

Pulse Oximeter

SP62B

EN



IP 22



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Importer



Distributor

INSTRUCTION MANUAL

Please read this instruction manual carefully
before using your Pulse Oximeter

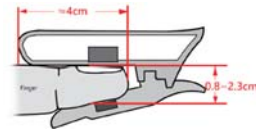
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Introduction

Intended Use:

The AVITA Pulse Oximeter is intended for measuring functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR) for adults as non-invasive spot checking in professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches to 0.9 inches) and for patients during no-motion condition. The device is prescription only.



Device Features:

- Two color OLED display
- Press the  key to rotate the screen
- Lanyard Hole
- Battery Cover

Contraindications:

1. Presence of an ongoing need for measurement of pH, PaCO₂, total hemoglobin, and abnormal hemoglobin may be a relative contraindication to pulse oximeter
2. A pulse oximeter cannot distinguish the differences and the reading will show the total saturation level of oxygen and carbon monoxide. Carbon monoxide molecules, even in a small amount, can attach to the patient's hemoglobin replacing oxygen molecules.
3. A high level of methaemoglobin would cause a pulse oximeter to have a reading of around 85% regardless of the actual oxygen saturation level. The higher percentage of methaemoglobin can be genetic or caused by exposure to certain chemicals and medications.

Device Description

The subject device AVITA Pulse Oximeter is non-invasive spot checking, not provided sterile, multi-use device, which can measure and display user's oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) through finger during no-motion condition. The subject device is not for life-supporting or life-sustaining, not for implant and does not contain drug or biological products. The device is for prescription use only.

The subject device consists of sensor, electronic circuits, display and plastic enclosures. It is a battery powered device and is adopted with two color OLED screen to display SpO2 and PR. It is software-driven and does not include alarms.

Physiological Principle:

SP62B determines SpO2 by measuring the absorption of red & infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular

bed are used to determine SpO₂ reading and pulse rate.

Principle of Operation:

AViTA pulse oximeters work by the principles of spectrophotometry, emitting two different wavelengths of light, typically red and infrared, through a pulsating capillary bed, such as a fingertip. The sensor on the other side of the tissue detects the light that emerges from the tissues. The device then measures the intensity of red and infrared light that is transmitted through the capillary bed.

Based on the differences in absorption between oxygenated and deoxygenated blood at specific wavelengths, the device can calculate the ratio of oxygenated hemoglobin (HbO) to total hemoglobin in the blood, which is known as oxygen saturation (SpO₂).

It's important to keep the finger or the measurement site stationary during the reading

to avoid introducing motion artifacts that could affect the accuracy of the measurement. Do not use for continuous monitoring.

Pulse Indicator:

The Pulse Indicator displays a loading bar when detect a pulse. When the pulse rate is detected, the bar will continue to show to indicate the connection of reading, but it does not mean it is the signal strength, nor will it affect the strength of signal.

Pulse Waveform Display:

The display provides the pulse waveform to detect the real-time sensor signal. The relative pulsation rate of the input signal can be observed.

Content of Package

- Fingertip Pulse Oximeter, 1 unit
- User Manual, 1 sheet
- AAA-Size Alkaline Battery, 1 piece

- Lanyard, 1 piece
- Bag, 1 piece (optional)

Please make sure all items are packed. All items are non-sterile. If any item is missing or damaged, contact your distributor.

Warnings

1. Do not use the oximeter in an explosive atmosphere to avoid explosion hazard.
2. Do not use the oximeter when applied part temperature is over 41°C (105.8°F).
3. The oximeter has to measure the pulse properly to obtain accurate SpO₂ reading. Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the oximeter.
4. SP62B is a no SpO₂ alarm device. Please do not use SP62B under alarm-required situation.
5. Exposure to strong external light while taking measurement may result in inaccurate readings. Shield the sensors from bright lights. Strong electro-magnetic fields

