User Manual

User Manual

Note

Thanks very much for purchasing the pulse oximeter produced by Shenzhen Narig Bio-Medical Technology Co., Ltd.

Read this manual carefully for correct operation before using the pulse oximeter.

Keep the manual properly for reference at any time when necessary.

Product Name	Pulse Oximeter
Model	FRO-200, FRO-201, FRO-202, FRO-203, FRO-204, FRO-100, FRO-101, FRO-102, FRO-103, FRO-104, CF-100B，CF-100
Medical device registration certificate No.	U.S. Food and Drug Administration
Product structure and component	The device consists of probe, electronic circuits, OLED/LED display (differentiated by models) and plastic housing which powered by two alkaline AAA batteries.
Indication for use	The pulse oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric (≥10Kg) patients during both no motion and motion conditions, and for patients who are well or poorly perfused.
Manufacturer	Shenzhen Narig Bio-Medical Technology Co., Ltd.
Registration Address	1106 Room, East Tower, Digital Culture Industry Base No.10128 Shennan Road, Nanshan District 518052 Shenzhen City, Guangdong PEOPLE'S REPUBLIC OF CHINA
Production Address	1007 Room, A Building of Quanju High-Tech Industrial Park, No. 21 Pinggang Industrial Avenue, Jiangshi Road, Gongming County, Guangming District, 518106 Shenzhen City, Guangdong, PEOPLE'S REPUBLIC OF CHINA

After-Sale Service

Shenzhen Narig Bio-Medical Technology Co., Ltd. (hereinafter referred to as “the company”) shall assume responsibilities for the return, replacement and repair of the equipment in case of quality problems caused by non-human factors within one week from the date of sale. The company will provide maintenance free of any charge for quality problems occurring during the course of normal use and storage within one year from date of production; If the equipment has quality problems after one year from the date of production, users may carry invoice and warranty card to our after-sale service department or agency and the company will provide spare parts for maintenance with reasonable charge. The warranty period will be one month since the date of production if users fail to provide invoice.

Warranty does not apply under the following circumstances:

A. Failure caused by disassembling, repairing or transforming the equipment without authorization;

B. Malfunction caused when the product falls carelessly during the course of use and transportation;

C. Damage caused by improper use;

D. Malfunction caused by operation not complying with the manual;

E. Damage caused by unforeseen natural disasters (earthquake, flood, etc.).

After-sales service Unit	Shenzhen Narig Bio-Medical Technology Co., Ltd.
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Production Address	1007 Room, A Building of Quanju High-Tech Industrial Park, No. 21 Pinggang Industrial Avenue, Jiangshi Road, Gongming County, Guangming District, 518106 Shenzhen City, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Postal Code	518052
Telephone Number	+86 0755-86566930
Website	http://www.narigmed.com (could get electronic random documents)

1 Safety

1.1 Safety Information

1.1.1 Description

1. functional tester (for example: Fluke Index II, SmartsSet, ProSim8, etc) are only suitable for pulse oximeter function test, and could not be used for pulse oximeter performance test.

2. This oximeter does not provide an alarm function. User can get hinds on whether physiological signal disturbed by refer to ***Section 7*** Specification.

3. The working temperature of the pulse oximeter is no more than 41℃. The test method is as follows: put NTC resister between light emitter and finger, in order to get regional tissue's temperature. The temperature should not exceed to 41℃ while under 35℃ environments. User should change measure position regularly to avoid temperature accumulative effect if take long-term measurement state. It might get harmful burns if keeps long-term using under 37℃.

4. The performance of the pulse oximeter is guaranteed by blood gas analysis which accord with International Standard ISO80601-2-61 and YY0784 (refer to ***Section 8*** Clinical Performance).

5. There is no need to re-calibrate because the pulse oximeter has already calibrated. User can use Fluke Index II functional tester to validate the function of the pulse oximeter during maintaining. Please contact manufacturer to get the validate curve type for the functional tester.

1.1.2 Warning

1. Only qualified personnel designated by the manufacturer is allowed to maintain the equipment. Users themselves are not allowed to repair the equipment.

2. Explosion hazard: not use the equipment in environment with inflammable substances such as anesthetics.

3. Not use the equipment in MRI and CT examination.

4. When used with electrosurgical equipment together, the user shall ensure the safety of the monitored patient.

5. Users who are allergic to silicone rubber is forbidden to use this equipment.

6. The equipment, accessories and packaging (batteries, plastic bags, foam and cartons, etc.) shall be scrapped in compliance with local laws and regulations.

7. Forbid to use the equipment once the equipment is found damaged, or have material deterioration.

8. Do not use the equipment under the application conditions beyond its declared specification scope.

9. Check the sensor site every hour to ensure adequate circulation, skin integrity, and sensor alignment. Skin damage, pressure necrosis, or inaccurate readings may result.

