

FORA[®] *TN'G SpO₂*

Fingertip Pulse Oximeter



Operations & Procedures Manual
Long-Term Care and Home Health Care

Thank you for purchasing the **FORA TN'G SpO₂** Fingertip Pulse Oximeter. This manual provides important information to help you to use the device properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the place of purchase or call Customer Service at 1-888-307-8188.

The **FORA TN'G SpO₂** is intended for multi-patient use in a long-term or home health care setting. Please note that the following procedures are provided only as a model to help your facility establish its own policy and procedures. Your own policy may differ depending upon the existing procedures. Please consult with the Director of Nursing for further guidance.

CAUTION: Please carefully read the User's Manual and all product instructions before using this Long-Term Care and Home Health Care Manual.

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WARNINGS

- Do not use the oximeter in an MRI or CT environment.
- The oximeter is not intended for use in the diagnosis or screening of any symptoms or diseases. The data measured is for reference only, do not base a definitive diagnosis on the results of a single test. A physician or healthcare provider should make a diagnosis after all other clinical and laboratory findings are evaluated.
- If subjects' monitoring sites have trauma, disability or other medical status that make inaccurate results, operators should consult doctors before use.
- The oximeter has to measure the pulse properly to obtain an accurate SpO₂ measurement. Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the oximeter.
- Rx only.
- Keep the batteries out of the reach of children. The batteries from the device may result in a choking hazard for children if swallowed or inhaled.
- The device is only intended to be used in an indoor environment.
- Wireless communication equipment can affect the functionality of the device and should be kept away from the equipment.

CAUTIONS

- The oximeter determines the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Cardio green and intravascular dyes, depending on the concentration, may affect the accuracy of SpO₂ measurements.
- The performance of the oximeter might be affected by the presence of a defibrillator.
- The oximeter may not work on all subjects. If you are unable to achieve stable readings, discontinue use.
- Do not use caustic or abrasive cleaning agents on the oximeter or probes.
- Do not mix new and old batteries at the same time. It may cause the batteries to leak. Dispose of batteries properly.
- Batteries might leak chemicals if unused for a long period of time. Remove the batteries if the oximeter is going to be stored for more than one month.
- The oximeter is a precision electronic instrument and must be repaired by trained personnel only.
- Follow local governing ordinances and recycling instructions when disposing or recycling the device and its components.
- Always store the oximeter in a cool and dry place: temperature range of -13°F to 158°F (-25°C to 70°C) at relative humidity less than 95%. Avoid direct sunlight.

INTENDED USE

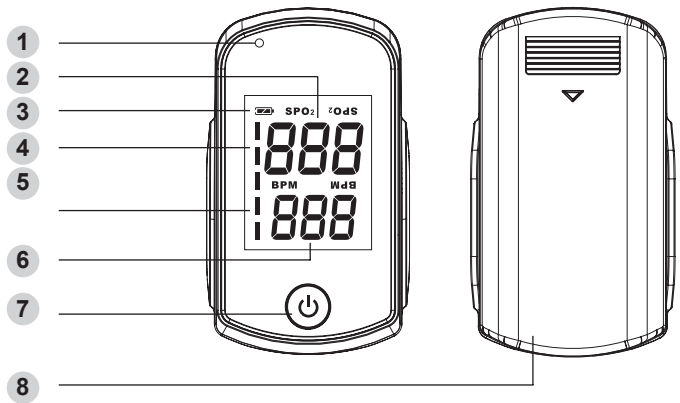
The Fingertip Pulse Oximeter is indicated for use in measuring oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. It is intended for patients during no-motion condition. The patients are limited to adults with weight above 88 lb. This device is indicated for non-invasive spot checking or monitoring.

METER OVERVIEW

Principle of Measurement

The Fingertip Pulse Oximeter determines functional oxygen saturation of arterial hemoglobin (SpO₂) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.

Meter Appearance and Key Function



1 Bluetooth Indicator

Blue light appears when bluetooth is turned on.

2 SpO₂%

The measurement result of oxygen saturation in percentage.

3 Battery Indicator

4 Pulse Amplitude

The strength of the signal is detected by the oximeter.

