

# **Operation Manual**

### SIMCMS60D

## BlueTooth Wireless HandHeld Pulse Oximeter For Both Adult and Pediatric Application



NatureSpirit

#### Instructions

This manual provides the instructions necessary to operate Pulse Oximeter in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

Content of this manual is subject to change without prior notice. Issued date: 2019/07/01 Version: 2.1

#### Statement

The manufacturer is responsible for safety, reliability and performance of this product only in the condition that:

■ All installation operations, expansions, changes, modifications and repairs of this product are conducted by manufacturer authorized personnel; and

■ The electrical installation of the relevant room complies with the applicable national and local requirements; and

■ This product is operated under strict observance of this manual.

#### Guarantee

Free service scope

■ The manufacturer provides free service to any product which conforms to the warranty regulations.

Chargeable service scope

■ The manufacturer's obligation or liability under his warranty does not include the service of any factitious damage, or misuse, or irresistible natural disaster, or delay resulting from the improper use or application of the product, or repairs by people other than the manufacturer authorized personnel.

#### **Return Policy**

In the event that it becomes necessary to return a unit to the manufacturer, please obtain a return authorization first. Please contact us and provides the model number, serial number, and a brief description of the reason for return. Return shipments will not be accepted if the serial number is not clearly visible.

The customer is responsible for freight charges when this product is shipped to the manufacturer for service (including any relevant customs fees or other freight related charges).

#### **Safety Information**

#### WARNING:

It indicates a potential hazard situation or unsafe practice that if not avoided, could result in death or serious injury.

#### CAUTION:

It indicates a potential hazard or unsafe practice that if not avoided, could result in minor personal injury or product/property damage.

#### NOTE:

It provides application tips or other useful information to ensure that you get the most you're your product.

#### WARNING

- The person who uses the pulse oximeter should read this user manual before use.
- The pulse oximeter is intended only as adjunct in user assessment. It must be used in conjunction with clinical signs and symptoms. It is not intended as a device used for treatment purposes.
- When using the pulse oximeter together with the electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
- EXPLOSION HAZARD: Do not use the pulse oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.
- Make sure not to use the pulse oximeter during MRI (magnetic resonance imaging) scanning or CT (Computed Tomography)environmentbecause induced current could potentially cause burns.
- The pulse oximeter is without alarm function. Continuous monitoring for a long time is not suitable.
- No modification of the pulse oximeter is allowed. Maintenance should be operated by professional maintenance personnel who are approved by manufacturer.
- Please shut off the power before clean the pulse oximeter. Never permit high-pressure and high-temperature disinfection of the device. Never use cleaning agents/disinfectants other than the recommended.
- The pulse oximeter is commonly seal product. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
- The pulse oximeter is precision and fragile. Avoid pressure, knock, strong vibration or other mechanical damage. Hold it carefully and lightly. If it is not in use, it should be appropriately placed.
- For disposal of pulse oximeter and accessories, follow local regulations or your hospital's policy regarding disposal of such pulse oximeter and accessories. Do not dispose randomly.
- Use AA alkaline batteries. Do not use carbon or poor quality batteries. Remove the batteries if the product is not to be used for a long time.
- Please use the SpO<sub>2</sub> sensor matching with the product or use the SpO<sub>2</sub> sensor which the manufacturer has approved of it. The operator is responsible for checking the compatibility of the pulse oximeter, sensor and cable before use. And incompatible components can result in degrading performance. If there are signs of damage, please stop using.
- If the accessories are intended for single-use, please scrap according to relevant regulations after use. It is forbidden to re-use.
- Avoid static electricity, before using the pulse oximeter, confirmed direct or indirect static electricity of all the operators and patients who contact with the instrument.
- When in use, try to make the pulse oximeter keep away from radio receiver.

- If the pulse oximeter uses unspecified and without EMC test system configuration, it can enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration.
- Portable and mobile radio frequency communication equipment can affect the normal use of the pulse oximeter.
- The pulse oximeter should not be close to or stacked with other equipments, if you must be close to or stacked them in use, you should observed and verify that it can run normally with the configuration which it uses.

#### CAUTION

• Federal law restricts this device to sale by or on the order of a physician.

#### NOTE

□ Important! Before use, carefully read this manual, all safety information and specifications.

