FondCircle

Smart Devices. Connected Care.

Pulse Oximeter User Manual



Model: FPO-F1

Version: 1.0.0_2507

FOREWORD

The FondCircle Pulse Oximeter is intended for non-invasive spot-checking of oxygen saturation (SpO_2) and pulse rate by measuring the absorption of light through the fingertip. It is suitable for use with adult patients. The device is designed for use by healthcare professionals or at home to monitor the respiratory status of patients, and is not intended for continuous monitoring or use on newborns or infants.

This user manual contains important safety and care information, and provides step-by-step instructions for using this pulse oximeter. FondCircle assumes no liability and provides no warranty for any damage (including indirect damage) resulting from failure to comply with this user manual. Please read through this user manual carefully before using the product and strictly follow all safety precautions.

Video Tutorials

Scan the QR code to watch the tutorial videos, which demonstrate how to use the pulse oximeter safely.

Online Manual

Scan the QR code to get the manual as a PDF, which can be enlarged and viewed on your mobile device.

Quick Start Guide

Scan this QR code to download the Bluetooth Quick Start Guide as a PDF, which can be enlarged and viewed on your mobile device.

App Download

Scan the QR code with your

PACKAGE CONTENTS

No.	Name	Quantity
1	Pulse Oximeter	1
2	User Manual	1
3	Quick Start Guide	1
4	AAA Battery	2

CONTENTS

WARNINGS AND PRECAUTIONS 1
Warnings 1
Safety Precautions 6
1. Contraindications 6
2. Electrical and Fire Safety 7
3. Precautions 8
SYMBOLS 12
FEATURES 15
PRODUCT DESCRIPTION 16
Usage Guide 16
1. Components 16
2. General Description 17
3. Declaration 18
Structure 19

Operation Principle 22
Intended Use 24
1. Intended User 24
2. Intended Patient 25
3. Indications for Use 25
Contraindications 26
HOW TO USE 27
Preparation Before Use 27
1. App 27
2. Setup 27
Operation Instructions 29
Battery Replacement 32
Checking Pleth Wave Quality and SpO_2 Stability 34
Important Notes Regarding Accuracy and Signal Quality 35
Quality 38
CLEANING AND DISINFECTION 38

Cleaning 38
Disinfection 41
ERRORS AND TROUBLESHOOTING 43
SPECIFICATIONS 50
STORAGE AND TRANSPORTATION CONDITIONS 55
Storage Conditions 55
1. Working Environment 55
2. Post-Cleaning Storage 56
3. Battery Storage 56
Transportation Conditions 57
1. Packaging for Transport 57
2. Environmental Requirements During Transport 58
3. Precautions During Transport 58
Maintenance During Storage and Transport 59
DISPOSAL 60
EMC STATEMENT 61
WARRANTY AND CUSTOMER SUPPORT 73

WARNINGS AND PRECAUTIONS

WARNINGS

- Federal law restricts this device to sale by or on the order of a physician.
- Do not use this device in environments with flammable anesthetic gases or other explosive materials.
- Do not use the device while the patient is undergoing MRI or CT scans.
- Avoid using the device near active high-frequency surgical equipment, RF-shielded

MRI rooms, or other areas with strong electromagnetic disturbances.

- Do not use this device adjacent to or stacked with other equipment as it could cause improper operation.
- Portable RF communications equipment, including antennas and cables, should be kept at least 30 cm (12 inches) away from the device to avoid degradation of its performance.
- This device is not intended for use on newborns or infants. The patient's finger thickness should be between 8 mm and 25.4 mm.
- Always inspect the device before use. If there is visible damage, discontinue use immediately.

- Prolonged use, especially in patients with microcirculation issues, may cause discomfort or pain. The device should not be used on the same finger for more than 10 minutes continuously.
- Do not use the device on areas with fragile or swollen skin.
- This device is for clinical diagnosis assistance only. The data displayed is for reference and should not be used for diagnostic interpretation.
- Do not use the device in high-frequency environments such as electrosurgical equipment.
- Do not immerse the device in any form of liquid. If it gets wet, discontinue use and dry it thoroughly before reuse.

- Keep the device and its accessories out of reach of children to prevent accidental swallowing. Children should be supervised while using the device.
- Follow local ordinances and recycling instructions for proper disposal of the device and batteries.
- Do not attempt to service, maintain, or repair the device while it is in use.
- Users are not authorized to perform any maintenance or repair tasks on the device.
- The device contains no replaceable parts. Do not attempt to open the device or replace internal components.

- Do not use the device on nails coated with enamel, artificial nails, or other types of fingernail polish as this may affect the accuracy of the readings.
- Ensure the user's fingernail is not excessively long as it may obstruct the device’s ability to capture accurate measurements.
- If you are allergic to rubber or any materials used in the device, do not use it.
- Do not use a functional tester to measure the device’s performance as this could result in inaccurate readings or damage to the device.
- Remove the batteries if the device will not be

used for over a month to prevent battery leakage.
- This device is designed for adults weighing between 40 kg and 110 kg. It may not provide accurate readings for patients outside this weight range.

