FORA®

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TN'G SpO2

Fingertip Pulse Oximeter

Operating Instructions

Distributed by ForaCare, Inc.
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Moorpark, CA 93021 USA
Products made in Taiwan
Toll Free: 1-888-307-8188
(8:30 am-5:00 pm PST, Monday-Friday)
For assistance outside of these hours, please contact your healthcare professional.
www.foracare.com

Read instructions before use.
Caution, consult accompanying documents

⚠ 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 accurate SpO_2 measurement. Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the oximeter.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Keep the batteries out of reach of small unsupervised children. The batteries detached from the device may result children choking from inhaling or swallowing.
- The device is only applied to use under indoor environment.
- The device is not recommended to wear for a long period.
- Wireless communications equipment can affect the device and should be kept at least a distance away from the equipment.

⚠ CAUTIONS

- The oximeter is not an apnea monitor.
- The oximeter determines the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carbonxyhemo globin or methemoglobin may affect the accuracy of the measurement.
- Cardio green and intravascular dyes, depending on the concentration, may affect the accuracy of SpO_2 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. Disposed 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 regards disposal or recycling of the device and device 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.

INTRODUCTION

► Intended Use

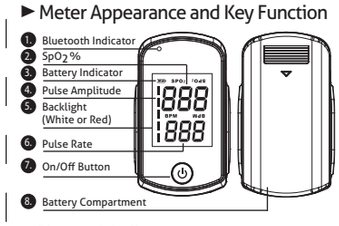
The Fingertip Pulse Oximeter is indicated for use in measuring oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for patients during no-motion condition. The patients are limited to adults with weight above 88 lb.

This device is indicated for non-invasive spot checking.

► Principle of Measurement

The Fingertip Pulse Oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) 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. SpO_2%
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

► Contents of the System

The Fingertip Pulse Oximeter includes the following items:

A. Fingertip Pulse Oximeter
B. Operating Instructions x 1
C. AAA-Size Alkaline Batteries x 2
D. Warranty Card

Confirm that the items listed are packed with the Fingertip Pulse Oximeter. If any item on this list is missing or damaged, contact your distributor. **All of the system with accessories is provided non-sterile.**

BEFORE USE

► 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.

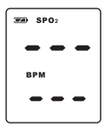
1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover carefully and make sure the cover is snug and fits correctly. It is important that the cover is closed correctly to ensure the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

NOTE

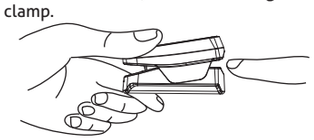
Use only 1.5V AAA new batteries with this device. Replace the batteries as soon as possible after a low battery symbol appears.

► Operation

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



STEP 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. **The recommended maximum application time at a single site is 4 hours.**

STEP 3. After detecting the pulse signal, the oximeter shows the readings of SpO_2 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.

STEP 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%.

STEP 5. Keep pressing ⏻ and the oximeter will turn off.

NOTE

Below is the description of the effect on displayed and transmitted SpO_2 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.

DATA TRANSMISSION VIA BLUETOOTH

You can transmit your SpO_2 and pulse rate data from the meter to your device (e.g. smart phone, tablet, PC...) via Bluetooth. Please contact your local customer service or place of purchase for assistance.
Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

1. With the meter off, press and hold ⏻ for 4 seconds. The meter enters pairing mode.
2. Turn on the Bluetooth function of your device so that it can begin searching for the meter. When the name of the meter appears on the pairing list, select and add it to the list.
3. On your device, the meter will be shown as a paired device, suggesting successful pairing.

NOTE

Under which situations the pairing is required: (A) you first receive and use the meter; (B) change a new device for re-pairing.

Bluetooth indicator on the oximeter:

BLUETOOTH INDICATOR	STATUS
Flash Fast	The meter is pairing and connecting
Lit Solid	The connection is established. The meter is transmitting data now.

NOTE

- While the meter is in transmission mode, it will be unable to perform a test.
- The meter is compatible with the following devices, iOS (6 or above) and Android system (4.3 or above). Make sure device is in proper receiving range of the meter before transmitting data.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers, the compatibility issue between your mobile device and the meter may occur.

CLEANING THE OXIMETER

Cleaning 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.

MAINTENANCE AND STORAGE

- Replace the batteries timely 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.

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 unstably.	Finger might be trembling or place 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.

SPECIFICATION

Model No.	TN'G SpO_2
Dimension & Weight	63(H)x37(W)x32(D) mm, 40g without 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)
Power Source	Two 1.5V 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

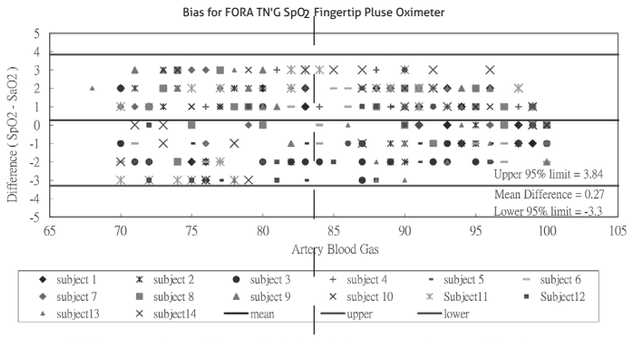
CLINICAL PERFORMANCE

Tables below show Arms values measured using Fingertip Pulse Oximeter in a clinical study. The individual and pooled measured Arms values in the discrete SpO_2 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	-0.17	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

Pooled	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 (SpO_2 - SaO_2) versus artery blood gas (SaO_2) 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

FEDERAL COMMUNICATIONS COMMISION (FCC) STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

Federal Communications Commission (FCC) Statement

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 and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does 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 separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

This device complies 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 of the device.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.

EMC TABLE

Guidance and manufacturer's declaration-electromagnetic emissions

The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below.
The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Fingertip Pulse Oximeter 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	The Fingertip Pulse Oximeter is suitable for use in all establishments, including domestic establishments 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below.
The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not appli cable Not appli cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV line(s) to line(s) + 2kV line(s) to earth	Not appli cable Not appli cable	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% UT(>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not appli cable Not appli cable Not appli cable Not appli cable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Fingertip Pulse Oximeter requires continued operation during power mains interruptions, it is recommended that the Fingertip Pulse Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The Fingertip Oximeter power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic immunity

The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below.
The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	Not appli cable	Portable and mobile RF communications equipment should be used no closer to any part of the Fingertip Pulse Oximeter including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 √P d = 1,2 √P 80MHz to 800 MHz d = 2,3 √P 800MHz to 2,5 GHz 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:
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 Fingertip Pulse Oximeter is used exceeds the applicable RF compliance level above, the Fingertip Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Fingertip Pulse Oximeter b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications

equipment and the Fingertip Pulse Oximeter

The Fingertip Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of Fingertip Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fingertip Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d =1,2√P	80 MHz to 800 MHz d =1,2√P	800 MHz to 2,5 GHz d =2,3√P
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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.
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.