

# USER MANUAL

## **Smart Pulse Oximeter**

Simple Operation

High Measuring Accuracy

**Model Name : OF4.0**

**Brand Name : NantLife**

**FCC ID: OXJOF40**



# NantLife

# NantLife

## Smart Pulse Oximeter

NantCare LLC, 2929 N 44th Street  
Phoenix, Arizona, 85018-7239 - USA

1-855-NANTCARE - Email: [support@nantcare.com](mailto:support@nantcare.com)  
[www.nantcare.com](http://www.nantcare.com)

## Table of Contents

### 1 Table of Contents

1.1	Introduction	P 4
1.2	Intended Use	P 5
1.3	Safety Information	P 5-8
1.3.1	Operating the device	P 6
1.3.1.1	Warnings	P 6
1.3.1.2	Cautions	P 8
1.4	Before taking a measurement	P 9
<b>2</b>	<b>Operating Instructions</b>	P 11
2.1	Know your Pulse Oximeter	P 11
2.2	Unit Display	P 12
2.3	Display Symbols	P 13
2.4	Batteries Installation	P 14
2.5	Batteries Replacement	P 15
2.6	Using the Pulse Oximeter	P 16
2.7	Taking a Measurement	P 17
2.8	Menu Setting	P 18

2.9	Bluetooth activation & pairing	P 20
2.9.1	Pairing for smart phone/tablet	P 20
2.9.2	Pairing with the HBox®	P 20
2.10	Data Transmission	P 21
2.11	Using the software	P 21
2.12	Evaluation by a care provider	P 23
<b>3</b>	<b>Care and Maintenance</b>	P 23
3.1	Cleaning	P 23
3.2	Maintenance	P 23
<b>4</b>	<b>Troubleshooting</b>	P 24
4.1	Error Indicator	P 24
4.2	Troubleshooting Tips	P 25
<b>5</b>	<b>FCC Statement</b>	P 26
<b>6</b>	<b>CE mark</b>	P 29
<b>7</b>	<b>Warranty</b>	P 30
<b>8</b>	<b>Specifications</b>	P 32
<b>9</b>	<b>Manufacturer</b>	P 34

## 1.1 Introduction

Thank you for purchasing the NantLife Pulse Oximeter. With its unique wireless integrated technology, the NantLife Smart Pulse Oximeter enables you to perform first-class, comfortable and extremely gentle non-invasive measurements of the oxygenation of a user's hemoglobin. You have chosen the most up-to-date form of healthcare management. Measured values are transmitted automatically to a data-base via a Bluetooth-enabled mobile phone and/or the HBox® hub.

Choose between 2 basic configurations:

- 1) **Smart Medical Home** with **NantLife HBox®**
- 2) **Mobile Health** with your Bluetooth-enabled smartphone or tablet

The NantLife Smart Pulse Oximeter comes with the following components:

- **Color OLED screen display (organic light-emitting diode)**
- **Uni-size Finger probe**
- **Interval Bluetooth® data transmission**
- **Real-time inner clock (for transmission only, not for display)**
- **User Manual**
- **User Guide**
- **Warranty card**

## 1.2 Intended Use

The fingertip NantLife Smart Pulse Oximeter is for the home use.

- NantLife Smart Pulse Oximeter is intended for spot-checking in measuring and displaying functional arterial oxygen saturation (SpO<sub>2</sub>) and pulse rate in the home.
- It is intended for adult and pediatric patients on finger between 0.3-1.0inch (0.8-2.5cm) thick.
- Never change your medication on the basis of results you have obtained. The treating physician may only carry out the evaluation of the measurements and the treatment based on them.
- The NantLife Smart Pulse Oximeter is not intended to be a diagnostic device.
- This device is intended for use in measuring oxygen saturation in blood pressure and pulse rate in the adult and pediatric population. Do not use this device in infants or person who cannot express their intention.

## 1.3 Safety Information

*To assure the correct use of the pulse oximeter, basic safety measures should always be followed including the warnings and cautions lifted in this instruction manual.*

### **1.3.1.1 Warnings**

Read all of the information in the instruction manual and any other instruction in the box before operating the unit. If you experience discomfort during a measurement, open the clamp and remove immediately your finger from the device. Stop using the device, turn it off and please contact NantLife Customer Service.