SAFETY PRECAUTIONS

1. Contraindications

Not suitable for newborns, infants, or patients with abnormal hemoglobin types (e.g., methemoglobin, carboxyhemoglobin), as these can affect the accuracy of measurements.

Do not use the device on patients with severe peripheral vascular disease or poor peripheral circulation as this may result in inaccurate readings.

2. Electrical and Fire Safety

- Do not use the device near sources of strong
- electromagnetic interference, such as MRI or CT machines, high-frequency surgical equipment, or radiofrequency (RF) devices.
- Ensure the device is kept free from water and moisture to prevent electrical short circuits and malfunction.
- Do not attempt to open the device for servicing as this may result in electrical hazards.

- Use the device only with the specified power sources and ensure the batteries are properly

3. Precautions

- Pulse oximetry measurements may be affected by various factors. Ensure the following conditions are met for accurate readings:
  - Do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter, or infusion line(s). Avoid excessive ambient light, such as sunlight or direct home lighting.
  - Ensure that the device is dry as moisture can affect its performance.
  - Ensure the user’s finger is within the

recommended size range (8 mm to 25.4 mm).

- Ensure good pulse quality as poor circulation can lead to inaccurate readings.
- Avoid venous pulsations that may interfere with the measurement.
- Anemia or low hemoglobin concentrations may affect the accuracy of the readings.
- Intravenous dyes or abnormal hemoglobin types may interfere with measurements.
- Artificial nails or fingernail polish may distort the readings.
- Excessive movement during testing can result in inaccurate readings. Ensure the patient remains still during measurement.

- Proper device placement is crucial for accurate readings. Improper alignment may

- The light emitted by the device is harmful to the eyes. Avoid direct exposure to the emitted light.
- Ensure the device is correctly positioned on the finger. If the waveform is unstable, wait until it stabilizes before taking the reading for optimal accuracy.
- If abnormal conditions or error messages appear on the screen during measurement, remove the finger and reinsert it to restore normal operation.

- Cold fingers or very thin fingers may affect the accuracy of the readings. In such cases, use a larger finger and ensure it is fully inserted into the probe.
- Do not immerse the device in liquid. To clean, wipe it with a soft cloth moistened with medical alcohol. Avoid spraying any liquid directly onto the device.
- The pulse oximeter calculates and averages SpO2 and pulse rate values over a set period of time. Wait for the waveform to stabilize before taking the reading for optimal accuracy.

SYMBOLS

Symbol	Description
	Type BF applied part
	Caution
SpO_2%	Oxygen saturation
/Min	Pulse rate
	The equipment should be sent to the special agencies according to local regulation for separate collection after its useful life
	Alarm inhibit

	Refer to user manual
IP22	2: Protected against solid objects with a diameter of 12.5 mm or larger 2: If the thermometer is kept at a 15-degree angle, it can still withstand dripping water
	Date of manufacture
	Manufacture
	Non-ionizing electromagnetic radiation
	General symbol for recovery

LOT	Batch code
	MR unsafe

Note: The illustration used in this manual may differ slightly from the appearance of the actual product.

FEATURES

- Lightweight, portable, and easy to use
- OLED screen shows pulse rate, SpO_2, and perfusion
- Index large font display
- Low battery indicator
- Auto shut down if no signal is detected within 15 seconds

PRODUCT DESCRIPTION

USAGE GUIDE

1. Components

The oximeter consists of the following components:

- Probe: The probe is the applied part of the equipment, which is inserted into the user's finger to measure SpO_2 and pulse rate.
- Electronic Circuits: Responsible for processing the data and displaying the results.
- Display: The screen where the SpO_2 and pulse rate measurements are shown.

- Plastic Enclosures: The external casing that houses the components.