10.Do not use pulse oximeter for continuous monitoring. It is intended for spot-check use only. No alarms are provided to support continuous monitoring.

11.Misapplication of continuous monitoring with excessive pressure for prolonged periods might induce pressure injury.

12. Keep the device away from electrical equipment that emits radio frequencies to minimize radio interference, such as diathermy, electrocautery, RFID and security systems (e.g., electromagnetic anti-theft systems, and metal detectors). Radio interference may result in no or inaccurate readings.

13. The frequency bands of this device (2.4 GHz) are only for indoor use, in accordance with international telecommunication requirements.

1.1.3 Note

1. Take out batteries if the equipment is not used for a long time.
2. Performance of the equipment will be affected by electromagnetic field and therefore instruments used near the pulse oximeter shall meet EMC requirements. Mobile phones, X-ray or MRI equipment may produce electromagnetic radiation interference.
3. Properly carry the equipment and prevent it from falling, collision, strong vibration or other mechanical external force damage.
4. In accordance with international telecommunication requirements, the frequency band of 2.4 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.
5. 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.
6. 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.
- ✧ Consult the dealer or an experienced radio/TV technician for help.
- ✧ Connect the equipment into an outlet on a circuit different from that to which the receiver is connected..

7.Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

1.1.4 Caution

1. The equipment is only used to assist clinic diagnosis and the measurement data shall not be directly applied in clinical diagnosis.

2. It is not recommended to use the equipment in high frequency interference environment (eg. electric knife).

3. Children are not recommended to operate the equipment directly and they must operate the equipment under adult supervision.

4. Keep the application environment free of dust, vibration, corrosion or combustible substances, and avoid temperature and humidity too high or too low.

5. Turn off immediately if water splash the equipment or there is condensate in the equipment.

6. Do not use the equipment when it is transferred from cold environment to warm and humid place.

7. Incorrect battery installation will damage equipment, please check the polarity mark in the battery housing when installing the battery.

8. There is a visual indicator of low battery capacity in the equipment. Replace batteries in time when the low battery indicator appears.

9. When the pulse oximeter is transferred from one place to another, the difference of temperature or humidity may lead to the condensation phenomenon. At this time, user must wait for the condensation to disappear before starting the pulse oximeter.

10. When using Oximeter with a smart device, relocate the devices away from sources that may interfere with the Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service of the Bluetooth connection. Devices that may cause RFI include but are not limited to the following: other cellular telephones, wireless PC and tablets, pagers, Bluetooth devices, devices with remote controls, and baby monitors.

1.1.5 FCC RF Radiation Exposure Statement

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

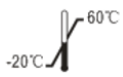
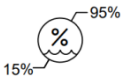
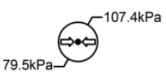
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

4. This equipment should be installed and operated with minimum distance of 0 mm between the radiator and your body.

1.2 Symbol of Equipment

There are all or partial symbols in the equipment provided to you.

Symbol	Implication	Symbol	Implication
	BF application part		No SpO2 alarm indication (The equipment has no SpO2 alarm function)
	Batch number		Note: refer to attached documents
IP22	Degrees of protection provided by enclosures		Date of manufacture
	Fragile		Manufacturer information
	No rain		This side up
	Range of storage temperature		Stacking level
	Range of storage humidity		Range of atmospheric pressure

--	Invalid measurement	Qty.	Internal quantity
	Dispose of in accordance to your country's requirements	EC REP	Authorized representative in the European Community
MD	This is medical device	Rx ONLY	Caution: Federal law prohibits dispensing without prescription.
P/N	Part number	⎓	Direct current
FC	Federal Communications Commission (FCC) Licensing	(optional)	For connection with a smart device. Enables or disables Bluetooth LE.
CE 0123 ***note**	The product bears CE mark indicating its conformity with Medical Device Regulation (MDR) and fulfils the essential requirements of Annex I of this Regulation.		

Note*: CE mark is only used for EU region, and is not appilicable for North America.

2 Overview

2.1 Product Introduction

2.1.1 Measurement Principle

Pulse oximeter have red and infrared low voltage light emitting diodes (LEDs) which serve as light sources. The emitted light is transmitted through the tissue, then detected by the photodetector and sent to the microprocessor of the pulse oximeter.

The pulsating of arterial blood results in changes in the absorption to added hemoglobin (Hb) and oxygenated hemoglobin (HbO_2) in the path of the light. Since HbO_2 and Hb absorb light to varying degrees, this varying absorption is translated into plethysmographic waveforms at both red and infrared wavelengths. The relationship of red and infrared plethysmographic signal amplitude can be directly related to arterial oxygen saturation by using Beer–Lambert law.

