Wellue 60FB

Wellue Fingertip Pulse Oximeter Model 60FB User Manual

Blood Oxygen Saturation Monitor with Built-in Memory

1. Important Safety Information

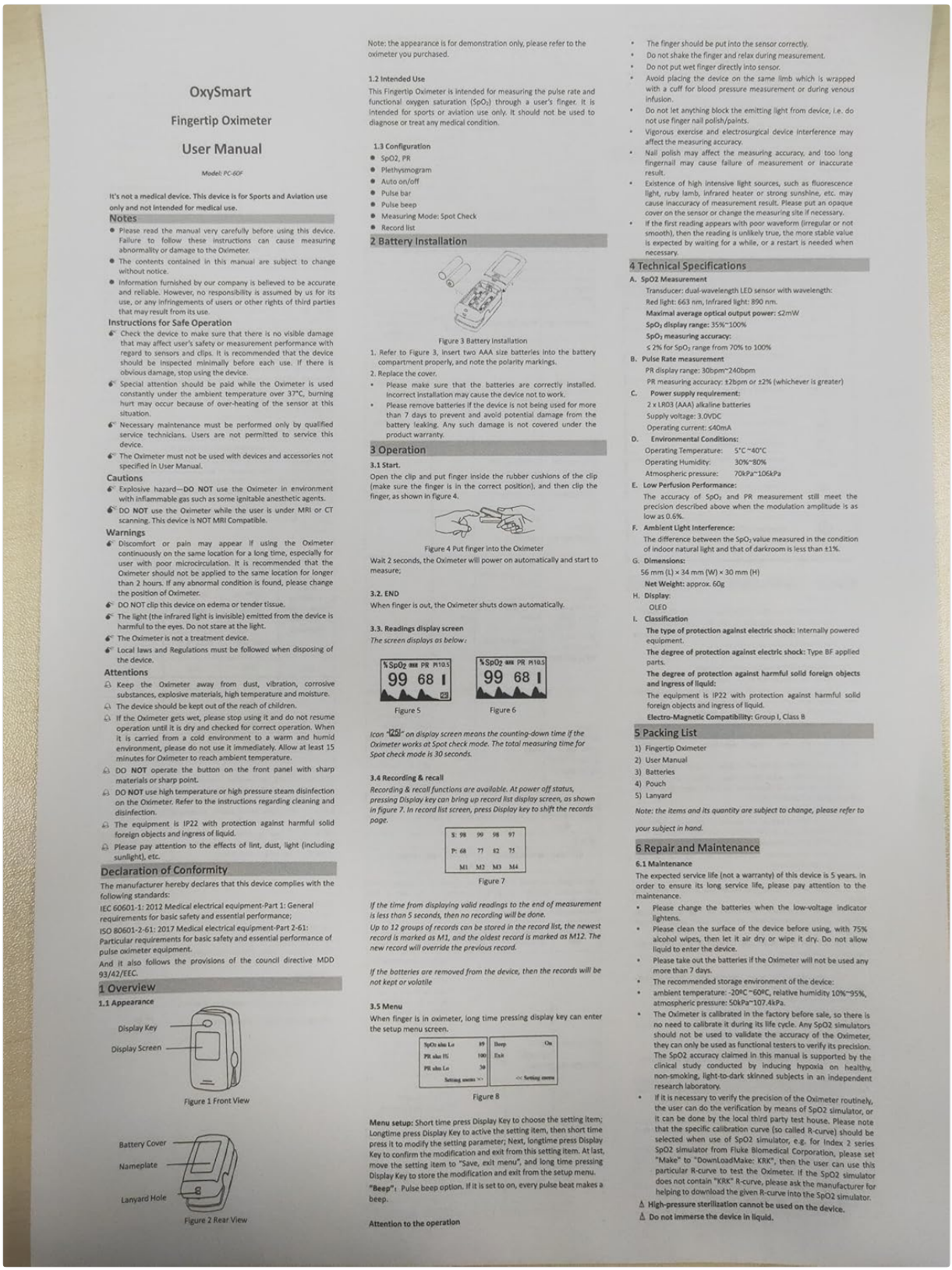
This device is intended for sports and aviation use only. It is not a medical device and is not intended for medical diagnosis or treatment.

