Instructions for Use – English

Onyx®3 Model 9591 Finger Pulse Oximeter

℞ Only CE 0123

Installing Batteries

Two 1.5 volt AAA-size batteries power the device for about 2,000 spot checks or 25 hours of operation. Nonin recommends using alkaline batteries (included with each new device). When batteries are low, the numeric displays flash once per second. Remove batteries if the device will be stored for more than 30 days. Replace low batteries as soon as possible, using the instructions below.

WARNING: Before changing batteries, make sure the device is off and is not applied to a digit.

1. Hold the device as shown in **Figure 1**. To release the device's battery tray, press upward and then pull outward slightly with the thumb.
2. Remove the old batteries from the battery tray. Dispose of the batteries properly.
3. Insert two new 1.5 volt AAA-size batteries. Follow the polarity markings (+ and -) as illustrated in **Figure 2**. *Proper positioning of the batteries is essential for operation.*
4. Carefully guide the battery tray back onto the device. Press downward and then push inward slightly to re-secure the battery tray (**Figure 3**). *Do not force it into place; it fits only when properly positioned.*
5. Insert your finger into the device to verify operation. See the *Activating the Onyx3 Device and Verifying Operation* section for more information.

Figure 1

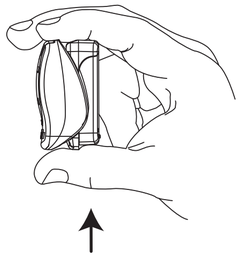


Figure 2

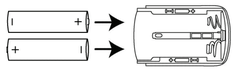
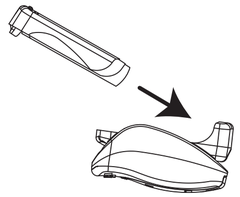


Figure 3



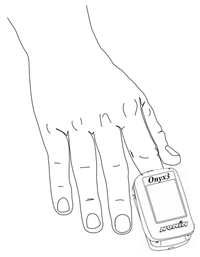
Activating the Model 9591 and Verifying Operation

The device contains an LCD screen that displays oxygen saturation, pulse rate and respiration rate. The multicolor LCD display provides a visual indication of the poor signal quality described in the Display Symbols table.

Activate the device by inserting the patient's finger into the device. The device detects the inserted finger and automatically illuminates the display. Correct positioning of the device on the finger is critical for accurate measurements.

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

1. Insert the patient's finger, nail side up, into the device until the fingertip touches the built-in stop guide.



2. Make sure the finger is lying flat (not on its side) and is centered within the device. For best results, keep the device at the patient's heart or chest level.
3. If the CorrectCheck screen (see *Display Symbols* table) displays, slide finger further into device. Correct positioning of the finger is critical for accurate measurements.
4. If the device does not turn on, remove the finger and wait a few seconds before reinserting it.

When a finger is inserted, the device performs a brief startup sequence. Verify that the LCD screen illuminates during the startup sequence. If any part of the screen is not lit, do not use the device; contact Nonin Technical Service for repair or replacement.

After the startup sequence, the device begins sensing the pulse. Allow the device to stabilize and observe about 4 seconds before relying on the displayed values. Continually verify operation. It is common for the displayed values to fluctuate slightly over a period of several seconds. If the poor signal quality indicator continually blinks, try another finger.

A ⃠ appears in the display when the device senses the finger has been removed. The last measured SpO_2, pulse rate and respiration rate values display for 10 seconds while the device automatically turns off. The device will automatically shut off (to conserve battery life) approximately 10 seconds after the finger is removed, or after a 2-minute period of inadequate pulse signals.

If the device does not turn on or if it shuts off unexpectedly:

- Verify batteries are correctly inserted.

NOTE: If batteries are installed backwards, the unit will not function.

- The batteries are depleted. Replace batteries.

If the problem persists, remove the batteries and contact Nonin Technical Service.

The Oxitest^{Plus7} by Datrend Systems, Inc. can be used to verify operation of the pulse oximeter.

Connection via *Bluetooth* Wireless Technology

When the Model 9591 is placed on the finger and turns on, it is ready for a *Bluetooth* wireless connection. The 9591 stays in this mode until it is shut off or the *Bluetooth* radio turns off. The ᛒ symbol is white when the *Bluetooth* radio is on, green when the 9591 is connected, and flashes when there is a communication error.