Functional Oxygen Saturation (SpO_2)	Functional oxygen saturation (SpO_2) is the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.
Pulse Rate (PR)	Pulse rate (PR), measured in beats per minute (BPM), is based on the optical detection of peripheral flow pulse.
Perfusion Index (PI)	The Perfusion Index (PI) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. PI thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.
Respiration Rate (RR)*Note	The Respiration Rate from the Pleth (RR) can be determined by the plethysmographic waveform. This method measures respirations per minute (RPM) based on changes in blood volume that correspond to the respiratory breathing cycle
Plethysmograph Waveform (Pleth)	The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well. Clinicians have attempted to utilize this waveform and its variation for assigning signal integrity, physiological and artifactual changes such as perfusion changes, dysrhythmia, motion artifact, and electrical interference. For this reason, accurate and reliable presentation of the plethysmograph waveform is of importance.
Bargraph	Showing the instantaneous state of blood pulse which is proportional to pulse intensity.

***Note**: The parameter of respiration rate (RR) is not applicable for North America.

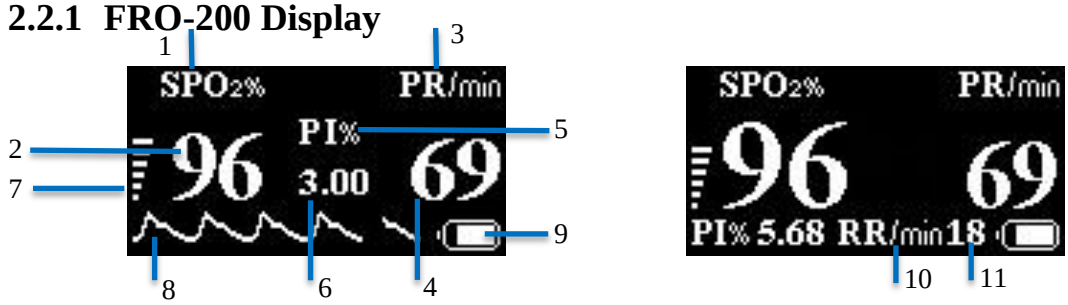
2.1.2 Basic Information

Intended Use	The pulse oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric (≥ 10Kg) patients during both no motion and motion conditions, and for patients who are well or poorly perfused.
Population	Adult and pediatric (≥10Kg).
Indication for Environment	Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments.
Operator	Doctors, nurses, and individuals (Consult clinical professionals before using).

Model of Operation	Spot-check.
Measurement Position	Finger.
Indications	None.
Contra-indications	None.
Side-effects	None.

2.2 Product Display

2.2.1 FRO-200 Display



1. Unit of blood oxygen saturation: SpO_2%

2. Measured value of SpO_2: the display range is [1 ~ 100] and the sign "---" means invalid value.

3. Unit of pulse rate: PR/min

4. Measured value of PR: the display range is [25 ~ 250] and the sign "---" means invalid value.

5. Unit of perfusion index: PI%

6. Measured value of PI: the display range is [0.02 ~ 20.0]and the sign "---" means invalid value.

7. Bar chart: showing the instantaneous state of blood pulse which is proportional to pulse intensity.

8. Tracing wave: display physiological pulse waveform, and non-normalized processing.

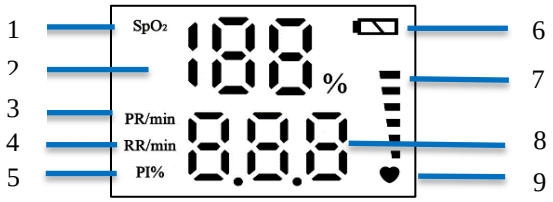
9. Battery capacity: the indicator's lighting length varies with remaining battery capacity.

10[*Note].Unit of respiration rate: RR/min

11[*Note]. Measured value of RR: the display range is [4 ~ 70] and the sign "---" means invalid value.

***Note**: The parameter of respiration rate is not applicable for North America.

2.2.2 FRO-100 Display



1. Unit of blood oxygen saturation: SpO_2%

2. Measured value of SpO_2: the display range is [1 ~ 100] and the sign "---" means invalid value.

3. Unit of pulse rate: PR/min

4[*Note]. Unit of raspiration rate: RR/min

5. Unit of perfusion index: PI%

6. Battery capacity indicator: the indicator flashes when the battery capacity is low.

7. Bar chart: the bar chart lights up with pulse, and its height varies with perfusion index.

8. According to the selection, display contents are different:

- When the unit of pulse rate (3) lights up, display the measured value of pulse rate. The display range of pulse rate is [25 ~ 250] and the sign "---" means invalid value.
- *Note When the unit of respiration rate (4) lights up, display the measured value of respiration rate. The display range of pulse rate is [4 ~ 70] and the sign "---" means invalid value.
- When the unit of perfusion index (5) lights up, display the measured value of perfusion index. The display range is [0.02 ~ 20.0], and the sign "---" means invalid value.