- Do not apply the oximeter to the same location for longer than 2 hours.
- If any abnormal condition is observed, change the position of the oximeter.
- Keep the device away from dust, vibration, corrosive substances, explosive materials, high temperature, and moisture.
- Avoid using the oximeter in an environment with strong electromagnetic interference.
- The device is not suitable for continuous monitoring during sleep.

2. Package Contents

Verify that all items are present in the package:

- Wellue Fingertip Pulse Oximeter (Model 60FB)
- Lanyard
- 2 x AAA Batteries
- User Manual (this document)
- Carry Pouch



OxySmart

Fingertip Oximeter

User Manual

Model: PC-60F

It's not a medical device. This device is for Sports and Aviation use only and not intended for medical use.

Notes

- Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the Oximeter.
- The contents contained in this manual are subject to change without notice.
- Information furnished by our company is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of users or other rights of third parties that may result from its use.

Instructions for Safe Operation

- Check the device to make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally before each use. If there is obvious damage, stop using the device.
- Special attention should be paid while the Oximeter is used constantly under the ambient temperature over 37°C, burning hurt may occur because of over-heating of the sensor at this situation.
- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to service this device.
- The Oximeter must not be used with devices and accessories not specified in User Manual.

Cautions

- Explosive hazard—**DO NOT** use the Oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO **NOT** use the Oximeter while the user is under MRI or CT scanning. This device is NOT MRI Compatible.

Warnings

- Discomfort or pain may appear if using the Oximeter continuously on the same location for a long time, especially for user with poor microcirculation. It is recommended that the Oximeter should not be applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of Oximeter.
- DO NOT clip this device on edema or tender tissue.
- The light (the infrared light is invisible) emitted from the device is harmful to the eyes. Do not stare at the light.
- The Oximeter is not a treatment device.
- Local laws and Regulations must be followed when disposing of the device.

Attentions

- Keep the Oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- The device should be kept out of the reach of children.
- If the Oximeter gets wet, please stop using it and do not resume operation until it is dry and checked for correct operation. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately. Allow at least 15 minutes for Oximeter to reach ambient temperature.
- DO **NOT** operate the button on the front panel with sharp materials or sharp point.
- DO **NOT** use high temperature or high pressure steam disinfection on the Oximeter. Refer to the instructions regarding cleaning and disinfection.
- The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid.
- Please pay attention to the effects of lint, dust, light (including sunlight), etc.

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following standards:

IEC 60601-1: 2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;

ISO 80601-2-61: 2017 Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

And it also follows the provisions of the council directive MDD 93/42/EEC.

1 Overview

1.1 Appearance

Display Key
Display Screen

Figure 1 Front View

Battery Cover
Nameplate
Lanyard Hole

Figure 2 Rear View

Note: the appearance is for demonstration only, please refer to the oximeter you purchased.

1.2 Intended Use

This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through a user's finger. It is intended for sports or aviation use only. It should not be used to diagnose or treat any medical condition.

1.3 Configuration

- SpO2, PR
- Plethysmogram
- Auto on/off
- Pulse bar
- Pulse beep
- Measuring Mode: Spot Check
- Record list

2 Battery Installation

Figure 3 Battery Installation

1. Refer to Figure 3, insert two AAA size batteries into the battery compartment properly, and note the polarity markings.
2. Replace the cover.

- Please make sure that the batteries are correctly installed. Incorrect installation may cause the device not to work.
- Please remove batteries if the device is not being used for more than 7 days to prevent and avoid potential damage from the battery leaking. Any such damage is not covered under the product warranty.

3 Operation

3.1 Start.

Open the clip and put finger inside the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger, as shown in figure 4.

Figure 4 Put finger into the Oximeter

Wait 2 seconds, the Oximeter will power on automatically and start to measure;

3.2. END

When finger is out, the Oximeter shuts down automatically.

3.3. Readings display screen

The screen displays as below:

Figure 5

Figure 6

Icon "25" on display screen means the counting-down time if the Oximeter works at Spot check mode. The total measuring time for Spot check mode is 30 seconds.

3.4 Recording & recall

Recording & recall functions are available. At power off status, pressing Display key can bring up record list display screen, as shown in figure 7. In record list screen, press Display key to shift the records page.

S:	98	99	98	97
P:	68	77	82	75
	M1	M2	M3	M4

Figure 7

If the time from displaying valid readings to the end of measurement is less than 5 seconds, then no recording will be done.

Up to 12 groups of records can be stored in the record list, the newest record is marked as M1, and the oldest record is marked as M12. The new record will override the previous record.