#### Product Description

The SIMCMS60D Pulse Oximeter is handheld device with detachable SpO<sub>2</sub>sensor (BST09001S), and it has following features:

- Simple and convenient usage of product.
- Memory storage capable to store 24 hours measurement data
- BLE4.0 compatible wireless connectivity with Apple IOS and Android phone APP support, cloud storage backup through mobile APP.
- Small volume, light weight, convenient to carry.
- Lower consumption, original two AA batteries can continuously work for 14 hours at least.
- Low voltage reminder shows in screen when there's low battery, may influence the normal working.
- The machine will automatically power off when there's no signal generated.
- Daily maintenance and calibration is unnecessary.
- Intelligent reminder function: buzzer automatically reminder when the value exceeds the normal range. Numerical value flickers.

#### Intended Use

The pulse oximeter is reuse device and intended use for spot checking of the pulse oxygen saturation and pulse rate for adult and pediatric in clinic environment. This medical device can be reused. Not for continuously monitoring.

#### Applicable people and scope

The pulse oximeter is suitable for monitoring adults and pediatric. It is used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom, emergency treatment. It can also be used in the recovery and health care organizations, the community medical treatments.

#### Contraindications

The pulse oximeter only applies to adults and pediatric, please don't use the product for children under the age of three, infant and neonatal.

#### Structure and Composition

The pulse oximeter is composed of a pulse oximeter and a SpO<sub>2</sub> sensor.

#### **Measurement Principle**

An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of hemoglobin (Hb) and Oxyhemoglobin (HbO<sub>2</sub>) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LEDs through process in electronic circuits and microprocessor.

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin (called spectrophotometer principle). It measures how much light, sent from light sources on the other side.



**Diagram of Operation Principle** 

#### **Cleaning and Disinfection**

#### CAUTION

- Never immerse or soak the pulse oximeter.
- Exercise caution during cleaning/disinfection to avoid wetting the pins.

- We recommend that the pulse oximeter be disinfected only when necessary as determined by your hospital's policy, to avoid long term damage to the pulse oximeter.
- Never use cleaning agents/disinfectants other than the recommended.
- Please shut off the power before clean the pulse oximeter. Never permit high-pressure and high-temperature disinfection of the pulse oximeter.

#### Cleaning

- 1. Clean the pulse oximeter with cotton or soft cloth moistened with water.
- 2. After cleaning, wipe off the water with a soft cloth.
- 3. Allow the pulse oximeter to air dry.

#### Disinfection

The recommended disinfectants include: 70% ethanol, 70% isopropanol, glutaraldehyde (2%) solution disinfectants.

- 1. Clean the pulse oximeter as instructed above.
- Disinfect the pulse oximeter with cotton or soft cloth moistened with one of the recommended disinfectants.
- 3. After disinfection, be sure to wipe off the disinfectant left on the pulse oximeter with a soft cloth moistened with water.
- 4. Allow the pulse oximeter to air dry.

#### **Technical Specifications**

#### 1. Product specifications:

Display mode: LCD Size:  $150 (H) \times 90 (W) \times 26(D)$  mm Weight: 120g (Do not contain batteries and sensor)

#### 2. Electrical specifications:

Working voltage: D.C. 2.2V~D.C.3.4V Battery type: Two common 1.5V AA alkaline batteries. Power consumption: smaller than 50mA

3. SpO<sub>2</sub>:

Measurement range: 0~100% Resolution: 1% Accuracy: ±3% (70%~100%)

#### NOTE

### • The method of confirming the blood oxygen measurement accuracy is to compare the oximetry measurement value with the value of blood gas analyzer.

#### • Pulse Rate:

Measurement range: 25~250bpm Resolution: 1% Accuracy: ±2bpm

#### • Low perfusion:

Range: 0.5%~20% SpO<sub>2</sub> accuracy: ±3% (70%~100%) PR accuracy: 25~250bpm ±2bpm

#### • Environment requirements:

Temperature: Operation: +5~+40°C Transportation and storage: -10~+50°C Humidity: Operation: 15%~80% (noncondensing) Transportation and storage: 10%~90% (noncondensing) Atmospheric pressure: Operation: 860hPa~1060hPa Transportation and storage: 700hPa~1060hPa

### **Packing List**

The standard configuration			
Pulse oximeter	1pcs		
SpO <sub>2</sub> sensor	1pcs		
The operation manual	1pcs		
APP operation guide	1pcs		

Expected	service		life:
Pulse	oximeter:	3	years
SpO <sub>2</sub> sensor:	2 years (expect the disposable SpO <sub>2</sub> sensor)		
Appearance Introduction			



Figure 1

#### **Battery Installation**

- 1. Push the locking bar to the right, and then open the battery cover. (as shown in Figure 2)
- Install batteries into the slots per the "+" and "-" symbol. Cover the battery cover. (as shown in Figure 2)
- □ The positive and negative electrodes of batteries should be installed correctly. Otherwise the device may be damaged.
- □ When install or remove batteries, please follow the correct operation sequence to operate. Otherwise the battery compartment will be damaged.



