Operator's Manual

Model 3250
TruO2® OTC Pulse Oximeter

English

	Follow Instructions for Use.
	Consult Instructions for Use.

Before using the TruO2 OTC Pulse Oximeter (Model 3250), please carefully read and follow all the information presented in this Operators Manual.

Thank you for trusting Nonin with your healthcare needs.

We sincerely appreciate your business. Please read this document carefully and direct any further questions to a Nonin Technical Service representative.

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Have other questions or want to learn more?
Visit **nonin.com** to read more about our history, product offerings, and more.

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Contents

Glossary

Accuracy	How close the displayed value is to the true value.
A_{rms}	The value that represents accuracy (Accuracy Root Mean Square).
Arterial Oxygen Saturation (SaO_2)	Percentage of oxygen measured in blood circulating in arteries.
Bias	How much the displayed value is expected to shift from the true value.
Co-Oximeter	A medical device used by professional healthcare workers to accurately measure SaO_2.
Defibrillation	The use of a carefully controlled electric shock to the heart to restart it or to return its beating to a normal rhythm.
Magnetic Resonance setting (MR)	A hospital setting where radio waves and a powerful magnet are used to create pictures of a person's internal organs.
Oxygen Saturation (SpO_2)	The percentage of oxygen measured in blood circulating in veins and capillaries.
Low Perfusion	A decrease in blood flow.
Pulse Oximeter	A device used to estimate the percentage of oxygen in blood.
Pulse Rate (PR)	The number of heart beats in one minute.

Symbols

Displays and Indicators

	Nonin's CorrectCheck™ senses that the finger has not been correctly inserted.
% SpO_2	The number next to this symbol is the amount of oxygen measured in the blood (functional oxygen saturation of arterial hemoglobin).
	The number next to this animated symbol is the measured pulse rate. Pulse rate is the number of times the heart beats per minute.
— — —	Dashes replace the readings when the TruO2 OTC is unable to detect a usable signal.
	White symbol – Radio is on. Green symbol – TruO2 OTC is connected. Flashing symbol – Connection error. The radio will reset. No symbol – Radio is off.
	Poor signal. Steady 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.
	† Spot-check complete. While spot-check is in progress, a clockwise spinning circular icon displays.
	† Measurement complete (full screen).

† These indicators only display when the associated feature has been activated by an integrator.

Additional symbols can be found at www.nonin.com/symbols.

Indications for Use

The Nonin Medical 3250 Finger Pulse Oximeter is a small, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate of individuals who are well or poorly perfused under no motion conditions for medical use without a prescription. It is intended for spot-checking of individuals 18 years and older with finger thickness between 0.8-2.5 cm (0.3-1.0 inch). It is not intended for the diagnosis or screening of lung disease, for use in treatment decisions, and should only be used for making healthcare decisions under the advice of a healthcare provider.

Clinical Benefits

Nonin pulse oximeters provide fast, accurate, real-time, professional grade noninvasive oxygen measurement for individuals who are well or poorly perfused, with all skin colors, and under no motion conditions for medical use without a prescription. It is intended for spot-checking of individuals 18 years and older with finger thickness between 0.8-2.5 cm (0.3-1.0 inch).

The Monk Scale shows the range of all skin colors. Additional performance information is included in the Operator's Manual (see QR code).