2. General Description

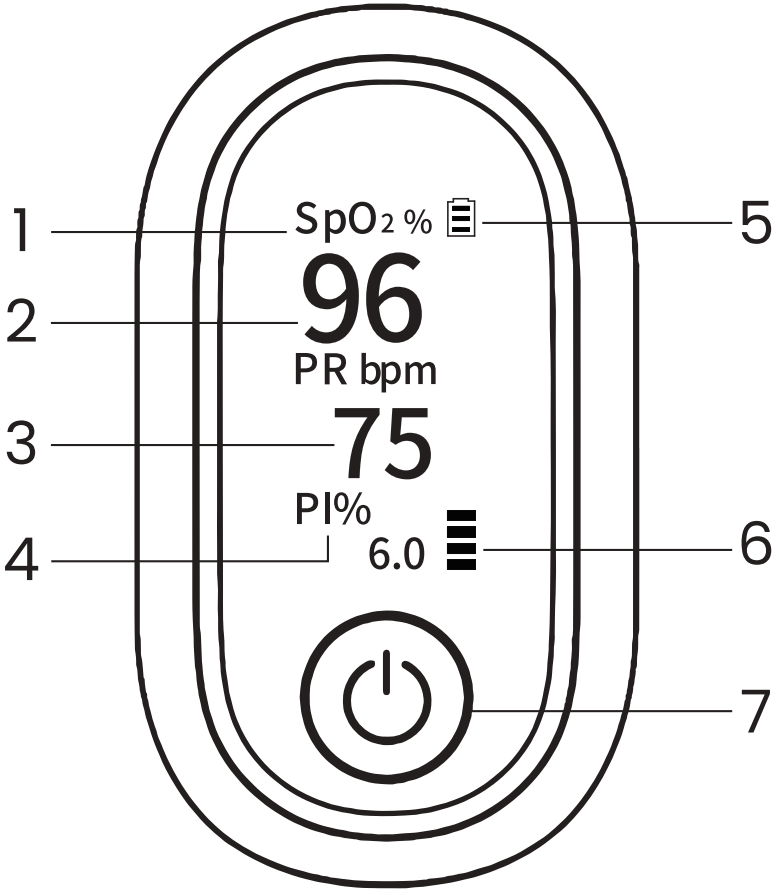
- The pulse oximeter measures peripheral capillary oxygen saturation (SpO_2), which represents the ratio of oxyhemoglobin (HbO_2) to the total concentration of hemoglobin (oxyhemoglobin + reduced hemoglobin) in the blood. SpO2 is a key physiological parameter for monitoring respiration and circulation.
- This device is small, portable, non-invasive, and easy to use. To take a reading, the user simply inserts their finger into the chamber, and the

oximeter both SpO_2 and pulse rate. The device is designed for home healthcare environments, providing convenient, at-home monitoring of

3. Declaration

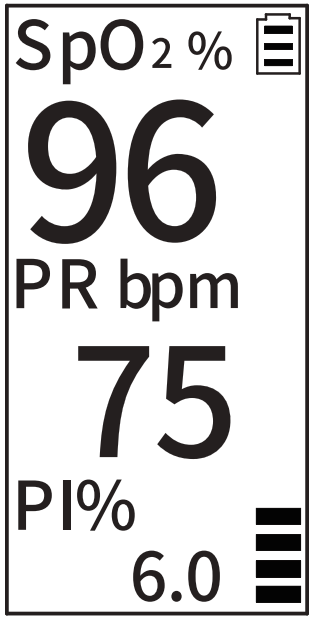
- The oximeter complies with the IEC60601-1-2 standard for Electromagnetic Compatibility (EMC).
- The materials that come into contact with the user meet the ISO10993-1, ISO10993-5, and ISO10993-10 standards, ensuring they are non-toxic and safe for contact with skin.

STRUCTURE



1. Symbol of Oxygen
2. Measured Value of Oxygen Saturation
3. Measured Value of Pulse Rate
4. Perfusion Index
5. Battery Indicator
6. Plethysmogram
7. Power On

The pulse plethysmogram display corresponds with the user's pulse beat. The height of the plethysmogram shows the user's pulse strength.



（Signal inadequacy display interface）

When the oxygen saturation and pulse rate signals are incomplete, the measured values are not displayed.