If the batteries are removed from the device, then the records will be not kept or volatile

3.5 Menu

When finger is in oximeter, long time pressing display key can enter the setup menu screen.

SpO2 alm Lo	89	Beep	On
PR alm Hi	100	Exit	
PR alm Lo	50		
Setting menu >>		<< Setting menu	

Figure 8

Menu setup: Short time press Display Key to choose the setting item; Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter; Next, longtime press Display Key to confirm the modification and exit from this setting item. At last, move the setting item to "Save, exit menu", and long time pressing Display Key to store the modification and exit from the setup menu.

"Beep": Pulse beep option. If it is set to on, every pulse beat makes a beep.

Attention to the operation

- The finger should be put into the sensor correctly.
- Do not shake the finger and relax during measurement.
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device, i.e. do not use finger nail polish/paints.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- Nail polish may affect the measuring accuracy, and too long fingernail may cause failure of measurement or inaccurate result.
- Existence of high intensive light sources, such as fluorescence light, ruby lamb, infrared heater or strong sunshine, etc. may cause inaccuracy of measurement result. Please put an opaque cover on the sensor or change the measuring site if necessary.
- If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

4 Technical Specifications

A. **SpO2 Measurement**
Transducer: dual-wavelength LED sensor with wavelength:
Red light: 663 nm, Infrared light: 890 nm.
Maximal average optical output power: ≤2mW
SpO_2 display range: 35%~100%
SpO_2 measuring accuracy:
≤ 2% for SpO_2 range from 70% to 100%

B. **Pulse Rate measurement**
PR display range: 30bpm~240bpm
PR measuring accuracy: ±2bpm or ±2% (whichever is greater)

C. **Power supply requirement:**
2 x LR03 (AAA) alkaline batteries
Supply voltage: 3.0VDC
Operating current: ≤40mA

D. **Environmental Conditions:**
Operating Temperature: 5°C ~40°C
Operating Humidity: 30%~80%
Atmospheric pressure: 70kPa~106kPa

E. **Low Perfusion Performance:**
The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.

F. **Ambient Light Interference:**
The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

G. **Dimensions:**
56 mm (L) × 34 mm (W) × 30 mm (H)
Net Weight: approx. 60g

H. **Display:**
OLED

I. **Classification**
The type of protection against electric shock: Internally powered equipment.
The degree of protection against electric shock: Type BF applied parts.
The degree of protection against harmful solid foreign objects and ingress of liquid:
The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid.
Electro-Magnetic Compatibility: Group I, Class B

5 Packing List

1) Fingertip Oximeter
2) User Manual
3) Batteries
4) Pouch
5) Lanyard

Note: the items and its quantity are subject to change, please refer to your subject in hand.

6 Repair and Maintenance

6.1 Maintenance

The expected service life (not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the device before using, with 75% alcohol wipes, then let it air dry or wipe it dry. Do not allow liquid to enter the device.
- Please take out the batteries if the Oximeter will not be used any more than 7 days.
- The recommended storage environment of the device:
- ambient temperature: -20℃~60℃, relative humidity 10%~95%, atmospheric pressure: 50kPa~107.4kPa.
- The Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any SpO2 simulators should not be used to validate the accuracy of the Oximeter, they can only be used as functional testers to verify its precision. The SpO2 accuracy claimed in this manual is supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark skinned subjects in an independent research laboratory.
- If it is necessary to verify the precision of the Oximeter routinely, the user can do the verification by means of SpO2 simulator, or it can be done by the local third party test house. Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO2 simulator, e.g. for Index 2 series SpO2 simulator from Fluke Biomedical Corporation, please set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the Oximeter. If the SpO2 simulator does not contain "KRK" R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO2 simulator.

⚠ **High-pressure sterilization cannot be used on the device.**
⚠ **Do not immerse the device in liquid.**

Image: Package contents showing the oximeter, lanyard, batteries, and user manual.

3. Product Overview

The Wellue Fingertip Pulse Oximeter is designed to measure blood oxygen saturation (SpO2) and pulse rate (PR) non-invasively. It features an OLED screen for clear display and a built-in memory function.

