Model 3231 Pulse Oximeter
OEM Integration Guide and Specification

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

nonin.com

9751-000-03

Contents

1 Change Log

This section provides a brief description of the changes incorporated into the release document.

- Initial release of specification.

Revision 02

- Corrected pulse amplitude definition.
- Changed the SpO_2 and Pulse Rate averaging from 8 beats to 4 beats to be consistent with other Nonin eHealth products.

2 Acronyms and Abbreviations

AC	Alternating Current
A_{rms}	Accuracy (root mean square)
BPM	Beats per Minute
C	Celsius
cm	Centimeter
dBm	Decibel
DC	Direct Current
DF	Data Format
EU	European Union
F	Fahrenheit
ft	Feet
GHz	Gigahertz
IEC	International Electrotechnical Commission
in.	Inches
ISO	International Standards Organization
IPA	Isopropyl Alcohol
LSB	Least Significant Byte
mm	Millimeter
MSB	Most Significant Byte
mW	Milliwatts
OEM	Original Equipment Manufacturer
PI	Pulse Amplitude Index
PR	Pulse Rate
R	Reserved
RoHS	Restriction of Hazardous Substances
s	Second
SaO_2	Arterial Oxygen Saturation
SPA	SmartPoint™ Algorithm
SpO_2	Saturation Peripheral Oxygen
TX	Transmit

3 Definitions

Term	Definition
%SpO_2	Percent functional hemoglobin oxygen saturation.
Digit	Fingers and thumbs for oximetry measurement.
Operator	Person handling equipment. In telemedicine applications, the operator is typically the patient.
Patient	A person receiving care or treatment from a clinician.
Pulse Rate	The number of times the heart beats in each minute – expressed as Beats per Minute (BPM).
SmartPoint™	An eHealth algorithm that determines when a quality measurement is available. See SmartPoint section for more information.
Spot-check	A pulse oximeter measurement that is short in duration, for example less than 1 minute.

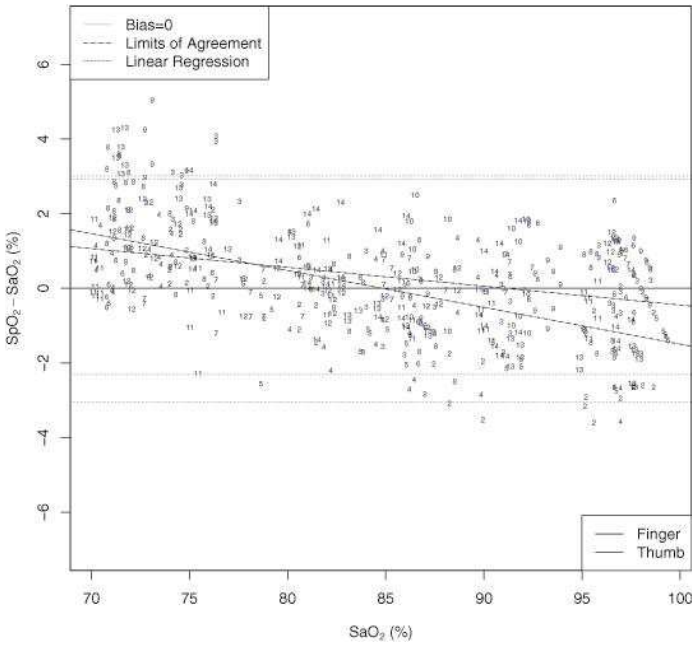
4 Specifications

Oxygen Saturation Range (SpO_2)	0 to 100%
Pulse Rate Range	18 to 321 beats per minute (BPM)
Declared Accuracy The table below shows A_{rms} values measured in a clinical study.	

NOTE: If your national regulatory authority recognizes accuracy in motion, please contact regulatory@nonin.com for accuracy data.

Accuracy Summary – Finger and Thumb

Range	Specified Oxygen Saturation (A_{rms})	Finger Oxygen Saturation (A_{rms})	Thumb Oxygen Saturation (A_{rms})	Low Perfusion Oxygen Saturation (A_{rms})
70 – 100%	± 2	± 1.31	± 1.56	± 2
70 – 80%	± 2	± 1.65	± 1.91	± 2
80 – 90%	± 2	± 1.05	± 1.21	± 2
90 – 100%	± 2	± 1.18	± 1.49	± 2



This graph shows plots of the error (SpO_2-SaO_2) by SaO_2 using the oximeter data with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study in non-motion conditions.