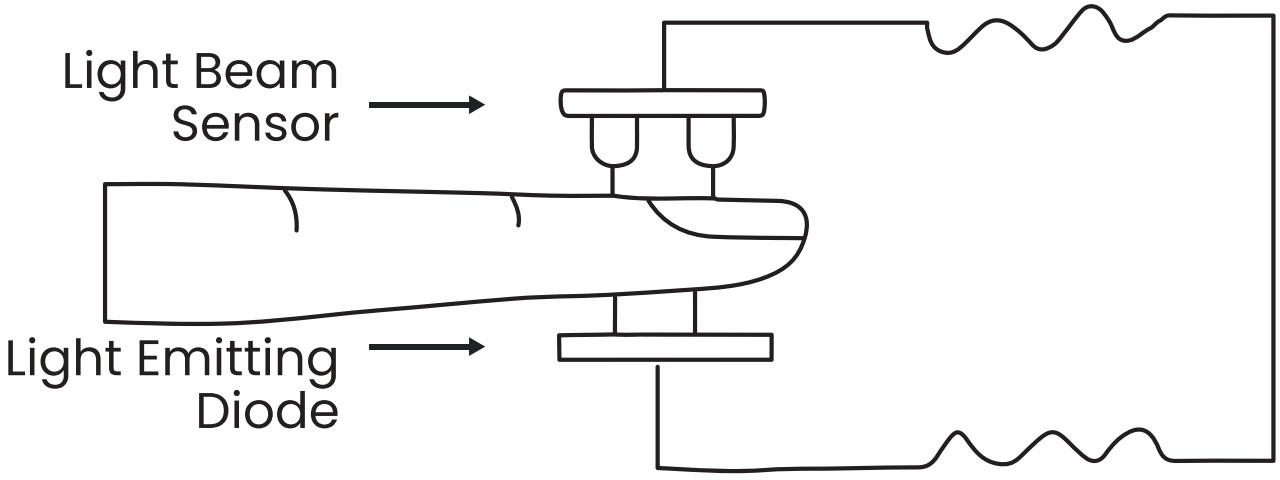
⚠ Caution

The bar graph acts as an indicator of signal incompleteness. The higher the bar graph, the stronger the pulse. When the bar graph is not beating smoothly, the accuracy of the measured value may be reduced at this time. When the bar graph tends to be beating smoothly, the measured value read is the best value.

OPERATION PRINCIPLE

Oxygenated blood absorbs light preferentially at 905nm (near infrared light), whereas deoxygenated blood absorbs light preferentially at 660nm (red light). A pulse oximeter works by passing a beam of red and infrared light through a pulsating capillary bed and then measures the amount of red and infrared light emerging from the tissues via a sensor. To improve accuracy, the oximeter uses a proprietary algorithm to collect data from pulsatile arterial blood and excludes local noise from the tissues. The relative absorption of light by oxyhemoglobin (HbO) and deoxyhemoglobin is

then calculated according to the Beer-Lambert's Law and a quantitative measurement of the users' oxyhemoglobin status (i.e. oxygen saturation level (SpO_2)) is derived. Due to the sensitivity of the pulse oximeter, the finger should be kept stationary during measurement. It is recommended that you use this device for measurement before or after sports. Do not use for continuous monitoring.



INTENDED USE

The pulse oximeter is a reusable medical device intended for the spot-checking of oxygen saturation (SpO_2) and pulse rate in adult patients. The device is designed to be used on the finger to non-invasively estimate and monitor peripheral blood oxygen

1. Intended User

The pulse oximeter may be used by healthcare professionals as well as at home. It is designed for ease of use by both trained medical personnel and individuals for self-monitoring.

2. Intended Patient

The pulse oximeter is intended for use on adult patients only. It is not intended for use on newborns, infants, or pediatric patients.

3. Indications for Use

The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult. It is not intended to be used under motion or low perfusion scenarios.

The product is not intended for diagnostic of any diseases or conditions.

CONTRAINDICATIONS

It is not intended to be used when the following happens:

- Pulse oximeter should not be fixed on the tissue injury site.
- Not used for blood oxygen monitoring in hyperkinetic patients.
- Not used for blood oxygen measurement under hypoperfusion.

HOW TO USE

PREPARATION BEFORE USE

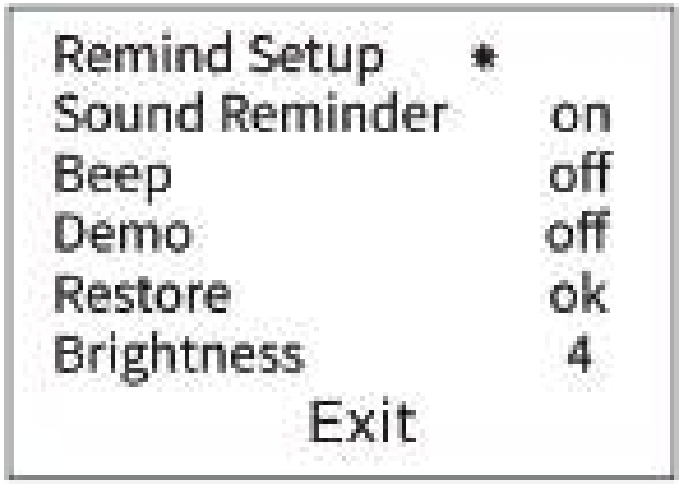
1. App

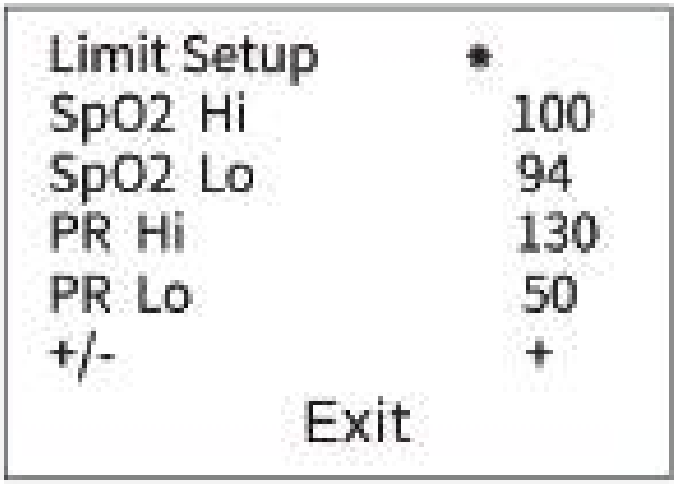
Before using the Pulse Oximeter, download and install the FondCircle® app. Always use the latest version of the app. You can download it from Google Play or the App Store.