Warnings

SpO_2 provides an estimate of oxygen levels in the blood but should always be used together with other health information.
When using the Bluetooth® connection, keep the device within 10 meters (32 feet) of the connected device. Moving outside this range may cause missing and/or loss of data to the connected device.
Avoid excessive pressure to the application site as this may cause damage to the skin and/or cause inaccurate readings.
Keep the device away from young children. Small items such as the battery door and batteries are choking hazards.
Do not use the device in a Magnetic Resonance (MR) setting or in an explosive area.
Do not use the device when defibrillation is applied.
Skin sensitivity to the device may vary based on your medical status or skin condition.
Do not only rely on this device for determining your health status. This device is to be used in combination with other methods to properly determine your health status. Contact your healthcare provider for medical advice as needed.
Before changing the batteries, make sure the device is not on a finger and is turned off.
Always inspect the device before use. Do not use a damaged device. If the device is damaged or has unacceptable deterioration (e.g. cracking, corrosion, discoloration), discontinue use immediately.
Self-monitoring does not mean diagnosis or treatment. Unusual values must always be discussed with your healthcare provider. Under no circumstances should you independently alter oxygen delivery settings or medical treatment prescribed by your healthcare provider.
Pulse oximeter measurements can vary depending on age and medical history.
Normal resting SpO_2 levels are typically 95% or greater. This can vary from person to person. Normal values can be lower for individuals with lung disease, advanced age, or those living in high altitude. Please consult with your healthcare provider to define your normal values. You should be aware of your normal (baseline) SpO_2 levels for the device's reading to be most meaningful.
A pulse oximeter measurement should be interpreted while considering other signs and symptoms and health history. Otherwise, the measurement may be misleading. You should also focus on the change from your baseline level over time and not solely on a single measurement at any given time.
Focusing solely on a pulse oximeter measurement may give a false sense of security. This is because in some cases one may have lung problems before having trouble breathing. It can also show normal measurements while struggling to breathe. Seek medical attention if you are not feeling well even if your reading is normal.

NOTE: Be aware of the many factors listed in the Limitations section that can limit or lower this device's accuracy.

Limitations - Device Accuracy

Some things can limit or decrease the device's accuracy. Examples of such things may include:

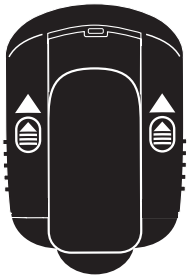
Simultaneous use of a blood pressure cuff on the same arm.
Direct exposure of the device to sunlight or home lighting while in use.
Movement, including tremors, of the hand or finger on which the device is being used.
Moisture or wetness in the device.
Placing the device on a toe instead of a finger.
A fingertip that is thinner or thicker than 0.8 – 2.5 cm (or 0.3 – 1.0 inch).
Nail polish or fake/glued-on fingernails.
A weak/poor pulse or an irregular heartbeat.
Use of the device after recently receiving dyes used for medical imaging of heart-function.
Use of the device on a person with a blood disorder such as anemia.
Use of the device when blood circulation is lower than usual (e.g., when hands are cold). In such a case, warm or rub hands/finger before using the device.
Skin pigmentation at low oxygen saturation levels (less than 80%).
Carbon monoxide.
Smoking and smoke inhalation.

Cautions

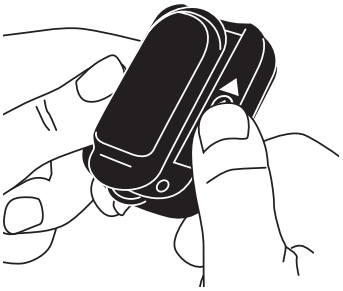
This device has no alarms and is not meant for continuous monitoring (monitoring for a long period of time).
Keep the device away from flammables, sources of fire, or direct heat.
The device is designed to be attached to one finger at a time.
This device will shut off after 30 seconds of poor or no readings.
In some circumstances, motion will affect the accuracy of the device. Minimize motion during use as much as possible.
Clean the device promptly after each use to prevent dirt from drying on the device.
Do not drop the device in liquid. Do not pour or spray any liquids directly onto the device.
Do not heat-sterilize the device.
Device repairs must be done by a qualified technical professional. Do not attempt to open the case or repair the device as it may cause damage and void the warranty.
When the device is connected via Bluetooth, other Wi-Fi devices within 6 meters (20 feet) could interrupt the Bluetooth connection.
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. Use only alkaline batteries. Do not use 1 new and 1 old battery at the same time. These actions may cause the batteries to leak.
Follow local, state, and national rules regarding disposal or recycling of the device and device components, including batteries.

To set up and use the TruO2 OTC (Model 3250) pulse oximeter, please follow the simple instructions below.