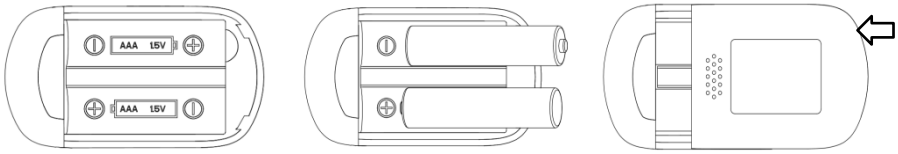
8. Pulse sign: flicker with pulse beat.

***Note**: The parameter of respiration rate is not applicable for North America.

3 Basic Operation

3.1 Installment

3.1.1 Battery Installment

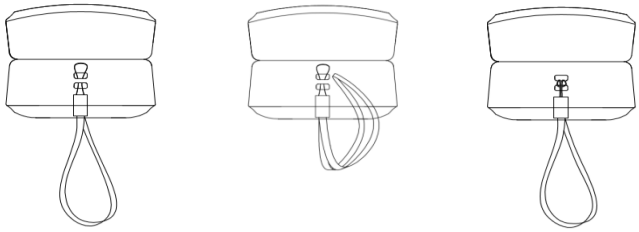


1. Ensure the polarity of two AAA batteries in consistent with the polarity mark in the battery compartment.

2. Place two AAA batteries into the battery compartment gently.

3. Make the battery compartment covered rightly.

3.1.2 Tie Rope



1. Put the thin end of the rope through the hanging hole.

2. Put the thicker end of the role through the thin end.

3. Tighten the rope.

3.2 Navigating the Menu

From the Main Screen, press the button to access the Menu (Only for FRO-20x serials).

Display Button	*Menu Options*	*Description*
	Manual Direction Rotation	Allows the user to switch screen display direction.
	Parameter Trend	Allows the user to review parameter trend during measurement period.
	Settings	Enter the menu.
	Power Off	Power off the pulse oximeter.
	Exit	Exit the selected screen.
	Automatic Direction Rotation	Enable/Disable automatic screen display direction.
	Brightness Settings	Screen brightness, default is ‘MID’.
	Reset	Reset to default settings.
	Sensitivity Settings	Sensitivity under low perfusion condition, default is ‘MID’.
	Average Settings	Parameter average times, default is 6 seconds.
	Statistics of measuring duration	Statistics for saturation and pulse rate at measurement duration
	***Note** Alarm Tip	Alarm tip for the limits of saturation and pulse rate

***Note**: Menu of Alarm Tip is not applicable for North America.

4 Measurement

4.1 Alarm

1. Carefully check the measurement part before wearing the pulse oximeter. Do not wear the oximeter to the damaged skins or tissues.

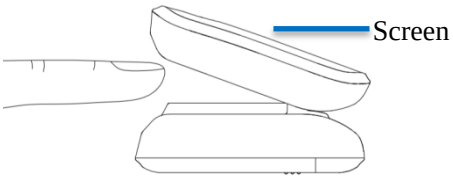
2. Do not place the pulse oximeter on the side of body with artery catheter or intravenous injection tube.

3. Do not put the pulse oximeter and blood pressure cuff on the same side of body as the blood flow occlusion during the course of blood pressure measurement may affect the reading of blood oxygen saturation.

4.2 Measurement Procedure

1. Press ON/OFF Button to turn on the pulse oximeter.

2. Open the finger clip, put the finger into cavity, and then release the finger clip. Make the display screen above the finger clip when putting the finger.



4.3 Measurement Precautions

1. Put the proper finger into the oximeter. The measured value may be affected if the finger is too cold or too thin.

2. The finger shall be inserted to the finger clip cavity deeply enough, and otherwise, the measured value may be inaccurate. Ensure the light between the PD and the LED of the oximeter shall passes through the small artery bed of the subject's finger.

3. Keep the place where the light path passes free from light barriers such as adhesive tape to ensure the accuracy of parameter measurement.

4. The product is suitable for children and adults with finger thickness of 7mm ~ 25.4mm.

5. The recommended measurement position are: forefinger, middle finger, ring finger.

6. The measurement will be affected by excessively strong ambient light, including but not limited to fluorescent lamp, double Ruby lamp, infrared heater, direct sunlight, etc.

7. The measurement accuracy will be affected if the subject performs strenuous activities.

8. The interference of electrical surgical equipment may affect the measurement accuracy.

9. The nail on the test site shall be free from nail polish and other cosmetics. To ensure measurement accuracy, remove nail polish or other cosmetics if any.

10. The parameters may be inaccurate in case there is high content of the dye dilution drugs (such as methylene blue, indigo cyanide green, acid indigo carmine), carbon monoxide hemoglobin, methemoglobin or thiohemoglobin and others.

11. Dopamine, Procaine, Procaine, Lidocaine, Benzocaine, and other drugs will cause serious deviation in the measurement of blood oxygen saturation.

