**USER MANUAL**

**SureLife® Clearwave Pulse Oximeters**

Thank you for purchasing the SureLife Pulse Oximeter. This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observation of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety. Read this manual carefully before using the fingertip pulse oximeter. This product is a reusable medical device. The lifespan of the product is 2 years. This device is a prescription use device.

### 1 - SAFETY

**1.1 Contraindications**
Do NOT use oximeter in a magnetic resonance (MR) environment.

**1.2 Warnings**
Keep the oximeter away from young children. Small parts such as the battery door, battery, and lanyard may be choking hazards.

**1.3 Cautions**
- Do not use the oximeter in the presence of flammable anesthetics.
- The oximeter needs to be used according to information provided in this user manual.
- The equipment is NOT intended for neonate and infant.
- Do not use a damaged oximeter as it may affect measurement performance.
- Do not place the oximeter in a place away from monitor or cuff.
- Do not use the oximeter for more than 30 minutes without reactivating the device to another finger.
- Do not use the oximeter for any other purpose.
- Do not use the oximeter as the only basis for making medical decisions, it is intended only to be used as additional information that you can give to your licensed healthcare professional.
- Do not use the oximeter in high frequency environments such as near electro-surgical equipment.
- Do not place the oximeter in liquid.
- Follow local disposal and recycling laws for the oximeter and its components, including the batteries.

### 2 - THE BASICS
The pulse oximeter is intended for use in home health care and medical facilities. This pulse oximeter is intended for use in home health care and medical facilities.

### 3 - INTRODUCTION

#### 3.1 Intended Use
The Pulse Oximeter is a portable, convenient, non-invasive device, used to monitor arterial hemoglobin oxygen saturation (SpO2) and pulse rate. The personal application are adult patients (weight > 10lbs) and pediatric patients (weight > 5-10 lbs). We recommend using the index fingers middle finger, or ring finger as suitable positions for the monitor. It is intended for spot-checking or attended-care monitoring in home health care and medical facilities.

**WARNING:**
- This pulse oximeter is intended to be used only by clinical professionals or under their guidance.

**CAUTIONS:**
- The oximeter is the opening in the middle of the equipment in which the finger is inserted.
- The probe is the Applied Part of the equipment.

#### 3.2 Features
- The oximeter is small in size, lightweight, and easy to carry.
- Low in power consumption (600 spot-checks on two AAA batteries.)
- Easy, one-button operation.
- There are two modes: sleep mode and automatic sleep mode after 8 seconds with no signal.

**NOTES:**
- Press the power button to activate oximeter (measure mode) from sleep mode.
- Automatic sleep mode after 8 seconds with no signal.
- Low in power consumption (600 spot-checks on two AAA batteries.)
- The pulse oximeter is small in size, lightweight, and easy to carry.

### 4 - BATTERY INSTALLATION

1. Put the two AAA batteries into battery compartment in correct polars.
2. Push the battery cover horizontally along the arrow shown in Figure 3.

**WARNING:**
- Battery polarities should be correctly installed, otherwise, damage may be caused to the equipment.
- Please remove the batteries of the oximeter if stored for more than 30 days.
- Do not use the batteries if you want turn off the oximeter. Otherwise it is always in sleep mode.
- The displayed parameters might be unreliable with un-periodic bar change.
- The displayed parameters will show invalid indicator as “---” if signal quality is very low.
- The displayed parameters will show invalid indicator as “---” if oximeter fault occurs.
- The oximeter will shut down after 5 minutes if continuous testing.

### 6 - SPECIFICATIONS

#### 6.1 Classification
**Type of protection against electric shock**: Type II (Internally powered equipment)

**Degree of protection against electric shock**: Type BF-Applied part (non-defibrillation proof)

**Operating mode**: Spot checking

**Degree of protection against hazards of explosion**: Ordinary equipment: Not protected

**Equipment type**: Fingertip oximeter

### 2.1 Principle
The Principle of the oximeter is as follows: an empirical formula of data process is making use of the Lambert Beer law according to Spectrum Absorption Characteristic of reducible hemoglobin (Hb) and oxyhemoglobin (HbO2). We recommend using the index fingers middle finger, or ring finger as suitable positions for the monitor. It is intended for spot-checking or attended-care monitoring in home health care and medical facilities.

**WARNING:**
- A finger, middle finger, and ring finger are suitable positions for the monitor.
- Excessive or rapid movement may affect measurement accuracy.
- Improper sensor placement may affect the measurement accuracy.
- The oximeter can be reused after cleaning and disinfection.
- The measurement is most accurate when the oximeter and the heart are at the same level.
- Only for Cerebrovascular patients.

