TruO2 OTC

Model 3250 Instructions for Use

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).

Specifications

*Additional specifications are available in the Operator's Manual that can be located using the QR Code on the front cover.

Accuracy

- 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.
- Clinical studies have shown that the device's accuracy is not affected by differences in skin pigmentation.

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

Operating Conditions

- Temperatures no lower or higher than -5°C to 40°C (23°F to 104°F).
- Humidity no lower or higher than 10 to 95%.

Battery Life

- Approximately 2,200 uses or stored for 1 month.
- If stored for more than 30 days, remove the batteries.

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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 you have trouble breathing. It can also show normal measurements while you could be 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.
- Use only recommended cleaning solutions, as permanent damage could happen.
- Using recommended cleaning products will not affect the device's safety or performance. However, over time, some may cause minor surface wear or changes in appearance.
- Ensure the unit does not exceed 40 degrees during cleaning.
- 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.

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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.

More information can be found using this QR code.

https://www.nonin.com/support/truo2-otc

For summary of safety and clinical data see above QR code.

Please refer to the Operator's Manual on nonin.com/support/truo2-otc for troubleshooting guidance and more detailed operating instructions.

Contact Customer Service or Technical Service
Toll Free: 800.356.8874 (U.S. and Canada only)
Phone: +1 763.553.9968
Email: customerservice@nonin.com

Nonin Medical Inc.
13700 1st Avenue North
Plymouth, MN 55441-5443, USA

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

Warranty

The device warranty is 2 years.

nonin.com/warranty

Symbol Glossary

nonin.com/symbols

Compliance

This product complies with ISO 10993.
Not made from natural rubber latex.

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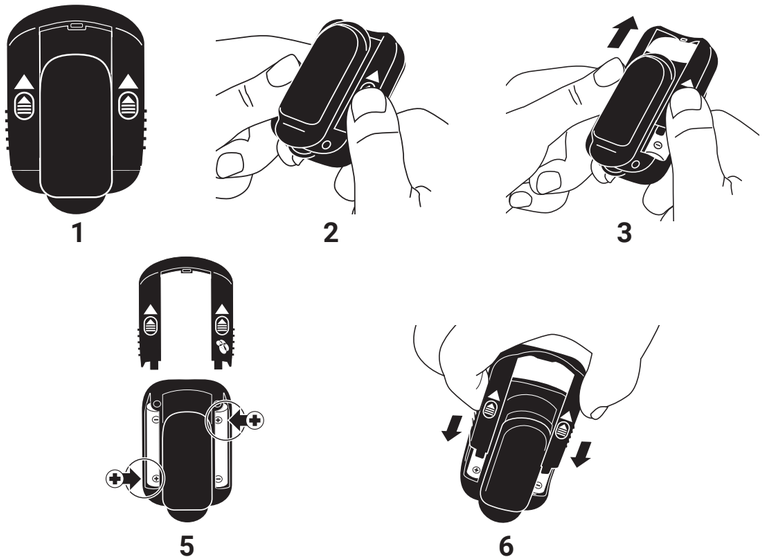
To set up and use the TruO2 OTC (Model 3250) pulse oximeter, please follow the simple instructions below.

Installing Batteries

1. Hold the pulse oximeter so you see the back of the device and the arrows on the battery door point away from you.
2. Place your 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.



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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 properly inserted correctly.
   - Replace batteries.
   - If the problem persists, remove the batteries, and contact Nonin Technical Service.

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 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.

Instructions on the mobile app can be found by using this QR code. Instructions can also be found on the website by clicking on the app instructions.

https://www.nonin.com/support/truo2-otc

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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.

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.

- 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) or isopropyl alcohol (IPA) (up to a 70% concentration) for low-level disinfection.
- Wipe the cleaned surfaces with a soft, clean cloth lightly dampened with warm water to remove residue of soap or bleach mixture.
- 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.