

# healthsmart®

## Pulse Oximeter

### Package Includes:

- 1 Pulse Oximeter
- 1 Lanyard
- Two (2) AAA batteries
- Instructions in English & Spanish

### INSTRUCTIONS FOR:

Item # 40-815-000 (FS10D)

Item # 40-816-000 (FS10K)

Item # 40-817-000 (FS20K)

### IMPORTANT

Thank you for purchasing this Pulse Oximeter.

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Please read this manual in its entirety for proper product performance, correct operation, and to ensure patient and operator safety.

- Read this manual carefully before using the fingertip pulse oximeter.
- Product lifespan is 2 years.

### SAFETY

**CONTRAINDICATIONS:** Do not use oximeter in a magnetic resonance (MR or CT) environment.

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

### CAUTIONS:

- Do not use oximeter in the present of flammable anesthetics.
- The oximeter needs to be used according to information provided in the user manual.
- The equipment is NOT intended for neonate or infants.
- Do not use a damaged oximeter which may affect measurement performance.
- Do not place the oximeter on the same hand/arm when using a blood pressure cuff or monitor.
- Do not use the oximeter for more than 5 minutes without relocating the device to another finger.
- Do not place the oximeter on edema or fragile/tender tissues.
- Do not use the oximeter as the basis for making medical decision, it is intended only to be used as additional information that you can give to your licensed health care professional.
- Do not use the oximeter in high frequency environment such as electro-surgical equipment.
- Do not place the oximeter in liquid.
- Follow local disposal and recycling laws for the oximeter and its components, including the battery.
- Do not stare at the light (the infrared is invisible) which emitted from the oximeter is harmful to the eyes.
- Carefully review the "Troubleshooting" section of this manual if any problems are encountered during use.
- The physiological data displayed on the equipment are for reference only and can not be directly used for diagnostic interpretation.
- Not suitable for the users with arrhythmia / heart failure / low perfusion (PI <0.3) / finger trembling.
- Not suitable for the users with large finger size or exceeding pulse oximeter's finger measurement cavity size.
- Do not use the thumb or little finger for measurement.
- Discomfort or pain may appear if using the equipment continuously, especially for micro-circulation barrier patients, it recommended that the equipment should not be used on the same finger more than 5 minutes.
- The oximeter is designed to measure the percentage of arterial oxygen saturation of functional hemoglobin
- Any of the following conditions may reduce the performance of the oximeter.
  - Flicking or very bright light
  - Moisture in the oximeter
  - The individual weight less than 44 lbs. (20kgs)
  - Week pulse quality (low perfusion)
  - Venous pulsations
  - Low hemoglobin
  - Cardiogreen and other intravascular dyes
  - Carboxyhemoglobin
  - Methemoglobin
  - Dysfunctional hemoglobin
  - Artificial nails or fingernail polish
  - Cold hands or fingers
  - Patients with abnormal circulation of finger endings caused by COPD.

### INTRODUCTION

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for respiration.

### INTENDED USE:

The pulse oximeter is a portable, convenient, non-invasive device, used to monitor arterial hemoglobin oxygen saturation (SpO2) and pulse rates. This unit is designed for adult patients (weight: >60 lbs.) and pediatric patients (weight: 44 ~ 60 lbs.). We recommend using the index finger, middle finger or ring finger as the best suitable locations for measurement. **THIS DEVICE IS INTENDED TO MONITOR HEART RATE AND OXYGEN SATURATION DURING EXERCISE AND NOT INTENDED FOR MEDICAL DIAGNOSIS, TREATMENT OR CONTINUOUS USE MONITORING.**

### CAUTION:

- The pulse oximeter is NOT designed for newborns or infants. For adults and children, we recommend the person's finger thickness should be between 0.31" ~ 1.0" (8 ~25.4mm)

### NOTES:

- The probe is the hole in the middle of the equipment in which the finger is inserted
- The probe is the Applied part of the equipment

### FEATURES:

- The pulse oximeter is small and lightweight making it easy to carry with you anywhere.
- One button for easy operation
- Three operating modes: power off, sleep and measure.
- Automatically goes into sleep mode within 8 seconds after the finger has been removed and no signal is detected.

