21
Communication Rate	2 21
Serial Data Format #1 Definition	21
Serial Data Format #2 Definition	
Serial Data Format #7 Definition	
Serial Data Format #8 Definition	30
Serial Data Format #13 Definition	31
Indications for Use	25
Contraindications	
Warnings	
Cautions	



Regulatory Information	38
Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility	38
Federal Communications Commission (FCC) Notice	38
Using the Model 3150	39
Guide to Symbols on the Module	39
Manufacturer's Declaration	40
Testing Summary	43
SpO ₂ Accuracy Testing	43
Pulse Rate Motion Testing	43
Low Perfusion Testing	43
Additional Information	43

Figures

Figure 1.	Bluetooth Profiles	4
Figure 2.	Data Formats 1, 2, 7, 8, and DF13* Connection Diagram	6
Figure 3.	DF13 Connection with ATR Enabled Diagram	7
Figure 4.	Activation Switch	8
Figure 5.	Comparison of Full and Partial Display	9

Tables

Table 1.	Available Legacy Configuration Commands	11
Table 2.	Configuration Sector Parameters	16
Table 3.	Electromagnetic Emissions	40
Table 4.	Electromagnetic Immunity	40
Table 5.	Guidance and Manufacturer's Declaration—Electromagnetic Immunity	41
Table 6.	Recommended Separation Distances	42



Specifications

Oxygen Saturation Range (SpO ₂): 0 % to 100 %						
Pulse Rate Range:	18 to 321 beats per minute (BPM)					
Display Features:						
SpO ₂ :	3-digit	numeric				
Pulse Rate:	3-digit	numeric				
	Pulse s	strength bar grap	h: 9 levels			
Battery Status:	4 level	s (full, half, low, c	critical)			
Indicators:	Sensor	r Fault, Bluetooth	connectivity, S	martPoint, Pulse		
	Signal					
SpO ₂ Accuracy (A _{rms} *) Adult/Pediatric:		SpO ₂ : 70% to 100%				
Reusable Sensors:		No Motion	Motion	Low Perfusion		
8000AA**, 8000AA-WO**, 8000AA	A-WO2:	±2 digits	±3 digits	±2 digits		
8000J**, 8000J-WO**, 8000J	J-WO2:	±3 digits	N/A	±2 digits		
8000S se	ries***:	±2 digits	±3 digits	±2 digits		
800)0Q2**:	±3 digits	N/A	±2 digits		
80)00R**:	±3 digits	N/A	±2 digits		
Disposable Sensors**:						
6000CA, 6000CP, 6000CI,7000A, 7000P,	70001:	±2 digits	±3 digits	±2 digits		
Pulse Rate Accuracy (A _{rms} *) Adult/Pediat	ric:	BPM: 18-300	20-250	40-240		
		No Motion	Motion	Low Perfusion		
All sensors:		±3 digits	±3 digits	±3 digits		

* $\pm 1 \ A_{rms}$ represents approximately 68% of measurements.

** With 3150I interface cable.

*** 8000S series includes 8000SS**, 8000SM**, 8000SL**, 8000SS-WO**, 8000SM-WO**, 8000SL-WO**, 8000SS-WO2, 8000SM-WO2, 8000SL-WO2,



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
Internal Power:	
Battery:	Two 1.5 volt AAA alkaline batteries
Operating Life Bluetooth OFF:	48 hours minimum
Operating Life Bluetooth on, class 2 range:	24 hours minimum
Operating Life Bluetooth on, class 1 – max. power:	8 hours minimum
Storage Life:	9 months
Weight (approx. with strap and sensor):	71 grams (2.5 oz)
Temperature:	
Operating:	-5 °C to +40 °C (+23 °F to +104 °F)
Storage/Transportation:	-40 °C to +70 °C (-40 °F to +158 °F)**
Device temperature will not exceed 41 °C as	
measured during a controlled environment test.	
Operating Altitude:	Up to 12,192 meters (40,000 feet)
Hyperbaric Pressure:	Up to 4 atmospheres
Humidity:	
Operating:	10 % to 95 % relative humidity, non-condensing
Storage/Transportation:	10 % to 95 % relative humidity, non-condensing
	Allow to stabilize
Bluetooth Information:	
Bluetooth Compliance:	Version 2.0
Operating Frequency:	2.4 to 2.4835 GHz
Output Power:	<20dBm
Operating Range:	100 meter (328 foot) radius indoors ¹
Network Topology:	Point-to-point (factory default)
Operation:	Slave: Model 3150
Antenna Type:	Internal
Modulation Type:	Frequency Shift Keying
	Frequency Hopping Spread Spectrum
Band Width:	1 MHz
Bluetooth Profiles Supported:	Health Device Profile (HDP) Serial Port Profile (SPP)

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

** When the Model 3150 is transferred from a non-operating temperature/humidity condition, allow 1 hour of stabilization to operating temperature/humidity specifications prior to use.

¹ Line of sight when connected to a class 1 device; dependent on host connection.



Dimensions (without strap and sensor):	56 mm x 74 mm x 20 mm (H x W x D)
	(2.20 in. x 2.91 in. x 0.79 in.)
Memory:	
Туре:	Non-volatile
Capacity:	1,080 hours (4 second data storage rate)
	540 hours (2 second data storage rate)
	270 hours (1 second data storage rate)
Classification per IEC 60601-1 / CAN/CSA-C22.2 No.	. 601.1 / UL60601-1:
Type of Protection:	Internally powered (battery power)
Degree of Protection:	Type BF-Applied Part
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	IP33
This product complies with ISO 10993-1, Biological eva and testing	luation of medical devices – Part 1: Evaluation
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
Warranty:	3 years from the date of purchase.

DINONI

Model 3150 Bluetooth[®] Profiles

The 3150 supports both the Serial Port Profile (SPP) and Health Device Profile (HDP). These two profiles are available through the Bluetooth connection. The default communication profile is SPP. If the host device uses the HDP, the 3150 automatically switches to the HDP mode.