12. The measured value of blood oxygen saturation is for reference only to anemic hypoxia and toxic hypoxia. Some patients with severe anemia may still have higher measured value of blood oxygen saturation due to physiological reasons.

13. SpO_2 accuracy is not assured in those with arrythmias.

5 Maintenance

Regular maintenance is of great importance to ensure the normal operation of equipment.

Warning

1. The integration and verification of software function have been completed before the product leaving the factory, and the user does not need to install, upgrade or maintain.

2. All safety inspection or maintenance work of equipment to be disassembled shall be carried out by professional maintenance personnel, and the non-professional personnel may cause equipment failure.

3. If there is any problem with the equipment, please contact the maintenance personnel or our company.

5.1 Cleaning and Disinfection

Keep the equipment clean and observe the following regulations to prevent equipment from being damaged:

1. Use the designated cleaning disinfectant to clean and disinfect the equipment, otherwise the equipment performance or service life may be affected.

2. Forbid to immerse the equipment in liquid.

3. Forbid to dump liquid on the equipment.

4. Do not make liquid into to enter frame of equipment.

5. Forbid to use abrasive materials (such as steel velvet or silver polishing agent), and any strong solvent (such as acetone or detergent containing acetone component).

6. High temperature, high pressure or gas disinfection method are inapplicable to disinfect the equipment.

Warning

7. The equipment shall be cleaned or disinfected with materials and methods listed in this chapter. Nairgmed shall not assume any responsibility for damage caused by the using other materials or methods.

8. Narigmed shall not assume any responsibility for the effectiveness of the listed chemicals or methods as a means of infection control. If used in a hospital, consult the infection prevention department or epidemiologist of the hospital.

5.1.1 Cleaning

The equipment shall be cleaned regularly. In case the equipment is used in areas with serious environmental pollution or windy sand, the equipment shall be cleaned more frequently. ***70% ethanol*** and ***clean water*** are recommened for cleaning.

When cleaning the equipment:

1. Shut down the equipment and take out batteries.
2. Make a soft cotton ball absorb a proper amount of detergent, and then use it to wipe the display screen and the surface of the equipment.
3. If necessary, use a dry cloth to wipe off excess detergent.
4. Make the equipment dry in a cool and ventilated environment.

5.1.2 Disinfection

To disinfect the equipment may cause certain damage to the appearance of Pulse Oximeter. It is recommended to disinfect the equipment only when necessary. ***70% ethanol*** is recommended.

5.2 Maintenance

The design life of the product is 3 years. Please maintain the equipment as follows:

1. Clean and disinfect the equipment according to this instruction before using.
2. Replace batteries in time when the low battery indicator appears.
3. Take out batteries if the equipment will not be used for a long time.
4. The equipment shall be stored indoor, with temperature at - 20℃~ + 60 ℃, relative humidity no higher than 95%, free of corrosive gas and good ventilation. Moisture and light may affect the service life of the equipment, and even induce equipment damaged.

5.3 Trouble-Shooting

Only professional maintenance personnel are allowed to disassembled the oximeter. There are no parts inside the equipment to be adjusted.

Malfunction	***Possible Cause***	***Solution***
Unable to turn on the equipment	Low or dead battery	Replace batteries
	No install batteries correctly	Install batteries correctly and ensure correct polarity
	Equipment is damaged	Contact the local customer service center
Blood oxygen saturation or pulse rate fail to display	Not insert fingers correctly	Put fingers correctly
	The patient's fingers are too thin, resulting in light leakage.	Put a thicker finger
	The patient's finger is cold so that the blood perfusion is too low.	Keep the finger warm and put another finger for measurement.
	nail polish or manicure	Remove nail polish or manicure
Unstable display of blood oxygen saturation or pulse rate	No insert finger deep enough	Put the finger correctly
	Movement interfaces signal	Stay still
LED goes out suddenly	The product is designed to shut down automatically when no signs is detected.	Normal
	Low battery	Replace battery
Measurement does not display on the smart device using optional Bluetooth	• Bluetooth LE not connected • Compatible app not installed on smart device • Device damaged • Smart device damaged	• Confirm Bluetooth is on for the Oximeter and the smart device • Confirm a compatible app is installed on the smart device • Close and re-launch the compatible app on the smart device • Check that Oximeter is connected to the correct smart device • Contact Narigmed Technical Services

6 Accessories

Not involved.

7 Connecting to a Smart Devcie via Bluetooth (Optional)

Bluetooth LE is an optional feature available on specific versions of Oximeter for use with compatible smart devices.

7.1 Bluetooth Connection

The Oximeter provides a Bluetooth wireless option to allow connection to a compatible smart device. The Bluetooth communication is only available to smart devices using the NarigMed App. When a Bluetooth connection is established, the Bluetooth connected icon will appear. Oximeter can only communicate to a single smart device at one time to minimize the risk of unauthorized access.