The *Bluetooth* symbol is useful for the product installer.

Due to the wide variety of wireless environments, the *Bluetooth* connection between the 9591 and the host device must be tested before using the 9591's *Bluetooth* capabilities.

Indications for Use

The Nonin® Model 9591 Finger Pulse Oximeter is a small, lightweight, portable and reusable spot-check device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. The Respiration Rate parameter provides a non-invasive measurement of respiration rate, in breaths per minute.

For %SpO2, pulse rate, and respiration rate the 9591 is intended for use in professional healthcare and home healthcare settings in adult and pediatric patients who are well or poorly perfused, with digits that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.

Warnings

- Use the device within its designated range (approximately 10 m/32 ft, spherical radius, line of sight when connected to a Bluetooth Smart Ready device). Moving outside this range may cause missing, lost, and/or inaccurate data.
- Do not use the device in an MR environment, in an explosive atmosphere, or on infant or neonatal patients.
- This device is not defibrillation proof per IEC 60601-1.
- Inspect the device application site at least every 4 hours to ensure correct device alignment and skin integrity. Patient sensitivity to the device may vary due to medical status or skin condition.
- Avoid excessive pressure to the device application site as this may cause damage to the skin beneath the device.
- This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- The device must be able to measure the pulse properly to obtain an accurate SpO_2 and respiratory rate measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 and respiratory rate measurement.
- Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
- General operation of the device may be affected by the use of an electrosurgical unit (ESU).
- 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.
- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Certain activities may pose a risk of injury, including strangulation, if lanyard should become wrapped around your neck.
- Before changing batteries, make sure the device is off and is not applied to a digit.

Cautions

- This device has no audible alarms and is intended only for spot-checking.
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin and respiration rate. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - applying the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s) (IVs)
  - excessive light, such as sunlight or direct home lighting
  - excessive motion
  - moisture in the device
  - improperly applied device
  - digit is outside recommended size range
  - poor pulse quality
  - patient talking
  - respiration outside the range of 3-44 breaths per minute
  - venous pulsations
  - anemia or low hemoglobin concentrations
  - cardiogreen and other intravascular dyes
  - carboxyhemoglobin
  - methemoglobin
  - dysfunctional hemoglobin
  - artificial nails or fingernail polish
  - residue (e.g., dried blood, dirt, grease, oil) in the light path
- Respiration rate provides an indicator of central ventilatory drive and not a direct indication that air is moving through the upper airway. Always consider clinical signs and symptoms when assessing the patient and before intervening.
- Respiration Rate should not be used on patients with significantly irregular cardiac rhythms (defined as three or more events of irregularity observed within 30 seconds) because the presence of these irregular cardiac rhythms may cause inaccurate respiration rate values or the loss of displayed respiration rate information. Safety and effectiveness of Respiration Rate in patients with significantly irregular cardiac rhythms have not been established. Use an alternate means of monitoring ventilatory status for patients with significant cardiac dysrhythmia.
- Respiration rate may present inaccurate respiration rate values when respiration rate exceeds 50% of heart rate. This situation, though rare, may occur under conditions including, but not limited to, any of the following: patients with high respiration rate and low heart rate, patients taking beta blockers, or patients with specific medical conditions such as sick sinus syndrome.
- The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
- This device's display will go blank after 2 minutes of no readings or poor readings.
- In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.
- Clean the device before applying it to a patient.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids onto the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride.
- This device is a precision electronic instrument and must be repaired by Nonin Technical Service. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- A flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring. Do not hang the lanyard from the device's flexible circuit.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter.
- This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Portable and mobile RF communications equipment including CT, diathermy, RFID, and electronic article security systems can affect medical electrical equipment.
- Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for more than 30 days. Do not use different types of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.
- Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. If you are unsure how to reach your distributor, please call Nonin for your distributor's contact information.
- When using the device in the home, avoid exposing the device to lint and dust.