	Pulse Ox	imeter						
tinua Agent	IEEE 11073-10404 [ISBN: 978-0-7391-5890-8] Pulse Oximeter Device Specialization [Dev-Configuration-Id 0x191 and 0x190]	Nonin Proprietary OEM Data Formats [Data Formats 13, 2, 7, 8]	Proprietary Agent					
Con	IEEE 11073-20601 [ISBN: 978-0-7391-5927-3] Optimized Exchange Protocol	Nonin Proprietary Command Protocols [Get-Set Date/Time, Set Data Format/Options]	Nonin					
Bluetooth Source	HDP	SPP	Acceptor / Initiator (ATR)					
	Lower Bluetooth Protocols							

Figure 1. Bluetooth Profiles

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 3150 default communication mode is SPP.

The 3150 features a SPP command protocol interface that enables the configuration of internal settings and the selection of predefined data format solutions.

Data Format Solutions supported by SPP:

Data format 2 (default) – provides real-time oximetry measurements with compressed waveform.

Data format 7 – provides real-time oximetry measurements with full resolution waveform.

Data format 8 – provides real-time oximetry measurements every second.

Data format 13 – provides a single spot-check measurement.

The 3150 features an Attempt to Reconnect (ATR) option for data format 13. When the ATR option is enabled, the 3150 acts as an initiator and requires two channels for communications. When the ATR option is disabled, the 3150 acts as an acceptor and requires only one channel for communications.



Health Device Profile (HDP)

When the host device uses HDP, the 3150 automatically switches to the HDP Bluetooth mode (Continua). 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 (such as the 3150), weight scales, glucose meters, thermometers and blood pressure monitors. Sink devices include mobile phones, desktop and laptop computers, and health appliances.

The 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 3150 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 <u>www.ieee.org</u>.

For more information on HDP specification, please refer to <u>www.bluetooth.com</u> for publically available HDP and MCAP specifications. Further information regarding testing can be obtained by joining the Bluetooth SIG at <u>www.bluetooth.org</u>. Further information regarding Continua Health Alliance and related specifications can be obtained by applying for membership at <u>www.continuahealthalliance.org</u>.

All further information in this document refers to the Serial Port Profile.

Establishing a Bluetooth Connection

The 3150 offers the option of five different data formats, 1,2,7,8, and 13, so that the integrator can select one to specifically meet the needs of their product. The details of these data formats are described later in this document, but depending on the configured data format, the 3150 makes use of two methods to establish a Bluetooth connection. Data formats 1, 2, 7, and 8 require one Bluetooth channel. Serial data format #13 requires two Bluetooth channels. A connection between the host and the 3150 must be made. To establish the initial connection, the devices must first be paired. Once paired, the host device must establish the connection to the 3150.

Initial Bluetooth Connection Process

In Bluetooth communications terms, the 3150 is a slave device. To connect the 3150 to a master device, the master device must first associate with the 3150 by inquiring for the 3150. For the initial pairing of a new host device (master) to the 3150, the 3150 is discoverable for a minimum of 2 minutes after poweron. During the discovery period, the 3150 will broadcast a friendly name to the master. The name starts with "Nonin_Medical_Inc._", followed by a 6-digit number, referred to as the PIN. The PIN is etched on the back of the 3150 enclosure. To complete the pairing process once the master (host) device finds the 3150, the PIN must be provided to the master device. Once paired, the master must establish the connection to the 3150.

Note: If you cannot discover the 3150, make sure any previous master device is off, disabled, or out of range. If a previous master device is in range of the 3150, the 3150 may not be discoverable.

Connection using One Bluetooth Channel

For data formats 1, 2, 7 and 8, the 3150 will *not* initiate the connection using the attempt to reconnect (ATR) option. If your system has only one COM port available, use data format 2, 7, 8, or 13 with the ATR disabled. The master device must initiate the connection by occasionally polling for the 3150 (refer to figure 2). For an automatic wireless reconnection, design your software to periodically poll for the 3150. If polling for the 3150 is not possible, manually start the Bluetooth connection. Because the manual method typically requires the user to initiate the Bluetooth connection, the seek/polling method has advantages.



The 3150 will be discoverable when not paired to an existing master. Make sure any previous master devices are off. Once your device pairs and establishes the Bluetooth connection with the 3150, the 3150 will automatically send continuous data to your device as defined in the Serial Port Profile (SPP) Data Format Definition sections for data formats 2, 7, and 8.



Figure 2. Data Formats 1, 2, 7, 8, and DF13* Connection Diagram

* with ATR parameter disabled



Connection Using Two Bluetooth Channels – DF13 with ATR Enabled

When the 3150 device is configured to send Serial Data Format 13 and the ATR feature is enabled, your host device must have two Bluetooth channels. Once the 3150 is powered on, the master device must pair and connect with it. Note: The 3150 remembers the previous master device it was connected with, therefore it and will not be discoverable unless the previous master device is turned off or is out of range. During the connection process, COM ports will be assigned to two Bluetooth virtual com ports. After the initial com ports are established, power down the 3150.

The next time the 3150 is powered up, it will send a connection request to the last paired master device using the first SPP server channel. The 3150 will connect as a preferred slave acting as a master. Your host 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 3150 back to being a slave and promote the receiving device to be the master. This two channel connection method is similar to the way a Bluetooth headset communicates to a cell phone. The advantages of the two com port solution as compared to the one com part are: a) the host device does not have periodically poll for the 3150, and as a result less complex host software design, c) this solution does not require any intervention to manually start the Bluetooth connection – it's all automatic and easier for the end user.

If the host device is not available or the Bluetooth connection cannot be made, the 3150 will store the oximetry measurement into memory. All stored measurements will be transmitted on the next operating session with Bluetooth connection.

After the initial pairing process, the Bluetooth PIN number may need to be re-entered. After this pin number is entered, all future connections should be made without requiring pin number entry. 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 pin key. Figure 3 illustrates the connection process for Data Format 13 with ATR enabled.



Figure 3. DF13 Connection with ATR Enabled Diagram

MONI

Operation Modes

The 3150, has three operation modes: Cable, Standby, and On.