**In addition, please note:**

- Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your physician or licensed healthcare provider.
- Do not under any circumstances use the device in the bath or the shower. If, however, liquid get into the device, you must remove the batteries immediately and refrain from further use. Contact our service department (see front cover).
- The device may not be used near a nuclear magnetic tomographic resonance.
- Using components that are not part of the scope of delivery can produce faulty measurements (Exception: battery replacement).
- DO NOT subject the monitor to strong shocks such as dropping the unit on the floor.
- DO NOT damage the batteries. If battery fluid gets in your eyes, immediately rinse with plenty of clean water and contact a physician immediately.
- Keep away from source of fire and/or heat.

- Store the device in a clean, safe location.
- DO NOT disassemble the Smart Pulse Oximeter.
- DO NOT use the Smart Pulse Oximeter in a MRI or CT environment.
- DO NOT use the Pulse Oximeter in the presence of flammable anesthetics.
- Explosion Hazard: DO NOT use the Smart Pulse Oximeter in an explosive atmosphere.
- Chemicals from OLED panel are toxic if ingested. Use caution if the blood pressure meter display screen is broken.
- The Smart Pulse Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Check the Pulse Oximeter application site frequently to determine skin sensitivity of the patient.
- Prolonged use or the patient's condition may require changing the site periodically. Change finger and check skin integrity, circulatory status.
- Use only 1.5V alkaline batteries with this device. Other type of battery may damage the unit.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device components, including batteries.
- Only the authorized service personnel can repair this device.

### **1.3.1.2 Cautions**

- Significant levels of dysfunctional hemoglobin may cause inaccurate readings.
- Measurements may be affected by dyes such as indocyanine green and methylene blue.
- Measurements may be affected by upper ambient light (e.g. direct sunlight).
- Excessive user movement may cause inaccuracy.
- Upper-frequency electro-surgical interference may cause inaccurate readings.
- Venous pulsations may cause inaccurate readings
- Placement of Pulse Oximeter on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may cause inaccurate readings.
- Users with hypotension, severe vasoconstriction, anemia, and/or hypothermia may cause inaccuracy.
- Autoclaving, ethylene oxide sterilizing, or immersing the pulse oximeter in liquid may cause inaccurate measurements.
- Excessive user movement may cause inaccurate readings
- All NantLife devices are designed to be compliant with rules and regulations in locations they are sold and are labeled as required.
- Any changes or modifications to NantLife equipment, not expressly approved by NantLife void the user's authority to operate the device.



## 1.4 Before taking a measurement

General information about oxygen saturation in blood:

Your oxygen saturation in blood fluctuates throughout the day. Hypoxemia, or low blood oxygen, describes a lower than normal level of oxygen in your blood. In order to function properly, your body needs a constant level of oxygen circulating in the blood to cells and tissues. When this level of oxygen falls below a certain amount, hypoxemia occurs and you may experience shortness of breath.

Your doctor determines whether you have hypoxemia by measuring your blood oxygen level — the amount of oxygen traveling in your arteries. Your blood oxygen can be measured by testing a sample of blood from an artery.  
*(Resource: Mayo Family Health Book, Fourth Edition)*

NantLife pulse oximeter, a small device that clips on your finger, measures the saturation of oxygen in your blood; the results are often used as an estimate of blood oxygen levels. Normal pulse oximeter readings range from 95 to 100 percent, under most circumstances. Values under 90 percent are considered low.

If you monitor your blood oxygen regularly, you will discover more about your body's reactions to external influences (e.g. stress, air pollution or exercise), and you will be able to consciously develop a healthier lifestyle.

Your healthcare providers want to get an accurate picture of your blood oxygen levels and chart what happens over time. Your doctor will evaluate the data you have stored, once you share it with her/him, and will immediately have a better overview of the course of your blood oxygen measurements. You will be controlling and supporting the monitoring of your doctor's treatment.

- Avoid eating, drinking alcohol, smoking, exercising, and bathing for more than 30 minutes before taking your measurement.
- Rest for 10 minutes before taking the measurement.
- Do not take measurement during stressful times.
- Remain still during measurement.
- Try to measure your oxygen saturation in blood at about the same time every day for consistency.