Symbols

Symbol	Definition
⚠	Caution!
	Follow Instructions for Use.
	MR unsafe
	Type BF Applied Part (patient isolation from electrical shock)
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1, UL 60601-1 and CAN/CSA-C22.2 No. 601.1.
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
	Date of Manufacture
	Continua Certified™ signifies this device meets Continua certification testing requirements, which support interoperability in personal health devices (continuaalliance.org).
	Indicates separate collection for electrical and electronic equipment (WEEE)

Symbol	Definition
	Not for continuous monitoring (no alarm for SpO_2)
	Battery orientation
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm (0.1 in.) in diameter per IEC 60529.
SN	Serial Number
BDA	*Bluetooth* Device Address
	Storage/shipping temperature range
	Handle with care
	Keep dry
℞ Only	Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.
	Country of Manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue number
QTY	Quantity

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

Display Symbols

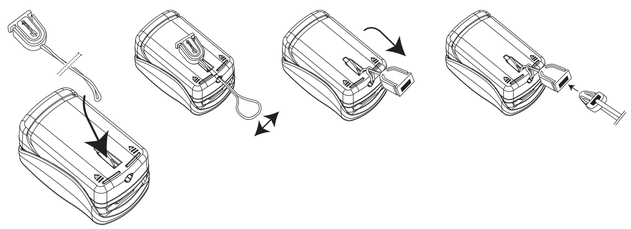
Symbol	Description
	Nonin's CorrectCheck™ senses that the finger has not been correctly inserted. If you see this symbol, slide finger further into device.
% SpO_2	The number next to this symbol is the amount of oxygen in your blood (functional oxygen saturation of arterial hemoglobin).
	The number next to this animated symbol is your pulse rate. Pulse rate is the number of times your heart beats per minute.
RR	The number next to this symbol is Respiration Rate in breaths per minute.
---	Dashes replace the readings when the Model 9591 is unable to detect a usable signal.
	Bluetooth Symbols: **White symbol** – Radio is on. **Green symbol** – Model 9591 is connected. **Flashing symbol** – Connection error. The radio will reset. **No symbol** – Radio is off.
	Poor signal. Steady your hand, reposition finger, warm finger by rubbing, or select a different finger.
	Low battery. Replace batteries.
	Critical battery. Flashing indicator on full screen. The device will not work until the batteries are replaced.

Using the Lanyard

WARNING: Certain activities my pose a risk of injury, including strangulation, if lanyard should become wrapped around your neck.

⚠ **CAUTIONS:**

A flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring. Do not hang the lanyard from the device's flexible circuit.



Model 9591 Care, Maintenance, and Cleaning

The advanced digital circuitry within the device requires no calibration or periodic maintenance other than battery replacement. The device's expected service life is 2 years. Field repair of the device circuitry is not possible. Do not attempt to open the case or repair the electronics. Opening the case will damage the device and void the warranty. Do not open the Device more than 90°, and do not twist or pull on the device when cleaning.

Cleaning the Model 9591

⚠ **CAUTIONS:**

- Clean the device before applying it to a new patient.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids into the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning products containing ammonium chloride.

1. To clean, wipe the surfaces with a soft cloth dampened with mild detergent, isopropyl alcohol or a 10% bleach solution (household bleach [5.25% sodium hypochlorite]). Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result.
2. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry.

Equipment Response Time

If the signal from the device is inadequate, the last measured SpO_2, pulse rate and respiration rate values freeze for 10 seconds and are then replaced with dashes.

Table 1: Equipment Response Time

SpO2 Values	Average	Latency
Standard/Fast Averages SpO_2	4 beat exponential	2 beats
Pulse Rate Values	**Response**	**Latency**
Standard/Fast Averages Pulse Rate	4 beat exponential	2 beats
Respiration Rate Values	**Response**	**Latency**
Fast Estimation of RR	3 breath average	20 Seconds
Average RR	9 breath average	45 Seconds
Equipment Delays	**Delay**	
Display Update Delay	1.5 seconds	

Example: SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second; pulse rate = 75 BPM
The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 and respiration rate accuracy and low perfusion testing was conducted by Nonin Medical, Inc. as described below.

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 aged 18 years 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.

Low Perfusion Testing

This test uses an 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).

Respiration Rate Accuracy Testing

RR accuracy testing is conducted during spontaneous breathing studies on healthy, male and female, light-to-dark-skinned subjects that are aged 18 to 50 years old. The measured fingertip respiratory rate value (RR_{FT}) of the device is compared to capnography based respiratory rate (RR_{Capno}) value. The accuracy of the device is in comparison to the capnography based values measured over during 30 minutes of stable breathing.