Cable

The device is in Cable mode when it is connected to a PC using the USB interface cable. While in Cable mode, the device does not collect or save data and the Bluetooth radio is off.

Standby

When the device is in Standby mode, the screen is blank and the device appears to be off. In Standby, it is ready for a signal that will turn the device on (e.g., pressing activation switch, inserting finger in sensor [Spot Check mode], connecting sensor [Sensor Activation mode], or programmed start time [Programmed mode]). While in Standby mode, the device does not collect or save data and the Bluetooth radio is off.



Figure 4. Activation Switch

On – Activation Modes

When the device is on, it can collect and save data. The device features three activation modes:

- Spot Check mode
- Sensor Activation mode
- Programmed mode

The device is delivered in Spot Check mode. The device recalls the previous configured settings when the device is shut off and turned on again.

Spot Check Mode

Spot Check mode is the default activation operation mode.

The device automatically turns on when a finger is inserted into the sensor. It enters Standby mode 10 seconds after the finger is removed. If the sensor is disconnected, the device enters Standby mode immediately.

In this mode, the sensor can be left connected to the device.

NOTE: If the device determines that a sensor fault exists (a sensor failure, misalignment, or incompatibility with the device) or if a pulse oximeter sensor signal cannot be detected, the device enters Standby mode after 3 minutes.



Sensor Activation Mode

Sensor Activation mode may be selected by sending the configuration command. In this mode, the device turns on when the activation switch is pressed or when the sensor is disconnected and reconnected. This mode is useful when using a sensor that is not easily removed from the sensor site (e.g., disposable or wrap sensor).

If the sensor is not used for at least 10 minutes or if an inadequate pulse signal is detected, the device automatically enters Standby mode. To turn the device on again, press the activation switch or disconnect and reconnect the sensor.

This mode allows for Full or Partial display (see figure 4 for display comparison). When using Partial display, the SpO_2 and pulse rate readings do not display. The user will only see the battery indicator and the animated pulse strength indicator.



Figure 5. Comparison of Full and Partial Display

Programmed Mode

Programmed mode may be selected and setup through software. With the software, the user can program the device to start and stop for up to three sessions. Once programmed, the next start time displays on the LCD every 30 seconds in HH:MM format.

A sensor must be connected for Programmed mode to function.

If the programmed device is in Standby mode and the activation switch is pressed, the user activates the Bluetooth radio and the device for 3 minutes. During this time, the user is able to take and store measurements. After 3 minutes, the device returns to Standby mode.

This mode allows for Full or Partial display (see figure 4 above for display comparison). When using Partial display, the SpO_2 and pulse rate readings do not display. The user will only see the battery indicator and the animated pulse strength indicator.

NOTE: A programmed device reverts to Spot Check mode if the clock is not set or if the clock settings are lost when replacing the batteries.

Command Protocols

The 3150 features two levels of commands. The Level 1 commands are intended for real-time operation and do not interrupt patient recording. The Level 2 commands are intended for use when not recording real-time patient measurements, for example when retrieving recorded data using the memory playback command. When a Level 2 command is received, the 3150 device switches to computer mode. Any open patient recording is closed out and the display is configured with a CP to indicate computer mode.

The 3150 device settings can be changed from the factory default settings. Once changed, the 3150 retains the new settings and will operate using the new settings until otherwise changed.

Level 1 Commands – Real-time Operation

Level 1 Commands allow you to configure the 3150 device without interrupting the patient recording.

During an active Bluetooth Connection, there are several Level 1 Commands available. These commands include:

- Set the Data Format and Activation
- Set Multiple Parameters
- Set the Date and Time in the 3150
- Set Bluetooth Radio timeout (power saving feature)
- Get the Date and Time from the 3150
- Get the Serial Number in the 3150
- Get revision number

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. Examples: <NAK> = 0x15, <ACK>=0x06

Communication Rate

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



Set Data Format and Activation

Serial Data formats 1, 2, 7, and 8 and one of two activation modes can be selected by sending a Level 1 Configuration command to the 3150 device after the Bluetooth connection is established. If no configuration command is received within 5 seconds after a Bluetooth connection is established, the 3150 will operate and send data based on the last saved configuration settings. The following Level 1 Configuration legacy commands are supported:

1. Set Configuration

Command: "Dn" where n is configuration value in ASCII (1,2,7,8,A,B,C,D) per table 1 Response: <ACK> Denied Response : <NAK> not accepted

Table 1 describes the available legacy configuration commands. See Serial Data Format Definitions sections for information on each data format.

Level 1 Configuration Command in ASCII	Level 1 Configuration Command in Hex	Serial Data Format	Turn-on Mode
D1*	0x44 0x31	1 (3 bytes, 1 per/sec)	Sensor
D2	0x44 0x32	2 (5 bytes, 75 per/sec, 8-bit pleth)	Sensor
D7	0x44 0x37	7 (5 bytes, 75 per/sec, 16-bit pleth)	Sensor
D8	0x44 0x38	8 (4 bytes, 1 per/sec)	Sensor
DA**	0x44 0x41	1 (3 bytes, 1 per/sec)	Spot-check
DB	0x44 0x42	2 (5 bytes, 75 per/sec, 8-bit pleth)	Spot-check
DC	0x44 0x43	7 (5 bytes, 75 per/sec, 16-bit pleth)	Spot-check
DD	0x44 0x44	8 (4 bytes, 1 per/sec)	Spot-check

Table 1. Available Legacy Configuration Commands

* Retained for legacy purpose. When possible use D8 instead of D1.

** Retained for legacy purpose. When possible use DD instead of DA.

Notes: Because the 3150 will respond with a NAK or ACK, the current serial data will be interrupted by the NAK or ACK response. Make sure your serial data processing routine is capable of recovering from a possible NAK or ACK interruption.

Set Multiple Parameters

Four data formats, two activiation modes, and additional parameters can be configured using a command string. The Bluetooth enable/disable parameter configurable for the continuous data formats. The Attempt-To-Reconnect (ATR) setting can be enabled or disabled with the episodic data format. Continuous data formats consist of serial data that repeats. The episodic data format consists of a single point measurement that does not repeat.