## 2 Operating Instruction

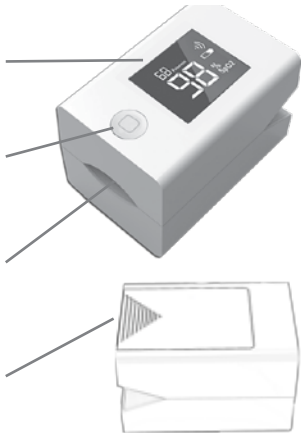
### 2.1 Know your NantLife Smart Pulse Oximeter

**OLED display**

**One Touch Button**

**Finger Probe**

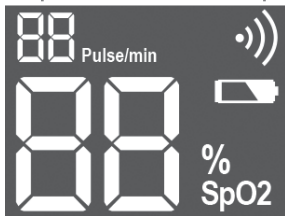
**Batteries Compartment**



## 2.2 Unit Display

Pulse rate beats per minutes




Wireless Transmission Signal




Low Power Indicator

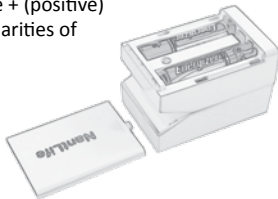
Percentage of oxygen saturation in blood

## 2.3 Display Symbols

Symbols	Operation	Measure/Solution
SpO2%	oxygen saturation in blood	Percentage
Pulse/min	Display pulse	Pulse beats per minute
	Low Power Indicator	Replace batteries
	Wireless Data Transmission ON	see section 2.8 to change setting
	Wireless Data Transmission OFF	See section 2.8 to change setting
3s	Transmission every 3 seconds	See section 2.10
5s	Transmission every 5 seconds	See section 2.10
8s	Transmission every 8 seconds	See section 2.10

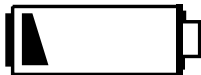
## 2.4 Batteries Installation

1. Press the  indicator on the battery cover and slide the cover off in the direction of the arrow.
2. Install 2 “AAA” size batteries so the + (positive) and the – (negative) match the polarities of the battery compartment.
3. Replace the battery cover



## 2.5 Batteries Replacement

When the low battery indicator appears on the display screen, turn off the Pulse Oximeter and remove all the batteries.



*Low batteries signal*

Replace with 2 new “AAA” 1.5V alkaline batteries.

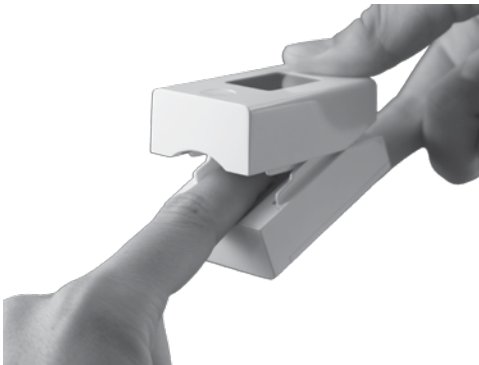
**WARNING:** If battery fluid gets in your eyes, rinse with plenty of clean water and contact a physician immediately.

**CAUTION:** Dispose of the device and empty batteries according to applicable local regulations.

Unlawful disposal may cause environmental pollution.

## 2.6 Using the Smart Pulse Oximeter

1. Open the clamp and insert a finger into the Smart Pulse Oximeter as illustrated below.





## 2.7 Taking a Measurement

1. Sit in a chair and make sure your hand is not moving.
2. Once your finger is inserted properly, the display will light up automatically and after a few seconds, the Pulse Oximeter will display SpO2% and a pulse rate. Stay still for a minimum of 5 seconds.
3. The NantLife Smart Pulse Oximeter will also transmit the recorded information via Bluetooth® to other Bluetooth® enabled devices (e.g. HBox®, Smart phones and tablets). List of compatible devices at [www.NantLife.com](http://www.NantLife.com).
4. The measurement is sent automatically to your virtual Health Diary. You can access your data by login in the Nantlife portal or by using the NantLife Application on your smart mobile devices (enabled phones and tablets only)
5. After transmitting the data, the Smart Pulse Oximeter will shut down automatically after 20 seconds.

### Notes:

Keep your hand still during the measurement. Do not pour or spray liquids onto the sensor. The Smart Pulse Oximeter will shut down after 20 seconds if no measurement is being taken.

For best accuracy and consistency, we recommend taking your measurement after a 5 minutes rest.

## 2.8 Menu Setting

**Bluetooth Settings:** By default, the Pulse Oximeter Bluetooth function is active. The Bluetooth can be turned off in the menu setting screen.