Installing Batteries



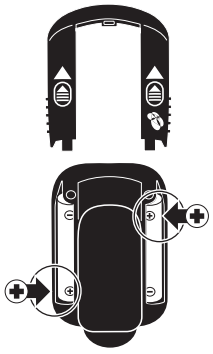
1. Hold the device so the back is facing up and the arrows on the battery door point away from you.



2. Place thumbs on the ovals.

3. Slide the battery door away from you and off the device.

4. If applicable, remove the old batteries. Properly dispose of the batteries.



5. Insert two new 1.5 volt AAA-size alkaline batteries. Carefully match the polarity markings (+ and -). The device will not work if the batteries are inserted the wrong way.

6. Carefully slide the battery door back onto the device.

To set up and use the TruO2 OTC (Model 3250) pulse oximeter, please follow the simple instructions below.

Using the Device

1. Insert finger up to the end of the device slot. This will turn the device on.

NOTE:

- Center the flat part of finger in the slot (not on its side). The device display should be on the palm side of the finger.
- During startup, observe the display to make sure that it is working correctly.

2. If the CorrectCheck™ icon appears on the display (as shown below), reposition the finger. It is important to ensure the finger is inserted correctly into the device for proper performance.

3. The device begins sensing the pulse and displaying readings.

4. If the device does not turn on or if it shuts off unexpectedly:
   - Check batteries are installed correctly.
   - Replace batteries.
   - If the problem persists, remove the batteries, and contact Nonin Technical Service.

Cleaning Instructions

To avoid damaging the device, follow the warnings, cautions, and cleaning instructions as described.

Gently wipe the display screen with a soft, clean, dry cloth.

1. Clean all other surfaces of the device with a soft, clean cloth that is lightly dampened with warm, soapy water (use liquid dish soap) for general cleaning. Use watered-down bleach (1-part bleach added to 10-parts water) for low-level disinfection.
2. Wipe the cleaned surfaces with a soft, clean cloth lightly dampened with warm water to remove residue of soap or bleach mixture.
3. Dry the device with a soft, clean, dry cloth.

How to know if the device is clean?

- The display screen should be clear and readable.
- The surfaces should not be soiled, dirty, dusty, or sticky.
- The finger slot should not have any signs of soiling or dirt or nail polish residue.
- If the device still appears dirty after cleaning, repeat cleaning steps.
- If the device is still dirty after repeated cleaning, the device may need to be discarded.

Specifications

Display Range

- Oxygen saturation display range: 0%-100% SpO_2.
- Pulse rate display range: 18bpm-321bpm.

Accuracy

- SpO_2 Accuracy (Arms): (See Table 1).
- SpO_2 Low Perfusion Accuracy (Arms): 70 to 100% ±2 digits.
- Pulse Rate Declared Accuracy Range (Arms): 20 to 250 BPM ±3 digits.
- Low Perfusion Pulse Rate Declared Accuracy Range (Arms): 40 to 240 BPM ±3 digits.
- Clinical studies have shown that the device's accuracy is not affected by differences in skin pigmentation (See Table 2).

Battery Life

- Approximately 2,200 uses or stored for 1 month. If stored for more than 30 days, remove the batteries.
- Measurement Wavelengths and Output Power**:
- Red: 660 nanometers @ 0.8 mW max. average.
- Infrared: 910 nanometers @ 1.2 mW max. average.

Temperature and Humidity Conditions

- Operating: -5 °C to 40 °C / 23 °F to 104 °F. df
- Storage/Transportation: -40 °C to 70 °C / -40 °F to 158 °F.
- Time (from storage) for device to be ready for its intended use:
  - 3 minutes to warm from -40 °C to -5 °C.
  - 8 minutes to cool from 70 °C to 40 °C.
- Humidity: 0 to 95%.