Set Operation for Continuous Data Formats

Specific to Data Formats 1, 2, 7, and 8, to select the Data Format, Activation, and Bluetooth, send the 3150 the following 8 byte command string:

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5	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 (01,02,07,08,0D)	CDF Byte	Sum of Byte 2 through Byte 6	0x03

9	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
YTE CDF	R	SC	AB	R	R	R	R	MC
ΞΩ T	0	0 or 1	0 or 1	0	0	0	0	1*

SC Activation Mode Bit	AB Bluetooth Enabled Bit
0 = Sensor Activation Mode	0 = Bluetooth Disabled at power on
1 = Spot Check Mode Turn ON (default)	1 = Bluetooth Enabled at power on (default)

* Bit 0 of byte 6 must be set

For more information regarding activation modes, see Operation Modes section.

Response: the 3150 will respond with an ACK (0x06) for a supported format or NAK (0x15) for an unsupported format.

Setting Operation for Episodic Data Format 13

The 3150 features the episodic data format 13. Data format 13 is designed for applications requiring a single SpO_2 and Pulse Rate measurement. When configuring the 3150 for data format 13, the 3150 is automatically configured for Spot-Check Mode and Bluetooth Enabled.

When the ATR is enabled, the 3150 acts as an initiator and requires two channels for communications. When the ATR is disabled, the 3150 acts as an acceptor and requires only one channel for communications. The ATR feature is further described in the section - Connection Using Two Bluetooth Channels.

Optional data can be enabled. The optional data includes the programmed device serial number. The device serial number can be used to link a specific 3150 device to a specific patient record. See Data Format 13 Definition section for more information.

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5	Byte 6	Byte 7	Byte 8
Start(STX)	Op Code	Data Size	Data Type	Data Format	Options	Checksum	ETX
0x02	0x70	0x04	0x02	0x0D	EDF Byte	Sum of Byte 2 through Byte 6	0x03

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
TE 6 DF	ATR	R	R	E4	E3	E2	E1	E0
ΒΥ	0=Enabled	0	0	0	0	0	0	0=Optional data off
	1=Disabled							1=Optional data on

Response: the 3150 will respond with an ACK (0x06) for a supported format or NAK (0x15) for an unsupported format.

Example: To set the data format to DF13 with the optional data enabled and ATR enabled, send the following command: 0x02 0x70 0x04 0x02 0x0D 0x01 0x84 0x03



Date and Time Settings

The host device can set and get the date and time from the 3150. The date and time must conform to the ranges defined below. The date and time will be lost when loss of power is greater than 30 seconds.

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

Set the Date and Time in the 3150

To set the date and time in the 3150 the host device must send the 3150 a 10 byte command:

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5	Byte 6	Byte 7	Byte 8	Byte 9	Byte 10
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	Byte 2	Byte 3	Byte 4	Byte 5	Byte 6	Byte 7	Byte 8	Byte 9	Byte 10
Start(STX)	Op Code	Data Size	Year	Month	Day	Hour	Minute	Second	ETX
0x02	0x72	0x06	0x32	0x0C	0x1F	0x0E	0x1E	0x0F	0x03

Response: an ACK (0x06) for command accepted. No response for commands not accepted.

Get Date and Time from the 3150

To retrieve the date and time from the 3150, the host device must send a 4 byte command:

Byte 1	Byte 2	Byte 3	Byte 4	
Start (STX)	Op Code	Data size	End(ETX)	
0x02	0x72	0x00	0x03	

Response: The 3150 sends the date and time as part of the following 10 bytes:

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5	Byte 6	Byte 7	Byte 8	Byte 9	Byte 10
Start(STX)	Op Code	Data Size	Year	Month	Day	Hour	Minute	Second	ETX
0x02	0xF2	0x06	YY	MM	DD	hh	mm	SS	0x03

L'ANDN

Get Serial Number from 3150

To retrieve the serial number from the 3150, the host 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)
0x02	0x74	0x02	0x02	0x02	0x03

Response: The 3150 sends the serial number as part of the following 15 bytes:

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5 through Byte 13	Byte 14	Byte 15
Start (STX)	Op Code	Data Size	ID Code	Serial Number, MSB first	Checksum	ETX
0x02	0xF4	0x0B	0x02	9 digit Serial Number (ASCII)	Sum of Byte 4 through Byte 13	0x03

Set Bluetooth Timeout Period

When the host device and the 3150 are out of range or when there is no Bluetooth connection, as a power saving feature a timeout period can be programmed to turn off the Bluetooth radio. The Bluetooth timeout period can be set to a value of 2 to 255 minutes. Once the timeout period is met, the 3150 will turn off the Bluetooth. After a timeout, to reactivate the Bluetooth connection, press the activation button on the side of the 3150. A zero timeout value will disable the Bluetooth timeout.

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5	Byte 6	Byte 7	Byte 8
Start (STX)	Op Code	Data size	ID Data Code	Module	Time	Checksum	End(ETX)
0x02	0x75	0x04	0x04	0x00	0xZZ	Sum of Byte 4 through Byte 6	0x03

Where ZZ in Byte 6 equals the Bluetooth time-out period in minutes (max of 255 minutes)

Valid Byte 4 Settings: where XX can be 00 and 02 to FF

Accepted Response: 0x02 0xF5 0x04 0x04 0x00 0x01 0x05 0x03

Not Supported Response: 0x02 0xF5 0x04 0x04 0x01 0x01 0x06 0x03 or 0x02 0xF5 0x04 0x04 0x02 0x01 0x07 0x03

Note: if the Bluetooth Configuration Setting is disabled, a 00 will not enable the Bluetooth. Make sure the Bluetooth Auto On is enabled. See section "Bluetooth Configuration" in the Level 2 command section under "Set Configuration Sector" for more information. Because the Bluetooth discovery can take more than 1 minute, setting the timeout period to 1 minute is not allowed.