5 Backlight (White or Red)

Backlight is white while in measuring mode. Backlight is blinking red while the oxygen saturation value is below 85%. (high priority visual alarm)

6 Pulse Rate

The measurement result of pulse rate in beats per minute.

7 On/Off Button

It is used to turn on or turn off the oximeter by pressing On/Off button

8 Battery Compartment

Battery Replacement

Make sure the oximeter is off when replacing the batteries.

The oximeter is powered by two 1.5V AAA size alkaline batteries. You can replace new batteries by the following steps.


1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover carefully and make sure the cover is snug and fits correctly. It is important that the cover is closed correctly to ensure the oximeter remains waterproof.

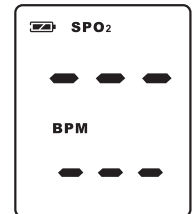
NOTE:

- Use only 1.5V AAA new batteries with this device. Replace the batteries as soon as possible after a low battery symbol appears.

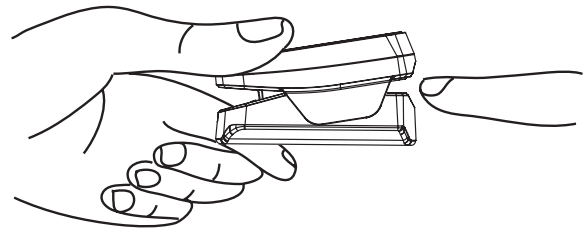


OXYGEN SATURATION AND PULSE RATE TESTING

1. Turn on the oximeter by pressing . Do not move your finger when starting test. Do not move your body while testing.



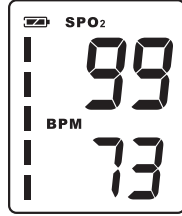
2. Open the clamp and put one of your fingers into rubber hole of the oximeter (it is better to let your finger touch the bottom) before releasing the clamp.



NOTE:


1. Consult healthcare professionals before you start to use the oximeter.
2. The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
3. Check the sensor application site frequently to determine circulation, positioning and skin sensitivity.

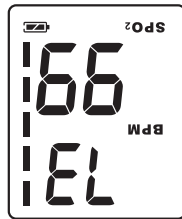
3. After detecting the pulse signal, the oximeter shows the readings of SpO₂ and pulse rate on the display. The readings will be updated based on the signal received with each pulse.



NOTE:

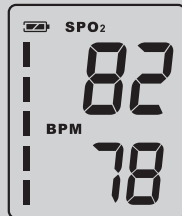
The pulse rate reading with the maximum (250) or minimum (30) values may not be the actual pulse rate, it may be inaccurate.

4. While testing, if you press , the screen will rotate 180 degrees.



NOTE:

The backlight will turn to blinking red if the oxygen saturation value is below 85%.



5. Hold  and the oximeter will turn off.

NOTE:

Below is the description of the effect on displayed and transmitted SpO₂ and pulse rate data values by:

- data averaging and other signal processing for 8 seconds,
- the data update period for 1 second,
- the alarm condition delay for 1 second,
- alarm signal generation delay for 1 second including the effects of any selectable operating mode that affects these properties.

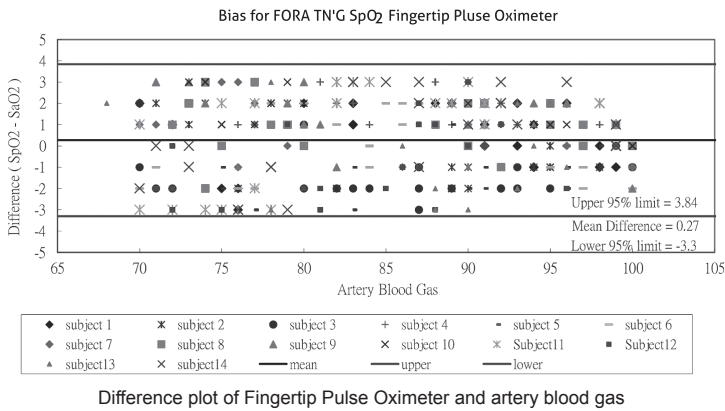
CLINICAL PERFORMANCE

Tables below show Arms values measured using Fingertip Pulse Oximeter in a clinical study. The individual and pooled measured Arms values in the SpO₂ ranges of all 14 subjects are reported.