Table 1.
Accuracy of 3250 Device

Accuracy Summary	
SaO_2	Measured Accuracy (A_{rms})
70 – 100%	2.27
70 – 80%	2.85
80 – 90%	1.86
90 – 100%	1.97

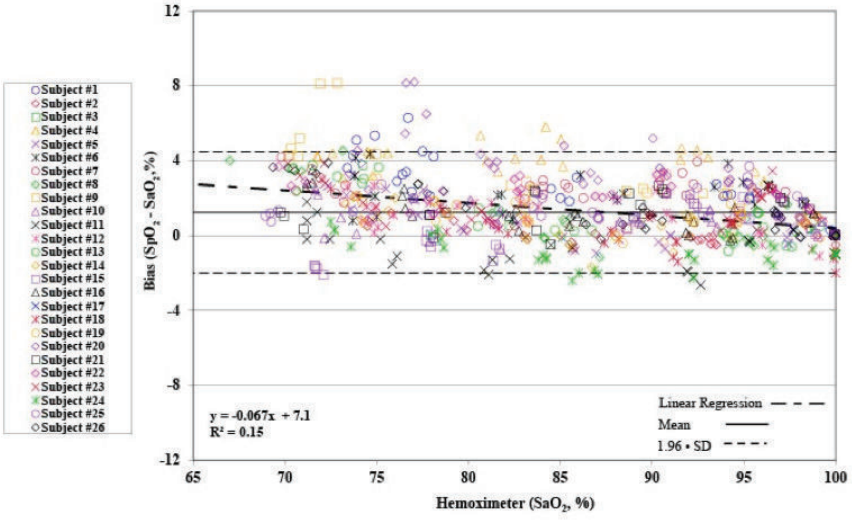
Declared Accuracy: The table above shows A_{rms} values measured during a clinical study in non-motion conditions.

Table 2.
Bias

	SaO_2 Range	
Skin Pigmentation	70-85%	85-100%
Light	1.9	0.98
Medium	1.14	0.43
Dark	2.57	1.08

Bias: The table above shows the Bias values measured during a clinical study in non-motion conditions.

Figure 1.



This graph shows the calculated error (SpO_2 minus SaO_2) of the device versus the oxygen saturation (SaO_2) of a co-oximeter. Each point is a measurement for each subject. Ideally, points should be randomly scattered about the horizontal mean-zero line, with no more than 5% of points being outside of the agreement lines, and with no apparent trend across the range of the SaO_2 values (i.e., 70% to 100%). The points that are above the mean-zero line show over-estimated SaO_2 values and the points that are below the mean-zero line show under-estimated SaO_2 values. The regression lines show the estimated errors across the range of SaO_2 values. An ideal regression line is one that is horizontal at the mean-zero line.

The TruO2 OTC (Model 3250) pulse oximeter estimates the amount of oxygen in the blood without a blood sample. SpO_2 is the estimate of the blood oxygen level, but it is not a perfect estimate. If SpO_2 reads 95%, then the amount of oxygen in the blood will be between 92.35 and 99.25% in most cases.

Figure 2.

This graph is a representation of Figure 1 broken down by skin pigmentation.