2. Setup

After the oximeter is turned on, press the power on button for a second to enter the setting interface.

Press the power on button once to switch among the settings. Keep pressing the button for a second to change the current settings of sounds on or off and other parameters.





- A sound is sounded when the blood oxygen level falls below the set threshold to alert the user.

- A sound is sounded when the pulse rate exceeds the set threshold to alert the user.

Note: The sound function is only used to remind the user to check their blood oxygen level and is not used for any alarm purposes. Any time users have doubts about their blood oxygen saturation, they should check their blood oxygen measurement in time.

OPERATION INSTRUCTIONS

- Install two AAA batteries into the battery compartment.

- Insert one of your fingers into the finger chamber of the pulse oximeter.

Note: The fingernail should be facing the top chamber (which contains the sensor). The finger should also be inserted completely into the chamber. Otherwise, measurement will be inaccurate.

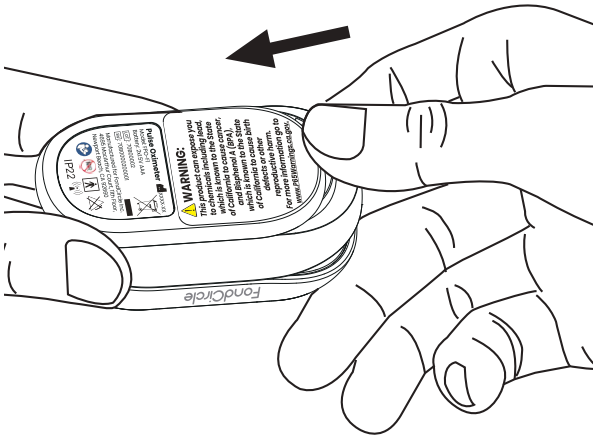
- Press the power on button to turn on the pulse oximeter.
- The finger and body should not tremble during measuring.
- Read correct data from displayed screen.

Note:

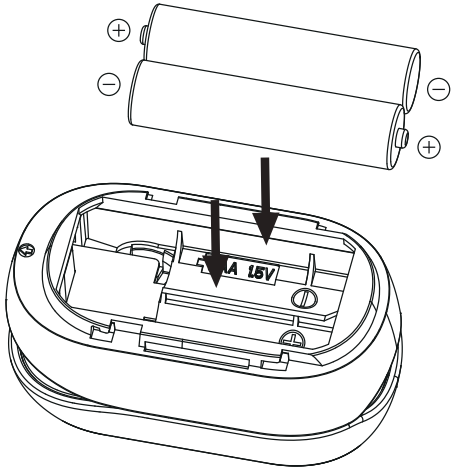
- When your finger is inserted into the oximeter, your nail surface must be upward.
- The results may be wrong if you do not place your finger thoroughly in the oximeter.
- Use medical alcohol to clean the silicone which touches the finger inside of oximeter, and use alcohol to clean the test finger before and after each test. (The silicone inside of the oximeter belongs to medical silicone, which has no toxins and does no harm to the skin).

BATTERY REPLACEMENT

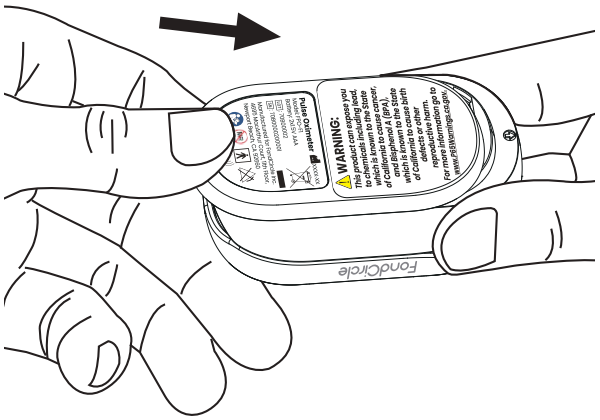
Insert two AAA batteries into the battery compartment, ensuring the correct polarity.



1. Open the battery cover: Push firmly with your finge.



2. Put the battery into the battery compartment.



3. Close the battery cover: Push firmly with your finger.

Note:

- Battery polarities should be correctly installed. Otherwise, damage may be caused to the device.
- Remove the batteries if the oximeter will not be used for a long time.
- This product should be kept away from children,
- because small parts such as battery cases can cause children to choke.