Level 2 Commands – Computer Mode

The Level 2 protocol commands allow the 3150 to be configured for patient recording and memory playback purposes. A new patient record is stored in the non-volatile memory when the record is at least one minute in length. After each Level 2 command is received, the 3150 will change the display to "CP", close out the current patient record, and stop sending real-time data for 15 seconds. After the 15 seconds transpires, the 3150 display will go back through the display startup sequence and return to normal operation. Level 2 commands are in ASCII unless otherwise noted. Supported Level 2 commands are:

- Set Configuration Sector
- Get Configuration Sector
- Set Date and Time
- Get Date and Time
- Set Bluetooth Time-out Period
- Memory Playback
- Cancel Memory Playback
- Clear Memory (all stored patient records)

Communication Rate

Condition	Bits per Second	Data Bits	Parity	Stop Bits	Flow Control
All conditions except memory playback	9600	8	None	1	None
Memory Playback	38400	8	None	1	None

Set Configuration Sector

With the sector write command, multiple settings are configured at one time. To write the configuration section, send the command and 136 bytes of configuration information as defined below:

CFG=(appended with 136 bytes of configuration information)<CR><LF>

Response to the Configuration Sector Write command is: if the 3150 receives the command and the 136 byte content is in range, then an <ACK><CR><LF> is sent. If the 3150 receives the command and the 136 byte content is not within range or is invalid, then the 3150 will send a <NAK><CR><LF>.

Note: Real-time data transmission will be suspended for 15 seconds after receiving a valid Level 2 command. Any open patient record will be closed and a new patient record started 15 seconds after receiving the last valid Level 2 command.

The configuration sector includes 136 bytes of data (136 bytes: 0 through 135). See Table 2.



Byte	Description	Length	Format
0	Reserved	1	N/A
1	Bluetooth Enable	1	Char ASCII
2	Activation Option	1	Char ASCII
3	Patient Data Storage Rate	1	Char ASCII
4	Display Option	1	Char ASCII
5 through 14	Programmed start time 1 (YYMMDDhhmm)	10	Char ASCII
15 through 24	Programmed stop time 1	10	Char ASCII
25 through 34	Programmed start time 2	10	Char ASCII
35 through 44	Programmed stop time 2	10	Char ASCII
45 through 54	Programmed start time 3	10	Char ASCII
55 through 64	Programmed stop time 3	10	Char ASCII
65 through 114	Programmable Identification	50	Char ASCII
115 through 118	Software Part Number (1 st 4 Digits)	4	Char ASCII
119, 120, 121	Software Revision	3	Char ASCII
122 through 127	Software Rev Date (YYMMDD)	6	Char ASCII
128 through 133	Reserved	6	N/A
134,135	Checksum (lower 16bits of bytes 0 to 133 summation)	2	Bin

Table 2.	Configuration	Sector	Parameters
----------	---------------	--------	------------

Reserved Bytes

Bytes 0, 128, 129, 130, 131, 132, and 133 are reserved bytes. Write a zero value to these bytes when writing to the configuration sector.

Bluetooth Enable

Set this parameter to 1 for Bluetooth enabled and 2 for Bluetooth disabled. Factory Ship Default =1 enabled.

1	Bluetooth Enabled	1	Char ASCII
---	-------------------	---	------------

Valid ASCII Settings: 1, 2

Settings outside of the defined valid settings will cause the entire sector write to be discarded.

When the 3150 is programmed to a 2 value, the user must activate the Bluetooth by pressing the activation switch.



Activation Option

The Activation Option determines how a device turns on and off. The settings are:

- Sensor Connect Activation = 1
- Programmed Time On/Off = 2
- Spot Check Activation = 3 (factory ship default)

Valid ASCII Settings: 1, 2, 3

Settings outside of the defined valid settings will cause the entire sector write to be discarded.

2	Activation Option	1	Char ASCII	
---	-------------------	---	------------	--

Note: Setting the activation option to Spot Check Activation will cause the display option value to be "Full Display" regardless of what is received for display option setting.

Patient Data Storage Rate

The 3150 is capable of storing the SpO2 and PR data to memory. The Patient Data Storage Rate determines how often pulse rate and %SpO₂ are recorded. The settings are 1, 2, and 4 seconds. The factory ship default is 4 seconds.

Valid ASCII Settings: 1, 2, 4

Settings outside of the defined valid settings will cause the entire sector write to be discarded.

3	Patient Data Storage Rate	1	Char ASCII
---	---------------------------	---	------------

Display Option

The display can be programmed to full or partial display. In partial display, all indicators still work except the SpO2 and Pulse Rate values are not displayed. The settings are:

- 1 Full Display (default)
- 2 Partial Display (not an option when configured in spot-check mode)

Partial display is not possible when spot-check activation is selected. If partial display with spot-check activation is received, the 3150 will change the display value to a Full Display and a new checksum is calculated and stored in to the configuration sector.

Valid ASCII Settings: 1, 2

Settings outside of the defined valid settings will cause the entire sector write to be discarded.

4	Display Option	1	Char ASCII
---	----------------	---	------------



Programmed Start and Stop Times

The 3150 features three programmable start and stop time pairs. When using the sector write command, you must program a total of six programmable time values. If the programmable time period is not used, simply program these time values with a valid date and time, which can be in the past or future. Each time setting requires the time to be in the following format.

Format: YYMMDDhhmm

Name	Decimal Range
YY (year)	00-99
MM (month)	1-12
DD (day)	1-31*
hh (hour)	0-23
mm (minute)	0-59

*Depends on leap-year and month for accurate range

5	Programmed start time 1 (YYMMDDhhmm)	10	Char ASCII
15	Programmed stop time 1	10	Char ASCII
25	Programmed start time 2	10	Char ASCII
35	Programmed stop time 2	10	Char ASCII
45	Programmed start time 3	10	Char ASCII
55	Programmed stop time 3	10	Char ASCII

Programmable Identification

The programmable identification allows fifty characters to be programmed for any desired information.