- may also affect readings.
6. Nail polish and pressed-on nails may interfere with readings.
 7. Intravenous dyes (such as methylene blue, indigo carmine, and indocyanine green) can cause inaccurate readings.
 8. Seek professional advice if measured irregular reading. SP62B is designed to monitor user health condition, not diagnosis or interpretation of health condition.
 9. Irregular heartbeats or by patient's movements can post irregular signal.
 10. Do not rely only on a pulse oximeter to assess health condition or oxygen level
 11. Only a health care provider can diagnose a medical condition such as hypoxia (low oxygen levels)
 12. Changes or trends in measurements may be more meaningful than one single measurement
 13. Pulse oximeters are not intended for continuous real-time monitoring and as such do not have alarms or alerts
 14. Consider accuracy limitations when using the pulse oximeter. For example, a pulse

oximeter saturation of 90% may represent an arterial blood saturation of 87-93%

- Use pulse oximeter readings as an estimate of blood oxygen saturation
 - Pulse oximeters are least accurate when oxygen saturations are less than 80%, at lower perfusion, at low signal or high noise
15. If monitoring at home, pay attention to other signs of symptoms of low oxygen levels, such as:
 - Bluish coloring in the face, lips, or nails;
 - Shortness of breath, difficulty breathing, or a cough that gets worse;
 - Restlessness and discomfort;
 - Chest pain or tightness; and
 - Face or racing pulse rate.
 - Be aware that some patients with low oxygen levels may not show any or all of these symptoms.
 16. Be aware that multiple factors can affect the accuracy of a pulse oximeter reading, such as incorrect sensor placement, poor circulation, skin pigmentation, skin thickness, skin temperature, current tobacco use.

17. If you are concerned about the pulse oximeter reading, or your symptoms are serious or getting worse, contact a health care provider
18. Device should only be used over intact skin
19. The Pulse Oximeter is MR Unsafe. Do not use the oximeter in an MRI or CT environment.
20. The oximeter is intended as an adjunct in subject assessment. It must be used in conjunction with other methods to assess clinical signals and symptoms.
21. When replace a battery of the device, a user shall not to touch the battery contact or battery and the patient simultaneously.
22. Please do not leave the device to a child and always keep the battery cover in attach to avoid swallowing by a child.

Symbols and Terminology



1	SpO2%	oxygen saturation in percentage.
2		PR bpm – The pulse rate symbol shows pulse rate in beats per minute
3		Pulse Indicator – It shows the signal being detected by the oximeter.
4		Battery condition symbol
		When battery is at low voltage.
5		The bluetooth icon indicates that SP62B is under broadcast condition

 CAUTION

- This oximeter is not an apnea monitor.
- Significant levels of dysfunctional hemoglobin such as carbonxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Cardio green and intravascular dyes may affect the accuracy of SP62B.
- The performance of the oximeter might be affected by the presence of a defibrillator.
- The oximeter may not work on all subjects. If you are unable to achieve stable readings, please discontinue use.
- The oximeter has motion tolerant algorithm to minimize the possible motion artifact. However, the oximeter may be still interpreted by motion. Please minimize subject motion as much as possible.
- All the materials of the oximeter in contact with a patient or a user have passed ISO 10993 Biological Evaluation of Medical

Devices accordingly. It shall be no toxicity harm to children, pregnant or nursing women.

- SP62B can be operated by either a patient or trained personnel. Consult healthcare professionals before use.
- The oximeter might not work on cold extremities due to poor circulation. Please warm or rub the finger, or reposition the device to improve it.
- Check the applied site of a patient frequently to evaluate body circulation and skin sensitivity. The recommended maximum applied time at a single spot is 30 minutes. Misapplication of the oximeter on applied site with excessive pressure for prolonged periods can introduce pressure injury.
- This oximeter is not an apnea monitor.
- Significant levels of dysfunctional hemoglobin such as carbonxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Cardio green and intravascular dyes may

- affect the accuracy of SP62B.
- The performance of the oximeter might be affected by the presence of a defibrillator.
- The oximeter may not work on all subjects. If you are unable to achieve stable readings, please discontinue use.
- The oximeter has motion tolerant algorithm to minimize the possible motion artifact. However, the oximeter may be still interpreted by motion. Please minimize subject motion
- **Not intended use for low perfusion condition. Low perfusion degrades pulse oximeter performance and results in nondisplayed saturation values.**
- Federal law restricts this device to sale by or on the order of a physician
- When the ambient temperature is 20 °C, at least 2 hours without condensing observed is required for the Pulse Oximeter to warm from the minimum storage temperature between uses until the Pulse Oximeter is ready for its intended use.