Subject	70% - 80% SaO ₂		80% - 90% SaO ₂		90% - 100% SaO ₂	
	Mean Bias	Arms	Mean Bias	Arms	Mean Bias	Arms
1	-1.00	1.89	1.25	1.80	0.00	1.03
2	1.27	1.71	-1.07	1.58	-0.81	1.20
3	-2.00	2.00	-1.90	1.97	-1.15	1.33
4	2.17	2.27	1.14	1.51	0.81	1.64
5	-1.11	2.11	1.25	1.94	-0.74	1.26
6	-0.57	2.07	-1.25	1.94	-1.00	1.22
7	1.00	1.78	2.00	2.00	0.20	1.06
8	1.30	1.97	0.50	0.71	-0.64	1.16
9	2.29	2.33	0.40	1.79	0.78	1.63
10	1.30	2.07	1.20	2.00	0.50	0.89
11	-2.18	2.73	1.33	1.73	1.90	1.97
12	-1.71	2.26	-1.00	1.96	0.07	1.07
13	0.25	2.54	-1.50	1.87	-0.25	1.53
14	-1.56	1.94	1.20	1.67	0.83	1.35

Subject	70% - 80% SaO ₂	80% - 90% SaO ₂	90% - 100% SaO ₂
Mean Bias	0.16	0.21	0.21
Arms	2.00	1.87	1.29

Figure 1 Plot of difference (SpO₂ - SaO₂) versus artery blood gas (SaO₂) with linear regression fit and upper 95% and lower 95% limits of agreement of all subjects. Each color or symbol represents a different patient in the clinical study.



Difference plot of Fingertip Pulse Oximeter and artery blood gas

MAINTENANCE AND STORAGE

- Replace the batteries immediately when low voltage indicator is on.
- Clean surface of the Fingertip Oximeter before use.
- Remove the batteries inside the battery compartment if the oximeter will not be operated for a long time.
- It is best to preserve the product in a place where ambient temperatures range from -25°C to 70°C (-13°F to 158°F) and humidity range below 95% R.H.
- It is recommended that the product be kept in a dry place. A damp ambient might affect its lifetime and even might damage the product.

CLEANING THE OXIMETER

Cleaning the oximeter is just as important as proper use. For surface cleaning and disinfecting the oximeter, we recommend the following procedures:

1. Turn off the oximeter before cleaning.
2. Wipe the exterior surfaces thoroughly with a soft cloth containing 75% isopropyl alcohol solution.
3. Remove the wipe. Allow the oximeter surface to air dry completely.
4. Discard the used wipes and never reuse them.

NOTE:

Do not spray, pour, or spill any liquid on the oximeter, accessories, switches or openings.

TROUBLESHOOTING

Symptom	Possible Causes	Solutions
The oximeter cannot be turned on.	The batteries are dead.	Replace all batteries.
	The batteries are installed incorrectly.	Verify correct battery orientations.
SpO ₂ or pulse rate displays are missing.	Defective LCD displays.	Displayed values may not be reliable; discontinue use of the oximeter.
SpO ₂ or pulse rate displays unstable.	Finger might be trembling or placed incorrectly on the probe.	Try not to move or retry by placing the finger at the correct position on the probe.
Disruption in the oximeter performance.	Electromagnetic interference (EMI).	Remove the oximeter from the EMI environment.
Battery is low and "↳ bAt Lo" is shown on LCD.	The batteries are low.	Replace the batteries immediately.
Backlight turns to blinking red (visual alarm is activated)	Oxygen saturation value is below 85%.	Consult healthcare professional immediately.

SPECIFICATIONS

Model No.: TN'G SpO₂

Dimension & Weight:

63(H) x 37(W) x 32(D) mm, 40g (Without Battery)

Power Source:

two 1.5V size AAA alkaline batteries

Display: LCD

Battery Life:

Batteries can be used continuously for 8 hours (for reference only, it depends on different brands of AAA alkaline batteries)

External Output: Bluetooth

Measurement Range: 0% to 100%

Resolution: 1%

Accuracy: 100% ~ 80% ±2%; 79% ~ 70% ±3%; others are undefined.