65 Programmable Identification 50 Char ASCII**
--

**Fill unused characters with a zero value; Range limited to: 0x20 to 0xFF

To ensure correct termination when storing the ID as an independent string, consider storing the ID string as 50 characters + one single null.

Software Revision, Part number, Date

The software part number, revision, and revision date are not programmable. When writing to the configuration section fill these thirteen bytes with a zero value.

115	Software Part Number (1st 4 Digits)	4	Char ASCII
119	Software Revision	3	Char ASCII
122	Software Rev Date (YYMMDD)	6	Char ASCII



Checksum

The last two bytes of the configuration section contain the lower 16 bits of the sum of bytes 0 through 133.

134	Checksum (2 LS bytes of sum of bytes 0 to 133)	2	Binary
-----	--	---	--------

Get Configuration Sector

The current configuration sector can be read by sending the get configuration sector command:

CFG?<CR><LF>

Response to the get configuration sector command is: <ACK> followed by the 136 bytes of configuration sector information as defined in table 2. *A CP will be displayed and real-time data transmission will be suspended for 15 seconds after receiving this command. Any open patient record will be closed and new patient record started 15 seconds after receiving the last valid level 2 command.*

Set Date and Time Command

The date and time can be set by sending the following command:

DTM=(appended YYMMDDhhmmss)<CR><LF> where YY is year, MM is month, DD is day, hh is hour, mm is minute, and ss is second.

Response: <ACK> if the command is received and date and time are valid; <NAK> if date or time is invalid. A CP will be displayed and real-time data transmission will be suspended for 15 seconds after receiving this command. Any open patient record will be closed and new patient record started 15 seconds after receiving the last valid level 2 command.

Get Date and Time Command

When the 3150 receives the Get Date and Time Command, the 3150 will send the date and time. The get date and time command is:

DTM?<CR><LF>

Response: <ACK> (appended with YYMMDDhhmmss<CR><LF> where YY is year, MM is month, DD is day, hh is hour, mm is minute, and ss is second. A CP will be displayed and real-time data transmission will be suspended for 15 seconds after receiving this command. Any open patient record will be closed and new patient record started 15 seconds after receiving the last valid level 2 command.

Set Bluetooth Time-out Period

As a power saving feature the 3150 can be configured to turn off the Bluetooth after a 2 to 255 minutes from power on. The Bluetooth power saving feature can be enabled by setting the following command:

SBT=XXX<CR><LF> where XXX is a three character ASCII number in the range 0, 2 to 255 minutes. A zero value = no Bluetooth time-out period. Because the Bluetooth pairing process can take more than one minute, a 1 minute Bluetooth time-out period is not an option.

Response: After the command is received, the 3150 will send a <ACK> or <NAK>. A CP will be displayed and real-time data transmission will be suspended for 15 seconds after receiving this command. Any open patient record will be closed and new patient record started 15 seconds after receiving the last valid level 2 command.



Memory Playback Command

With the memory playback command, the 3150 will send the contents of the stored patient data beginning with the newest record and ending with the oldest record. To initiate the memory playback, send the following command:

MPB?<CR><LF>

Response: After the command is received, the 3150 will send a <ACK> and proceed to transmit the patient data memory. A CP will be displayed and real-time data transmission will be suspended for 15 seconds after receiving this command. Any open patient record will be closed and new patient record started 15 seconds after receiving the last valid level 2 command.

Because of the complexity of the patient data storage real-time memory playback, the memory playback information will be made available upon request.

Cancel Memory Playback Command

When the 3150 receives the Cancel Memory Playback command, the 3150 will stop the memory playback if the 3150 is actively sending memory playback data.

CAN!<CR><LF>

Response: If in memory playback, then respond by stop memory playback. If the 3150 is not in memory playback mode, the 3150 will send a <NAK>. A CP will be displayed and real-time data transmission will be suspended for 15 seconds after receiving this command. Any open patient record will be closed and new patient record started 15 seconds after receiving the last valid level 2 command.

Clear Stored Patient Data Records from Memory

With the clear stored patient data recordings command, the 3150 will clear all stored patient memory. To initiate a memory clear, send the command:

MCL!<CR><LF>

Response: For each successful memory clear, the 3150 will send a <ACK> <CR> <LF>. If the memory clear failed, the 3150 will send a <NAK> <CR> <LF>. A CP will be displayed and real-time data transmission will be suspended for 15 seconds after receiving this command. Any open patient record will be closed and new patient record started 15 seconds after receiving the last valid level 2 command.



Serial Data Format Definition (SPP Profile)

The 3150 features five serial data formats using the SPP communication profile.

- Serial data format #1 This data form is retained for legacy purposes and is similar to DF8. For new product development that need measurements every second, use DF8.
- Serial data format #2 (default) Real-time oximetry measurements is sent every 1/3 of a second. Compressed 8 bit waveform is sent every 1/75 of a second.
- Serial data format #7 Real-time oximetry measurements is sent every 1/3 of a second. Full resolution 16 bit waveform is sent every 1/75 of a second.
- Serial data format #8 Real-time oximetry measurements is sent every second.
- Serial data format #13 Single point spot-check meaurement is sent after the SmartPoint Algorithm completes. Store and forward capability.

Serial data formats 2, 7, 8, and 13 feature Nonin's SmartPoint Technology. The SmartPoint algorithm automatically determines when a high quality measurement is present.

Communication Rate

All data formats:

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

Serial Data Format #1 Definition

This data format is supported by the 3150 for legacy purpose. DF1 is not described in this document. For new product development and compliance to ISO9919 standards, please use data formats 2, 7, 8, or 13.

Serial Data Format #2 Definition

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 SpO_2 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.