Figure 2

#### **Directions for use**

1. Insert the plug of the sensor into the socket of the pulse oximeter. (Socket as shown in Figure 3)

2. Open the power of the pulse oximeter, monitoring interface appears on LCD display.

**3.** Installing the sensor on the appropriate part of the patient's body. (The correct placement as shown in **Figure 4**)

4. Wait a moment, data can be read from the screen. (as shown in Figure 4) Display screen data refresh time for one second.







Figure 4

NOTE:

- Data update period is less than 30 seconds.
- Don't put the SpO<sub>2</sub> sensor on extremities with arterial catheter or venous syringe.
- It's the same as other medical equipment, should connect the cable carefully. And avoid patient is winded or suffocates. Electric surgical equipment cable can't entwine with sensor cable.
- Cover the sensor with opaque material under the condition of strong light. Failure to do so will result in inaccurate measurement.
- Try to keep the patient still (specially the arm) and avoid the measured site suffering excessive motion.
- Don't use the pulse oximeter to measure patients whose pulse rate is lower than 30bpm, which may cause incorrect results.
- Make sure no contamination or scar exists in the size where the SpO<sub>2</sub> sensor is placed. Otherwise, the measured result may be incorrect because the signal received by the sensor is affected.
- When used on different patients, the pulse oximeter is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the pulse oximeter on other patients.
- Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least even 2 hours.
- Don't perform SpO<sub>2</sub> monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO<sub>2</sub> value.
- Testee's fingernail can't be too long. Otherwise the finger can't be inserted into the sensor to a suitable depth and the SpO<sub>2</sub> measurements may be inaccurate.
- Make sure to place the SpO<sub>2</sub> sensor on the finger in a correct direction. The LED part of the sensor should be at the backside of the patient hand and photodetector part at the inside. Make sure to insert the finger to suitable depth into the sensor so that the fingernail is just opposite to the light emitted from the sensor.
- The highest temperature of SpO<sub>2</sub> sensor contacts with patient's skin don't be allowed more than 41°C.
- Shock, anemia, hypothermia and the application of vasoconstriction drug may decrease arteria blood flow to an unmeasurable level.
- Pigment, or deep color (for example: nail polish, artificial nails, dye or pigmented cream) may cause inaccurate measurements.

#### **Operating Button Explanation**

#### 1. Power on and power off

Power on: Press "POWER" button, machine starts up and enter main menu.

Power off: Press "POWER" button for 3 seconds, machine power off, or the sensor dropped for 10 seconds, the machine automatically power off.

When the battery level is low, the battery borders will continue to shine. If you do not replace the battery in time, system will shut down and not start up by "POWER" button for the battery is too low.

#### 2. Parameter setting:

Long press "FN" button for system displays Settings interface, a total of seven parameters can be set:

"1"- means  $SpO_2$  upper limit, default value is 99, when  $SpO_2$  value is higher than 99, system automatically reminds, buzzer alarm. Press "UP" button for increasing SpO<sub>2</sub> upper limit and press "DOWN" button for reducing SpO<sub>2</sub> upper limit.

"2"- means  $SpO_2$  lower limit, default value is 85, when  $SpO_2$  value is lower than 85, system automatically reminds, buzzer alarm. Press "UP" button for increasing SpO<sub>2</sub> lower limit and press "DOWN" button for reducing SpO<sub>2</sub> lower limit.

"3"- means pulse rate upper limit, default value is 120, when pulse value is higher than 120, system automatically reminds, buzzer alarm. Press "UP" button for increasing pulse rate upper limit and press "DOWN" button for reducing pulse rate upper limit.

"4"- means pulse rate lower limit, default value is 50, when pulse value is lower than 50, system automatically reminds, buzzer alarm. Press "UP" button for increasing pulse rate lower limit and press "DOWN" button for reducing pulse rate lower limit.

"5"- means sound value. Press "UP" button for increasing the sound value and press "DOWN" button for reducing the sound value.

"6"- means automatic screen out. Press "UP" button or "DOWN" button for starting or stopping the Automatic screen out function, "on" means that the Automatic screen out function has been started-the screen is automatically turned off after the display interface keeping the 30s, "OFF" means that the Automatic screen out function has been stopped.

"7"- means the Bluetooth. Press "UP" button or "DOWN" button for stopping or starting the Bluetooth. "ON" means that the Bluetooth has been started and "OFF" means that the Bluetooth has been stopped.