**Transmission Frequency:** By default, the Pulse Oximeter transmits readings **at an interval of 3 seconds (3s)**. Transmission interval can be change to every **5 seconds (5s)** or to every **8 seconds (8s)** in the menu setting screen.



To enter the Menu Setting:

- 1) Press and hold the button for 3 seconds to enter in the menu screen (figure 1)
- 2) The white dot shows in front of the Bluetooth line. Press the button quickly one more time to switch the Bluetooth function off. The wireless signal is now crossed (figure 2)
- 3) Press and hold the button for 3 seconds to go down to the Interval line (figure 3) Press the button quickly to reach the desired interval time (figure 4, 8 seconds in that example, [8s])
- 4) Press and hold the button to exit, the white dot shows on the Exit line (figure 3)

## 5) Press the button quickly to exit the settings menu



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5

Menu Symbols	Operation	Explanation
○	White dot	Indicate active setting
	Wireless Data Transmission ON	see section page 20 to change the setting
	Wireless Data Transmission OFF	See section page 20 to change the setting
Interval 3s	Transmission every 3 seconds	See section 2.11
Interval 5s	Transmission every 5 seconds	See section 2.11
Interval 8s	Transmission every 8 seconds	See section 2.11

## 2.9 Bluetooth Activation & Pairing

### 2.9.1 Pairing with Smartphones: 3 easy steps

First, set up your mobile phone to receive data by Bluetooth (see your mobile phone user guide). If your phone is already activated, go to Step 1.

(If NantLife has already prepared the pairing of the device, go directly to 2.10 page..... “transmitting readings”).

Step 1: Press the button to activate the Smart Pulse Oximeter.

The screen turns on. The device is activated.

Step 2: On your smartphone NantLife application, hit the “Scan” button

Step 3: When the Pulse Oximeter icon is highlighted, select it to pair.

Caution: Your mobile phone must have a wireless Bluetooth LE Interface. You can find more information at [www.nantlife.com](http://www.nantlife.com)

### 2.9.2 Pairing with HBox®: 3 easy steps

Step 1: Press the button of the Pulse Oximeter to activate it.

The screen turns on. The sensor is activated.

Step 2: Plug the HBox® in a wall electrical outlet. The LED green light turns on.

Step 3: Gently tap to pair the activated Smart Pulse Oximeter with the HBox®.

The LED yellow light will flash or a music will play to confirm pairing.



## 2.10 Data Transmission

The measurements saved in the Pulse Oximeter are transmitted automatically to your Bluetooth® enabled smartphone and/or to the HBox® hub. The wireless sign blinks rapidly on the screen showing successful data transmission. The Pulse Oximeter stores the latest 50 records if it cannot transmit the data to the paired device.

## 2.11 Using the software and the application

NantLife Health Management Software and Application allow you to connect, control and share your vital signs with the persons of your choice on a secured Healthcare dedicated platform.

To create your Virtual Health Diary, you can access NantLife portal at [NantLife.com](http://NantLife.com) and/or download for free NantLife application from the Apple store and Android Apps stores.



NantLife Application Health Diary

NantLife Application Menu

## **2.12 Evaluation by your care provider**

Your measurements are now stored in your virtual NantLife virtual Health Diary. You can share them with care providers, nurses, and family members. For more information on sharing, please go [www.NantLife.com](http://www.NantLife.com)

## **3 Care and Maintenance**

### **3.1 Cleaning**

If required, wipe the plastic casing with a damp cotton cloth only.

Do not use abrasive or volatile cleaners.

Clean the rubber touching the finger and the probe inside the Pulse Oximeter with a soft cloth dampened with 70% isopropyl alcohol before and after each measurement.

### **3.2 Maintenance**

Remove the batteries if the unit will not be used for three months or longer. Use the unit in a manner that is consistent with the user guide manual provided. Store the Pulse Oximeter in a cool and dry location, free from dust and direct sunlight.

## 4 Troubleshooting

### 4.1 Error Indicator

Error	Cause	Solution
" — — "	the measure is out of preset range	Keep your hand still and repeat the measurement. See 2.6 & 2.7

### 4.2 Troubleshooting tips

Description	Cause	Solution
SpO2% or pulse rate does not show on display	a) The finger is not inserted properly b) User's SpO2 value is too low to be measured	a) Retry a correct insertion of the finger. b) Measure other users to make sure that no problem exists in the device. Go to a hospital in a timely manner for an exact diagnosis.