Packet	Frame								
	Byte 1	Byte 2	Byte 3	Byte 4	Byte 5				
1	01	STATUS	PLETH	HR MSB	СНК				
2	01	STATUS	PLETH	HR LSB	СНК				
3	01	STATUS	PLETH	SpO ₂	СНК				
4	01	STATUS	PLETH	SREV	СНК				
5	01	STATUS	PLETH	reserved	СНК				
6	01	STATUS	PLETH	TMR MSB	СНК				
7	01	STATUS	PLETH	TMR LSB	СНК				
8	01	STATUS	PLETH	STAT2	СНК				
9	01	STATUS	PLETH	SpO ₂ -D	СНК				
10	01	STATUS	PLETH	SpO ₂ Fast	СНК				
11	01	STATUS	PLETH	SpO ₂ B-B	СНК				
12	01	STATUS	PLETH	reserved	СНК				
13	01	STATUS	PLETH	reserved	СНК				
14	01	STATUS	PLETH	E-HR MSB	СНК				
15	01	STATUS	PLETH	E-HR LSB	СНК				
16	01	STATUS	PLETH	E-SpO ₂	СНК				
17	01	STATUS	PLETH	E-SpO ₂ -D	СНК				
18	01	STATUS	PLETH	reserved	СНК				
19	01	STATUS	PLETH	reserved	СНК				
20	01	STATUS	PLETH	HR-D MSB	СНК				
21	01	STATUS	PLETH	HR-D LSB	СНК				
22	01	STATUS	PLETH	E-HR-D MSB	СНК				
23	01	STATUS	PLETH	E-HR-D LSB	СНК				
24	01	STATUS	PLETH	reserved	СНК				
25	01	STATUS	PLETH	reserved	СНК				

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 1/75 of second.

Range: 128 to 255

Byte 2 - Status								
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0	
1	Б	ADTE	ООТ	SNSE	YP	RF	SVNC	
1			001	SNOF	RPRF	GPRF	STNC	
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 plethysmographic 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 serial data format #7.

Range: 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 – STAT 2								
BIT7	BIT6	BIT5	BIT4	BIT3	BIT2	BIT1	BIT0	
					R	R		
Note: Bit 7 is always set.								

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

Operation Modes

The 3150 offers two operation modes that can be selected based on the user requirements.

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 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.



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 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. 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 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

SpO₂ 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 Definition

This data format provides the same information as serial data format #2, except that the waveform value provides the full resolution of 16-bits instead of 8-bits. It is recommended for applications where a high resolution waveform is desired.

Packet Description

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

Packet	Frame								
	Byte 1	Byte 2	Byte 3	Byte 4	Byte 5				
1	STATUS	PLETH MSB	PLETH LSB	HR MSB	СНК				
2	STATUS	PLETH MSB	PLETH LSB	HR LSB	СНК				
3	STATUS	PLETH MSB	PLETH LSB	SpO ₂	СНК				
4	STATUS	PLETH MSB	PLETH LSB	SREV	СНК				
5	STATUS	PLETH MSB	PLETH LSB	reserved	СНК				
6	STATUS	PLETH MSB	PLETH LSB	TMR MSB	СНК				
7	STATUS	PLETH MSB	PLETH LSB	TMR LSB	СНК				
8	STATUS	PLETH MSB	PLETH LSB	STAT2	СНК				
9	STATUS	PLETH MSB	PLETH LSB	SpO ₂ -D	СНК				
10	STATUS	PLETH MSB	PLETH LSB	SpO ₂ Fast	СНК				
11	STATUS	PLETH MSB	PLETH LSB	SpO ₂ B-B	СНК				
12	STATUS	PLETH MSB	PLETH LSB	reserved	СНК				
13	STATUS	PLETH MSB	PLETH LSB	reserved	СНК				
14	STATUS	PLETH MSB	PLETH LSB	E-HR MSB	СНК				
15	STATUS	PLETH MSB	PLETH LSB	E-HR LSB	СНК				
16	STATUS	PLETH MSB	PLETH LSB	E-SpO ₂	СНК				
17	STATUS	PLETH MSB	PLETH LSB	E-SpO ₂ -D	СНК				
18	STATUS	PLETH MSB	PLETH LSB	reserved	СНК				
19	STATUS	PLETH MSB	PLETH LSB	reserved	СНК				
20	STATUS	PLETH MSB	PLETH LSB	HR-D MSB	СНК				
21	STATUS	PLETH MSB	PLETH LSB	HR-D LSB	СНК				
22	STATUS	PLETH MSB	PLETH LSB	E-HR-D MSB	СНК				
23	STATUS	PLETH MSB	PLETH LSB	E-HR-D LSB	СНК				
24	STATUS	PLETH MSB	PLETH LSB	reserved	СНК				
25	STATUS	PLETH MSB	PLETH LSB	reserved	СНК				

Notes:

Byte number 1 in each frame is greater than 127.

Reserved bytes are undefined (range of 0 to 127).



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	Б	ADTE	ООТ	SNSE	YP	RF	SYNC			
I	ĸ	ARTE	001	SNOF	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 plethysmographic 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 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 – STAT 2										
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 soc	n as possible.

SPA: High quality SmartPoint Measurement

R: Reserved (range - 0 or 1), for future use

Operation Modes

The 3150 offers two operation modes that can be selected based on the user requirements.

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 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.



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 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. 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 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

SpO₂ 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 Definition

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: SpO_2 and pulse rate formatted for display, status of the measurement, and status of the battery.

Packet Description

Four bytes of data are transmitted once per second.

Byte 1 - Status									
BIT7	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 BIT									
0	HR6	HR5	HR4	HR3	HR2	HR1	HR0		
*Note: Bit	*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	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	Reserved for future use.
	(range – 0 or 1)	



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

SpO₂-D: 4-beat SpO₂ 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.

Serial Data Format #13 Definition

Data Format 13 sends a single SpO_2 and PR value from a given point in time. The oximeter does the work of selecting a valid measurement by using its SmartPoint algorithm. It is commonly used for spotchecking applications. Assuming a Bluetooth connection is present, serial data format #13 will first send any stored measurements and then send the new SmartPoint measurement.