### SPECIFICATIONS

#### Classification

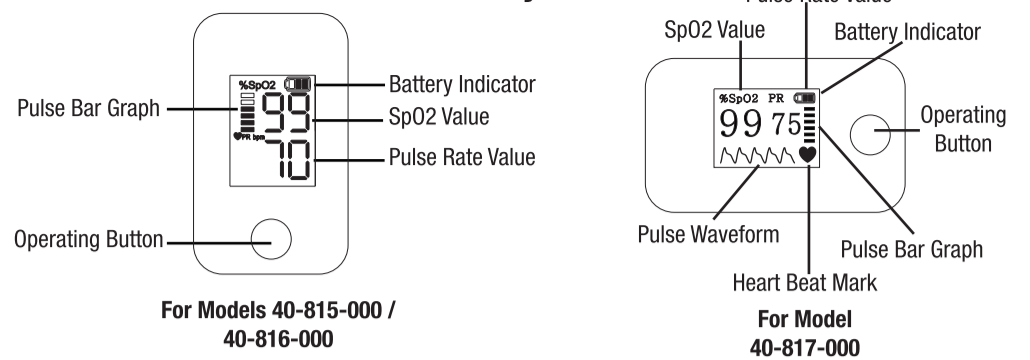
Type of protection against electric shock .....II (Internally powered equipment)  
 Degree of protection against electric shock.....Type BF-Applied part (non-defibrillation proof)  
 Operating Mode .....Spot Checking  
 Degree of protection against hazards of explosion .....Ordinary Equipment: Not Protected  
 Equipment Type .....Fingertip Oximeter

#### Power Requirements

Specification of Batteries .....Two 1.5V (AAA)  
 Operation Voltage .....DC 2.5~3V

**NOTE:** Product specifications are subject to change without prior notice. Illustrations used in this manual may differ slightly from the actual product. Illustrations are for reference only.

### Screen Symbols



### FUNCTIONS

Function	40-815-000 / 40-816-000	40-817-000
Display	LED	OLED
SpO2 Parameter Measurement	Yes	Yes
Pulse Rate Parameter Measurement	Yes	Yes
Bar Graph Display	Yes	Yes
Battery Display	Yes	Yes
Automatically Enters Sleep Mode	Yes	Yes
Pulse Waveform Display	--	Yes
Four Direction Display	--	Yes

### SYMBOLS

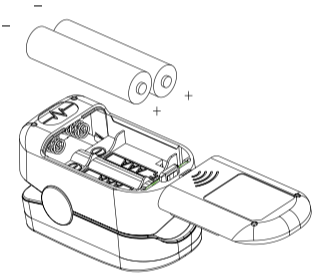
Symbols	Definition	Symbols	Definition	Symbols	Definition
%SpO2	Pulse Oxygen Saturation	SN	Serial Number	+	Battery Positive Electrode
PR	Pulse Rate (BPM)	⚠	This device has no Alarm System	-	Battery Negative Electrode
IPX2	This product is protected against harmful effects of dripping water per IEC 60529.	🏭	Date of Manufacturer	📖	Operating Guide Must be Read
🚶	BF Applied Part	🏭	Manufacturer	🔋	Low Battery Indicator

### BATTERY INSTALLATION

1. Slide cover off of the backside of pulse oximeter.
2. Insert two 'AAA' batteries into the compartment, matching the indicated polarity symbols.
3. To close, slide cover back into place.

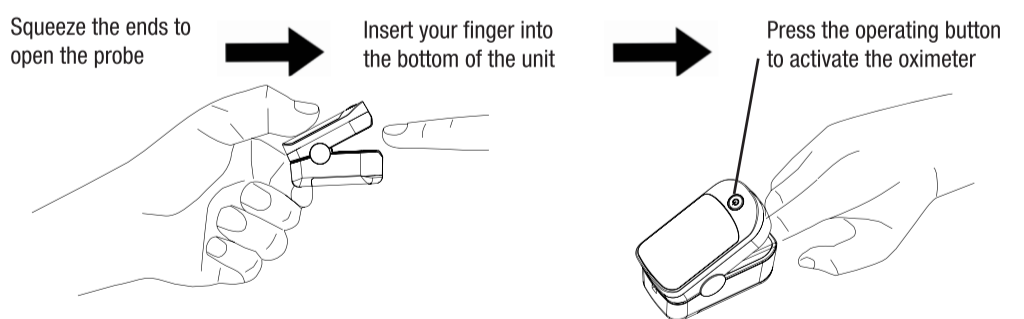
### WARNING:

- Battery polarities should be correctly installed, otherwise, it may damage the unit.
- Remove batteries if unit will be stored for more than 30 days.
- To completely turn off the unit, please remove the batteries. Otherwise the unit is always in sleep mode, but may still be using some battery power.
- Batteries may leak or explode if used or disposed of improperly



### OPERATING GUIDE

1. Remove the battery cover and insert the two 'AAA' batteries noting the polarity markings indicated inside of the battery compartment. Replace the cover.
2. Hold the oximeter with the display facing toward you. Slide your finger into the opening probe of the device (as show below) until the fingertip touches the built-in stop guide. For best results, make sure the finger is centered within the finger guide.
3. Press the button to activate the oximeter from sleep mode. The measurement interface will appear in 3 seconds.
4. The measurement results will show on the screen.
5. The oximeter will turn back to sleep mode automatically within 8 seconds after the finger has been pulled out.