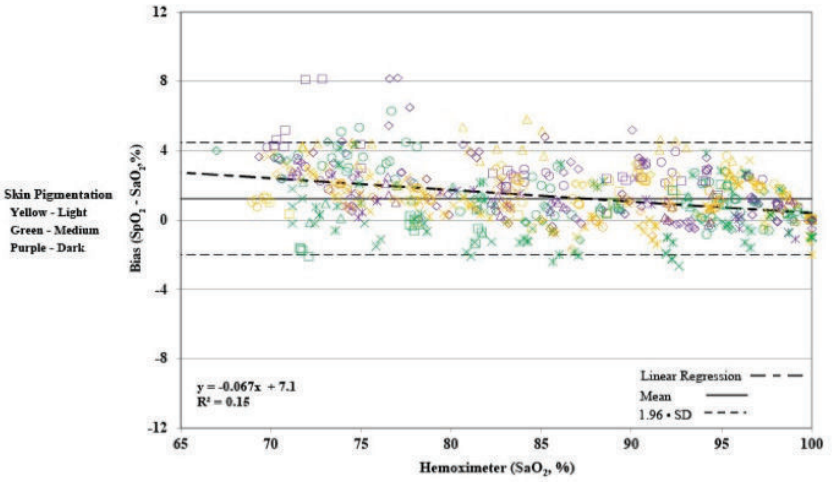
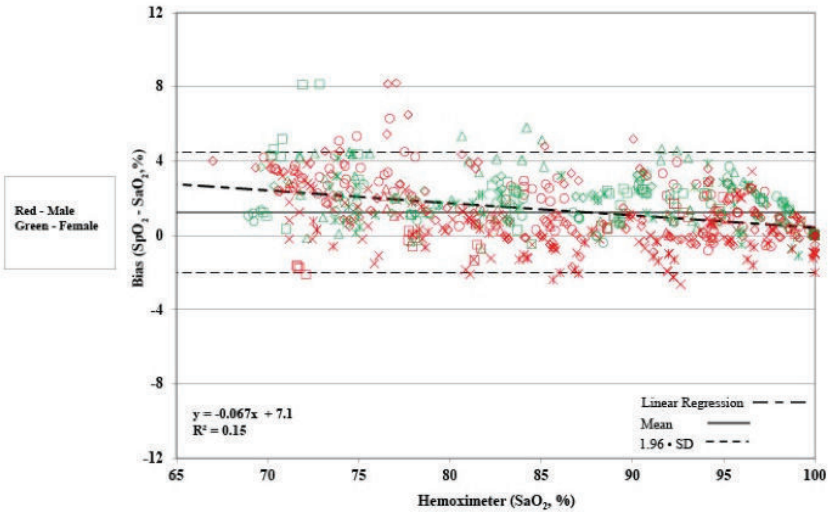


Figure 3.

This graph is a representation of Figure 1 broken down by gender.



These graphs (Figures 4-8) show the Oxygen Saturation (SpO_2) versus the Co-Oximeter (SaO_2) utilized in a clinical study. Each point is a measurement for a subject and the diagonal line represents SpO_2 and SaO_2 being equal. Ideally, points should be randomly scattered about the diagonal line with no apparent trends. The points that are above the diagonal line show over-estimated SaO_2 values and the points that are below the diagonal line show under-estimated SaO_2 values.

Figure 4.

This graph is a representation of light skin pigmentation.

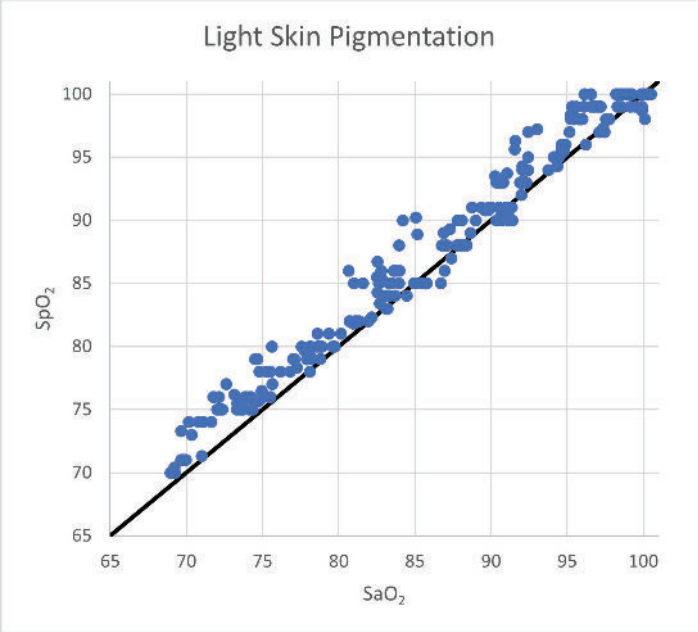


Figure 5.

This graph is a representation of medium skin pigmentation.