- When the ambient temperature is 20 °C, at least 2 hours without condensing observed is required for the Pulse Oximeter to cool from the maximum storage temperature between uses until the Pulse Oximeter is ready for its intended use.

Before Use

First Time Use

For the first time use, a protective plastic membrane is attached to the front panel of the oximeter. Please remove the plastic membrane to allow the OLED display to show its best performance.

The oximeter is calibrated in the factory before delivered, there is no need to calibrate it during its life cycle.

Battery Replacement

Before start any measurement, please make sure the battery power is sufficient and the setting is correct. When replacing the battery, please make sure the oximeter is off, then open the battery cover and install a new battery.



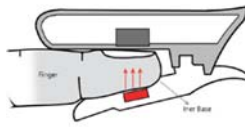
CAUTION

- Please use alkaline battery to ensure the best performance of device.
- Please dispose the battery according the proper procedure.
- It is recommended not to use rechargeable, unqualified or different spec battery may damage the device or cause circuit shortcut.

Operation

STEP1. Open up the oximeter and put one of your fingers into the opening.

Please make sure that your finger face up and touch the bottom (Inner Base) of the opening before releasing the clamp.



- STEP2. The device will turn on automatically after finger is inserted.
- STEP3. After detecting the pulse signal, the oximeter shows SpO2 and pulse rate on the display. The readings will be updated based on the signal received with each pulse.
- STEP4. During the operation, if you press the  key, the screen will rotate in different direction to allow users in desired view angle.
- STEP5. If the finger is not detected or removed, the oximeter will show "Finger Out" . As no motion is being detected, the device will turn off automatically in about 8 seconds.

STEP6. After finish use, follow the cleaning instruction to clean the device thoroughly.

Data Transferring

This product is a Pulse Oximeter. Design without entering personal information. If the device has a transmission function, the transmission measurement data is designed to be encrypted and transmitted, and will not be tampered with or retrieve user-related information during the transmission process. The firmware and software of the product have been programmed in the production process, and the programming interface is different from the data transmission interface. When programming to the microcontroller, use an encrypted programmer, so there is no need to worry about the software being tampered with during transmission.

Bluetooth function requirement:

- An Android device with Android version 4.3 or above and hardware support for Bluetooth 4.2.
- An iOS device with iOS version 5 or above and hardware support for Bluetooth 4.2.

How to activate the Bluetooth function:

- Please refer to the instruction manual of your mobile phone or computer for how to activate the Bluetooth function.

Set Up Process

- 1 Download an app which supports Bluetooth GATT Service from the iTunes App Store or Google Play.
- 2 Enable Bluetooth on your mobile device.
- 3 Open the app and activate the function.
- 4 Turn on the SP62B (put your finger into the pulse oximeter), when the Bluetooth icon shows on the device, it means SP62B is under broadcast condition.
- 5 Enable Bluetooth function from your mobile phone or computer. Check for available Bluetooth connection, the device name should be "SP62B" .
- 6 It require manual Bluetooth connection for first time, once the connection is connected the measure reading will automatically transfer to your mobile phone or computer.

**FEDERAL COMMUNICATIONS COMMISSION
INTERFERENCE STATEMENT**

This equipment has been tested and found to comply 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 in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**CAUTION**

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment. The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

This equipment is suitable for use in domestic establishments and is tested to CISPR emissions Class B Group 1 as well as home healthcare immunity criteria found in IEC 60601-1-2 Table 4, 6, and Table 9. During the IEC 60601-1-2

immunity tests performed the pulse oximeter will accurately measure oxygen saturation of arterial hemoglobin (SpO2) and pulse rate or display no data when no detection. To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations. Keep out of reach of young children, elderly and pets. FCC WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Trouble Shooting