### OPERATING NOTES

1. Only use your ring finger, middle finger or index finger for measurements.
2. Excessive or rapid movements may affect measurement accuracy.
3. Improper sensor placement may affect the measure accuracy.
4. The oximeter can be reused after cleaning and disinfection.
5. Be sure to keep the oximeter at the same level as your heart.
6. The display will show invalid indicator as '---' if the signal is very low.
7. The display will show invalid indicator as '---' if an oximeter error occurs.
8. Do not use the oximeter for more than 5 minutes without relocating the device to another finger.

#### Measurement Specifications

**SpO2 Declared Accuracy**  
 Range.....70%~99% ± 2 digits  
 Resolution.....1%  
 Update Period.....1 second  
 Averaging Time.....8 seconds  
**PR Declared Accuracy**  
 Range.....25~250 ± 3 digits  
 Resolution.....1 bpm  
 Update Period.....1 second  
 Averaging Time.....8 Seconds

#### Environmental Specifications

**Temperature**  
 Operating.....+41°F~104°F (5°C~40°C)  
 Storage.....-4°F~140°F (-20°~60°C)  
**Humidity**  
 Operating.....10~95%, noncondensing  
 Storage/Transport.....10~95%, noncondensing  
**Atmosphere Pressure**  
 Operating.....70~106 kpa  
 Storage/Transport.....50~107.4 kpa

## SPECIFICATIONS CONT.

### Physical Specifications

Width x Height x Depth .....About 1.29" x 1.41" x 2.28" (33x36x58mm)  
Weight.....2.1 oz. (60 grams)

### Display

	40-815-000 / 40-816-000	40-817-000
Display Type	LED	OLED, 0.96", 128x64 pixel
Display Content	SpO2%, Pulse rate, Battery Indicator, Bar Graph	SpO2%, Pulse rate, Battery Indicator, Bar Graph, Pulse Waveform, Heart Beat Mark

### LED Wavelengths

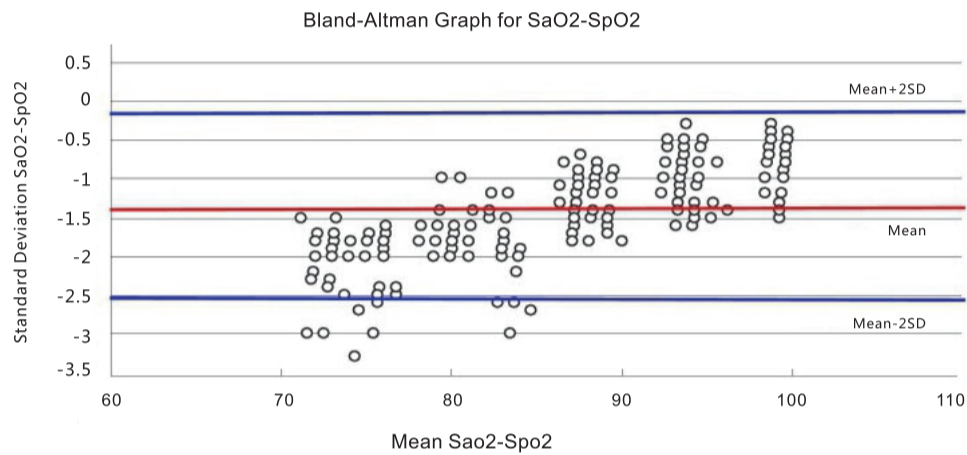
	Wavelength	Radiant Power
RED	660±6mm	1.8mW
IR	905±10mm	2.0mW

## TECHNICAL DESCRIPTION

The below table shows statistic conclusion of an invasive controlled desaturation study which guided by "ISO 80601-2-61, Annex EE, Guideline for evaluating and documenting SpO2 Accuracy in human subjects". The statistic result displayed the accuracy distribution between the range of 70% - 100%, which may be helpful to the user.

Bias Analysis	SaO2 - Radiometer A BL800 FLEX-CO-Oximeter			
	70-80 (%)	80-90 (%)	90-100 (%)	70-100 (%)
SpO2 Pulse Oximeters				
Mean Bias (Bs)	1.94	1.45	0.89	1.4
Precision (Sres)	2	1.55	0.98	1.53
Accuracy (Arms)	1.98	1.53	0.96	1.52

The below is the Bland-Altman graphical plot of samples from invasive controlled desaturation study.