Description	Cause	Solution
SpO2% and/or pulse rate are unstable	a) The finger is not inserted properly b) Excessive user movement	a) Retry by inserted the finger to the end of the sensor b) Stop moving the finger, hand and body.
The Pulse Oximeter cannot be powered on	a) No Battery or low power b) Batteries installed incorrectly c) The Pulse Oximeter may be damaged	a) Replace the batteries b) Reinstall the batteries c) Contact the customer service department, see page
Display suddenly turns off	a) The Pulse Oximeter turns off after 8 seconds if no activity is detected b) The battery power is too low to work	a) Relocate the sensor on another finger to reactivate it. Make sure the signal strength is strong for stable display b) Replace the batteries

## 5 FCC Statement

### POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for U.S.A. only)

This equipment has been tested and complies 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 when the equipment is operated in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the user guide manual, might cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determine by turning the product on and off, the user is encourage to try to correct the interference by one of the following actions:

- Reorient or relocate the receiving antenna
  - Increase the separation between the product and the receiver
  - Consult the dealer or an experience radio/TV technician for help
  - Plug the product (if relevant) in an outlet on a circuit different from that to which the receiver is connected.
- NantLife is not responsible for any radio or television interference caused by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device might not cause harmful interference, and (2) this device must accept any interference received, including interference that might cause undesired operation.

#### POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for Canada only)

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the interference-causing equipment standard entitled “Digital Apparatus”, ICES-003 of the Canadian Department of Communications. Cet appareil numérique respecte les limites de bruits radioélectriques applicables aux appareils numériques de Classe B prescrites dans la norme sur le matériel brouilleur: “Appareils Numériques”, ICES-003 édictée par le ministre des communications.

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

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Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to use the equipment.

## 6 CE mark

NantLife Smart Pulse Oximeter complies with the provisions of Council Directive 93/42/EEC of 14 June 1993 as well as national laws concerning medical devices. NantLife Smart Pulse Oximeter complies with the provisions of Council Directive 99/5/EC(R&TTE). It carries the CE mark as proof of this.



## 7 Warranty

1. The Smart Pulse Oximeter is warranted to be free from defects in material and workmanship appearing within one year from the date of purchase when the meter is used in accordance with the instructions provided with the monitor. Proof of purchase must be supplied in the form of a correctly completed warrantee card or a receipt. Include a \$5.00 for return shipping and handling. Include a letter with your name, address, phone number, and description of the problem. Pack the product carefully to prevent damages during transportation.
2. Defects due to faulty material or workmanship will be repaired free of charge during the warranty period.
3. The warranty period is not extended as a result of warranty services being provided, either for the devices as a whole or for any components.
4. The warranty excludes:
  - Any damage caused by improper use, e.g. through failure to observe the operating instructions,
  - Damage caused by maintenance or interventions carried out by the purchaser or unauthorized third parties
  - Damage resulting from transport, either from the manufacturer to the consumer, or on the way to the customer services.
  - Component parts subject to normal wear and tear (cuff, batteries etc.)

5. Liability is excluded for direct or indirect damage caused by the device, even if the damage to the device falls within the terms of the warranty
6. The above warranty extends only to the original retail purchaser.
7. Unauthorized modification of the warranty card invalidates it.
8. NantLife shall not be liable for loss of use or any other incidental, consequential or indirect costs, expenses or damages.

To obtain warranty service contact NantLife for the address of the repair location.

## **For Customer Service**

**Visit our website at [www.NantLife.com](http://www.NantLife.com)**

**Call toll free at 1-855-NANTCARE - 1-855-626-8227**

## 8 Specifications

Measuring Accuracy	SpO2: 35%-99% Accuracy: 75%-99% $\pm 2\%$ 50%-75% $\pm 3\%$ PR: 30-240 bpm $\pm 2$ bpm or $\pm 2\%$
Operating temperature	+ 4°C to + 42°C + 41°F to + 107.6°F
Operating humidity	10 to 95%
Storage temperature	-20°C to 70°C -4°F to 158°F
Storage Humidity	10% to 95%RH no condensation
Resolution	SpO2%: 1 Pulse Rate: 1 beat per minute (1/min)
LED Wavelengths and Output Power	Red: approximately 660nm@0.8W maximum average Infrared: approximately 940nm@0.8W maximum average
Wireless transmission distance	Recommend used in 10 meters
Operating elements	One button: start/stop
Data transmission	Bluetooth Class II – Bluetooth Class 4