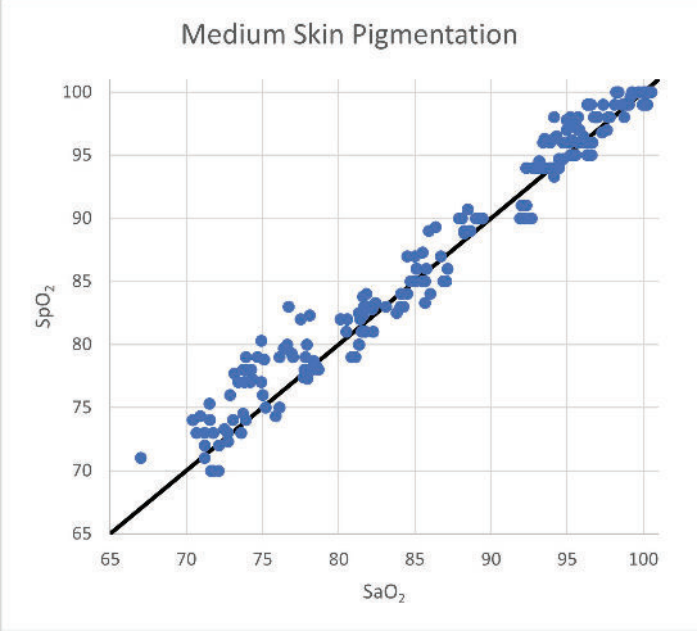


Figure 6.

This graph is a representation of dark skin pigmentation.

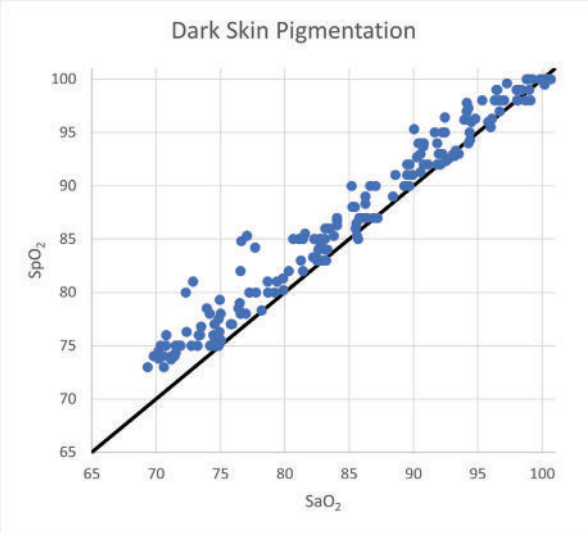


Figure 7.

This graph is a representation of females.

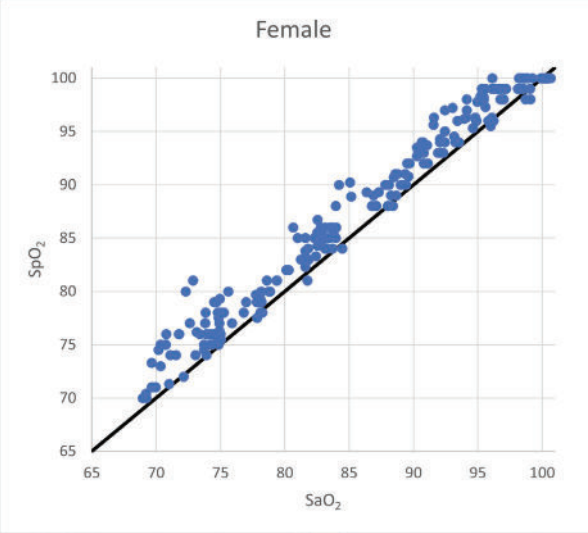
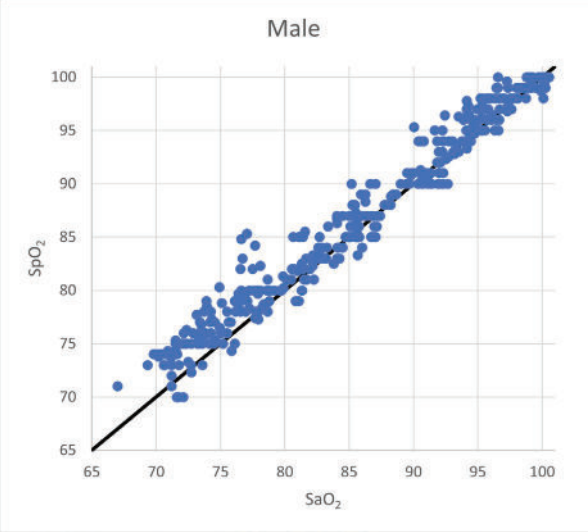


Figure 8.