Accuracy data is calculated using mean error for all subjects.

Principles of Operation

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well- oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse. Additionally, the pulse oximeter uses variations in the pulse volume fluctuation's amplitude, baseline shift, and timing to determine the respiratory rate.

Specifications

Oxygen Saturation Display Range: 0% to 100% SpO_2
Pulse Rate Display Range: 18 to 321 beats per minute (BPM)
Respiration Rate Display Range: 2 to 80 breaths per minute
Declared Accuracy: The table below shows A_{rms} values measured using the Model 9591 in a clinical study in non-motion conditions:

Table 2: Accuracy - Finger

Range	Specified Oxygen Saturation (A_{rms})	Finger Oxygen Saturation (A_{rms})	95% Limits of Agreement	Low Perfusion Oxygen Saturation (A_{rms})
70 – 100%	± 2	± 1.31	(-2.3 - 2.9)	± 2
70 – 80%	± 2	± 1.62	(-1.7 - 3.7)	± 2
80 – 90%	± 2	± 1.05	(-2.3 - 2.2)	± 2
90 – 100%	± 2	± 1.18	(-2.4 - 2.4)	± 2

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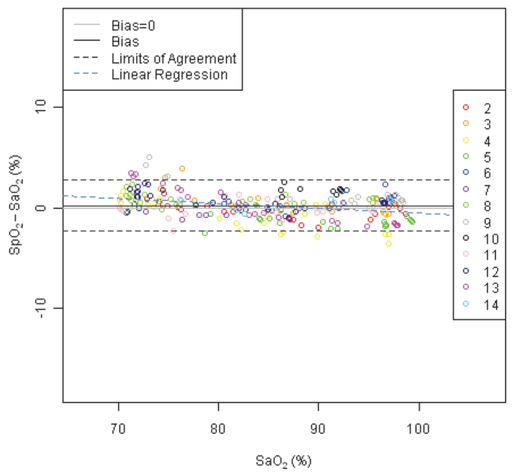

This graph shows plots of the error ($SpO_2 - SaO_2$) by SaO_2 using the Model 9591 with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study in non-motion.

SpO_2 Low Perfusion Accuracy (A_{rms})*: 70 to 100% ±2 digits
Pulse Rate Declared Accuracy Range (A_{rms})*: 20 to 250 BPM ±3 digits
Low Perfusion Pulse Rate Declared Accuracy Range (A_{rms})*: 40 to 240 BPM ±3 digits
Respiration Rate Accuracy: (Mean Error): 3-44 ± 1 Breath per minute
Measurement Wavelengths and Output Power:**
Red: 660 nanometers @ 0.8 mW max. average
Infrared: 910 nanometers @ 1.2 mW max. average
Temperature:
Operating: 23 °F to 104 °F (-5 °C to 40 °C)
Storage/Transportation: -40 °F to 158 °F (-40 °C to 70 °C)
Time (from storage) for device to be ready for its intended use:
3 minutes to warm from -40 °C to -5 °C
5 minutes to cool from 70 °C to 40 °C
Humidity:
Operating: 10% to 95% non-condensing
Storage/Transportation: 10% to 95% non-condensing
Altitude:
Operating: Up to 13,123 feet (4,000 meters)
Hyperbaric Pressure: Up to 4 atmospheres
Battery Life:
Operating: Approximately 2,000 spot checks, or 25 hours of continuous operation using new alkaline batteries.
Storage: 1 month, with batteries installed. **CAUTION:** Remove batteries if the device will be stored for more than 30 days.
Classifications per IEC 60601-1/UL 60601-1 / CAN/CSA-C22.2 No. 601.1:
Degree of Protection: Type BF-Applied Part
Enclosure Degree of Ingress Protection:
IP32
Mode of Operation: Continuous

This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.

This device is not made with natural rubber latex.

This product complies with RoHS.

This product complies with REACH.

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

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

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 2 years from the date of purchase, each Model 9591 exclusive of the batteries, spring, lanyard, and lanyard lock.

Nonin shall repair or replace any Model 9591 found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Onyx3 delivered to the purchaser which is found to be defective in any manner whether such remedies be in contract, tort or by law.

This warranty excludes cost of delivery to and from Nonin. All repaired units shall be received by the purchaser at Nonin's place of business. Nonin reserves the right to charge a fee for a warranty repair request on any Model 9591 found to be within specifications.