Long press "FN" button for exiting setup, after that the system stays in display.

#### 3. Pause the reminder

System default alarm limit: SpO<sub>2</sub> value higher than 99%, or lower than 85%, pulse rate value higher than 120bmp, or lower than 50bmp. When measured value exceeds to the threshold value, system will remind, buzzer will be on and the numerical value will flicker. Press "FN' button for a short time when machine reminds, system reminder is cancelled, reminder sound stop, screen flicker remain still. Press "FN" again, system will remind again.

#### **Bluetooth Communication Function**

SIMCMS60D pulse oximeter is with the Bluetooth communication function. It can send data to intelligent terminal or computer (Related software has been installed.) with communication

function. Bluetooth is enabled when no Bluetooth icon "<sup>3</sup>" is displayed: Bluetooth is enabled when

the Bluetooth icon "," flickered, but there is no connection to the terminal device: When the 10/17

Bluetooth icon "?" did not flicker and continues to display, the Bluetooth is connected to the terminal device successfully.

**NOTE:** The usage of Bluetooth communication software which is installed in the computer or intelligent terminal is written into the "APP operation guide".

### Troubleshooting

Trouble		Possible reason		solution	
The SpO <sub>2</sub> and PR	1.	The finger is not properly positioned.	1.	Please the finger properly and	
can't be displayed	2.	The patient's SpO <sub>2</sub> is too low to be		try again.	
normally and		detected.	2.	Try again; Go to a hospital for	
the value	3.	The plug of sensor falls off.		a diagnosis if you are sure the	
disappeared.	4.	Bluetooth signal is interrupted.		device works all right.	
			3.	Please insert the plug of	
				sensor tight.	
			4.	Check the Bluetooth	
				connection and reconnect.	
The SpO <sub>2</sub> and PR	1.	The finger is not placed inside	1.	Place the finger properly and	
display instable.		enough.		try again.	
	2.	2. The finger is shaking or the testee is 2. Let the testee keep ca		Let the testee keep calm.	
		moving.			
The device can't	1.	The batteries are drained or almost	1.	Change batteries.	
be powered on.		drained.	2.	Reinstall batteries.	
	2.	The batteries are not inserted	3.	Please contact the supplier.	
		properly.			
	3.	The device's malfunction.			
The screen is	1.	The product is automatically	1.	Normal.	
suddenly off.		powered off when no signal is	2.	Replace the batteries.	
		detected longer than 10 seconds.			
	2.	Power quantity of the batteries is			
		exhausted.			

### **Symbol Meaning**

Symbol	Meaning
2	"CAUTIOUS"! Please refer to the operation manual.
×	Type <b>BF</b> Equipment.
$\otimes$	The product does not contain alarm function.
X	When the end-user wishes to discard this product, it must be sent to separate
	collection facilities for recovery and recycling.
***	Information of manufacture, including name and address.
2	Date of manufacture.
CE	European Union for approval.

2	Single use only.
$\geq$	Service life.
SN	Serial Number.
LOT	Batch Code.
REF	Type Number.
IP21	The product is protected against harmful effects of dripping water per IEC 60529.

### Appendix A EMC Declaration

# Guidance and manufacturer's declaration-electromagnetic emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic emission					
The Pulse Oximeter is	The Pulse Oximeter is intended for use in the electromagnetic environment specified				
below. The customer of	r the user of the P	Pulse Oximeter should assure that it is used in such			
an environment.					
Emission test	Compliance	Electromagnetic			
		environment-guidance			
RF emissions	Group 1	The Pulse Oximeter uses RF energy only for its			
CISPR11		internal function. Therefore, its RF emissions are			
		very low and are not likely to cause any			
interference in nearby electronic equipment.					
RF emissions	Class B	The Pulse Oximeter is suitable for use in all			

Not applicable

establishments,

including

establishments and those directly connected to a

domestic

CISPR11

Harmonic emissions

IEC 61000-3-2		low voltage power supply network which supplies
Voltage	Not applicable	buildings used for domestic purposes.
fluctuations/flicker		
emissions		
IEC61000-3-3		