This graph is a representation of males.



Testing Summary

SpO_2 Accuracy Testing

SpO_2 accuracy testing was conducted during studies on healthy, male and female, non-smoking, light, medium, and dark-skinned subjects that were 18 years of age and older. The measured SpO_2 of the device was compared to SaO_2 values determined from blood samples. The accuracy of the device was compared to the blood samples measured over the SpO_2 range of 70 – 100%. Accuracy data was calculated per ISO 80601-2-61.

Pulse Accuracy Testing

This test used a simulator to provide pulse rate without motion. The device must maintain accuracy as stated in ISO 80601-2-61.

Low Perfusion Accuracy Testing

This test used a simulator to provide a pulse rate, with adjustable amplitude settings at various SpO_2 levels for the device to read. The device must maintain accuracy as stated in ISO 80601-2-61.

Connecting via Bluetooth® Wireless Technology

Download the NoninConnect™ mobile app from the iOS app store.

When the pulse oximeter is placed on the finger and turns on, it is ready for a Bluetooth wireless connection. The device stays in this mode until it turns off or the Bluetooth radio turns off. When the symbol is white, the Bluetooth radio is on. If the symbol is green, the device is connected. When the symbol flashes, there is a communication error.

The mobile app instructions can be found here:
https://www.nonin.com/support/truo2-otc

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: Peripheral
TruO2 OTC: (Model 3250)
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 3250 is a **Bluetooth Smart single-mode, low-energy radio**. The Model 3250 supports an encryption key size of 128 bits. While the Model 3250 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.

Manufacturer's Declaration

Refer to the following tables for information regarding this device's compliance to 60601-1-2. Component compliance level is determined by system compliance level.

Essential Performance

Essential performance of the TruO2 OTC (Model 3250) is defined as SpO_2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected by electromagnetic disturbances that are outside of the home healthcare environments. If issues are experienced, move the device from the source of disturbances.

Table 3.
Electromagnetic Emissions

This device is intended for use in the home healthcare environment. The user of this device should ensure that it is used in such an environment.	
Emissions Test	**Compliance**
RF Emissions CISPR 11	Group 2, Class B

Table 4.
Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
Radiated RF IEC61000-4-3	80 MHz – 2.7 GHz	10 V/m
	380 – 390 MHz	27 V/m
	430 – 470 MHz	28 V/m
	704 – 787 MHz	9 V/m
	800 – 960 MHz	28 V/m
	1.7 – 1.99 GHz	28 V/m
	2.4 – 2.57 GHz	28 V/m
	5.1 – 5.8 GHz	9 V/m

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Not applicable: Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3), Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6)

Warranty

Nonin warranties the TruO2 OTC (Model 3250) device for 2 years from the date of purchase.

If the device is defective during the warranty period, please contact Nonin Medical **(https://www.nonin.com/technical-support)**.

If Nonin Medical determines that the device is defective, it will be repaired or replaced with the same or similar model, free of charge, during the warranty period.

Refer to Nonin's website for full warranty policy. **(https://www.nonin.com/warranty)**

Important Notes:

- Do not try to open or repair the device, as doing so may void the warranty.
- Any sign of misuse or altering of the device will void the warranty.
- The warranty does not include the cost of shipping to or from Nonin Medical.
- Nonin Medical may choose to charge a fee for warranty repair.

Service Life

With proper use and care, the device should work for up to 5 years.

After the 2-year warranty period, if the following issues happen, the device should be disposed of:

- The display is not clear or readable even after cleaning it or installing new batteries.
- The device does not hold on to the finger.
- There are cracks in the plastic casing.

Device Disposal

The TruO2 OTC Pulse Oximeter (Model 3250) is safe for the environment because it does not have harmful materials like lead. When throwing it away, follow the rules in the area for recycling electronic devices and batteries.