Display	<p>OLED display</p> <p>SpO2 display range: 35~99%</p> <p>SpO2 Measuring range: 50~99%</p> <p>PR display range: 30~240 bpm</p> <p>PR measuring range: 30~240 bpm</p> <p>PR display mode: Amplitude Bar</p> <p>Data update period: &lt;15 s</p>
Power supply	2 alkaline 1.5V AA batteries (AA, LR6)
Unit Dimensions	40mm x 40mm x 60mm, 1.57" x 1.57" x 2.36"
Weight	50g (1.8oz) not including batteries

## 9 Manufacturer

Manufactured by NantCare LLC - Made in China  
Distributed by NantCare LLC dba NantLife  
2929 N 44th Street - Phoenix, Arizona 85018  
Toll free phone 1-855-NANTCARE - [www.NantLife.com](http://www.NantLife.com)

The manufacturer has calibrated the Smart Pulse Oximeter for a period of two years. Metrological inspection and adjustment must take place of two years. Metrological inspection and adjustment is subject to a fee and can be carried out by NantLife, a responsible authority, or an authorized maintenance service.

NantLife certifies that: (SP10) ??? I need the text

This model complies with the provisions of the European Standard ISO 9919:2009 Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use; EN 60601-1:2006 Medical electrical equipment, Part 1: General requirements for safety; EN60601-1-2:2007 Medical electrical equipment- Part 1: General requirements for safety -2: Collateral standard- Electromagnetic compatibility- Requirement and tests.



The NantLife Smart Pulse Oximeter meets the relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

## KNOW YOUR MONITOR

## INSTALL THE BATTERIES

## BOX CONTENTS

1 USER GUIDE



1 USER MANUAL



1 PULSE OXIMETER



2

OLED SCREEN

Clip

FINGER  
PROBE

BUTTON



3

- To open,  
Slide the compartment  
cover following the arrow

- Install 2 "AAA"1.5V  
batteries in the compartment  
at the bottom of the monitor

- Follow the polarity signs  
in the compartment when  
placing the 2 "AAA" batteries

- Close the compartment



## TURN THE MONITOR ON

## TAKE YOUR MEASUREMENT

## READ YOUR MEASUREMENT

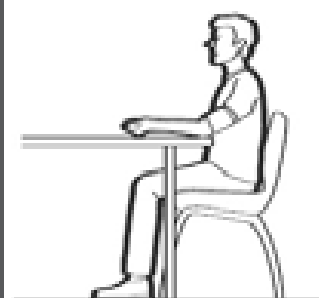
4



- Turn the Pulse Oximeter on by pushing the Button once  
or by inserting your finger into the probe
- The screen turns on and the NantLife logo displays
- Then the screen shows zero values as in the illustration above



5



- Sit comfortably in a chair
- Insert your finger into the probe
- keep your hand still
- When the wireless signal flashes  
several times on the screen,  
your measurement is complete

**Warning:***If you experience any discomfort:*

- Remove your finger from the probe immediately.
- Stop using the device and contact our customer support  
at [support@NantCare.com](mailto:support@NantCare.com)

6

- After a successful measurement,  
the display shows like the example below:

Pulse Value Display



Wireless Signal Indicator

Battery Level Indicator  
(will only show if batteries  
are empty)Percentage of oxygen  
saturation in blood

- The Pulse Oximeter shuts down  
automatically

Please refer to your user manual section 1.4 page 6 for more  
general information about Oxygen in Blood Level.

**Smart Body Scale**



**HCube  
3 in 1**



**Smart Ear  
Thermometer**



**Complete your  
Health Management  
with a full range  
of NantLife Wireless  
Medical Devices**

**[www.NantLife.com](http://www.NantLife.com)**

**Smart Pulse  
Oximeter**



**HPod for  
Glucometer**



**HBox Hub**



**Add a Nurse  
to monitor your  
vital signs**



**[www.NantCare.com](http://www.NantCare.com)**

**Add a Nurse to your wireless monitoring**  
**Visit us at [www.NantCare.com](http://www.NantCare.com)**



**Vital Signs Monitoring, Medication Management, Coaching, Training**

## IMPORTANT REGULATORY INFORMATION

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 that is received, including any interference that may cause undesired operation.

### WARNING:

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