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
Pulse Rate Accuracy (A_{rms})**	
Pulse Rate Accuracy (20 – 250 BPM):	±3 digits
Low Perfusion Pulse Rate Accuracy (40 – 240 BPM):	±3 digits
Voltage Input	USB Interface
Weight	< 72 grams (2.5 oz) including cable and connector
Temperature	
Operating:	-5 °C to +40 °C (+23 °F to +104 °F)
Storage/Transportation:	-40 °C to +70 °C (-40 °F to +158 °F)***
Operating Altitude	0 to 5,000 meters (0 to 16,404 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.
Enclosure Degree of Ingress Protection	IP32
Dimensions	46 mm x 69 mm x 31 mm (Cable length: 1 meter)
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

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

** ±1 A_{rms} represents approximately 68% of measurements.

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

4.1 USB Technology Information

USB Compliance	Specification Release 2.0 Compliant
USB Modes	Single
USB Speed	Full
Power Source	USB Bus
Data Rate	12 Mbit/second
Data Latency	Less than 1 ms
Data Format	Sends data packets once per second. Includes a second counter that allows the host to detect if packets are missing from the data stream.
Quality of Service	This device uses USB technology for wired communications. To provide error detection, the USB standard uses a checksum called a cyclic redundancy check (CRC) on all data packets. If a corrupted packet is received, the packet will be re-transmitted. Testing has been completed to show that the 3231 has passed the USB-IF Full Speed Device Compliance Testing, including device framework testing, electrical testing, and interoperability testing. The 3231 transmits physiological data once per second. If data is lost, the device will transmit data again one second later.
Security	The 3231 USB interface is wired and is therefore secure from unintended data interception.

4.1.1 Connectivity

The 3231 uses USB technology for wired communications and as a power source. Failure of the USB connection could result in loss of transmitted data and power to the device.

4.1.2 Connection of the 3231 into a Medical System

Incorporating the 3231 into a medical system requires the integrator to identify, analyze, and evaluate the risks to patient, operators, and third parties. Subsequent changes to the medical system after 3231 integration could introduce new risks and will require additional analysis. Changes to the medical system that must be evaluated include:

- Changing the system configuration
- Adding devices to or disconnecting devices from the system
- Updating or upgrading equipment connected to the system

5 Connectivity

The 3231 standard connectivity is USB.

5.1 USB Connector

Input: USB Port power and ground

Output: USB 2 wire interface TX/RX – Nonin-proprietary data format

5.2 Data Output on USB Connector

The 3231 data output is Nonin's proprietary Data Format 19.

5.2.1 Data Format 19 Packet

Oximeter Data Packet		
Byte	**Field**	**Description**
STX	02	START OF PACKET
1	Length	The number of bytes used including this one
2	Status	Indicates the current device status (defined below).
3	Reserved	Reserved for future use.
4-5	Pulse Amplitude Index (PI)	PI = AC/DC×100%. Units 0.01% (hundredths of a percent)
6-7	Counter	Value increases on each second. Value is incremented on each second from turn-on (between 0 – 65535). Counter can be used to confirm no data loss.
8	SpO_2	SpO_2 percentage, 0 – 100 (4-beat average as displayed).
9-10	Pulse Rate	Pulse rate in beats per minute, 0 – 321 (4-beat average as displayed).
>10	Reserved	Reserved for future use.
ETX	03	END OF PACKET

Byte 1 Length Field – This field contains the length of the data included in this format. It will be inclusive of this field.

Byte 2 Status Field –

Status Field (Active High)		
Bit	**Field**	**Description**
6-7	Reserved	Reserved for future use
5	Reserved	Reserved for future use.
4	CorrectCheck	1 = Pass 0 = Slide finger further into device*
3	Searching	Oximeter is searching for a consecutive pulse signals.
2	SmartPoint	Used to indicate that the data successfully passed the SmartPoint Algorithm (SPA).
1	Low/Weak Signal	Pulse signal strength is 0.3% modulation or less
0	Display Sync Indication	Indicates that the display is in sync mode with the collector.

* If CorrectCheck = 0, the pulse oximeter reading may be marginal. If the finger is not inserted completely to finger stop, the light may shunt around the finger, which may cause invalid pulse oximeter readings.

Byte 3 Reserved – This byte is reserved for future use.

Bytes 4 and 5 Pulse Amplitude Index Field – PI = AC/DC×100% where AC is the pulsatile component of the infrared signal and DC is the non-pulsatile component of the infrared signal. Range 0.00% to 20.00%. Byte 4 and 5 contains the value of PI multiplied by 100.

Example: The value of 0x02FF (decimal value = 767) would indicate that the value of PI is 7.67%.

Byte 6 and 7 Packet Number Field – This value increases on each second. The value shall increase from 0 to 65535, then roll-over and restart to 0.

Byte 8 SpO_2 Field – SpO_2 percentage, 0 – 100 (4-beat average as displayed). In the case of missing SpO_2 data, the value reported shall be 127.

Byte 9 and 10 Pulse Rate Field – Pulse rate in beats per minute, 0 – 321 (4-beat average as displayed). In the case of missing pulse rate data, the value reported shall be 511. Byte 9 will contain the MSB of the pulse rate. Byte 10 will contain the LSB of the pulse rate.