Problem	Possible Causes	Solutions
The oximeter won't turn on.	The battery is dead.	Replace with a new battery.
	The battery is installed incorrectly.	Verify correct battery orientations.
	Finger might be trembling or place incorrectly.	Keep the finger steady or align the finger inward at vertical-middle of the device.
Display lockup or blank. If the device is on a finger, changes do not appear at wave form or pulse indicator.	The measuring function is malfunction.	The reading might not be reliable; discontinue using the device.
	Electromagnetic interference (EMI).	Remove the surrounding electronic devices away. eg. MRI, CT at hospital, or microwave at home environment.
	Finger might be	Keep the finger

	trembling or place incorrectly.	steady or align the finger inward at vertical-middle of the device.
No reading of SpO ₂ or pulse rate and shows dash-line.	Low finger pulse quality.	Please try the following. 1. Reposition the finger 2. Warm the finger by rubbing. 3. Select another finger.
SpO ₂ or pulse rate warning/indicator appears	A patient's condition is abnormal.	Provide immediately medical attention to this patient.
Low battery "🔋" appears on display.	The battery power is low.	Replace with a new battery.

Note: If you have followed the actions recommended above but the problem keeps unresolved, please call your local distributor for assistance.

Clinical Trial Results

Table A – “Study Summary”

	70-100	70-78	78-85	85-92	92-97	97-100
#pts	255	43	46	50	56	60
Bias	-0.254	-0.804	0.48	0.032	-0.135	-0.708
Arms	1.89	1.55	3.38	1.61	1.39	0.88

Table B – “Subgroup - Accuracy for male group”

	70-100	70-78	78-85	85-92	92-97	97-100
#pts	21	4	3	4	5	5
Bias	-0.68	-0.94	-0.60	-0.02	-0.66	-0.76
Arms	1.51	1.49	1.58	1.76	1.43	0.37

Table C – “Subgroup - Accuracy for female group”

	70-100	70-78	78-85	85-92	92-97	97-100
#pts	21	3	4	5	5	5
Bias	0.19	-0.26	1.44	0.15	0.29	-0.65
Arms	2.07	1.31	4.32	1.21	1.25	0.31

Table D – “Subgroup - Accuracy for Light skin pigmentation (Fitzpatrick 1 or 2)”

	70-100	70-78	78-85	85-92	92-97	97-100
#pts	18	2	3	4	4	5
Bias	-0.15	0.79	0.62	1.07	-0.99	-0.93
Arms	2.11	1.06	2.77	2.32	1.91	0.36

Table E – “Subgroup - Accuracy for Normal skin pigmentation (Fitzpatrick 3 or 4)”

	70-100	70-78	78-85	85-92	92-97	97-100
#pts	23	5	4	4	5	5
Bias	-0.38	-0.96	0.56	-0.30	-0.10	-0.67
Arms	1.66	1.55	2.78	1.27	1.14	0.35

Table F – “Subgroup - Accuracy for Dark skin pigmentation (Fitzpatrick 5 or 6)”

	70-100	70-78	78-85	85-92	92-97	97-100
#pts	20	2	3	5	5	5
Bias	0.07	-1.40	-0.38	-0.14	0.73	-0.50
Arms	1.17	0.42	3.10	1.41	1.00	0.22

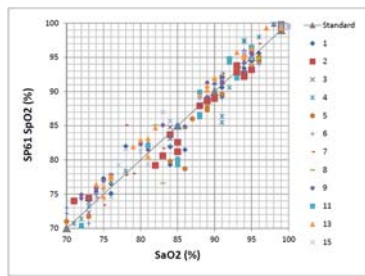


Figure 1: The linearity of SpO2 accuracy result compare to SaO2 across saturation range

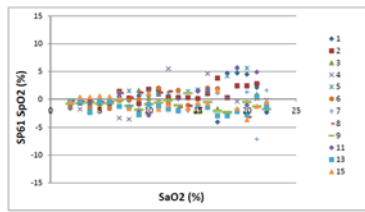


Figure 2: The bias of SpO2 accuracy result compare to SaO2 across saturation range