## 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:

1. Please clean the equipment before use. Remove the batteries inside the battery compartment if the equipment will not be operated for a long time (30 days).
2. Replace the batteries when the low battery signal appears on screen.
3. It is recommended that the equipment should be kept in a dry environment with no corrosive gases and good ventilation. The moisture and high-light environments will affect its lifetime and might even damage the equipment.
4. It is best to store the product in a place where the temperature is between -4° to 140°F (-20°C to 60°C) and the relative humidity is less than 95%.
5. The packed equipment can be transported by ordinary conveyance. The equipment can not be transported mixed with toxic, harmful, corrosive materials.

**WARNING: Do NOT make any modification to this equipment.**

**DISPOSAL:** Please dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations.

## CLEANING & DISINFECTING

### CAUTION

- Never immerse or soak the oximeter in water or other solution.
- We recommend the oximeter be cleaned after every use.
- Never use other cleaning agents or disinfectants than what is recommended.

### Cleaning

To properly clean the unit follow the steps below:

1. Turn off the pulse oximeter and remove the batteries.
2. Gently wipe unit with cotton or a soft cloth moistened with water.
3. After cleaning, wipe off excess water with a soft dry cloth.
4. Allow to air dry.

### Disinfecting

To disinfect the unit, follow the cleaning steps above.

1. Then, use a soft cloth moistened with 70% ethanol or 70% isopropanol to gently clean the unit.
2. Use a soft cloth moistened with water to gently wipe clean the unit.
3. Allow the oximeter to air dry.

## TROUBLESHOOTING

### WARNING

- There are no replaceable or serviceable parts on the pulse oximeter.

Trouble	Possible Reason	Solution
The oximeter will not begin measurements	The batteries are completely exhausted	Replace with new batteries
	The batteries are not installed correctly	Verify and correct the battery orientations
	The oximeter is broken	
The display turns off suddenly	The device will automatically go into sleep mode if no signal detected after 8 seconds	Press the button again to reactivate the oximeter
	The batteries are completely exhausted	Replace with new batteries
The SpO2 and Pulse Rate display are unstable	The luminescent or photoelectric window is being blocked	Check the luminescent and photoelectric window
	Excessive movement	Remain still. Do not move your fingers or hands
	The finger is not placed inside far enough	Reposition finger further into the probe
	Finger size is not within the recommended range	Use another finger measurement
	Excessive ambient light	Move to a room with less ambient light
The SpO2 and PR are not displayed normally	Pulse rate value of the cyclical fluctuations	The measurement is normal and the patient has arrhythmia
	The finger is not properly positioned	Reposition finger further into the probe
	The patient's SpO2 is too low to be detected	Try to measure again. Consult with your physician

## APPENDIX

The equipment complies with the requirement of standard EN60601-1-2 "Electromagnetic Compatibility-Medical Electrical Equipment".

Guidance and manufacturer's declaration – electromagnetic immunity			
The 40-815-000 / 40-816-000 / 40-817-000 pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or user of the pulse oximeter should ensure 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	±8kV contact ±8kV, ±15kV air	±8kV contact ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50/60Hz) magnetic field	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the 40-815-000 / 40-816-000 / 40-817-000 pulse oximeter including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter. $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2,7 GHz	10V/m	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$ 80MHz to 800 MHz
			$d = \left[ \frac{7}{E_1} \right] \sqrt{P}$ 800MHz to 2.7 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic field strength meter.			
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.			

Guidance and manufacturer's declaration – electromagnetic emissions		
The 40-815-000 / 40-816-000 / 40-817-000 pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or user of the pulse oximeter should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The 40-815-000 / 40-816-000 / 40-817-000 pulse oximeter uses RF energy only for its internal function. 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 40-815-000 / 40-816-000 / 40-817-000 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 IEC 61000-3-2	N/A	
Voltage fluctuations flicker emissions IEC 61000-3-3	N/A	

Recommended separation distances between portable and mobile RF communications equipment and the Medical 40-815-000 / 40-816-000 / 40-817-000 PULSE OXIMETER			
The 40-815-000 / 40-816-000 / 40-817-000 pulse oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the pulse oximeters as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter(W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2,7 GHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0,01	0.12	0.04	0.07
0,1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

## WARRANTY

A one year limited warranty is available from date of purchase, excluding user-caused failures listed below:

1. Failure resulted in unauthorized disassembly and modification
2. Failure resulted in unexpected drop during application or transportation
3. Failure resulted in operation away from proper instruction in user's manual.