5.3 Features

5.3.1 PureSAT SpO_2 and Pulse Rate Algorithm

Nonin Medical's clinically-proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements – even in the presence of motion, low perfusion or other challenging conditions. By reading the entire plethysmographic waveform, PureSAT signal processing prefilters the pulse signals to remove undesirable signals and advanced algorithms then separates the pulse signals from artifact and interference – leaving only the true pulse. With Nonin's smart averaging technology, PureSAT automatically adjust to each patient's condition to provide fast and reliable readings you can trust.

5.3.2 SmartPoint eHealth Algorithm

The SmartPoint algorithm provides a fast and accurate snapshot of the patient's SpO_2 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 available.

As part of the serial data, a SmartPoint indicator is sent with each SpO_2 and pulse rate value. The SmartPoint condition is also used to enter display sync mode.

5.3.3 CorrectCheck Finger Placement Technology

Nonin's proprietary CorrectCheck technology provides feedback via a digital display and serial data if the finger is not placed correctly in the device. This is helpful because improper finger placement may lead to incorrect readings. The information is provided on the device screen at turn-on if the finger is not placed properly and indicates the patient should insert his or her finger further into the device. This information is also provided in the data stream to allow a remote nurse to coach the patient on proper finger placement.

6 Indications for Use

The Nonin Model 3231 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients with digits that are between 0.8 – 2.5 cm (0.3 – 1.0 inch) thick.

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

CAUTION: Regulatory authorities outside the U.S. recognize the use of this device in motion conditions.

7 Testing Summary

7.1 SpO_2 Accuracy Testing

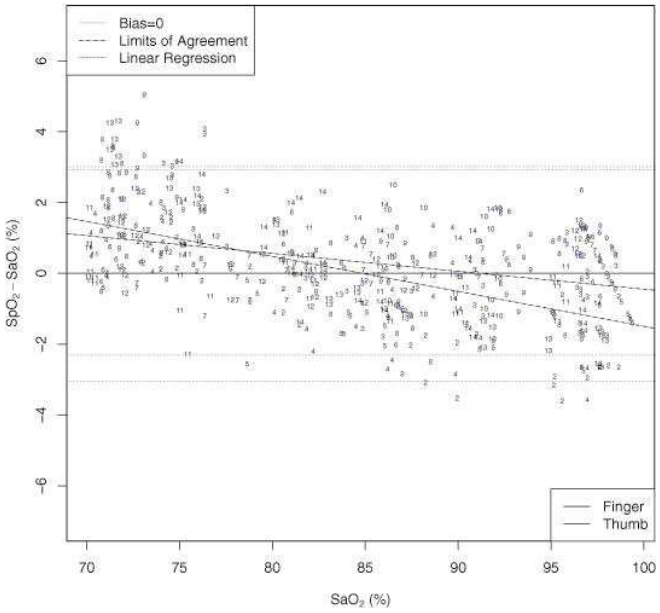
At an independent research laboratory, SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light-to-dark-skinned subjects that are 18 years of age and older. The measured arterial hemoglobin saturation value (SpO_2) of the device is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the device is in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61 and ISO 9919, Standard Specification for Pulse Oximeters for Accuracy.

NOTE: If your national regulatory authority recognizes accuracy in motion, please contact regulatory@nonin.com for accuracy data.

The table below shows A_{rms} values measured in a clinical study in non-motion conditions.

Accuracy Summary – Finger and Thumb

Range	Specified Oxygen Saturation (A_{rms})	Finger Oxygen Saturation (A_{rms})	Thumb Oxygen Saturation (A_{rms})	Low Perfusion Oxygen Saturation (A_{rms})
70 – 100%	± 2	± 1.31	± 1.56	± 2
70 – 80%	± 2	± 1.65	± 1.91	± 2
80 – 90%	± 2	± 1.05	± 1.21	± 2
90 – 100%	± 2	± 1.18	± 1.49	± 2



This graph shows plots of the error (SpO_2-SaO_2) by SaO_2 using the oximeter data with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study in non-motion conditions.

7.2 Low Perfusion Testing

This test uses a SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings of various SpO_2 levels. The device must maintain accuracy in accordance with ISO 80601-2-61 and ISO 9919 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

7.3 Performance in Motion

Motion artifact simulation introduced by a pulse oximeter tester determines whether the oximeter meets the criteria of ISO 80601-2-61 and ISO 9919 for pulse rate during simulated movement, tremor, and spike motions.

Contact regulatory@nonin.com for more information regarding motion testing.

8 Compliance

ISO 9919

ISO 80601-2-61

IEC 60601-1-2

IEC 60601-1

Contact regulatory@nonin.com for more information.

9 Other

For all other information, refer to the Model 3231 instructions for use.