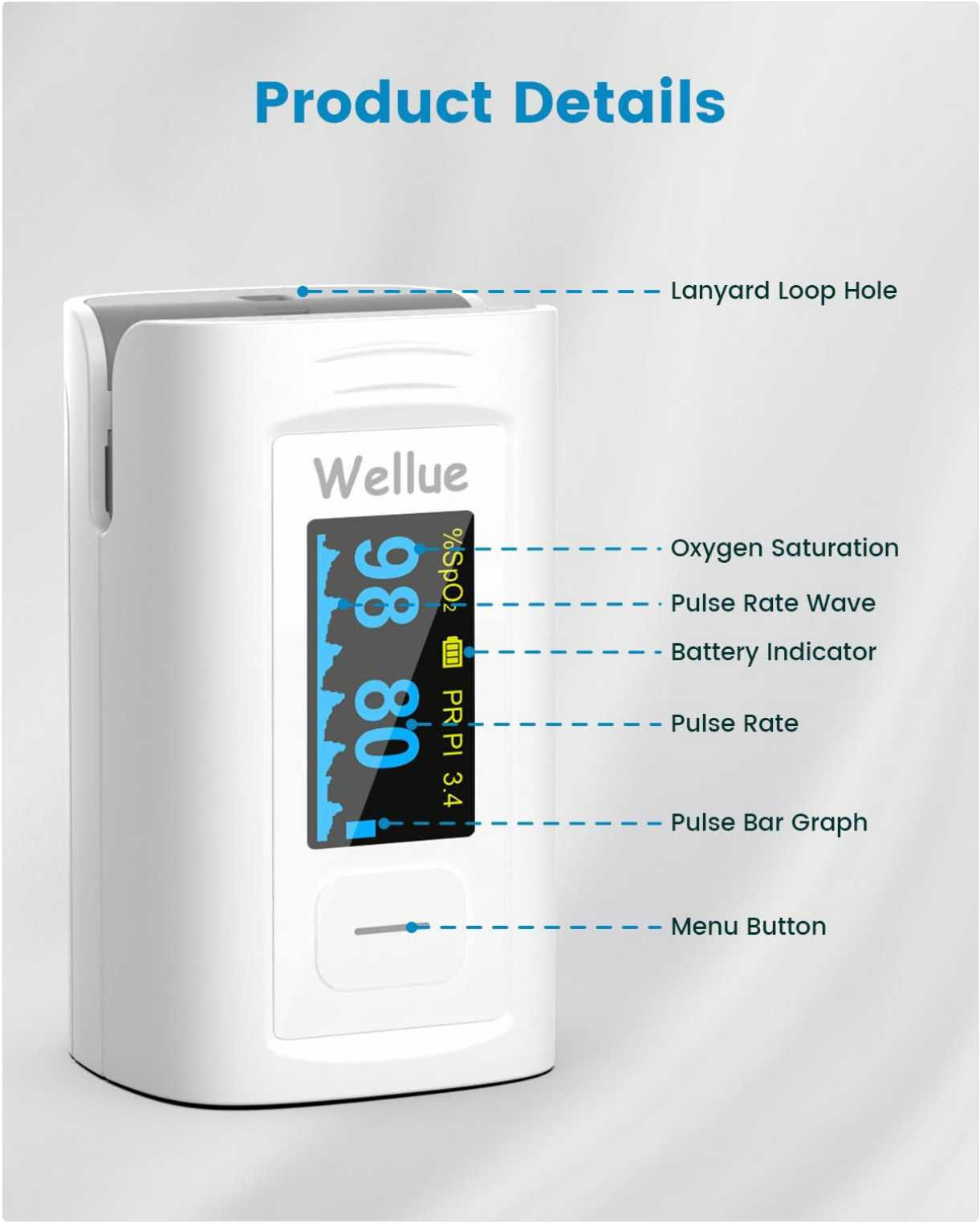


Image: Labeled diagram of the Wellue Pulse Oximeter components.

Key Features:

- **Accurate & Reliable:** Provides Plethysmograph waveform and Perfusion Index (PI) for reading accuracy assessment.
- **Built-in Memory:** Stores up to 12 sets of SpO2 and Pulse Rate data.
- **Spot Check Mode:** Analyzes SpO2 and pulse rhythm over 30 seconds.
- **Audible & Visual Reminders:** Alerts when SpO2 or Pulse Rate values exceed preset limits.
- **Auto On/Off:** Automatically powers on when a finger is inserted and off when removed.
- **OLED Screen:** Clear display of readings.

4. Setup

4.1 Battery Installation

The device requires two AAA batteries for operation. Ensure correct polarity during installation.