CHECKING PLETH WAVE QUALITY AND SPO_2 STABILITY

- To ensure the pulse oximeter is functioning properly and the SpO_2 readings are accurate, it is essential to monitor both the quality of the pleth wave and the stability of the SpO_2 values during use. Always evaluate both parameters simultaneously to assess the validity of the SpO_2 readings.
- Pleth Wave Quality: The pleth wave reflects the quality of the light signals received by the sensor. A poor-quality pleth wave indicates a decline in signal validity. Ensure that the pleth

wave is stable and clear for accurate readings.

- SpO_2 Stability: Stability of SpO_2 values is crucial for validating the measurement. Unstable SpO_2 values could indicate sensor interference or incorrect sensor placement, leading to inaccurate readings. Ensure that the SpO_2 values remain stable during the monitoring process.

IMPORTANT NOTES REGARDING ACCURACY AND SIGNAL QUALITY

- SpO_2 Accuracy: The accuracy of the SpO_2 measurements has been validated through human studies comparing the readings to arterial

blood samples obtained using a CO-oximeter Pulse oximeter measurements are statistically distributed, and approximately two-thirds of the measurements are expected to fall within the specified accuracy range compared to CO-oximeter readings. These studies involved healthy adults aged 18 to 46, with varying skin pigmentation. It is important to note that accuracy cannot be assessed using a function tester.

- Pulse Rate Accuracy: Pulse rate accuracy is determined by comparison with a pulse generated by an arterial oxygen simulator (also an electronic pulse simulator).

- Factors Affecting Accuracy: The quality of the pleth wave reflects the sensor's ability to capture light signals. A poor-quality wave indicates that the signal validity has declined. Similarly, instability in the SpO_2 readings can indicate sensor malfunction or interference, which may result from patient movement, incorrect sensor placement, or other factors. To obtain accurate and reliable SpO_2 readings, it is crucial to minimize patient movement and ensure correct sensor placement.

CLEANING AND DISINFECTION

CLEANING

To ensure the proper functioning and hygiene of the pulse oximeter, it is important to clean the device regularly. The frequency of cleaning should be increased if the equipment is exposed to heavy pollution, dust, or sand.

Recommended Cleaning Agents

- Ethanol (70%) is recommended for cleaning.

Cleaning Instructions

- Please shut down and remove the battery before cleaning.

- Clean the oximeter with a clean soft cloth moistened with ethanol 70% for 1 minute.
- Visual inspection for residual soil. If the residual soil remains, please repeat the cleaning with ethanol 70% until there is no residual soil.
- After cleaning, wipe off the ethanol 70% with a soft cloth for 1 minute. If the oximeter’s enclosure is cracked, it must be returned to manufacturer for service.
- Allow the oximeter to air dry at least 5 minutes.

Precautions to Avoid Damage

- Always dilute cleaning agents according to the manufacturer's instructions or use the lowest

possible concentration.

- Do not immerse the device in liquid or pour liquid directly onto the device or its accessories.
- Avoid abrasive materials (e.g., steel wool, silver polish) and erosive cleaners (e.g., acetone or acetone-based cleaners).
- If liquid is spilled on the device, immediately contact customer support or authorized service personnel.Do not immerse the device in liquid or pour liquid directly onto the device or its accessories.
- Avoid abrasive materials (e.g., steel wool, silver polish) and erosive cleaners (e.g., acetone or

acetone-based cleaners).
- If liquid is spilled on the device, immediately contact customer support or authorized service personnel.

DISINFECTION

The pulse oximeter should be cleaned thoroughly before disinfection.

Recommended Disinfectant

- Ethanol (70%) is recommended for disinfection.

Disinfection Instructions

- The recommended disinfectants are the low-level disinfection: ethanol 70%.
- Please shut down and remove the battery before disinfecting the device.
- Clean the oximeter as instructed above.
- Disinfect the oximeter with cotton or soft cloth moistened with ethanol 70% for 3 minutes.
- After disinfection, be sure to wipe off the ethanol 70% left on the oximeter with a soft cloth moistened with water.
- Allow the oximeter to air dry.

Note: Never use ETO or formaldehyde for disinfection.

ERRORS AND TROUBLESHOOTING

Problem	Potential Cause	Solution
Display does not light up.	Batteries are depleated.	Replace with new batteries.
	Batteries are inserted incorrectly.	Insert the batteries correctly.
	The equipment is malfunctioning.	Contact FondCircle Customer Support.
The display is off suddenly.	The equipment is set to shut down automatically in 8 seconds when there are no correct physiological signals.	This is normal.

The SpO_2 and pulse rate are not displayed stably.	The thoroughfare from photo detector to light emitting diode was sheltered by some objects.	Check and clean the inside of the oximeter (especially the two sensor windows.)
	The finger is shaking or the patient is moving.	Keep still and try again.
	The finger is not placed inside deep enough.	Place the finger properly and try again.
	The finger's size is too big or too small.	Select a different finger and try again.