To provide a quality measurement for the patient recording, the patient pulse signal is analyzed during the first 15 to 40 seconds. During this period the displayed SmartPoint indicator will flash. Once the analysis is complete, the SmartPoint indicator stops flashing and remains solidly on for 10 seconds before turning off. If a quality SmartPoint measurement is not possible within 40 second from turn-on, the 3150 will turn off the SmartPoint indicator and send the current unqualified measurement. If a SmartPoint measurement is not sent using the Bluetooth connection, the measurement is stored in to the non-volatile memory at power down. As a power saving feature, the 3150 turns off the Bluetooth shortly after the measurement is sent.





Packet Description

The serial data format #13 packet includes 6 bytes of header information, a minimum of 14 bytes of spotcheck 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).

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	7	20	Hundredths place of Year (default to 20)	BCD
Spot-check	8	Year of Measurement	Year of Measurement (00-99)	BCD
Data	9	Month of Measurement	Month of Measurement (01-12)	BCD
[See notes]	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

The spot-check data consists of the time of spot-check, SpO₂, pulse rate, and status.

* 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).

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
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 or choose a different finger.

Serial Data Format #13 - Memory Storage of Spot-Check Measurements

The 3150 has memory capacity to store 20 measurements. When a wireless connection is made the 3150 oximeter will forward the oldest stored measurements prior to sending the new measurement. After stored measurements are sent they are removed from memory.

Note: If the finger is removed before 40 seconds and a SmartPoint measurement is not available, no data will be sent or stored in memory.



Optional Data

The following data is available when the expansion option is set to Enabled (see Selecting Data Format in Command Protocols section).

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	21	S9	Serial Number	ASCII
Option	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).



Indications for Use

The Nonin Model 3150, WristOx₂^m Pulse Oximeter is a small, wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (%SpO₂) and pulse rate. It may be used for spot-checking and/or data collection and recording of adult and pediatric patients, during both no motion and motion conditions, and for patients who are well or poorly perfused. The intended use environments are hospitals, medical facilities, ambulatory, subacute, and sleep study environments.

▲ Caution:

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

Contraindications

Do not use this device in a Magnetic Resonance (MR) environment or in the presence of flammable anesthetics or gases.

This device is not defibrillation proof per IEC 60601-1:1988/A2:1995 clause 17h.

Warnings

This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

Carefully route patient cables and connections to reduce the possibility of patient entanglement or strangulation.

Use only Nonin-branded PureLight[®] pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.

This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of this device is not possible. Except to replace batteries, do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

The USB cable must be unplugged from the device before replacing batteries.

This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

The use of accessories, sensors, and cables other than those listed in this manual may result in increased electromagnetic emission and/or decreased immunity of this device.

Do not use the device when alarms are required.

Do not use a damaged sensor.

This equipment complies with International IEC 60601-1-2:2007 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.

Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

DNONIN

A Cautions

If this device fails to respond as described, refer to "Troubleshooting" or discontinue use until the situation has been corrected. Contact Nonin Technical Service.

This device has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the device may still interpret motion as good pulse quality.

Check the pulse oximeter sensor application site every 6-8 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition.

Do not place liquids on top of this device.

Do not place the WristOx₂, Model 3150, in liquid or clean it with agents containing ammonium chloride or isopropyl alcohol. Refer to the "Care and Maintenance" section of this operator's manual.

Use a detergent that is safe for skin and washable surfaces. Most detergents can be high sudsing, so use sparingly. Wipe with a damp, detergent free cloth to remove residue.

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.

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:

- excessive ambient light
- excessive motion
- electrosurgical interference
- blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
- moisture in the sensor
- improperly applied sensor
- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiogreen and other intravascular dyes
- carboxyhemoglobin
- methemoglobin
- dysfunctional hemoglobin
- artificial nails or fingernail polish

Do not perform any testing or maintenance on this device while it is being used to monitor a patient.

Verify all visible indicators appear during the start-up (initialization) sequence. If any indicator does not appear, do not use the device. Contact Nonin Technical Service for assistance.

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.



A Cautions

To avoid the risk of confusing or misinterpreting patient data when transmitting data via Bluetooth, verify the device is paired with the correct display unit.

The pulse oximeter may not work when circulation is reduced. Warm or rub the finger or reposition the sensor.

A functional tester cannot be used to assess the accuracy of the oximeter or sensor.

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

ENON

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 3150, 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 device 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. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
- The WristOx₂, Model 3150, 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 device has been shown to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.
- 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 3150

Guide to Symbols on the Module

Symbol	Description
\wedge	Caution!
i	Consult Instructions for Use.
EC REP	Authorized Representative in the European Community
€ 01230	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
Ŕ	Type BF Applied Part (Patient isolation from electrical shock).
∭ Sp0₂	No alarms
	Indicates separate collection for electrical and electronic equipment (WEEE).
5	Continua Certified [™] signifies that this product has been tested and proven to be interoperable with other products that carry the Continua Certified symbol.
œ	Bluetooth®
$(((\bullet)))$	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.
c Us	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.
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.



Manufacturer's Declaration

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

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 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.				
RF Emissions CISPR 11	Class B					
Harmonic Emissions IEC 61000-3-2	N/A	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-				
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	voltage power supply network that supplies buildings used for domestic purposes.				

 Table 3.
 Electromagnetic Emissions

Table 4.	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	±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	$\pm 5\% U_T$ (>95% dip in U _T) for 0.5 cycle $\pm 40\% U_T$ (60% dip in U _T) for 5 cycles $\pm 70\% U_T$ (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.						



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 V _{rms} 150 kHz to 80 MHz	N/A	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 800 MHz			
			d = 2.33 \sqrt{P} 800 MHz 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: $((\bullet))$			
Notes:						

Table 5. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

• At 80 MHz and 800 MHz, 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.

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

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.



Table 6. 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.37	0.37	0.73	
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 800 MHz, 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 and low perfusion testing was conducted by Nonin Medical, Inc., as described below.

SpO₂ 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 (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Pulse Rate Motion Testing

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

Low Perfusion Testing

This test uses an SpO₂ Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO₂ levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 9919:2005 for heart rate and SpO₂ at the lowest obtainable pulse amplitude (0.3% modulation).

Additional Information

Refer to the WristOx₂, Model 3150, Operator's Manual for additional information.