**Note:**
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- **Only for Cerebrovascular** patients.
- The displayed parameters might be unreliable with an-periodic bar change.
- The displayed parameters will show invalid indicator as “---” if signal quality is very low.
- The displayed parameters will show invalid indicator as “---” if oximeter fault occurs.
- The oximeter will shut down after 5 minutes if continuous testing.

### 6.2 Measurement Specifications
**SpO2 declared accuracy**

Range(%).... 70% ~ 99% ± 2 digits

Resolution.... 1%

Update Period.... 1s

Average Time.... 8s

Polar declared accuracy

Range(%).... 0% ~ 69%: unspecified

Resolution.... 1%

Update Period.... 1s

Average Time.... 8s

#### 6.3 Power Requirements
- Specification of alkaline batteries... Two AAA
- Operating current... Less than 30mA
- Run time... 600 spot checks on two full-power batteries at ambient temperature 25°C

#### 6.4 Environmental Specifications
**Temperature**

Operating... -41°F to 104°F / -9°C to 40°C

Storage/Transportation... -40°F to 140°F / -60°C to +60°C

**Humidity**

Operating... 10 ~ 95%, non-condensing

Storage/Transportation... 10 ~ 95%, non-condensing

**Atmosphere Pressure**

Operating... 70 ~ 1016pa

Storage/Transportation... 50 ~ 1014pa

#### 6.5 Physical Specifications
- Wtishi x Height x Depth... 62x35x11 mm
- Weight.... 60 g (including the batteries)

#### 6.6 Display
- Wavelength... 670-850 nm (including the batteries)

### 3.4 Functions

<table>
<thead>
<tr>
<th>Function</th>
<th>Clearwave</th>
<th>Clearwave II</th>
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<td>Display</td>
<td>OLED</td>
<td>OLED</td>
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<tr>
<td>SpO2, pulse measurement</td>
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<td>Y</td>
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<tr>
<td>Pulse rate measurement</td>
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#### 3.5 Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Y</td>
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<td>T</td>
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### 3.6 LED Lamp Specifications

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<tr>
<th>Display Type</th>
<th>Wavelength</th>
<th>Radiant Power</th>
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<tbody>
<tr>
<td>LED</td>
<td>670-850 nm</td>
<td>0.5 mW</td>
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### 3.7 LED Wavelengths

- 6.7 LED Wavelengths: 670-850 nm
Below is the Bland-Altman graphical plot of samples from invasive controlled desaturation study.

APPENDIX A

The equipment complies with the requirement of standard EN 60601-1-2-2002 "Electromagnetic Compatibility - Medical Electrical Equipment".

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The SureLife Pulse Oximeters are intended for use in the electromagnetic environment specified below. The customer or the user of the SureLife Pulse Oximeters should ensure that this is a suitable environment.

- Immunity Test
  - BC: Basic Level
  - LD: Limiting Level
  - Compliance Level

- ElectroMagnetic Environment - Guidance
  - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Recommended separation distances between portable and mobile RF communications equipment and the SureLife® Pulse Oximeters

The SureLife Pulse Oximeters are intended for use in an electromagnetic environment that is regulated by certain international and regional standards. The SureLife Pulse Oximeters are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supply buildings used for domestic purposes.

All transmitters listed at a maximum output power not listed above, the recommended separation distance is not less than ten times the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

- The SureLife® Pulse Oximeters are intended for use in the electromagnetic environment specified below. The customer or the user of the SureLife Pulse Oximeters should ensure that this is a suitable environment.

- Power frequency magnetic fields should be at levels characteristic of a typical location commercial or hospital environment.

- Power frequency magnetic fields should be at levels characteristic of a special location commercial or hospital environment.

- It is recommended that the oximeter be cleaned and disinfected after every use as determined by your judgment.

- Never immerse or soak the oximeter.

- Dust and dirt, and follow these rules:

- 8.1 Maintenance
  - The equipment's design life expectancy is about 2 years, keep your equipment and accessories free of dust and dirt, and follow these rules:
  - A. Please clean the equipment before use according to section 8. Remove the batteries inside the battery cassette if the equipment will not be operated for more than 30 days.
  - B. Replace the batteries when the low battery indicator is on.

- 8.2 Disposal
  - Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations.

- 9 - CLEANING / DISINFECTION

- 9.1 Cleaning
  - The recommended cleaning agent is water.

- 9.2 Disinfection
  - The recommended disinfectants include ethanol 70%, isopropanol 70%.

- 10 - INCLUDED ACCESSORIES

- 11 - TROUBLESHOOTING

- 11.1 Troubleshooting WARNING

- **NOTE 1**: At 80 MHz and 800 MHz, the higher frequency range applies.

- **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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