Note: The Oximeter requires the use of the NarigMed app to communicate to a compatible smart device.

7.2 Pair Oximeter to Smart Device

1. Ensure the Bluetooth is enabled on the smart device through the device settings.

2. From your compatible smart device, perform one of the following:

- ✧ For AndroidTM-powered devices, please scan the right icon.
- ✧ For Apple® devices, go to the App Store.

3. Search and download the “NarigMed” app.

4. Launch the “NarigMed” app.

5. Default the Bluetooth switch is turned on; you can find setup at Menu option.

6. Follow the Narigmed app on-screen instructions to pair a device.

7. When the Narigmed app identifies the Oximeter, data from Oximeter will displayed on app screen.

8. Place Oximeter on the patient's finger. Confirm that readings on Oximeter and readings displayed on the Narigmed app are the same without a delay greater than 10 seconds.

Note: If the delay is greater than 10 seconds, move the Oximeter closer to the smart device and repeat the connection process.

Note: To prevent unauthorized connection to the Oximeter, turn off the optional Bluetooth feature on the Oximeter when a connection is not required.

CAUTION: When using Oxiemter (optional Bluetooth version) with a smart device, keep both devices within range of each other; moving out of range may cause a loss in connection with the smart device.

CAUTION: When using Oximeter (optional Bluetooth version) with a smart device, relocate the devices away from sources that may interfere with the Bluetooth connection. Interference may result in loss of Quality of Service of the Bluetooth connection.

7.3 Disconnect Paired Oxiemter

1. On the smart device, access the Narigmed app Options.

2. Press/select the Paired Device information.

3. Select Forget this Device. Oxiemter will be disconnected from the smart device. Oximeter will need to be paired if it is to be used with this smart device again.

8 Specification

8.1 Product Specification

1. The product uses internal power supply.

2. Power requirements: 2 AAA batteries.

3. Liquid inlet protection degree: IP22.

4. Operation mode: run continuously.

5. Electrical safety classification: BF type application part.

6. Not suitable to use in places with flammable anesthetic gas.

7. Normal working conditions: ambient temperature range: 0 ~ 40 ℃; ambient humidity range: 15% ~ 95% non-condensing; atmospheric pressure range: 79.5kPa ~ 107.4kpa.

8. Storage environment: environment temperature range: -20 ~ 60 ℃; environment humidity range: 15% ~ 95%, non-condensing; atmospheric pressure range: 79.5kPa ~ 107.4kpa.

9. Physical dimension: 62mm ×35mm ×31mm.

10. Product weight: ≤75g (including battery).

11. Parameters of LED light source.

Light Source	*Central Wavelength*	*Radiant Power*
Red light	660nm	<15mW
Infrared light	905nm	<15mW

8.2 Parameter Specification

1. Functional Oxygen Saturation (SpO_2):

Condition	*Range*	A_{RMS}*
No Motion [1]	70% - 100%	2%
Motion [2]	70% - 100%	3%
Low Perfusion [3]	70% - 100%	2%
Range [0% - 69%] is undefined.		

2. Pulse Rate (PR):

Condition	*Range*	A_{RMS}*
No Motion [4]	25 bpm - 250 bpm	2 bpm
Motion [4]	25 bpm - 250 bpm	4 bpm
Low Perfusion [4]	25 bpm - 250 bpm	2 bpm

*A_{rms} accuracy is statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/– A_{rms} of the reference measurements in controlled study.

(1) The FRO series Pulse Oximeter has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70% - 100% against a laboratory co-oximeter.

(2) The FRO series Pulse Oximeter has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies while performing rubbing and tapping motions, at 2 ~ 4 Hz at an amplitude of 1 ~ 2 cm and a non-repetitive motion between 1 ~ 4 Hz at an amplitude of 1 ~ 2 cm in the range of 70% - 100% against a laboratory co-oximeter.

(3) The FRO series Pulse Oximeter has been validated for low perfusion accuracy in bench top testing against a Fluke Index II simulator with signal strengths of greater than 0.025% and transmission of default level 4000 for saturations ranging from 70% ~ 100%.

(4) The FRO series Pulse Oximeter has been validated for pulse rate accuracy for the range of 25 ~ 250 bpm in bench top testing against a Fluke Index II simulators with signal strengths of greater than 0.025% and transmission of default level 4000 for saturations ranging from 70% ~ 100%. Pulse rate accuracy under motion was verified by bench top testing in the range of 45 ~ 180 bpm against a Fluke Index II simulator using the motion preset settings (Preset Motion Type: Leve_0 and Level_1).

3. Respiration Rate*Note

The measurement scope of respiratory rate is between 4rpm~70rpm with measurement accuracy not specified.

***Note**: The parameter of respiration rate is not applicable for North America.

4.Plethysmogram

Provide non-normalized plethysmogram.