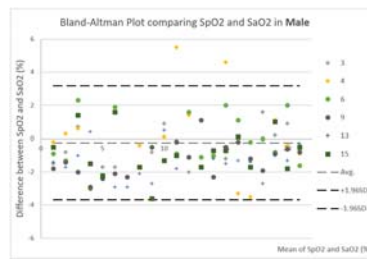


Figure 3: The bias of SpO2 accuracy result compare to SaO2 across saturation range in Male (subgroup analysis)

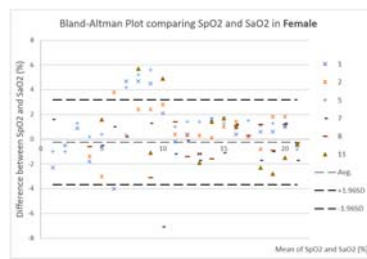


Figure 4: The bias of SpO2 accuracy result compare to SaO2 across saturation range in Female (subgroup analysis)

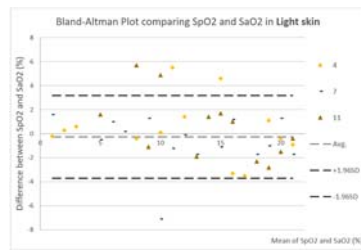


Figure 5: The bias of SpO2 accuracy result compare to SaO2 across saturation range in Light skin pigmentation (Fitzpatrick 1 or 2) (subgroup analysis)

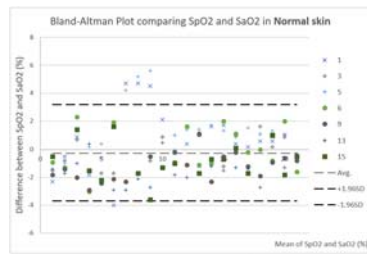


Figure 6: The bias of SpO2 accuracy result compare to SaO2 across saturation range in Normal skin pigmentation (Fitzpatrick 3 or 4) (subgroup analysis)

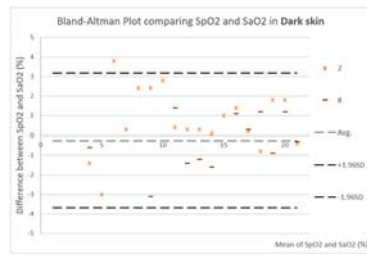


Figure 7: The bias of SpO2 accuracy result compare to SaO2 across saturation range in Dark skin pigmentation (2 subjects, Fitzpatrick 5 or 6) (subgroup analysis)

Maintenance and Storage

- Remove the batteries inside the battery compartment if the oximeter will not be operated for more than one month.
- It is best to preserve the product in a place where ambient temperature range is from -30°C ~ 70 °C (-22 °F ~ 158 °F), humidity range from 10% to 90%, and atmospheric pressure range from 700hPa to 1060 hPa.
- The commercially available bench top functional testers and patient simulators may only be suitable to validate the pulse rate, but may not be able to verify the proper oximetry of this pulse oximeter. Please consult with your distributor or the manufacturer proper model and the usage of functional testers and patients simulator for this oximeter.
- Furthermore, after a long term operation, the light sensor within the device may degrade with time. The testers and simulators may be useful for verifying that the pulse oximeter is working normally. A functional tester cannot be used to assess the accuracy of pulse oximeter device.
- During the warranty period, if the evident shows that the device is misused or the device

has been opened or tampered with the components within the casing by non-authorized service personnel, the warranty will be invalidated and a charge for repair will be assessed.



CAUTION

- Do not spray, pour, or spill any liquid on the oximeter, accessories, switches or openings.
- Do not use caustic or abrasive cleaning agents on the oximeter.
- This is a precision medical instrument and must be repaired by qualified personnel from manufacturer only.
- Please follow local governing ordinances and recycling instructions regards disposal or recycling of the device and components.

Clean and Disinfection

SP62B is intended for low level of disinfection

- For home use device disinfection, use 75% alcohol (available in the pharmacy) with damp cloth for cleaning and disinfection, the device can be clean up to 1000 times. Clean it thoroughly the body and the finger groove.