Method: Dual wavelength LED

Pulse Rate

Measurement Range: 30 to 250bpm

Resolution: 1bpm

Accuracy: ±1bpm or ±1%, whichever is greater

Operating Conditions: 50°F to 104°F (10°C to 40°C); Below 95% R.H. (non-condensing)

Meter Storage/ Transportation Conditions:

-13°F to 158°F (-25°C to 70°C); Below 95% R.H. (non-condensing)

Product Life Time: 12 months

Classification

Type BF Applied part: Type BF Applied part

Safety: IEC60601-1

EMC: IEC60601-1-2

Harmonized Standard: ISO 80601-2-61:2011

Water-resistance: IP22

Mode of Operation: Spot Check / Monitoring

TRAINING TOOLS

Attachment 1: FORA TN'G SpO₂ Fingertip Pulse Oximeter Training Checklist

Use the following checklist to assess the trainee's understanding and knowledge of the following areas:

	TASK	(✓)
AREA	CLINICAL USE OF DEVICE	
Knowledge	Knows key features of TN'G SpO₂ Fingertip Pulse Oximeter meter.	
	Principles of quality testing and QC materials.	
	Understands the important features, benefits and limitations of the FORA TN'G SpO₂ Fingertip Pulse Oximeter .	
	Understands the displayed error messages and corresponding actions to take.	
	Understands the appropriate steps to take for troubleshooting.	
	Knows the actions to be taken when the results are abnormally high or low.	
	Understands the information required to be documented by law and by institution.	
Equipment	Locates the serial number on the device.	
	Knows the proper storage conditions of the pulse oximeter.	
	Knows how to maintain the device.	
Practical	Demonstrates proper safety procedures.	
	Demonstrates the correct SpO ₂ testing procedures using the TN'G SpO ₂ Fingertip Pulse Oximeter.	
	Demonstrates the proper cleaning and disinfecting techniques for the FORA TN'G SpO₂ Fingertip Pulse Oximeter .	
	Demonstrates the proper actions to take for inaccurate results.	

Training Completed by:

Name of Trainee	Date	Name of Instructor	Signature of Instructor

The trainee must complete the training of the FORA TN'G SpO₂ before performing pulse measurement testing on residents.

Attachment 2: FORA TN'G SpO₂ Fingertip Pulse Oximeter

Training Quiz

Complete the following questions to assess your understanding about using the FORA TN'G SpO₂ Fingertip Pulse Oximeter to perform oxygen saturation measurement tests on patients:

NO.	QUESTIONS	ANSWER
1	The FORA TN'G SpO ₂ Fingertip Pulse Oximeter measures: a) weight b) oxygen saturation c) both weight and oxygen saturation	
2	Only use the FORA TN'G SpO ₂ pulse oximeter to measure oxygen saturation on patients weighing at least: a) 100 lbs. b) 88 lbs. c) 50 lbs.	
3	The FORA TN'G SpO ₂ easily pairs to your tablet device using what type of communication? a) Bluetooth b) cellular c) cable	
4	The backlight will turn to blinking red if the oxygen saturation level is below: a) 65% b) 75% c) 85%	
5	When do you clean and disinfect the device? a) After each use b) Daily c) Weekly d) Monthly	
6	If you saw the following message on the meter's display, what action should you take? <ul style="list-style-type: none"> a) Replace the battery b) Turn the meter off and on c) Both of the above d) None of the above ⇨ bAt Lo	
7	The SpO ₂ device should be stored: a) At 39.2°F to 104°F (4°C to 40°C), below 85% humidity b) At -13°F to 158°F (-25°C to 70°C), below 95% humidity c) In the freezer d) None of the above	

Training Completed by:

Name of Trainee	Date	SCORE

Answers:

1. (b) 2. (b) 3. (a) 4. (c) 5. (a) 6. (a) 7. (b)

Attachment 3: FORA TN'G SpO₂ Fingertip Pulse Oximeter Quality Control Results Record

Meter #: _____ Month/Year: _____ Results reviewed by: _____

Date	Time	Station / Shift	Operator	Meter Cleaned (Y/N)	Corrective Action

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