5. Bargraph

Bargraph is an instantaneously physiological index, which the maximum amplitude reflects the strength of blood perfusion and the rhythm reflect the stability of the physiological signal.

6. Update period

The data update period is less than 16s. The default average time is 6s, and provide 2s, 4s, 6s, 8s, 10s, and 12s levels for user selection. Saturation and pulse rate are routinely calculated for each second.

Short average time selection will get good physiological following feature, while long average time selection will get steadily physiological output by restrict the short-term physiological fluctuation.

7. Signal incompleteness

There will prompt invalid output as "--" when parameters turned into invalid state during bad condition such as too large noise signal, bad signal quality, or physiological signal disappear.

8. Signal Sensitivity

Signal Sensitivity allows users to select the probability of valid parameter under low perfusion condition. High sensitivity means more parameter output under low perfusion condition, which might increase probability of unreliable parameter value. Low sensitivity means less parameter output under low perfusion condition, which can reduce probability of unreliable parameter value. Use high sensitivity settings will get fast respond to the parameter, otherwise low sensitivity will get slow respond to the parameter.

According to industry convention, low perfusion condition is defined as less than 0.3%. Default sensitivity configuration is recommended for most population. Anyway, if people in week perfusion condition (<0.3%), high sensitivity might be useful.

9 Clinical Performance

9.1 Summary

According to the principle of ISO80601-2-61 and YY0784, the FRO-200 and FRO-100 were selected as representive for clinical trial investigation, and both quiet state and motion state are studied in this trial. The motion types are defined as follows:

Type I: Rubbing & Tapping, Frequency [2 ~ 4] Hz, amplitude [1 ~ 2] cm.

Type II: Non-Repetitive Motion, Frequency [1 ~ 4] Hz, amplitude [1 ~ 2] cm.

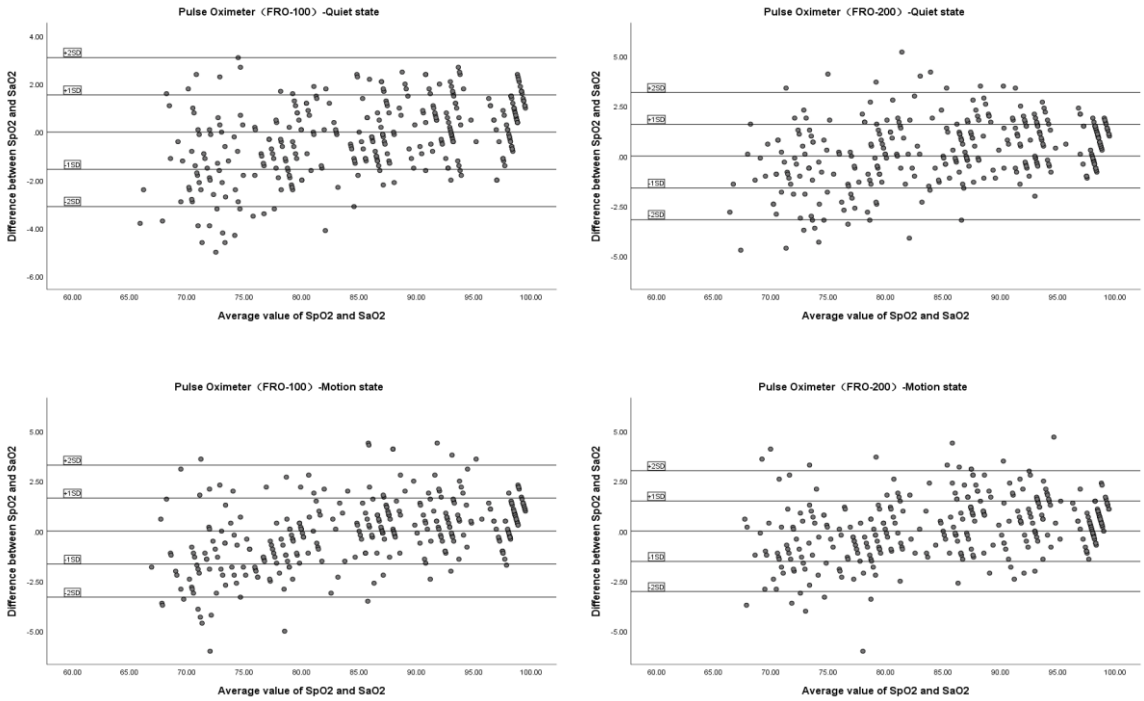
Totally 13 subjects were enrolled in this clinical trial. Among them, 3 cases were male, 10 cases were female, 2 cases were dark-skinned, 3 cases were light-skinned, and aged from 21 to 33 years old.