1. Open the battery cover located on the back of the device.
2. Insert two AAA batteries according to the polarity indicators (+/-) inside the compartment.
3. Close the battery cover securely.

Note: Remove batteries if the device will not be used for an extended period to prevent battery leakage.

5. Operating Instructions

5.1 Powering On and Off

- **Power On:** Insert a finger into the oximeter. The device will automatically power on within 8 seconds and begin measurement.
- **Power Off:** Remove your finger from the oximeter. The device will automatically power off within 3 seconds.

Image: Auto power on and off mechanism.

5.2 Taking a Measurement

1. Ensure the oximeter has sufficient battery power.
2. Open the clip and place one of your fingers (preferably the index finger) into the rubber opening of the oximeter. Ensure the finger is fully inserted and resting flat.
3. Release the clip. The oximeter will automatically turn on and begin measuring.
4. Keep your hand still during measurement. Readings for SpO2, Pulse Rate (PR), and Perfusion Index (PI) will be displayed on the OLED screen. A plethysmograph waveform will also be shown.
5. Once readings stabilize, you can record the values.

5.3 Measurement Modes

- **Spot Check Mode:** After approximately 30 seconds of measurement, the device will display the SpO2 and pulse rhythm analysis result. This mode provides a quick, average reading.
- **Continuous Monitoring:** The device continuously displays real-time SpO2, PR, and PI values. Note: The device is not recommended for continuous use at night.

Image: Spot Check Mode display and analysis.

5.4 Built-in Memory

The oximeter can store up to 12 sets of SpO2 and Pulse Rate data. To view historical data:

- When the device is off, press the main button to recall the last 12 records.
- The records will be displayed sequentially.

Image: Built-in memory display showing stored SpO2 and Pulse Rate data.

5.5 Audible and Visual Reminders (Alarms)

The device features audible beeps and flashing values on the screen if your SpO2 or Pulse Rate exceeds or falls below preset limits.

Image: Audible reminder in action.

5.6 Menu Setup

To access the setup menu:

- While measuring, long-press the main button to enter the setup menu.
- In the menu, you can adjust parameters such as SpO2 alarm limits (SpO2 alm Lo, SpO2 alm Hi) and Pulse Rate alarm limits (PR alm Lo, PR alm Hi).
- You can also toggle the beep reminder on or off.
- Short-press the button to cycle through options, long-press to confirm or exit.

Image: Menu setup options for alarm limits and beep settings.

6. Maintenance and Care

- **Cleaning:** Clean the surface of the oximeter with a soft cloth dampened with 70% isopropyl alcohol. Do not immerse the device in liquid.
- **Storage:** Store the device in a cool, dry place, away from direct sunlight and extreme temperatures.
- **Battery Replacement:** Replace batteries when the low battery indicator appears on the screen.
- **Disposal:** Dispose of the device and its components according to local regulations for electronic waste.

7. Troubleshooting

Problem	Possible Cause	Solution
No display after power on	Batteries are dead or incorrectly installed.	Replace batteries or reinstall them with correct polarity.
Inaccurate readings	Finger not properly inserted, excessive movement, cold finger, nail polish.	Reinsert finger correctly, remain still, warm hands, remove nail polish.
Display shows 'Error' or '---'	Signal too weak or sensor obstruction.	Ensure finger is clean and properly positioned. Try a different finger.
Device powers off unexpectedly	Low battery or automatic power-off after 3 seconds of inactivity.	Replace batteries. This is normal behavior if no finger is detected.

8. Specifications

Parameter	Detail
Product Dimensions	1.37 x 1.25 x 2.37 inches
Weight	2.82 ounces (with batteries)
Item Model Number	60FB
Batteries	2 x AAA batteries (included)
SpO2 Measuring Range	35% ~ 100%
SpO2 Measurement Accuracy	<2% (70-100%)
Pulse Rate Measuring Range	30 bpm ~ 240 bpm
Pulse Rate Measurement Accuracy	±2 bpm or ±2% (whichever is greater)
Display Type	OLED
Operating Temperature	5°C ~ 40°C (41°F ~ 104°F)
Storage Temperature	-20°C ~ 55°C (-4°F ~ 131°F)
Manufacturer	Creative Industry

9. Warranty and Support

For warranty information and technical support, please refer to the documentation included with your purchase or visit the official Wellue website. Keep your purchase receipt as proof of purchase for warranty claims.

Contact Information:

- Brand: Wellue
- Website: www.wellue.com