- Never use abrasive cleaning agents, thinners or benzene for cleaning. Do not scratch the surface of the lens or the display. Do not expose the oximeter to extreme temperatures, humidity, direct sunlight, or shock.
- Do not immerse the pulse oximeter into water, as the liquid can penetrate and damage the device nor ever place any heavy objects on the device.

Technical Specification

Dimension	L 68 x W 37.8 x H 28.5mm
Weight	without battery: approx. 26.5g
Display	Two color OLED
Auto on/off	Whenever user inserts a finger, the device will turn on automatically. Vice versa, the device will turn off automatically when the finger is removed from it.
Input key	 key for screen rotate
Measurement Method	wavelength
SpO ₂ Range & Resolution	Range: 0% to 100% resolution: 1%
SpO ₂ Accuracy	Range 70% to 100% range $\pm 2\%$, less than 70% are unspecified
Pulse Rate Range & Resolution	Range: 30 to 250 bpm; resolution: 1 bpm
Pulse Rate Accuracy	± 2 bpm or $\pm 2\%$, whichever is greater
Water-resistance	Against water splash (IP22 Approved)
Battery Type	1 AAA-size Alkaline battery
Usage Life	> 18 hrs typical operation under default

	setting
Shelf Life	3 years
Ambient Temperature	Operation: 5 °C - 40 °C (41 °F - 104 °F); Storage: -30°C ~ 70 °C (-22 °F ~ 158 °F)
Atmospheric Pressure	Operation & storage are both 700 hPa - 1060 hPa
Humidity	Operation & storage are both 10% - 90%, non-condensing

EMC Tables

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment			
Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Pulse Oximeter 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 $d=1.17\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2.5 GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

Declaration - electromagnetic emissions		
Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	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	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	

Pulse Oximeter declaration – electromagnetic immunity				
Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Pulse Oximeter should assure that it is used in such an environment.				
Immunity test	IEC 60601 test level		Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms ; 6 Vrms 150 kHz to 80 MHz		N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m 80 MHz – 2.7 GHz 80%		10 V/m 80 MHz – 2.7 GHz 80%	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m	385 MHz	27 V/m	
	28 V/m	450 MHz	28 V/m	
	9 V/m	710 MHz	9 V/m	
		745 MHz		
		780 MHz		
		810 MHz		
28	810	28	810	

	V/m	MHz	V/m	MHz	equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
		870 MHz		870 MHz	
		930 MHz		930 MHz	
	28 V/m	1720 MHz	28 V/m	1720 MHz	
		1845 MHz		1845 MHz	
		1970 MHz		1970 MHz	
	28 V/m	2450 MHz	28 V/m	2450 MHz	
	9 V/m	5240 MHz	9 V/m	5240 MHz	
		5500 MHz		5500 MHz	
		5785 MHz		5785 MHz	



Declaration – electromagnetic immunity			
Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Pulse Oximeter should assure 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	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient /burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage	0 % UT ;	N/A	Mains power quality

dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0, 5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT ; 1 cycle and 70 % UT ; 25/30 cycle Single phase: at 0°		should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Essential Performance:

The essential performance of SP62B Pulse Oximeter is defined as SpO₂ accuracy and pulse rate accuracy. The specification of SP62B Pulse Oximeter in non-motion conditions is ± 2 which is in compliance with the specified oxygen saturation, Arms of 2. The essential performance will not be affected under the electromagnetic environment specified as above.

Explanation of Symbols

	Medical Device
	Manufacturer
	Date of manufacture (YYYY-MM-DD or YYYY-MM)
	Batch code (YYMMWWWW)
	Serial number (YYMMWWXXXXX)
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

	Caution
	Consult the instruction for use
	Device classification type BF
IP 22	This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm Ø and greater and against vertically falling water drops when enclosure tilted up to 15°)
	Model Number
	Country of Manufacturer
	Unique Device Identifier
	Keep away from sunlight

	No alarm
	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 received, including interference that may cause undesired operation.
	Prescription Use
	WARNING Projectile Hazard The Pulse Oximeter is MR Unsafe.

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