# Guidance and manufacturer's declaration-electromagnetic immunity-for all EQUIPMENT and SYSTEMS

Guidance an	Guidance and manufacturer's declaration-electromagnetic immunity				
The Pulse Oxime	The Pulse Oximeter is intended for use in the electromagnetic environment specified				
below. The custon	ner or the user of the l	Pulse Oximeter sho	ould assure that it is used in such		
an environment.					
Immunity test	IEC 60601 test	Compliance	Electromagnetic		
	level	level	environment-guidance		
Electrostatic	±6 KV contact	±6 KV contact	Floors should be wood,		
discharge (ESD)	±8 KV air	±8 KV air	concrete or ceramic tile. If floor		
IEC 61000-4-2			are covered with synthetic		
			material, the relative humidity		
			should be at least 30%.		
Electrical fast	±2KV for power	Not applicable	Not applicable		
transient/burst	supply lines				
IEC 61000-4-4					
Surge	±1KVdifferential	Not applicable	Not applicable		
IEC 61000-4-5	mode				
	±2KVcommon				
	mode				
Voltage dins	< 5% 11-( > 05%	Not applicable	Not applicable		
vollage ulps,	$< 3\% 0_{\rm T} (> 95\%)$	Not applicable			
interruptions and					
voltage	cycle				
variations on	40% U⊤ (60% dip				
power supply	in $U_{T}$ ) for 5 cycles				
input lines					
IEC 61000-4-11	70% U⊤ (30% din				
	in $U_{T}$ ) for 25 cycles				
	<5% U <sub>T</sub> (>95%				
	dip in $U_T$ ) for 5 sec				

Power	3A/m	3A/m	Mains power quality should be
frequency			that of a typical commercial or
(50/60Hz)			hospital environment.
magnetic field			
IEC 61000-4-8			
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

# Guidance and manufacturer's declaration-electromagnetic immunity-for all EQUIPMENT and SYSTEMS that are not LIFE - SUPPORTING

Guidance a	nd manufactur	er's declaration	on-electromagnetic immunity
The Pulse Oxim	eter is intended t	for use in the el	lectromagnetic environment specified
below. The custo	mer or the user of	the Pulse Oxime	ter should assure that it is used in such
an environment.			
Immunity	IEC 60601	Compliance	Electromagnetic
test	test level	level	environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter including cables, than the recommended separation distance calculated from the equation applicable to the frequencty of the transmitter.
Conducted RF IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E}\right]\sqrt{P} \text{ 80 MHz to 800 MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{7}{E_1}\right]\sqrt{P}  800 \text{ MHz to } 2.5 \text{ GHz}$ Where <i>P</i> is the maximum output power rating of the transmitter is watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity

of the equipment marked with the
following symbol:
(((•)))

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range supplies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse Oximeter. <sup>b</sup>Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m.

# Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM- for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF					
com	munications equipme	ent and the Pulse Oxin	neter		
The Pulse Oximeter	is intended for use in	n an electromagnetic e	environment in which		
radiated RF disturban	ces are controlled. The	e customer or the user of	of Pulse Oximeter can		
help prevent electrom	nagnetic interference b	y maintaining a minim	um distance between		
portable and mobile F	RF communication equ	ipment(transmitters) ar	d the Pulse Oximeter		
as recommended belo	ow, according to the ma	aximum output power o	of the communications		
equipment.					
Rated maximum	Separation distance	according to frequen	cy of transmitter (m)		
output power of	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz		
transmitter (W)	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$		
0.01	0.1167	0.1167	0.2333		
0.1	0.3689	0.3689	0.7379		
1	1.1667	1.1667	2.3333		
10	3.6893	3.6893	7.3786		
100 11.6667 11.6667 23.3333					
For transmitters rated at maximum output power not listed above, the recommended					
separation distance d in meters (m) can be estimated using the equation applicable to the					

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.

### Appendix B Graphical Plot of all sampled data points

#### SIMCMS60D Pulse Oximeter with SpO<sub>2</sub> Sensor BST09001S

HemoximeterRange	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	-1.07	0.16	-0.28	-0.32	3.23	-1.21	0.33	-0.27
Count	102	185	287	284	3	99	131	54
Missing Data	0	2	2	2	0	0	0	2
Standard Deviation	2.14	1.66	1.93	1.91	0.67	2.03	1.59	1.78
Standard Error	0.21	0.12	0.11	0.11	0.38	0.20	0.14	0.24
Upper LOA	3.19	3.44	3.54	3.45	N/A	2.83	3.47	3.22
Lower LOA	-5.34	-3.13	-4.10	-4.08	N/A	-5.24	-2.80	-3.76
Maximum	3.80	4.40	4.40	4.40	3.80	3.40	3.70	4.40
Minimum	-6.90	-5.10	-6.90	-6.90	2.50	-6.90	-4.30	-5.10
Root Mean Square	2.38	1.67	1.95	1.93	3.28	2.35	1.61	1.79

SIMCMS60DPulse Oximeter with SpO<sub>2</sub> Sensor BST09001S





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If you need additional information, please contact with us.