Onyx3 9591 is a precision electronic instrument and must be repaired by trained Nonin personnel only. Any sign or evidence of opening the Model 9591, field service by non-Nonin personnel, tampering, or any kind of misuse of the Model 9591, shall void the warranty. All non-warranty work shall be done at Nonin's standard rates and charges in effect at the time of delivery to Nonin.

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Manufacturer's Declaration

Refer to the following tables for specific information regarding this device's compliance to IEC 60601-1-2.

Table 3: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 4: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage before application of the test level.

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device 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.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
Radiated RF per ISO 9919 clause 36 and ISO 80601-2-61 clause 202.6.2.3	20 V/m 80 MHz to 2.7 GHz	N/A	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:

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

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.

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

Essential Performance

The essential performance of this device is defined as SpO_2 accuracy and pulse rate accuracy, or an indication of abnormal operation. When SpO_2 accuracy and pulse rate accuracy cannot be achieved by the device, abnormal operation is indicated by the poor signal indicator. If this condition persists, the device will also blank the measurement of the display with dashes.

Table 6: Recommend Separation Distances

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Bluetooth Wireless Technology Information

***Bluetooth* Compliance:** Version 4.0 single mode low energy
Operating Frequency: 2.4 to 2.4835 GHz
Output Power: TX: +3 dBM
Operating Range: 10 meter radius (line of sight)
Network Topology: Star - bus
Operation: Slave
Model 9591
Antenna Type: Integrated chip type antenna
Modulation Type: Frequency Hopping Spread Spectrum
Data Rate: 1 Mbit/second
Data Latency: 6 ms
Data Integrity: Adaptive Frequency Hopping
24-bit CRC (cyclic redundancy check)
32-bit message integrity check
Data Format: Nonin Proprietary: Sends data packets once per second. Includes a second counter that allows the host to detect if packets are missing and the device to retransmit.
Bluetooth SIG Standard: Compliant with *Bluetooth* SIG Pulse Oximeter Profile specifications adopted by Continua.

Quality of Service: This device uses *Bluetooth* Smart technology for wireless communications, which allows for reliable communications in electrically noisy environments, and transmits physiological data. If the connection is lost, the device will become available for a connection in a few seconds.

***Bluetooth* Profiles Supported:** GATT-based Nonin Proprietary Oximeter Profile; GATT-based *Bluetooth* SIG Pulse Oximeter Profile
Authentication and Encryption: Supported
Encryption Key Size: 128 bits AES (advanced encryption standard)

Bluetooth Security

The *Bluetooth* radio contained in the Model 9591 is a *Bluetooth* Smart single-mode, low-energy radio. Model 9591 supports an encryption key size of 128 bits. While the Model 9591 is in a *Bluetooth* connection, it will be unavailable for other connections. Apart from the standard *Bluetooth* security measures, Nonin has two non-standard security measures that are available.

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 9591, 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.

Déclaration de conformité aux règles de la FCC et du ministère canadien de la Santé en matière de compatibilité électromagnétique

- Nonin Medical, Inc., sise à 13700 1st Avenue North, Plymouth, Minnesota, 55441, assumant ses pleines responsabilités, déclare que le modèle 9591, auquel cette déclaration est liée, est conforme à la partie 15 des règles de la FCC. Le fonctionnement du système est sujet aux deux conditions suivantes : (1) cet appareil ne peut pas causer d'interférences nuisibles et (2) cet appareil doit accepter toute interférence reçue, y compris des interférences susceptibles de causer un fonctionnement indésirable.
- Ministère de la Santé (Canada), Code de sécurité 6 : les normes incluent une marge de sécurité substantielle visant à assurer la sécurité de toutes les personnes, indépendamment de leur âge et de leur état de santé. La norme d'exposition pour les téléphones mobiles sans fil emploie une unité de mesure connue sous le nom de « taux d'absorption spécifique » (SAR). La limite SAR définie par la FCC est de 1,6 W/kg.

Federal Communications Commission (FCC) Notice

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

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for assistance.
- RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components and provide a separation distance of 15 mm (0.6 inches) to the body. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
- The Model 9591 is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the United States FCC. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005 and has been tested in accordance with the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. 1528-2003.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

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