	Excessive ambient light.	Avoid the excessive ambient light.
	Pulse rate value is fluctuating.	The measurement is normal, and the patient has arrhythmia.
The SpO_2 and pulse rate can't be displayed normally.	The finger is not properly positioned.	Place the finger properly and try again
	The patient's SpO_2 is too low to be detected.	Try again. Go to a hospital if you are concerned with your results.
	Finger is too wet or dirty.	Clean and dry the finger before measurement.

	Finger temperature too low.	Warm the finger in warm water for a few minutes before measurement.
Pulse sound can't be turned off.	The button is not working.	Check the button and try again.
	The button was not pressed for long enough.	Make sure to press the button for 2-3 seconds.
Measurement results are inaccurate.	Incorrect measurement method.	Carefully read the user manual to ensure the correct measurement method.

	Unsuitable measurement environment.	Perform measurements in a suitable environment, avoiding extreme temperatures and bright light.
Oximeter clip not tight or unstable.	Spring malfunction or damage.	Check if the spring in the clip is functioning correctly; if malfunctioning, contact customer service for replacement.
	Clip part deformation.	Ensure the clip part is not deformed or damaged; if damaged, contact customer service.

Measurement takes too long.	Finger not correctly placed.	Ensure the finger is correctly placed in the oximeter clip and remains still.
	Unstable environment (e.g., vibration).	Perform measurements in a stable environment avoiding vibration or movement.
Oximeter frequently shuts down automatically.	Battery power is low.	Replace with new batteries.
	The auto power-off function is set to shut down automatically.	Check the user manual to understand the auto power-off function and adjust settings as needed.

⚠CAUTION

- There are no user-serviceable parts inside the oximeter.
- The cover should only be removed by qualified service personnel. If you are uncertain about the accuracy of any measurement, check the user's vital signs by alternate means; then make sure the oximeter is functioning correctly.
- Do not spray, pour, or spill any liquid on the oximeter, its accessories, connectors, switches, or openings in the enclosure as this may damage the oximeter.

SPECIFICATIONS

Display Type	OLED
SpO_2	Display range: 35-100% Resolution: 1% Accuracy: ±2% for 70-100%; less than 70% is unspecified
Pulse Rate	Measurement range: 25-250 bpm Resolution: 1 bpm Accuracy: ±2 bpm
Pulse Intensity	Bargraph Indicator

Perfusion Index	Measurement range: 0%-50% Resolution: 1% Accuracy: 0.1% (0-1%); 1% (1-20%); >20% no definition
Battery	Power Requirements: Two AAA Alkaline Batteries Power Consumption: 30mA (Normal) Low Battery Indication: When the battery voltage is 1.9V ±0.2V, the oximeter will automatically shut down. Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 24 hours.

Dimension	63.4 × 36.0 × 33.6 mm
Operating Conditions	Temperature: 10-40°C (50-104°F) Humidity: 15-95% RH, non-condensing Atmospheric Pressure : 70-106 kPa
Storage & Transportation Conditions	Temperature: -20-50°C (-4-122°F) Humidity: 15-95% RH, non-condensing Atmospheric Pressure: 70-106 kPa
Measurement Performance in Low Perfusion Condition	0.3%

Weight	38.1 g (excluding batteries)
Safety Classification	Type of Protection Against Electric Shock: Internally powered equipment Degree of protection against electric shock: Type BF-Applied part (non-defibrillation proof) Operating Mode: Continuous operation Degree of Protection Against Hazards of Explosion: IP22
Range of the Peak Wavelengths	RED: 660nm/IR: 905nm

Other Parameters	Maximum Optical Output Power: 1.2mW Use-life: 5 years Communication Mode: Bluetooth 4.0

Note:

- SpO_2 and pulse rate accuracy are the essential
- requirements.
- There is no alarm that includes the capability to detect an SpO_2 or pulse rate physiological alarm condition is available.
- Data update duration is not applicable since it is not intended to be connected with other device to display the reading.
- The oximeter is for spot checking, Frequency of use is notapplicable.

STORAGE AND TRANSPORTATION CONDITIONS

STORAGE CONDITIONS

1. Working Environment

- Store the pulse oximeter in a dry, cool, and well-ventilated environment.
- The ambient temperature should be between 10°C to 40°C, and relative humidity should be between 15% and 95% (non-condensing).
- Avoid exposure to direct sunlight, excessive infrared radiation, or ultraviolet rays.
- Keep the device away from moisture, as a wet

environment may affect its lifetime and potentially cause damage.

2. Post-Cleaning Storage

- After cleaning and disinfection, ensure the device is completely dry before storing it.
- Store the device in its original protective case or a clean, dust-free container to maintain its hygiene and prevent physical damage.