9.2 Results

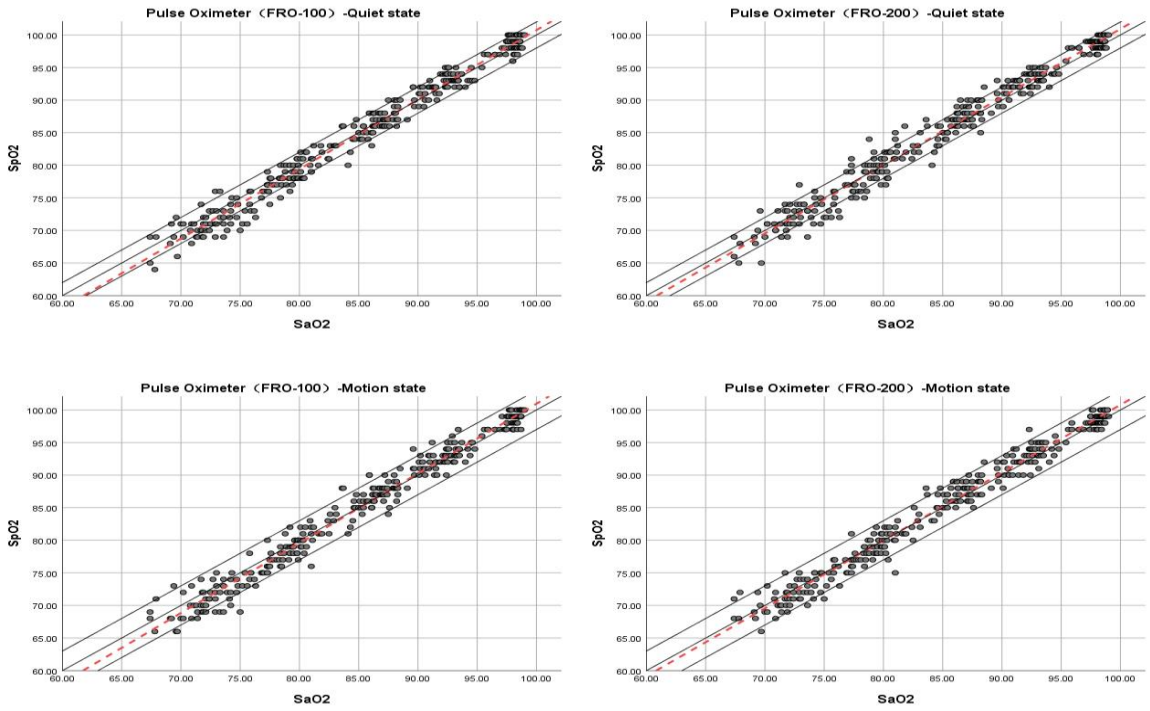
Estimate the accuracy based on the root mean square (A_{rms}) of measurements obtained by the pulse oximeter and the reference equipment. The results are as follows:

Pulse Oximeter	***Accuracy (A_{rms}) with Range (%)***				
	[100-60]	**[100-90]**	**(90-80]**	**(80-70]**	**(70-60]**
FRO-100 (Quiescence)	1.57	1.20	1.43	1.97	2.31
FRO-200 (Quiescence)	1.61	1.20	1.70	1.87	2.31
FRO-100 (Motion)	1.65	1.24	1.56	1.96	2.54
FRO-200 (Motion)	1.53	1.25	1.60	1.56	2.41

The ***scattergrams of difference distribution*** are as follows:



The ***linear fit distribution*** are as follows:



9.3 Conclusion

The study was conducted as expected with no adverse events and no deviations from the protocol.

The measurement parameters of Narigmed's pulse oximeter meets the requirement of the standard ISO 80601-2-61 and YY0784during both ***quiet state*** and ***motion state***. The SpO2 accuracy of type FRO-100 and FRO-200 pulse oximeters is equivalent to the invasive blood gas measurement results, and the pulse rate accuracy is equivalent to the heart rate measurement from an ECG monitor.

10 EMC Specification

10.1 Instructions for Use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pulse Oximeter (model name: FRO-200, FRO-201, FRO-202, FRO-203, FRO-204, FRO-100, FRO-101, FRO-102, FRO-103, FRO-104), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g., shielded cable, load impedance) or specifically (e.g., by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

10.2 Technical Description

1.All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions	
Emissions test	**Compliance**
RF emissions (CISPR 11)	Group 1
RF emissions (CISPR 11)	Class B
Harmonic emissions (IEC 61000-3-2)	Not application
Voltage fluctuations/ flicker emissions (IEC 61000-3-3)	Not application

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (1)

Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV 100 kHz repetition frequency	Not application
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV.	Not application
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle at 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle and 70% 25/30 cycles Single phase: at 0% 300 cycles	Not application
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Not application
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (2)							
	Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1 700 –	GSM 1800;	Pulse	2	0.3	28

	1845	1 990	CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	modulation 217 Hz			
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						