3. Battery Storage

- Remove the batteries if the device will not be operated for an extended period to prevent battery leakage or corrosion.

- Store batteries separately in a cool, dry place according to the manufacturer's instructions.
- Replace the batteries promptly when the low battery indicator is illuminated.

TRANSPORTATION CONDITIONS

1. Packaging for Transport

- Use the original packaging or a sturdy protective case to transport the device. Ensure the device is securely placed to avoid movement during transport.
- Include protective padding around the device to prevent mechanical shocks or damage during handling.

2. Environmental Requirements During Transport

- The transport environment should meet the following conditions:
  - Temperature: -20-50°C
  - Humidity: 10-95% (non-condensing)
- Avoid exposure to rain, vibration, or strong magnetic fields during transport.

3. Precautions During Transport

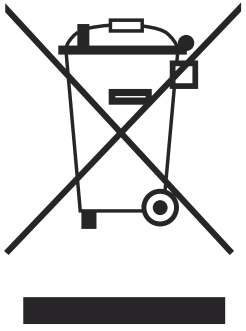
- Do not place heavy objects on the packaging to prevent deformation or damage to the device.
- Handle the device with care to avoid drops or impacts that could affect its performance.

MAINTENANCE DURING STORAGE AND TRANSPORT

- Regularly inspect the device during storage for signs of wear, corrosion, or physical damage.
- If the device has been stored or transported in extreme environmental conditions, perform a functional check before use to ensure it operates as intended.
- Dispose of used batteries according to local government regulations and environmental standards to ensure proper handling and recycling.

DISPOSAL

- Please follow local ordinances and recycling instructions for proper disposal of the device and batteries.
- Remove batteries if the device will not be used for an extended period (over one month) to prevent battery leakage.



EMC STATEMENT

Guidance and Manufacturer's Declaration: Electromagnetic Emission		
The FondCircle Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the model FPO-F1 should assure that it is used in such an environment.		
Emissions	**Compliance**	**Electromagnetic Environment: Guidance**
RF emissions CISPR 11	Group 1	The FondCircle Pulse Oximeter uses RF energy only for its internalfunction. 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 FondCircle 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 IEC61000-3-2	N.A.	N.A.
Voltage fluctuations/flicker emissions IEC61000-3-3	N.A.	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
The FondCircle Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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	Not applicable	Not applicable	
Surge IEC 61000-4-5	Not applicable	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	

Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC61000-4-6	Not applicable	Not applicable	
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: UT is the a.c. mains voltage prior to applicatiaon of the test level			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity
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Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE REPORT IMMUNITY to RF wireless communications equipment)

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance Level(V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27

450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN	Pulse modulation 18 Hz	2	0.3	28	28
870							

930		820, CDMA 850, LTE Band 5					
1720 1845 1970	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28

2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	2	0.3	9	9
5500							
5785							

Guidance and Manufacturer's Declaration: Electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance Level (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

⚠ Caution

- The Pulse Oximeter needs special precautions regarding EMC and needs to be installed and put

into service according to the EMC information provided for in the ACCOMPANYING DOCUMENTS.

- Portable and mobile RF communications equipment can affect pulse oximeter.
- The pulse oximeter should not be used adjacent to or stacked with other equipment.

Guidance and Manufacturer's Declaration: Electromagnetic Emission for All EQUIPMENT AND SYSTEMS.

- EMC affects on pulse oximeter, please keep EMC away from pulse oximeter in operation.
- The following RF emitters may be a source of electromagnetic disturbance: diathermy,

electrocautery, WPT, 5G, EAS and RFID. Please avoid to be exposed to these potential electro magnetic disturbance sources.

- RFID and EAS may be concealed in the environment, if electromagnetic disturbance appeared, please check the potentially sources in the surrounding one-meter area.
- Do not use the device near active HF surgical equipment and the MRI room.

WARRANTY AND CUSTOMER SUPPORT

Warranty

The device is covered by a 12-month warranty from the date of purchase,
subject to the following terms and conditions.
The warranty does not cover:

- The batteries, packaging, or any other consumables.
- Damage resulting from improper use, including but not limited to:
  - Unauthorized disassembly or modification of the device.

- Accidental dropping or impact during use or transportation.
- Failure to follow the instructions provided in the user manual.

To claim warranty service, users must provide proof of purchase and comply with the terms outlined in the user manual.

Customer Support:

✉ Email: support@fondcircle.com

Tel: 1-877-899-7770 (US)
(Mon-Fri, 8:00 AM-5:00 PM PST)

Web: www.fondcircle.com

⚠ **WARNING:**

This product can expose you to chemicals including lead, which is known to the State of California to cause cancer, and Bisphenol A (BPA), which is known to the State of California to cause birth defects or other reproductive harm.
For more information go to www.P65Warnings.ca.gov.

Manufactured for FondCircle Inc.
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